

NATIONAL CERVICAL SCREENING PROGRAMME LABORATORY STRATEGY

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1 Executive Summary

The National Cervical Screening Programme (NCSP) requires stable, sustainable, safe and cost effective laboratory services of high quality. These services should also be sufficiently flexible to adapt to future technological advances.

One of the core functions of the National Screening Unit (NSU) is the purchasing and funding of programme services. In July 2001, the NSU became responsible for directly purchasing gynaecological cytology and histology laboratory services for the NCSP. As a result of the shift in responsibility, the associated laboratory services were unbundled from the Health Funding Authority Community Laboratory Agreements and incorporated into new Service Provision Agreements between community laboratory/District Health Board (DHB) hospital laboratory providers and the NSU of the Ministry of Health.

The laboratory services provided to the NCSP represent a specialist niche market, which is part of the much larger medical laboratory market, funded on a region by region basis by DHBs.

Structural changes to the broader medical laboratory market are being initiated by DHBs. The DHBs are implementing new funding and service delivery strategies, largely in an effort to extract efficiency gains through rationalisation of production capacity, for both primary referred and hospital referred laboratory services. Such significant changes to the general medical laboratory services sector are directly impacting the NCSP niche laboratory market resulting in a period of uncertainty and instability.

In addition to the uncertainty and instability in the laboratory sector, the following risks also exist for the NCSP:

- a lack of workforce capacity and mobility,
- provider concerns over the adequacy of funding levels for the services
- the competitive relationship between laboratories and referrers
- the ad-hoc nature of multi-disciplinary meetings in some regions
- limited laboratory input into programme coordination or health promotion activities in the regions
- limited investment into workforce development by providers.

The NSU has reviewed its requirements for the provision of laboratory services to the NCSP, taking into consideration technological changes to the services that will be introduced over the next five years and also looked at options for ensuring cost effective continuity of supply of services by laboratory providers to the Programme.

The NSU is currently assessing the use of liquid based cytology (LBC), Human Papillomavirus (HPV) testing and automation in the delivery of laboratory services to the Programme.

The current service provision model is an open model which allows any medical laboratory provider in New Zealand who is interested in delivering services to the NCSP to do so providing they meet the NCSP Laboratory Services Agreement terms and conditions. It is up to each Provider to secure referrals to enable them to undertake and deliver the testing services.

In November 2006, the NSU consulted with laboratories, DHBs, professional bodies and consumer groups on a range of options for the purchasing of NCSP Laboratory Services. There was high degree of consistency between the submissions received, with a clear preference for a regional configuration of laboratories (see Appendix 1). As an outcome of that consultation, the NSU has chosen to consult further on two regional configuration options. The NSU proposes that the laboratory regions could either be based on the four Regional Cancer Networks regions established under the Cancer Control Strategy or the six Regional Cancer Centres regions. Once the number of regions has been determined a tendering process will be run for each region.

This Strategy sets out the respective strengths and weaknesses of the four and six region options and requests feedback on your preferred option and the identification of any issues you may have with the implementation of either option. This Strategy is being circulated to the laboratories, DHBs, professional bodies and consumer groups involved in the first round of consultation and also to local Primary Health Organisations, NCSP Independent Service Providers, DHB colposcopy services and NCSP Regional Services. Feedback is requested by 5 October 2007, addressed to:

NCSP Laboratory Strategy
National Screening Unit
Ministry of Health
Private Bag 92522
Wellesley Street
AUCKLAND.

Email: marc_smith@moh.govt.nz.

An electronic version of the Strategy is available on the NSU's website at: <http://www.nsu.govt.nz>.

The NSU expects to make a final decision on the Strategy by 30 November 2007. This Strategy focuses on the provision of gynaecological cytology services and excludes the provision of colposcopy and gynaecological histology services.

2 Introduction

The purpose of this Strategy is to describe the future provision of gynaecological cytology laboratory services to the National Cervical Screening Programme (NCSP).

The National Screening Unit's (NSU) vision 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.'¹

The NSU has a number of core functions which includes the purchase of programme services in accordance with provider agreements and robust financial and contract management. Since July 2001 the NSU has contracted and funded the provision of gynaecological cytology and histology services through community and hospital laboratories.

In October 2005, the NSU published *Improving Quality: A Framework for Screening Programmes in New Zealand*. Requirement six of that document relates to appropriate resources, including diagnostic and treatment services. Under this requirement the NSU 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.

Under requirement six, providers are 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 changes currently occurring in the medical laboratory marketplace are impacting on providers of laboratory services to the NCSP. Impacts on providers include reductions in the number of providers and significant proportions of the workforce either leaving or threatening to leave their professions. This in turn is impacting on the delivery of the service in some regions, such as increased turn around times. Therefore, the NSU has

¹ National Screening Unit (2003). Strategic Plan 2003-2008.

reassessed its purchasing strategy to ensure services to the NCSP are able to be secured that meet its ongoing requirements.

The range of laboratory services purchased by the NSU is narrow and represents less than 6% of the estimated total value of publicly funded medical laboratory services. However, the NSU is responsible for purchasing all gynaecological cytology and practically all gynaecological histology services.

Laboratory services required to support the NCSP must be stable, sustainable, safe and cost effective and in addition must be flexible and adaptable to take advantage of future technological advances. The NSU will ensure that high quality laboratory services are maintained.

3 Background and Context

Laboratory services market

The restructuring of the health care sector in 2001, resulted in the DHBs assuming responsibility from the former HFA for the funding of all diagnostic laboratory services. Laboratory services pertaining to the NCSP were unbundled and transferred to the NSU.

At the time of the establishment of the DHBs there were two distinct markets for diagnostic laboratory services with fundamentally different funding structures: primary care and secondary care medical laboratory services.²

The primary care (or community) medical laboratory services provided analysis of samples referred by general practitioners (GPs), private specialists and private hospitals. The primary care related tests were predominately carried out by privately-owned community laboratories. The laboratory tests listed in the National Community Schedule (approx 160 individual tests) were funded on a fee-for-service basis with varying prices across the country.

The secondary care diagnostic services were mostly located at DHB hospital laboratories. Their primary function was to provide testing for DHB-owned inpatient and outpatient services and the provision of these services were generally bulk funded.

NCSP laboratory services

The laboratory services contracted to the NSU relate to gynaecological cytology and histology services which are delivered from a number of privately owned community laboratories and DHB owned public hospital laboratories. The services funded by the NCSP Laboratory Services Agreement relate to community referred specimens and include specimens associated with private colposcopies.

The NSU also funds DHBs for the provision of colposcopy services for women referred through the Programme. These services are provided as a hospital out patient service and any associated gynaecological cytology or histology testing is funded as part of the colposcopy service.

When the NSU assumed responsibility for funding NCSP related services it implemented new Service Agreements with providers who had the capability to meet the contractual terms and conditions, including meeting the specified minimum volumes associated with the NCSP Operational Policy and Quality Standards. The services were funded on a fee-for-service basis. The NSU implemented a national pricing regime for gynaecological cytology tests, while preserving regional prices for histology tests.

As a consequence of the historic funding split between the primary referred services and secondary services, privately owned community laboratories had the direct

² Pauls, R. (2002). Options for Reform of Diagnostic Laboratory Service Markets.

relationship and specimen collection mechanisms in place with primary healthcare professionals and were receiving and processing the bulk of the gynaecological cytology volumes.

The majority of DHB hospital laboratories and a small number of community laboratories could not meet the minimum throughput volumes and were not offered NCSP Laboratory Service Agreements for gynaecological cytology. However, most DHB hospital laboratories were contracted to provide community referred cervical histology services, as the provision of this service is not constrained by minimum volumes.

The introduction of the NCSP Laboratory Services Agreements resulted in an initial rationalisation of the number of laboratories and number of providers of gynaecological cytology laboratory services across the country. The Agreements did not place any restrictions on a Service Providers ability to process referred samples originating from any location around the country, unlike the DHB Community Laboratory Agreements which do place restrictions based on their defined geographic areas.

The NSU did not go to tender at the time of the unbundling as laboratories were entitled to provide the services under existing agreements. The NSU's objective at the time was to achieve a successful unbundling of the service and a smooth transition to new Agreements containing enhanced obligations. The focus was more on the provision of a high quality service with appropriate accountability than on testing the price of the service.

The NSU currently has NCSP Laboratory Agreements in place for gynaecological cytology with eight providers (9 laboratories), comprising:

- two DHB owned laboratories (Auckland and Christchurch)
- seven private providers who operate community laboratories (Auckland, Tauranga, Palmerston North, Wellington, Christchurch and Dunedin).

In addition, the NSU has NCSP Laboratory Agreements in place with fourteen DHB owned laboratories and two privately owned community laboratories (New Plymouth and Whangarei) (covering just gynaecological histology).

All current NCSP Laboratory Service Agreements will expire on the 30 June 2009.

Market changes

The current laboratory market is in a state of change and consolidation of the number of participants is occurring. The historic split between providers of community referred and secondary referred services is disappearing with some merging of the providers on a regional basis brought about by DHBs' new tendering / contracting arrangements.

A number of DHBs have now contracted out the provision of their secondary care laboratory services and community referred diagnostic laboratory services to private laboratory service providers. Some DHBs have entered into risk sharing arrangements with the successful providers, in some cases capping the funding stream for service provision.

To date, privately owned community laboratories have sought revenue growth by competing for volume. Volume growth has been achieved through developing close working relationships with primary care referrers, having sample collection facilities conveniently located next to or part of the primary care referrers practice, increasing the range of tests available and through the acquisition of competing laboratories.

Over the past 10 years automation has enabled laboratories to process samples more efficiently. In comparison however, gynaecological cytology has remained relatively labour intensive and requires a highly skilled workforce.

Workforce development

A key requirement for successful screening programmes is a well-trained, competent workforce. The NCSP developed a Workforce Development Strategy with an emphasis on the laboratory workforce. The Strategy includes piloting an individual competency assessment for staff involved in interpreting cytology, provision of funding for the New Zealand Society of Cytology Scientific Meeting, funding for the 'Challenges in Cytology' workshops and a National Gynaecological Cytology Training Centre.

A stable workforce with long-term career prospects creates an environment that is attractive to recruit to and retain staff. Staff should be given the opportunity for ongoing further education, supported through their orientation time with ongoing competency testing, continuing education and training. In addition, study grants towards a 4th year cytology options paper are offered as well as vocational registration programme in gynaecological cytology with Clinical Training Agency funding available for new graduates commencing a career in gynaecological cytology.

Redevelopment of the NCSP-Register

The NSU expects the redeveloped NCSP-Register to deliver new functionality that will strengthen and streamline current business processes while enabling new methods of interaction with key stakeholders and provider organisations. The specific improvements are anticipated to be:

- elimination of multiple and manual points of data entry and re-entry
- implementation of data quality checks at source
- secure web-based access to cervical screening histories
- integration with provider systems and support for secure web-based access
- streamlined, electronic cancer registry interface
- use of centralised data repositories available within the sector
- specific support for population-based screening
- reduced costs for providers, smear takers and the NCSP.

4 Future Service Enhancements

The NSU is developing policy on the use of liquid based cytology (LBC), Human Papillomavirus (HPV) testing and the use of automation within the NCSP. These enhancements will improve on the quality of current laboratory services.

These developments will alter the NSU's requirements for laboratory services and require new funding models to cover the provision of the enhanced services.

The introduction of new technologies to the NCSP will generate the need to review workforce requirements. The impact of LBC, HPV testing and automation is expected to lead to a reduction in the number of screeners required.

The introduction of LBC, HPV testing and automation may increase the cost of NCSP Laboratory Services. These will be offset by a corresponding savings to the NCSP through the reduction in referrals to colposcopy and efficiencies achieved through the redevelopment of the NCSP-Register.

Liquid Based Cytology (LBC)

There are currently two proprietary products in use in New Zealand for LBC (ThinPrep and SurePath) and any decision to fund LBC within the NCSP will involve full consideration of these products. Some submissions from the November 2006 consultation on the Strategy queried the need to continue with the two products within New Zealand. There would be potential economies of scale from adopting only one technology, however, there would be risks from having a monopoly supplier. Monitoring could be enhanced if technologies were consistent across laboratories. The NSU has decided to leave it up to a laboratory to choose the LBC product for its region, subject to IANZ accreditation, to ensure contestability between products.

Women who choose to utilise LBC are usually either required to pay for the vial used (as in the case of ThinPrep) or the laboratory funds the cost of the vial (as in the case of Canterbury Health Laboratories using SurePath). Some women and their smear takers who currently have access to SurePath may lose that access (eg, those in some areas of the North Island) as a result of the new service configuration.

The NSU is investigating the benefits to the Programme of utilising LBC and has commissioned an economic evaluation.

Human Papillomavirus (HPV) Testing

The introduction of HPV testing may require multiple laboratory involvement for the processing of the samples. Laboratory A may have the capability to process and interpret the LBC smear sample but may need to send a sub-sample or swab off to laboratory B to carry out the HPV test.

Depending on the type of HPV testing adopted the HPV test may need to be carried out by molecular biology scientists rather than cytology scientists and the laboratories

providing molecular biology services may in some cases differ from those who are currently providing NCSP Laboratory Services.

At this early stage it is thought that the annual volume of these tests would be in the vicinity of 30,000 – 40,000. The volume of HPV testing required may lead the NSU to restrict the number of laboratories that provide this service to the NCSP, to ensure the quality of the service.

A policy on HPV testing has yet to be developed, however the test is likely to be used as a secondary test in limited circumstances following an LBC test, for example for the management of abnormal smears or for proof of cure.

HPV vaccine

It is not anticipated that the HPV vaccine will significantly impact upon the requirements for NCSP Laboratory Services over the next five to 10 years. However, in the longer term the rate of abnormal smears is expected to reduce and the starting age for screening may be raised, which will have quality and workforce implications.

Automation

The introduction of gynaecological cytology automation may increase costs but will decrease workforce requirements for laboratories providing services to the NCSP. Overseas studies suggest that the minimum cost-effective size for introducing automated assisted screening is 50,000 LBC slides per year. However, the economies of scale continue to increase above 50,000. This is in part due to the pricing models based on a per-test price rather than based on fixed and variable costs, with cheaper prices available to higher volume laboratories.

The NSU is currently examining the potential use and implications of automation within the Programme, including changes to the NCSP Operational Policy and Quality Standards.

5 Risks to NCSP Laboratory Service Provision

Any purchasing strategy needs to mitigate existing risks whilst not creating new ones.

Stable providers

The provision of NCSP Laboratory Services represents a small niche segment of the overall diagnostic market. Laboratories providing these services to the NCSP are also servicing the much larger primary referred diagnostic laboratory market funded by DHBs. The DHBs are making decisions on restructuring regional diagnostic laboratory markets without necessarily taking into consideration the implications and ramifications on the provision of services to the NCSP. The NSU has to ensure that it has strategies in place to manage the fall out from the restructuring should changes directly impact on laboratories or providers currently servicing the NCSP.

Standalone boutique laboratories servicing the specific needs of the NCSP would provide protection from changes occurring in the broader laboratory services market place, however, this approach has not been tried in New Zealand. In Australia the Victorian Cytology Service (VCS) is an example of this type of provider. VCS is located in the grounds of a public hospital and is the largest single laboratory in Australia reporting gynaecological cytology, examining approximately 280,000 cervical smears per year. VCS's courier service collects smears and delivers reports in the greater Melbourne area and major Victorian country centres. Another example is the San Diego Pathologists Medical Group in the United States, which provides gynaecological and non-gynaecological histology and cytology laboratory services.

However, VCS has a record of staff recruitment difficulties due to the narrow scope of the work provided with both pathologists and scientists preferring a broader range of work than just gynaecological cytology. VCS does provide a useful training ground for staff who then move on to other laboratories in the region and occasionally return to VCS. Such a model would be less applicable in New Zealand, where the population is more geographically dispersed. The San Diego Pathologists Medical Group may therefore be a more useful model as it offers staff variety through testing both gynaecological and non-gynaecological histology and cytology specimens.

Workforce availability

As mentioned previously, the NCSP laboratory services are labour intensive and restructuring of the broader laboratory market may result in resourcing difficulties if volumes have to be shifted to alternate laboratories in geographically spread locations.

The introduction of new technology in the form of automation may mitigate some of the risk associated with the lack of workforce mobility as the overall testing process is expected to be less labour intensive, although this has yet to be verified. It is also possible that automation may not be as cost effective as increasing the size of the current workforce.

HPV testing may require an expansion of current molecular biology services.

Sustainable funding

Providers have argued that the unbundling of NCSP Laboratory Services from the National Community Laboratory Schedule has meant that the services can no longer be cross subsidised by funding from other tests on the Schedule and should be funded at a level that reflects the true cost of providing these services.

The basis of the fee-for-service prices covering NCSP Laboratory Services are historic and no in-depth analysis has been undertaken to test their reasonableness, nor has any competitive tendering occurred to test market pricing for the services.

Providers have been very reluctant to sign up to NCSP Laboratory Services Agreements for a term of longer than one year. It is presumed that this stance is being taken by providers in the belief that it is the only leverage they have in trying to achieve an increased price offer from the NSU.

Whilst questions are being raised by providers about the adequacy of the funding for Laboratory tests some providers have continued to seek out volume growth opportunities outside their home regions.

Quality relationships

Laboratories provide support and training to smear takers, NCSP Regional Services, and providers of smear taker training and update courses. Laboratory staff are also involved in multidisciplinary meetings with clinicians to review results from colposcopy, in accordance with NCSP Operational Policy and Quality Standards.

In some regions the multi-disciplinary meetings (eg, for cyto/histo correlation) occur in an ad-hoc manner because of competitive arrangements or because of difficulties in holding face to face meetings due to geographical distances. In other regions there is little collegial response leading to inconsistent messages. This reduces the degree of continuous quality improvement undertaken and can impact on the clinical management of women.

There is also limited regional influence or input into programme coordination or health promotion activities in some regions. This is partly due to the geographical splits and the presence of multiple providers in a region.

Efficient specimen collection

Laboratories gain referrals by developing and providing convenient specimen collection facilities and systems for referrers and their patients covering the broad range of community referred diagnostic laboratory tests. The collection of NCSP specimens from referrers utilises the same collection systems as for all other community referred diagnostic laboratory test specimens and samples. A laboratory wishing to compete for volumes may need to duplicate existing collection systems if it wishes to secure volumes, leading to cost and resource inefficiencies in the service.

If a laboratory doesn't hold an NCSP Laboratory Services Agreement, then it collects the NCSP specimens from the referrers in its catchment and sends them to another laboratory (one holding an NCSP Laboratory Services Agreement) for processing. Specimens can therefore be collected in one region and processed and read elsewhere in the country.

Under the current contracting arrangements the NSU does not 'control' the collection and allocation of specimens to providers or to their laboratories. The NSU could impose geographical boundaries on laboratories in a similar way to that used by DHBs for community laboratory services.

Workforce development

Sector investment into workforce development has been limited in the past. Due to a shortage of the cyto-screening workforce staff, regional 'poaching' has been occurring with a wage war that has driven salaries up. Retention of senior staff is a problem as the rates of pay compared to international rates mean staff are attracted overseas. In an uncertain laboratory market with no guarantee of business, and a fee-for-service funding structure, there is a restrictive environment for continued workforce planning and development.

To partially meet the training gap identified in the sector the NSU has contracted with Canterbury Health Laboratories, in a joint venture with Medlab South, to deliver a national gynaecological cytology training service.

6 Key Requirements for Future NCSP Laboratory Services

Underlying assumptions

In developing this strategy, the NSU has made a number of assumptions:

- the NCSP is a national programme requiring nationally consistent service provision
- service provision will be provided by laboratories located in New Zealand
- there is no mandate for the NSU to acquire a laboratory and establish it as the NCSP national testing laboratory where all testing for the Programme would be directed, ie, move service provision in-house.

Stability

The NSU wishes to secure a stable environment that supports long term mutually beneficial working relationships between providers, the NSU and stakeholders in the NCSP. This implies stability of providers and the workforce that is required to deliver the services.

The NSU's purchasing/funding strategy for NCSP Laboratory Services must help ensure stability is achieved despite requiring niche services within a much larger and currently changing laboratory marketplace.

The NSU assumes that providers prefer:

- certainty and clarity relating to service provision obligations and responsibilities
- certainty as to revenue and a fair return on their investment in the resources used to deliver the services.

Sustainability

For a stable environment to exist the services must be sustainable over time. The factors that influence sustainability are:

- providers who are committed to providing the service
- providers with adequate resources to deliver the services including access to a qualified and skilled workforce
- an adequately funded service that enables re-investment in resource development and innovation
- services being delivered efficiently and effectively.

Quality and safety

For population health screening programmes to be widely accepted and valued they must be of high quality and must be delivered safely. Minimum quality standards must be set and monitoring undertaken to ensure the standards are being met on an ongoing basis.

Cost-effectiveness

The NSU must ensure that public monies expended on the NCSP are used in a cost effective manner. The NSU must purchase services in a manner that ensures the government maximizes value for public money and contract in a manner that ensures there are high levels of accountability.

To date benchmarking of the actual cost of services has not been feasible. Under the current service provisioning model the NSU maintains a national price for gynaecological cytology on a fee for service basis and competitive tendering of service provision has not occurred. As a consequence, pricing for the service hasn't been tested in a contestable environment.

If the NSU moves away from the current provisioning model to one where the smear volumes are directed to particular regional laboratories the NSU could either retain the current national pricing regime or move to competitive tendering for specified smear volumes.

The NSU encourages the use of new technology and innovation in the provision of the services if it is cost effective to do so for the overall Programme.

7 New Service Configuration

In November 2006, the NSU consulted laboratories, DHBs, professional bodies and consumer groups on a range of options for the purchasing of NCSP Laboratory Services. The following service delivery model options were identified for consideration:

- Option 1.** One centralised laboratory processing and reading all cytology specimens.
- Option 2.** Regional laboratories processing and reading all cytology specimens for their respective geographic regions.
- Option 3.** One centralised laboratory processing all cytology specimens with slides being directed to regional laboratories for reading and reporting.
- Option 4.** Services provided by any laboratory that meets NCSP service specifications and minimum standards for processing and reading of specimens. (This option reflects the current service delivery model).
- Option 5.** DHBs contract with laboratories for the gynaecological cytology specimens from their regions. DHBs would direct where specimens from their regions would be processed (provided the laboratory met the NCSP Operational Policy and Quality Standards).

There was a high degree of consistency between the submissions received, with a clear preference for a regional configuration of laboratories. As an outcome of that consultation, the NSU has chosen to consult further on two regional configuration options. The NSU proposes that the NCSP Laboratory Services regions will either be based on the four Regional Cancer Networks regions (see Table 7.1) being implemented under the Cancer Control Strategy or the six Regional Cancer Centres regions (see Table 7.2). This decision was based on the submissions on the consultation document (see Appendix 1) and an analysis of future requirements for the NCSP.

Once the number of regions has been determined, a tendering process will be run for each region in 2007/08.

Table 7.1: Regional Cancer Network Regions

Regional Cancer Network Regions	DHB Regions	Cytology Volumes (2004)³	Percentage of Total Volume
Northern District	Northland, Waitemata, Auckland, Counties Manukau	145,078	36.3%
Midlands	Waikato, Bay of Plenty, Lakes, Taranaki, Tairāwhiti	76,668	19.2%
Mid-Central	Hawke's Bay, MidCentral, Whanganui, Wairarapa, Hutt Valley, Capital and Coast	82,231	20.6%
South Island	Nelson Marlborough, West Coast, Canterbury, South Canterbury, Otago, Southland	95,729	23.9%
Total		399,706	100.0%

Table 7.2: Regional Cancer Centre Areas and Volumes

Regional Cancer Centre Regions	DHB Regions	Cytology Volumes (2004)⁴	Percentage of Total Volume
Auckland	Northland, Waitemata, Auckland, Counties Manukau	145,078	36.3%
Waikato	Waikato, Bay of Plenty, Lakes	60,463	15.1%
MidCentral	Taranaki, Tairāwhiti, Hawke's Bay, Whanganui, MidCentral, Wairarapa	53,888	13.5%
Wellington	Hutt Valley, Capital and Coast	44,548	11.1%
Christchurch	Nelson Marlborough, West Coast, Canterbury, South Canterbury	66,218	16.6%
Dunedin	Otago, Southland	29,511	7.4%
Total		399,706	100.0%

A number of benefits and risks were identified for a regional configuration of NCSP Laboratory Services and these are described below.

Determination of Boundaries

There are a number of factors to be considered in deciding the optimal determination and permeability (whether laboratories could provide services from outside of a region) of regional boundaries for NCSP Laboratory Services, including:

- efficient specimen collection
- co-location of ancillary and related testing

³ National Screening Unit (2007). NCSP Annual Monitoring Report 2004.

⁴ National Screening Unit (2007). NCSP Annual Monitoring Report 2004.

- participation in multidisciplinary meetings and liaison with smear takers and NCSP Regional Services
- contestability
- boutique versus integrated laboratories
- alignment with Cancer Control Strategy.

Specimen Collection

Ideally, specimen collection systems should be cost-effective, minimise transportation time and handling of specimens, and one person should be accountable for the oversight of the process in each region. To be cost-effective, NCSP Laboratory Services regions should correspond as closely as possible with existing specimen collection systems. Most DHBs or groups of DHBs (eg, Waitemata, Auckland and Counties Manukau; Bay of Plenty and Waikato; etc) now have only one community laboratory provider collecting specimens within their regions. Therefore, it makes sense for NCSP Laboratory Services regional boundaries to be based upon DHB or groups of DHBs' regions to simplify specimen collection.

It would not be cost-effective to set up separate NCSP specimen collection systems in parallel, particularly systems that would be collecting specimens as often as community laboratories. NCSP Laboratory Service providers will still be able to subcontract specimen collection to other providers in areas that they don't collect from directly, eg other community laboratories.

Ancillary testing

It is desirable for all specimens from the same patient episode to be processed at the same laboratory if possible. Ancillary tests include cervical histology specimens, microbiology swabs, and tests for HPV, chlamydia, herpes, etc. This allows a laboratory to provide a more comprehensive report and clinical advice to the referrer. This also allows a referrer to more easily follow up overdue results. Therefore, NCSP Laboratory Service providers should be based within the region they serve to maximise the potential collocation of ancillary tests.

Multidisciplinary meetings and liaison

Staff from NCSP Laboratory Service providers are required to participate in regular multidisciplinary team meetings and liaise with smear takers and NCSP Regional Services. Participation and liaison are likely to be increased if participants do not have large distances to travel. Therefore, NCSP Laboratory Service providers should be based within the region they serve to maximise participation in multidisciplinary meetings and liaison with smear takers and NCSP Regional Services.

Contestability

NCSP Laboratory Services should be openly contestable to ensure that services are cost-effective and of high quality. However, contestability can lead to disruption of relationships with referrers and disincentives to investment. One solution is to extend

the length of the Agreements to minimise the number of potential disruptions and provide for better returns on investment.

Contestability for NCSP Laboratory Services is impacted by the number of providers able to enter the market. If the NSU were to limit new providers to laboratories already or willing to establish the service within a geographic region this would reduce contestability as opposed to allowing laboratories to compete for work from geographic regions that they were not sited in.

The number of regions decided upon may conceivably reduce the number of providers who would be able to participate in the subsequent contracting rounds. However, NCSP Laboratory Services can be potentially delivered from any existing community or hospital laboratories of significant size, which would continue to be able to bid for NCSP Laboratory Services in subsequent rounds.

Arguably, fewer regions would support a higher number of potential providers within each region, although there may be fewer providers with the potential capacity to tender for a larger volume of specimens. Therefore, any existing medical laboratory will be eligible to tender for the NCSP Laboratory Service within their respective region.

The NSU could have proposed to tender NCSP Laboratory Services on a DHB by DHB basis. This would have allowed a provider to enter new markets over time. However, the NSU considers that such an approach would lead to inefficient specimen collection and would not be conducive to developing effective relationships with other regional stakeholders.

There is a possibility that there may be no hospital providers of NCSP Laboratory Services as a result of the tendering process. However, the NSU does not propose to discriminate between hospital and community providers in either the first or future tendering rounds.

Boutique versus integrated laboratories

A boutique NCSP laboratory would be one which only provide testing to the NCSP, including gynaecological cytology, histology and HPV testing. An integrated NCSP laboratory would one be sited within an existing community or hospital laboratory and would be processing a range of specimens from local hospitals and / or communities as well as from a NCSP Laboratory Services region.

Boutique NCSP laboratories would have the advantage of being immune to the potential disruption of future DHB laboratory contracting decisions. However, boutique laboratories would not have the same economies of scale as integrated laboratories, particularly if they had separate specimen collection systems. Boutique laboratories may not have access to ancillary test results (eg, gynaecological microbiology swabs), although integrated laboratories may only have access to ancillary tests performed in their respective laboratories. Boutique laboratories would be likely to have staff recruitment and retention problems from the narrower scope of work offered.

The NSU considers that NCSP Laboratory Service providers, to be efficient and sustainable, should be integrated wherever possible. The NSU may allow a NCSP Laboratory Service provider to subsequently become a boutique provider until the

expiry of its NCSP Laboratory Services Agreement, if it were to lose its DHB contract as a result of a tendering process. This decision does not exclude a provider based outside a particular NCSP Laboratory Services region from tendering for a boutique service within that region.

Cancer Control Strategy

Regional Cancer Networks have been established as a result of the New Zealand Cancer Control Strategy (Ministry of Health, 2003) and the New Zealand Cancer Control Strategy Action Plan 2005-2010 (Ministry of Health, 2005).

Although informal collaboration already exists at a regional level, the establishment of regional networks will formally recognize these activities. The networks will facilitate the co-ordination of services across health providers at the primary, secondary and tertiary levels by regularly bringing the various providers and consumer organisations together to ensure effective co-operation and the integration of services, where appropriate. The networks will also provide a mechanism for organisations and people to work with each other to plan and co-ordinate services in line with clearly defined national standards of treatment. As well, they could provide a forum to look at issues that are of particular concern to patients, such as referral patterns, access and service provision.⁵

Regional cancer networks:

- span the cancer control continuum
- are based on regional geographic coverage
- are structured and managed
- incorporate strategic and service level networking
- engage and include all stakeholder organisations.⁶

Aligning each NCSP region with its respective Regional Cancer Network would facilitate the above features and simplify relationships. Regional Cancer Centre boundaries do not all align with Regional Cancer Network boundaries, but are aligned with specimen collection areas of most current DHB community laboratories.

⁵ Ministry of Health (2005). New Zealand Cancer Control Strategy Action Plan 2005-2010, p.7.

⁶ Presentation by John Childs, Principal Advisor Cancer Control, Ministry of Health 'introducing cancer networks across New Zealand' (30 March 2006). Retrieved from the World Wide Web on 4 May 2007 at [http://www.moh.govt.nz/moh.nsf/pagesmh/2408/\\$File/john-childs.ppt](http://www.moh.govt.nz/moh.nsf/pagesmh/2408/$File/john-childs.ppt)

8 Strengths and Weaknesses of Four Regions

Strengths

Strengths identified for the four region configuration include:

- cost-effective automation
- cost-effective HPV testing
- monitoring equivalency
- potential future changes to screening volumes
- support for staff development
- participation in Regional Cancer Networks.

Cost-effective Automation

Overseas studies suggest that the minimum cost-effective size for introducing automated assisted screening is 50,000 LBC slides per year. However, the economies of scale continue to increase above 50,000. This is in part due to the pricing models based on a per-test price rather than based on fixed and variable costs, with cheaper prices available to higher volume laboratories. The four region configuration ensures that cost-effective automation could be introduced in each region.

Cost-effective HPV testing

A policy on human papilloma virus (HPV) testing has yet to be developed, however the test is likely to be used as a secondary test in limited circumstances, for example for the management of abnormal smears or for proof of cure.

The NSU estimates that under the circumstances described above it would require up to 40,000 HPV tests a year. This equates to 769 tests per week. The cost of running the HC2 High Risk HPV DNA test, as an example, begins to be efficient at patient runs above 50 tests a batch. To run this test cost-effectively on a daily basis it would be necessary to limit the test to three equal sized regions (see Table 8.1).

Table 8.1: Frequency of HPV Testing by Number of Regions

Number of Regions	Frequency of HPV Test Batches (per lab per week)*
3	5.1
4	3.8
5	3.1
6	2.6

*assumes approximately 50 tests are done in each batch and laboratory regions are of similar size.

Regional Cancer Network regions are not of equal size, so for the sake of efficiency either fewer laboratories could be processing HPV tests or HPV tests could be run less often. Sending specimens away to other laboratories may not be as efficient or timely as testing less frequently in-house. Table 8.2 and Table 8.3 show the expected volumes of HPV tests if these were run three times a week in the four Regional Cancer Network regions or six Regional Cancer Centres regions. Three times a week was chosen as a benchmark as this would maximise turn around times relative to sending HPV tests away to one or two laboratories nationally who could run the test daily.

Table 8.2: Expected Batch Size of HPV Tests by Regional Cancer Network Region

Regional Cancer Network Region	Percentage of National Volume From Region	Size of HPV Test Batches (3 times per week)*
Northern District	36.3%	93.0
Midlands	19.2%	49.2
Mid-Central	20.6%	52.8
South Island	23.9%	61.3
Total	100.0%	256.3

*Target is >50 per batch

Table 8.3: Expected Batch Size of HPV Tests by Regional Cancer Centre Region

Regional Cancer Centre Region	Percentage of National Volume From Region	Size of HPV Test Batches (3 times per week)*
Auckland	36.3%	93.0
Waikato	15.1%	38.7
MidCentral	13.5%	34.6
Wellington	11.1%	28.5
Christchurch	16.6%	42.5
Dunedin	7.4%	19.0
Total	100.0%	256.3

*Target is >50 per batch

HPV testing would be both efficient and timely in the four region configuration. The NSU may decide to purchase HPV testing from fewer than four laboratories to begin with until actual volumes reach a sufficient level.

Monitoring equivalency

Monitoring providers is easier if there are fewer variables between them. The volumes for the four Regional Cancer Networks regions (see Table 7.1) are not only higher but also show less variation than for the six Regional Cancer Centres regions (see Table 7.2). This lower degree of variation would remove the size factor and resulting economies of scale, which may otherwise mask performance differences. Therefore, for monitoring purposes, the four region configuration may be preferable to the six region configuration, even with a reduced number of regions for comparison.

Individual internal and external quality assurance programmes should ensure that performance variations of individuals are monitored.

Potential Future Changes to Screening Volumes

There are a number of factors that could change the volume of cervical cytology in the next ten to twenty years, including:

- improvements in coverage
- future programme changes (eg, age range, screening interval, HPV vaccine)
- future funding changes (eg, under 20s, short interval rescreening)
- future demographic changes.

The NSU expects NCSP coverage to improve (percentage of women who have been screened within the last three years), particularly for Maori and Pacific women. This would potentially increase gynaecological cytology volumes by 5-10% nationally, particularly in areas with large Maori and / or Pacific populations (eg, Auckland).

The NSU may in the future give consideration to changing the age range and / or screening interval as a result of HPV vaccination and evidence on the progression of cervical cancer. HPV vaccination should ultimately reduce the volume of abnormal smears seen leading to a greater number of women on normal recall and a reduction in the total volume of smears read each year. It is now widely accepted that the progression of cervical intraepithelial neoplasia to invasive cancer is in the order of 10 to 15 years with the majority of premalignant low grade squamous lesions in young women clearing spontaneously and infrequently progressing to invasive cancer. These factors could potentially reduce gynaecological cytology volumes by 5-30%.

The NSU will continue to discourage the screening of women outside recommendations, eg, women under 20 or short interval rescreening (women screened more often than recommended, which is more prevalent in the Auckland region). This could potentially reduce gynaecological cytology volumes by up to 10%.

The working age (15-64) population of New Zealand is expected to increase by 11% over the next 20 years⁷. However, two thirds of that growth is expected to be in the Auckland region, whose population is expected to grow by 46% between 2001 and 2026⁸.

Therefore, it would be reasonable to assume that overall gynaecological cytology volumes are likely to remain stable or decrease slightly in the long term, except in the Auckland region where volumes are expected to rise.

A NCSP Laboratory Services provider in the Auckland region may achieve better economies of scale than laboratories in other regions, particularly over time, but would create a greater risk to the Programme if the provider failed and would become less equivalent to other laboratories for monitoring purposes. One option would be to divide the Auckland region in half, however this would not have been efficient (in terms of specimen collection) or improve quality (except in terms of back-up and monitoring).

⁷ Statistic New Zealand (16 December 2004). National Population Projections 2004 (base) – 2051.

⁸ Statistics New Zealand (28 February 2005). Subnational Population Projections 2001(base) – 2026 Update.

The four region configuration would ensure that services would remain relatively viable if the volumes of specimens were to reduce slightly over time.

Support for Staff Development

A smaller number of larger laboratories should provide a greater capacity to take on trainees and provide greater continuing professional development opportunities than the current configuration of laboratories. Four regional laboratories should be able to support greater staff development.

Participation in Regional Cancer Networks

Some Regional Cancer Centre regions overlap with more than one Regional Cancer Network regions. Therefore, four NCSP Laboratory Services regions aligned with Regional Cancer Network regions would facilitate better engagement with these Networks.

Weaknesses

Weaknesses identified for the four region configuration include:

- distribution of current workforce and future employment opportunities
- providing back-up for provider failure
- ancillary testing
- multidisciplinary meetings and liaison with smear takers and NCSP Regional Services.

Distribution of current workforce and future employment opportunities

Currently the NCSP cytology workforce is located in six cities. The four region configuration would reduce the location of these laboratories to four cities. A proportion of this workforce may be unwilling to change employers or move cities. This would be a particular problem in the South Island, which currently processes a significant volume of specimens from the North Island.

A proportion of the workforce, from time to time, shift around the country for job opportunities, lifestyle or family reasons. Reducing the number of cities would provide less opportunity to move between cities while maintaining a career in cervical cytology.

Both these risks may lead to a workforce shortage. This risk may in part be reduced by the introduction of automation in the long term. However, in the short to medium term there is also a potential workforce shortage due to the number of expected retirements in the next five years. The NSU will examine ways it can support the workforce to adjust to the new service configuration.

The reduction in the number of laboratories processing gynaecological cytology could have a negative impact on the recruitment and retention of cytology staff in cities which

do not have a locally based NCSP Laboratory Service provider. Economies of scale may also be reduced in cytology departments without gynaecological cytology.

The NSU will examine mechanisms to support the workforce during the transition period as part of its workforce strategy.

Providing Back-up for Provider Failure

If one regional laboratory's performance became unsatisfactory, eg, through staff recruitment and retention issues then some / all of their work could be sent to the other regional laboratories until the performance failure was addressed or a new provider found. The larger the volumes each lab is processing the harder it would be to reallocate these volumes across the other regional laboratories, without significantly impacting on their own performance. However, larger regional laboratories may also be less vulnerable to provider failure due to temporary staffing fluctuations.

Ancillary Testing

From a referrer's perspective, it may be desirable for all specimens from the same patient episode to be processed at the same laboratory if possible. Ancillary tests relating to cervical cytology can include cervical histology specimens, microbiology swabs, and tests for HPV, chlamydia, herpes, etc. This allows a laboratory to potentially provide a more comprehensive report and clinical advice to the referrer. Fewer ancillary tests are likely to be done in the same laboratory under the four region configuration.

Multidisciplinary Meetings and Liaison

Staff from NCSP laboratories are required to participate in regular multidisciplinary team meetings and liaise with smear takers and NCSP Regional Services. Participation and liaison may decrease if participants have larger distances to travel. The four region configuration may increase the travelling distances in some regions.

Strengths and Weaknesses of Six Regions

Strengths

Strengths identified for the six region configuration include:

- distribution of current workforce and future employment opportunities
- providing back-up for provider failure
- ancillary testing
- multidisciplinary meetings and liaison with smear takers and NCSP Regional Services.

Distribution of current workforce and future employment opportunities

Currently the NCSP cytology workforce is located in six cities. The six region configuration would be unlikely to change the number of cities with laboratories providing NCSP Laboratory Services.

A proportion of the workforce, from time to time, shift around the country for job opportunities, lifestyle or family reasons. Maintaining the number of cities at six would provide more opportunity to move between cities while maintaining a career in cervical cytology.

In the short to medium term there is likely to be a potential workforce shortage due to the number of expected retirements in the next five years. The six region configuration is therefore more likely to ensure retention of the current workforce.

Providing Back-up for Provider Failure

If one regional laboratory's performance became unsatisfactory, eg, through staff recruitment and retention issues then some/all of their work could be sent to the other regional laboratories until the performance failure was addressed or a new provider found. The smaller the volumes each lab is processing the easier it would be to reallocate these volumes across the other regional laboratories, without significantly impacting on their own performance. The six region configuration is therefore more able to support provider back-up.

Ancillary Testing

From a referrer's perspective, it may be desirable for all specimens from the same patient episode to be processed at the same laboratory if possible. Ancillary tests relating to cervical cytology can include cervical histology specimens, microbiology swabs, and tests for HPV, chlamydia, herpes, etc. This allows a laboratory to potentially provide a more comprehensive report and clinical advice to the referrer. More ancillary tests are more likely to be done in the same laboratory under the six region configuration as it is more likely that the same laboratory that is collecting and

testing the community laboratory specimens will also be the NCSP Laboratory Services provider. However, this assumes that the major community laboratory in the region is also the NCSP Laboratory Services provider, which may not always be the case.

Multidisciplinary Meetings and Liaison

Staff from NCSP laboratories are required to participate in regular multidisciplinary team meetings and liaise with smear takers and NCSP Regional Services. Participation and liaison are likely to be increased if participants do not have large distances to travel. Travel distances would be shorter for some health practitioners in the six region configuration.

Weaknesses

Weaknesses identified for the six region configuration include:

- cost-effective automation
- cost-effective HPV testing
- monitoring equivalency
- potential future changes to screening volumes
- support for staff development
- participation in Regional Cancer Networks.

Cost-effective automation

Overseas studies suggest that the minimum cost-effective size for introducing automated assisted screening is 50,000 LBC slides per year. However, the economies of scale continue to increase above 50,000. Under the six region configuration only some NCSP Laboratory Services providers may find it cost-effective to implement automation. This is likely to lead to wider performance variations between laboratories and differing economies of scale. One option could be to allow NCSP Laboratory Services regions to merge at a later date to allow the introduction of automation. However, the NSU would prefer to set the foundations now rather than make further changes at a later date. This would also give providers greater certainty to then make long term capital investments.

Cost-effective HPV testing

A policy on human papilloma virus (HPV) testing has yet to be developed, however the test is likely to be used as a secondary test in limited circumstances, for example for the management of abnormal smears or for proof of cure.

The NSU estimates that under the circumstances described above it would require up to 40,000 HPV tests a year. This equates to 769 tests per week. The cost of running the HC2 High Risk HPV DNA test, as an example, begins to be efficient at patient runs

above 50 tests a batch. To run this test cost-effectively on a daily basis it would be necessary to limit the test to three equal sized regions (see Table 8.1). HPV testing is unlikely to be efficient or timely in almost all of the six regions (see Table 8.3) and would therefore need to be sent away to one or two laboratories nationally.

Monitoring equivalency

Monitoring providers is easier if there are fewer variables between them. The volumes for the four Regional Cancer Networks regions (see Table 7.1) are not only higher but also show less variation than for the six Regional Cancer Centres regions (see Table 7.2). This lower degree of variation would remove the size factor and resulting economies of scale, which may otherwise mask performance differences. Therefore, for monitoring purposes, the six region configuration may be less preferable to the four region configuration, even with a greater number of regions for comparison.

Potential Future Changes to Screening Volumes

There are a number of factors that could change the volume of cervical cytology in the next ten to twenty years, including:

- improvements in coverage
- future programme changes (eg, age range, screening interval, HPV vaccine)
- future funding changes (eg, under 20s, short interval rescreening)
- future demographic changes.

The NSU expects NCSP coverage to improve (percentage of women who have been screened within the last three years), particularly for Maori and Pacific women. This would potentially increase gynaecological cytology volumes by 5-10% nationally, particularly in areas with large Maori and / or Pacific populations (eg, Auckland).

The NSU may in the future give consideration to changing the age range and / or screening interval as a result of HPV vaccination and evidence on the progression of cervical cancer. HPV vaccination should ultimately reduce the volume of abnormal smears seen leading to a greater number of women on normal recall and a reduction in the total volume of smears read each year. It is now widely accepted that the progression of cervical intraepithelial neoplasia to invasive cancer is in the order of 10 to 15 years with the majority of premalignant low grade squamous lesions in young women clearing spontaneously and infrequently progressing to invasive cancer. These factors could potentially reduce gynaecological cytology volumes by 5-30%.

The NSU will continue to discourage the screening of women outside recommendations, eg, women under 20 or short interval rescreening (women screened more often than recommended, which is more prevalent in the Auckland region). This could potentially reduce gynaecological cytology volumes by up to 10%.

The working age (15-64) population of New Zealand is expected to increase by 11% over the next 20 years⁹. However, two thirds of that growth is expected to be in the Auckland region, whose population is expected to grow by 46% between 2001 and 2026¹⁰.

It would be reasonable to assume that overall gynaecological cytology volumes are likely to remain stable or decrease slightly in the long term, except in the Auckland region where volumes are expected to rise. Therefore, the six region configuration risks NCSP Laboratory Services becoming less viable over time in most regions.

Support for Staff Development

A larger number of smaller laboratories would provide a lesser capacity in each laboratory to take on trainees and provide fewer continuing professional development opportunities.

Engagement in Regional Cancer Networks

Some Regional Cancer Centre regions overlap with more than one Regional Cancer Network regions. Therefore, six NCSP Laboratory Services regions would make engagement with Regional Cancer Networks more complicated and less efficient.

⁹ Statistic New Zealand (16 December 2004). National Population Projections 2004 (base) – 2051.

¹⁰ Statistics New Zealand (28 February 2005). Subnational Population Projections 2001(base) – 2026 Update.

9 Implementation

The implementation of this Strategy will involve:

- a financial review
- tendering
- transitional planning.

Financial Review

A key requirement for achieving viable and sustainable NCSP Laboratory Services is ensuring that the funding of the services encourages efficiency while allowing a reasonable return on investment. In 2007/08 the NSU will form a working group to design and implement a financial review of NCSP Laboratory Services. The working group will be made up of representatives from the Ministry of Health and NCSP Laboratory Services providers. The working group will look at both the costs of current and future NCSP Laboratory Services and a variety of different funding models that could be used, eg, fee-for-service, risk sharing, population based funding.

Tendering

In 2007/08 the NSU will run a tender process for each of the NCSP Laboratory Services regions. This will be a closed tender as only existing laboratories within each region will be eligible to tender. Successful tenders will be determined by 30 June 2008 and the new Agreements will be effective from 1 July 2009.

Transitional Planning

In 2007/08 the NSU will discuss transitional arrangements with laboratories to ensure continuity of NCSP Laboratory Services through a smooth transition process. Current NCSP Laboratory Services Agreements will then be varied to cover transitional arrangements.

10 Appendix 1: NCSP Laboratory Strategy Feedback

Respondents

Eighteen submissions were received on the National Cervical Screening Programme (NCSP) Laboratory Strategy. There was a good response from laboratories providing NCSP Laboratory Services and relevant professional groups but a comparatively low response from District Health Boards (DHBs) (See Table 1).

Table 1: Submissions by Type of Respondent

Type	Number of Submissions
NCSP Laboratory Services provider	5
Pathologist	1
Professional group (including comments from a NCSP Laboratory Services provider)	1
Professional Group	4
District Health Board	5
Consumer Group	2
Total	18

Preferred Option

Ten submissions expressed a clear preference for option two – regional laboratories processing and reporting all cytology from their respective geographic regions (see Table 2).

Table 2: Preferred Option by Respondent Type

Type	Preferred Option						
	1	2	3	4	5	Combined or alternative options*	No stated preference**
NCSP Laboratory Services Provider		2				3	
Pathologist		1					
Professional group (including comments from a NCSP Laboratory Services provider)		1					
Professional Group		2		1			2
District Health Board		3				1	1
Consumer Group		2					
Total	0	10	0	1	0	4	3

*All combined or alternative options included variations of option two

** Submissions generally acknowledged that option two had the most benefits and least risks

Most submissions considered that option one (a single laboratory) would have workforce recruitment and retention issues as well as limiting the ability of the Programme to compare and monitor laboratory performance.

Most submissions considered that option three (one processing laboratory and regional reading laboratories) would be inefficient and had the greatest risks associated with the transport of specimens.

Most submissions considered that option four (the status quo open market) was no longer sustainable and was often counterproductive.

Most submissions considered that option five (devolvement to DHBs) would lead to regional variation and inconsistency.

General Comments

Submissions generally stated that the implementation of the strategy should be accompanied by a review of the funding of the service to ensure it is not cross-subsidised and is sustainable.

Many submissions preferred that the service remain within general pathology services (rather than standalone) even with sustainable funding. Reasons for this include efficiencies in specimen collection, maintaining regional non-gynaecology cytology services, workforce retention and providing a more complete cytology report if there is access to other relevant test results.

The number of regions preferred ranged from three to six. Some submissions recommended aligning NCSP Laboratory Services regions with the six regional cancer services. Other submissions favoured an increase in the minimum volumes of specimens to determine viable regions. Suggested minimums ranged from 50,000 to 80,000. 50,000 was suggested, partly as a result of a recent Australian automation pilot.

Many submissions preferred an option that produced only a small disruption in current services, which still provided for future improved stability, sustainability and quality improvement.

More detail on the submissions can be found in Table 3.

Table 3: Summary Feedback Table

Key Point	Summary of Feedback
<p>Option 1: one centralised laboratory processing and reading all cytology specimens</p>	<p>Significant workforce issues were identified with this option, particularly:</p> <ul style="list-style-type: none"> • the relocation of the current workforce • retention of staff within a gynaecological cytology only service. <p>Significant quality issues were also identified, including:</p> <ul style="list-style-type: none"> • the difficulty for a single provider to stay consistent • a lack of local comparisons for monitoring • that it would be more difficult to liaise with clinicians and that in future greater interaction between cytologists, histopathologists and colposcopists may be required • that adjunctive tests including microbiology, Chlamydia and HPV testing, and histology should be processed in the same lab to provide a more comprehensive report • the impact on the sustainability of local non-gynaecological cytology and histology services. <p>The following risks were raised:</p> <ul style="list-style-type: none"> • being dependent on a single provider with no back-up • loss of competition leading to decreases in the quality of the service • inability to have more than one technology brand in operation • transportation costs and risks were expected to be higher with the risk of longer delays in testing. <p>Some submissions commented that a private provider would be unlikely to be found given the risks involved and the government would, by default, need to provide the service. Some submissions also suggested that as a “stand alone” service it is likely to be more expensive. One submission was in favour of a single laboratory if economies of scale could not be achieved in more than one laboratory.</p>
<p>Option 2: regional laboratories processing and reading all cytology specimens for their respective geographic regions</p>	<p>Some submissions noted the recent trend towards regionalisation of laboratory services by DHBs and another noted that the geography of New Zealand lends itself to the provision of regional services. The option may also be consistent with a population health approach and PHO Performance Management Programme view. However, the option was criticised by one submission for lacking the necessary mechanism to compel DHBs to consider impacts to the NSU when tendering for laboratory services.</p> <p>Some submissions argued that regional laboratories should be tightly integrated with hospital histopathology laboratories to support staff retention and quality services.</p> <p>There were differing opinions on the number and determination of laboratory regions:</p> <ul style="list-style-type: none"> • 3-4 (one submission) • 4-5 (one submission) • 4-6 regions (two submissions) • >50,000 smears (two submissions) • 80,000 smears (one submission) • Aligned with the six regional cancer services (two submissions)

	<p>The conversion to 100% LBC, HPV testing and the introduction automation were seen as key drivers for the size of regions. Fewer laboratories than the current situation should allow faster uptake of new technologies.</p> <p>The more regions there are:</p> <ul style="list-style-type: none"> • the less the impact on the current workforce in terms of relocation • the more specimens would be able to be sent to another laboratory for quality assurance • the less the impact of a laboratory getting into difficulties. <p>Some submissions suggested that limiting the number of regions would make attending multidisciplinary meetings more difficult unless electronic viewing sessions could be arranged. Limiting the number of regions could also adversely impact on consumers in terms of turn around times and separation of related laboratory tests (eg, microbiology).</p> <p>Some submissions suggested that providers need not be located in the regions they serve, to ensure long-term contestability, and could be tendered on a DHB by DHB basis simultaneously. However, this could reduce the ease of liaison with clinicians. Requiring location of laboratories within geographic regions would limit the ability to compete on price, but having laboratories out of region would increase transport costs and risks, and potential testing delays.</p> <p>One submission argued that a proportion of the total volume could be processed and read in Australia to improve contestability. However, more submissions expressed a clear preference for all NCSP Laboratory Services to be provided in New Zealand.</p> <p>The benefits of regional laboratories were identified as:</p> <ul style="list-style-type: none"> • removal of intraregional competition freeing up resources for service development • keeping the movement of specimens to an appropriate level • enhanced monitoring as regional laboratories would have more comparable case mixes • avoiding the risk of cross-technology incompatibilities • stronger working relationships with referrers on a regional basis • laboratories of sufficient size to support workforce development and training.
<p>Option 3: one centralised laboratory processing all cytology specimens with slides being directed to regional laboratories for reading and reporting</p>	<p>Some submissions commented that this option has few of the advantages of option 2 and most of the disadvantages of option 1, with only small laboratories achieving any cost savings, while for other providers this option would add complexity, risk and cost.</p> <p>The option would have a minimal impact on the current workforce. Depending on the economies of scale for automation there could be fewer processing laboratories than reporting laboratories.</p> <p>Splitting processing from reporting would make it more difficult for GPs to discuss quality issues with multiple laboratories, and would spread responsibility for the service too thinly.</p>
<p>Option 4: services provided by any laboratory that meets NCSP service specifications and minimum standards for processing and</p>	<p>Some submissions suggested that this option:</p> <ul style="list-style-type: none"> • was no longer tenable given the service is subject to the tendering decisions made by DHBs who are not compelled to consider impacts on the NSU • does not support the introduction of new technology • leads to instability • results in inefficient duplication of service components (eg, specimen collection) • may compromise the quality of services provided

reading of specimens	<ul style="list-style-type: none"> consumes effort that could be better directed at improving services. <p>One submission suggested raising the minimum volume to 50,000 but otherwise keeping the status quo as this would support investment in new technologies. Another suggested that regional geographic constraints could be introduced into this option.</p>
<p>Option 5: DHBs contract with laboratories for the gynaecological cytology specimens for their regions. DHBs would direct where specimens from their regions would be processed (provided the laboratory met the NCSP Operational Policy and Quality Standards).</p>	<p>Two submissions considered that the option aligns risk and responsibility. Option 5 combined with option 2 could therefore be the most attractive and achievable option as it would require DHBs to protect the interests of the NSU.</p> <p>However, two other submissions commented that DHBs do not consistently purchase services between regions leading to disincentives for providers in investing in service development. Other submissions claimed that DHBs do not have a good understanding of the complexities of gynaecological cytology services and that the option would require some duplication of resources (eg, several DHBs separately contracting with the same provider).</p> <p>Two submissions were concerned that the NSU would lose control of quality standards, etc.</p> <p>Benefits identified for the option included:</p> <ul style="list-style-type: none"> simplifying the management of laboratory service contract arrangements ensuring the long term provision of quality cytology services are maintained within a region allowing swabs to be processed in the same laboratory as smears.
<p>Preferred Option</p>	<p>Preferences for the options were as follows:</p> <ul style="list-style-type: none"> Option one – no support Option two – ten submissions Option three – no support Option four – one submission Option five combined with option two – one submission (who had good experience with DHBs considering gynaecological cytology as part of community laboratory contract) Option two or five – one submission No stated preference – three submissions (although the submissions generally acknowledged that option two had the most benefits and the least risks). <p>On submission preferred a modified option two, followed by option four, and then option two. The Modified option two was:</p> <ul style="list-style-type: none"> That there are no more than six regions and no fewer than four. These could be aligned with the regional oncology centres. The more centres there are, the less impact this will have on staff that currently provide this service, as they are more likely to find employment near where they live. Provider laboratories need not be located in the regions they serve but must meet NCSP Operational Policy and Quality Standards. This would ensure that there is contestability for each regional market but would remove the contestability that is currently within the market. Sample collection and transport should be dealt with in any change in this service and this would be important in the modified option we envisage. <p>One submission proposed the following alternative option:</p> <ul style="list-style-type: none"> Creation of a Cervical Screening Agency that would act as a service co-ordinator and directly fund laboratory providers. A network of several larger regional laboratories tightly integrated with hospital histopathology laboratories and with ring-

	<p>fenced funding for cervical cytology and other related analyses.</p> <ul style="list-style-type: none"> • Creation of a national grid for CSP laboratory capacity with laboratory systems able to operate seamlessly with tightly aligned business processes and IT systems. • The ideal laboratory providers will all have a similar case mix of abnormalities and primary and secondary referred smears. All will have the same / standardised technology and common method and procedure documents for accreditation. • The provision of the service should be managed as an autonomous business unit.
<p>Financial review</p>	<p>Many submissions agreed that it is essential that laboratory services are appropriately funded and resourced in order to provide high quality services. The NCSP should undertake an analysis of the fee for service prices and market pricing for services given that current levels are historic and appear to be creating issues in contracting for laboratory services. It will be important to ensure that cross subsidisation within public provider organisations is addressed otherwise the government overall will not reap the maximum gains from the tender process.</p> <p>The concept of funding on the basis of competitive tendering is much less likely to achieve the “stated aim” than an independent costing of the test on a realistic basis reaching a price that reflects the actual cost of doing the test and allows for the training, continuing education and monitoring activities associated with doing the test. An agreed national cost per test would be more likely to yield the outcomes desired, and perhaps avert further expensive consequences of suboptimal testing.</p> <p>Cost-effectiveness must not be used to drive prices down at the expense of quality. Quality laboratory services must be adequately and appropriately funded. Competitive tendering to test market pricing is an indicator of provider need not a fair and reasonable price for a quality service.</p> <p>Population based funding may provide the incentives for laboratories to work regionally and to seek to maximise coverage within their geographic areas of responsibility. A population based funding approach rather than fee for service approach for NCSP laboratory services may be more appropriate and would decrease laboratories seeking out volume growth opportunities outside their home regions. There could be a fixed price for a region rather than fee for service. This would involve an annual growth path for price to account for any volume growth or cost inflation. This is now an accepted model for the New Zealand laboratory industry. This is easily adopted with the cytology or histology testing but may be more difficult when adding new testing such as HPV or LBC as volumes may not be so well understood, at least initially. Fee for service may be appropriate when new tests are introduced.</p> <p>Submissions also proposed that:</p> <ul style="list-style-type: none"> • all funding for the total service should be transparent with annual audits of all laboratory providers • the purchase price should be set for a given minimum volume with a fee for service for additional volumes as this would give stability and certainty for both the NCSP and the laboratories • the purchasing framework should include a training and research component for all laboratories involved • tests above specified volumes could be funded at lower rates • alternative funding arrangements include funding caps, risk sharing and differential pricing • national prices should be abandoned in favour of conventional negotiation, particularly during a period of restructuring. <p>One submission suggested that funding could be withdrawn for short interval rescreens. Laboratories could continue to provide the tests and charge the women concerned at a rate at the discretion of individual practices.</p> <p>One submission argued that if the Government extends the charging of tests ordered by private specialists nationwide it is quite</p>

	<p>possible that many women who currently have private colposcopy (estimated to be approximately 50% of all colposcopy performed in New Zealand) will elect to go through the public sector as it will obviously cost more to have this done privately. Public clinics may not be able cope with the increased volumes. If charging of tests happens it is likely that some private practice colposcopists may choose to direct their specimens to a laboratory they currently use (rather than that favoured by the Ministry of Health). The likely result is that this will lead to fragmentation of the service.</p>
Association with other laboratory services	<p>Some submissions argued that there are many synergistic effects of integrating the provision of community and specialist cytology in terms of continuity of care, maintenance of clinical networks, quality monitoring and increased training opportunities. Likewise gynaecological cytology and histology service provision should be linked.</p> <p>Some submissions argued that HPV should be performed in the same laboratory and included in the cytology report to reduce clinician confusion and as a quality control tool for the screening laboratory. Similarly, there would be duplication of collection services if swabs and cytology were collected and processed by different laboratories and reporting would be less comprehensive on total patient conditions.</p> <p>Some submissions stated that boutique laboratories, while feasible, were not the best option. Workforce was seen as the key constraint to sustainable boutique laboratories. Some submissions commented that:</p> <ul style="list-style-type: none"> • many pathologists like reporting gynaecological cytology in order to retain a broad range of skills but few pathologists have a major interest in this field • technical staff may not want to work in professional isolation and have their employment options restricted if they are unable to keep up their non-gynaecological cytology skills • if cytology was taken away from some laboratories it might further destabilise laboratory services in some regions.
Private vs Public provision	<p>There was some support for retention of hospital-based gynaecological cytology services. However, recently there has been a trend towards consolidation of community and hospital laboratory services. Some submissions argued that there is no justification for maintaining low volume hospital laboratories engaged in gynaecological cytology simply because of their association with regional oncology services or workforce training as the weight of evidence shows that quality of output is consistently poorer from laboratories reporting small numbers of cases.</p> <p>Some submissions argued that a shift to new technologies will need considerable investment. If this is left in the realm of commercial providers, they will naturally want to extract maximum possible return on that investment which will end up being an extra cost to the taxpayer. Conversely, the funding of new technologies within the public sector (DHB sector) has the constraints of having to provide positive financial outcomes rather than positive clinical outcomes.</p>
LBC	<p>Some submissions argued that:</p> <ul style="list-style-type: none"> • any shift to LBC technologies and/or automation will create the risk of being dependent on proprietary technologies and a potential monopoly on supply and maintenance of this technology • one LBC product is adequate and appropriate • New Zealand is probably too small to achieve much of a competitive reduction in price from having both LBC products • with the introduction of automation the Programme should choose one or other of the LBC products for uniformity of services provided • one product should be settled on as soon as possible to allow laboratories to set up for one, not both LBC products • funding for LBC may be better spent on providing more free cervical smears • if there is a gradual move to more LBC then the NSU should not assume that the higher cost of LBC processing will be absorbed by laboratories

	<ul style="list-style-type: none"> the impact of HPV testing and automation will impact on the feasibility of continuing with both ThinPrep and Surepath, particularly within a region for Surepath there is a current arrangement in place where vials are free – this is not likely to be a sustainable long-term arrangement and the cost of the vials should be properly included in the LBC economic evaluation.
HPV	<p>Some submissions commented that:</p> <ul style="list-style-type: none"> HPV testing and vaccination will reduce the total number of cervical smears by a yet undetermined proportion an economic evaluation of HPV testing should be undertaken there is still considerable clinical debate about the utility of HPV testing in clinical practice if HPV testing was to be introduced it should be at the level of the regional scale laboratories while the testing could be consolidated on one laboratory nationally, it is hard to see the advantage of this relative to the additional costs and risks of transport and the issues around reporting the test results it is much simpler to keep all the testing related to a patient in one laboratory.
New Technologies including Automation	<p>Some submissions proposed that new technologies should be introduced after robust cost/benefit analysis assessed against demonstrable improved clinical outcomes, workforce impacts considered and stakeholders consulted. New technologies should not place any extra financial burden on the women being screened as this would potentially alienate those women from the very groups within which we need to achieve improved screening coverage.</p> <p>In regards to automation, submissions commented that:</p> <ul style="list-style-type: none"> the daily maximum primary screenings performed by an individual will need to be revisited if automated screening is to be introduced locally and internationally there are insufficient cytoscreeners in training to cope with the large bolus of retirements from the sector between 2008 and 2015 and this will necessitate the widespread introduction of automated screening by 2010 this technology is most effective for smear numbers at or even above 80,000 given the considerable lead time to establish this technology and the substantial capital investment required by providers certainty of contracting and supply need to be established to encourage ongoing investment in cervical cytology. <p>Some submissions proposed that future technology changes need to be monitored and incorporated into forward planning and education. It was suggested that any decisions taken now should not compromise the effective and efficient introduction of these new technologies.</p>
Specimen Collection	<p>Some submissions commented that currently it is hard to get access to NCSP samples if you do not also have a contract with the local DHB for diagnostic testing in the region. With exclusive long-term contracts for a region – it would be possible to have a subcontracted cytology collection service using the DHB contracted laboratories collection service or for the NCSP contracted laboratory to set up its own collection service.</p> <p>The collection and transportation of gynaecological smears from smear takers rooms to the laboratory is an area where there is potential for duplication with the transportation of other clinical samples being collected by DHB provider laboratories. A number of options can be considered:</p> <ul style="list-style-type: none"> the Ministry of Health could direct DHBs to amend their contracts with the community pathology provider laboratories to ensure that gynaecology cytology samples are collected along with other clinical samples and are then delivered to the regional cytology laboratory the screening programme could introduce a fee to cover the cost of this.

	Some submissions commented that specimen collection and transportation is part of the cycle of pathology services overseen by the pathologist in order to protect the integrity of specimens for accurate testing.
Contract term	<p>There were a few comments on suggested lengths of contracts:</p> <ul style="list-style-type: none"> • five years as this will provide more stability and certainty for both the NCSP and the laboratories • 5-10 years as this allows the advantage of competition at the tendering stage but then allows the laboratories to focus on efficient production between tendering rounds, while maintaining agreed quality and service levels • longer term contracts for services will contribute to certainty and stability • regional laboratories offers the prospect of the parties entering into longer term contracts and closer relationships, under which individual laboratories may be willing to enter into open book arrangements to ensure fees sustainably cover costs and margins for reinvestments.
Training	Some submissions commented that traditionally the training of registered medical officers and scientists has been carried out by DHB owned laboratories. With the reduction in the number of these laboratories now performing gynaecological cytology there has been a negative impact on training in this area. Therefore, the purchasing framework should include a training and research component for all laboratories involved. However, one of the synergistic effects of integrating the provision of community and specialist cytology will be increased training opportunities.
Transition	<p>Some submissions commented that if significant changes are to be made it is essential that suitable transitional arrangements are made so a relatively seamless service can be maintained. Changing the macro-organisation of pathology services for the NCSP needs to be accompanied by a change in culture. NCSP service planning, relationships and accountabilities between the NSU and laboratories should be mutual, negotiable and agreeable.</p> <p>A regional model would require reorganisation of the workforce and submit that the magnitude of such change should not be underestimated especially in the laboratory workforce where change fatigue is already a significant issue. There is no evidence that staff would relocate to follow the workload and this could see a significant reduction in resource. Some options for this could include:</p> <ul style="list-style-type: none"> • a transition period to allow for the workforce demographic changes • provision of flexibility such as contracting out of screening work to other IANZ accredited labs • allowing working from home arrangements for screeners with appropriate controls. <p>If a decision is made in 2007 about future configuration but implementation is not until 2009 it will be difficult, if not impossible, for laboratories to hold staff, for that length of time, or recruit new staff, and maintain current services when staff may well be more intent on exiting to find an alternative job in their current home town, or leave for secure employment further a field.</p>