NATIONAL SCREENING UNIT

SUMMARY OF KEY INFORMANT INTERVIEWS
ANTENATAL DOWN SYNDROME SCREENING

FINAL REPORT

Suite 1, 51 Stephen Terrace, St Peters SA 5069
(PO Box 1038, Kent Town SA 5071)
Ph 08 8363 3699 Fax 08 8363 9011
email: info@hoi.com.au
ABN 80 081 950 692
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ACKNOWLEDGMENTS

The evaluation team wish to acknowledge the input and support provided by the National Screening Unit (NSU) of the Ministry of Health, the individuals and organisations involved in the Antenatal Down syndrome Advisory Group (ADSAG) for their review and feedback on this document.

GLOSSARY OF TERMS

ACRRM	Australian College of Rural and Remote Medicine
ADSSAG	Antenatal Down syndrome Advisory Group
ART	Assisted Reproductive Technology
CME	Continuing Medical Education
CVS	Chorionic Villus Sampling
DQASS	Down Syndrome Quality Assurance Support Service
EU	European Union
FAQs	Frequently Asked Questions
FMF	Fetal Medicine Foundation
GP	General Practitioner
HOI	Health Outcomes International
LMC	Lead Maternity Carer
MOH	Ministry of Health
MSS	Maternal Serum Screening
NATA	National Association of Testing Authorities
NHS	National Health Service
NSC UK	National Screening Committee United Kingdom
NSU	National Screening Unit
NT	Nuchal Translucency
NZCOM	New Zealand College of Midwives
NZDSA	New Zealand Down syndrome Association
OSCAR	One Stop Clinical Assessment of Risk
PHO	Primary Health Organisation
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RANZCR	Royal Australian and New Zealand College of Radiologists
SURUSS	Serum, Urine and Ultrasound Screening Study
TOP	Termination of Pregnancy
UK	United Kingdom
USA	United States of America

E

EXECUTIVE SUMMARY

The National Screening Unit (NSU), a business unit of the Ministry of Health (the Ministry) has responsibility for the strategic management, operation and oversight of three screening programmes, and is conducting preliminary work on other strategic screening programmes. Screening is an important part of disease prevention. The NSU vision aligns with the strategic direction of the New Zealand Health Strategy[1] and assists toward achieving the aim of improving health and reducing inequalities.

The NSU is currently undertaking a comprehensive policy process to assess the various options for antenatal screening for Down syndrome and to determine feasible processes for a national antenatal screening for Down syndrome programme should it be established in New Zealand. As part of this process, the NSU engaged Health Outcomes International (HOI) to undertake research to analyse the capability and capacity of the New Zealand workforce to deliver a national antenatal Down syndrome screening programme.

E.1 PROJECT OBJECTIVES

The intention of this report is to provide the National Screening Unit of the Ministry of Health information to inform its decision as to whether a national antenatal screening programme for Down syndrome should be established in New Zealand. A qualitative analysis of information gained through interviews with key stakeholders identified by the NSU was conducted. The qualitative data identified:

- solutions for minimising any negative workforce/ service impacts
- other issues which may create barriers in terms of the capability and capacity of the New Zealand workforce to deliver such a national screening programme.

Specifically the NSU stated that the purpose of this report was to provide information that would inform workforce planning and identify systemic capacity issues as well as identifying health professional attitudes towards a proposed Antenatal Down syndrome Screening programme.

Having stated the intent it needs to be acknowledged that the proposed methodology was significantly altered and the study was redesigned to collect qualitative data only and from a limited number of informants (20 in total). As such the intended project objective could not be fully met, however the findings of this study assists the Ministry of Health in confirming issues that have been raised in other forums and in identifying key target areas that need to be addressed in the design and implementation of a national Down syndrome Screening programme.

E.2 PROJECT METHODOLOGY

Initially it was intended to conduct a statistically robust analysis of the capability and capacity of the New Zealand workforce to deliver a national Down syndrome screening programme through the development and distribution of a set of surveys containing questions to each cohort of health service professional involved in the delivery and supportive roles associated with the implementation of a Down syndrome screening programme. These surveys were to provide the

[1] http://www.moh.govt.nz/nzhs

basis for a quantitative analysis of the workforce establishment, capacity and likely impact of introducing Down syndrome screening as per the initiative being proposed by the Ministry. Various circumstances, including problems incurred in attempting to access databases providing the contact details of sonographers and midwives and concerns raised by members of the Antenatal Down syndrome Advisory Group (ADSSAG) regarding the workforce survey questionnaires led to the NSU deciding to instruct HOI to proceed with key informant interviews only and to summarise the findings in a report. The NSU confirmed that they expected the Final Report to contain a synthesis of the review of available literature pertaining to recent workforce and capability studies for antenatal screening for Down syndrome, especially those conducted in Australia and the United Kingdom.

The purpose of the key informant interviews was to gain input from key stakeholders in the identification of solutions for minimising any negative workforce or service impacts and identify other issues including attitudinal issues which may create barriers in terms of the successful implementation and adoption of a national Down syndrome screening programme.

The areas of questioning were identified in consultation with the ADSSAG and the NSU. A set of questions for each professional cohort was developed and forwarded to the Ministry for review, comment and sign off. The question went through several iterations including the addition of some of the questions that were to have been included in the proposed survey of the professional health service providers. The final questionnaires (refer Appendices C-K) were then distributed to the 20 key informants identified by the ADSSAG and the NSU. The questions outlined the type of information that would be addressed during the interviews which were conducted face to face and over the telephone depending on the individual's preference and availability.

Table E.1 identifies the number of key informants consulted by professional grouping.

Table E.1: Number of Key Informants by Professional Cohort

Health Professional Group	Number of participants (n=20)
General Practitioners	3
Midwives	4
Obstetricians	3
NT Practitioners	3
Laboratory Biochemist & Cytogeneticist	2
Clinical Geneticists	2
Paediatrician	1
Genetic Counsellor	1
Support Services (NZDSA)	1

These numbers clearly indicate that the process adopted is not a robust statistically representative study and this was clearly articulated to the Ministry at the time of proceeding with the interviews. As such caution needs to be extended in the interpretation placed on some of the issues raised. In particular the authors do not purport that the comments and views expressed in this report are necessarily representative of the respective professions, neither are the comments always factually based. The views expressed in this report are those of the interviewees and may related to personal opinion or local issues. It is not for the interviewers to provide comment on the erroneous nature or otherwise of the comments provided. Importantly the views that have been expressed do exist in the sector, and if erroneous in nature need to be addressed by the Ministry as a matter of urgency and within the overall context of establishing a national Down syndrome screening programme.

The detailed methodology for this project involved the following key tasks:

- Identification of reports and publications relevant to the project and receipt of same from the NSU;
- Desktop review of this documentation to facilitate the development of survey instruments and key informant questionnaires;
- Background literature review pertaining to recent workforce and capability studies regarding antenatal screening for Down syndrome to inform key informant interview question development;
- Conduct of key informant interviews and documentation of same;
- Synthesis of findings to answer key research questions and provide recommendations; and
- Presentation and reporting of findings and documentation that would inform workforce planning and identify systemic capacity issues as well as identifying health professional attitudes towards a proposed antenatal Down syndrome screening programme in New Zealand.

The names of individuals involved in the consultation process are not included in the report as at the time of undertaking the interviews it was agreed that anonymity would be maintained. This assurance was given for a number of reasons, but in particular because of the small number of individuals involved in the study from each profession enables readers to readily ascribe comments to an individual or organisation.

E.3 General Findings of Consultation Process

Interviews were undertaken either face-to-face or over the telephone with 20 key informants identified by the NSU and the ADSSAG (refer Appendix A).

The interviews focused on:

- ensuring that the individuals participating in the interview understood the scope of the study;
- eliciting the views of key stakeholders regarding the introduction of a national antenatal screening programme for Down syndrome;
- identifying issues and concerns regarding current antenatal screening practice in New Zealand;
- determining solutions for minimising any negative workforce or service impacts; and
- ascertaining any barriers in terms of the capability and capacity of the New Zealand workforce to deliver a national antenatal Down syndrome screening programme.

In general participants in the interview process considered that the current antenatal screening practice in New Zealand is:

- random
- inefficient
- follows outdated recommendations
- influenced by practitioners personal bias, and
- potentially dangerous to the woman and foetus.

There was unanimous consensus that a national antenatal screening programme should be introduced although several of interviewees were concerned that it would be referred to as 'Down syndrome screening' with the implication that this would be the only focus of the programme, or that funding constraints would limit the screening to Down syndrome only.

Common themes that arose in the consultations across all professionals groups included:

- the need for the development of guidelines that clearly articulate the roles and responsibilities of health care professionals and support services in the roll out of a

national antenatal screening programme. Within these guidelines, clear indication of what tests are to be ordered, when and under what circumstances. The responsibility for the development of these guidelines vests with the Ministry of Health through the National Screening Unit (NSU);

- the implementation of a national antenatal screening programme should not commence until such time as a detailed education and training strategy has been developed targeting all health care professionals and support services involved in the provision of antenatal services. The training programme should focus on informing all health care professionals about the intent of the national antenatal screening unit, the various processes, referral mechanisms, reporting mechanisms, support mechanisms and roles and responsibilities of the respective health professionals groups. Training programmes should be linked with continuing professional development activities recognised by the respective professions. The training programmes should represent minimal impost on time, and be undertaken on a regular basis;
- the national antenatal screening programme should respect the rights of the individual pregnant woman and be constructed in such as way that it is considered voluntary;
- women should be provided with easy to understand information that outlines the screening programme, the pathways and screening options available to her. This information should also describe what each screening option entails, what it can and can't detect, when the results will be made available and by whom, and were she can go to get support. The information should be presented in several languages other than English and in pictorial form as well;
- consideration be given to developing information for women on a national basis such that it is the same consistent message and information being disseminated across the country describing the various elements of national antenatal screening programme;
- standardised reporting and referral documentation be introduced nationally that informs each health professional of what information has or has not been provided to the pregnant woman;
- greater clarity be given about what test or combination of tests are being considered within the context of the roll out of a national antenatal screening programme;
- consideration be given to the manner in which the national antenatal screening programme and the Disability Strategy of the Ministry of Health inter-relate. Specifically, concern exists that the national antenatal screening programme promotes the concept that termination of a foetus with Down syndrome is the preferred option and this devalues those individuals and families living with Down syndrome. Such a message is incongruent with the philosophy of the Ministry of Health's Disability Strategy;
- in the absence of having a clear understanding of what a national antenatal screening programme entails, workforce capacity and workload implications were approximated at best. In the majority of instances, anticipated areas of workload increase were identified but absolute or relative numbers were not quoted. Further the interviewees in the majority of instances discussed workload implications from their own practices perspective, although the respondents from the laboratories did consult with their peers before participating in the interview;
- one of the greatest workforce challenges will be the ability to recruit suitably trained and experienced staff to the respective professional cohorts with a number of professions indicating that they would in all likelihood have to recruit from overseas;
- there is mixed views on who should discuss the results of a positive test with the pregnant woman and when this should take place. Some respondents felt that it is appropriate for the clinician referring or ordering the test to discuss the results, whilst others felt that it was appropriate for the LMC to discuss the results. For NT scanning, given the visual nature of the test, there is a school of thought that the NT practitioner, if accredited, should provide feedback to the pregnant woman of the results of the scan. The issue of who provides the feedback and when the feedback should occur is a critical aspect of the

national antenatal screening programme that needs to be encapsulated in the national guidelines governing the overall programme.

The themes arising from the key informant interviews conducted by HOI are outlined in Section 4 with Sections 5 to 12 detailing the outcomes of the interviews by the respective professional and support groups.

1

BACKGROUND TO THE STUDY

1.1 INTRODUCTION

The intention of this study is to provide the National Screening Unit of the Ministry of Health information to inform its decision as to whether a national antenatal screening programme for Down syndrome should be established in New Zealand. Specifically the NSU stated that the purpose of this report was to provide information that would inform workforce planning and identify systemic capacity issues as well as identifying health professional attitudes towards a proposed Down syndrome Screening programme.

Down syndrome (Trisomy 21) is a life-long condition that causes delays in learning and development. First described in detail in 1866, it is a congenital condition which randomly affects approximately one in 1000 babies; that figure equates to one or more babies with Down syndrome born in New Zealand every week. The majority of cases of Down syndrome are related to maternal age. With the median maternal age for pregnancy increasing in New Zealand, it is likely that the incidence of Down syndrome will increase.

There are a number of antenatal screening tests for Down syndrome. The following seven options were investigated by Stone and Austin (2006)[2] as potential options for a New Zealand screening programme:

- **Nuchal Translucency (NT)** screening uses ultrasound to measure the clear ("translucent") space in the tissue at the back of the developing baby's neck. Babies with abnormalities tend to accumulate more fluid at the back of their neck during the first trimester, causing this clear space to be larger. NT screening does not provide a definite diagnosis but it is painless and involves no risk to mother or baby. NT screening must be done between the 11th and 14th weeks of pregnancy;[3]
- **The combined test** is a combination of the first trimester (11 weeks) blood test and an NT scan;
- **The second trimester blood test** is taken via amniocentesis between 14 and 20 weeks gestation and tests for substances produced by the placenta or foetus;
- **The serum integrated test** combines the results of the first and second trimester blood tests to produce an integrated estimate of Down syndrome risk;
- **The integrated test** combines the results of the NT scan with those of the first and second trimester blood tests to produce an integrated estimate of Down syndrome risk;
- **The Nuchal Translucency and second trimester blood test** combines the NT scan and second trimester blood test results in a formula which produces a risk assessment for Down syndrome; and
- **Age alone** whereby women are offered a diagnostic test based on their age only. The typical 'cut-off' age has been 35 years. However, research has shown that this is not an appropriate screening tool in itself to determine whether further testing (such as

[2] Stone, P. & Austin, D. (2006) Report to the National Screening Unit Assessment of Antenatal Screening for Down syndrome in New Zealand.

[3] http://www.babycenter.com/refcap/pregnancy/antenatalhealth/118.html

amniocentesis) is offered, due to the combination of increased pregnancies among older women, and the risk of pregnancy loss as a result of amniocentesis compared to the number of positive results.

Stone and Austin have recently (2006) conducted research into the state of antenatal screening for Down syndrome in New Zealand. They found that antenatal screening for Down syndrome is currently offered on an ad hoc, inconsistent, or selective basis and none of the District Health Boards have policies on offering antenatal screening. A small percentage (3.5%) of health practitioners do not offer screening to any woman, a situation which potentially deprives women of information and choice. The most commonly offered screening tests offered are NT scans and maternal age, whilst there are significant impediments to the use of second trimester maternal serum screening relating to poor knowledge and cost. [4] A study conducted in the United Kingdom in 1998 found that about 90% of those found to have a pregnancy with Down syndrome chose to have a termination[5].

Key findings from the work of Stone and Austin (2006) include:

- The current system of screening for Down syndrome is not best practice and is not sustainable.
- Approximately 46% of practitioners offer screening on a selection basis, based generally on maternal age or previous abnormality.
- General Practitioners (GPs) are less likely to offer screening than other practitioners.
- Accurate data collection and monitoring of both screening and diagnostic tests does not currently occur.

1.2 PROCESS

Initially it was intended to conduct a statistically robust analysis of the capability and capacity of the New Zealand workforce to deliver such a national screening programme through the development and distribution of a set of questions to each professional cohort of health service providers involved in the delivery and supportive roles associated with the implementation of a Down syndrome Screening programme. These surveys in the form of questionnaires were to provide the basis for a quantitative analysis of the workforce establishment, capacity and likely impact of introducing Down syndrome screening as per the initiative being proposed by the Ministry of Health. However, problems were encountered due to the lack of a central registry of practitioners and facilities which led to the NSU deciding to instruct HOI to proceed with key informant interviews only.

The purpose of the key informant interviews was to gain input from key stakeholders in the identification of solutions for minimising any negative workforce or service impacts and identify other issues including attitudinal issues which may create barriers in terms of the successful implementation and adoption of a Down syndrome Screening programme.

The areas of questioning were identified in consultation with the Antenatal Down syndrome Screening Advisory Group (ADSSAG) and the NSU. A set of questions for each professional cohort was developed and forwarded to the Ministry for review, comment and sign off. These questionnaires went through several iterations including the addition of some of the questions that were to have been included in the proposed survey of the professional health service providers. The final profession specific questionnaires (refer Appendices B-K) were then distributed to the 20 key informants based on the professional cohort they were representing, where the key informants were identified by the ADSSAG and the NSU. The questions outlined the type of information that

[4] Stone, P. & Austin, D. (2006) *Assessment of Antenatal Screening for Down syndrome in New Zealand*. Report to the National Screening Unit

[5] http://www.hta.nhsweb.nhs.uk/execsumm/summ201.htm

would be addressed during the interviews which were conducted face to face and over the telephone depending on the individual's preference and availability.

The twenty key informants consulted included 3 General Practitioners (GPs), 4 midwives, 3 obstetricians, 3 NT practitioners (I of whom was a radiologist and 2 were obstetricians) , a laboratory biochemist and a laboratory cytogeneticist, 2 clinical geneticists, a paediatrician, a genetic counsellor and a representative from the New Zealand Down syndrome Association (NZDSA). This is depicted in Table 1.1.

Table1.1: Number of Key Participants by Professional Cohort involved in the Consultation Process

Health Professional Group	Number of participants (n=20)
General Practitioners	3
Midwives	4
Obstetricians	3
NT Practitioners	3
Laboratory Biochemist & Cytogeneticist	2
Clinical Geneticists	2
Paediatrician	1
Genetic Counsellor	1
Support Services (NZDSA)	1

1.3 METHODOLOGY

1.3.1 DATA COLLECTION

The approach adopted by HOI in the conduct of this project included the development of a plan incorporating the detailed tasks to address the requirements of the NSU as specified in the original project brief. The original project methodology included:

- Undertaking a background literature scan of approaches to addressing health workforce and capacity issues relevant to the screening programme which would then inform the questionnaire development;
- Conducting a survey and key informant interviews with sonographers, laboratories, maternity care providers, counselling and support services and genetic counsellors, and other relevant staff; and
- Analysing data of workforce capacity including assessment of staff shortages and possible misdistribution of workforce, availability of facilities and equipment.

It was initially intended to conduct approximately 260 telephone interviews with a representative sample of participants across the identified groups of sonographers, laboratory staff, maternity care professionals, counselling and support services and genetic counsellors. However, on the 1st September 2006 following a meeting between the NSU and HOI, the methodology was revised significantly.

The changed methodology included the development and utilisation of survey instruments which would be distributed to sonographers, maternity care providers such as obstetricians, general practitioners and midwives and health service facilities as well as interviews with smaller cohorts of key informants. These surveys (in the form of questionnaires) were to provide the basis for a quantitative analysis of the workforce establishment, capacity and likely impact of introducing Down syndrome screening as per the initiative being proposed by the Ministry of Health, thereby providing the Ministry of Health with a set of baseline data.

The project methodology was revised to include key informant interviews as well as surveys in order to:

- inform the refinement of the survey tools, to ensure concerns and considerations from the perspectives of screening service providers were addressed,
- gather information on capacity that is centrally held within service providers,
- involve stakeholders as key agents of change in the outcomes of the consultancy that affect them as members of the workforce and as service providers.

Various circumstances, including problems incurred in attempting to access databases providing the contact details of sonographers and midwives and advice from the NSU informing HOI that a 'number of concerns had been raised by members of the Antenatal Down syndrome Advisory Group regarding the workforce survey questionnaires ... related to the use of an anonymised survey, the length and content of the drafts and the timing available to carry out the survey without compromising the quality of the data or the goodwill of the professional organisations'[6] led to the NSU informing HOI that they did not wish to proceed with work related to the surveys but that they would like work involving the key informant interviews to proceed and the findings to be summarised in a report. The NSU confirmed that they still expected the Final Report to contain a synthesis of the review of available literature pertaining to recent workforce and capability studies for antenatal screening for Down syndrome, especially those conducted in Australia and the United Kingdom.

Importantly, the ability to revert back to the original proposed methodology of surveying a representative sample of health professionals involved in Down syndrome screening could not be pursued either as this required access to the demographics and distribution of the respective professional cohorts across the country. This information resides with the professional bides, not the Ministry of Health and in the absence of providing this information statistical sampling could not proceed.

The ultimate methodology for this project involved the following key tasks:

- Identification of reports and publications relevant to the project and receipt of same from the NSU;
- Background literature review pertaining to recent workforce and capability studies regarding antenatal screening for Down syndrome;
- Desktop review of this documentation to facilitate the development of survey instruments and key informant questionnaires;
- Conduct of key informant interviews and documentation of same;
- Synthesis of findings to answer key research questions and provide recommendations; and
- Presentation and reporting of findings and documentation that would inform workforce planning and identify systemic capacity issues as well as identifying health professional attitudes towards a proposed Antenatal Down syndrome Screening programme in New Zealand.

Interviews were undertaken either face-to-face or over the telephone with 20 key informants identified by the NSU and the ADSSAG (refer Appendix A). Notably the basis for selection of informants was outside of the control of the consultants. Selection was undertaken by the NSU and ADSSAG and the criteria for selection was never articulated.

The interviews focused on:

- Ensuring that the individuals participating in the interview understood the scope of the study;

[6] Email from NSU – dated 24 October 2006

- Eliciting the views of key stakeholders regarding the introduction of a national antenatal screening programme for Down syndrome;
- Identifying issues and concerns regarding current antenatal screening practice in New Zealand
- Determining solutions for minimising any negative workforce or service impacts; and
- Ascertaining any barriers in terms of the capability and capacity of the New Zealand workforce to deliver a national antenatal Down syndrome screening programme.

It is important to note at the outset that the views expressed in this report do not represent that of the overall professions as the interviews did not cover a statistically robust sample. However, the information collected through this process does:

1) Demonstrate significant divergence in practice and opinion across a relatively small cohort of service and support providers which gives rise to concern about the degree of variance that is likely to exist in the broader sector.
2) Corroborates opinion and expectations previously expressed to the Ministry of Health and the Advisory Group through various other media (i.e. other reports, submissions, etc.).
3) Identifies some key issues that need to be addressed from a workforce perspective prior to the implementation of a national Down syndrome screening programme such as:
    - The need to clearly define each health professionals role and responsibility in terms of providing:
        - woman with background information;
        - ordering of tests
        - reporting tests
        - informing women of outcomes of test
        - informing women of options available to them.
    - Development of well defined pathways and concentrated/integrated training and communication strategies targeting health professionals.

The themes arising from the key informant interviews are presented in Section 4 and the subsequent sections of the report present the findings of the interviews by professional cohort.

2

LITERATURE SCAN

A literature scan was undertaken as part of the study assessing workforce impacts of introducing a national Down syndrome Screening programme. The literature scan focused on identifying workforce issues faced and addressed by other similar health systems to that of New Zealand where national Down syndrome Screening programmes have been established. In the absence of such examples, a broader view was taken in terms of addressing common workforce issues that have arisen as a result of the introduction of national screening programmes/services. The purpose of the scan was to provide guidance to the study team in terms of areas to be investigated through the key stakeholder consultation. Specifically, questions that were posed to key stakeholders sought opinion as to whether experiences in other jurisdictions were likely to be felt here in New Zealand and whether some of the strategies that have evolved elsewhere to address workforce related issues are relevant or appropriate within the current context and environment.

2.1 LITERATURE SCAN METHODOLOGY

The aim of this literature scan is to highlight the key workforce issues that have been identified in other Down syndrome Screening programmes/services, as well as highlight any workforce information of relevance to the planning, implementation and management of a national screening programme.

To identify the literature relevant to a Down syndrome screening programme in a New Zealand context, a key matrix and search strategy was developed to enable a search that catered for varying terminology used in reference countries.

The following matrix (refer Table 2.1) details the search parameters used to locate relevant literature for the scan. The terms were used in multiple combinations usually starting with Down syndrome or another key topic word/subject (e.g. midwives).

Table 2.1: Literature Scan Matrix

Key Words/Topics	Related Words/Topics
Down syndrome; Down's syndrome; Screening; Antenatal; workforce; manpower; capacity; programme; genetics; ethics; fetal medicine; fetal abnormality; midwives; general practitioners; obstetricians, radiology; pregnancy; ethics; women; consumers; patient experience; impact; Decision-making; review; New Zealand; overseas; international; Policy; reform; evidence	Benefits; effectiveness; public health; testing; outcomes; diagnosis; information; education; training; chromosomal abnormalities; staff; pregnancy; antenatal; nuchal translucency; sonographers; informed consent; health professionals; services; antenatal care; genetic medicine; termination of pregnancy; serum testing; aminocentesis; quality assurance; acceptability; cost; rural; urban; attitudes; awareness; anxiety; risk; support; perceptions; first trimester; second trimester; third trimester; tests; timing. Implications; prevalence; intervention. Accreditation; governance; integrated; audit. Primary care; secondary; maternity care; maternal age; early detection; assessment; false positives; utilization; uptake; barriers; implementation; practice; knowledge; counselling;

2.1.1 SEARCH RESULTS

Based on the search strategy HOI undertook an initial search and added this to the documents that had been provided by the Ministry of Health. Once articles on the technical aspects of Down syndrome screening were excluded the total number of documents found was ninety nine (99). Of these twenty one (21) were not found to be useful for the purposes of this literature scan either due to age of the article or the topic/issues being covered being outside of the scope of this project.

Overall seventy eight (78) documents were used in the literature scan. These documents were a mixture of published journal articles, abstracts, official government reports or strategy documents, and web pages. The majority originated from the United Kingdom, and New Zealand, but also included a range of articles or abstracts from the United States of America, Canada, Netherlands, Australia, Scotland and Ireland. An article originating in Taiwan was also included recognising that the country's health system is not as closely aligned to the New Zealand health system as some of the other reference countries.

The following outlines a summary of the findings of the literature scan.

2.2 ANTENATAL SCREENING FOR DOWN SYNDROME

Screening is a public health measure aimed at targeting population cohorts, whom are considered at risk of developing certain diseases and/or health deficits. Screening differs from other clinical practice in that screening tests are offered to target populations, therefore creating ethical obligations to ensure that the benefits and costs of the screening outweigh any potential harm that may result from the screening[7].

A range of rationales exist to justify the investment towards initiating screening programmes as part of health service provision. These include:

- Protection of other citizens
- An alternative to personal health services
- Acquisition of clinical baseline information
- The early detection of disease and
- For life insurance purposes[8].

The World Health Organisation has identified seven criteria to be used in the evaluation of screening programmes. These criteria include:

- Screening must lead to an improvement in end results either in those diagnosed early or in the community;
- The effectiveness of potential components of multi-phasic screening must be determined before they are combined
- If the benefits accrue to the community rather than, or in addition to, the individual, the community benefit claimed must withstand scientific scrutiny.
- The cost benefit and cost effectiveness of mass screening and long term therapy must be known.
- The cost, sensitivity, specificity and acceptability of the screening test must be known.
- Ideally an estimate of the social benefit of preventing, slowing or curing the condition should be known [9].

[7] UK National Screening Committee,(2004). National Down's Syndrome Screening programme for England: A Handbook for Staff. *National Health Service,* United Kingdom

[8] McQueen, M.J. (2002). Screening for the early detection of disease, the need for evidence. *Clinica Chimica Acta* 315,5-15

[9] Ibid

In the context of screening for Down syndrome the aim is to identify affected pregnancies, to enable a woman to make decisions about whether she wants to continue with the pregnancy or otherwise. Conversely pregnant woman may wish to undergo screening for reassurance that their unborn child is healthy.

In New Zealand there is a large range of different health professional staff involved in provision of maternity, antenatal and paediatric services across primary, secondary and tertiary services. Antenatal screening for Down syndrome has been available for approximately 30 years but the development of less invasive biochemical and imaging technology has lead to simpler and less risky screening tests introduced into antenatal clinical practice[10]. Formalised antenatal screening programmes for Down syndrome have been established and implemented in several countries or regions in the world – England, Scotland, Wales, France, Netherlands, Toronto, Taiwan, the United States and Canada.

2.3 DIMENSIONS OF A SCREENING PROGRAMME

The assumption underpinning the establishment of a national Down syndrome screening programme is that the benefits of a formal programme on the health status of the population outweigh the disadvantages and the antenatal detection of Down syndrome will have a demonstrable impact on morbidity and mortality[11].

Issues about the benefits, risks, cost, rationale and ethics of antenatal screening for Down syndrome have significant direct and indirect workforce implications.

2.3.1 BENEFITS OF SCREENING

Evidence exists that populations support antenatal screening programmes and that Down syndrome screening programmes are effective in detecting Down syndrome abnormality.

A report prepared for the Human Genetics Commission in May 2005, outlined the results of a public consultation process conducted to research opinion about developments in genetic medicine and medical technology. Respondents had been questioned about antenatal screening, conditions subjected to screening, the accuracy of screening and risk of diagnostic tests, the impact on services, and the issue of opting in. This research found support for antenatal genetic screening programmes existed because of the resultant health benefits to mother and/or child; the benefits accruing to society from scientific advancement, and thirdly because such programmes allowed individuals to take "responsibility " for their own reproductive decisions[12].

Other research highlights the change in women's expectations with regard to antenatal screening and how more women now want to know definitely, early and privately if there is a problem with the pregnancy[13].

A range of studies have demonstrated the potential benefits of antenatal screening and the effectiveness of different approaches[14],[15],[16]. Specific research aimed at evaluating the effectiveness of local services and programmes was identified through this scan. An English study evaluated the impact of a large scale population screening programme on the birth incidence of

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[10] Alderson, P. (2001). Antenatal screening, ethics and Down's syndrome: a Literature review. *Nursing Ethics* 8 (4): 360-7

[11] Ibid

[12] People Science & Policy Ltd. (2005). Choosing the Future: Genetics and Reproductive Decision-Making. Analysis of responses to Consultation. *Human Genetics Commission*: London

[13] Evans, M. (2006). Let's incorporate first-trimester screening into obstetric practice. *Obstetric Gyn News* 41.5: p42(2).

[14] Wald, N.J., Rodeck.C., Hackshaw, A.K. et al (2003). First and second trimester antenatal screening for Down's syndrome: the results of the Serum, Urine and Ultrasound Screening Study (SURUSS) *Journal Medical Screening* 10:56-104. Reported in Health Technology Assessment 2003; 7: 1-77)

[15] Wald,N.J. Watt, H.C.,& Hackshaw, A.K. (1999) Integrated screening for Down's syndrome based on tests performed during the first and second trimesters. North England Journal of Medicine 341:461-467.

[16] Cicero, S., Bindra, R., Rembouskos, Spencer,K., & Nicolaides, K.H. (2003). Integrated ultrasound and biochemical screening for trisomy 21 using fetal nuchal translucency, absent fetal nasal bone, free beta-hCG and PAPP-A at 11-14 weeks. *Antenatal Diagnosis*. 23(4): 306-10.

Down syndrome in the west of Scotland over a 12 month period. They concluded that biochemical screening for Down syndrome is practical and effective in routine clinical practice, enabling women to make an informed choice about antenatal diagnosis and provide better use of scarce resources when a suitable protocol is applied[17]. Similarly, an evaluation of the effectiveness of a programme for antenatal screening for Down syndrome in Bristol was conducted in 1995. This research confirmed the effectiveness of the programme using second trimester serum marker as the screening tool. They confirmed that over a period of two years, approximately 84% of the pregnant population were screened; 32 Down syndrome pregnancies were identified. Amniocentesis uptake was 70% in patients with reported risks of greater than or equal to 1:300. Overall the screening programme was effective but screening before 17 weeks was very much more effective than screening later [18].

In Taiwan a study of the impact of second trimester maternal serum screening concluded that the policy of antenatal diagnosis programme including amniocentesis for pregnant women aged 35 or more and the liberal application of maternal serum screening for Down syndrome in younger women was responsible for the marked decrease in the live births affected with Down syndrome in Taiwan from 1993 to 2001[19]. Likewise a very recent evaluation of the performance of screening service providers in Western Australia which directly linked pregnancy outcomes with screening data illustrated the effectiveness of screening tests for the detection of Down syndrome[20].

2.3.2 COST EFFECTIVENESS

A further assumption regarding the establishment of formal screening programmes is that the programme will be cost beneficial for the population, and the health system.

The scan highlighted literature that supported the premise that the economic costs of screening outweigh the high costs associated with the long term care needs of an individual with Down syndrome. For example Wald and colleagues assessed the implementation of antenatal screening for Down syndrome in practice using individual risk estimates based on maternal age and three serum markers. This study assessed the uptake of screening, detection rates, false positive rate, probability of Down syndrome relative to the positive result, the uptake of amniocentesis in women with a positive result together with the costs of the screening programme. The findings concluded that antenatal maternal serum screening for Down syndrome is effective practice and can be readily integrated into routine antenatal care. It is cost effective as the estimated cost of avoiding the birth of a baby with Down syndrome (about 38,000 pounds) is substantially less that the lifetime costs of care[21].

Further support for this view also suggested that while screening costs will vary depending on the testing format, and while some may feel that the cost of about 40,000 pounds sterling to prevent the birth of a baby with Down syndrome to a woman under 30 may be expensive, it is low compared with the costs of caring for someone with Down syndrome [22].

A Health Technology Report, "First and second trimester antenatal screening for Down syndrome: the results of the Serum, Urine and Ultrasound Screening Study", (known as the SURUSS report),

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[17] Crossley, JA, Aitken, D A., Berry, E. & Connor, J.M. (1994). Impact of a regional screening programme using maternal serum alpha fetoprotein (AFP) and human choronic gonadotrophin (hCG) on the birth incidence of Down's syndrome in the west of Scotland. *Journal of Medical Screening*. 1(3): 180-3.

[18] Goldie, D.Jj., Astley, J.P_., Beaman, J.M., Bickley, D.A., Gunneberg, A. and Jones, S.R. (1995). Screening for Down's Syndrome: the first two years experience in Bristol. *Journal of Medical Screening*. 2 (4): 207-10.

[19] Jou, HJ, Kuo,Y., Hsu,J et al. (2005). The evolving national birth prevalence of Down syndrome in Taiwan. A study on the impact of second-trimester maternal serum screening. *Antenatal Diagnosis*. 25(8):665-70.

[20] Breheny N, O'Leary P, Dickinson J, Bower C, Goldblatt J, Hewitt B, Murch A and Stock R (2005). Statewide evaluation of first trimester screening for Down syndrome and other fetal anomalies in Western Australia. Genomics Occasional Paper 5. Antenatal Diagnosis Committee, Department of Health Western Auswtralia

[21] Wald,NJ., Kennard,a., Densem,J.w. et al (1992) Antenatal maternal serum screening foe Down's syndrome: results of a demonstration project. *British Medical Journal*. 305 (6850) : 391-4.

[22] Reynolds, T.M. (1995) Costs were overestimated. Letter to the editor. *British Medical Journal* 311: 1372

contains detailed cost analyses of the screening test options. This study concluded that on the basis of efficacy, safety and cost, an integrated screening test format was the test of choice[23].

Other literature emphasises that the implementation of new strategies for the detection of Down syndrome all have economic implications, these are unique to antenatal diagnoses, and must be considered prior to implementation. Indirect and intangible costs must be included in the analysis, not just direct medical costs[24].

2.3.3 ETHICAL ISSUES

Screening differs from ordinary clinical practice in that all screening activity involves ethical questions. These flow from the public health rationales underpinning screening in that individuals are targeted, offered the opportunity to participate in screening tests which in themselves involve risk, false positive or negative results occurring and individuals may be faced with making difficult moral decisions about their values to life and health that may not have arisen, had they not been subjected to screening processes. Antenatal screening is particularly controversial as Down syndrome is incurable and if detected women can choose between continuing the pregnancy and accepting they will have a disabled child or termination.

Harper highlights many of the fundamental ethical, moral and legal debates that are central to the dilemmas created by Down syndrome screening. As well as questioning the rationale for Down syndrome screening, he references the legal and moral aspects that screening emphasises, and questions how antenatal screening aligns with the government's Disability Strategy. He concludes that there are several outcomes that should be considered ranging from not offering antenatal screening for Down syndrome at all, to accepting the position that antenatal screening should be part of routine antenatal care and programmes delivered through a structured national programme [25].

In a literature review on antenatal screening, ethics and Down syndrome, and a research paper on Down syndrome specifically, Alderson highlights the need for a balance in the debates about screening policy and programme development. These papers highlight the tensions between the aims of antenatal screening policies to support women's personal choices, preventing distress, and reducing the suffering and costs of disability versus the inadvertent risks of screening which can undermine the original purpose of the screening programme policy [26],[27].

A comprehensive review of many psychosocial aspects of antenatal screening programmes by studying five questions related to participation and outcomes generated by antenatal screening was also located in the scan of the literature. The study conducted by Green et al [28] reviews the knowledge base, anxiety, influences on participation/non-participation in screening and the long term impacts of false positive, true positive in newborns and true negative results. The conclusions of this study highlighted sub optimal practices in various areas including the inadequacy of current procedures for achieving consent; the cost of providing a satisfactory service; the unmet needs of women receiving false-positives results and also the unmet needs of women's partners.

A good example of how ethical dilemma evolve in clinical practice is outlined in a study of experiences of practitioners involved in routine antenatal nuchal translucency (NT) screening in a London hospital. This research highlights the different rationales between the practitioners conducting the NT and the women participating – the former was screening for abnormalities and the women welcoming the opportunity to see the baby. The underlying ethical dilemmas in

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[23] Wald, N.J., Rodeck.C., Hackshaw, A.K. et al (2003). Op Cit

[24] Macones, G.A. and Odibo,A. (2005) First trimester screening: economic implications. *Seminars in Perinatology*. 29(4):263-6.,

[25] Harper, P. (006). Antenatal Screening for Down syndrome: Social and Ethical Issues Paper prepared for the Antenatal Down syndrome Screening Advisory Group, Ministry of Health, Wellington

[26] Alderson, P. (2001). Op Cit

[27] Alderson, P. (2001) Down's syndrome: cost quality and value of life. *Social Science Medicine* 53 (5) 627-38.

[28] Green J.M., Hewison, J., Bekker, H.L. et al (2004) Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review. Health Technology Assessment Report 8 (33).

regard to information giving, informed consent, and promoting individual choice were highlighted and the need for debate on optimal management of such issues within the context of formal screening programmes was also highlighted in the study [29].

2.3.4 GENETICS, REPRODUCTION AND ANTENATAL SCREENING

Genetics and reproduction technology are two further areas of direct relevance to the respective workforces concerned with antenatal screening services.

A July 2004 discussion document 'Choosing the Future', developed by the Human Genetics Commission in the United Kingdom details developments in human genetics and their effects on health and healthcare. This document discusses the kinds of choices facing people having children and the wider social impact of these choices. Chapter 3 focuses on antenatal screening and antenatal diagnosis and highlights the growth in amniocentesis procedures being undertaken as increasing numbers of women are participating in antenatal screening programmes[30].

This document also emphasises the extent to which current health policy is increasingly focused on offering women choices about whether to accept screening, to accept to undergo invasive diagnostic procedures when there may be an increased risk of having a baby with a genetic disorder and then choose between the options of termination or plan how best to care for a disabled child in the future.

Secondly this document highlights concerns about the timing and type of information people receive prior to screening and diagnostic tests, as well as the support they get before and after making a decision. These concerns relate to questions about how much information and choice is acceptable, how much of a burden the decision becomes, and how screening may send out particular signals about whether or not certain disabilities and/or genetic disorders are acceptable.

The analysis of the responses to this consultation document are contained in its follow up report authored by People Science & Policy[31]. Of most relevance in a New Zealand context are the following précised main findings:

SUPPORT FOR ANTENATAL SCREENING PROGRAMMES –

Three main reasons for supporting screening were – the resultant health benefits for mother and/or child; benefits to society from scientific advancement and increase in medical knowledge; and because screening allows individuals to take "responsibility' for their own reproductive decisions.

SELECTION OF CONDITIONS TO BE INCLUDED –

Expansion of screening programme supported only where certain criteria for the inclusion of conditions are met. (e.g. The condition is severe, has a known and clear form of inheritance or where no known treatment is available).

ACCURACY OF SCREENING AND THE RISK OF DIAGNOSTIC TESTS –

Respondents have concerns about the accuracy of the tests used for screening and the potential for both false positive results (and unnecessary invasive diagnostic testing) and false negative results (leaving parents unprepared for child with a genetic disorder).

[29] Williams,C., Sandall, J., Lewando-Hundt, et al (2005) Women as moral pioneers? Experiences of first trimester antenatal screening. *Social Science & Medicine* 61: 9 1988-1992

[30] Human Genetics Commission (2004) Choosing the Future: Genetics and Reproductive Decision-Making.

[31] Human Genetics Commission (2005) Choosing the Future: Genetics and Reproductive Decision-Making. Analysis of responses to consultation.

IMPACT ON SERVICES –

Expansion in antenatal screening programmes will require additional resources, in terms of cost of the technology, but also staff. Also concerns about consistency of available tests and quality of services offered.

OPTING IN -

Concern was expressed that the existence of antenatal screening programmes puts pressure on individuals to take part. There is some support, for voluntary "opt-in" screening programmes, where opting-out is presented as a real option.

OPPOSITION TO ANTENATAL SCREENING -

Antenatal diagnosis which follows screening is felt to pressurise parents to terminate after a positive result. Termination is felt to encourage stigmatisation of those living with genetic disorders and undermine the value of human life. Screening and antenatal diagnosis may be supported to allow early treatment and preparation.

CURRENT PROVISION –

Both screening and diagnostic services thought to vary between services as well as the standard of training and expertise of different types of health professionals.

ADEQUACY OF COUNSELLING –

Counselling in diagnostic services thought to be of high standard. However screening was perceived as routine and high pressurised. The suggestion that midwives be trained as counsellors was made as was research into the effects of different types of counselling and professionals providing counselling.

SUFFICIENCY OF INFORMATION –

Mixed responses with some preferring standardised information, others indicating information needs to be tailored to individual needs. The need to cater for different languages, formats and educational abilities was highlighted.

TIMING OF INFORMATION –

Responses suggested that the majority of information in screening context is too heavily concentrated on the booking stage, in competition with other matters. Information to be provided at other stages was emphasised.

ACCESSIBILITY OF INFORMATION –

Responses felt that the volume and complexity of information can be too much for some women particularly in a situation where pressure exists to make an early decision. Information also perceived to be less accessible to minority and isolated groups.

NON DIRECTIVE COUNSELLING

The majority view was that Genetic counselling needed to be non-directive. Tension exists between non-directive counselling and those patients that expect or want to be given advice.

OPTING FOR DIAGNOSIS MAKES TERMINATION MORE LIKELY –

Respondents felt termination more probable the more severe the disorder, where there is previous family history or experience, if counselling is adequate and there is insufficient time to make considered decisions.

SCREENING AND DIAGNOSIS ALLOWS FOR PREPARATION –

Some patients choose to accept screening and diagnosis as it enables them to be better informed about the baby, prepare for birth of affected infant particularly if treatment options are available or to ensure a safer pregnancy or delivery.

THE INFLUENCE OF SOCIETAL VIEWS ON DECISION MAKING

While it was highlighted that discrimination is real and independent of matters pertaining to genetic screening and diagnosis, many respondents feel that the decision to terminate is influenced by broader social values, widespread ignorance about disability and lack of support for parents with disabled children.

TERMINATION DECISIONS –

Many respondents felt the desire to prevent future suffering is not inconsistent with support for those who live with disabilities. The decision to terminate is influenced by many factors in a person's life.

The future advancement of genetic services and options for greater integration of genetics into public health screening programmes is noted in other literature. The potential role and responsibility to ensure that health policy makers, the general public and health professionals are well informed about genetics, its impact on health and the ethical, legal and social issues that are important to the provision of genetic services and the use of genetic information is discussed. The rapid developments in alternative reproductive techniques are promising an ever expanding set of specialised approaches to the primary prevention of genetic disorders [32],[33].

Two further examples of how new emerging technology is generating new and more complex ethical dilemmas related to modern clinical practice were identified from the literature.

The increasing demand and utilisation of assisted reproduction technology (ART) has implications for Down syndrome screening in that the increasing prevalence of ART pregnancies and their biochemical makeup must influence decisions about the most appropriate screening modality and programme design[34].

Similarly moral dilemmas have also emerged as a result of emerging technology and resulted in unnecessary and inappropriate loss of healthy foetus' as illustrated in a paper discussing how advances in fetal ultrasound screening have lead to inappropriate use in clinical practice, and women being counselled on the basis of insufficient data, and undergone invasive testing for diagnosis. This paper stresses the need for close attention to be paid to the crucial distinction between technology development and technology implementation[35] .

2.4 WOMEN'S KNOWLEDGE, PREFERENCE, EXPERIENCES AND EXPECTATIONS

An appreciation of women's perspectives, knowledge, attitudes, decision making and acceptance or otherwise of antenatal screening is important to highlight as any screening programme design will need to factor in a range of human variables to ensure any programme is acceptable to women.

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[32] Emergy, J. & Hayflick,S. (2001) The Challenge of ilntegrating genetic medicine into primary care. *British Medical Journal* 322:1027-1030 April

[33] Al-Jader,L. & Hopkins, S. (2000). Development of an Antenatal Screening programme for Congenital Abnormalities in a South Wales District: Lessons Learnt for Clinical Governance. *Community Genetics* 3,31-37

[34] Maymon, R. (2005) Current Concepts of Down syndrome screening tests in assisted reproduction twin pregnancies: another double trouble. *Antenatal Diagnosis* 25((): 746-50.

[35] Getz, L., Kirkengen, A. (2003) Ultrasound screening in pregnancy: advancing technology, soft markers for fetal chromosomal aberrations, and unacknowledged ethical dilemmas. *Social Science & Medicine*. 56(10):2045 -57.

The literature reveals a wide variation in women's knowledge, their attitudes, preferences, experiences and expectations regarding antenatal screening and decision making in relation to participation in screening. An awareness of these perspectives will suggest areas where education, increasing awareness and training of the professional workforces may be required to support the introduction and implementation of a national Down syndrome screening programme.

A snapshot of this range of research is outlined.

2.4.1 PRE-EXISTING KNOWLEDGE

The literature highlighted a range of knowledge, awareness, understanding exists in relation to women's previous knowledge about screening for Down syndrome.

A study measuring the magnitude of informed choice in a large cohort of pregnant woman sought to investigate the association between knowledge, uptake and attitudes towards screening. The researchers concluded that knowledge was not associated with uptake, attitude or the extent to which uptake was consistent with women's attitudes undergoing the test[36].

Similarly a survey conducted during a woman's first hospital antenatal visit to assess woman's pre-existing level of Down syndrome and available antenatal tests conducted in Australia found that overall the women had limited knowledge about Down syndrome, and the availability of screening tests. Importantly the study highlighted the fact that women with a history of a previous pregnancy and women over 35 years were no more aware of Down syndrome or the available tests than other women[37].

A second study by the same researcher focussing on what pregnant women over the age of 37 years knew and expected from antenatal testing, found that many had heard about Down syndrome (61%) and those undergoing both screening and diagnosis were more likely than those having other tests to mention Down syndrome [38].

2.4.2 DECISION MAKING

A strong theme highlighted in the reviewed literature indicated that women themselves are the dominant decision maker of matters to do with their pregnancy, their health and that of their unborn child.

The woman and secondly their partner were found to be the primary decision makers when it came to antenatal screening in research undertaken in Victoria. Notably approximately 30% of women who had both screening and diagnosis and 20% of women who had no antenatal testing would like to have discussed antenatal testing with women who had previously had testing. Face to face counselling with a doctor or counsellor was the preferred source of information, followed by a pamphlet as the second choice of information[39].

Similarly a comparison between the decision making of women undergoing serum screening with a second group of women who did not, found that with age variations excluded, those undergoing serum screening had more knowledge about the test and made decisions less systematically than those not being screened [40].

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[36] Michie, S., Dormandy,E., Marteau, T.M. (2003). Informed Choice: understanding knowledge in the context of screening uptake. *Patient Education & Counselling*. 50(3):247-53.

[37] Mulvery ,S., Wallace, E.M. (2001). Levels of knowledge of Down syndrome and Down syndrome testing in Australian women. *Australian & New Zealand Journal of Obstetrics & Gynaecology*. 41 (2): 167-9.

[38] Jaques, A.M., Halliday,J.L.,Bell,R.J.,(2004) Do women know that antenatal testing detects fetuses with Down syndrome? *Journal of Obstetrics & Gynaecology*; 24 (6) 647:651

[39] Jaques, A.M., Bell, R., Watson, L., & Halliday, J. (2004) People who influence women's decisions and preferred sources of information about antenatal testing for birth defects. *Australian and New Zealand Journal of Obstetrics and Gynaecology.* 44,(3) 233 – 2004

[40] Michie, S., Smith, D., & Marteau, T.M. (1999) Antenatal Tests: How are Women Deciding? *Antenatal Diagnosis* 19:743-748

Crang- Svalenius et al sought to examine women's feelings when making a theoretical choice to accept a new screening procedure, before its introduction and concluded that the ease with which woman were able to make their choice of antenatal diagnosis had bearing on their degree of acceptance of serum screening for Down syndrome [41].

2.4.3 INFORMED CHOICE

Ethical clinical practice demands that women make the decision to accept/otherwise antenatal screening and the potential to have to make further difficult decisions about the pregnancy, based on their having a complete and comprehensive understanding of the benefits, risks and limitations of the various procedures involved. The concept of making an informed choice about screening is a central issue for all clinicians involved in the screening process.

The literature about informed choice varies in its focus and scope but the following examples all concluded that the overall level of informed choice in their research populations was actually quite low.

One prospective study sought to examine whether the relationship between being well informed about the consequences of screening, was associated with the level of distress of the women, but concluded that only 37% of the decisions made by the research participants were informed; 31% did not know that miscarriage was a possible consequence of diagnostic testing and only 62% identified the option of termination should Down syndrome be diagnosed [42].

Another different research project, based on a randomized trial designed to measure the degree of informed choice in pregnant women undergoing screening tests for Down syndrome during antenatal visits did not find any association between the method of conducting an antenatal screening test and rates of informed choice. This study concluded that while it was uncertain how much of the variance in the level of informed choice was related by the way screening is conducted, the overall level of informed choice amongst the population offered screening was low[43].

In addition, Martaeu et al sought to explore the differences in communicating screening test risk information to women using numbers rather than words. This team concluded that using numbers did have a small beneficial effect of increasing awareness of the risks in the short term without causing excessive anxiety[44].

2.4.4 DECISION MAKING, TIMING AND TEST TYPE

The concept of general acceptance and satisfaction with newer screening tests, and the opportunity to have a degree of reassurance that the baby is alright or, if not, to know earlier rather than later in the pregnancy were similar notions in the literature.

Williams et al explores the experiences of 14 women offered innovative first trimester screening and the consequences on the ethical dilemmas faced by women. This paper highlighted the fact that many women had thought through their own moral beliefs and values prior to screening, and the emphasis women placed on the decision making being a very individual, private process.

A group of women whom had requested antenatal ultrasound (no clinical indications) were researched with the aim of identifying their reasons for the request:

- Ninety percent (90%) were in the first trimester of pregnancy;

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[41] Crang-Svalenius, E., Dykes, A., Jorgensen, C. (2003) Maternal serum screening for Down syndrome – opinions on acceptance from Swedish women. *Scandinavian Journal of Caring Sciences*. 17(1):30-4.

[42] Rowe, H., Fisher, J., Quinlivan, J. (2006) Are pregnant Australian women well informed about antenatal genetic screening? A Systematic investigation using the Multidimensional Measure of Informed Choice. *Australian and New Zealand Journal of Obstetrics and Gynaecology*; 46: 433-439

[43] Dormandy, E., Michie, S., Hooper, R., & Marteau, T. (2006) Informed Choice in antenatal Down syndrome screening: A cluster-randomised trial of combined versus separate visit testing. *Patient Education and Counseling*. Article in Press

[44] Marteau, T., Saidi, G., Goodburn, S. et al (2000) Numbers or words? A randomized controlled trial of presenting screen negative results to pregnant women. *Antenatal Diagnosis* 20: 714-718

- Sixty percent (60%) wanted to check for fetal abnormality;
- Fifty-five percent (55%) to check that everything was normal and 44% for their own re-assurance [45].

De Graff et al assessed the knowledge base of pregnant woman about antenatal tests as well as the woman's preferences for second trimester or first trimester screening. A high response rate of over 80% was noted, with a clear preference for first trimester testing using a combination of nuchal translucency and serum screening being identified as the option of choice. Knowledge of screening opportunities were less well known to woman in the low risk group compared with the higher risk group and the offer of screening would have been declined by more than 30% of women at low risk for carrying a foetus with Down syndrome[46].

Nicilaides, K. also advocates for first trimester screening on the basis of the clinical evidence of the effectiveness of nuchal translucency and serum testing. He believes women want to know whether their foetus has Down syndrome regardless of the pregnancy outcome; and that they value the knowledge of the underlying reason for a miscarriage if one was to occur[47].

The preference for first trimester screening and immediate disclosure of findings amongst older women and those with a better understanding of screening tests was found in study by Sharma G and colleagues. This research also concluded that these factors were associated with the higher likelihood of preferences to terminate an affected pregnancy[48].

Evidence is growing that women are accepting serum marker screening. A Canadian study[49] concluded that there was evidence to offer triple marker screening through a comprehensive programme to pregnant women under 35 years of age and women given detailed information about serum screening, show more satisfaction with the screening than those not provided with this information.

A study of how pregnant women experience serum screening in the Netherlands concluded that older women welcomed the availability of second trimester serum screening to the decision making process about whether to undergo amniocentesis, and it reduced the rate of amniocentesis considerably. Most said they would apply for serum testing in a following pregnancy but would favour the idea of first trimester screening. In the second group of younger women reassurance was identified as the main reason for undergoing serum screening. All women experienced some degree of anxiety when informed about a screen positive result and 13% continued to be anxious after negative amniocentesis test. The majority of respondents support serum screening and thought it should be offered to all pregnant women in the Netherlands [50].

NEGATIVE EXPERIENCES

In contrast, the literature is not completely silent on research which discusses the potentially negative consequences of screening with potential long term implications for the mental health of the mother and potentially the child. Two of these were located as a result of the literature scan.

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[45] Gudex, C., Neilsen, B., Madsen, M. (2006) Why women want antenatal ultrasound in normal pregnancy. *Ultrasound in Obstetrics and Gynaecology* 27(2): 145-150.

[46] De Graaf, I., Tijmstra, T., Bleker, O., van lith, J.M. (2002) Women's preference in Down syndrome screening. *Antenatal Diagnosis* 22:624-629

[47] Nicolaides, K (2004) Nucal translucency and other first trimester sonographic markers of chromosomal abnormalities. *American Journal of Obstetrics and Gynaecology* 191, 45-67.

[48] Sharma,G., Gold, H., Chervenak, F. et al (2005) Patient preference regarding first-trimester aneuploidy risk assessment. American *Journal of Obstetrics & Gynaecology* ,1429 -36.

[49] Dick, P.T. (1996) Periodic health examination,1996 update:1. Antenatal screening for and diagnosis of Down syndrome. Canadian Task Force on the Periodic Health Examination. *Canadian Medical Association Journal*. 154(4):465-79

[50] Weinans, M.,Huijssoon, A., Tymstra, T., et al (2000) How women deal with the results of serum screening for Down syndrome in the second trimester of pregnancy. *Antenatal Diagnosis*, 20: 705-708

In a Swedish study [51]to investigate women's responses to information about increased risk of carrying a baby with Down syndrome the researchers concluded that for the majority risk information caused strong reactions of anxiety and worries about the future. Of concern was the conclusion that a false positive test may cause strong reactions of anxiety and even rejection of the pregnancy. Prevalence of such reactions and possible long term effects need further investigation. Similarly, Grobman compared perceptions of miscarriage and birth of a child with Down syndrome among pregnant women and to evaluate the implications of preferences for the traditional 35 year old maternal age- risk boundary. This study found that women who desire antenatal diagnosis do not perceive the birth of child with Down syndrome and a pregnancy to be equivalent health states[52].

2.5 WORKFORCE

The workforce involved in antenatal and paediatric services is broad in scope with a range of professional disciplines – general practitioners, midwives, neonatal nurses, genetic counsellors, sonographers, obstetricians, fetal medicine specialists, geneticists, paediatricians, neonatologists, psychologists, chaplains and clinical practice across primary, secondary, tertiary and community services. An overview of the evidence on the pre-existing level of knowledge, attitudes, experiences and preferences about antenatal screening practice of this professional workforce provides different insights into the complexities of clinical practice, and these factors will need to be assessed in the context of planning for a national screening programme within a New Zealand context.

2.5.1 PRE-EXISTING KNOWLEDGE

Several studies have been undertaken to explore health professionals' knowledge about Down syndrome screening and the various technical aspects of the various screening tests.

The results of this evidence suggest that there is significant variation in the level and accuracy of pre-existing knowledge about Down syndrome screening amongst key professionals, and the need for education and up-skilling of this workforce is likely to be a priority for action in New Zealand.

A structured survey tool completed by health professionals (general practitioners, midwives, obstetricians, and geneticists) involved in the delivery of antenatal services allied to a tertiary hospital in Melbourne found that overall there was a high level of awareness regarding the stage at which the various tests are used but a poor understanding of the relative technical performance of the tests. Sixty percent (60%) of those counselling women indicated that they discussed detection and screen positive rates specific for the age of the woman, but less than ten percent (10%) were able to cite those rates as expected [53].

Likewise an experimental study aimed at investigating the accuracy of interpretation of screening information by different stakeholder groups including midwives, and obstetricians found a high incorrect response rate from both professional groups albeit the obstetrician group gave significantly more correct answers than midwives. Many health professionals were confident in their incorrect responses. Conclusions drawn included how frequently stakeholders draw incorrect inferences from probabilistic information and that they needed to be aware of the difficulties of imparting this type of information to women[54].

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[51] Ohman, S., Saltvedt, S., Waldenstrom, U., et al (2006) Pregnant Women's Responses to Information about an Increased Risk of Carrying a Baby with Down Syndrom. *Birth* 33:1 March

[52] Grobman,W., Dooley, S., Welshman, E., et al (2002) Preference Assessment of antenatal diagnosis for Down syndrome: is 35 years a rational cutoff? *Antenatal Diagnosis*. 22(13):1195-2000 0

[53] Tyzack, K. & Wallace, E. (2003). Down syndrome screening: What do health professionals know? *Australian and New Zealand Journal of Obstetrics and Gynaecology*. 43 (3) 217

[54] Ramwell, R., West, H., & Salmon,P. (2006) Health Professionals' and service users' interpretation of screening test results: experimental study. *British Medical Journal* 332:7562 p284-286

The need for health professionals to be regularly updated on the new technology and application to clinical practice is demonstrated by the findings of two studies identifying deficiencies in clinicians knowledge.

Deficiencies in midwives knowledge about nuchal transluency and positive results and the ethical issues generated by the use of such technology was highlighted in a study of midwives attitudes and knowledge about newer screening tests[55]. Similarly deficits in the knowledge and practice patterns of Obstetricians and Gynaecologists related to Down syndrome screening was identified in the United States. This latter research also suggested that the deficiencies need to be addressed before first trimester screening becomes more widely implemented[56].

Rural or isolated practitioners have special needs when it comes to keeping up to date with current and new clinical and technical knowledge and developments.

The extent of the unmet educational needs of rural and remote non specialist doctors with respect to obstetric ultrasound was highlighted in a 2004 study undertaken in Australia. This needs analysis was used to develop the Australian College of Rural and Remote Medicine national obstetric ultrasound professional development programme[57].

2.5.2 HEALTH PROFESSIONALS ATTITUDES AND PREFERENCES TO SCREENING

Screening policies, protocols and performance standards and the technical elements of the programme have to be acceptable to both women and the healthcare professional workforce involved in screening services**.** Knowledge of what is proving to be acceptable elsewhere or otherwise, could inform the design and operational policies for a screening programme in a New Zealand context.

Studies vary with regard to their findings about health professional attitudes and preferences to screening.

A study of midwives attitudes to the implementation of screening coordinator roles and maternal serum screening undertaken in the United Kingdom found that there was unanimous support for the principle of screening, and that most midwives considered the offer of screening should be a universal one, and not age related[58].

Similarly research to establish and compare obstetricians' and midwives' preferences for hypothetical antenatal screening tests for Down syndrome undertaken in London and Australia found that both obstetricians and midwives shared similar relative values regarding the importance of the detection rate of the screening tests. But there were variations between the groups with regard to timing and risks associated with the antenatal testing – with obstetricians placing higher value on these factors than did midwives. Younger midwives placed higher value on these variables than did older midwives. Female obstetricians placed higher value on the timing of a test than male obstetricians[59].

Another perspective was presented in a study into the association between healthcare professionals' attitudes towards antenatal screening and screening uptake in women who consult them. This research concluded that while there was no relationship between these variables, the

[55] Ekelin, M. & Crang-Svalenius, E. (2004) Midwives attitudes to and knowledge about a newly introduced fetal screening method. *Scandavian* Journal of Caring 18,287-293

[56] Cleary-Goldman, J., Morgan, M. Malone, F. et al. (2006) Practice Patterns and Knowledge of Obstetricians and Gynaecologists. *American College of Obstetricians and Gynaecologists* 107, (1) 11- 17

[57] Glazebrook R., Manahan,D., Chater,B. et al (2004) Educational Needs of rural and remote Australian non-specialist medical practitioners for obstetric ultrasound. *Australian Journal of Rural Health*. 12(2):73-80

[58] Fairgrieve,s., Magnay,D., White,l., Burn,J. (1997) Maternal serum screening for Down's syndrome, a survey of midwives views. *Science Direct Public Health* 11 (6) 383-385

[59] Lewis, S., Cullinane,F., Bishop, A., et al (2006) A comparison of Australian and UK Obstetricians' and midwives preferences for screening tests for Down syndrome. *Antenatal Diagnosis* 26: 60-66.

associations between healthcare attitudes and uptake rates by hospitals might influence systems of care, and not just communication with pregnant women[60].

Two studies comparing women's preferences for screening tests with those of heath care professionals highlight interesting differences in preferences and attitudes to screening tests.

A 2004 British study found that while pregnant women and health care professionals shared broadly similar values regarding the importance of safe tests, health care professionals placed a higher value on earlier tests in contrast to the women, relative to risk and detection rates [61]. Similar findings resulted from recent research undertaken in Australia where comparisons were made between women's and health professionals' preferences for antenatal screening tests. Again while there was general agreement between pregnant women and health professionals regarding the relative importance they attached to the different attributes of a test, the women placed greater emphasis on the safety of the actual tests, whereas the health professionals placed more importance on timing variables and relative risks associated with follow on diagnostic tests [62].

2.5.3 HEALTH PROFESSIONAL EDUCATION AND TRAINING

There is an abundance of literature related to the formal education and training needs of the workforce involved in Down syndrome screening services, particularly in relation to the development and implementation of a formal screening programme for Down syndrome in the United Kingdom. The relevance of this information needs to be explored in the key stakeholder consultations. Accordingly, the development of the key questions needs to incorporate these areas of interest.

The issue of the need to improve the level of education and training opportunities of the screening workforce was initially highlighted in a 1998 United Kingdom National Screening Committee report[63]. This report alluded to the inequity and inequality of services, absence of performance standards, and the inability of maternity services to cope with the introduction of screening on a nationwide basis.

A Nuffield Institute for Health Report made the following recommendation to the National Steering Committee with regard to training and information for staff.

> " Training should be developed for staff involved in each national screening programme, on a programme by programme basis, but adhering to the ideal requirements set out above. The training should be developed by each of the national standard setting bodies together with the relevant professional bodies and with a strong input from user groups" [64]

and with regard to information for staff about Down syndrome screening and the details of the governance and management of the national screening programme itself,

> "Essential written information (and possibly also video and audio taped information) about the procedure of each screening programme should be developed at a national level in order to ensure that it is consistent and based, as far as possible, on firm evidence. This information should be developed by the national standard setting bodies with input from professional and user bodies." [65]

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[60] Dormandy, E.& Marteau, T. (2004) Uptake of antenatal screening test: the role of healthcare professionals' attitudes towards the test. *Antenatal Diagnosis*. 24 (11):864-8.

[61] Bishop, A., Marteau,T., Armstrong,D., et al (2004) Women and healthcare professionals' preferences for Down's Syndrome screening tests: a conjoint analysis study. *British Journal of Obstetrics and Gynaecology*. 111(8) p 75

[62] Lewis, S., Cullinane, F., Carlin,J. & Halliday,J. (2006) Women's and health professionals' preferences for antenatal testing for Down syndrome in Australia. *Australian & New Zealand Journal of Obstetrics & Gynaecology*. 46 (3):205-211.

[63] UK National Screening Committee Programmes Directorate (2002). Antenatal Screening Service for Down syndrome in England: 2001 A Report to the UK National Screening Committee , NSU, England.

[64] Nuttfield institute of Health (200o). Quality Management for Screening: Report to the National Screening Committee. University of Leeds , Leeds, UK

[65] Ibid pg 19.

Key principles for education and training of screening professionals were developed following introduction of national working standards for screening in the National Health Service (NHS) in 2004[66]. The education and training standard encompasses the following content:

- Initial induction and annual updating
- Appropriate education and clarity of responsibilities for their role
- Nationally and regionally agreed policies re: training and education (factoring in requirements and guidance from the appropriate Royal Colleges and National Screening committee)
- Recording and monitoring of completion of education
- The provision of multidisciplinary antenatal screening education programmes
- Screening midwife/coordinator explicit responsibilities for education, assessment and evaluation and accountability to clinical governance board
- Audit programme for local multidisciplinary antenatal screening programme
- Staff appraisals to include training requirements.

In addition to the above generic requirements, specific standards re: education and training exist for each profession involved in Down syndrome screening and the education and training courses attended by professionals involved in the national screening programme must be recognized by the UK National Screening Committee [67].

The recently revised specific standard pertaining to 'Education and Training' also now includes the requirement for Providers to provide ongoing multidisciplinary antenatal screening education/induction programmes of a minimum of 6 hours per year, in addition to ongoing staff training and education [68].

Supporting these workforce education and training standards is a range of hard copy, and web based resources. Those currently freely available are the United Kingdom NHS dedicated Down Screening programme website accessed at http://www.screening.nhs.uk/downs/home.htm .

The Impact for the professional workforce involved with any aspect of Down syndrome screening services is that the presence of these resources offers all accessible, nationally developed, consistent and specific information on the programme and up to date clinical knowledge tailored to their specific professional speciality. In short, Clinical practice is well supported by evidence based resources. In addition, these resources and training programmes and the standards themselves have been developed in conjunction with the various professional colleges, which secures a shared and ongoing commitment to investment and professional leadership in supporting the professional workforce to meet (or exceed) the appropriate clinical practice standard/s as well as remain up to date with current and new information.

There are many similarities in the health systems and clinical environments between the United Kingdom and New Zealand, and this pre-existing resource base could be assessed for it's suitability to the New Zealand health services environment.

2.6 Planning, Implementation and Management of National Screening programme

A range of literature was located on topics relevant to the planning, implementation and management of Down syndrome screening programmes. This is included as it provides additional insights into some of the methods, challenges and barriers faced by other jurisdictions in relation to

[66] UK national Steering Committee (2004). Antenatal screening – working standards. NHS, UK

[67] UK National Screening Committee (2006). Antenatal Screening – Working Standards – National Down's Syndrome Screening programme for England. NHS, UK.

[68] IBID

large scale implementation of new or reconfigured services. In addition, workforce issues – capacity, capability and management are central to the establishment and implementation of a formal screening programme.

2.6.1 APPROACHES TO PLANNING

Responsibility for implementing the structures and standards specified by the National Screening Committee was devolved to regional health authorities, responsible for the planning and provision of services across a particular geographical region. National programme establishment in the United Kingdom was based on forward planning being based on very accurate health service status and needs assessment data highlighting information specific to each particular region or workforce group.

A mapping survey of Down syndrome Screening in the London Region[69] provides a good example of how one health authority went about establishing baseline data about existing service provision in the region. Their report also reinforced the challenges and frustrations and workforce issues such as recruitment and retention, highlighting them as constraints that may (have) prevented them from meeting the minimum service performance targets within the governments [then] 2004 timeframe.

A 2004 National Training Needs analysis for antenatal screening services across England made 16 recommendations pertaining to the scope, priorities, and mode of education and training needs of screening services with particular emphasis on the needs of the new Antenatal Screening Coordinator roles. This research highlighted the fragmentation and inequitable nature of the current state of education and training as well as pre existing gaps in some subjects central to antenatal screening. This study found gaps in the provision of education and training surrounding infectious diseases, laboratory techniques, feedback and communications skills, genetics and technical knowledge of some diseases. Furthermore education and training on ethics, fetal abnormalities and support following diagnosis and counselling were identified as other deficits [70],[71].

Recommendations also encompassed skill training deficits such as familiarity with using computer software and teaching and facilitation by the screening coordinator workforce and also use of internet, CD – ROM as well as hard copy resources[72].

2.6.2 SERVICE DELIVERY

Evidence exists to suggest that there may be relationships between service delivery models and the level of women's acceptance, participation and informed consent. A paper located during the literature scan aimed to determine the extent to which variation in the uptake of serum screening for Down syndrome reflected the way in which the screening tests are provided. This study found that service delivery may impact on the uptake of serum screening tests but also that service delivery has an impact on whether women's choices are based on well founded information (the measure of being well informed) [73].

A 'One Stop Shop" model of screening service delivery is available in the United Kingdom which comprises specialist services collocated enabling a pregnant women to receive counselling, NT scan, maternal serum screening and individualised follow up[74].

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[69] Kennedy, J. & Saunders D. (2002). Mapping Survey of Down syndrome Screening in the London Region. NHS, UK

[70] Harcombe, J & Fairgrieve, S. (2004) National Training Needs Analysis for Antenatal Screening Services Across England. Report to the UK National Screening Committee by the Regional Antenatal Screening Teams. NHS, UK

[71] Armstrong, V. (2003). Training Needs Analysis for Antenatal Screening Provision South East Region. [accessed on web]

[72] Harcombe, J & Fairgrieve, S. (2004). Op Cit

[73] Dormandy, E., Michie, S., Weinman,J., & Marteau, T. (200). Variation in uptake of serum screening: the role of service delivery. *Antenatal Diagnosis*. 22:67-69.

[74] The Fetal Medicine Foundation Web Site : accessed on http://www.fetalmedicine.com/banner-downs.htm

The subject of communication of antenatal screening and diagnosis was the topic of one paper and this study highlights the relationship between the service delivery model and communication challenges can evolve when there are multiple health professionals and a mixture of independent, primary, secondary and tertiary providers involved in service provision.

A study which sought to investigated how antenatal screening and diagnostic test results are communicated to primary care health professionals found:

- Sixteen percent (16%) of primary care professionals reported that they were not usually informed of high risk results after serum screening for Down syndrome;
- Twenty eight percent (28%) were either not usually told about the possibility of abnormalities detected on ultrasound or only heard of such abnormalities from the woman herself.

In addition, when informed twenty eight percent (28%) of midwives and general practitioners did not know what action they were expected to take. Only twenty nine percent (29%) were told soon enough about diagnosed abnormalities and only seventeen percent (17%) of health professionals reported that the information they were given was always sufficient to allow them to discuss issues with their patients. The presence of specialist screening coordinators was perceived to be helpful by seventy six percent (76%) of health professionals [75].

2.6.3 CONSTRAINTS TO IMPLEMENTATION

The evidence located suggests that there have been two main constraints to the implementation of other national or regional screening programmes for Down syndrome – workforce capacity and workforce capability.

EVIDENCE OF WORKFORCE CAPACITY CONSTRAINTS:

Examples of direct and indirect workforce capacity constraints were located during the literature scan.

The insufficient capacity of Nuchal Translucency services to cope with increased demand for NT, is highlighted in two studies.

Challenges related to Sonographer training, standardised nuchal translucency sonography protocols, quality assurance programmes, interpretation of risk data, availability of first trimester diagnosis and combining screening tests across different stages of the pregnancy have been highlighted in both the United Kingdom, Ireland and the United States[76],[77],[78].

In addition, constraints on ensuring equality of access to services for isolated and rural communities is also documented in one study which highlights the variations in current rates of antenatal diagnosis between metropolitan based pregnant women versus those living in rural locations. This study found the lowest rates in farming districts and suggested the likely reasons to be a combination of a lack of access to services (remoteness) and individual opportunity (lack of transportation, low levels of support and income)[79].

Similarly in the United Kingdom, the most recent National Down's Syndrome Programme 2005/2006 Annual report identifies capacity constraints in relation to ultrasound scanning resources with

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[75] Statham, H., Solomou, W. & Green, J. (2003). Communication or antenatal screening and diagnosis results to primary-care health professionals. *Science Direct Public Health*, 117(5) 348-357.

[76] Malone,F. (2005) Nuchal Translucency – Based Down syndrome Screening: Barriers to Implementation. Science Direct *Antenatal Screening*. 29(4) 272-276.

[77] Fuchs, K & Peipert,J. (2005). First trimester Down syndrome screening: public health implications. *Seminars in Perinatology* 29(4):267-71.

[78] Ward P. (2003) Report of the Progress of the Groups of the National Down syndrome Screening programme. National Screening Committee, NHS UK

[79] Muggli, E., McCloskey, D., & Halliday, J. (2006) Health behaviour modeling for antenatal diagnosis in Australia: a geodemographic framework for health service utilization and policy development. *BioMed Central Health Services Research* 6:109

capacity issues still relevant, and previous reports contain suggestions that the worldwide shortage of nurses and midwives has also constrained some regions from meeting programme standards due to the difficulties with the recruitment, retention and turnover of staff [80].

Similarly there is also the inference in these reports and government policy documents that some regions/services have created capacity to cope with the demands of the national screening programme standards by the application of other strategies involving role design and reconfiguration of service delivery. The application of such strategies in the context of workforce challenges within the Radiology profession is also currently being explored by the Royal Australian and New Zealand College of Radiologists [81]. These initiatives create additional capacity by the achievement of improved utilisation and efficiency of pre-existing capacity and/or modifying the traditional clinical roles and scope of practice of pre-existing practitioners by considering one or more of the following strategies:

- Changing to skill-mix (ie moving tasks or roles up or down an existing hierarchy);
- Job widening (ie expanding the content of existing roles);
- Job deepening (ie providing additional responsibilities);
- Autonomy and opportunity for development to existing roles; and
- The development of new job roles (e.g. by combining new and/or existing roles and functions in innovative ways).[82]

It is reasonable to predict that many of the challenges outlined above, are of equal relevance to the New Zealand context.

New Zealand experiences many ongoing challenges related to the availability, recruitment and retention and training of sufficient specialised staff across many services and/or professional groups and has previously experienced workforce failures with respect to the health screening services. The disparately low number of Maori and Pacific health personnel in the health workforce is also a well acknowledged challenge for all categories of health service [83],[84].

Similarly the national screening unit has previously reported that staff retention rates were low due to low morale, low pay and New Zealand graduates (nurses and specialist laboratory staff)) being employed overseas. Retention of laboratory staff is also an ongoing issue for New Zealand. They also stated that the number of Maori and Pacific people working in the pre existing screening programmes was too low and that an ideal screening workforce would include a greater representation of Maori, Pacific and other ethnic groups to ensure culturally safe services[85].

Workforce capacity in rural or provincial New Zealand has also been highlighted as a workforce challenge where innovative solutions will be necessary should a national Down screening programme be introduced.

Furthermore the workforce challenges related to the current organisation and funding of maternity services and their relationship to the introduction and development of primary health care organisations and investments in improved access and delivery of primary health care services is another area of relevance with significant workforce leadership and governance challenges that

[80] UK National Screening Committee (2006) National Down's Syndrome Screening programme for England - 3rd Annual Programme Report 2005/2006. NHS UK

[81] Sutton,E. & Koenig K (2006) Literature Review – Establish Roles and Standards for Non Medical Diagnostic and Imaging Staff – Quality Use of Diagnostic Imaging Program (QS3) Royal Australian and New Zealand College of Radiologists, Sydney NSW.

[82] NHS Modernisation Agency (2002) Workforce matters a good practice guide to role redesign in primary care. NHS UK

[83] Health Workforce Advisory Committee (2002) The New Zealand Health Workforce: A Stocktake of Issues and Capacity 2001. Wellington : Health Workforce Advisory Committee.

[84] Health Workforce Advisory Committee (2003) The New Zealand Health Workforce: Future Directions – Recommendations to the Minister of Health 2003. Wellington: Health Workforce Advisory Committee

[85] National Screening Unit (2004). Workforce Development Strategy and Action Plan 2002 – 2007 NSU, Auckland

will need exploring as part of the planning, implementation and management of a national Down screening programme[86].

2.7 QUALITY MANAGEMENT SYSTEMS

The literature shows that quality management systems are integral to screening programmes. They are essential in order to ensure services are managed and provided in such a way that quality can be assured and the potential for harm minimized. The Quality management framework guiding the introduction and operation of a national screening programme impacts on all aspects of workforce capacity, capability, training and development, professional development, governance and leadership and audit and monitoring and performance of clinical services.

There is a large volume of literature, reports, policies regarding topics central to Quality Management in screening programmes from the United Kingdom, which is relevant to the New Zealand context.

The comprehensive report by the Nuttfield Institute of Health recommended a British wide framework for ensuring the quality of NHS population screening programmes[87]. In regard to the then proposed implementation of a national screening programme, such a programme would be governed at the national level by a new body established to manage all antenatal screening.

A survey of antenatal screening for Down syndrome in 2000 highlighted the variations in pre existing service delivery and quality performance[88]. Likewise a national survey of the education and training status for antenatal screening services undertaken in 2003 highlighted the importance for quality to be the top priority for attention of the National Screening programme [89].

Preliminary programme screening standards were originally introduced in 2003[90]. These define the minimum standards that providers have to meet in terms of the provision of Down syndrome screening services in their area. These standards encompass:

- Governance/clinical arrangements
- management
- administrative standards
- consent policies for women
- information for women
- staff education and training (refer above)
- women with specials requirements
- Ultrasound screening
- Nuchal Translucency
- Multiple pregnancies
- Laboratory
- Diagnostic Testing
- Information Technology and
- Audit and Monitoring.

For each of these components, specific operational policies and standards are outlined. For example:

- Nuchal Transluceny services – There are 7 specific standards pertaining to NT services.

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[86] [moh – press statement]

[87] Nuttfield institute of Health (200o). Op Cit

[88] UK National Screening Committee (2000) Second Report of the UK National Screening Committee. Department of Health UK

[89] Harcombe, J & Fairgrieve, S. (2004) Op Cit

[90] UK national Steering Committee (2004). Op Cit

(i) There must be an agreed written policy defining the purpose of screening for Down syndrome by measurement of the nuchal translucency.

(ii) All sonographers/clinicians performing nuchal translucency measurements must be appropriately trained and accredited.

(iii) All sonographers/clinicians performing nuchal translucency measurements must have their results subjected to rigorous and valid audit.

(iv) To ensure satisfactory performance each sonographer must perform a minimum of 50 nuchal translucency measurements per year.

(v) The ultrasound scanning equipment should have a cineloop function and callipers that have a precision to one decimal point, ie 0.1mm standard.

(vi) The risk calculation software package must adhere to the specification set by the UK National Screening Committee.

(vii) To demonstrate satisfactory performance the scanning department must take part in an approved internal and external quality assurance programme, such as Down syndrome Quality Assurance Support Service (DQASS).[91]

- and for Laboratory services –

(i) Laboratories must have an agreed written policy, which adheres to national standards and defines the purpose of serum screening for Down syndrome.

(ii) The laboratories must be represented on a Clinical Steering Group and be part of a clinical governance framework.

(iii) The laboratory must be accredited by an appropriate body.

(iv) The laboratory must participate in an accredited external quality assessment scheme and be able to demonstrate satisfactory performance.

(v) The laboratory must submit screening data to DQASS at least twice a year.

(vi) There must be a senior member of the laboratory staff at consultant level, with relevant experience in screening, taking overall responsibility for all laboratory aspects of the Down syndrome screening service.

(vii) There must be a defined managerial structure for the responsibilities of other members of staff involved in the screening work.

(viii) There must be a documented risk assessment policy for the laboratory aspects of the Down syndrome screening service, showing an analysis of the possible areas where mistakes may occur and the steps that have been taken to minimise their occurrence.

(ix) Appropriate internal quality assurance procedures must be undertaken and documented eg. Weekly or monthly checks of screen positive rates, results of the analysis of internal QC specimens, regular checks of median MOM marker values.

(x) The laboratory must participate in audit of the screening service at local and regional level and provide an annual report, or the necessary data for the preparation of an annual report, to the Clinical steering group.

(xi) Laboratories with a workload of less than 10,000 specimens a year must be part of a 'managed network' of no less than 3 laboratories, with each having a minimum workload of 5,000 specimens per year and identical screening policies and analytical procedures in force.

[91] UK National Screening Committee (2006). Antenatal Screening – Working Standards – Op Cit

(xii) The manager of a combined screening service should have the authority to monitor the performance of each of the screening laboratories and effect changes when necessary.

(xiii) A stand alone screening laboratory must have a workload of at least 10,000 Down syndrome screening specimens per annum to have sufficient confidence in the quoted annual screen positive rates, and to have sufficient specimens to calculate reliable monthly median values for the biochemical markers.

(xiv) 97% of Down syndrome serum screening reports must be issued within 3 working days of receipt of the specimen at the laboratory.

(xv) 95% of results on rapid tests should be available within 3 working days.

(xvi) Laboratories undertaking Down syndrome serum screening must comply with the national standards in force at any particular time regarding detection rates, screen positive rates and the cut off used to define the higher risk population.

(xvii) The computer software used to calculate the Down syndrome risk must comply with the current National Specification for Risk calculation Software, published by the UK National Screening Committee. It must also be CE marked and comply with EU directives.[92]

In addition to these detailed and explicit national standards all service providers (across the board) are expected to establish internal quality assurance systems to ensure their local services perform at their optimum. Audit and monitoring processes are implemented locally, and nationally using web based information and database systems. In respect of the security of the information technology infrastructure, appropriate procedures for ensuring authorized interconnectivity, audit, security and access have been established.

At the operational level, local or regional programme managers are required to establish or reconfigure all the components of their local policies and practices to be consistent with the national framework and regional/local service needs.

More recently the Department of Health has issued a best practice guide for the commissioning and management of screening programmes in the NHS in England which explicitly details the role, elements and application of quality management and quality assurance systems in screening programmes [93] .

In New Zealand there are a range of pre existing frameworks and activities in progress that are relevant to Quality improvement in the context of Down syndrome screening, for example, the National Screening Unit's pre-existing Quality Framework[94], and Workforce Development strategy[95].

The Radiology/Diagnostic Imaging Profession & the Royal Australian and New Zealand College of Radiologists (RANZCR) is developing a Quality and Accreditation Programme for medical imaging practices in Australia with the ultimate aim of developing minimum standards of accreditation for all modalities of medical imaging including ultrasound. At present a voluntary accreditation scheme, jointly administered by the college and the National Association of Testing Authorities (NATA) is available.

Similarly the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) is facilitating an education and credentialing programme for all practitioners performing Nuchal Translucency Screening, including obstetricians, radiologists, GPs, midwives, sonographers and genetic counsellors.

[92] UK National Screening Committee (2006). Antenatal Screening – Working Standards – Op Cit

[93] Department of Health (2005). Commissioning and Managing screening programmes in the NHS in England. Department of Health UK

[94] National Screening Unit (2004), Op Cit

[95] National Screening Unit (2005). Op Cit

Flinders University (Centre for Remote Health) is developing, piloting and evaluating a training programme in basic ultrasound for Central Australia for remote health professionals. The Australian College of Rural and Remote Medicine (ACRRM) is organising and delivering an intermediate obstetric ultrasound and emergency medicine ultrasound education programme for rural and remote doctors.

In addition there are more generic workforce development and Quality Assurance initiatives that have been initiated and implemented by national, regional policy agencies and/or service providers. Examples include -

- Mentoring programmes for graduate midwives in their first year of clinical practice (in response to chronic shortages, recruitment and retention challenges)
- Clinical governance systems and policies
- Increasing emphasis on accreditation and credentialing systems of health care professionals.
- Maori workforce development agencies.

These initiatives collectively will have an impact on the management of a Down syndrome screening programme in New Zealand and their influence on the planning, design, implementation and management of such a programme will need to be assessed as part of the Ministry of Health's strategic decisions regarding Down syndrome screening services in New Zealand.

2.8 CONCLUSION

This scan of the literature on Down syndrome screening programmes or services around the world has identified a wide range of experiences, questions, challenges, ideas and knowledge about many aspects central to a formal screening programme.

It is reasonable to assume that many of these variables have direct or indirect implications for the workforce presenting challenges that are central to the planning, implementation, management and leadership of a national Down syndrome screening programme as part of New Zealand's antenatal health services.

This scan has identified the priority subject areas for progressing the key informant interviews forming part of the wider work on a Down syndrome Screening programme for New Zealand. These include questions about consumer information and knowledge, health professionals' information, knowledge and acceptance of screening, capacity, service configuration, testing formats, service configuration challenges, and quality assurance. In addition there are challenges specific to each service component and professional discipline involved in the screening process.

These key subjects will form the basis for preparing appropriately targeted questions for the project team to discuss with the key stakeholders during the informant interviews.

3

METHODOLOGY

3.1 KEY INFORMANT INTERVIEWS

The purpose of interviewing key informants was to gain input from key stakeholders in the identification of solutions for minimising any negative workforce/service impacts and identify other issues for consideration should a national antenatal Down syndrome screening programme be implemented by the NSU.

Twenty (20) Key Informants identified by the NSU and the ADDSAG were interviewed over a period of four weeks. Participants were contacted by telephone initially and asked whether they would be prepared to participate in the study through key informant interviews. Despite extremely busy work schedules, the 20 key informants whose names were forwarded to the interview team by the Ministry of Health agreed to be interviewed. Arrangements were made to conduct the interviews at mutually agreeable times and venues.

Letters confirming the arrangements were sent to individual participants together with an agreed list of questions that were to be covered in the conduct of the interview in order for them to prepare their responses, if they so desired. All participants were informed in the letter and at the beginning of each interview that the interview might not adhere to the sequencing of the questions as represented in the attachment forwarded to them and that the principle focus of the interview was to explore a range of issues while ensuring all the matters raised in the questions in the attachment were covered off by the conclusion of the interview.

The key informants were also informed that the comments received from individuals through the interviewing process would not be attributed to individuals, and the report back to the Ministry would be based on themes that arose throughout the consultation process.

Seventeen interviews were carried out in a face-to-face meetingand three were conducted by telephone.

Of those interviews completed over the telephone; two occurred for logistic reasons due to time constraints. The length of the interviews ranged from 34 minutes to 1 hour and 40 minutes with the average duration being an hour .

The key informants interviewed comprised of 3 GPs, 4 Midwives, 3 Obstetricians, 3 NT Practitioners, 2 Laboratory Staff (a Biochemist and a Cytogeneticist), 2 Clinical Geneticists, a Paediatrician, a support service representative from the New Zealand Down syndrome Association (NZDSA) and a Genetic Counsellor. The participants were also spread geographically across New Zealand (refer Table E.1).

4

COMMON THEMES ACROSS THE PROFESSIONAL GROUPS

Sections 5 to 12 summarise the opinions and issues expressed to the interview team by the respective professional and support groups represented in the key informant interviews. This chapter presents the common themes that arose across the majority of the professional cohorts.

4.1 COMMUNICATION WITH STAKEHOLDERS

The General Practitioners (GPs) and, midwives interviewed did not appear to have sighted the recent guidelines regarding antenatal screening made available by the Ministry of Health.

The GPs interviewed indicated that in general they were unaware of serum screening and that they had not received any information from the Ministry for quite some time on this issue. The use of New Zealand Doctor as a medium through which such information could be advertised was suggested by one GP obstetrician. The coverage of this publication would ensure that the majority of general practitioners would have exposure to information relevant to any new screening programme.

4.2 INTRODUCTION OF A NATIONAL ANTENATAL SCREENING PROGRAMME

The majority of key informants (apart from the clinical geneticists who had a few reservations) were unanimous in their agreement that a national antenatal screening programme for Down syndrome should be introduced. A general perception exists across the health profession cohorts that screening at present is too random and as such the current processes should not be left unaddressed.

Some debate also existed over whether the national screening programme should be referred to as the national Down syndrome screening programme or the national Antenatal screening programme. Feedback from the clinical geneticist supporting the latter terminology pointed out that screening technology and processes are able to pick up other abnormalities and accordingly should not be restricted to Down syndrome detection alone.

The key informants also concurred that it would be important to decide what the national policy is going to be and adopt a consistent equal approach across the country.

In order to modify existing processes, a national policy covering national Down syndrome (or national antenatal) screening should be developed as an initial step and this needs to be promulgated as soon as possible and in a consistent manner across the country.

4.3 INFORMATION PROVIDED TO WOMEN ABOUT ANTENATAL SCREENING

The interviews identified a divergence in the level and type of information different health care professionals felt they would be prepared (or equipped) to provide to women about the screening process and associated outcomes. For example, the clinical geneticists believe women need to be fully informed about what screening entails prior to it being offered to them and before undergoing any screening tests. Informing women in this respondent's opinion would involve providing women with an understanding of what is meant by:

- the term 'screening';
- the limitations of a screening test;

- the concepts of 'false positive' and 'false negative' results;
- the meaning of the term 'risk';
- the possibility that other abnormalities apart from Down syndrome may be detected by the tests.

Importantly this respondent indicated that in their opinion it was critically important that women should give informed consent to all of the tests they undergo as part of a screening programme.

Women also need to be informed that whilst participation in a screening programme is voluntary it entails involvement over a continuum and may give rise to being faced with having to make decisions about their pregnancy.

The topics that an obstetrician would include in a conversation with a woman about screening would include:

- clarification of the types and details of different screening tests;
- assessment of the woman's risk profile;
- the worth and value of various screening procedures;
- ensuring the woman understands that tests are about screening and not diagnosis; and
- discussion and explanation about the 'what if' scenarios that exist specific to the history and circumstances of individual women.

Of note there is also divergence in opinion as to the most appropriate stage at which information about screening is presented for the first time to a pregnant woman and what indicators prompt a health professional to provide this information. For example, one GP indicated that they would probably provide information to a woman if they already had a child with Down syndrome. Another general practitioner indicated that they would not generally provide information to women about screening as in their opinion appropriate information is not available; however, they may refer a woman for screening.

Some midwives for example, undertake their own risk assessment and make decisions based on the outcomes of the assessment as to whether or not to discuss screening options with a woman. Others indicated that that the best time to provide women with information would be prior to them reaching 12 weeks of their pregnancy and that it was basically too late once they had reached 20 weeks.

In the opinion of the interviewed midwives their profession should inform women of their options within the framework of what is available; the element of reliability around what is available and the current guidelines.

There was some congruence of opinion between respondents in terms of their perceptions of what they thought women would want to know about screening. For example, the Paediatrician felt that women would want to know that it is possible to be screened and what their chances of having a baby with Down syndrome are or were. They would want information on the accuracy of tests, what the tests are about whether they are ultrasound tests or blood tests, the risks associated with diagnostic tests and other conditions that may be detected as well as Down syndrome. If they have received a positive test result they would want information about what the child is likely to be like, what medical complications to expect and what it would be like to bring up a child with an intellectual disability.

The NZDSA believed that women need and want to know everything they can about antenatal screening options available to them and often have no idea that the initial routine scan is also a 'screening test' for abnormalities. When they receive a positive antenatal screening test result or learn that there is a possibility of something being wrong with the pregnancy, they find themselves caught up in a process without any understanding of how they came to be there, what processes they are now party to and the associated advantages and disadvantages. They mentioned that they have found that meeting families with a child with Down syndrome is often quite helpful in aiding families to make a decision.

4.3.1 WAYS OF PROVIDING INFORMATION

Communication of information was seen as a pivotal issue in the development and implementation of a national screening programme. Two target groups for a communication strategy were identified by the respondents, namely women (notably limited mention of their partners) and health care professionals.

With respect to health care professionals, it was felt that some exposure to information about:

- disability and living with disability;
- what it means to live with Down syndrome;
- the implications of testing, (not just the technical implications) but the emotional impact of the decisions that follow; and
- about counselling, support and follow up

would ensure that they obtain a greater appreciation and understanding of what Down syndrome is. Importantly it was felt that exposure to information such as that listed above would be critical in ensuring the health professionals adopted a well rounded and less valued approach to consulting with women on issues associated with Down syndrome.

With respect to women, two levels of information dissemination were discussed. Firstly exposure of women to more general information about new developments in antenatal screening was thought to be best achieved through 'popular media' such as running advertisements on the TV or using women's magazines, pregnancy magazines, newspapers and the internet. Midwives also indicated that they would like information to be available for use in antenatal classes and said that information in the form of pictures would be useful.

Access to more technical information about screening programmes and what they entail through pamphlets was identified as an appropriate medium by the majority of informants. However, significant difference in opinion was expressed in terms of the level of sophistication and detail of information contained in these pamphlets. School of thought ranged from exclusion of any statistical and technical information about procedures through to inclusion of information about absolute and relative risk.

Obstetricians considered that the information provided to women should cover expectations, risks, explanations of tests, the 'what if' scenarios and about informed consent regarding the diagnostic procedure being considered. They pointed out that doctors should be skilled at distilling information on behalf of their patients and that women need clear information to enable decision making and that details of procedures and written information should be supplied, similar to an operative process. It was emphasised that at the specialist level women should be receiving specialist level information; that they should be informed as to the true range of options available to them; that verbal information should be backed up with written information, whether that be sourced from the College or from the Ministry of Health and that Information should be both interpretative and explanatory in content.

The Clinical Geneticists believed that it was important that women understand the risks associated with diagnostic tests i.e. the risk of miscarriage, the risk of not getting any result, or the risk of getting the wrong result as well as what the test tells them and what it doesn't tell them. They thought that this information should be provided in a pamphlet and reiterated by the LMC. Reiteration by the LMC was considered important for a variety of reasons. It cannot be assumed that all women when issued with written materials will read the entire document and having verbal reinforcement from an alternate source will ensure exposure of the individual to the critical information in an appropriate timeframe.

It was noted by the interview team that the majority of respondents indicated that they had access to pamphlets or leaflets containing relevant information, although one of the GPs mentioned that they do not have any information to give to women. This individual indicated that they refer to the UK National Screening Committee (NSC) website which they rated very highly and accessed information through this portal. This respondent suggested that people were using internet websites to inform themselves and suggested that a multimedia package may be

appropriate in terms of disseminating relevant information about screening options available to pregnant women.

As indicated above, other respondents indicated that they have access to information via a number of pamphlets and leaflets (e.g. pamphlets obtainable through RANZCOG were cited as being good visual aids providing information on screening, amniocentesis and CVS). It was mooted that some consideration should be given to the development of a national pamphlet to replace those currently in existence thus ensuring consistent information about what happens in pregnancy and screening options is used across the country.

Of note all professional cohorts involved in the consultation process indicated that the method of disseminating information to women must use language women understand and relate to and that the 'national pamphlet' should be made available in different languages. Experiences observed in the literature, particularly from the UK were cited as examples. It was acknowledged that to achieve this appropriate resources and time would need to be allocated to the task to ensure that the translation is correct. Respondents also pointed out that this information should be available for all women regardless of ethnicity and that it should take into account belief systems.

As to who would be charged with the development of a national pamphlet there was different opinions expressed. Some respondents suggested that the ADSSAG and Paediatricians should be involved in drawing up leaflets for women. Others indicated that a group of experts should be used (including input from a variety of users to gain cultural perspectives) in the drawing up of relevant information packages or pamphlets.

A few respondents also thought that any leaflets that are produced regarding a screening programme should alert women to the fact that there are some difficult ethical issues regarding screening that people need to grapple with.

4.3.2 Responsibility for Providing information about Screening Options to women

The majority of informants agreed that all women should be informed about and offered screening. Importantly irrespective of whichever health professional the woman saw, whether it was an obstetrician, GP or LMC respondents indicated that these health professionals should know who to refer a woman to and should have appropriate access to educational/informative materials about screening which can be provided to the pregnant woman.

As to where the responsibility lies in terms of provision of relevant information to women there was some variation in opinion expressed to the interviewing team. The most common thought was that the first person a woman sees regarding her pregnancy should be the person responsible for informing women of the screening options available to them. Typically the first point of contact is the Lead Maternity Carer (LMC) and as such respondents felt that matters relating to screening should be raised by the LMC and resources made available to women through the LMC. Accordingly, key informants interviewed believed that all LMCs should have the skills to inform, counsel and explain to women about antenatal care, genetic abnormalities and screening options. As a consequence the need to include appropriate education of LMCs and dissemination of information to LMCs as part of the overall implementation and design strategy of a national antenatal screening programme was highlighted by all respondents.

In addition to these views, key informants from NZCOM indicated that midwives are perfectly capable of providing relevant information to women. They consider midwives to be confident and well versed in this area of health care and that they are appropriately equipped and are the appropriate professional to provide screening information to pregnant women.

Alternate views were also put by general practitioners and obstetricians involved in the consultation process. One GP said that primary care workers have the responsibility to inform pregnant woman about screening options and this implies that it would be the responsibility of Primary Health Organisations (PHO) through GPs and their other staff. They also felt that it was the midwives responsibility although they did not belong to PHOs. Obstetricians said that there were different levels of information and responsibility regarding the provision of information about

screening options. This included community, medical and, industry responsibility at strategic levels with one obstetrician also indicating that in their opinion RANZCOG had a role to play.

Due to the diversity of service delivery models in existence, respondents highlighted the need for the existence of some form of a safety net or secondary system which ensured that if women did not access information through LMC's then other health providers were also capable of providing the relevant information to women.

4.4 SCREENING OFFERED TO WOMEN

Based on the feedback from respondents, current practice does not ensure consistency in the type of screening offered to women, nor the time at which screening is undertaken. For example, one of the GPs interviewed said that they offered screening for Down syndrome to every woman whilst another said that they prefer maternal serum screening (MSS) at 16 weeks and would refer women for a NT scan at 12 weeks.

The midwives said that they were aware that midwives do not necessarily offer screening to all women they see.

Obstetricians suggested that the most appropriate screening programme would be combined first trimester screening (i.e. 1st trimester NT combined with 1st trimester MSS) and that this would give a unified test and would identify at least 90% for a 5-10% amniocentesis rate and a study published by the Department of Health, Western Australia in 2005[96] was cited supporting this.

One obstetrician cited a preference for 1st trimester NT scanning and 2nd trimester MSS and said that whatever is decided, the programme must be simple, consistent, clear and have quality control monitoring systems. They stressed that provision should be made for specialists to vary the programme according to circumstances and that these parameters should be set by the Ministry.

The obstetricians concurred that they would offer NT scanning and MSS depending on their assessment of the circumstances specific to the women and their pregnancy. They all agreed that high quality NT scanning should be a priority.

4.5 NT SCANS

The GPs and midwives interviewed felt that more research needed to be conducted on NT scanning in relation to cost and time. They said that whilst the NT scan puts womens' minds at rest they do not consider it to be a very reliable test and consequently the cost effectiveness of this form of testing needs to be considered over a longitudinal study.

Obstetricians said that they were concerned that women either:

- had difficulty accessing NT scanning, or
- accessed it at the wrong time.

Obstetricians expressed concern that women are not necessarily told that the purpose of the scan is to screen for a genetic disorder and that the purpose of the scan is trivialised to simply "needing a 12 week scan". Accordingly, women place low priority on the scan and could inappropriately delay having the scan. Also some concern was expressed that access issues may arise because screening options are not necessarily offered by the LMC in time or that the LMC does not think that that screening test is necessary.

Of significant note, the sonographers felt that they would only need to explain to the woman on presentation what they were doing during the procedure and that they should be able to make the assumption that the woman has already been counselled by another health care professional referring them for NT scanning.

[96] Breheny N, O'Leary P, Dickinson J, Bower C, Goldblatt J, Hewitt B, Murch A and Stock R (2005). Statewide evaluation of first trimester screening for Down syndrome and other fetal anomalies in Western Australia. Genomics Occasional Paper 5. Antenatal Diagnosis Committee, Department of Health Western Australia

4.5.1 ACCREDITATION

Not withstanding the comments from some respondents relating to the reliability of the NT scan, NT scanning is a very highly skilled procedure from the perspective of accuracy of measurements. It was generally believed that all practitioners, including sonographers undertaking antenatal NT should be accredited. It was also suggested that they should not receive funding or be able to use the Fetal Medicine Foundation (FMF) software unless they were accredited.

The obstetric NT practitioners interviewed were not aware of any sonographers conducting NT scanning who were not trained or accredited to do so. However, the radiologist NT practitioner said that in big practices one person will have completed the course thereby having access to the software which they then allow others in the practice to use via their FMF ID.

4.6 REFERRALS MADE BY GPS FOR CVS OR AMNIOCENTESIS PROCEDURES

The GP Obstetrician said that they see about 90 pregnant women a year and of those probably 10 percent would be referred for Chorionic Villus Sampling (CVS) or amniocentesis. They did point out that they were aware that this percentage was relatively high, but said that they cover an older population in relation to those covered by many other GPs.

One of the other GPs said that GPs may refer about 2-3 women out of the obstetric caseload that they were managing and that referral was probably based primarily on age risk.

One obstetrician in private practice said they felt that every woman has the right to have an amniocentesis irrespective of age provided they receive good counselling. The other two obstetricians did not think that women had the right to an amniocentesis if they were over the age of 35 as amniocentesis is no longer the best screening test. One obstetrician said that they do more amniocenteses now as a result of NT scanning than they did with the age criteria of over 35.

The Clinical Geneticists felt that women should have the right to have an amniocentesis if they were over the age of 35, but with provisos; they stressed the importance of enabling women to make an informed decision.

4.7 DISCUSSION OF SCREENING AND DIAGNOSTIC TEST RESULTS

There is a difference of opinion at what point in the screening process a woman should be told of her results. Linked to this issue then is which health care professional has the responsibility of having the discussion with the woman of the screening and diagnostic test results.

One school of thought has the woman attending and having the screening and diagnostic tests, the results then being sent back to the LMC at which point the LMC discusses the antenatal screening results with the woman. If a woman does not have a LMC at this point, then it would be the GP who would discuss the results with her. Under each scenario it was considered important to educate midwives, LMC and GP skills in this area.

Another GP indicated that the Practice Nurse may be another resource who could become involved in this process.

The other school of thought involves the NT practitioners discussing the results with the woman during or straight after the diagnostic test. NT practitioners were of the opinion that If the screening programme's design dictated that NT Practitioners did not discuss the results with the woman this would this create issues for them as the test is visual, the woman can see straight away and it is hard to conceal information from them. The option was put that if the practitioner was accredited in NT screening they could give results and if necessary they would be able to refer the woman to a specialist or back to their LMC. This process of discussing the screening and diagnostic results with the woman during or straight after the testing would be viable only if women were informed prior to the conduct of the diagnostic test that this was a possibility. Then it would become a matter of choice on behalf of the woman as to whether the practitioner conducting the scan gave them their result or whether they chose to wait to receive it from their LMC.

All respondents stressed that there should be no or only a small time delay in informing women of results and emphasised the importance of having a well developed and recognised pathway. Respondents did recommend that DHBs also have a system in place and that they should be able to ensure that this process is followed too.

The key informants interviewed were unanimous in saying that it would be inappropriate and unethical if other fetal anomalies were found and this information was withheld from women.

4.7.1 Delivering Results of Positive Screening and Diagnostic Tests

It was considered to be essential that before any woman has any genetic test, a plan is made before the test is undertaken as to who should deliver the result and that it is important to adhere to that decision.

In general, the views expressed to the interview team did not vary significantly from that stated above in Section 4.7. It was thought that the LMC should have the responsibility of discussing the outcomes of the screening and diagnostic test even if the results are positive. In stating this different practices were noted as occurring with GPs providing information as well as midwives, clinicians within Fetal Medicine units and obstetricians.

The clinical geneticists were of the opinion that in relatively low risk situations it should be the LMC who gives the initial result. If the result is abnormal they would still need to give the result because they are the people who talked to the woman beforehand and they have a relationship with the woman. However, they should be encouraged to talk to the genetic services before giving out the result and a Clinical Geneticist would be very happy to see every woman who had an abnormal amniocentesis result, particularly if it concerned something that was not what the test was originally for.

Importantly feedback from the midwives suggested that it was critical that whoever discusses positive screening results with women have knowledge of and access to immediate support and referral to other services, such as counselling.

4.8 Education and Training

Health professionals ensure that they maintain the currency of their knowledge in a fragmented manner including accessing information:

- through peer reviewed journals;
- through attendance at conferences;
- by referring to best practice guidelines (where they exist);
- from their professional peak bodies;
- by referring to policies and procedures and government documents;
- via the networking with their peers, etc.

The introduction of a national antenatal screening programme or a national Down syndrome screening programme will need to address the challenge this fragmented approach creates. Specifically it is imperative that the introduction of any new screening programme incorporates an educational phase that targets health professionals in a systematic manner ensuring that all health professionals involved in the provision of antenatal and maternity services are appropriately informed of the new screening programme and in particular of the best practice the programme seeks to emulate.

There was a view expressed that any education of health professionals should occur concurrently to the roll out of the screening programme. Undertaking education to far ahead of the actual initiation of the screening programme may create difficulty in engaging appropriate numbers of clinicians. There was consensus of opinion in that education of health professionals cannot be left too late into the implementation of the screening programme.

Of note, it was put to the interview team that linking an education programme about the screening programme to a series of presentations of an hours duration that are recognised as contributing towards Continuing Medical Education (CME) would be a strategy worth pursing particularly as it would be recognised as part of the ongoing training of the clinician.

4.9 CAPACITY ISSUES

4.9.1 IMPACT ON GENERAL PRACTITIONERS

Initially the GP obstetrician did not think that the introduction of a national antenatal screening programme would affect their workload until it was mentioned that it was intended that screening would be available for all pregnant women, not just women over 35 years old. This changed their opinion significantly and they said that if this was the case it would increase their workload considerably and that further education and funding would need to be made available. Their workload was likely to increase in terms of the frequency of visits made by the pregnant woman and the duration of the visit if education and counselling were to take place.

One of the other GPs interviewed said that it would not make a great difference as high risk women are being screened now and that it may improve communication and information provision.

4.9.2 IMPACT ON DHBS

The midwife working under the auspices of the DHB said the introduction of a national Down syndrome screening programme would result in significant funding and resourcing issues for the DHB. This would be particularly true if NT scanning, CVS and amniocentesis were part of the proposed programme. The respondent did not think the DHB would have the capacity to inform and offer all pregnant women screening. Capacity issues would also be compounded if the number of women with an ambiguous results increased as they would be referred on to the Fetal Medicine unit (as is current practice). Additional work in the areas of counselling and further testing was anticipated however the magnitude of increase could not be determined. Specifically it was thought that DHBs would not have the staffing or equipment to cope with the expected increase in throughput.

4.9.3 IMPACT ON MIDWIVES

The independent midwife did not think that the introduction of a screening programme would affect their workload as women are already attending for booking and regular blood tests.

The impact on midwives is likely to differ depending on the type of practice they are working in. Size of the practice, the number of midwives involved in the practice and the geographic location of the practice would all impact upon the overall capacity issues facing the respective midwives. An increase in the duration of the consult is expected to occur to enable adequate education, counselling and support to occur.

4.9.4 IMPACT ON OBSTETRICIANS

One obstetrician thought that the introduction of a screening programme, if done well, would decrease their workload as they would only be screening those at risk as better and targeted testing should improve the detection rate sooner in pregnancy. However the other two obstetricians interviewed disagreed. They believed that it would increase their numbers and workload especially in the first six months.

Capacity issues were likely to arise if more abnormalities were picked up through the NT scan requiring follow up diagnostic procedures. The capacity issues would not be restricted to obstetricians alone but would also impact upon laboratories, NT scanning facilities and hospitals should an increase in terminations occur.

With respect to obstetric services, respondents indicated that they knew that there were already capacity issues occurring in Christchurch where there are only 2 obstetricians who perform CVS and also in Wellington where women are already having problems obtaining surgical TOPs.

4.9.5 IMPACT ON NT PRACTITIONERS

The NT practitioners interviewed agreed that they would be able to cope with demand as NT scanning is accepted now and that at present the majority of women are presenting for NT scanning without a screening programme being in place.

4.9.6 IMPACT ON CYTOGENETIC LABORATORIES

The cytogeneticist thought that the introduction of a screening program would increase their workload initially. However, they hoped that the long term aim would be to target the right pregnancies and actually reduce the number of diagnostic procedures while increasing the detection rates. Some quantitative figures were quoted to the interview team. Specifically mention was made that if the volume of work was to increase by 200 or 300 samples, the cytogenetic laboratory would require the services of an additional scientist. Recruitment was identified as being problematic and that there was a high likelihood that the laboratory would consider recruiting from overseas or would train a trainee in-house. The introduction of new technologies to the laboratory also presents additional workload and workforce capacity issues as staff need to be appropriate trained in the use of the new technologies, and there is a lead up time in which proficiency is achieved.

4.9.7 IMPACT ON BIOCHEMISTRY LABORATORY

The biochemist said that they would not experience the same degree of difficulties as cytogeneticists as biochemistry tests are more straightforward and easier to undertake. They felt that they would experience problems sourcing staff but would be able to find them if they were funded to do so.

4.9.8 IMPACT ON CLINICAL GENETICISTS

The clinical geneticists thought that increased knowledge about a proposed antenatal screening programme for Down syndrome would certainly increase demand for their services although it was felt that in the long run, with a good programme in place, they would have less work than they have at the moment.

4.9.9 IMPACT ON PAEDIATRICIANS

The paediatricians did not think that a proposed antenatal screening programme for Down syndrome would increase their workload as they may only talk to one or two women regarding making a decision on screening for a baby with Down syndrome. In fact, they thought there may even be a small reduction in their workload if the number of births of children born with Down syndrome decreased.

4.9.10 IMPACT ON GENETIC COUNSELLORS

The introduction of a national antenatal screening programme for Down syndrome is seen as being very important. However, currently there is uncertainty regarding the plan for providing information to women, gaining informed consent and the identification of who would be responsible for doing each component of this process. It may mean an increase in Genetic Counsellors' workload in terms of an increase in the amount of people they see who have been given a high risk screening result. Overall workload and workforce capacity issues will be dependent upon the pathway, roles and responsibilities defined by the new national Down syndrome screening programme.

4.9.11 IMPACT ON SECONDARY SERVICES

One obstetrician in private practice believed that the impact would be felt particularly in secondary care, in the public hospital outpatient clinics specifically as a result of increased time that would be needed regarding the education and counselling of women. They thought that this may result in increased waiting times to access clinics, not just in obstetrics, but also gynaecology clinics.

4.10 CONCERNS

4.10.1 RURAL URBAN DIFFERENCES

Some midwives, GPs and obstetricians interviewed indicated that a number of rural women find it difficult to access hospital based services and to find adequate and appropriate support especially when English is their second language.

In particular concern was expressed that rurally based women would have to travel to urban centres to participate in the screening process and for diagnostic tests. They may have to travel back into town to discuss their results with a designated health care professional and would in all likelihood have to access support services in urban locations as well. This creates a significant barrier for these women and presents economic barriers as well which are exacerbated if they have to par part/user charges.

Disparities in the care that Pacific Island and Māori women in Counties Manukau receive, was also cited as an a potential area of concern.

A few of the respondents felt that these disadvantages were not too great as rural women are used to travelling and that the majority travel now to receive their antenatal care.

The NZCOM midwives broached the subject of TOP facilities and said that there are no termination services in many of the areas where women who have a positive screening result live.

In general it was felt that the programme, when introduced, would have to provide the same service to all women across New Zealand. Specifically interviewees indicated that there should not be a two tiered, rural and urban system created as a result of introducing a new national Down syndrome screening programme.

Genetic Counsellors indicated that they could be called upon to assist smaller hospitals implement the national Down syndrome screening programme given their specialist training in dealing with antenatal screening and experience in dealing with high risk patients.

4.10.2 SCREENING COORDINATORS

Respondents indicated that the Ministry of Health is introducing a number of screening programmes including a:

- Down syndrome programme;
- newborn hearing programme;
- HIV programme, and
- Chlamydia screening programme.

A number of these programmes target the same health professionals, and when viewed as a collective the impact upon workload for these health professionals will increase significantly. The resultant impact will be seen in issues faced by the community trying to access already stretched resources.

Accordingly consideration was given by a number of respondents to the introduction of Screening Co-ordinators on a regional or geographic location basis. However, there was considerable variation in the interpretation placed on the roles and responsibilities such a position would assume within the overall national screening programmes.

The roles and responsibilities of screening co-ordinators ranged to include provision of professional education, advice, support, and help with audits.

The midwives whilst agreeing in principle to the notion of introducing screening coordinators did highlight the requirement that screening co-ordinators be:

- aware of everything that is screened for antenatally;
- cognisant of a midwife's skill, role and responsibility in the provision of antenatal care;
- possessed of an overview of all expectations of health care professionals and pregnant women and
- be able to provide access to additional resources.

The biochemist however, perceived the role of a screening coordinator quite differently. They thought that their role would be to provide information and advice and support at a local level. They felt that because of New Zealand's relatively dispersed and low population the model used in the UK would not work well here. They thought that they should be available in every obstetric unit in the country and felt that they would have to live locally, know their local people and their local circumstances and that they would be interacting with the people that have the test results, their local specialists and the local midwives and possibly with pregnant women regarding positive test results. They would be able to co-ordinate the follow up diagnostic tests and procedures and make appointments for the women. From a laboratory point of view they felt that if the co-ordinator were situated locally the laboratory staff would know who to talk to and would be able to speak to people directly about the way forms are completed, and problems with samples being sent away late or being handled incorrectly.

The Clinical Geneticists believed that Screening Coordinators would fulfil a very important role and thought that they would be able to assist with making screening and the whole process more acceptable to women. This would include accessing or receiving appropriate counselling and audit functions. The co-ordinators role included the collation of information for people to access and the updating of that information as well. The location of a co-ordinator in each main centre (i.e. Auckland, Wellington and Christchurch) was identified as a suitable geographic dispersion of these new positions. Clinical Geneticists suggested the co-ordinator role also incorporate the:

- organisation of ongoing education;
- dealing with any problems associated with the interpretation of results, and
- looking at different ways of presenting the results to women such that it was easier to interpret and understand.

The Paediatrician thought that screening coordinators should provide seminars and help with leaflet preparation at the outset. They could also monitor and advise the NSU (and/ or ADSSAG) on issues that crop up that weren't anticipated in the implementation of the national screening programme. They would be familiar with the programme and available for people to talk to although it was felt that most questions should be answerable by phone, email and through frequently asked questions (FAQs) on a website. The Paediatrician thought that more co-ordinators would be needed initially, and possible attrition could occur once the programme stabilised and reached a steady state.

The NZDSA were concerned that a Screening Co-ordinator role would be based on a medical model. Representatives from NZDSA indicated that they thought it important that the co-ordinators were aware of the New Zealand Disability Strategy and the positions should be put into place before any testing commenced under the new national Down syndrome screening programme.

4.10.3 SCREENING AS A PUBLIC HEALTH ISSUE

The participants from NZCOM were concerned that the focus on provision of information to woman about antenatal screening programmes is purely concentrated during pregnancy. Some views around the need to place screening as a pubic health issue and exposure at times other than pregnancy was thought to be worth further consideration.

4.10.4 CONSISTENCY WITH THE DISABILITY STRATEGY

New Zealand has a Disability Strategy which has an all inclusive policy. The policy states that New Zealand society should be an inclusive society which encompasses and supports people and families with a disability. The introduction of a national Down syndrome screening program utilising language such as 'risk' and 'chance' could have connotations that a disability is a reason to devalue the person. Caution needs to be extended that the introduction of a national Down syndrome screening programme is consistent with the tenor contained in other Ministry of Health and government policies and strategies including the Disability Strategy.

Consistent with this view was the concern that health professionals, support services and the community would infer the screening programme for Down syndrome was implying the Ministry of Health was of the opinion that it would be best if a baby with Down syndrome was not born. Inadvertently the screening programme could be seen as encouraging the termination of pregnancies. The Ministry will need to work hard to ensure that this impression is not promoted in any capacity.

4.10.5 CENTRAL HELP LINE

It was thought that it would be useful to have a facility that can answer phone calls when the screening programme first starts running to provide help and assistance not only to the community but health care and support service providers. Some respondents indicated that a central facility would be appropriate, whilst others thought that regional help lines may be more appropriate dependent upon the structure and roll out of the screening programme.

4.10.6 FUNDING

A number of funding issues were raised in the context of discussions. Some related to the existing payment rates available to specific health professionals whilst others were more global in focus.

The view was also put to the interviewers that concern exists that funding for support services for Down syndrome children would contract over the years once the national Down syndrome screening programme was introduced. Contraction of funds would occur at government level based on the premise that there would be a progressive decline in the population living with Down syndrome.

The GPs mentioned that no funding was available at the present time for GPs to be involved in antenatal consultations or counselling. This was seen as a barrier to GPs being involved in maternity cases. They believe that GPs are not motivated to provide information to pregnant women presenting in their clinics because the payment rate is set at $32.50 for a single episode appointment whereas the GP could claim $60 for a normal consult. The remark was made that if funding was improved and more closely aligned to a standard consult rate then GPs would in all likelihood be prepared to take on maternity cases. The exodus of GPs from obstetrics was attributed to this funding discrepancy.

Midwives said that they would expect a significant commitment of resources to be made available to support the profession to provide antenatal screening properly. Suggestions were made that midwifery payments for screening to women could be linked to s88payments.

The individual views of each of the professional groups not covered in Section 4 are presented in the subsequent sections of this report.

5

GENERAL PRACTITIONERS

Three General Practitioners participated as key informants in this study one of whom is a GP Obstetrician. The view of the respondents is one that depicts general practitioners in New Zealand playing a diminishing role in maternity care with large cohorts of general practitioners existing from provision of obstetric services. The involvement of general practitioners was described as being limited in the majority of instances to the first trimester where encounters with pregnant women are typically brief. The encounters cover confirmation of the pregnancy, ordering of blood tests and referring the woman on to an LMC, where at times the referral is more instruction based and the pregnant woman is provided with an 0800 number to locate a LMC within close vicinity to her.

The attrition of general practitioners from the obstetric field and the brevity of encounters have been brought about, in the opinion of the respondents, by a number of factors including but not limited to:

- The private health organisation's (PHOs) not being proactive in taking a co-ordination role for maternity and antenatal services;
- Funding being set at a level that does not support the provision of counselling, education and support services so critical in the provision of services to pregnant women.

As a result over time it is anticipated that the skill level and knowledge levels of general practitioners will decline when it comes to obstetric services. The decline is exacerbated when the number of pregnant women seen by any one individual decreases. This decline is expected to be most noticeable in terms of maintaining an awareness of the most current advances in the treatment of maternity patients and the best practice and clinical pathways that should be followed.

With recent initiatives being considered by the Ministry (refer Section 6) and the likelihood that workloads for LMC's, laboratories, midwives and obstetricians will increase as a result of the introduction of a national Down syndrome screening programme, general practitioners present a potential workforce that can assist in the uptake of some of this workload. Capacity exists within this workforce to provide better early advisory services, referral and follow up of screening and diagnostic test results. However, it will require a co-ordinated training and support programme being instituted focussing on general practitioners (and potentially their Practice Nurse Managers). Linking the training to CME points will give greater incentives for general practitioners to enrol and participate in the training programme.

In order for the training to be effective clear policies governing the screening programme, pathways defining health care professionals roles, referral processes, packages of care, type of screening and tests to consider, conditions under which tests should be ordered etc. need to be developed. Within this context the role of the PHO needs to be more fully considered as well. The training should also include access to and training in the use of 'national materials' that general practitioners can call upon when informing women of their options and what to expect during their pregnancy (i.e. in terms of visits to health professions, types of tests, scans, etc.).

Whilst not all of the respondents advocated for a national Down Syndrome screening programme, all agreed a more co-ordinated approach to the management of pregnant women was highly desirable. This included clear definition of roles and responsibilities, referral pathways, definition of what is required through the screening programme and what services should be offered and at what stage of the pregnancy. Until such time as this is in place, the value of introducing Screening

Co-ordinators remains a moot point and is seen by some as only adding to the confused state of understanding that currently surrounds maternity and antenatal services delivery in particular.

In order to attract general practitioners back into the obstetric field, and to ensure that a quality service is available to pregnant women, the fee associated with consulting time with pregnant women needs to be revised nationally. The current fee structure perpetuates a short consult which creates a barrier to the clinician being able to spend adequate time with the individual to fully inform them of their options and discuss the various pathways that may be available to the pregnant woman.

6

MIDWIVES

Three key informant interviews were conducted with four midwives, two of whom represented the New Zealand College of Midwives (NZCOM), one is a Maternity Manager in a DHB managed hospital and the other an independent midwife.

A range of issues were raised in the consultations with this profession covering:

- Implementation issues associated with a national screening programme
- Communications between health professionals involved in the pregnancy pathway of the woman
- Training requirements, and
- The level of information provided to pregnant women about screening options, outcomes and consequences.

All of the respondents supported the introduction of a national antenatal screening, or a national Down syndrome screening programme on the strict proviso that it was not mandatory, and women were given the option to opt out of the screening programme. Pregnancy is an individual experience, poignant and emotionally intense for the majority of women and the rights of individuals needs to be embodied in the development and implementation of any national antenatal screening programme. Having made this statement, the midwives also questioned whether the intent behind a national antenatal screening programme needs to be embodied in a public health programme that targets women before they become pregnant to educate and inform them of the benefits of healthy lifestyle, encourage debate around folic acids etc. There was strong opinion expressed that the development of a national antenatal screening programme should not be undertaken within the confines of the National Screening Unit (NSU) of the Ministry of Health but should also be extended to be incorporated into the public health programmes, strategies and policies.

Prior to embarking on the implementation of a national antenatal screening programme, the respondents felt that a fundamental question associated with the cost effectiveness of the tests embraced by the screening programme should be considered and documented at a government level.

However, the benefits of introducing a national screening programmed were also espoused in the interviews. Current variation is known to exist amongst midwives in terms of risk assessment methods and what level of information is provided to women regarding screening options. Whilst it is recognised that this variation is no different to what occurs amongst general practitioners, LMC and obstetricians, it was felt that the introduction of a national screening programme will assist in minimising its occurrence.

Other benefits of introducing a national screening programme relate to improved communication and referral mechanisms between health professionals and an expected improvement in the quality of the associated documentation. Specifically, at this moment women typically visit midwives at the beginning of the second trimester. They may or may not attend the first visit with their blood result and their 12 week scan result from their general practitioner. At this stage there has been limited to no communication between the general practitioner and the midwife. Accordingly, the midwife will have limited awareness of the level of discussion that may have taken place between the general practitioner and the pregnant woman around the results of the scan. The absence of a formal, well documented and communicated hand over creates stressors

between the two professions as often an action may be interpreted as crossing interprofessional boundaries. More importantly the process does not appear integrated to the pregnant woman who may have to go through and explain her discussions with the general practitioner to the midwife. The introduction of a national screening programme with standard national documentation that follows the pregnant woman and is used by the respective health professionals to communicate to one another the level of information that has been provided to the woman to date is seen as a significant advancement on current practice and one that would be strongly supported. However, to achieve this, the processes, policies, pathways and responsibilities have to be clearly articulated, documented and signed off before reporting processes are developed. This will require appropriate management skills, leadership, co-operation between professions and resources to implement.

Furthermore in light of the Ministry of Health's new proposal within the Section 88 maternity notice, (namely that women remain under the care of a general practitioner for the entire1st trimester)then the opportunity presents in the enforcement of this proposal to instil better referral mechanisms and reporting between the general practitioner, midwife/LMC.

Screening options discussed throughout this study included NT scans, maternal serum screening, CVS or amniocentisis. Not withstanding the degree of precision that is required of the individual undertaking some of these scans, health professionals including midwives expressed concern that the level of confidence attached to the quality of the tests is not necessarily high. In some instances this is due to the fact that non-accredited individuals may be undertaking the test, and in other instances it relates to the error rates that may apply to the test itself. The introduction of a national antenatal screening programme will have to incorporate a specific training component that targets all health professionals and seeks to address this issue. A lack of confidence in tests invariably will result in variation in the manner in which the screening programme will be implemented or operationalised. This needs to be addressed at the onset of the programme.

Other training issues were identified in the interviews, some of which are specific to the midwifery profession. Specifically, it was noted that all midwives receive a lecture on Down syndrome and screening during their current training. There is a recertification process that takes place every three years through the Midwifery Council post graduation. In between this time any other training that is pursued is done so on a voluntary basis. There are however some basic technical skills such as breast feeding, CPR and neonatal resuscitation which are mandatory. It may be appropriate with the advent of a national antenatal screening programme for the Ministry of Education to approach the Midwifery Council and request that they consider placing the topic of antenatal screening into its mandatory training programme. This would ensure future graduates are appropriately educated and informed in the current screening protocols of the country. For the current workforce the College of Midwives could be approached to run workshops across the country, linking the workshops to continuing professional education and associated Midwifery education credits which would provide an incentive for midwives to attend. This formalised process could also be used as an induction for overseas trained midwives practicing in New Zealand. For example, one of the interviewees indicated that they had not received any training since arriving in New Zealand. Their knowledge and experience base came from the United Kingdom (UK). Together with other colleagues from similar backgrounds, these midwives often visit the UK website to maintain currency of information. By having a training programme such as the one described above run by the College of Midwives the training needs of overseas trained midwives can be readily addressed and they can be appropriately inducted into the New Zealand national antenatal screening programme.

Establishment of an appropriate training strategy that is recognised and appropriately resourced as part of the overall implementation strategy of the national antenatal screening programme was seen as a critical success factor impacting upon the overall effectiveness of the resultant screening programme. Of note, this sentiment was supported by each individual professional group, with specific strategies considered for their respective needs.

With respect to the workforce capacity issues, the midwives could only speak from personal experience relating to their individual practice setting. Those working in a DHB environment indicated that there would be likely increase in workload for them with concern being expressed

that potentially the volume of women that they may have to see will detract from the available time that can be allocated to each to consult and discuss issues around screening. The independent midwife did not share the same concerns and did not estimate the workload to increase significantly. All respondents anticipated increased volume of work for other professions or sectors including laboratories, sonographers and potentially hospitals in terms of increased terminations, increased outpatient visits to the obstetric clinics and referrals to specialist units such as Fetal Medicine Unit. No attempt was made to estimate the quantum of this increase or whether this can be accommodated within the existing workforce.

Considerable discussion also took place in terms of the type of information that needs to be provided to a pregnant woman about screening options, the supporting material the supports the provision of this information and who should be discussing positive results with the pregnant woman. There was uniform consensus that the development of national material would streamline the information that is being presented to pregnant women. It was recognised that the development of such materials does not obviate the need for the LMC, general practitioner of the midwife to discuss screening options with the pregnant woman, as it can not be assumed that all written materials provided will be read. Written materials should also be overlaid with a literacy component that ensures it is easy to understand, culturally appropriate and available in several languages other than English. Picture based information (rather than the written word) would also be useful in some instances.

There is no clear consensus on who should be discussing the positive results with the pregnant woman post screening, and this is true across all professions. What was agreed was that the individual responsible for discussing the positive result needs to be a clear and effective communicator and must be aware of and able to call upon relevant support mechanisms in a timely manner if the pregnant woman requires them.

Midwives are involved in a number of other screening initiatives and the Ministry of Health has the following expectations of midwives involvement in:

- NIR (immunisation);
- assessing family violence;
- breast feeding;
- hand over to Child Welfare;
- social issues, and
- possibly, HIV screening.

Within this context the role of Screening Co-ordinators were discussed. There was a view that the role would be welcomed particularly if antenatal screening, immunisation and HIV screening portfolios could be assumed by the one co-ordinator in each location. The inclusion of an audit and monitoring function into this role was considered appropriate particularly once the screening programmes were implemented, however there is some divergence of opinion about the possible role and responsibility of this co-ordinator role would be from inception.

A clear pathway that identifies under what criteria and when should screening be offered, what needs to be done with the results and who has the responsibility of informing the pregnant woman of the results and what support and ongoing follow up is offered and available to pregnant women needs to be established and well documented prior to the implementation of a national antenatal screening programme.

7

OBSTETRICIANS

Three obstetricians were interviewed as key informants for this study. Two worked out of their own private practices and the other is a Consultant in a Hospital Obstetric Department as well as being an NT practitioner. Accordingly, their comments regarding NT screening have been considered within this section of the report.

The intent of a national antenatal screening programme from the perspective of the interviewed obstetricians was articulated as improving the accuracy of diagnosis and limiting the number of unnecessary tests to be performed. Within this context the most appropriate screening programme would be combined first trimester screening that is 1st trimester Nuchal Translucency (NT) combined with 1st trimester Maternal Serum Screening (MSS) and that this would give a unified test and would identify at least 90% for a 5-10% amniocentesis rate. A study published by the Department of Health, Western Australia in 200597was cited as supporting evidence for this point of view. If this is pursued, then this will have implications for general practitioner training, as the general practitioner in most instances is still the focal point for the pregnant woman in the first trimester.

Other models were also presented including provision of 1st trimester NT followed by early 2nd trimester biochemistry or provision of 1st trimester NT scanning and 2nd trimester MSS. Irrespective of what model or sequencing of tests is decided upon within the context of the national antenatal screening programme it was stressed that the programme must be simple, consistent, clear and have quality control monitoring systems in place. Provision should be made for specialists to vary the programme according to circumstances and that these parameters should be set by the Ministry of Health.

Currently multiple screening processes and referral pathways exist and this has lead to confusion existing amongst the general public as well as amongst health care professionals. Obstetricians are not often the first point of contact for a woman regarding their pregnancy. Women are usually only in communication with obstetricians once their pregnancy has been confirmed and they have received basic information related to the pregnancy from another health care practitioner. The referral is usually made to the obstetrician usually because a problem has arisen or the woman has some prior medical history which may be of concern. In such circumstances the obstetrician may be the lead maternity carer (LMC).

Topics relating to screening typically covered by an obstetrician with a pregnant woman would include:

- details of different screening tests;
- assessment of the woman's risk profile;
- the worth and value of various screening procedures;
- ensuring the woman understands that tests are about screening and not diagnosis; and
- discussing and explaining the 'what if' scenarios that exist specific to the history and circumstances of individual women.

[97] Breheny N, O'Leary P, Dickinson J, Bower C, Goldblatt J, Hewitt B, Murch A and Stock R (2005). Statewide evaluation of first trimester screening for Down syndrome and other fetal anomalies in Western Australia. Genomics Occasional Paper 5. Antenatal Diagnosis Committee, Department of Health Western Australia

There are numerous written leaflets available that obstetricians indicated they access and provide to women when having these discussions. The material is provided so that the individual woman can take the information home and digest it at home. Examples of pamphlets obtained through Royal Australian New Zealand College of Obstetrics and Gynaecology (RANZCOG) were cited as being good visual aids providing information on screening, amniocentesis and CVS.

In addition to ensuring that women are adequately informed of the screening options available to them, another are where the national antenatal screening programme will need to provide clear direction relates to who has responsibility for discussing the outcomes of a positive screening test with the pregnant woman. There was mixed opinion on this. Some respondents felt that whoever organises the screening test should be able to interpret the results and provide this information to the pregnant woman. Others were of the opinion that it should be the LMC or the clinician requesting the tests. The sequencing of when the results are provided are totally dependent upon the decision as to which health care professional has the responsibility for discussing the results.

Other variation in opinion was noted, particularly with respect to a woman's right to an amniocentesis. One obstetrician, in private practice, indicated that they felt every woman has a right to have an amniocentesis irrespective of age. This is contingent on the individual being in receipt or sound counselling beforehand. Other respondents did not share this opinion and felt that for women over the age of thirty-five (35) amniocentesis did not present the best screening test. There was however strong consensus of opinion that to maintain skills, volume of activity undertaken on an annual basis.

The obstetricians identified a number of workforce or workload impacts of introducing a national antenatal screening programme. There was a view that secondary services including hospital theatres, inpatients and outpatient clinics would record increases due to increased numbers of terminations, testing and counselling service provision.

With respect to their own profession, there was mixed views expressed. Once obstetrician thought that the introduction of a screening programme would decrease their workload as they would ultimately only be seeing those at risk. Others disagreed, and thought that there would be a marked increase in the number of pregnant women referred to them. In some areas where there is a known shortage of obstetricians, such as Christchurch, the anticipated impact would be one where the existing workforce would not be able to absorb the increased activity.

A number of funding issues were raised as well. The current funding for a consultation covers a 20-30 minute period and the payment covered by the Ministry of Health or DHB ranges between $86 to $90 which is a significant disincentive for obstetricians to have a high obstetrics workload. Much of their income and work is supplemented with gynaecology patients and hence there is a propensity amongst the profession to limit themselves in terms of the number of obstetric patients they have on their books at any one time. This is creating workforce pressures already and access issues for pregnant women trying to gain see an obstetrician locally.

Currently government does not fund MSS but does fund NT scanning. Some women have difficulty accessing NT as the service may not be readily available in their region or town whilst they could potentially have an MSS but the option is not necessarily discussed because it is not deemed to be a recognised funded screening option. This also compounds access issues faced by the community. This disparity needs to be addressed as a matter of principle within the development of suitable guidelines governing a national antenatal screening programme.

If a national antennal screening programme for Down syndrome is to be introduced it needs to be done properly, that is designed, implemented, funded and monitored with professional resources using the right people in the right positions. It should also be endorsed by the professional bodies

and RANZCOG in particular. There is a view that the programme should be flexible enough to provide for the contingency to manage individual pregnant women's needs and issues. Accordingly appropriate referral mechanisms need to be established and women should be appropriately counselled prior to screening and diagnostic procedures. This mandates the obstetricians maintain their currency of knowledge regarding antenatal screening techniques and more importantly the requirements of a national antenatal screening programme. Linking methods of up-skilling or maintenance of current knowledge to CME points and processes would be strongly encouraged.

Concern was expressed about rural and urban variables. It was felt that rural women were particularly disadvantaged both socio-economically and with regard to access to services as travel and attendance at clinics could create barriers to timely access to services. This could potentially be exacerbated if the pregnant woman had to pay part or incurred user charges. This was viewed by the obstetricians as presenting the most pronounced workforce challenge for the national antenatal screening programme. Introduction of screening co-ordinators to provide professional education, advice, support and help with audits may assist the workforce, but would not necessarily address the specific needs of the community which is geographically dispersed.

Overall if a national antenatal screening programme is to be introduced a detailed training programme targeting all health care professionals and support services involved in antenatal care needs to be established. This training strategy needs to be included in the documentation governing or oversighting the screening programme and should be implemented prior to the roll out of the screening programme itself.

8

NUCHAL TRANSLUCENCY (NT) PRACTITIONERS

Four Nuchal Translucency (NT) practitioners participated in this study as key informants. One was a radiologist in private practice and the other three were obstetricians; one of whom worked in private practice and the other two as hospital based obstetricians and NT practitioners.

The four NT practitioners interviewed are all accredited with the Fetal Medicine Foundation (FMF); with the radiologist and one obstetrician trained in England and the two obstetricians trained in New Zealand, one in Wellington and the other in Christchurch. Three of the NT practitioners interviewed are certified for nasal bone measurement as well.

They are all involved in an annual audit of their NT practice by the FMF and said that all other NT practitioners who have been trained and accredited by the FMF would view audit as an integral part of their practice.

To become an accredited practitioner a practitioner has to attend FMF training in NT. This is a one day course after which the participant has to submit hard copy images of NT scans they have undertaken. These NT scans are sent to London. The FMF assess five scans and decide whether they are satisfactory. The practitioner is also expected to attend a practical session with one of three NT examiners in New Zealand. They adhere to FMF requirements and do not have a local committee or organisation.

The time taken to do a scan is dependent on several variables such as whether the baby is in a good position or not. In a straight forward situation the scan typically takes between 20 to 25 minutes and the average allowance is for approximately 30 minutes. For more complex scans a 45 minute time frame is considered to be more realistic.

In addition to this, it takes approximately 10 to 15 minutes to document the results of a NT scan. The process involves data input and then printing of two reports, one for the FMF risk calculation and one from the ultrasound machine. The NT practitioners interviewed used either the Fetal Medicine Foundation or Viewpoint software for their risk assessment and said that several software packages are available for reporting purposes.

The consensus opinion by not only the NT practitioners but other health professionals interviewed in this study indicated that they do not consider it appropriate for NT scans to be undertaken by non-accredited health care professionals. All respondents concur with the government held view that if there is going to be a minimum standard that must be attained, practices should be accredited and have the software and pointed out that NT practitioners should not be using the software unless they are accredited.

Accordingly one of the basic policies and tenors of a national antenatal screening programme should be that NT scanning and reports can only be produced by accredited NT practitioners. This stance should also be supported by the Royal Australian New Zealand College of Radiologists.

If such a policy were mandated through section 88, it is expected to impact upon the workforce. In particular respondents indicated that they anticipate an increase in the number of NT scans hospital departments would undertake if all sonographers are required to be accredited to perform NT as a number will elect not to pursue accreditation.

The introduction of a national antenatal screening programme is likely to result in increased activity and there is some concern as to whether the sector has the capacity to adequately respond to this expected increase. Specifically demand is likely to not only occur in the number of

women presenting for NT scans, but additional work is anticipated if there is an increase in the number of detected abnormalities which will then require follow up diagnostic procedures.

NT practitioners indicated that since commencing practice there has been a notable increase in the number of presentations for NT scanning, and they have coped to date through the employment of additional staff. However, as to whether this is a viable and sustainable strategy in the long term remains to be tested. If the requirement for staff to be accredited is overlaid then it is unlikely that there will a sufficient labour market available from which to draw additional staff.

Demand for follow up services is expected to increase if there is an increase in abnormality detection rates and respondents were able to identify specific regions which are already operating under workforce constraints and that are unlikely to have any capacity to meet the additional needs. These workforce issues do not necessarily directly relate to NT practitioners but are noted here nevertheless. In Christchurch there are only two (2) obstetricians who perform CVS and at times they are unable to do so even though it may be clinically appropriate and refer some women for amniocentesis instead. This region of the country has a significant capacity issue that needs to be dealt with. In Wellington women are already experiencing problems obtaining surgical termination of pregnancies, and if there is increased demand for this surgical intervention then the region will have limited or no capacity to respond.

An increase in workload is also anticipated if there is a requirement to combine NT results with serum results. This increased workload would impact upon laboratories, but would in all likelihood also result in a benefit to the clinician. The sensitivity for first trimester serum testing is higher hence this may reduce the need for more invasive procedures later on. Another practitioner did not envisage any capacity issues as long as the serum results were timely and available by the time the NT scan was done. The ability to affect this combination of results would be totally dependent upon how the screening programme is rolled out. Access to a one stop shop approach to that trialled in the UK may be a possible model worth considering within the New Zealand context.

This view was not uniformly held with the radiologist indicating that it would not be necessary to combine NT scanning with biochemistry. This respondent held the view that NT scanning, if done in the way that it should be, would be sensitive enough to detect those women who needed to go ahead and have biochemistry.

In addition to the type of tests being ordered and reporting mechanisms put in place between health care professionals, the introduction of a national antenatal screening programme will need to address the manner in which women are provided with information about NT scanning. Currently the practice is highly variable, and most NT practitioners assume that the pregnant woman has been informed about what the NT scan will entail prior to attending for the scan. Accordingly, the respondents indicated that they were aware of some NT practitioners did not discuss the NT scan before, during or after the scan. This practice is not uniform however, with others discussing the results with the woman. It was suggested that it would be useful if the request forms forwarded by the referring clinician to the sonographers contained information on it that indicated whether or not the woman had been counselled or advised about what to expect from an NT scan. Consistent with this suggestion is another put to the interviewers by one of the hospital based obstetric NT practitioner. This respondent suggested that a specific request form for NT, amniocentesis and CVS be designed via the auspices of the national antenatal screening programme. One side of the form should contain demographic information identify the procedure being requested, while the other side contains a list of topics which can be marked of under the heading 'this topic has been discussed with the woman'. This should be investigated as part of the overall operational requirements of a national antenatal screening programme.

In addition to receiving some notification of the level of information provided to the pregnant woman, the NT practitioners indicated that they should also have access to relevant resources that they can provide to the woman during the scan. In particular information about what the scan entails, what it can and can't identify and what false positive, false negative results mean should be included in the information package. Some thought around having a national resource was mooted to ensure the same consistent information is presented. It was felt appropriate that accredited sonographers have input into the development of such materials.

Apart from providing women with information about NT scanning, the other level of involvement with the presenting woman centres on obtaining some indication of the nature of the results of the scan. Again the practice at the moment is highly variable. The respondents in private practice indicated that they most definitely felt that they should provide, repeat or reassure women regarding all the information known to date regarding the status of the foetus and what further testing or assessment is required. However, the hospital based obstetric NT practitioners indicated that sometimes limited information was given if a radiographer performed the scan and this depended on the radiologist. The provision of information to the woman at the time of undertaking the scan was acceptable as long as the woman had been properly counselled by the LMC beforehand.

In a significant number of instances, the woman requests the information or some form of confirmation that "everything is alright". This request occurs as the scan is visible to the woman. The NT practitioners concurred that if the screening programme's design dictated that NT practitioners did not discuss the results with the woman this would this create issues for them as the test is visual, the woman can see straight away and it is difficult to conceal information from them. The view was put that if the practitioner was accredited in NT screening they could give results and if necessary they would be able to refer the woman to a specialist or back to their LMC. However, prior to implementing such a process, it is important to ensure that at the time of referring the pregnant woman for a NT scan they are adequately informed that they may receive the results directly from the NT practitioner. Accordingly, under such a scenario it becomes the woman's choice as to whether the practitioner conducting the scan gives them their result or whether they chose to wait to receive it from their LMC.

There was a general view that if NT practitioners are to be expected to provide the results of the scan to the pregnant woman, then this would mandate a level of training be undertaken particularly focussing on counselling skills and all NT practitioners would have to undertake the training programme.

Irrespective of which health professional is charged with the responsibility of discussing the NT scan results with the pregnant woman, there was a consensus view put that a set of guidelines need to be developed that clearly articulates each element of a national screening programme, including this stage. The development of the guideline should vest with the Ministry of Health but will need to be communicated to the wider health sector and support sector involved in the provision of antenatal care. Accordingly, a well defined training and communication programme will need to be developed prior to the implementation of a national antenatal screening programme.

The development of such a guideline will also help to address variation in practice and acceptance of NT scanning. For example, one respondent indicated that they operate the only NT practice in New Plymouth. In this location NT is currently not supported by the respondent's obstetric colleagues as this practice does not receive any referrals from obstetricians. The majority of this practices referrals originate from midwives and some general practitioners are now referring women too. The respondent was unclear why obstetricians were not referring women for NT scanning and questioned whether there was a need to undertake information sessions for the obstetricians to familiarise them with NT technology. Similar exercises with midwives had been conducted, and referrals had increased as had the overall working relationship. The other respondents indicated that NT technology was well recognised where they were practicing and obstetricians were readily referring women for NT scanning services.

The introduction of a national screening programme will also need to incorporate a training and education programme to ensure all health professionals are kept up to date and informed of the various developments in antenatal screening and the various roles and responsibilities envisaged for the national antenatal screening programme planned for roll out in New Zealand.

9

LABORATORY STAFF

Laboratory staff input was obtained via the interviews of a cytogeneticist and a biochemist. Both respondents indicated that the current method of screening for Down syndrome in the country lacks co-ordination and as a result has created a number of concerns. Specifically the lack of co-ordination has resulted in the current not being standardised with significant regional differences occurring and the general perception of a lack of cohesion across the range of health professionals providing antenatal services. Uniform in opinion, both respondents indicated that despite the challenges that geography creates, women should have equal access to appropriate services, the right education, the right information and the availability of testing and resources.

The introduction of a national screening programme would ensure direction and coordination. Specifically in terms of cytogenetic laboratories, currently there is no national direction re seeking follow up from pregnancies, monitoring their detection rates, monitoring and understanding the miscarriage rates as a consequence of diagnostic tests. A register of Down syndrome pregnancies is not maintained and each of these could potentially be addressed through the introduction of a national screening programme.

Some concern was expressed about the NSUs proposed model focussing on the identification of one disorder or condition. Whilst it is possible to establish a biochemical and cytogenetic screening for Down syndrome only, this was not thought to be particularly sensible. Ultimately the pregnant woman wishes to establish an awareness and knowledge about the state of health of the foetus. If the national screening programme is being introduced in a manner which is seeking to have the support of New Zealand women then it is likely to have to be based on addressing the question of 'do we really want to know about fetal anomalies in utero'. If this is the case, then further consideration needs to take place in terms of defining what the national screening programme is truly trying to establish. In turn this will give rise to determining:

- what tests should be undertaken;
- what information should be made available to the pregnant woman;
- when this information around screening options should be presented;
- under what conditions are screening options initiated;
- at what stage and by whom are the results of the scans/tests provided and discussed with the pregnant woman.

Accordingly there is a requirement of the Ministry of Health through the NSU to develop clear guidelines that address these issues. Once the guidelines have been developed, then attention and turn to focussing on the development of relevant materials targeting pregnant women. From the respondent's perspective, they thought that women should be fully informed and counselled on the fact that the tests would pick up abnormalities other than Down syndrome and that tests should be ordered that best address each individual's circumstances.

The respondents thought that women would need to know what the test will do, how long it will take, what the results will and won't tell them, what false positives and false negative results are. Both interviewees considered it was important that the results were given to patients as soon as possible and that the laboratories work in a manner which ensures this process is facilitated in a timely as possible manner. Having stated this it was acknowledge that results go to the clinician ordering the tests and sometimes this is not then relayed to the LMC. This is outside of the control of the laboratories. There is a need, within the context of developing a national screening

programme to ensure the laboratory results get to the right place (and health professional) at the right time.

The impact on workforce and workload on laboratories brought about through the introduction of a national screening programme was discussed. The perspectives of the two laboratories are presented below in separate sections.

CAPACITY OF CYTOGENETIC LABORATORIES

Currently there are four cytogenetic laboratories within New Zealand with the largest centre in Auckland with 25 staff. The laboratories tend to serve the geographic areas around where they are situated. There is a very small laboratory in Waikato with about 4 staff; the Wellington laboratory has 19 staff and Christchurch has about 12 staff. Prior to meeting with the interviewer, the representative from the cytogenetic laboratory contacted each of the four laboratories to get their input into this process.

Antenatal work is seen as the most stressful work undertaken by these laboratories due to the fact that the laboratory staff know that they have to report as promptly as they possible. Accordingly, antenatal samples are dealt with as an urgent request and virtually the whole laboratory stops when they have a big harvest of antenatal work. The cytogenetic laboratories anticipate an initial increase in workload will occur through the introduction of a screening programme. However, it is hoped that the long term aim would be to target the right pregnancies and thereby actually reduce the number of diagnostic procedures (whilst increasing the detection rates).

Feedback from the four laboratories indicated that if the volume of work was to increase by 200 or 300 samples, then there would be a need to employ an extra scientist. Recruitment would of itself present a challenge and the expectation is one of having to look to recruit overseas or alternatively to train a trainee in-house. Both presents challenges as the laboratories would expect that to be able to cope with 200 or 300 antenatal samples a year a new recruit would need 3 to 5 years experience and there is a view that this level of experience would be difficult to find.

The introduction of new technologies to the laboratory would also bring with it workforce and workload challenges. A staged implementation of the screening programme is therefore advocated by this group of health professionals as it potentially will be easier to manage. For example, if PCR, which is not used or available in New Zealand at present, is recommended in the national screening programme, then laboratories would need time to set this up. Additionally, the respondent indicated that PCR is a cheaper test than the FISH test and PCR utilises a DNA analyser. Whilst a DNA analyser exists in Auckland and Christchurch they are not located in the cytogenetics laboratory. Thus if PCR was to be introduced one DNA analyser would be required in each main centre. This is likely to require 12-18 months for equipment to be available and staff to trained and confident with the technique.

Not withstanding the above, the cytogenetics laboratories consider it would be more cost effective to introduce PCR even though it would require more equipment and trained staff. The laboratories felt that in terms of a screening programme, a decision should be made that either the FISH or PCR test is used. A certain level of co-ordination will be required between centres if a recommendation is made in favour of PCR. Specifically it was mooted that the possibility of PCR being offered by the diagnostic molecular service might arise and create duplication or overlap in disciplines with genetic laboratories conducting FISH tests and karyotyping. The personal view was expressed that cytogenetics should be kept in-house.

Other requirements a national screening programme necessitates cytogenetics laboratories implement includes the use of good quality databases which provide full reports. Additional microscopes and image analysers are also likely to be required to meet an increase in workload.

CAPACITY OF BIOCHEMISTRY LABORATORIES

The same workload implications as identified by the cytogeneticists are unlikely to arise in the biochemistry laboratory as the biochemistry tests are less complex.

It was anticipated that biochemistry laboratories would however experience problems in terms of sourcing staff but would be able to find them if they were funded to appropriate levels.

Maternal serum screening (MSS) does not receive funding at present accordingly to the biochemist and this will create problems in terms of uptake. Based on a pilot programme conducted in Auckland in the mid 1990's there was an enthusiastic uptake for MSS which dropped off when people had to pay for the test themselves. In the opinion of the respondent MSS would need to be priced to cover costs including staff costs so that when the volume of specimens increases as a result of the introduction of the national screening programme, the laboratories would be able to employ more staff and acquire more equipment. It was noted that cytogenetics operates on a volume capped contract and that this option would be harder to pursue in their case.

ADDITIONAL BENEFITS OF A NATIONAL SCREENING PROGRAMME

The national screening programme presents the sector with the opportunity to develop a common database for genetics across the country where the four centres are able to share information, offer training to other centres and support one another in terms of maintaining or improving quality.

A similar vision was put forward by the biochemist who suggested the national screening programme presents biochemistry laboratories with the opportunity to develop a universally accessible web base where new results could be entered and where providers would be able to access the results of the women they were caring for through an access code. This has the potential to work well for other screening and diagnostic tests that form part of a new screening programme providing the LMC and other health professionals with a comprehensive view of the pregnant woman prior to her presentation. Software is currently available that would be able to serve this purpose ensuring both confidentiality and access to data. It is acknowledged that privacy issues would govern access to general data.

Screening tests could also be conducted by separate laboratories and results entered onto a central database similar to overseas experiences documented in California. California has multiple laboratories (newborn baby and antenatal) controlled by the Genetic Disease Branch of the Department of Health, who also do all the follow-up and confirmatory testing. This is done through a public-private partnership with the government laboratories and it was felt that this model[98] could also work with the government owning all the laboratories. The central or controlling laboratory is able to release the results and also audit and monitor the population benefits[99]. In order to obtain meaningful statistics a significant number of samples (thought to be approximating in the thousands) would need to be performed a year. The respondents were unaware of any providers in New Zealand currently processing such a volume of samples, but a co-ordinated central repository of information would assist in being able to draw relevant inferences from a research and statistical perspective.

COST EFFECTIVENESS OF TESTS

The biochemist indicated that screening was safer if it had either a higher sensitivity or specificity. Accordingly, the more markers that were used the safer the test would be however, the cost would increase too. Age was used as one marker and NT another. There a number of biochemistry analytes used; one the 1st trimester and four that were commonly used in the 2nd trimester. In the view of biochemistry laboratories, the best screening would be for a woman to have an ultrasound and one blood test in the first trimester, not to be given the results and to be given her total result once the blood test in the 2nd trimester had been taken. The 2nd trimester blood test should be offered at 18 or 19 weeks, but it worked up until 20 weeks. There was a view that New Zealanders would be more comfortable with an earlier cut off, although the basis for this conjecture was not discussed.

[98] http://www.dhs.ca.gov/pcfh/gdb/html/GDL/AboutGDL.htm#ppp

[99] Personal communication with Dr Dianne Webster – 16 November 2006

Reservations were expressed with respect to the utility or cost benefit of the FISH test as it was recognised as providing an early result but only a partial picture that was to all effect inconclusive and further testing would be required at a later stage.

Accordingly clear guidance is required from the Ministry of Health on what tests are to be administered and at what stage as part of the overall national screening programme.

It was felt that consideration should be given to other countries experiences and administrative processes developed as a result of implementing a national antenatal screening programme. Examples cited to the interviewers included the follow up form developed in the UK. This form was developed transferring information from every antenatal testing site to clinicians ordering the test. These forms would be returned to laboratories on the birth of the baby with information regarding the sex, weight and any clinical problems or other phenotypic abnormalities. This information, together with the information supplied to the Down syndrome registry (which also monitored the incidence of referrals for tests) was audited. This relatively straightforward procedure is considered to provide amongst other things, vital information concerning procedures being offered in different centres. It also enables laboratories to increase their awareness of the effectiveness of the overall national antenatal screening programme, monitoring and changing their practice appropriately. The respondents also indicated that such a mechanism would assist some staff such as cytogeneticists who are quite detached from those receiving tests to feel as though they are an integral part of a programme and would increase their awareness and knowledge of how the screening programme works form a national perspective.

Divergence of opinion was expressed in terms of the perceived role of a screening co-ordinator. The cytogeneticist believed that it would be helpful if screening co-ordinators were available to provide professional education, advice, support and help with audits; but not to counsel every woman or deal with every positive result. They viewed the position as an administrative one, and therefore those chosen for this position should have an understanding of the health sector and the inherent problems of the screening programme. The incumbent would be expected to possess good educational skills and be able to work well with computers to extract data, assuming the laboratories would be reporting in some way.

The biochemist however, perceived the role of a screening coordinator quite differently. They thought that their role would be to provide information and advice and support at a local level. They felt that because of New Zealand's relatively dispersed and low population the model used in the UK would not work well here. This respondent was of the opinion that screening co-ordinators could liaise with midwives around screening issues and difficulties in the antenatal period and they thought that they would also be able to help with their new born programme as a natural extension of this role. This respondent thought that a screening co-ordinator should be available in every obstetric unit in the country and felt that they would have to live locally. The scope of work envisaged by this respondent covered interacting with the people that have the test results, the local specialists and the local midwives and possibly with pregnant women regarding positive test results. The screening co-ordinators would be expected under this model to co-ordinate the follow up diagnostic tests and procedures and make appointments for the women.

10

CLINICAL GENETICISTS

Two Clinical Geneticists participated in the study and both of them agreed that Down syndrome screening should be conducted through a national programme. They acknowledged that New Zealand already has a screening programme but that it was far from satisfactory being ad hoc in application. Specifically, the respondents held the view, whether founded or not, that the current screening processes were biased to enable access for those in the community who are in the high socio-economic bracket.

Having indicated support in principle for a national screening programme, both respondents indicated that this support was contingent on a programme that supported the individual woman's right of choice. Namely the programme needs to be constructed in such a manner that enables a woman to opt in or out of the programme as they see fit.

Neither clinical geneticist support independent first and second trimester screening. Both respondents felt that such a scenario increased the risk of obtaining conflicting results. Their preference was to introduce quadruple testing (combined) with NT and serum testing in the first trimester rather than just NT scanning in the first trimester.

In addition to having a voluntary process, other factors that were identified that would make a screening programme more acceptable to clinical geneticists included:

- Primary and secondary care providers being fully educated;
- Having good counselling available for positive screening results;
- Availability of information regarding diagnostic tests;
- Ensuring the programme was sensitive and possible to extend to detection of other abnormalities other then just Down syndrome (albeit keeping the number of false positive rates to the minimum), and
- Having all women with an abnormal result being offered genetic counselling services if they wish.

In the opinion of the respondents, the introduction of a national screening programme is seen to go hand in hand with education of all health professionals involved in antenatal care. Both respondents considered this training should occur concurrently with the roll out of the national screening programme. It was suggested that written information backed up with further information on websites could be utilised as a way of informing health professionals, though given the limitations of distance/e-based learning it was recognised that at some point face-to-face education would also be required. It was suggested that Genetic Counsellors as well as Clinical Geneticists would be able to educate health professionals, however there a limited numbers in the two professions and this may be a limiting factor to pursuing such a model.

Apart from educating the health professionals, a need to educate or increase the awareness of the general public was also discussed. Specifically if the focus is to undertake screening at an early stage of pregnancy, then there is a requirement to ensure that women present early and this can only be achieved if the level of awareness of the community is increased prior to becoming pregnant. Several ways in which awareness raising could take place were discussed including utilising Women's magazines and TV advertising. It was acknowledged that most women are quite knowledgeable in their second and subsequent pregnancies and that it was during their first pregnancy where the knowledge gap is most obvious.

General practitioner surgeries were mentioned as a place where information in the form of pamphlets could be accessed by women. It was felt, however, that women are given too much information all at once in the antenatal period and that it needed to be provided in various mediums and not just through pamphlets. Several ideas such as the use of touch screens that provide information and the internet were mooted as ways of informing women. Both suggested media were thought to be user friendly for those who may have literacy issues. E-learning options were also suggested and it was felt that women should be provided with details as to where they could access further information or contact a person directly to discuss particular issues.

Availability of information in languages other than English was seen as essential characteristics of a communication and education strategy targeting pregnant women.

Apart from the dissemination of information to women, the respondents felt that the national screening programme faced a significant challenge in terms of ensuring equity of access to services. In particular, it was felt that the programme, when introduced, would have to provide the same service to all women across New Zealand irrespective of geographic location. Failure to do so would, in the opinion of the respondents, run the real risk of introducing a two tiered (rural and urban) screening system.

Other challenges faced by the introduction of a national screening programme include determining at what stage screening should occur, what tests should be undertaken, who discusses the outcomes of the screening with the pregnant woman and determining what follow up is required. One of the respondents indicated that they were of the view that the Ministry of Health and the ADSSAG were advocating for an integrated first and second trimester serum testing. The other respondent indicated that based on their understanding of the literature a complicated method of deciding what to do after the initial screening required allocating the woman into one of three groups based on an assessment of risk.

Irrespective of what model is endorsed in the national screening programme, the clinical geneticists indicated that it was mandatory that before any woman has a genetic test, a plan is made before the test is undertaken as to who should deliver the result and that it is important to communicate this decision to all parties and to adhere to the decision.

Consistent with the need to clearly articulate a pathway to the pregnant woman and health professionals interacting with her, the clinical geneticists indicated that they would like the type of testing that NSU is proposing to be clearly stated and believe that this should include clearly defined roles and acknowledgment regarding where extra expertise may be required.

Currently this is not clear and accordingly it is difficult to provide an accurate estimate of what the impact the introduction of a national screening programme would be on the workforce. Whilst anticipating an initial increase in workload for clinical geneticists, over time it was anticipated that the workload may lessen as the programme would streamline those being referred to their service.

Of other services, the clinical geneticists felt that the genetic counsellors are likely to experience a significant increase in their workload, particularly as this workforce is relatively small. The clinical geneticists identified areas of need for genetic counsellors as being in Hamilton and Whangarei.

There was divergence in opinion in terms of capacity to undertake cytogenetic tests. One opinion expressed was that there would be insufficient capacity, particularly if full karyotypes formed a part of the available screening options. This was purported by the individual as the best option with FISH and PCR tests available as back up. The other clinical geneticist had spoken to their head of cytogenetic services prior to engaging with the interview team. Based on this discussion the view was expressed that in the long run the national screening programme would probably have limited impact on the cytogenetic workload. This view was based on the assumption that the programme would ensure that screening would be targeting the appropriate group of people rather than the ad hoc basis that currently exists (i.e. the numbers are likely to remain static, but the cohorts are likely to change in characteristic). This expectation is also based upon the evidence documented from the UK which found that when the country introduced a well run screening programme the actual diagnostic workload went down.

Having stated the above, qualifiers were also introduced. These qualifiers arose due to the current lack of clarity around what tests are being envisaged by the NSU and the Ministry of Health. A significant difference in workload would arise if only the simpler tests formed part of the screening programme.

Some discussion still needs to take place between whether a FISH or PCR are being proposed or whether obtaining amniotic fluid or the placental tissue warrants pursing a full karyotype. Clearly this should be discussed in terms of risk exposure to the pregnant woman as well as giving due consideration to the cost effectiveness of the tests.

Overall the clinical geneticists indicated that an integrated well defined national screening programme was thought to be a positive advancement in New Zealand. However, in order to attain this appropriate infrastructure needs to be established and clear documentation needs to be developed by the Ministry of Health that sets out the roles and responsibilities of the programme, the pathways available to pregnant women and the points at which respective health professionals interact with the women. This needs to be articulated to health professionals via educational and training programmes and to the general public and woman using a range of communication mediums.

11

PAEDIATRICIAN

A paediatrician was also interviewed as part of this study. During the discussions the respondent indicated that paediatricians may occasionally work with pregnant women who are unsure what to do with regard to antenatal screening for Down syndrome, but that this would only occur if they were already looking after a child with Down syndrome and the mother was pregnant again. Apart from such a scenario, the role and involvement of paediatricians in a national antenatal screening programme would be limited. Accordingly, the introduction of a national antenatal screening programme would present limited capacity issues for the paediatrician workforce.

Within this context, the respondent indicated that they thought that women would want to know:

- about their options regarding access to screening services;
- what the risks of their having a baby with Down syndrome was;
- about the accuracy of tests;
- what the tests are for and why different ones are used (i.e. why order ultrasound tests or blood tests etc.);
- the risks associated with diagnostic tests, and
- other conditions that may be detected as well as Down syndrome.

Should a positive test be indicated, then the paediatrician considered that the pregnant woman would want access to information about (or discuss) what to expect in terms of medical complications to the child and life for an individual and family living with Down syndrome.

With respect to the latter issue, the paediatrician felt that their profession had a good knowledge base to draw upon in terms of developing relevant national material that could be provided to pregnant women addressing some of these key issues. It was also important to ensure that any materials developed for pregnant women identifies that the screening process will potentially bring with it ethical considerations that will have to be made by the pregnant woman.

According to the respondent, paediatricians would need to be educated regarding the introduction of a national antenatal screening programme for Down syndrome. This education programme could be linked to CME points and provided via discussion forums or one hour seminars. During the education session, paediatricians should be exposed to the written information provided to women.

The major concern identified by the respondent related to the potential message or ethos the national screening programme will be seen as endorsing. Namely there was concern expressed that the national screening programme would suggest that it was acceptable or a preferable option to terminate a fetus diagnosed with Down syndrome, thereby devaluing those individuals living in the community with Down syndrome.

12

SUPPORT SERVICES

A representative from the New Zealand Down Syndrome Association (NZDSA) was interviewed as a key informant regarding support services. This respondent indicated that that the NZDSA works with a range of women, families, professionals and organisations who contact them seeking information about antenatal screening for Down syndrome. They provide a "listening ear", explanations, advice and information on what screening tests are available, services available and what the results of the tests mean.

Interestingly, pregnant women tend to contact the NZDSA themselves once they have had some type of screening test, whereas other referrals are more likely to occur in the post natal period once a baby with Down syndrome has been born.

The NZDSA noted that there are divergent messages currently being provided to pregnant women. For example from the experiences of NZDSA it is apparent that a significant number of pregnant women have no idea that the initial routine scan is also a 'screening test' for abnormalities. This lack of information or awareness creates significant challenges to pregnant women after the scan has occurred as they are often ill-equipped to deal with or understand the outcomes of the scanning process.

Accordingly, the NZDSA believes that health care professionals need to change both the nature of and the manner in which information is currently provided to pregnant women. Modifications to the language used in pamphlets and resource materials including a change in the tone of voice were identified as essential requirements. The stage at which information is presented also needs to be revised within the context of defining a national screening programme.

The need for a national screening programme was in part challenged by the NZDSA. Specifically consideration needs to be given to the message such a programme is permeating or perpetuating amongst the community about the worth of an individual with Down syndrome. Careful consideration needs to take place as to who a national antenatal screening programme for Down syndrome fits in with, or integrates with the Ministry of Health's Disability Strategy.

The role of the NZDSA will need to be clearly defined within the context of establishing a national antenatal screening programme for Down syndrome. Existing services offered by NZDSA (i.e. written information. DVD, website and an 0800 number) should be recognised and utilised where appropriate.

According to the NZDSA the term 'screening programme' infers a comprehensive programme that would include education and ongoing counselling and support. They are concerned that if a national antenatal screening programme for Down syndrome is introduced, it would have a very narrow, medical approach with little real consideration being given to genuine education, counselling and support services. Consistent with their concerns about how the screening programme dovetails with other government strategies, the NZDSA expressed concern that appropriate consideration needs to be given to the way in which language is used in the development and implementation of any screening programmed. For example, the terms 'risk' and 'chance' have connotations potentially results in devaluing a person with a disability.

Overall, if a national antenatal screening programme for Down syndrome is to proceed, the NZDSA considers that this has to be an integrated programme where all roles and responsibilities are clearly defined, relevant education of health professionals is undertaken, and appropriate

infrastructure and information is made available to support the pregnant woman. Importantly, women should be accorded choice to opt in or out of the programme.

The Association has in the past been asked to be involved in undergraduate training programmes. Based on their experiences the NZDSA is of the opinion that better training and a more balanced view of a disability should be provided in the basic training of all health professionals although this would require additional time and resources. They are of the opinion that training should include meeting people with Down syndrome as many health professionals have not ever had any contact with a person with Down syndrome using textbooks instead as their sole method of gaining their necessary knowledge.

The NZDSA also have trained support workers and would certainly be keen to offer and have input into the planning and development of a screening programme in this capacity.

Whilst the Association indicated that they would be prepared to share their resources with the NSU this would have to occur at cost. The NZDSA membership is made up of women, families and professionals, all of whom are volunteers. The use of such an organisation in a national screening programme would have to recognise that there are costs associated with involving and mobilising a volunteer based membership.

Some other capacity issues were also raised by the NZDSA, specifically relating to rural families. People living in rural localities currently struggle to access professional services now. If a screening programme were to be introduced, the need for extra capacity in rural locations would have to be addressed. The use of metropolitan based services to bridge this gap may not be possible if resources are already stretched in urban areas.

The NZDSA also identified the need to increase counselling services, especially genetic counselling if a national screening programme were introduced. The current scenario of a one off visit is insufficient and should not be perpetuated in a new screening programme.

The NZDSA did not fully support the introduction of screening co-ordinators as it was though that the role would be based on a medical model which the NZDSA does not support. If screening co-ordinators were to be utilised in the future, then the NZDSA considers it mandatory that these positions embrace the New Zealand Disability Strategy and that the positions would need to be in place before the programme is fully implemented.

13

GENETIC COUNSELLOR

The Genetic Counsellor interviewed as a key informant for this study was adamant that a more sophisticated approach to antenatal screening for Down syndrome is needed as the present system is ad hoc and confusing not only to the general public but also to health care professionals.

A lack of clarity around what the intended national screening programme entails (in terms or roles and responsibilities of health care professionals, whether it is an all in or an optional programme affording women choice) restricted this respondent from being able to articulate what the expected impact would be on the workforce of genetic counsellors. Recognising that there are only 10 genetic counsellors in the country of New Zealand it is reasonable to expect that capacity issues will arise, particularly in rural and regional locations if the national screening programme will require all pregnant women in the country to participate. This will have to be monitored and alternate strategies put in place to address the potential shortfall. One possible strategy identified by the respondent was to form small expert groups of health professionals (e.g. Genetic Counsellors or similarly trained professionals such as expert nurses, midwives or obstetricians). Through a core group of people such as this located in strategic places across the country may obviate the risk of pregnant women being given vastly different information, or not being able to access counselling.

It was suggested that the NSU should work out a process and establish guidelines regarding the amount of information, the type of information and who gives the information to women, explaining how to manage this process from the commencement of pregnancy covering all possible outcomes for women during their pregnancies.

The Genetic Counsellor indicated that their profession regards the results of screening tests as neither positive or negative results but rather as a shift in risk. This is not the way the public perceives the screening test to operate, and in the opinion of the genetic counsellor neither do most health professionals. The debate is on how to provide information to a pregnant woman if the "results are positive" rather than how to discuss the "increased risk" identified by a screening test. In the opinion of the respondent, this scenario is a good indicator for the need to ensure that any national antenatal screening programmed incorporates an educational programme for health care professionals.

The respondent also indicated that Genetic Counsellors should have a very pronounced role in such an educational programme. Specifically it was thought that the educational programme should be linked to CME points, and that the Genetic Counsellor would present the details of the new screening programme to other health professionals. This was seen as a logical extension of functions currently being performed by genetic counsellors across the country who already work with midwives, students, registrars and house surgeons. The ability to undertaken this activity may however be restricted given that there are only 10 genetic counsellors in the country.

If this model of education is not supported, then it was considered critical by the respondent that a model of delivery that ensured consistency in information dissemination was adopted by the NSU and that this should also be reflected in the national guidelines.

Public education was also raised in discussions with this respondent. They felt that it would be beneficial if some form of general public awareness campaign was entered into that informed the general community of the existence of a national antenatal screening programme. Pamphlets could be left in general practitioner rooms and other strategies may need to be considered.

Concern was expressed that the level and nature of information presented to women in relation to screening and in particular diagnostic procedures is extremely variable and is dependent on who is providing the information. For example, many pregnant women are unaware that the first scan undertaken early in the pregnancy is also a screening test for abnormalities. Information needs to be provided to women early in the pregnancy that enables them to understand the options available to them, the fact that they have choice and what respective diagnostic tests entail. They should also be made aware who will provide them with feedback on the results and how to interpret these results. The development of a national set of guidelines that will monitor the implementation of the national screening programme should address and facilitate these issues. It was the opinion of the respondent that the person ordering the antenatal screening test should be the health professional charged with the responsibility of discussing the results with the pregnant woman.

The respondent also highlighted the need for any communication strategy and media targeting pregnant women to be well written, easy to understand and available in multiple languages other than English. Accordingly it was felt that any information packages and materials should be drawn up by a group of experts and to include input from a variety of users (and that this should include cultural perspectives).

Genetic Counsellors were of the opinion that it would require a great deal of coordination right from the start if Screening Co-ordinators were made available to provide professional education, advice, support and help with audits. They thought it would be useful to have a facility that can answer phone calls when the screening programme is first introduced to provide help and assistance, although it was not clear whether this was for the benefit of health professionals or the general public. A single centre was not considered desirable, although this would depend on the type of programme being offered. It was suggested that it might be useful to use Maori health initiatives and emphasised that the work process must be non-directive.

In general, genetic counsellors have concerns regarding the introduction of a national antenatal screening programme for Down syndrome in that they foresee significant issues in implementation and the management of the operational processes of the programme. Specifically clarity is required defining the roles and responsibilities and intent of the national screening programme, and once this is achieved the necessary infrastructure in terms of service delivery and associated supports need to be in place before New Zealand women are exposed to the programmes processes. Although genetic counsellors acknowledge that it is not going to be an easy task, they are emphatic that a programme is needed and that their concerns should not put a stop to the introduction of a national programme.

A

APPENDIX A: KEY PARTICIPANTS

Group	Date of meeting
GPs	13 November 12:45
	25 October 13:00
	27 November 09:00
Midwives	26 October 15:30 – 16:30
	26 October 15:30 – 16:30
	21 November 11:30
	25 October 11:00 – 12:00
Obstetricians	27 October 16:15 – 17:45
	30 October 12:15 – 13:00
	10 November 15:00
NT Practitioners	24 October 10:30 – 11:30
	13 November 17:30
	22 November 16:00
Laboratory (biochemist)	16 November 11:00
Laboratory (cytogenetic)	10 November 11:30
Clinical Geneticists	13 November 09:00
	25 October 16:30

Group	Date of meeting
Paediatrician	25 October 14:30 -15:15
Support services	30 October 10:00
Genetic Counsellor	26 October 11:00 – 12:00

B

APPENDIX B: KEY INFORMANT INTERVIEW-GPS

ANALYSIS OF THE WORKFORCE FOR ANTENATAL DOWN SYNDROME SCREENING

KEY INFORMANT INTERVIEW: GENERAL PRACTITIONERS

The following set of questions will be covered during the conduct of the interview. We are enclosing them should you wish to prepare your response to them. We will not necessarily adhere to the exact sequencing of questions as they appear here as we would like to explore a range of issues during the interview. However, we will ensure that all the issues raised by these questions are covered. The National Screening Unit of the Ministry of Health has reviewed and agreed to these questions being included in the interview.

The purpose of this interview is to identify any workforce/service issues, including attitudinal issues which may arise in implementing a national Antenatal Down syndrome Screening programme. This includes workforce requirements, training, capability, recruitment, retention and capacity issues and forecasting future workforce needs. It would be useful to understand your views on educating the workforce, continuing education and best practise as well as the perceived counselling role of health professionals who have direct contact with pregnant women.

Current Down syndrome screening carried out in New Zealand is variable across the country and includes age based screening (offering diagnostic tests such as Chorionic Villus Sampling (CVS) or amniocentesis and karyotyping) to women over 35 or 37 years of age; NT screening (offering diagnostic tests to women considered to be at increased risk on the basis of their age and NT measurement) and a small amount of serum screening (offering diagnostic tests when increased risk is shown by age and 2nd trimester serum analytes with or without NT). This does not represent safe practice. The Ministry of Health is considering improving this situation by making better information and more reliable tests available; standardising the investigations offered throughout NZ and introducing audit and monitoring, i.e. replacing *ad hoc* testing with a screening programme.

Questions:

1. Do GPs work with women who are unsure what to do with regard to screening for Down syndrome?
2. What information do you think women need/want to help them with this?
3. How many patients would be referred by a GP for CVS or amniocentesis in a year?
4. Do GPs provide information to women about screening for Down syndrome?
   - If not, do you think they should?
   - If so, at what stage would they do so and what topics would they include in their discussion?
5. Whose responsibility do GP's think it is to inform pregnant women of screening options?
   - Please can you elaborate?

6. What types of screening would GP's refer women to (e.g. Nuchal Translucency (NT), Maternal Serum Screening (MSS) or other)?

7. What issues do GPs have with regard to the provision of information to women in relation to diagnostic procedures with regard to the level and nature of information given to them?
8. Do you think that GPs would need to change how they provide this information?
9. What information would GPs need/ want in relation to this?

10. Do GPs offer Down syndrome screening to all women?
    - If not, why?
11. Who should discuss the results of antenatal screening tests with women?
12. Do you think GP's are comfortable about giving results, especially positive results?
    - If not, who would they refer the pregnant woman to?
13. Do you think that further training and support would assist GP's in discussing positive screening and diagnostic results?
14. How do GP's keep their knowledge and training in antenatal screening current?
15. Where do GP's get new information on best practice for antenatal screening?
16. Do you think Down syndrome screening should be done through a programme or left as is?
17. What do you believe is the best clinical approach for such a programme?
18. What concerns would you have about a screening programme for Down syndrome?
19. How do you think a national Down syndrome Screening programme would affect your workload?
20. Do you think GPs will be concerned about the time required to understand the screening programme and communicate effectively with their patients about this?
21. What possible capacity issues (including rural/urban differences) would the introduction of a screening programme generate?
22. What information would GP's want to provide to their clients?
23. If written information is required, what would the nature and level of this information be in terms of languages, etc?

C

APPENDIX C: KEY INFORMANT INTERVIEW-MIDWIVES

ANALYSIS OF THE WORKFORCE FOR ANTENATAL DOWN SYNDROME SCREENING

KEY INFORMANT INTERVIEW: MIDWIVES

The following set of questions will be covered during the conduct of the interview. We are enclosing them should you wish to prepare your response to them. We will not necessarily adhere to the exact sequencing of questions as they appear here as we would like to explore a range of issues during the interview. However, we will ensure that all the issues raised by these questions are covered. The National Screening Unit of the Ministry of Health has reviewed and agreed to these questions being included in the interview.

The purpose of this interview is to identify any workforce/service issues, including attitudinal issues which may arise in implementing a national Antenatal Down syndrome Screening programme. This includes workforce requirements, training, capability, recruitment, retention and capacity issues and forecasting future workforce needs. It would be useful to understand your views on educating the workforce, continuing education and best practise as well as the perceived counselling role of health professionals who have direct contact with pregnant women.

Current Down syndrome screening carried out in New Zealand is variable across the country and includes age based screening (offering diagnostic tests such as Chorionic Villus Sampling (CVS) or amniocentesis and karyotyping) to women over 35 or 37 years of age; NT screening (offering diagnostic tests to women considered to be at increased risk on the basis of their age and NT measurement) and a small amount of serum screening (offering diagnostic tests when increased risk is shown by age and 2nd trimester serum analytes with or without NT). This does not represent safe practice. The Ministry of Health is considering improving this situation by making better information and more reliable tests available; standardising the investigations offered throughout NZ and introducing audit and monitoring, i.e. replacing *ad hoc* testing with a screening programme.

Questions:

1. How do you think a national Down syndrome Screening programme would affect midwives workload?
2. Do midwives inform all women of screening options now?
   - If not, do you think that they should?
   - If so, what topics do you think should be included by the midwife when providing information about screening?
3. Whose responsibility do you think it is to inform the pregnant woman of screening options?
4. Do midwives offer screening to all women now?

- Please can you elaborate?

5. Do you think screening should be left as it is or organised as a national screening programme?
6. What training have midwives received about screening/diagnostic tests for Down syndrome specifically (none, Maternal Serum Screening (MSS) and/or Nuchal Translucency (NT) scanning)?
7. Where do midwives currently get new information on best practice for antenatal screening?
8. What issues do you have with regard to the provision of information to women in relation to diagnostic procedures with regard to the level and nature of information given to them?
9. Do midwives work with women who are unsure what to do with regard to screening for Down syndrome?
10. What information do you think women need/want to help them with this?
11. Do you think midwives are comfortable about giving this information?
12. Who should discuss the results of antenatal screening tests with women?
13. Do you think midwives are comfortable about giving results, especially positive results?
14. If not, do you think further training and support would assist them in discussing positive screening and diagnostic results?
    - Please can you elaborate?
15. What concerns are midwives likely to have about a screening programme for Down syndrome?
16. Will midwives worry about the time required to understand the screening programme and communicate effectively with their clients about this?
17. What may midwives need/want to help them understand the concepts?
18. What possible capacity issues (including rural/urban differences) would the introduction of a screening programme generate?
19. What information would midwives want to provide to their clients?

    - If written information is required, what would the nature and level of this information be in terms of languages, etc?

20. Would it be helpful if Screening Coordinators were available to provide professional education, advice, support, help with audits etc (not to counsel every woman or deal with every positive result)?

D

APPENDIX D: KEY INFORMANT INTERVIEW-OBSTETRICIANS

ANALYSIS OF THE WORKFORCE FOR ANTENATAL DOWN SYNDROME SCREENING

KEY INFORMANT INTERVIEW: OBSTETRICIANS

The following set of questions will be covered during the conduct of the interview. We are enclosing them should you wish to prepare your response to them. We will not necessarily adhere to the exact sequencing of questions as they appear here as we would like to explore a range of issues during the interview. However, we will ensure that all the issues raised by these questions are covered. The National Screening Unit of the Ministry of Health has reviewed and agreed to these questions being included in the interview.

The purpose of this interview is to identify any workforce/service issues, including attitudinal issues which may arise in implementing a national Antenatal Down syndrome Screening programme. This includes workforce requirements, training, capability, recruitment, retention and capacity issues and forecasting future workforce needs. It would be useful to understand your views on educating the workforce, continuing education and best practise as well as the perceived counselling role of health professionals who have direct contact with pregnant women.

Current Down syndrome screening carried out in New Zealand is variable across the country and includes age based screening (offering diagnostic tests such as Chorionic Villus Sampling (CVS) or amniocentesis and karyotyping) to women over 35 or 37 years of age; NT screening (offering diagnostic tests to women considered to be at increased risk on the basis of their age and NT measurement) and a small amount of serum screening (offering diagnostic tests when increased risk is shown by age and 2nd trimester serum analytes with or without NT). This does not represent safe practice. The Ministry of Health is considering improving this situation by making better information and more reliable tests available; standardising the investigations offered throughout NZ and introducing audit and monitoring, i.e. replacing *ad hoc* testing with a screening programme.

Questions:

1. Do you have women referred to you who are unsure what to do with regard to screening for Down syndrome?
2. If so, what services would obstetricians provide for these women themselves or through referral to other health care providers?
3. Which health care providers would obstetricians refer women to with regard to screening and what services would they be you be expecting from specific providers?
4. Whose responsibility do you think it is to **inform** the pregnant woman of screening options?
5. Whose responsibility do you think it is to **offer** the pregnant woman screening options?
6. Do obstetricians currently **inform and offer** all pregnant women screening options for Down syndrome?

7. If obstetricians currently provide information about screening, what topics would be included in the conversation?
8. If obstetricians currently offer screening, what screening would be offered?
    - Nuchal Translucency scanning
    - Maternal Serum Screening
    - Other
9. Do you think it should be the Obstetrician who delivers the results of positive screening tests?
    - If not, who would be the best person?
10. Where a screen positive result is provided to a pregnant woman, would obstetricians provide further discussion and options to the woman?
11. If so, would this information be provided verbally, through specific written information and/ or contact information for counselling support services?
12. Do you consider that women should have a right to have an amniocentesis if they are over the age of 35?
    - Could you explain why?
    - What if they have a lower risk screening result (are screen negative)?
    - How would this affect a screening programme?
13. How many amniocentesis and CVS procedures have you done in the last 12 months?
14. Do you think a screening programme would increase these numbers and your work load and that of your colleagues?
    - Could you explain how and why?
15. Do obstetricians keep their own statistics on miscarriage rates following invasive testing?
16. Would they be prepared to have this data recorded and available nationally?

    If not, under what conditions would obstetricians be prepared to have the data recorded and available nationally?
17. What are some of the issues with regard to the provision of information to women in relation to diagnostic procedures especially keeping in mind the level and nature of information given?
18. What influence do early screening and diagnostic test results and the surgical termination of pregnancy have on information given to women and decisions taken – would you choose one type of screening/diagnostic test over another because of these factors?
19. What is your opinion on the possible capacity issues associated with the implementation of the screening programme (diagnostic testing)?
20. Do you think a national antenatal Down syndrome screening programme will be acceptable to women and if it is, do you think that this may increase the uptake of diagnostic tests?
21. What factors would make the screening programme more/less acceptable to Obstetricians?
22. How do obstetricians keep their knowledge and training in antenatal screening current and where do you get new information on best practice for antenatal screening?
23. Should training and support be available to assist obstetricians to discuss positive screening and diagnostic test results?
24. Do you believe that a national screening programme for Down syndrome is necessary?
25. What do you believe the best clinical approach for such a programme would be?

26. If a national screening programme were introduced, would this impact on an obstetrician's workload?
27. If so, how and in which areas do you anticipate the resultant increased workload would occur?
28. What factors would impact on an obstetrician's ability to effectively implement a national screening programme (i.e. staffing, access to suitable facilities, existing waiting lists, cultural beliefs etc.)?

Questions for Obstetricians who perform NT:

29. IF a Down syndrome screening programme pathway includes NT and IF there is an increase in demand for NT, what problems do you foresee (e.g. with regard to workforce capacity and capability, accreditation, consumer access, equipment, etc)
30. Have you been specifically trained to do NT?
31. If so, are you accredited by FMF or RANZCOG or other body?
32. Where did you do the course (in NZ or which country)?
33. IF changes to section 88 required all sonographers to be accredited to perform NT, how would this affect you?
34. IF you had to combine your NT results with serum results, what workforce issues would there be? (E.g. workforce issues, time issues)
35. IF the screening programme design dictated that you did not discuss the results with the mother, would this create issues for you?
    - What would these be (E.g. ethical issues)?
36. How much discussion do you currently have with women regarding NT scans – what sort of information is provided before, during, after the scan?
37. What other information would you need to be able to do this?
38. Do you think that NT Practitioners should give this information to women or should the LMC or another practitioner?
39. Are you aware of any non-accredited sonographers carrying out NT screening tests?
40. Are you involved in any audit of NT quality (E.g. do you submit a number of images per year to your accreditation body for assessment)?
41. Are you involved in recording pregnancy outcomes of all women you have done NT measurements on (or do you only record positive results/ keep no record of pregnancy outcomes)?

E

APPENDIX E: KEY INFORMANT INTERVIEW-NT PRACTITIONERS

ANALYSIS OF THE WORKFORCE FOR ANTENATAL DOWN SYNDROME SCREENING

KEY INFORMANT INTERVIEW: NT PRACTITIONERS

The following set of questions will be covered during the conduct of the interview. We are enclosing them should you wish to prepare your response to them. We will not necessarily adhere to the exact sequencing of questions as they appear here as we would like to explore a range of issues during the interview. However, we will ensure that all the issues raised by these questions are covered. The National Screening Unit of the Ministry of Health has reviewed and agreed to these questions being included in the interview.

The purpose of this interview is to identify any workforce/service issues, including attitudinal issues which may arise in implementing a national Antenatal Down syndrome Screening programme. This includes workforce requirements, training, capability, recruitment, retention and capacity issues and forecasting future workforce needs. It would be useful to understand your views on educating the workforce, continuing education and best practise as well as the perceived counselling role of health professionals who have direct contact with pregnant women.

Current Down syndrome screening carried out in New Zealand is variable across the country and includes age based screening (offering diagnostic tests such as Chorionic Villus Sampling (CVS) or amniocentesis and karyotyping) to women over 35 or 37 years of age; NT screening (offering diagnostic tests to women considered to be at increased risk on the basis of their age and NT measurement) and a small amount of serum screening (offering diagnostic tests when increased risk is shown by age and 2nd trimester serum analytes with or without NT). This does not represent safe practice. The Ministry of Health is considering improving this situation by making better information and more reliable tests available; standardising the investigations offered throughout NZ and introducing audit and monitoring, i.e. replacing *ad hoc* testing with a screening programme.

Questions:

1. If a Down syndrome screening programme pathway includes NT and IF there is an increase in demand for NT, what problems do you foresee (e.g. with regard to workforce capacity and capability, accreditation, consumer access, equipment, etc)
2. Have you been specifically trained to do NT?
    - If so, are you accredited by FMF or RANZCOG or other body?
3. Where did you do the course (in NZ or which country)?
4. If changes to section 88 required all sonographers to be accredited to perform NT, what possible effects would this have on NT Practitioners?
5. Are you aware of any non-accredited sonographers conducting NT tests?

- If so, what professional groups do they belong to?

6. Would there be any impact if it became compulsory to be accredited to perform NT in order to provide publicly funded NT?
   - If so, please could you elaborate?
7. How do NT practitioners keep their knowledge and training in antenatal screening current?
8. How long does an NT scan usually take?
9. How long does it usually take to document the results of an NT scan?
10. Is software used to calculate risk?
    - If so, what software packages are used for this purpose?
11. If NT Practitioners had to combine their NT results with serum results, what workforce issues would there be? (E.g. workforce issues, time issues)
12. How much discussion do NT Practitioners currently have with women regarding NT scans – what sort of information is provided before, during, after the scan?
    - How long would this normally take?
13. Do NT practitioners currently discuss the results of the scan with the woman?
    - If so, what type of information is provided when discussing the results?
    - If not, please can you elaborate?
14. If the screening programmes design dictated that NT Practitioners did not discuss the results with the mother, would this create issues for them?
    - What would these be (E.g. ethical issues)?
15. Do you feel that NT Practitioners are equipped to do this aspect of the work?
    - What other information would they need to be able to do this?
16. Do you think that NT Practitioners should give this information to women or should the LMC or another health care practitioner?
17. What process do NT practitioners follow re reporting results of scans?
18. Do NT Practitioners produce any information for women?
19. Are you involved in any audit of NT quality (E.g. do you submit a number of images per year to your accreditation body for assessment)?
    - What about other NT Practitioners?

20. Are NT Practitioners involved in recording pregnancy outcomes of all women you have done NT measurements on (or do they only record positive results/ keep no record of pregnancy outcomes)?
    - If so, who would they submit this information to?
21. Would NT practitioners be prepared to have this data recorded and available nationally?
    - If so, what would the likely impacts of this be?
22. If not, under what conditions might NT practitioners be prepared to have the data recorded and available nationally?

F

APPENDIX F: KEY INFORMANT INTERVIEW- LABORATORY BIOCHEMIST & CYTOGENETICIST

ANALYSIS OF THE WORKFORCE FOR ANTENATAL DOWN SYNDROME SCREENING

KEY INFORMANT INTERVIEW: CYTOGENETICIST AND BIOCHEMIST

The following set of questions will be covered during the conduct of the interview. We are enclosing them should you wish to prepare your response to them. We will not necessarily adhere to the exact sequencing of questions as they appear here as we would like to explore a range of issues during the interview. However, we will ensure that all the issues raised by these questions are covered. The National Screening Unit of the Ministry of Health has reviewed and agreed to these questions being included in the interview.

The purpose of the interview is to identify solutions for minimizing any negative workforce/ service impacts and any other issues, including attitudinal issues which may create barriers in terms of the successful implementation and adoption of the proposed Down syndrome Screening programme. This includes workforce requirements, training, capability, recruitment, retention and capacity issues and forecasting future workforce needs. It would be useful to understand your views on educating the workforce, continuing education and best practise as well as the perceived counselling role of health professionals who have direct contact with pregnant women.

Questions:

1. Do you think Down syndrome screening should be done through a programme or left as is?
2. What concerns would you have about the introduction of a screening programme for Down syndrome?
3. What possible capacity issues (including rural/ urban differences) would the introduction of a screening program generate?
    - Would these differ depending on full karyotype, FISH or PCR?
4. How do you think the proposed Down syndrome Screening programme would affect the workload in laboratories?
    - In what way do you think this may be addressed?

5. Would extra hardware or software be required to process and record laboratory tests?
    - Would this have an impact on staff?
    - Could you explain how?
6. Do you think any training issues will arise for laboratory staff?
    - If so, how do you think that these could be addressed?
7. What possible capacity issues (including rural/urban differences) would the introduction of a screening programme generate?
8. If Screening Coordinators were available to provide professional education, advice, support, help with audits etc (not to counsel every woman or deal with every positive result), would you anticipate that they may provide any help or assistance to laboratory staff?
9. If so, could you explain what you think they could do that would be of benefit to you and your staff?

G

APPENDIX G: KEY INFORMANT INTERVIEW-CLINICAL GENETICISTS

ANALYSIS OF THE WORKFORCE FOR ANTENATAL DOWN SYNDROME SCREENING

KEY INFORMANT INTERVIEW: CLINICAL GENETICIST

The following set of questions will be covered during the conduct of the interview. We are enclosing them should you wish to prepare your response to them. We will not necessarily adhere to the exact sequencing of questions as they appear here as we would like to explore a range of issues during the interview. However, we will ensure that all the issues raised by these questions are covered. The National Screening Unit of the Ministry of Health has reviewed and agreed to these questions being included in the interview.

The purpose of the interview is to identify solutions for minimizing any negative workforce/ service impacts and any other issues, including attitudinal issues which may create barriers in terms of the successful implementation and adoption of the proposed Down syndrome Screening programme. This includes workforce requirements, training, capability, recruitment, retention and capacity issues and forecasting future workforce needs. It would be useful to understand your views on educating the workforce, continuing education and best practise as well as the perceived counselling role of health professionals who have direct contact with pregnant women.

Questions:

1. Do you think Down syndrome screening should be done through a programme or left as is?
2. What concerns would you have about the introduction of a screening programme for Down syndrome?
3. Do you have women referred to you who are unsure what to do with regard to screening for Down syndrome?
4. Do you feel that women should have a right to have an amniocentesis if they are over the age of 35? How would this affect the proposed screening programme?
5. What are some of the issues with regard to the provision of information to women in relation to diagnostic procedures especially keeping in mind the level and nature of information given?
6. Who do you think should deliver the results of positive diagnostic tests?
    - Could you explain why?

7. What influence do early diagnostic test results and the surgical termination of pregnancy have on information given to women and decisions taken – would you choose one type of test over another because of these factors?
8. What information would Clinical Geneticists want to provide to their clients?

    - If written information is required, what would the nature and level of this information be in terms of languages, etc?

9. What is your opinion on the possible capacity issues associated with the implementation of the screening programme (diagnostic testing)?
    - Would these differ depending on full karyotype, FISH or PCR?
10. Do you think a screening programme would increase your work load?
    - Could you explain how and why?
11. Do you think the proposed screening programme will be acceptable to women and if it is, do you think that this may increase the uptake of diagnostic tests and procedures?
12. What factors would make the screening programme more/less acceptable to Clinical Geneticists?
13. Would it be helpful if Screening Coordinators were available to provide professional education, advice, support, help with audits etc (not to counsel every woman or deal with every positive result)?

APPENDIX H: KEY INFORMANT INTERVIEW- PAEDIATRICIAN

ANALYSIS OF THE WORKFORCE FOR ANTENATAL DOWN SYNDROME SCREENING

KEY INFORMANT INTERVIEW: PAEDIATRICIAN

The following set of questions will be covered during the conduct of the interview. We are enclosing them should you wish to prepare your response to them. We will not necessarily adhere to the exact sequencing of questions as they appear here as we would like to explore a range of issues during the interview. However, we will ensure that all the issues raised by these questions are covered. The National Screening Unit of the Ministry of Health has reviewed and agreed to these questions being included in the interview.

The purpose of the interview is to identify solutions for minimizing any negative workforce/ service impacts and any other issues, including attitudinal issues which may create barriers in terms of the successful implementation and adoption of the proposed Down syndrome Screening programme. This includes workforce requirements, training, capability, recruitment, retention and capacity issues and forecasting future workforce needs. It would be useful to understand your views on educating the workforce, continuing education and best practise as well as the perceived counselling role of health professionals who have direct contact with pregnant women.

Questions:

1. Do Paediatricians work with women who are unsure what to do with regard to screening for Down syndrome?
2. What information do you think women need/want to help them with this?
3. Do Paediatricians provide information to women about screening for Down syndrome?

- If so, at what stage would they do so?

4. What issues do Paediatricians have with regard to the provision of information to women in relation to diagnostic procedures with regard to the level and nature of information given to them?
5. Do you think screening should be done through a programme or left as is?
6. What concerns would Paediatricians have about a screening programme for Down syndrome?
7. How do you think the proposed Down syndrome Screening programme would affect their workload?

8. Do you think Paediatricians will be concerned about the time required to understand the screening programme and communicate effectively with their patients about this?
9. Would the introduction of a screening programme generate any capacity issues (including rural/urban factors) for Paediatricians?
10. What information, if any, would Paediatricians want to provide to their clients?

- If written information is required, what would the nature and level of this information be in terms of languages, etc?

11. Would it be helpful if Screening Coordinators were available to provide professional education, advice, support, help with audits etc (not to counsel every woman or deal with every positive result)?

I

APPENDIX I: KEY INFORMANT INTERVIEW-SUPPORT SERVICES

ANALYSIS OF THE WORKFORCE FOR ANTENATAL DOWN SYNDROME SCREENING

KEY INFORMANT INTERVIEW: SUPPORT GROUPS

The following set of questions will be covered during the conduct of the interview. We are enclosing them should you wish to prepare your response to them. We will not necessarily adhere to the exact sequencing of questions as they appear here as we would like to explore a range of issues during the interview. However, we will ensure that all the issues raised by these questions are covered. The National Screening Unit of the Ministry of Health has reviewed and agreed to these questions being included in the interview.

The purpose of the interview is to identify solutions for minimizing any negative workforce/ service impacts and any other issues, including attitudinal issues which may create barriers in terms of the successful implementation and adoption of the proposed Down syndrome Screening programme. This includes workforce requirements, training, capability, recruitment, retention and capacity issues and forecasting future workforce needs. It would be useful to understand your views on educating the workforce, continuing education and best practise as well as the perceived counselling role of health professionals who have direct contact with pregnant women.

Questions:

1. Does the NZDSA work with women who are unsure what to do with regard to screening for Down syndrome?
2. What information do you think women need/want to help them with this?
3. Does the NZDSA provide information to women about screening for Down syndrome?
4. What issues does the NZDSA have with regard to the provision of information to women in relation to diagnostic procedures with regard to the level and nature of information given to them?
5. Does the NZDSA think that health care providers would need to change how they provide this information?
6. Does the NZDSA think screening should be done through a programme or left as is?
7. What concerns would the NZDSA have about a screening programme for Down syndrome?

8. How do you think the proposed Down syndrome Screening programme would affect your workload?
9. Do you think Support Groups will be concerned about the time required to understand the screening programme and communicate effectively about this?
10. What possible capacity issues (including rural/urban differences) would the introduction of a screening programme generate?
11. What information would Support Groups want to provide?

- If written information is required, what would the nature and level of this information be in terms of languages, etc?

12. Would it be helpful if Screening Coordinators were available to provide professional education, advice, support, help with audits etc (not to counsel every woman or deal with every positive result)?

J

APPENDIX J: KEY INFORMANT INTERVIEW-GENETIC COUNSELLOR

ANALYSIS OF THE WORKFORCE FOR ANTENATAL DOWN SYNDROME SCREENING

KEY INFORMANT INTERVIEW: GENETIC COUNSELLORS

The following set of questions will be covered during the conduct of the interview. We are enclosing them should you wish to prepare your response to them. We will not necessarily adhere to the exact sequencing of questions as they appear here as we would like to explore a range of issues during the interview. However, we will ensure that all the issues raised by these questions are covered. The National Screening Unit of the Ministry of Health has reviewed and agreed to these questions being included in the interview.

The purpose of the interview is to identify solutions for minimizing any negative workforce/ service impacts and any other issues, including attitudinal issues which may create barriers in terms of the successful implementation and adoption of the proposed Down syndrome Screening programme. This includes workforce requirements, training, capability, recruitment, retention and capacity issues and forecasting future workforce needs. It would be useful to understand your views on educating the workforce, continuing education and best practise as well as the perceived counselling role of health professionals who have direct contact with pregnant women.

Questions:

1. Do Genetic Counsellors work with women who are unsure what to do with regard to screening for Down syndrome?
2. What information do you think women need/want to help them with this?
3. What issues do Genetic Counsellors have with regard to the provision of information to women in relation to diagnostic procedures with regard to the level and nature of information given to them?
4. Do Genetic Counsellors provide information to women about screening for Down syndrome?
    - If so, when would they do so?
5. Do you think that Genetic Counsellors would need to change how they provide this information?
6. What information would Genetic Counsellors want to provide to their clients?

- If written information is required, what would the nature and level of this information be in terms of languages, etc?

7. Do you think screening should be done through a programme or left as is?
8. What concerns would Genetic Counsellors have about a screening programme for Down syndrome?
9. Do you think Genetic Counsellors will be concerned about the time required to understand the screening programme and communicate effectively with their patients about this?
10. How do you think the proposed Down syndrome Screening programme would affect your workload?
11. What possible capacity issues (including rural/urban differences) would the introduction of a screening programme generate?
    - Would these differ depending on full karyotype, FISH or PCR?
12. Would it be helpful if Screening Coordinators were available to provide professional education, advice, support, help with audits etc (not to counsel every woman or deal with every positive result)?