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Newborn Metabolic Screening Programme

Annual Report

January to December 2012

National Screening Unit

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Contents

Glossary

CAH	Congenital Adrenal Hyperplasia
CF	Cystic Fibrosis
CH	Congenital Hypothyroidism
FAOD	Fatty Acid Oxidation Disorder
GP	General Practitioner
HIPC	Health Information Privacy Code
LMC	Lead Maternity Carer
MCAD	Medium Chain Acyl-CoA Dehydrogenase
MSUD	Maple Syrup Urine Disease
NICU	Neonatal Intensive Care Unit
NMSP	Newborn Metabolic Screening Programme
NSU	National Screening Unit
PKU	Phenylketonuria
SCBU	Special Care Baby Unit

Executive summary

Almost all babies born in New Zealand have been screened since the NMSP began in 1969, and as a result, over 45 babies are identified with and treated for a metabolic disorder each year. When a baby is diagnosed with a metabolic disorder in early infancy, treatment can commence immediately, preventing life-threatening illness and limiting the impact on the baby's development potential.

Key points for January to December 2012

- 61,422 babies were tested and 62,842 born giving coverage of 98%.
- 73% of samples were collected 48-72 hours timeframe. No DHB and no ethnic group met the standard of 95%. Babies of lower NZDep and European ethnicity are more likely to have the sample collected in the appropriate timeframe.
- Overall 99% of samples were suitable for testing. Eleven DHBs met the standard of 99% suitable. This is a significant improvement from 2011. The main reasons samples were unsuitable are taken too early or not sufficient/contaminated sample card. Follow-up of unsuitable samples was 95%.
- 69% of samples were received by the laboratory in four days or less. No DHB met the standard of 95%.
- The laboratory testing standard of 100% was not met for any disorder however was 99% except for fatty acid oxidation / amino acid breakdown disorders.
- Of 59 clinical critical results 55 were notified within the timeframe, three were notified one day late and one two days late.
- Although only 44% of second samples were received in ten days or less (the standard is 100%) 97% of follow-up was completed appropriately; and there is an improvement from 36% in 2011.
- Of babies with diagnosed disorders, treatment was commenced by the specified age for between 33-70% however most of the remainder were just outside the range and there were no clinical ill-effects from the delays.
- 99% of 602 requests for card returns were made in 28 days or less (the standard is 100%).
- 53 cards were used for additional testing for family health reasons, mostly for CMV testing. One sample was used in a coronial investigation.
- Screening sensitivities were 93-100% with specificities 99.7-100% and positive predictive values 2-30%.
- Follow-up of positive tests was between 96-100%. All clinical critical results had appropriate follow-up.
- 51 cases of screened disorders were detected by the programme and in 43 of these there was no clinical suspicion of the disorder before the screening test result.
- The screening cut-off for congenital hypothyroidism was reviewed and remains unchanged although the level for paediatric endocrine referral has been lowered from 50 to 30 mIU TSH/L blood.

1 Introduction

The purpose of this Annual Report is to provide information on the Newborn Metabolic Screening Programme (NMSP) and the performance of the NMSP against the agreed set of national indicators.

Regular analysis of data against programme indicators is a key monitoring and evaluation tool of the NMSP. The development of quarterly, biannual and annual reports has been a priority for the NMSP during 2012. Reports are published on the NSU website.

This is the second annual report of the NMSP following the development of national indicators and completion of the NMSP Monitoring Framework in November 2010.

Appendix 1 outlines the NMSP standards and indicators.

Further information on the NMSP Monitoring Framework can be found at:
http://www.nsu.govt.nz/files/NSU_Screening_Programme_2_0.pdf

1.1 Background to the Newborn Metabolic Screening Programme

Newborn babies in New Zealand have been screened for congenital metabolic disorders in a national screening programme since 1969. New Zealand was one of the first countries in the world (with Eire), to have a national screening programme. The National Testing Centre (the laboratory arm of the programme) was established by the late Professor Arthur Veale working with the late Professor Bob Guthrie in the Human Genetics Research Unit at the School of Medicine in Dunedin. The laboratory moved to Auckland in 1973 when Professor Veale became the foundation professor of Community Health and Human Genetics in what was then the new medical school.

The National Testing Centre moved into the public healthcare system in 1991. Since 2005, the NMSP has been overseen nationally by the National Screening Unit (NSU) of the Ministry of Health. Significant milestones for the programme include the introduction of expanded newborn screening (adding fatty acid oxidation and more amino acid breakdown disorders) in 2006. In 2009 educational and training resources (DVDs and videos) about newborn screening and best practice for Lead Maternity Carers (LMCs) were produced and distributed.

Almost all babies born in New Zealand have been screened since the NMSP began and approximately 45 babies are identified with and treated for a metabolic disorder each year. When a baby is diagnosed with a metabolic disorder in early infancy, treatment can commence immediately, preventing life-threatening illness and limiting the impact on the baby's development potential.

Newborn metabolic screening involves collecting blood samples from babies' heels (the 'heel prick test') onto a blood spot card (a 'Guthrie card'). Blood samples must be collected between 48 and 72 hours of baby's age for maximum utility. The blood samples are screened for over 20 metabolic disorders.

The NMSP is monitored and evaluated by the NSU to ensure it continuously meets high standards. A multi-disciplinary advisory group provides expert leadership and advice for the

programme. The NMSP Governance Team and the Technical Group reviews Monitoring Reports and makes recommendations.

Timing of sample taking (Indicator 2) is now reported in hours unless the date and time of birth and sample collection are not provided. The improvement in the quality of data to monitor this indicator is a significant achievement for the NMSP.

1.2 The aim of the Newborn Metabolic Screening Programme

The aim of the NMSP is to reduce newborn morbidity and mortality through high-quality screening that facilitates early detection and treatment of specific metabolic disorders in pre-symptomatic babies.

The objectives of the programme are to:

- enable early detection of pre-symptomatic newborns
- ensure appropriate early referral to treatment of newborns
- ensure babies born with congenital metabolic disorders have their development potential impacted as little as possible from the disorder
- facilitate early diagnosis, appropriate treatment and continuous monitoring of specific metabolic disorders
- maintain high uptake of screening, community participation and trust
- facilitate continuous quality improvement through the development of quality assurance, reporting, education and the strategic planning framework
- inform the community of all aspects of newborn screening including the storage and use of blood spot cards.

1.3 Data included in this report

Data is first obtained from the LabPLUS Delphic laboratory information system (Delphic). The extracted data is then placed in a temporary table on the Delphic Data Warehouse and imported into a MS Access database for analysis.

Data on DHB, ethnicity and NZ Deprivation Index (NZDep) is obtained from the Ministry of Health National Collections and merged with the LabPLUS data based on each individual's national health index (NHI). This method follows a matching and data retrieval process that is defined within the business rules.

Samples selected for inclusion in this report are based on the date they are received at the laboratory. For this reporting period, only valid samples from 1 January to 31 December 2012 are included. Samples are only included if they are a first sample received from a baby. Follow-up samples are excluded, because if a baby is screened in one reporting period, and has follow-up in the next period, they would be counted twice.

Ethnicity is prioritised based on the NHI ethnicity information. All reporting by NZDep is based on the extraction against the NHI associated with residential addresses. Decile 1 is the highest deprivation and decile 10 is the lowest decile rating.

While many Lead Maternity Carers (LMCs) are not directly responsible to a particular DHB, data is reported by DHB region, as this is the most usual way of comparing health information across New Zealand.

1.4 National Monitoring Indicators

Table 1 summarises all the NMSP indicators used in 2012 for regular monitoring with their reporting frequency and detail included in Appendix 2. This report, as an annual report, provides information on all nine indicators in addition to detected disorders. These indicators have been developed following consultation with key NMSP stakeholders. Indicators will be further refined as data is collected over time, and will be subject to regular review by the NMSP Advisory Group.

Table 1 NMSP indicators and monitoring frequency

Indicators	Biannually	Annually	Detail
1. Newborn Metabolic Screening Coverage		**X**	• DHB • Ethnicity • Deprivation status
2. Timing of sample taking	**X**	**X**	• DHB • Ethnicity • Deprivation status
Laboratory reporting			
3. Quality of Blood Samples	**X**	**X**	• DHB
4. Sample dispatch and delivery	**X**	**X**	• DHB
5. Laboratory testing timeframes	**X**	**X**	
6. Timeliness of reporting - notification of screen positives	**X**	**X**	
7. Collection and receipt of second samples		**X**	• DHB
Incidence		**X**	
8. Diagnosis and commencement of treatment by disorder: • Biotinidase deficiency • Cystic fibrosis • Congenital hypothyroidism • Congenital adrenal hyperplasia • Galactosaemia • Amino acid disorders • Fatty acid oxidation disorders		**X**	
9. Blood spot card storage and return	**X**	**X**	

2. Indicator 1: Screening coverage

Overall samples were received from 61,422 newborns between January and December 2012. The number of newborns screened is determined by the number of unique NHI numbers for each DHB. Some instances of the same NHI number used for more than one infant in a DHB have been found which explains why the total of infants counted in this way is slightly less than when counted by other parameters.

Data from National Maternity Collection of the Ministry of Health shows 62,842 babies were born in 2012. For screening, the numbers counted are babies screened within the calendar year. This might vary slightly from the number of babies in the calendar year. Approximately 98% of babies were screened.

Table 2 outlines the numbers of babies' screened and annual coverage from 2007 to 2012.

Table 2 Number of babies screened and coverage 2007 – 2012

Year	Births	Babies screened	Coverage %
2007	64,040	65,121	97.7
2008	65,333	63,794	97.6
2009	63,285	63,516	100.4
2010	64,699	63,727	98.5
2011	62,733	61,859	98.6
2012	62,842	61,422	97.7

Table 3 outlines babies screened by DHB. Coverage by DHB ranges from 95.9% to 100.8%. The coverage rate for 13 DHBs was around or above the national average.

Table 3 Number of babies screened by DHB, January to December 2012

DHB Region	Births	Babies screened	Coverage %
Northland	2,315	2,292	99.0
Waitemata	8,090	7,893	97.6
Auckland	6,750	6,519	96.6
Counties Manukau	8,843	8,660	97.9
Waikato	5,527	5,372	97.2
Lakes	1,565	1,501	95.9
Bay of Plenty	2,996	2,977	99.4
Tairawhiti	750	724	96.5
Taranaki	1,580	1,593	100.8
Hawkes Bay	2,275	2,261	99.4
Whanganui	880	897	101.9
Mid Central	2,202	2,144	97.4
Hutt Valley	2,042	2,012	98.5
Capital and Coast	3,889	3,770	96.9
Wairarapa	506	505	99.8
Nelson Marlborough	1,541	1,551	100.6
West Coast	415	404	97.3
Canterbury	6,053	6,036	99.7
South Canterbury	662	651	98.3
Southern	3,624	3,583	98.9
Not recorded*	337	77	22.8
Total	**62,842**	**61,422**	**97.7**

*includes babies born to Mothers who usually reside overseas

Table 4 outlines the number of births and number of babies screened by ethnicity. In 2012 the coverage rate for Maori (83.3%) and Middle Eastern, Latin American and African (MELAA) (90.4%) was significantly lower than the national average (97.7%).

Table 4 Number of babies screened by ethnicity, January to December 2012

	Births	Babies screened	Coverage %
Maori	16,673	13,887	83.3
Pacific	7,019	6,691	95.3
Asian	8,634	8,350	96.7
European	29,212	31,167	106.7
MELAA	1,176	1,063	90.4
Other	128	264	206.3
Total	**62,842**	**61,422**	**97.7**

Table 5 outlines the number of births and number of babies screened by NZDep. In 2012, coverage ranges from 86.0% to 111.2%.

Table 5 Number of babies screened by NZDep, January to December 2012

NZDep	Births	Babies screened	Coverage %
1	4,634	3,985	86.0
2	4,411	4,883	110.7
3	4,888	4,759	97.4
4	5,330	4,713	88.4
5	5,165	5,743	111.2
6	6,517	5,734	88.0
7	6,250	6,563	105.0
8	7,898	7,602	96.3
9	8,612	8,468	98.3
10	8,756	8,883	101.5
Not recorded	381	89	23.4
Total	**62,842**	**61,422**	**97.7**

3 Indicator 2: Timing of sample taking

This indicator is monitored by the number of screens performed. It is noted that some infants have more than one screen. In 2012, 61,422 babies had a screen and 61,616 screens were done. This includes 194 babies that had more than one screen.

The standard for this indicator is 95% of first samples are taken between 48 and 72 hours after birth. No DHB met the standard of 95%.

Table 6 identifies the percentage of samples taken by DHB. Nationally 71.5% of samples were collected at 48 to 72 hours, and 23.7% at greater than 72 hours.

Table 6 Percentage of samples taken at 48 to 72 hours, by DHB, January to December 2012

DHB region	Sampled at 48-72 hours		Sampled less than 48 hours		Sampled greater than 72 hours		No Collection Date and/or Date of Birth		Total number of screens*
	No.	%	No.	%	No.	%	No.	%	No.
Northland	1,493	64.9	19	0.8	703	30.6	85	3.7	2,300
Waitemata	5,835	73.8	54	0.7	1,796	22.7	226	2.9	7,911
Auckland	5,288	80.9	56	0.9	891	13.6	303	4.6	6,538
Counties Manukau	5,440	62.6	66	0.8	2,638	30.3	550	6.3	8,694
Waikato	3,054	56.6	41	0.8	2,007	37.2	291	5.4	5,393
Lakes	986	65.6	4	0.3	444	29.5	69	4.6	1,503
Bay of Plenty	1,491	49.9	20	0.7	1,332	44.6	146	4.9	2,989
Tairawhiti	501	69.1	6	0.8	187	25.8	31	4.3	725
Taranaki	1,335	83.7	12	0.8	202	12.7	46	2.9	1,595
Hawkes Bay	1,697	74.7	20	0.9	486	21.4	69	3.0	2,272
Whanganui	568	63.1	6	0.7	304	33.8	22	2.4	900
Mid Central	1,616	75.1	11	0.5	437	20.3	88	4.1	2,152
Hutt Valley	1,292	63.9	13	0.6	644	31.9	72	3.6	2,021
Capital and Coast	2,841	75.1	31	0.8	778	20.6	135	3.6	3,785
Wairarapa	373	73.6	3	0.6	107	21.1	24	4.7	507
Nelson Marlborough	1,258	81.1	8	0.5	241	15.5	45	2.9	1,552
West Coast	315	77.8	8	2.0	71	17.5	11	2.7	405
Canterbury	5,407	89.4	34	0.6	465	7.7	143	2.4	6,049
South Canterbury	538	82.6	5	0.8	96	14.7	12	1.8	651
Southern	2,676	74.6	20	0.6	784	21.9	107	3.0	3,587
Not recorded	54	62.1	2	2.3	20	23.0	11	12.6	87
Total	**44,058**	71.5	**439**	0.7	**14,633**	23.7	**2,486**	4.0	**61,616**

*Total includes babies who have had more than one screen

Figure 1 outlines the percentage of samples taken at 48 to 72 hours and shows that in 2012 no DHB met the 95% standard.

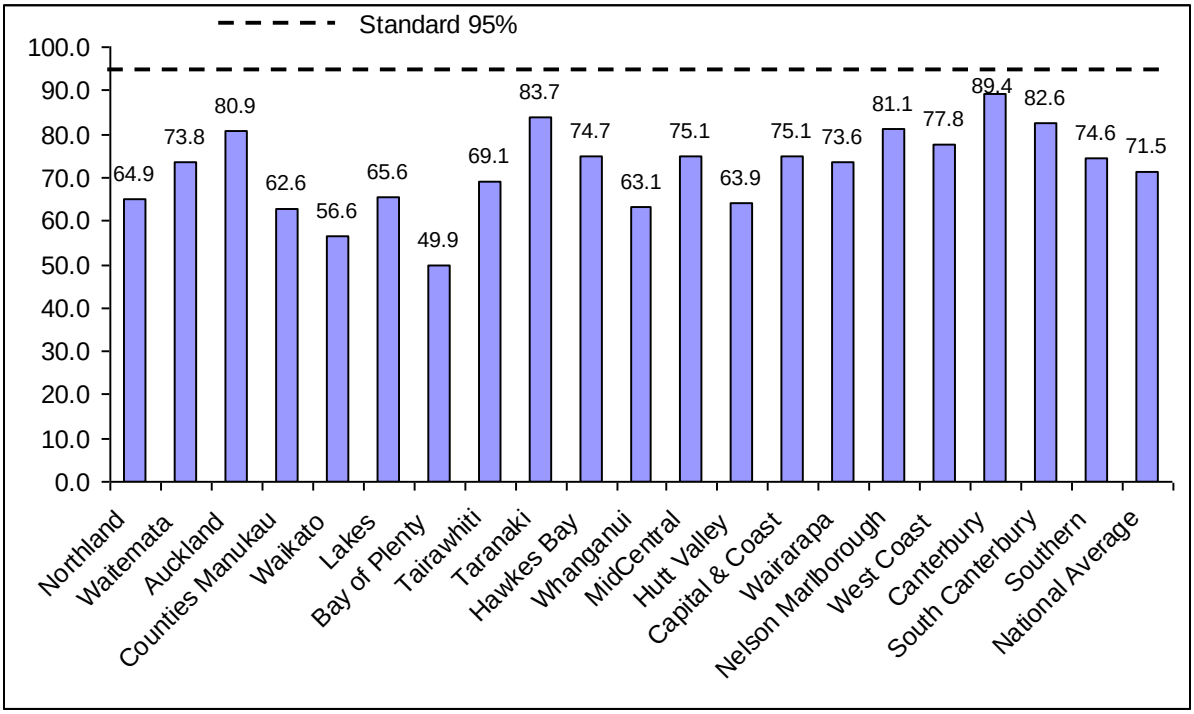

Figure 1 Percentage of samples taken at 48 to 72 hours, by DHB, January to December 2012

Table 7 shows detailed information by ethnicity. Maori (41.7%) and Pacific (42.1%) babies appear to be less likely than European (52.2%) and Asian (49.9%) babies to have a sample collected at two days. It is noted that the 95% standard was not met by any ethnic group.

Table 7 Percentage of samples taken at 48 to 72 hours, by Group 1 and Group 2 Ethnicity, January to December 2012

Ethnicity (*Group 1 Group 2*)	**Sampled at 48-72 hours**		**Sampled less than 48 hours**		**Sampled greater than 72 hours**		**No Collection Date and/or Date of Birth**		**Total number of screens***
	No.	%	No.	%	No.	%	No.	%	No.
Maori	8,973	64.4	102	0.7	4,277	30.7	574	4.1	13,926
Pacific	4,351	64.8	51	0.8	1,932	28.8	379	5.6	6,713
Cook Island Maori	602	61.5	6	0.6	326	33.3	45	4.6	979
Fijian	323	66.7	3	0.6	129	26.7	29	6.0	484
Niuean	247	68.4	1	0.3	92	25.5	21	5.8	361
Samoan	1,863	64.8	29	1.0	830	28.8	155	5.4	2,877
Tokelauan	84	70.6		0.0	31	26.1	4	3.4	119
Tongan	1,033	64.3	10	0.6	451	28.1	112	7.0	1,606
Other Pacific	199	69.3	2	0.7	73	25.4	13	4.5	287
Asian	6,274	74.8	65	0.8	1,696	20.2	351	4.2	8,386
Chinese	2,613	78.2	13	0.4	587	17.6	130	3.9	3,343
Indian	1,717	69.5	30	1.2	592	24.0	132	5.3	2,471
Southeast Asian	626	76.5	7	0.9	154	18.8	31	3.8	818
Other Asian	1,318	75.1	15	0.9	363	20.7	58	3.3	1,754
European	23,675	75.1	208	0.7	6,506	20.6	1,130	3.6	31,519
NZ European	20,678	75.0	181	0.7	5,728	20.8	996	3.6	27,583
Latin American / Hispanic	210	76.4	1	0.4	53	19.3	11	4.0	275
Other European	2,787	76.1	26	0.7	725	19.8	123	3.4	3,661
Other	853	73.5	14	1.2	237	20.4	56	4.8	1,160
African	256	70.7	2	0.6	85	23.5	19	5.2	362
Middle Eastern	327	75.3	9	2.1	79	18.2	19	4.4	434
Other/not known	202	73.2	2	0.7	58	21.0	14	5.1	276
Total	**44,058**	**71.5**	**439**	**0.7**	**14,633**	**23.7**	**2,486**	**4.0**	**61,616**

Figure 2 outlines the percentage of samples taken at 48 to 72 hours by ethnicity. In 2012 the standard of 95% was not met for any ethnic group.

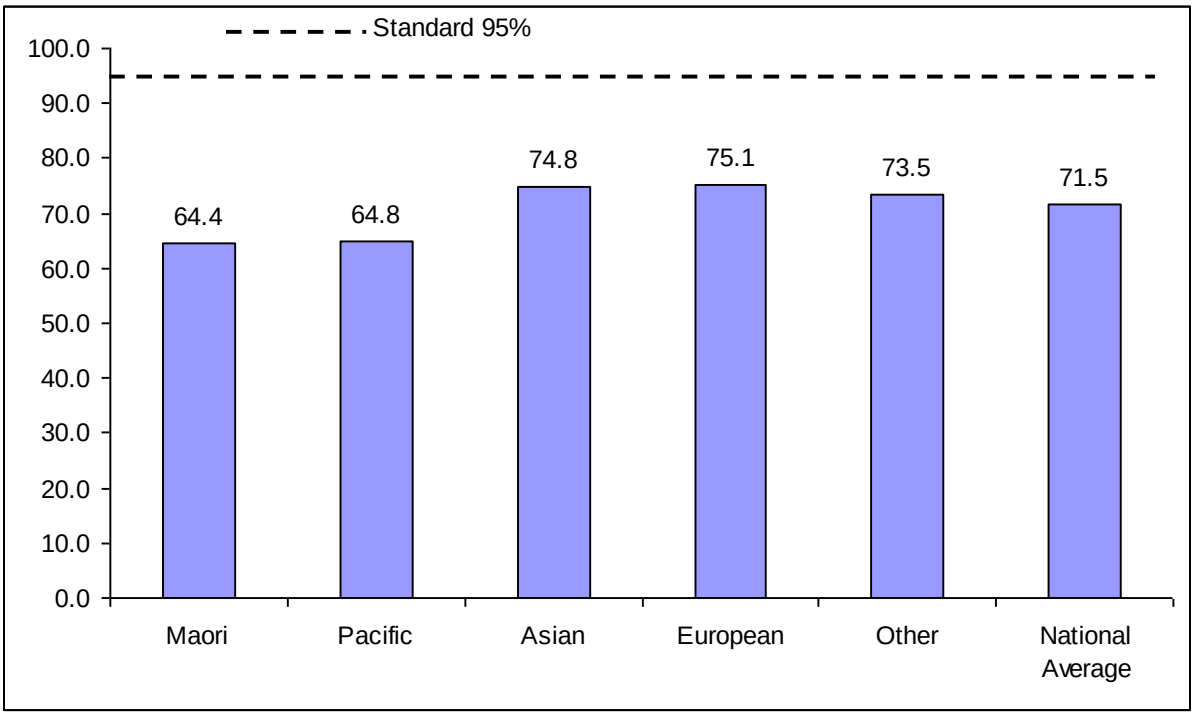

Figure 2 Percentage of samples taken at 48 to 72 hours, by ethnicity, January to December 2012

Table 8 shows the number of samples taken at two days by NZDep. The data does seem to indicate a slightly lower percentage of samples taken by the recommended time for babies in the five groups with the highest levels of deprivation (NZDep 6 to 10).

Table 8 Percentage of samples taken at 48 to 72 hours by NZDep, January to December 2012

NZDep	Sampled at 48-72 hours		Sampled less than 48 hours		Sampled greater than 72 hours		No Collection Date and/or Date of Birth		Total number of screens*
	No.	%	No.	%	No.	%	No.	%	No.
1	3,080	77.0	27	0.7	759	19.0	133	3.3	3,999
2	3,811	77.9	30	0.6	877	17.9	176	3.6	4,894
3	3,621	75.9	38	0.8	933	19.6	178	3.7	4,770
4	3,610	76.4	25	0.5	923	19.5	169	3.6	4,727
5	4,239	73.7	33	0.6	1,269	22.1	213	3.7	5,754
6	4,157	72.2	51	0.9	1,334	23.2	212	3.7	5,754
7	4,765	72.4	41	0.6	1,560	23.7	219	3.3	6,585
8	5,343	70.1	52	0.7	1,929	25.3	298	3.9	7,622
9	5,766	67.8	63	0.7	2,269	26.7	409	4.8	8,507
10	5,608	63.0	77	0.9	2,756	30.9	466	5.2	8,907
Not recorded	58	59.8	2	2.1	24	24.7	13	13.4	97
Total	**44,058**	**71.5**	**439**	**0.7**	**14,633**	**23.7**	**2,486**	**4.0**	**61,616**

Figure 3 identifies the percentage of samples taken at 48 to 72 hours by NZDep. In 2012 no New Zealand deprivation level decile reached the 95% target.

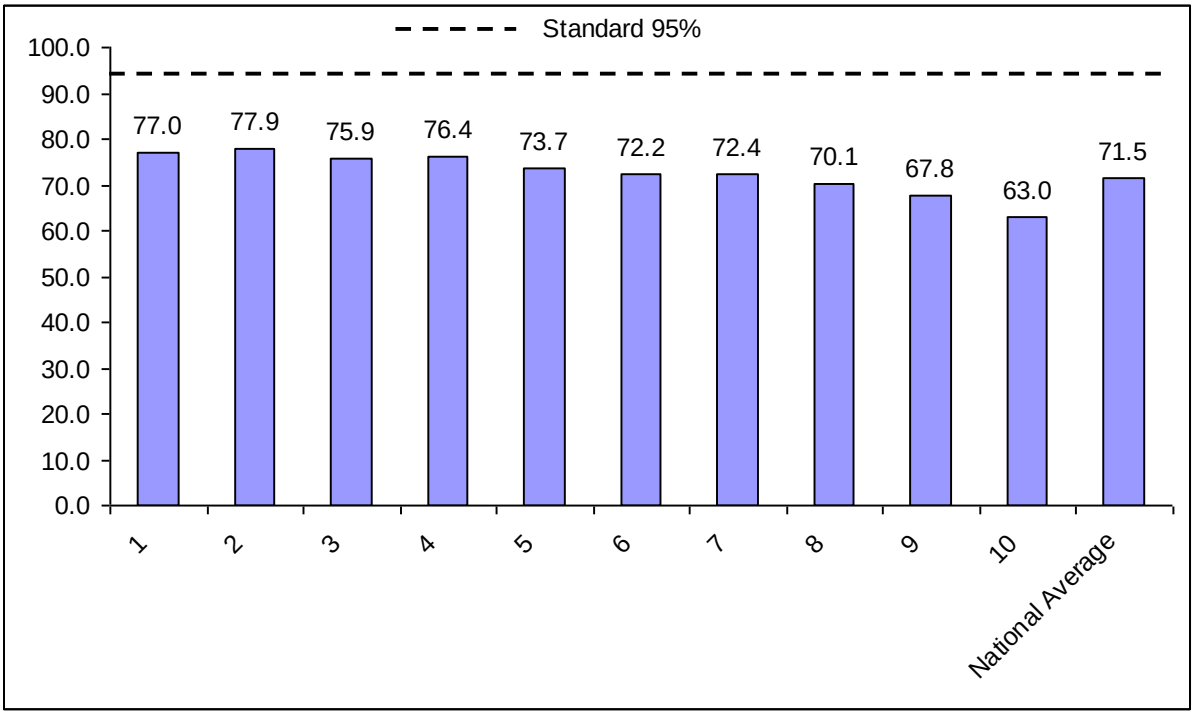

Figure 3 Percentage of samples taken at two days, by NZDep, January to December 2012

4 Indicator 3: Quality of blood samples

Accurate testing of blood spot samples is reliant on the quality of the blood spot sample. Unsatisfactory samples require a repeat sample which could have been avoided. Table 9 shows that there has been an improvement in this indicator from previous years with 11 DHBs meeting or exceeding the standard of 99% of blood spot samples suitable for testing. This is a significant improvement from 2011, and this can be attributed to the distribution of high quality lancets to specimen submitters. The improvement overall of 0.3% means 185 less babies required a second sample because of the quality of the first sample.

Table 9 Percentage of blood samples that meet quality standards by DHB, January to December 2012

DHB region	Satisfactory		Unsatisfactory		Total samples
	No.	%	No.	%	No.
Northland	2,268	98.6	32	1.4	2,300
Waitemata	7,839	99.1	72	0.9	7,911
Auckland	6,490	99.3	48	0.7	6,538
Counties Manukau	8,591	98.8	103	1.2	8,694
Waikato	5,339	99.0	54	1.0	5,393
Lakes	1,480	98.5	23	1.5	1,503
Bay of Plenty	2,971	99.4	18	0.6	2,989
Tairawhiti	715	98.6	10	1.4	725
Taranaki	1,575	98.7	20	1.3	1,595
Hawkes Bay	2,252	99.1	20	0.9	2,272
Whanganui	888	98.7	12	1.3	900
Mid Central	2,130	99.0	22	1.0	2,152
Capital & Coast	3,736	98.7	49	1.3	3,785
Hutt Valley	1,999	98.9	22	1.1	2,021
Wairarapa	504	99.4	3	0.6	507
Nelson Marlborough	1,542	99.4	10	0.6	1,552
West Coast	399	98.5	6	1.5	405
Canterbury	6,012	99.4	37	0.6	6,049
South Canterbury	648	99.5	3	0.5	651
Southern	3,559	99.2	28	0.8	3,587
Not recorded	77	88.5	10	11.5	87
Total	**61,014**	**99.0**	**602**	**1.0**	**61,616**

Figure 5 outlines the reasons why samples were unsatisfactory. These included:

- 285 samples were collected too early (before 48 hours of age)
- 270 had a problem with the blood collection (such as insufficient blood, no demographics on the card or the sample was contaminated)
- 46 had a problem in transit (such as took longer than one month, flap folded onto wet blood causing significant loss onto the flap, damaged in transit or put wet into a plastic bag)
- One family declined testing so an empty card was sent.

Second samples were requested from 602 babies and received from 570 (94.7%). The request was declined by eight families (1.3%); three babies died (0.5%) and the remaining 21 were lost to follow-up.

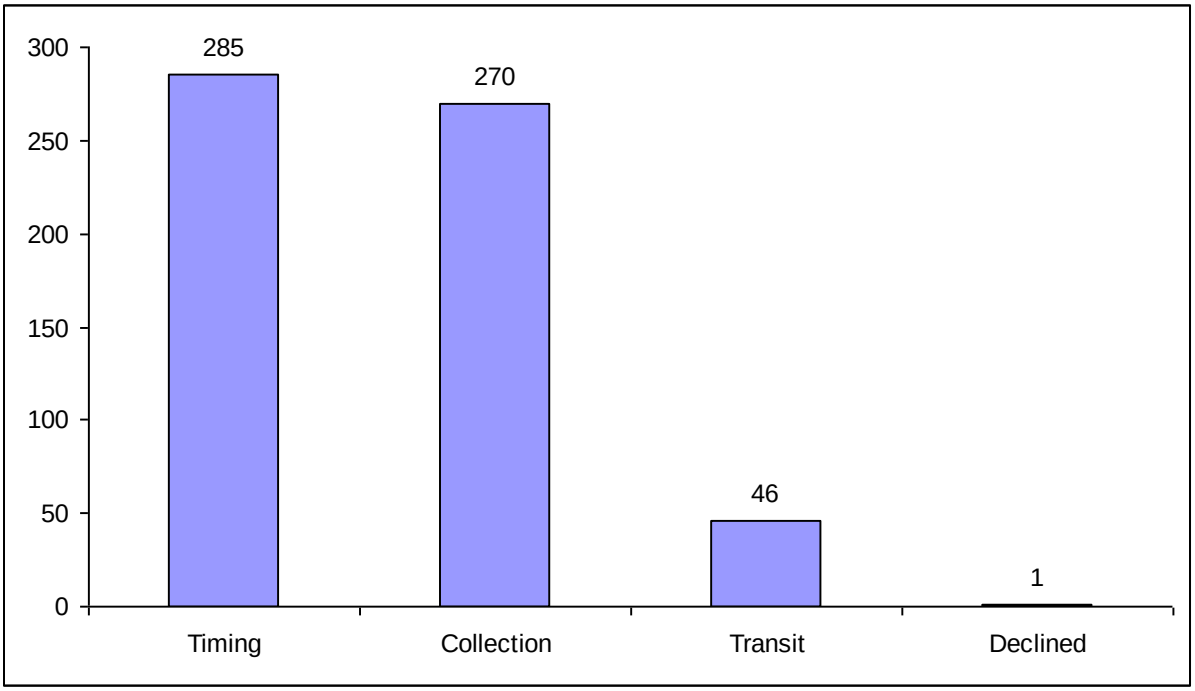

Figure 4 Reasons for unsatisfactory samples

5 Indicator 4: Sample dispatch and delivery

The NMSP relies on timeliness of sample dispatch and delivery. The standard is for 95% of samples are received by the laboratory within four calendar days of being taken.

Table 10 shows that nationally 68.8% of samples were received within four days, and 27.3% received after four days. The range was 59.4% to 80.0%. Although postage paid envelopes have been supplied to specimen submitters and this has greatly improved transit times across all DHBs, no DHB met the standard of 95%. However there has been an improvement from 65.1% meeting the standard in 2011 to 68.8% in 2012.

Table 10 Percentage of samples received by the laboratory within four days by DHB, January to December 2012

DHB region	Less than or equal to 4 days		Greater than 4 days		Unknown		Total samples
	No.	%	No.	%	No.	%	No.
Northland	1,661	72.2	614	26.7	25	1.1	2,300
Waitemata	6,112	77.3	1,716	21.7	83	1.0	7,911
Auckland	5,233	80.0	1,244	19.0	61	0.9	6,538
Counties Manukau	6,424	73.9	2,185	25.1	85	1.0	8,694
Waikato	3,986	73.9	1,326	24.6	81	1.5	5,393
Lakes	1,096	72.9	378	25.1	29	1.9	1,503
Bay of Plenty	2,021	67.6	921	30.8	47	1.6	2,989
Tairawhiti	431	59.4	284	39.2	10	1.4	725
Taranaki	1,198	75.1	377	23.6	20	1.3	1,595
Hawkes Bay	1,379	60.7	871	38.3	22	1.0	2,272
Mid Central	705	78.3	184	20.4	11	1.2	900
Whanganui	1,476	68.6	635	29.5	41	1.9	2,152
Capital and Coast	1,292	63.9	694	34.3	35	1.7	2,021
Hutt Valley	2,693	71.1	1,050	27.7	42	1.1	3,785
Wairarapa	358	70.6	141	27.8	8	1.6	507
Nelson Marlborough	1,026	66.1	509	32.8	17	1.1	1,552
West Coast	290	71.6	109	26.9	6	1.5	405
Canterbury	3,642	60.2	2,327	38.5	80	1.3	6,049
South Canterbury	447	68.7	202	31.0	2	0.3	651
Southern	2,492	69.5	1,056	29.4	39	1.1	3,587
Not recorded	65	74.7	19	21.8	3	3.4	87
Total	**42,366**	**68.8**	**16,842**	**27.3**	**747**	**1.2**	**61,616**

Figure 5 details the percentage of samples received by the screening laboratory within four days or less from the date of sample taking. No DHB met the standard of 95% received within four days.

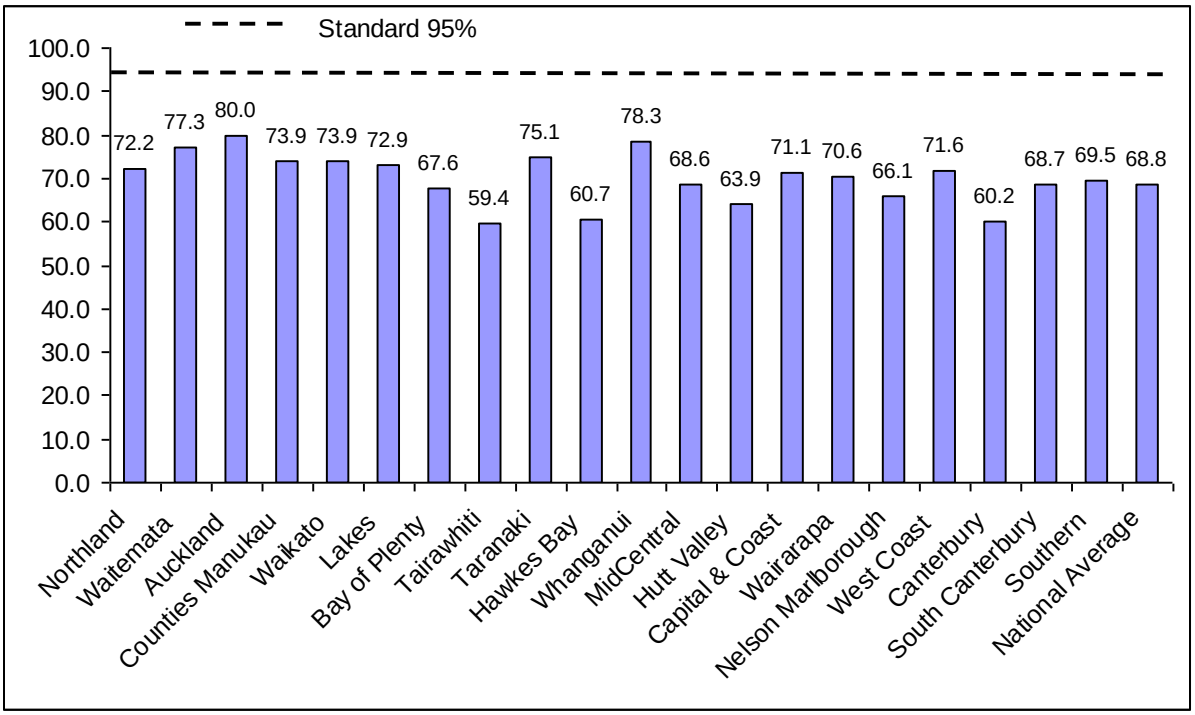

Figure 5 Percentage of samples received by the laboratory in four days or less, January to December 2012

6 Indicator 5: Laboratory testing timeframes

Table 11 identifies the percentage of samples that met the specified laboratory testing standard. The standard requires that 100% of samples meet the specified laboratory turnaround times. The range was 97.6% to 99.9%, and no disorder met the 100% standard. Delays in results for amino acid disorders and fatty acid oxidation disorders were due to instrument breakdowns as without a backup instrument analyses either wait for repair or for tests to be done by the New South Wales screening laboratory in Sydney. Delays in cystic fibrosis screening were due to delayed mutation analysis results.

Table 4 Percentage of results available within specified timeframes, by disorder, January to December 2012 (n= 61,616 samples)

Disorder	Standard for turnaround time (days)	Number met timeframe	% met timeframe
Congenital Adrenal Hyperplasia	2	61,424	99.7
Galactosaemia	2	61,481	99.8
Amino acid disorders	2	60,154	97.6
Fatty acid oxidation disorders	2	60,154	97.6
Biotinidase deficiency	5	61,547	99.9
Cystic fibrosis	5	60,963	98.9
Congenital hypothyroidism	5	61,547	99.9

7 Indicator 6: Timeliness of reporting – notification of screen positives

The NMSP relies on early detection and treatment. This ensures babies with congenital metabolic disorders have their development potential impacted as little as possible from the disorder. The standard for this indicator is that 100% of babies with positive results are notified to their LMC or referring practitioner by the timeframe specified for each disorder.

Most screening tests have a two-tier reporting system. Where results are highly likely to indicate the disorder is present, the results are telephoned to the LMC and referral made to an appropriate subspecialist paediatrician. All results in this category were reported inside the timeframes as shown in Table 12. Marginal test results are reported by mail, and in this case the written report is not generated until all the screening test results are available. The results are available and will be phoned if there is a clinical reason to do so.

Table 12 Percentage of positive test results reported within specified timeframes, by disorder, January to December 2012

Reason for report	Standard: Calendar days (from receipt in laboratory to report)	Number of positive test reports	Number met timeframe	% met timeframe
Amino acid & fatty acid oxidation disorders	3	350	212	62.3
CAH	3	110	65	62.9
Galactosaemia	3	5	5	100
CH	3	39	32	54.9
Biotinidase deficiency	4	3	1	33.3
Cystic fibrosis	9	49	30	62.0

Table 13 outlines the percentage of urgent clinical critical positive reports reporting by timeframes and disorder. Of the reports which did not meet the turnaround time, the reasons include:

- waiting for cystic fibrosis gene testing or biotinidase deficiency screening results (all the delayed cystic fibrosis screen reporting was due to delayed gene results)
- waiting for amino acid and fatty acid oxidation screening results delayed due to breakdowns in the tandem mass spectrometer
- delay in sign-out
- a small number for other reasons.

It is noted that the testing turnaround times are specified in working days but reported in calendar days. For example congenital adrenal hyperplasia (CAH) is two days for test result being available and three days for reporting. A sample which arrives on Friday and has a test result available and reported on Monday meets the testing timeframe but not the reporting timeframe.

Table 13 Percentage of urgent clinical critical positive results reported within specified timeframes, by disorder, January to December 2012

Reason for report	Standard: Calendar days (from receipt in laboratory to report)	Number of urgent critical positive test reports	Number met timeframe	% met timeframe
Amino acid and fatty acid oxidation disorders	3	40	38	95
CAH	3	4	2	50
Galactosaemia	3	0	0	0
CH	4	15	15	100
Biotinidase deficiency	9	0	0	0
Cystic fibrosis	12	0	0	0

8 Indicator 7: Collection and receipt of second samples

Second samples are requested when samples are not suitable for testing or there are minor elevations of screened metabolites. Table 14 outlines the follow-up of second samples requested by the screening laboratory by DHB. No DHB met the standard of 100% of second samples received by the laboratory, or declined, within ten calendar days of the request. The national average is 44.3%. Improvements have been made by the NMSP working closely with lead maternity carers (LMCs) to ensure follow-up is completed before the baby is discharged from midwifery care at 4 to 6 weeks of age. There was less follow-up in 2012 due to the improvement in sample quality. Although no DHB meets the standard of 100% the national average has improved from 36.8% in 2011 to 44.3% in 2012.

Performance improved in 17 DHB regions and key to the improvement has been the work of the screening educator. Further quality improvement initiatives in this area will be trialled in 2013.

Table 14 Follow-up of requested second samples by DHB, January to December 2012

DHB region	Less than or equal to 10 days		Other follow up		No follow up		Follow up complete		Total samples
	No.	%	No.	%	No.	%	No.	%	No.
Northland	20	43.5	26	56.5	0	0.0	46	100.0	46
Waitemata	56	49.6	55	48.7	2	1.8	111	98.2	113
Auckland	55	58.5	39	41.5	0	0.0	94	100.0	94
Counties Manukau	79	43.2	98	53.6	6	3.3	177	96.7	183
Waikato	36	40.9	52	59.1	0	0.0	88	100.0	88
Lakes	10	35.7	17	60.7	1	3.6	27	96.4	28
Bay of Plenty	16	43.2	20	54.1	1	2.7	36	97.3	37
Tairawhiti	6	50.0	5	41.7	1	8.3	11	91.7	12
Taranaki	15	48.4	16	51.6	0	0.0	31	100.0	31
Hawkes Bay	20	48.8	21	51.2	0	0.0	41	100.0	41
Whanganui	14	70.0	6	30.0	0	0.0	20	100.0	20
Mid Central	16	41.0	23	59.0	0	0.0	39	100.0	39
Hutt Valley	14	40.0	20	57.1	1	2.9	34	97.1	35
Capital and Coast	31	38.8	44	55.0	5	6.3	75	93.8	80
Wairarapa	2	33.3	4	66.7	0	0.0	6	100.0	6
Nelson Marlborough	6	35.3	10	58.8	1	5.9	16	94.1	17
West Coast	2	28.6	5	71.4	0	0.0	7	100.0	7
Canterbury	36	45.6	41	51.9	2	2.5	77	97.5	79
South Canterbury	2	33.3	4	66.7	0	0.0	6	100.0	6
Southern	16	31.4	35	68.6	0	0.0	51	100.0	51
Not recorded	3	21.4	1	7.1	30	214.3	4	28.6	14
Total	**455**	**44.3**	**542**	**52.8**	**31**	**3.0**	**997**	**97.1**	**1027**

Note: follow-ups are not counted in the total number of screens. Follow-up samples include those that were unsuitable for testing or were suspected of a disorder.

9 Indicator 8: Diagnosis and commencement of treatment by disorder

The NMSP relies on confirmed detection and timely treatment to ensure babies with congenital metabolic disorders have their development potential impacted as little as possible from the disorder.

The standard is for 100% of babies who receive a screen positive result are diagnosed and commence treatment by the time specified for each disorder.

The time to diagnosis and commencement of treatment is determined by the age of the baby when the specimen was collected, the transit time to the laboratory, the time to confirmation and reporting of test results and the time to make the diagnosis and commence treatment. The summarised numbers of detected cases of the screened disorders and the number treated by the specified age are given in Table 15.

Table 15 Age at treatment, January to December 2012

Disorder	Standard: Calendar days of age of baby at treatment commenced	Number of cases	Number treated by specified age
Biotinidase deficiency	14	0	n/a
Cystic fibrosis	28	9	3
CH	10	18	7
CAH	10	3	2
Galactosaemia	10	0	n/a
Amino acid disorders	10	9	3
Fatty acid oxidation disorders	10	10	7

Of the babies diagnosed with cystic fibrosis, the NMSP have data on six and all were treated by 30 days of age.

There were seven cases of CH diagnosed outside the timeframe as their initial levels of TSH were between 15 and 29 mIU/L and notification was made following the results of a second sample. Of the remaining five, three had delayed transit times (7 to 10 days), one a slightly delayed collection time (three days instead of two days, and was in transit for four days) and one delayed diagnosis and treatment (six days after notification).

Two cases of CAH were treated in the timeframe. The other case had treatment commenced at 19 days. This is a case of simple virilising CAH diagnosed after a second sample had an elevated level of 17-hydroxyprogesterone.

Of the six patients with amino acid breakdown disorders not treated by the specified age, four had mild disease diagnosed following a second blood sample. The other two were PKU treated at 11 days (both samples were taken at 2 days, one in transit for four days and the other for six days; results available at four days and three days respectively). The three patients with fatty acid oxidation disorders not treated by the specified age had mild disease diagnosed following a second blood sample.

Some of the amino acid breakdown disorders and fatty acid oxidation disorders do not require urgent treatment (for example PKU). In all cases where a delay of diagnosis could have clinical consequences there was metabolic physician consultation with the LMC and a subsequent decision made by the metabolic physician about the urgency of follow up, hence some patients diagnosed outside the timeframe on a second sample had earlier metabolic physician involvement.

10 Indicator 9: Blood spot card storage and return

Where requested, blood spots are to be returned to parents/guardians/individuals by tracked courier within 28 days of the request. All samples are returned by tracked courier.

Of 706 requests for blood spot returns, 699 (99.0%) were returned in the timeframe. Five cards were not returned as they had insufficient information. This was requested but not provided. The remaining two samples were returned in 31 days. In general samples are returned very quickly with a median time over this period of 2.1 days.

The NMSP Policy framework lists possible secondary uses for residual screening cards (section 4.1(b)). For the period 1 January 2012 to 31 December 2012 cards have been used for the following secondary purposes.

The NMSP Policy framework lists possible secondary uses for residual screening cards (section 4.1(b)). Table 16 shows that of the 53 cards used for the benefit of the individual and family/whanau, 41 were for cytomegalovirus (CMV) testing to determine whether congenital CMV was the cause of symptoms in the baby or child. The remaining 12 were used for other genetic studies, some related to newborn screening (for example expanded screening on a child born pre-screening) or testing of siblings of diagnosed cases.

Table 16 Reasons for secondary use, January to December 2012

Secondary use	Number
Benefit of the individual and family/whanau	53
Forensic/police/coroner investigations	1
Mortality review	0
Research	0
Other	0
Total	**54**

11 Screening performance and incidence

11.1 Screening performance

The screening performance from 2008 to 2012 for the NSMP is provided in Table 17. For this timeframe, 314,269 infants were screened. A longer time period of five years is used to calculate this as these conditions are rare and it is important to have sufficient numbers for comparison, as this adds power to the data.

The table shows that during 2008 to 2012:

- screening sensitivities ranged from 92.79 to 100%
- screening specificities ranged from 99.59 to 100%
- positive predictive values ranged from 1.7 to 29.5.

Table 17 Newborn screening performance, 2008-2012

Condition	Sensitivity %	Specificity %	Positive Predictive Value %
Aminoacid breakdown disorders	100.00	99.59	3.2
Biotinidase deficiency	100.00	100.00	6.3
Congenital adrenal hyperplasia	93.33	99.74	1.7
Congenital hypothyroidism	92.79	99.92	29.5
Cystic fibrosis	95.08	99.93	20.2
Fatty acid oxidation disorders	100.00	99.88	9.7
Galactosaemia	100.00	99.99	6.0

11.2 Follow-up of positive tests

Follow-up of positive tests are detailed in Table 18. Appropriate follow-up may be:

- a specialist paediatrician visit
- a further dried blood sample
- a test done elsewhere
- notification that baby has died.

Overall 1,285 babies were referred for paediatric examination or had a request for a second sample (of these 130 the follow-up sample was a scheduled NICU protocol sample so no additional sample was required). Of the requested follow-up, 53% was because of disorder screen positive results and 47% because of unsuitable samples.

The number of babies with follow-up requested is down from 1,464 in 2011 (to 1,285 in 2012), due to the improvement in sample quality.

Table 18 Newborn screening follow-up by condition, 2012

Condition	Number of positive tests	Follow-up by scheduled NICU or requested sample (e.g. sample taken too early)	Other follow-up (paediatric referral, second test)	Number with appropriate follow-up	% with appropriate follow-up
Aminoacid breakdown disorders	289	66	218	284	98
Biotinidase deficiency	3	0	0	0	100
Congenital adrenal hyperplasia	155	50	102	152	98
Congenital hypothyroidism	78	2	74	76	97
Cystic fibrosis	54	0	54	54	100
Fatty acid oxidation disorders	101	12	84	96	96
Galactosaemia	3	0	3	3	100

11.3 Clinical utility

Newborn screening is justified for conditions in which there is clinical benefit from diagnosis made earlier by screening than it would be made by clinical presentation and diagnosis. Screening audit forms contain a question about whether the diagnosis was suspected before the screening test result is available. Reasons for clinical detection are:

- family history (FH)
- meconium ileus (MI)

The numbers are given in Table 19.

Table 19 Clinical Utility of screening, 2012

Disorder	Number of cases	Diagnosis suspected before screen result	Reason for suspicion
Biotinidase deficiency	0	0	
Cystic fibrosis	9	2	1 MI 1 abdominal distention
CH	19	0	
CAH	3	2	1 FH, 1 ambiguous genitalia
Galactosaemia	0	0	
Amino acid disorders	9	3	2 FH, 1 severe citrullinemia symptomatic
Fatty acid oxidation disorders	10	1	FH
Total conditions	51	8	

One baby with citrullinemia had appropriate diagnostic samples taken at the same time as the screening sample. Overall 51 cases of screened disorders were detected by the programme and in 43 of these there was no clinical suspicion of the disorder before the screening test result.

11.4 Incidence of screened disorders

Aminoacid breakdown disorders

Since screening started in 2006, 446,660 infants have been screened and 53 cases detected, giving an incidence of 1:8,400. This includes PKU, MSUD and hyperphenylalaninemia.

PKU

There were two cases of PKU and one of hyperphenylalaninemia found in 2012. Since screening started in 1969 2,525,393 infants have been screened for PKU and 118 cases found, none notified missed, to give an incidence of 1:21,400. Benign hyperphenylalaninemia is not counted in this incidence figure. It is problematic comparing PKU incidence as the definition of the disorder is 'a level of phenylalanine that requires treatment' and the level has varied time to time.

MSUD

One case of MSUD was found in 2012 (the sibling of a known case). Since screening started in 1969, 2,525,393 infants have been screened for MSUD, ten classical cases found; none were notified missed, giving an incidence of 1:253,000.

Biotinidase deficiency

Since screening started in 1986, 1,591,935 infants have been screened and eight cases detected giving an incidence of 1:199,000.

Congenital adrenal hyperplasia

Since screening started in 1986, 1,638,884 infants have been screened and 70 cases detected giving an incidence of 1:23,400.

Congenital hypothyroidism

Since screening started in 1981, 1,859,464 infants have been screened and 486 cases detected giving an incidence of 1:3830. There is a trend to an increasing incidence of CH in New Zealand. The increase is in dyshormonogenesis. This condition is more common in people of Asian and Pacific origin and the increase coincides with an increase in Asian births as immigration changes the New Zealand demographic.

Cystic fibrosis

Since screening started in 1983, 2,574,516 infants have been screened and 376 cases detected giving an incidence of 1:6,847. There were 61,422 babies screened in 2012 (of whom approximately 55% were of European ethnicity) and 9 cases of CF detected. This gives an incidence in the European births of 1:3,750.

Fatty acid oxidation disorders

Since screening started in 2006, 446,660 infants have been screened and 51 cases detected giving an incidence of 1:.8,760.

Galactosaemia

Since screening started in 1973, 2,413,324 infants have been screened and 24 cases detected giving an incidence of 1:100,600.

Appendix 1: NMSP National Indicators

1: NEWBORN METABOLIC SCREENING COVERAGE
DESCRIPTION The proportion of babies who have had newborn metabolic screening.
RATIONALE All babies whose parents/guardians consent to screening should have screening.
RELEVANT OUTCOME All babies whose parents/guardians consent to newborn metabolic screening are screened.
STANDARD 100% of babies whose parents/guardians consent to screening are screened.
METHODOLOGY ***Indicator 1.1*** Numerator: Number of babies screened. Denominator: Number of live births.
NOTES • Denominator limitations to be explained in published reports • Reporting by: ➢ DHB ➢ Ethnicity ➢ Deprivation status

2: TIMING OF SAMPLE –TAKING

DESCRIPTION

1. The proportion of eligible babies who have a newborn metabolic screening sample taken.
2. The proportion of eligible babies who have a newborn metabolic screening sample taken between 48 and 72 hours of birth.

RATIONALE

Timely sample collection leads to the best possible chance of a baby receiving early diagnosis and treatment where necessary. Severe forms of some of the disorders screened for can be fatal within seven to ten days. Many may not show any signs or symptoms of disease until irreversible damage has occurred. However, the baby must have been independent of their mother long enough for their indicator biochemicals to show an abnormality. Therefore the optimum window for sample collection is between 48 and 72 hours of birth.

RELEVANT OUTCOME

Babies screened should have a newborn metabolic screening sample taken between 48 and 72 hours of birth.

STANDARD

95% of first samples are taken between 48 and 72 hours of birth.

METHODOLOGY

Indicator 2

Numerator: Number of babies who have a newborn metabolic screening sample taken between 48 and 72 hours of birth. (see data limitations above, the measure used in this report is the number of babies screened at 2 days)

Denominator: Number of babies who have a newborn metabolic screening sample taken.

NOTES

- Samples for screening must be taken in accordance with Programme Guidelines and Policy and Quality requirements.
- Reporting by:
  - DHB
  - Ethnicity
  - Deprivation status

3: QUALITY OF BLOOD SAMPLES
DESCRIPTION The quality of the blood spot sample.
RATIONALE Accurate testing of blood spot samples is reliant on the quality of the sample. Unsatisfactory samples require a repeat sample which could have been avoided.
RELEVANT OUTCOME Blood spot samples are of sufficient quality for laboratory testing for screened disorders.
STANDARD 99% of blood spot samples are of satisfactory quality.
METHODOLOGY ***Indicator 3*** Numerator: Number of samples of satisfactory quality as reported by the laboratory. Denominator: Number of samples taken.
NOTES • Requirements for a satisfactory sample are detailed in Chapter 7, page 21-22 of Programme Guidelines. • Reporting by DHB

4: SAMPLE DESPATCH AND DELIVERY

DESCRIPTION

The time taken for the sample to be received by the laboratory after being taken.

RATIONALE

The NMSP relies on timeliness. Samples must be sent to the laboratory as soon as they are dry. Samples must be received by the laboratory as soon as possible after they are taken.

RELEVANT OUTCOME

Samples are received by the laboratory within four days of being taken.

STANDARD

95% of samples are received by the laboratory within four calendar days of being taken.

METHODOLOGY

Indicator 4

Numerator: Number of samples received by laboratory within four calendar days of being taken.

Denominator: Number of samples received by laboratory.

NOTES

- Requirements for sending samples to the laboratory are detailed in Chapter 7, page 23 of Programme Guidelines
- Reporting by DHB

5: LABORATORY TESTING TIMEFRAMES

DESCRIPTION

The time taken by the laboratory to test each sample for each of the specified disorders (turnaround time).

RATIONALE

Samples should be tested as soon as possible to ensure that screen positives can be acted on as quickly as possible to reduce / minimise avoidable harm.

RELEVANT OUTCOMES

All samples are tested within the specified timeframes.

Samples received before 07:30am are tested the same day.

STANDARD

100% of samples meet the following laboratory turnaround times:

Disorder	Working days (from receipt by laboratory)
Congenital Adrenal Hyperplasia	2
Galactosaemia	2
Amino acid disorders	2
Fatty acid oxidation disorders	2
Biotinidase deficiency	5
Cystic fibrosis	5
Congenital Hypothyrodism	5

METHODOLOGY

Indicator 5

Numerator: Number of samples tested and reported within specified timeframes.

Denominator: Number of samples tested.

6: TIMELINESS OF REPORTING – NOTIFICATION OF SCREEN POSITIVES

DESCRIPTION

The time taken for a baby with a positive screening result to be referred for diagnostic testing.

RATIONALE

The NMSP relies on early detection and treatment. This ensures babies with congenital metabolic disorders have their development potential impacted as little as possible from the disorder.

RELEVANT OUTCOME

All babies with positive screening results are referred for further testing within the specified timeframes after results become available.

STANDARD

100% of babies with positive results are notified to their LMC / referring practitioner by the laboratory within the following timeframes:

Reason for report	Calendar days (from receipt in lab test result)
Amino acid disorders	3
Fatty acid oxidation disorders	3
CAH	3
Galactosaemia	3
CH	4
Biotinidase deficiency	9
Cystic fibrosis	12

METHODOLOGY

Indicator 6

Numerator: Number of babies who are notified to their referrer for further testing for a particular disorder within the number of calendar days specified for that disorder.

Denominator: Number of babies who receive a positive screening result for a particular disorder.

7: COLLECTION AND RECEIPT OF SECOND SAMPLES

DESCRIPTION

The number of babies that have had second samples taken, sent, and received by the laboratory. **Note**: this indicator does not cover highly positive samples. It is for those around the cut off who have letters sent to them.

RATIONALE

If a second sample is required it means that a baby has not been fully screened, or that his/her results were borderline. Second samples should be taken as soon as possible so that the baby can be treated early if he/she has a disorder.

RELEVANT OUTCOME

Second samples are taken, sent, and received by the laboratory as soon as possible.

STANDARD

100% of second samples are received by the laboratory, or declined, within ten calendar days of request.

METHODOLOGY

Indicator 7.1

Numerator: Total number of second samples collected, declined, or baby died.

Denominator: Number of second samples requested.

Indicator 7.2

Numerator: Number of second samples received within ten calendar days.

Denominator: Total number of second samples received and declined.

NOTES

- Requirements for repeat samples are detailed in Chapter 7, page 24-25 of Programme Guidelines.
- Reporting by DHB

8 DIAGNOSIS AND COMMENCEMENT OF TREATMENT BY DISORDER

DESCRIPTION

The number of babies with a positive screening result who receive a confirmed diagnosis and timely commencement of treatment.

RATIONALE

The NMSP relies on confirmed detection and timely treatment to ensure babies with congenital metabolic disorders have their development potential impacted as little as possible from the disorder.

RELEVANT OUTCOME

All babies with a metabolic disorder and a screen positive result receive a confirmed diagnosis and timely commencement of treatment.

STANDARD

100% of babies who receive a screen positive result are diagnosed and commence treatment by:

Disorder	Calendar days
Biotinidase deficiency	14
Cystic fibrosis	28
CH	10
CAH	10
Galactosaemia	10
Amino acid disorders	10
Fatty acid oxidation disorders	10

METHODOLOGY

Indicator 8

Numerator: Number of babies who are diagnosed and commence treatment within the timeframes specified.

Denominator: Number of babies who receive a screen positive result and are diagnosed with and treated for a metabolic disorder.

NOTES

- Clinically-diagnosed babies will be reported separately.
- Measurement may also be by case review or periodic audit / evaluation.

9: CARD STORAGE AND RETURN

DESCRIPTION

The time taken for the laboratory to return requested blood spot cards to parents/guardians/individuals.

RATIONALE

Where requested blood spot cards should be returned within:

- 28 days of completion of screening
- 28 days of valid (fully completed) request for return.

RELEVANT OUTCOME

All blood spot cards are returned to parents/guardians/individuals by tracked courier within 28 days.

STANDARD

1. Where requested, 100% of blood spot cards are returned to parents/guardians within 28 days of completion of screening.
2. 100% of blood spot cards are returned to the authorised person by tracked courier within 28 calendar days of valid request.

METHODOLOGY

Indicator 9

Numerator: Number of blood spot cards returned within 28 days.

Denominator: Number of blood spot cards requested by parents/guardians/individuals.

NOTES

- Complete information is required by the laboratory in order to process requests for return of blood spot cards, as per Programme Guidelines in Chapter 11.