New Zealand Government

Folic acid fortification: both society and individuals benefit

Ministry for Primary Industries
Manatū Ahu Matua

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Folic acid fortification: both society and individuals benefit

Report prepared for the Ministry for Primary Industries

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1. Is it cost effective to fortify?

1.1 Folic acid fortification reduces neural tube defect prevalence

Neural tube defects (NTDs) are severe birth defects that impact the health of those affected and impose large societal costs. Consuming sufficient levels of folate and folic acid prior to and during the early stages of pregnancy has been shown to reduce the risk of an NTD. Fortifying staple foods with folic acid is one method to increase consumption during this periconceptual period.

Many countries, including the United States, Canada and Australia, have mandated folic acid fortification in various foods. This has reduced the rates of neural tube defects in these countries (Office of the Prime Minister's Chief Science Advisor & Royal Society Te Aparangi [PMCSA], 2018).

New Zealand does not currently mandate folic acid fortification. However, voluntarily fortification of some products with folic is permitted. Some of these products are:
- bread
- breakfast cereals
- yeast-based spread
- fruit and vegetable juices
- milk alternatives (e.g. those derived from soya and rice).

Currently, a voluntary code of practice to fortify bread is in place. It has been agreed between the New Zealand Association of Bakers (NZAB) and the Ministry for Primary Industries (MPI). This code sets out a fortification target of 25% to 50% of packaged sliced bread produced by NZAB members by volume. The latest report estimates that 38% of packaged sliced bread was fortified in 2017 (Watson, 2018).

1.2 MPI is considering four options to strengthen fortification

MPI are assessing options to reduce the prevalence of neural tube defects via strengthened fortification. These options are:
- increasing the voluntary fortification target to 80% of packaged sliced bread produced by NZAB members
- mandatory fortification of all non-organic bread
- mandatory fortification of all non-organic bread-making wheat flour
- mandatory fortification of all non-organic wheat flour.

These options target bread as the primary food vehicle for folic acid. Bread has been chosen by MPI for the following reasons:
- bread is one of the most commonly consumed foods amongst women of child-bearing age
- bread is possible to fortify, unlike fruit, vegetables and meat
- there is a low risk of overconsumption of folic acid via fortification of bread unlike milk.

More information on each of the options can be found in the consultation document produced by MPI.

1.3 Three of the four options are cost-saving

We perform a cost-utility analysis to evaluate the economic impact of the options. Our cost-utility analysis finds that three of the four options for strengthening fortification are cost-saving compared to status quo. Every dollar spent under these options returns a benefit to society of more than three dollars. There are also health-related quality of life benefits gained by society in addition to the monetary benefits. We measure these health benefits in quality-adjusted life years (QALYs).[1]

The mandatory fortification of non-organic bread option is costly when compared to the other options. This option results in a net cost to society, albeit with health gains. Due to the large number of bakers (estimated to be 2,500 to 3,500), there are high costs of testing the levels of folic acid in bread. This cost alone more than offsets any monetary benefits to society from preventing NTDs.

We estimate an NTD-affected live birth results in a loss of health equivalent to more than half an average life. The lower range of the enhanced voluntary option is the equivalent of saving 13 full lives. The higher range of the all wheat flour option is the equivalent of saving 95 full lives.

The net monetary benefits and health benefits of each option are depicted in Figures 1 and 2. The detailed results are in Table 1. As the level of fortification increases the net monetary benefits and health benefits increase for the cost-saving options (positive net monetary benefits).

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[1] A quality-adjusted life year (QALY) is a commonly used unit of health. One QALY represents one year lived at perfect health.

Figure 1 Summary of net monetary benefits from fortification
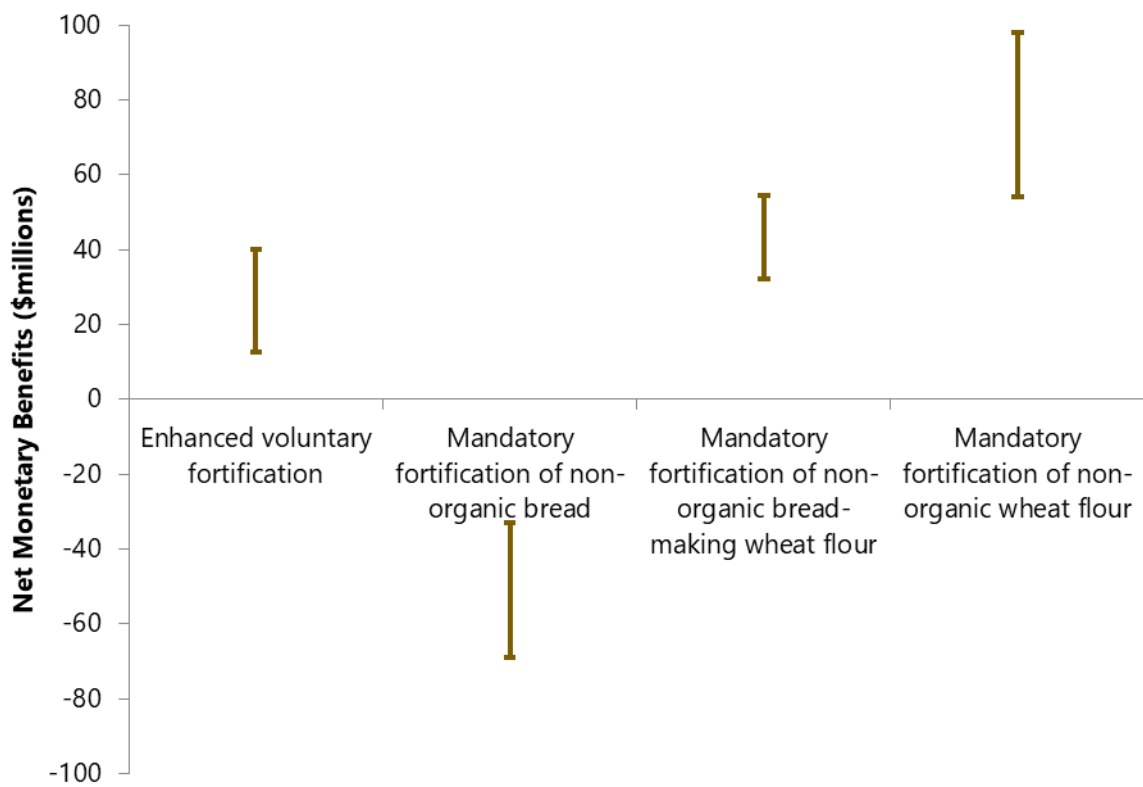
Figure 2 Summary of health benefits from fortification
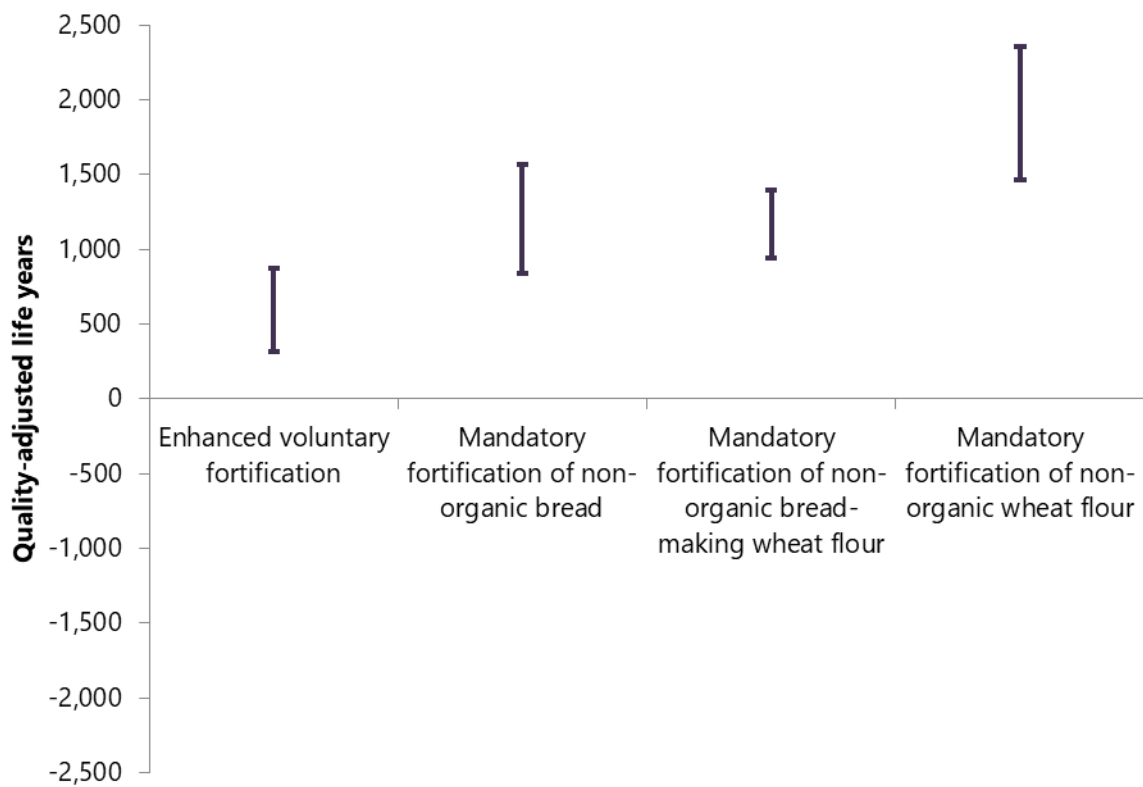
Table 1 Summary of results

Fortification option	NTDs prevented (live births and foetal deaths)	Monetary benefits (millions)	Monetary costs (millions)	Net monetary benefit (millions)	Health benefits (QALYs)
Enhanced voluntary fortification	19 to 52	$15.5 to $43.0	$2.9	$12.6 to $40.1	310 to 870
Mandatory fortification of non-organic bread	50 to 94	$41.3 to $77.3	$110.3	-$69.1 to -$33.0	840 to 1,570
Mandatory fortification of non-organic bread-making wheat flour	57 to 84	$46.4 to $68.7	$14.1	$32.2 to $54.6	940 to 1,400
Mandatory fortification of non-organic wheat flour	88 to 141	$72.1 to $116.1	$18.1	$54.0 to $97.9	1,470 to 2,360

Results are based on 30 years of fortification and are discounted at 3.5% per annum

1.4 Favourable results compared to PHARMAC's investments

We compare the investment in folic acid fortification with the average health investment made by the Pharmaceutical Management Agency of New Zealand (PHARMAC). PHARMAC only considers health sector offsets in its cost-utility analyses (although there are other considerations in the wider Factors for Consideration), and only include the treated person's health effects.[2] To align with PHARMAC, we narrow our focus to consider health sector costs only, and exclude the deadweight loss of taxation. This is a narrower approach than our societal approach. Using this approach, the cost-saving options for folic acid fortification compare favourably with PHARMAC's investments, even at the lowest end of the benefit range. This comparison is shown in Figure 3.

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[2] These other considerations are used by PHARMAC to help inform investment decisions. However, they are not included in their cost-utility analyses, and include many non-quantified (by PHARMAC) factors including the suitability of the treatment and the need of the patient(s). PHARMAC may include health benefits for family, whanau and society in sensitivity analysis, or qualitatively.

Figure 3 Cost-effectiveness of fortification compared with PHARMAC investments
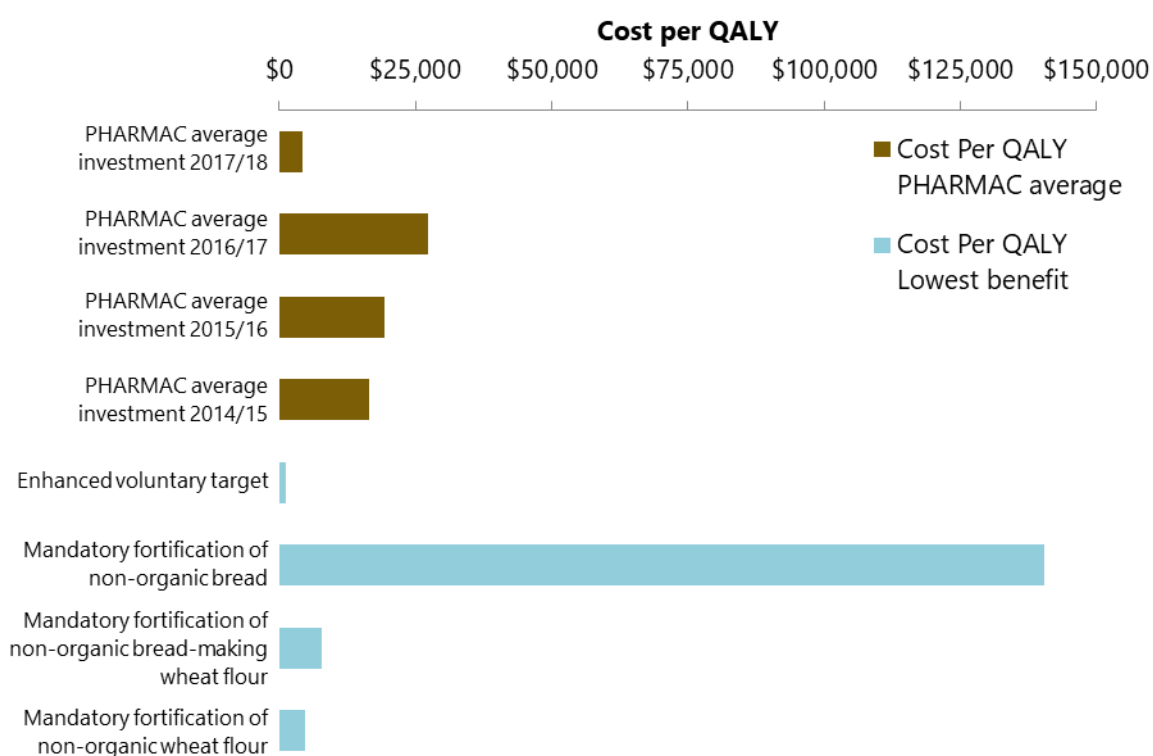
Source: PHARMAC (2015, 2016, 2017, 2018), Sapere modelling

1.5 Additional benefits from preventing NTDs

A number of pregnancy terminations would also be prevented by increased fortification. These are summarised in Table 2.

Table 2 Terminations prevented by fortification

Fortification option	Terminations prevented
Enhanced voluntary target	24 to 68
Mandatory fortification of non-organic bread	65 to 122
Mandatory fortification of non-organic bread-making wheat flour	73 to 108
Mandatory fortification of non-organic wheat flour	113 to 182

Results are based on 30 years of fortification. These numbers are not discounted.

There are also significant disruptions to family and whānau due to an NTD-affected live birth. We do not model these, and only capture productivity and health-related quality of life losses for the primary caregivers.

2. Four important assumptions

We use a cost-utility analysis (CUA) to evaluate the fortification options. This produces a result that relates the monetary costs and benefits to the health outcomes (measured in QALYs).

We undertake a CUA, instead of a cost-benefit analysis, as this is the commonly used approach in health technology assessments. Mathes et al. (2013) found that most agencies in their study preferred or exclusively accepted CUA to perform economic evaluation of health technology.

In the remainder of this section, we set out the main assumptions that underpin our analysis. Discounting and time horizon are the two major assumptions other than our assumption of a societal perspective.

2.1 A benefit to society methodology is the most appropriate

The methodology for estimating benefits depends upon the perspective from which the benefits are to be measured. We take the perspective of the overall benefits to society. This produces an estimate that reflects the benefit to society from preventing early death or ongoing disability associated with NTDs. This benefit to society approach allows us to measure the impact of reducing high perinatal and infant mortality rates and, in particular, the cost of lost productivity.

We compare the costs faced by society of a person affected by an NTD and the general population. We then use this result as the estimate of the benefit to society from preventing an NTD.

We use a life stage approach that identifies direct and indirect productivity and societal costs for different stages of life. The life stage approach is necessary as estimates differ significantly by age group. Life expectancy also differs significantly between those with NTDs and the general population.

We consider the following costs in our model:
- productivity losses:
  - lower employment rates, lower paid jobs, and lost productivity from early death
  - lost productivity of caregivers
- healthcare costs:
  - all costs, including surgeries, intensive care, and mobility assistance
- education costs:
  - primary and secondary school, including additional resources for those with cognitive impairment
- deadweight cost of taxation:
  - additional costs due to distortions from taxation. This applies to healthcare and education costs.

2.2 We use a discount rate of 3.5 per cent

We consider a number of different options when determining an appropriate discount rate. We use a discount rate of 3.5% per annum for this analysis for both costs and benefits.

Discounting is widely accepted and used in economic and financial modelling to compare interventions that have costs and benefits that occur at different times. A way to think about the need for discounting is the preference of people to receive a dollar today, rather than a dollar in a year's time. People would prefer to receive the dollar earlier rather than later. Therefore, to make the two options of equal value, people would have to receive more than a dollar in a year's time. This concept can be extended to non-financial costs and benefits.

The assessment of folic acid fortification is a health technology assessment. We therefore look to the discount rates used by health technology assessment agencies for guidance. Mathes et al. (2013) assessed the rates used by a number of agencies around the world. The discount rates used ranged between 1.5% to 5% for benefits, and 3% to 5% for costs. The study also found that most agencies recommend using the same rate for costs and benefits. In comparison, the New Zealand Treasury (2018) recommends the use of a discount rate of 6% as the default rate for both costs and benefits.

We select a discount rate of 3.5% per annum based on this information. This is the rate that is used by PHARMAC, New Zealand's agency that performs health technology assessments for pharmaceuticals.

2.3 We use a 30 year time horizon

We choose this time horizon based on the expected lifetime of capital investments. This allows for the alignment of the different scenarios. We believe that this also provides a sufficiently long period to assess the costs and benefits over time. With our chosen discount rate of 3.5% per annum, an additional year of analysis would add, on average, less than 2% to the total costs and benefits (diminishing further for each additional year added).

2.4 NTDs included: spina bifida, anencephaly and encephalocele

NTDs are severe congenital malformations that arise when the neural tube fails to close completely (Greene & Copp, 2014). These malformations may result in stillbirth or permanent disability.

Two main forms of NTDs are spina bifida and anencephaly. While both are NTDs, they have very different outcomes for those born with these defects. Anencephaly affected neonates rarely survive even one week from birth (Jaquier et al., 2006), while some spina bifida cases result in similar life spans as the general population (Barf et al., 2007). A decrease in the birth prevalence of these two forms of NTD has been shown to occur following mandatory folic acid fortification programs (PMCSA, 2018).

Encephalocele is another birth defect often included in the definition of an NTD alongside spina bifida and anencephaly. Literature suggests encephalocele may not come under the strict definition of an NTD (Copp & Greene, 2012). However, some studies (for instance Wang et al., 2016) show there has been a reduction in the birth prevalence of encephalocele in countries following folic acid fortification,

and that encephalocele is more similar than different when compared to spina bifida and anencephaly. We therefore include encephalocele in our model and when we refer to NTDs.

More information regarding these three congenital defects included in our model is contained in Appendix A.

3. Benefits of fortification

We quantify the benefits of fortification in this section. The primary outcome of strengthening folic acid fortification is to reduce the prevalence of NTDs. We therefore estimate the societal benefits from preventing an NTD. We multiply this estimate by the modelled reduction in the birth-prevalence of NTDs to estimate the benefits of fortification under each option.

This section also summarises the other benefits and risks of folic acid fortification that we do not include in the model.

3.1 A wide range of results depending on the regulatory option

Benefits range from $15 to $116 million plus 310 to 2,360 QALYs saved, depending on the regulatory option that might be implemented.

We base our benefit estimates on NTD reductions modelled by MPI. Table 3 shows the results of this modelling. MPI modelled the intakes of folic acid under each scenario compared to the status quo. These intakes were then used in further modelling to determine the number of NTDs prevented for each scenario. MPI used three different models to ensure reliability. We present the results of MPI's modelling as a range as we do not consider that there is a preferred or 'most accurate' model. We use this range for all subsequent calculations and therefore any benefits or net benefits from fortification are also presented as a range.

Table 3 NTDs prevented per year

Fortification option	Live births	Foetal deaths
Enhanced voluntary target	0.7 to 2.1	0.3 to 0.7
Mandatory fortification of all non-organic bread	2.0 to 3.7	0.7 to 1.3
Mandatory fortification of all non-organic bread-making wheat flour	2.2 to 3.3	0.8 to 1.1
Mandatory fortification of all non-organic wheat flour	3.4 to 5.5	1.2 to 1.9

Source: MPI Science and Risk Assessment

The benefits from each of the fortification options are in Table 4. The results are shown as the present value (PV) of 30 years of fortification.

The societal benefits increase as the level of fortification increases. In addition to the monetary benefits, there are also health benefits that we measure in QALYs. The QALYs gained are the equivalent of 13 full lives for the lower bound of the enhanced voluntary target, and 95 full lives for the higher range of the all non-organic wheat flour option.

Table 4 Benefits of fortification over 30 years

Fortification option	NTDs prevented (live births and foetal deaths)	Monetary benefits ($millions)	Health benefits (QALYs)
Enhanced voluntary target	19 to 52	$15.5 to $43.0	314 to 873
Mandatory fortification of all non-organic bread	50 to 94	$41.3 to $77.3	837 to 1,571
Mandatory fortification of all non-organic bread-making wheat flour	57 to 84	$46.4 to $68.7	943 to 1,396
Mandatory fortification of all non-organic wheat flour	88 to 141	$72.1 to $116.1	1,467 to 2,358

Results are based on 30 years of fortification and are discounted at 3.5% per annum.

3.2 Lifetime societal benefits of $938,000 from preventing an NTD

We compare the lifetime costs of a person affected by an NTD, who survives birth, with that of the general population.[3] This comparison results in a lifetime cost to society of $938,000. By preventing an NTD, society benefits by the same amount. With an average of approximately 26 live births per annum, society incurs present value costs of $24 million per year (MPI, 2018).

Our cost estimates are in Table 5. The differences between the NTD-affected population and general population are in Figure 4.

The largest contribution to lifetime cost is lost productivity, primarily due to increased mortality and lower employment rates. Healthcare costs are also significantly higher for an NTD-affected person, with large first year of life costs, and considerable ongoing costs. Loss of productivity of caregivers, educational support and the deadweight cost of taxation together contribute almost $300,000 to the overall cost of an NTD affected birth.

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[3] We calculate the monetary benefit from preventing foetal deaths in Section 3.

Table 5 Summary of lifetime estimates ($000s, discounted 3.5% p.a.) – NTD-affected compared to general population

Societal cost	NTD-affected	General Population	Difference[1]
Productivity – affected person[2]	-$213	-$645	$433
Healthcare costs	$279	$73	$206
Productivity loss – caregiver[3]	$157	$0	$157
Education costs	$152	$69	$84
Deadweight cost of taxation	$86	$28	$58
Total[1]	**$462**	**-$476**	**$938**

1. Figures are rounded to the nearest thousand, and therefore may not sum to the total
2. Figures are shown as negative as productivity offsets other costs
3. Only a cost for the NTD-affected column as this figure already compares to the general population

Figure 4 Lifetime societal costs due a NTD
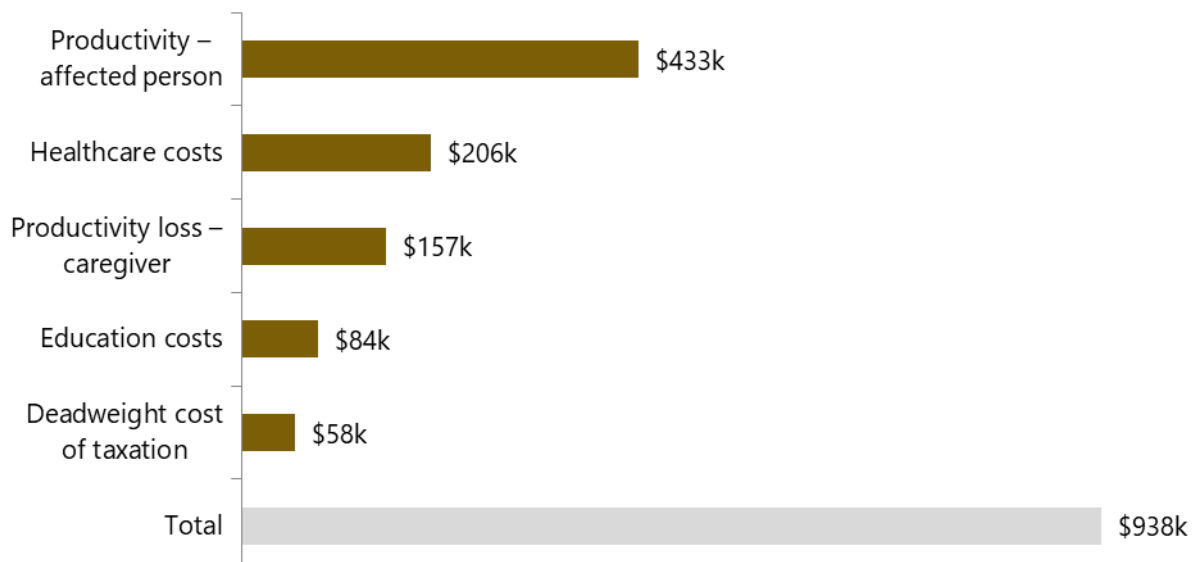
3.2.1 Life expectancy of an NTD-affected person is 65 years

There are a number of steps in estimation of lifetime impacts. First, we estimate life expectancy. We estimate life expectancy for the different NTD subgroups and use the weighted average of these subgroups. For spina bifida and encephalocele, we use survival rates for the first eight years from Wang et al. (2015), and assume that they experience the same life expectancy as the general population thereafter. This results in average life expectancies for live births affected by spina bifida and encephalocele of 74 and 57 years, respectively. For anencephaly, we assume all individuals die within the first year of life, with almost all dying within the first week. This results in a weighted average of 65 years. The survival curves are shown in Figure 5.

Figure 5 Life expectancy – NTD population compared to NZ general population
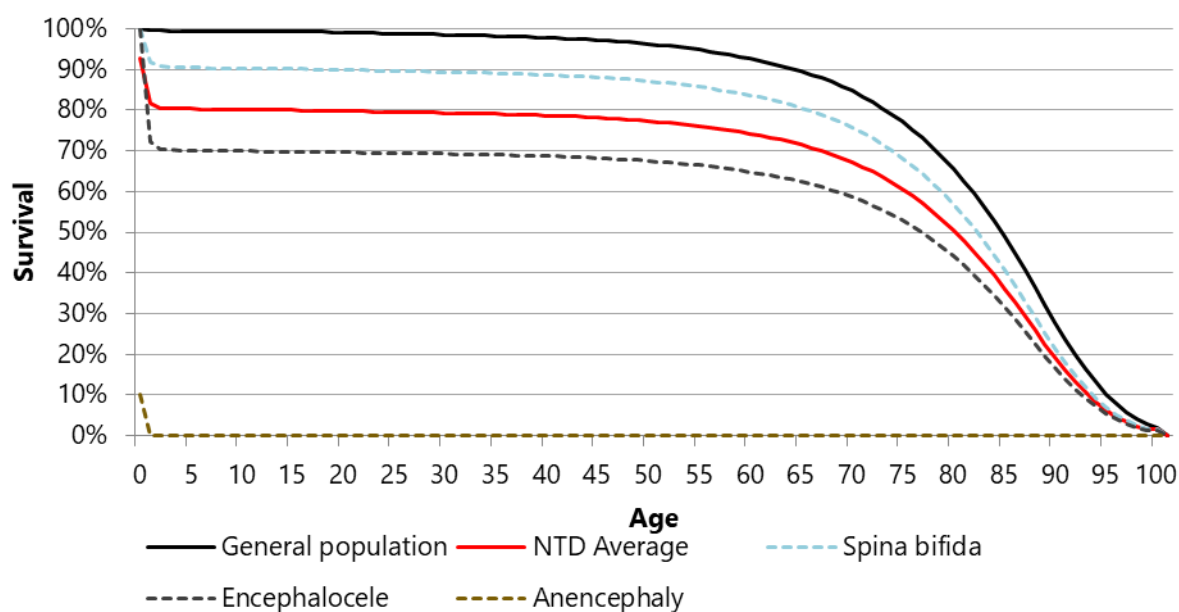
Reference points in calculating life expectancy

We take into account a range of different perspectives when coming to the view that **65 years** is an appropriate point estimate for the average life expectancy of a person affected by an NTD.

The literature suggests that both morbidity and mortality rates after infancy are decreasing over time. This decrease is due to improved healthcare and technology such as the use of shunts for the treatment of hydrocephalus in spina bifida patients (Shin et al., 2012).

Research also suggests that if a person with spina bifida survives beyond the first few years of life it is likely they will have a life expectancy close to the average (Barf et al., 2007).

There are several studies that have estimated life expectancy for a person with spina bifida. Jetink et al. (2008) estimated 64 years, while Access Economics (2006a) estimated 71 years.

Some literature, such as Oakeshott et al. (2009), argues that the spina bifida population have much lower life expectancy, even if they survive to adulthood. However, these studies are based on older cohorts, and most literature points towards higher survival rates now.

Our model's rates differ sharply from the life expectancy at birth for New Zealanders. For the general population, life expectancy is 82 years, with 99% of the population expected to pass their 21st birthday (Statistics New Zealand, 2015a). In contrast, our modelling shows that people affected by an NTD have much shorter average life expectancy of 65 years and 18% die within their first year of life.

3.2.2 Averages may mask a wide range of individual costs

The life expectancy of the whole population with NTDs is complex, and a single measure hides some of the distinctly different experiences of subgroups with different NTD conditions. Some examples of the variation are detailed below.

- The impact of NTDs can vary from high rates of mortality in the first few days of life for anencephaly patients, to a life expectancy on par with the rest of the population for some groups of spina bifida patients.
- Morbidity can range wildly. For instance, the mobility of a person affected by spina bifida can vary from not needing any assistance walking through to paraplegia.
- The prevalence of learning disability can also vary markedly.

The heterogeneity of these groups means that the average value of life expectancy (or of other elements that contribute to the cost estimate) can mask a wide distribution of underlying life expectancy and costs. From the literature, and discussions with a paediatrician, we understand that the outlier, upper-end costs are very substantial.

3.2.3 Spina bifida costs as a proxy for all subgroups

There is little in the literature that breaks down costs for anencephaly or encephalocele. In addition, the majority of the NTD population who live past infancy have spina bifida. We therefore use spina bifida costs as a proxy for all NTD subgroups. For the purposes of this analysis, we assume that the social costs are the same for all three NTD subgroups at each stage of life. However, the lifetime estimates change due to differing rates of mortality.

We do not expect this simplifying assumption to have a material impact on the outcome for a number of reasons, including:

- the high proportion (78%) that spina bifida makes up of the affected live births
- the short life expectancy of an anencephaly live birth; the large majority do not survive a week (Jaquier et al, 2006)
- the majority of social costs relate to lost productivity.

3.3 Productivity losses are the most material cost

The second step was calculating costs, with productivity costs being the most significant of the cost categories.

- People affected by spina bifida are less likely to participate in the workforce. In addition, when they do participate, they tend to work fewer hours, have lower income jobs, and take more sick days per year. These impacts equate to an average loss in productivity to society of **$433,000** (discounted 3.5% p.a.) per NTD affected live birth.
- There is also a material productivity loss associated with caregivers working less time to care for their child affected by spina bifida. This equates to a further loss in productivity of **$157,000** (discounted 3.5% p.a.) per NTD affected live birth.

We use the human capital approach to estimate the losses in productivity due to morbidity and mortality. This approach is commonly recommended and used in health technology assessments where productivity losses are measured (Steinmann et al., 2018). The human capital approach is

founded on the economic theory that profit-maximising firms will employ workers up to the point where their marginal contribution equals their wage. We therefore equate productivity to be equal to income for this analysis.

Estimating productivity losses for an NTD affected person

Estimates of employment rates in the literature vary significantly. Some studies report rates as low as 19% (Lonton et al., 1984). However more recent studies show higher rates of employment, with many of these in the range of 36% to 42% (for instance Roach et al. 2011; Valtonen et al., 2006; Bellin et al., 2011). One study, showed employment rates as high as 63% (Van Mechelen et al., 2006). All these studies were for the working age population (15-64).

Statistics New Zealand (2018) income data statistics show an employment rate of 39% for all disabled persons. This aligns with the middle range and a number of the studies for those affected by spina bifida. We therefore use the income data for people with disabilities as a suitable proxy to represent the working age spina bifida population. We extend this assumption to include the 65+ age band. A similar approach was used in the cost utility analysis completed by the Australian Health Ministers' Advisory Council (2017).

For people with disabilities of working age and in employment, the mean annual income from wages and salaries, or self-employment is $47,000. With an employment rate of 39%, we estimate the average productivity for a person affected by spina bifida per working age year to be $18,400. Using the same methodology for the total population, we estimate the average productivity per person in the working age general population to be $44,500. Table 6 contains the income estimates that we use in our analysis.

Bowles et al. (2014) estimated that the average number of sick days for a person with spina bifida as 10.8 days per year. The average number of sick days for the general population is estimated to be 4.4 (Business New Zealand, 2017). While an employed person affected by spina bifida has more sick days per year, the lower income and employment rate offset this, which results in an immaterial difference compared to the general population.

Table 6 Income estimates for people with and without disability

Population	Age band	Income[1,2] (employed)	Employment rate[1]	Income[1] (average for population)
With disability	15-64	$47,000	39%	$18,400
With disability	65+	$46,500	7%	$3,100
Without disability	15-64	$57,500	77%	$44,500
Without disability	65+	$46,800	23%	$10,900

1. Dollar figures are rounded to the nearest hundred, and percentages to the nearest whole percentage point.

2. Income is the weighted average of self-employed, and wages and salaries for this, weighted by employment rates.

Estimating productivity losses for the caregiver

We estimate that the primary caregiver of a child (aged 0 to 17 years) with spina bifida works an average of 9.2 fewer hours per week than the average (Tilford et al., 2009). Using the average hourly rate of $29.70 (Statistics New Zealand, 2018), we estimate the annual cost of the lost productivity from the primary caregivers' work to be $14,000 per year.

There is little consistency in the literature on how long to apply this cost for, although most analyses use a cut off age in line with the end of childhood. For instance Access Economics (2006a) applied the loss for the first 20 years of life, while The Australian Health Ministers' Advisory Council (2017) applied the loss for 17 years. The York Health Economics Consortium [YHEC] (2015) applied this lost productivity for 18 years. We apply this cost through childhood, up to the age of 18 for the spina bifida population, to match the data collected by Tilford et al. (2005).

3.4 Healthcare costs are significant

There are a number of additional healthcare costs for people affected by spina bifida over and above the healthcare costs for the general population, including:
- neonatal surgery to close the lesion and put spinal cord back in to the spine
- potential shunt insertion to drain cerebrospinal fluid in hydrocephalus cases
- ongoing in- and out-patient treatment
- assistive technology to aid in mobility.

We estimate the additional lifetime healthcare costs for an NTD case to be **$248,000** (discounted 3.5% per annum).

3.4.1 Lifetime healthcare costs of spina bifida differ in the literature

The range of healthcare cost estimates in the literature vary widely. For example two New Zealand specific papers estimated very different results.
- Bowkett and Deveral (2012) estimated $944,000 for the first 21 years of life, which only included inpatient costs.
- Singh and Elliott (1996) estimated $355,000 for the first 20 years of life, which included healthcare costs and some income support estimates.

The estimate by Bowkett and Deveral (2012) is much higher, and encompasses fewer areas of healthcare expenditure. We believe that the study population is likely to be more severe (and therefore more expensive) than the average.
- One of the selection criteria for this study was for sequential contacts with the paediatric surgical service at Wellington Regional Hospital. Therefore spina bifida patients were more likely to be selected if they visited more frequently (with more frequent visits implying a more severe disability). Young et al. (2014) estimated that more than 40% of youths were not admitted to hospital in a four year period, and therefore it is likely that a large proportion of spina bifida patients were not represented in the Bowkett and Deveral (2012) study.
- The study group had a high rate of paraplegia (six out of the seven patients). This is high in comparison to the literature; almost 70% of the spina bifida population is estimated to be able to walk (with or without assistance) (Dicianno et al., 2015).

The results of this study shows that the average spina bifida patient costs do not represent the entire group and that there are very severe and expensive cases of spina bifida.

The healthcare estimate by Singh and Elliott (1996) is more closely aligned with other estimates such as Access Economics (2006) and our estimate. However, we cannot account for approximately $50,000 of their expenditure based on the information provided in the paper.

3.4.2 Our calculation is based on conservative assumptions

We estimate the utilisation rates of healthcare services by the spina bifida population using published literature. We then multiply these by New Zealand specific unit costs to estimate a New Zealand specific healthcare cost. For example, Ouyang et al. (2007) reported an average of 27 outpatient visits in the first year of life for people with spina bifida. Applying NZ costs results in an estimate of $5,100 per year for outpatient costs in the infant population.

The most expensive healthcare costs are in the first year of life, which we estimate to be $63,000. This is mostly due to surgeries and associated activity. In the following years, we estimate the additional healthcare costs for the spina bifida population over and above the New Zealand average annual cost of healthcare to be in the range $7,400 – 8,000.

Table 7 summarises the annual cost by age group. Table 23 and Table 24 in Appendix B of this report show further details of the New Zealand specific costs and health care utilisation rates.

Table 7 Additional healthcare costs for spina bifida – annual cost by age group

Age group	In patient	Out patient	Assistive technology	Total
0	$57,500	$5,100	$0	**$62,600**
1 – 17	$3,400	$3,600	$400	**$7,400**
18 – 64	$3,500	$4,000	$400	**$7,800**
65+	$3,400	$4,300	$400	**$8,000**

Figures are rounded to the nearest hundred and therefore may not sum to the total.

3.4.3 Comparing the lifetime healthcare costs for the general population

We estimate the average annual health care cost by year of age for the New Zealand population, and apply this to the general population in our model. We use the Ministry of Health's National Collection datasets and other health data, to attribute $10.8 billion in health care expenditure to individuals (for the year ending December 2015). This includes inpatient, outpatient, emergency departments, general practice, pharmaceuticals, lab tests, community services, mental health and addiction, aged residential care and disability costs.

We assume that these expenditures are representative of the proportion of all health expenditure by age. As Vote Health was $15.7 billion in that year, we apply a multiplier of 1.46 to scale up the

healthcare costs from the aforementioned $10.8 billion to the full value of Vote Health of $15.7 billion across the population.

3.5 Additional education costs

Children with spina bifida may need additional educational support. This is because many of these children face physical and cognitive impairments. We estimate this adds an additional cost of **$83,000** (discounted 3.5% p.a.) to the average lifetime cost of an NTD case.

We estimate education costs for primary and secondary school education. The literature suggests that between 35% and 55% of children will need education support beyond normal schooling (Roach et al., 2010; Bowman et al., 2001; Cope et al., 2013). We use the midpoint rate of 45% for this analysis.

The Ongoing Resourcing Scheme provides special education support to high need students. We estimate that this scheme costs approximately $30,000 per student per year (Kiernan & Olsen, 2017; Johnston, 2015; Budget 2018, 2018). This results in an increase in education costs of $13,500 per year per child affected by spina bifida. This cost is in addition to the average yearly cost of education of $7,700 per child (Education Counts, 2018).

3.6 Deadweight cost of taxation

Taxation generates distortions in choices. It encourages people toward choices with lower tax burden, and away from those with higher burden. The change in the choices made due to a tax generates a loss in welfare over and above the direct value of the tax. This is known as the deadweight cost of taxation.

The New Zealand Treasury (2015) suggests a rate of 20% to be applied to items funded through tax to estimate this deadweight cost. We apply this additional 20% to the healthcare costs and the education costs. This equates an additional lifetime cost to society of **$58,000** (discounted 3.5% p.a.) per NTD case.

3.7 Comparison with previous estimates

There are a number of studies that have attempted to estimate various costs associated with NTDs. Most of the literature focuses on spina bifida and health costs, although some include further costs such as productivity, special education and welfare costs.

Our model input values are typically based on midpoints or averages of the relevant literature. As such, it is logical that our cost estimates should sit within the wider range of previous estimates. This also means that our estimate is unlikely to match individual study estimates. However, the analyses that included a wider range of costs, and those that based inputs off literature searches are similar to our equivalent estimates (Access Economics, 2006a and Waitzman et al., 2004).

The exact methodology and costs included in each study are not always available. However, we attempt to estimate an equivalent figure based on our understanding for comparison. Where a study was completed overseas, we also convert the currency to New Zealand Dollars using an exchange rate adjustment to provide a very crude comparable estimate. These values are shown in Table 8.

A main area of variation is seen in the healthcare cost estimates. For instance:

- $567,000 for total lifetime healthcare costs (Bowles et al., 2014)
- $944,000 for inpatient costs to the age of 21 (Bowkett and Deveral, 2012)
- $1,400,000 for total healthcare costs to the age of 64 (Ouyang et al., 2007).

Countries can have very different unit healthcare costs, and therefore we expect some variation in estimates.

Table 8 Summary of other NTD cost studies

Study	Cost[1]	Our equivalent estimate	Comments
Access Economics (2006a)	$1,200,000 Lifetime cost per NTD saved (discounted 2% p.a.)	$1,360,000 Our calculation discounted 2% p.a.	Weighted average of all NTD types. Includes healthcare, productivity, welfare costs. We exclude the report's burden of disease estimate in the comparison.
Bowkett and Deveral (2012)	$944,000 Cost to age 21	$129,000 Our calculation of inpatient costs to age 21	Inpatient costs for paediatric spina bifida patients. Likely to be skewed towards higher cost patients.
Bowles et al. (2014)	$567,000 EUR4,532 per year multiplied by our calculated average life expectancy of 74 years	$811,000	Included the total healthcare costs for a spina bifida affected person.
Ouyang et al. (2007)	$1,400,000 USD1.0m over 64 years of life	$717,000 Our calculation for 64 years of life	Included the total health costs for a spina bifida affected person.
Singh and Elliot (1997)	$355,000 20 years of life	280,000 Our calculation for 20 years of life	Included healthcare costs and some income support. Note that we cannot account for approximately $50,000 of their estimate from the information provided in the paper.
Waitzman et al. (2004)	$888,000 USD636,000 lifetime cost (discounted at 3% p.a.)	$909,000 Our calculation discounted at 3% p.a.	Included productivity losses for the affected person, healthcare costs (but no offsets for the general population) and additional education costs.

1. All currency conversions have been made using the average of the relevant daily exchange rate from 1 January to 30 June 2018

3.8 A societal benefit of $476,000 per foetal death prevented

We calculate the societal cost of a foetal death to be approximately half the costs of a person who survives birth with an NTD. There are other ways of valuing life and we take a narrow and conservative perspective on costs, and not the value of a life.

We equate a foetal death to a life expectancy of zero in our model. This assumption results in no productivity or societal costs incurred due to a foetal death. We therefore estimate the net monetary societal benefits of preventing a foetal death to be **$476,000** (discounted at 3.5% per annum); the net benefit from a general population live birth.

3.9 More than half a life is gained from preventing an NTD

In addition to the monetary costs in the previous section, there are reductions in quality and length of life that occur due to neural tube defects. We estimate the lifetime loss in health to be **13.9 QALYs** (discounted at 3.5% per annum per NTD). **24.8 QALYs** (discounted at 3.5% per annum) are lost for a foetal death.

3.9.1 We measure the health losses in quality-adjusted life years

The health-adjusted life years framework considers both mortality and morbidity; that is, it accounts for both the quality (in regards to health) and the length of life experienced. This provides for some perspective on the relative health and life of those affected by neural tube defects versus the general population. The commonly used measure of health-adjusted life year is the quality-adjusted life year (QALY). A QALY is a unit of health, where one QALY represents one year of life lived in perfect health.

3.9.2 Preventing an NTD saves 14.9 QALYs over a lifetime

Based on data from the Global Burden of Disease (2016) database, we estimate that the disability weight for an average New Zealander affected by an NTD is between 0.27 and 0.30.[4] This value has been adjusted for comorbidities, and therefore represents the reduction in quality of life due to NTDs only, i.e. the marginal loss in health compared to the general population. Applying this to our life expectancy estimates, and including mortality rates, we estimate a lifetime loss of approximately 11.3 QALYs per person (discounted at 3.5% p.a.) relative to the general population.

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[4] A disability (or disease) weight is the severity of a health state, where zero represents perfect health and one represents complete health loss (equivalent of being dead). A disease weight of 0.2 that is experienced for one year is the equivalent of 0.8 QALYs. We note that the Global Burden of Disease study measures its burden of disease in disability-adjusted life years (DALYs). DALYs are measured on the opposite of QALYs, that is, one DALY represents a loss of one year of perfect health. While one QALY gained is not a perfect substitute for one DALY averted, due to ranges around estimation, and simplicity, we equate them for the purposes of this analysis. We use QALYs as this unit is more frequently used in New Zealand.

Other studies have also attempted to estimate the health loss due to neural tube defects.

- Access Economics (2006a) estimated approximately 23.4 to 25.5 disability-adjusted life years (DALYs) per live NTD birth (due to rounding it is difficult to determine their exact figure). This was based off an average disability weight of 0.52 (not adjusted for comorbidities). It does not appear that this was compared to a general population disability weight, and therefore is likely to overestimate the loss in health. Based on the Global Burden of Disease (2016) data, we estimate the general population disease weights to be between 0.04 and 0.31, increasing with age. Accounting for this, the marginal impact would be more in line with our estimates.
- YHEC (2015) estimated a loss in quality-adjusted life years of 13.9 and 11.3 per case of spina bifida depending on the source of their data. This was calculated as the difference between the QALYs for a spina bifida affected person and the general population. These estimates are similar to ours.

In addition, we model a loss in QALYs for the primary caregiver. Tilford et al. (2005) estimated a utility value of 0.76 for the primary caregiver of a child with spina bifida. We therefore estimate a corresponding disability weight of 0.24. Applying this weight to the first 18 years of life (as in the productivity loss of caregivers) results in a further loss of 2.6 QALYs per NTD (discounted 3.5% per annum).

These two losses total 13.9 QALYs lost per NTD. We estimate that a person in the general population would, on average, accrue 24.8 QALYs over a lifetime once discounted at 3.5% (the methodology for calculating this is discussed in the section below). Therefore we estimate that loss from an NTD is the equivalent to more than half the average person's life.

3.9.3 Preventing a foetal death saves 24.8 QALYs

The disability weights for the general population increase with age. For instance, a New Zealand infant, on average has a disability weight of 0.04, increasing to 0.31 for 90 year olds (Global Burden of Disease, 2016). We apply the age specific disability weights from the Global Burden of Disease (2016) database to our general population life expectancy tables. This results in an average estimate of 24.8 QALYs (discounted at 3.5% per annum) per person. We estimate this value to be the QALYs lost due to a foetal death caused by an NTD.

3.10 Other impacts not quantified

There are a number of benefits that we do not quantify, either due to materiality or ability to monetise values.

3.10.1 Wider impacts on family and whānau

In the previous section, we quantified the utility loss for the primary caregiver of an NTD-affected child. However there are also impacts on the wider family and whānau. For instance, Vermaes et al. (2005) found that the presence of a spina bifida child in a family is correlated with higher levels of psychological strain in parents. In addition, other studies have found higher proportion of single parent households among the presence of a disabled child (Blackburn, Spencer & Read, 2010).

3.10.2 Terminations of pregnancies due to NTDs

There are a number of terminations of NTD-affected pregnancies that could be avoided from increased fortification. Estimates of the terminations prevented over 30 years based on MPI's modelling are in Table 9.

Table 9 Terminations prevented by fortification

Fortification option	Terminations prevented
Increased voluntary target	24 to 68
Mandatory fortification of non-organic bread	65 to 122
Mandatory fortification of non-organic bread-making wheat flour	73 to 108
Mandatory fortification of non-organic wheat flour	113 to 182

Results are based on 30 years of fortification. These numbers are not discounted.

We do not model the impact on society due to avoided terminations of pregnancies. This impact is difficult to quantify and ethically challenging. However, avoided terminations are additional benefits to our results.

3.10.3 Health impacts on family from foetal deaths and terminations

There is distress experienced from foetal deaths and terminations due to an NTD. We do not model this as it is not likely to have a significant impact on our model. For instance, the YHEC (2015) applied a QALY loss of 0.022 per event. Under the mandatory fortification of non-organic wheat flour option, this would equate to less than 0.2 QALYs saved per year.

3.10.4 Reduced NTD severity is possible but not measured

The PMCSA (2018) report found that there are suggestions that increased periconceptual supplementation and food fortification with folic acid may also decrease the severity of NTDs. Taking a conservative approach, we do not model this decrease in severity, but note that there would be additional monetary and health benefits if we included this impact.

3.10.5 Decreasing rates of folate deficiency are likely but not counted

Folate deficiency can cause a form of anaemia. By increasing the levels of folic acid in the food supply, it is logical that there is likely to be a decrease in the rates of folate deficiency. Approximately 2% of the population aged 15 years and older have low blood folate status. This is an indicator of potential deficiency (University of Otago & Ministry of Health, 2011). We do not model reductions in folate deficiency. However, this would have a positive impact on the benefits from strengthening fortification.

3.11 An equity benefit: those with the lowest supplement use consume more bread

Folic acid supplementation rates during the periconceptual period are lowest in the highest need groups. This includes the lowest income, least educated, highest children and single mother households. In addition, there are large ethnic disparities with Māori supplementation rates of around 9% and Pasifika rates of less than 3%, compared to Asian rates of 26% and European rates of 42% (Mallard, Gray & Houghton, 2012). This study also found that the groups with the lowest supplement use were also those that were most likely to consume three or more slices of bread per day.

It is therefore likely that the groups with the highest need are also the most likely to benefit from a fortification policy that targets bread. This has been seen in other countries that have introduced mandatory fortification. Post-fortification, many countries have found higher reductions in NTDs in indigenous peoples and in those who have lower socioeconomic status. For instance, Australia had improved equity outcomes in teenage and indigenous mothers (Saing et al., 2019).

3.12 Changes in behaviours could change the pattern of benefit

We do not model changes in behaviours of the population from the status quo. These changes in behaviour could modify the profile of benefit but the changes in behaviours would have to be very material to change our results. Some of the changes that could impact the modelled benefits from increased fortification are below.

- Changes in consumption patterns of the fortified food vehicle within the women of child-bearing age population. As the number of products fortified under each option increases, it is less likely that this would occur. This is due to a lower likelihood that a food switched to would not be fortified.
- Changes in consumption patterns of other folic acid fortified foods, or foods naturally containing folate.
- Changes in periconceptual use of supplements containing folic acid.
- Changes to the level of voluntary folic acid fortification in the absence of one of the strengthened fortification options being chosen.

3.13 No evidence of any likely side effects

There are other impacts on health that may come from increased dietary intake of folic acid. We do not include these in our model due to difficulties in estimation, immateriality or lack of substantial evidence. Based on our further research we agree with the research and findings of the PMCSA (2018) report. The report concludes that:

> **There is no evidence that folate/folic acid is associated with adverse health effects other than (possibly) some types of cancer.**

We summarise some of the findings made in this report and refer readers to the full report for more detail.

3.13.1 Weak or no evidence that cancer rates increase

The PMCSA (2018) authors assessed the evidence across a range of different types of studies. They found the overall evidence of links between folic acid and cancer to be inconsistent, with no strong evidence of adverse effects on the risk of cancer. Their findings are summarised in Table 10.

Table 10 Summary of evidence between folic acid and cancer

Study type	Advantages and disadvantages of study type	PMCSA conclusion
Clinical trials, including randomised control trial	**Advantages** Usually provide the **best quality evidence** to suggest causality. **Disadvantages** Often use **higher doses** (via supplementation) compared to fortification. Often have **shorter follow-up duration and exposure, and smaller trial size** compared to other studies.	**No evidence** to suggest adverse effects from folic acid supplementation at low doses. The lack of a statistically significant effect suggests that even if there were a true effect, it is likely to be small at a population level.
Genetic studies	**Advantages** An emerging area that can be used to study **potential causal effects**. **Disadvantages** The findings may be **subject to biases** due to other pathways/impacts from the genes studied.	**Weak associations** between life-long high blood folate levels and certain cancers; increased risk of prostate and colorectal cancer, decreased risk of breast and total cancer.
Observational studies	**Advantages** Use **'real-life' populations** and often have a **large study size** and **long follow-up duration**. **Disadvantages** Can only find **associations** due to **potential confounding** of results by other related factors.	Mostly, but not consistently, show **no evidence** to suggest adverse impacts on cancer. On balance observational studies may suggest a **protective effect** on cancer

Study type	Advantages and disadvantages of study type	PMCSA conclusion
Ecological studies	**Advantages** A **'natural experiment'** comparing populations before and after a change. Use **'real-life' populations** and often have a **large study size** and **long follow-up duration**. **Disadvantages** Can only find **potential associations** due to other changes may have occurred that also impact on outcomes e.g. changes in smoking rates or cancer screening programs. **Requires a large effect** to be seen as statistically significant in the population. **Requires short lag times** between the intervention and the impact.	**No evidence** to suggest increased cancer rates following from mandatory fortification in other countries, or increased voluntary fortification in New Zealand.

All the study types have advantages and disadvantages. This is especially so when looking at the relatively lower increases in folic acid intakes from fortification compared to supplementation. Only the genetic studies show any potential adverse effects between folic acid intake and some cancers. However, they also show potential protective effects too.

The PMCSA (2018) authors conclude:

> **Clinical trials do not consistently point to any net benefit or harm. However, there is a lack of evidence for very long-term effects.**
>
> **Genetic studies suggest that having higher blood folate levels may be associated with increased colorectal and prostate cancer rates, and decrease breast and total cancer rates. This evidence is not universally endorsed and the associations are not necessarily causal.**

We believe that the evidence for cancer harm from fortification is sufficiently uncertain to include impacts in our model. In addition, overall population impacts would be difficult to determine given the uncertain potential for both protective and adverse effects

3.13.2 Exceeding the upper dietary limit is not recommended

As the level of fortification increases, there is an increased likelihood of people exceeding the upper limit for the dietary intake of folic acid. For adults, this is set at 1,000 µg per day. This level is reduced for those aged 18 years or younger. MPI's modelling estimates that less than 1% of the adult population would have folic intakes over the daily limit under any of the scenarios.

However, the high limits of the fortification concentrations of the mandatory bread and wheat flour options result in a large proportion of children exceeding the upper limit (14% and 36% respectively). The impacts of exceeding the upper limit for children are unknown as the upper limit was set for adults, and then adjusted for body weight due to a lack of clinical evidence (PMCSA, 2018).

Further, The PMCSA authors go on to note that the original data used to set the upper limit were incorrectly interpreted. Once the data was adjusted for the number of patients in each group, high doses were no longer associated with neuropathological progression (the original reason for the upper limit).

Despite this finding, the upper limit is still in place for New Zealand (and many other countries). As such, exceeding this limit should be treated with caution.

3.13.3 No evidence for other health risks from folic acid

The PMCSA (2018) report also assessed the evidence relating to many other potential health impacts from folic acid and found no evidence to suggest any further adverse effects. These include:

- neurological/cognitive impairment
- diabetes
- adverse events in offspring, including:
  - asthma
  - wheezing
  - eczema
  - susceptibility to respiratory infection
  - childhood cancer
  - autism spectrum disorders
  - Down syndrome
  - twinning/multiple births
- cardiovascular disease (with potential evidence for a reduction in risk of stroke and cardiovascular disease)
- adverse effects of unmetabolised folic acid.

4. Costs of fortifying

In this section we estimate the costs of four different options for strengthening folic acid fortification. These four options are:

- increase the voluntary fortification target to 80% from 50% of all packaged sliced bread
- requiring all non-organic bread to be fortified with folic acid
- requiring all non-organic bread-making wheat flour to be fortified
- requiring all non-organic wheat flour to be fortified

4.1 Three of the four options are relatively inexpensive

The PV of costs over 30 years of each fortification option compared to the status quo are summarised in Table 11. The costs of enhanced voluntary fortification are low compared to the mandatory options. This is due to lower levels of fortification and regulation required. The mandatory fortification of bread option is an outlier due to the high costs from testing the products of 2,500-3,500 bakers. The other two mandatory options require capital outlays to implement.

Table 11 Summary of fortification costs

Fortification option	PV ($millions)
Enhanced voluntary fortification	$2.9
Mandatory fortification of non-organic bread	$110.3
Mandatory fortification of non-organic bread-making wheat flour	$14.1
Mandatory fortification of non-organic wheat flour	$18.1

Results are based on 30 years of fortification and are discounted at 3.5% per annum.

Estimating the costs of the status quo

To estimate the incremental costs of these four options, we must estimate the cost of the current voluntary fortification regime. The current goal is for NZAB members to fortify between 25% and 50% of their packaged sliced bread at a level of 200 µg per 100 g of bread.

We use the target fortification concentration in our estimates below. The most recent industry audit found a mean concentration of 166 µg per 100 g of bread of those sampled (Watson, 2018). However, as this value is not weighted by volume, it may not be representative of the average level of folic acid in fortified bread consumed. We also understand that the industry is working to achieve the target concentration.

The audit is completed every six months, and, from industry, we estimate the annual cost of this is approximately $50,000.

MPI also completes an analytical survey to monitor the levels of folic acid in bread every five years. This involves sampling approximately 200 products at a cost of $300 each. In addition there are

sampling costs incurred of approximately $5,000 per survey. As this is funded by taxation, we apply the same 20% deadweight cost that we used in the benefits of fortification section.

Currently, 38%, or approximately 52,000 tonnes, of packaged sliced bread are fortified (Watson, 2018). From meetings with representatives of the plant bakers, fortification is currently achieved by adding a 'premix' that contains folic acid in a flour carrier. This is due to the small levels of folic acid required, and this process allows more accurate dosing.[5]

From the plant bakers, we understand that a 0.27% premix is often used. In other words, even the premix is almost entirely the flour carrier. It is therefore important that we only include the differential in cost between the premix, and the cost of plain flour. We estimate this to be $1,000 for premix that contains one kilogram of folic acid.[6] We use this same estimate for the marginal cost of folic acid for all fortification options, regardless of the carrier used.

Based on this information, we estimate the following costs in Table 12.

Table 12 Status quo fortification costs

Cost area	Cost
Cost of folic acid premix per annum	$129,000
Analytic audit/testing per annum	$50,000
MPI monitoring survey every five years	$78,000

Over a 30 year time horizon this equates to costs of fortification of $3.7 million (discounted 3.5% per annum) compared to no fortification of bread.

4.2 Enhanced voluntary target costs $2.9 million

This option would set the target for fortification of packaged sliced bread to 80% by volume with the same 150 µg per 100 g of bread concentration.[7]

When compared to the status quo, slightly more than double the volume of packaged sliced bread would need to be fortified. However, as the folic acid concentration is slightly lower, the cost of the folic acid is slightly less than double that of the status quo. Based on conversations with industry, we understand that there would be some economies of scale for the analytical audit.

From MPI, we understand that there would be no change to the costs and timing of their monitoring surveys. We therefore model the same $78,000 as in the status quo for this survey every five years.

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[5] We estimate that just 4.2 grams of folic acid need to be added to one tonne of flour. This is based on the following assumptions:
- flour makes up 60% of the final product weight
- an overage of 25% (equivalent of a 20% loss) is required due to losses from baking (Food Standards Australia New Zealand [FSANZ], 2007).

[6] From industry, 0.27% folic acid premix costs approximately $3.41 per kg, whereas bread making flour is approximately $0.75 per kg.

[7] The same 20% overage allowance for baking losses used in the status quo estimate is used in this scenario

As folic acid must be listed in the ingredients list of packaging, there could also be costs due to packaging write-offs and changes. However, given the voluntary nature of this scenario, we believe it is likely that any changes would be scheduled to fit in with other packaging changes. Therefore no additional costs for this are modelled.

4.2.1 Enhanced voluntary target may not be achieved

We believe that it is unlikely that the 80% target for the enhanced voluntary fortification would be achieved. This is due to a number of reasons that are detailed below.

- The language used in the current code of practice between NZAB and MPI; that is an aspirational target of 50% fortified by volume. In other words, it is already believed to be a high level.
- The percentage of NZAB packaged slice bread fortified went from approximately 32% to 38% between 2015 and 2016, and stayed at roughly the same percentage in 2017. This slow rate of growth does not imply confidence.
- NZAB members may consider it unfair that are targeted. In addition, there is a perception that they may lose market share if they are the only ones fortifying, and some consumers prefer non-fortified bread.
- If some NZAB members do not choose to fortify, then other members would need to fortify all or almost all of their products to achieve a higher target. Members may lose market share if this is the case due to consumer preference.
- If a private label partner chooses to change their supplier or recipe to one that is not fortified, this would impact the fortification rate.

Even if the 80% target is achieved at some point, given the current growth rate in fortification, it is likely that this option would take longer to achieve than the mandatory options. Therefore, relative to the mandatory options, there would be less NTDs prevented over the next few years than the modelling might suggest. As this option is for a voluntary target, there are also no guarantees that any fortification levels would be sustained into the future.

4.2.2 A low cost option

Our estimates for this fortification option are summarised in Table 13.

Table 13 Enhanced voluntary fortification target cost summary

Cost area	Cost
Cost of folic acid premix per annum	$255,000
Analytic audit/testing per annum	$75,000
MPI monitoring survey every five years	$78,000

After deducting the status quo fortification costs, this enhanced voluntary fortification scenario would cost an additional $2.9 million over 30 years (discounted 3.5% per annum).

4.3 Mandatory fortification of bread costs $110.3 million

This scenario would require all non-organic bread to be fortified with folic acid between 100 µg and 200 µg per 100 g of bread. We use the midpoint of 150 µg per 100 g of bread as the target level. Similar to the status quo we account for baking losses of 20%, and therefore this scenario requires input levels of 188 µg per 100 g of bread.

We estimate that 289,000 tonnes of bread are produced by 2,500 – 3,500 establishments in New Zealand each year (Australian Health Ministers' Advisory Council, 2015). As this policy is for mandatory fortification, compliance to the regulation must be shown. This would consist of the following costs.

- Industry testing the folic acid levels of their products. This option would require each baker testing three products (a white, wholemeal and wholegrain bread) every six months. Using the same analytical testing cost of $300, and a midpoint estimate of 3,000 bakers, this equates to an annual cost of $5.4 million.[8]
- An audit of the systems in place for correct addition of folic acid. This is estimated to occur six months after implementation, and would consist of a sample of bakers. We do not have an estimate of this cost, but it is likely to be immaterial to the overall costs of fortification.
- Ensuring compliance. This is estimated to require 0.25 FTE for the first three years, and every five years starting from year five. Based on figures from MPI, and including a 20% adjustment for the deadweight cost of taxation, this cost is estimated to be $22,500 per year required ($18,750 before the adjustment).

To help with implementation, MPI would provide guidance for bakers complying with the new regulations. This is estimated to require half of a full-time equivalent staff member (FTE) for two years. From MPI, we use a midpoint estimate of $40,200 for each of the two years. This figure includes the deadweight cost of taxation (it equates to $33,500 before the adjustment).

MPI would continue to monitor the levels of folic acid in the food supply, similar to the status quo. However, due to the magnitude of the change, an additional survey would take place and the timing of subsequent surveys would also differ. These surveys would take place in the first, third and fifth years, and every five years thereafter. The cost of each of these surveys remains unchanged at $78,000 per survey.

There could also be costs due to packaging write-offs and changes. Due to a proposed two year transition period, we consider it likely that most of these changes could be timed to coincide with other changes that would have occurred through the normal course of business. Australian Health Ministers' Advisory Council (2015) found one-off costs of $300,000 were incurred due to the mandatory use of iodised salt in bread. This included label and packaging changes as well as administrative costs in formulation and specification changes. We estimate that a similar cost would be incurred under this option.

Our cost estimates are summarised in Table 14.

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[8] Many bakers produce more than three bread products. Testing three products may not provide sufficient evidence that the standard is adhered to under this option. However, the large cost of testing just three products results in the costs for this option being far and above the other three options. Increasing the testing requirements will only further increase the cost difference between this option and the others.

Table 14 Mandatory fortification of bread cost summary

Cost area	Cost
Cost of folic acid premix, per annum	$541,900
Industry testing of folic acid levels, per annum	$5,400,000
Systems audit, one off cost	–
Implementation guidance costs, first two years	$40,200
MPI monitoring survey, first, third and fifth years, and every five years thereafter	$68,000
Compliance costs, first three years, and every five years from year five	$22,000
One off packaging, labelling and other costs	$300,000

After deducting the status quo fortification costs, this mandatory fortification of bread scenario would cost an additional $110.3 million over 30 years (discounted 3.5% per annum).

4.4 Mandatory fortification of bread making flour costs $14.1 million

This scenario would require all non-organic bread making wheat flour to be fortified with folic acid between two and three milligrams per kilogram of flour. We use the mid-point of 2.5 mg per kg of flour for our folic acid cost estimates. There are currently seven flour milling sites in New Zealand. From talks with industry, we estimate New Zealand production of bread making wheat flour to be 192,000 tonnes.

Rather than just being another ingredient added to the dough, this would require the purchase of capital equipment. The flour millers would require micro-feeders to add a folic acid premix to their milled flour, as well as separate silos to segregate their fortified and non-fortified flour.

Based on industry provided information and a previous analysis of a fortification program (Access Economics, 2006a) we estimate the following costs.

- 14 micro-feeders at a cost of $30,000 each. We assume a lifespan of 10 years.
- 7 additional silos at a cost of $300,000 each. We assume a lifespan of 30 years. We also cost maintenance such as painting and repair of these silos at $20,000 per silo every five years.[9]
- Additional mill and silo cleaning costs of $20,000 and $10,000 respectively for each site, per annum.
- Similar to the mandatory fortification of bread scenario, we model one-off costs for packaging, labelling and other costs incurred due to the change. Our model assumes

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[9] Some companies may choose to fortify all their flour under this option, and therefore may not need additional silos to segregate the fortified and non-fortified flours. However, as we are estimating the costs (and benefits) of fortifying as per the proposed standard under each option, we include the cost of each mill requiring a silo.

$500,000 for these costs. This is higher than under the mandatory fortification of bread scenario due to:

- More products that would be fortified with folic acid; more than just bread is produced from bread-making flour.
- Potentially more write-off of packaging due to less ability of individual bakers to time changes of ingredients with changes in packaging. This is because the timing of fortification will be controlled by the flour millers rather than the bakers themselves.

As with the mandatory fortification of bread option, there would also be monitoring and compliance costs under this option. This would consist of the following costs.

- Industry testing the folic acid levels of their products. This would consist of each mill testing two products (a white and a wholemeal bread-making flour) every six months. Using the same analytical testing cost of $300, this equates to an annual cost of $8,400.
- An audit of the systems in place for correct addition of folic acid. This is estimated to occur six months after implementation, and would be for all millers. We do not have an estimate of this cost, but it is likely to be immaterial to the overall costs of fortification.
- Ensuring compliance.
    - Staff requirements are estimated to be 0.25 FTE for the first three years, and every five years starting from year five. This cost is estimated to be $22,500 per year required; the same value as in the mandatory fortification of bread option.
    - MPI will also complete a compliance survey. This would analytically test the folic acid content in flour to ensure compliance to the regulation. This is expected to take place in years one, three and five, and every five years thereafter. MPI would test two different products per mill each survey, resulting in a cost of $5,040 per survey, including the deadweight cost of taxation ($4,200 before the adjustment).

MPI would continue to monitor the levels of folic acid in the food supply. This would be the same as under the mandatory fortification of bread option. In addition, there would be implementation costs for guidance for millers in complying with the new regulations. We do not have a cost estimate for this. However, as it is a one-off cost and there are very few mills, it is likely that this cost is immaterial.

Our cost estimates are summarised in Table 15.

Table 15 Mandatory fortification of bread making flour cost summary

Cost area	Cost
Cost of folic acid premix, per annum	$480,000
Silo capital cost, every 30 years	$2,100,000
Silo and mill cleaning, per annum	$210,000
Silo maintenance, every five years	$140,000
Micro-feeder capital cost, every 10 years	$420,000
One off packaging, labelling and other costs	$500,000
Industry testing of folic acid levels, per annum	$8,400
Systems audit, one off cost	–
Compliance costs – staff, first three years, and every five years from year five	$22,500
Compliance costs – analytical testing survey, first, third and fifth years, and every five years thereafter	$5,040
Implementation guidance costs, one off cost	–
MPI monitoring survey, first, third and fifth years, and every five years thereafter	$78,000

After deducting the status quo fortification costs, this mandatory fortification of bread making wheat flour scenario would cost an additional $14.1 million over 30 years (discounted 3.5% per annum).

4.5 Mandatory fortification of wheat flour: costs $18.1 million

This scenario would require all non-organic wheat flour to be fortified with folic acid between two and three milligrams per kilogram of flour. We assume that the only differences in cost between this and the bread making wheat flour option are the following.

- The total cost of the folic acid due to more flour being fortified. We estimate that 270,000 tonnes of wheat flour is produced in New Zealand (Access Economics, 2006b, original source: New Zealand Flour Millers Association).
- The one off packaging, labelling and other costs. To estimate this, we scale the costs from the previous option by the volume of flour in this scenario. We estimate this cost to be approximately $700,000.
- Industry testing of folic acid levels costs. Again this is scaled up from the previous option by the volume of flour. We estimate this to be $11,800 per annum including the deadweight cost of taxation adjustment ($9,800 before the adjustment).
- Cost of analytical testing for compliance survey. This is also scaled up from the previous option by the volume of flour. We estimate this to be $7,100 per survey including the deadweight cost of taxation adjustment ($5,900 before the adjustment).. This survey would occur at the same intervals as in the previous option.

Based on this, our estimates for this option are summarised in Table 16.

Table 16 Mandatory fortification of wheat flour cost summary

Cost area	Cost
Cost of folic acid premix, per annum	$675,000
Silo capital cost, every 30 years	$2,100,000
Silo and mill cleaning, per annum	$210,000
Silo maintenance, every five years	$140,000
Micro-feeder capital cost, every 10 years	$420,000
One off packaging, labelling and other costs	$700,000
Industry testing of folic acid levels, per annum	$11,800
Systems audit, one off cost	–
Compliance costs – staff, first three years, and every five years from year five	$22,500
Compliance costs – analytical testing survey, first, third and fifth years, and every five years thereafter	$7,100
Implementation guidance costs, one off cost	–
MPI monitoring survey, first, third and fifth years, and every five years thereafter	$78,000

After deducting the status quo fortification costs, this mandatory fortification of wheat flour scenario would cost an additional $18.1 million over 30 years (discounted 3.5% per annum).

4.6 Other costs not quantified

We have chosen not to quantify a number of other costs or potential costs.

4.6.1 Impact on sales

Consumer purchasing may change if increased fortification occurs. We believe that this impact is likely to be minimal. A previous survey run by MPI found that only 2% of respondents currently avoid products that contain folic acid (MPI, 2017). If fortification were to be made mandatory it is difficult to determine what proportion of people would cease to consume all products that are fortified when little choice exists. Based on talks with industry players, they anecdotally found no immediate impacts of the requirement to use iodised salt in bread.

4.6.2 Impact on export market

A number of industry players were opposed to mandatory fortification due to the impact on the export market in the previous assessment process in 2004-2007. This was due to two main reasons.

- Adding folic acid would detract from the 'natural' image as it is a non-natural additive (noting claims such as 'contains natural ingredients' can be made).

- Adding folic acid would mean that products could no longer market themselves as made with only locally or New Zealand produced ingredients.

From discussions with a number of industry representatives, we understand that some have a similar sentiment this time. However, the opposition due to impacts on exports appears to have decreased since the previous process; many exports are currently fortified with folic acid. In addition, one of the reasons for choosing bread and flour as the vehicle for increasing folic acid intakes is the relatively small export market.

The mandatory option to fortify all non-organic bread would provide bakers more flexibility compared to the other two mandatory options. This is because the bakers would be able to choose to not fortify exported products under this option.

5. Our results are resilient to changes in assumptions

In this section we run a number of scenarios and assumptions to test the resilience of our model. We find some assumptions have material impacts on the costs and benefits, but none are significant enough to change the overall conclusions.

The cost-saving options remain cost-saving under our testing. These results are expected due to the large benefits (relative to costs) these options produce. At a minimum of $3 gained for every $1 invested (plus health benefits), it would require large adjustments to multiple assumptions to change this story.

The mandatory fortification of non-organic bread option continues to compare unfavourably to the other options. Again, this is expected; the large testing costs under this option remain.

5.1 Changing the discount rate

Discounting is used to allow comparison of different timings of costs and benefits in present value terms. While discounting is widely used and accepted, the discount rate used is more variable. Table 17 summarises the impact of a change in discount rate. We test no discounting (0%) and the Treasury default rate (6%).

Table 17 Impact of changing discount rates

Scenario	Discount Rate	Net Monetary Benefits ($millions)	Health Benefits (QALYs)
Enhanced voluntary fortification	3.5%	$12.6 to $40.1	310 to 870
	0%	$65.6 to $190.2	1,350 to 3,750
	6%	$4.9 to $17.6	160 to 440
Mandatory fortification of non-organic bread	3.5%	-$69.1 to -$33.0	840 to 1,570
	0%	$13.4 to $176.9	3,600 to 6,750
	6%	-$65.6 to -$49.0	420 to 800
Mandatory fortification of non-organic bread-making wheat flour	3.5%	$32.2 to $54.6	940 to 1,400
	0%	$189.7 to $291.0	4,050 to 6,000
	6%	$9.9 to $20.2	480 to 710
Mandatory fortification of non-organic wheat flour	3.5%	$54.0 to $97.9	1,470 to 2,360
	0%	$300.4 to $499.4	6,300 to 10,130
	6%	$18.6 to $38.9	740 to 1,200

Using no discount rate increases the net monetary benefits and QALYs gained under each scenario. This is expected as the benefits accrue over a long time (up to the length of a life). The fortification

costs occur in the short-term and therefore are subject to a lesser change from discounting. This changes the mandatory fortification of bread option to be cost saving. However, it does not compare favourably with the other options with no discounting.

The converse is also true. A higher discount rate of 6% generally decreases the net monetary benefits and QALYs gained under each scenario. The three cost-saving scenarios in the base case (3.5% discounting rate) scenario remain cost saving under this scenario.

5.2 Sensitivity to societal benefits of an NTD-affected live birth

Our estimates of fortification benefits are most sensitive to changes to the two productivity impacts. This is expected as these are two of the largest impacts and have large ranges in estimates.

5.2.1 Changing the employment rate

In our base case, we assume that employment rates for spina bifida affected people are the same as those for the disabled population (as defined by Statistics New Zealand survey methodology). This results in a 39% employment rate. However, some studies show employment rates as low as 19% or as high as 63%. Table 18 shows the results of altering the employment rates for an NTD affected person. We choose to test the impact of reducing the employment rate by half, or increasing the employment rate by 50% to approximate the upper and lower limits of our literature search.

Table 18 Impact of adjusting employment rates

Employment rate	Net societal cost of an NTD ($000s, discounted 3.5% p.a.)	Percentage change
15-64: 39%, 65+: 7% (base case)	$938	
15-64: 20%, 65+: 3% (halved employment rate)	$1,045	11%
15-64: 59%, 65+: 10% (+50% employment rate)	$832	-11%

The employment rate has a material impact on our estimates of preventing a single NTD. This is due to productivity losses contributing almost half of all our estimated costs. However, this assumption does not impact overall analysis. The mandatory fortification of bread option remains a net cost, while the other three remain cost-saving. Also, the studies we use for sensitivity analysis are on the extreme ends of the literature employment rate estimates.

5.2.2 Altering the cut-off age for caregiver productivity losses

In our base case, we assume that the productivity losses due to less employment hours for the primary caregiver of a spina bifida affected child are applied for the first 18 years of life. This cut-off point is

somewhat arbitrary; however sensitivity analysis shows that altering this value has only has a material impact on the overall societal costs at the extreme end.

Other analyses (Access Economics, 2006; The Australian Health Ministers' Advisory Council, 2017; YHEC, 2015) have used age cut-offs in line with the traditional end of childhood (17 to 20 years of age). We test the impact of adjusting the cut-off by two years. We also test the impact of a high upper limit of 35 years of age. This is based on:

- the average New Zealand mother's age at birth of 30 (Statistics NZ, n.d.) as an estimate for the average primary caregiver's age at birth
- a retirement age of 65.

Applying a 35 year cut-off overestimates the impact of extending the cut-off age to 35. This is due to decreasing productivity beyond the age of 55. Both labour force participation rate and average hours worked for those employed for the general population decrease after this age (Statistics New Zealand, 2015b). We also believe that this scenario is likely to not eventuate in all cases. Nonetheless, we test this scenario to check the resilience of our model.

Altering the cut-off age by two years has very little impact. Increasing the cut-off age to 35 years has a material impact. However, this is likely to be an overestimate of the true scenario. Even with this included, it does not change the direction of our cost-utility analysis results. Again, the mandatory fortification of bread option remains a net cost, while the other three remain cost-saving.

Table 19 Impact of primary caregiver productivity loss age cut-off

Age cut-off for caregiver productivity loss	Net societal cost of an NTD ($000s, discounted 3.5% p.a.)	Percentage change
18 (base case)	$938	
16	$925	-1%
20	$950	1%
35	$1,018	8%

5.2.3 Other sensitivity testing results

We test a number of other scenarios to assess the resilience of our societal benefit of preventing a live birth from being affected by an NTD. None of these scenarios materially change the results. The results of these scenarios are in Table 20.

Increasing costs for encephalocele

In the base case, we assume that encephalocele has the same societal impacts as spina bifida at each life stage. It is likely that this is not true. However there is little literature on the societal costs of encephalocele specifically. We test a 20% increase in costs for encephalocele relative to spina bifida. This is based on the Australian Health Ministers' Advisory Council (2017) analysis, which applied a

multiplier of 1.2 for ongoing healthcare costs for encephalocele relative to spina bifida. We apply it to all cost categories to test for materiality.

Reducing productivity after primary caregivers return to the workforce

We consider the potential for reduced productivity after returning to the workforce for a primary caregiver. This is due to leaving the workforce to care for their child. We estimate this cost based on the following.

- 17 years of reduced productivity following the return to the workforce. This is based on an average primary caregiver age at birth of 30 years, a retirement age of 65, and 18 years of non-participation in the workforce (as per our base case).
- An absolute 23% reduction in workforce participation during the 18 years of childhood. This is based on Tilford et al. (2009) where there was an absolute 23% reduction in primary caregivers that worked in the previous year of spina bifida affected children compared to the control group.
- A 17% reduction in productivity due to a long-term break from the workforce. This is based on Arun et al. (2004). This study estimated a 17% reduction in pay for women that return to the workforce after a long, child-related break
- The average income figure for the general population.

Healthcare costs are the same after 65 years of age

The Australian Health Ministers' Advisory Council (2017) analysis assumed that there were no differences in costs after 65 years of age between a person affected by spina bifida and the average person. This was based on literature showing that the differences in healthcare costs reduce as age increases.

Altering the cost of inpatient admissions

Inpatient costs make up a large proportion of the healthcare costs for the NTD affected population. We also saw very high estimates of these in the Bowkett and Deveral (2012) study. We test the lower and upper values of the confidence intervals in Ouyang et al. (2007). The confidence intervals are much larger for the youngest and older age groups.

Education support costs

For the base case, we use the midpoint of a number of studies on the proportion of spina bifida patients that might need additional educational support. We test the impact of the lower and higher estimates of our literature search.

Table 20 Testing for materiality of societal cost assumptions

Scenario	Net societal cost of an NTD ($000s, discounted 3.5% p.a.)	Percentage change
Base case	$938	
Encephalocele has a 20% increase in costs relative to spina bifida	$959	2%
Lower productivity for the primary caregiver returning to the workforce	$948	1%
65+ healthcare costs are the same for the NTD population and the general population	$928	-1%
Ouyang (2007) 95% confidence interval lower limit and upper limit for inpatient admissions	$892/$984	±5%
Additional education support rate adjusted by ± 10 %	$912/$964	±3%

5.3 Sensitivity to the costs of fortification

Similar to the societal benefits sensitivity analysis, we run a number of different scenarios to test the resilience of our results.

5.3.1 Differing initial capital costs

We test a halving and doubling in the capital and ongoing maintenance costs required for the mandatory fortification of bread-making and all wheat flour. These large changes materially impact our cost estimates. However, with at most a 53% increase in costs, this would not change the overall result of the cost-utility analysis, with these two options remaining cost-saving with additional health benefits.

5.3.2 Differing costs of folic acid

This could be caused due to variations in estimates of the food vehicle (i.e. volume changes) or the price of the folic acid itself. We estimate a variation in the price for folic acid of 20%, and also a change in volume under each scenario of 20%. These changes materially impact the costs of fortification. This is most seen in the enhanced voluntary fortification option as folic acid costs represent a large proportion of the total costs of this option. However, none of these changes are significant enough to change the overall nature of the cost-utility analysis results.

5.3.3 Differing costs of labelling changes and packaging write-offs

To test resilience we test a large change (a halving and a doubling) in the costs of labelling changes and packaging write-offs under the mandatory fortification scenarios. These changes have very little impact on the overall costs of any of the proposals. This is expected as it is a one-off cost and therefore makes up a small proportion of the total costs.

Table 21 Testing for materiality of fortification cost assumptions

Scenario	Enhanced voluntary fortification	Mandatory fortification of non-organic bread	Mandatory fortification of non-organic bread-making wheat flour	Mandatory fortification of non-organic wheat flour
Base case	$2.9	$110.3	$14.1	$18.1
Capital and maintenance costs halved/doubled	No change	No change	$10.4/$21.6 -26%/53%	$14.4/$25.6 -21%/41%
Folic acid price adjusted ± 20 %	$2.4/$3.3 ±17%	$108.8/$111.9 ±1%	$12.8/15.5 ±9%	$16.0/$20.2 ±11%
Food vehicle volume adjusted ± 20 % (no change to status quo)	$1.9/$3.8 ±34%	$108.3/$112.4 ±2%	$12.3/$16.0 ±13%	$15.5/$20.7 ±14%
Labelling changes and packaging write-off costs halved/doubled	No change	$110.2/$110.6 0%/0%	$13.9/$14.6 -2%/4%	$17.8/$18.8 -2%/4%

Dollar values are in millions. Percentage changes are shown below

Appendix A: Types of NTD

The three forms of congenital defects we include under the definition of NTD in our report are spina bifida, anencephaly and encephalocele. A breakdown of the proportions of live birth-prevalence over the past few years are in Table 22. These proportions are used in our calculation of the weighted average life-expectancy.

Spina bifida is the most common type of NTD. It occurs when the opening, from the neural tube failing to close, occurs in the spine. The severity of the defect is related to location of the opening; openings in the upper spine are more severe than those in the lower spine.

Anencephaly occurs when the neural tube fails to at the head end. This results in the absence of large portions of the brain and skull. As such, if the child survives birth, it is unlikely that they will survive past a week.

Encephalocele occurs when brain tissues protrude through an opening in the skull. The severity can depend on the location of the opening and the type of brain tissue involved.

Table 22 Proportion of NTDs by type

	Spina bifida	Anencephaly	Encephalocele
Proportion of live births	78%	8%	14%

Source: Ministry for Primary Industries, (2018)

Appendix B: Detailed health care cost estimates

The detailed estimates we use in our health care cost estimates are provided in this appendix. The unit costs of the health care services and products are detailed in Table 23. Table 24 details the units of each health care service and product used by age group.

Table 23 Unit costs for healthcare services and products

Health Care Category	Cost	Source
Intensive care unit, cost per day	$5,500	Pharmaceutical Management Agency (2018)
Inpatient admission, cost per day	$1,250	Pharmaceutical Management Agency (2018), Fraser & Nolan (2017) The NCCP Casemix – Cost Weights Project Group (2018)
Assistive technology – walking aids, cost per year	$50	Mobility Centre
Assistive technology – orthoses, cost per year	$200	Mobility Centre
Assistive technology – wheelchair, cost per year	$450	Mobility Centre
Outpatient specialist visit (initial), cost per visit	$350	Pharmaceutical Management Agency (2018)
Outpatient specialist visit (subsequent), cost per visit	$250	Pharmaceutical Management Agency (2018)
GP Visit, cost per visit	$80	Pharmaceutical Management Agency (2018)

Table 24 Health care cost for people with spina bifida – by age group

Health Care Category	Units	Annual Cost	Comment	Source for Units
Age: 0				
Inpatient costs	12 days (10 days ICU, 2 days other)	$57,500	Includes cost of neonatal surgeries and other inpatient days	Spina Bifida Association (2015), Ouyang, et al. (2007), Centers for Disease Control and Prevention (2007)
Outpatient costs	27 visits	$5,100	Includes 6 initial specialist visits, 7.5 subsequent and 13.5 GP visits	Ouyang, et al. (2007)

Health Care Category	Units	Annual Cost	Comment	Source for Units
Age: 1 – 17				
Inpatient costs	2.7 days	$3,400		Ouyang, et al. (2007), Bowles, et al. (2014)
Outpatient costs	22 visits	$3,600	11 specialist and 11 GP visits	Ouyang, et al. (2007), Bowles, et al. (2014)
Assistive technology	N/A	$400	Weighted average of the various assistive technology	Dicianno, et al. (2009), Johnson, et al. (2007)
Age: 18 – 64				
Inpatient costs	2.8 days	$3,500		Ouyang, et al. (2007), Bowles, et al. (2014)
Outpatient costs	24 visits	$4,000	12 specialist and 12 GP visits	Ouyang, et al. (2007), Bowles, et al. (2014)
Assistive technology	N/A	$400	Weighted average of the various assistive technology	Dicianno, et al. (2009), Johnson, et al. (2007)
Age: 65+				
Inpatient costs	2.7 days	$3,400		Ouyang, et al. (2007), Bowles, et al. (2014)
Outpatient costs	26 visits	$4,300	11 specialist and 11 GP visits	Ouyang, et al. (2007), Bowles, et al. (2014)
Assistive technology	N/A	$400	Weighted average of the various assistive technology	Dicianno, et al. (2009), Johnson, et al. (2007)

Figures are rounded to the nearest hundred

Appendix C: Differences between dietary intakes and production levels

The reduction in NTD prevalence was estimated by MPI, and further information on their modelling can be found in their technical report. Their modelling used nutritional surveys to assess the impacts of each fortification option on the dietary intake of folic acid, based on the different foods consumed. This type of modelling looks at food intakes by individuals.

Our modelling of the required levels of folic acid is based on research on the production levels of the relevant food vehicle. This methodology takes a more natiational/population approach.

As can be expected from using different data sources, there are some differences in folic acid consumption modelled by MPI and our modelling of folic acid used in production. The main differences occur under each of the mandatory fortification options; where our estimates are higher. We believe that the differences between our two models can be explained by a number of factors including the below.

- The definition of the relevant foods. The MPI modelling only increased folic acid concentrations in foods that fell under the strict definition of the relevant food vehicle. Our modelling uses data that was often sourced from industry, and therefore may include products that are not in the strict definition. These products may be similar from a producer point of view and therefore may be fortified as well.[10] This is highlighted by the closeness in our estimates of folic acid intakes in the status quo and enhanced voluntary fortification scenarios. The definition of packaged sliced bread produced by NZAB member in these scenarios is more likely to be well understood.

- Foods produced, but not consumed. There are a number of areas where foods might be produced but not consumed by New Zealanders. These include food wastage and exports, although, as previously noted exports are low. Bread wastage by the consumer has been estimated to be approximately 15,200 tonnes per year (Love Food Hate Waste, n.d.). In addition to this, there is wastage that occurs before the consumer (e.g. thrown out by the retailer or the producer).

Both approaches take a conservative approach to modelling. The MPI approach ensures that only foods that will definitely be fortified and consumed impact on NTD birth-prevalence. Our approach ensures that all costs of fortification will be included in the model. On balance, we believe that, by taking the conservative approach on both the benefit and costs, the cost-effectiveness results in this report are likely to be understated.

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[10] For instance, bread is defined as "*the product made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water*" in the Australia New Zealand Food Standards Code. Some similar products that do not meet this definition but might be included by industry are: crumpets, pancakes, scones, croissants, muffins and donuts.

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