Aortic Stenosis – 
Tier 2 Overview
National Health Committee (NHC)

The National Health Committee (NHC) is an independent statutory body charged with prioritising new and existing health technologies and making recommendations to the Minister of Health.

It was re-formed in 2011 to establish evaluation systems that would provide the New Zealand people and the health sector with greater value for money invested in health.

The NHC executive is the secretariat that supports the committee. The NHC executive’s primary objective is to provide the committee with sufficient information for it to make decisions regarding prioritisation and reprioritisation of interventions and services. They do this through a range of evidence-based products chosen according to the nature of the decision required and timeframe within which decisions need to be made.

The New Zealand Government has asked that all new diagnostic and treatment (non-pharmaceutical) services, and significant expansions of existing services, are to be referred to the NHC.

In August 2011 the NHC was appointed with new terms of reference and a mandate to establish the capacity to assess new and existing health technologies. Its objectives (under Section 4.2 of its terms of reference – www.nhc.health.govt.nz) include contributing to improved value for money and fiscal sustainability in the health and disability sector by:

- providing timely advice and recommendations about relative cost-effectiveness based on the best available evidence;
- providing advice and recommendations which influence the behaviour of decision-makers, including clinicians and other health professionals;
- providing advice and recommendations which are reflected in resource allocation at national, regional and local levels; and
- contributing to tangible reductions in the use of ineffective interventions and improved targeting to those most likely to benefit.

In order to achieve its objectives under Section 4.2 and to achieve ‘value for money’, the NHC has adopted a framework of four assessment domains – clinical safety and effectiveness; economic; societal and ethical; and feasibility of adoption – in order that assessments cover the range of potential considerations and that the recommendations made are reasonable.

It is intended that the research questions asked will fall across these domains to ensure that when the committee comes to apply its decision-making criteria, it has a balanced range of information available to it. When the NHC is setting those questions, they will have the decision-making criteria in mind.

The 11 decision-making criteria will assist in the determination of the NHC work programme and in the appraisal and prioritisation of assessments.
Executive summary

Aortic stenosis (AS) is responsible for the deaths of about 300 New Zealanders a year. The primary cause of AS is ageing, where calcium deposits build up in the aortic valve, narrowing it over time. Calcification of the valve happens more frequently in people who are born with abnormal aortic valves. Unlike other heart conditions, there are very few preventative strategies for AS. Patients face a poor prognosis once the disease becomes clinically evident, either with the onset of symptoms or with deterioration in left ventricular function. The life expectancy of patients with clinically evident AS without intervention is two to three years, with sudden death occurring in up to a third of these patients.

For clinically evident AS, the standard of care is surgical aortic valve replacement, which is a highly effective intervention that can return patient quality of life and life expectancy to normal. Today, about $30 million is spent annually on aortic valve replacement (AVR) operations for patients with aortic stenosis. Assuming today’s cost for AVR, public expenditure is expected to increase to about $40 million per annum by 2025/26.

The past decade has seen a significant increase in the number of AVR operations undertaken and a technology shift away from mechanical valves, towards bioprosthetic valves and less invasive surgery. At the same time, mortality from AS has declined significantly, from about four deaths per 100,000 New Zealanders in 2000 to about three deaths per 100,000 New Zealanders in 2011. As part of a global trend, two AVR technologies have emerged in New Zealand since 2008. These are transcatheter aortic valve implantation (TAVI) and sutureless AVR. Whilst the technologies hold promise for high-risk surgical patients, it is important that they are properly assessed to ensure their appropriate use.

AVR is an exceptionally effective intervention for many patients. It is important, however, that new forms of AVR, namely TAVI and sutureless AVR, are used appropriately to continue to improve patient outcomes in the context of prudent use of available public funding. The main conclusion of this Tier 2 assessment, therefore, is that TAVI and sutureless AVR are assessed and that New Zealand relevant data be collected to guide their appropriate use.
Purpose

This report synthesises current evidence about the use of transcatheter aortic valve implantation (TAVI) for the treatment of severe aortic stenosis (AS) in New Zealand. Its purpose is to enable the National Health Committee to make recommendations on the role and value of TAVI in the model of care for severe aortic stenosis that ensure that the New Zealand public get the highest quality care, and that as a nation, we can afford that care.
## Contents

Executive summary .............................................................................................................................. 3  
Purpose ............................................................................................................................................... 4  
Introduction .......................................................................................................................................... 7  
Causes of aortic stenosis ..................................................................................................................... 8  
Burden of disease ................................................................................................................................ 8  
Aortic stenosis comorbidities .............................................................................................................. 13  
Treatment for aortic stenosis ............................................................................................................. 15  
Indications for aortic valve replacement ............................................................................................. 16  
Trends in aortic valve replacement .................................................................................................... 18  
Transcatheter aortic valve implantation .............................................................................................. 20  
Sutureless aortic valve replacement .................................................................................................. 21  
Minimally invasive aortic valve replacement surgery ........................................................................ 21  
Risk stratification ................................................................................................................................ 22  
Forecast aortic valve replacement demand and expenditure ............................................................. 30  
Model of care for severe aortic stenosis ............................................................................................. 31  
Conclusion ......................................................................................................................................... 37  
References ........................................................................................................................................ 39  
Appendix 1: Projected expenditure on publicly funded AVR by region .............................................. 43  
Methods ............................................................................................................................................. 44
Introduction

The aorta is the main artery that carries blood out of the heart to the rest of the body. Stenosis means narrowing. In aortic stenosis (AS), the aortic valve is narrowed to the point that it does not open fully, decreasing blood flow from the heart. In the early stages of the disease, people with AS may be asymptomatic without any increased risk of death \(^{(1)}\) or detriment to quality of life.\(^{(2)}\) Symptoms of AS include angina (chest pain), breathlessness when exercising, fatigue, heart palpitations, and syncope (fainting).\(^{(3)}\) Patients face a poor prognosis once the disease becomes clinically evident, either with the onset of symptoms or with deterioration in left ventricular function. Left untreated, clinically evident AS can lead to heart failure and sudden death. The life expectancy of patients with clinically evident AS without intervention is two to three years, with sudden death occurring in up to a third of patients.\(^{(4,5)}\)

This Tier 2 assessment paper sits within the National Health Committee's (NHC's) cardiovascular disease (CVD) work programme.\(^{(6)}\) In New Zealand valvular disease is the third-largest burden of disease within CVD after ischaemic heart disease and stroke (Figure 1). The NHC has a concurrent work stream for ischaemic heart disease (IHD), and has produced a similar Tier 2 assessment paper for IHD.\(^{(7)}\) With respect to stroke, the NHC has undertaken two Tier 3 assessments on interventions for atrial fibrillation: catheter cardiac ablation,\(^{(8)}\) and percutaneous left atrial appendage occlusion.\(^{(9)}\)

Figure 1: Disability adjusted life years lost attributed to CVD 2010

![Diagram showing disability adjusted life years lost attributed to CVD 2010]

Source: NZBDS 2013\(^{(10)}\)

This paper gives background to the burden of AS in New Zealand, including its prevalence, incidence and treatment. It outlines trends in AVR including the emergence of TAVI and sutureless AVR, and estimates current and future expenditure on all AVR.
Causes of aortic stenosis

Severe AS has been defined as a peak aortic valve velocity of >4 m per second, corresponding to a mean aortic valve gradient >40 mm Hg, and an aortic valve area of < 0.8 cm²(11, 12) There is also a small group of patients that may benefit from aortic valve replacement who have asymptomatic AS, but have left ventricular dysfunction, with a left ventricular ejection fraction of less than 50%. About 5-10% of patients with severe AS have LV dysfunction (LVEF<50%). (13)

The primary cause of AS is ageing, where calcium deposits build up in the aortic valve, narrowing it over time. Age-related AS is also sometimes referred to as ‘degenerative AS’. A normal (tricuspid) aortic valve has three leaflets, whereas about 1% of people are born with a bicuspid aortic valve, and a very small number of people (~0.02%) are born with a unicuspid aortic valve.(14, 15) Calcification of the valve happens more frequently in people who are born with abnormal aortic valves(3) – congenitally bicuspid valves are the second most common cause of AS. (16)

Rheumatic fever can also cause AS, when the body’s immune response to strep throat or scarlet fever attacks the heart. Although New Zealand has a high rate of rheumatic fever compared with other developed countries,(17) it remains a relatively uncommon cause of aortic stenosis. Less than 2% of AS hospital presentations in New Zealand for aortic stenosis are for rheumatic AS (discussed below).

Burden of disease

In 2011, 295 deaths were attributed to aortic stenosis in New Zealand. The age standardised rate of AS mortality has declined from about 4.0 deaths per 100,000 in the year 2000 to 3.0 deaths per 100,000 population in 2011. This trend is statistically significant when controlling for gender (p= <0.001) (Figure 2).

Figure 2: Age standardised aortic stenosis mortality in New Zealand 2000-2011

Source: National Mortality Collections, using ICD procedure codes I060, I062: Rheumatic AS, I350,I352: Non-rheumatic AS. ASR = Age standardised rate which is standardised to WHO standard world population.
More than 80% of deaths were for people aged 80 years or older. Just two of these deaths were for people diagnosed with rheumatic AS. Māori have a lower rate of AS mortality than non-Māori, with an age standardised rate of 1.3 per 100,000 population compared with an age standardised rate (ASR) of 3.1 for non-Māori (Table 1).

### Table 1: Crude and age standardised aortic stenosis mortality 2011

<table>
<thead>
<tr>
<th></th>
<th>Rheumatic aortic stenosis</th>
<th>Non-rheumatic aortic stenosis</th>
<th>Total aortic stenosis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Deaths</td>
<td>Deaths</td>
<td>Deaths</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>293</td>
<td>295</td>
</tr>
<tr>
<td>Māori</td>
<td>0</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Non-Māori</td>
<td>2</td>
<td>289</td>
<td>291</td>
</tr>
</tbody>
</table>


### 1.1 Prevalence and incidence of aortic stenosis

In the absence of published data, we have used the New Zealand National Minimum Dataset (NMDS)\(^1\) to estimate the prevalence of publicly-funded hospital diagnosed AS. Through the NMDS, we identified people with any diagnosis of AS (either rheumatic or non-rheumatic) between July 2005 and June 2013.\(^2\) Methods are described in detail from page 44. In brief, patients with any diagnosis of AS were identified and counted if they were still alive at 30 June 2012/13 and had not been recorded as having received an aortic valve replacement. Incidence was recorded as the number of new diagnoses of AS during the financial year 2012/13.

In 2012/13, the prevalence of any hospital diagnoses of AS was 103 per 100,000 population or approximately 4,700 patients (Table 2). Of these patients, 48 were recorded as having rheumatic AS. Patients were recorded as having AS if they were still living in 2012/13 and had received any diagnosis of AS since 2005/06. Incidence was 36 cases per 100,000 population, counting any patient who received a publicly funded hospital diagnosis of AS in 2012/13. Both incidence and prevalence estimates are likely to undercount the true population affected by aortic stenosis. Some patients may only receive a primary care diagnosis of AS whilst others may be left undiagnosed (particularly asymptomatic cases).

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1 The NMDS records all publicly funded inpatient and day case events.

2 All patients were alive and diagnosed in hospital. Due to coding changes, data on aortic stenosis specifically are only available since 2000 in the NMDS.
Table 2: Prevalence and incidence of any hospital diagnosis of aortic stenosis 2012/13

<table>
<thead>
<tr>
<th></th>
<th>0-49</th>
<th>50-69</th>
<th>70+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>3,088,446</td>
<td>1,019,153</td>
<td>423,432</td>
<td>4,531,031</td>
</tr>
<tr>
<td>Incidence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incidence rate per 100,000</td>
<td>53</td>
<td>294</td>
<td>1,264</td>
<td>1,611</td>
</tr>
<tr>
<td>Prevalence</td>
<td>177</td>
<td>708</td>
<td>3,790</td>
<td>4,675</td>
</tr>
<tr>
<td>Prevalence rate per 100,000</td>
<td>6</td>
<td>68</td>
<td>865</td>
<td>103</td>
</tr>
<tr>
<td>Rheumatic fever AS prevalence</td>
<td>13</td>
<td>12</td>
<td>23</td>
<td>48</td>
</tr>
<tr>
<td>Prevalence rate for AS rheumatic fever per 100,000</td>
<td>0</td>
<td>1</td>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>

Source: NHC analysis of NMDS

1.1.1 Prevalence and incidence of severe aortic stenosis

Just over a third of all patients with a hospital diagnosis of AS in 2012/13 had a primary diagnosis of aortic stenosis. A primary hospital diagnosis is likely to represent a more severe population. The prevalence of severe AS is estimated at 38 per 100,000 population or approximately 1,703 patients. Of these patients, 23 were recorded as having rheumatic aortic stenosis. Prevalence is roughly twice incidence. Incidence was 19 cases per 100,000 population, ranging from one patient per 100,000 population for those under 50, to 145 per 100,000 population for those aged over 70. There were 860 new cases of severe AS in 2012/13 (Table 3).

Table 3: Prevalence and incidence of a primary hospital diagnosis of aortic stenosis 2012/13

<table>
<thead>
<tr>
<th></th>
<th>0-49</th>
<th>50-69</th>
<th>70+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
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<td>1,019,153</td>
<td>423,432</td>
<td>4,531,031</td>
</tr>
<tr>
<td>Incidence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incidence rate per 100,000</td>
<td>34</td>
<td>213</td>
<td>613</td>
<td>860</td>
</tr>
<tr>
<td>Prevalence</td>
<td>91</td>
<td>345</td>
<td>1,267</td>
<td>1,703</td>
</tr>
<tr>
<td>Prevalence rate per 100,000</td>
<td>3</td>
<td>33</td>
<td>289</td>
<td>38</td>
</tr>
<tr>
<td>Rheumatic fever AS prevalence</td>
<td>6</td>
<td>7</td>
<td>10</td>
<td>23</td>
</tr>
<tr>
<td>Prevalence rate for AS rheumatic fever per 100,000</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Source: NHC analysis of NMDS

1.1.2 Incidence of asymptomatic severe aortic stenosis with left ventricular dysfunction

American Heart Association/American College of Cardiology guidelines indicate that aortic valve replacement may be indicated in both patients with severe symptomatic AS, and patients with severe asymptomatic AS with LV dysfunction (LVEF<50%).

This group of patients is likely to be very small. About 5-10% of patients with severe AS have LV dysfunction (LVEF<50%). About 75% of severe AS patients are symptomatic, and the proportion may be greater for severe AS with LV dysfunction. Assuming that 25% of severe AS patients with LV dysfunction are asymptomatic, this implies about 1.25% to 2.5% of severe AS patients have asymptomatic AS with LV dysfunction and may be eligible for aortic valve replacement. The patient group is discussed further below, but in practical terms we expect that annual incidence of severe asymptomatic AS with LV dysfunction is less than 30 patients (discussed further p26).
1.1.3 International estimates of severe symptomatic aortic stenosis prevalence

Two large prospective general population based studies have used echocardiography to assess the population prevalence of aortic stenosis. A US study (n=11,911) pooled the records of three large US population based epidemiological studies. It reported population prevalence for moderate or severe AS of 0.4% in adults aged 18 years or older, with a prevalence of 1.8% in those aged 65 or older. A Norwegian study (n=3,273) reported rates of aortic stenosis increasing from 3.9% in those aged 70-79 to 9.8% in those aged 80-89. Approximately two-thirds of the 164 cases of AS were mild or moderate. Thirty-four of the identified patients underwent AVR, with an additional 26 cases identified as severe AS and not treated with AVR. Applying New Zealand population weights, and assuming 75% of severe cases are also symptomatic, the data implies that a little less than 2% of patients aged between 50-89 had severe symptomatic AS (Table 4).

Table 4: Estimation of severe aortic stenosis population using Norwegian data

<table>
<thead>
<tr>
<th></th>
<th>70-79</th>
<th>80-89</th>
<th>Sum</th>
</tr>
</thead>
<tbody>
<tr>
<td>NZ population</td>
<td>3.90%</td>
<td>9.80%</td>
<td>3.90%</td>
</tr>
<tr>
<td>AS patients</td>
<td>268,518</td>
<td>132,593</td>
<td>401,111</td>
</tr>
<tr>
<td>Symptomatic severe AS*</td>
<td>32.6%</td>
<td>3416</td>
<td>4239</td>
</tr>
</tbody>
</table>

Source: Statistics NZ population for 2012/13. * We assume all patients who received AVR were symptomatic severe and 75% of severe cases were symptomatic.

We would expect to derive a lower estimate of the prevalence of AS compared with an active strategy of surveying the general population using echocardiography. Our estimate, using hospital records alone, is however, useful in understanding demand as it presents at hospital. Table 5 places our New Zealand estimate of severe symptomatic AS, which counts cases of primary diagnosed AS, alongside estimates recorded in a systematic review, where all studies used echocardiography to assess population prevalence. As is evidenced, rates vary significantly across studies. The studies considered are all cross-sectional in nature and use differing ages for inclusion. Differences in estimates of prevalence between the studies may be partly explained by methodological differences; recruitment, response rates, and criteria used to define severe AS.

The methods of recruitment make some studies more prone to selection bias than others. Lindroos used random selection from a population register; Van Bemmel recruited from all inhabitants in a district; and Vaes selected patients from general practice registers. These may be expected to provide a representative sample of the general population. In contrast Nkomo selected patients who were undergoing echocardiography, presumably after presenting to health services; while Lin sampled individuals presenting for health checks. Nkomo is likely to over-estimate prevalence as the individuals are likely to be less healthy, having presented at health service. The Lin method may inflate or deflate the estimate: whether individuals present to check-ups because they are prompted by a health concern or because more healthy individuals tend to use preventative services more than unhealthy ones.
The response rate is unclear for Lin, and Vaes, and at least 71% in the other studies. All the studies used doppler echocardiography to assess the aortic valves. The criteria used to define an individual as a case of severe AS vary between studies. Lin used the sole criterion of pressure gradient cross the valve with a cut-off of >50mmHg. This value is more strict than the standard definition of >40mmHg, so tending to under-estimate prevalence. Van Bemmel used a single criterion of pressure gradient with the same cut-off value standard definition. Lindroos and Nkomo use two criteria for valvular area but are less strict than the standard definitions and so would tend to over-estimate prevalence of severe AS.

The largest of these studies is a cross-sectional study of Olmsted County Minnesota in the United States. The study is a sub-study of the aforementioned US study of 11,911 patients. Again, we have assumed that 75% of severe AS cases are symptomatic.

### Table 5: Estimation of severe symptomatic aortic stenosis in those aged 70 or older

<table>
<thead>
<tr>
<th>Year/author</th>
<th>Country</th>
<th>Cases/sample</th>
<th>% (95% CI)</th>
<th>Severe symptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993 (Lindroos)</td>
<td>Finland</td>
<td>18/476</td>
<td>3.78 (2.26, 5.91)</td>
<td>2.86%</td>
</tr>
<tr>
<td>2005 (Lin)</td>
<td>Taiwan</td>
<td>5/82</td>
<td>6.10 (2.01, 13.66)</td>
<td>4.61%</td>
</tr>
<tr>
<td>2006 (Nkomo)</td>
<td>USA</td>
<td>87/6663</td>
<td>1.31 (1.05, 1.61)</td>
<td>0.99%</td>
</tr>
<tr>
<td>2010 (Van Bemmel)</td>
<td>Netherlands</td>
<td>1/81</td>
<td>1.23 (0.03, 6.99)</td>
<td>0.93%</td>
</tr>
<tr>
<td>2012 (Vaes)</td>
<td>Belgium</td>
<td>33/556</td>
<td>5.94 (4.12, 8.23)</td>
<td>4.49%</td>
</tr>
<tr>
<td>2012/13</td>
<td>NZ</td>
<td>1,703/269840</td>
<td>0</td>
<td>0.24%</td>
</tr>
</tbody>
</table>

Source: (19)

### 1.1.4 Projected incidence of severe aortic stenosis

As incidence of AS is greatest in older age groups, population ageing can be expected to increase the incidence of AS. A straight line extrapolation of current AS incidence using Statistics New Zealand population forecasts indicates that there will be approximately 1,300 admissions with a primary diagnoses of AS by 2025/26.

The northern region is expected to see the greatest growth in AS at 3.7% per annum, while the central region is expected to see the lowest growth at 2.7% per annum (Figure 3).
Figure 3: Forecast incidence of severe aortic stenosis

Note: A table of the above data is available in appendix one

Source: NHC analysis of NMDS, using annual population projections supplied by Statistics NZ

**Aortic stenosis comorbidities**

The majority (85%) of patients with severe AS in 2012/13 were suffering from at least one of nine comorbid conditions, and over a quarter (27%) had at least three of these conditions. Figure 4 presents the proportions of AS patients experiencing the conditions analysed. These patients are a lot more likely to have ischaemic heart disease and heart failure than a similarly aged group of people (the 65+ years group has a mean age 76).
To adjust for age more systematically, a logistic regression was carried out (Table 6). This confirmed the significant effects of IHD and heart failure. Dementia was significantly less likely to be experienced by patients with severe AS compared with the general population aged 65 or older. While not large, the odds of severe AS patients experiencing gout, stroke and diabetes are higher than those without severe AS when adjusting for age.
Table 6: The odds of severe aortic stenosis patients suffering comorbid specific long-term conditions, when adjusting for age – 2012/13

<table>
<thead>
<tr>
<th>Long-term condition</th>
<th>Odds ratio</th>
<th>95% Confidence Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischaemic heart disease</td>
<td>10.512</td>
<td>9.816</td>
</tr>
<tr>
<td>Heart failure</td>
<td>2.347</td>
<td>2.14</td>
</tr>
<tr>
<td>Stroke</td>
<td>1.348</td>
<td>1.25</td>
</tr>
<tr>
<td>Gout</td>
<td>1.304</td>
<td>1.213</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1.164</td>
<td>1.089</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>1.07</td>
<td>0.997</td>
</tr>
<tr>
<td>Mood or anxiety disorder</td>
<td>1.023</td>
<td>0.933</td>
</tr>
<tr>
<td>Cancer</td>
<td>0.913</td>
<td>0.776</td>
</tr>
<tr>
<td>Dementia</td>
<td>0.615</td>
<td>0.533</td>
</tr>
</tbody>
</table>

Source: 2015 NHC executive analysis of 2012/13 New Zealand Health Tracker data

People with IHD have insufficient blood and oxygen flow to the heart muscle. This means not only are these patients suffering from severe AS, but for two-thirds, their heart function is additionally compromised due to IHD, warranting aggressive treatment.

**Treatment for aortic stenosis**

There are few preventative measures for AS and no proven medical therapy to prevent its progression.3(16, 25) Medical therapy is instead focused on symptom relief.(26) Patients with asymptomatic AS mostly do not require treatment. The focus of the NHC’s work has, therefore, been concentrated on patients with clinically evident aortic stenosis. For patients with severe symptomatic aortic stenosis, or severe AS with significant left ventricular dysfunction, surgical AVR is the standard of care.(26) AVR can restore a patient’s quality of life and life expectancy to close to that seen in the absence of AS.27(24) Standard surgical AVR involves open heart surgery, requiring cardiopulmonary bypass to replace the diseased aortic valve with a prosthetic valve. There are two types of prosthetic valve: mechanical valves that may last up to 25 years but require the recipient to take anticoagulants to prevent stroke, and bioprosthetic (‘tissue’) valves that last 10-15 years but do not require anticoagulation.(16, 28, 29)

Not all patients with aortic valve disease are candidates for surgical AVR. Operations are complex and durability is limited.(16) Other treatment options for AS include surgical valve repair and balloon aortic valvuloplasty, which have a very limited role in adults with aortic stenosis. Balloon aortic valvuloplasty may occasionally be used as a bridge to surgical AVR, to test if AVR is likely to be beneficial, or for palliative care.

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3 Rheumatic fever can be prevented, and there is a significant government programme focused on this, but rheumatic fever is not a major cause of aortic stenosis: [http://www.health.govt.nz/our-work/diseases-and-conditions/rheumatic-fever](http://www.health.govt.nz/our-work/diseases-and-conditions/rheumatic-fever)

4 Aortic valve replacement also has indications outside of aortic stenosis including aortic regurgitation, aortic dissection, and endocarditis. This overview is concerned only with aortic valve replacement for aortic stenosis.
1.1.5 Medical management

We identified patients as 'medically managed' if they had a primary diagnosis of AS from 1 July 2005 to 30 June 2012 and had no aortic valve replacement recorded up to 30 June 2013. Using this method (described in full p.44), there were 810 prevalent cases of which 296 cases were new (incident cases).

The estimate is limited in that not all patients may be receiving appropriate medical management and some may have privately funded an aortic valve replacement for which our records are limited. Nevertheless, the estimate does correspond with Australian data, where the Medical Services Advisory Committee (MSAC) has estimated that about 4,200 Australians receive medical management for severe symptomatic AS. On a population basis (23.13 million vs 4.47 million, 2013) that roughly translates to 812 medically managed patients in New Zealand.

1.1.6 Volume of aortic valve replacements

In 2012/13 there were 776 publicly funded aortic valve replacements, of which 572 had any diagnosis of AS and 511 had a primary diagnosis of AS. Publicly funded procedures include those performed in public and private hospitals. Reporting on privately funded cases is limited, but a recent Ministry of Health paper on privately funded hospital discharges reported 38 aortic valve replacements, for any cause, in 2012/13.

<table>
<thead>
<tr>
<th>Number of AVR (surgical, TAVI or sutureless)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any diagnosis</td>
</tr>
<tr>
<td>Any diagnosis of AS</td>
</tr>
<tr>
<td>Primary diagnosis of AS</td>
</tr>
</tbody>
</table>

Source: NHC analysis of NMDS

Indications for aortic valve replacement

As noted, the primary cause of AS is ageing, where calcium deposits build up in the aortic valve, narrowing it over time. Aortic valve replacement is a treatment, mostly for older people, when their AS becomes symptomatic or with deterioration in left ventricular function. Mostly aortic valve replacement is for AS. More than three-quarters of aortic valve replacements were undertaken on people with (any diagnosis of) AS or a combination of AS and aortic insufficiency in 2012/13. Aortic insufficiency (failure of the valve to close properly), alone accounts for 10 percent of valve replacements; 13% had a diagnosis of multiple valve disease; and 8% were diagnoses with congenital malformations of the aortic valve (Figure 5).

http://data.worldbank.org/indicator/SP.POP.TOTL
Amongst patients with AS, the primary reason for receiving an aortic valve replacement changes with age. A United States study of 932 adults who underwent surgery with non-rheumatic AS found 46% of patients had normal (tricuspid) valves, while 54% had congenitally abnormal valves – unicuspid (5%) or bicuspid (49%). The study excluded patients under the age of 26. In the younger age groups (under 50), surgery was predominantly the result of congenitally abnormal valves, whilst in the older age groups calcific AS was more important cause of treatment (Table 8). Of the 932 patients in the study:

- 7% were aged 26-50 years, with just under two-thirds having a bicuspid valve and one-third having a unicuspid valve.
- 40% of patients who underwent surgery were between the ages of 51 and 70, about two-thirds had a bicuspid valve and one-third a tricuspid (normal) valve.
- 53% of patients who underwent surgery were over age 70, about 60% had a tricuspid valve and 40% had a bicuspid valve.

In 2012/13, similar proportions of patients in New Zealand received surgical AVR by age cohort as demonstrated in the US study. There were 489 publicly funded surgical aortic valve replacements in 2012/13 with any diagnosis of AS (including bioprosthetic and mechanical valves, but excluding TAVI and sutureless AVR and valve replacement for rheumatic aortic stenosis). We report the split in Table 8 to indicatively suggest the possible disease etiology in New Zealand.
Table 8: Age and indications for patients receiving publicly funded surgical AVR

<table>
<thead>
<tr>
<th></th>
<th>0-25</th>
<th>26-50</th>
<th>51-70</th>
<th>≥71</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roberts and Ko</td>
<td>NA</td>
<td>7%</td>
<td>40%</td>
<td>53%</td>
<td>100%</td>
</tr>
<tr>
<td>Total patients</td>
<td>NA</td>
<td>1%</td>
<td>65%</td>
<td>4%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>NZ 2012/13</td>
<td>20</td>
<td>2%</td>
<td>35%</td>
<td>61%</td>
<td>100%</td>
</tr>
<tr>
<td>Surgical AVR</td>
<td>150</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total patients</td>
<td>318</td>
<td></td>
<td></td>
<td></td>
<td>489</td>
</tr>
</tbody>
</table>

Source: (32), NHC analysis of NMDS. AVR includes any diagnosis of AS but rheumatic aortic stenosis

Trends in aortic valve replacement

Two major trends have been observed over the past decade in AVR. Firstly, there has been a worldwide shift towards increased use of bioprosthetic valves. (33) Bioprosthetic valves avoid the need for anticoagulation but are less durable than mechanical valves. There appears to be little difference in patient survival between mechanical and bioprosthetic valves. (12) Bioprosthetic valves are, however, recommended for patients over the age of 70, where valve durability may be less important, and for younger patients with an absolute contraindication to anticoagulation. (11) The majority of patients undergoing valve replacement are over the age of 70, partially explaining the current preference for bioprosthetic valves. Secondly, there has been an emergence of less invasive aortic valve procedures, (33) both percutaneous and minimally invasive surgery, that are reporting similar safety and effectiveness to conventional surgery. Two relatively new AS technologies: transcatheter aortic valve implantation (TAVI) and sutureless aortic valve replacement (discussed below), exemplify the trends. Both interventions use bioprosthetic valves and may be undertaken less invasively than conventional surgery. Both interventions have been referred to the NHC for assessment, and are proposed for high surgical risk patients.

Figure 6 shows the rise in the total number of publicly funded AVR’s for any diagnosis of AS over the past 12 years. Of note are the increased use of bioprosthetic valves, and the emergence of TAVI and sutureless AVR in the past five years. Between 2002/03 and 2013/14 the total number of publicly funded valve replacements more than doubled, from 277 to 602. The volume of surgical AVR using a mechanical valve has remained relatively flat over the past 12 years; averaging a little more than 110 procedures; while the volume of AVR using a bioprosthetic valve has increased markedly; growing from 171 procedures in 2002/03 to 421 procedures in 2013/14. Transcatheter Aortic Valve Implantation (discussed below) was first undertaken in 2008; with volumes remaining relatively flat until 2011/12, while sutureless aortic valves (discussed below) are still infrequently used. Over the time period the average age of patients receiving AVR has increased from 63 years to 68 years of age, which may explain, or be explained by, some of the shift toward bioprosthetic valves.
Figure 6: Publicly funded AVR for any diagnosis of aortic stenosis in New Zealand from 2002/03 to 2013/14

Source: NHC analysis of NMDS

Standard surgical AVR valve replacement includes patients with any publicly funded hospital diagnosis of AS. ‘Other valves’ includes replacement of aortic valve with homografts or replacement of aortic valve with unstented heterografts for patients with any diagnosis of AS. TAVI and sutureless cases are not limited by diagnosis as they are all assumed to be for AS. About 20 records of sutureless AVR are excluded from the time series, as we could not accurately identify the date at which they were performed.
Transcatheter aortic valve implantation

Transcatheter aortic valve implantation (TAVI) involves implanting a bioprosthetic valve inside the diseased native valve through a catheter and has a much shorter recovery time than open heart surgery. It was first performed in New Zealand in 2008 where Waikato DHB drove a pilot programme in the public sector, and has since expanded to Auckland and Canterbury DHBs. The number of TAVI operations remains relatively few, with 65 publicly funded in 2013/14.

There are various approaches to TAVI: the transfemoral approach is the most common route whereby the femoral artery is used to access the heart; the transsubclavian approach is a variant where the subclavian artery is used as the peripheral conduit; and the transaortic and transapical approaches are performed with minimally invasive surgical techniques. TAVI does not require cardiopulmonary bypass; and when performed via a peripheral route may not always require general anaesthesia.\textsuperscript{(34)} The life of a TAVI valve is likely to be comparable to other bioprosthetic valves.\textsuperscript{(35)}

According to 2014 American Heart Association/American College of Cardiology guidelines TAVI represents an option for the management of patients who are at high risk of complications from aortic valve replacement (class 2a recommendation) and those at prohibitively high risk with surgery (class 1 recommendation), but in New Zealand and internationally its role among patients who are candidates for surgery is still in the process of being defined.\textsuperscript{(36)} TAVI cannot be offered to all patients with severe AS. Patients must undertake a preoperative assessment to ensure anatomical appropriateness for the procedure. Contraindications endorsed by the European Society of Cardiology include among others:\textsuperscript{(12)}

- less than one year of life expectancy;
- little potential to improve quality of life due to comorbidities;
- severe disease of other valves requiring surgery; and
- inadequate annulus size.

Trials have demonstrated improvements in survival and symptoms after TAVI compared with medical therapy. However, there remains a substantial group of patients who die or lack improvement in quality of life soon after TAVI.\textsuperscript{(37)} This raises important questions about the need to identify and acknowledge futility in some patients considered for TAVI and aortic valve intervention in general. A geriatric approach with consideration of factors such as frailty, cognition and comorbidity, in addition to traditional risk stratification tools such as the STS Score or Euroscore II, is advocated by experts to assess the anticipated benefit of TAVI.\textsuperscript{(38)}
Sutureless aortic valve replacement

Sutureless aortic valve replacement involves the surgical replacement of a diseased aortic valve with a bioprosthetic valve that requires very few or no stiches to keep in place. It was first performed in New Zealand in 2011 at Canterbury DHB and has since expanded to Auckland and Waikato DHBs. The number of sutureless AVR operations performed remains very low, with just 19 publicly funded in 2013/14.

By removing the need for sutures, operative and cardiopulmonary bypass times may be reduced compared with conventional surgery. This may enable high-risk surgical patients with concomitant cardiac surgery such as CABG (coronary artery bypass graft) to undergo long cardiac surgery procedures. It may also reduce the risk to patients who have anatomical features that make surgery particularly risky. Sutureless AVR can be undertaken using conventional open heart surgery or minimally invasive surgery. Minimally invasive aortic valve surgery involves smaller incisions, allowing patients to recover more rapidly, and is associated with reduced hospital and intensive care length of stay without elevated risk of death. It is still uncertain, however, if these benefits are applicable to minimally invasive sutureless AVR. Internationally, the procedure is often undertaken minimally invasively but this is not yet the case in New Zealand. Unlike TAVI, sutureless AVR allows the stenosed valve to be replaced with decalcification of the annulus. Stroke and paravalvular leak, where blood flows around the valve due to inappropriate sealing, are complications of TAVI hypothesised to be related to the lack of valve decalcification.

Minimally invasive aortic valve replacement surgery

While TAVI and sutureless AVR are high profile procedures today, minimally invasive aortic valve replacement has been developing since the mid 1990s and is now established in many centres internationally. In New Zealand, national data collections do not record the occurrence of minimally invasive cardiac surgery. It has been reported to the NHC, however, that minimally invasive AVR is routinely performed at Waikato DHB – comprising about 30% of procedures.

Minimally invasive aortic valve surgery involves a variety of techniques, with less injury to the body than conventional surgery by using special surgical tools to operate on the heart with small incisions. A comprehensive review of minimally invasive cardiac surgery has not been undertaken by the NHC, nevertheless, five systematic reviews on minimally invasive aortic valve replacement have been identified (Table 9). As a whole, the systematic reviews show that hospital and intensive care length of stay may be reduced using minimally invasive aortic valve surgery with no increased risk of death for patients. Minimally invasive surgery may also improve patient satisfaction and appearance post-surgery. The reviews did not report pooled mortality beyond 30 days. Their findings are limited by the inclusion of few randomised controlled trials (RCTs); although where RCTs are included, results point in the same direction as observational studies. The meta analyses were not limited purely to AS patients, and pooled results were not stratified by surgical risk or the severity of the patient’s condition.
Table 9: Meta analyses of minimally invasive aortic valve replacement

<table>
<thead>
<tr>
<th>Author</th>
<th>Surgical comparator</th>
<th>In-hospital or 30 day mortality (relative risk)</th>
<th>ICU LOS (weighted mean difference in days)</th>
<th>Total hospital LOS (weighted mean difference in days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phan et al (2014) (43)</td>
<td>Mini-sternotomy and mini-thoracotomy (n=5,162) v.s conventional sternotomy (n=7,624)</td>
<td>0.83</td>
<td>-0.69*</td>
<td>-1.16*</td>
</tr>
<tr>
<td>Phan et al (2014) (44)</td>
<td>Any mini-invasive AVR for patients with previous sternotomy (n=441) v.s conventional sternotomy (n=1,145)</td>
<td>0.77</td>
<td>No difference</td>
<td>-0.62</td>
</tr>
<tr>
<td>Khoshbin et al (2011) (42)</td>
<td>Mini-sternotomy (n=110) v.s conventional sternotomy (n=110)</td>
<td>NA</td>
<td>RCT only -0.57*</td>
<td>RCT only -2.03 (p=0.06)</td>
</tr>
<tr>
<td>Brown et al (2009) (41)</td>
<td>Mini-sternotomy (n=2,054) v.s. conventional sternotomy (n=2,532)</td>
<td>RCT only 0.98</td>
<td>-0.47</td>
<td>-0.24</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All studies 0.71</td>
<td>-0.46*</td>
<td>-0.91*</td>
</tr>
<tr>
<td>Murtuza et al (2008) (40)</td>
<td>Any mini-invasive AVR (n=2,249) v.s conventional sternotomy (n=2,642)</td>
<td>RCT Only 0.73</td>
<td>-0.39*</td>
<td>-0.67*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All studies 0.73*</td>
<td>-0.43*</td>
<td>-1.23*</td>
</tr>
</tbody>
</table>

Source: (41) (40, 42-44),

* Results are statistically significant to the 5% level; RCT, randomised controlled trial

Risk stratification

Patients with severe AS may be broadly categorised into operable or inoperable patients. Operable patients may be further stratified by their preoperative risk of mortality from surgical (or transcatheter) aortic valve replacement. There are standard preoperative algorithms for stratifying patients into low, moderate or high risk of operative mortality. The best of these algorithms in cardiac surgery, the Society of Thoracic Surgeons Predicted Risk of Mortality Score (STS-PROM), stratifies patients risk using about 30 variables (including, among other factors, presence of significant comorbidities, age, ethnicity, and prior cardiac surgery). Low risk is defined as an operative risk of death of less than 4% (STS-PROM <4%). Moderate or intermediate risk and high risk are defined as STS 4%≤ 8%, and STS>8%, respectively. The algorithm has shown a high degree of accuracy in international and New Zealand specific studies.

A study of 142,000 first-time isolated surgical aortic valve replacements performed in the United States between 2002 and 2010 found higher preoperative risk (STS-PROM) was significantly associated with higher postoperative mortality, complications, and length of stay. (48) Actual mortality versus predicted mean mortality was 1.4% vs 1.7% for low-risk patients (STS <4%), 5.1% vs 5.5% for intermediate-risk patients (STS 4%≤ 8%), and 11.8% vs 13.7% for high-risk patients (STS >8%), p<0.0001. Eighty percent of patients were low risk, 14% intermediate risk, and 6% high risk.

A retrospective study of 620 patients who underwent isolated surgical AVR at Auckland City Hospital, from January 2005 to December 2012, compared the prognostic utility of the STS score, against alternative algorithms including EuroSCORE, EuroSCORE II, and Aus-AVR score. (49) The STS score
was found to be the best calibrated score in high-risk patients, with expected mortality closely tracking observed mortality across all risk quintiles. Further detail on risk stratification is contained in our report, *National Health Committee Transcatheter Aortic Valve Implantation; Tier 3 Assessment Report (2015)*.

### 1.1.7 Inoperable patients

International studies estimate that between a third and a half of all patients with severe symptomatic AS may be ineligible for open heart surgery.\(^{50-52}\) Between January 2005 and December 2009, about half the patients presenting at Waikato hospital with severe symptomatic AS were declined for AVR, mostly due to multiple comorbidities and age. We estimate that about 40% of patients a year, or 349 patients, diagnosed with severe AS do not receive publicly funded AVR (Table 10).

Table 10: Incidence of aortic stenosis and publicly funded AVR including TAVI by region 2012/13

<table>
<thead>
<tr>
<th>Region</th>
<th>Incidence of severe AS</th>
<th>Incidence per 100,000 population</th>
<th>AVR including TAVI and sutureless</th>
<th>AVR per 100,000 population</th>
<th>Total AVR per incident population</th>
<th>Estimated AS population without AVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northern</td>
<td>172</td>
<td>18</td>
<td>116</td>
<td>12</td>
<td>67%</td>
<td>56</td>
</tr>
<tr>
<td>Midland</td>
<td>202</td>
<td>22</td>
<td>104</td>
<td>11</td>
<td>51%</td>
<td>98</td>
</tr>
<tr>
<td>Central</td>
<td>290</td>
<td>17</td>
<td>162</td>
<td>9</td>
<td>56%</td>
<td>128</td>
</tr>
<tr>
<td>Southern</td>
<td>196</td>
<td>22</td>
<td>129</td>
<td>14</td>
<td>66%</td>
<td>67</td>
</tr>
<tr>
<td>Total</td>
<td>860</td>
<td>19</td>
<td>511</td>
<td>11</td>
<td>59%</td>
<td>349</td>
</tr>
</tbody>
</table>

Source: NHC analysis of NMDS, AVR cases include surgical AVR patients with a primary hospital diagnosis of AS and any TAVI or sutureless AVR patients (regardless of diagnosis) for 2012/13.

Inoperable patients may also be stratified into technically inoperable patients (surgery contraindicated due to anatomical reasons such as a porcelain aorta or chest deformity) and clinically inoperable patients, where patients are deemed unsuitable due to significant comorbidities, e.g. end-stage cancer or chronic obstructive pulmonary disease. Roughly three-quarters of inoperable patients may be classed as (predominantly) clinically inoperable, while a quarter are technically inoperable.\(^{53}\) Again, further detail on the stratification of inoperable patients is contained in our report *National Health Committee Transcatheter Aortic Valve Implantation; Tier 3 Assessment Report (2015)*.

### 1.1.8 Aortic stenosis interventions by risk

A 2013 meta analysis of European and US aortic valve replacement intervention rates found about 59% of elderly patients with severe symptomatic AS were receiving valve replacement, whereas the remaining 41% were considered inoperable.\(^{19}\) This corresponds almost exactly to our prior estimate of the inoperable population in New Zealand, suggesting that our current intervention rate is in the ballpark compared with other developed countries. Figure 7 shows that of the 59% of patients considered operable, approximately 5% were high operative risk, 16% moderate operative risk, and 79% low operative risk. Preoperative risk was stratified according to the STS-PROM score. Here, slightly higher thresholds were used than specified above (based on an earlier analysis of the Society of Thoracic Surgeons cardiac surgery database\(^{54}\)). High risk was defined as an STS-PROM >10%,
Moderate risk was an STS-PROM 5<10%, and low risk was an STS-PROM <5%. Of the inoperable patients approximately 29% were estimated to be potential candidates for TAVI based on a meta-analysis US and European studies of TAVI use in inoperable patients. We further stratified the inoperable population using recent data suggesting that most inoperable patients receiving TAVI are inoperable due to clinical reasons other than anatomical features. Here, we have approximated 95% confidence intervals, reflecting wide uncertainty as to the precise split between technically inoperable and clinically inoperable patients. Again, we provide further detail on this matter in our report National Health Committee Transcatheter Aortic Valve Implantation; Tier 3 Assessment Report (2015).

Overall then, Figure 7 shows that there are relatively few patients with severe symptomatic AS that might be classified as high risk, approximately 26 per annum. This is the pool of patients that TAVI is currently indicated for nationally, and internationally. As discussed in our respective tier three assessments on sutureless AVR and TAVI, both technologies are competing in this very small pool of patients. The evidence for the technologies in the moderate risk population, approximately 81 patients per annum, is only beginning to emerge, where surgical AVR remains the gold standard. In the inoperable population there is a significant issue regarding TAVI relating to cost-effectiveness, as medical management appears relatively inexpensive in New Zealand. Again, this issue is discussed in our Tier 3 assessment of TAVI.
1.1.9 Sensitivity analysis

The analysis in Figure 7 is limited by uncertainty around the estimation of the operable and inoperable populations for severe symptomatic AS. We do not know precisely how many patients with severe symptomatic AS or severe AS with LV dysfunction are operable or inoperable. As described above, we estimate the incidence of severe symptomatic AS through (new) annual hospital presentations with a primary diagnosis of AS. For consistency, we then limited the count of valve replacements to patients with a primary diagnosis of AS. Arguably, however, we have been too conservative in our estimate of both the patient population with severe symptomatic AS (or severe AS with LV dysfunction) and the number of such patients treated with AVR.

1.1.9.1 An alternative analysis of the operable population

To test our assumptions, we ran an alternative (sensitivity) analysis. To start with, the true number of patients treated for severe AS might better be reflected by the number of AVR patients with any diagnosis of AS, not purely a primary diagnosis of AS. In 2012/13 572 patients received publicly funded AVR with any diagnosis of AS. As about 90% of patients undergoing AVR with any diagnosis of AS have a primary diagnosis of AS, this change makes little difference to the overall estimate of the operable patient population. It implies about 30 patients per annum are high risk rather than 26 (Table 11).
Table 11: Sensitivity analysis - publicly funded risk stratified volumes of AVR (surgical AVR, TAVI and sutureless) with any diagnosis of AS 2012/13

<table>
<thead>
<tr>
<th>Total AVR (any AS)</th>
<th>572</th>
</tr>
</thead>
<tbody>
<tr>
<td>High risk</td>
<td></td>
</tr>
<tr>
<td>5.2%</td>
<td>30</td>
</tr>
<tr>
<td>Moderate risk</td>
<td></td>
</tr>
<tr>
<td>15.8%</td>
<td>90</td>
</tr>
<tr>
<td>Low risk</td>
<td></td>
</tr>
<tr>
<td>79.1%</td>
<td>452</td>
</tr>
</tbody>
</table>

Source: NHC analysis of NMDS with TAVI and sutureless AVR numbers provided by DHBs

1.1.9.2 An alternative analysis of the inoperable population

The inoperable patient population might also be under-estimated consequent to under-estimating the incidence of severe symptomatic AS (or severe AS with LV dysfunction). An alternative approach to estimating incidence is to retrospectively estimate cases based on the number of valve replacements.

Assuming the high estimate of 572 publicly funded AVRs, international evidence suggests a plausible inoperable range of between a third and 41%.(19, 51, 55) Or between 59% and 67% of patients with severe symptomatic AS are receiving intervention in other developed countries. Specifically, the European/US meta analysis suggests that about 41% of patients may be considered inoperable for surgical AVR.(19) This is a little higher than the 2001 European Heart Survey on Valvular Heart Disease (n=216) which found that surgery was denied in 33% of elderly patients with severe symptomatic AS. Likewise, a 2005 Michigan study (n=369) found one-third of patients with severe symptomatic AS did not undergo aortic valve replacement. In New Zealand, a Waikato hospital study (2005-2009) found about half of patients with symptomatic severe AS in its region did not receive aortic valve replacement. With the approximate doubling of aortic valve replacements in New Zealand between 2006/07 and 2013/14, our expectation is that the number of patients presenting at hospital with severe symptomatic AS and not undergoing valve replacement would now be much less than half. In this context, our current estimate of 41% (aligning with the meta analysis of European and US data) appears defendable, and arguably on the high side. Assuming a plausible range of inoperability of between 33% and 41% implies a severe symptomatic AS incidence of about 850 to 970 patients (Table 12). Of note, we assume that incidence captures both severe symptomatic cases and severe asymptomatic AS cases with LV dysfunction. We make this assumption on the basis that AVR is indicated for both populations, and we expect that a small number of patients in the numerator (572) are asymptomatic with LV dysfunction.
Table 12: Sensitivity analysis – incidence of severe symptomatic aortic stenosis or severe aortic stenosis with LV dysfunction – 2012/13

<table>
<thead>
<tr>
<th></th>
<th>Low estimate</th>
<th>High estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total AVR with any diagnosis of AS</td>
<td>572</td>
<td></td>
</tr>
<tr>
<td>Inoperable population</td>
<td>33%</td>
<td>41%</td>
</tr>
<tr>
<td>Incidence of severe symptomatic AS or severe (asymptomatic) AS with LV dysfunction</td>
<td>854</td>
<td>969</td>
</tr>
</tbody>
</table>

Source: NHC analysis

Again, this alternative analysis makes only a modest difference to our initial estimate, with the inoperable patient population in which TAVI may be considered feasible ranging from 81 to 114 patients (with our original estimate of 100 patients fitting roughly in the middle of the range, Figure 7) and the technically inoperable patient population ranging from 19 to 26 patients per annum (compared with 23 in Figure 7) (Table 13).

Table 13: Sensitivity analysis – inoperable population with aortic stenosis – 2012/13

<table>
<thead>
<tr>
<th></th>
<th>Low estimate</th>
<th>High estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence of severe symptomatic AS or severe (asymptomatic) AS with LV dysfunction</td>
<td>854</td>
<td>969</td>
</tr>
<tr>
<td>Inoperable population</td>
<td>33%</td>
<td>41%</td>
</tr>
<tr>
<td></td>
<td>282</td>
<td>397</td>
</tr>
<tr>
<td>TAVI feasible</td>
<td>28.7%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>81</td>
<td>114</td>
</tr>
<tr>
<td>Clinically inoperable</td>
<td>77%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>62</td>
<td>88</td>
</tr>
<tr>
<td>Technically inoperable</td>
<td>23%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>26</td>
</tr>
</tbody>
</table>

Source: NHC analysis

We assume the low and high incidence estimates capture both cases of symptomatic severe AS and asymptomatic AS with LV dysfunction. As previously mentioned, the latter group is likely to be very small. If it is assumed that 5-10% of severe AS cases have LV dysfunction (13) and about a quarter of these cases are asymptomatic (19), then incidence of severe asymptomatic AS with LV dysfunction can be approximated. Here, we estimate an incidence of 14 to 31 patients per annum (Figure 8).
Figure 8: Estimated incidence of asymptomatic aortic stenosis with LV dysfunction

<table>
<thead>
<tr>
<th>Total incidence (z) = severe symptomatic AS (x) + severe asymptomatic AS with LV dysfunction (y)</th>
</tr>
</thead>
<tbody>
<tr>
<td>z (low estimate) = 854</td>
</tr>
<tr>
<td>z (high estimate) = 969</td>
</tr>
<tr>
<td>x = 0.75 * severe AS (q) = 0.75q</td>
</tr>
<tr>
<td>y (low estimate) = 0.05<em>q</em>0.25 = 0.0125q</td>
</tr>
<tr>
<td>y (high estimate) = 0.1<em>q</em>0.25 = 0.025q</td>
</tr>
</tbody>
</table>

Therefore,

- z (low estimate) = 0.0125q + 0.75q = 854
- 0.7625q = 854
- So, q = 1120, x = 840, y = 14

- z (high estimate) = 0.025q + 0.75q = 969
- 0.775q = 969
- So, q = 1250, x = 938, y = 31

Source: NHC analysis

1.1.9.3 Estimating the prevalence of inoperable AS

Still it might be argued that we are under-counting the inoperable population using annual incidence, as medically managed patients may live several years with severe aortic stenosis. We estimated above that the prevalent population of medically managed severe AS was about 810 patients in 2012/13, corresponding with Australian data.³⁰

An alternative analysis is to estimate the inoperable prevalent population based on the estimated mortality of medically managed patients. Recent data from a randomised controlled trial of TAVI gives insight into the life expectancy of medically managed patients with severe symptomatic AS. It shows that roughly half of all patients are dead within a year, with nearly all patients dead within five years. Assuming an equivalent mortality rate for medically managed patients in New Zealand and applying our high and low estimates of inoperable incidence implies a prevalence of between 634 and 895 medically managed patients with severe AS in New Zealand. The range suggested from this alternative analysis is consistent with our original estimate of 810 patients.
Table 14: Sensitivity analysis: population prevalence of inoperable aortic stenosis – 2012/13

<table>
<thead>
<tr>
<th>Year</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Total estimated prevalence of medically managed AS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low incidence estimate</td>
<td>282</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High incidence estimate</td>
<td>397</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated survival of medically managed patients</td>
<td>100%</td>
<td>49%</td>
<td>32%</td>
<td>20%</td>
<td>16%</td>
<td>7%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Low estimate</td>
<td>282</td>
<td>139</td>
<td>91</td>
<td>57</td>
<td>45</td>
<td>21</td>
<td>0</td>
<td>634</td>
</tr>
<tr>
<td>High estimate</td>
<td>397</td>
<td>196</td>
<td>129</td>
<td>81</td>
<td>63</td>
<td>29</td>
<td>0</td>
<td>895</td>
</tr>
</tbody>
</table>

Source: NHC analysis

Any new technology for medically managed patients, be it TAVI or any other intervention, would thus be presented with a short run backlog of demand consequent to accumulated prevalence. For severe symptomatic AS, this upfront demand diminishes rapidly. Given the short life expectancy of patients, roughly half may be dead within a year. Short run supply would also be limited by the learning curve associated with the technology, and the capacity and capability of the sector to deliver the service in the immediate-term. Thus whilst a prevalence view may imply higher volumes of patients in the short run, there are both demand and supply side short-term constraints that suggest an incidence view may be more appropriate (Table 15).

Table 15: Sensitivity analysis – estimated volume of inoperable patients potentially eligible for TAVI including clinically inoperable and technically inoperable patients 2012/13

<table>
<thead>
<tr>
<th>Estimated inoperable prevalence</th>
<th>Low estimate</th>
<th>High estimate</th>
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<tbody>
<tr>
<td>TAVI feasible</td>
<td>29%</td>
<td>182</td>
</tr>
<tr>
<td>Clinically inoperable</td>
<td>77%</td>
<td>140</td>
</tr>
<tr>
<td>Technically inoperable</td>
<td>23%</td>
<td>42</td>
</tr>
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</table>

Source: NHC analysis
Forecast aortic valve replacement demand and expenditure

In 2012/13, the average cost of aortic valve replacement (AVR) was about $45,000 per patient for AS patients across all risk classes. In the same year, there were 572 publicly funded aortic valve replacements for patients with any diagnosis of aortic stenosis. In cost terms, this equates to roughly $26 million in government expenditure. On the basis of projected population growth alone, it is expected that AVR volumes will grow to nearly 900 patients by 2025/26. Population growth is modelled on an expected annual growth rate of 3.45% in the 65+ population over the period. Alternatively, if there were a continuation in trend of AVR volumes since 2001/02, representing an annualised growth rate 6.9%, there would be approximately 1,400 AVR operations undertaken by 2024/25 (Figure 9). Growth in AS incidence is projected to grow at the same rate as the 65+ population.

Figure 9: Projected aortic stenosis incidence and demand for publicly funded aortic valve replacement to 2025/26

Note: The AVR estimate is limited to patients with a diagnosis of AS. AS incidence is estimated assuming a primary hospital diagnosis of AS.

Source: NHC analysis of NMDS and Mortality records, Modelled on Statistic New Zealand population projections.

6 Cost Schedule 7 from 512 records available in the NCCP data including TAVI, sutureless and conventional AVR.
The number of publicly funded aortic valve replacements for AS grew at 6.9% per annum between 2001/02 and 2012/13, while the number of hospital primary diagnoses of AS grew at 4.75% per annum. Consequently, a greater proportion of patients with severe AS are now receiving surgical treatment. The high rate of growth seen in the past decade for aortic valve replacement cannot be sustained indefinably. As illustrated in Figure 9, if AVR continues to grow at 6.9% per annum, volumes will outstrip expected hospital presentations (with a primary diagnosis of AS) by 2025/26. As not all patients with severe AS can be treated with AVR, supply of AVR will always be less than hospital presentations. Of note, this historic growth path for AS is well in excess gross domestic product (GDP) growth expectations. Real GDP growth is forecast to average 2.8% per year over the four years to 2019.15

1.2 The historic context to the growth in aortic valve replacement volumes

As illustrated in Figure 9, the number of valve replacements undertaken remained relatively flat between 2001/02 to 2006/07. Subsequently, a service development process for cardiac surgery services in New Zealand was requested by the Minister of Health and initiated in May 2008 by the Ministry of Health with the New Zealand Branch of the Cardiac Society of Australia and New Zealand.15 A Cardiac Surgery Service Development Working Group was established to lead the development process. In 2008, the working group released a report that recommended increasing cardiac surgery intervention rates (including for aortic valve replacement), by a third between 2007/08 and 2012/13.15 In 2009, the National Cardiac Surgery Network was established to lead the implementation of the working group’s recommendations. National cardiac surgical targets were introduced in 2009, and in conjunction with increased funding for elective surgery from 2006/07, have led to a substantial growth in the number of AVR operations undertaken.

1.3 Forecast aortic valve replacement expenditure

Given the preceding demand estimates, we expect government expenditure on AVR to grow to between $40 million and $60 million by 2025/26, representing an annual rate of growth of between 3.5% and 7%. Both rates are greater than expected GDP growth, presenting an issue around affordability (and societal choices) presented by costly interventions for AS. The range estimate assumes an average cost for AVR of $45,000, using 2012/13 cost data. The low estimate corresponds to a scenario where demand grows in accordance with AS incidence – which is modelled to grow in line with the growth rate of the 65+ population. The high estimate is a straight line extrapolation of the trend in AVR growth from 2001/02. The high estimate is a ceiling estimate, which is unlikely to be reached without greater growth in AS cases or a significant increase in the unit cost of intervention. A forecast of expenditure growth by region is contained in Appendix 1 (Figure 11).

Model of care for severe aortic stenosis

Figure 10 outlines the typical model of care for severe AS. There are multiple points of patient entry into the model of care, including referral from primary care and referral from general medicine or geriatrics electively or after an acute episode. A decision is then made around patient appropriateness for intervention – normally by a cardiologist – although other internal medicine specialists may screen out unsuitable candidates. After referral, most patients are seen at their local DHB cardiology outpatient clinic or reviewed by cardiology services as an inpatient at their local DHB secondary care hospital. Diagnostic assessments, including echocardiogram, are undertaken to confirm diagnosis and an initial patient management decision is made by the cardiologist. If a patient is a potential candidate for surgery or TAVI, a central part of the evaluation is an assessment of surgical risk – generally identified through a tool such as the EuroSCORE or the STS score. This
Aortic Stenosis – Tier 2 Overview

The decision of the conference is the key determining factor around acceptance for AVR. All high-risk operable patients undergoing consideration for TAVI must then be presented at the multidisciplinary heart team meeting. The final decision about operability is made at the cardiac surgical conference and the heart team meeting determines whether an operable patient is suitable for TAVI. If the cardiac surgery/cardiology conference does not think the patient is operable, they cannot proceed to TAVI – they go back to medical management or to palliative care. Only operable patients may have TAVI. The operability decision needs to be made by at least two surgeons. Patients deemed to be appropriate candidates for valve replacement undergo workup prior to surgery by their local cardiology service. Interventional management, including surgical AVR, TAVI and sutureless AVR, for severe aortic stenosis is provided by the regional cardiac centres (Auckland, Waikato, Capital and Coast, Canterbury and Southern DHBs). After treatment and discharge from hospital, patients are managed through established follow-up clinics.

The New Zealand Cardiac Network (NZCN) provides national clinical leadership and supports the National Cardiac Surgery Network and the four regional cardiac networks. The National Health Board/Ministry of Health develops national policy and monitors elective performance and intervention rates to ensure equitable access across New Zealand.

1.4 Issues identified with the current model of care

The NHC met with CSANZ in October 2013 to discuss progress around interventions for AS. It was agreed that stakeholders from the various Colleges, specialist societies, DHB planning and funding and provider arm management and the Ministry of Health should come together to discuss the development of national criteria for patient selection for aortic stenosis interventions, with a multidisciplinary focus. The NHC held its first stakeholder workshop on 28 February 2014 and involved the following groups: the Cardiac Society of Australia and New Zealand (CSANZ), the Australian and New Zealand Society of Cardiothoracic Surgeons (ANZSCTS), the New Zealand Cardiac Network (NZCN), the College of Intensive Care Medicine of Australia and New Zealand (CICMANZ), Australian and New Zealand Society of Geriatric Medicine (ANZSGM). The second meeting held on 15 August 2014 also included representatives from DHB funding and planning, the national Health IT Cluster, and DHB clinical services directors. The meetings were valuable in identifying several issues with the current model of care. We discuss these issues and others that have been identified through engagement with stakeholders below.

1.4.1 Identification of need

It has been identified by the sector that there can be issues with appropriate identification and diagnosis of patients in primary care with AS. The New Zealand Cardiac Network (NZCN) has identified that there are “blockages in patient pathways between primary care and cardiology, which may be impacting on cardiac referral.” The NZCN work plan has a specific work stream which focuses on improving service delivery and performance to respond to this issue. There are also specific examples in the sector such as the central region DHBs who have implemented an outreach service in primary care to improve the assessment of AS patients in primary care, which has also increased the volume of patients being referred to secondary care.

The NZCN also identified access to cardiac investigations and diagnostics as a barrier to accessing treatment due to long waiting times and workforce constraints, and plan to address these issues in their work plan.
1.4.2 Frailty

Historically there has not been a robust scoring tool for clinical frailty to screen patients for cardiac surgery and interventional cardiology procedures. Frailty has been shown to be a strong independent predictor of life expectancy and surgical outcomes in the literature. \(^{(60,61)}\) Patients with high frailty indices are unlikely to survive for reasons other than their primary cardiac condition and this can make invasive and expensive interventions like aortic valve replacement clinically futile and cost-ineffective.

There appears to be a developing acceptance that frailty needs to be assessed prior to assessment of operative risk. A formal scoring tool developed by the Ministry of Health, the Cardiac Surgical Appropriateness tool, is now under evaluation and includes measures of patient frailty, comorbidities, cognitive function, and surgical complexity. The NHC has also contributed to the evaluation of the scoring tool through the provision of Health Innovation Partnership funding for the ‘Evaluation of Frailty and Comorbidity in Patients with Ischaemic Heart Disease’ by Professor Ralph Stewart at Auckland DHB.

1.4.3 National registries

Recently, the Ministry of Health has established two registries: one for cardiac surgery (National Cardiac Surgery Registry, Dendrite Clinical Systems) and the other for cardiology (Acute Predict, Enigma solutions), which includes data on acute coronary syndromes and interventional cardiology procedures. Both registries are operational and neither registry is capturing any data on TAVI at the current time. DHBs are collecting information on TAVI in local databases.

Lack of interoperability of registries for the treatment of aortic stenosis is a serious flaw in the current system. The establishment of two registries (cardiac surgery and cardiology) has potentially created a ‘disconnect’ in the model of care for AS. While cardiac interventions are currently included in the cardiac surgery registry, the workup prior to surgery is managed through local cardiologists who may not have access to the surgery registry. The alignment of the entry of information into the registries with the AS model of care will need to be resolved if a TAVI module in the registry is established and embedded. This will be an additional cost to the sector.

The cardiology registry has been recently updated to include the fields for the cardiac surgical appropriateness tool currently being evaluated. These fields are only available and used for those patients in the trial.

To be useful for the sector, a national registry for AS would need to be mandatory and collect clinical and business data. AS procedures, such as TAVI, involve a medical device therefore the ability to track the device through a national registry for recall purposes is essential. In addition to device tracking, a quality registry requires good governance to operate within the accountability for reasonableness framework and potentially form part of continuing professional development and accreditation.

1.4.4 Quality of life and the national cardiac registry

The new cardiac surgical appropriateness tool commendably involves an assessment of frailty. However, the registry does not include an assessment of patient quality of life. World leading registries, including the United States national Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC) TVT Registry, the French national FRANCE-2 registry, and the German national GARY registry all include measurement of patient quality of life. In the GARY registry, patient quality of life is measured through a simple and well-established tool, known as the
EQ-5D. Quality of life is recorded at baseline and at one, three, and five years post-intervention for TAVI and surgical AVR patients.\(^7\)

Quality of life data provides invaluable feedback to clinicians looking to avoid unnecessary and harmful intervention. It can also provide the health sector with the evidence required for cost-effective diffusion of emerging technologies. European and United States guidelines for valvular disease note the need for clinicians to consider the likely quality of life of patients post-intervention – where an anticipated life expectancy of one year or less, or no expectation of improved quality of life, are considered contraindications for aortic valve replacement.\(^{12, 62}\)

It is also accepted that many medically managed patients may be missed from the New Zealand cardiac registries, but a multidisciplinary framework that involves medical specialists in the early decision-making process around severe AS will likely increase engagement in capturing clinical, frailty and cognition information on patients.

1.4.5 Multidisciplinary ‘Heart Teams’

Current New Zealand guidelines require a heart team (TAVI selection group) approach. In sector engagement workshops held between the NHC and key stakeholders, it emerged; however, that one centre had replaced its multidisciplinary TAVI selection group with a 'high-risk valve' clinic.

European and American guidelines recommend the use of heart teams in the selection of patients for all types of valve replacement.\(^{12, 62}\) They recommend that the heart team should include cardiologists, cardiac surgeons, imaging specialists, anaesthetists and, if needed, general practitioners, geriatricians, or intensive care specialists.\(^{12}\) With the acknowledged importance of cognitive and frailty testing prior to surgery, including a geriatrician might be considered essential in the multidisciplinary team. Heart teams ensure patients are clinically suitable for intervention and ensure decisions are based on objective evidence, scoring tools and consensus. Standardisation of a heart team approach is important to secure consistent and equitable access to TAVI across the country.

Cardiac surgery/cardiology conferences are long-standing joint multidisciplinary decision-making bodies in New Zealand. For the centres providing TAVI, these are suitable decision-making mechanisms (ie multidisciplinary heart teams) for the final TAVI decision. However, for those cardiac centres referring potential TAVI patients to other cardiac centres, it would be appropriate for the referral to come through the existing cardiac surgery/cardiology conference or directly from the referring cardiologist to ensure consistent, timely, cost-effective decision-making for patients and for providers and alignment with professional guidelines and consistent patient selection and management for these patients.

The decision made at the multidisciplinary heart team conference, ie to perform the TAVI, refer the patient back to the regional cardiac surgery/cardiology team conference or refer the patient directly to palliative care, must be recorded in the national AS registry.

1.4.6 Workforce

DHBs suggest that there may be enough clinicians to respond to the increasing demand in the short to medium-term. However, the skills required from these clinicians may not be aligned with forecast demand for new cardiovascular interventions. The sector still needs to maintain and support clinicians with a broad range of cardiothoracic surgical and cardiology skills to manage procedures

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\(^7\) https://clinicaltrials.gov/ct2/show/NCT01165827?term=GARY&rank=2
such as complex multiple valve issues and paediatric cardiac surgery, as well as non-interventional cardiology services in local DHBs.

Questions to be considered include the number and optimal balance between cardiothoracic surgeons and cardiologists and the sub-specialty skill mix within these clinical specialties required to respond to forecast demand as well as new interventions at the regional centres as well as local district services.

There are other staff required to support cardiac surgery and transcatheter aortic valve replacement including perfusionists, technicians and specialist nurses, where increases or changes in the volume of new interventions may require national workforce planning. DHBs have reported that there may be shortages in the medium-term for some of these professional groups.

There is also training required before a clinician is able to perform TAVI and achieve optimal outcomes. TAVI has a learning curve that is specific to the TAVI device and delivery system.

1.4.7 Facilities

Any increase in volumes or services provided to manage patients with AS impacts on the need for catheterisation laboratories, cardiac surgical theatres and hybrid laboratories across each region and nationally. This is in addition to increased pressure on intensive care, coronary care and ward facilities. These facilities require significant capital investment, ongoing revenue streams, they depreciate and are used for a mix of specialties and procedures so require efficient operating models to be sustainable.

Further analysis is needed to better understand when a step change in the facilities and other infrastructure may be required to respond to cardiovascular forecast demand or whether this can be managed by extending the hours of use of existing facilities. There have been significant volume increases in cardiac procedures and interventional radiology of which the implementation of additional AS interventions is only one element.

In response to the increased demand, DHBs have made plans for additional capacity. A new hybrid catheterisation laboratory has recently been commissioned at Auckland DHB; a decision is to be made in the near future about the next catheterisation laboratory in the northern region. Bay of Plenty DHB is making plans for a new hybrid laboratory (with no established on site cardiac surgical service) and two additional laboratories are planned for the Christchurch Hospital re-development. However, these capital planning decisions have been made in the absence of a current national plan for cardiovascular services.

1.4.8 Funding issues

Funding for aortic valve replacement including TAVI, is based on the diagnostic related group (DRG) the event appears in, predominantly F03A, F03B, F04A, and F04B. For surgical AVR, TAVI and sutureless AVR, these events involve an expensive implant. As these interventions are only provided by regional cardiac centres (tertiary providers) they are funded through the inter-district flow (IDF) prices paid by referring DHBs (ie DHB of domicile).

The National Cost Collection and Pricing Program (NCCP) collects costs from DHBs annually to review the IDF prices for DHB hospital services, including the cost weights used in the casemix funding that includes TAVIs and other high cost implants. The Casemix Project Group within NCCP are aware of the need to ensure that implant costs are incorporated at the right level in the weighting model and continue to monitor the costs. Checks on the cost of surgical AVR and TAVI are made at DRG level rather than at the individual procedure/unit cost level. While individual line items may appear under or overvalued, it is the overall DRG view that is taken into account.
However, the NCCP does not always recognise the fully absorbed costs of running a service. These costs include the capital expenditure (facilities and equipment) and associated depreciation, workforce costs, consumables (pharmaceuticals, medical devices/implants, theatre linen, disposable sterile packs, ward costs etc) and contribution to organisation overheads. There is an inherent tension between the national price paid by the funder for the episode of care (including procedure and inpatient stay) and the actual fully absorbed cost incurred by the provider who delivers the care. There is also a tension between the population funding provided to a DHB, the services to be delivered as part of the production plan by the DHB provider arm and those provided by other DHBs for that same population.

This is particularly relevant to TAVI as a shortfall is indicated in the 2013/14 data for TAVI events and for all events in the four DRGs identified. This DRG will have been a loss-maker for the five cardiac centres, and more particularly the three that provide TAVI. Resolving this issue has been identified by the Casemix Project Group and steps are in place to address the issue, however this can take one to two years. There is also another revenue stream called the tertiary adjuster which supplements base casemix funding for variations from the norm experienced by tertiary providers, and including an allowance for new technology. This stream, too, should be taken into account when considering the revenue due for aortic valve replacement including TAVI.

1.4.9 Prioritisation of resources

There is an opportunity cost in providing more AS interventions which could result in the wrong mix or balance of procedures being provided for the New Zealand population. Aortic stenosis and cardiac procedures have a significantly higher case weight than the average of other surgical procedures. An increase in cardiovascular procedures could have a detrimental impact on the volume of patients that can be treated overall.

Currently, the TAVI guidelines require all patients receiving TAVI to be operable. The introduction of TAVI in New Zealand is as a substitute for other valve replacement procedures. Were TAVI to be extended to higher risk comorbid (‘sicker’) patients, ie patients who previously had access to medical management only, then the ability to treat more healthy patients with lower risk and improved potential outcomes may be compromised. Workforce, infrastructure and financial constraints limit the volume of patients who can be treated using operating theatres and catheterisation laboratories.

Questions to be considered include whether the right patients are being treated, ie those that will benefit most from the mix of interventions in the model of care and the commensurate improved outcomes, and what is the right mix of interventions for AS for the New Zealand population. This also leads to the question of the optimal size of cardiac surgery and cardiology services to respond to the health needs of New Zealanders.

1.4.10 Specific cost and volume data

New Zealand-specific cost and volume data across AS interventions is limited. The issue is particularly pertinent for new interventions such as TAVI and sutureless AVR where routine recording of events in the national collections (using specific diagnostic codes) can take several years before becoming standardised. Only recently have specific ICD-10 codes come available for TAVI, seven years since the intervention became available in New Zealand. In terms of patient selection, there are no clinically recognised markers for surgical risk, such as the EuroSCORE or the STS score in national data collections. Reliable data may also inform and enable greater equity of access to new technologies; ensuring, where feasible, that New Zealanders get fair access regardless of their locality, ethnicity or other extraneous factors.
Conclusion

Aortic stenosis is responsible for the deaths of about 300 New Zealanders a year. Unlike other heart conditions, there are very few preventative strategies for the condition. When AS becomes symptomatic the standard of care is aortic valve replacement, which is a highly effective intervention that can return patient quality of life and life expectancy to normal. The past decade has seen a significant increase in the number of AVR operations undertaken and a technology shift away from mechanical valves, towards bioprosthetic valves and less invasive surgery. At the same time, mortality from AS has declined significantly, from about four deaths per 100,000 New Zealanders in 2000 to about three deaths per 100,000 New Zealanders in 2011. As part of this global trend, two AVR technologies have emerged in New Zealand since 2008 being TAVI and sutureless AVR. Whilst these technologies hold promise for high-risk surgical patients, it is important that they are properly assessed to ensure their appropriate use.
Figure 10: Current model of care for severe aortic stenosis
References

31. MOH. Privately Funded Hospital Discharges - 1 July 2012 to 30 June 2013. 2015.
### Appendix 1:
Projected expenditure on publicly funded AVR by region

Figure 11: Projected expenditure on publicly funded aortic valve replacement by region (2012/13 dollars)

<table>
<thead>
<tr>
<th>Year</th>
<th>Northern AVR</th>
<th>Northern Expenditure $m</th>
<th>Midland AVR</th>
<th>Midland Expenditure $m</th>
<th>Central AVR</th>
<th>Central Expenditure $m</th>
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<td>221</td>
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<td>903</td>
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Source: AVR volume data from NMDS. Cost data for AVR from NCCP 2012/13 – where the average cost of AVR is $45,000.

Figure 11 projects demand and expenditure for all publicly funded AVR, regardless of diagnosis, based on population growth in each region, where the growth rate is that of the 65+ population, provided by statistics New Zealand. The base rate of AVR intervention here is marginally higher than in Figure 9 as we included an additional 24 publicly funded AVRs occurring in 2012/13 which did not have ‘aortic stenosis’ in their admission code.
Methods

1.5 Prevalence and incidence of aortic stenosis 2005/06 to 2012/13

National Minimum Dataset (NMDS) records were used to identify relevant private and public hospital events for measuring aortic stenosis. Aortic stenosis events include ICD codes I35.0, I35.2, I06.0 and I06.2 (Table 16). With I06.0 and I06.2 being rheumatic aortic stenosis. Aortic valve replacements were identified where a hospital event had one of the following procedure codes: 3848800, 3848801, 3848900, 3848901. The population dataset used for this analysis is the 2012/13 New Zealand Health Tracker of New Zealand health service users alive from 1 July 2012. We used a look-back period of seven years from the beginning of the year of interest (to 1 July 2005). If someone had received an aortic valve replacement then they were considered as likely to no longer have 'severe symptomatic AS'. Patients with a current (2012/13) primary diagnosis of AS had had a primary diagnosis between 1 July 2005 and 30 June 2013 and they had either had no aortic valve replacement, or they had had one in the 2012/13 year (so were prevalent at some point in that year). Patients with any current diagnosis had had a diagnosis (not necessarily as a primary diagnosis) between 1 July 2005 and 30 June 2013, likewise they had had no replacement, or had had one in the 2012/13 year. The same process was followed for separating out rheumatic aortic stenosis.

Table 16: International statistical classification of diseases version 10 diagnostic and procedure codes used for the estimation of prevalence, incidence and volume of aortic valve replacements

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>I35.0</td>
<td>Aortic (valve) stenosis</td>
</tr>
<tr>
<td>I35.2</td>
<td>Aortic (valve) stenosis with insufficiency</td>
</tr>
<tr>
<td>I06.0</td>
<td>Rheumatic aortic stenosis</td>
</tr>
<tr>
<td>I06.2</td>
<td>Rheumatic aortic stenosis with insufficiency</td>
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<tr>
<td>3848800</td>
<td>Replacement of aortic valve with mechanical prosthesis</td>
</tr>
<tr>
<td>3848801</td>
<td>Replacement of aortic valve with bioprosthesis</td>
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<td>3848900</td>
<td>Replacement of aortic valve with homograft</td>
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<td>3848901</td>
<td>Replacement of aortic valve with unstented heterograft</td>
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</tbody>
</table>

Patients identified as 'medically managed' had a primary diagnosis from 1 July 2005 to 30 June 2012 and had no aortic valve replacement recorded up to 30 June 2013.

A caution in the interpretation of our data is that not all private hospital events are reported to the NMDS, this means that some of the patients identified with a diagnosis in the NMDS records may have had a subsequent privately funded aortic valve replacement that is not recorded.
1.6 Crude and age standardised aortic stenosis mortality 2012

Mortality data for the 2012 calendar year was sourced from the Ministry of Health’s Mortality Collection, events were selected where the cause of death was AS (as defined using the ICD codes above).

Age group population data was obtained from the World Health Organisation (WHO) website and aggregated into age groups. Statistics New Zealand population estimates for the 2012 calendar were aggregated using:

a) Māori and non-Māori ethnicity;

b) Age group.

The age adjusted rate was found by dividing the aggregated mortality data by the Statistics New Zealand population estimates which were then weighted by proportions derived from the WHO standard population.

1.7 Publicly funded aortic valve replacement by diagnosis 2012/13

Publicly funded aortic valve replacement events for the 2013 financial year were sourced from the NMDS. The primary diagnosis code was used to group events into one of the following classifications (Table 17).

<table>
<thead>
<tr>
<th>ICD code</th>
<th>ICD code description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I080</td>
<td>Disorders of both mitral and aortic valves</td>
</tr>
<tr>
<td>I083</td>
<td>Combined disorders of mitral, aortic and tricuspid valves</td>
</tr>
<tr>
<td>I214</td>
<td>Acute subendocardial myocardial infarction</td>
</tr>
<tr>
<td>I350</td>
<td>Aortic (valve) stenosis</td>
</tr>
<tr>
<td>I351</td>
<td>Aortic (valve) insufficiency</td>
</tr>
<tr>
<td>I352</td>
<td>Aortic (valve) stenosis with insufficiency</td>
</tr>
<tr>
<td>Q230</td>
<td>Congenital stenosis of aortic valve</td>
</tr>
<tr>
<td>Q231</td>
<td>Congenital insufficiency of aortic valve</td>
</tr>
<tr>
<td>Other</td>
<td>Other</td>
</tr>
</tbody>
</table>

1.8 Incidence of aortic stenosis and publicly funded aortic valve replacement including TAVI by region 2012/13

Publicly funded events for the 2013 financial year were sourced from the NMDS and the New Zealand Health Tracker where the primary diagnosis code was AS. The data were aggregated in to the following regions:
Northern: Northern, Waitemata, Auckland, Counties Manukau District Health Boards (DHBs)

Midland: Waikato, Bay of Plenty, Tairawhiti, Taranaki, Lakes DHBs

Central: MidCentral, Hawkes Bay, Whanganui, Wairarapa, Hutt Valley, Capital Coast DHBs

Southern: Nelson Marlborough, West Coast, Canterbury, South Canterbury, Southern DHBs.

Rates per 100,000 were estimated using Statistics New Zealand population data aggregated into the regions described above as the denominator, the numerator was the events extracted from the NMDS and the New Zealand Health Tracker.

TAVI and sutureless events were identified using the information recorded in the free text field of the NMDS.

The TAVI and sutureless events were then sent to the relevant DHBs which performed the procedures for confirmation and amendment where necessary. The information supplied by the DHBs was used to ensure that the records used in the analysis were correct and there was no duplication of records.

Cost data from the National Cost Collection Project (NCCP) was used to estimate the costs of AVR, sutureless and TAVI events. Data collected in the NCCP project is sourced from the costing systems employed by DHBs to allocate the cost of care across events occurring in their hospitals. Costs are allocated on the basis of the length of stay in hospital and the procedures included in the care of the patient. Costs were identified by linking the unique patient identification code recorded in the verified NMDS data and the NCCP data.

1.9 Comorbidities

A small set of potential comorbidities were analysed in the same way as outlined in *Ischaemic Heart Disease: A Pathway to Prioritisation*(7)

2013 cancer registrations were only available for selected sites, so cancer may be slightly underestimated. The list of selected sites is available on the Ministry of Health website.8

The data used for diabetes was the Virtual Diabetes Register9 which uses similar methodology to the New Zealand Health Tracker indicator used previously.

Due to the incomplete cancer registration data, the gout indicator data has only been updated to 2011/12 so may be slightly underestimated.

Note that while a couple of these measures may be very slightly underestimated, the same data are used for comparing those with severe aortic stenosis and those that don't have diagnosed severe aortic stenosis.


National Health Committee (NHC) and Executive

The National Health Committee (NHC) is an independent statutory body which provides advice to the New Zealand Minister of Health. It was re-formed in 2011 to establish evaluation systems that would provide the New Zealand people and health sector with greater value for the money invested in health. The NHC executive are the secretariat that supports the committee. The NHC executive’s primary objective is to provide the committee with sufficient information for them to make recommendations regarding prioritisation and reprioritisation of interventions. They do this through a range of evidence-based reports tailored to the nature of the decision required and timeframe within which decisions need to be made.

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