Assessment of the Business Case for the Management of Adult Morbid Obesity in New Zealand
About NSTR

The National Service & Technology Review Advisory Committee (NSTR) is part of the Service Planning and New Health Intervention Assessment (SPNIA) Framework process. NSTR is responsible for horizon scanning, coordinating business case development, and analysing and evaluating proposals for change and business cases that are developed through the SPNIA Framework. NSTR currently makes recommendations to all the District Health Board (DHB) Chief Executive Officers (CEOs) and to the Ministry of Health’s Executive Leadership Team (ELT) on national service matters and new health interventions that have a national impact.

NSTR’s role is to:

- provide technical and strategic policy advice to the DHB CEOs and the Ministry’s ELT on health service configuration and health interventions that have a national impact
- horizon scan for new health interventions that could be considered for formal assessment because of their potential value
- horizon scan for services and health interventions that are obsolete, ineffective or inadequate, and therefore exit or cessation is likely to be appropriate
- maintain a register of health interventions and potential disinvestments that have been recommended for assessment, and their status
- develop, over time, a precedent-based threshold against which health interventions can be ranked on their appropriateness for introduction to the New Zealand public health system, or for their provision to cease
- provide timely recommendations to the National Capital Committee on the service aspects of capital projects that require National Capital Committee approval
- co-ordinate the development of business cases, including the evidence component
- analyse and evaluate proposals for change and business cases and recommend their adoption or rejection to the DDG-CEO Group.

Printed copies of the report can be obtained from:

NSTR Convener
Ministry of Health
PO Box 5013
Wellington
New Zealand.

Enquiries about the content of the report should be directed to the above address.
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NSTR Recommendations

Context
The National Service and Technology Review Advisory Committee (NSTR) considered the Management of Adult Morbid Obesity in New Zealand in the context of:

- the New Zealand Health Strategy to improve nutrition, increase physical activity and reduce obesity
- high obesity levels in New Zealand and accurate statistics for the prevalence of morbid obesity
- the Health Select Committee in its August 2007 report “Inquiry into Obesity and Type 2 Diabetes in New Zealand” recommended ‘that the provision of publicly-funded bariatric surgery be explored as a last resort for people who are morbidly obese’
- ensuring co-ordinated equity of access to publically funded bariatric surgery across New Zealand.

Recommendations

NSTR recommends that the District Health Board (DHB) CEOs and the Ministry of Health’s Executive Leadership Team (ELT) note that:

1. the cost of a 0.5% intervention rate is ~$17.1 million in the first year in which the intervention rate is reached, as per the modelling provided in the business case, declining to a net cost of ~$15.9 million in Year 2, ~$14.5 million in Year 3, ~$13.2 million in Year 4 and ~$11.2 million in Year 5 as savings are realised

2. bariatric surgery should be prioritised using existing patient selection criteria and that this should occur alongside prioritisation for other general surgical procedures

3. based on expert opinion, DHBs may consider including wrap-around services as an adjunct to bariatric surgery. It is acknowledged, however, that there is currently insufficient evidence in the literature to support this more strongly. This is the subject of the Counties Manukau DHB pilot study

4. there is a mix of public and private capacity available to provide the service

5. further research into non-surgical interventions is required for those who are not suitable for surgery, although such research is outside the scope of this business case

6. normal project assurance will apply.

NSTR recommends that the DHB CEOs and the Ministry’s ELT support:

7. new funding being made available for standard care pathway (bariatric surgery and dietary advice) for bariatric surgery based on the strength of the findings of the business case

8. that funding is available through additional Elective Services initiatives to undertake bariatric surgery.

NSTR recommends that the DHB CEOs and the Ministry’s ELT agree that:
9. DHBs use their existing nationally recognised general surgery prioritisation criteria to assign priority for bariatric cases amongst their wider general surgical cases

10. the standard care pathway for bariatric surgery be publicly funded in New Zealand for the management of those who are morbidly obese

11. to achieve geographic equity, each DHB agree to aim for an intervention rate of 0.5% of its morbidly obese population – at current estimates this equates to 915 bariatric procedures nationally

12. provision of bariatric surgical units be dependent upon each DHB or region having the surgeon capacity and volume, and the physical capacity, required for a clinically and financially viable service

13. the development of bariatric surgical units follow the guidelines of the International Federation for the Surgery of Obesity guidelines for Bariatric Institutions

14. a National Implementation Group be established to support the implementation of bariatric surgery. This Group would in principle be led and supported by the Ministry of Health’s Elective Services Team

15. there will in time be a nationally funded longitudinal study of equity of access, outcomes, and other key performance indicators to plan for the future of the service. This study should be initiated and co-ordinated by the National Implementation Group.
NSTR Considered Judgement Guide

This form outlines the issues considered by the National Service and Technology Review Advisory Committee (NSTR) when reviewing and making recommendations on proposals for change and business cases. This form will be used by NSTR members to record their comments when reviewing proposals for change and business cases, and to record the meeting discussion and NSTR recommendations.

<table>
<thead>
<tr>
<th>Meeting date:</th>
<th>For NSTR discussion at May 2008 meeting</th>
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<tbody>
<tr>
<td>Proposal topic:</td>
<td>Management of Adult Morbid Obesity in New Zealand</td>
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| Background and purpose: (description of the proposed service change or new health intervention) | The business case is presented to NSTR to: 
- approve the attached business case (refer to Attachment 1) for the management of adult morbid obesity. |

In June 2007 NSTR approved the development of a full business case to address the management of adult morbid obesity in the New Zealand public health system. Counties Manukau District Health Board (CMDHB) sponsored the business case, with the process being overseen by a steering group consisting of representatives from primary care, public health, surgery, Maori, Pacific Island and consumers throughout the district health boards (DHBs).

New Zealand, along with the vast majority of developed countries, is experiencing an obesity pandemic. The most recent figures show that 20% of males and 22% of females in New Zealand are obese. Obesity is evident across all age groups, ethnicities, socioeconomic groups and genders in New Zealand. However, it is more prevalent among Maori, Pacific and Asian Indian ethnicities.

The consequences of obesity include increased risk of mortality, illness and disease, reduced quality of life and opportunities to whanau, and increased costs, both direct and indirect. These problems continue to worsen more significantly amongst the group for whom the consequences are most dire, i.e., those who are ‘morbidly obese’. In general terms, the greater the morbid obesity, the greater the impact of diseases and co-morbidities.

The business case considered alternative options for the treatment of morbid obesity and following assessment and analysis of both surgical and non-surgical options, it recommends the provision of bariatric surgery in the New Zealand public health system for the treatment of some morbidly obese individuals.
Considered judgement guide – business case

Rating definitions

1. Very poor – little detailed information and analysis for decision making
2. Poor – some detailed information and analysis for decision making
3. Good – sufficient detailed information and analysis for decision making
4. Very good – exceeds detailed information and analysis required for decision making
5. Excellent – exceeds and provides additional information and analysis for decision making

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<td>Expert clinical evidence and health technology assessment</td>
<td>Is the information comprehensive?</td>
<td>The Steering Group commissioned a Health Technology Assessment (HTA) which looked to address the safety, effectiveness and cost effectiveness of surgical and non-surgical interventions for patients with morbid obesity. The HTA concluded that surgical interventions were significantly more effective than non-surgical interventions in terms of weight loss among morbidly obese patients and thus in turn leads to the improvement and often resolution of obesity-related co-morbid conditions. There is a lack of available New Zealand-specific information in this area – as might well be expected. If the proposals for bariatric surgery are supported, it is hoped that high quality New Zealand-based data is collected, providing the information recommendations in the business case are followed. At this formative stage, the business case is reliant on reasonably small sets of data upon which to generate a number of assumptions and costs.</td>
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<td>Does the evidence support the proposed change?</td>
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<td>What is the evidence for the effectiveness and clinical safety of the proposal, the effectiveness of the counterfactual and the relative effectiveness?</td>
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<td>Are there other likely future users/applications for the technology?</td>
<td>Projections are that the morbidly obese population in New Zealand will continue to grow at around 3% per annum.</td>
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<td>Bariatric surgery will only be suitable for a relatively small cohort of patients and will be limited by capacity constraints. Pending resource availability and an evaluation of the effectiveness of bariatric surgery, there could possibly be an expansion in the number of procedures per annum from the planned initial surgical provision rate of 0.5% of the morbidly obese population. The business case also provides information about a possible bariatric surgical programme that would cover 1% of the morbidly obese population.</td>
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<td>Are the units in which effectiveness has been measured appropriate?</td>
<td>Yes.</td>
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<td>Can the effectiveness and safety of the proposal and the counterfactual be compared?</td>
<td>The HTA identified seven systematic reviews which examined the evidence comparing non-surgical and surgical interventions for morbid obesity. The general consensus of the reviews was that there was adequate evidence to support the effectiveness and safety of bariatric surgery. The HTA found that the clinical effectiveness of different bariatric surgical procedures, mainly due to the lack of evidence available, was less clear. The business case does not support or recommend the use of one type of bariatric surgical technique over another, but the business case does provide sound statements that should be followed/considered.</td>
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<td>Population health gain</td>
<td>Has the population group affected by the proposal been clearly identified?</td>
<td>Yes, there is good general information available on the obese population within New Zealand and also on the numbers of morbidly obese population across all DHB areas. Assumptions have had to made within the business case about the patient group that would be eligible for bariatric surgery. Patient prioritisation will be important given that resources will be limited. A proposed patient selection criteria for eligibility for bariatric surgery is provided within the business case. The business case indicates that the development of a National Scoring Tool for General Surgery is about to be commenced, and that this should include consideration of bariatric surgery within its scope.</td>
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<td>What is the impact the proposal will have on the relevant population group?</td>
<td>The expected health gains for the relevant population group are well documented in the business case in terms of weight loss, but of potentially greater significance is the impact of bariatric surgery on risk factors, co-morbid conditions, quality of life and ultimately mortality.</td>
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<td>What is the timeframe?</td>
<td>The business case recommends a phased approach to the introduction of bariatric surgery. It indicates that the establishment of bariatric surgical units will be dependent upon physical and surgeon capacity and volume of each DHB or within a region. It will be an individual DHB decision as to whether or not bariatric capacity is developed locally. The business case recommends that all bariatric surgical units will follow the guidelines of the International Federation for the Surgery of Obesity guidelines for Bariatric Institutions.</td>
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<td>What is the alternative, either currently provided or as an alternative new intervention?</td>
<td>The business case identified and considered four options for the management of morbid obesity, which included current care pathway and alternative interventions.</td>
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<td>How does the proposal contribute to the delivery of modern models of care (see Appendix 1)?</td>
<td>The proposal should fit well with modern models of care and for the proposed bariatric surgery programme to be successful it must link, support and work with the range of initiatives and programmes underway for reducing obesity across New Zealand. The proposed bariatric surgical programme must also ensure appropriate links with the Elective Services Programme.</td>
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<td>Cost effectiveness</td>
<td>Are there any estimated savings that will accrue from the proposal, and when?  Are there any potential efficiency gains?  What is the relative value for money of the proposal when compared with the counterfactual?  Have the costs and the benefits (effectiveness) been adjusted for differential timing?</td>
<td>The business case authors must be commended for the economic analysis work undertaken given the limitations on the availability of information. LECG have undertaken a peer review of the economic analysis of an earlier of the business case and LECG’s comments have been incorporated into the final business case. Based on the eligibility criteria for surgery and the expected referral pathways, it is expected that patients would be drawn from those with significant co-morbidities, or risks of same. In cost terms, that would mean looking at the more expensive end of the morbid obesity spectrum in terms of expected health care costs going forward over time. From the economic analysis work undertaken, the analysis demonstrated that bariatric surgery could potentially range from being cost saving to DHBs through to having a cost of up to $8000/QALY. Cost savings can actually be converted into actual savings. The financial uncertainty inherent in the business case is the assumption that the population cost savings modelled for will be very similar to the future population selected for surgery when the proposed programme is running. The possibility exists that future treatments savings may take longer to realise than suggested by the modelling, if lower risk patient with fewer comorbidities are selected. However this type of bias in selection by arresting progression of comorbidities earlier, may ultimately avoid greater future treatment costs. This is impractical to model and it is appropriate to accept the uncertainty in the cost benefit modelling presented within the business case.</td>
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<td>Cost effectiveness (continued)</td>
<td>Based on the positive conclusions of the HTA, the business case did not fully quantify the health savings, they are noted but not quantified. The emphasis in the business case is on the impact of morbid obesity and bariatric surgery on health costs. The business case is therefore innately conservative in that respect, particularly given that the benefits to be gained outside of hospital (primary care, employment/ social welfare, family issues, etc) of a bariatric surgical programme.</td>
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<td>Do all the costs all come at once and do the benefits come a long time into the future?</td>
<td>The business case identifies the potential full year costs involved in undertaking a programme of bariatric surgery across all DHBs. Indicative cost estimates are provided for each DHB area over a 10-year period. It is estimated that cost savings will be derived from year two.</td>
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<td>Has an incremental analysis (eg, has the number or severity of people treated been varied to see what difference this makes to effectiveness and cost) been done?</td>
<td>Analysis work has been undertaken as part of the economic analysis work undertaken. Relative assumptions have been made in the business case.</td>
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<td>Has a sensitivity analysis (eg, how far costs would have to fall/rise to make the proposal cost effective/not cost effective) been done?</td>
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<td>Equity and opportunity cost</td>
<td>What are the alternatives to compare this proposal to? Who benefits? What could be done instead? Who would benefit then? Are the right options reflected in the options analysis? What consideration has been given to the opportunity costs of funding this over other potential proposals?</td>
<td>The Steering Group supporting the business case undertook an option identification and analysis exercise, which considered four options for the management of morbidly obese population. There are no alternatives to compare this model too apart from the current pathway for the management of morbidly obese people. Information is provided within the business case in relation to the ethical/moral debate around the proposed programme of support for the management of morbidly obese. The patient group who would benefit from the proposal are identified and proposed patient selection criteria is outlined in the business case, which are based on supporting principles. Bariatric surgery is a branch of general surgery and the expectation should be that people will be prioritised for access to bariatric surgery alongside other general surgical procedures.</td>
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<td>Will the proposal help to reduce current disparities in health and wellbeing compared with the alternative (i.e., the counterfactual)? Is this quantified?</td>
<td>Yes, the evidence within the business case indicated that the proposal would support health gain for the targeted population and so look to reduce current disparities faced.</td>
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<td>What is the impact on equity, both between DHBs and between different groups in the community, in particular those with low health status?</td>
<td>The business case proposes that a national roll-out programme takes place so looking to ensure equitable service coverage across the country. It will be important given the capacity issues that access is equitable and it is proposed that a national programme of data collection is implemented to ensure that a programme of bariatric surgery is achieving equity of access. It is expected that the eligibility selection criteria will end up prioritising Maori and Pacific patients – due to the prevalence of morbid obesity and co-morbidities in those populations and thus their need. No explicit targets are set as that would then give the appearance of one patient being favoured over another. The addition of CPAC scores has resulted in a large increase in equity in other procedures being achieved without explicit targets being set and we would expect a similar scenario to occur in the case of bariatric surgery.</td>
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<td>Whanau ora</td>
<td>The proposal will be effective in helping to looking to reduce disparities in health and wellbeing for Maori given that Maori people have higher proportion of morbidly obese individuals.</td>
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**Whanau ora**

- How will the proposal contribute to whanau ora compared to the alternative?
- Is there evidence that the proposal will address a problem that is significant to Maori or affects Maori disproportionately?
- Is the proposal (in particular its delivery) likely to be effective for Maori and thus help to reduce disparities in health and wellbeing for Maori compared to the alternative?
- What is the evidence on this?
- Will this proposal reduce costs and other barriers to access for Maori, or could it impose costs? Are those costs identified?

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<td>Funding stream and affordability</td>
<td>Funding stream</td>
<td>The business case seeks new funding to support the proposal as there is no capacity within existing funding streams to support the proposed programme.</td>
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<td>What funding streams are planned or potentially available for fund the proposal?</td>
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<td>What consultation has taken place with funders?</td>
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<td>How will the capital costs be funded?</td>
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<td>How will the annual operating costs be funded?</td>
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<td>Does the proposal rely on any new funding? If so is it approved or likely to be?</td>
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<td>What impacts on inter-district flows would result?</td>
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<td>What are the implications/consequential impacts of a decision to fund?</td>
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<td>Would a decision to fund contribute to a break-even DHB environment?</td>
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<td>If not, what would need to take place to ensure that the proposal would contribute to a break-even DHB environment?</td>
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<td>Have all the relevant costs for each alternative been identified?</td>
<td>Yes as far as possible given the economic constraints faced. The costs outlined in the business case are good and are based on data from CMDHB.</td>
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<td>Have the boundaries of what costs are included been defined?</td>
<td>Yes</td>
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<td>Has the proposal and the counterfactual been compared under the same boundaries?</td>
<td>Yes</td>
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<td>Are the physical units in which the costs have been counted comparable?</td>
<td>Yes</td>
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<td>Are all the consequential or downstream costs accounted for?</td>
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<td>Will the proposal free up resources that can be used for other services?</td>
<td>Yes, the business case indicates that bariatric surgery will based on the assumptions considered in the business case be either cost saving or at worst have a relatively low cost per QALY.</td>
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<td>Have any potential efficiency gains and savings been identified and is there a sound plan to realise the gains?</td>
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<td><strong>Community acceptability and ethical issues</strong></td>
<td>Is the proposal consistent with community values? Are there significant ethical, social, political or legal issues or other patient concerns surrounding the use of the technology? What is proposed to address any such issues?</td>
<td>The business case authors must be commended on the survey work undertaken as part of the business case development. A brief commentary is made within the business case and how these issues could be supported. The business case outlines some survey work undertaken. This indicated that Pacific people who have higher rates of prevalence of morbidly obese people were less in favour of surgical management. This may create some difficult issues when looking at inequalities and ensuring equity of access.</td>
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<td><strong>Service configuration and implementation planning</strong></td>
<td>Have the flow-on effects been identified and planned for? What consultation has taken place with groups (eg, the New Zealand Health Information Service or Information Liaison Group) on information requirements, or the consequential information flow impacts of the proposal? How will the information flow impacts be accommodated and at what cost?</td>
<td>The business case identified that there was currently no standardised data collection systems for bariatric surgery. The business case recommends the establishment of a national Implementation Group to support the implementation of bariatric surgery. This will include work on data collection. As DHBs take forward the implementation of the service, they will have to as part of their plans ensure that consideration is given by DHBs to flow impacts.</td>
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<td>Does the proposal reflect clinical realities and available resources?</td>
<td>Yes, as it is not possible within current available resources for the proposal to progress and so new resources are sought.</td>
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<td>Have any resource constraints that may impede implementation of the proposal been identified (eg, workforce constraints, capital constraints, timing issues)?</td>
<td>Yes, issues highlighted and identified.</td>
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<td>What training is required to ensure there is a workforce with the required skills to implement the proposal?</td>
<td>Good information identified within the business case around the quality assurance mechanisms (International Federation of Surgery for Obesity (IFSO)) for the proposed programme, which include guidelines for workforce and institutions.</td>
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<td>What are the timeframes and steps/components required to implement the proposal and manage risks?</td>
<td>The business case indicates that establishment of bariatric surgical units will be dependent upon physical and surgeon capacity and volume of each DHB or within a region. It will be an individual DHB decision as to whether or not bariatric capacity is developed locally.</td>
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<td>Are there capital requirements or impacts? If so, how will these be addressed?</td>
<td>Yes. Many of the capital costs are being incurred by DHBs currently anyway – they still have to routinely operate on this subset of the population (appendicitis, gall stones etc) irrespective of whether or not bariatric surgery is part of the DHB’s surgical programme. It would be assumed that DHBs pick up capital costs with the proposed programme.</td>
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## Criteria

<table>
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<tr>
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<th>Questions</th>
<th>Comments (value judgement of evidence) and Rating (quality of evidence)</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria</td>
<td>What service configuration changes are required?</td>
<td>It will for individual DHBs to look at service configuration issues in taking forward the implementation of the proposed programme of bariatric surgery.</td>
<td></td>
</tr>
<tr>
<td>Criteria</td>
<td>How will the outcomes and benefits of the proposal be reviewed and how will the risks be managed?</td>
<td>The business case indicates that as part of the work programme for the national Implementation Group that as part of the data collection for bariatric surgery this looks at assessing equity of access, outcomes, and other key performance indicators.</td>
<td></td>
</tr>
<tr>
<td>Priority in relation to other proposals in the annual decision making round, and against past precedents</td>
<td>How does this proposal relate to previously considered proposals?</td>
<td>NSTR decided not to score this option.</td>
<td></td>
</tr>
<tr>
<td>Priority in relation to other proposals in the annual decision making round, and against past precedents</td>
<td>Rating (out of 5 where 1 = low, 5 = high)</td>
<td>Not considered by NSTR</td>
<td></td>
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</table>
| Recommendations | Record your recommendations and any conditions. | The clinical evidence to support a programme of bariatric surgery for the management of adult morbid obesity is sound, but there are some gaps around the economic analysis. However given the constraints faced in undertaking the economic analysis, NSTR should:  
- Agree that within the current profiles and data available that no further economic modelling needs to be undertaken.  
Therefore: NSTR should support this business case for the introduction of a publicly funded standard care pathway for bariatric surgery for the management of those who are morbidly obese. |       |
### Appendix 1 – Modern Models of Care

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<tr>
<td>Culture of independence</td>
<td>Collaborative</td>
</tr>
<tr>
<td>Little sector leadership</td>
<td>Confident, strong sector leadership</td>
</tr>
<tr>
<td><strong>Traditional models of care</strong></td>
<td><strong>Modern models of care</strong></td>
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<tr>
<td>• ‘silo-focused’ care</td>
<td>• collaborative care</td>
</tr>
<tr>
<td>• hospital focused care</td>
<td>• ambulatory</td>
</tr>
<tr>
<td>• reactive</td>
<td>• integrated with primary care</td>
</tr>
<tr>
<td>• emergent</td>
<td>• futures, long-term</td>
</tr>
<tr>
<td>• ‘clinical services firm’</td>
<td>• Inter-disciplinary</td>
</tr>
<tr>
<td>• focus on the individual</td>
<td>• inclusive of public health</td>
</tr>
<tr>
<td>• episodic care</td>
<td>• anticipatory</td>
</tr>
<tr>
<td>• uni-causality approach to care</td>
<td>• focus on population patterns</td>
</tr>
<tr>
<td>• doctor oriented</td>
<td>• continuity of care</td>
</tr>
<tr>
<td>• passive recipients</td>
<td>• chronic / complex condition capability</td>
</tr>
<tr>
<td></td>
<td>• multidisciplinary teams</td>
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<tr>
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<td>• enabled participants</td>
</tr>
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<td>Multiple ad hoc decision-making structures</td>
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<td>Unsustainably fragmented services</td>
<td>Service critical mass</td>
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Management of Adult Morbid Obesity in New Zealand

(a project convened by the New Service & Technology Review Committee - NSTR)
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Background

- In June 2007 the National Service & Technology Review Committee approved the development of a full business case proposal to address the management of adult morbid obesity in the New Zealand public health system. Counties-Manukau District Health Board (CMDHB) has been the Sponsor of this work. The business case was developed using the Service Planning and New Health Intervention Assessment (SPINIA) Framework.

- A Steering Group has overseen the development of this business case. The Steering Group includes representatives from primary care, public health, surgery, Maori, Pacific Island and consumers throughout the District Health Boards (DHBs) of New Zealand.

- This business case addresses the management of obesity among adults (those aged 18 years and older). It should not be interpreted that the findings of this work apply to those below 18 years of age.

- There has been extensive verbal and written communication on this business case. Presentations have been made to the Sector Information Group (SIG), Sector Funding Group (SFG), Regional Forums and clinicians throughout different DHBs. Written updates have been provided to a wide range of stakeholders including Chief Executive Officers, Chief Medical Officers, clinicians and funders.

- Obesity in New Zealand, and other developed countries, is a pandemic. New Zealand has good information on obesity as a result of a series of cross-sectional prevalence surveys conducted over 26 years, between 1977 and 2003. The most recent figures show that between 1977 and 2003 obesity has increased from 9% to 20% for women and 11% to 22% for men. The increase in the prevalence of obesity in New Zealand has occurred despite increased knowledge, awareness and education about nutrition, physical activity and obesity. There are no signs of a slowing in obesity, and Prime Minister Helen Clark has described it as ‘a time bomb for New Zealand and the Pacific.’

- For the purposes of this work, morbid obesity is defined as Body Mass Index (BMI) $\geq 40$ kg/m$^2$ and BMI $\geq 35$ kg/m$^2$ in the presence of significant comorbidities. Nearly 153,000 (5.8%) of the adult New Zealand population (aged 15-64 years of age) can be classified as being morbidly obese. Updated to 2008/2009 figures, the number of morbidly obese more closely approximates 183,000. Maori and Pacific people are significantly disproportionately represented in morbid obesity statistics. Worryingly high proportions of Maori women and men (13% and 14% respectively) and Pacific women and Pacific men (28% and 18% respectively) are morbidly obese. These figures exclude those with BMI $\geq 55$ kg/m$^2$.

- There is enormous variability throughout the country in terms of the absolute number of people with morbid obesity ranging from 910 in West Coast DHB up to 22,830 in CMDHB. The five DHBs with the highest prevalence of morbidly
obese are (in order) CMDHB, Tairawhiti DHB, Lakes DHB, Northland DHB and Auckland. The DHBs with the five absolute highest numbers of morbidly obese are (in order) Counties-Manukau DHB, Auckland DHB, Waitemata DHB, Canterbury DHB and Waikato DHB.

- Traditionally, the development of obesity was largely attributed to overeating. Today it is well accepted that New Zealanders live in an ‘obesogenic environment’ – characterised by ready access to poor nutrition combined with reduced physical activity. Over time genes have not changed but significant changes in the environment have occurred. Processed, high energy (sugar, starch, industrial fats) foods, coupled with low micronutrients (vitamins, cofactors minerals), persistent advertising of food, and lack of habitual, daily physical activity are major contributors to the increase in obesity.

- The increase from obesity to morbid obesity is characterised by the markedly increased risk of mortality and comorbidities as a consequence of additional fat. The consequences of obesity are well established. They include mortality, morbidity, reduced quality of life and increased direct and indirect costs. The risk of death doubles for individuals with morbid obesity and their life expectation is reduced by between 5 and 20 years, in comparison with the lean population. Hypertension, dyslipidemia, sleep apnoea, type 2 diabetes, cancer and increased risk for cardiovascular disease are common examples of the morbidity associated with obesity. Studies have demonstrated increased rates of prejudice and stigmatisation, as well as social isolation and depression amongst obese and morbidly obese groups. The direct costs of obesity in New Zealand have been conservatively estimated at $303 million per annum. These exclude indirect costs which have been reported as being substantial.

- CMDHB is currently conducting a randomised controlled trial comparing the effect of intensive wrap-around support (health psychologist and cultural support in addition to surgeon, anesthetist, dietician) versus standard pathway of care (surgeon, anesthetist, dietician) to maximise weight loss among high-risk subjects with type 2 diabetes mellitus and morbid obesity, treated with bariatric surgery. Sixty participants are being recruited for the trial and participants will be treated for an 18 month period. One of the key components of the wrap-around service includes intensive individual and group input by a health psychologist over the 18 month wrap-around programme duration. Efficacy, safety and the effects of the interventions on healthcare costs will all be evaluated and reported in approximately 12 months.

- The Health Select Committee recently has released its report “Inquiry into Obesity and Type 2 Diabetes in New Zealand.” The report was based on a wide range of information sources including scientific literature, expert opinion, public submissions and expert evidence from the Ministry of Health. Recommendation 32 of the report specifically relates to the management of morbid obesity and has been agreed upon by Government, that is, “That the provision of publicly-funded bariatric surgery be explored as a last resort for people who are morbidly obese (and that) the outcomes of the pilot research project being conducted by Counties-Manukau District Health Board be monitored for cost-effectiveness to this end.” The report notes that this business case is in progress and will be considered by the National Service and Technology Review Advisory Committee early 2008.

- This work has coincided with widespread media coverage about the management of morbid obesity through bariatric surgery. The Steering Group wish to note that some of those contacted during the business case process
expressed opposition to the idea that people with morbid obesity receive public health funding to manage their obesity and comorbid conditions. This appears to be based on a premise that individuals with morbid obesity should be held individually accountable for their obesity. This business case clearly demonstrates the complex interaction of many different factors that bring about morbid obesity. It also notes the prejudice and stigmatisation faced by people with morbid obesity.

Health Technology Assessment

- One of the first tasks of the Steering Group was to commission a Health Technology Assessment (HTA) to review high quality scientific literature evaluating the effectiveness of different strategies to manage morbid obesity. Specifically, the HTA addressed the safety, effectiveness and cost effectiveness of surgical and non-surgical interventions for patients with morbid obesity. The main conclusions of the HTA were that bariatric surgery is a more clinically effective and cost effective treatment option for those with morbid obesity compared with non-surgical treatments. Surgical intervention results in significantly greater weight loss and this in turn leads to the improvement and often resolution of obesity-related comorbid conditions. Very little evidence was available regarding the effect of pre- and post-operative services (wrap-around) on the effectiveness of surgical procedures.

- Mortality rates were judged to be relatively low (<2%) for all the considered procedures but the quality of studies available for the calculation of rates was overall poor and often based on data from case series. A meta-analysis suggested a 30 day mortality rate of 0-2.1% for Roux-en-Y gastric bypass, adjustable gastric banding, and vertical gastric banding surgical procedures based on controlled trials, and a rate of 0-0.8% using case series data for the same procedures. Surgeon experience was highlighted by several reviews as a possible source of variation in mortality and complication rates. In well-selected patients operated on by experienced surgeons, the perioperative mortality rate could be expected to be very low.

- Less clear is the relative clinical effectiveness of different surgical procedures, mainly due to a lack of randomised controlled trials with long-term follow-up of an adequate proportion of patients. It appears that the choice and success of bariatric procedures depend largely on patient characteristics, such as baseline BMI, comorbidities, food habits and psychological differences, as well as patient and surgeon preference. Whilst no recommendation on the specific type of bariatric surgery can be made at this stage, it is important to note that the HTA found that most obesity-related comorbid conditions, in particular, diabetes, hyperuricemia, hyperlipidemia, and sleep apnoea resolved or improved with postoperative weight loss and that this was not dependent on surgical procedure. Whilst not a specific finding of the HTA, the clinician representatives on the Steering Group strongly recommend that gross malabsorptive procedures should not be implemented, for example, biliopancreatic diversion due to safety concerns.

- Based on the findings of the HTA the Steering Group concluded that whilst no clinical trials were New Zealand studies, the findings are generalisable to the New Zealand population. The studies demonstrate broadly similar findings, irrespective of the country of origin and study participants. Notwithstanding New Zealand’s unique cultural composition, it is reasonable to assume that the
outcomes reported in the HTA are applicable to a New Zealand public health setting.

**Bariatric surgery**

- The most common bariatric surgical techniques performed today (internationally) are gastric bypass (open or laparoscopic), laparoscopic gastric banding and to a lesser extent biliopancreatic diversion. In New Zealand, the most common bariatric surgical procedure performed is the Roux-en-Y gastric bypass, the majority of them done laparoscopically, followed by laparoscopic gastric banding and more recently the sleeve gastrectomy (public and private settings).

- The reported number of bariatric surgical procedures in the United States has increased 800% between 1998 and 2004 (n=121,055 operations in 2004). Bariatric surgery is the most rapidly growing area of surgical practice currently in Australia.

- In New Zealand two public hospitals (North Shore Hospital and Dunedin Public Hospital) offer a small number of publicly funded bariatric operations each year (24 at North Shore Hospital in 2006/2007 and 17 at Dunedin Public Hospital for the same period). Bariatric surgery has been offered through the private system in New Zealand for over thirty years. Today, it is made available through private practices in a number of centres including the North Shore, Auckland Central, Waikato, Wellington, Christchurch and Dunedin. A number of DHBs are also funding some bariatric surgery and this is being undertaken in the private setting (Counties Manukau, Waikato and Wellington DHBs, among others).

- Based on the high-level scientific evidence at the time of this paper, the Steering Group does not support the use of one type of bariatric surgical technique over another. Bariatric surgeons working in New Zealand public hospitals should be able to perform the commonly performed operations, i.e. adjustable gastric banding and Roux-En-Y gastric bypass.

**Options analysis**

- Given the findings of the HTA, identifying the options for inclusion in the business case was reasonably straightforward. The Steering Group was of the view that the following four options should be included:
  - standard care pathway for bariatric surgery (surgeon, anaesthetist, dietician)
  - bariatric surgery with wrap-around services (surgeon, anaesthetist, dietician and cultural support and a health psychologist)
  - intensive non-surgical support and
  - usual care.

- The HTA reported no evidence of effectiveness for wrap-around services in the management of morbid obesity. Wrap-around services pre-surgery often includes meal replacement, general diet and physical activity advice and sessions with a psychologist. The same therapies are delivered after surgery to help with weight loss. It was the view of the Steering Group, that the role of wrap-around is likely to be important. Patients undergoing bariatric surgery are a relatively high risk group for surgery. Undertaking bariatric surgery requires major lifestyle changes. Patients (and family and whanau also) are required to make major changes in relation to their eating behaviours and attitudes towards
food. For the purpose of defining the wrap-around services used in the analysis, the wrap-around component of the CMDHB randomised controlled trial was included.

- The rationale for including intensive non-surgical support in the business case was that for the purpose of completion, comparison, and on the basis of expert advice, it should be included.
**Costs and benefits of options**

- The initial economic analysis and modelling carried out for the purpose of this business case was externally peer reviewed. Based on the findings of the peer review further analysis was undertaken for the final version of the business case.

- Probabilities of effectiveness were based on the findings of the HTA and expert opinion. Health care costs were based on actual experience where possible. Cost data related to morbid obesity were derived from the CMDHB Chronic Care Management dataset. Two methods were triangulated to address the cost of usual care for the morbidly obese group and the healthcare savings if significant weight loss was achieved. Based on the HTA it was assumed that 90% of those undergoing a programme of bariatric surgery would have successful outcomes at five years. Success was defined as >50% excess weight loss at five years post bariatric surgery and/or resolution of comorbidities. Based on expert opinion it was assumed that 40% of bariatric surgical patients would require abdominoplasty surgery post bariatric surgery to remove significant excess skin as a result of major weight loss.

- The most reliable estimates for costs and effectiveness of surgery is that of standard care pathway for bariatric surgery. Based on this analysis, of a cohort of 1,000 patients receiving standard care pathway bariatric surgery, the intervention would give:
  - 827 patients an excess weight loss of >50% and resolution of most comorbidities (such as diabetes)
  - An excess of 10 deaths at five years, but 2.8 less deaths per annum thereafter
  - Bariatric surgery showing a potential cost saving for the health sector, with a payback time of around 8 years post surgery.

- For the purpose of this business case a 3 percentage point increase in effectiveness was modelled for wrap-around, with costs based on the protocol for that trial. 32 additional successes compared with standard care bariatric surgery would be achieved, at an extra cost of $1.8 million over five years. The payback time to cover the five year cost would be a little over 8 years.

- Sensitivity analyses were undertaken to assess the robustness of the model. If the current cost of care estimate is reduced from $23,700 to $20,500 then the payback period is extended to around 10 years for standard care pathway. Modelling this same scenario of reduced current cost of care for wrap-around, the payback period is 10.5 years. If one drops the effectiveness of bariatric surgery from 90% to 80% of survivors at 5 years then the payback time after extends to 8.5 years for standard care pathway. 26 additional successes are achieved at a marginal cost of $2.02m for wrap-around.

- Based on the standard model of care described above, and assuming that the referral and selection process operated as expected (i.e. the top 25%-costing morbidly obese people are targeted) then bariatric surgery would be cost-saving to DHBs. At a discount rate of 3% DHBs would gain 2-3 Quality Adjusted Life Years (QALYs) QALYs per patient at a savings of $6-7,000. For a women aged 40 years with a BMI of 40, bariatric surgery results in a gain of 6.4 QALYs (no discount), or 3.3 QALYs (3% discount). For a male aged 40 years and BMI 40, bariatric surgery results in a gain of 5.6 QALYs (no discount) or 2.9 QALYs (3% discount).
Even at the higher end of the range the intervention would still be a reasonable buy for DHBs at $7-9,000 per QALY (for example if referral processes and surgical selection were less effective in selecting higher risk patients). It is likely that bariatric surgery will be either cost saving or at worst have a relatively low cost per QALY. The addition of factors outside the hospital sector (primary care, employment/social welfare, other members of the patient’s family, etc) serve to increase the attractiveness of the intervention.

The cost path estimates for providing standard care pathway bariatric surgery by DHB over ten years were developed. Three scenarios were modelled: 0.5% prevalence operative rate, 1% prevalence operative rate and a rollout model (0.5% for the first three years, 1% thereafter). A 0.5% prevalence operative rate would require $47.5m for the first three years, and $80.9m for the first six years. A 1% prevalence operative rate would be about double that of the former rate (i.e. require $95m for the first three years, and $161.6m for the first six). A roll-out model of implementation (0.5% prevalence operate rate for the first three years, 1% thereafter) would require $47.5m for the first three years and $128.3m at six years.

The total cost of bariatric surgery as per the cost model in Year 1 is $17.02 million (inclusive complications, deaths, DRG and non DRG services) based on a 0.5% prevalence intervention rate. 915 morbidly obese individuals would receive the operation at an average cost of $18,600 per patient. The cost of including 40% of these patients requiring reconstructive surgical intervention is an additional $5.0 million.

The basis of the cost modelling is on information the CMDHB Transition data base. Given however that there is a small amount of surgery and plastic intervention for bariatric carried out through public sector now, it is acknowledged that the data is limited. It is also acknowledge that there is a direct relationship between starting up a service and its relativity of cost/price. As with other services, it is anticipated that with experience and volume costs will fall.

Funding and prioritisation

It is proposed that ~$17million be spent in Year 1 (adjusted for demographic growth and inflation and type of procedure). As implementation progress it is expected there will be a reasonable dataset of bariatric surgery utilisation, better information available regarding models of care and outcome data from the CMDHB RCT would also be available. This would enable a submission to the National Pricing Programme in time. At this point a national price could be reviewed and confirmed and bariatric surgery would be accessed alongside other general surgical interventions on a prioritised basis.

The work conducted within this business case does not enable clear statements to be made regarding the prioritisation of bariatric surgery. However, given that the worst case scenario of a higher cost per case QALY is in the order of $7-9,000 this gives a better result than many interventions currently being provided. Therefore bariatric surgery has much merit for implementation.

It is acknowledged that there is not a national scoring tool available currently within the public health sector to prioritise across all areas of General Surgery. Development of a national scoring tool for General Surgery is about to begin and bariatric surgery will be considered within this scope.

Community acceptability and bioethical considerations
In order to better understand the acceptability of bariatric surgery in the New Zealand public health system a research company was approached to develop a nation-wide telephone survey. Approximately 400 people were telephoned and asked for their views on obesity, morbid obesity and the management of morbid obesity. Most (84%) consider obesity in New Zealand to be a serious problem and 61% also consider morbid obesity to be a serious problem. When advised of the benefits of surgery for the management of morbid obesity, 61% reported they were in favour (to some degree) of this approach, although significant differences were reported by ethnic group, with Pacific people being less in favour of this method of management compared with the remainder of the survey sample. Twenty percent of respondents felt strongly that surgery should not be made publicly available for the management of morbid obesity.

It is important to note that the health sector responds to the population at large based on need, and ability to benefit, rather than on perceptions of right or wrong. Those who contract AIDS from illicit drug taking or lung cancer as a result of smoking, for example, are treated for their health needs, and the same approach should be afforded to those with morbid obesity.

Service Planning and Configuration

For the purpose of determining service configuration and planning a number of assumptions were made. Firstly, in line with international trends it is estimated that the proportion of morbidly obese who will receive treatment will be ~0.5%. As per standard quality requirements internationally, each surgeon would need to perform at least 50 cases per annum. A minimum unit load (i.e. bariatric centre) would accommodate a minimum of 150 cases per year. Based on these assumptions and using a 0.5% intervention rate initially there is potential for 5-7 bariatric centres in main New Zealand centres. Should surgery be offered to 1% of the target population a further two centers could be considered.

There are a number of widely accepted quality assurance programmes for bariatric surgery centres. These programmes have some key features in common including the requirement for centres to: participate in a full audit programme; undertake a minimum of 50 cases per surgeon per year; have facilities that are ‘fit for purpose’ and use a multi-disciplinary approach. The Australasian Obesity Surgery Group is a member of the International Federation for the Surgery of Obesity (IFSO) organisation and the quality and excellence guidelines proposed by IFSO are considered to be applicable to the New Zealand public health setting. One of the main objectives of IFSO’s Safety and Excellence Guidelines is to offer advice to institutions and surgeons worldwide regarding the safe and efficient establishment of bariatric surgery programmes (Primary Bariatric Institutions). It is envisaged that a New Zealand publicly funded bariatric surgery programme would operate under these guidelines, and be consistent with Australian standards of care.

Clearly readiness to proceed depends on demand, desire, existing expertise and resources. It is the view of the Steering Group that the best approach for implementing a programme of bariatric surgery in New Zealand is a phased approach. This would allow bariatric surgery to be identified as a valued skill-set, and encourage surgeons to obtain training in the bariatric surgical field. Senior general surgical trainees are a reliable resource pool and upon nearing completion of their training could be targeted for training specifically in this area. It is absolutely essential that training opportunities for bariatric surgery are made available. Larger, higher volume centres will be well placed to attract
New Zealand trained bariatric surgeons. With the appropriate support and resourcing, it is very possible to work towards at least 10 FTEs of bariatric surgeons in NZ over a 3-5 year time frame.

- During the course of this work, the Chair of the Steering Group met with DHBs throughout the country to explore a number of issues. One of these was whether or not there is sufficient capacity for bariatric surgery to be introduced. Feedback provided through a high level survey conducted (Appendix XI) indicates there is a mix of public and private capacity available at Year 1. The potential use of the private sector in the short term is an interim step before public capacity can be established throughout. Coinciding with the development of this business case the Ministry of Health’s Elective Services Project has commissioned an extensive piece of work looking at physical bed and theatre capacity among all 21 DHB. Although this is not completed at the date of finalising our business case, early indications support that there is a level of physical public capacity available for additional surgery in many DHBs.

- A further key theme received by the Chair was that any implementation of bariatric surgery in New Zealand public hospitals requires a whole systems change and approach. For a programme to be successful it must be endorsed and supported collectively. This includes working closely with primary care which is likely to become a major source of referral of morbidly obese patients over time.

Concluding statements

- There are real opportunities to address inequalities amongst Maori and Pacific people with regard to the management of morbid obesity. Maori and Pacific people have particularly high proportions of morbidly obese. The evidence for cost savings and health gains through the standard pathway of care for bariatric surgery is very strong. Benefits extend well beyond improvements in health and function, and include improved quality of life and wellbeing. To ensure that any programme of bariatric surgery can readily demonstrate that it is achieving equity of access, a national programme of data collection is required.

- This business case is proposing the New Zealand public health system gear up to provide bariatric surgery for around 0.5% of the prevalent morbidly obese population in Year 1. However projections at this point are that this population will continue growing at around 3% per year. In addition to any surgical provision DHBs must support initiatives and work in ways that make changes to the obesogenic environment that New Zealanders live in, and which hinders the ability of communities to manage obesity.

The Steering Group has considered the following four options for the management of adult morbid obesity:

- Standard care pathway for bariatric surgery (surgeon, anaesthetist, dietician)
- Bariatric surgery with wrap-around services (surgeon, anaesthetist, dietician, cultural support and health psychologist)
- Intensive non-surgical care
- Usual care.
The Steering Group has been closely involved in the development of the business case. The Steering Group met to consider the key findings of the business case and the recommendations presented here reflect the unanimous view of the Steering Group. The Steering Group recommends:

1. That standard care pathway for bariatric surgery be publicly funded in New Zealand for the management of those who are morbidly obese

2. That an intervention rate of 0.5% of the morbidly obese prevalent population be set in Year 1, as a starting point, equating to 915 bariatric procedures nationally.

3. That 0.5% be the minimum level of intervention for each DHB for its population in Year 1 to ensure consistency of access nationally

4. That there is a mix of public and private capacity and workforce available to enable this. Where private capacity is used this will be an interim step prior to provision of adequate public capacity

5. That the decision to implement standard care pathway for bariatric surgery should not be dependent on the outcomes of the CMDHB pilot (the Steering Group considers the evidence of effectiveness and supporting cost-benefit analysis for the standard care pathway sufficiently strong to recommend immediate implementation)

6. That new funding is made available for standard care pathway for bariatric surgery based on the strength of the findings of this business case. The cost of a 0.5% intervention rate is ~$17million in Year 1.

7. That the funding should be made available through Additional Elective Services initiatives and that the eligibility criteria provided in the business case should be applied as a scoring mechanism in the first instance.

8. That the development of a National Scoring Tool for General Surgery about to be commenced, should include consideration of bariatric surgery within its scope

9. That, based on expert opinion, DHBs may consider including wrap-around services as an adjunct to bariatric surgery. It is acknowledged there is currently insufficient evidence in the literature to support this more strongly. This is the subject of the CMDHB pilot study.

10. That establishment of bariatric surgical units will be dependent upon physical and surgeon capacity and volume of each DHB or within a region. It will be an individual DHB decision as to whether or not bariatric capacity is developed locally. However the development of bariatric surgical units will follow the guidelines of the International Federation for the Surgery of Obesity guidelines for Bariatric Institutions.

11. That a national Implementation Group be established to support the implementation of bariatric surgery. This Group would have an appropriate governance structure and full time project management support in Year 1.
12. That a detailed implementation plan should be developed by each bariatric unit (which may include exploring options for partnership with the private sector in the short term).

13. That as part of the work programme of the Implementation Group a national programme of data collection for bariatric surgery be scoped aimed at assessing equity of access, outcomes, and other key performance indicators. The Steering Group strongly supports this monitoring being undertaken as part of a nationally funded longitudinal study.

14. That further work should be explored as to the possibilities for caring for morbidly obese individuals who are unwilling or otherwise unsuitable for bariatric surgery. Given the current lack of evidence for the management of morbidly obese using non-surgical methods, such work should be conducted as part of a rigorous research trial.
3.1 Introduction

New Zealand, along with the vast majority of developed countries, is experiencing an obesity pandemic. The risk of dying from obesity is now approaching the risk of dying from tobacco related diseases. Early last century approximately 3% of the white population was thought to be obese. In 1977 10% of New Zealanders were reported as being obese. The most recent figures (2002/2003 New Zealand Health Survey) recorded 20% of males and 22% of females as being obese (BMI > 30kg/m²).

The increasing prevalence of obesity has occurred despite increased knowledge, awareness and education about nutrition, physical activity and obesity.¹ Genes have not changed but significant changes in the environment have occurred. Processed, high energy (sugar, starch, industrial fats) foods, coupled with low micronutrients (vitamins, cofactors minerals) and lack of habitual, daily physical activity are major contributors to the increase in obesity. Apart from much processed food being extremely palatable, westernised socioeconomics allows refined types of foods to be persistently and widely advertised. The combination of ready access to poor nutrition together with reduced physical activity characterise what is commonly referred to as the ‘obesogenic environment.’

Obesity is evident across all age bands, ethnicities, socioeconomic groups and genders in New Zealand. However, it is more prevalent among Maori, Pacific and Asian Indian ethnicities. The problem is expected to continue to worsen most significantly amongst the group for whom the consequences are most dire – those who are ‘morbidly obese.’ The increase from obesity to morbid obesity is characterised by the markedly increased risk of mortality and comorbidities as a consequence of additional fat.

Obesity has wide-ranging consequences including increased mortality, morbidity, reduced quality of life and increased direct and indirect costs. The risk of death doubles for individuals with morbid obesity and their life expectation is reduced by between 5 and 20 years, in comparison with the lean population.² Hypertension, dyslipidedemia, sleep apnoea, type 2 diabetes and increased risk for cardiovascular disease are common examples of the morbidity associated with obesity. Studies have demonstrated increased rates of prejudice and stigmatisation, as well as social isolation and depression amongst obese and morbidly obese groups. A New Zealand study of participants with mean (standard deviation) BMI 35.4 (5.3) kg/m² reported significantly impaired health related quality of life particularly in the vitality, bodily pain and physical domains.³ A study of severely obese children and adolescents (age 5 to 18 years) reported significantly lower health related quality of life scores, compared with healthy children of the same age, and furthermore the

² Fontaine et al. Years of life lost due to obesity. JAMA 2003; 289: 187-193
scores were similar when compared with those diagnosed with cancer. The direct costs of obesity in New Zealand have been conservatively estimated at $303 million per annum.

Historically, most people including health professionals viewed obesity as the result of overeating that is easily corrected by reducing the amount of food ingested. Because of this view obesity was not recognised as an important health issue for many years. More recently obesity has been accepted as a disease in its own right. The seriousness of obesity as a leading public health issue has increased in traction, with Prime Minister Helen Clark describing it as ‘a time bomb for New Zealand and the Pacific.’

### 3.2 Classification of obesity

There are a number of ways to estimate and classify body fat, the most common of which is the Body Mass Index (BMI). BMI is defined as body weight (in kilograms) divided by height (in metres squared). Table 1 shows the classification of weight by BMI. For adult New Zealanders (aged 19 years and older) obesity is defined as BMI ≥ 30.0 kg/m² for European, Asian and Other peoples, and BMI ≥ 32.0 kg/m² for Maori and Pacific peoples. In practice, morbid obesity is defined most commonly as BMI ≥ 40 kg/m² or BMI ≥ 35 kg/m² in the presence of a co-existing morbidity. No distinction is made between ethnic groups with regard to the classification of morbid obesity.

#### Table 1 WHO Classification of weight by BMI

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI (kg/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt; 18.5</td>
</tr>
<tr>
<td>Normal</td>
<td>18.5-24.9</td>
</tr>
<tr>
<td>Overweight</td>
<td>25-29.9</td>
</tr>
<tr>
<td>Obese</td>
<td>30.0-39.9</td>
</tr>
<tr>
<td>“Morbid” obesity</td>
<td>&gt;40.0</td>
</tr>
<tr>
<td></td>
<td>(or BMI 35-39.9 with obesity related co morbidity)</td>
</tr>
<tr>
<td>“Super” obesity</td>
<td>&gt;50.0</td>
</tr>
</tbody>
</table>

The BMI classification of weight was developed by the World Health Organisation (WHO) and largely based on study findings of Western populations. It generally correlates highly with adiposity, although misclassification can occur in non-Caucasian populations, those who are fit and well muscled, and a few other small groups. Studies of Polynesians show that they tend to have a lower percentage fat than Caucasians at any given BMI, due to bulkier muscle and denser bones. The reverse has been demonstrated for Asian Indian people. In a study of body

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composition among women of five ethnic groups, differences were found between ethnicities in terms of the relationship between body mass and percentage body fat.\textsuperscript{5} This international study included participants from New Zealand (173 European, 76 Maori, 84 Pacific and 93 Asian). The investigators found that for a BMI of 30 in NZ Europeans equivalent to 43% body fat, the corresponding BMIs for NZ Maori, Pacific and Asian Indian women were 34, 36 and 26 respectively. Pacific women had the lowest central fat mass and Asian Indian women the highest. The difference in the relationship between percentage body fat and BMI may be partly attributable to differences in muscle mass and central fatness. In addition, some of these ethnic groups have a high prevalence of excess upper body fat. Rush et al (2004) found that Asian Indian men, like women, had more body fat for the same BMI compared with Pacific Island and European men in a study of 114 male participants.\textsuperscript{6}

Other measures of obesity include waist to hip ratio (WHR), waist circumference and percentage body fat. Waist circumference and WHR is used as a measure of abdominal obesity. Waist circumference is a quick and simple measurement that correlates well with risk for metabolic syndrome, diabetes and CVD risk. It does not correlate very closely with BMI but BMI has been effectively used for a long time and more frequently measured in the population. In addition, change in waist circumference does not correlate well with change in waist hip ratio in men. Percentage body fat is simply the percent of fat the body contains, which is the unhealthy upper body fat and healthy peripheral body fat.

It is the actual distribution of fat, together with the amount of body fat that is important with regard to the risk of obesity related comorbidities. Men and postmenopausal women have an increased tendency to accumulate abdominal fat.

### 3.2.1 Origins of ‘morbid obesity’

For decades obesity was viewed as purely the consequence of poor individual choice and behaviour. ‘Morbid obesity’ was coined by surgeon J Howard Payne in the early 1960s to highlight the resistance of those in the medical and surgical communities and within health insurance companies to viewing obesity as a disease.\textsuperscript{7} His work and that of colleagues resulted in the development of widely accepted guidelines and indications for the surgical treatment of morbid obesity in 1991 in the National Institutes of Health (NIH) consensus conference. Only as recently as 2004 was the wording “obesity itself cannot be considered an illness” removed by the Center for Medicare and Medicaid services in their National Coverage Determinations Manual\textsuperscript{8} in the United States.

### 3.3 Prevalence of obesity

\textsuperscript{5} Rush et al. BMI, fat and muscle differences in urban women of five ethnicities from two countries. \textit{Int J Obes} 2007 Mar 6.


The prevalence of obesity in New Zealand is 20% for men and 22% for women. The critical threshold set by WHO for epidemics requiring intervention is 15%. Table 2 shows the mean BMI and prevalence of obesity internationally. Obesity prevalence was lowest for New Zealand women compared with the other countries, and the same as England and higher than Australia and Scotland for New Zealand men. The mean BMI for both New Zealand men and women, and elsewhere, is classified as overweight.

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Table 2 International comparisons of mean body mass index (BMI) and the prevalence of obesity

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>Survey age range</th>
<th>Mean BMI (kg/m²)</th>
<th>Obesity (%)†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Males</td>
<td>Females</td>
</tr>
<tr>
<td>Australia</td>
<td>1999/2000</td>
<td>≥ 25 years</td>
<td>26.9</td>
<td>26.4</td>
</tr>
<tr>
<td>England</td>
<td>2001</td>
<td>≥ 16 years</td>
<td>27.0</td>
<td>26.7</td>
</tr>
<tr>
<td>Scotland</td>
<td>1998</td>
<td>16-74 years</td>
<td>26.5</td>
<td>26.5</td>
</tr>
<tr>
<td>USA</td>
<td>1999/2000</td>
<td>≥ 20 years</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

† Obesity defined as BMI greater than or equal to 30 kg/m² except for New Zealand Maori and Pacific groups, where a BMI equal to or more than 32 is used.

New Zealand has good information on obesity as a result of a series of cross-sectional prevalence surveys conducted over 26 years, between 1977 and 2003. These surveys were the 1997 National Diet Survey (random sample of n=1,761; age 20-64 years), the 1989 Life in New Zealand Survey (n=2,924; age 15 years and older), the 1997 National Nutrition Survey (n= 4,100; age 15 years and older) and the 2003 New Zealand Health Survey (n=10,813; age 15 years and older). The combined findings of these surveys are reported in the paper ‘Tracking the Obesity Epidemic’.¹⁰ For Maori the number of respondents was too low in the 1977 survey for inclusion, therefore data on Maori is from 1989 onwards. A key strength of these studies is the use of actual measurement of BMI which is more accurate than self-report. A further survey (2005-2007) will add significantly to the information base on obesity amongst New Zealanders.

Encouragingly, the surveys show that the mean BMI of the New Zealand obese subpopulation has increased only slightly over the observation period. However, as Figure 1 shows, there has been a sustained and significant increase in the proportion of New Zealanders classified as morbidly obese. It is thought that there is a trend for people to move into the overweight category whilst the overweight move through to the obese category, thus not impacting so significantly on the overweight statistics. Therefore a minimal change in the mean BMI hides a significant shift in the distribution of obesity, with a marked increase in the prevalence of morbid obesity taking place. This trend is more evident for males compared with females although women have maintained an overall higher prevalence of morbid obesity. A similar picture exists for Maori and Pacific people.

In a cross-sectional study that aimed to assess the attitudes of Samoans (n=106 aged 25-55 years) to body size and obesity, the researchers found that traditional

views have changed. Like Western societies the Samoan study participants viewed slim body sizes as the ideal. Unlike Western societies however, being large did not have such negative associations.

Figure 1. Prevalence of morbid obesity (BMI > 40kg/m²) in New Zealand 1977–2003

Table 3 presents the estimated prevalence of adults (aged 15-64) with BMI ≥ 35 kg/m² by ethnicity. The Counties-Manukau DHB Chronic Care Management (CCM) programme identified that 4,854/5,096 (94%) of enrolled patients have diabetes mellitus and a BMI between 35-40 kg/m². This is consistent with findings in America where it has been shown that 83% of people with a BMI between 35-40 kg/m² were diagnosed with type 2 diabetes. The table clearly shows the alarmingly high proportion of morbidly obese in New Zealand. Over a third (34.7%) of Pacific women and 21.5% of Pacific men have a BMI ≥ 35 kg/m². Similar proportions of Maori female and male (15.7% and 16.6% respectively) have a BMI ≥ 35 kg/m². Figure 2 shows the 95% confidence interval for BMI groupings by ethnicity and gender and further illustrates the extent of the problem.

Table 3. Estimated prevalence of adult morbid obesity by ethnicity, based on 2002/03 NZ Health Survey

<table>
<thead>
<tr>
<th></th>
<th>Females</th>
<th></th>
<th></th>
<th></th>
<th>Males</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maori</td>
<td>Pacific</td>
<td></td>
<td>Other</td>
<td>Total</td>
<td>Maori</td>
<td>Pacific</td>
<td>Other</td>
</tr>
<tr>
<td>BMI 35-39</td>
<td>8.9</td>
<td>21.1</td>
<td>4.4</td>
<td>5.6</td>
<td>9.0</td>
<td>11.9</td>
<td>3.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>


Figure from: Ministry of Health. Tracking the obesity epidemic: New Zealand 1977-2003

Gregg et al. Trends in the prevalence and ratio of diagnosed to undiagnosed diabetes according to obesity levels in the US. *Diabetes Care* 2004; 27: 2806-2812.

Public Health Intelligence, Ministry of Health December 2007
<table>
<thead>
<tr>
<th>BMI 40-54</th>
<th>6.6</th>
<th>13.2</th>
<th>1.8</th>
<th>2.8</th>
<th>7.6</th>
<th>9.6</th>
<th>0.9</th>
<th>2.0</th>
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<tbody>
<tr>
<td>BMI 55+</td>
<td>0.2</td>
<td>0.4</td>
<td>0.1</td>
<td>0.1</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Total 35+</td>
<td>15.7</td>
<td>34.7</td>
<td>6.3</td>
<td>8.5</td>
<td>16.6</td>
<td>21.5</td>
<td>3.9</td>
<td>6.0</td>
</tr>
</tbody>
</table>
Table 4 shows the estimated number and prevalence of morbidly obese adults by DHB for adults, as per the findings of the 2002/2003 New Zealand Health Survey. They include BMI \( \geq 35 \, \text{kg/m}^2 \) with comorbidities and BMI >40 kg/m\(^2\). The figures do not include BMI >55 kg/m\(^2\). Based on these figures nearly 166,000 of the New Zealand population (6.3\%) are classified as being morbidly obese.

- There is enormous variability throughout the country in terms of the absolute number of people with morbid obesity by DHB, ranging from \( n=970 \) in West Coast DHB up to 24,350 in Counties-Manukau DHB.

- The five DHBs with the highest prevalence of morbidly obese are (in order) Counties-Manukau DHB, Tairawhiti DHB, Lakes DHB, Northland DHB and Auckland DHB.

- The DHBs with the five absolute highest numbers of morbidly obese are (in order) Counties-Manukau DHB, Auckland DHB, Waitemata DHB, Canterbury DHB and Waikato DHB.
### Table 4  Estimated number and prevalence of adult morbid obesity by DHB and ethnicity, based on 2002/2003 NZ Health Survey

<table>
<thead>
<tr>
<th>DHB</th>
<th>Female</th>
<th>Pacific</th>
<th>Other</th>
<th>Male</th>
<th>Pacific</th>
<th>Other</th>
<th>Total</th>
<th>Overall prevalence</th>
<th>Total</th>
<th>Rank</th>
<th>%</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maori</td>
<td></td>
<td></td>
<td>Maori</td>
<td></td>
<td></td>
<td></td>
<td>Female</td>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>011 Northland</td>
<td>1,860</td>
<td>140</td>
<td>1,550</td>
<td>820</td>
<td>110</td>
<td>930</td>
<td>5,410</td>
<td>7.6%</td>
<td>4.2%</td>
<td>5.9%</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>021 Waitemata</td>
<td>1,860</td>
<td>2,790</td>
<td>6,700</td>
<td>880</td>
<td>1,670</td>
<td>3,970</td>
<td>17,860</td>
<td>7.0%</td>
<td>4.2%</td>
<td>5.6%</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>022 Auckland</td>
<td>1,510</td>
<td>4,490</td>
<td>5,800</td>
<td>680</td>
<td>2,660</td>
<td>3,460</td>
<td>18,600</td>
<td>8.0%</td>
<td>4.8%</td>
<td>6.5%</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>023 Counties Manukau</td>
<td>2,940</td>
<td>7,230</td>
<td>4,450</td>
<td>1,260</td>
<td>4,270</td>
<td>2,680</td>
<td>22,830</td>
<td>10.4%</td>
<td>6.2%</td>
<td>8.4%</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>031 Waikato</td>
<td>2,910</td>
<td>650</td>
<td>4,190</td>
<td>1,320</td>
<td>420</td>
<td>2,530</td>
<td>12,020</td>
<td>7.0%</td>
<td>4.0%</td>
<td>5.5%</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>042 Lakes</td>
<td>1,390</td>
<td>180</td>
<td>1,040</td>
<td>610</td>
<td>130</td>
<td>620</td>
<td>3,980</td>
<td>8.0%</td>
<td>4.4%</td>
<td>6.2%</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>047 Bay of Plenty</td>
<td>1,890</td>
<td>160</td>
<td>2,200</td>
<td>860</td>
<td>120</td>
<td>1,280</td>
<td>6,500</td>
<td>7.0%</td>
<td>4.0%</td>
<td>5.6%</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>051 Tairawhiti</td>
<td>860</td>
<td>50</td>
<td>360</td>
<td>380</td>
<td>40</td>
<td>220</td>
<td>1,920</td>
<td>8.9%</td>
<td>4.7%</td>
<td>6.8%</td>
<td>2</td>
<td>18</td>
</tr>
<tr>
<td>061 Taranki</td>
<td>620</td>
<td>50</td>
<td>1,400</td>
<td>310</td>
<td>40</td>
<td>840</td>
<td>3,270</td>
<td>6.2%</td>
<td>3.6%</td>
<td>4.9%</td>
<td>15</td>
<td>15</td>
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<td>071 Hawkes Bay</td>
<td>1,450</td>
<td>310</td>
<td>1,740</td>
<td>640</td>
<td>230</td>
<td>1,040</td>
<td>5,410</td>
<td>7.3%</td>
<td>4.1%</td>
<td>5.7%</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>081 MidCentral</td>
<td>1,030</td>
<td>280</td>
<td>2,110</td>
<td>480</td>
<td>190</td>
<td>1,250</td>
<td>5,340</td>
<td>6.5%</td>
<td>3.8%</td>
<td>5.2%</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>082 Whanganui</td>
<td>580</td>
<td>70</td>
<td>730</td>
<td>260</td>
<td>50</td>
<td>440</td>
<td>2,130</td>
<td>7.0%</td>
<td>4.0%</td>
<td>5.5%</td>
<td>12</td>
<td>17</td>
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<tr>
<td>091 Capital &amp; Coast</td>
<td>1,250</td>
<td>1,910</td>
<td>3,880</td>
<td>550</td>
<td>1,160</td>
<td>2,260</td>
<td>11,010</td>
<td>7.3%</td>
<td>4.4%</td>
<td>5.9%</td>
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<tr>
<td>092 Hutt</td>
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<td>420</td>
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<td>9</td>
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<tr>
<td>093 Wairarapa</td>
<td>220</td>
<td>40</td>
<td>510</td>
<td>100</td>
<td>40</td>
<td>310</td>
<td>1,220</td>
<td>6.3%</td>
<td>3.7%</td>
<td>5.0%</td>
<td>14</td>
<td>20</td>
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<tr>
<td>101 Nelson</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
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<tr>
<td>Marlborough</td>
<td>450</td>
<td>80</td>
<td>1,870</td>
<td>210</td>
<td>70</td>
<td>1,140</td>
<td>3,820</td>
<td>5.7%</td>
<td>3.4%</td>
<td>4.6%</td>
<td>18</td>
<td>14</td>
</tr>
<tr>
<td>111 West Coast</td>
<td>110</td>
<td>10</td>
<td>440</td>
<td>50</td>
<td>10</td>
<td>290</td>
<td>910</td>
<td>5.6%</td>
<td>3.3%</td>
<td>4.5%</td>
<td>21</td>
<td>21</td>
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<tr>
<td>120 Canterbury</td>
<td>1,290</td>
<td>730</td>
<td>6,940</td>
<td>670</td>
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<td>4,150</td>
<td>14,290</td>
<td>5.8%</td>
<td>3.5%</td>
<td>4.7%</td>
<td>16</td>
<td>4</td>
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<tr>
<td>123 South Canterbury</td>
<td>250</td>
<td>20</td>
<td>730</td>
<td>120</td>
<td>10</td>
<td>450</td>
<td>1,580</td>
<td>5.9%</td>
<td>3.4%</td>
<td>4.7%</td>
<td>17</td>
<td>19</td>
</tr>
<tr>
<td>131 Otago</td>
<td>490</td>
<td>230</td>
<td>2,910</td>
<td>240</td>
<td>160</td>
<td>1,730</td>
<td>5,760</td>
<td>5.6%</td>
<td>3.4%</td>
<td>4.5%</td>
<td>19</td>
<td>8</td>
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<tr>
<td>141 Southland</td>
<td>320</td>
<td>80</td>
<td>1,470</td>
<td>160</td>
<td>70</td>
<td>910</td>
<td>3,000</td>
<td>5.7%</td>
<td>3.4%</td>
<td>4.5%</td>
<td>20</td>
<td>16</td>
</tr>
<tr>
<td><strong>Total NZ</strong></td>
<td>24,170</td>
<td>20,400</td>
<td>52,780</td>
<td>11,030</td>
<td>12,520</td>
<td>31,550</td>
<td>152,44</td>
<td>7.2%</td>
<td>4.2%</td>
<td>5.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Overall prevalence</strong></td>
<td>13%</td>
<td>28%</td>
<td>4.9%</td>
<td>6%</td>
<td>18%</td>
<td>3.0%</td>
<td></td>
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</tbody>
</table>

**Notes:**
Based on 2002/03 NZ Health Survey (personal communication, PHI), modeled by DHB
Assumes that 70% of those with BMI 35-39 will have obesity-related comorbidities
Assumes that extreme obesity over the age of 65 is rare - i.e. almost all the 0203 health surveys modeled 15+ are in fact 15-64
In a discussion of some of the key features of the *Tracking the Obesity Epidemic* report, the researchers note:

- The obesity epidemic did not really begin to accelerate until the late 1980s or early 1990s. It is most probable that it began first among middle-aged females. Today it is largely concentrated in the middle-aged groups (especially among males), although some spread into both older and younger age groups has already occurred (especially among females).
- Possible explanations for the observed shift in BMI distribution over the 26-year period (14 years for Māori) include demographic trends, and changes in dietary and physical activity patterns.
- The strong trend towards 1) the consumption of highly energy dense, nutrient poor, pre-processed foods and 2) sedentary electronic pastimes and work modes, with both areas utilising vast resources in advertising.
- Changes in the age structure of the population and ethnic mix and socioeconomic conditions account for little of the observed BMI distributional shifting for the New Zealand population as a whole.
- Reduction in the prevalence and intensity of smoking over the 1980s and 1990s has also been shown to explain very little of the shift in population BMI distribution, both in this study and another (Simmons et al 1996).

The researchers conclude that the major drivers of the epidemic have been changing dietary and physical activity patterns, themselves largely reflections of an increasingly obesogenic environment.

Another important point to note is the increase in childhood obesity rates over the observation period. The 2002 cross-sectional population survey of children aged 5 to 14 years reported Pacific children’s levels of overweight/obesity at 62%, Māori 41% and New Zealand European and Others at 24%. Childhood obesity is strongly associated with adult obesity, and the high prevalence of childhood obesity will continue to fuel the obesity epidemic in New Zealand.

### 3.4 Causes of obesity

One of the great frustrations of the obesity epidemic is that its effective management relies on certainty of the aetiology of obesity, and this is not always straightforward in all cases. Obesity arises because of the complex interaction of many different factors. A huge literature exists debating the exact causes and pathway for the development of obesity. In broad terms obesity is the consequence of complex interactions between metabolic, endocrine, genetic, socio-economic, environmental, cultural, psychological and behavioural factors. Changes that occur in genes are very slow, whereas changes that occur in the socio-economic environment happen rapidly. Even small imbalances in the energy intake-expenditure can lead to large changes in weight over time. However,

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there is evidence that it is not a simple energy in – energy out equation. Other nutrients appear to be involved in controlling energy balance. Some people appear to be more efficient at storing fat, while others appear to metabolise the same kilojoules faster at any given activity. This uncertainty continues to fuel debate over the major drivers of increased obesity prevalence, throughout the world.

It has been readily thought that overeating and easy, sustained access to a high-fat diet is the sole cause of obesity. A study of 11,600 Scottish men and women found that obesity rates were highest amongst those consuming the highest proportion of energy as fat.16 Interestingly, studies show that average recorded energy intake has in fact reduced significantly in the face of increasing obesity rates in Western countries. This suggests that physical activity levels have rapidly declined and it is thought therefore that reductions in physical activity play a significant role in the development of obesity. A prospective study of 12,000 Finns addressing the relationship between behavioural and sociodemographic factors and obesity, found that low levels of physical activity was a more important risk factor for excess weight gain than any feature of the habitual diet of the study sample.17 It is generally accepted that, in Western countries at least, eating too much and doing too little are the primary contributors to obesity.18 Lean (2005) estimates that 90% of obesity in the United States could be abolished by walking an extra 2,000 steps a day (equivalent to using up 0.418MJ) and reducing food and drink intake by 0.418MJ per day.19

Egger and Swinburn (a leading New Zealand authority on obesity) note that behavioural factors influencing obesity such as nutrition and physical activity are the result of complex psychological factors including habits, emotions, attitudes, beliefs and cognitions.20 The researchers have proposed that obesity is caused by an “ecological” model, as are other major epidemics such as smoking, infectious diseases and injuries. The model has three main influences on equilibrium levels of body fat – biological, behavioural, and environmental. These influences are mediated through energy intake or expenditure (or both) and moderated by physiological adjustments during periods of energy imbalance. The level of body fat depends on the net effects of the components of the model and therefore effectively managing obesity is more about making changes to the environment rather than the individual. Fat intake is an important determinant of total energy intake and total energy expenditure is a major determination of fat oxidation for output.

At a population level it appears that dietary fat and energy intake have not fallen as fast as energy output, the result being energy imbalance leading to obesity. The intensity of physical activity that is required for optimal oxidation of fat is controversial. It is thought

that aerobically fit people may oxidise fat most effectively during vigorous exercise but unfit people (who are typically obese) tend to oxidise less fat at all levels of intensity. For population benefits, the best results will be through modest increases in even low levels of physical activity for many people rather than increases in high intensity exercise among a few. Environmental influences include macro and micro levels and represent the public health arm of the obesity problem. Egger and Swinburn (1997) state that when the macro-environment is obesogenic, obesity will become more prevalent, and initiatives that are aimed at influencing individual behaviour will most likely have limited impact.

There are numerous examples of the characteristics of an “obesogenic” environment. They include plentiful fast food outlets, consumption of high sugar drinks, more sedentary environments and leisure activities, greater urbanisation, less incidental exercise, large serving portions and low cost of high fat foods. New Zealand research shows that on average only three meals per week are cooked in the home. Typically, the fat content of meals eaten away from home is higher than home cooked meals. A strong association between neighbourhood deprivation and geographic access to fast food outlets in New Zealand was found in a study of the location of fast food stores, supermarkets and convenience shops. The travel distance to fast food outlets were at least twice as far in the least socially deprived neighbourhoods compared with the most deprived neighbourhoods. In a 26 year follow-up of a Dunedin birth cohort, watching television for more than two hours a day during childhood and adolescence was associated with overweight, poor fitness and raised cholesterol in adulthood, amongst other factors. In a study of the obesogenic food environment in New Zealand primary schools (n=122) the most commonly available food were pies (79%), juice (57%) and sausage rolls (54.5%). Less healthy choices dominated food sales by more than 2:1 and pies were the top selling item, with over 55,000 sold per week. It has been postulated that the energy expenditure from modern countries is now so low that most people will have to restrict their energy intake to compensate and not gain weight. Boyd and Egger (1995) argue that the obesogenic environment is easily overwhelming the individual’s ability (social, personal, cognitive, physiological) to avoid weight gain. A further example of the influence of the obesogenic environment, are the recent findings suggesting that obesity spreads through social ties.

There are many genes involved in the control of appetite, energy balance and muscle fuel metabolism. Obesity and insulin resistance alter the expression and control of these genes. There are also genes for leanness in some people, who are obesity-resistant in the face of an obesogenic diet and environment. A stronger degree of familial resemblance for morbid obesity (BMI > 40) has been reported than for more moderate

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21 AC Nielsen Survey data 1999
levels of obesity (BMI < 40). First-degree relatives of severely obese people are five times more likely to develop obesity than the general population, whereas first-degree relatives of overweight people are twice as likely to develop obesity compared with the general population.

Animal research conducted in New Zealand shows that the intrauterine experience may be important in the development of obesity and diabetes.\(^{26}\) The researchers investigated the effect of newborn offspring of both well-fed and undernourished female rats when dosed with leptin – a hormone that sends a signal to the body when it has eaten sufficient. The researchers found that when these rats became adults, those from well-fed mothers responded to leptin in the opposite way to those from undernourished mothers. When a mother is undernourished, her children’s bodies are set up to cope with a life of scarcity. When exposed to excess amounts of food, weight gain is more pronounced and risk for diabetes and cardiovascular disease increases, compared with those from normally fed mothers.

Those with mental health disorders such as schizophrenia and bipolar disorder have an increased prevalence of metabolic syndrome. One of the causes of increased risk is the adverse metabolic side effects associated with psychotropic medications, such as antipsychotic drugs which are associated with weight gain. Among the second-generation antipsychotic medications, clozapine and olanzapine are associated with the highest risk of substantial weight gain.\(^{27}\) An increased risk of diabetes and dyslipidemia is also reported. Some studies have reported that the use of metformin and rosiglitazone may assist in correcting some of the biochemical problems associated with psychotropics.\(^{28}\) Based on the medical risk profile of people with major mental illnesses, and the evidence that certain medications can contribute to increased risk of weight gain, it is recommended that screening and regular monitoring of metabolic parameters such as weight (body mass index), waist circumference, plasma glucose and lipids, and blood pressure are part of the patient’s management and treatment programme.

A number of studies have reported increased maternal and foetal risks among morbidly obese pregnant women.\(^{29,30}\) The types of complications reported include gestational diabetes mellitus, proteinuric pre-eclampsia, delivery by caesarean section and high (over 90\(^{th}\) percentile) birth weight.

\(^{26}\) Gluckman et al. Metabolic plasticity during mammalian development is directionally dependent on early nutritional status. *PNAS* 2007; 103: 12896-12800.


Based on a review of the evidence of the diet and nutrition causes of obesity Swinburn et al (2004) graded protective and risk factors as ‘convincing’ and ‘probable.’ Protective factors against obesity that were graded as ‘convincing’ included: regular physical activity and a high intake of dietary non-starch polysaccharides. Factors graded as ‘probable’ included supportive home and school environments for children and breastfeeding. Risk factors for obesity that were graded as ‘convincing’ included sedentary lifestyles and a high intake of energy-dense and micronutrient-poor foods. ‘Probable’ factors included include heavy marketing of energy-dense foods and fast food outlets, sugar-sweetened soft drinks and fruit juices and adverse social and economic conditions in developed countries, especially in women.

3.5 Patterns and consequences of fat storage

When people store fat they do so in several ways – peripherally, centrally or both. Peripheral fat is characterised by large hip and thigh fat subcutaneous fat deposits and is usually seen in women. This pattern tends to start early in life, and people tend to have narrower waists, normal cholesterol and blood fats, normal blood pressure and low risk of diabetes and cardiovascular disease but may have a very high BMI. Medical problems can include respiratory restriction and failure, and eccentric heart dilation. Additionally, they may have functional problems of limb mal-alignment (joint problems), pedal oedema and pain (lower limb fluid accumulation in tissue), poor locomotion, poor skin and perineal hygiene, pendulous and heavy skin / subcutaneous tissue, problems fitting clothes and furniture, and high psychological morbidity. Peripheral fat depots are hard to move.

Those with central obesity may appear only modestly overweight, with subcutaneous fat in the upper body (upper back and chest, neck). They also gain huge fat reserves around their abdominal organs and waist measurements are very useful to gauge the pattern of fat in this group. Central obesity tends to occur later in life after physical activity stops. Severe sleep apnoea as a result of fat around the necks and tongue can develop and people may also acquire hypertension, dyslipidaemia, (abnormal cholesterol) insulin resistance, high levels of blood insulin and glucose (glucose intolerance) and high urate levels. Those with the metabolic syndrome also have fatty or fibrosing livers, clotting problems, inflammatory change and many degenerative problems, such as gout. The end result is organ damage – diabetes affecting many small blood vessels (kidney failure, blindness, leg ulcers, nerve damage), atherosclerosis causing heart attacks and failure, and stroke, and liver damage (cirrhosis, liver failure). The inflammatory problems and faulty immune function of central obesity allow cancers to form especially in glandular tissue – bowel, breast, prostate, uterus, and other active organs – kidney, liver and cervix.

There is now an increasing incidence of people with a mixture of both fat distributions. These people are typically younger women or long term obese men. Worryingly, there is now a whole cohort of teenagers with the metabolic syndrome and/or high BMI obesity.

Body fat is an efficient energy store for its volume and is easy for the body to retain. Fat is safe if stored in normal fat cells, mostly under the skin and structural fat pads around kidneys and in limbs. The body can tolerate short periods of central fat, but not long term. Fat becomes toxic if pushed into normally “minimal fat” areas. This toxicity gradually increases when going from 1) deeper neck and upper body tissues, 2) around gut organs (stomach, liver intestines) and finally 3) into muscle cells (limb, heart, vessel muscles) and other organ cells (liver, pancreas etc).

3.6 Consequences of obesity

The consequences of obesity include increased risk of mortality, illness and disease, reduced quality of life and opportunities to whanau, and increased healthcare costs.

3.6.1 Mortality

Around 3,154 people die each year from obesity related health problems in New Zealand. Studies now consistently show that the relationship between mortality ratios (deaths per 100,000 people) and BMI is either linear or curvilinear (Figure 3). This is consistent for men and women, although may be modified by age, race and fitness level. The main disorders causing the increased mortality are likely to be cardiovascular disease and cancer. In a prospective study of more than 900,000 US adults with 16 years of follow-up, death rates from cancer were 52% higher for men and 62% higher for women with $\text{BMI} \geq 40 \text{ kg/m}^2$ than the rates in men and women of normal weight. The authors concluded that being overweight or obese may contribute to 14% of all cancer deaths in men and 20% of cancer deaths in women in the US. A further large prospective study found that increased BMI was associated with increased risk of death for men and women, in all ethnic groups and across all age bands.

In a prospective follow up (the Framingham Heart Study) of 3,457 participants, being overweight and obese were associated with significant reductions in life expectancy. Forty year old female non-smokers lost 3.1 years of life expectancy because of overweight and this increased to 7.1 years for obesity. Forty year old males lost 3.1 years because of overweight which increased to 5.8 years for obesity.

An analysis of three major data sets of BMI for adults aged 18 to 85 years found that morbid obesity appears to greatly lessen life expectancy and that this is most marked

amongst younger people. For those with BMI >45 kg/m² aged 20-30 years, the years of life lost was 13 for white men and 8 for white women. Black people with severe levels of obesity had a maximum of 20 years of life lost for men and 5 for women.

3.6.2 Morbidity

Obesity is now a disease in its own right, but it is also a risk factor for a wide range of comorbidities and major diseases making it the consummate “pathogen”\textsuperscript{38} (Table 4). Generally, the greater the morbid obesity, the greater the impact of diseases and comorbidities. Increases in weight may result in complications such as hernias, joint problems, breathing problems, social isolation and depression. The metabolic syndrome has been described as the paradigm of obesity disease. It is a group of problems which centre on abdominal obesity and insulin resistance and culminate in type 2 diabetes, hypertension and dyslipidaemia. These diseases work together to amplify the effects on cardiovascular disease – the major contributor to mortality. In a study of the prevalence of the metabolic syndrome amongst the multicultural Auckland population the investigators estimated prevalence of 32\% among Maori, 39\% Pacific people and 16\% in others.\textsuperscript{39} They concluded that measures of obesity accounted for much of the differences for Maori and Pacific people compared with others.

Table 5 shows the increased relative risks of various diseases and conditions associated with metabolic consequences of increased fat and excess weight gain.

\textsuperscript{37} NHMRC from Bray G. Overweight is risking fate. Definition, classification, prevalence and risks. \textit{Ann NY Acad Sci} 1987;499:14–28.
Table 5. Diseases and conditions associated with obesity

<table>
<thead>
<tr>
<th>Relative risk</th>
<th>Metabolic consequences</th>
<th>Excess weight consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greatly increased</td>
<td>Type 2 diabetes and insulin resistance</td>
<td>Sleep apnoea</td>
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<tr>
<td>(RR &gt;3)</td>
<td>Gall bladder disease</td>
<td>Breathlessness</td>
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<td></td>
<td>Hypertension</td>
<td>Asthma</td>
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<td></td>
<td>Dyslipidemia</td>
<td>Social isolation and depression</td>
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<tr>
<td></td>
<td>Fatty liver disease (non alcoholic)</td>
<td>Daytime sleepiness and fatigue</td>
</tr>
<tr>
<td>Moderately increased</td>
<td>Coronary heart disease</td>
<td>Osteoarthritis</td>
</tr>
<tr>
<td>(RR 2-3)</td>
<td>Stroke</td>
<td>Respiratory disease</td>
</tr>
<tr>
<td></td>
<td>Gout/hyperuricaemia</td>
<td>Hernia</td>
</tr>
<tr>
<td>Slightly increased</td>
<td>Cancer (breast, endometrial, colon, and others)</td>
<td>Psychological problems</td>
</tr>
<tr>
<td>(RR 1-2)</td>
<td>Reproductive abnormalities/impaired fertility</td>
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<tr>
<td></td>
<td>Polycystic ovaries</td>
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<td></td>
<td>Skin complications</td>
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<tr>
<td></td>
<td>cataract</td>
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<td></td>
<td>Varicose veins</td>
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<td></td>
<td>Musculoskeletal problems</td>
<td></td>
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<td></td>
<td>Bad back</td>
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<td></td>
<td>Stress incontinence</td>
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</tr>
<tr>
<td></td>
<td>Oedema/cellulitis</td>
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</table>

The following figure shows the relationship between BMI and all-cause mortality, stroke, coronary heart disease, and type 2 diabetes, as expressed by relative risk (the Y-axis represents relative risk, which is a measure of the risk of disease compared with a baseline measure of BMI 20). As the figure shows, the risk of diabetes type 2 is alarmingly high, even in the presence of quite modest weight gain. The US Nurses Health Study (on which these findings are based) shows an increased relative risk of mortality ranging from 1.25 for a weight gain of 5 to 8 kilograms from the age of 18 years, to 2.65 for a weight gain of 20 kilograms or more. These findings have been corroborated by research throughout the world.

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3.6.3 Quality of life and whanau ora

The impact on reduced quality of life and lost opportunities to whanau is best captured through the following Case Study.

*When I look back on my life my weight is the result of an accumulative effect of events in my life. My husband committed suicide when he was thirty years old and my daughter who was ten at the time witnessed that event. We were living in Australia, there was no family support. I started comfort eating. My daughter had a really difficult time and became severely depressed and suicidal when she was 15. It was so stressful helping her through. I gave up my studies to look after her. We moved to Melbourne and my daughter started taking drugs. We came back to New Zealand and were home for six years and my son committed suicide. I’ve always known those events made me what I am.*

*I grew up one of eight kids. Money was tight; there was lots of bread and mince, stews and boil-ups to fill us up. That’s where the eating starts from. In Maori families it’s important to get babies eating solids and everyone wants big bonnie babies. We had meat every night. It’s hard to stop a lifetime habit. All my brothers and sisters are big but I’m the biggest. They are not the ideal weight but*

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they are active. I am the only one who can’t keep up. My mum and dad are 70 and 75, they’re fitter than me. Dad would do my chores for me even though he’s older than me. In my family there is a lot of concern about me. I didn’t speak to my gran for six months because every time I saw her she would say how worried she was about me.

My weight is more and more, I’m the heaviest now I’ve ever been. I’m now 154 kgs. Exercise is an issue and it’s gotten worse and worse. I can’t stand for long periods. I have a cleaner; I can’t clean windows or do the vacuuming. I can’t clean the car. I have got rid of the remote to make myself move more. If I go for a walk it’s for about 100 metres. I don’t fly anywhere, I used to fly all the time but I can’t get into the seat. That’s not what actually worries me though, it’s the walk to the plane; it can be a long distance. I prefer not to drive. If I have to go somewhere and there are stairs I panic. I have to ask if there is an elevator. I hate it if people want to meet at a café. I need to know if I can park close and I worry about fitting into the chair. Supermarketing is hard but I try to make an effort. If I miss things and I’ve had enough I will go home. My daughter helps me until I’ve finished. If I go to the opera or theatre I have to book two seats on the aisle. Even if I go I have to park close by or be driven.

I always avoid going places where there will be kids. They make comments about my weight. I don’t get as much cheek from Maori kids about my weight. It’s probably because I look like their nana or auntie.

I’m lucky with the people I work for. I feel OK. We tussle about other issues, not my weight. I have lots of help at work every day. If I can’t get a plug in to the wall some-one will come and get down and get it in for me. In terms of work I try to avoid doing presentations. I know people make assessments on physiology. You look at a person not the content. I know how people think and process and it may actually detract from what I’m trying to achieve. If I travel to a meeting I wonder where I can park; I have to leave very early so that I am not too puffed when I arrive. I always have to plan ahead to make decisions. I am now starting to get panicky about traveling to meetings. Because I have to leave so early for meetings I then have to make up the hours at work. As well as full time work I am doing postgraduate study. With study and full time work it’s been easy - I don’t have a life. Everyone says my study is great but I’m sitting down the whole time. One of the main reasons for my study is that I’m worried I’ll never get another job the way I am. Because I can’t get much physical stimulation the study is great. Now my pleasure is study. It’s affirming.

My dream is to have a dog and go for walks on the beach. I used to do that in Hobart. I’d walk for miles and work in the garden. I would do all that a lot more if I lost weight. I would engage a lot more.

I know I’ve been depressed through my life for a long time. It’s a cycle – being depressed and binge eating – having takeaways, living alone – I just got bigger and bigger. When I was younger and overweight it was ok. Now that I’m older
It’s a different ball game. In the last few years my ankles and knees have started aching and I’m finding it harder to get up the stairs out of the pool. Sometimes I have problems sleeping. I got diagnosed with diabetes five years ago. I take diabetes medication and a heart pill. If I don’t take my diabetes medication my eyesight is not good. If I don’t do something it will just get worse. I’m getting to the stage where my body is not in a stage of repair. From here on in if I don’t do something it will get worse and quickly. Between 40 and 50 I should have addressed my weight. Now everything is accelerating from here on in.

My daughter has just told me she is having a child. It will be my first grandchild; I want to be around for the next 20 years for my grandchild. My son in law, he says if you want to look after whakapapa you have to look after yourself. He’s right (Maori woman, aged 50).

3.6.4 Cost

It is well accepted that obesity has massive direct and indirect economic implications. Loss of productivity and consummate increased health care costs associated with morbid obesity present an economic burden. The economic cost of obesity is made up of three main components: direct costs to the individual and the service provider associated with treating obesity; opportunity costs to the individual, and thirdly, indirect costs which are usually measured as lost production due to absenteeism from work and premature death. Irrespective of exact figures it is clear that obesity represents one of the largest items of expenditure in health care budgets around the globe.

Estimates of these exact costs vary enormously between countries. The United Kingdom House of Commons, Health Committee Obesity report, shows the estimates of the direct costs of obesity for a range of comparable countries. The report clearly illustrates the wide range of estimates of costs and an inconsistent link between higher obesity and higher costs. The authors attribute this to the different methodologies utilised by different countries in determining costs. It would appear that the United States has the most regularly updated information on the cost of obesity (six updates since 1986), and these updates vary considerably. The most recent update (2000) has the direct costs of obesity at $61 billion, and indirect costs at $56 billion.

A recently released comprehensive report of the economic costs of obesity in Australia clearly shows the economic impact of obesity. This report estimated the net cost of obesity in 2005 at $21 billion. This figure includes productivity costs ($1.7 billion), health

system costs ($873 million), carer costs ($804 million), deadweight loss (DWL) from transfer ($358 million), indirect costs ($40 million) and the net cost of lost wellbeing ($17.2 billion). The cost of obesity was measured in terms of the costs of four major types of disease that have been shown to be linked to obesity – type 2 diabetes, cardiovascular disease including coronary heart disease, stroke and hypertension, osteoarthritis and cancer (breast, colorectal, uterine and kidney).

In the developed world, WHO has attributed 2% to 7% of total health care costs to obesity. For New Zealand, this equates to approximately $303 million. In 2004 in the Pacific Islands, the economic impact of noncommunicable diseases – of which obesity and diabetes were identified as the main group, amounted to $195 million. This figure represents almost 60% of the health care budget of Tonga (WHO 2006).

The direct health care costs of obesity in New Zealand were most recently formally estimated at $135 million in 1991 (2.5% of total health care costs). Health care costs of a number of major obesity related comorbidities were estimated and multiplied by the population attributable factor for obesity for each condition. Actual costs included hospital, general practitioner, pharmaceutical, laboratory and ambulance costs. The authors note that this estimate was conservative as it did not include the health care costs of a number of other obesity related conditions and indirect costs, among other factors. An example of indirect costs can be found from the Counties-Manukau DHB waiting list for assessment for morbid obesity surgery, which shows that 19% of those on the waiting list are not in paid employment (sickness benefit, unemployed, mothers, retirees).

Type 2 diabetes is one of the most serious and prevalent comorbidities of obesity. Approximately 85% of people with diabetes can be classified as type II and of these 90% are obese. PricewaterhouseCoopers Ltd undertook an analysis of the cost of type 2 diabetes in New Zealand in 2001. They estimated that the cost was approaching NZ$400 million and that it would rise to more than NZ$1,000 million by 2021.

As part of the analysis of the House of Commons, Health Committee Obesity report, the economic costs of obesity in England were determined, and an update on the previous figures (1998 – Tackling Obesity in England report) provided. The investigators utilised the same methodology previously employed. For the cost categories of: GP consultations, ordinary admissions, day cases, outpatient attendances and prescriptions, the estimated costs of treating obesity in 2002 were £45.8-49.0 million. This is up considerably from the cost estimate of 1998 (£9.5). The bulk of the increase is attributed to the rapid increase in the prescribing of orlistat – an obesity reducing medication. It is worth noting that there are now other obesity reducing medications, more public obesity management clinics and increasing subsidies for bariatric surgery in some countries.

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3.7 At risk groups

According to the NHMRC report, some people are more at risk of developing obesity than others. Those with an endocrine or medical abnormality are at increased risk of becoming obese and there are other rare genetic disorders which greatly increase the risk of developing obesity. For the most part however, obesity is thought to be the result of the interaction and relationship of a number of genes. This same mix and response which results in some people developing obesity would once have helped individuals in the face of food shortages and improved their chance of survival. People from lower socio-economic groups, those with poor education and people from rural areas have all been shown to be more prone to undesirable increases in weight. This group is also the subject of high levels of advertising of fast and processed foods, and has less control over an obesogenic environment. For example more fast food outlets and gaming machines are found in low socio-economic areas compared with higher socio-economic areas. Ethnic and racial genetic changes have also been found. The white population may be less at risk of diabetes for a given weight compared with other ethnic groups.49

In a cross-sectional study of data from 1,175 Pacific Island people aged 20 years and over from church communities in Auckland, information on obesity and diabetes risk factors was obtained.50 Based on ethnic-specific definition of obesity (BMI > 32 kg/m²), 45% of men in the sample and 66% of women were classified as being obese. The age-standardised prevalence of known diabetes was 12%. The authors conclude that Pacific people living in New Zealand warrant high priority with regard to obesity prevention efforts.

The high prevalence of central body fat observed among Asian Indians, high prevalence of type 2 diabetes (higher than Maori and Pacific Island people), together with the fact that Asian people make up the fastest growing ethnic group in New Zealand (projected to account for 13% by 2021) define this group as a further at risk group.51

As previously reported in this section, Maori and Pacific people have alarmingly high levels of obesity and morbid obesity, and it is well established that more Maori and Pacific people are socio-economically deprived compared with non-Maori and non-Pacific. The consequences of overweight and obesity can be more severe, for example there are higher rates and younger presentations of obesity-related gout and damage to small vessels supplying kidneys (renal failure), eye (blindness) and nerve and feet (requiring food amputations) in Maori and Pacific peoples.

3.8 Benefits of weight loss in obesity

49 Rush et al. BMI, fat and muscle differences in urban women of five ethnicities from two countries. Int J Obes 2007 Mar 6
For those who are obese, losing weight is associated with a wide range of positive outcomes. Depending on the percentage of weight loss achieved, these benefits may extend to resolution of comorbidities, improved quality of life and reduced healthcare costs and costs to the individual. Interestingly, there is a growing body of evidence demonstrating that people who are overweight and even obese but who have good cardio-respiratory fitness are at lower risk of heart disease compared with those who may not be obese but have poor cardio-respiratory fitness – this highlights the importance of physical activity and exercise.

Even moderate weight loss can significantly decrease the severity of obesity-associated risk factors. For example, a weight loss of 5kg is equivalent to a loss of around 6% in body weight for a man or woman of average height with a BMI of 30 kg/m². Clinically, this weight loss may improve back and joint pain, breathlessness and the frequency of sleep apnoea, improve lung function and psychological health. A ten percent fall from an initial weight of 100kg in people with obesity related comorbidities may result in a significant fall in systolic and diastolic blood pressure, 10% reduction in total cholesterol, reduction in the risk of developing diabetes by more than half, 40-50% fall in obesity related cancer deaths and 20-25% fall in total mortality.

The HTA reported bariatric surgery, irrespective of the type of surgery, resulted in resolution or improvement of most obesity-related comorbid conditions, in particular, diabetes, hyperuricemia, hyperlipidemia, and sleep apnoea. A systematic review of the effect of bariatric surgery on psychosocial functioning reported improvements in mental health and psychosocial status including social relations and job opportunities, leading to improved quality of life, post surgery. A prospective study of health-related quality of life after gastric banding reported significant improvements over 5 years in general well-being, health distress, depression, perceived attractiveness and self-worth, as assessed by the Health Related Quality of Life questionnaire. Increases in physical activity and work productivity were also reported.

### 3.9 Strategies for managing obesity

Despite lack of hard evidence for the effective management of obesity, the Public Health Advisory Committee (PHAC), a subcommittee of the National Health Committee, advises that the obesity crisis in New Zealand is so pronounced that efforts to prevent and manage obesity must be immediately and comprehensively developed. It stresses that research efforts must continue and all programmes and initiatives be carefully evaluated.

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53 Royal College of Physicians, London 1998. Clinical management of overweight and obese patients with particular reference to the use of drugs


Figure 4 shows the different types of strategies which may be employed in the management or avoidance of weight gain. The bottom level of Figure 4 represents the population at large and refers to a public health approach towards the management of healthy normal weight. The second level represents people who are overweight or obese mainly because of over eating and sustained periods of physical inactivity. The main interventions proposed are education and lifestyle skills management. The third step builds on the previous one but in addition to education and lifestyle skills management; behavioural and/or cognitive modification strategies are recommended. The target group for this intervention are those with a long history of repeated dieting and weight loss then weight gain. The smallest group, or ‘top step’ are those who are morbidly obese or obese with comorbidities. For those who are morbidly obese, surgical intervention (bariatric surgery) is proposed.
3.9.1 Psychological therapy

The terms behavioural treatment, lifestyle modification and behavioural weight control are often used interchangeably. However, there are a number of important aspects within each approach. In some therapies the patient is helped to understand what is going on and then to try and apply that understanding towards many life issues, and also toward their attitude to food. Behaviour therapy is the term given to the set of principles and techniques to help people develop and maintain good eating and physical activity habits. Behaviour therapies concentrate more on setting up new ways of doing things and getting new habits established, even before the patient really understands or feels that is what is needed. Usually cognitive-behavioural therapies are used together. There are other modalities that have varying degrees of success. Often the different approaches translate into the patient feeling better and perhaps modifying binge eating patterns but with no real weight loss achieved. These techniques are used with general functioning, body shape attitude, distress with eating patterns and attitudes to food and attitudes and behaviours related to physical activity.

In a review of the evidence of lifestyle modification for the management of obesity, Wadden et al (2007) draw on the Diabetes Prevention Program as a good example of the different components of behavioural treatment. Examples of interventions in this

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comprehensive programme included 16 individual treatment sessions for the first six months with a dietician and with a weigh-in at the start of sessions; dietary modification including reducing fat intake to fewer than 25% of total daily calories; recording fat and calorie intake; recording minutes of physical activity and attending supervised exercise sessions. After the six months was up participants attended group or individual meetings at least once every two months.

Wadden et al (2007) describe lifestyle modification delivered from academic medical centres as typically being for 16 to 26 weeks and taking place in a group setting. Treatments are delivered by health specialists and sessions often begin with a weigh-in and review of patients’ diet and physical activity records.

More recently with greater understanding of appetite biology, there is reason to believe that pure psychology will not overcome imbalances in hunger and energy intake, and a marrying together of these disciplines indicates potential for greater success.\textsuperscript{58}

3.9.2 Diet

There are a multitude of dietary options for weight loss. Key to all these diets is finding the right energy reducing eating plan that the individual can adhere to for the longer term. People taking part in behavioural programmes are typically encouraged to consume a high carbohydrate, low fat (less than 30% of calories from fat) diet that emphasises high intake of fruit, vegetables and whole grains. There is evidence for the modest effect of low glycaemic index and or high protein diets that usually are as efficacious as low fat, high carbohydrate diets over a year or so. Two groups have reported longer-term randomised studies that compared instruction in the low-carbohydrate diet with a low-fat calorie diet in obese patients.\textsuperscript{59,60} Both trials showed better weight loss on the low-carbohydrate diet after 6 months but no difference after 12 months.\textsuperscript{61} In an evaluation of the literature on diet and lifestyle in the prevention of type 2 diabetes, the researchers claimed that regular physical activity be maintained throughout adulthood and saturated fat intake be less than 7% of the total energy intake.\textsuperscript{62}

Examples of different diets include very low calorie diets, meal replacement diets, portion controlled servings of conventional food, low-carbohydrate, high protein and/or fat diets and low glycemic index diets, and various combinations of these diets. The whole food and fibre aspect of these diets is likely to be very important.

\textsuperscript{58} Boey et al. Peptide YY ablation in mice leads to the development of hyperinsulinaemia and obesity. \textit{Diabetologia} 2006; 49: 1360-1370.
When very low energy (calorie) diets are served in liquid or set portion form they can form the basis of meal replacement programmes, and are considered safe when overseen with appropriate medical support. Once patients feel ready to start the full meal replacement programme with a small helping of leafy green vegetables then these diets are associated with quite dramatic early weight loss. In the past re-feeding has been an area that has not been done well and high weight regain has been seen as the patient stops the meal replacements. Recently more emphasis has been placed on refeeding regimens and better long term results are seen. As with all bariatric measures including surgery, regular follow-up and help with the psychology, nutrition, physical activity for weight loss and maintenance, and management of comorbidities is imperative. Treatment costs have been thought to be high due to the high cost required to oversee patients but a proportion of these costs need to be factored into any treatment modality.

Food based meal replacements give the patients a fixed amount of food with specific known calorie content. The advantages of meal replacements are that the meals are quick and easy to prepare and help the patient avoid contact with problem foods. This approach is thought to promote better control of appetite, and this may be due to sensory specific satiety.

Portion controlled servings of conventional foods are when patients are given the actual food they will consume at specific meal times. This diet is thought to be an alternative for patients who do not like liquid diets. Low-carbohydrate, high-protein/fat diets have had resurgence in popularity in the last two years, the most common one being the Atkins diet. The Atkins diet works by removing much carbohydrate content. A lot of focus of the effect of the diet has been on its safety. It is thought that at least in the short term (one year) the diet is safe. Concerns have been expressed on the high protein load and kidney function however often the absolute protein load on the Atkins diet is little different from the previous high overall dietary intake and it is the proportion of protein that is increased.

A low glycemic index diet encourages consumption of whole grains, legumes, vegetables and fruits that have the potential to bring about satiety and do not constrain the patient too severely in terms of the amount of food ingested. The glycemic index of a food is calculated by measuring the change in blood glucose following 50g ingestion of a target food, compared with an equal amount of a control food, such as white bread. However, there are issues with the glycaemic load – a measure of a meal’s glycemic index and total effect of all the food producing raised blood sugar together.

### 3.9.3 Physical activity

As with dieting, there are many different types of physical activity programmes which patients may be prescribed in order to lose weight. In the absence of dieting, physical activity alone is of little benefit in achieving weight loss in those already overweight, although the prevention of weight gain or regain is better. In theory, it is much easier for individuals to reduce energy intake than increase energy expenditure. For example, an individual eating 8.5 to 12.5 megajoules a day can reduce this amount by half fairly easily. To increase energy expenditure by 4 megajoules a day however would require
the individual to increase their daily walking by around 10 kilometres. However, physical activity is critical for long-term maintenance of weight loss and obese patients are encouraged to exercise simply for the benefit on their cardiovascular health. The mechanism of weight management through physical activity is becoming clearer with muscle contraction activating similar pathways to a number of both natural and medicinal chemicals that regulate energy metabolism such as adiponectin and metformin.

Physical activity involves increasing energy expenditure throughout the day by choosing to walk rather than drive, take the stairs rather than the escalator, housework and gardening. 63 If patients can increase their daily physical activity by using stairs rather than a lift or escalator, parking further away from shop entrances and getting off the bus early and walking the rest of the distance, this equivalent energy expenditure may be up to 3 miles per day. In contrast, exercise usually consists of regular planned activity that is engaged in for a specific period of time and achieves a relative high level of intensity such as 60% to 80% of maximum heart rate. Examples of exercise include running, swimming and biking.

The following consensus statement was developed in 2002 by experts and scientists in the field of physical activity, energy expenditure and body-weight regulation. 64 ‘The current physical activity guidelines for adults of 30 minutes of moderate intensity activity daily, preferably all days of the week, is of importance for limiting health risks for a number of chronic diseases including coronary heart disease and diabetes. However for preventing weight gain or regain this guideline is likely to be insufficient for many individuals in the current environment. There is compelling evidence that prevention of weight regain in formerly obese individuals requires 60-90 minutes of vigorous intensity activity. Although definitive data are lacking, it seems likely that moderate intensity activity of approximately 45 to 60 minutes per day, is required to prevent the transition to overweight or obesity. For children, even more activity time is recommended. A good approach for many individuals to obtain the recommended level of physical activity is to reduce sedentary behaviour by incorporating more incidental and leisure-time activity into the daily routine. Political action is imperative to effect physical and social environment changes to enable and encourage physical activity. Settings in which these environmental changes can be implemented include the urban and transportation infrastructure, schools, and workplaces.’

### 3.9.4 Drug treatment

The following information is quoted directly from the New Zealand Health Technology Assessment report ‘Evidence Based Assessment of Weight Loss Medicines: a report commissioned by the Accident Compensation Corporation (ACC). 65

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The evidence suggests that phentermine, diethylpropion, orlistat, sibutramine and specified meal replacement plans/products are all effective at achieving a moderate weight loss in obese individuals. On average, an additional weight loss of approximately 4.0 kilograms may be achieved when these products are used as part of an appropriate weight loss program. Clinically important weight loss is considered to be a loss of ≥ 5% of initial body weight; a substantial proportion of patients were reported to have achieved this goal with the aid of weight loss drugs.

In comparative studies, the newer weight loss drugs orlistat (XenicalR) and sibutramine (ReductilR) are reported to be safer, more acceptable and more effective weight loss agents than the earlier amphetamine related drugs, phentermine and diethylpropion. They can be prescribed for longer periods than the older drugs and both orlistat and sibutramine are currently being tested in adolescents. Sibutramine use has been cautioned in this age group outside a clinical trial while orlistat has recently been approved by the Food and Drug Administration (FDA) for use in adolescents. Sibutramine may result in a higher weight loss than orlistat but with side effects that may limit its use in patients with hypertension or cardiovascular disease. For these patients, orlistat may provide a useful alternative although the accompanying gastrointestinal (GI) side effects may not be acceptable to all patients. Meal replacement plans may be useful for patients who cannot tolerate or do not respond to either of these medications.

Sibutramine is reported to be cost-effective under most scenarios; with a lower estimated cost per quality adjusted life year (QALY) gained in patient groups with significant obesity related co-morbidities such as diabetes. The cost per QALY gained with orlistat is reported to be high and for healthy obese patients orlistat may not be cost-effective.

However, for patients with obesity related co-morbidities such as hypertension and/or hypercholesterolemia, orlistat may be considered to be good value for money. It is not clear if phentermine, diethylpropion or meal replacement plans are cost-effective treatments for obesity as no economic analyses of these therapies were identified, however, the direct cost of a course of phentermine or diethylpropion is much lower than the cost of orlistat or sibutramine.

3.9.5 Bariatric surgical techniques

The recommended management of morbid obesity contrasts strongly with the approach to the management of obesity. The WHO has stated the ineffectiveness of a range of counseling, behavioural and lifestyle interventions to address physical inactivity and poor diet amongst the morbidly obese subpopulation. According to the WHO the only effective treatment for this group is bariatric surgery. The reported number of bariatric surgical procedures in the United States has increased 800% between 1998 and 2004.
Bariatric surgery is the most rapidly growing area of surgical practice currently in Australia.

The main types of surgical intervention employed in the management of morbid obesity are restrictive and malabsorptive surgery, and a combination of both techniques.

1. Restrictive surgery reduces the size of the stomach such that a sense of fullness can be achieved in the presence of less food

   - Two types of gastroplasty (restrictive techniques) performed in the past included horizontal and vertical banded gastroplasty. Less than satisfactory results were reported at 10 years post procedure and these have essentially been abandoned. Sleeve gastrectomy involves removing 3/4 of the stomach leaving a long, thin tube which causes volume restriction. Long-term results are not yet available and this procedure should therefore be considered to be still under investigation.

   - Gastric banding is where a fixed or adjustable band is implanted to form a small-volume gastric reservoir (restrictive technique). It has also been described as being relatively easy to perform and has the added benefit of being reversible. Adjustable gastric banding has been reported as the bariatric surgery technique that is most often performed laparoscopically. The objective of the procedure is to achieve, by means of a restrictive mechanism, a reduction in dietary intake by creating a small gastric pouch. The fibres of the pouch stretch more quickly, which stimulates the vagus nerve fibres and triggers satiety reflexes.

   - Gastric bypass has evolved over 30 years and now includes many modifications. The size of the gastric pouch has gradually been reduced to the present 20-30mL capacity. The primary objective of the current form of gastric bypass is restriction and a change in the hormonal status. This procedure induces marked weight loss but is associated with a range of complications. The ‘gold standard’ of bariatric surgery is reported as the Roux-en-Y gastric bypass. This surgery creates a small proximal gastric pouch that is anastomised to a segment of the jejunum. It is the commonest primary bariatric surgery used in the United States, but does require patients to take supplemental vitamins (especially vitamin B₁₂) and minerals (calcium and iron).

2. Malabsorptive surgery works to limit the absorption of food by bypassing sections of the gastrointestinal tract. It is conceptually attractive in that it allows patients to consume greater amounts of energy than would otherwise be allowed to achieve and maintain weight loss. Techniques that combine gastric restriction with the principle of intestinal malabsorption work by creating a bypass system or a diversion system. Two types of biliopancreatic diversion can be used –

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i. Scopinaro’s biliopancreatic diversion. This procedure is very similar to the Roux-En-Y gastric bypass but involves a complete resection of the lower part of the stomach.

ii. The biliopancreatic diversion with duodenal switch. This technique applies a duodenal switch with an end to end duodenileal anastomosis. It has the advantage of permitting near normal functioning of the stomach. Supplemental vitamins and calcium are required.

Other than the detail of the surgical access itself, the anatomical differences between laparoscopic and open surgery are minimal. However, the laparoscopic approach offers all the advantages of minimally invasive surgery. Laparoscopic Roux-En-Y gastric bypass is being widely used in the US and is accounting substantially for the major increase in bariatric procedures being performed.69 Laparoscopic adjustable gastric banding is the most common procedure being performed outside the US and is steadily increasing in use in the US. Laparoscopic adjustable gastric banding accounts for more than 90% of bariatric surgical cases in Australia.70 Laparoscopic biliopancreatic diversion is used only in rare cases because of its complexity and is still a new technique.

In summary the most common techniques performed today (internationally) are gastric bypass (open or laparoscopic), laparoscopic gastric banding and to a lesser extent biliopancreatic diversion. In New Zealand, the most common bariatric surgical procedure performed is the Roux-en-Y gastric bypass, the majority of them done laparoscopically, followed by laparoscopic gastric banding, and more recently the sleeve gastrectomy. The BPD is not routinely performed in this country.

### 3.9.6 Reconstructive surgery post bariatric surgery

A proportion of patients post bariatric surgery will require a form of reconstructive surgery. There is very little information on the percentage of patients that will require an apronectomy, or the more complicated abdominoplasty operation following bariatric surgery. One of the main reasons for requiring reconstructive surgery is that after bariatric surgery, and once substantial weight loss has occurred (1-2 years post surgery), there may be significant amounts of redundant excess skin. This skin may hang down to below the patient’s knees, is extremely functionally limiting and prone to serious infections. Older patients who have higher BMIs and who lose substantial amounts of weight post bariatric surgery may be more likely candidates for reconstructive surgery.

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Based upon expert advice and for the purpose of this business case it has been estimated that 40% of those undergoing bariatric surgery will require an abdominoplasty. It has also been suggested that for those requiring an apronectomy this may be able to be performed by General Surgeons.

3.10 Case studies

To illustrate the process of weight loss and outcomes associated with significant reductions in weight, from the patient's perspective, interviews with morbidly obese individuals were conducted. Those who were willing to take part in these case studies included people who had lost weight non-surgically with the support of an expert medical weight loss GP, and those who had elected to have bariatric surgery in the New Zealand private health setting.

3.10.1 Case studies – non-surgical

The following case study describes the experience of a 46 year old European woman, interviewed during the course of this work, who achieved significant weight loss (non-surgically), following close supervision by a medical doctor.

My weight was over 100 kilograms (kgs) around two years ago; I had a BMI of 40. When I was younger I was always a size 16-18 then I had children and from the second pregnancy (1993) my weight stabilised and I moved from being overweight to being obese. For years I was back and forth on various diets – Weight Watchers and Jenny Craig mainly. I’d lose 5 or 6 kilograms and then I’d put that weight back on, and more.

Because I have a medical background (research nurse) I knew the consequences of being obese, I knew where it was going. My insulin levels were up; I was having sleep problems and snoring, back pain and joint problems. Most significantly I couldn’t participate in everyday activity with my three boys and husband. I realise now that I made a lot of choices to opt out of activities because it was easier, when I was heavy. If my husband and the kids were going off to do something I would say I was too tired or that things needed to be done around the house. Looking back I realise that I was avoiding getting involved in activities because of my weight. We went kayaking and white water rafting and I didn’t participate in either of those activities. I was worried I wouldn’t fit in the kayak and I always avoided any water sports. Even having a casual dinner with friends was hard – if you are sitting down with your meal at a friend’s place you can’t actually fit the plate on your lap when you’re big. I made many adjustments to my life – mainly by withdrawing and not participating, and thereby accommodating my extra weight.

I went to my doctor and told her I didn’t know where to go. I’d tried every diet multiple times for years and had no joy in losing weight. She referred me to a weight control medical doctor who I started seeing two years ago. When I first met with her I weighed 95.5kg. For the first year with the specialist I lost about 5kg. But most importantly I achieved a total mental shift about food, eating, my weight, my expectations –
everything. We spent that first year talking about why we should eat what we eat and the many lifestyle contributors that compound weight in addition to food. She explained about the role of stress, and the everyday battle we face in our environment with readily accessible fast food options constantly being advertised and made (cheaply) available to us.

I started to look at food differently, to shop for food differently and to cook differently. I changed the food we were consuming at home. The kids and my husband changed to eating healthy foods. There was some reluctance but it was not a major obstacle. The doctor made sure my family was totally involved, this wasn’t about diet – it was about a lifestyle change. One year later though I was keen to lose some weight and the doctor said I should go on a liquid diet (Optifast), which she would supervise. I started on Optifast in November 2006 with a weight of 95.5kg. For four months I drank 3x (200ml) liquid meals a day with one small serving of green vegetables. It was not hard. I had the mental attitude to do this, I was well prepared. I stayed on this liquid diet over Christmas even. I did not crave food and I was thrilled to lose nearly 20kg (weighed 79.6kg by mid January). I have very supportive friends and family and I was closely supervised by my doctor. These factors were very important in the weight loss process.

The weight loss has changed my life. I went to the USA for a month. It was the biggest challenge to keep the weight off. I put on a couple of kg but that was all. I’m walking and have all this energy to do things that I never had before.

When I first met my doctor she gave me a range of options for managing my weight including the surgical option. I didn’t want to take that option – I would have felt like I had failed. I truly believe that with the right support anyone can do this. I had struggled for years with my weight, and yo-yo dieting. This approach is slow and careful – it helps you make the necessary mental mindshift and is all about lifestyle change, not diet. I want to lose another 10kg and this will mean medically that I’m doing well. It’s hard but I absolutely know I’ll get there – the right way. And I know how to keep weight off now too.

I am so much more confidant. I have a whole lot of options and choices in my life that were not open to me before. I had the confidence to change jobs, to travel and enjoy totally new experiences after I lost the weight. Now, when my husband and I go out now it’s great – I made excuses not to go out before. I used to occasionally buy clothing and it was for comfort only. Now I can buy clothing that looks good and I feel good in. The kids have a new mum. We live near a park. The kids have always played soccer and rugby at the park. One day I was playing with them and they all stopped and stared at me. I asked them what they were doing. They said it was the first time they had ever seen me kick the ball around. My youngest son was ten at that time; the eldest fourteen years of age.

The following case study describes the experience of a 39 year old European male, interviewed during the course of this work, who achieved significant weight loss (non-surgically), following close supervision by a medical doctor.

I have pretty much been overweight for as long as I can remember. My parents always hassled me to do something about my weight but I never really did. I was very sporty – I ran around a lot as a kid but I was always big. About 20 years ago I was in hospital and
while I was there I was persuaded to see a dietician. I saw the dietician for a while and initially it was quite good. I changed my eating habits a bit and we worked on my diet and talked about some of my food problems. I have a lot of allergies to foods and if I had the choice I would eat the same thing each day for all meals. Bread, cheese and some limited meat has been my diet for life. With the dietician I lost about 20 kg, and reduced my weight from 140kg to 160kg. The dietician wanted to make further changes and I was put off and stopped seeing her.

Some five years ago I was back in hospital. This time with a severely infected leg. I was very unwell and there was some concern that I would lose my leg. What I found with my increasing weight was that I needed to take a lot of time off work and my weight was starting to affect my work. Previously, when my weight was less, I never ever took a sick day.

I have never sought out health professionals. I’ve had bad experiences with doctors – the first thing they pick on when you visit is weight. At my heaviest my weight got up to over 240kgs, with a BMI over 60. A few years back I was with a GP who I had found OK to talk to and one of the things that pushed me into talking to her about my weight was my wife became unwell. My GP referred me to a weight control medical doctor.

This weight control medical doctor was very good. She talked through a range of different options for managing my weight, one of which was surgery. I wasn’t keen on that at all. She came up with different food strategies for me to try and I mostly gave them a go. For me I would give things a go and then after a week I might slip up. My work would become busy and stressful; I’d work late and pick food up on the way home. My wife can get away with it as she exercises at the gym every day. In the first couple of months I lost some weight, but then it got to the stage where I wouldn’t let her weigh me. We dribbled along for around 4-5 months with her trying to gently push me in the right direction. Finally she said to me, we can continue as we’re going (and not really achieve anything) or we can really do something about your weight. She told me about the Optifast liquid diet and suggested I try it. This involved having four liquid drinks a day, with no other forms of food. She said it would need to be for longer than six months. I agreed but wasn’t taking it too seriously at that stage. I started on four rather than three drinks a day as the doctor thought it would be safest for my body (three is the norm). On the first day I was absolutely starving at the end of it and I thought I wouldn’t do it again. On the second day the same thing happened, but I just took each day as it came. After about 7 months, I cut it back to three drinks a day. I could have a black coffee with equal and drink diet drinks. I lost 10kg a month, the best month was 15kgs; the worst was 7 kgs. I lost 135 kgs in 14 months. My wife only bought food for her which I couldn’t eat so I wouldn’t be tempted. Every day I expected to crack. There’d be big cooks up at work, with food that I enjoy and can eat, and still I wouldn’t have any. You can’t lock yourself away from food. You have to be able to cope with other people eating. Our going out (my wife and I) was to grab McDonalds - we stopped that. My wife got her diet better too.

It took a long time to reintroduce foods. I started to make a shake with milk – I’d have one every other day; after all that time on the Optifast liquid diet (water and powder) it tasted glorious! My first real solid meal after about 10 months of being on a liquid diet was a small handful of yams and some steak – it was my birthday dinner. From that point on (up until 14 months), I would have one meal every other day, and the rest of the time have shakes with low fat milk. Throughout the process I was having regular blood
tests to check how I was going. This was really important because my doctor found I was malnourished and showing signs of anorexia. I needed to get back to proper eating. It was really difficult as my body rejected food and I ended up getting very sick. My weight had got down to 94kgs and 15-20kgs of that was loose skin that needs to be removed with plastic surgery. I am now at 100kg and my doctor doesn’t want me to go any lower than that.

I still see my doctor and will for a while. We’re going through a period of sorting out meals and trying to get me stabilised and to sit around the same weight. I have found a whole lot more meals I can cope with, they taste OK and I don’t have any reactions to the food.

Losing the weight and trying to find a way for me to eat, get some form of exercise going, and restore my body back to normal has been a huge challenge. I now have the cholesterol level of a young person. I walk ½ hour each morning, plus walk with a friend every lunch time. Putting on shoes and socks each morning was hard; I didn’t walk anywhere, all my hobbies and recreational time centred round computers. People treat you differently when you’re bigger. The biggest change is in how people react to you – it’s positive.

I am now at point where every so often we will have meal out. Going out is still rare though. We cook a lot at home. Going out is mostly about heading out for a coffee.

I still found it hard to believe I’ve lost anything; I still feel big. If I look at a passport photo of myself I can’t recognise the person. People who know me who have not seen me for a while walk straight past me. Friends and colleagues been very supportive. Work has been amazing. I have enormous determination not to go back there.

3.10.2 Case studies – surgical

The following quotes were obtained from people contacted during the course of the development of this business case, who have undergone some form of bariatric surgery in the New Zealand private health setting.

I used to hate going to the marae and sitting on the floor and having to get up afterwards – I always needed help. I remember going to the marae and being on the floor and I looked around and there was no-one to help me up. I got on to my knees, and thought I would have to crawl to a wall to help me get up. I was five months down the track after the operation. I said to myself, ‘get up,’ and I stood up from the floor on my own. I have never looked back.

I find that people take me more seriously – people interact with me differently now that I have had the operation and lost a lot of weight. Before the surgery when I was big and Head of School of Nursing, if parents came in and asked to see the Head of School they would walk right past me to talk to the person standing next to me. When I was big you couldn’t miss me but quite often I got the sense that people couldn’t see ‘me.’ People dismissed me as not being particularly bright (Maori woman, operation 2004).
A couple of things happened which prompted me to think about significantly reducing my weight. The first was that I was diagnosed with elevated cholesterol, a fatty liver and high blood pressure. I had to take 5-6 medications daily. The second thing was that my wife and I decided to have children. You think about your mortality in a different way once you start a family. One day I was sitting on the deck watching the kids. I made a suggestion to them as they played but my brother-in-law simply got up off the deck and joined in. I'm sitting watching them and thinking it's not the picture I had in my mind. I thought I would be rolling around in the grass with my kids and being active with them, rather than sitting back.

The weight was a cloak I wore. I didn’t think of the fat as belonging to me. I’ve taken the cloak off. I’m still who I am but it’s the quality of everyday experiences that is completely different (European male, operation 2006).

I was 148 kgs and although I was big I was reasonably fit as I was working on the farm. Increasingly though I was starting to get to the stage where I couldn’t do a lot of things I enjoy, most especially being active with my kids. I tended to withdraw with my weight; my self-esteem was gone. I was a hermit out on the farm, I never went to town. I didn’t want to see people.

I became diabetic and I went on to every medication imaginable. I also tried every diet. I lost about 42 kgs on Jenny Craig, but within two years it was all on again and more; I tried Reductil and Zenical. I lost nothing on Reductil and 16 kgs on Zenical. I also lost 16kgs on the Aitkins diet but it was not possible to keep eating that food long-term.

I’ve had the surgery and I’m now sitting at 92 kg and I’m really happy with that weight. I’m back doing everything that I want to do and I’m sure it’s extended my life. I was on as much medication as possible for diabetes. I’m now on no medication whatsoever. I’ve played touch rugby, tennis, and am totally involved in family holidays which are very active. I have self-esteem and confidence. I don’t mind being in crowds, going to movies; I’m on the board of trustees at the kids’ school. I would never have done any of these activities before. It’s just huge [the surgery] what it’s done for me (Male European, operation 2005).

I thought if I could look normal that would be absolutely amazing. I lost 40 kg in the first 12 months after the surgery and subsequent to that I gradually lost a further 30 kgs over about eight years. You can’t estimate the impact on your life. It’s mind-blowingly huge. It’s the comfort with which I live my life – I don’t stand out in a crowd. I can walk into any shop; I can try on any clothes. Every single thing I do in the day is done in a different way now. I haven’t regretted it for a second. My quality of life is so good. My knee pain has totally gone. Since the operation I have probably cost the government $50 a year in healthcare over 10 years. When I think about the cost of the operation and the likely health savings it’s amazing. If I hadn’t had that operation I expect I would have many serious health problems as a result of obesity, all of which would require a lot of attention (Female European, operation 1998).
3.11 Strategies for reducing obesity in New Zealand

There are many strategies and programmes aimed at reducing and better managing New Zealand’s persisting obesity problem. This section outlines some strategies and initiatives that are underway. It is by no means a comprehensive picture of the wide range of organisations which are devoted to addressing obesity.

- The Health Select Committee released its report “Inquiry into Obesity and Type 2 Diabetes in New Zealand” in August 2007.\(^{71}\) The report was based on a wide range of information sources including scientific literature, expert opinion, public submission and expert evidence from the Ministry of Health. Among other key findings, the report notes that “an urgent, concerted, and sustained public-health approach is needed to manage the complex issues associated with the rapid rise in obesity.” Fifty-five recommendations were made to achieve two broad objectives: 1) to create an environment in New Zealand that encourages and maintains healthy eating and physical activity patterns, especially among children. 2) to develop and implement a coordinated national cross-sectoral response to the prevention and management of obesity and type 2 diabetes. Of the 55 recommendations were made to Government, 47 have been accepted.\(^{72}\) Recommendation 32 (below), specifically relates to the management of morbid obesity and has been agreed upon by Government. The Government Response to the Health Select Committee report also notes that this business case is under development and that a Ministry project is underway to develop national guidelines for the management of overweight and obesity, which will be mainly primary care based.

Recommendation 32: That the provision of publicly-funded bariatric surgery be explored as a last resort for people who are morbidly obese. We recommend that the outcomes of the pilot research project into bariatric surgery being conducted by Counties Manukau District Health Board be monitored for cost-effectiveness to this end.

- Fight the Obesity Epidemic’ (FOE) is a voluntary organisation that has made and continues to make petitions and submissions to Government requesting urgent action to change the New Zealand social, cultural, physical and regulatory environment so that it is easier for all New Zealanders, especially children, to stop and reverse the rise of obesity and Type 2 diabetes in children.\(^{73}\) A key aspects of their submission on the Inquiry into Obesity and Type 2 Diabetes in New Zealand mentioned above includes focusing on the total environment in which children live rather than relying on individuals alone to make the necessary changes and voluntary steps by industry.

\(^{71}\) Report of the Health Committee, New Zealand House of Representatives. Inquiry into Obesity and Type 2 Diabetes in New Zealand August 2007.

\(^{72}\) Government Response to the Inquiry into Obesity and Type 2 Diabetes 2007.

\(^{73}\) www.foe.org.nz
One of the 13 priority objectives of the 2000 New Zealand Health Strategy\textsuperscript{74} is to reduce the rate of obesity and overweight. Items two and four of the strategy are closely related to this goal, being improve nutrition and increase the level of physical activity. For each of the priority objectives DHB ‘toolkits’ have been developed and are updated as new evidence emerges. The DHB toolkit ‘obesity’ has been developed to highlight the importance of obesity in New Zealand and the role of DHBs in the effective prevention and management of obesity.\textsuperscript{75} The obesity toolkit has close links with other toolkits, including ‘improve nutrition,’ increase the level of physical activity’ and ‘reduce the incidence and impact of cardiovascular disease.’ The obesity toolkit clearly states that obesity prevention is about preventing the development of overweight in normal-weight individuals, the progression of overweight to obesity in those who are already overweight and preventing weight regain in those who have been overweight or obese in the past but have since lost weight.

The PHAC published a report about obesity prevention and reversal in 2006.\textsuperscript{76} The overwhelming recommendation of the report is that a comprehensive, whole of government, whole of society approach be taken in New Zealand towards addressing obesity. To support this the following rationale is provided, the evidence for the effectiveness of initiatives that focus on creating supportive environments for daily living is much stronger than the evidence for the effectiveness of initiatives that focus solely on the health education of individuals. The PHAC report describes four levels of intervention and stresses that the greatest focus must be on the ‘structural’ level of intervention as these will have the greatest and most sustained effect on health outcomes throughout the population. The structural level of intervention is about policies which influence the larger environment within which health and health inequalities are established. Policies relate to housing, education, labour market, welfare, taxation, education, transport, and agriculture.

There is a strategy aimed at improving New Zealanders’ nutrition and physical activity: Healthy Eating Healthy Action: A Strategic Framework (HEHA).\textsuperscript{77} The HEHA strategic framework provides an example of structural level of intervention as its effective implementation relies on collaboration across different sectors. Following the development of HEHA, the Healthy Eating, Healthy Action Implementation Plan was developed with inter-sectoral input and co-ordination from a broad range of stakeholders. Inter-sectoral initiatives under the umbrella of HEHA include Towards Improving the Wellbeing of New Zealand Children. This initiative is the result of collaboration between the Ministry of Health, Ministry of Education and SPARC and aims to encourage children to make healthy choices.

\textsuperscript{75} Ministry of Health. New Zealand Health Strategy DHB Toolkit Obesity. October 2001
\textsuperscript{76} Public Health Advisory Committee. Public Health Advisory Committee (PHAC) Advice on Obesity Inquiry. 11 May 2006.
about what they choose to eat and to become more physically active. Maori are a priority group targeted in the HEHA implementation plan.

- The *Green Prescription* is a primary health initiative and is an example of ‘health and disability’ services level of intervention. It involves the provision of advice, encouragement and counseling on physical activity levels. In a prospective cost-effectiveness evaluation of the Green Prescription, the incremental cost of converting one additional ‘sedentary’ adult to an ‘active’ state over a twelve month period was NZ$1,756. The authors concluded that the programme has the potential to have major economic benefits through the lowering of morbidity and mortality.

- Obesity related outcomes are clearly reflected in many District Strategic Plans (DSPs) and District Annual Plans (DAPs) produced by District Health Boards (DHBs). There are a range of local programmes throughout District Health Boards (DHBs) to promote healthy eating and increased exercise, many of which address the goals of HEHA. These may have been developed directly by DHBs or through Regional Public Health Services or PHOs. Most PHOs offer lifestyle improvement, physical exercise and nutrition advice and information as part of their health promotion programmes.

- Two public hospitals conduct a small number of bariatric surgery volumes per annum. Twenty-four operations for the management of obesity took place at North Shore Hospital in 2006/2007, and 17 at Dunedin Public Hospital for the same period.

- CMDHB is currently conducting a randomised controlled trial aimed at comparing the effect of intensive wrap-around support (psychological, dietary and cultural management) versus standard guidelines-based care to maximise weight loss among high-risk subjects with type 2 diabetes mellitus and morbid obesity treated with bariatric surgery. Sixty participants will be recruited for the trial and participants will be treated for an 18 month period. Efficacy, safety and the effects of the wrap-around intervention on healthcare costs will all be evaluated and reported.

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4.0 Health Technology Assessment

4.1 Introduction

A Health Technology Assessment (HTA) was requested by the project Steering Group. A technical brief is a rapidly produced assessment of the best available evidence for a topic of highly limited scope. They are less rigorous than systematic reviews. Best evidence is indicated by research designs which are least susceptible to bias according to the National Health and Medical Research Council’s criteria. Where methodologically acceptable and applicable, appraised evidence is limited to systematic reviews, meta-analyses, evidenced based clinical practice guidelines, health technology assessments and randomised controlled trials.

The major findings of the HTA were presented to the Steering Group by the HTA researchers. Three major studies were highlighted by the HTA for their significant contribution toward establishing the effectiveness of surgery for the management of morbid obesity. These three studies are highlighted below:

- The best evidence for the relative effectiveness of surgical and non-surgical interventions comes from a prospective cohort study of 4,000 participants – the Swedish Obese Subjects study. This study (discussed in further detail in the executive summary of the HTA) provides long-term evidence of the effectiveness of surgical intervention on morbid obesity in terms of maintaining significant weight loss, improvement of obesity related comorbid conditions and reducing mortality risk. Whilst the study is not a randomised controlled trial it provides a strong evidence base for the effectiveness of surgery amongst morbidly obese.

- Christou et al (2004) reported mortality rates of 0.68% in the surgical group (n=1,035) versus 6.17% in the matched control group (n=5,746) over two years in a retrospective cohort study. Improvements in diabetes, hypertension, dyslipidemia were also reported amongst the surgical group.

- A retrospective cohort of early risk of mortality among Medicare beneficiaries highlighted the association between bariatric surgery and increased risk of death amongst older patients (aged 65 years and older), male patients and lower surgeon volume of bariatric procedures.

79 Stephenson, MI, Hogan, S. The safety, effectiveness and cost effectiveness of surgical and non-surgical interventions for patients with morbid obesity. NZHTA Technical Brief 2007; 6(8).
80 Ryden and Torgerson. The Swedish Obese Subjects Study-what has been accomplished to date? Surgery for Obesity and Related Diseases 2006; 2: 549-560.
The HTA yielded very little evidence for the effectiveness of bariatric surgery among indigenous populations – indeed very little research has been undertaken addressing morbid obesity amongst indigenous people. Previous research has found the use of bariatric surgery to be highly inequitable. Further research involving high-risk groups including indigenous populations is critical. The CMDHB RCT that is currently underway is expected to have a high proportion of Maori participating. CMDHB are the Sponsor of this work and the impetus has been the high proportion of Maori and Pacific Island people within the CMDHB catchment, with morbid obesity.

On conclusion of the presentation of the findings it was the view of the Steering Group that, despite none of these studies being New Zealand trials, the findings are generalisable to the New Zealand population. The studies demonstrate broadly similar findings, irrespective of the country of origin of the different research trials. Notwithstanding New Zealand’s unique cultural composition, it is reasonable to assume that the outcomes reported below are applicable in a New Zealand public health setting.

Not included within the HTA, as it did not meet the inclusion criteria, but noted here is a paper describing the outcomes of 310 patients who have undergone gastric bypass surgery in the New Zealand private setting.83 No peri-operative mortality was reported although reoperation was necessary for 43 patients. At five years percentage weight loss was 59%. Nearly all of those with type 2 diabetes (49 of 52) had their diabetes resolved.

The executive summary of the HTA is provided below.

4.1.1 Aim

This technical brief provides an update on the literature examining the safety, effectiveness and cost effectiveness of surgical and non-surgical interventions for patients with morbid obesity (BMI $\geq 40$ or $\geq 35$ with serious obesity-related comorbidities). A previous NZHTA technical brief (Day 2005) reviewed reports published up to 2004 and the current report aimed to summarise the literature published subsequent to that report. Recent primary studies were included where the secondary evidence was lacking. Of interest were studies focussing on the effectiveness, safety and cost effectiveness of surgical interventions in comparison with non-surgical (diet, exercise, psychological, pharmacological) interventions, and studies or reviews comparing the relative effectiveness and cost effectiveness of different surgical procedures. Where possible, information was included regarding the safety of different interventions, including long-term and short-term complications, and the effect of interventions on obesity-related comorbid conditions.

4.1.2 Methods

Databases Searched:
• Medline, PubMed (last 90 days), Embase, Cochrane Central Register of Trials, Current Contents, Cochrane
• Database of Systematic Reviews, DARE database, BMJ Clinical Evidence, NHS Economic Evaluation

Comparisons
• Included comparisons:
  • Studies reporting on the relative effectiveness, safety and/or cost effectiveness of different bariatric surgical procedures for morbidly obese patients. Surgical procedures could be performed either as open procedures or laparoscopically, and included vertical banded gastroplasty, horizontal gastroplasty, gastric banding, gastric bypass and biliopancreatic diversion.
  • Studies reporting on the effectiveness, safety and/or cost effectiveness of surgical interventions compared with non-surgical interventions (medical management or no treatment) for morbidly obese patients.

Excluded comparisons:
• Comparisons of variations in surgical techniques rather than different procedures
• Jejunoileal bypass procedures
• Studies which examined the effectiveness of an intervention in obese patients rather than morbidly obese patients.

Outcomes
Studies which included measures of weight change, fat content or fat distribution, quality of life, obesity-related comorbidities, mortality, adverse effects and short- and long-term complication rates.

Study design
1) Systematic reviews and health technology assessments
2) Randomised controlled trials comparing surgical interventions with other surgical interventions
3) Randomised controlled trials, controlled clinical trials and prospective cohort studies comparing surgical interventions with non-surgical treatment (medical management or no treatment)
4) For the economic analysis, studies that compare one intervention with another intervention in terms of incremental costs and benefits of those interventions.

4.1.3 Key results and conclusions

Effectiveness of bariatric surgery
Seven systematic reviews or HTAs were identified which included an examination of the evidence comparing non-surgical and surgical interventions for morbid obesity. The general consensus of the reviews included in this section was that there is adequate evidence that surgical interventions are significantly more effective than non-surgical interventions in terms of weight loss in morbidly obese patients. These findings were
based on lower quality evidence with several prospective or retrospective cohort studies being commonly cited, but no randomised controlled trials being identified. The best evidence for the relative effectiveness of surgical and non-surgical interventions comes from the Swedish Obese Subjects study, a prospective cohort study which included more than 4000 obese subjects (BMI ≥ 34 for men, BMI ≥ 38 for women) who were assigned to non-surgical or surgical intervention groups based on patient preference and eligibility for surgery. Using the most recently available follow-up data, at 10 years postsurgery the surgical group had achieved on average a 16.1% weight loss while the non-surgical group had a weight gain of 1.6%. Improvement or resolution of obesity-related comorbidities was more favourable in the surgical group. This study, which is ongoing, continues to show better weight loss and improvement of obesity related comorbid conditions for surgical patients compared with patients who did not undergo bariatric surgery. In addition, the cumulative mortality rate, which includes data for 99.9% of the original study members, shows that patients who underwent bariatric surgery have a 29% lower risk of death compared with non-surgical intervention patients (adjusted hazard ratio = 0.71, 95% CI 0.54-0.92).

**Effectiveness and safety of different surgical procedures**

The evidence for the relative effectiveness and safety of different bariatric procedures for morbidly obese patients was less clear. Fourteen secondary and two primary studies were included in this part of the report, with the quality of secondary reviews varying substantially. Several high quality reviews which included only randomised controlled trials or well-controlled comparative studies were identified, however many reviews opted to include lower level evidence, such as case series data, and this limited the reliability of their findings. Amongst the studies included in secondary reviews, there was wide variation in patient populations, the length of follow-up, the reporting of loss-to-follow-up, and baseline and postoperative measures of comorbidities. The reporting of weight loss varied as well, being presented as kilograms or pounds lost compared with pre-surgery weight, pre- and post-operative BMI, percent of excess weight lost, or change in BMI. All of these factors made it very difficult for authors to provide reliable estimates of the benefits and risks associated with different procedures or to recommend one surgical treatment over another. Some conclusions were able to be drawn however.

- Many reviews suggested that excess weight loss of at least 50% could be expected following bariatric surgery
- Some studies suggested procedures with a malabsorptive component, such as gastric bypass and biliopancreatic diversion, are associated with higher weight loss compared with restrictive procedures, such as adjustable gastric banding or gastroplasty. A limitation of these studies was the length of follow-up data provided with most including data up to a maximum of 3 years post-surgery. Some data suggests that there is no difference in weight loss between gastric bypass and other procedures when long-term outcomes are considered.
- It seemed that most obesity-related comorbid conditions, in particular, diabetes, hyperuricemia, hyperlipidemia, and sleep apnoea resolved or improved with postoperative weight loss and that this was not dependent on surgical procedure. Less clear was the effect of surgery on hypertension, with some evidence being presented that this did not always resolve following surgery or that the improvement did not hold in the long-term.
- Reviews relied on inconsistently reported data when considering comorbid conditions. High loss-to follow-up rates and a lack of baseline measures made it difficult for reviewers to ascertain the relative effectiveness of different procedures.
Mortality rates were judged to be relatively low (<2%) for all the considered procedures but the quality of studies available for the calculation of rates was overall poor and often based on data from case series. A meta-analysis suggested a 30 day mortality rate of 0-2.1% for Roux-en-Y gastric bypass, adjustable gastric banding, and vertical banded gastroplasty based on controlled trials, and a rate of 0-0.8% using case series data for the same procedures. The mortality rate for biliopancreatic diversion was 0.5 – 1.3% based on case series alone. Surgeon experience was highlighted by several reviews as a possible source of variation in mortality and complication rates. In well-selected patients operated on by experienced surgeons, the perioperative mortality rate could be expected to be very low.

The incidence and type of complications varied depending on the type of surgical procedure performed and there was wide variation in the incidence rates reported in the literature. This was partly due to inconsistency in the definition of early and late complications. While the overall mortality rate associated with bariatric surgery is low, well-controlled studies comparing the relative safety and complication rates of different procedures are still needed to aid in the selection of the most appropriate procedure.

Very little evidence was available regarding the effect of pre- and post-operative services on the effectiveness of surgical procedures. One randomised controlled trial suggested that weight loss prior to laparoscopic Roux-en-Y gastric bypass surgery had no effect on weight loss or resolution of comorbidities, but that shorter operating times were experienced by patients in the weight loss group.

Cost effectiveness of bariatric surgery
The search identified five primary economic research studies and five secondary research studies which met the inclusion criteria for this review. The quantity and quality of evidence was poor as has been previously suggested in other systematic reviews. The primary research studies addressed the following questions and provided some evidence toward an understanding of the cost effectiveness of bariatric surgery:

- Bariatric surgery in general was compared with no treatment in terms of the cost of the treatment and its effectiveness at reducing ongoing obesity-related medical expenses. Results suggest that bariatric surgery is more effective at reducing medical costs associated with obesity and that for patients incurring average costs pre-surgery, the surgery would take between 10.5 and 13.5 years to pay itself off. For patients who are likely to make greater productivity gains or who incur greater obesity-related medical expenses, the payback period is likely to be shorter.

- Adjustable gastric banding and gastric bypass were compared with conventional treatment in three European countries (Germany, France, and the U.K.). Both adjustable gastric banding and gastric bypass were found to be costsaving in two countries (Germany and France) and cost effective in one (the U.K.). These results remained true whether effectiveness was defined in terms of QALYs gained, BMI reduction, or diabetes-free years gained.

- Vertical banded gastroplasty was compared with LapBand surgery in an economic evaluation associated with a randomised controlled trial. Only twelve months follow-up data was available and this revealed no difference in quality of life and no significant difference in cost. Vertical banded gastroplasty was found to result in greater weight loss over twelve months, although this was expected as LapBand surgery is thought to result in slower weight loss. The results were, therefore, inconclusive.
• Laparoscopic gastric bypass was compared with open gastric bypass in two economic evaluations which both concluded that the laparoscopic technique is the preferred treatment owing to a lower cost as well as lower rates of complications and mortality and a shorter hospital stay.

All the economic evaluations were subject to major limitations including a failure to include all relevant costs (particularly the cost of plastic surgery, which could significantly affect results) and a heavy reliance on assumptions where data were not available, mainly due to the short follow-up time for which primary data were available. The overall conclusion should be, as found by other systematic reviews, that the evidence on cost effectiveness of bariatric surgery is not sufficient to inform a decision of which treatment option should be preferred. However, the small burden of evidence is indicative of bariatric surgery being a cost effective treatment for morbid obesity.

Final comments
Overall, bariatric surgery appears to be a more clinically effective and a more cost effective treatment option for patients with morbid obesity compared with non-surgical treatments. Surgical intervention results in significantly greater weight loss and this in turn leads to the improvement and often resolution of obesity-related comorbid conditions. Less clear is the relative clinical effectiveness of different surgical procedures, mainly due to a lack of randomised controlled trials with long-term follow-up of an adequate proportion of patients. The cost effectiveness literature is also limited and does not allow for the recommendation of one surgical procedure over another.

Many reviews suggest that the choice and success of bariatric procedures should depend largely on patient characteristics, such as baseline BMI, comorbidities, food habits and psychological differences, as well as patient and surgeon preference. Current research is focusing on the identification of the best treatment options for patients with differing risk profiles and characteristics but there is still a need for well-controlled long-term trials to ascertain which procedures may be the most appropriate and most effective for different patient groups.

5 Option identification and analysis

After receiving the completed HTA the Steering Group met to consider the findings and agree which options to pursue for the purpose of this business case. The Steering Group was confidant that the findings of the HTA were sufficiently conclusive to further evaluate the role of standard care pathway bariatric surgery in the management of morbid obesity but the HTA was less clear about the evidence of ‘wrap-around’ services. Wrap-around services pre-surgery often includes meal replacement plus or minus drug treatment (usually dietitian or bariatrician supervised), and general diet (via dietitian) and physical activity advice (if not engagement of therapist), and a session with a psychologist. The same therapies are delivered after surgery to help with weight loss. It was the view of the Steering Group, that the role of wrap-around is likely to be highly important. Patients undergoing bariatric surgery are a relatively high risk group for surgery. An intense weight loss programme prior to surgery if only to just shrink the liver.
to make surgery easier and safer is typically recommended. Undertaking bariatric surgery requires major lifestyle changes. Patients (and family and whanau also) are required to make major changes in relation to their eating behaviours and attitudes towards food.

Despite the lack of evidence for the effectiveness of intensive non-surgical interventions for the management of morbid obesity, for the purpose of completion and comparison, and based on expert advice, the Steering Group elected to include this as a further option for analysis.

Therefore the four options under consideration are:

- Standard care pathway for bariatric surgery
- Bariatric surgery with wrap-around
- Intensive non-surgical intervention
- Usual care.

### 5.1 Standard care pathway for bariatric surgery

This section outlines the standard care plan for patients pre-surgery and post-surgery. The standard care plan involves the surgeon, anesthetist and dietician. A full copy of the standard care pathway for bariatric surgery is provided in Appendix I. Further details on the functions of the dietician are provided in the Appendix II.

The preoperative assessment includes the following:

- Assessment of general health and nutritional status
- Explanation of dietary changes that are required after surgery
- Optimising treatment of comorbidities
- Assessment of patient motivation and willingness to adhere to follow up programmes
- Ensuring the patient is fully informed on the benefits, consequences and risks of the surgical options and the necessity of life-long follow up (informed consent)
- Ensuring the patient understands the potential (limited) outcomes of surgery.

Patients will be commenced on Optifast 3-6 weeks prior to surgery, or as deemed appropriate by the dietician. They will be followed up by the dietician and/or nurse coordinator. Any issues with progress will be discussed with the surgeon. A preoperative assessment will be undertaken by the anesthetic team and the usual blood tests etc will be completed.

The post operative phase includes the following:

- Provision of dietetic information
- Written information made available to the patient and family
- Medication discussion
- Follow-up appointment scheduled for 2 weeks post operatively with the surgeon
- Follow-up appointment scheduled for 3 weeks post operatively with the dietician.

There may be a small proportion of people who will require support and monitoring over and above the usual post-operative care plan.
5.2 Bariatric surgery with wrap-around

The wrap-around service that the following analysis is modeled on is that which is currently being piloted by Counties-Manukau DHB as part of their randomised controlled trial. Wrap-around participants are seen over 6 months pre-surgery and for 12 months post-surgery. The wrap-around service includes the involvement of a health psychologist who works with surgical patients individually and in groups as well as a cultural support worker.

The types of activities the study participants are required to take part in pre-surgery with the health psychologist include goal setting, problem solving, stress management, assertiveness training and relapse prevention. Participants also have the opportunity to meet with those who have undergone surgery and hear about their experience. Post-surgery the types of activities covered by the health psychologist include managing eating after surgery, managing changes, social support, body image and self-esteem, overcoming barriers to physical activity, family/whanau session (changes in the home), weight maintenance and support group sessions. Exercise support is being delivery via the community based Green Prescription programme.

Cultural support is provided via the CMDHB Maori Cultural unit and a representative from the Pacific team. Once participants have been accepted to the trial and randomised to the intervention group they are offered the opportunity to have access to a cultural support worker. The cultural support worker attends the first treatment session with the health psychologist and the participant. The cultural support worker is then available for contact on an as needed basis.

Appendix III provides further information on the wrap-around care pathway. Appendix IV details the role of the Health Psychologist in the CMDHB RCT bariatric surgical trial.

5.3 Aim

To determine the costs and benefits of standard pathway of care for bariatric surgery and wrap-around bariatric surgery compared with a programme of intensive non-surgical care and usual care. Note that there is no evidence in the literature that a programme of non-surgical care can be successful in a morbidly obese population. The comparison here is for straw man purposes – what if such a programme was feasible, and was able to give (in this case) a 25% success rate.

5.4 Methods

- Viewpoint is of the publicly-funded health service; costs and benefits outside of the health sector have not been modeled
- The time-frame is over a 5-year period, with an initial cohort of 1,000 cases. In addition a cost per QALY has been estimated.
• The risk profile of the cohort is assumed to be the same at the start of each programme of care
• Usual care costs (the comparator) are based on current actual experience, uplifted to 2008/2009 figures (see usual care costs below for further detail)
• Probabilities and assumptions are based on the HTA and expert opinion from the technical working group, as noted. Sensitivity analyses were carried out for each assumption, examples of which are shown below
• Costs are based on actual experience where possible, as noted, uplifted to 2008/09 figures.

Assumptions for bariatric surgery:
• 90% cohort experience uncomplicated bariatric surgery
• 8% experience complications (sufficiently complicated to severely affect recovery and some will require re-operation)
• 2% die peri-operatively (first 30 days)
• 90% achieve meaningful weight loss at five years post-bariatric surgery (>50% excess weight loss and/or resolution of comorbidities; remainder assumed to still have health benefits compared with usual care).

Assumptions for reconstructive surgery:
• 40% will require reconstructive surgery such as abdominoplasty (expert opinion)
• 88% experience uncomplicated reconstructive surgery
• 11.5% experience complications post surgery (this is a significant procedure, which may result in infective/skin necrosis complications; those requiring re-operation or experiencing severely interrupted recovery are included in the figure)
• 0.5% die peri-operatively (first 30 days).

Assumptions for intensive non-surgical interventions:
• 50% drop-out rate associated with intensive non-surgical programme
• 50% enrollees using pharmaceutical treatment
• 25% successfully using pharmaceutical treatment (meaningful weight loss after 5 years of intensive treatment and pharmaceutical intervention)
• 4.5% die on pharmaceutical treatment after 5 years, when response to treatment is beneficial
• 6% die on pharmaceutical treatment after 5 years, when response lowered (i.e. same as usual care)
• 25% enrollees successful on non-pharmaceutical treatment
• 6% die on non-pharmaceutical treatment after 5 years, when response to treatment is beneficial
• 6% die on non-pharmaceutical treatment after 5 years, when response lowered.

Assumptions usual care:
• 6% die in 5 years, in absence of any change to current practice.

Cost data usual care
• Two methods are triangulated to address two crucial questions:
  o What is the cost of usual care for the morbidly obese group?
  o What would be the savings if significant weight loss was achieved?
Method 1

- 445 patients with morbid obesity as ICD code E668 at CMDHB provider 2000-2007 have an average cost inpatients/outpatients of $9,700/ year
- The 445 patients with morbid obesity ICD code represent ~3% of the Counties-Manukau DHB morbidly obese population. It is assumed that they represent the high risk/medically intensive resource group and those who would be prioritised for surgery. For the purpose of this analysis it is assumed that this group represents the 5% of the highest cost morbidly obese group. Given that the surgery pool is likely to be drawn from the top 25% (highest cost) of all morbidly obese, the average cost of the 25% was determined, based on costs rising exponentially (i.e. next 10% of the group having 0.5 of the cost, then the next 10% having half the cost), giving an average cost of $5,580 per person per year based on 2008/2009 figures.

Method 2

- As part of the data collection agreed for the CCM programme in CMDHB the BMI is collected. All costs were examined in the CMDHB provider arm services (inpatient, outpatient, emergency care and renal dialysis) for the duration individuals were enrolled in the programme. 3,076 enrollees had a recorded BMI >35, by definition had a chronic condition that would make them eligible for bariatric surgery, and were enrolled for one year or more. Of these 3,076 people:
  - Average cost per annum = $2,310
  - Upper quartile cost per annum = $1,680
  - Mid-point of upper quartile = $4,230 (i.e. 12.5% of the cohort have costs equal to or higher than this per year)
  - 5% of the individuals had costs of more than $10,000 per year (i.e. a very highly skewed distribution of costs per annum was evident)
- Assuming that the selection of patients for surgery will select for patients who have the most to gain (as in method 1), the mid-point of the top quartile of patients according to cost is taken to derive average cost of care. This gives $4,860 per person per year based on 2008/2009 figures.

Triangulation

- Taking the average cost of care estimates for both methods described above gives a cost of care estimate for those most likely to be referred to surgery among the morbidly obese in CMDHB aged 20-64 years of $5,220.
- Analysis of hospital inpatient and outpatient costs for all New Zealanders for 2006/2007 and moving to 2008/2009 figures gives an average cost of $477 per head
- Therefore the difference between morbidly obese top 25% and usual secondary and tertiary hospital costs is $4,743 per annum, or $23,700 over 5 years.

QALY estimates

- An average QALY estimate was derived for a 40 year old with BMI of 40.
• The quality of life estimates were taken from Craig & Tseng (2002)\textsuperscript{84}. These are US-based, but are likely to provide a reasonable estimate. No NZ figures are available.
• Life expectancies were extrapolated from Pope et al (2006)\textsuperscript{85}. Again US-based.
• A discount rate of 3% was used.

### 5.5 Results

#### 5.5.1 Costs and benefits standard pathway of care bariatric surgery

Table 6. Costs and benefits of standard care pathway bariatric surgery versus intensive non-surgical care and usual care (base scenario)

<table>
<thead>
<tr>
<th>Scenario 1</th>
<th>Bariatric</th>
<th>non-surgical</th>
<th>usual care</th>
<th>At 5 yrs, surg v usual care</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. No wraparound</td>
<td>70</td>
<td>58</td>
<td>60</td>
<td>10</td>
</tr>
<tr>
<td>2. 40% reconstructive surgery rate</td>
<td>930</td>
<td>942</td>
<td>940</td>
<td>-10</td>
</tr>
<tr>
<td>3. Bariatric surgery 90% effective after 5 years</td>
<td>837</td>
<td>119</td>
<td>10</td>
<td>827</td>
</tr>
<tr>
<td>4. Non-surgical intensive care drop out rate 50%</td>
<td>$31,400</td>
<td>$27,900</td>
<td>$23,700</td>
<td>7,700</td>
</tr>
<tr>
<td>5. Non-surgical intensive care pharm rate = 50%</td>
<td>$37,500</td>
<td>$234,100</td>
<td>$2,370,000</td>
<td></td>
</tr>
<tr>
<td>6. Non-surgical intensive care effective in 25%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cohort cost, 5 yrs</td>
<td>$31,395,900</td>
<td>$27,947,900</td>
<td>$23,700,000</td>
<td>7,695,900</td>
</tr>
<tr>
<td>$$ diff from usual care</td>
<td>$7,695,900</td>
<td>$4,247,900</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Est mort difference pa post 5 yrs for cohort</td>
<td>2.8</td>
<td>2.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Est per head pa cost saving post 5 yrs for successes</td>
<td>$ 3,390</td>
<td>$ 3,420</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Est cohort savings pa 5 yrs+</td>
<td>$2,841,200</td>
<td>$408,300</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payback time post 5 yrs to cover the 5 yr cost</td>
<td>2.71</td>
<td>Years</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## 5.5.2 Costs and benefits bariatric surgery with wrap-around

Table 7. Costs and benefits of bariatric surgery with wrap-around versus intensive non-surgical care and usual care

**Scenario 2**

1. All bariatric patients offered wraparound
   - assumed to increase effectiveness by 3%
2. 40% reconstructive surgery rate
3. Bariatric surgery now 93% effective after 5 years
4. Non-surgical intensive care drop out rate 50%
5. Non-surgical intensive care pharm rate = 50%
6. Non-surgical intensive care effective in 25%

<table>
<thead>
<tr>
<th></th>
<th>Bariatric w wrap around</th>
<th>non-surgical</th>
<th>usual care</th>
<th>At 5 yrs, surg v usual care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>65</td>
<td>58</td>
<td>60</td>
<td>5</td>
</tr>
<tr>
<td>Patients at 5 years</td>
<td>935</td>
<td>942</td>
<td>940</td>
<td>-5</td>
</tr>
<tr>
<td>&quot;Successes&quot;</td>
<td>869</td>
<td>119</td>
<td>10</td>
<td>859</td>
</tr>
<tr>
<td>$$ per head</td>
<td>$33,300</td>
<td>$27,900</td>
<td>$23,700</td>
<td>9,600</td>
</tr>
<tr>
<td>$$ per success</td>
<td>$38,300</td>
<td>$234,100</td>
<td>$2,370,000</td>
<td></td>
</tr>
<tr>
<td>cohort cost, 5 yrs</td>
<td>$33,281,400</td>
<td>$27,947,900</td>
<td>$23,700,000</td>
<td>$9,581,400</td>
</tr>
<tr>
<td>$$ diff from usual care</td>
<td>9,581,400</td>
<td>4,247,900</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Est mort difference pa</td>
<td>3.6</td>
<td>2.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>post 5 yrs for cohort</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Est per head pa cost</td>
<td>3,530</td>
<td>3,420</td>
<td></td>
<td></td>
</tr>
<tr>
<td>saving post 5 yrs for</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>successes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Est cohort savings pa</td>
<td>$3,069,100</td>
<td>$408,300</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 yrs+</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>marginal gain for wrap</td>
<td>32</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>marginal cost for wrap</td>
<td>$1,885,500</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$$ per extra success</td>
<td>$50,700</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payback time post 5 yrs to cover the 5 yr cost</td>
<td>3.12 years</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5.5.3 Discussion

The model on which the analysis is based (see methods) appears relatively robust over a range of estimates and scenarios.

Standard care pathway for bariatric surgery

The most reliable estimates for costs and effectiveness of surgery is that of standard care pathway for bariatric surgery. Based on this analysis, of a cohort of 1,000 patients receiving standard care pathway bariatric surgery, the intervention would give:

- 827 patients an excess weight loss of >50% and resolution of most comorbidities (such as diabetes)
- An excess of 10 deaths at five years, but 2.8 less deaths per annum thereafter
- Bariatric surgery showing a potential cost saving for the health sector, with a payback time of around 8 years post surgery.

This payback does not include primary care savings, disability support savings, social welfare cost savings or the costs associated with improved quality of life – all of which are known to be substantial and would theoretically shorten the payback time.

Wrap around

There is little evidence in the literature about the effectiveness of wrap-around services to support morbidly obese individuals undergoing surgery. There is some suggestion of decreased risks of surgery with increased pre-operative work. Counties-Manukau DHB is currently hosting a trial to investigate possible differences in adding wrap-around services to a bariatric surgery randomised controlled trial. For the purpose of this business case a 3 percentage point increase in effectiveness was modelled for wrap-around, with costs based on the protocol for that trial. 32 additional successes compared with standard care bariatric surgery would be achieved, at an extra cost of $1.8 million over five years. The payback time to cover the five year cost would be a little over 8 years.

Sensitivity analysis

If the current cost of care estimate is reduced from $23,700 to $20,500 then the payback period is extended to around 10 years for standard care pathway. Modelling this same scenario of reduced current cost of care for wrap-around, the payback period is 10.5 years.

If one drops the effectiveness of bariatric surgery from 90% to 80% of survivors at 5 years then the payback time after extends to 8.5 years for standard care pathway. 26 additional successes are achieved at a marginal cost of $2.02m for wrap-around.
Non-surgical approaches

There is little success reported in the literature for non-surgical approaches for the effective management of morbid obesity. Whilst this project must run with the interventions with evidence of effectiveness, the decision model was also used to test approaches to intensive non-surgical case management of morbid obesity. It assumes patients were carefully selected such that 50% were able to remain in the programme for 5 years, an intervention was able to be offered costing around $28,000 per head and that 25% had sufficient weight loss to reduce comorbidities. While the cost per success is significantly more expensive compared with surgery ($234,100 versus $37,500) it is well below the cost of usual care. If wrap around services become established, then for people not currently suitable for surgery – e.g. those at too high risk – non-surgical case management may well be worth considering, both in its own right and as a pathway for patients to get to the surgical option. This would require specific evaluation/research to test.

QALY calculations

Based on the standard model of care as described above, and assuming that the referral and selection process operated as expected (i.e. the top 25%-costing morbidly obese people are targeted) then bariatric surgery would be cost-saving to DHBs. At a discount rate of 3% DHBs would gain 2-3 QALYs per patient at a savings of $6-7,000. For a women aged 40 years with a BMI of 40, bariatric surgery results in a gain of 6.4 QALYs (no discount), or 3.3 QALYs (3% discount). For a male aged 40 years and BMI 40, bariatric surgery results in a gain of 5.6 QALYs (no discount) or 2.9 QALYs (3% discount).

What if GP referral processes and surgical selection were not effective in selecting higher risk patients? If one reduces the usual care costs to be that of the average morbidly obese person then the reduction in usual care costs averted means the net cost rises to $7-9000 per QALY. This would represent a higher end estimate.

Even at the higher end of the range the intervention would still be a reasonable buy for DHBs. For example at PHARMAC so-called “high cost pharmaceuticals” are ones for which the cost per QALY “is significantly higher than the less than $10,000/QALY of most Pharmaceutical Schedule listings.” (PHARMAC 2003, pp. 1-2). Two examples of high cost pharmaceuticals are Pulmozyme and Beta-interferon, which cost between $41,000 and $81,000 per QALY.

Summary

In summary, based on the assumptions given it is likely that bariatric surgery will be either cost saving or at worst have a relatively low cost per QALY. The addition of

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86 Ref: PHARMAC, Medical Team/Analysis & Assessment Team, A Discussion of High Cost Pharmaceuticals, October 2003.
factors outside the hospital sector (primary care, employment/social welfare, other members of the patient’s family, etc) only serve to increase the attractiveness of the intervention.

The initial economic analysis and modelling carried out for the purpose of this business case was externally peer reviewed. Based on the findings of the peer review further analysis was undertaken for the final version of the business case. All the comments raised by the reviewers were considered by the Steering Group and a response to the peer review is provided in Appendix V.
6 Community acceptability

For the purpose of obtaining a view of community acceptability regarding the use of bariatric surgery for the management of morbid obesity, a research company was approached to undertake a nationwide telephone survey.

6.1 Aim

The Steering Group was primarily interested in the response of the tax-payer as to whether surgery should be made available for morbidly obese individuals through the public health system. A telephone survey was considered the most appropriate method for addressing this question.

6.2 Methods

This survey was undertaken by telephone with a fully national sample representative of the population aged 18 years and over. A total of 401 interviews were undertaken over the week Monday 3rd to Sunday 9th December 2007.

Interviewing was done by the Phoenix Contact Centre, using CATI (Computer Aided Telephone Interviewing). The Contact Centre is fitted out with a state-of-the-art CATI system, including digital voice recording of all interviews for quality control and assurance purposes. Fieldwork procedures include extensive training of all interviewers, and face-to-face briefing of the full fieldwork team including supervisors, by the project director. All interviewing is monitored live by supervisors, as well audited using the digital voice recordings. The Phoenix Contact Centre is independently audited and accredited as meeting IQS standards, the industry standard for this type of work.

The questionnaire for this survey was developed in consultation with the Steering Group and its advisors, then subject to pre-testing over the weekend prior to live interviewing, by two Pacific interviewers. Further pre-testing was done to ensure that the CATI version of the questionnaire was delivering the questionnaire to interviewers' screens exactly as intended, including the skips and routing instructions.

The sample for the survey was in three parts:
- The national sample, structured by geographic area (a 9-way split based on Urban Areas as defined by Statistics New Zealand), with the numbers of interviews in each area proportional to the population aged 18 years or over in each area. Telephone numbers for this part of the sample were obtained as electronic files from Yellow Pages, based on their random sampling procedures which have been worked over and had quality control checks applied to, extensively.
- A booster sample of Maori, needed to top up the number of Maori in the sample, because without this, Maori would have been marginally under-represented, an outcome of sampling for all such telephone surveys. This booster sample was also structured by area, proportional to
Maori population. Households were sampled from telephone books in almost all areas of the country based on identifiable Maori names (a commonly used practice in survey research).

- A booster sample of Pacific peoples, needed as for Maori, to top up the number of Pacific peoples in the sample, because without this, Pacific peoples would have been marginally under-represented, an outcome of sampling for all such telephone surveys. Households were sampled from telephone books in Auckland and Wellington (which account for the very large majority of the Pacific population in New Zealand) based on identifiable Pacific names (a commonly used practice in survey research).

For both Maori and Pacific peoples, approximately half the required numbers of people were interviewed as part of the general national sample, and half by the booster sampling methods.

All Maori and Pacific people contacted for the survey were offered the opportunity to be interviewed by a Maori or Pacific interview if preferred.

Within each household contacted, interviewers randomly selected one person aged 18 years or over for interview. One of the many steps we take to minimise bias is to call households back where on a first or later call either the household does not answer the phone, or the selected person is not available. For this survey we attempted up to six calls where possible, if earlier calls were not successful. However with the extremely short period available for interviewing, this standard could be fully applied.

The above procedures ensured that the sample was representative of the population, controlled for geographic spread and ethnic representativeness. The sampling was also controlled to ensure equal numbers of males and females were interviewed. To balance the sample by age group, the statistical technique of weighting was applied, again to match the sample to the population spread as determined by 2006 Census results.

### 6.3 Results

Just over 400 people (n=401) responded to the survey. Of the 401 respondents, 13% classified themselves as New Zealand Maori, 7% as Pacific people and the remainder (71%) as New Zealand European and other. The key findings of the survey are shown below. Unless stated otherwise, there was no significant difference in response by ethnic group.

- The majority of respondents (84%) considered obesity to be a serious problem in New Zealand.
- Two-thirds (61%) considered morbid obesity to be a serious problem in New Zealand.
- The most common ways of reducing extreme overweightness were considered to be diet (88%), exercise (89%) and intensive counseling (73%).
- When asked to select the single most effective treatment for extreme overweightness, diet was most frequently cited (48%), followed by exercise (39%) and intensive counseling (29%). Significantly more Pacific people considered diet (68%) and exercise (62%) to be the most effective means of reducing weight compared with Maori and New Zealand European and others.
- Over half (61%) were in favour (either strongly agreed, agreed or agreed a little) of surgery for extreme overweightness being made available to people through the
New Zealand public health system. Of the 23% who ‘agreed’ that surgery should be made available, significant differences were noted among Pacific people responders compared with the rest of the survey responders. Only 4% of Pacific people agreed funding should be publicly available, compared with 30% of Maori and 27% of New Zealand European and others.

### 6.4 Appropriateness for Maori

The following information was provided by the Maori representative on the business case.87

During the early 19th century contact between Maori people and European explorers, traders and colonists was quite common but there are no documented cases of obesity amongst Maori at that time. Obesity has progressively become common, after the introduction of the potato (which largely replaced the fern root and kumara as staple foods), bread, alcohol and other European foods.

With the rapid urbanisation of Maori communities in the post World War II period, Maori became less active in terms of cultivating and harvesting major food supplies and took on more “western” lifestyles, which were considered “modern”. A community acceptance of being “large” or “big” developed and it was associated with prosperity and “being healthy”.

However, it is only in recent times as non-Maori have started to understand that “being big” is actually being overweight and like the rest of the general public, they are increasingly concerned about the growing “obesity epidemic”. The concept of morbid obesity is only just starting the considered problematic amongst Maori and consequently, there is no widely accepted Maori world view around obesity itself, or the potential treatments that might be appropriate.

From a Maori world view, any surgery is invasive and potentially dangerous to one’s own taha tinana and taha wairua (physical and spiritual wellness). Maori are therefore often resistant to surgical options and agree to accepting surgery only when other options have been extinguished.

Historically, Maori people have been very pragmatic and in the early contact period, Maori people were quick to adopt new technologies that added to their economic and social development and acceptance of bariatric surgery as an option to treat morbid obesity is expected to fall into this category. Since bariatric surgery does not involve the importing of body parts from other people (such as organ donors) it should have less cultural barriers for whanau who are considering this option.

All Maori patients who wish to have bariatric surgery to be referred to the Maori Health Services

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87 Te Aniwa Tutara, GM Maori Health for Waitemata DHB, 20 December 2007
Overnight accommodation facilities with a whanau room are available in most hospitals and will be very important for those Maori who wish to have bariatric surgery.

A Chaplain should be available for spiritual guidance and support and should be part of existing hospital health services.

### 6.5 Appropriateness for Pacific people

The following information was provided by the Pacific peoples’ representative on the business case.88

A high proportion of Pacific people are morbidly obese therefore the appropriate of bariatric surgery to this group is very important. The appropriate communication of the surgery, which considers the following is vital:

- preparation of the message
- how the message/info is presented/communicated to the consumer, and the means used
- choice of communicators.

Campaigns which have worked effectively amongst Pacific people should be assessed and key learnings taken from them. If it is not well communicated then the appeal of the surgery to Pacific people is likely to be low. Any form of surgery for Pacific people is a major process. It is a family discussion and a family decision – not the morbidly obese individual versus the family. This is important as the family will play a major support role for the individual after the surgery. Support for the family and the individual together, after the operation, is especially important as a major lifestyle change will be required for all.

The following advice was given to midwives during their annual prize-giving ceremony and should be kept in mind for the post-operative period for Pacific people:

> “if your journey with Pacific mothers is currently for just one kilometre, I plea with you to increase this distance by adding another 500 meters both at the beginning and at the end. Top this up with extra tonnes of understanding, patience and love.”

All Pacific patients who wish to have bariatric surgery to be referred to the Pacific Health Services in their respective DHB.

A Chaplain should be available for spiritual guidance and support and should be part of existing hospital health services.

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Quality assurance in Bariatric Surgery

A number of countries have observed a rapid uptake in bariatric surgery. In the United States the high demand for bariatric surgery resulted in some poorly or inadequately trained surgeons undertaking bariatric operations. The increase in serious side effects was significant and lawsuits quickly followed. In response to this, a range of credentialling and quality standards programmes were set up. There are now three widely accepted quality assurance programmes operating through three organisations – the American Society for Bariatric Surgery Centers of Excellence, the American College of Surgeons and the International Federation of Surgery for Obesity (IFSO). There are many similar features in each of the quality assurance guidelines proposed by the different organisations. Some of the common features include a requirement to:

- Participate in a full audit programme
- Undertake a minimum of 50 cases per surgeon per year conducted
- Have facilities that are ‘fit for purpose’
- Use a multi-disciplinary approach.

The requirements for ‘provision status’ and ‘full approval’ through the American Society for Bariatric Surgery Centers of Excellence are provided in Appendix VI.

The American College of Surgeons has developed standards for the physical resources, human resources, clinical standards, surgeon credentialing standards and data reporting standards for American College of Surgeons Bariatric Surgery Centers. Appendix VII describes the standards required for four different levels of inpatient facilities as well as standards for outpatient surgical care. Level 1a and 1b Bariatric Centres provide complete care, including physical and human resources devoted to bariatric surgery. These centres have the capabilities to manage the most complex and challenging patients. Level 2a and 2b Bariatric Centres provide high quality care to a lower volume of patients which have less obesity and fewer obesity related comorbidities. Outpatient surgery centres provide for the application and adjustment of laparoscopic gastric bands.

International Federation of Surgery for Obesity (IFSO)

The Australasian Obesity Surgery Group is a member of IFSO and the quality and excellence guidelines proposed by IFSO are considered to be applicable to the New Zealand public health setting. One of the main objectives of IFSO’s Safety and Excellence Guidelines is to offer advice to institutions and surgeons worldwide regarding the safe and efficient establishment of bariatric surgery programmes. It is envisaged that a New Zealand publicly funded bariatric surgery programme would operate under these guidelines, and be consistent with Australian standards of care.

7.2 IFSO guidelines for Primary Bariatric Institutions (PBIs)

Institutional requirements: For any medical institution considering the surgical management of morbidly obese patients it would be necessary to:

- Ensure that surgeons performing bariatric surgery have the appropriate certification, training and experience to treat severely obese patients as described in the surgeon's credentials.
- Ensure that individuals who provide services in the bariatric surgery programme are adequately qualified to provide such services.
- Provide ancillary services such as specialized nursing care, dietary instruction, counseling and psychological assistance if and when needed.
- Have readily available consultants in cardiology, pulmonology, psychiatry and rehabilitation with previous experience in treating bariatric surgery patients.
- Have trained anesthesiologists with experience in treating bariatric surgery patients.

Keep records of the adverse events that occur during the management of the patients.

- Ensure that basic equipment necessary for the obese patients such as scales, operating room tables, instruments and supplies specifically designed for bariatric laparoscopic and open surgery, laparoscopic towers, wheelchairs, various other articles of furniture and lifts that can accommodate stretchers are available, as well as a recovery room capable of providing critical care to morbidly obese patients and an intensive care unit with similar capacity.
- Ensure that radiology department facilities can perform emergency chest x-rays with portable machinery, abdominal ultrasonography and upper GI series.
- Ensure that blood tests can be performed on a 24-hour basis.
- Ensure that blood bank facilities are available and blood transfusion can be carried out at any time.

Surgeon's credentials
- Appropriate certification to perform general surgery.
- Training and experience in gastrointestinal open and/or laparoscopic surgery.
- Successful completion of a training course in an existing bariatric Institution or at least a minimum of two days bariatric training course including live demonstrations and laboratory hands-on-training.
- Testimonials by mentors (proctors) of satisfactory bariatric surgical ability.
- Careful maintenance of a database of all bariatric cases, including outcomes, which can be audited by the appropriate national authorities.
- Commitment to postoperative life-time follow-up of the patients.
- Carrying out of operations in approved facilities as described above.

IFSO strongly advises PBIs not to accept super obese patients for the first period (1-2 years) of their practice. It is also recommended for this early period that the management of morbidly obese patients be confined to more simple bariatric procedures. PBIs may proceed to more complex bariatric techniques and to treat super obese patients only when significant experience has been gained (i.e. after performing a minimum of 50 cases) Obviously, more technically demanding procedures requiring stapling and division of the stomach and gut and revisional surgery, should not be
carried out until the conditions described for PBI are completely reached.

IFSO also has guidelines for existing Bariatric Institutions and Centre of Excellence Institutions. These are provided in Appendix VIII.

For the purpose of determining service configuration and planning a number of assumptions have been made. In line with international trends it is estimated that the proportion of morbidly obese who will receive treatment will be between 0.5 and 1.0%. As per standard quality requirements internationally, it is required that each surgeon would perform at least 50 cases per annum. A minimum unit load (i.e. bariatric centre) would accommodate a minimum of 150 cases per year. Table 8 reflects these key assumptions per individual surgeon.

Table 8. Workload per surgeon
Individual surgeon

<table>
<thead>
<tr>
<th>Weeks per year operating</th>
<th>42</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients per week</td>
<td>2</td>
</tr>
<tr>
<td>Patients per annum</td>
<td>84</td>
</tr>
<tr>
<td>Minimum number of surgeons</td>
<td>2</td>
</tr>
<tr>
<td>Minimum unit size</td>
<td>168</td>
</tr>
</tbody>
</table>

The following table shows the number and location of potential bariatric centres, based on the number of morbidly obese individuals by DHB (Table 9). This has been given as a guide only and would be firmed up during implementation phase. Based on the above assumptions and 0.5% surgical intervention per annum, there is potential for 5-8 bariatric centres in main New Zealand. This could change as/if the intervention rate increased, for example should surgery be offered to 1.0% of the target population a further two centers could be contemplated. Please note it is certainly acknowledged that other centres (not indicated in Table 9 as potential hubs) have expertise in the management of morbid obesity and consideration of future hubs will always take account of factors in addition to morbid obesity prevalence (expertise, resources, funding, desire).

The one year's costs covered here are the operating costs in the first year of each patient’s course – i.e. mainly covering the initial surgery. After the first year the patient’s care is likely to be cheaper than usual care. The cost per patient in the first year for standard care pathway bariatric surgery is estimated at $18,916 per head.

The costs shown in Table 9 exclude set up costs and capital requirements. Please refer to Appendix X for indicative capital costs for bariatric surgery.
Table 9. Potential configuration and costs at one year of bariatric centres in New Zealand public hospitals

<table>
<thead>
<tr>
<th>DHB</th>
<th>Estimated 2002/03 &gt;=35 BMI</th>
<th>Growth to 08/09</th>
<th>Patients pa @ 1%</th>
<th>Possible configuration</th>
<th>Patients pa @ 0.5%</th>
<th>Possible configuration</th>
<th>Estimated one year costs @1%</th>
<th>Estimated one year costs @0.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northland</td>
<td>5,410</td>
<td>6,492</td>
<td>65</td>
<td>32</td>
<td>1,228,000</td>
<td>614,000</td>
<td>1,228,000</td>
<td>614,000</td>
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<tr>
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<td>107</td>
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<tr>
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<tr>
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</tr>
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<td>86</td>
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<td>18</td>
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<td>340,000</td>
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<tr>
<td><strong>All NZ</strong></td>
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<td><strong>182,916</strong></td>
<td><strong>1,829</strong></td>
<td><strong>8</strong></td>
<td><strong>915</strong></td>
<td><strong>34,600,000</strong></td>
<td><strong>17,300,000</strong></td>
<td></td>
</tr>
</tbody>
</table>

Notes:
1. Survey figures are for >=35, entry criteria suggested is >=35 with cc and >40. Estimated 70% of 35-39 with cc included in the first column. See *Extreme obesity adults 2003.xls*
2. Estimated prevalence growth of 3% per year (PHI Diabetes Surveillance, Bulletin 46, 2007), or 20% from 02/03 to 08/09.
It is the view of the bariatric surgical representatives on the Steering Group that the best approach for implementing a programme of bariatric surgery in New Zealand is a phased approach. This would allow bariatric surgery to be identified as a valued skill-set, and encourage surgeons to obtain this training. Senior general surgical trainees are a reliable resource pool and upon nearing completion of their training, will be looking for opportunities to extend their expertise. It is absolutely essential that training opportunities for bariatric surgery are made available. Larger, higher volume centres will be well placed to attract New Zealand trained bariatric surgeons. With the appropriate support and resourcing, it is very possible to work towards at least 10 FTEs of bariatric surgeons in NZ over a 3-5 year time frame. Readiness to proceed can only reasonably start where resources already exist.

During the business case development, the Chair of the Steering Group met with a number of DHBs and explored whether or not there was sufficient capacity for bariatric surgery to be introduced. DHBs general response is that there is a mix of public capacity (in some DHBs this would mean a reallocation of resources) and private capacity. Private capacity would only be used as an interim step to establishing full public capacity and workforce. A key theme received by the Chair during visits with DHB clinicians, managers and funders was that any implementation of bariatric surgery in New Zealand public hospitals requires a whole systems change and approach – it is about much more than the surgeon per se. For a programme to be successful it must be endorsed and supported collectively.

Coinciding with the development of this business case the Ministry of Health’s Elective Services Project has commissioned an extensive piece of work looking at physical bed and theatre capacity among all 21 DHB. Although this is not completed at the date of finalising our business case, early indications support that there is a level of physical public capacity available for additional surgery in many DHBs.

### 8.1 Funding

Table 10 below provides information on the operative workload and the indicative costs, per DHB in Year 1 at an intervention rate of 0.5 %. The 0.5% is a rate that has been set in Year 1 as a starting point to give some level of consistency for the prevalent population throughout the country.

If this business case is approved, provision of bariatric surgical services will be new to many DHBs. The reader should note that part of the role of the Implementation Group (refer Section 10) will be to reassess the appropriate intervention rate once the surgery is established and further data are collected and analysed.

On the basis of discussions between the business case Project Manager and the Ministry of Health and information to date, it is forecast that additional funding will be made available from 01 July 2008 to enable bariatric surgery to be implemented at 0.5% in Year 1. The value of this as identified is ~$17.0m

The principles that apply currently to accessing additional Elective services funding would remain. Specifically each DHB would apply to the Elective Services Fund for the
volume of procedures identified through our modelling in Table 10. The price on the IDF schedule would be based on NZDRG50 K04A Major Procedures for Obesity without Laparoscopy (3.94 WIES), and DRG K04B Major Procedures for Obesity with Laparoscopy (3.7 WIES) and assumes that where private sector capacity is utilised, the price will be similar.

Further the eligibility criteria (Appendix XI) would be adopted in the initial phase of the implementation as the tool to assess which patients are eligible on a prioritised basis. The workstream about to commence with the Elective Services team and representatives from the general surgical community to develop a national prioritisation tool for all general surgery will also include bariatric surgery.

Appendix IX provides further information on the cost path estimates for providing standard care pathway bariatric surgery by DHB over ten years. These cost estimates are indicative only and exclude capital/set up costs over and above what is already included in the WIES price. Appendix X provides information on indicative capital requirements for bariatric surgery.

For the purpose of the business case three scenarios were modelled: 0.5% prevalence operative rate, 1% prevalence operative rate and a rollout model (0.5% for the first three years, 1% thereafter).

- A 0.5% prevalence operative rate would require $47.5m for the first three years, and $80.9m for the first six years
- A 1% prevalence operative rate would be about double that of the former rate (i.e. require $95m for the first three years, and $161.6m for the first six)
- The roll-out would require $47.5m for the first three years and $128.3m at six years.

Key assumptions of this analysis include:

- Cost savings are able to be derived from year two
- Costs averted are not offset by other demands and can be converted into actual savings
- Cost savings made in areas such as medicine and dialysis can be converted into actual savings
- Cost being included as savings as part of the ‘usual care’ of the morbidly obese will be funded
- All DHBs place equal priority for this surgery.
Table 10. Cost pathway estimate by DHB assuming 0.5% intervention rate

**Rough cost path estimates for each DHB - indicative only**
Based on standard bariatric surgery model, expected net costs if reasonable targeting of eligible patients

**At a 0.5% prevalence operative rate**

<table>
<thead>
<tr>
<th>DHB</th>
<th>procs/yea</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 6</th>
<th>Year 7</th>
<th>Year 8</th>
<th>Year 9</th>
<th>Year 10</th>
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</thead>
<tbody>
<tr>
<td>Northland</td>
<td>32</td>
<td>610</td>
<td>560</td>
<td>520</td>
<td>470</td>
<td>400</td>
<td>310</td>
<td>230</td>
<td>160</td>
<td>90</td>
<td>20</td>
</tr>
<tr>
<td>Waitemata</td>
<td>107</td>
<td>2,010</td>
<td>1,860</td>
<td>1,700</td>
<td>1,550</td>
<td>1,310</td>
<td>1,040</td>
<td>770</td>
<td>520</td>
<td>290</td>
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<tr>
<td>Auckland</td>
<td>112</td>
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<td>1,770</td>
<td>1,610</td>
<td>1,370</td>
<td>1,080</td>
<td>810</td>
<td>550</td>
<td>300</td>
<td>70</td>
</tr>
<tr>
<td>Counties</td>
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<td>2,170</td>
<td>1,980</td>
<td>1,680</td>
<td>1,330</td>
<td>990</td>
<td>670</td>
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<td>80</td>
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<td>1,040</td>
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<td>700</td>
<td>520</td>
<td>350</td>
<td>190</td>
<td>40</td>
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<td>410</td>
<td>380</td>
<td>350</td>
<td>290</td>
<td>230</td>
<td>170</td>
<td>120</td>
<td>60</td>
<td>10</td>
</tr>
<tr>
<td>Bay of Plenty</td>
<td>39</td>
<td>730</td>
<td>680</td>
<td>620</td>
<td>560</td>
<td>480</td>
<td>380</td>
<td>280</td>
<td>190</td>
<td>100</td>
<td>20</td>
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<td>Tairawhiti</td>
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<td>80</td>
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<td>160</td>
<td>90</td>
<td>20</td>
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<td>MidCentral</td>
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<td>120</td>
<td>90</td>
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$$ required up to 3 years

$$ required up to 6 years

80,79
8.2 Patient selection guidelines

In a review article, Flum et al (2007) report on the inequitable use of bariatric surgery in the United States.\(^\text{90}\) It is noted that nearly 84% of patients are women, more than 90% are white and most have higher income levels. Part of the problem is attributed to lack of clarity as to which of the eligible population will benefit the most from undertaking the surgery. However, those who appear to be most affected by morbid obesity have not received the surgery to date. In general, healthier, better-insured and lower-risk patients are those who are offered and inclined to opt for bariatric surgery. He recommends cultural differences and gaps in knowledge and beliefs that make certain groups less inclined to consider surgery should be better identified and programmes developed to reduce those gaps, such that equitable and rationale use of bariatric surgery is achieved.

The 1991 National Institutes of Health (NIH) patient selection guidelines have been widely adapted internationally. This section provides an outline of selection criteria utilised by different organisations in the United States, which has pioneered the development of clinical criteria for bariatric surgery. The proposed selection criteria for eligibility for bariatric surgery in New Zealand are provided in Appendix XI.

8.2.1 National Institutes of Health

The America National Institute of Health (NIH) criteria are the most commonly used criteria for identifying candidates for bariatric surgery. However, the criteria are overly inclusive for the purpose of the New Zealand public health setting. It is estimated that 8,200 people in the Auckland District Health Board (ADHB) alone would meet the NIH criteria.

The National Institutes of Health (NIH) have defined patient selection guidelines in their 1991 Consensus Statement on Gastrointestinal Surgery for Severe Obesity.\(^\text{91}\) Criteria include:

- Surgery should be considered for individuals whose BMI exceeds 40kg/m\(^2\) and who strongly desire weight loss because obesity severely impairs their quality of life
- Surgery should be considered for individuals whose BMI is between 35 and 40 kg/m\(^2\) and who suffer from a high-risk of comorbidities
- Non-surgical treatments should be attempted first
- Patients must be well-informed
- Patients must be highly motivated.


8.2.2 Agency for Healthcare Research and Quality Evidence-based Practice Center

The Agency for Healthcare Research and Quality Evidence-based Practice Center and the guidelines published by the American College of Physicians corroborated the NIH Consensus Statement stating that:

- Appropriate candidates for surgery were patients with BMI >40kg/m² who had implemented, but failed at, previous non-surgical treatments for weight loss
- Candidates for surgery should be motivated to avoid unhealthy pre-surgical eating habits.

8.2.3 National Institute for Clinical Excellence (NICE) guidelines

NICE stipulates that surgery is recommended as a treatment option for those with morbid obesity providing all of the following criteria are fulfilled:

- This type of surgery should be considered only for people who have been receiving intensive management in a specialised hospital obesity clinic
- Individuals should be aged 18 years or over
- There should be evidence that all appropriate and available nonsurgical measures have been adequately tried but have failed to maintain weight loss
- There should be no specific clinical or psychological contraindications to this type of surgery
- Individuals should be generally fit for anaesthesia and surgery
- Individuals should understand the need for long-term follow-up.

8.2.4 American Society for Bariatric Surgery

The American Society for Bariatric Surgery Statement maintained the earlier NIH guidelines and added several recommendations including:

- Candidates should have a comprehensive medical evaluation before the operation
- The surgical team should be receptive to change in selecting procedures as techniques evolved
- Laparoscopic and open techniques are standards of care
- Need for consideration and further investigation of the benefits of bariatric surgery for adolescents and individuals with Class I obesity
- Participants should have attempted to lose weight through non-surgical means, but participating in a formal non-operative obesity treatment programme should not be a prerequisite for weight loss surgery.

Many surgical centres also require patients to undergo a pre-surgical psychological evaluation to determine their suitability for surgery. Psychological evaluation practices are not standard and recent research shows that psychological assessment varies enormously. Until longer term studies can clearly identify reliable indicators of outcome it is thought that assessment practices will continue to vary. Based on the available information, it is generally recommended that psychological evaluations be used to help
identify those patients who may benefit from additional pre and post operative support, rather than be used to determine eligibility for the surgery.

### 8.2.5 Proposed selection criteria bariatric surgery in New Zealand

The Steering Group has developed a patient selection criteria check-list and this is provided in Appendix XI. This list was circulated to bariatric surgeons throughout New Zealand for their input and feedback. The criteria include identifying patient demographics, comorbidity and risk factors, the NIH criteria components, surgical exclusion criteria and classification of operative risk to determine suitability of proceeding to a multidisciplinary team assessment for consideration of surgery. Once finalised the selection criteria should be made available on Healthpoint, for all potential referrers to access.

In addition to the assessment by eligibility criteria it is proposed that all operative candidates will be assessed by a multi-disciplinary team to confirm appropriateness for surgery. All operative candidates will be placed in a pre-operative multi-disciplinary weight-loss programme which may include input from a dietician, exercise physiologist, psychologist, nurse practitioner and surgeon. This serves as both risk reduction pre-surgery, and a measure of compliance with lifestyle interventions – an important predictor of long-term success. Inadequate weight loss pre-surgery may be taken as failure of compliance and result in exclusion from programme. Please note, that for the purpose of this business case standard care pathway refers to the input of the surgeon, anesthetist and dietician. Wrap-around refers to the input of the surgeon, anesthetist, dietician, together with the input of a cultural advisor and health psychologist.

The New Zealand criteria have been developed based on the following principles:

- Scarce resource of publicly funded bariatric surgery must be appropriately targeted
- The criteria and process of selection for surgery should be fair, transparent and equitable
- Patients particularly well suited to bariatric surgery are those whose comorbidities are poorly managed by intensive non-surgical treatment, including those with type II diabetes (particularly requiring high doses of Insulin), obstructive sleep apnoea, and those with impaired mobility due to weight.
- Risk must be carefully monitored and managed and as such higher risk patients should not enter the programme, at least initially during the learning curve. As experience increases, there may be potential to review surgical risk thresholds, if appropriate.

It is acknowledged that there is not a national scoring tool available currently within the public health sector to prioritise across all areas of General Surgery. Development of a national scoring tool for General Surgery is about to begin and bariatric surgery will be considered within this scope.

### 8.3 Preferred bariatric surgical technique
Based on the high-level scientific evidence at the time of this paper, the Steering Group does not support the use of one type of bariatric surgical technique over another. The following statements outline the Steering Group’s position on the type of bariatric surgical technique.

- Each patient must be appropriately and thoroughly assessed in terms of the patient’s health status including comorbidities and the patient’s desired goals and outcomes when discussing surgical procedure.

- Bariatric surgeons working in New Zealand public hospitals should be able to perform the commonly performed operations, i.e., adjustable gastric banding and Roux-En-Y gastric bypass.

- With the current range of procedures available and lack of consensus or high level comparative data in the scientific literature, it is not prudent to make ‘black and white’ statements regarding the type of bariatric procedure. This will come down to a decision between the patient and surgeon.

### 8.3.1 American Society for Bariatric Surgery position statement on sleeve gastrectomy

In their position statement on sleeve gastrectomy, the American Society for Bariatric Surgery state that: “performance of sleeve gastrectomy may be an option for carefully selected patients undergoing bariatric surgical treatment, particularly those who are high risk or super-super-obese, and that the concept of staged bariatric surgery may have value as a risk reduction strategy in high-risk patient populations. It is suggested that surgeons performing sleeve gastrectomy prospectively collect and report outcome data for this procedure in the scientific literature. In addition, it is suggested that surgeons performing sleeve gastrectomy inform patients regarding the lack of published evidence for sustained weight loss beyond 3 years and provide them with information regarding alternative procedures with published long-term (> 5 years) data confirming sustained weight loss and comorbidity resolution based upon available literature at this time.”

The Steering Group endorses this position statement.

### 8.4 Expertise of health professionals working with bariatric patients

Throughout the feedback process a number of reviewers commented on the need for specialist training of those involved in the care pathway (be it standard or wrap-around) of the bariatric patient. The members of the Steering Group commented in the following way on this particular issue:

- Every day, anesthetics are given to bariatric patients but under the guise of orthopaedic, gynaecological and other specialties without any extra training. We certainly do not want to underemphasise the importance of anesthetists knowing how to deal with these patients appropriately, but there are already a number of established bariatric practices here in New Zealand (Stubbs, Schroeder), with
experienced anesthetists, who would likely share their knowledge with their colleagues. Overseas experience may also have a role.

- For the purpose of the business case the CMDHB standard care pathway for bariatric surgery which includes the input of a surgeon, anesthetist and dietician was modeled. For the wrap-around the CMDHB wrap-around pathway which includes the additional input of a health psychologist six months pre-operatively and 12 months post-operatively and cultural support was modeled. It is expected that current training for all these health professionals would include the management of morbidly obese and that these health professionals would already have had contact and experience in the management of morbidly obese within most DHBs.

- Given the increasing prevalence of morbidly obese, ‘continuous learning’ for the medical, surgical and allied health professions that includes a focus on the management of morbidly obese is expected.

- Cross-cultural training of health professionals should be part of DHB initiatives. Health professionals working with morbidly obese are likely to be working with Maori and Pacific people and therefore should have access to and be able to demonstrate cross-cultural competence.

- The Obesity Surgery Society of Australia and New Zealand website (www.ossanz.com.au) reports there are eight bariatric surgeons operating throughout New Zealand (private sector). It is understood that three of these surgeons have an appreciable public hospital component. There are between a further six to ten surgeons who are at differing stages of ‘start-up’ with regard to the provision of bariatric surgery. It is assumed they will perform a mix of private and public work.
There appears to be no standardised data collection systems for bariatric surgery, although there are weight loss surgery databases and systems in use. There are clear benefits of a standardised database programme, including:

- Definition of patient demographics
- Patient risk stratification and risk prediction both locally and nationally
- Benchmarking
- Development of effective, quality improvement programmes
- Assessment of resource use.

The key questions identified in a systematic review of data collection registries related to weight loss surgery and a further systematic review of data collection registries of other surgical fields are:

- How should data be collected?
- Who should collect information?
- How should regulatory bodies be involved?
- How should data be shared or reported?
- How should the data collection system be funded?

The use of standardised data collection systems appears to be related to improving patient safety and decreasing surgical mortality rates, as demonstrated in the field of cardiac surgery. In a review of data collection and outcomes in cardiac surgery, institutions that participate in regional or national risk-adjusted data collection systems show improved quality of care, a decreased number of outlier institutions and a greater decrease in surgical mortality rates compared with national averages.

There is only one established centralised database in the United States – the International Bariatric Surgery Registry (IBSR). This was developed in 1979 to foster optimum patient care and the system provides members with standardised clinical data collection and analysis, including individual and pooled reports.

The NIH, together with six clinical centers and one data coordinating center, has established the Longitudinal Assessment of Bariatric Surgery (LABS). The overall goal of the programme is to standardise definitions and data collection instruments across different centres and to study the risks and benefits of the different procedures.

The American Society for Bariatric Surgery is developing a data capture system for its Centers for Excellence programme. Those participating centers must standardise surgical procedures and care plans, meet outcomes data requirements and include all patients in their databases.

Table 11. Appropriate data for a weight loss surgical database

Preoperative
- Age
- Height
- Weight
- BMI
- Obesity-related comorbidities
- Other comorbid conditions

Intraoperative
- Procedure type and specifics
- Surgeon
- Level of assistant
- Intraoperative variables
- Complications

Postoperative
- Length of stay
- Postoperative complications (e.g. leaks, sepsis, strictures, bleeding, deep venous thrombosis, pulmonary embolus)
- Readmissions
- Subsequent procedures 30 days
- Subsequent procedures 1 year

Long-term follow-up
- Overall weight loss and reduction of comorbidities over time, as well as morbidity and mortality

Hutter et al (2005) recommend that:
- The data collection system be confidential, prospective, risk-adjusted, multicenter, benchmarked, and based on standard definitions of data points
- That data include preoperative, intraoperative, postoperative and long-term follow-up information
- That data be collected by a sophisticated, trained, unbiased, and audited reviewer.

During the feedback process a number of reviewers commented on the requirement for monitoring of longer term holistic outcomes such as return to work and quality of life. This business case recommends the establishment of an expert technical group to research and recommend a national programme of data collection. It is expected that variables collected pre and post operatively (short term and longer term) and in addition to demographic factors including ethnicity may include weight, comorbidity type and status, medications resulting from morbid obesity, employment status and functional health and well-being (SF-36) among others. The Steering Group strongly supports this monitoring being undertaken as part of a nationally funded longitudinal study.
10 Implementation

Should this business case be approved a national Implementation Group will need to be immediately established. It is envisaged such a group would consist of one or two representatives from the following key groups: hospital services general managers, funders/planner, general surgeons with bariatric interest, the National Elective Services Project, technical experts and primary care.

It is acknowledged that implementation of bariatric surgery in the New Zealand public health sector on a consistent basis will be an iterative process. The role of this Group will be to provide expert guidance to DHBs by:

- establishing a set of key performance indicators
- establishing a national programme of data collection for bariatric surgery to ensure outcomes are appropriate
- evaluating implementation of the project based on the key performance indicators
- communicating the results to the sector and strategies to address any issues arising
- informing the development of a national general surgery scoring tool, which would build on the criteria provided in this business case for the bariatric component
- advising the sector on indications for increasing the intervention rate and equity of access
- advising the sector on indications for plastic surgical intervention
- advising the sector of any changes to the model of care once the Counties Manukau DHB randomised control trial on wrap around services is complete.

The governance of this Implementation Group does not fall within the remit of NSTR but could be provided either through an existing DHBNZ/MOH collaboration, or through the Service Improvement Group.

The Implementation Group will also require a full time project manager resource in Year 1 and possibly beyond this time on a part time basis.
Appendices
Appendix I  Standard care pathway for bariatric surgery (CMDHB RCT)

Patient selection

Patient’s who have a BMI of >40 (or >35 with comorbidities) will be eligible for selection for the bariatric service. A referral would be accepted from GPs and hospital specialists. The patient needs to have failed conventional dieting measures or maintained long term weight loss and expressed a desire to undertake the lifestyle change required for bariatric surgery.

Contraindications:

- Absence of a period of identifiable medical management
- Patient who is unable to participate in prolonged medical follow up
- Patients who are unable to care for themselves and have no long-term family or social support that will warrant such care

Patients will be assessed in a clinic environment by a Bariatric surgeon, a dietician and an anesthetist. If deemed appropriate they will also be seen by the physiotherapist and/or the psychologist.

The patient may need to be seen several times in the clinic prior to being deemed ‘ready’ for surgery. This decision is made by the surgeon in consultation with the MDT.

Once patients have met the criteria set down by the surgeon and have demonstrated a commitment to changing their lifestyle (weight loss and exercise) they will be added to the Inpatient Waiting List (IPWL). Priority will be allocated using the MOH approved grading criteria that is utilised in General Surgery.

Preoperative phase

The preoperative assessment will include the following:

- Assessment of general health and nutritional status
- Explanation of dietary changes that are required after surgery
- Optimizing treatment of comorbidities
- Assessment of patient motivation and willingness to adhere to follow up programmes
• Ensuring patient is fully informed on the benefits, consequences and risks of the surgical options and the necessity of life-long follow up (informed consent)
• Ensuring the patient understands the potential (limited) outcomes of surgery

Patients will be commenced on Optifast 3-6 weeks prior to surgery, or as deemed appropriate by the dietician. They will be followed up by the dietician and/or nurse coordinator. Any issues with progress will be discussed with the surgeon. A preoperative assessment will be undertaken by the anesthetic team and the usual blood tests etc will be completed. If a sleep study is deemed appropriate this will completed privately until internal capacity is established.

Operative phase

The literature suggests that 20% of morbidly obese patients undergoing a laparoscopic procedure require an ICU admission. Patients will be thoroughly assessed preoperatively to limit any risk. Patients must complete a rigorous dieting programme on the Optifast 3-6 weeks prior to surgery.

Patients will be managed using a Bariatric Care plan attached.

Post Operative Phase

Patients will be reviewed by the surgeon and dietician prior to discharge. They will then be followed up in the clinic as per the process map.

Refer to process map for further details.

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SUGGESTED CARE PLAN:

BARIATRIC SURGERY CARE PATHWAY

Pre-operative phase

Proposed Procedure: 

History:

Date: 

Diabetes: Yes/No

Medication: 

ALLERGIES:

Last taken:

Pre operative intervention

☐ Seen by surgeon and explanation given re: bariatric surgery

☐ Seen by dietician and explanation given re: diet and optifast

☐ Start optifast for __________ weeks before surgery

☐ Call patients on optifast twice a week to see how they are coping.

☐ Inform dietician if pts is not coping.

☐ Admission pack, blood forms and prescription to be sent to patient before surgery with clear instructions.

☐ Pre-operative weight ___________kg

☐ Amount of weight lost prior to surgery __________kg

Pre-operative instructions

☐ Operation area free of hair and skin intact

☐ Below knee TEDs or SCDs

☐ Bowel Preparation –20mls Lactulose night before surgery

☐ FBC and U+E and Group and Hold completed and results available

☐ DVT Prophylaxis administered (Upper thigh not abdomen)

☐ Preoperative checklist completed

Education:

☐ Deep breathing, coughing and leg exercises

☐ Importance of early mobilisation

☐ Pain and nausea management

☐ Proposed discharge date, usually 2 nights
### BARIATRIC SURGERY CARE PATHWAY

#### Post operative: Day 1

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#### Part A

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<td>Operation explained</td>
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<td>Plans/Goals for the day</td>
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<td>Discharge planning</td>
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#### 4. Anti-embolic stockings

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#### 5. Intravenous lines checked

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#### 6. Respiration/Circulation

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**Cerebral function**

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**Sleep and Rest**

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3. Pain Assessment

Score

7. Nutrition

NBM for 12 hours

Oral fluids – sips 12 hours post op

NG on free drainage

Nursing Observations and Interventions

Care Plan completed by:
Initial Night
Initial AM
Initial PM
**BARIATRIC SURGERY CARE PATHWAY**

Post operative: Day 1  |  Date:  | Part B
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### 8. Nausea and Vomiting

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### 11. Intestinal Function

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### 12. Mobilisation

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- Mobilised 2 X 2 hrs AM
- Mobilised 2x2hrs PM
- Walked x 3
- Personal Hygiene

### 9. Wound Check

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### 10. Urination

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### 13. Discharge & Planning

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- Dietetic information
- Information to family
- Transport arranged
- Medications discussed

**Nursing Observations and Interventions**

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**BARIATRIC SURGERY CARE PATHWAY**

**Post operative: Day 2**

**Date:**

**Care Plan completed by:**

- Initial Night
- Initial AM
- Initial PM

**Patient identification label**

**Prescriptions**

- Standard Analgesia
- Clexane 1800hrs
- NG removed
- IV removed

**Fluid Balance**

**Information:**

- Plans/Goals for the day
- Discharge planning

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Nursing Observations and Interventions
### BARIATRIC SURGERY CARE PATHWAY

**Post operative: Day 2**

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#### Nursing Observations and Interventions

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BARIATRIC SURGERY CARE PATHWAY
Post operative: Day 3  Date: 

Prescriptions

- Standard Analgesia [□ □ □ □] [□ □ □ □] removed
- Clexane 1800hrs [□ □]

Information:

- 1. Cerebral function [□ □ □]
- 4. Anti-embolic stockings [□ □ □]

Care Plan completed by:
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<td>Oral fluids – aim 90ml/hour (1-2 L/ day)</td>
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Nursing Observations and Interventions

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BARIATRIC SURGERY CARE PATHWAY

8. Nausea and Vomiting

9. Wound Check

11. Intestinal Function
   Flatus +/-
   Defaecation +/-

12. Mobilisation
   Mobilised 2 X 2 hrs AM
   Mobilised 2x2hrs PM
   Walked x 3
   Personal Hygiene

Care Plan completed by:
Initial Night
Initial AM
Initial PM
### 10. Urination

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### 13. Discharge & Planning

- **Dietetic information**
- **Information to pt/ family**
- **Transport arranged**
- **Medications discussed**
- **Follow up appointment**
  - @ 2 weeks post op with the surgeon
  - @3 weeks post op with the dietitian
- **Discharge summary**

### Nursing Observations and Interventions

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**Care Plan completed by:**

Initial Night  Initial AM  Initial PM
# BARIATRIC SURGERY CARE PATHWAY

## Post-operative follow-up

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| **Dietitian assessment** |                                          |
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Nursing

Care Plan completed by:
Appendix II  Standard care pathway (CMDHB RCT); role of the Dietician

Dietetic Intervention

- Nutrition Assessment pre surgery - approx. 1 hour
  - Full assessment of current diet and lifestyle
  - Includes discussion re lifestyle changes needed.
  - Optifast protocol discussed. (Commenced for 2 - 4 weeks prior to surgery)
  - Expectations post surgery.
- Day 1 or 2 post surgery dietitian visit (30 - 45 minutes)
  - Discuss in detail post surgical dietary progression. Particular emphasis on puree diet.
  - Multivitamins.
  - Written guidelines given for the progression from FOF – Puree diet – Soft diet.
- Week 3 – 4 post surgery (30 minutes)
  - Full diet history
  - Review of nutritional adequacy of intake. The following nutrients are discussed and guidelines for intake given:
    - Calcium
    - Iron
    - Protein
  - Review wt loss
  - Education re dietary progression from here i.e. soft – normal consistency foods.
- 6 month post surgery review (30 minutes)
  - Full diet history
  - Review of nutritional adequacy of intake. The following nutrients are discussed and guidelines for intake given:
    - Calcium
    - Iron
    - Protein
  - Review wt loss and discuss weight loss goals.
  - Discussion and education re: maintaining weight loss
  - Patients’ often have numerous questions at this appointment.

At each session patients are given individual goals and information to ensure adequate nutrient intake and maintenance of weight loss.
Appendix III – Wrap-around pathway of care (CMDHB RCT)

**WRAP AROUND CARE PATHWAY**

- Participant cleared by Study Nurse for Study
- Psychological Assessment
- Accepted?
- Randomised to Group
  - Control
    - See Standard Care Pathway & Study ‘Schedule of Assessments’
  - Wrap Around
    - As follows in conjunction w Study ‘Schedule of Assessments’

- 1 individual post-surgery session

**SURGERY**

- 9 Groups Pre-surgery Wk9 – wk17
- Progress to Group Work (3 groups of n=10)
- Five individual sessions Wk3 – wk7
  - 8 Post-surgery Groups Wks24 - 39
  - 7 Monthly Support Groups Wks43 – 12 months post surgery

*Note:* Participant will be seen on an individual basis alongside group work – see timeline.
Appendix IV – Wrap-around pathway of care (CMDHB RCT); role of the Health Psychologist

- This 18 month CBT based intervention is aimed at providing participants with the tools to maximise self-management as they go through the bariatric surgery process. The wrap around service can be seen as three separate phases and is based on Marcus & Elkins’ (2004) identification of each phase in the process requiring different needs. They outline these as Pre-surgery: Period of Preparation, Post-Surgery 0-6 months: Period of Adaptation and finally, Post-surgery 6-12 months: Period of Long-term Adjustment. The wrap around service meets these distinctions and is delivered in 4 major components as follows;

1) **Assessment**
   This psychological assessment explores the participant’s understanding of the surgery and its requirements, their reasons for seeking surgery as an option, their level of motivation and readiness to engage in the lifestyle changes required and, finally, any psychological sequelae that may effect their being accepted for surgery. This assessment is intended to sit alongside standardised questionnaires examining mood and quality of life.

2) **Individual work**
   These initial face-to-face sessions allow the participant and their support people to get a better understanding of what the wrap around service involves. It provides rationale for the intervention and sets the participant up to use behavioural techniques to monitor and adjust their own problematic behaviours. These techniques are continued into the remainder of the intervention.

3) **Pre-surgery group work**
   These group sessions enable participants to gather information about self management and begin to build a “tool kit” of skills they can draw on throughout the process.

4) **Post-surgery group work**
   The focus here begins on navigating and gaining mastery in managing the required physical and emotional adjustments that arise after surgery. Participants are encouraged to continue pursing goals and becoming self-reliant. Group work phases into long-term adjustment allowing participants to consolidate on skills learnt.

*Note:* Participation in a support group can facilitate after-care for both patients and physicians and may enhance weight loss outcomes (Grothe, Dubbert & O’jile, 2006).

*References*


Health Psychologist Assessment - final pre-surgical session with the patient.
Introduction
• Name/Position – explain role
• Confidentiality, how information will be shared
• Introductions of whanau support worker, any support people attending session
• Offer karakea
• Goal: to understand what has lead them to seek surgery, whether surgery is the best option for them and if it is, see what tools you would need to manage the surgery
• There are some specific questions we need to go through to help us determine if this is right for you.
• A lot of things will be covered in this session - feel free to ask questions and there will be an opportunity at the end to ask questions too. May be overlap with other appointments - important to look at the information from a slightly different angle.

Topic
Knowledge of Bariatrics
• Acknowledge had lots of information so far, can be overwhelming
• How are you going with all the info - nature of the operation, potential risks & benefits, changes required to eating/lifestyle habits, complications/risks.
• Any other source of information - GP, internet, know people who had surgery
• Anything don't understand/want more info on?

Motivation
• What brought you here today/why do you want this surgery/why now?
• People can be in different stages of readiness to make big changes - where would you put yourself? (indicate on wheel of change)

Expectations
• **Note**: 60% excess weight lost on average = may remain overweight after surgery.

• What are your expectations for this surgery? (write down their exact words, allow time before prompting)

Circle:
• Weight loss/improvements in health/how you feel about yourself/mood/social life/relationships?
• Do you have any goals?

Barriers
• What do you see as being the barriers to you having this operation successfully?
• Is there anything going on in your life right now (or coming up in the next 18 months) that would make it difficult for you to change eating habits/be more physically active/attend weekly sessions (ind/grp)/complete homework assignments/read handouts?

Past Adherence
• What sorts of medical regimes have you been required to manage in the past.
• How successful do you think you've been with the above?
• What did you find went well with managing 'x'?
• What did you find difficult about managing 'x'?
Current Eating Habits
- What's a typical food day like for you?
- Week vs. weekend?
- Any specific times when you feel like you eat the most/find it hard to control your eating?
- Who prepares the meals/does the shopping
- What time of day do you eat most of your food?

Binge eating
- Ever have times when you eat unusually large amounts of food and feel that your eating is out of control?
- How often?
- Eat more rapidly than usual?
- Eat till uncomfortably full?
- Eat when not hungry?
- Eat alone cause embarrassed?
- Feel disgusted/depressed/guilty for over eating?
- Eat large amounts of food with no planned meal times?
- What times of day does this happen?
- Ever take steps to correct binge - vomit, excessive exercise etc.
- How important is your weight/size/shape to how you feel about yourself?

Night Eating Syndrome
- Cravings when wake up
- Eat to get back to sleep
- How often snack in middle of night
- How aware that eating in middle of the night
- How much control have when in middle of night
- How long had difficulties with night eating
- Assess their concern for the effect their eating disorder may have on pre-/post-op diet

Food Attachment
Preamble: attachment to food can occur from a very young age, to understand your eating patterns now it is useful to look at how your attachments to food were formed in the formative years of your life (0-23yrs).
- What was it like for you growing up?
- How would you describe mother/father? What kind of relationship did you have with each of them? Anyone in family have a weight problem? What messages do you remember getting about food? What was the ritual/emotional experience attached to food - what were meals times like in your family?
- Which foods do you love (sweet/savoury)? Can you recall any early experiences that strengthened this attachment?

Weight & Dieting History
- What age first overweight? How do you remember this (pictures, clothing size, others telling you
- What has your weight been like in the past 6 months?
- Are any members of your family overweight?
- Have you ever tried to lose weight before?
- How many times, what methods, how successful?
• Encourage their weight loss attempts - sets up the idea not failures but demonstrates tenacity.

Problematic Thinking Patterns & Self-sabotage
• Have you had unrealistic weight goals in the past?
• Have you/do you feel deprived of food?
• Do you give up completely once you go off track slightly? "What the Hell Effect"
• Do you tell yourself you will be good starting tomorrow? "Last Supper Effect"
• What are your excuses (disinhibitors)? i.e. how do you justify over eating/eating bad food?

Relationship History
• First major relationship - how long did it last? When did it end? What message did this give you about relationships? What was your eating habit around the end? Did food/weight play a role in this relationship? Any other relationships?

Self Esteem & Body Image
• How important is your weight/size/shape to how you feel about yourself?
• What activities have you avoided because of your shape/size.

Weight Attachment
• Explore individual's attachment to their weight - are there any positives to being over weight? What would it be like if you lost weight?
• What might be the negatives of losing weight?
• What is appealing about staying the same?

QoL
• Impact obesity had on life - physical health/mobility/sleep/work/social & relationships/body image/self-esteem/public distress.

Social/Psychological Status
• Mood screen/suicide assessment
• Enjoyment/energy/sleep/worthlessness/guilt/concentration

• Anxiety screen
• Worrier?

History of psychological disturbance

History of Abuse
• Ever experienced (experienced/witnessed) a trauma - (event involving actual or threat of death or serious injury to you or someone else) may be abuse, accident? Other such experiences.
• Ever had any help in dealing with abuse?
• Feel as if you've recovered?

Ways of Coping
• How do you cope with stress/distress?
• Do you use food as a comfort?
• Do you take any drugs? Did you in the past?
• Do you drink alcohol? How often, what kind, how much, ever cause problems?
• Do you smoke? Cigarettes? Pot? Other? How often?

Family/Social
• Is there anyone you are not telling about the surgery? If so why?
• Living arrangements - whose in your family
• Relationship satisfaction (spouse & other close relations)
• Family & friends supportive of surgery - if not try to clarify patient's concerns ("what did your partner/family/friends do that hindered/helped your weight control efforts last time you tried?")

Patient's concerns family may try to sabotage their weight loss efforts
Ensure patient has identified someone to act as their support through the process and especially during surgery stage i.e. help with childcare

Questions/concerns

Wrap up
We have covered a lot today, thank you for being so open and honest, can stir up feelings discussing such personal things – how are you feeling at the end of this?
Next step – I will go back and discuss with the surgeon/anaesthetist/dietician. If we all agree surgery is right for you and you feel you want to go ahead with it then we will progress forward
Firstly the Steering Group would like to thank LECG for their peer review of the economic analysis and modelling of the first draft of the Management of Adult Morbid Obesity business case. The review was very timely and has enabled many of the suggestions to be incorporated into the final business case. This appendix briefly outlines the response to the main points raised by the reviewers. Specifically, noting what changes were made to the final business case based on the peer review, providing rationale as to why suggested changes were not made, and providing more information as to the basis for some of the decisions made.

One important item to note is the lack of available NZ-specific information in this area – as might well be expected. If bariatric surgery becomes publicly funded in NZ we would certainly hope to collect high quality NZ-based data, providing the information recommendations in the business case are followed. At this formative stage, we are reliant on reasonably small sets of data upon which to generate a number of assumptions and costs. We will be much better placed to assess the cost-effectiveness of the programme once we have had it up and running for a suitable period. However, in stating this the Steering Group wish to be clear that we are confident that bariatric surgery is a cost-effective intervention for the management of adult morbid obesity.

1. Referral criteria.
Based on the eligibility criteria for surgery and the expected referral pathways it is expected that patients would be drawn from those with significant co-morbidities, or risks of same. In cost terms then, we are looking for the more expensive end of the morbid obesity spectrum in terms of expected health care costs going forward over time. In the sensitivity analysis variances in assumptions as to how patients were selected for surgery made the largest difference to costs. This analysis demonstrated that bariatric surgery could potentially range from being cost saving to DHBs through to having a cost of up to $8000/QALY.

In thinking about this cost of “usual care” for the morbid obesity business case:

a. The existing very high cost individuals themselves may not generate any cost-savings for the bariatric surgery decision tree as they are unlikely to be eligible for surgery - certainly for the introductory phase/next 5-10 yrs as high operative risk patients will not be selected

b. But they do indicate the potential path of future costs for some individuals, albeit at some future point in time.

For the purpose of this business case we have then attempted to define the average cost of those with the highest quartile of costs. Cost data is highly skewed, so taking the high cost patients identifiable in data sets will overestimate the cost savings, however using averages is likely to underestimate the cost savings. The upper quartile was chosen as a mid-point proxy. Two different data sets were used to triangulate some NZ-specific data; one using ICD10 morbid obesity codes on inpatient records, the other the CMDHB Chronic Care Management BMI data as described in the business case. The
highly skewed distribution is verified (albeit using the same DHBs data set), although the
generalisability of patients enrolled in chronic care programmes warrants discussion.
Notwithstanding these limitations the dataset is the largest set of NHI-numbered BMI
data that we are aware of, and represents 20% or so of the total morbidly obese
population in CMDHB.

Once referral patterns and surgeon eligibility/selection criteria are established and
working it will be possible to much more explicitly model the costs of usual care. Without
this detail a pragmatic estimate was made.

Little analytical work was carried out on specific non-surgical care programmes because
nothing has been shown to be effective at a population level. A simplified add-on to the
decision tree explores that a little further, showing even with optimistic assumptions it is
not a great buy at the population level. For some individuals it would work well; but the
difficulty of identifying these individuals remains. There is no systematic programme of
care for these patients at any DHB, no pathways as such – just responses to acute
events associated with being morbidly obese as needed - diabetes admissions, dialysis,
heart attacks etc.

3. Analysis viewpoint.
The choice of the relatively simple decision tree and 5 year time frame were made on
pragmatic grounds (time, cost, lack of detailed NZ data). It was felt that based on the
positive conclusions of the HTA that the case didn’t need to fully quantify the health
savings – they are noted but not quantified as such. The emphasis in the business case
is on the impact of morbid obesity and bariatric surgery on health costs. Therefore the
business case is innately conservative in that respect, particularly given that the benefits
to be gained in primary care, employment, quality of family life following bariatric surgery
have not been factored into the analysis. Based on the peer reviewers comments a $$
per QALY estimate was made for the final business case. This was based on US data,
and was very much a back of the envelope calculation. Once local data is available this
should be revisited. Discounting was also incorporated on the reviewers advice, based
at 3% per year, with sensitivity analysis at 0%, 5% and 10% also.

4. Success criteria
As noted above we did not attempt to fully enumerate the various health benefits
expected from bariatric surgery. However we were able to incorporate some nuances by
varying other cost assumptions in the various decision tree arm results. Following the
peer review this was made more consistent and explicit. Future work could explore co-
morbidities and their resolution in more detail. Most importantly, whichever approach
one uses it is evident that there are large cost savings in usual care following resolution
of morbid obesity.

5. Costs.
Capital costs issues were made more explicit as a result of the peer reviewers
comments. Many of the capital costs are being incurred by DHBs currently anyway –
they still have to routinely operate on this sub-set of the population (appendicitis, gall
stones etc) irrespective of whether or not bariatric surgery is part of the DHB’s surgical
programme.

6. Equity.
We expect that the eligibility selection criteria will end up prioritising Maori and Pacific patients – due to the prevalence of morbid obesity and comorbidities in those populations and thus their need. No explicit targets are set as that would then give the appearance of one patient being favoured over another. The addition of CPAC scores has resulted in a large increase in equity in other procedures being achieved without explicit targets being set and we would expect a similar scenario to occur in the case of bariatric surgery.
Appendix VI  American Society for Bariatric Surgery – Centers of Excellence

Requirements for provisional status include the following:

- There is an institutional commitment at the highest levels of the applicant medical staff and the institution’s administration to excellence in the care of bariatric surgical patients as documented with an ongoing regularly scheduled in-service education programme in bariatric surgery.

- The applicant institution has performed at least 125 bariatric surgical cases in the preceding 12 months, and each application surgeon has performed at least 125 total bariatric cases and performed at least 50 cases in the preceding 12 months.

- The applicant maintains a Medical Director for bariatric surgery who participates in the relevant decision-making administrative meetings of the institution.

- The applicant maintains a full complement of the various consultative services required for the care of bariatric surgical patients including the immediate availability of full in-house critical care services. This requirement includes the availability of, at the least, an anaesthesiologist, a pulmonologist, a cardiologist, an interventional radiologist, and an infectious disease specialist, plus nutritional and psychology/psychiatry support. The facility must have an ICU that has a full-time staff with experience managing critically ill morbidly obese patients with ventilators and invasive hemodynamic monitoring technologies. An outpatient surgical centre does not qualify as a bariatric surgical Center of Excellence.

- The applicant maintains a full line of equipment and instrument for the care of bariatric surgical patients including furniture, wheel chairs, operating room tables, beds, radiologic facilities, surgical instruments, and other facilities suitable for morbidly obese and super obese patients.

- The applicant has a bariatric surgeon who spends a significant portion of his or her efforts in the field of bariatric surgery and who had qualified coverage and support for patient care.

- The applicant uses clinical pathway orders that facilitate the standardisation of perioperative care for the relevant procedure. In addition, all bariatric surgical procedures are standardised for each surgeon.

- The applicant uses designated nurses or physician extenders who are dedicated to serving bariatric surgical patients and who are involved in continuing education in the care of bariatric patients. The hospital should have a subset of nurses who routinely care for the bariatric patients and receive regular in-service education on their care, preferably assigned to a designated bariatric floor or wing. A bariatric coordinator should be designated to supervise the bariatric programme.

- The applicant makes available organised and supervised support groups for all patients who have undergone bariatric surgery at the institution.
The applicant provides documentation of a programme dedicated to a goal of long-term patient follow-up for at least 75% for bariatric procedures at 5 years with a monitoring and tracking system for outcomes and agrees to provide annual outcomes summaries to the SRC.

The applicant agrees to enter all patients who undergo surgery in the group’s or individual practice; no patients will be excluded.

Full approval – Bariatric Surgery Centre of Excellence

The application for full approval includes the same specifications listed above but also requests specific data regarding percentage of follow-up, surgical outcomes in terms of weight loss, change in BMI, resolution of comorbidities, perioperative and long-term mortalities, re-operations, readmissions revision, and academic activities.
Appendix VII  American College of Surgeons – Bariatric Surgery Centres’ requirements

Level 1a and 1b Bariatric Surgery Centres

- Level 1a centres will have provided bariatric surgery for 24 months and will continue to provide no less than 125 primary weight loss operations annually. A Level 1a Centre will have 2 or more participating bariatric surgeons on staff and at least 2 bariatric surgeons will perform 50 weight loss operations annually. These surgeons will be capable of managing the full range of complications associated with surgery of the obese and will be responsible for patients 24/7/365.

- Level 1a Bariatric Surgery centres must have staff including pulmonology, cardiology, intensivist, infectious disease, nephrology, psychiatry/psychology, gastroenterology, thoracic surgery, otorhinolaryngology, and orthopaedic expertise.

Anesthesiology Services

- Level 1a centres must have anesthetists will special competence in managing obese patients and complex airway problems, and they must have major time commitments to bariatric surgery patients. Anesthesiologists must provide perioperative and postoperative active pain control services including drug management, patient controlled analgesia, and epidural techniques.

Critical Care Services

- The Critical Care Unit will have physician/surgeon staffing 24/7/265 and be equipped for morbidly obese patients.

Comprehensive Endoscopy Services

- Trained nursing staff will manage complete facilities for upper GI endoscopy and bronchoscopy equipped for obese patients. These facilities will be available 24/7/365.

Comprehensive Minimally Invasive Surgery

- Complete staff, equipment, and experience in minimally invasive surgery of the GI tract, biliary system, and abdominal organs including anastomotic procedures will be available. A dedicated nursing team with training, experience and interest in bariatric surgery and minimally invasive surgery will also exist.

Comprehensive imaging services

- Radiology Unit will have equipment for morbidly obese patients with over-sized CT and MR equipment, which are adequate for patients undergoing bariatric surgery, and provide complete interventional radiology services.

Full Service Operating Rooms

- Level 1a Bariatric Surgery Centre will provide special operating room tables and equipment to accommodate morbidly obese patients such as retractors suitable for bariatric surgical procedures, specifically designed stapling instruments, and long surgical instruments.

Recovery room
• The Recovery Room nursing staff will be experienced in managing obese patients and will have special stretchers, lifting devices, and other equipment for managing obese patients.

Emergency Room
• The Centre will maintain a staffed Emergency Room 24/7.

Dialysis facilities for acute renal failure
• The Renal Unit provides care for acute renal failure including haemodialysis.

Accommodations for the morbidly obese patients
• Patient care units will include shower rooms large enough for super obese patients, and furniture, beds, scales, wheel chairs, litters, floor mounted toilets, doorways, blood pressure cuffs, abdominal binders, gowns, walkers, SCD boots, and patient movement and transport systems for morbidly obese patients.

Trained staff
• Staff will include nurses, nurse practitioners, physician assistants, physical therapy/exercise, nutritionist/dietician all with dedicated training and experience in the care of bariatric surgical patients.

Education and training of bariatric surgeons
• Level 1a Bariatric Surgery Centres will participate in training surgeons in weight loss operations.

Level 1b Bariatric Surgery Centres have the same standards as Level 1a except that the American College of Surgeons National Surgical Quality Improvement Program (adapted for Bariatric Surgery) is not required.

Level 2a and 1b Bariatric Surgery Centres
General acute care hospitals will house Level 2a Bariatric Surgery Centres for primary weight loss operations for morbidly obese patients under the age of 60 years in the absence of significant cardiac or pulmonary comorbidities. These centres are not approved for operations on high-risk patients, such as males with a BMI ≥ 55, females with a BMI ≥ 60, or any non-ambulatory patients or elective revisional operations. Bariatric surgery will have been performed for the previous 24 months and no less than 25 primary weight loss operations will have been performed annually. Each bariatric surgeon will have performed 50 weight loss operations during the previous two years.

Certified surgeons capable of managing the full range of complications associated with surgery of the obese would be available for bariatric surgery patients 24/7.
Anesthesiology Services
- These centres must have anesthetists with special competence in managing obese patients and complex airway problems.

Critical Care Services
- The Critical Care Unit will have physician/surgeon/intensivist staffing and a trained critical care nurse staff, and be equipped for morbidly obese patients.

Availability of other services
- These centres will have endoscopy services, minimally invasive surgery facilities, and imaging services suitable for morbidly obese patients.

Operating Rooms
- Operating Rooms will provide tables and equipment to accommodate morbidly obese patients, retractors suitable for bariatric surgical procedures, specifically designed stapling instruments, and long surgical instruments.

Recovery Room
- The Recovery Room nursing staff will be experienced in managing obese patients and will have special stretchers, lifting devices, and other equipment for managing obese patients.

Emergency Room
- The Centre will maintain a staffed Emergency Room 24/7.

Accommodations for the morbidly obese patients
- Patient care units will include furniture, beds, scales, wheel chairs, litters, toilets, doorways, blood pressure cuffs, abdominal binders, gowns, walkers, SCD boots, and patient movement and transport systems for obese patients.

Trained staff
- Staff will include nurses, nurse practitioners, and physician assistants as needed, physical therapy/exercise, nutritionist/dietician.

Education and training of bariatric surgeons
- Level 1a Bariatric Surgery Centres will participate in training surgeons in weight loss operations.

Level 2b Bariatric Surgery Centres have the same standards as Level 2a except some different requirements for outcome data reporting exist.

Outpatient Bariatric Surgery Centres
The only procedure currently being considered in the outpatient setting is laparoscopic adjustable gastric banding. Such centres must meet full criteria for outpatient surgical centres and an inpatient surgical centre must be available for patient transfer whenever the need arises 24/7/365. No less than 50 operations per annum will be performed by a bariatric surgeon. Identified physician teams will provide long-term medical management of lap banded patients. Anesthesiology services, operating rooms, recovery rooms, accommodations and a range of other processes are the same as required for Level 2b centres.
Appendix VIII  IFSO guidelines for existing Bariatric Institutions and Centers of Excellence

IFSO guidelines for existing Bariatric Institutions:

- Institutional requirements: Any medical institution undertaking the management of morbidly obese, super obese and super-super obese patients with LABG and/or bariatric procedures requiring stapling of the stomach and the gut such as Sleeve Gastrectomy, RYGBP and BPD or revisional cases should, apart from points described in guidelines for PBIs, ensure they fulfill the following additional conditions:
  - Ensure that the director of bariatric surgery has at least 5 years experience in the field and is capable of performing advanced bariatric procedures successfully.
  - Have comprehensive and full in-house consultative services required for the care of the bariatric surgical patients, including critical care services.
  - Have the complete line of necessary equipment, instruments, items of furniture, wheel chairs, operating room tables, beds, radiology facilities such as CT scan and other facilities specially designed and suitable for morbidly and super obese patients.
  - Have a written informed consent process that informs each patient of the surgical procedure, the risk for complications and mortality rate, alternative treatments, the possibility of failure to lose weight and his/her right to refuse treatment.
  - Maintain details of the treatment and outcome of each patient in a digital database.
  - Provide all necessary assistance and advise the staff to attend relevant meetings, subscribe to international journals and become members of a national bariatric society.
  - Have experienced interventional radiologists available to take over the non-surgical management of possible anastomotic leaks and strictures.

Surgeon's credentials:
Each interested surgeon should:
- Have performed at least 50 bariatric cases per year.
- Be able to perform revisional surgery by open and/or laparoscopic approach.
- Be committed to a long-term (life-time) follow-up of his patients.
- Attend bariatric meetings regularly, subscribe to at least one bariatric journal, and report his/her experience by presenting at local or international congresses or by publishing articles in peer-reviewed journals.
- Perform advanced bariatric surgery at the appropriate facilities.

IFSO guidelines for Center of Excellence Bariatric Institutions

Institutional requirements: Apart from the described requirements for PBIs every medical centre willing to be evaluated and approved as an IFSO Center of Excellence Bariatric Institution, should prove to the IFSO authorised Review Committee that:

It is committed to the highest level of excellence in bariatric surgical patient care and maintains a regular program of education for medical, nursing, administrative and allied health staff in bariatric surgery.
• Performs at least 100 bariatric surgical cases per year including revisional cases. The peri-operative care and the surgical procedures have to be standardized for each surgeon.
• Has a bariatric surgeon who spends the main portion of his or her effort in the field of bariatric surgery.
• Has supervised support groups for bariatric patients.
• Provides life-time follow-up for the majority and not less than 75% of all bariatric surgical patients. Details of the patients’ outcome should be included in a digital database and confidential information should be available on request by IFSO authorities.

Surgeon's credentials:
• Each surgeon additionally to the described in EBIs credentials should:
• Perform at least 50 bariatric cases per year including a number of revisional cases among them.
• Be involved in the training and the accreditation of less-experienced bariatric surgeons.
• Be committed to complete and life time follow-up of his/her patients and prove that his/her follow-up for at least 75% of them for 5 or more years.
• Report his/her results in international conferences and publish articles in international peer-reviewed journals.
### Appendix IX – indicative cost path by DHB for bariatric surgery

**At a 1% prevalence operative rate**

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| Total          | 1829       | 34,240  | 0       | 0       | 0       | 22,430  | 17,710  | 13,220  | 8,950   | 4,910   | 1,100   |

| **$$ required up to 3 years** | 95,00 | 0 |
| **$$ required up to 6 years** | 161,60 | 0 |
Assumptions used on the above tables

1. Net operating cost to provider arms
2. Excludes any capital/set up costs above and beyond what is already included in the WIES price
3. Cost savings are able to be derived from 2nd year on (i.e. no savings in first year, full savings thereafter)
4. Costs averted are not swallowed by other demands, and can be converted into actual savings
5. Cost savings made in areas such as medicine, dialysis etc can be converted into surgical $$
6. The costs being included as savings as part of the 'usual care' of the morbidly obese were actually going to be funded. Costs in this area are growing much faster than FFT; hard savings will be difficult to extract. May be able to say "cost neutral" from Year 8 onwards?
7. All figures in 0809 $$ terms, excluding GST
8. All DHBs would place equal priority for this surgery. (In reality local priority setting would see variances from these estimated procedure numbers)

So for example, if a 0.5% rates was deemed sustainable by MOH an initial injection of $47.5m for 3 years, then a further $33.29m for a total of $80.79m over 6 years (with suitable inflation adjustment) would suffice to build a sustainable service, at least as far as operational costs were concerned. After Year 7 surgery costs might be deemed to be largely covered by the savings being made by the DHB elsewhere. For a 1% rate would be $95m and $161.6m at 3 and 6 years respectively. For a mix of the two (see below) $47.5m and $128.29m
## Rollout model - 0.5% for 3 years, 1% thereafter

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$$ required up to 3 years

$$ required up to 6 years

47,50

128,290
Appendix X  Indicative capital costs bariatric surgery

**Bariatric Surgery - *INDICATIVE* Capital Requirements**

*Based on 150 cases per unit/year :*

*Sleeve Gastrectomy and 15% Gastric Banding*

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<td>6,000</td>
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<td>Large walking frame (2 Front wheels, 2 Rear s stoppers)</td>
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<td>Elbow Crutches (up to 400kg)</td>
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<td>Large BP Cuffs for propak</td>
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<td>Large Scales</td>
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<td>Babcocks</td>
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<td>De Bakey Grasping forceps</td>
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<td>$2,600.00</td>
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<tr>
<td>Reddik-Olsen Dissecting &amp; grasping Forcep Insert, Outer tube &amp; Handle</td>
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<td>Bowel Grasper Forceps Insert, Outer tube &amp; Handle</td>
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<td>Laparoscopic - Trocars - 6mm With Tap</td>
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<td>Hassons Trocar</td>
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<td>Laparoscopic Needle holders</td>
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<tr>
<td>Telescopes - 42cm x 10mm 45o</td>
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<td>Gold finger - reusable</td>
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<td>Extra Large Nathanson liver retractor</td>
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<td>Reusable Grasping handle with on/off lock</td>
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<tr>
<td>DOYEN RASPATORY, RIGHT, LARGE</td>
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<td>DUVAL FORCEPS, LARGE, 20CM</td>
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<tr>
<td>38fr bougie</td>
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<td>Bariatric table attachments</td>
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<td><strong>Total</strong></td>
<td></td>
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Appendix XI  Proposed selection criteria bariatric surgery New Zealand public hospitals

1  **Patient Demographics**  
- Name  
  - Surname  
  - First name(s)  
- NHI  
- Ethnicity  
- Age  
- Gender  
- BMI(kg/m²)  
- Height(m)  
- Weight (kg)  
- Referral GP  
  - Specialist

2  **Co-Morbidity and Risk Factors**  
- **Endocrine**  
  - Type 2 Diabetes Mellitus  
  - Medication  
  - Most recent HbA1c  
  - Insulin Resistance  
  - Fasting Glucose  
- **Respiratory**  
  - Obstructive Sleep Apnoea  
  - CPAP Yes/No  
  - Obesity Hypoventilation Syndrome  
  - Asthma/Breathlessness  
  - Medication  
  - Pulmonary Hypertension  
  - Right Heart Pressure  
- **Cardiovascular**  
  - Hypertension  
  - Medication  
  - Most recent Blood Pressure  
  - Dyslipidaemia  
  - Medication  
  - Most recent total Cholesterol  
  - *Ischaemic Heart Disease*  
  - *Congestive Heart Failure*  
- **Musculo-Skeletal**  
  - Osteoarthritis  
  - Joint pain  
  - Back Pain  
  - Immobility  
  - Gout  
- **Gastrointestinal Tract**
Gastro-oesophageal Reflux Disease
Non Alcoholic Fatty Liver Disease

- Skin/Venous
  - Intertrigo
  - Cellulitis
  - Venous Hypertension
- Genitourinary/O & G
  - Polycystic Ovary Syndrome
  - Stress incontinence
  - Impaired fertility
- Neurological
  - Benign Intracranial Hypertension
- Psychiatric/Socioeconomic
  - Depression/Anxiety
  - Social isolation
  - Inability to maintain employment
- Surgical Factors
  - Crohns Disease
  - High risk of gastric malignancy
  - Radiation treatment abdomen
  - Steroid dependant disease
  - Recurrent peptic ulcer disease
  - Previous abdominal surgery
    Including previous Bariatric Surgery

3 National Institute of Health (NIH) Criteria 1991
- BMI > 40(or > 35 with obesity-related co-morbidity)
- Age 18-55
- Obesity > 5 years
- Failed non-surgical attempts at weight loss
- No substance abuse disorder
- No psychiatric condition (or controlled)
- Understands surgery
- Committed to follow-up

 NIH Criteria Fulfilled

4 Exclusion Criteria
- Inability to tolerate surgery
- Severe Pulmonary hypertension
- Portal hypertension
- Dilated cardiomyopathy
- Established end-organ failure
(End stage renal failure, congestive heart failure, respiratory failure)

- History of malignancy (other than low risk)
- Personality disorder
- Brain Injury/Prader Willi
- Smoker who will not stop pre-surgery
- Weight over 160kg
- BMI over 55

Absence of Exclusion Criteria

5 Risk of Operative Mortality Estimate

- Age > 45
- BMI > 50
- Male
- History hypertension
- History thromboembolic disease

Class A: 0-1 criteria, estimated mortality risk 0.31%
Class B: 2-3 criteria, estimated mortality risk 1.90%
Class C: 4-5 criteria, estimated mortality risk 7.56%

Mortality Estimate

6 Overall Recommendation

- Mortality risk A
  No exclusion, satisfies NIH,
  Proceed to Multi-Disciplinary Team (MDT) assessment

- Mortality risk B
  No exclusion, satisfies NIH,
  Proceed to MDT assessment

- Learning curve exclusion criteria only, otherwise satisfies NIH
  Mortality risk A or B
  **Decline surgery 6 months (or more), then re-assess**

- Mortality risk C
  Mortality risk unacceptably high
  If mortality risk modifiable: MDT for 6 months, then re-assess
  If mortality risk not modifiable: Decline surgery

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• Fails NIH criteria
  Decline surgery

• Fixed exclusion criteria present
  Decline surgery