



**Literature review of interventions to reduce the burden of
harm from tobacco smoking, poor nutrition, alcohol
misuse and physical inactivity.**

**Stage 1 Report to the Australian Government,
Department of Health and Ageing, Population Health Division, Canberra**

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TABLE OF CONTENTS

CHAPTER 1: Introduction	1
1.1 Introduction to the Risk Factor Project	1
CHAPTER 2: Methods	4
2.1 Conceptual Issues	4
2.2 Approach to Stage 1	5
2.3 Identification of Interventions for Evaluation	7
2.4 Other Issues – inter-relationship between risk factors and interventions	9
CHAPTER 3: Risk Factors and Disease Burden	11
3.1 Overview: Lifestyle risk factors and chronic disease burden	11
3.2 Poor Nutrition – Disease Burden	14
3.3 Physical Inactivity: Disease Burden	17
3.4 Tobacco Smoking - Disease Burden	18
3.5 Alcohol Consumption: Disease Burden	20
SECTION II: INTERVENTION OPTIONS	27
CHAPTER 4: Physical Inactivity	29
4.1 Introduction	29
4.2 Population Approaches	33
4.3 Individual Approaches	33
4.4 Conclusion	36
CHAPTER 5: Poor Nutrition	44
5.1 Poor Nutrition: Intervention Options	44
5.2 Evidence of Efficacy of Dietary Interventions	45
5.3 Summary of Key Dietary Interventions Studies	50
CHAPTER 6: Smoking	67
6.1 Overview of Intervention Options	67
6.2 Specific Interventions	70
6.3 Summary of Smoking Cessation Interventions	80
CHAPTER 7: Alcohol	88
7.1 Interventions to Reduce the Burden of Harm Associated with Alcohol Misuse	88
7.2 Specific Interventions	89
CHAPTER 8: Interventions Selected for Economic Evaluation	112
8.1 Selection Criteria	112
8.2 Recommended Interventions for Cost-Utility Analyses	113
8.3 Interventions Concerning Physical Activity	113
8.4 Nutrition - Interventions for Evaluation	119
8.5 Smoking: An Overview of Interventions for Evaluation	127
8.6 Alcohol: An Overview of Interventions for Evaluation	132
CHAPTER 9: Work Plan for Stage 2	136
9.1 Background	136
9.2 Interventions Selected for Cost-Effectiveness Analysis	136
9.3 Research Method for Stage 2	140

REFERENCES	160
References to Chapter 3: Risk Factors and Disease Burden	160
References to Chapter 4: Physical Inactivity	164
References to Chapter 5: Poor Nutrition	167
References to Chapter 6: Smoking	171
References to Chapter 7: Alcohol	176
References to Chapter 9: Work Plan for Stage 2	187

LIST OF TABLES

Table 2.1: Key activities in Stage 1	6
Table 2.2: Role of team members in literature review	6
Table 3.1: The Attributable Burden of Lifestyle Risk Factors by Condition, Australia 1996	13
Table 3.2: The prevalence of poor diet	17
Table 3.3: Prevalence of Insufficient Physical Activity in Australia % 1997 – 1999	17
Table 3.4: NHMRC Definitions - descriptive	21
Table 3.5: NHMRC Guidelines: Quantitative	21
Table 3.6: Risk for long term harm - Proportion of the population over 14 years	22
Table 3.7: Risk for short term harm - Proportion of the population over 14 years	22
Table 3.8: Proportion of the population 14+ at risk of long term harm by age group	23
Table 3.9: Proportion of the population over 14 years at risk of short term harm	23
Table 3.10: Prevalence of DSM-IV alcohol abuse and dependence by age group	23
Table 3.11: Frequency of hazardous drinking last 12 months	24
Table 3.12: Alcohol consumption and road accidents, Australia 1998	25
Table 4.1: Types of Interventions to promote Physical Inactivity	30
Table 4.2: Examples of environmental interventions	32
Table 4.3: Examples of mass media interventions	32
Table 4.4: Physical activity interventions in general practice and primary care settings (RCTs only)	38
Table 4.5: Computerised interventions in primary care setting	39
Table 4.6: Interventions with older people	40
Table 4.7: Workplace based interventions	41
Table 4.8: School based interventions	42
Table 4.9: Community based interventions	43
Table 5.1: Possible Interventions for Poor Nutrition	44
Table 5.2: Prevention of Coronary Heart Disease Events and Mortality, and Total Mortality by Dietary Interventions	50

Table 5.3: Prevention of Development of Coronary Heart Disease Risk Factors in Children by Dietary Interventions	54
Table 5.4: Control of Coronary Heart Disease Risk Factors in Workplace Settings by Dietary Interventions	57
Table 5.5: Control of Coronary Heart Disease Risk Factors in Primary Care by Dietary Interventions	59
Table 5.6: Control of Coronary Heart Disease Risk Factors in Community Settings by Dietary Interventions	61
Table 5.7: Primary Prevention of Diabetes	62
Table 5.8: Randomised Controlled Trials of Dietary Change using Information Technology and Related Materials	63
Table 6.1: Smoking Intervention Options	67
Table 6.2: Conclusions of Task Force regarding preferred tobacco control interventions	69
Table 6.3: Patient Preferences for Smoking Cessation Programs (Owen and Davies, 1990)	70
Table 7.1: Overview of key interventions to reduce harm associated with alcohol misuse	88
Table 7.2: Key studies re alcohol harm reduction	107
Table 8.0: Criteria for the selection of interventions for analysis in Stage 2	112
Table 8.1: INACTIVITY (note overlap with 'Nutrition')	115
Table 8.2: NUTRITION (overlaps with Inactivity – refer Table 5.1)	120
Table 8.3: SMOKING (refer Table 6.1).	128
Table 8.4: ALCOHOL	133
Table 9.1: Interventions selected for Economic Analysis	136

LIST OF FIGURES

Figure 3.1: Burden of Disease (DALYs) – Australia	12
Figure 6.1 Per Capita Cigarette Consumption in Australia	69
Figure 6.2: Changes in per capita cigarette sales in state with large, comprehensive tobacco control campaigns versus the rest of the US	72

Literature review of interventions to reduce the burden of harm from tobacco smoking, poor nutrition, alcohol misuse and physical inactivity.

CHAPTER 1: Introduction

1.1 Introduction to the Risk Factor Project

A risk factor may be defined as an attribute or exposure that is associated with an increased probability of a specified outcome, such as occurrence of disease. In relation to lifestyle behaviours, a causal relationship is postulated, based on evidence, between the risk factor and harm. While the term 'risk factor' may also be used to denote a marker of ill-health, rather than a causal factor, causation is central to the logic of seeking to modify risk factor behaviours, and is the meaning adopted in this report.

This report represents the first report in a two-stage project, the ultimate objective of which is to or reduce the burden of illness and harm associated with:

- Tobacco smoking;
- Poor nutrition;
- Alcohol misuse, and;
- Physical inactivity.

These risk factors are all viewed as modifiable and are often contrasted with 'non-modifiable' factors such as genetics and ageing, although the distinction may at times be more one of degree rather than absolute.

The task of this study is to compare the performance of interventions designed to modify the above four risk factors. The aim is to identify interventions that are more effective at modifying behaviours and improving outcomes for the community, for a given resource commitment, and those that are less effective, to provide a basis for the redirection of resources between services and programs, to enhance community health and wellbeing.

The first stage of the project required a sufficient understanding of the four risk factors and their role in disease burden to be gained in order to describe and classify the options for modifying life style behaviours to reduce the associated harm. This has been achieved largely through a review of the literature and by drawing on the considerable experience of study team members. The primary output of this stage is selection of a number of interventions about which to compare performance – these are listed in Chapter 8.

The second stage of the project will comprise the economic evaluation of the interventions selected in Stage 1 in a way that allows a comparison between them, so as to contribute to resource allocation decisions. The work plan for this second stage is reported in Chapter 9.

The four risk factors that are the subject of this study (tobacco smoking, poor nutrition, alcohol misuse, and physical inactivity) are major sources of disease burden and harm, resulting in substantial loss of quality of life and excess mortality. Modification of these behaviours thus provides a means to enhance community health and wellbeing. As described in Chapter 2, the four risk factors are both direct contributors to loss of quality of life (and in some cases mortality), and indirectly responsible for ill health through their contribution to a wide variety of diseases.

The adoption of more healthy life style behaviours can improve health outcomes both directly and via a reduction in disease incidence and prevalence. Any reduction in disease incidence/rate of disease progression may also result in a reduction in health service costs. Such cost reductions may be viewed as offsets against the costs of achieving the life style change.

The challenge is, given that all four risk factors are potentially modifiable via a wide variety of programs, what set of interventions will result in a pattern of behaviour that will minimise the associated disease burden and harm, for a given level of resourcing. A separate, but related, question concerns the optimal level of resourcing that should be applied to risk factor modification – compared with other means to enhance health and well-being.

A range of approaches could, in principle, be applied to encourage the adoption of more healthy life style behaviours in order to reduce the associated harm. One useful classification is to consider firstly target group and intent and secondly modality and delivery setting – as illustrated below:

Target

I General Population/Population at Risk

- *intent* - reduce incidence of the risk factor by discouraging persons adopting the particular behaviour (taking up smoking, eating poorly, becoming physically inactive, misusing alcohol).

Examples are varied but include school-based programs to discourage tobacco smoking, promote physical activity or more healthy eating; or a media/community based information campaign to inform the community about what constitutes a healthy diet.

II Persons who have adopted the high-risk behaviours

- *intent* - reduce the prevalence of the risk factor by persuading those who currently smoke, have a poor diet, are physically inactive or abuse alcohol to discontinue their unhealthy behaviour or at least reduce their level of risk.

Examples include a targeted media campaign to promote physical activity in those who are now sedentary, the Quit line or nicotine replacement to assist current smokers to quit.

III Persons who have morbidity consequences of high-risk behaviours

- *intent* – to reduce the likelihood of further harm in those who have already suffered as a consequence of their high risk behaviours, and minimise associated harm incurred by others. The focus can be the individual and/or others affected.

Examples include out-patient programs to promote the adoption of improved lifestyle behaviours (diet, quit smoking and increase physical activity) for persons who have suffered a stroke or heart attack; or group therapy or an intensive live-in program for persons with a serious alcohol abuse problem or family therapy support for affected family members; or a drink driving campaign to reduce potential harm to all road users.

Modality and form of delivery

Delivery setting/modality - Programs might be offered through the health sector - such as a community health centres, in-patient or out-patient facility, at a GP clinic, at a generalist or specialist facility, or outside the health sector – for example through transport policy, urban form, food policy, education, sport and recreation, corrective services, industry policy/taxation etc.

Delivery mode might include one-on-one (eg individual dietitian consultation), one-to-many (eg group exercise class); many to one (eg multi-disciplinary team approach to a person with an alcohol abuse problem); many to many (team approach in a group setting). Programs may incorporate various philosophies and may make use of direct service delivery, media, legislation/regulation or other approaches to information.

Only limited resources can be allocated to modification of life style behaviours. The challenge is to establish which interventions are likely to be most effective and cost-effective and thus able to make the greatest contribution to harm reduction for the resources allocated. This is the problem to which this study is addressed, in two stages. The task of this report is to identify a set of interventions options for modifying high- risk behaviours to be subject to economic analysis in Stage 2. The results of these evaluations may contribute to resource allocation policy.

This report is structured in three sections as follows:

Section I *Introduction and Methods*

Chapter 2: Describing the framework adopted for the selection of intervention options to be subject to cost-effectiveness analysis and introducing key methodological issues.

Chapter 3: Describing the nature of disease burden and harm imposed by the four risk factors – to explain the importance of this research and to suggest the types of interventions and target populations, to reduce associated harms.

Section II *Interventions to reduce harms associated with physical inactivity, poor nutrition, alcohol abuse, tobacco smoking*

Interventions potentially available to modify subject behaviours and associated harms are identified and classified and the key literature covering effectiveness summarised. This is used to identify a number of interventions for which economic analyses might be conducted to compare performance across interventions.

Chapter 4: Physical inactivity.

Chapter 5: Poor nutrition.

Chapter 6: Smoking.

Chapter 7: Alcohol abuse.

Section II *The next study stage*

Chapter 8: The list of intervention options to be evaluated in Stage 2.

Chapter 9: Contains an outline of the Work Plan for Stage 2.

CHAPTER 2: Methods

2.1 Conceptual Issues

The health of the community and its members is influenced by non-modifiable and modifiable factors. The most important of the non-modifiable factors are demography (age and gender) and genetics, while the key modifiable factors are use of health care services, life style behaviours and social and economic variables. The incidence and progression of the common chronic diseases of modern societies of heart disease, type II diabetes, stroke, some types of cancers and arthritis are highly influenced by life style behaviours. The most important of these life style behaviours are tobacco use, physical inactivity and nutrition, (relevant separately but also for their influence on obesity), and alcohol abuse. The government has a potential role to encourage and support members of the community to adopt more-healthy lifestyle behaviours.

The role of government arises from several considerations:

- i. firstly that citizens should have adequate information to make informed choices,
- ii. secondly that citizens should be protected from making 'unwise' choices – that is society may believe it has an obligation to seek to improve health and wellbeing of citizens regardless of expressed preferences, especially as consumer choices are compromised by the various distorting influences on the health care market,
- iii. thirdly lifestyle behaviours can have consequences for persons other than the person indulging in the high risk behaviour – this applies most notably to alcohol abuse and tobacco smoking, and
- iv. finally indulging in high risk behaviours is not without cost consequences for society, notably in terms of downstream costs of treating associated illness or addressing harms, which are not necessarily considered adequately by the individual.

Programs or interventions that target groups seeking help or that seek to inform are not controversial. However, where a program or intervention endeavours to over-ride individual preferences and where the individuals concerned are fully cognisant of the consequences of their lifestyle or behaviour, there may be debate about the justification for intervening.

This research program has proceeded on the assumption that reducing high-risk behaviours – where these are associated with an expected loss in quality of life or increased mortality or harm to others, is a valid objective of society. The possible means to influence life style behaviours are wide ranging and including for instance; i) programs to inform and educate and empower citizens and patients and ii) information and training for providers, iii) modification to financial incentives, for instance through taxation and subsidies, adjusting the level of co-payments etc., iv) direct service provision and v) regulatory arrangements and enforcement.

Each plausible set of policies or strategies for influencing life style behaviours will have cost (resource use) implications, for individuals, the community and governments, and a level of influence on life style behaviours and subsequent health status of individuals directly affected plus the wider community.

The purpose of this study is to explore the options for intervening to modify the four risk factors of physical inactivity, poor nutrition, alcohol abuse and tobacco smoking in order to enhance community health and wellbeing. This requires an understanding of each risk factor in terms of its impact upon disease incidence and disease progression and health and wellbeing and of the options for reducing harm.

2.2 Approach to Stage 1

The study is to be completed in two stages with this the report of Stage 1.

Stage 1 was described as a literature review and is to conclude with the selection of intervention options, about which performance is to be compared in Stage 2 of the research program. In describing the approach taken, the first thing to understand is the massive size of the literature potentially relevant to this research question. It would take several person years of study to be confident of achieving a reasonable level of comprehensiveness in accessing and reviewing the literature pertinent to the modification of the four risk factors. Potential intervention options range across the full spectrum of health sector services – public/population health, primary care, secondary and tertiary sector but also regulation, taxation, industry policy, urban planning, agriculture policy, welfare policy/programs, occupational health and safety, aged care programs, transport policy, disability services, corrections, income support, education, community empowerment/capacity building etc. This potential breadth of scope has posed a major difficulty for the research team, which we were not entirely able to resolve. Our approach to this issue is discussed below in Section 2.3 and again in Chapter 8, where we discuss the process for recommending a set of interventions for economic analysis in Stage 2.

Overview of study tasks for Stage 1

Six key activities were undertaken in Stage 1 and are listed in Table 2.1. While most time was allocated to the collation and summary of the literature (Tasks iii and iv), the most challenging analytical task was establishing a logical basis for containing the scope of the literature review (Task ii) and determining and applying criteria for selecting intervention options to be explored in Stage 2 from the many hundred possible interventions (Task v). The latter task was accomplished in close consultation with a working group from the Department of Health and Ageing.

Table 2.1: Key activities in Stage 1

<p><i>i) Summarise role of risk factor in disease burden</i></p> <p>A brief description is provided of disease burden attributable to each of the four risk factors. In this way potential target groups, those who are most vulnerable, in relation to incidence and prevalence of risk factor and associated harms can be identified. It also supports identification of possible approaches to intervening to reduce harm. The role of the risk factors as a source of harm and the groups most affected is reported in Chapter 3. Much of this draws on the AIHW Burden of Disease study, which describes the impact of the four risk factors on mortality and morbidity of Australians. Other data sources have also been used as noted in Chapter 3.</p>
<p><i>ii) Refine scope of literature review and develop criteria for selecting seminal articles and interventions for evaluation</i></p> <p>Given the vast number of means to reduce disease burden from the four risk factors, it was necessary to establish some filters to contain the scope of the literature review. The criteria developed are also to inform the selection of interventions for evaluation in stage 2. A set of nine criteria have been developed, which cover three broad elements: quality of evidence, the constraints of cost-utility analysis, and government priorities.</p>
<p><i>iii/iv) Collate literature on intervention options/ Summarise key information from seminal articles</i></p> <p>Agreed criteria for the literature review were developed at initial meetings of the research team, and further refined throughout the study. Literature searches were performed separately for each risk factor. There were two separate tasks for the literature review:</p> <ul style="list-style-type: none"> • to establish the nature of disease burden and harm associated with each risk factor, and to identify most vulnerable groups (as described above); and • to identify the literature on interventions and programs for reducing harm. <p>Reviews of the literature relating to each of the four behaviours were performed under the direction of a nominated team member, with specific expertise in the relevant area, see Table 2.2. A core team from the Health Economics Unit reviewed the material and brought it together into the current report format. The knowledge and experience of each researcher was used to tailor the approach to the literature review of each risk factor. See also section 2.2.2.</p>
<p><i>v) Identify Interventions for economic evaluation</i> in Stage 2 – see Section 2.3.</p>
<p><i>vi) Prepare work plan and budget for stage 2</i> - see Chapter 9</p>

Literature Review

Team members took responsibility for different research areas as listed in table 2.2.

Table 2.2: Role of team members in literature review

Risk Factor	Primary responsibility for literature review
Poor nutrition	Dr. Iain Robertson, Health Economics Unit, Monash University
Physical inactivity	Dr. Jane Sims, Department of General Practice, University of Melbourne, and Dr Iain Robertson
Smoking	Michelle Scollo, Anita Lal, VicHealth Centre for Tobacco Control
Alcohol misuse	Prof. Richard Mattick, Julia Fawcett, Jennifer Gales, Fiona Shand, Chris Doran, National Drug and Alcohol Research Centre and Andrew Dalton

The search framework entailed access to the following data bases: the Cochrane library, MEDLINE, AustHealth, CINAHL and PsychINFO using combinations of pertinent search terms. Additional relevant references cited in the bibliography of collected articles were followed up as far as possible within the time frame. The review complemented and updated previous literature reviews of team members.

The literature review proceeded in two stages. The first task was to identify 'all' relevant articles and the second to find a number of seminal articles and to summarise key information.

The process of identifying the pertinent literature required an understanding of the disease burden and associated harms to indicate the possible approaches to intervening. A classification system was also developed, firstly to facilitate identification of a wide range of possible intervention options, and secondly to classify intervention options identified.

Some prior exclusions were adopted, as explained below. Without this, the task would have been quite unmanageable. The types of intervention options pertinent to each risk factor are outlined in Chapters 4, 5, 6 and 7, which report on the literature for each risk factor. It was not possible to be fully comprehensive, given the nature of the risk factors and the incredible breadth and diversity of the possible approaches to reducing harm. Establishing a logical basis for restricting the scope of the literature review, and to guide the selection of interventions for analysis proved challenging. The criteria adopted to focus the literature review are explained in Section 2.3. The selection of seminal articles was guided by the matters noted below:

- *Comprehensiveness of coverage* – select articles to cover a wide range of interventions to cover most potential target groups, and several modalities. This criterion proved difficult to meet given the enormous breadth of scope of possible interventions. As discussed below some containment of scope was necessary from a practical perspective, but also warranted from a theoretical perspective;
- *Precision of description of intervention* – to ensure the nature of the intervention can be understood and resources (or inputs) allocated;
- *Quantification of outcomes/ use of final rather than intermediate outcome measures* – objective measures of the impact of the intervention on the target risk factor are reported, preferably reported in terms of final outcomes such as quality life, mortality or other direct measure of harm reduction. Process measures such as 'audience reach', recall of campaign etc. would normally be inadequate. Where only intermediate outcome measures are reported a precise relationship between the intermediate factor and final outcomes is required. (This requirement is rarely met and relaxation of this criteria may be necessary);
- *Long term follow-up* – preferred studies will involve long term follow-up. This is necessary to determine whether any effect on behaviours is maintained, and to allow any impact on quality of life or mortality (or other final outcome) to be observed;
- *Scientific rigour* (level of evidence). A capacity to separate out the influence of the intervention/program from potential confounders is important. This would normally be achieved through a randomised or less satisfactorily a matched control. The use of 'program logic' to establish a causal pathway may also provide a valid means to establish program impact.

Data from the literature review has been collated, critically appraised and independently reviewed by members of the research team. A standardised proforma was developed for preparing summaries of seminal articles. The result of the literature review is reported in Chapters 4 to 7.

2.3 Identification of Interventions for Evaluation

The primary output of this Stage 1 report is a list of interventions recommended for economic analysis in Stage 2. Given the vast number of possible intervention options, from within and outside the health sector, it has been necessary to establish some filters to contain the scope of the literature review and to refine the selection of interventions for recommendation for stage 2. This process has been guided by the task of Stage 2, which is the comparison of several

(probably between 15 and 30) possible interventions for reducing burden of harm from the four risk factors, using cost-effectiveness or cost-utility analysis.

Thus interventions recommended for inclusion in Stage 2, need to be suitable for such analysis. The criteria adopted for this purpose are described below and summarised again in Chapter 8 prior to a listing of recommended interventions. Both the basic criteria, which relate primarily to the quality of the evidence, and the additional filters, which relate to suitability for cost-effectiveness analysis and Department priorities are outlined below.

I Criteria related to quality of evidence:

1. *Precise description of intervention* – a precise description of the intervention is required for the assessment of performance.
2. *Quality of trial evidence* - acceptable level of scientific rigour such that the influence of the intervention can be established with some certainty and confidence;
3. *Quantified outcomes* – objective measures of the impact of the intervention on the target risk factor and associated harms, ideally based on long term follow-up;
4. *Capacity to generate cost data* from program description.

II Suitability for cost-effectiveness analysis in the context of a study designed to compare many interventions:

5. *Health is the primary objective* - so that benefits are largely captured by health related quality of life and mortality. This is not to infer that policies directed at other objectives might not have a major beneficial impact on risk factor behaviour, (such as higher tax on tobacco or urban planning regulations) but in such cases the analysis would need to take account of the wider portfolio affects. The performance of such interventions can not be established through a simple cost-utility analysis.
6. *The intervention is focused on the margin* - rather than broad system change. The former include the consumption of health care services – such as a dietitian service, a physical exercise program, or the quit campaign. The latter have a more pervasive and complex influence, such as urban planning policy to create more compact cities, which amongst other impacts would support greater pedestrian/cycle and public transport use. The nature of the impacts of system level initiatives are exceedingly complex, and not amenable to simple cost-effectiveness analysis.
7. *The intervention is not designed primarily to address market failure*. The issue here, is not that such interventions are not warranted, but rather that their justification cannot be established via a simple cost-utility analysis. Their justification lies primarily in their support consumers to play an effective role in the health/health care market¹. Such interventions are central to the role of government. A complementary study to establish how governments can best support the more effective interaction between consumers and providers and to address externalities is what is required. The key example of this type of intervention is the provision of information to the community about the nature of risk factors, their role in disease burden and harm. Other activities that represent part of the fundamental role of government arising out of market failure, include consumer protection through for instance quality control of, food preparation, water, air quality, and occupational health and safety regulation. Such initiatives cannot be evaluated through simple cost-utility analysis. Rather they are best assessed through a program logic model, which allows the theoretical underpinnings to be examined. Their inclusion in Stage 2 of this research program is not appropriate. This is not to no

¹ For an explanation see Segal L., 1998 Patient empowerment and Health system reform' Health Policy 44: 31-44.

suggest that such programs should be curtailed - although decisions need to be made about the optimal level, but rather that the current study is not the appropriate context to explore that research question.

III Criteria which reflect specific interests of the Department of Health and Ageing

8. *Health delivery setting* – A specific interest of the Department of Health and Ageing is the role of primary care in modifying high risk behaviours and specifically the possible performance of general practice,
9. *Population target* – the inclusion of interventions that may address those with a greater likelihood of harm from the four risk factors. Such groups need to be identified and include, for instance, indigenous Australians, teenagers, and pregnant women. Targeting those at greatest risk is also likely to contribute to a reduction in inequity in health status, which is a documented society objective.

2.4 Other Issues – inter-relationship between risk factors and interventions

While the ‘risk-factor’ approach may form a logical focus for priority setting, the evaluations in Stage 2 will be complex, given the myriad of diseases and conditions that can be influenced by a single risk factor. This complexity is further confounded by the inter-relationship between some of the risk factors, most notably physical inactivity and nutrition. A portfolio analysis of risk factors might therefore be preferable. This is relevant both in how interventions are described and in determining the impact of an intervention on behaviours and health and quality of life. The relationships will often be indirect, and influenced by the passage of time, and may be cumulative.

Another related issue is the capacity to isolate the influence of a single intervention on behaviour. It is clear that behaviour reflects a range of influences and that both conceptually and empirically, attribution of life style change to any single intervention is at best a simplification, and at worse erroneous. For example, smokers are exposed to a wide variety of ‘quit’ smoking messages over many years. These messages occur through mass media advertising, but also through bans on smoking in public places, health warnings on cigarettes, pressure from family and friends etc. Chapman and colleagues (1993) highlight the implications for public health research, and the evaluation of smoking prevention and cessation programs in this regard. They give four reasons why the results of evaluations may be suspect. These are summarised below. Whether they can be adequately dealt with is not certain, and undoubtedly they will represent a major challenge for the second stage of the study. Concerns arise in relation to:

- *Reductionist epistemology*: The scientific principles that underpin the design of trials focus upon isolating the effect of specific variables. This approach necessarily ignores ‘how cultural, economic, organisational and education factors combine to influence smoking behaviour’.
- *Privileging of recent factors*: Recent interventions are favoured as these are considered less likely to be confounded than interventions in the past. Chapman argues these may be precipitating factors, but do not reveal the ‘historical precursors’.
- *Concern for policy tractable factors*: Priority is given to factors amenable to government policy, such as taxation, regulation, advertising, packaging. Factors relevant to age, sex, social class, school performance, occupation, parental and peer smoking etc., may be overlooked.
- *Relationship of evaluation to funding*: The dependency upon evaluation results to sustain funding often leads to a lack of impartiality in the evaluation.

These issues will be important in stage 2, but are also relevant to the selection of interventions – and the logic of considering interventions in isolation.

Finally, the group of risk factors we discuss does not include “psychosocial stress”. There has been considerable effort made to investigate the causes of the effects of social class and socio-economic status on disease rates, of which the “Marmot Hypothesis” might be the most successful. However, to date there has not been a clear description of the nature of “psychosocial stress”, or importantly, of effective interventions. Nevertheless, the persistence of demonstrated associations between psychological factors and disease, despite the imprecision of the measurement instruments, suggests the issue is important. There is also a suspicion that “psychosocial stress” influences the success of interventions for the other risk factors.

CHAPTER 3: Risk Factors and Disease Burden

3.1 Overview: Lifestyle risk factors and chronic disease burden

In epidemiology, disease causation assumes a definite sequence of events whereby an exposure leads with a predictable probability to a pathological consequence. This means those subject to the exposure have an elevated risk of the pathological consequence.

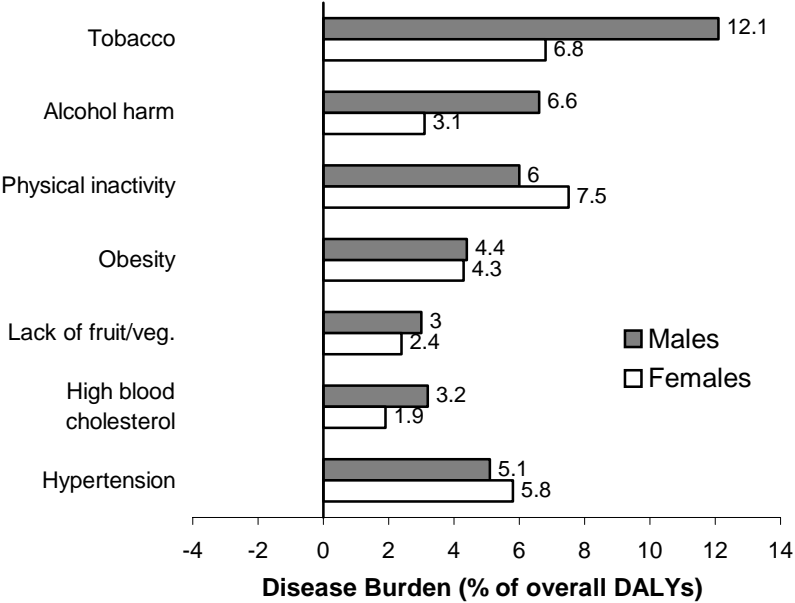
The discovery in the 19th century of pathological microbes led to the Germ Theory of disease where a single causative agent was considered to cause a disease. This produced a series of effective public health and therapeutic interventions that contributed to the large reduction in infectious disease of the 20th century. For many chronic disease conditions, however, the Germ Theory did not appear to apply. A number of causative exposures have been identified for each of these diseases, and each exposure may increase the probability of the disease by a relatively small amount. The disease may occur with or without the identified causative exposures. It may not be possible to measure the true causative exposure in all cases and markers of these exposures may exist that may substitute for the true causative agent. It may not be possible at any point in time to be sure whether a putative cause is a true causal exposure or a marker of an unidentified exposure. From this situation the concept of a risk factor was developed.

A risk factor is an attribute or exposure that is associated with an increased probability of a specified outcome, usually disease occurrence. While the term 'risk factor' may be used to denote a marker of ill-health, causation is central to the logic of seeking to modify risk factor behaviours. It is the concept of risk factor adopted in this report. Considerable scientific endeavour has been devoted to establishing the relationship between various attributes or pathogens and disease. This is central to the identification and adoption of strategies for disease prevention. Recent interest has focused on the role of life style behaviours in disease and as a source of harm. The World Health Organisation has a major research program to describe the mortality and disability consequence of diseases and the role of attributable risk factors. This work has been replicated in Australia by the AIHW and the Department of Human Services, Victoria. The estimated attribution of life style behaviours to disease burden in Australia is summarised in Figure 3.1.

An estimate of the contribution of each risk factor to total disease burden can be calculated if the prevalence of exposure to the risk factor in the community is known and the size of the excess risk. The AIHW 1999 Australian Burden of Disease Study (Mathers et al 1999) used this approach to estimate the mortality and morbidity burden attributable to tobacco smoking, alcohol abuse, obesity, physical inactivity and other factors such as high blood cholesterol and hypertension. The results of their analysis are summarised in Figure 3.1. As acknowledged by the AIHW, these estimates are approximations, incorporating a number of simplifying assumptions, and are not additive across risk factors. They estimate tobacco smoking to be responsible for 12.1% of disease burden in men and 6.8% in women, as measured by disability adjusted life years DALYs, (a combined mortality/ morbidity measure). Alcohol abuse is estimated to be responsible for 6.6% and 3.1% of DALYs in men and women respectively, physical inactivity 6% for men and 7.5% for women, and lack of fruit and vegetables at 3% for men and 2.4% for women. Other risk factors such as obesity, high blood pressure and high blood cholesterol while risk factors in their own right, are also in part a response to physical inactivity, poor nutrition and possibly excessive alcohol consumption.

While the complexities of the interaction between risk factors are not captured by this method and the attributable fractions on which the attributions are based are subject to debate, it can still be concluded that the four risk factors covered in this study are responsible for a substantial share of disease burden. This also suggests that large health gains can be expected from effective interventions that reduce the incidence and prevalence of these risk behaviours.

Figure 3.1: Burden of Disease (DALYs) – Australia



Source: The Burden of Disease and Injury in Australia, AIHW 1999 (but excluding 'alcohol benefit'²)

It can be seen that the disease burden from the dominant non-communicable diseases of our society of heart disease, cancers and stroke are in part attributable to the subject risk factors (see Table 3.1). The pattern of disease burden associated with alcohol consumption is different from the other three, with far less impact via chronic diseases. Rather the major burden is through the direct impact of alcohol abuse and dependence representing 37% of all DALYs attributable to alcohol abuse, with accidental deaths also important at 19.4% of DALYs. If calculated DALYs also included the impact on family members, the difference from the other risk factors would be even more marked. Understanding these patterns is useful in considering the possible interventions for moderating disease burden.

² The postulated beneficial effects of “moderate” alcohol intake reported in the Australian and Victorian and Global burden of disease studies, are not included in this figure, which focuses on harms. If it were to be included, the benefits from good nutrition would also have to be identified. Further, the postulated beneficial effects of modest alcohol consumption have not been confirmed in RCTs and even if confirmed it is most unlikely that any responsible public health authorities would promote alcohol consumption in current non-drinkers. Finally any benefits would not in any way reduce the harm associated with alcohol abuse.

Table 3.1: The Attributable Burden of Lifestyle Risk Factors by Condition, Australia 1996

Risk Factor Condition	Attributable burden				
	Deaths	YLL	YLD	DALYs	% of DALYs attributable to risk factor
Alcohol					
Alcohol dependence/ abuse	406	4,308	41,065	45,372	36.6
Road traffic accidents	510	12,647	2,715	15,363	12.4
Stroke and hypertension	775	7,488	4,029	11,517	9.3
Cirrhosis of the liver	710	10,525	415	10,940	8.8
Accidental falls, drowning, poisoning, fires	397	6,316	2,139	8,701	7.0
Cancer of mouth, pharynx, larynx	387	4,852	2,369	7,221	5.8
Breast cancer	289	4,374	1,441	5,815	4.7
Suicide and self-inflicted injury	228	5,128	42	5,170	4.2
Colorectal cancer	417	4,545	356	4,901	4.0
Homicide and violence	139	3,173	1,382	4,555	3.7
Inflammatory heart disease	86	1,231	643	1,874	1.5
Liver cancer	133	1,600	60	1,660	1.3
Miscellaneous.	55	692	265	856	< 0.1
Total	4,492	67,005	56,881	123,885	100.0
Obesity					
obesity *					not calculated
Ischaemic heart disease	2,302	28,135	5,323	33,458	30.7
Type 2 diabetes mellitus	1,388	13,105	17,624	30,729	28.2
Osteoarthritis	28	169	17,869	18,038	16.5
Colorectal cancer	748	8,460	1,761	10,221	9.4
Ischaemic stroke, hypertension	927	7,361	2,417	9,787	8.9
Post-menopausal breast cancer	182	2,664	886	3,550	3.3
Gall bladder disease	76	615	408	1,023	0.9
Back problems	1	11	970	981	0.9
Uterus cancer	45	527	215	742	0.7
Kidney cancer	37	449	62	511	0.5
Total	5,735	61,496	47,544	109,040	100.0
Smoking					
Lung cancer	6,262	69,662	6,267	75,929	31.4
COPD	4,645	40,464	19,322	59,786	24.7
Ischaemic heart disease	2,507	32,317	6,254	38,571	15.9
Cancer of the mouth, oropharynx and larynx	1,117	12,637	3,761	16,390	6.8
Stroke	740	8,788	5,302	14,090	5.8
Cancer of the kidney, bladder, pancreas	1,146	11,447	1,693	13,140	5.4
Age-related vision disorders	0	0	6,626	6,626	2.7
Peripheral vascular disease	65	582	2,572	3,153	1.3
Asthma	1	31	3,079	3,111	1.3
Low birthweight	64	1,951	1,031	2,982	1.2
SIDS	73	2,227	0	2,227	0.9
Inflammatory bowel disease	9	94	1,982	2,076	0.1
Stomach cancer	163	1,697	201	1,898	0.8
Lower respiratory infections	70	912	483	1,395	0.6
Cancer of the cervix & uterus	90	1,046	288	1,335	0.6
Fire injuries	34	644	438	1,083	0.4
Total	16,875	183,380	58,759	242,138	100.0

Literature review of interventions to reduce the burden of harm from tobacco smoking, poor nutrition, alcohol misuse and physical inactivity.

Risk Factor Condition	Attributable burden				
	Deaths	YLL	YLD	DALYs	% of DALYs attributable to risk factor
Physical Inactivity					
Direct impact on QoL	not calculated				
Ischaemic heart disease	6,853	61,882	5,439	67,321	40.0
Stroke and hypertension	3,079	24,730	9,766	34,496	20.5
Colorectal cancer	1,543	17,091	3,580	20,671	12.3
Breast cancer	691	9,855	3,257	13,112	7.8
Depression	0	37	12,013	12,050	7.2
Falls	591	5,111	6,219	11,330	6.7
Type 2 diabetes mellitus	256	2,607	4,423	7,030	4.2
Chronic back pain	5	43	2,127	2,171	1.3
Total	13,019	121,356	46,825	168,181	100.0
Inadequate Fruit and Vegetable Intake					
Cancers	3,143	42,854	8,467	51,321	75.4
Ischaemic heart disease	734	10,592	2,063	12,655	18.6
Stroke	180	2,517	1,584	4,101	6.0
Total	4,057	55,963	12,114	68,077	100.0

Source: Derived from Mathers et al, 1999, Australian Burden of Disease Study, AIHW

Notes * obesity is responsible, directly for substantial loss in quality of life, through for instance limitations on lifestyle and societal prejudice. This source of burden is not identified in the Australian burden of disease study

YLL – mortality burden in years of life lost

YLD – morbidity measured by disability weights applied to years lived with disability

DALYs – disability adjusted life years = YLL + YLD

Each risk factor not only causes morbidity and mortality consequences as summarised above, but is also associated with costs in the form of lost production and diversion of resources to the treatment of associated conditions. These costs are considerable and underscore the possible cost savings from a reduction in incidence and prevalence of high-risk behaviours, but as they are not central to an understanding of the possible approaches to reduction in disease burden, and thus the literature on these costs is not covered here. However, in the conduct of cost-effectiveness analyses of specific interventions, an estimate of these costs is required, as they represent a benefit of any projected reduction in high-risk behaviours. This literature will thus be covered in Stage 2.

A description of the relationship between risk factor and morbidity and mortality is discussed further below, as this is pertinent to consideration of the possible approaches to reducing disease incidence and prevalence and identifying potential target groups for interventions.

3.2 Poor Nutrition – Disease Burden

Overview

Poor nutrition may lead to disease through inadequate energy intake (starvation), or selective nutritional deficiencies (such as congenital iodine-deficiency mental retardation). Poor nutrition and over-eating also interact with physical inactivity causing obesity (French et al 2001), which is a major cause of disease burden, both directly but also through CHD, type 2 diabetes, osteoarthritis, stroke and hypertension and colorectal and breast cancers, (see Table 3.1).

The place of the food supply system and nutrition in Australia has been well described in an Australian Institute of Health and Welfare Paper *Australia's Food and Nutrition* (Lester 1994). Poor nutrition,

along with physical inactivity, differs in nature from the issues of alcohol and smoking. There is widespread recognition that the target level of smoking is zero, and the target level of alcohol consumption is “zero to moderate”. (Alcohol consumption is not necessary for a healthy life, despite uncertainty in interpretation of the J-curve in men for mortality and alcohol consumption). On the other hand some adequate level of food and physical activity are essential for life. Identification of target levels of nutrition represents a search for what is acceptable, with a wide range of options of diet and activity that are potentially acceptable and health promoting.

In the past, the fate of most of the population was continuous low-grade starvation interrupted by regular famines. Lives were usually short as a result, amongst other things, of starvation-induced immune-suppression, which led to high rates of lethal infectious diseases. In Western nations in the last two centuries, industrial agriculture has developed as an integral and essential component of the industrial economy. With mechanical power, chemical fertilisers and widespread transport systems, along with economic systems that distribute financial purchasing power widely through the population, agricultural production has risen dramatically.

The resulting improvement in nutrition of the people has contributed substantially over the last century to the virtual elimination of mortality from infectious diseases in young people, in advanced economies and a continuous rise in life expectancy. With the control of infectious diseases in these societies, the mid-twentieth century saw the commencement of an epidemic of mortality from non-infectious diseases, notably cardiovascular disease (CVD) and cancers. These are, in part, nutritionally-related. In many countries, including Australia, CVD reached a peak age-adjusted incidence in the late 1960s and has declined substantially since. This improvement is in part associated with better diets. However, there is increasing concern about the rise in obesity – reflecting predominantly a decrease in physical activity (AIHW 2002a). This is of concern as obesity is associated with a number of conditions, such as type 2 diabetes, as highlighted in Table 3.1. But as obesity is not one of the risk factors that is the subject of this study, the nature of disease burden is not considered further.

A small minority of the Australian population, notably Aborigines and Torres Strait Islanders, suffer significant nutritional deficits in the womb and in the first years of life (Cunningham et al 1994). This is associated with high rates of nasopharyngeal streptococcal contamination, leading to high rates of rheumatic fever, rheumatic heart disease and renal failure. This results in much higher rates and severity of coronary heart disease and diabetes when combined with adult over-nutrition.

Interpretation of the observational epidemiological evidence concerning the association between diet and disease is not simple. Measurement of the dietary intake of individuals is not precise and the use of sample surveys problematic given vast variation in intakes across the population. Specific nutritional deficiency diseases or nutritional toxicities are uncommon in Australia today. The major role of diet is as a risk factor for disease. For example people with higher fat intake may have a two-to three-fold increased risk of heart attack compared to those with lower fat intakes, or in relation to fruit and vegetable intake, excess risks of low consumption is perhaps 20 to 50% for some cancers. These excess risks are small, compared for instance, with smoking that is associated with about a 20-fold increased risk of lung cancer. Thus prediction of which people will suffer nutrition-related degenerative diseases is more difficult.

Nevertheless, there is now strong evidence from observational and interventional epidemiological studies that diet has a pervasive influence on CVD, on Type 2 diabetes and its complications, and some cancers and that modification of the diet of people at risk can improve health outcomes. The literature relating diet and health is very large, covering a diverse range of both dietary elements and diseases. The nature of the relationships and the evidence is illustrated below with reference to Coronary Heart Disease.

Nutrition and Coronary Heart Disease (CHD)

Observational Epidemiology: Ecological studies in the 1950s and 1960s (Keys et al 1970) demonstrated a strong association between the mean level of saturated fat in the diet and CHD mortality rates in Westernised countries. Cohort studies within populations (e.g. the Framingham Study) examined and demonstrated the associations between diet and CHD risk factors within populations, and between those risk factors and CHD events and mortality (Sonnenberg et al 1992; Wilson 1994, Kannel et al 1971). These studies identified a number of CHD risk factors; i) life style behaviours - high dietary saturated fat intake, low fruit and vegetable intake, physical inactivity, cigarette smoking; ii) physiological intermediates – hypertension, dyslipidaemia, homocysteinaemia, obesity, and glucose intolerance / diabetes; and iii) genetic susceptibility such as familial hypercholesterolaemia.

Interventional Epidemiology: The multitude of different CHD risk factors, particularly dietary risk factors, raised concerns about whether the risk factors were truly causal, and therefore whether their alteration would reduce CHD risk. A number of randomised controlled trials (RCTs) were conducted to investigate causality. Early trials in the 1950s and 1960s examined the effect of specific modifications of fat intake. In the 1970s and later, the RCTs generally examined the effect of multiple risk factor modifications. In the 1980s and 1990s, a more sophisticated approach to the nature of the dietary interventions was taken with the examination of the so-called “Mediterranean diets” (De Lorgeril et al 1999) and very-low fat diets (Ornish et al 1998). These studies demonstrate that dietary modification reduces both CHD rates and total mortality (Truswell 1994), and that the magnitude of the benefits depends on the magnitude of the changes made. Diets high in saturated animal fat diets and low in fruit and vegetables are associated with dyslipidaemia and cardiovascular disease (Kwiterovich 1997). Dietary change can reduce CHD risk through various means, including an improved lipid profile, reduced coagulation, reduced homocysteine levels (Dwyer 1995) and blood pressure reduction.

While the relationship between diet and CHD is complex, a causal relationship between diet and CHD has been definitively demonstrated. Major changes in diet can produce large reductions in CHD event rates, that are at least as large, if not larger, than those produced by the most effective drugs (the cholesterol-lowering statins) (LaRosa et al 1999). Furthermore, the benefits appear to be achieved within a few months (De Lorgeril et al 1999). The modifications proven to be effective by randomised controlled trials were derived from, and are consistent with, the observational epidemiology. As many intervention studies are undertaken in selected, ‘willing’ study groups the means to achieve the same results in entire populations at risk is a remaining challenge.

Prevalence of Poor Nutrition

Estimates of sub-optimal food intake in Australia have been made, based on a comparison of food habits derived from the National Nutrition Survey (1995) with the recommended daily intakes based on the NH&MRC Dietary Guidelines. The results are summarised in Table 3.2 and indicate substantial under-consumption of fruit and vegetables.

Table 3.2: The prevalence of poor diet

Food group	Percent with inappropriate intake	Recommended level
Vegetables	66% eat too little	300g per day (minimum)
Fruit	80% eat too little	300g per day (minimum)
Cereal foods	50% males, 66% females eat too little	210g per day (minimum)
Fat	66% males, 50% females eat too much	30% of energy (maximum)
Saturated fat	66% eat too much	10% of energy (maximum)

Source: Anti-Cancer Council of Australia

3.3 Physical Inactivity: Disease Burden

A physically active lifestyle has many benefits, including reduced risk of CHD, hypertension, colorectal cancer, obesity, and osteoporosis and osteoarthritis (Blair et al 1996; Carpenter et al 1999; Manson et al 1999). Benefits also include reduced stress and depression and increased emotional well-being, energy level, self-confidence, and satisfaction with social activity (Gauvin et al 1996). The major diseases associated with physical inactivity are identified in table 3.1. The direct impact of a sedentary lifestyle on quality of life has not however been identified in this table.

Benefits of physical activity are evident at low as well as high-intensity activity levels (Costas et al 1978; Magnus et al 1979; Paffenbarger et al 1986; Powell et al 1987). The greatest potential for health benefits may accrue by having sedentary adults become moderately active (Pate et al 1995). Physical activity appears to confer substantial benefits at any age and regardless of prior physical activity history. Despite the well-documented health benefits of physical activity, current estimates suggest that Australia is in the midst of an epidemic of sedentary behaviour. Mechanization of work and of many domestic chores and the widespread use of motor cars has, for the most part, eliminated obligatory physical activity from modern life. Voluntary or recreational physical activity has thus assumed central importance in filling physical activity needs. The situation is exacerbated by the role of television and computers in leisure activities.

The population that is essentially sedentary has been steadily increasing in the last decade, with almost 50% of people over the age of 30 undertaking little physical activity (Table 3.3). This has contributed to the risk of selected diseases (see Table 3.1), to the rise in levels of overweight and obesity and contributed directly to disease burden via the loss in quality of life from a reduced capacity to complete activities of daily living.

Table 3.3: Prevalence of Insufficient Physical Activity in Australia % 1997 – 1999

Age group	1997	1999
18 – 29	26	31
30 – 44	37	46
45 – 59	45	50
60 – 75	46	45

Source: AIHW (Armstrong 2000).

3.4 Tobacco Smoking - Disease Burden

Overview

In Australia, of all risk factors for disease, tobacco smoking is responsible for the greatest burden on the health of Australians, killing more than 19,000 people each year (Ridolfo et al 2001). In 1996 smoking was responsible for 12% of the total disease burden in males and 7% in females (Mathers et al 1999). See Table 3.1

Tobacco use is associated with increased risk of many diseases including the following:

- Lung cancer
- Chronic Obstructive Pulmonary Disease
- Other cancers: kidney & bladder, oropharyngeal and oesophagus, cervical etc.
- Heart disease
- Stroke
- Peripheral vascular disease

The majority of deaths caused by smoking occur through the development of heart disease and lung cancer, followed by chronic bronchitis, stroke, peripheral vascular disease and other circulatory diseases and cancers other than lung. Around 21% of all deaths caused by cancer and 13% of deaths from cardiovascular disease can be attributed to smoking (AIHW 2000a).

If individuals commence smoking as teenagers and do not quit, about half of them will be killed by tobacco in middle or old age. Smokers between the ages of 45-64 are three times more likely to die prematurely, than lifelong non-smokers of the same age (Doll et al 1994). Stopping smoking before middle age avoids more than 90% of the risks attributable to smoking (Peto et al 2000).

Smoking and risk of disease

Cardiovascular disease - Smoking acts together with the other risk factors (notably high cholesterol and high blood pressure) to greatly increase the risk of CVD. It aggravates and accelerates atheroma formation. Smoking increases the heart rate and blood pressure, raising the body's demand for oxygen, but at the same time reduces oxygen delivery by the blood through the effects of carbon monoxide binding to haemoglobin. This can lead to ischaemia (insufficient oxygen delivery due to impaired blood supply), with angina pectoris (chest pain or tightness) (Steenland 1992). Smokers are at greater risk of coronary heart disease, sudden cardiac death, stroke, atherosclerotic peripheral vascular disease (PVD) and aortic aneurysm.

Lung cancer - Cigarette smoking causes lung cancer (US Surgeon General 1982). The risk of developing lung cancer is dose response related: longer duration and heavier consumption increase the probability of developing lung cancer. Overall smokers are 10 times more likely to die from lung cancer than are non-smokers, and heavy smokers are 15 to 25 times more at risk than non-smokers (Peto et al 2000). Lung cancer accounts for 77% of male tobacco related cancer deaths and 75% of female tobacco-related cancer deaths (Ridolfo et al 2001).

Other cancers caused by or associated with smoking - Tobacco smoke contains 43 known carcinogens (US Surgeon General 1989), including organ specific carcinogens and compounds which assist with the formation of carcinogens within the body. The largest number of tobacco related deaths are caused by cancer in men (43%) and women (32%). Cigarette smoking is a major cause of cancers of the oral cavity, oesophagus and larynx (Winstanley et al 1995). Heavy smokers have a laryngeal cancer mortality risk 20 to 30 times that of non-smokers. Smoking is a cause of bladder cancer and at least a contributory factor and possibly a causal factor in cancers of the pelvis, kidney

and pancreas (English et al 1995), and stomach and anus (US Surgeon General 1989), and some types of leukemia.

Chronic obstructive pulmonary disease (COPD) - The permanent airflow obstruction that develops in smokers produces COPD. The pattern of COPD reflects three separate disease processes (mucous gland overgrowth leading to chronic bronchitis, loss of lung elastic tissue with early airways closure leading to emphysema, and airway cell lining pre-malignant changes). These three processes lead to progressive loss of lung function. Almost all long-term smokers of more than 20 cigarettes per day will have excess loss of lung function relative to a similar aged cohort. Smoking cessation slows the loss of lung function.

Other - Diabetic smokers have a 3 times greater risk of CVD than other smokers (Moy et al 1990). Smoking is a major risk factor for surgery and post-operatively. This is due to the effects of smoking on tissue oxygenation, heart rate, airways clearance, immune response and circulation (FARACS 1991). Smoking in parents has been identified as a risk factor for asthma in children (ABS 1995).

Smoking and specific risk groups

Young people: Smoking related cancers may begin in people in their 30s if they have been smoking for over 15 years (Ridolfo et al 2001). The influence of smoking on heart disease is also greater in younger people. In persons between 35 and 44 years, 73% of deaths from coronary heart disease are due to smoking. In general, smokers are less fit than non-smokers and perform less well in endurance and short-term exercise (Ridolfo et al 2001). These effects are directly related to duration of smoking and amount smoked. Teenage smokers experience more asthma and allergic symptoms than non-smokers, a greater degree of shortness of breath on exertion and develop more respiratory tract infections than non-smokers.

Women: The risk of cardiovascular diseases in women is increased if they smoke. This risk is increased if they also use the oral contraceptive pill (US Surgeon General 2001). They experience a greater prevalence of secondary amenorrhea (absence of menstruation) and irregularity of periods. Australian research has shown cigarette smoking contributes to osteoporosis (Hopper et al 1994). Women smokers are also at greater risk of developing cancers of the cervix and vulva (Ridolfo et al 2001).

Women and babies - Several studies have found that women who smoke have lower fertility (Ridolfo et al 2001). Smoking affects the well being of the fetus and of the pregnant woman. Spontaneous abortions and complications of pregnancy and labour occur more frequently in smokers (Ridolfo et al 2001). They have a greater risk of ectopic pregnancy and a greater tendency to deliver preterm (Ridolfo et al 2001).

Women who smoke during pregnancy have a 25 to 50% higher rate of fetal and infant deaths compared with non-smokers (Peto et al 2000). Maternal smoking has a direct growth retarding effect on the fetus, with double the risk of a low birth weight baby and a decrease in all dimensions (eg length and circumference of the chest and head, Ridolfo et al 2001). Smoking during pregnancy and in the infants first year of life is considered one of the major risk factors for sudden infant death syndrome (Haglund et al 1990; DiFranza et al 1995; Klonoff-Cohen et al 1995; Golding 1997).

Men: Studies have shown an increased abnormal sperm morphology among smokers. Cigarette smoking has been associated with impotence. Possible causes include a deterioration of the blood vessels in the penis, lower penile blood pressure among smokers and impaired hormonal activity (Ridolfo et al 2001).

Aboriginal Peoples and Torres Strait Islanders: Smoking rates are much higher among aboriginal and islander peoples than the rest of the population, and as a result there is a greater burden of tobacco caused illness, and this occurs at a younger age. Of hospital admissions attributable to tobacco

smoking, 60% of male and 62% of female admissions occurred among aborigines aged 55 or younger. This compares to 27% and 31% respectively in non-indigenous Australians (Ivers 2001). The most frequent causes of tobacco related hospitalisation is chronic bronchitis and ischaemic heart disease. Overall tobacco related diseases contribute an estimated 13% of all Indigenous Australian deaths (ABS 1999).

3.5 Alcohol Consumption: Disease Burden

Overview

The relationship between alcohol consumption and harm is complex:

i) The burden of harm is not restricted to the drinker. While alcohol misuse, harms the drinker, there are also substantial social costs born by others (family members and the wider society). Despite this, much of the research into disease burden is focused on the costs borne by the individual, such as the health consequences. Some of the impacts on the wider society are also studied, for instance alcohol induced car accidents and homicide. The more complex implications for families and society of alcohol abuse and the associated dysfunctional behaviours are less often quantified, despite their undoubted importance. The estimated burden from alcohol misuse in Australia is summarised in Table 3.1.

ii) The pattern of drinking is also important, not just the quantity. Although harm is caused by excessive/ dependent drinking (see definitions below) in a minority, considerable alcohol-related harm also emanates from the larger numbers of problem drinkers who are not highly alcohol dependent (Kreitman 1986; Ryder et al 1988). Recent NHMRC guidelines consider pattern as well as quantity of consumption in determining level of risk associated with drinking, recognising the potential harm from “binge” drinking. Reducing harm associated with low-dependent drinking patterns, such as episodes of intoxication, is at least as important as reducing harm associated with average consumption level.

Terminology and definitions

There has been considerable work on the classification of drug and alcohol problems, as described below. However, no single set of definitions adequately reflects the range of problems or levels of dependence (Mattick et al 1993).

Excessive drinking: refers to those drinkers who consume alcohol beyond the ‘low risk’ levels defined by the NHMRC 2001 guidelines (NHMRC 2001), but who do not necessarily suffer from alcohol abuse or dependence.

Abuse and dependence: Alcohol abuse and dependence refer to a pattern of substance use that is causing clinically significant distress or impairment (Degenhardt et al 2000). It is the primary source of disease burden shown in Table 3.1. Alcohol abuse and dependence are described in the Diagnostic and Statistical Manual of Mental Disorders (APA 1994), DSM-IV:

- Abuse is defined by a pattern of substance use that is causing clinically significant distress or impairment. This distress or impairment may involve a failure to fulfil role obligations, use in hazardous situations, or legal, social or interpersonal problems.
- DSM-IV Dependence criteria require a cluster of three or more indicators that a person continues to use the substance despite significant substance related problems. These include: tolerance to the effects of alcohol or other drugs; a withdrawal syndrome on ceasing or reducing use; substance used in larger amounts or for a longer period than intended; a persistent desire or unsuccessful efforts to reduce or cease use; a disproportionate amount of

time spent obtaining, using and recovering from use, social recreational or occupational activities are reduced or given up due to substance use; and use continues despite knowledge of physical or psychological problems induced by substance use.

Table 3.4: NHMRC Definitions - descriptive

<p><i>Long-term</i> risk refers to the level of risk associated with regular daily patterns of drinking defined by the total amount of alcohol typically consumed per week;</p> <p><i>Short-term</i> risk refers to the risk of harm in the short-term that is associated with given levels of drinking on a single day;</p> <p><i>Low risk</i> levels define a level of drinking at which there is only minimal risk of harm (and a possibility of health benefits);</p> <p><i>Risky</i> levels are those at which risk of harm is significantly increased beyond any possible benefits;</p> <p><i>High risk</i> drinking levels are those at which there is substantial risk of serious harm, and above which risk continues to increase rapidly.</p>

Table 3.5: NHMRC Guidelines: Quantitative

a) risk of harm in the short-term – daily/weekly consumption

	Low risk (standard drinks)	Risky (standard drinks)	High risk (standard drinks)
Males	Up to 6 on any one day, no more than 3 days per week	7 to 10 any one day	≥ 11 on any one day
Females	Up to 4 on any one day, no more than 3 days a week	5 to 6 any one day	≥ 7 on any one day

b) risk of harm in the long term

	Low risk (standard drinks)	Risky (standard drinks)	High risk (standard drinks)
Males: an average day overall weekly level	Up to 4 per day Up to 28 per week	5 to 6 per day 29 to 42 per week	≥7 per day ≥43 per week
Females: an average day overall weekly level	Up to 2 per day Up to 14 per week	3 to 4 per day 15 to 28 per week	≥5 per day ≥29 per week

Source: NHMRC guidelines 2001

Prevalence of alcohol consumption in Australia

Current patterns of alcohol consumption can be determined from the 2001 National Drug Strategy Household Survey (NDSHS) and are similar to those reported in the 1998 NDSHS (AIHW 2002b). The 1998 NDSHS estimated that between 5.6% and 10.5% of the population aged 14 years and over were consuming alcohol at hazardous or harmful levels (NHMRC 2001). Based on the NDSHS 2001 survey, it was estimated that 34.4% of persons aged 14 years and over put themselves at risk of alcohol-related harm on at least one drinking occasion over a 12-month period, and 7% do so at least weekly. Intermittent episodes of at-risk consumption are a feature of Australian drinking patterns. While 2.3% are estimated to drink at levels that have long term health consequences. With regard to frequency of consumption, 8.3% of 2001 NDSHS respondents drank daily, compared with an estimated 11% in 1995.

There has been a decline in per-capita consumption of alcohol between 1990 and 1998 from 11.5 litres of pure alcohol per capita per annum to 10.1 litres (Higgins et al 2000). This was due mostly to a decline in consumption of regular strength beer. Consumption patterns appear to have been relatively stable between 1998 and 2001.

The 1997 National Survey of Mental Health and Well-Being (NSMHWB) was the first national survey conducted in Australia, which examined the prevalence of alcohol use disorders in the population. The prevalence of DSM-IV alcohol dependence was estimated at 4.1% and the prevalence of alcohol abuse was estimated at 1.9% in persons over 18 years of age. Age and gender differences in prevalence of alcohol use disorders occur as discussed below (Ryder et al 1988). It appears that rates of alcohol use disorders in the Australian population are similar to rates in the United States (Kessler et al 1997; Grant 1997 (cited in Ryder et al 1988)).

Gender differences in patterns of consumption

Gender differences in patterns of alcohol consumption exist as summarised in Tables 3.6 and 3.7. Men usually begin drinking at a slightly younger age than women (16 years compared to 18 years) (NEACAAA 2001), and widespread problems from alcohol misuse and related violence are identified as a major health policy issue for men (Connell et al 1998). However, female teenagers (14.6%) are more likely than male teenagers (8.8%) to consume alcohol at high risk levels for long-term harm (NHMRC 2001). The data suggest that 243,177 males and 158,885 females aged 14+ are at high risk of harm in the long term (2001 NDSHS). Females are more vulnerable to the both the acute and chronic effects of alcohol misuse than males (Mattick et al 1993). In 1998, 8% of males and 4% of females *usually* drank at levels considered harmful or hazardous to their health. Thirty eight percent of males had recently consumed 7 or more drinks per drinking occasion (AIHW 2000b). An estimated 15.3% of males and 11.6% of females put themselves at risk of harm at least monthly (NHMRC 2001). Data from the NSMHWB suggest that gender differences in DSM-IV diagnoses of alcohol abuse and dependence exist. Males are more likely than females to meet criteria for both alcohol abuse (2.9% cf 0.9%) and dependence (6.1% cf 2.3%) (Ryder et al 1988). Females are more likely than males to be non-drinkers (20.8% cf 14.1%).

Table 3.6: Risk for long term harm - Proportion of the population over 14 years

	Abstinent (%)	Low risk (%)	Risky (%)	High risk (%)
Males	14.1	75.6	6.7	3.5
Females	20.8	69.8	7.2	2.2

Table 3.7: Risk for short term harm - Proportion of the population over 14 years

	Risky and high risk (%)		
	At least yearly	At least monthly	At least weekly
Males	15.5	15.3	8.5
Females	12.7	11.6	5.3

Source of Tables 3.6 & 3.7: 2001 NHMRC guidelines

Age differences in patterns of alcohol consumption

Alcohol consumption varies by age group as well as gender, as shown in Tables 3.8 and 3.9 (2001 NDSHS). Rates of abstinence are lowest in the 20-29 year age group and increase with age. The proportion of the population drinking at risky and high-risk levels in the short and long-term is highest in the 20-29 age group, followed by the 14-19 age group. The latter is of note, given the high rate of

abstinence in this group,(2001, NDSHS). Data from the NSMHWB reveals an age-related pattern of involvement with alcohol. The youngest age group (18-24 years) was most likely to meet criteria for alcohol abuse (5.2%) and dependence (9.3%) with prevalence decreasing among older groups, (Table 3.10).

Table 3.8: Proportion of the population 14+ at risk of long term harm by age group

	Abstinent	Low risk	Risky	High risk
14-19	26.2	62.1	8.0	3.7
20-29	9.9	75.4	10.2	4.5
30-39	13.0	78.3	6.3	2.5
40-49	13.9	76.5	7.1	2.6
59-59	17.1	73.3	6.6	2.9
60+	27.1	66.8	4.4	1.6

Table 3.9: Proportion of the population over 14 years at risk of short term harm

	At risk and high risk of harmful events		
	At least yearly	At least monthly	At least weekly
14-19	13.4	20.5	10.7
20-29	21.1	27.3	12.0
30-39	20.5	16.5	6.3
40-49	16.0	11.1	6.2
59-59	10.2	6.4	5.8
60+	3.7	2.4	2.6

Source of data in Tables 3.8 & 3.9: 2001 NHMRC guidelines

Table 3.10: Prevalence of DSM-IV alcohol abuse and dependence by age group

Age group	Alcohol abuse % (SE)	Alcohol dependence % (SE)
18-24	5.2 (0.8)	9.3 (1.9)
25-34	2.4 (0.4)	5.7 (0.6)
35-44	1.9 (0.6)	4.0 (0.4)
45-54	1.1 (0.6)	3.0 (0.6)
55-64	0.3 (0.2)	1.7 (0.4)
65-74	0.3 (0.2)	0.8 (0.3)
75+	0.1 (0.1)	0.7 (0.4)

Adapted from Degenhardt et al 2000.

Consumption of alcohol among Aboriginal and Torres Strait Islander peoples

Misuse of alcohol is high amongst Aboriginal and Torres Strait Islanders. Although the overall proportion of Aboriginal and Torres Strait Islanders who drink alcohol (62%) is smaller than in the general population (72%), those who do drink, tend to drink at more harmful levels (Grant 1997). Table 3.11 shows the frequency of hazardous drinking for Aboriginal and Torres Strait Islanders and the general population. Hazardous drinking in the Aboriginal population is most common in the 25-34 year age group.

**Table 3.11: Frequency of hazardous drinking last 12 months
Aboriginal and Torres Strait Islanders and the general population**

Frequency of hazardous or harmful levels of consumption past 12 months	Aboriginal and Torres Strait Islanders (1994 survey)		General population (1993 survey)	
	Males	Females	Males	Females
Never	7%	9%	17%	21%
At least once in past 12 months	13%	24%	22%	29%
At least once a month	21%	29%	24%	24%
At least once a week	48%	35%	32%	23%
Every day	10%	3%	4%	2%

Source: National Drug Strategy Household Survey: Urban Aboriginal and Torres Strait Islander Peoples Supplement 1994

Regional differences in drinking patterns

There are clear regional differences in alcohol consumption, alcohol-related harm and deaths caused by alcohol (NHMRC 2001), with men and women outside the major cities at greatest risk. In rural and remote areas, high alcohol consumption in men is inversely proportional to the size of the population, ranging from 5% in a large rural centre to 8% in remote areas (populations of less than 5,000 people). However, levels of consumption in women do not follow the same pattern seen for men. Increased levels of alcohol consumption in women are observed only in small rural centres and in remote areas with less than 5,000 people. In small rural centres, 2.4% of women consume high levels of alcohol whilst in remote areas the proportion is 2.1%. These rates are higher than the 1.2% observed in capital cities (NHMRC 2001).

This pattern is reflected in rates of treatment differences between metropolitan and non-metropolitan areas identified in the 2001 Clients of Treatment Service Agencies (COTSA) Census (Shand 2002). Of those in treatment for drug and alcohol problems, non-metropolitan clients are more likely to be in treatment for alcohol problems than other drug problems (47.8%), compared to their metropolitan counterparts (31.4%).

Consumption of alcohol by rural youth is greater than metropolitan youth. In 1998, 82% of rural youth aged 14-19 years consumed alcohol compared to 71.5% of youth in urban areas (NHMRC 2001). Rural youth were slightly more likely than urban youth to have consumed alcohol at hazardous and harmful levels (68.6% compared to 65.7%). This pattern was also found for persons aged 20-24 years.

Estimated disease burden from alcohol abuse

Health costs

In general, higher overall levels of alcohol consumption in a population are associated with higher levels of alcohol-related problems such as alcohol related deaths and morbidity from liver cirrhosis, traffic accidents, suicide and criminal violence (Edwards et al 1995). But the pattern of alcohol consumption is also important, with particularly high rates of alcohol-related harm found among low and moderate level drinkers on the occasions they drink to intoxication (NHMRC 2001).

In Australia, in 1996 an estimated 4,492 deaths were attributed to alcohol consumption (AIHW 1998), accounting for an estimated 67,005 years of life lost. In 1998, 43,032 hospital episodes were attributed to the consumption of alcohol (NHMRC 2001).

Social cost

Alcohol abuse has substantial negative consequences for the general community (Godfrey 1997). Alcohol abuse is implicated in a high proportion of violent crime and in child and spouse abuse, homicide, domestic violence, fires, suicide, financial problems and poverty, as well as motor vehicle and industrial accidents, (English et al 1995; Institute of Medicine 1990; Tai et al 1998; WHO 1995; Young 1994; Tolley et al 1991; NHMRC 2001).

Although social morbidity is not well documented and is difficult to estimate reliably, the seriousness of alcohol-related problems as a public health issue in Australia was emphasised by the Senate Standing Committee on Social Welfare in 1977, which described them as having reached epidemic proportions (Ivers 2001). Although, a small decrease in the proportion of people reporting themselves as victims of alcohol-related social harms appears to have occurred in Australia between 1993 and 1995, (Tai et al 1998). Some of this social impact is quantified in the AIHW Burden of Disease study summarised in Table 3.1.

The estimated contribution of alcohol to national motor vehicle accidents and pedestrian hospitalisations are immense as shown in Table 3.12.

Table 3.12: Alcohol consumption and road accidents, Australia 1998

Accident type	Males		Females	
	<i>Blood alcohol concentration</i>		<i>Blood alcohol concentration</i>	
	<i>>0.05 - <0.10</i>	<i>>= 0.10</i>	<i>>0.05 - <0.10</i>	<i>>= 0.10</i>
Motor vehicle driver and motorcycle rider deaths: all ages	2.3%	30.5%	Data not provided	10.7%
Motor vehicle and motorcycle accident hospitalisations: all ages	3.4%	21.2%	1.4%	9.2%
Pedestrian hospitalisations: 16+	Data not provided	37%	Data not provided	6%

Source: Adapted from Ridolfo et al 2001.

In New South Wales, alcohol was estimated as a causal factor in 33% of road traffic deaths in 1985 (Commonwealth of Australia 1987). By 1995, this proportion had decreased, although 23% of all fatal road accidents were alcohol-related, of which 26% involved the death of passengers and pedestrians. A further 298 non-drivers were injured seriously (English et al 1995). An estimated 18% of all regular drinkers report driving while drunk, at least once in the previous 12 months.

Regular substance users, males and younger persons are all more likely to have perpetrated an alcohol-related crime (NHMRC 2001). Similar data are reported for the United States, where an estimated 30% of all arrests are for public drunkenness and approximately 55% of all arrests are alcohol-related (Grant 1997), while alcohol was implicated in 44% of all traffic fatalities in 1993 (US Preventive Services Task Force 1996).

Relationship between consumption and harm

A substantial proportion of the Australian population consume alcohol at high-risk levels, even though the majority do not exceed NHMRC defined levels of low-risk weekly drinking (NHMRC 2001) and do not necessarily consume alcohol daily or almost daily. The importance of episodic at-risk drinking, or drinking to intoxication, is formulated in the preventive paradox. It is postulated that the greatest alcohol-related harm emanates from problem drinkers who are not alcohol dependent, rather than the minority who are - due to the larger numbers of the former (Ryder et al 1988). Although there has been some dispute regarding the validity of this paradox (Roche 1997; Stockwell et al 1996). But

certainly it is agreed that “binge” drinking can be harmful, and that reducing harm associated with episodes of intoxication in low-dependent drinking, may be as important as reducing harm associated with alcohol abuse.

Skinner argued that only a small minority of the population who drink alcohol experience severe problems as a result, while the majority experience no problems, with a small number at increased risk of alcohol-related harm (Skinner 1990). The relationship between consumption and harm varies substantially among age and sex cohorts and over a person’s lifetime. Example, young people and males are at greater risk of harm, as are indigenous groups, those operating machinery and pregnant women. Different drinking situations also affect the level of risk

SECTION II: INTERVENTION OPTIONS

OVERVIEW

Possible intervention options to reduce the burden of harm from the four risk factors are considered in this Section, reflecting an understanding of disease burden described above. A Chapter is devoted to each risk factor, but commencing with a discussion of multiple-risk factor options – interventions designed to target several risk factors.

Multiple-risk factor Options

Multi-risk factor options can be thought of in two ways:

- firstly as interventions that impinge on more than one risk factor – such as a school-based ethics/empowerment program that may assist young people to adopt more healthy life choices – potentially covering all four risk factors that are the subject of this research program; that is where one intervention may influence several behaviours; or
- secondly where behaviour change is required across several risk factors to achieve the objective - for instance to address obesity it will normally be necessary to consider nutrition as well as physical activity, or to address poor child/maternal outcomes through a multi-faceted approach covering poor nutrition, alcohol abuse, tobacco smoking, and other behaviours. Thus a suite of interventions, focused on an at risk population will be needed.

Both reasons for a multiple risk factor strategy will be important. However, in the context of the current study, with its massive breadth, it simply is not possible to consider adequately the literature relative to multiple-risk factor options fully. Obesity is specifically excluded from the risk factors to be covered in this literature review. Rather very limited consideration is given of this issue, firstly and only briefly in relation to obesity (the risk factors for consideration specifically excluded obesity) and then not excluding from consideration, interventions that might have a wider impact, affecting several life style choices.

Those at risk of life style based illnesses, or diagnosed with such illnesses – such as CHD and diabetes, will often be physical inactive and have an unhealthy diet and be obese. They are also more likely to be smokers. A reduction in food intake, an increase in physical activity and smoking cessation are all desirable in this group. These can be addressed by risk factor specific interventions or ones that are target several life style behaviours.

Another group that may require a multiple risk factor approach are ‘persons at risk’ – vulnerable groups within society who may experience a combination of alcohol abuse, smoking, poor nutrition and be physically inactive. Poor life style choices will be compounded by unemployment, low incomes, limited education and a sense of disempowerment. Harms will be mediated through anti-social behaviours as well as ill health. High risk groups will include some ethnic groups, mothers and babies and the frail aged.

Three types of interventions that may be relevant to address these problems are briefly outlined below.

Community-based health promotion activities can be used to improve knowledge and a range of lifestyle behaviours. These can, be directed at school students, the general public, or targeted at high risk groups, including those with life-style related conditions, those exhibiting unhealthy lifestyle behaviours and vulnerable groups. Programs could include mass media, community based initiatives, involve legislative or regulatory changes.

Use health professionals in the management of people with risk factors to modify behaviours. Interventions can be undertaken following opportunistic or systematic screening of health services users, potentially as part of routine general practice or community health centre services, or through a dedicated health-screening program.

Out-patient or clinic-based program to modify risk factor behaviours, following hospital admissions for major disease events. This could occur as part of the routine management of people with lifestyle related diseases, in an out-patient setting, or general or specialist practice. Examples include life-style programs within cardiac rehabilitation services for persons who have suffered a heart attacks or following heart surgery, and the inclusion of risk factor management in the routine care of people with CHD disease symptoms hypertension, diabetes etc.

CHAPTER 4: Physical Inactivity

4.1 Introduction

There are many ways of intervening to promote increased physical activity and strength training in persons who are largely sedentary. These can occur both within and outside the health sector, occur through system-wide initiatives, or marginal change, addressed at the individual or populations, at every stage of development of risk factor. The breadth of scope of potential means to intervene is illustrated by the intervention types listed in table 4.1.

Interventions can focus on the general community, those who are already sedentary or those with the disease consequences of a sedentary life-style:

i Primary prevention:

Interventions to promote physical activity in the general community, to prevent a sedentary life-style from developing. Health promotion activities can be used to improved knowledge and behaviour about the role of physical activity. These can be directed at school students, the general public, targeted community groups, and general health services users. A range of mechanisms can be used including the mass media, community media, school classes etc. Broad infrastructure policies will be relevant here as well as education. These include:

- Transport policies at national and local level to encourage physical activity (eg safe cycling, public transport);
- Community development to enhance access to and engagement in social and physical activities – such as local sporting teams. Schools and other educational institutions are an important potential setting to promote physical activity and discourage a sedentary life style;
- Fiscal policies can encourage healthy lifestyles rather than unhealthy ones – such as high tax on cars and petrol and subsidies on public transport, bicycles etc.

ii Strategies for those who are already sedentary

Management of people who are already sedentary to modify their behaviours can be undertaken following opportunistic or systematic screening of the community or of health services users. Screening and interventions can be undertaken as part of routine general practice or community health centre services, or as dedicated health screening and management clinics.

iii Management of people with disease consequences of a sedentary life style

Strategies to promote a more active life-style in those with disease consequences of this behaviour (such as CHD, type 2 diabetes), can be undertaken following hospital admissions for major disease events, or as part of the routine management of people in general or specialist practice. This may, for instance take the form of prevention activities in cardiac rehabilitation services following heart attack or cardiac operations, and the inclusion of risk factor management in the routine care of people with CHD disease symptoms hypertension, diabetes etc.

Table 4.1: Types of Interventions to promote Physical Inactivity

Stage/Therapy/ Focus	Modality	Intervention Strategy
I PRIMARY PREVENTION		
Infrastructure Modifications		
		<ul style="list-style-type: none"> • City residential and work zone planning • Transport system planning • Cycleways and walkways • Community activity development
Health Promotion		
	Media	<ul style="list-style-type: none"> • Mass media campaigns focussed at general population • Leisure activity programs
	School based programs	<ul style="list-style-type: none"> • Health promotion programs in schools to develop student self-efficacy / self-control • Development of a range of competitive and non-competitive physical activity programs
	Workplace	<ul style="list-style-type: none"> • Physical exercise facilities and time • Transport to work issues / parking restrictions • Health advice as part of Health & Safety programs
II INTERVENTIONS FOR THOSE WITH RISK FACTOR – WHO ARE SEDENTARY		
Non-pharmacological		
	Large scale community	<ul style="list-style-type: none"> • Generic Self Help Materials • Physical activity • Life skills and stress management
	Small scale community	<ul style="list-style-type: none"> • Community activities (e.g. tree-planting, walking clubs, dancing)
	Advice from clinicians	<ul style="list-style-type: none"> • Brief advice from doctors delivered opportunistically during routine consultations • Green Script (Active Script) prescription of physical activity • Formal CHD risk factor clinics in general practice
	Psychosocial screening	<ul style="list-style-type: none"> • Screening for depression • Screening for social isolation • Screening for poverty
	Healthy lifestyle programs in separate facilities	<ul style="list-style-type: none"> • Fitness programs for adults • Fitness and balance programs for maintenance of activity / falls prevention in the elderly • Weight-control programs (e.g. Gut-busters) • Stress management programs
	Training of health professionals	<ul style="list-style-type: none"> • Training of health care professionals in brief intervention methods • Training of health care professionals in education principles and practice
	Social support	<ul style="list-style-type: none"> • Peer-group support and learning circles

Possible attributes of health sector interventions

Even within the health sector there are many choices covering:

- the type of message conveyed (what),
- the means of communicating the health message and the nature of supports for behaviour change* (how),
- by whom (health professionals, government and non-government organisations),
- the setting (where) and;
- stage of intervening, such as at a particular stage in the lifecycle or via primary, secondary or tertiary prevention (when);
- the type of physical activity people might pursue, e.g. aerobic exercise or resistance training.
- the frequency, intensity and duration of activity – related to evidence concerning what is needed to produce a health benefit. (Physical activity research indicates that, across the population, interventions that encourage moderate rather than vigorous exercise and that do not require attendance at a special facility are more likely to be successful, Hillsdon et al 1996.)

* Behaviour change interventions: there has been an increase in the use of theoretically based behavioural interventions. Goal setting (King et al 1988), decisional balance (Marcus et al 1994) and social support (King et al 1991) are some of the techniques that have been incorporated. Motivationally tailored interventions, whereby advice is tailored to an individual's potential to participate in physical activity (Activity Counseling Research Group 2001) have drawn upon the Transtheoretical Model (Prochaska et al 1983). These techniques appear to have assisted the promotion and implementation of physical activity. For example, Marcus et al (1992) report on an intervention using stage-matched self-help manuals that was influential in initiating exercise.

4.2 Population Approaches

Population interventions are based upon ecological models of behaviour. Population approaches have the potential to reach a larger proportion of the community than individual approaches. However, the techniques need to be sufficiently effective to achieve genuine behaviour change, not solely greater reach.

Policy: Policy interventions have the capacity to reach and influence many people. A swathe of policy documents – for improve fitness of the community, have been produced by both government and non-governmental agencies in Australia. Their impact upon physical activity behaviour remains to be evaluated. The main role of policy is to lend support to population-wide behaviour change.

Environmental strategies (see Table 4.2): Environmental interventions have the potential to raise population prevalence of physical activity (Sallis et al 1994). To date, there is little evidence for the success of environmental strategies in Australia (Salmon et al 2000). There are a few international reviews (Patrick et al 2001; Dunn et al 1998) that note the limitations of previous research in the area. Prompts encouraging physical activity are promising, including encouraging stair use and marking of walking routes. (These approaches increased walking participation in an Irish initiative.)

The outcomes of longer term strategies e.g. the US Center for Disease Control's 'Physical Activity: It's Everywhere You Go' program and the Victorian Department of Human Services cross-sectoral 'Active for Life' planning framework (Department of Human Services 1998) remain to be reported upon. In Australia, the city of Bunbury (Western Australia) has conducted a three-year program (Walk-It Bunbury) that aimed to increase the number of adults fulfilling the National Physical Activity Guidelines. GPs have been trained in behavioural skills and encouraged to refer to the structured walking programs. The program's findings are soon to be published.

Table 4.2: Examples of environmental interventions

Study	Participants	Study design	Outcomes
Roberts et al 1989	City of Belfast	Longitudinal study o' 7 yrs. Opened 14 leisure centres across city.	Findings- increased activity in young adults, more modest changes in other age groups.
Linenger et al 1991	Two military bases	RCT of environmental and policy changes. Bike trails, exercise equip, women's fitness centre, new running and cycling clubs. Time release for activity. Budgets for environmental changes.	Findings- intervention group improved their fitness compared to controls. Methodological concerns limit confidence in study's conclusions.
Vuori et al 1994	Workplace, Finland	Walking or cycling to work promoted. Through advertising, lotteries, showers at work. Lobbying to improve safety of commuting routes.	Findings- 7% employees walked/cycled to work. 19% increase leisure physical activity.

Financial incentives: Sallis et al's review (1998) of environmental strategies noted the value of reinforcement strategies. Monetary or other incentives e.g. discounted health insurance have some potential: however, the evidence base to date is mixed. In the UK, Harland (1999) conducted an RCT of various methods to promote physical activity in primary care. The most effective intervention for promoting the adoption of physical activity was the most intensive which included six motivational interviews based on the stages of change model, plus financial incentives in the form of vouchers for free access to leisure facilities. However, even this intervention did not promote long term adherence to exercise.

Mass media (see Table 4.3): Mass media strategies are generally multi-faceted, using TV and radio advertisements, print materials and community events. Reviews have reported that mass media campaigns can raise awareness and understanding and create more positive attitudes towards physical activity (Marcus et al 1998a). They can also provide a good context for other interventions. For example, campaigns may support community or individual interventions. They have less impact upon actual behaviour change (Carlson et al 1999). To date, Australian mass media campaigns have had modest success (Heaney et al 1997). Overall evidence for the mass media strategy is equivocal, but based on very few good quality trials. Cavill's review (1998) revealed only three studies concerned with the effectiveness of national health promotion campaigns using mass media to promote physical activity. Although he reports that these campaigns supported changes in knowledge and attitudes, there was limited, short-term impact on physical activity participation.

A more recent evaluation (Hillsdon et al 2001) see table reports modest impact on knowledge but no increase in physical activity.

Table 4.3: Examples of mass media interventions

Study	Participants	Study design	Outcomes
Wimbush et al 1998	Scottish population	Quasi-experimental (pre and post intervention surveys) TV ads, telephone helpline, support booklets	Findings- 70% awareness. Modest attitudinal changes. No change in activity behaviour.
Hillsdon et al 2001	Recruited national sample (selected via a multi-stage, cluster random probability design). 3189 adults, 16-74 years. UK	3- yr prospective survey of national 'Active for Life' campaign. TV ads, print communication, support of community based project workers. Messages to population sub-groups.	Findings- 38% participants aware of main advertising images. Between waves 1 and 3. 3.7% increase in knowledge of physical activity recommendations. Change in proportion of active people fell from -9.8 (-7.9 to -11.7). No evidence of improved physical activity.

Campaigns have greater influence upon those considering change - in the contemplation stage of change (Marcus et al 1998a; Simons-Morton et al 1998). There is scope for campaigns to be tailored to high-risk sub-groups. Several mass media campaigns have promoted physical activity as part of multi-faceted cardiovascular risk reduction initiatives, e.g. the Minnesota Heart Health program (Eakin et al 2000) and the Stanford Five-City Project (Young et al 1996).

Sponsorship and product labelling have been used to support particular disease areas e.g. CVD. These strategies may add to the impact of mass media approaches.

Population health approaches: summary

Some population health approaches have been outlined in this section. The range of population strategies that warrant further exploration have been summarised by Salmon and colleagues and King (Salmon et al 2000; King et al 1995). These include; targeting of incidental activity; transport policy changes, the establishment of intersectoral coalitions and training programs. However these lie outside the parameters of interventions to be included for the cost-effectiveness analysis and are not further considered.

4.3 Individual Approaches

In this section, we will discuss the use of counselling and screening in the health sector. The use of print and other media for health education will be considered. Interventions in non-health settings, namely, the community, schools and workplaces will then be overviewed. Strategies for reaching particular population sub-groups will be reviewed.

Health professional screening and counselling (see Table 4.4): The healthcare sector has been involved in promoting physical activity using primary, secondary and tertiary prevention strategies. The primary care sector offers access to the broadest sector of the community to provide health promotion advice. In particular, general practitioners (GPs), as gatekeepers and providers of continuity of care, are acknowledged as useful health promoters. Research shows that advice given by GPs is highly regarded by the public and can bring about behavioural change.

The most popular strategy employed in recent years has been the use of the exercise prescription approach. Exercise prescription has been effective as a public health initiative. The first scheme was the Green Script in New Zealand (Swinburn et al 1998). Such schemes have been well received, and produced positive short-term effects. However, some researchers (Harland et al 1999; Fielder et al 1995) have concluded from existing level II evidence that there is insufficient evidence that exercise prescription schemes are effective in achieving long-term behaviour change. An investigation of the sustainability and cost effectiveness of the New Zealand Green Prescription program is currently underway.

Although health practitioner counselling has been studied more than other individual information giving approaches, reviewers have noted the lack of robust, unequivocal evidence concerning the efficacy of physical activity counselling by primary care physicians (King et al 1992; Simons-Morton et al 1998; Eakin et al 2000; Ashenden et al 1997; Eaton et al 1998). Whilst level II evidence is supportive of a short-term impact of brief interventions upon (self-reported) behaviour change, the sustainability of the effect remains elusive. For example, Eaton and Menard (1998) concluded that there is limited evidence from well designed trials that office-based physical activity promotion in primary care settings is efficacious in promoting change in physical activity that could potentially have lasting clinical benefits.

Eakin et al (2000) provided a broader systematic review of primary care-based physical activity interventions details their positive facets. Those tailored to a patient's characteristics and preferences and including supplemental written materials were more likely to produce successful outcomes.

Short-term improvements in physical activity were observed across all types of intervention deliverers (physicians, nurses and combinations of physicians and health educators). Interestingly, more extensive interventions focusing on multiple risk activities, but without the use of written materials did not achieve significant short term results for physical activity. Unlike the findings elsewhere in the health behaviour change literature, follow-up support after initial intervention is not consistently found to increase the likelihood of positive short-term results.

In addition, possibly because of methodological limitations of the studies being compared, theory based interventions have not proved to be more successful than those not explicitly theory-based. Finally, whilst primary care physical activity interventions can reach large segments of the sedentary population, current study findings have limited generalisability, as men, smokers and older adults are infrequently represented.

Multi-faceted interventions: The efforts of one health professional group may be of value when they are incorporated within broader interventions to promote physical activity. This approach was investigated in the US Activity Counselling Trial (ACT), a trial that aimed to evaluate the efficacy of two primary care, practice-based physical activity behavioural interventions relative to a standard care control condition. The trial compared the effectiveness of physician advice alone with physician advice plus behavioural counselling, provided by trained health educators, to increase level of physical activity in healthy sedentary patients. Physicians were trained to integrate 3-4 minutes of initial physical activity advice into the routine office visits of sedentary patients with no acute or serious chronic conditions. Advice included assessment of current physical activity, advising patients about an appropriate physical activity goal, and referring patients to a health educator (King et al 1998a). At two-year follow-up, maximum oxygen uptake was significantly higher in the assistance and counselling group women compared to those in the advice group, but there was no difference in reported physical activity. For men, there were no significant differences for either cardiorespiratory fitness or reported physical activity (Activity Counselling Research Group 2001). This suggests that extended interventions have no added value.

Information resources: There is a range of media for disseminating and delivering physical activity advice. Above, we discussed face to face counselling by health professionals.

A more passive approach is the use of written material. This can be distributed in print form or electronically. Print-based self-help materials have been trailed in a variety of settings. Pertinent studies will be discussed in subsequent sections. Interventions targeting self-efficacy and decision making strategies, in line with behavioural theory, have shown promise (Marcus et al 1998b).

Whilst face to face strategies can be more effective than mass media approaches at the individual level, a review of lifestyle interventions (Dunn et al 1998) highlighted the limitations of face to face communications with small groups upon population health. There is scope to use new technologies for more interactive communication (Marcus et al 2000) to provide greater reach. Computer mediated systems have recently been trailed in the PACE+ studies (Patrick et al 2001) (see Table 4.5). Comparisons of different forms and intensities of media-based interventions require further examination (White et al 1997).

Settings

Whereas mass media reaches people in their homes or as they go about their business, different sub-groups can be targeted in specific locations. The clinical setting was discussed earlier and is clearly a means of reaching the patient population. Many studies have focused upon schools and workplaces to promote physical activity. They have usually employed an individual level approach.

Community settings (see Table 4.9): Marcus et al (1998a) noted that many of the mass-media trials also incorporated community-based interventions. However, there have been few trials evaluating the effects of community-based physical activity programs alone. A review of interventions for

community-dwelling older people (King et al 1998b) revealed that cognitive behaviour strategies were most effective in promoting behaviour change in this population. Home and group based activity and on-going telephone supervision were also helpful strategies. Further studies are needed in this setting, to determine the impact on different population groups with regard to awareness, knowledge and behaviour change.

Workplace settings (see Table 4.7): Whilst the workplace has been proposed as a potentially valuable setting for physical activity promotion, we have limited evidence of this to date. There have been a range of studies and reviews (Shepard 1996; Pelletier 1999; Heaney et al 1997) but interpretation of the evidence base has been restricted by the methodological flaws of the existing research, such as poor recruitment, high attrition and poor maintenance. A meta-analysis of workplace interventions (Dishman et al 1998) indicated that behaviour modification and workplace incentives were helpful strategies. However, none of the effects on physical activity were statistically significant in the meta-analysis. Examples of more recent studies are given in Table 4.7.

The way forward may be to target those at greatest health risk (Bauman et al 2001) and to use an organisational as well as an individual-based approach, that is, supporting workplace interventions with policy and environmental strategies at this level.

School settings (see Table 4.8): Several school-based interventions have been trailed. Only one University based intervention was identified (Sallis et al 1999). The female students demonstrated some behaviour change, but there were no significant differences for the males. This was possibly due to a ceiling effect, as more males were already active at baseline.

As a sub-population, children and adolescents are very important. Opportunities for primary prevention clearly exist, with the scope to promote healthy lifestyle behaviours. Overseas reports (Pelletier 1999; Biddle et al 1998) have recommended an hour of physical activity per day for adolescents, but no guidelines exist for children.

Sub-populations

Older people have the highest absolute risk for inactivity-related conditions. They can attain health benefit from even small increments in physical activity. There are additional gains regarding quality of life and falls and fracture prevention. The evidence for physical activity falls prevention programs has been documented elsewhere (Hill et al 2000). King et al (1991) reviewed interventions for older people. More recent studies have benefited from longer follow-up periods than those they reported upon. Examples of interventions targeting older people are given in Table 4.6.

Others who can benefit include those with chronic illness, disabilities and CALD groups. However, there is limited population data and few guidelines available for these groups. Some illustrative evidence is overviewed below.

Chronic illness: Physical inactivity was noted at the outset to contribute to a range of chronic health problems. The converse is that activity can assist the prevention and management of illnesses (Carlson et al 1999).

Most of the associated research has focused upon CVD management. Simons Morton and colleagues (Simons-Morton et al 1998) reviewed cardiac rehabilitation programs. Although findings are limited by the attrition rates and short-term follow-up, adherence has been assisted by use of moderate intensity activities; equipment loan; behavioural components; supervision and/or frequent contact and specific maintenance interventions. Two examples where longer term follow-up occurred are the Treatment of Mild Hypertension study (Elmer et al 1995) and the MULTIFIT trial (De Busk et al 1998). The NSW 'HeartMoves' project aims to increase the number of at risk clients participating in exercise classes in leisure centres (National Heart Foundation, personal communication).

Disability: The disabled are a heterogeneous group with varied needs. They are more likely to be inactive than able bodied people. Nevertheless, the aetiological evidence suggests that they can benefit from suitably tailored physical activity in a similar manner to the general population (Heath et al 1997). The maintenance of function and independence via physical activity requires further research. Levels of physical activity are lower for people with disabilities. Taylor et al (1998) have documented interventions for disabled and ethnic minorities. Jette et al (1999) reported that a US program incorporating home based resistance training has potential for people with disabilities. Strength, balance and mobility improved in older people with disabilities. Such a home based approach may overcome some of the access and psychological barriers that disabled people face (King 1994) until these can be addressed. All population-based strategies should aim to encompass people with disabilities to enable equity.

CALD groups: Several projects have been established in Australia to promote physical activity in minority groups (Bauman et al 2000). Brown et al (1996) have reported fitness improvement and decreased BMI and BP in migrant women. Key features were the use of bilingual community educators and culturally appropriate venues.

Indigenous population: In spite of clear evidence of greater cardiovascular and diabetes morbidity in the Indigenous population, there is a paucity of published or evaluated physical activity interventions for this community. As for other cultural groups, community involvement in the development of such interventions is likely to be helpful. White et al (1997) have described the Looma Healthy Lifestyles program that has been operating for some years in Northwest Australia to reduce diabetes morbidity. Other programs such as this are needed.

Methodological considerations

The evidence base contains relatively few randomised controlled trials of population based physical activity interventions. There are more at the individual level. However, these tend to focus upon particular sub-groups, especially those with existing health problems. This limits the generalisability of the findings. Few studies have evaluated the long-term effects: where this has occurred, the evidence is weak.

There is also a need for more standardised means of measuring physical activity. This has been discussed in detail elsewhere (Bauman et al 2001). With standardised measurement tools we will be better equipped to evaluate interventions across a range of settings to determine their relative cost effectiveness.

4.4 Conclusion

Multi-level, multifaceted approaches that combine environmental, policy and individual strategies are likely to have the greatest potential to promote and sustain physical activity behaviour change (Sallis & Owen, 1999). Egger et al (1999) recently stated :

‘Future approaches to increasing physical activity at a population level will need to incorporate environmental influences into program planning and these influences should (where possible) be attempted to be modified’ (p 120).

With regard to overall efficiency, further research is needed on interventions and the settings/clinic characteristics associated with adoption. This may include investigating how patients can be assisted to use physical activity resources available in the local community. Technological supports e.g. the Internet, phone prompts may be valuable. Different delivery models e.g. provider versus computer delivered physical activity counselling could be explored.

Individual approach interventions also need to be tested on a larger scale, examining the cost-effectiveness for different modes of delivery. More research regarding their efficacy in sub-groups such as the elderly, minorities, socio-culturally disadvantaged, and individuals with concurrent disease. Basic dose-response studies will help us understand the health effects of accumulated moderate intensity activity.

Although interventions appear efficacious in producing short term changes in physical activity, maintenance is difficult. For sustained impact, the issue of continuity and maintenance of support needs to be addressed. Further research is needed to explore how to maintain any short-term gains, with a view to determining cost effective means to provide appropriate advice and follow-up to all age groups.

Table 4.4: Physical activity interventions in general practice and primary care settings (RCTs only)

Study	Study participants	Study design	Outcomes
Fielder et al 1995 UK	Patients (38) aged 18-64. Recruited from 4 general practices	Verbal advice and/or written prescription and/or invitation to subsidised leisure centre programs. All had exercise promotion booklet. Three month follow-up.	Outcomes :Health status, physical activity, exercise record Findings- Needed to recruit 900 over 4 months to have power to detect 5% difference in activity. Study abandoned. Barriers discussed.
Graham-Clark & Oldenberg 1994 Australia	Patients with >1 modifiable CVD risk factor n=758. mean age 52. Recruited from 75 practices.	Stages of change program advocating walking, with or without self help materials. Assessed baseline, 4 and 12 months	Outcomes Physical activity, CAD risk, intention to change Findings- Increased activity over time, especially in least active. No treatment effect. More controls progressed towards change.
Bull et al 1999 Australia	Sedentary patients (763) Recruited from one general practice	GP brief verbal advice, with or without written advice. One year follow-up.	Outcomes: % physically active, frequency/duration of sessions Findings- Intervention more active than controls at 6 months, but no difference at 12 months. Improved frequency at 1 month
Harland et al 1999 UK	Sedentary patients (523) Aged 40-64. Recruited from one general practice	Motivational interviewing by health visitor. 1(max 6) sessions. Referral to leisure centre with or without vouchers. Follow up at 12 weeks, one year	Outcomes: Physical activity score, sessions of moderate and vigorous activity Findings- Intervention higher score at 12 wks, particularly from intensive, incentive group. More vigorous activity than controls.
Stevens et al 1998 UK	Sedentary patients (714), 45-74 yrs. Recruited from 2 general practices.	Consult with exercise specialist, plus 10 week personalised exercise program. 8 months follow-up.	Outcome: Physical activity frequency Findings- Fewer in intervention were sedentary at follow up, whilst more reported an increase in episodes of activity.
Naylor et al 1999 UK	Adult patients (294) attending for health checks in 4 practices.	Nurse led intervention. One session of counselling with or without stage tailored materials vs. materials alone or usual care. 6 months follow-up.	Outcomes: Stage of exercise adoption, exercise level, self efficacy Findings- Stage based interventions enhanced motivation to change but no impact on behaviour or self efficacy. Study possibly underpowered
Hillsdon et al 2001 UK	Sedentary 45-65 yr olds. Recruited from 2 primary health care centres	Encouragement of walking via brief motivational interview vs advice giving. 5 minute maintenance calls. Follow up at 12 months	Outcomes: Physical activity Health check. Results not yet available
Swinburn et al 1998 New Zealand	Patients (491) sedentary < 1 hr vigorous or 3hrs mod. activity/ wk 'most likely to benefit and succeed' health status, motivation level. Mean age 49. Recruited from 37 GPs.	GPs trained to assess and prescribe activity. Written prescription and/or verbal advice (5 mins) to walk 30 mins 5/wk. Six weeks follow up.	Outcomes: Proportion recreationally physically active, duration of activity sessions. Findings- Intervention more active than controls OR 1.81 (1.42-2.3). (Note: most did not reach target frequency) 59% still active at 1 month. No difference in average duration.
Continued next page			

Study	Study participants	Study design	Outcomes
Taylor et al 1998 UK	Patients (142) with CHD risk factors. Recruited from two health centres	Prescribed 20 exercise sessions at leisure centre (half price) over 10 weeks. Moderate/vigorous aerobic activity, semi supervised. Assessed at 8,16,26 and 37 weeks	Outcomes: Adherence, BP, sum skinfolds (SSKF). Findings- Most used the 'script', 28% attending 15+ sessions. Exercisers significantly reduced SSKF to 16 weeks. High adherers reduced SBP to 37 weeks Obese and non smokers attended more
Norris et al 2000 US	32 primary care offices. Recruited 812 patients 30+ years.	GP brief behaviour-based exercise counselling plus 1 month phone reminder. Enhanced intervention group received four additional reminders. Follow-up at 6 months.	Outcomes: Energy expenditure, activity, mental and physical health, socio-behavioural characteristics Findings- No group differences. Intervention contemplators advanced (on stages of change score), but no difference in energy expenditure.

Table 4.5: Computerised interventions in primary care setting

Study	Study participants	Study design	Outcomes
Calfas et al 2002 US	Patient-centred Assessment and Counselling on Exercise plus nutrition (PACE+) 173 adults	4-month intervention All patients completed computerized assessment then made a tailored "action plans" to change a physical activity and a nutrition behaviour. Discussed with provider. Subsequent intervention arms: control; mail; infrequent phone and mail; frequent phone and mail.	Primary outcomes: moderate and vigorous physical activity stage of change, dietary fat, fruit/vegetable intake, and overeating behaviours Assessment baseline and 4 months Findings- All conditions improved on all behaviours over time. No benefit from mode or intensity of subsequent intervention.
Patrick et al 2001 US	Patient-centred Assessment and Counselling on Exercise plus nutrition (PACE+). 117 adolescents (11 to 18 years). Recruited from 4 paediatric and adolescent medicine outpatient clinics	All patients completed computerized assessment then made a tailored "action plans" to change a physical activity and a nutrition behaviour. Discussed with provider. Subsequent intervention arms: control; mail; infrequent phone and mail; frequent phone and mail.	Primary outcomes: moderate and vigorous physical activity stage of change, dietary fat, fruit/vegetable intake, and overeating behaviours Assessment baseline and 4 months Findings- All outcomes except vigorous physical activity improved over time. No additional benefit from the extended interventions. Those who targeted a behaviour tended to improve more than those who did not target the behaviour.

Table 4.6: Interventions with older people

Study	Study participants	Study design	Outcomes
King et al 1998 US (Review)	Community dwelling older people (50+ years)	Community-based, RCT or quasi-experimental design studies included. (29).	Outcomes: Participation rates, physical activity. Findings- studies were of reasonable duration and had reasonable participation rates. Behavioural approaches limited, but promising. Few studies focused on sub-groups or cost-effectiveness.
Kerse et al 1999 Australia	Older patients (>65yrs) (267) seen by 42 GPs	GPs given education (and audit program) on health promotion counselling – trial assessed impact upon patient consults and outcomes One year follow-up.	Outcomes: Physical activity, functional and immunisation status, health and psychological wellbeing, drug usage. Rate of influenza vaccination. Findings - Intervention patients reported increased walking, improved health and more frequent pleasurable activities than the control group
Halbert et al 1999 Australia	Older patients (>60yrs) (299). Recruited from two practices	Counselling by exercise specialist, reinforced at 3 and 6 months. One year follow-up	Outcomes: Physical activity, BP, weight, blood lipids, quality of life. Findings - Intervention group increased physical activity more than controls. No differences on clinical measures.
Goldstein et al 1999	Older adults (mean age 65.6 years). Recruited from 24 primary care medical practices.	'Physically Active for Life' RCT. Intervention: Brief, physician delivered counselling, based upon the Transtheoretical Model. (181) Control: Standard care (174).	Outcomes: Physical activity, motivational readiness for physical activity. Assessed baseline, 6weeks and 8 months. Findings- Intervention subjects more likely to be in advanced readiness stage at 6 weeks (89% in preparation or action vs. 74% controls. OR 3.56 , 95% CI 1.79- 7.08, p <.001), but effect not maintained at 8 months. No impact on physical activity.
Munro et al 2000 UK	Older people recruited from 12 general practices. Least active over 65's invited to attend free supervised exercise sessions in community.	RCT community-based program, 2 years duration.	Outcomes: all-cause and exercise related mortality, service use, health status. Findings 26% attended 1 or more session (women, younger, least sedentary). 50% at least 28 sessions. No significant differences in mortality rates or survival times. Trend for fewer declines in health status (sf 36) in intervention group. Cost £70k/yr or average session cost £5. Cost per QALY gain £9807.

Table 4.7: Workplace based interventions

Study	Study participants	Study design	Outcomes
Working Healthy Research Trial. Marcus et al, 1998c US	Eleven worksites. Participants (n = 1559) a subsample of <i>these employees</i> .	Printed self-help exercise promotion materials given baseline and 1 month Intervention: matched to the individual's stage of motivational readiness for exercise adoption (M) Comparison: standard materials (C) <i>903 completed the interventions.</i>	<i>Primary outcomes: Stage of motivational exercise readiness, 7-Day Physical Activity Recall.</i> Assessed baseline and 3 months Findings - M more likely to increase readiness stage (37% vs. 27%); less likely not change (52% vs. 58%) or regress (11% vs. 15%). <i>Changes in stage of readiness significantly associated with changes in self-reported time spent exercising</i>
Working Healthy Project Emmons et al 1999 US	Recruited from 26 manufacturing worksites. 2055 individuals who completed three health-behaviour assessments	Multiple risk factor approach (smoking, nutrition, and physical activity) Randomized matched-pair design	2,761 (53%) completed the baseline assessment and interim survey Findings- At both the interim (intervention midpoint) and final assessments, intervention participants significantly increased their exercise behaviour, compared with the controls. Also increased consumption of fruit, vegetables and fibre in intervention condition at final assessment, compared with the control condition.

Table 4.8: School based interventions

Study	Study participants	Study design	Outcomes
Manios et al 1999 Greece	Recruited from all 4,171 pupils registered in grade 1 in two counties of Crete. 1,510 pupils registered in a third county served as controls.	School-based RCT intervention plus parent seminars to improve diet, fitness and physical activity Intervention (288) Controls (183)	Primary outcome: health knowledge, diet, fitness, and physical activity, anthropometric, and biochemical indices. Assessed at baseline and after 3 years of program Findings – Greater positive serum lipid level changes, health knowledge, physical activity and fitness levels. BMI increased less in intervention group than for controls.
Gortmaker et al 1996 US	6 intervention and 8 matched control schools. Recruited children in grades 4,5. 479 students (91% African American) Yearly cross-sectional surveys of all (2103) grade 5 students. 1995 to '97.	Quasi-experimental (pre-post) design. Intervention: Interdisciplinary health behaviour intervention for diet and physical activity. Education in different subject classes, for families, teachers and other staff.	Outcomes: fat, fruit, vegetable intake, TV viewing duration, activity. Findings - controlling for baseline covariates, % total energy from fats reduced in intervention school students cf controls (-1.4%); p = .04; -0.60%; p = .05). Increase in fruit/vegetable intake (0.36 servings/4184 kJ; p=.01), vitamin C intake (8.8 mg/4184 kJ; p=.01), fiber cons. (0.7 g/4184 kJ; p =.05). Television viewing marginally reduced (-0.55 h/d; 95% CI, -1.04 to 0.04; p=.06).
Gortmaker et al 1998 US	Boys and girls in grades 6 to 8. Recruited from 5 intervention and 5 control schools (1295).	RCT over 2 years. Interdisciplinary intervention. 'Planet Health' sessions incorporated in curricula across 4 subjects. Aimed to decrease television viewing, consumption of high-fat foods, to increase fruit and vegetable intake and moderate and vigorous physical activity	Outcomes: prevalence, incidence, and remission of obesity. Measured using BMI and triceps SKF Findings- Reduced obesity among intervention girls cf controls, controlling for baseline obesity (OR 0.47). No diff. for boys. Greater remission of obesity among intervention girls vs. controls (OR 2.16). Reduced TV hours across sexes. Increased fruit and vegetable consumption, smaller increment in total energy intake in girls. Reductions in TV viewing predicted obesity change and mediated intervention effect. For girls, each hour's reduction in TV viewing predicted reduced obesity prevalence (OR 0.85; 95% CI 0.75-0.97).
Robinson 1999 US	Two elementary schools. Grade 3 and 4 pupils (192)	RCT school based. Intervention aimed to change adiposity, physical activity and dietary intake via reduced TV, video and computer game viewing. Intervention: 18 lesson classroom curriculum over 6-months.	Primary outcome measure: BMI, height, weight, triceps SKF, waist/hip circumferences, cardiorespiratory fitness; self-reported media use, physical activity, diet ; parental report of child & family behaviours. Findings- Interv. children sign. rel. decreases in BMI I: 18.38 to 18.67 vs C: 18.10 to 18.81 adj. diff. -0.45, P = .002), triceps SKF (change: I:14.55 to 15.47 mm vs C:13.97 to 16.46 mm adj. Diff., -1.47 mm, p =.002), waist circumference (change: I 60.48 to 63.57 cm vs C 59.51 to 64.73 cm, adj. diff., -2.30 cm 95% p<.001), waist-to-hip ratio (change: I: 0.83 to 0.83 vs C: 0.82 to 0.84, adj. diff., -0.02, p<.001). Interv. group changes assoc. with sign. decrease in reported TV viewing, meals eaten in front of TV. no sign. group diff. on other outcomes.
Sallis et al 1999 US	<i>Project GRAD. 388 students. 321 completed</i>	RCT Intervention: University course to promote physical activity. Behaviour change skills taught via lectures and peer-led labs. <i>Control: knowledge oriented course</i>	Outcomes: 7-day Physical Activity Recall. Findings- no impact on males. Females increased leisureactivity, strengthening and flexibility exercise. Men more active than women at baseline, so a possible ceiling effect.

Table 4.9: Community based interventions

Study	Study participants	Study design	Outcomes
Sevick et al 2000 US	235 sedentary adults	RCT 'Project Active' Intervention: compared lifestyle (centre-based behavioural skills training) vs. structured exercise (supervised, centre-based) program.	Primary outcomes: cost, cardiorespiratory fitness, physical activity. Findings – Both interventions increased activity and fitness. At 6 months, costs were \$46.53 and \$190.24 per participant/ month respectively. At 24 months, costs were \$17.15 and \$49.31 per participant/ month respectively. At both time points, lifestyle intervention was more cost-effective than the structured intervention for most outcomes measures.
Marcus et al 2001 US	194 sedentary adults recruited through newspaper advertisements.	Motivation-matched intervention with feedback reports Intervention: individually tailored (IT) to psychological variables (from social cognitive theory and the Transtheoretical Model) via computer expert system Control: standard, print-based intervention (ST)	Primary outcomes: physical activity, motivational readiness. Other: Factors that influence physical activity participation (e.g., self-efficacy), affect status. Assessment at baseline, 1, 3, 6 months and 6 months post intervention. Findings- more IT subjects met/ exceeded participation goals and maintained to follow-up. Influenced by intervention and pre-existing psychological factors.

CHAPTER 5: Poor Nutrition

5.1 Poor Nutrition: Intervention Options

At the level of national infrastructure, food councils can bring together governments, the food industry and health professional and consumer groups to identify policies for encouragement of healthy eating. There are a number of intervention settings for promotion of healthy eating. These are summarised in Table 5.1 below.

Infrastructure changes have the potential to be the most effective, and in many ways have been the dominant determinants of change in adverse and beneficial directions. However they are largely unstudiable. Health promotion activities take place in a variety of settings, a number of which have been described and evaluated. Much of the literature on the health effects of nutrition relates to the management of individual clients in primary care or hospital settings. The effect on CHD risk factor clinics in primary care have been evaluated, and in the context of cardiac rehabilitation and management of diabetes, with a large number of weight loss programs evaluated.

Table 5.1: Possible Interventions for Poor Nutrition

Stage Therapy/ Focus	Modality	Intervention Strategy
I PRIMARY PREVENTION		
Infrastructure Modifications		
	Fiscal policy	<ul style="list-style-type: none"> • Government / Food industry / Health service councils • Development of healthy fast-food franchises • Community activity development • Differential GST for fresh and highly-processed foods
Health Promotion		
	Media	<ul style="list-style-type: none"> • Mass media campaigns focussed at general population • Healthy cooking programs
	Retailing	<ul style="list-style-type: none"> • Food labelling. • Food store promotions • Functional food advertising
	Catering	<ul style="list-style-type: none"> • Healthy food education in conjunction with food hygiene training of catering staff
	School based programs	<ul style="list-style-type: none"> • Health promotion programs in schools to develop student self-efficacy / self-control • Development of food and cooking skills in all students
	Workplace policy	<ul style="list-style-type: none"> • Healthy food choices in canteens • Health advice as part of Health & Safety programs
II INTERVENTIONS FOR THOSE WITH RISK FACTOR		
Community based		
	Large scale	<ul style="list-style-type: none"> • Generic Self Help Materials • Healthy eating • Life skills and stress management
	Small scale	<ul style="list-style-type: none"> • Personally tailored computer generated advice • Local cooking clubs promoting healthy eating

Stage Therapy/ Focus	Modality	Intervention Strategy
Clinician - individual		
	Advice from clinicians	<ul style="list-style-type: none"> Brief advice from doctors delivered opportunistically during routine consultations Formal CHD risk factor clinics in general practice
	Psychosocial screening	<ul style="list-style-type: none"> Screening for depression, for social isolation, for poverty
	Advice from other health professionals	<ul style="list-style-type: none"> Individual counselling provided by dietitian High intensity health educator intervention
Group programs	Healthy lifestyle	<ul style="list-style-type: none"> Cooking and food classes Weight-control programs (e.g. Gut-busters) Stress management programs Group counselling from allied health professionals
	Social support	<ul style="list-style-type: none"> Peer-group support and learning circles
Training of health professionals		<ul style="list-style-type: none"> Training of health care professionals in brief intervention methods Training of health care professionals in education principles and practice
Pharmacological		<ul style="list-style-type: none"> Lipid-lowering (Statins) Anti-hypertensive medications Anti-diabetic
III WITH RISK FACTOR AND MORBIDITY		
Management following AMI, cardiac re-vascularisation procedures		<ul style="list-style-type: none"> Cardiac rehabilitation programs Routine secondary prevention screening with coordination of post-discharge prevention management
Management of Type 2 Diabetes		<ul style="list-style-type: none"> Screening for diabetes and complications Comprehensive diabetes education/management
Management of morbid obesity		<ul style="list-style-type: none"> Surgical procedures (e.g. gastric banding) Drugs

5.2 Evidence of Efficacy of Dietary Interventions

Overview

Only a small number of studies have measured effects of dietary change on mortality and disease event rates, (the main studies are listed in Table 5.2). More frequently, studies measure the effect of interventions on dietary intake or clinical parameters, such as CHD risk factors. None-the-less, there is clear evidence of benefit from dietary interventions derived from randomised-controlled trial (RCT) data in which mortality and major disease event rates have been measured (see Table 5.2).

Dietary fat reduction and modification alone: A small number of RCTs were conducted in the 1950s through to the 1970s to examine the effect of dietary fat change alone on mortality and disease rates. The main focus has been on the incidence of coronary heart disease (CHD) event rates. There have been three very small trials in people recovering from heart attacks, and three larger studies in institutionalised subjects (either mental hospital or US Veterans Administration nursing home residents).

Taken individually, these trials do not provide very convincing evidence of benefit because of their small size and relatively small dietary changes. But when combined in a meta-analysis (Truswell 1994) a significant mean reduction in total mortality of 8% and of CHD event rate of 24% was demonstrated.

Diet as a component of multi-factorial interventions: It has been common in the last three decades to include dietary change as components of multi-factorial interventions. A number of large RCTs were conducted to test the efficacy of such interventions, with the beneficial effects of dietary changes deduced by multiple regression analysis. Advised dietary change usually consisted of reduction and modification of fat intake, and sometimes increase in dietary fibre and fresh fruit and vegetables. The trials taken together demonstrate a similar beneficial effect as seen in the diet-alone trials, with the magnitude of the benefit dependent on the magnitude of the dietary change. For example, the Oslo Heart Trial (Hjermann et al 1981) achieved a 47% reduction in CHD events (with 60% of the benefit attributed to dietary change, 20% to smoking cessation and 20% to control of hypertension) following a 13% reduction in blood cholesterol levels due to dietary change. In the MRFIT trial dietary change was less substantial in the intervention group. There was evidence that control group subjects also changed their diets, with the result that no difference in mortality was detected at the end of the trial (MRFIT Research Group 1982). However, four years later a 10% reduction in CHD event rate was observed, possibly due to better persistence of dietary behaviours (MRFIT Research Group 1990). In the WHO European Collaborative Trial of workplace multi-factorial interventions (WHO European Collaborative Group 1986), the same interventions produced large differences in dietary change. These ranged from no change in the British subjects (Rose et al 1983) to substantial changes in the Belgian subjects (Kornitzer et al 1983), and these differences associated with differences in CHD event rate changes.

Mediterranean diet trial: It has been observed that CHD and general mortality rates are lower in Mediterranean countries compared to other Westernised countries, when adjusted for the level of fat in the diet and other known risk factors. It was thus hypothesised that something to do with the general pattern of diet in the Mediterranean countries was having a specific beneficial effect. This was the basis for the Lyon Heart Study in which survivors of heart attacks were managed with specific dietary change to a Mediterranean pattern (specifically a Cretan diet) compared to general fat-lowering dietary advice. A 67% reduction in CHD events was observed as well as reductions in other cardiovascular events (de Lorgeril et al 1999) and also reduction in incidence of cancers (de Lorgeril et al 1998). To date, this is the only RCT of this hypothesis and needs to be repeated. The trial was neither small nor large. If the result were to be repeated in different subjects, it would prove to be one of the most substantial treatment effects available in chronic disease prevention. As it is, the trial results were quite consistent with the observational epidemiology, the dietary change is likely to be culturally appropriate for the majority of Australians, and therefore there is good reason to advocate this as the basis of the standard nutritional health promotion.

In summary, dietary change has been demonstrated to change mortality and specific disease rates in compliant selected populations. The magnitude of the benefits depends on the qualitative nature of the dietary change, and the magnitude of the changes made in the diet. The next question is what specific health promotion interventions are effective at achieving the efficacious dietary change.

Child-based Individual and School Interventions (see Table 5.3)

School programs have been studied in a number of RCTs. Most school interventions are based on social learning theory. The most effective interventions focus on either diet alone or diet and exercise, or if multifactorial they include cholesterol screening with results reported to parents. Most of the school interventions were directed at children aged 8 to 12. The 'CATCH' program (Luepker et al 1996) and the 'Know Your Body' (Bush et al 1989) programs (long-term, randomised, multi-contact interventions) resulted in a decrease in fat intake of between 2 to 3.5% of energy, although blood cholesterol levels were only lowered in the middle-income population. In good quality studies, a more

sustained effect of interventions was associated with longer and more frequent classroom contact. Parental involvement was a feature of many of the more effective school interventions. An added home activity was not found to be effective in the large CATCH program. Smaller studies did show that the addition of a home activity was effective, but this was not sustained or consistent.

Workplace Interventions (see Table 5.4)

Six randomised-controlled trials directed at whole workplace populations were identified. The most effective interventions were focused on changing diet or blood cholesterol rather than a diversity of other lifestyle factors. They also involved individual screening and counselling sessions. Although effective large-scale interventions did not necessarily have to be intensive, they did tend to require re-organisation of the workplace and substantial resources. These interventions represent special cases of primary care intervention, and illustrate the benefits that can be achieved in motivated, relatively effective clients. The European studies (WHO European Collaborative Group 1986) were undertaken as a way of efficiently accessing stable populations of people to receive the intervention. The USA studies (Sorensen et al 1996; Tilley et al 1999; Buller et al 1999) derive their relevance from the responsibility that is placed on employers for healthcare financing (so employers have strong incentives to improve the risk profile of their workforce, thereby reducing their health insurance premiums). In present-day Australia, the less-stable nature of employment, and the reduced responsibility of employers for health matters diminishes the direct relevance of this particular type of intervention.

Primary care interventions (see Table 5.5)

In the UK in the late 1980s and 1990s, a number of studies were performed to determine the impact of nurse-administered health checks in general practices (ICRFOS Group 1995; Cupples et al 1994; Roderick et al 1997; Campbell et al 1998; Steptoe et al 1999). The interventions involved a single health check, take-home materials, brief advice and follow up, and referral to the general practitioner for clients with high blood pressure and cholesterol levels. The rationale for this pattern of care was to provide a low-cost CHD risk reduction intervention to a large proportion of the population by the clients' usually health-care providers. The results showed changes in diet, and a reduction in blood cholesterol of 2 to 3 % in large populations. Studies providing educational materials with minimal personal contact were found to be less effective than those with more intensive interventions from more highly trained staff. In this setting, personalisation of the intervention to individual characteristics enhances its effectiveness. The provision of more intensive intervention for those at increased risk was associated with sustained reductions in blood cholesterol levels. Short-term weight reduction (sustained over one year) of 6kg in overweight people was observed in an Australian population (Pritchard et al 1999) where weight reduction was the focus, and lesser degrees of weight reduction in other groups where dietary change was the main focus (Steptoe et al 1999).

Community interventions (see Table 5.6)

At least four large community intervention projects have been reported, the Stanford Five City Project (Winkleby et al 1996), Heartbeat Wales (Tudor-Smith et al 1998), the North Karelia Project (Puska et al 1985), and the Minnesota Heart Health Project (Winkleby et al 1997). These involved a number of components, including mass advertising messages, local community infrastructure modification, training of food retailers, and local community group development. The focus was usually multiple behavioural risk factor (diet, physical activity, smoking) modification. Long-term community studies showed some changes in diet and physical activity levels, and also reductions in blood cholesterol over time in the intervention groups. The comparison with the control groups depended on whether a change in the control group occurred. Reductions in CHD morbidity were detected in the large studies when this effect was sought. Interpretation of these trials is difficult due in part to lack of a true non-intervention comparison group, the transient nature of community populations, and the

insensitivity of cholesterol measurement to dietary change when this outcome is used to measure the impact of the interventions.

Interventions using Information Technology and Related Media (see Table 5.9)

A number of RCTs have been conducted to determine the effect of dietary advice delivered through information technology and related media. These trials have demonstrated variable but sometimes quite large changes in diet. The technology may be simple, such as the US National Cancer Institute Cancer Information Service telephone help-line run by volunteers providing stereotyped diet advice (Marcus et al 1998a; Marcus et al 1998b; Marcus et al 2001), or quite complex, such as a computer-controlled tailored telephone advice system.

The former demonstrated that a centralised, cheap, low-skill system can have a significant modest impact on people's diet whilst being widely available. The latter demonstrates that people can adapt to the use of an "early-phase" expert system. For example, a central computer can be used to automatically contact registered clients by telephone, and provide interactive tailored nutrition and cooking advice (Delichatsios et al 2001b).

The impact on fruit and vegetable intake was as large as that achieved by dietitian counselling (increase in average of 1.1 serves per client per day), and double that achieved by the same investigators using conventional advice materials. There are several advantages in such systems. They can be integrated into existing primary care delivery arrangements or stand alone as semi-commercial services. They can be made continuously available at times convenient for clients rather than convenient for health professionals and are cheaper the more they are used. The same systems can be made available via the internet, which can deliver much greater information volumes, with greater feedback possibilities. Information can be delivered by fewer people, and can be updated more flexibly and rapidly. The scarce supply of nutritional professional knowledge available for individual direct assessment and counselling can be reserved for clients with more complex and serious problems.

Interventions to Reduce Overweight and Obesity

There appears to be a widespread view that weight reduction interventions are ineffective (Wing et al 2001). This appears to have arisen from definitions of success that have been excessively ambitious (greater than 10% loss for over four years), and a relatively small evidence base. It should be remembered that weight reduction has both health-related (reduction in morbidity and mortality) and social-related ("improved" appearance and social acceptance) goals. Where weight reduction is conducted as part of interventions with specific health-related goals, such as prevention and treatment of type 2 diabetes (Eriksson et al 1999; Pan et al 1997) (see Table 5.7), hypertension or dyslipidaemia more modest weight reduction has been associated with worthwhile reductions in disease and morbidity. The causes of the current "epidemic" of obesity are rooted in unintended consequences of technological and social developments in Westernised societies (French 2001). Thus, modest benefits from interventions targeted at high-risk individuals can be achieved within the constraints of the health service, more comprehensive primary prevention of obesity-related ill-health would require interventions that lie outside the constraints of the present study.

Other Interventions

Supermarket interventions: A large proportion of studies show a beneficial effect on food purchases, but none measure effects beyond the duration of the study and none provide information on total diet content. The most common intervention involved signs at the point-of-choice, although some used video education and feedback on purchases. Three good quality studies used shelf signs supported by brochures and advertising. One study used in-store videos and automated feedback on intended purchases that resulted in a decrease in the fat content of purchases of 4% of energy, which was not sustained at one-month follow-up.

Catering interventions: A large proportion of catering studies showed a beneficial effect of intervention on food choice. Types of intervention methods included promotion of healthier items by signs or stickers, information signs on all foods, changes in the placement and number of healthier items, and reduction in the fat content of food items without customer awareness of the intervention. The promotion of healthier items at the point-of-choice (e.g. signs or stickers) resulted in increased sales of 2 to 12 % of total market share while the interventions were in place. Interventions were rarely carried out for longer than 3 months. Providing nutritional information on all food items was not shown to be effective. One long-term study in which the fat content of meals were unobtrusively changed resulted in a reduction in saturated fat content of 2% of energy over one year.

5.3 Summary of Key Dietary Interventions Studies

Table 5.2: Prevention of Coronary Heart Disease Events and Mortality, and Total Mortality by Dietary Interventions

Study	Participants	Study Design	Outcomes
Morrison 1951	100 patients: recent AMI survivors	Over a 3 yr period, effect of a low cholesterol-low fat diet on mortality and morbidity rates. 50 consecutive patients placed on 20 to 25 Gm. Fat diet, and 50 alternate control patients were observed on the normal pre-thrombosis diet.	It was found that there was a trend toward a reduction in mortality and morbidity rates in coronary atherosclerotic patients on a 20 to 25 Gm. daily cholesterol-fat diet. these studies suggest that a low cholesterol-low fat diet merits further controlled studies for the treatment of coronary atherosclerosis.
Finnish mental hospital study (Turpeinen et al 1979; Miettinen et al 1983)	The subjects were hospitalised middle-aged men and women.	Trial in 2 hospitals nr Helsinki 1959-71. Cross-over alternative controlled design. Aim reduce incidence of CHD through cholesterol-lowering diet. At one hospital, diet low in saturated fats and cholesterol and high in poly-unsaturated fats, the other served as control with a normal hospital diet. Six years later the diets were reversed, and the trial was continued another six years.	The use of the SCL diet was associated with markedly lowered serum cholesterol values. The incidence of CHD, as measured by the appearance of certain ECG patterns and by the occurrence of coronary deaths, was in both hospitals during the SCL-diet periods lower than during the normal-diet periods. The differences, however, failed to reach statistical significance. An examination of a number of potential confounding variables indicated that the changes in them were small and failed to account for the reduction in the incidence of CHD. It is concluded that the use of the serum-cholesterol-lowering diet exerted a substantial preventive effect on CHD.
The Minnesota Coronary Survey (Frantz et al 1989)	It involved 4393 men and 4664 women in six Minnesota state mental hospitals and one nursing home.	4.5-year, open enrolment, double-blind, RCT. The trial compared the effects of a 39% fat control diet (18% saturated fat, 5% polyunsaturated fat, 16% mono-unsaturated fat, 446 mg dietary cholesterol per day) with a 38% fat treatment diet (9% saturated fat, 15% polyunsaturated fat, 14% mono-unsaturated fat, 166 mg dietary cholesterol per day) on serum cholesterol levels and the incidence of myocardial infarctions, sudden deaths, and all-cause mortality. The mean duration of time on the diets was 384 days, with 1568 subjects consuming the diet for over 2 years.	The mean serum cholesterol level in the pre-admission period was 207 mg/dl, falling to 175 mg/dl in the treatment group and 203 mg/dl in the control group. For the entire study population, no differences between the treatment and control groups were observed for cardiovascular events, cardiovascular deaths, or total mortality. A favourable trend for all these end-points occurred in some younger age groups.

Study	Participants	Study Design	Outcomes
WHO European collaborative trial (1986) (Rose et al 1983; Kornitzer et al 1983)	60 881 men employed in 80 factories in Belgium, Italy, Poland, and the UK	In a randomised controlled evaluation of multifactorial prevention of coronary heart disease (CHD)	Intervention was associated with reductions of 10.2% in total CHD, 6.9% in fatal CHD, 14.8% in non-fatal myocardial infarction, and 5.3% in total deaths, with a neutral result for non-CHD deaths. Benefit was significantly related to the extent of risk factor change. The observed reduction in total CHD was 62% of that predicted by means of a multiple logistic function summary of risk factor changes. Advice on risk factor reduction in middle-aged men is effective to the extent that it is accepted, and it appears to be safe.
Rome Project of Coronary Heart Disease Prevention (1986)	6,027 working men ages 40-59; 3,131 in the treatment group and 2,896 in the control group	Primary preventive trial aimed at reduced serum cholesterol (through dietary prescription and in a small number of subjects drug treatment), high blood pressure (by drugs), smoking habits (advice), overweight (diet), and sedentary lifestyle (by increased physical activity). Treatment over a 6-year period. Consisted of individual sessions administered to one-third of higher-risk subjects, while mass education was administered to all men allocated to treatment. No intervention was offered to the control group.	The mean changes in levels of the main coronary risk factors in the treatment vs the control group were computed in different ways. Net changes in the treatment group after 6 years, after adjustment for several confounding variables, were -0.71% for body weight, +0.77% for the cigarette consumption, -3.00% for systolic blood pressure, -5.39% for serum cholesterol, and -18% for the estimated multivariate coronary risk. After 8 years of observation, mortality from all causes was lower by 9.8% (one-tailed P = 0.140) in the treatment than in the control group, whereas mortality from coronary heart disease was lower by 23.7% (one-tailed P = 0.059). The incidence of fatal plus nonfatal coronary heart disease events (hard criteria), which could be measured only for the first 6 years, was reduced by 30.9% (one-tailed P = 0.005) in the treatment as compared with the control group.
Oslo Heart Study (Hjermann et al 1981)	1232 healthy, normotensive men, TC: 7.5-9.8 mmol/l, CHD risk scores upper quartile, SBP < 150 mm Hg, drawn from 16,202 men, 40-49 yrs screened for CHD risk factors.	5-year randomised trial to show whether lowering of serum lipids and cessation of smoking could reduce the incidence of CHD. The men in the intervention group were recommended to lower their blood lipids by change of diet and to stop smoking.	Mean serum cholesterol concentrations ~13% lower in intervention group than control group during the trial. Mean fasting serum triglycerides fell by 20% in the intervention group cf controls. 80% of men in both groups smoked daily at study start. Mean tobacco consumption decreased by 45% more in the intervention group than in the control. 25% of smokers in the intervention group stopped smoking cf 17% in the control. At the end of the observation period the incidence of myocardial infarction (MI) (fatal and non-fatal) and sudden death was 47% lower in the intervention group than in the controls (p = 0.028, two-tailed log rank test). When the incidence of strokes was added, the difference between the groups was still significant. Conclusion: in healthy middle-aged men at high risk of CHD, advice to change eating habits and stop smoking significantly reduced the incidence of the first event of MI and sudden death. Endpoints were correlated with reduction in total cholesterol and to a lesser extent smoking reduction.

Study	Participants	Study Design	Outcomes
Multiple Risk Factor Intervention Trial (1982; 1990)	12,866 high-risk men aged 35 to 57 years	A randomized primary prevention trial to test the effect of a multifactor intervention on mortality from CHD. Men randomly assigned either to a special intervention (SI) program of stepped-care treatment for hypertension, counseling for cigarette smoking, diet advice for lowering blood cholesterol levels, or to their usual sources of health care in the community (UC)..	Mean follow-up 7 yrs, risk factor levels declined in both groups, but to a greater degree for the SI men. Mortality from CHD 17.9 deaths/1,000 in SI group and 19.3/1,000 in UC group, statistically nonsignificant difference of 7.1%. Total mortality rates 41.2/1,000 (SI) and 40.4/1,000 (UC). Possible explanations for findings: (1) intervention program did not affect CHD mortality; (2) intervention does affect CHD mortality, but benefits not observed in seven years' average duration, (3) measures to reduce cigarette smoking and lower blood cholesterol may have reduced CHD mortality within subgroups of the SI cohort, but possible unfavorable response to antihypertensive drug therapy in some hypertensive subjects. Last possibility considered most likely, but needs further investigation. During the post trial years, death rates were lower for SI than for UC men by 26% ($p = 0.09$) for CHD and 23% ($p = 0.02$) for all causes.
Lyon Diet Heart (de Lorgeril et al 1998; de Lorgeril et al 1999)	605 patients with coronary heart disease	A randomised secondary prevention trial aimed at testing whether a Mediterranean-type diet may reduce the rate of recurrence after a first myocardial infarction. This report presents results of an extended follow-up (with a mean of 46 months per patient) and deals with the relationships of dietary patterns and traditional risk factors with recurrence.	In the Mediterranean diet group, CO 1 was reduced (14 events versus 44 in the prudent Western-type diet group, $P=0.0001$), as were CO 2 (27 events versus 90, $P=0.0001$) and CO 3 (95 events versus 180, $P=0.0002$). Adjusted risk ratios ranged from 0.28 to 0.53. Among the traditional risk factors, total cholesterol (1 mmol/L being associated with an increased risk of 18% to 28%), systolic blood pressure (1 mm Hg being associated with an increased risk of 1% to 2%), leukocyte count (adjusted risk ratios ranging from 1.64 to 2.86 with count $>9 \times 10^9/L$), female sex (adjusted risk ratios, 0.27 to 0.46), and aspirin use (adjusted risk ratios, 0.59 to 0.82) were each significantly and independently associated with recurrence. During a follow-up of 4 years, there were a total of 38 deaths (24 in controls vs 14 in the experimental group), including 25 cardiac deaths (19 vs 6) and 7 cancer deaths (4 vs 3), and 24 cancers (17 vs 7).
Diet and Reinfarction Trial (Burr et al 1989)	2033 men who had recovered from MI	A randomised controlled trial with a factorial design to examine the effects of dietary intervention in the secondary prevention of myocardial infarction (MI). Subjects were allocated to receive or not to receive advice on each of three dietary factors: a reduction in fat intake and an increase in the ratio of polyunsaturated to saturated fat, an increase in fatty fish intake, and an increase in cereal fibre intake.	The advice on fat was not associated with any difference in mortality, perhaps because it produced only a small reduction (3-4%) in serum cholesterol. The subjects advised to eat fatty fish had a 29% reduction in 2 year all-cause mortality compared with those not so advised. This effect, which was significant, was not altered by adjusting for ten potential confounding factors. Subjects given fibre advice had a slightly higher mortality than other subjects (not significant). The 2 year incidence of reinfarction plus death from ischaemic heart disease was not significantly affected by any of the dietary regimens. A modest intake of fatty fish (two or three portions per week) may reduce mortality in men who have recovered from MI.

Study	Participants	Study Design	Outcomes
Indian Experiment of Infarct Survival (Singh et al 1996)	480 patients either with CAD or with risk factors. India – urban setting	To test whether a fat modified, fruit and vegetable enriched diet, with moderate physical activity reduces cardiac events in patients with coronary artery disease (CAD) and its risk. Those with definite or possible CAD including angina pectoris (n = 210) based on WHO criteria and patients with risk factors were assigned to diet A (n = 231) or diet B (n = 232) for a period of 3 years. Both groups were advised to follow a fat modified diet. Group A was also advised to consume at least 400 g/day of fruits, vegetables and legumes according to WHO advice and include moderate physical activity.	Waist-hip ratios, fasting and post-prandial blood glucose, plasma insulin levels, blood pressure and weight fell significantly in patients in group A compared with those in group B. While triglycerides in group A showed a significant decrease, high density lipoprotein cholesterol showed a significant increase. Both groups showed a significant reduction in total and low density lipoprotein cholesterol, although the decrease was greater in group A than group B. Central obesity decreased by 6.2% in group A vs. 1.2% in group B, 95% confidence interval of difference 2.3 to 7.8. The incidence of cardiac events was significantly lower in group A than group B (29 vs. 43 patients, p < 0.01). All-cause mortality also significantly declined in group A compared with group B (16 vs. 24 died, p < 0.05). The group A patients with better adherence to exercise and diet showed greater reduction in central obesity and greater decline in cardiac event rates and total mortality compared to control group B. It is possible that moderate physical activity in conjunction with dietary changes in patients with CAD may cause substantial reductions in central obesity and associated disturbances corresponding to a significant decrease in cardiac events and mortality during the follow-up of
Linxian Trials (Mark et al 1996)	3,318 men and women from a region in rural China	3,318 persons were randomised to receive daily either a multiple vitamin/mineral supplement or a placebo. Deaths were classified according to cause over the 6-year period from 1985 to 1991. At the end of supplementation, blood pressure readings were taken, and the prevalence of hypertension was determined.	There was a slight reduction in overall mortality in the supplement group (relative risk (RR) = 0.93, (95% CI 0.75-1.16), the decreased relative risk most pronounced for cerebrovascular deaths (RR = 0.63, 95% CI 0.37-1.07). Benefit greater for men (RR = 0.42, 95% CI 0.19-0.93) than for women (RR = 0.93, 95% CI 0.44-1.98). In survivors, high systolic and diastolic blood pressures was less common in those who received the supplement (RR for men = 0.43; RR for women = 0.92,). The study indicates that supplementation with a multivitamin/mineral combination may reduce deaths from cerebrovascular disease and prevalence of hypertension in a rural Chinese population with a micronutrient-poor diet.

Table 5.3: Prevention of Development of Coronary Heart Disease Risk Factors in Children by Dietary Interventions

Study	Participants	Study Design	Outcomes
Special Turku Coronary Risk Factor Intervention Project (Rasanen et al 2001; Tammi et al 2000)	1062 infants were randomised at 7 months of age into an intervention group (n = 540) or a control group (n = 522)	RCT: Repeated, individualized counselling to reduce fat intake and a 1:1:1 ratio of saturated to mono-unsaturated to polyunsaturated fat. Brief nutrition discussion with families of the control children. Children's food intake was evaluated using scores that reflected quality and quantity of fat and salt in 4-day food diaries recorded between 5.5 and 7 y of age.	Children's knowledge of heart-healthy foods (intervention 42.6% vs control 34.9% correct answers, P = 0.057). The food diaries comprised more foods low in saturated fat and high in unsaturated fat (intervention 57.1% vs control 41.7% of the maximum score for low fat foods, P = 0.0001; 48.9% vs 37.7% for high unsaturated fat foods, P = 0.0009, respectively), but the intervention and control children consumed similar amounts of low-salt foods (P = 0.23). Nutrition knowledge and food use scores correlated poorly (r = -0.20-0.35). Serum cholesterol, non-HDL cholesterol, and HDL-cholesterol concentrations were 3-6% lower in the intervention children than in the control children. The intervention had no effect on height, weight, or head circumference gain. Fat intake did not predict children's growth patterns.
The Child and Adolescent Trial for Cardiovascular Health. CATCH collaborative group (Luepker et al 1996)	A total of 5106 initially third-grade students from ethnically diverse backgrounds in public schools located in California, Louisiana, Minnesota, and Texas.	A randomised, controlled field trial at four sites with 56 intervention and 40 control elementary schools. Outcomes were assessed using prerandomisation measures (fall 1991) and follow-up measures (spring 1994). Twenty-eight schools participated in a third-grade through fifth-grade intervention including school food service modifications, enhanced physical education (PE), and classroom health curricula. Twenty-eight additional schools received these components plus family education.	In intervention school lunches, the percentage of energy intake from fat fell significantly more (from 38.7% to 31.9%) than in control lunches (from 38.9% to 36.2%)(P<.001). The intensity of physical activity in PE classes during the Child and Adolescent Trial for Cardiovascular Health (CATCH) intervention increased significantly in the intervention schools compared with the control schools (P<.02). Self-reported daily energy intake from fat among students in the intervention schools was significantly reduced (from 32.7% to 30.3%) compared with that among students in the control schools (from 32.6% to 32.2%)(P<.001). Intervention students reported significantly more daily vigorous activity than controls (58.6 minutes vs 46.5 minutes; P<.003). Blood pressure, body size, and cholesterol measures did not differ significantly between treatment groups. No evidence of deleterious effects of this intervention on growth or development was observed.
"Know Your Body" (Bush et al 1989)	1,234 black students in the District of Columbia, who were in grades 4-6 at baseline	A five-year RCT intervention study of the effectiveness of the "Know Your Body" program in reducing coronary heart disease risk factors. The "Know Your Body" curriculum focuses on nutrition, fitness, and the prevention of cigarette smoking.	After two years of intervention, results indicated that the program may have had a favourable impact on the following risk factors: systolic and diastolic pressures, HDL cholesterol, ratio of total to HDL cholesterol, fitness (postexercise pulse recovery rate), and smoking. Significant net changes in the favourable direction also were found for health knowledge and attitude toward smoking. Blood pressure reduction was associated with decreased ponderosity and improved fitness, and increased HDL cholesterol was associated with decreased ponderosity. These results are consistent with other evaluations of the "Know Your Body" program, suggesting that the program may be effective in reducing chronic disease risk in diverse school populations.

Study	Participants	Study Design	Outcomes
Killen et al 1988	All tenth graders in four senior high schools (N = 1447) from two school districts participated in a cardiovascular disease risk-reduction trial.	Within each district, one school was assigned at random to receive a special 20-session risk-reduction intervention and one school served as a control.	At a 2-month follow-up, risk factor knowledge scores significantly greater for students in treatment group. Cf controls, higher % of those in the treatment group not exercising regularly at baseline reported regular exercise at follow-up. Almost twice as many baseline experimental smokers in treatment group reported quitting at follow-up, only 5.6% of baseline experimental smokers in treatment group graduated to regular smoking cf 10.3% in control. Students in the treatment group more likely to report they would choose "heart-healthy" snack. Beneficial treatment effects were observed for resting heart rate, BMI, skin fold thickness. Results suggest it is feasible to reduce CVD risk through school-based primary prevention approaches.
Gore et al 1996 South Australia	12 priority-project schools: 736 students. Ea school allocated to control or to intervention.	Body owner's Manual (BOM) healthy life style programs for teachers and school-canteen interventions (BOM+) over two school years in socially disadvantaged primary schools.	In contrast to the findings of the earlier South Australian trials, no statistically-significant changes in aerobic fitness, body fatness or HDL cholesterol; there were significant reductions in diastolic blood pressure, total cholesterol and triglyceride concentration for those in the BOM+ schools. There were significant increases in health and nutrition knowledge for the BOM+ schools, and in health knowledge for the BOM schools.
The Cardiovascular Health in Children (CHIC) study (Harrell et al 1996)	12 schools across North Carolina, stratified by geographic region urban/rural setting. 1274 third and fourth graders (48% boys)	Randomized, controlled field trial: the intervention, taught by regular classroom and physical education teachers, provided all children an 8-week exercise program and 8 weeks of classes on nutrition and smoking.	Children in the intervention group had significantly greater knowledge (7.9% more correct) and a significant increase in self-reported physical activity than children in the control group. Trends for the intervention group were a reduction in total cholesterol level (-5.27 mg/dl), an increase in aerobic power, a reduction in body fat, and smaller rise in diastolic blood pressure than control children. CONCLUSIONS: This classroom-based, public health approach improved children's cardiovascular disease risk profiles; it is practical and fairly easy to incorporate into the school day. All children directly receive the potential benefits of the intervention without a risk of labelling. This program can improve health knowledge, habits, and health outcomes of young children at a time when health habits are being formed.

Study	Participants	Study Design	Outcomes
Burke et al 1998	800 11-year-olds Cluster analysis identifying the 29% or so highest risk children used systolic blood pressure, percent body fat, physical fitness, and blood cholesterol.	Randomized controlled trial with the standard physical activity and nutrition program in six schools, the standard program in a further seven schools but with the addition of physical activity enrichment for higher risk children in those schools, and no program in five control schools.	Fitness improved significantly in program schools, particularly with enrichment in higher risk boys. Substantial improvements persisted 6 months later in girls from program schools. At "Enrichment" schools, cholesterol showed significant benefits in higher risk girls and, 6 months later, in both boys and higher risk girls. Sodium intake and, in girls, subscapular skinfolds were lower in "Enrichment" schools when the program ended, but not 6 months later. CONCLUSION: Two-semester health programs with physical activity enrichment for higher risk children can produce benefits sustained for at least 6 months. Improvements extend to lower risk children exposed indirectly to the enrichment. Attenuation of effects on diet and body composition in the longer-term suggest the need for on-going programs.

Table 5.4: Control of Coronary Heart Disease Risk Factors in Workplace Settings by Dietary Interventions

Study	Participants	Study Design	Outcomes
Working Well Trial (Sorensen et al 1996)	The study was conducted in 111 work sites (n = 28,000 workers).	Randomized, matched-pair evaluation design, with the work site as the unit of assignment and analysis. The effects of the intervention were evaluated by comparing changes in intervention and control work sites, as measured in cross-sectional surveys at baseline and follow-up. The 2-year intervention targeted both individuals and the work-site environment.	There occurred a net reduction in the percentage of energy obtained from fat consumption of 0.37 percentage points (P = .033), a net increase in fibre densities of 0.13 g/1000 kcal (P = .056), and an average increase in fruit and vegetable intake of 0.18 servings per day (P = .0001). Changes in tobacco use were in the desired direction but were not significant. CONCLUSIONS. Significant but small differences were observed for nutrition. Positive trends, but no significant results, were observed in trial-wide smoking outcomes. The observed net differences were small owing to the substantial secular changes in target behaviours.
Next Step Trial (Tilley et al 1999)	Twenty-eight worksites (5,042 employees at baseline)	RCT 2-year nutrition intervention: classes, mailed self-help materials, personalised dietary feedback. Control worksites no intervention. Nutrition outcomes assessed by mailed FFQs. Outcomes incl. % energy from fat and fibre density (g/1,000 kcal) at 1 year, servings of fruits/vegetables, other dietary measures at 2 years.	At 1 year, there were modest but statistically significant intervention effects for fat (-0.9 %en), fibre (+0.5 g/1,000 kcal), and fruits/vegetables (+0.2 servings/day) (all P < 0.007). At 2 years, due to significant positive changes in control worksites, intervention effects were smaller, significant for fibre only. Intervention effects were larger in younger (<50 years), active employees and class attendees. CONCLUSION: The nutrition intervention produced significant but modest effects on dietary fat and fibre and fruits/vegetables in these high-risk employees. Age and dose effects suggest younger employees may be more responsive to this intervention.
Buller et al 1999	Employees (n = 2091). Ninety-three social networks (cliques) of employees were identified, which were pair matched on intake.	RCT of peer education to test for increase in fruit and vegetable intake in lower socioeconomic, multicultural labour and trade employees. 18-month intervention through standard communication channels (e.g., workplace mail, cafeteria promotions, and speakers). Employees who were central in the communication flow of the peer intervention cliques served as peer educators during the last 9 months of the program.	By use of multiple regression, statistically significant overall effects of the peer education program were seen in the intake recall (increase of 0.77 total daily servings; P<.0001) and the food-frequency (increase of 0.46 total daily servings; P = .002) questions at the outcome survey. The effect on the total number of servings persisted at the 6-month follow-up survey when measured by the intake recall (increase of 0.41 total daily servings; P = .034) but not the food-frequency (decrease of 0.04 total daily servings; P = .743) questions. CONCLUSIONS: Peer education appears to be an effective means of achieving an increase in fruit and vegetable intake among lower socioeconomic, multicultural adult employees.
World Health Organization European Collaborative Group Trial (1986)	60 881 men employed in 80 factories in Belgium, Italy, Poland, and the UK	In a randomised controlled evaluation of multifactorial prevention of coronary heart disease (CHD)	Intervention was associated with reductions of 10.2% in total CHD, 6.9% in fatal CHD, 14.8% in non-fatal myocardial infarction, and 5.3% in total deaths, with a neutral result for non-CHD deaths. Benefit was significantly related to the extent of risk factor change. The observed reduction in total CHD was 62% of that predicted by means of a multiple logistic function summary of risk factor changes. Advice on risk factor reduction in middle-aged men is effective to the extent that it is accepted and it appears to be safe.

Study	Participants	Study Design	Outcomes
Bruno et al 1983	Employees at the New York Telephone Company corporate headquarters	Treatment consisted of an 8-week group cholesterol reduction program comprising a multiple-treatment approach--food behaviour change techniques combined with nutrition education, physical activity planning, and self-management skills. The treatment group showed substantial change compared with the control group at the program's completion.	Those treated displayed a significant 6.4% reduction in total serum cholesterol (266 mg% average at baseline) as compared with control subjects with a corresponding decrease in high-density lipoprotein levels. A significant increase in nutrition knowledge and moderate weight loss were also documented for this group. The magnitudes of a participant's baseline serum cholesterol level and his/her reduction in percentage of ideal body weight were positively and independently correlated with percentage changes in serum cholesterol levels. Over the same period, decreases in high-density lipoprotein levels and no changes in serum cholesterol, weight, and nutrition knowledge were observed for the control group. Overall, participants in the treatment program successfully reduced the coronary heart disease risk factors of elevated cholesterol and weight. Directions for future study are suggested.
Sasaki et al 2000	186 men at high risk of coronary heart disease (i.e., high cholesterol, hyperglycemia, and/or overweight).	We examined how dietary habits (i.e., intake of nutrients and food groups) were changed by intervention and how once adopted diets were maintained thereafter using the data of a 12-wk worksite dietary intervention trial. The intervention method was a brief individual counselling based on the results of a pre-intervention assessment and a weekly distribution of newsletters. At the pre- and post-intervention points, a control group selected from the workers was used for comparison.	The Keys score, and the changes in intake of saturated fatty acids (SFA), monounsaturated fatty acid, total fat, and cholesterol (the decrease), as well as dietary fibre, potassium, calcium, and iron (the increase) were significantly different between the intervention (n = 63) and control (n = 123) groups (p < 0.05). The changes were almost maintained with little recidivism at the 1 y follow-up point in the intervention group (i.e., for the decrease in SFA and Keys score, p < 0.001). The decrease in serum cholesterol level expected from the change in Keys score and body weight, taking possible regression to the mean into consideration, was almost identical to and slightly greater than (18%) those observed at the post-intervention and 1 y follow-up points, respectively. The results suggest that the favourable changes in dietary habits adopted during an intervention period were almost maintained for the subsequent 1 y period.

Table 5.5: Control of Coronary Heart Disease Risk Factors in Primary Care by Dietary Interventions

Study	Participants	Study Design	Outcomes
Cupples et al 1994	18 Belfast GPs: 688 patients aged < 75 years and with angina for at least six months	Randomised controlled trial of personal health education given every four months. 342 randomised to receive education and 346 to no education.	Outcomes - Restriction of everyday activities, diet, smoking, exercise; BP, BMI, total cholesterol at trial entry and after two years. Results - 317 in the intervention group and 300 in the control group completed the trial. At 2-year review more intervention group (140, 44%) reported daily physical exercise cf control group (70, 24%). Intervention also reported a healthier diet cf control and less restriction by angina in everyday activity. No significant differences between the groups in smoking, BP, cholesterol, or BMI.
Pritchard et al 1999	75 men, 198 women. 25-65 with 1+ of: o'weight, high BP, type 2 diabetes. Most in the lower two SEI quartiles.	RCTI. Consecutive patients randomly allocated to one of two intervention groups (doctor/dietitian or dietitian) or a control group. Both intervention groups received six counselling sessions over 12 months from a dietitian. University group general practice setting in a lower SEI outer suburb of Perth, WA.	Both intervention groups reduced weight and blood pressure compared with the control group. Patients in the doctor/dietitian group were more likely to complete the 12 month program than those in the dietitian group. Patients in the doctor/dietitian group lost an average of 6.7 kg at a cost of \$A9.76 per kilogram, while the dietitian group lost 5.6 kg at a cost of \$A7.30 per kilogram.
Roderick et al 1997 England and Wales	473 in 'dietary advice' practices and 483 in 'usual care' practices aged 35-59, recruited by GPs opportunistically.	RCT 8 matched pairs of Gen Practices. 'Dietary advice' practices, subjects given dietary advice from specially trained nurses based on negotiated change principles, reinforced at follow up. In 'usual care' practices, subjects given standard health education materials.	Compared with 'usual care' practices, there was a mean 0.20 mmol/l lower serum cholesterol (95% CI -0.38 to -0.03 at 1 year) in 'dietary advice' practices. There was a small fall in weight of 0.56 kg (95% CI -1.04 to -0.07) and reductions in total and saturated fat. Factor VII coagulant activity fell by a mean of 6.7% of the standard (95% CI -15.4 to +2.0). Compliance with annual follow up was 80%.
Campbell et al 1998	19 random GPs in NE Scotland. 685 men, 488 women < 80 yrs with CHD, w/o terminal illness or dementia and not housebound.	Nurse run clinics promoted medical and lifestyle aspects of secondary prevention with regular follow up. At baseline and 1 year measured aspirin use, BP management; lipid management; physical activity, dietary fat; and smoking status.	There were significant improvements in aspirin management (odds ratio 3.22, 95% confidence interval 2.15 to 4.80), blood pressure management (5.32, 3.01 to 9.41), lipid management (3.19, 2.39 to 4.26), physical activity (1.67, 1.23 to 2.26) and diet (1.47, 1.10 to 1.96). There was no effect on smoking cessation (0.78, 0.47 to 1.28). Of six possible components of secondary prevention, the baseline mean was 3.27. The adjusted mean improvement attributable to intervention was 0.55 of a component (0.44 to 0.67). Improvement was found regardless of practice baseline performance.
Meland et al 1997	110 men with high coronary heart disease risk	Risk factor changes were evaluated in 22 participating general practice centres were randomly allocated to follow either a patient-centred, self-directive intervention or a conventional approach.	No significant between-group differences were found in any single risk factor or in the combined risk of coronary heart disease. The improvement of total risk from screening time to conclusion of the study corresponded with changes of relative risks of CHD to 0.64 (95% CI: 0.54-0.77) and 0.65 (0.54-0.77) in the patient-centred, self-directive and the conventional care group respectively (p < 0.0001 in both groups).

Study	Participants	Study Design	Outcomes
Nijmegen Family Practice Monitoring Project (Bakx et al 1997)	1337 patients with hypertension or a family history of premature cardiovascular disease.	In the intervention group, 840 patients were given health education every 2 mo by trained practice nurses for 1 y. There were 497 patients with similar coronary risk factors in the control group, who received usual care.	One year after intervention significant decrease in serum cholesterol and BP in the intervention group. At 1995 reexaminations, no sign. differences in coronary risk factors between the two groups. BP had come down, more in the control group, and the % smokers had decreased equally in both groups. No sign differences in intake of dietary fat or in type of fat. Lack of difference still found when the groups were divided into those with serum cholesterol > and < 6.5 mmol/L. It was found that those in stage 5 (desired changes in behaviour) had the lowest saturated fat intake. Since 1977 both groups have been treated equally if hypertension was diagnosed. The two groups were not managed differently with regard to dietary advice after 1977.
OXCHECK (ICRFOS Group 1995)	Five urban general practices in Bedfordshire, UK. 2205 men and women aged 35-64 were randomly allocated in 1989-90	Randomised controlled trial of health checks, performed by primary care nurses, in reducing risk factors for cardiovascular disease and cancer. Outcome measures: Serum total cholesterol, BP, BMI, and smoking prevalence (with biochemical validation); self reported dietary, exercise, and alcohol habits.	Mean serum total cholesterol was 3.1% lower in the intervention group than controls (difference 0.19 mmol/l (95% CI 0.12 to 0.26)); in women it was 4.5% lower (P < 0.0001) and in men 1.6% (P < 0.05). Self reported saturated fat intake was also lower in the intervention group. Systolic and diastolic BP and BMI were respectively 1.9%, 1.9%, and 1.4% lower in the intervention group (P < 0.005). There was a 3.9% (2.4 to 5.3) difference in % of subjects with a cholesterol concentration > or = 8 mmol/l, but no differences in the number with diastolic BP > or = 100 or BMI > or = 30. There was no difference between the two groups in smoking or excessive alcohol use. Annual rechecks were no more effective than a single recheck at three years, but health checks led to more visits to the nurse according to patients' degree of cardiovascular risk.
CELL Study (Lindholm et al 1995)	681 subjects aged 30-59 years, with at least two cardiovascular risk factors in addition to moderately high lipid levels	Prospective, randomised controlled clinical study of "intensive" health care advice through six group sessions, compared with the advice usually offered to subjects with multiple risk factors for cardiovascular disease lasting 18 months.	MAIN OUTCOME MEASURE--Percentage reduction in total cholesterol (target 15%); In the group receiving intensive health care advice total cholesterol decreased by 0.15 mmol/l more (95% CI 0.04 to 0.26) than in the group receiving usual advice. The overall Framingham risk dropped by 0.068 more (0.014 to 0.095) in the intensive advice group, and most of the risk factors showed a greater change in a favourable direction in this group than in the usual advice group, but the differences were seldom significant. The results from questionnaires completed at the group sessions showed that the subjects improved their lifestyle and diet.
Stephoe et al 1999	883 men and women with one or more risk factors: smoking; high TC; and high BMI (25-35) with low exercise.	Cluster randomised controlled trial. Brief behavioural counselling, on the basis of the stage of change model, carried out by practice nurses to reduce smoking and dietary fat intake and to increase regular physical activity.	MAIN OUTCOME MEASURES: Questionnaire measures of diet, exercise, and smoking habits, and BP, serum total cholesterol, weight, BMI, and smoking cessation (with biochemical validation) at 4 and 12 months. Favourable differences were recorded in the intervention group for dietary fat intake, regular exercise, and cigarettes smoked per day at 4 and 12 months. Systolic blood pressure was reduced to a greater extent in the intervention group at 4 but not at 12 months. No differences were found between groups in changes in total serum cholesterol, weight, BMI, diastolic BP, or smoking cessation.

Table 5.6: Control of Coronary Heart Disease Risk Factors in Community Settings by Dietary Interventions

Study	Participants	Study Design	Outcomes
Heartbeat Wales program (Tudor-Smith et al 1998)	Random, stratified samples of people 18-64 yrs (18,538 in 1985 and 13,045 in 1990) in Wales and in north east England (1483 and 4534, respectively).	Quasi-experimental design comparing results from two independent cross sectional population surveys conducted in 1985 and 1990 in Wales and matched reference area in NE England. Activities for heart health promotion in Wales entailed public education campaigns plus supportive policy and infrastructure change. In reference area no additional community heart health promotion.	MAIN OUTCOME MEASURES: Fifteen self reported behavioural indicators relating to dietary choice, smoking, frequency of exercise, and weight. Positive changes (for health) in behavioural outcomes were observed among the population in Wales, including a reduction in reported smoking prevalence and improvements in dietary choice. There was no net intervention effect for the program over and above observed change in the reference area. CONCLUSIONS: No definite conclusions can be drawn concerning the efficacy of the program in terms of behavioural outcomes since considerable health promotion activity did take place in the reference area. With hindsight, the difficulties of evaluating such a complex multifaceted intervention were underestimated. Further debate on the most appropriate methods for assessing the effectiveness of community based health promotion programs is called for.
Hoffmeister et al 1996	Three independent samples of the intervention three and three control regions in West German.	Community-oriented prevention program for CHD over 7-yr period. In intervention regions, CHD prevention activities were performed with special emphasis on healthy nutrition, increased physical activity, smoking cessation, HT, and lipid lowering.	In the pooled intervention regions, a net reduction in mean values of systolic (-2.0%) and diastolic (-2.0%) blood pressure, total serum cholesterol (-1.8%), as well as the percentage of smokers (- 6.7%) was observed compared with the nationwide trend. From the major CHD risk factors, only body mass index was not influenced in the intervention population. CONCLUSIONS. The community- oriented German Cardiovascular Prevention program can effectively be used to reduce CHD risk factors in a broad population
Reid et al 1995	1131 screened men and women from a community with low socioeconomic status in suburban Melbourne.	164 individuals at moderate risk of CHD participated in a RCT comparing two simple cardiovascular risk reduction interventions. Group A participated in a single group counselling session lasting between 1.5 and 2.0 h. Group B received brief written information concerning risk-factor modification. Both groups were assessed for risk factors 3 and 6 months after entry.	There were no significant difference in the change in risk-factor levels between those receiving information pamphlets and those attending the group counselling session after 3 or 6 months of follow-up. Small but significant decreases ($P < 0.05$) were seen in systolic and diastolic blood pressures (-5/4 mmHg for group A, -5/3 mmHg for group B), total plasma cholesterol level (-0.30 mmol/l for groups A and B) and overall coronary risk score (-14.4 and -13.9 for groups A and B, respectively). Body weight remained unchanged during the study period in both groups. CONCLUSION: Screening together with 1.5-2h group counselling had no more influence on cardiovascular risk factors than screening together with provision of information pamphlets in a population with low socioeconomic status.
Stanford Three Cities Project (Farquhar et al 1977)	Residents of three northern California towns: two intervention, one control	In 2 communities there were extensive 2-year mass-media campaigns, and in one, face-to-face counselling was also provided for a small subset of high-risk people. Sample assessment at 0, 1 and 2 years (diet, smoking, BP, relative weight, cholesterol).	In the control community the risk of cardiovascular disease increased over the two years but in the treatment communities there was a substantial and sustained decrease in risk. Initial effect in the community with face-to-face counselling was greater and health education was more successful in reducing cigarette smoking, but at 2 years the effect was similar in both treatment communities. These results strongly suggest that mass-media education campaigns directed at entire communities may be very effective in reducing the risk of cardiovascular disease.

Study	Participants	Study Design	Outcomes
North Karelia project (Puska et al 1985; Puska et al 1983; Salonen et al 1989)	Comprehensive community programme to control cardiovascular diseases in North Karelia, Finland, from 1972.	Comparison of an intervention county (North Karelia) and an adjacent control county. The effect of the programme during 1972-82 was evaluated by examining independent random population samples at the outset (1972) and five (1977) and 10 (1982) years later both in the programme and in a matched reference area. Over 10 000 subjects were studied in 1972 and 1977 and roughly 8000 subjects in 1982.	Main outcome measures: Reductions in smoking, serum cholesterol concentrations, and blood pressure: total mortality and CHD event rate and mortality. The effect of the programme (net reduction in North Karelia) at 10 years among the middle aged male population: 28% reduction in smoking, 3% reduction in mean serum cholesterol level, 3% fall in mean systolic BP, and 1% fall in mean diastolic BP. Among the female population the reductions were respectively, 14%, 1%, 5%, and 2%. During the first five years of the project (1972-7) the programme effectively reduced the population mean values of the major coronary risk factors. At 10 years the effects had persisted for serum cholesterol concentrations and blood pressure and were increased for smoking. There was a 20% decline in the CHD mortality rates in both populations, attributable to either physiological or lifestyle risk factor change in the first 5 years.

Table 5.7: Primary Prevention of Diabetes

Study	Participants	Study Design	Outcomes
Diabetes Prevention Study. (Eriksson et al 1999)	523 overweight subjects with impaired glucose tolerance ascertained by two oral glucose tolerance tests	RCT. Intervention subjects had seven sessions with a nutritionist during the first year and a visit every 3 months thereafter aimed at reducing weight, the intake of saturated fat and increasing the intake of dietary fibre. Intervention subjects also guided to increase their physical activity.	During the first year, weight loss in the first 212 study subjects was 4.7 +/- 5.5 vs 0.9 +/- 4.1 kg in the intervention and control group, respectively (p < 0.001). The plasma glucose concentrations (fasting: 5.9 +/- 0.7 vs 6.4 +/- 0.8 mmol/l, p < 0.001; and 2-h 7.8 +/- 1.8 vs 8.5 +/- 2.3 mmol/l, p < 0.05) were significantly lower in the intervention group after the first year of intervention. Favourable changes were also found in blood pressure, serum lipids and anthropometric indices in the intervention group. CONCLUSION/INTERPRETATION: The interim results show the efficacy and feasibility of the lifestyle intervention program.
Da Qing IGT and Diabetes Study (Pan et al 1997)	110,660 men and women from 33 health care clinics in the city of Da Qing, China, screened for IGT and NIDDM. 577 were classified (using WHO criteria) as having IGT	Subjects were randomised by clinic into a clinical trial, either to a control group or to one of three active treatment groups: diet only, exercise only, or diet plus exercise. Follow-up evaluation examinations were conducted at 2-year intervals over a 6-year period to identify subjects who developed NIDDM. Cox's proportional hazard analysis was used to determine if the incidence of NIDDM varied by treatment assignment.	The cumulative incidence of diabetes at 6 years was 67.7% (95% CI, 59.8-75.2) in the control group compared with 43.8% (95% CI, 35.5-52.3) in the diet group, 41.1% (95% CI, 33.4-49.4) in the exercise group, and 46.0% (95% CI, 37.3-54.7) in the diet-plus-exercise group (P < 0.05). When analysed by clinic, each of the active intervention groups differed significantly from the control clinics (P < 0.05). The relative decrease in rate of development of diabetes in the active treatment groups was similar when subjects were stratified as lean or overweight (BMI < or = 25 kg/m2). In a proportional hazards analysis adjusted for differences in baseline BMI and fasting glucose, the diet, exercise, and diet-plus-exercise interventions were associated with 31% (P < 0.03), 46% (P < 0.0005), and 42% (P < 0.005) reductions in risk of developing diabetes, respectively. CONCLUSIONS: Diet and/or exercise interventions led to a significant decrease in incidence of diabetes over 6-years among those with IGT.

Study	Participants	Study Design	Outcomes
Swinburn et al 2001	136 participants with glucose intolerance (2-h blood glucose 7.0-11.0 mmol/l) were recruited from a Workforce Diabetes Survey	5-year Follow-up of 1-year RCT of a reduced-fat ad libitum diet versus usual diet. The group that was randomised to a reduced-fat diet participated in monthly small-group education sessions on reduced-fat eating for 1 year. Body weight and glucose tolerance were measured in 136 participants at baseline 6 months, and 1 year (end of intervention), with follow-up at 2 years (n = 104), 3 years (n = 99), and 5 years (n = 103).	Compared with the control group, weight decreased in the reduced-fat-diet group (P < 0.0001); the greatest difference was noted at 1 year (-3.3 kg), diminished at subsequent follow-up (-3.2 kg at 2 years and -1.6 kg at 3 years), and was no longer present by 5 years (1.1 kg). Glucose tolerance also improved in patients on the reduced-fat diet; a lower proportion had type 2 diabetes or impaired glucose tolerance at 1 year (47 vs. 67%, P < 0.05), but in subsequent years, there were no differences between groups. However, the more compliant 50% of the intervention group maintained lower fasting and 2-h glucose at 5 years (P = 0.041 and P = 0.026 respectively) compared with control subjects. CONCLUSIONS: The natural history for people at high risk of developing type 2 diabetes is weight gain and deterioration in glucose tolerance. This process may be ameliorated through adherence to a reduced fat intake

Table 5.8: Randomised Controlled Trials of Dietary Change using Information Technology and Related Materials

Study	Participants	Study Design	Outcomes
Anderson et al 2001	Sample 277, 96% female; 92% white, median income ~ \$35,000, mean education 14.8 yrs.	Self-administered, computer-based intervention on nutrition behaviour, and outcome expectations in supermarket food shoppers. Intervention, in kiosks in supermarkets, based on social cognitive theory, used tailored information and self-regulation strategies delivered in 15 brief weekly segments.	Analysis of covariance immediately after intervention and at a 4- to 6-month follow-up found that treatment led to improved levels of fat, fibre, and fruits and vegetables. Treatment also led to higher levels of nutrition-related self-efficacy, physical outcome expectations, and social outcome expectations. The treatment group was more likely than the control group to attain goals for fat, fibre, and fruits and vegetables at post test and to attain goals for fat at follow-up. Self-efficacy and physical outcome expectations mediated treatment effects on nutrition. In addition, physical outcome expectations mediated the effect of self-efficacy on nutrition outcomes.
Brug et al 1996; 1998; 1999	347 employees of a major oil company	Randomized trial examining the impact of tailored nutrition information on changes in fat, vegetable, and fruit consumption. The experimental group received computer-generated feedback letters tailored to their personal dietary behaviour, attitudes, perceived social influences, self-efficacy expectations, and awareness levels. The control group received general nutrition information.	Respondents in the experimental group decreased their fat consumption significantly more than the control group between baseline and post test. A significant effect of tailoring was also found for changes in attitudes and intentions toward reducing fat intake and increasing fruit and vegetable consumption. Furthermore, respondents in the experimental group were more satisfied with the nutrition information they received and more often reported changing their diet or intention as a result of the information. These results do not support the hypothesis that additional psychosocial information is an essential component of effective tailored feedback. CONCLUSIONS. It is concluded that computer-tailored nutrition information is a promising means of stimulating people to change their diet toward dietary recommendations.

Study	Participants	Study Design	Outcomes
Campbell et al 1994	Adult patients from four North Carolina family practices	This randomised trial of the effect of individually computer-tailored messages designed to decrease fat intake and increase fruit and vegetable intake. The first intervention consisted of individually computer-tailored nutrition messages; the second consisted of non-tailored nutrition information based on the 1990 Dietary Guidelines for Americans.	The tailored intervention produced significant decreases in total fat and saturated fat scores compared with those of the control group ($P < .05$). Total fat was decreased in the tailored group by 23%, in the non-tailored group by 9%, and in the control group by 3%. Fruit and vegetable consumption did not increase in any study group. Seventy-three percent of the tailored intervention group recalled receiving a message, compared with 33% of the non-tailored intervention group. CONCLUSIONS. Tailored nutrition messages are effective in promoting dietary fat reduction for disease prevention.
Campbell et al 1999	378 low-income women enrolled in the Food Stamp program in Durham, North Carolina.	RCT computer-based intervention: tailored soap opera and interactive 'infomercials' with individualized feedback on dietary fat intake, knowledge and strategies for lowering fat, - based on stage of change.	At follow-up, intervention group participants had improved significantly in knowledge ($P < 0.001$), stage of change ($P < 0.05$) and certain eating behaviours ($P < 0.05$) cf control. Both groups reported lower fat intake at follow-up ($P < 0.001$), no significant difference between. Majority of participants rated the program as very helpful, interested in using a similar program in the future.
Delichatsios et al 2001a	504 subjects in 6 group practices in an HMO. 230 intervention, 274 control. mean age 54, 70% f, 91% white, 7% African American.	RCT: Intervention; mailed personalized dietary recommendations, educational booklets on fruits and vegetables, red meat, and dairy foods, tailored to patients' baseline intake and stage of readiness to change eating behaviours; GP verbal endorsement of recommendations; 2 motivational 'phone counselling sessions to set dietary goals.	89% of participants completed the follow-up survey. We measured change in intake of foods using results from the baseline and follow-up food frequency questionnaires. Using an intention-to-treat analysis and adjusting for age, sex, race, and baseline intake, the change in fruit and vegetable intake in the intervention group was 0.6 (95% confidence interval 0.3, 0.8) servings/day higher than in the control group. There was no intervention effect on red meat and dairy products. CONCLUSIONS: Tailored clinical nutrition interventions that combine brief physician endorsement with practice supports may be effective in changing patients' eating behaviour.
Delichatsios et al 2001b	298 adults: sedentary sub-optimal diet; age 45.9 yrs, 72% women, 45% African-American. Large multi-specialty group practice	RCTI. Weekly communication for 6 months via automated, computer-based voice system. Among intervention group subjects, the system monitored dietary habits and provided educational feedback, advice, and behavioural counselling. Control group subjects received physical activity promotion counselling.	RESULTS: Mean. Compared with the control group, the intervention raised fruit intake a mean of 1.1 servings per day (95% CI 0.4, 1.7). On a 0 to 100 global diet quality score combining all five food groups, intervention participants improved their mean score 9 (95% CI 4, 13) points more than in the control group. The intervention also raised dietary fibre intake 4.0 g/d (95% CI .1, 7.8) and decreased saturated fat, as a proportion of energy intake, by 1.7% (95% CI -2.7, -.7). CONCLUSIONS: This computer-based telecommunications dietary behaviour intervention helped improve participants' overall diet.
Hip-Hop to Health Jr. (Fitzgibbon et al 2002)	24 Head Start programs for children age 4-5	5-year randomised trial: each site is randomised to either a 14-week dietary/physical activity intervention or a general health intervention.	This paper presents the rationale and design of the study. Efficacy of the intervention will be determined by weight change for the children and parent/caretaker. Secondary measures include reductions in dietary fat and increases in fibre, fruit/vegetable intake, and physical activity. Baseline data will be presented in future papers.

Study	Participants	Study Design	Outcomes
Kristal et al 2000	1,205 adults from enrollees of a large HMO	RCT computer-generated personalized letter, a motivational phone call, a self-help manual, package of supplementary materials, computer-generated behavioural feedback based on self-administered food frequency questionnaire, and newsletters compared to no materials.	The intervention effect +/- SE for fat, based on a diet habits questionnaire, was -0.10 +/- 0.02 (P < 0.001), corresponding to a reduction of approximately 0.8 percentage points of percentage energy from fat. For fruits and vegetables, the intervention effect was 0.47 +/- 0.10 servings/day (P < 0.001). Intervention effects were similar across age and sex groups. CONCLUSIONS: Tailored, self-help interventions can effectively promote dietary change among both men and women and among younger as well as older adults.
Lutz et al 1999	573 HMO clients	The 4-group randomised trial with pre- and post-intervention measures consisted of a control group and 3 intervention groups receiving non-tailored newsletters, computer-tailored newsletters, or tailored newsletters with tailored goal-setting information. Intervention groups received 4 monthly newsletters.	OUTCOME MEASURES: Daily intake and weekly variety of fruits and vegetables were measured using a food frequency questionnaire. RESULTS: For persons completing post-intervention surveys, all 3 newsletter groups had significantly higher daily intake and variety scores compared with the control group. Although there was a trend of improved intake and variety with each added newsletter element, there were no significant differences at follow-up among the newsletter groups. CONCLUSIONS: Newsletters can be effective in improving the fruit and vegetable consumption of adults. In this study, a computer-tailoring system did not significantly enhance the effect of the nutrition newsletters on fruit and vegetable intake.
Mahler et al 1999	216 male and female CABG patients	RCT of either one of the two videotapes before discharge from the hospital or to receive only the standard discharge preparation provided by the hospital. Outcome measures: anxiety and self-efficacy at discharge, 1 month and 3 months after discharge; dietary fat consumption and activity level 1 and 3 months after discharge.	Relative to controls, patients who viewed either of the videotapes before hospital release reported higher self-efficacy for adhering to the recommended low-fat diet both at discharge and 1 month after surgery. Viewing either of the videotapes also resulted in significantly less dietary fat intake 1 month after hospital release compared with controls. Patients who viewed the tape that portrayed the recovery period as consisting of ups and downs also reported significantly more frequent moderate exercise at 1 month and more frequent strenuous exercise 3 months after discharge. CONCLUSIONS: The experimental videotapes proved to be an effective method for increasing dietary and exercise compliance during the first 3 months after CABG.
Marcus et al 1998a; 1998b; 2001	1,717 callers to the Cancer Information Service	Randomized trial: intervention was a brief proactive educational intervention over the telephone at the end of usual service, with two follow-up mailouts. Key educational messages and print material were derived from the NCI 5 A Day for Better Health program.	Fruit and vegetable consumption indicate a significant intervention effect of 0.88 servings per day at 4 weeks follow-up (P < 0.001), 0.63 servings per day at 4 months follow-up (P < 0.001), and 0.43 servings per day at 12 months follow-up (P < 0.001). The vast majority of callers (90%) endorsed the strategy of providing 5 A Day information proactively within the CIS. CONCLUSIONS: This brief educational intervention was associated with higher levels of self-reported fruit and vegetable intake at both short- and long-term follow-up.
Oenema et al 2001		A randomised controlled trial was conducted of the immediate impact of web-based computer-tailored nutrition education on personal awareness and intentions related to intake of fat, fruit and vegetables.	Significant differences in awareness and intention to change were found between the intervention and control group at post-test. The tailored intervention was appreciated better, was rated as more personally relevant, and had more subjective impact on opinion and intentions to change than the general nutrition information. Computer literacy had no effect on these ratings. The results indicate that interactive, web-based computer-tailored nutrition education can lead to changes in determinants of behaviour. Future research should be aimed at longer-term (behavioural) effects and the practicability of distributing tailored interventions via the WWW.

Study	Participants	Study Design	Outcomes
Stevens et al 2002	Healthy women HMO members (n = 616) aged 40 to 70.	Randomized controlled trial of a computer-assisted counselling intervention to reduce diet-related cancer risk. Intervention consisted of two 45-minute counselling sessions plus two 5- to 10-minute follow-up telephone contacts. Counselling sessions included a 20-minute, interactive, computer-based intervention using a touchscreen format.	OUTCOME MEASURES: 24 hour diet recalls and the Fat and Fibre Behaviour Questionnaire. RESULTS: analysis showed improvements on all dietary outcome variables. Compared to the control, intervention participants reported significantly less fat consumption (2.35 percentage points less for percentage of energy from fat), significantly greater consumption of fruit and vegetables combined (1.04 servings per day), and a significant reduction in a behavioural measure of fat consumption (.24 point change in the FFB). CONCLUSIONS: These 4-month results are comparable to several other moderate-intensity studies showing that, in the appropriate circumstances, moderate-intensity dietary interventions can be efficacious. Study limitations include the short follow-up period and the use of self-reported outcome measures.

CHAPTER 6: Smoking

6.1 Overview of Intervention Options

This section provides an overview of the nature and efficacy of approaches that can be adopted to reduce smoking in the community and lists the interventions recommended for evaluation. A comprehensive list of smoking cessation interventions is contained in table 6.1.

Table 6.1: Smoking Intervention Options

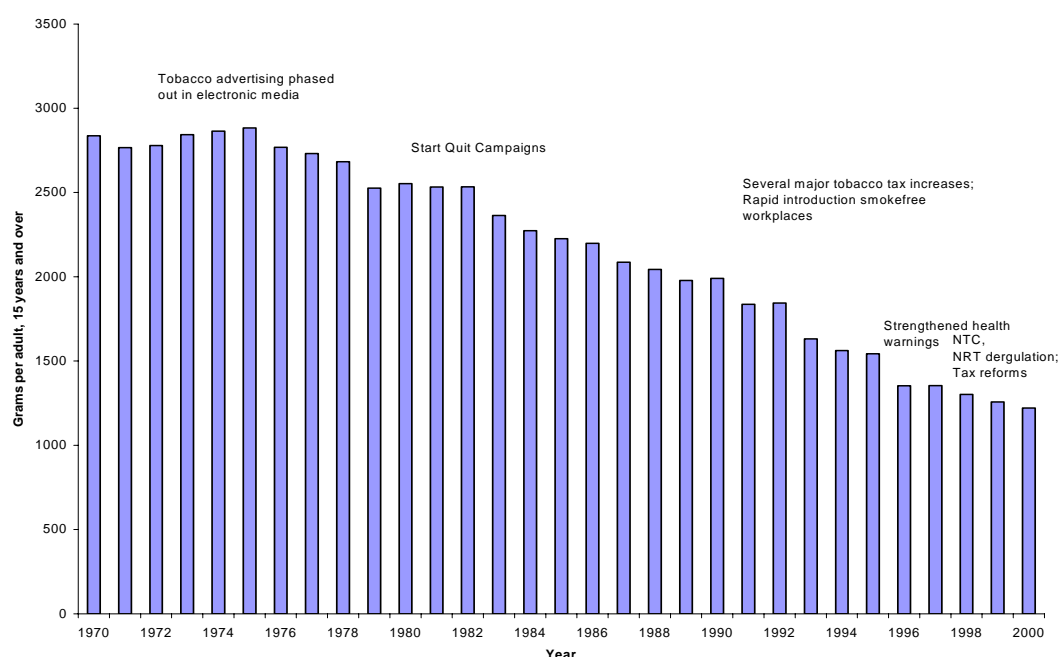
Stage/Therapy/ Focus	Modality	Intervention Strategy
PRIMARY PREVENTION		
Health Promotion		
	Media	<ul style="list-style-type: none"> • Mass media campaigns focussed at general population • Mass media campaign focussed on children
	School based programs	<ul style="list-style-type: none"> • Focussing on prevention of uptake of smoking - school based curriculum to discourage smoking • 'Smoke busters' club (competitions, outdoor events and discos) • Parent Programs
Policy Approaches		
	Taxation	<ul style="list-style-type: none"> • Financial disincentives for potential and current smokers
	Work place policy	<ul style="list-style-type: none"> • Universal adoption of smoke-free work places.
	Tobacco regulation	<ul style="list-style-type: none"> • Use of graphic health warnings on tobacco packaging. • Strengthen information on cigarette packs to disclose ingredients and additives,
II INTERVENTIONS FOR THOSE WITH RISK FACTOR		
Non-pharmacological		
	Large scale community	<ul style="list-style-type: none"> • Generic Self Help Materials
	Small scale community	<ul style="list-style-type: none"> • Personally tailored computer generated printed cessation advice • Quit-lines promoted in conjunction with ads that reach large populations.
	Advice from clinicians	<ul style="list-style-type: none"> • Brief advice from doctors delivered opportunistically during routine consultations • More intensive advice by usual doctor • Follow up visits with doctor • After an initial intervention with a doctor, referral to telephone support by counsellor or nurse • Implementing clinic screening systems designed to increase assessment and documentation of tobacco use
	Advice from other health professionals	<ul style="list-style-type: none"> • Brief cessation advice delivered by nurses • Individual counselling provided by a smoking cessation specialist counsellors • Group counselling • High intensity nurse intervention • Providing additional physiological feedback as an adjunct to nursing intervention • Repeated telephone support
	Training of health professionals	<ul style="list-style-type: none"> • Training of health care professionals in brief intervention methods
	Multi-factorial	<ul style="list-style-type: none"> • Self Help materials + follow up phone calls from counsellors • NRT or Bupropion (Zyban) + behavioural intervention

Stage/Therapy/ Focus	Modality	Intervention Strategy
Pharmacological	Behavioural	<ul style="list-style-type: none"> • Personally tailored computer generated printed cessation advice + NRT • Behavioural therapies: relaxation/breathing, contingency contracting, weight/diet therapy and cigarette fading • Aversion therapy. • Support of relapsed smokers to make another quit attempt
		<ul style="list-style-type: none"> • Nicotine gum, nicotine transdermal patch, nicotine nasal spray and nicotine inhaler • Bupropion (Zyban) ± patch • Clonidine • Mecamylamine • Naltrexone • Silver acetate
Other Non-Pharmacological therapies		
	Social support	<ul style="list-style-type: none"> • Providing social support as part of treatment • Providing problem solving skills training, helping smokers obtain social support outside of treatment • Physical activity as an adjunct to cessation program
	Alternative therapy	<ul style="list-style-type: none"> • Acupuncture • <i>Hypnotherapy.</i> • <i>Lobeline - an alkaloid derived from the leaves of an Indian tobacco plant. Classified as a partial nicotinic agonist</i>
III WITH RISK FACTOR AND MORBIDITY		
Non-Pharmacological		
	Inpatients	<ul style="list-style-type: none"> • Advice to inpatients • Direct mailing post-discharge
	Clinician advice	<ul style="list-style-type: none"> • Smoking cessation advice given at the time of diagnosis of smoking related disease.
Pharmacological		
		<ul style="list-style-type: none"> • Nicotine replacement therapy (NRT)

Numerous authoritative, independent bodies have systematically reviewed the evidence on the impact of tobacco control interventions. These include the World Bank (World Bank 1999; World Bank 1993), the World Health Organisation (WHO 1998), the Cochrane Collaboration (Sowden and Arblaster 2002); the UK Association for Public Health (Ried 1996); the US Centers for Disease Control (Centres for Disease Control and Prevention 1999; Centres for Disease Control and Prevention 2000; Centres for Disease Control and Prevention 2001); the National Cancer Institute of the US National Institutes of Health (National Cancer Institute 1991), the National Cancer Policy Board of the US Institute of Medicine and National Research Council (National Cancer Policy Board 1996) and the US Surgeon General (AHCPR 1996; US Dept of Health and Human Services 2000). All agree that realistically funded, comprehensive tobacco control programs that include anti-smoking advertising as a major component, do reduce tobacco consumption both among adult and teenage smokers.

There is evidence that, overall, efforts to reduce smoking in Australia are succeeding. There are now more ex-smokers than smokers. In 1995, 32.1% of men and 21.7% of women were past smokers, compared to current smokers (27.1% of men and 23.2% of women). Tobacco consumption has reduced steadily since the inception of tobacco control policies and programs. – refer Figure 6.1. Notwithstanding the methodological uncertainties raised by Chapman (Chapman 1993), is it possible to determine whether some interventions are likely to be more effective than others in reducing tobacco consumption?

Figure 6.1 Per Capita Cigarette Consumption in Australia



Sources: ABS, Customs and excise receipts and Winstanley M et al Tobacco in Australia; Facts and Issues 1995 (Winstanley et al 1995).

An independent Task Force on Community Preventive Services (Centers for Disease Control and Prevention 2000) with support from the US Department of Health and Human Services conducted a systematic review of 166 studies evaluating links between tobacco control interventions and improved health outcomes. For conclusions of task force see Table 6.2.

Table 6.2: Conclusions of Task Force regarding preferred tobacco control interventions

Interventions to reduce tobacco use initiation

Strongly Recommended

- Increase excise tax on cigarettes to increase the price of tobacco products.
- Inform (young people) through high intensity counter-advertising campaigns.

Interventions to reduce tobacco use

Strongly Recommended

- Increase excise tax on cigarettes to increase the price of tobacco products.
- Inform (adult smokers) through high intensity counter-advertising campaigns.
- Multi-component cessation interventions that include patient education materials, reactive telephone support, proactive telephone counselling including provider-maintained contact.
- Education and prompting of health care providers to identify, advise and assist tobacco-using patients.

Recommended

- Provider reminder systems for medical practitioners (stand alone).
- Reduction of patient co-payments for effective cessation therapies.

Insufficient evidence

- TV “how to quit” programs
- Quit Competitions
- Information to providers that they “should counsel to quit”
- Provider feedback on delivery of cessation advice

Interventions to reduce exposure to environmental tobacco smoke (ETS)

Strongly Recommended

- Bans or limits on tobacco smoking in workplaces and public areas.

Insufficient evidence

- Provision of information to persons about reducing ETS exposure in the home.

Source: Independent Task Force on Community Preventive Services, 2001

In choosing between individual programs, or in developing an overall strategy, another important consideration is patient preference. Owen and Davies, 1990, conducted a population survey in SA where smokers were asked to nominate the forms of assistance they thought would help them to stop. Options are shown in the table below. Some 46% of current smokers said they were interested in none of the options. Among smokers who nominated some form of assistance, 67% preferred services from a medical practitioner or other health professional; 12.4% a stop-smoking group; 23.1% a book, pamphlet or quit kit; and 2.9% for mail or telephone services. The strong preferences for indirect methods found elsewhere did not emerge in this survey. Preferences for personalised, as opposed to indirect forms of assistance, were more likely to be expressed by heavy smokers, those with less confidence of success at stopping, those with greater perceived difficulty of stopping, and those who had reported shorter periods of previous abstinence from smoking. Results are shown in Table 6.3.

Table 6.3: Patient Preferences for Smoking Cessation Programs (Owen and Davies, 1990)

Method of Assistance	Males %	Females %	Persons %	Persons n
A stop smoking group	5.1	8.7	6.7	21,477
A lecture	2.8	1.5*	1.8	5,895
A telephone counselling service	0.4**	0.8**	0.6*	1,872
A book, pamphlet, or quitkit	6.8	6.9	6.9	22,057
A television program or video	5.4	5.8	5.6	18,094
A program through the mail	1.2*	0.8**	1.0	3,224
A program through your doctor	22.1	25.8	23.7	76,413
A program through other health professional	10.8	14.7	12.5	40,168
None of these	48.2	43.4	46.1	148,081
Total	55.9	44.1	100	321,426

Notes Percentages sum to more than 100%, choices of methods not mutually exclusive: some respondents nominated more than one method.

* Subject to sampling variability between 30% and 40%. ** Subject to high sampling variability.

The VicHealth Centre for Tobacco Control (VCTC) in its publication *A Blue Chip Investment in Public Health* (VicHealth Centre for Tobacco Control 2001) draws upon the work of all of the major systematic reviews and provides an analysis of the current deficiencies in Australia's overall tobacco control effort, and barriers and opportunities for improvement.

The document claims that current levels of investment in mass media campaigns are in-adequate and that expenditure on school-based programs for which there is limited evidence of effectiveness is disproportionately high. It calls on the federal government to invest in revenue protection measures to ensure that tobacco products do not become more affordable. It calls on state governments to sunset exemptions to state legislation, which continue to allow smoking in pubs and clubs and many small work places. It calls for funding of programs and implementation of policy measures that would ensure referral by health professionals of smokers to non-pharmacological counselling services wherever pharmacological treatments for tobacco dependence are subsidised.

6.2 Specific Interventions

Health Promotion

Mass Media: Mass Media provides an important means for reaching and influencing smokers on a population wide basis. Properly designed and implemented programs can be efficient at dissemination of information and knowledge and realigning attitudes and social norms. Depending on the methods and strategies used, such as mass or segmented, population or subgroup focused, they can have broad, "ripple" effects as well as more selective, targeted social and behavioural

consequences (Sparks and Green 2000). Comparison of population smoking over time and between states with varying intensity of campaign effort provides very strong evidence for the effectiveness of mass-media led anti-smoking campaigns. Evidence suggests that media campaigns are most effective at eliciting smoking cessation when they are part of a comprehensive program of interventions.

The community antismoking campaign which began in Sydney in 1983, and in Melbourne in 1984 was analysed by Pierce et al 1990. These campaigns purchased prime-time television advertising spots. An intense effort was also made to ensure that antismoking activities were maximized at the school, organisational, and community level. During the years before the antismoking campaigns, there was no observable trend in smoking prevalence in either city. At the start of the campaigns, there was an immediate decrease of more than two percentage points in male and female smoking prevalence in both cities. Thereafter, a decline of about 1.5 percentage points per year was observed among males. No post campaign trend was observed in smoking prevalence for women in either city. These data support conducting coordinated community campaigns to reduce current smoking prevalence.

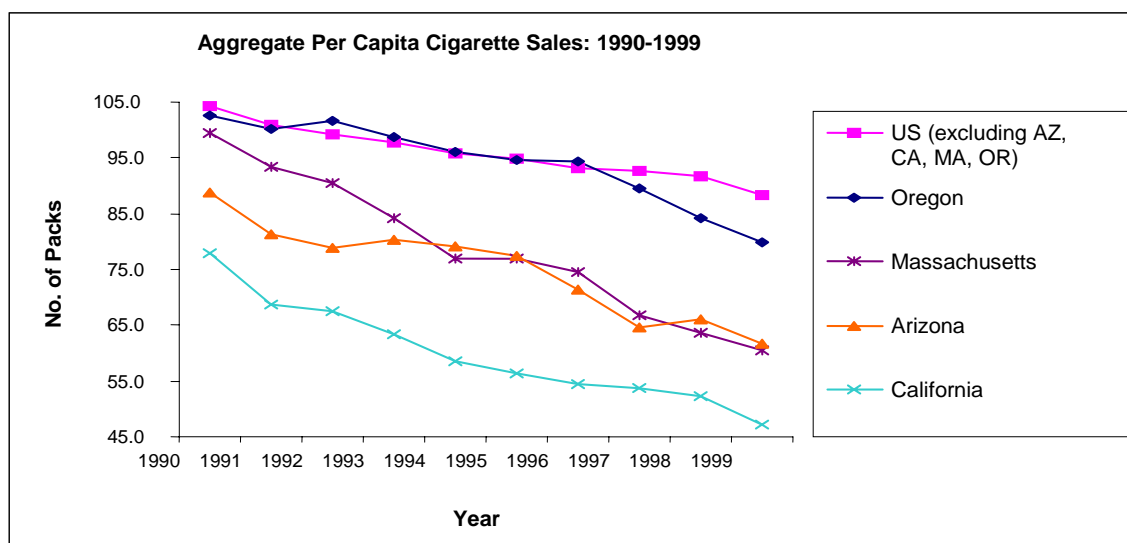
Hu et al 1995 conducted an econometric analysis of cigarette consumption in California between 1980 and 1992. The focus of the statewide media campaign was to change tobacco related attitudes and behaviours of target groups: adult smokers, pregnant women, ethnic minorities and children. Paid advertising delivered the message through television. They credit the media campaign with reducing cigarette sales by 232 million packs (7.7 per capita).

An evaluation of the impact of the Massachusetts campaign between 1993 and 1999 by Beiner et al 2000, showed a 25% decline in adult smoking prevalence compared to no detectable change in the rest of the US, excluding California. The campaign included an increase in tobacco taxes with funds devoted to anti-tobacco activities. However, due to industry discounting on wholesales prices, the price increase was eliminated. The evidence suggests that the media campaign in Massachusetts was the major factor contributing to the reduction in cigarette consumption.

Farrelly et al 2001, performed an economic analysis of the impact of a tobacco control program expenditure on cigarette sales across various US states, controlling for tax levels, smuggling, income and high school drop out rates. They found clear evidence that increased expenditure leads to reductions in cigarette sales. See Figure 6.2. The elasticity is low at -0.0006, meaning that expenditure needs to be increased significantly for sales to decline.

Results appear to be strongest approximately a year after expenditure. The elasticity of lagged tobacco control expenditure appears to be strongest in states with higher initial tobacco consumption (Farrelly et al 2001).

Figure 6.2: Changes in per capita cigarette sales in state with large, comprehensive tobacco control campaigns versus the rest of the US



Source: Farrelly, Pechacek and Chaloupka, 2001.

Drug education in schools: Studies indicate that anti-smoking education programs in schools, on their own and in the limited form in which they are invariably applied outside of initial pilot programs, are generally ineffective (US Dept of Health and Human Services 2000; Peterson et al 2000). “Even programs that have initially reduced uptake of smoking appear to have only a temporary effect; they can somewhat delay initiation of smoking but not prevent it” Jha & Chaloupka 1999, p 49. The most recent review by the US Surgeon General indicated that the *LifeSkills* Program developed by Dr Gilbert Botvin is the only drug education program for which long-term changes in smoking have been verified (US Dept of Health and Human Services 2000), but the cost of programs of this intensity is considerable, in terms of both training and curriculum time.

The impact of drug education in schools is undermined by a number of factors. These include: More frequent absences and truancy by those more likely to smoke (Charlton and Blair 1989; Charlton et al 2000).

The role of smoking as both cause and effect of alienation from school values (Nutbeam et al 1993).

The inability of teachers to frame learning tasks in a way that is suitable for existing smokers.

Inconsistency between school-based messages about smoking inside and outside the classroom.

Inconsistent messages from outside the school itself, including the continuing promotion of tobacco in venues that children frequent, and the apparent ease with which many children still appear to be able to purchase cigarettes (Charlton 1999).

Policy Approaches

Regulations to restrict smoking in the workplace: Smoke-free workplaces have a direct health benefit for non-smokers due to decreased exposure to environmental tobacco smoke. In addition restrictions on where smokers can smoke may influence their behaviour outside the workplace. Smokers may quit smoking when a smoke-free policy at work is implemented, they may reduce the number of cigarettes smoked. Smokers may make more quit attempts or may be more successful in their quit attempts. Improvement in cessation may be an indirect benefit of the current trend toward smoke-free workplaces.

In 1995, the Finnish government enforced legislation banning smoking in all work places, including the service sector. A year later researchers examined the perception of ETS exposure in the workplace,

the level of nicotine in the air and smoking prevalence among workers (Fichtenberg and Glantz 2000). Heloma et al., 2001, found that smoking prevalence decreased by from 29.6% to 25% ($p=0.21$) one year after the implementation of the legislation, and respondents stating that they were not exposed to ETS at all went from 19.2% to 54.2%. ($p < 0.001$). Smokers with less education showed a proportionally higher decrease in smoking prevalence after implementation, with the largest decrease amongst industrial workers. Legislation was shown to be more efficient than voluntary workplace-specific smoking restrictions in reducing passive smoking and cigarette consumption.

A recent review of 26 studies on the effect of smoke-free work places on smoking behaviour was conducted by Fichtenberg et al. They found that totally smoke-free workplaces are associated with reductions in smoking prevalence of 3.8% (95% confidence interval 2.8% to 4.7%) and 3.1 (2.4 to 3.8) fewer cigarettes smoked per day per continuing smoker (Heloma et al 2001). Smoke-free workplaces were found to protect non-smokers from passive smoking and are effective in encouraging smokers to quit or reduce consumption (Heloma et al 2001).

Increasing rates of tax on tobacco: As for any other commodity, demand for tobacco responds to price changes: when prices rise, demand for tobacco falls. Increasing prices through tax policy encourages cessation (Townsend 1996), reduces the average cigarette consumption among continuing smokers (Chaloupka and Wechsler 1997) and deters initiation (Emery et al 2001). Although cigarette smoking is an addiction, the “rational addiction” model is widely accepted by economists (Becker and Murphy 1988). Within the model, present consumption is influenced by past consumption and by the perception of the various costs of anticipated future consumption. Price increases must be sustained or the impact will be eroded by inflation. Like regulatory reforms, the imposition of taxes upon tobacco, are at no cost to government, and actually raise revenue.

In the study by Hu et al mentioned earlier under media campaigns, the researchers examined the effect of Proposition 99, involving the increase of tax on each pack of cigarettes by 25c and using 20% of revenue raised by the new tax for health educational programs for tobacco use (Hu et al 1995). They found that an additional 25c state tax increase reduced sales of cigarettes in California by an estimated 819 million packs (27.3 per capita) from 1990-1992 (Hu et al 1995).

In Canada from 1982 to 1991 there were rapid increases in the cost of cigarettes, caused primarily by large tax increases (Sweanor et al 1994). The real price of 20 cigarettes went from \$2.10 to about \$5.40. In terms of total per capita consumption, the decline among adults from 1982 to 1992 was about 40% and about 60% among 15-19 year olds (Sweanor et al 1994). The decline in smoking prevalence rates was 39.5% in 1981 to 31% in 1991 (Becker and Murphy 1991). The decline in prevalence amongst teenagers was more pronounced. In 1981, 43.5 % of 15 to 19 year olds were smoking, and 39.5 smoked daily. By 1991 only 22% were smoking at all and only 16 were smoking daily (Becker and Murphy 1991).

Reducing out of pocket costs for Nicotine Replacement Therapy (NRT): The aim of NRT is to replace some of the nicotine from cigarettes without the harmful constituents contained in tobacco smoke. NRT reduces withdrawal symptoms associated with smoking cessation and makes it easier to avoid smoking by replacing some, but not all, of the nicotine obtained from smoking (Gourlay and McNeill 1990). Nicotine replacement therapy (NRT) is considered a cornerstone of tobacco dependence treatment in the US, Fiore et al 2000) and the UK (Hopkins et al 2001). The US Food and Drug Administration (FDA) has approved nicotine gum, nicotine inhaler, nicotine nasal spray and nicotine patches as first line medications (monotherapy only) in tobacco dependence treatment.

In Australia, nicotine gum, patches, inhaler and lozenges are available from a pharmacist without a prescription. There is no subsidisation of the cost of NRT for consumers in Australia. A smoker using the patch for 10 weeks (an average course) will incur a cost of approximately \$350. This is comparable for many smokers to the cost of purchasing cigarettes over the same period. In other

countries such as the UK, NRT is available at a reduced rate under the National Health Service scheme.

In New Zealand, smokers who agree to undertake pharmacological treatment in combination with cessation counselling are eligible to purchase NRT at a subsidised rate.

From a review of a number of overseas studies, there is evidence to suggest that reducing out-of-pocket costs for NRT increases both use of NRT therapies and cessation outcomes (Hopkins et al 2001). The issue of price sensitivity pertaining to cessation products has been highlighted by the unanticipated demand for Zyban (bupropion) since its listing on February 1 2001 on the PBS (which has brought the cost of a single course down to approximately \$22 and less than \$4 on concession).

In the U.S., Curry et al compared the use and cost effectiveness of three forms of cover with those of a standard form of cover for smoking-cessation services that included a behavioural program and NRT (Curry et al 1998). The standard plan offered 50% cover of the behavioural program and full cover of NRT. The other plans offered 50% cover of both the behavioural program and NRT, full cover of the behavioural program and 50% cover of NRT or full cover of both the behavioural program and NRT. Estimated annual rates of use of smoking-cessation services ranged from 2.4% (among smokers with reduced cover) to 10% (among those with full cover). Smoking-cessation rates ranged from 28% (among users with full cover) to 38% (among those with standard cover). The estimated percent of all smokers who would quit smoking per year as a result of using the services ranged from 0.7% (with reduced cover) to 2.8% (with full cover).

A recent study in the U.S. indicated that despite a high interest in quitting among all demographic groups, the percentage of ever smokers who have quit is low among some populations (Trosclair et al 2002). In 2000 approximately 70% of smokers wanted to quit and 41 % had tried to quit in the previous year. By level of education, the percentage of smokers who had quit ranged from 33.6% (95% CI= \pm 4.7) to 74.4% (95% CI = \pm 3.4), with the highest level of success among those with graduate degrees. One of the factors that might account for this is the lack of access to pharmacotherapies for cessation due to their high cost. It is recommended that access to treatment should be increased by reducing out of pocket costs for cessation counselling and treatment (Trosclair et al 2002).

Addition of telephone counselling to pharmacotherapies: Physicians may prescribe NRT but generally do not provide follow up counselling for various reasons, such as time constraints or feeling insufficiently qualified to provide behavioural counselling. Zhu et al investigated the use of proactive telephone counselling as support for physician advice and providing adjuvant treatment for NRT users (Zhu et al 2000).

After receiving NRT, 79% of the participants continued with counselling and received 4.2 sessions on average, while 21% of them received only one session. Overall, 82.8% of all participants made a quit attempt. Nicotine patch users were more likely to make an attempt than nicotine gum users (85.2% vs 66.3%), but the relapse probability was the same for these attempts. Those who received multiple counselling were more likely to make an attempt than those receiving single counselling (84.4% vs 77.1%) and were more likely to stay quit for 1 year (25.6% vs 16.1%). Proactive telephone counselling appears to be a promising adjuvant treatment for NRT users in a "real-world" setting: a convenient referral service for supporting health plans or physicians who advise their patients to quit smoking (Zhu et al 2000).

Bupropion is a non-nicotine aid to smoking cessation originally developed and marketed as an antidepressant. Its mechanism of action is presumed to be mediated through its capacity to block the re-uptake of dopamine and norepinephrine centrally.

In a meta-analysis conducted by Hughes et al, pooling the results of four trials with twelve month abstinence rates and three with six month rates gave an estimated odds ratio of 2.54 (95% CI 1.90 - 3.41) (Hughes and Stead 2002). Similarly, Fiore conducted meta-analyses on 2 large multi-centre studies comparing bupropion to placebo (Fiore et al 2000). The odds ratio for abstinence rates using bupropion was 2.1 (95% CI 1.5, 3.0). The abstinence rates for Bupropion were 30.5 (23.2, 37.8) compared to 17.3 in the placebo groups. These reviews show that use of bupropion approximately doubles long-term abstinence rates when compared to a placebo.

The National Alcohol and Drug Research Centre is currently undertaking a study to investigate the extent to which telephone counselling increased quit rates for patients in Australia prescribed bupropion.

Non-pharmacological approaches: provider advice and referrals

Brief Advice from Health Professionals: Minimal clinical intervention consists of brief cessation advice from health care providers delivered opportunistically during routine consultations to smokers whether or not they are seeking help with stopping smoking. Brief opportunistic advice typically involves asking patients about their current smoking, advising them to stop, offering assistance either by providing further advice, a referral to a specialist service, or a prescription for pharmacotherapy, and arranging follow up where appropriate. This approach has been described as the 5A's approach. Ask, Advise, Assess, Assist, Arrange. Duration of minimal clinical intervention is usually defined as three to five minutes. Brief cessation advice is easy to deliver and is both expected and appreciated by patients if done in a caring and respectful manner (Schauffler et al 1996).

Fiore et al conducted a meta-analysis of the efficacy of physician advice to quit smoking from seven studies (Fiore et al 2000). In the studies used in this analysis, the modal length of clinician intervention was 3 minutes or less). Two studies in this analysis used interventions lasting about 5 minutes. Results suggest an odds ratio of 1.3(95% CI: 1.1-1.6) and abstinence rates of 10.2 (95% CI: 8.5-12.0) compared to abstinence rates of 7.9% in the groups where no advice to quit was given (Fiore et al 2000).

Physician Referral to telephone counselling: Physician advice to quit smoking is potentially an important population based approach to smoking cessation because most smokers see their physicians once a year. Although shown to be effective, an issue has been the disappointing rate at which GPs identify and counsel their smoking patients.

An approach to overcome this problem is to refer their patients out for telephone cessation counselling. The advantages of telephone counselling have been mentioned earlier. Physicians can be kept informed about the outcome of their referrals in the form of a progress report (with smokers' permission). When physicians realise that smokers are following up with the referral to cessation programs their referral behaviour will be reinforced.

A pilot study was conducted by Marcy et al to assess the feasibility of a central telephone smoking cessation service that would proactively call smokers who gave their provider consent for the referral (Marcy et al 2002). Over the four month duration of the resource there was a significant increase in those who had follow-up arranged, 17% at baseline compared to 34% post implementation, $p < 0.02$ (Marcy et al 2002).

Establishing Clinic or institutional systems for identification of smokers: A systematic approach to ascertaining and documenting tobacco use of patients is the first step in changing clinical culture and practice patterns to ensure that every patient who smokes is offered treatment.

The evidence for the effect of provider reminder systems for identifying smokers on cessation attempts is strong, and this is a relatively simple intervention that can be incorporated into routine

practice of most health services and practices in Australia. Peak health professional bodies may work with their profession to develop standard systems for identification of smokers. Individual health care providers, practices or health services may also adapt existing systems to accommodate smoker identification and provision of brief cessation advice (Miller and Wood 2001). Strategies such as expanding the vital signs to include tobacco use or placing tobacco use status stickers on all patient charts or to indicate tobacco use status using medical records or computer reminder systems can be implemented.

To assess the impact of screening systems on the rate of smoking cessation intervention by clinicians, Fiore et al analysed nine studies using a random-effects meta-analysis (Fiore et al 2000). Implementing clinic systems designed to increase the assessment and documentation of tobacco use status markedly increases the rate at which clinicians intervene with their patients who smoke, with an odds ratio of 3.1 (95% CI: 2.2-4.2) and an estimated intervention rate of 65.6 (58.3-72.6), compared to 38.5 where no screening took place (Fiore et al 2000).

Fiore et al analysed three studies to assess the impact of identifying smokers on actual rates of smoking cessation (Fiore et al 2000). When a screening system was in place the odds ratio was 2.0 (95% CI: 0.8-4.8) and abstinence rates of 6.4% (1.3-11.6) compared to 3.1% in the condition where no screening took place. This suggests that having a clinic system in place that identifies smokers, results in higher rates of smoking cessation, although this finding was not statistically significant and was based on a small number of studies (Fiore et al 2000).

Non-pharmacological approaches: smoker support services

Proactive telephone counselling: Telephone quit-lines have several advantages over formal treatment programs. The convenience of the telephone reduces barriers involved with the attendance of classes. Quitlines allow smokers to get help without having to leave home and allows them to receive counselling at a time convenient to them (Zhu 2000). This makes the service more accessible especially to those with limited mobility or living in remote or rural areas. Telephone counselling also appeals to those reluctant to get face-to-face help. In pro-active counselling, the smoker is called systematically, with scheduled sessions similar to traditional cessation clinics. Proactive counselling can significantly reduce drop out rates (Zhu 2000).

In a meta-analysis of 11 studies of efficacy of proactive phone counselling, at short term follow up, Lichtenstein et al found, when comparing cessation rates in the phone counselling versus control conditions, a significant odds ratio of 1.34 (95% CI: 1.19-1.51) (Lichtenstein et al 1996). At long term follow up, 9 studies produced an odds ratio of 1.20 (95% CI: 1.06-1.37). Proactive phone counselling appeared most effective when used as a sole intervention modality or when augmenting programs initiated in hospital settings (Lichtenstein et al 1996).

6.3 Summary of Smoking Cessation Interventions

Study	Intervention	Results	Odds Ratio Effect size
Lancaster and Stead 2002	Generic Self Help Materials eg printed leaflets or manuals, audiotapes and video tapes, compared to no intervention	Increase in odds of quitting at 6 months (OR= 1.23, 95% CI 1.02, 1.49)	OR: 1.23
	Tailoring materials to characteristics of individual smokers based on psychosocial factors or stage of cessation	More effective than standard material in achieving sustained cessation at 6 months (especially stage of change)(OR 1.41, 95% CI 1.14, 1.75)	OR: 1.41
	Self Help materials + follow up phone calls from counsellors	Adding follow up phone calls increases rate of quitting at 6 months by 60% (OR 1.62, 95% CI 1.33, 1.97)	OR: 1.62
Strecher 1999	Personally tailored computer generated printed cessation advice	Six of nine studies found positive effects	
	Personally tailored computer generated printed cessation advice + NRT	Two studies that combined tailored materials with NRT found particularly strong effects	
Wakefield and Miller 1999	Quit-lines promoted in conjunction with ads that reach large populations. Provide contact point for provision of written self help material and employ counsellors to assist and support.	Point prevalence of cessation for 12 months was between 18% and 24% at 12 months	
Lichtenstein et al 1996	Proactive telephone counselling	Proactive counselling compared to a control condition significantly increases quit rates at 6 months or more (OR 1.20, 95% CI 1.06, 1.37).	1.2
Fiore et al 2000		Meta-analysis showed increased abstinence rates for proactive telephone counselling (OR 1.2 95%CI 1.1,1.4) relative to no intervention	OR: 1.2
Zhu et al 2000	Repeated telephone support + NRT	With NRT for maintaining cessation for 12 months 25.5% v 16%	OR: 1.4
Sun et al 2000	<i>Quit and Win</i> competitions in conjunction with ads and support programs	Continuous abstinence of participants in 1996 at one year was 38% for Chinese adults and 12% for Finnish adults	
Fiore et al 2000	Implementing clinic systems designed to increase the assessment and documentation of tobacco use.	Est. intervention rate by clinicians w/o a screening system to identify smoking status was 38.5% cf 65.6% with a screening system (95% CI 58.3, 72.6), OR 3.1 (95% CI 2.2, 4.2). Rates of smoking cessation at >5 mnths were 3.1% w/o a screening system and 6.4% with screening system (95% CI 1.3, 11.6) OR 2.0 (95% CI 0.8, 4.8).	OR: 3.1, 2.0

Study	Intervention	Results	Odds Ratio Effect size
	Any health professional providing advice	Non-pharmacological smoking cessation interventions of various intensities delivered by any single type of health care provider, such as a doctor, nurse, psychologist, dentist or smoking counsellor or by multiple clinicians, increase abstinence rates relative to no clinician or self-help interventions (10.2% for no clinician, 15.8% for a non-doctor clinician and 19.9% for a doctor. OR 1.0, 1.7 and 2.2 respectively)	OR: 1.0, 1.7 & 2.2
	Brief advice from doctors delivered opportunistically during routine consultations	Brief cessation advice delivered by doctor, abstinence rate at five months or more of 10.2% (95% CI 8.5-12.0) compared to 7.9% without advice (OR 1.3 (95% CI 1.1-1.6).	1.3
Silagy and Stead 2002		Brief advice versus no advice (or usual care) from a doctor produced a small but significant increase in the odds of quitting at six months or more (OR 1.69, 95% CI 1.45 ,1.98)	1.69
Rice and Stead 2002	Brief cessation advice delivered by nurses	Brief advice versus no advice from a nurse produced a small but significant increase in the odds of quitting at six months or more (OR 1.67 (95% CI 1.14-2.22)	1.67
Senore et al 1998	Support of relapsed smokers to make another quit attempt	Previous antismoking advice by a doctor has been reported as a strong barrier to sustained quitting after 6-12 months (OR 0.19, 95%CI 0.07, 0.52) for healthy smokers but not those with shortness of breath (OR 0.63, 95%CI 0.39,0.92). This result could reflect the resistance of some smokers to cessation until they have a smoking-related medical problem.	0.19, 0.63
Marcy et al 2002	Physician referral to counselling	A pilot study was conducted to assess the feasibility of a central telephone smoking cessation service that would proactively call smokers who gave their provider consent for the referral. Over the four month duration of the resource there was a significant increase in those who had follow-up arranged, 17% at baseline compared to 34% post implementation, p < 0.02.	
Lancaster et al 2002	Training of health care professionals in brief intervention methods. 5A's -Ask about and record smoking status -Advise of benefit of stopping -Assess motivation to stop -Assist is their stop attempt if possible; might include the offer of support, recommendation to use NRT or bruponion	Those who received training 1.5-2.5 times more likely than untrained controls to perform tasks of smoking cessation eg counselling patients about smoking, setting quit dates, suggesting followup appointment, offering self help material or nicotine gum. Only two of eight RCTs with an untrained control group reviewed by Lancaster showed a significant effect of training of health professionals on quit rates at least six months after the intervention. The duration and nature of training varied between studies may explain the equivocal results.	1.5 to 2.5

Study	Intervention	Results	Odds Ratio Effect size
Butler et al	and accurate information and advice about them, referral to a specialist if necessary -Arrange follow up if possible	A randomised controlled trial in general practice of motivational consulting versus brief advice found that motivational consulting produced more activity aimed at quitting (delaying first morning cigarette, smoke free days, quit attempts) than brief advice, especially amongst those 'not thinking of giving up in the next six months', but sustained quit rates were low for both interventions	na
Fiore et al 2000	Individual counselling provided by a smoking cessation specialist counsellors	Meta-analysis showed increased abstinence rates for individual counselling (OR 1.7 95%CI 1.4, 2.0) relative to no intervention	1.7
	Group counselling	Meta-analysis showed increased abstinence rates for group counselling (OR 1.3 95%CI 1.1, 1.6) relative to no intervention	1.3
Stead and Lancaster 2002		Participation in group therapy sessions doubles cessation rates at six months compared to self help activities (OR 2.10, 95%CI 1.64, 2.70). Participation in group therapy sessions almost doubles cessation rates at six months compared to no intervention or minimal contact (OR 1.91, 95%CI 1.20, 3.04).	2.21, 1.91
Fiore et al 2000	Providing problem solving skills training as part of treatment helping smokers obtain social support outside of treatment	Compared to no counselling or behaviour therapy OR 1.5 (1.3, 1.8), effect size 5.0% (2.8, 7.3)	OR:1.5 ES: 5%
	Providing social support as part of treatment	Compared to no counselling or behaviour therapy OR 1.3 (1.1, 1.6) effect size 3.2% (1.1, 4.3)	OR:1.3 ES: 3.2%
Fiore et al 2000	Helping smokers obtain social support outside of treatment	Compared to no counselling or behaviour therapy OR 1.5 (1.1, 2.1) effect size 5% (0.6, 9.4)	ES 5%
	Behavioural therapies: relaxation/breathing, contingency contracting, weight/diet therapy and cigarette fading	Odds ratios and abstinence rates derived from meta-analysis of studies of interventions such as relaxation/breathing, contingency contracting, weight/diet therapy and cigarette fading were not significantly different from those for no counselling or behaviour therapy	
Marcus et al 1999 Usher et al 2002	Physical activity as an adjunct to cessation program	Vigorous exercise as an adjunct to multi-session cognitive behavioural intervention therapy, boosts quit rate of women (OR 2.36 (0.97, 5.70), effect size 6.5%). A Cochrane review examining exercise as an adjunct to a cessation program found that the sample size of most trials was too small and the interventions in different trials varied in intensity and timing of the smoking cessation and exercise programs. The review concluded that there was a need for larger trials meeting various intervention and study conditions.	OR:2.36 ES 6.5%
Lancaster and Stead 2002	Individual counselling compared to brief advice, usual care or provision of self help materials	Participation in individual therapy sessions delivered by a counsellor other than usual carer doubles increases cessation rates at six months by 50 to 75 per cent to compared to minimal intervention ((OR 1.55, 95%CI 1.27, 1.90) or	1.55, 1.7

Study	Intervention	Results	Odds Ratio Effect size
		no intervention (OR 1.7 95% CI 1.4, 2.0)	
Hajek and Stead 2002	Aversion therapy. Techniques include rapid puffing (smoke not inhaled), smoke holding, excessive smoking, paced smoking, self-paced smoking, focused smoking, covert sensitisation, symbolic aversion, electric shocks administered by therapist or subject, and behavioural treatments with bitter pills.	The meta-analyses of both ³ the Cochrane and US Clinical Guidelines reviews found that various aversion treatments, other than rapid smoking, did not significantly improve the odds of smoking cessation after five months or more compared to no aversion treatment: Cochrane OR 1.19, (95% CI 0.77,1.83). US Guidelines OR 1.7, (95% CI 1.04, 2.8)	1.19, 1.7
		There was a borderline dose-response to the level of aversive stimulation (OR 1.66, 95% CI 1.00, 2.78)	1.66
	Rapid smoking aversion therapy. Usually consists of asking subjects to take a puff every six to ten seconds for three minutes, or until they consume three cigarettes or feel unable to continue. This is repeated two or three times, and subjects are asked to concentrate on the unpleasant sensations it causes. Explanation and supportive counselling is usually provided with application of the rapid smoking technique	The meta-analyses of both the Cochrane and US Clinical Guidelines reviews found that rapid smoking aversion treatments significantly improved the odds of smoking cessation after five months or more compared to no aversion treatment. Cochrane OR 2.08 (95% CI 1.39,3.12) US Guidelines OR 2.07, (95% CI 1.04, 2.8)	2.08
Silagy et al 2002	More intensive advice by usual doctor ie more than 10 mins	Direct comparison of intensive v. minimal advice showed a small advantage of intensive advice (OR 1.44, 95% CI 1.23, 1.68). Indirect comparison showed no difference in effect	1.44
	Follow up visits with doctor	OR for cessation when follow-up provided was 2.54 (95% CI 2.03, 3.19) compared to 1.66 (95% CI 1.41, 1.95)	2.54
Rice and Stead 2002	High intensity nurse intervention	No significant difference between high intensity intervention trials and low intensity trials	
Silagy et al 2002	Nicotine gum, nicotine transdermal patch, nicotine nasal spray and nicotine inhaler	Cessation rates at 12 months of various forms of NRT with placebo or no treatment found an overall odds ratio 1.71 (95% CI 1.60, 18.2) for all forms and an overall effect size of 7%.	OR:1.71 ES 7%
Fiore et al 2000		Comparing various forms of NRT with placebo or no treatment found odds ratios ranging from 1.5 to 2.7 and effect sizes from 7 –17%	OR 1.5-2.7 ES 7-17%
Silagy et al 2002	NRT gum (2mg)	OR 1.63, 95% CI 1.49, 1.79 effect size 5-8%	OR:1.63 ES 5-8%

³ Although on face value there appears to be a difference in the odds ratios between reviews, neither is significantly different from 1.0. The apparent difference may be due to inclusion of different types of smoking aversion therapy and the different minimum length of follow-up (six months versus five months).

Study	Intervention	Results	Odds Ratio Effect size
Fiore et al 2000		OR 1.5, 95% CI 1.3, 1.8 effect size 7%	OR:1.5 ES 7%
Silagy et al 2002	Nicotine trans-dermal patch	OR 1.73, 95% CI 1.56, 1.93 effect size 5-6%	OR 1.73 ES 5-6%
Fiore et al 2000		OR 1.9, 95% CI 1.7, 2.2 effect size 8%	OR 1.9 ES 8%
Silagy et al 2002	Nicotine nasal spray (not available in Aus.)	OR 2.27, 95% CI 1.61, 3.20 effect size 13%	OR 2.27 ES 13%
Fiore et al 2000		OR 2.7, 95% CI 1.8, 4.1 effect size 17%	OR 2.7 ES 17%
Silagy et al 2002	Nicotine Inhaler	OR 2.08, 95% CI 1.43, 3.04 effect size 8%	OR 2.08 ES 8%
Fiore et al 2000		OR 2.5, 95% CI 1.7, 3.6 effect size 12%	OR 2.5 ES 12%
Silagy et al 2002	Sublingual tablets or lozenges	OR 1.73, 95% CI 1.07, 2.80 effect size 8%	OR: 1.73 ES 8%
Baille et al 1994	NRT + behavioural intervention	Adding NRT to any psychological (behavioural) intervention provides a net beneficial effect (OR 1.69 CI 1.0,2.7). Similarly, adding a behavioural intervention to NRT also provides a net beneficial effect (OR 1.78, CI 1.0, 3.1)	1.69, 1.78
Rice and Stead 2002	Providing additional physiological feedback as an adjunct to nursing intervention	Does not appear to have an effect. Pooled OR for 2 trials was 0.79 (95% CI 0.44, 1.44)	0.79
Jorenby et al 1999	Bupropion and nicotine patch	Combination of Bupropion and nicotine patch was significantly more effective than nicotine patch alone. Cessation rate at 12 months 35.5% vs 16.4%.	
Fiore et al 2000	Bupropion (Zyban). Its mechanism of action is presumed to be mediated through its capacity to block the re-uptake of dopamine and norepinephrine centrally.	Use of bupropion SR approximately doubles cessation rate compared to placebo 30.5%, (95% CI 23.2, 37.8) versus 17.3%. The odds ratio for sustained abstinence at five months or more 2.1(95% CI 1.5, 3.0)	OR 2.1 ES 13.2%
Hughes and Stead 2002		The odds ratio for sustained abstinence at 12 months using bupropion compared to placebo was estimated at 2.73 (95% CI 1.90, 3.94)	2.73

Study	Intervention	Results	Odds Ratio Effect size
	Nortriptyline. Blocks uptake of norepinephrine and serotonin.	The odds ratio for sustained abstinence at 5 months or more compared to placebo was estimated at 3.2 (95% CI 1.8, 5.7) and 2.83 (95% CI 1.59, 5.03). Estimated to triple abstinence rates at 5 months or more compared to placebo cessation rate 30.1% (95% CI 18.1, 41.6) v 11.7%	3.2, 2.83
Niaura et al 1997	Fluoxetine. Selective inhibitor of neuronal serotonin	In depressed smokers, increased abstinence rate from 20% in the placebo to 30% in two treatment groups at six months	
Fiore et al 2000	Clonidine – adrenergic agonist that dampens sympathetic nervous system activity	Doubles smoking abstinence rates at 5 months or more compared to placebo (OR 2.1, 95%CI 1.4, 3.2, effect size 11.7% (95% CI 3.8, 19.7)	OR 2.1 ES 11.7%
Rose et al 1994 Rose et al 1998	Mecamylamine – nicotine anagonist	Of two studies reviewed by Fiore et al. (2000), with one exception, comparisons of mecamylamine alone or combined with nicotine patches showed no significantly better effect than a placebo. Small sample sizes limited the power to show a statistically significant difference.	
Covey et al 1999 Wong et al 1999	Naltrexone - opioid antagonist	In a double-blind randomised placebo controlled trial of 68 heavy smokers (> 20 per day) cessation rate at 6 months was 27% (intervention) versus 16% (control), OR 1.9 (not statistically significant) In a randomised, partly blind trial of 100 smokers with naltrexone, placebo and added NRT groups followed for 6 months, there was no significant effect with or without NRT compared to placebo	OR: 1.9 not sig
Hughes et al 2002	<i>Anxiolytics – increase production of dopaminem serotonin and norepinephrine</i>	RCTs of five different medications in the anxiolytic class found no effect on smoking cessation at six months cf placebo. The medications considered were diazepam, meprobamate, metoprolol, oxprenolol and buspirone. The review of evidence to support the US Guidelines considered four trials and found no beneficial effects compared to placebo. The medications considered were diazapam, propranolol and buspirone. No meta-analysis was performed and no conclusions drawn.	
Hymowitz and Eckholdt 1996 Jensen et al 1991	<i>Silver acetate - produces an unpleasant taste when combined with cigarettes and acts as aversive therapy.</i>	Two randomised clinical trails reviewed by Fiore et al. (2000) and Lancaster and Stead (2000) showed no beneficial effects compared to placebo (OR 1.05 (95% CI 0.63, 1.73).	1.05
Stead 2002	Lobeline - an alkaloid derived from the leaves of an Indian tobacco plant. Classified as a partial nicotinic agonist	A number of the controlled short term trials concluded that lobeline had no effect on smoking; there are no well conducted trials with long term follow up. There is therefore no evidence that lobeline can aid smoking cessation.	

Study	Intervention	Results	Odds Ratio Effect size
Abbot et al 2002 Green and Lynn 2000	<i>Hypnotherapy. Attempts to modify patients' perceptions of smoking by using the potential of hypnotherapy to induce deep concentration. The most frequently used approaches are variants of the 'one session, three point' method developed by Spiegel (Spiegel 1964). The smoker is instructed that a) smoking is a poison, b) the body is entitled to protection from smoke, and c) there are advantages to life as a non-smoker.</i>	Insufficient evidence. Most of the studies in the scientific literature are either case reports or poor quality uncontrolled trials that show a great variability in quit rates (4-88%) six months after treatment. Nine randomised controlled trials compare hypnotherapy with 14 different control interventions, but the many different hypnotherapy regimens used and the variation in number and frequency of treatments prohibit meta-analysis.	
White et al 2002	<i>Acupuncture. Any treatment involving needle puncture of areas of the body, including points on the ear, face and body. Needles usually remain in position for the duration of a treatment session (often lasting 15 - 20 minutes).</i>	No evidence of a specific effect. There was no difference in cessation rates between 'active' acupuncture and 'inactive' or sham acupuncture procedures. The placebo effect of acupuncture is an 8.3% abstinence rate at five months or more. The effects may be produced by positive expectations of the procedure.	
Black et al 1998 Armstrong et al 1990 Best et al 1988	<i>Peer Support</i>	It is clear that interactive class-room techniques are superior to non-interactive programs, however the evidence relating to peer programs is extremely mixed with some indication that effects may be gender 69 and program specific	
Vartiainen et al 1998	<i>School based curriculum and mass communication and community organisation to reduce cardiovascular disease</i>	At 15 year follow up (when participants were aged 28) mean lifetime consumption was 22% lower among those in intervention community than those in control area (p = 0.01)	
Baxter et al 1997	<i>School based curriculum and local policies for health in young people to reduce cardiovascular disease</i>	During the three year period smoking prevalence increased by 20% overall in the three communities. Smoking prevalence for girls increased by 29% and for boys by 10% in the intervention groups and by 24% and 16% in the control community. In the cross-sectional analyses there were no significant differences in the change in smoking rates between control and intervention communities.	
Perry et al 1994	<i>School based curriculum and community organisation and activities to reduce cardiovascular disease</i>	In five annual assessments weekly smoking prevalence was lower in the intervention community than in the control. In 1989 smoking prevalence was 14.6% in intervention compared with 24.1 in control city (p = 0.04)	
Murray et al 1994	<i>Focussing on prevention of uptake of smoking - media broadcasts, school based curriculum and health department grants awarded to communities for activities to discourage smoking</i>	There was a 2.4% net decline in the intervention community compared with the control community over the four year period, but the net decline was not statistically significant.	

Study	Intervention	Results	Odds Ratio Effect size
Gordon et al 1997 Kaufman et al 1994	<i>Focussing on prevention of uptake of smoking -school based curriculum, homework sessions with parents, anti-smoking displays in public places, education for retailers of law about sales to minors</i>	After the six month program there were no statistically significant differences in smoking prevalence rates between the two intervention groups.	
Pentz et al 1989	<i>School based curriculum and mass media, parent involvement and community activities focussing on tobacco alcohol and drug use</i>	After three years of the program there was a statistically significant effect on smoking prevalence (in the past month) ($p < 0.05$): prevalence increased by 7.3% from baseline in the school-only condition and by 3.6% in the school and community condition. However, when samples of expired air carbon monoxide (CO) were compared there were no statistically significant differences between the groups.	
Pentz et al 1989	<i>School based curriculum, mass media and parent involvement focussing on tobacco alcohol and drug use</i>	One year after the intervention began results showed that smoking rates (previous month) had increased in both groups from baseline but that the rate of increase was significantly lower in the intervention group (15% versus 22%, $p < 0.05$ respectively). Intervention schools who reported a high level of program implementation had a decrease (from baseline) in cigarette use in the last month of 1.23% compared with a 6.72% increase in schools with a low level of program implementation.	
Piper et al in press	<i>School based curriculum and parent involvement focussing on tobacco alcohol and drug use</i>	Three years after the intensive condition and one year after the age appropriate condition, there was a statistically significant reduction in past months smoking prevalence for the intensive condition and a significantly higher rate of smoking for the age appropriate group compared with the control (28% versus 36% versus 30%, $p < 0.001$, $p < 0.01$ respectively).	
Sussman et al 1998	<i>School based curriculum and 'school as community component' including job training, sports, drug free parties, drug awareness week focussing on tobacco alcohol and drug use</i>	The classroom plus school as community component was compared with the classroom only. At one year follow-up no statistically significant main effect was found for the mean level of cigarette use in the past 30 days (means 34.53 vs 33.08 for classroom only and classroom plus community, respectively).	

Study	Intervention	Results	Odds Ratio Effect size
Bauer et al 2000	<i>Mass Media aimed at children</i>	In Florida current cigarette use dropped from 18.5% to 11.1% ($P < .001$) among middle school students and from 27.4% to 22.6% ($P = .01$) among high school students. Prevalence of never use increased from 56.4% to 69.3% ($P < .001$) and from 31.9% to 43.1% ($P = .001$) among middle school and high school students, respectively. Prevalence of experimenting decreased among middle school and high school students from 21.4% to 16.2% ($P < .001$) and from 32.8% to 28.2% ($P < .001$), respectively. Among never users, the percentage of committed nonsmokers increased from 67.4% to 76.9% ($P < .001$) and from 73.7% to 79.3% ($P < .001$) among middle school and high school students, respectively. Among experimenters, the percentage of students who said they will not smoke again increased from 30.4% to 42.0% ($P < .001$) in middle school and from 44.4% to 51.0% ($P < .001$) in high school	
Beiner et al 2000	<i>Mass Media aimed at the entire population</i>	The TV component of the largely health-focussed Massachusetts anti-smoking campaign, the largest to that date anywhere in the world, significantly reduced the rate of establishment of smoking among young Massachusetts adolescents compared to the rest of the US. Among younger adolescents (aged 12 to 13 years at baseline), those reporting baseline exposure to television antismoking advertisements were significantly less likely to progress to established smoking (odds ratio = 0.49, 95% confidence interval = 0.26, 0.93). From 1992 the prevalence of adult smoking in Massachusetts has declined annually by 0.43% (95% confidence interval 0.21% to 0.66%) compared with an increase of 0.03% (-0.06% to 0.12%) in the comparison states ($P < 0.001$).	0.49, 0.46
Pierce et al 1990 Australian Bureau of Statistics. May 2000, 2001.		The NSW Quit for life campaign launched in 1983 resulted in an abrupt drop in smoking prevalence in NSW. Following the introduction of Quit campaigns in most Australian states between 1983-1986 apparent consumption of tobacco products also declined sharply	
Hill et al 2000		Australia's National Tobacco Campaign commenced in April 1997. Prevalence at benchmark was 23.5% at 11/97 it had dropped to 22.1%, in 11/98 it was 21.8%	
Hu et al 1995	<i>Media Campaigns (continued)</i>	Hu et al conducted an econometric analysis of cigarette consumption in California between 1980 and 1992. The focus of the statewide media campaign was to change tobacco related attitudes and behaviours of target groups: adult smokers, pregnant women, ethnic minorities and children. Paid advertising delivered the message through television. They credit the media campaign with reducing cigarette sales by 232 million packs (7.7 per capita)	

Study	Intervention	Results	Odds Ratio Effect size
WHO 1998	<i>Parent Programs eg tips on how to discuss drugs, distribution of materials informing parents about drug education in school, involving parents in drug programs, courses helping parents to quit</i>	There is no good evidence one way or the other about the effects of such programs. However, there are sound theoretical reasons for believing that lowering the smoking rates of adults in the child's world is the most effective means we have of reducing the appeal of smoking as an "adult" activity	
Davidson 1991	<i>Focussing on prevention of uptake of smoking 'Smokebusters Club' including starter packs, merchandise, discount schemes, competitions, outdoor events and discos.</i>	At 12-month follow-up (also 12 months after the launch of the Smokebusters club) 3% of the intervention group and 11% of the control group reported smoking. However, at baseline more of the control group reported being smokers than the intervention group (8% versus 0.2% respectively). Interpretation of the results of this study are difficult as statistical tests were not carried out, apart from three chi squared tests.	
St Pierre et al 1992	<i>Youth club activities focussing on tobacco alcohol and drug use</i>	At the end of the intervention no statistically significant overall effect was found, although in post-hoc analyses both intervention groups reported less recent cigarette use than the control group (means 1.46, 1.48, 1.63, p <0.05).	
Urbis et al 2002	Zyban on PBS	Barriers to Zyban relate to public fears about the drugs harm profile and inconvenience o obtaining and then filling a prescription	
Hu et al 1995	Increase excise tax on cigs	The researchers examined the effect of Proposition 99, involving the increase of tax on each pack of cigarettes by 25c and using 20% of revenue raised by the new tax for health educational programs for tobacco use. They found that an additional 25c state tax increase reduced sales of cigarettes in California by an estimated 819 million packs (27.3 per capita) from 1990-1992	
Sweanor et al 1994		In Canada from 1982 to 1991 there were rapid increases in the cost of cigarettes, caused primarily by large tax increases. The real price of 20 cigarettes went from \$2.10 to about \$5.40. In terms of total per capita consumption, the decline among adults from 1982 to 1992 was about 40% and about 60% among 15-19 year olds. The decline in smoking prevalence rates was 39.5% in 1991 to 31% in 1991. The decline in prevalence amongst teenagers was more pronounced. In 1981, 43.5 % of 15 to 19 year olds were smoking, and 39.5 smoked daily. By 1991 only 22% were smoking at all and only 16 were smoking daily.	
Fichtenberg and Glantz 2000	Universal adoption of smoke-free work place bans	Totally smoke-free workplaces are associated with reductions in smoking prevalence of 3.8% (95% confidence interval 2.8% to 4.7%) and 3.1 (2.4 to 3.8) fewer cigarettes smoked per day per continuing smoker	

Study	Intervention	Results	Odds Ratio Effect size
Heloma et al 2001		In Finland smoking prevalence decreased by from 29.6% to 25% ($p=0.21$) one year after the implementation of the legislation, and respondents stating that they were not exposed to ETS at all went from 19.2% to 54.2%. ($p < 0.001$). Smokers with less education showed a proportionally higher decrease in smoking prevalence after implementation, with the largest decrease amongst industrial workers. Legislation was shown to be more efficient than voluntary workplace-specific smoking restrictions in reducing passive smoking and cigarette consumption	
	Reducing out of pockets costs for Nicotine Replacement Therapy	Estimated annual rates of use of smoking-cessation services ranged from 2.4% (among smokers with reduced coverage) to 10% (among those with full coverage). Smoking-cessation rates ranged from 28% (among users with full coverage) to 38% (among those with standard coverage). The estimated percentage of all smokers who would quit smoking per year as a result of using the services ranged from 0.7% (with reduced coverage) to 2.8% (with full coverage). Overall they found that use of smoking-cessation services varies according to the extent of coverage, with the highest rates of use among smokers with full coverage. Although the rate of smoking cessation among the benefit users with full coverage was lower than the rates among users with plans requiring co-payments, the effect on the overall prevalence of smoking was greater with full coverage than with the cost-sharing plan.	
West et al 2000	Overall state per capita tobacco control expenditure	Unfortunately, no information is available on what types of tobacco control interventions each program utilizes and how much is spent on each intervention. The overall contemporaneous tobacco control expenditure elasticity of demand ranges from -0.0228 to -0.0221 , and has an average elasticity of -0.0225 . The average overall elasticity suggests that a doubling of the expenditures toward tobacco control would decrease the amount of cigarettes consumed by youth by approximately 2.25 percent. More than fifty five percent of the effect of contemporaneous tobacco control expenditures on overall cigarette consumption is on the average number of cigarettes smoked by smokers (average smoking elasticity is -0.0125), with the remainder of the effect on the decision to smoke (prevalence elasticity is -0.0125).	

CHAPTER 7: Alcohol

7.1 Interventions to Reduce the Burden of Harm Associated with Alcohol Misuse

Table 7.1 provides a synthesis of the type of interventions for reduction in alcohol harm by ‘prevention category’ and groups targeted. This section provides an overview of the key intervention categories in order to assist in selecting a subset of interventions suitable for evaluation in Stage II. Given this purpose, and the time and resource constraints on this task, the review of the literature is neither exhaustive nor comprehensive, but rather selective reflecting the criteria for identifying interventions for economic analysis as described in Chapter 2 and further enunciated below in Chapter 8.

Table 7.1: Overview of key interventions to reduce harm associated with alcohol misuse

Stage	Intervention setting	Intervention strategy	Target groups/drinking behaviour
Primary Prevention	General community	Mass media campaign	Drink driving Underage drinkers Binge drinking
		Taxation	Usual consumption
		Advertising laws	Binge drinking
		Packaging	Usual/binge drinking
		RBT	Drink driving
	Point of sale	Licensed drinking environment	Binge drinking Underage drinkers
	Secondary schools	Education campaign	Underage drinkers Binge drinking
Secondary Prevention Avoid harm in current drinkers	GPs	Brief intervention	Usual/binge drinking Alcohol related problems Pregnant women Indigenous communities Adolescents
	Workplaces	EAP, OH&S legislation	Usual/binge drinking
	Community	Outreach	At risk youth
Tertiary Reduce harm in problem drinkers	D & A clinics	CBT	Usual consumption Individuals Couples Families
	D & A clinics, GPs	Pharmacotherapies	Usual consumption Alcohol dependent individuals
	Community	Outreach	Homeless and/or mentally ill individuals
	Community	AA/self help groups	Alcohol dependent individuals

For a comprehensive review of the prevention literature in regard to alcohol misuse the reader is referred to the recent report funded by the Commonwealth Department of Health and Aging “The prevention of substance use, risk and harm in Australia: A review of the evidence”, completed by the National Drug Research Institute in collaboration with the Centre for Adolescent Health (Loxely et al 2002). It should also be noted that much of the literature on the secondary and tertiary treatment interventions covered below is derived from the Management of Alcohol Dependence project, conducted by the National Drug and alcohol Research Centre for the Commonwealth Department of Health and Aging [MAD project]. The National Alcohol Research Agenda also provides a

comprehensive examination of the evidence of interventions to alleviate the burden of harm associated with alcohol mis-use (DHA 2002).

Key intervention trials are summarised in Table 7.2 at the conclusion of this chapter. Seminal trials that will provide the evidence for the economic evaluations will be drawn from this group.

7.2 Specific Interventions

Mass media campaign

Mass media campaigns conducted through television and newspapers for example, are most commonly associated with attempting to increase individual awareness about drinking in order to influence personal decisions to reduce occasions of heavy and/or high risk drinking. Scientific evidence about mass media campaigns has demonstrated that although public information efforts can increase public awareness about drinking problems they do not impact significantly on behaviour change (Hewitt 1984; Wallack 1987; Ashley 1988; Moskowitz 1989). In recent years, however, some studies have demonstrated that mass-media campaigns are more effective when used in combination with other broader community based approaches (Pentz et al 1989; Holder et al 1997). As an example, in the US Community Trials Project, media advocacy was focused on community awareness and support of local policy as well as specific community variables aimed to impact on individual behaviour. Results from this project indicate that, if used as part of a comprehensive community strategy, media campaigns can be an important and effective tool for community prevention (Holder et al 1997).

Taxation

Through tax, the government is able to increase the price of alcoholic beverages. One of the fundamental laws of economics is that of a downward sloping demand curve: as the price of product rises, the quantity demanded falls. Numerous researchers have attempted to estimate the responsiveness of consumers to increases in prices (Godfrey 1989; Crooks 1989; Osterberg 2001). Evidence from these studies is consistent in suggesting that price is a determinant of alcohol consumption. However, the size of the varies across countries by beverage and over time. Leung and Phelps reviewed 15 studies that analysed data on alcohol consumption (Leung 1993). They found that overall, a 10% increase in the price of alcohol lead to a 3% decrease in demand for beer, 10% for wine and 15 % for spirits. In terms of particular sub-groups of the population, evidence suggests that tax increases result in significant reductions in the consumption of alcohol by adolescents and female students (Crooks 1989; Laixuthai 1993; Chaloupka 1996).

Of particular interest is the extent to which price increases, through taxation, can reduce the harms associated with alcohol misuse. A number of studies in the US have examined the comparative effects of tax and alcohol control measures on drinking and driving. Saffer and Grossman (1987) and Chaloupka et al (1991) suggest that an increase in beer tax in the US would reduce drink-driving fatalities. Cook 1993, suggests that higher taxes on beer is associated with reduced incidence of some types of crime.

Licensed drinking environment

A number of areas of functional constraint, or physical availability, are relevant at the point of alcohol sale. These constraints include: changes in the legal drinking age, outlet densities, trading hours, and the practice of responsible service of intoxicated persons (Stockwell et al 2001).

The legal drinking age: An appropriate legal minimum drinking age has long been the subject of considerable debate, with different cultures holding different views. Evidence from the US suggests that the earlier a person commences drinking the greater the likelihood that they will develop alcohol-related problems (Grant 1997). Such evidence is further supported by research indicating that raising the minimum legal drinking age, typically reduces the use of alcohol among under-age drinkers

(Wagenar 1986), road traffic fatalities, juvenile crime, serious assault and drunkenness convictions for the affected age groups. Grube (1997) has observed that maintaining minimum legal drinking age restrictions requires supportive activities including police enforcement, server liability laws, responsible beverage server programs (Grube 1997).

Outlet densities: There is limited evidence that limits to outlet density may reduce alcohol-related problems and harm. However, much of this evidence is from cross-sectional studies, that report strong correlation between outlet densities and alcohol sales (Nelson 1990) or with self-reported alcohol use (Chaloupka 1996).

Trading hours: Research has been conducted regarding hours of trading and the number of days of trading. Gray (2000) has studied the effect of closure of liquor stores and bars on social security pay days in Aboriginal communities and reports that such restrictions are effective in reducing alcohol consumption and related harm. The international experience with trading hours and days appears to demonstrate that modifications in these have some impact on the pattern of problems of alcohol intoxication, across time and place (Stockwell et al 2001; Chikritzhs and Stockwell 1998).

Responsible server programs: Evidence suggests that continued service to intoxicated persons is a significant risk for those patrons experiencing alcohol-related harm (Bryant 2000). Responsible serving is increasingly seen as a key ingredient to improving the drinking environment (Saltz 1987; Single 1994). As such, responsible server programs have become a common way to reduce alcohol-related harms over the past decade. Such programs are associated with moderate success, especially when combined with law enforcement (Saltz 1987; Putnam 1993; Stockwell 1997).

School based education campaigns

School based alcohol education campaigns have evolved over time. Early campaigns focused on alcohol use and were based on the premise that fear arousal and/or information dissemination on the negative consequences of drug use would reduce use. Reviews of these studies concluded that none were effective in achieving this aim (Dielman 1994). Social influence programs became more widespread in the 1980s and 1990s with evidence suggesting that such an approach was effective in delaying the uptake of drinking (Perry 1992). Hansen (1993) reviewed 45 drug education studies and concluded that social influence and multiple component programs, demonstrated more success than either information-based or affective education approaches (Hansen 1993). Dusenbury and Falco (1995) in a later review of the research literature commented that certain types of school based education can achieve a moderate reduction in adolescent drug use. More recent drug education studies and reviews of school-based education campaigns indicate that these interventions can change behaviour, and while the change may be small, it occurs at a population level, so that the aggregate benefit of good programs could be large if effective programs were widely implemented (White 1998; Shope et al 1994; McBride et al 2000).

Workplaces

Although there is a wide body of evidence around workplace interventions, there is no consensus that workplace alcohol prevention strategies deliver benefits in terms of reduced alcohol consumption or lower levels of alcohol-related harm. Allsop et al (1997) reviewed 190 Australian papers on workplace interventions with the majority (90) being employee assistance programs. Allsop et al (1997) concluded that there was no clear evidence to suggest that any of the reviewed interventions minimises or reduced the harms or costs associated with alcohol use in the Australian workplace. Hutcheson et al (1995) considered that an effective alcohol policy must be constructed specifically for each company, with input from all key staff involved.

Brief Interventions

There is much variability in what constitutes a brief intervention (BI) although they are generally directed at problem drinkers with low levels of dependence and the goal is usually moderate drinking

rather than total abstinence. They vary in length, structure, target of intervention, personnel responsible for their delivery and method of communication. Summarising the literature on the effects of BI is a challenge because of these varying definitions (Moyer 2002).

There are two classes of BIs which should not be confused: those for treatment seeking populations and those for non-treatment seeking populations (Heather 1995). Progress in studying BIs has been hampered by conceptual confusion over what they are and what they hope to achieve. Opportunistic or primary care BIs are usually delivered to people who do not seek help for a problem with alcohol and who are identified via screening. Specialist BI are usually delivered in specialist treatment agencies to people who seek help for an alcohol problem.

Reviews and meta-analyses: There have been a number of reviews and meta-analyses examining the efficacy of BI. A recent meta-analysis provided a comprehensive review of the research in this area (Moyer 2002). This analysis took a broad view by considering comparisons between BIs and both control conditions and more extended treatments; and by summarizing effects across different categories at multiple follow-up points. They also distinguished treatment seeking from non-treatment seeking samples.

Thirty-four studies compared BIs to control conditions in non-treatment seeking populations. Significant, largely homogeneous, small to medium effect sizes in favour of BIs indicate that they are superior to control conditions. This result is consistent with results reported in previous, more focused meta-analytic reviews (Bien 1993a; Wilk 1997). These findings should only be applied to certain populations since the studies included participants identified opportunistically and the majority (79%) excluded individuals with severe alcohol problems.

Twenty studies compared BI to extended treatment in treatment seeking populations. For the most part, the effects of these investigations were statistically comparable and not significantly different from zero. These results are consistent with the overall effect size of 0.06 reported in a review by Bien et al (1993). For this group of studies there was no significant heterogeneity among the effect sizes. The results of this review concur with previous reviews that found little difference between brief and extended treatment conditions. It is important that generalizations be restricted to the populations, treatment characteristics and contexts represented in the particular study because the evidence regarding BIs comes from different types of investigation with different samples. Bien et al (1993) pooled the findings of 18 studies comparing BI with a control condition and 13 studies comparing BI with more extended therapy. The mean pooled effect size for BI versus a control condition moderately favoured BI (0.38) whereas the mean pooled effect size for BI versus extended treatment was negligible (0.06). In this review, mean effect sizes were not weighted by study size/variance and no homogeneity tests or significance tests for overall effect sizes were conducted.

Concentrating on BI delivered to primary health-care populations, Poikolainen (1999) examined studies that randomly assigned participants to intervention and control groups. The findings indicated that very BI (5-20 minutes) did not result in a significant change in alcohol consumption. For extended BI (several visits) the pooled effect estimate of change in alcohol intake was significant among women. Among men, the result was significant but lack of statistical homogeneity implied that the estimate was not meaningful.

Dunn et al (2001) conducted a systematic review of twenty-nine studies examining the effectiveness of brief motivational interviewing (MI) as an intervention across several behavioural domains. Ten of the fifteen studies regarding substance abuse were significant with the effect size varying from 0.30 to 0.95. MI was found to be most effective when used as an enhancement for more intensive treatment.

Kahan et al (1995) conducted a review of eleven randomised controlled trials examining the effectiveness of physician interventions to reduce alcohol consumption in problem drinkers. The four

studies that were deemed to have the highest validity obtained findings indicating that men in the intervention groups reduced their weekly consumption by between five and seven standard drinks more than controls. The results for women were inconsistent and there was no evidence of significant declines in alcohol-related morbidity or mortality. The articles included in this review were those published 1966-72.

Brief GP advice vs. Control: Anderson and Scott (1992) examined the effectiveness of advice from general practitioners to heavy drinking men. Participants (N=154 men) were randomly allocated to treatment (10 minute GP advice) and control groups. At one-year follow-up, the treatment group had reduced their consumption when compared to the control group. The same authors conducted a randomised controlled trial of 72 women who drank 21 units or more of alcohol per week. Women in the treatment group received ten minutes advice from their GPs. They found no evidence for a treatment effect. At one year follow-up, there was a significant reduction in alcohol consumption for the whole group.

In a similar study, Fleming et al (1997) examined the efficacy of brief physician advice in reducing alcohol use in problem drinkers. At twelve-month follow-up, there were significant reductions in 7-day alcohol use, episodes of binge drinking and frequency of excessive drinking in the experimental group, and the difference between the experimental and control groups on each of these measures was significant.

In a study designed to test a BI for reducing alcohol consumption among moderate to heavy drinkers in primary care settings Senft (1997) conducted a randomised controlled trial with 516 drinkers. Intervention included brief clinician advice (30 seconds) and a 15-minute motivational session by counsellors. At six-month follow-up, intervention participants reported fewer total standard drinks and fewer drinking days per week than controls over the previous three months but similar drinks per drinking occasion. At 12 months follow-up, intervention participants reported fewer drinking days per week but similar number of drinks and drinks per drinking day than controls. Intervention participants did not differ significantly from controls on other drinking outcomes.

In a study conducted in Australia, Richmond et al (1995) evaluated general-practitioner-based BI in 378 excessive drinkers. Patients were assigned to one of four groups: the Alcohol screen program (5-session intervention); a single 5-minute advice plus a self-help manual; an alcohol-related assessment or neither an intervention nor an assessment. The Alcohol Screen Program did not result in a significantly greater reduction in consumption at immediate follow-up than control conditions but did result in a greater reduction in alcohol-related problems at 6-month follow-up. Further, there was no evidence that minimal intervention or alcohol-related assessment were effective in reducing alcohol consumption or problems.

Comparison of differential effectiveness of brief interventions: As noted above, BI are not a homogeneous entity, but a collection of interventions. The following studies examined the differential effectiveness of BI.

Heather et al (1996) examined the effect of BI in general hospital wards on alcohol consumption among patients who drink heavily. Heavy drinkers (N=174) were allocated to either skill-based counselling, brief motivational interviewing or a non-intervention control group. At six-month follow-up patients who received counselling showed a greater reduction in a quantity-frequency measure of alcohol consumption than controls. There were no differences between the two intervention groups but patients considered "not ready to change" showed greater reductions if they had received brief motivational interviewing than if they had received skill-based counselling..

Maisto et al (2001) conducted a randomised clinical trial to evaluate the differential efficacy of two types of BI when delivered in the primary care setting. 301 patients were randomly assigned to

receive either brief advice (BA), motivational enhancement (ME) or standard treatment (SC). In the SC condition, patients were given selected feedback from their screening and baseline assessment. In the BA condition patients were given a 10–15 minute session that emphasized feedback from the baseline results and its implications for the patients' health. ME followed procedures from the MET condition in Project MATCH (Longabaugh et al 2001). The ME condition consisted of a longer initial assessment and two shorter assessments. Patients in the BA and ME groups also received booklets containing information about the physical, psychological and social effects of alcohol. At both six and 12 month follow-ups, there was a significant reduction in alcohol consumption and an increase in number of days abstinent in all groups. In addition, there was a moderator effect of readiness to change such that the BA intervention seemed more effective for patients relatively low in readiness to change compared to those high in readiness. Readiness to change did not seem to be related to change in drinking in the SC or ME conditions.

The WHO BI Study Group (1996) examined the relative effects of simple advice and brief counseling in 1559 heavy drinkers across eight countries. Patients were randomly assigned to a control group, a simple advice group or a group receiving brief counseling. Simple advice and brief counseling were effective in reducing average daily alcohol consumption in all patients, although the results for males were more convincing than results for females. These results suggest that BIs are robust across health care settings and socio-cultural groups.

Romelsjo et al (1989) investigated the effect of minimal intervention on alcohol consumption in eighty-three patients with high levels of alcohol consumption. The intervention group made an average of three visits to their GP who gave advice and general support whereas the comparison group was advised to cut down on their alcohol consumption. There were modest improvements in both groups together with small differences between groups. At one-year follow-up, there were greater but not significant reductions in GGT level, self-reported alcohol consumption and in a 'problem index' in the intervention group than the comparison group.

Spivak et al (1994) examined the effect of specific and non-specific advice in one-hundred and forty problem drinkers wanting to quit or cut down without professional help. Patients attended a 60-minute assessment session during which they were given brief guidelines (2 pages), a detailed manual (30 pages) or a general information about alcohol effects. At 12-months follow-up, subjects in the first two groups showed significantly greater reductions in heavy drinking days than subjects in the general information group. Furthermore, significantly fewer subjects in the first two conditions expressed a need for professional assistance with their drinking.

Together, the wealth of research on BIs suggests that they are more effective than no intervention in reducing alcohol consumption in problem drinkers with low levels of dependence. Further, the effectiveness of BI's appears to be comparable to that of other active treatments. Although more intensive treatments for alcohol misuse are always going to be necessary, particularly to treat patients with severe dependence, BIs appear to be one of the most promising treatments, as there is some evidence for their effectiveness.

Cognitive behavioural interventions

The cognitive-behavioural approach views the etiology and persistence of pathological drinking as a learned behaviour and has led to the application of learning-based clinical methods (WHO 1996). These clinical techniques include coping skills training, cue exposure, relapse prevention, BIs, marital or family interventions and broad-based social supports for clients.

Cognitive Behavioural Therapy: Rice et al (1993) conducted an RCT examining alcohol use in 239 patients who received either extended CBT, Relationship Enhancement (RE) or relationship and vocational enhancement (VE). In all conditions, up to 20 sessions of treatment were available to the patient. There were no significant main effects of treatment condition or age; however, there was a

significant treatment by age interaction. For the younger age group (18-29 years) no significant treatment differences were detected. For middle aged patients (30-49 years) the RE condition was most effective and for patients aged 50+ years the CBT condition was most effective.

As mentioned above, CBT encompasses a wide variety of treatments. Rohsenow et al (2001) studied the efficacy of cue exposure, coping skills and communication skills. A 2 X 2 design to investigate the effects of cue exposure with coping skills compared to a meditation-relaxation control, and communication skills training compared to an education control. These treatments were added to an intensive treatment program for persons dependent on alcohol. Both cue exposure therapy and communication skills training appeared to be effective in decreasing the amount of heavy drinking days at six and twelve month follow-ups. Cue exposure also resulted in greater reports of use of coping skills during follow-up.

Moderation-Oriented Cue Exposure (MOCE) was compared to Behavioural Self-control Training (BSCT) in a study of ninety-one clients receiving weekly sessions with trained therapists (Heather et al 2000). At six-month follow-up, results indicated that MOCE was effective in reducing alcohol consumption but there was no evidence to support the superiority of MOCE over BSCT, indicating that both cue exposure and self-control training are effective components of CBT.

Sitharthan et al (1997) examined the effectiveness of cue exposure compared to a 'standard' cognitive behavioural therapy consisting of goal setting, self-monitoring, and behavioural and cognitive strategies to moderate drinking. Both interventions were delivered in six 90-minute sessions by the investigators. Cue exposure produced significantly greater reductions than 'standard' CBT in participants' reports of drinking frequency and consumption at follow-up, suggesting that cue exposure is an important component of CBT. Supporting this finding, Drummond and Glautier (1994) found that cue exposure resulted in longer latencies to heavy drinking and total alcohol consumption compared to relaxation therapy in thirty-five severely dependent males.

Motivational Interviewing: Motivational interviewing (MI) was developed to enhance client motivation and is based on principles of cognitive therapy and the client-centred approach developed by Carl Rogers. The efficacy of MI has been evaluated in four RCTs which are described below.

Sellman et al (2001) examined the effect of Motivational Enhancement Therapy (MET) in comparison with no counselling and with nondirective reflective listening (NDRL) in one-hundred and twenty-two patients with mild to moderate alcohol dependence. Results indicated that MET was more effective than either NDRL or no counselling in the reduction of heavy drinking.

In an evaluation of the impact of counsellor style, Miller et al (1993) used a two-session motivational check-up in forty-two problem drinkers. Participants were randomly assigned to immediate check-up with directive-confrontational counselling, immediate check-up with client-centred therapy or delayed check-up (waiting list). Clients receiving immediate check-up showed significant reduction in drinking relative to controls. The directive-confrontational style yielded significantly more resistance from clients, which predicted poorer outcomes at 1-year follow-up.

Together, these studies provide modest support for the efficacy of motivational interviewing in the treatment of alcohol dependence.

Behavioural Couples Therapy: McCrady et al (1999) compared the effectiveness of standard behavioural couples therapy to two maintenance enhanced therapies. Ninety males with alcohol abuse or dependence were randomly assigned to treatment conditions and attended weekly therapy with their partners. Treatment conditions were Behavioural Couples Therapy (BCT), BCT plus Alcoholics' Anonymous or BCT plus Relapse Prevention. The men significantly reduced the frequency of drinking and heavy drinking during therapy, but the three conditions did not differ.

Self-help guided materials: Heather et al (1990) evaluated whether a controlled drinking self-help manual based on self-management principles was effective in assisting problem drinkers to reduce their drinking behaviours. One hundred and seven participants were randomly assigned to groups receiving a general information booklet, a behaviourally-based self-help manual, the manual and an opportunity to make progress reports to a telephone answering service and the manual and an opportunity to make progress reports to an interviewer. Results showed a higher proportion of drinking above recommended limits at six-months follow-up for the control group than in the groups receiving the manual. There were no differences due to presence or type of telephone contact.

Hester and Delaney (1997) investigated the efficacy of a computer-based version of behavioural self-control that was administered either immediately or 10 weeks after treatment. Results indicate that the program was effective in reducing drinking in those patients who received the program immediately following treatment. These gains were maintained at twelve-month follow-up.

Despite the range of treatments encompassed in psychosocial interventions, available evidence indicates that in general psychosocial interventions are more effective than no treatment in the treatment of alcohol abuse and dependence

Inpatient and outpatient treatment [From MAD project, in progress]

Much of the research on inpatient rehabilitation, particularly regarding therapeutic communities, is not specific to alcohol use disorders. However because so few well controlled, recent trials have been conducted, some of these non-specific studies are reported here.

Does inpatient treatment produce better outcomes for some patients?: In a review by Finney et al (1996) five studies reported a significantly better outcome for inpatient over outpatient treatment for alcohol use disorders, and seven reported a general equivalence between inpatient and outpatient treatment. For all but one study, more intensive treatment was associated with better outcomes. Where the outpatient treatment was as good as inpatient, the patients were likely to have had at least some immediately preceding inpatient care. In contrast, a meta-analytic review (Mattick and Jarvis 1993) comparing inpatient to outpatient treatment for alcohol found slightly a larger benefit for outpatient treatment.

Walsh et al (1991) randomly allocated alcohol-abusing or alcohol dependent employees to compulsory AA, compulsory inpatient treatment, or a choice of treatment type. The choices included no treatment, outpatient psychotherapy, inpatient treatment, or AA. The inpatient treatment was provided in hospitals, was abstinence oriented, and held AA meetings at the hospital. No other treatment details are provided. Although all three groups improved, those who received inpatient treatment had better outcomes overall. Additional inpatient therapy was needed over the following 2 years for 68% of those given AA treatment, 38% of those who were given a choice, and 23% of those who received inpatient treatment in the first instance. Unfortunately, there was no comparison with an outpatient treatment group, so it is not possible to conclude from this study that inpatient treatment is more effective than outpatient treatment. Further, the study group was recruited via an employee assistance program (EAP) and participation for two of the groups was compulsory, thereby limiting the generalisability of the findings.

Rychtarik et al (2000) compared inpatient, intensive outpatient, and standard outpatient treatment settings for alcohol dependent patients with varying levels of alcohol involvement and social network support for drinking. Participants were randomly assigned in cohorts to one of the three settings. The settings did not differ in post-treatment primary drinking outcomes. However, clients high in alcohol involvement benefited more from inpatient than outpatient care; the opposite was true at low alcohol involvement levels. Network drinking support did not moderate setting effects. Clients low in cognitive functioning also appeared to benefit more from inpatient than outpatient care.

How then do we resolve these apparently conflicting findings? Finney et al (1996) conclude that other variables apart from treatment setting, such as modality, amount and duration of treatment, and therapist variables, are more important in attaining positive outcomes for patients. Brown (2001), in her review of the effectiveness of treatment, suggests that for more severe or dual-diagnosis alcoholics, more intensive treatment may be more effective, but that in general, the data do not support intense inpatient treatment for all patients.

Are some types of inpatient treatment more effective than others?: A study of EAP referrals compared four treatment facilities: one inpatient program (IP1) using a traditional 12-step and therapeutic community approach, one inpatient program (IP2) which provided 12-step facilitation plus family and individual counselling, an outpatient program (OP1) providing 6 weeks of treatment for 8 to 12 hours per week, also using a 12 step and group therapy approach plus relapse prevention, and an outpatient program (OP2) providing 4 weeks of treatment for 4 hours per week using 12-step facilitation plus psychiatric and family counselling (McLellan et al 1993). Patients were not randomly assigned to treatment. All programs had similar treatment goals, operating philosophies and core treatment components, however the inpatient programs provided significantly more counselling and medical services than the outpatient programs. IP 1 also offered more services in almost all areas than IP 2. All groups achieved substantial improvements across a range of outcomes at 6-month follow up (eg, an average of 74% less alcohol use). The inpatient programs had higher rates of abstinence than the outpatient programs, with IP1 having a significantly better abstinence rate overall, and a lower re-treatment rate during the 6 months after treatment. In sum, the programs that provided the most services directed at a particular problem showed the best outcomes in that area. For example, inpatient programs offered significantly more alcohol and drug counselling sessions and showed higher rates of abstinence than the outpatient programs. Again, the study suffers from several limitations: there was no random assignment, participants were all employees from the same two companies, and the majority were coerced into treatment. And, given that the types (if not the intensity) of treatment was similar in all programs, it is not possible to draw conclusions about the effectiveness of particular inpatient interventions.

Within a therapeutic community (TC) model, there can be a large degree of variation in length of stay and treatment components. One study which examined length of stay (Gottheil 1992) also divided the treatment group according to the severity of their psychiatric symptoms. Overall, longer stays were associated with better outcomes at 6 month follow-up on a range of drinking, medical, psychiatric and employment outcomes, except for those with the most severe psychiatric symptoms. The study used retrospective analysis of an existing data set, so was not a controlled trial.

Messina et al (2001) analysed patient data from a therapeutic community setting and concluded that clients who received more vocational education fared better in terms of treatment completion, employment, and post discharge arrest. Those who received more group treatment were more likely to be employed at follow-up and to remain arrest-free. However this was not an experimental design so it is possible that client motivation was the crucial variable.

One trial of three different therapeutic community programs in homeless shelters for men found that the length of time in treatment rather than the type of program had an impact on outcomes (Liberty et al 1998). Once again, the trial had serious limitations: there was no random assignment to treatment groups and no control group (although the third program was a low-intensity program), and there were significant baseline differences in alcohol and drug use between the groups. Thus, it is difficult to draw any conclusions from the study. Drop out rates were estimated at 45% in the first 5 days for one of the programs. Retention rates at the end of treatment ranged (90 days) from 30.5% to 38.7%. One interesting finding of this study is that 3 months was sufficient to bring about significant improvements on a range of outcomes; typically, TC programs run for 12 months or more.

Project MATCH

Project MATCH was a national, multisite, randomised clinical trial initiated by the NIAAA in 1989 to test the patient-treatment matching hypothesis. The “matching hypothesis” states that clients who are appropriately matched to treatments will show better outcomes than those who are mismatched (Project MATCH Research Group 1997). Despite the intuitive appeal of the matching hypothesis, empirical evidence for the efficacy of matching as a strategy to enhance treatment response is mixed and suggests that matching is a promising, but not yet fully realised strategy for increasing treatment effectiveness.

The study consisted of two parallel but independent studies, one with alcohol dependent clients receiving outpatient therapy (N = 952) and one with clients receiving aftercare therapy following inpatient or day hospital treatment (N = 774). The overall objective of each of the studies was to determine whether various subgroups responded differently to treatments. Three manual-guided psychosocial treatments were delivered individually over twelve weeks: Cognitive Behavioural Coping Skills Therapy (CBT), Motivational Enhancement Therapy (MET) and Twelve-Step Facilitation Therapy (TSF). Ten client characteristics were considered as matching variables: (1) *severity of alcohol involvement*, (2) *cognitive impairment*, (3) *client conceptual level*, (4) *gender*, (5) *mean seeking*, (6) *motivational readiness to change*, (7) *psychiatric severity*, (8) *social support*, (9) *sociopathy* and (10) *typology*. The primary outcome measures were percent days abstinent (PDA) and drinks per drinking day (DDD), and patients were assessed at 3 (end of treatment), 6, 9, 12 and 15 months after the first therapy session.

There were substantial positive changes in amount (PDA) and intensity (DDD) of drinking for both aftercare and outpatient clients from baseline to each of the follow-ups. These improvements were sustained during the follow-up period with only slight deterioration and 1-year post-treatment and there was little difference in outcomes by type of treatment. Tests of the primary matching hypotheses demonstrated few matching effects. Psychiatric severity was the only attribute considered that showed a significant attribute by treatment interaction: In the outpatient study, clients low in psychiatric severity had more abstinent days after TSF than after CBT. Neither treatment was clearly superior for clients with higher levels of psychiatric severity.

Overall, evidence for matching effects was disappointing. Findings suggest that psychiatric severity should be considered when assigning clients to outpatient therapies. The Project MATCH Research Group concluded that the lack of robust matching effects suggests that, aside from psychiatric severity, providers need not take the client characteristics considered in Project MATCH when assigning patients to outpatient therapy.

Relapse prevention [From MAD project, in progress]

Despite the short-term effectiveness of several interventions, there is little evidence that treatments are effective in the long term. The conceptual model of relapse prevention views relapse as a natural part of the process of change. Lapses and relapses are viewed as opportunities for clients to understand their behaviour and develop new skills to deal with high-risk situations. Relapse Prevention Therapy (RPT) strategies are designed to address the immediate precursors of relapse and involve the training of coping skills, challenging positive outcome expectancies associated with alcohol use and coping with lapses. The aim of these treatments is the maintenance of long-term abstinence or moderate drinking behaviours.

Much of the research on relapse prevention (RP) examines its' effectiveness in relation to substance abuse rather than alcohol misuse in particular. There have been both a narrative review and a meta-analytic review that examined the efficacy of RP in *substance abuse*. Although not specific to alcohol treatment, these reviews are included as they give some idea about the efficacy of RP as a treatment for substance abuse in general.

In a narrative review of 24 randomised controlled trials, Carroll (1996) evaluated the effectiveness of RPT as a psychosocial treatment for substance abuse. Her selection criteria included “only those RCTs that evaluated a treatment approach defined as *relapse prevention* or that evaluated a coping skills approach that explicitly invoked the work of Marlatt” (Carroll 1996; p46). Carroll (1996) concluded that RP appears to be effective relative to no-treatment control groups and equally effective when compared to other active treatments. Three areas were noted as particularly promising in the effective application of RPT. First, while RPT may not always prevent relapse better than other treatments, it may reduce the intensity of relapse episodes if they do occur. Secondly, numerous investigations have found continued main effects or a delayed emergence of effects for RP after sessions have finished. Finally, Carroll (1996) suggests that RPT may be more effective for more impaired substance abusers.

In a meta-analytic review of 26 studies, Irvin et al (1999) examined the effect of RP on substance use behaviour and overall psychosocial adjustment as well as possible moderator variables that may relate to the effectiveness of RP. Irwin et al (1999) concluded that RP appears to be effective reducing substance abuse and improving psychosocial functioning, particularly for alcohol and poly-substance use disorders. Moreover, RP seemed to have more impact on psychosocial functioning than on reducing substance use. RP appears to be most effective when combined with the use of medications and when evaluated immediately following treatment using uncontrolled pre-post tests. The average effect sizes for alcohol studies were similar regardless of modality and treatment setting revealed no significant differences between inpatient and outpatient settings. These two reviews suggest that RPT is an effective treatment for alcohol problems.

Non-medicated Relapse prevention: Connors et al (1992) compared group aftercare, telephone aftercare and no aftercare in sixty-three problem drinkers without physical dependence. After participating in an 8 week drinking reduction program, participants were randomly assigned to one of the three aftercare conditions. A separately recruited no-treatment comparison group was also studied and participated only in data collection and follow-up. Treated participants significantly reduced their monthly heavy drinking days (64% reduction from pre-treatment to twelve-month follow-up), regardless of aftercare condition. Reductions in heavy drinking among the treated participants were associated with utilization of drinking reduction techniques. Similar reductions in heavy drinking were found for the no-treatment participants who were only followed over time.

Graham et al (1996) evaluated the differential effects of group and individual relapse prevention aftercare for participants who had graduated from one of two treatment programs. There were 12 weekly sessions of structured relapse prevention for both conditions. Presentation of relapse prevention appeared to be effective when delivered in both group and individual formats and neither condition appeared to produce superior effects.

Allsop et al (1997) conducted a controlled trial of a relapse prevention program with male problem drinkers (N= 60) allocated to relapse prevention, discussion or no-additional treatment conditions. The RP program was associated with significantly greater increases in pre- and post-treatment self-efficacy compared to the discussion control group and significantly greater probability of total abstinence than all controls over the first six-month follow-up. The relapse prevention program was also associated with significantly longer time to lapse and relapse than controls. At 12 month follow-up, there were no significant treatment effects. This study provides evidence for the short-term efficacy of relapse prevention programs but not for the longer term impact of these programs.

Pharmacotherapies

A number of pharmacotherapies have been used in preventing relapse in alcohol dependent patients including disulfiram, naltrexone and acamprosate. There are several methodological issues that arise when evaluating the efficacy of pharmacotherapies in RP. Firstly, there is a great deal of variability

across studies in terms of what relapse prevention actually consists of. Secondly, the sample size in some of the studies reported was small and thus had limited statistical power to detect differences between conditions. Thirdly, the primary outcome measure differed across studies, making comparability across studies difficult. Lastly, the duration and intensity of treatment varied widely. Thus the optimal dose and the extent to which dose of relapse prevention treatment may be associated with robustness or durability of effects has not been empirically evaluated for some of the minor pharmacotherapies.

Although a number of trials have examined the efficacy of SSRIs for preventing relapse in alcohol dependent patients, the evidence to date does not present a clear picture. Outcomes appear to depend to some extent on the presence of co morbid depression; the timeframe for follow up and evaluation; severity of dependence; and gender. It appears that there is little evidence for the long-term efficacy of SSRIs in preventing relapse in alcohol-dependent patients, except potentially with male heavy drinkers who are not severely dependent. SSRIs would appear to be contra-indicated for severely dependent drinkers.

The literature relating to the use of pharmacotherapies in alcohol dependent patients is extensive and, as for the other risk factors, could be the subject of an extensive amount of work in their own right. A further consideration is that the PBAC already undertakes a very thorough evaluation of pharmaceuticals in Australia. It is for these reasons that it is recommended in Chapter 8 that the evaluation of pharmacotherapies be discussed with the DHA before finalisation of the interventions to be included in Stage II.

Treatment issues

Gender differences: Gender differences in alcohol treatment outcome have often been ignored in research, primarily because both individuals suffering from alcohol related disorders and treatment-seeking individuals are far more commonly men than women (Vannicelli 1984; Schober 1996). Furthermore, it is often assumed that men and women with alcohol problems react to treatment in the same way. However, results from studies which have examined gender differences in treatment outcomes indicate that there may be gender differences in treatment response and outcome (Jarvis 1992). Further, findings of large-scale studies indicate that the proportion of women with alcohol use disorders in the population is increasing (Schober 1996), making the study of gender differences in treatment outcome for alcohol misuse an important and timely issue in alcohol treatment research.

Although research examining gender differences in treatment outcome is scant, baseline gender differences in alcohol abusing and dependent people are well documented (AIHW 2001). Men generally start to drink and have problems with alcohol earlier than women. Men also tend to experience more occupational and legal problems than women. Women are more likely to report that other members of their family have received treatment for alcohol problems and more psychological symptoms than men (Schneider et al 1995; Blume 1990). That there are well documented baseline differences between men and women indicates that they may respond differentially to treatment.

A meta-analysis of the implications of gender for alcohol treatment research (Jarvis 1992) examined the magnitude and direction of trends of gender differences in treatment outcome. The results indicated that women had better treatment outcome than men in the first 12 months after treatment while men showed greater improvement than women in follow-ups more than 12 months after the termination of treatment. Consistent with previous reviews, estimated differences were small and results were derived from a heterogeneous sample of studies. However, results highlighted certain gender related factors that may be related to the processes and outcomes of treatment. In particular, factors that may undermine long-term treatment success include treatment mode and setting, social support and stigmatization of women in treatment, low self-esteem and trauma related to sexual abuse.

In a study examining possible gender differences in reasons for relapse, Saunders et al (1993) assessed men and women attending an alcohol treatment facility on a range of demographic, social and psychological measures. Results suggested that predictors of a return to heavy drinking were gender related. Although social stability was predictive of return to heavy drinking for both men and women, different aspects of social stability related to gender. For women, the fewer the number of children living at home, the more likely they were to return to heavy drinking regardless of whether they had a partner or not. Men were more likely to relapse sooner if they didn't have a partner and were living alone. Aspects of cognitive functioning, premorbid intelligence, and confidence in remaining sober over time and belief about future control were related to women's but not to men's return to heavy drinking. Those predictors of a return to heavy drinking were gender related suggest that there is a need to individualise relapse prevention and management strategies.

Sanchez-Craig et al 1989, conducted a series of studies examining outcomes of brief treatment for the reduction of heavy drinking in men and women. Problem drinkers were randomly assigned to receive either three sessions of advice using a pamphlet (guidelines condition), three sessions of instruction in the use of a manual (manual condition) or six or more sessions of instruction in the methods outlined in the manual (therapist condition). Reductions in heavy drinking in women varied between 79 and 25% across the two studies. At 3, 6 and 12-month follow-ups, there were no significant differences among groups in reduction of drinking days. However, females had significantly greater reductions than males. In both studies, the number of moderate drinkers was significantly higher among women than men in the guideline and manual conditions but not in the therapist conditions and, at 1-year follow-up more women than men were moderate drinkers in all three conditions. This study indicates that for BIs, treatment outcomes for women were superior to outcomes for men, and rates of reduction were substantial.

Scott and Anderson (1990) conducted an RCT of GP intervention in women with excessive alcohol consumption. Seventy-two women were randomized to control or treatment conditions. Women in the treatment conditions received ten minutes advice from their GP. At one year follow-up, when analysed by intention to treat, women in the treatment group had reduced their consumption from 35 to 24 units per week. However, similar reductions occurred in the control group, and there were no treatment effects. These results indicate that screening alone may be effective in reducing alcohol consumption in women drinkers.

Using data from Project MATCH, Thevos and her colleagues (2000) tested the hypothesis that socially phobic women alcoholics treated with Cognitive Behavioural Therapy would have better treatment outcomes than those treated with Twelve Step Facilitation Therapy (TSF). Three hundred and ninety seven treatment seeking alcoholics with social phobia were compared retrospectively to matched samples of 397 alcoholics without social phobia. Results from survival analyses revealed that female outpatients with social phobia showed delayed relapse to drinking when treated with CBT rather than TSF; the reverse was true for female outpatients without social phobia. Survival analyses in male outpatients with and without social phobia revealed an opposite trend, though it was not statistically significant. These data suggest that Cognitive Behavioural therapy is superior to Twelve-Step Facilitation therapy for the treatment of alcohol problems socially phobic women seeking outpatient treatment.

Research regarding gender differences in treatment outcome for alcohol misuse has increased, and it appears that there are gender differences in treatment response and outcome. However, the evidence is not clear on precisely how outcomes differ for men and women or which aspects of treatment are responsible for different outcomes.

Implications for treatment: Women have been found to be more vulnerable to a rapid escalation of substance dependence, more likely to have pre-existing mental health disorders and severe early life-events, particularly sexual abuse (Sannibale et al 2001). A history of child sexual abuse has been

strongly linked to substance misuse and mental health problems (Wilsnack et al 1997). Since childhood trauma may have complex clinical presentations, treatment may require specialist care. The diverse patterns of risk factors must be recognized and considered in the planning and delivery of effective health services for women with alcohol use problems (Sannibale et al 2001). An enhanced sensitivity to different gender needs may encourage women with complex problems to participate in treatment.

Indigenous clients

The majority of indigenous Australians now live in rural towns and cities (Gray et al 2000). However a substantial proportion still reside in remote areas where the range and quality of general and specialist health care facilities are below that in other areas. The role of primary care providers in such a situation becomes even more critical. Although a number of evaluations of individual clinics or programs have been undertaken, we were unable to locate any randomised controlled trials for treatment of indigenous clients with alcohol use disorders. According to Gray et al (2000), the methodologies employed in evaluating interventions have been insufficient to allow robust generalisation.

Treatment in primary care settings: One survey of an indigenous community-controlled health service revealed that nearly half (42.6%) of all consultations were with indigenous health workers, not GPs, a finding with relevance for the implementation of alcohol screening and treatment services (Thomas et al 1998). Further, almost all patients (96.1%) saw an indigenous health worker before seeing a GP.

Evidence for the effectiveness of treatment specific to indigenous clients is scant. However, guidelines have been developed for the management of alcohol problems in indigenous primary care settings (Hunter et al 2000). This very practical guide provides information on managing intoxication, withdrawal, medical and psychiatric co morbidity, screening, BIs, and continuing care.

Treatment in specialist settings (e.g. drug and alcohol clinics; indigenous health clinics): In an article reviewing the relationship between indigenous culture and treatment for alcohol problems, Brady (1998) points out that indigenous drinkers show quite varied patterns of alcohol use and abuse, and that it should not be assumed that one treatment approach will be appropriate for all indigenous clients (Brady 1995). This comment was made with respect to a strong orientation towards the disease model of alcoholism and the 12-step facilitation model amongst indigenous treatment services (the same concern expressed by Mattick and Jarvis in 1993). Brady (1998) stresses the need for a range of treatment options, including BIs and motivational interviewing. She also points out that 'culture as treatment' (the notion that reclaiming culture will in itself heal the alcohol problem) will only work if:

'...they succeed in helping clients to form peer groups (both adolescent and adult) which disvalue drug and alcohol use and which assist individuals to deal with the persuasive pressures of their kin and associates'.

Gray (2000) concurs that of the 79 treatment services he identified for indigenous clients, the majority are based on Alcoholics Anonymous or abstinence principles. Few indigenous clients achieve the goal of continuing abstinence (O'Connor 1998). Gray (2000) found that results in most specialised treatment programs were equivocal, although there is some suggestion that sobering up centres have been a catalyst to further local actions to address alcohol misuse and associated harm. D'Abbs (1990), in an evaluation of two residential and one non-residential program, concluded that attendance at one family oriented program had modest effects on drinking behaviour, and that community-based field workers constitute an essential complement to residential programs. He also suggests that the effectiveness of all the services was limited because of a narrow range of treatment options.

Adolescents and young adults

Diagnosis and Assessment: Although the DSM-IV criteria for alcohol use disorders have shown some validity for adolescent populations, they may have limitations when used with adolescents (Martin et al 1998):

- Some symptoms have a very low prevalence, ie withdrawal and alcohol-related medical problems, which generally emerge only after several years of heavy drinking
- Other symptoms, such as hazardous use and alcohol-related legal problems are highly correlated to male gender, increased age, and symptoms of conduct disorder
- Some symptoms, such as tolerance to alcohol, may have low specificity for adolescents
- The one-symptom threshold for the DSM-IV diagnosis of alcohol abuse produces a great deal of heterogeneity among adolescents in the category

DSM-IV alcohol symptoms have been found to develop in three distinct stages among adolescents, with some dependence symptoms developing before some abuse symptoms (Martin et al 1998):

1. During the first stage, which generally occurred after 3-4 years of exposure to alcohol, adolescents typically developed 3 dependence symptoms (tolerance, drinking larger amounts or for a longer period of time than intended, and much time spent using alcohol) and 2 abuse symptoms (role obligation problems and social problems).
2. The second stage was characterised by 3 dependence symptoms (unsuccessful attempts to quit or cut down on drinking, reduced activities because of alcohol use, and continued use despite physical or psychological problems) and 2 abuse symptoms (hazardous use and alcohol-related legal problems).
3. The third stage was characterised by the dependence symptoms of withdrawal.

Treatment Outcomes: Research on long-term treatment outcomes for adolescents with alcohol problems is scarce, but it is widely accepted that the differences between adult and adolescent problem drinkers have important implications for treatment (Winters et al 2000). These differences include shorter drinking histories, more polydrug use, greater binge drinking, rapid social and physical changes, a wider range of co-existing life problems such as homelessness, poor performance at school, difficult parental relationships, and low employment prospects.

Much of the research on adolescents has examined treatment impact on substance abuse generally, not specifically alcohol. However, given the higher level of polydrug use noted in adolescent populations (Winters et al 2000), it may be appropriate to review such studies. Using an uncontrolled, descriptive study, Winters et al (2000) examined the effectiveness of the 12-step Minnesota model and found that the treatment group had better outcomes than the non-treatment group. Specifically, those in the treatment group had less drug use and higher abstinence rates than those in the non-treatment group. Best outcomes were obtained with longer treatment retention, although a short stay in treatment was better than no treatment at all. There were no significant differences between inpatient and outpatient treatment. All clients were involved in a range of treatment components that typically spanned 4 consecutive weeks for residential clients and 30 sessions during 6 consecutive weeks for outpatients. Components include group and individual therapy, family therapy, lectures about the 12 AA steps, a series of AA-based reading and writing assignments, school study sessions, and occupational and recreational therapy.

A long-term study of treatment outcomes for adolescents is less encouraging (Brown et al 2001). Following an initial drop post-treatment decrease at the 6-month follow-up, mean days of alcohol use increased at each subsequent follow-up point, and at 4 years, were approaching intake levels. The only alcohol intake variable to remain below intake levels for the 4 years was the percent of participants who reported getting drunk more than half the time. However, intake of other substances

remained lower at 4-year follow up than at intake. The treatment was provided at an inpatient facility, using a 12-step approach.

Spooner et al (2001), using a quasi-experimental design to evaluate the effectiveness of a residential treatment program for adolescent substance users, found similar improvements for both the treatment group and the comparison group at 3 and 6 month follow-up in substance use, criminal behaviour, social functioning, psychological distress, physical health, and HIV risk-taking behaviour. However, the comparison group was not a no-treatment group: they received treatment as usual from a range of treatment agencies. Further, there was a significant difference in dropout between the two groups (higher in the comparison group), which may have biased the results in favour of the comparison group.

One study of alcohol dependent or abusing patients (Rice et al 1993) found that for young adults (18-29), there was no significant difference in treatment outcome irrespective of treatment type (CBT, relationship enhancement, or relationship and vocational enhancement), whereas older adults (over 50) did best with CBT, and middle-aged adults did best with relationship enhancement. However, some limitations must be noted. Firstly, the young adult group was a relatively small sample of 53 so the lack of difference may have been due to low statistical power. Secondly, there was no control group, thus it might be inferred that all treatments were equally effective OR ineffective. Finally, it is not clear from the article whether the analysis was conducted according to the intent-to-treat principle.

Brief and motivational interventions appear to be effective for adolescent heavy drinkers. Monti and colleagues (1999) found that a BI, used with older adolescents in an emergency department setting after an alcohol-related event, resulted in fewer alcohol-related injuries and reduced likelihood to drink-drive compared with adolescents who received standard hospital care. Similar results were obtained by Marlatt et al (1998) in a high school setting. Borsari and Carey (2000) found that college student binge drinkers who received a single-session motivational interview exhibited significant reductions on number of drinks consumed per week, number of times drinking alcohol in the past month, and frequency of binge drinking in the past month exhibited significant reductions on number of drinks consumed per week, number of times drinking alcohol in the past month, and frequency of binge drinking in the past month, when compared to a no-treatment group.

Co-morbid disorders

A number of issues present special challenges in the course of treatment for alcohol problems. Not least amongst these is the co-occurrence of alcohol dependence with mental disorders. Little controlled research has been conducted to evaluate the effectiveness of treatment for co morbid clients, despite the fact that most alcohol dependent clients have a co morbid mental disorder (primarily mood or anxiety disorders).

Assessment and Diagnosis: The Alcohol Use Disorders Identification Test (AUDIT) has been evaluated in a psychiatric hospital setting and was successful in identifying hazardous, problem and dependent alcohol consumption amongst psychiatric patients (Hulse et al 2000). The authors make a number of recommendations for using AUDIT with psychiatric populations: first, the AUDIT provides a simple procedure for screening hazardous and harmful alcohol use among people with psychiatric disorders. Second, the AUDIT is best used following '*... subsidence of psychiatric sequelae, adjustment to medication, and improvement in cognitive functioning*'. Third, the AUDIT is best administered by staff, rather than self-administered, with this population. Fourth, the AUDIT should be incorporated into the routine assessment and management of psychiatric units. Finally, the AUDIT may best be administered by the primary nurse, who has the opportunity to build rapport with the patients as well as being aware of the patient's current condition.

Treatment: Psychosocial Interventions: Several treatment issues arise with co morbid disorders. Should treatment be integrated, parallel or adjunctive? If the latter, which disorder should be treated

first? What combination of therapies should be used? What implications does the order of onset have for treatment? The research to date, whilst providing some clues, does not adequately answer these questions.

It appears that it is possible to differentiate between primary and secondary depressive disorders (Schuckit et al 1997). Almost 42% of dependent drinkers in this study met criteria for a diagnosis of a major depressive episode at some time during their alcohol dependence. Of those, more than 60% reported a substance-induced depressive episode. Those with primary depression had a higher prevalence of independent depressive disorders in first-degree relatives. They were also more likely to be married, Caucasian, and female, or if male, to have a stable marital history. They typically had experience with fewer drugs and less treatment for alcohol problems, and were more likely to have attempted suicide. However, the clinical presentation of symptoms did not differ substantially between substance induced and primary depressive disorders.

Cognitive behavioural therapy (CBT) was shown to have greater benefits for depressed alcohol dependent patients than standard alcohol treatment combined with relaxation training in one study (Brown et al 1997). Post-treatment, patients in the CBT condition had greater reductions in depressive symptoms and a higher percentage of days abstinent than the standard treatment group. At 3 and 6 month follow up, the CBT group also had significantly better outcomes for total abstinence (47% v 13%), percent days abstinent (90.5% v 68.3%), and drinks per day (0.46 v 5.71). Similarly, CBT delayed relapse for female, alcohol dependent patients with co morbid social phobia. Using data from Project MATCH, patients receiving CBT were compared with those receiving twelve-step facilitation (TSF). Socially phobic women, but not men, who received CBT had a longer time to relapse than matched counterparts in the TSF group. For socially phobic males, there was a non-significant trend towards better outcomes in the TSF group (Thevos et al 2000).

In contrast, Bowen, D'arcy, Keegan and Senthilselvan (2000) found that for alcohol dependent patients with co morbid panic disorder, CBT was no better than a standard alcohol treatment program in reducing problem drinking. Unfortunately the article does not describe the standard treatment program, but the authors suggest that it may have contained enough active anxiety-treatment ingredients to reduce any differences between it and CBT.

An even greater contrast is presented by Randall et al (2001) where treatment for both alcohol dependence and social phobia produced worse alcohol use outcomes than treatment for alcohol dependence alone. Whilst both groups improved on alcohol-related and social anxiety outcomes, the dual treatment group had worse outcomes than the alcohol dependence treatment group on three of the four alcohol use measures.

Integrating motivational interviewing, CBT and family intervention with routine psychiatric care produced greater benefits for patients with co morbid schizophrenia and substance use disorders than routine psychiatric care alone (Barrowclough et al 2001). At 12 month follow-up, the integrated treatment group had better general functioning, a reduction in positive symptoms, and an increase in the percentage of days abstinent from alcohol or drugs.

Finally, Herman et al (2000) randomly assigned patients with a serious mental illness and a substance use disorder to either an integrated mental health and substance use treatment program or to a standard hospital treatment program. Two months after treatment, those receiving integrated treatment had fewer days of alcohol use than those in the standard treatment program. This study also found that patients who had no family involvement, low intentions at discharge to stay sober, and no attendance at self-help groups post-treatment had the worst outcomes. Having a diagnosis of schizophrenia was negatively related to the rate of alcohol use.

Treatment: Pharmacotherapy's: Evidence of the capacity SSRIs to reduce alcohol intake is mixed. A number of studies (Naranjo et al 1995; Naranjo et al 1996) have found no advantage for SSRIs over placebo in reducing alcohol consumption, but they have been effective in reducing depression scores in alcohol dependent patients (Kranzler et al 1995). Only one trial to date has specifically examined the effectiveness of SSRIs with co morbid patients. Cornelius et al (1997) administered fluoxetine or placebo to alcohol dependent patients diagnosed with major depressive disorder over a 12-week period, in an inpatient setting. Both depressive symptoms and total alcohol consumption over the trial were significantly lower in the fluoxetine group than in the placebo group.

Buspirone, an anxiolytic, has been tested with anxious alcohol dependent patients with some success (Kranzler et al 1994). Patients received 12 weeks of buspirone v placebo and weekly CBT/relapse prevention therapy. When evaluated 6 months after the treatment ceased, the buspirone group had greater retention in treatment, reduced anxiety, and fewer drinking days. It is important to note that patients only had to have anxiety symptoms, but about half of the patients in the study met diagnostic criteria for an anxiety disorder (predominantly generalised anxiety disorder).

Cognitive impairment

Brain damage associated with long-term alcoholism can be extensive and there is wide range of variability in both the severity and types of cognitive impairment that are present in alcoholic patients. The most severe impairments are the memory deficits caused by Wernicke Korsakoff syndrome or alcoholic dementia. Even among people admitted to alcoholism treatment facilities that do not show dramatic cognitive impairment, between 75 and 100 per cent of patients perform below normal for their age groups on tests of cognitive function.

At this stage, alcohol researchers do not know how severe cognitive impairment due to alcohol consumption is or whether cognitive impairment impedes alcoholism treatment. Some research indicates that cognitive functioning relates to various aspects of treatment, including treatment outcome, however findings are mixed. Some studies report that less cognitively impaired alcoholics are more likely to attend outpatient treatment, to complete a treatment program and to have a better outcome. Impaired cognitive functioning may impact on a variety of processes, such as impulsivity, planning and decision-making skills (Smith and McCrady, cited in Allsop 2000). Many studies conducted in the late 70's and early 80's reported that cognitive impairments were the best predictors of poor treatment outcome. However, other researchers have reported no relationship between cognitive deficits and treatment success.

Cognitive deficits apparent in alcoholics are often subtle and improve with a period of abstinence from alcohol (Goldman 1995). However, they can still hamper the effectiveness of treatment programs. If patients cannot comprehend the information imparted during therapy, they may not be able to use treatment strategies successfully. Therefore, adding strategies to enhance cognitive recovery could improve some alcoholics' chances of successful recovery.

In a study designed to test the patient-treatment matching hypotheses (Cooney et al 1991), patients with cognitive impairment had better outcomes in interactional treatment than in coping skills training, and patients without cognitive impairment did better in coping skills treatment than in interactional therapy. This finding was contrary to predictions and indicates that cognitively impaired participants may have found the coping skills treatment too complex, whereas the interactional therapy may have been less taxing. This explanation deserves further investigation.

Horner, Waid, Johnson, Latham and Anton (1999) examined cognitive functioning after a minimum of 4 days of abstinence in mild- to moderately dependent alcoholics. Decrements in reaction time and verbal memory were associated with higher amounts of alcohol consumption in the 90 days prior to enrolment in the study and amount of recent consumption was correlated with scores on numerous cognitive tests. However, longer drinking history was not associated with poorer performance on any

neuropsychological measures. That is, in this sample of patients, mild cognitive deficits were related to the amount of recent alcohol consumption but not to lifetime alcohol consumption.

Allsop, Saunders and Phillips (2000) conducted a study to investigate factors hypothesized to influence the relapse process. Poorer cognitive functioning was significantly associated with being categorized as a problem drinker at 6 month follow-up. This is consistent with results reported in other studies (Parsons et al 1990). Poorer cognitive function was also associated with higher risk of lapse over the 12 month follow-up. The authors speculated that those with comparatively poor cognitive functioning may have had difficulty in learning new skills. Further, poor cognitive functioning may impair the ability to make decisions to change and increase the likelihood of poor decision-making skills, increasing the risk of relapse. These claims are worth investigating further.

Recommendations for Treatment – Cognitively Impaired Patients: Although many studies have examined cognitive impairment in alcoholic patients, few studies have systematically examined the effect of cognitive impairment on treatment outcomes. The application of the impact of cognitive functioning on treatment outcome is in its early stages but several recommendations can be made (Goldman 1995). Many studies do suggest that impaired cognitive functioning is related to poorer treatment outcome, particularly for treatments that require the acquisition of new skills. Thus, assessment of cognitive functioning should be an integral part of the assessment procedure and results should be used to guide treatment planning (Allsop et al 2000). Where cognitive impairment is apparent, treatment elements that require heavy cognitive processing should not be employed as they are likely to be ineffective (Goldman 1995). Further, information presented to patients should be concrete and patients should be given opportunities to practice behaviours taught. Implementing these strategies may increase the efficacy of treatment in cognitively impaired alcoholics.

Table 7.2: Key studies re alcohol harm reduction

Intervention type Study/ Year	Description	Inclusion criteria	Treatment	Outcomes
Brief intervention				
Moyer, Finney, Swearington & Vergun (2002)	Meta-analysis including: (1) 34 studies comparing BIs with control conditions in non-treatment seeking samples (2) 20 studies comparing BIs with extended treatment in treatment-seeking samples	Studies investigating BIs that provided no more than four treatment sessions.	Brief interventions	For the first type of study, small to medium effect sizes (range 0.129 – 0.669) in favour of BI emerged over follow-up points ranging from 3–12 months indicated BI are superior to control conditions. For the second type of study, effect sizes (range – 0.028 – 0.415) were largely not significantly different from zero, indicating little difference between BI and more intensive treatments.
WHO BI study group (1996)	Randomised clinical trial with 1559 participants (1260 men, 299 women) from 8 different countries.	Participants were considered to be at risk of alcohol-related problems but had no prior history of alcohol dependence	Simple advice (5 minutes) or brief counselling (20 minutes)	Male patients receiving interventions reported 17% lower average daily alcohol consumption than those in the control group, and a 10% decrease in intensity of drinking. For women, significant reductions were observed for all groups. Five minutes of advice appeared to be as effective as 20 minutes of brief counselling.
Post detoxification treatment setting				
CBT Heather, Brodie, Wale, Wilkinson, Luce, Webb & McCarthy (2000)	Randomised clinical trial (N = 91)	Clients must request preference for moderate drinking over abstinence. Excluded if: continued consumption was contraindicated on medical grounds; clients had severe psychiatric disturbance, severe cognitive impairment or current dependence on other substances.	Moderation-Oriented Cue Exposure (MOCE) or Behavioural Self-Control Training (BSCT)	There was a significant decrease in drinks per drinking day (DDD) across the whole sample from intake to 6-month follow-up (F = 16.14, p<.001). There was no significant treatment effect for DDD. A sign. increase across the whole sample in number of days abstinent at follow-up cf baseline (z = 4.89; p<0.001). No significant effects of treatment group.

Intervention type Study/ Year	Description	Inclusion criteria	Treatment	Outcomes
Finney et al (1996)	Meta-Analysis 21 studies identified, 8 excluded	Randomised controlled trials	Inpatient vs. outpatient treatment for alcohol abuse or inpatient treatment versus detoxification	Inpatient treatment was superior to outpatient treatment in five studies. Day hospital treatment was superior to inpatient treatment in two studies. In the remaining seven studies, no significant differences were found in drinking related outcomes.
Motivational interviewing				
Sellman, Sullivan, Dore, Adamson & MacEwan (2001)	Randomised Controlled Trial (N = 122)	Primary diagnosis of mild to moderate alcohol dependence	Motivational Enhancement Therapy (MET)	Unequivocal heavy drinking (10+ standard drinks six or more times over the 6 month follow-up) was significantly lower in the MET group (42.9%), compared to both control conditions (non-directive reflective listening = 62.5%; no further counselling = 65.0%).
Couples behavioural therapy				
McCrary, Epstein & Hirsch (1999)	Randomised Clinical Trial (N = 90 participants and their partners)	Inclusion criteria were (i) male with a current drinking problem (ii) not psychotic (iii) no evidence of cognitive impairment (iv) did not meet criteria for other drug dependence (v) legally married, living as married for at least 6 months or separated but with hopes for a reconciliation (vi) spouse or partner willing to participate (vii) spouse or partner with no current drinking problem.	Three conjoint treatments: alcohol related behavioural couples therapy (ABCT); ACBT with relapse prevention (RP/ABCT); ABCT with Alcoholics Anonymous and Alanon (AA/ABCT)	There was a significant increase in percentage of abstinent days from baseline to 6-month follow-up (F = 111.3, p<0.001) but there was no treatment effect. Participants also reduced their proportion of heavy drinking days across time (F = 78.42, p<.001) but there was no treatment effect. ABCT appeared to be effective in reducing alcohol consumption in alcoholic males but the addition of maintenance-focused elements did not appear to improve treatment outcomes.

Intervention type Study/ Year	Description	Inclusion criteria	Treatment	Outcomes
Self-help				
Heather, Kissoon & Fenton (1990)	Randomised controlled trial (N = 107)	Age range 18-70 years	Four treatment conditions: 1) Control group; 2) Manual group: sent a 100 page, revised edition of the self-help manual given to the control group; 3) Ansafoone group: sent the same manual and group 2 and instructions on how to use telephone answering service to make progress reports; 4) Telephone interview group: same as group 3 but progress report was to trained interviewers	Mean alcohol consumption in the overall sample was reduced from 82.3 units to 52.5 units. At 6 month follow-up, there were significantly more subjects drinking above recommended levels in the control group than the other three groups, ($\chi = 4.29$, $p < .05$). There were no significant differences due to presence or type of telephone contact and poor use was made of the opportunity for telephone contact.
Relapse prevention Non-medicated				
Irvin, Bowers, Dunn & Wang (1999)	Meta-analysis. 26 studies representing a sample of 9,504 participants were included. 10 of these studies focused on alcohol use.	Studies concerning RP and reporting test statistics associated with hypothesis tests of the effectiveness of RP	RP consistent with Marlatt and Gordon's (1985) approach	The effect size was 0.37 (95% CI = 0.28 to 0.45, $n = 10$) for alcohol use. RP was effective in reducing alcohol use and improving psychosocial functioning. Results indicate that medication may contribute substantially to this effectiveness.
Pharmacotherapies Acamprosate				
Kranzler & Van Kirk (2001)	Meta-Analysis 11 acamprosate studies and 9 naltrexone studies included	Randomised, placebo-controlled trials using ITT analysis	Acamprosate or naltrexone and psychosocial treatment.	ACA: effect sizes for CAD was -0.33 – 0.294 (average 0.165); effect sizes for % of subjects reporting abstinence for study duration was -0.46 – 0.272 (average 0.125); % of subjects remaining in treatment at study completion was -0.007 – 0.271 (average 0.097)

Intervention type Study/ Year	Description	Inclusion criteria	Treatment	Outcomes
Sass, Soyka, Mann, & Zieglansberger (1996)	Randomised, double-blind, placebo-controlled trial. N = 272	Alcohol dependent, no mental or psychiatric impairment/ disease that required psychotropic medication or a stay in a psychiatric clinic, no multiple drug misuse, no severe neurological or physical disorders	48 weeks of ACA ^(a) vs placebo. All patients received routine counselling or psychotherapy (average 1 hour weekly over 18 weeks).	Higher continuous abstinence rate in first 60 days for ACA group (67% vs 50%) and at completion of treatment (43% vs 21%); longer cumulative abstinence duration (CAD) (224 vs 163 days); better retention (59% vs 40%). At the end of a further 48 weeks without medication, 39% (ACA) and 19% (placebo) remained abstinent.
Naltrexone				
Streeton & Whelan, 2001	Meta-analysis, N = 833	RCTs involving patients over 18 yrs, diagnosis of alcohol dependence or abuse, NTX vs placebo or another active drug licensed in Australia. Trials measured relapse rates, abstinence rates and percentage of patients discontinuing due to adverse events/% of patients with at least 1 adverse event.	12 weeks NTX vs placebo or other active drug. All patients received some form of psychosocial treatment in addition to the medication.	<ul style="list-style-type: none"> • Abstinence rates: 10% more NTX subjects remained abstinent for 12 week study period • Relapse rates: 14% fewer NTX subjects relapsed than placebo • Drinks/drinking day NTX subjects consumed 1.0 drink less per drinking day • Number of drinking days 3% less for NTX subjects • No difference in adverse events
Morris, Hopwood, Whelan, Gardiner & Drummond 2001	Randomised, double blind, placebo controlled trial N = 111.	Alcohol dependent males, 18-65 years, score of at least 5 on MAST, residing within 1.5 hours, maintenance of at least 3 days' sobriety before study entry.	NTX (50mg/day) vs placebo for 12 weeks. All patients received standardised weekly 1.5 hr sessions of group psycho-education and social support, including relapse prevention.	Longer time to relapse in NTX group (6.7 vs 4.2 weeks); fewer total standard drinks during treatment period (139 v 279); fewer relapsers.
SSRI's				
Pettinati, Volpicelli, Kranzler, Luck, Rukstalis & Caan, 2000	Randomised, double-blind, placebo controlled trial. Randomisation to medication took place within groups (depressed vs non-depressed). N = 100	Men and women who were alcohol dependent, over 18 yrs, abstinent for 3 days before randomisation, seeking treatment. Excluded if current substance use disorder other than alcohol or nicotine, serious or unstable physical illness, history of dementia or psychosis, currently needed other psychotropic medications	Sertraline and weekly twelve-step facilitation vs placebo and weekly twelve-step facilitation. Duration 14 wks. Dosage of sertraline increased to 200mg/day within 2 wks until final 2 wks of treatment, at which point dosage was tapered off.	No overall difference for sertraline vs placebo. However, sertraline provided a significant advantage on all three outcomes for subjects classified as Type A (low risk/low severity subjects), but not for subjects classified as Type B (high risk/high severity subjects). Outcomes for type A subjects (sertraline vs placebo): percent days drinking 0% vs 22.4%; percentage of subjects continuously abstinent 53.3% vs 16%; time to relapse 5 vs 4 weeks.

Intervention type Study/ Year	Description	Inclusion criteria	Treatment	Outcomes
Kranzler, Burleson, Korner, Del Boca, Bohn, Brown & Liebowitz, 1995	Randomised, double blind, placebo controlled trial. N = 101	Men and women who were alcohol dependent and had no substantial physical or laboratory abnormality	Fluoxetine (mean dose of 47.1mg/day) vs placebo. All patients received weekly individual or group cognitive behavioural therapy. Treatment 12 weeks	All subjects significantly reduced drinking days, drinks per drinking day, and drinks per day, but no differences between fluoxetine and placebo group.
Disulfiram				
Mattick & Jarvis, 1993	Meta-analysis	RCTs	Supervised vs unsupervised disulfiram, unsupervised disulfiram vs unsupervised placebo, unsupervised disulfiram vs no medication, unsupervised disulfiram and therapy vs regular medical check up, unsupervised disulfiram vs regular medical check up	Small but positive effect size for disulfiram overall (0.15 immediately post treatment; 0.30 at 6-11 months; 0.10 at 12-23 months).

(a) ACA dose varied by body weight: <60 kg 1332mg/day as 4 tablets (2 in the morning, 1 at midday, 1 in the evening); >= 60kg 1998mg/day as 2 tablets thrice daily

CHAPTER 8: Interventions Selected for Economic Evaluation

8.1 Selection Criteria

The aim is to select interventions to illustrate the range of goals, settings and methods of interventions. It is expected that interventions will vary in terms of efficiency with which they reduce disease burden, so that some will be “good buys” whilst others will be “poor buys”. Thus coverage is sought across a range of modalities, delivery settings and target groups to allow an appreciation of what can be achieved by choosing one option against another.

However, as has been noted, the extent of the literature relating to interventions to reduce the prevalence of four risk factors is substantial. To assist in the process of identifying specific interventions for economic evaluation, attention was given to categorisation of these interventions into generic groups. Given large number of intervention options, across the four risk factors, some additional criteria have been developed to further refine the selection process. These additional criteria are summarised in the Table 8.0. The application of these criteria have been used in the selection of interventions for review as described in the remainder of this Chapter. The results of this process are summarised in Chapter 9.

Table 8.0: Criteria for the selection of interventions for analysis in Stage 2

Attribute	Support inclusion or exclusion for economic evaluation in Stage 2
1. Precision with which intervention can be described	Support inclusion where Intervention can be described with precision.
2. Quality of trial evidence	Support inclusion where good quality RCTs are available of sufficient size and with good retention rates. For population health interventions a causal relationship is established between intervention and outcomes through program logic/theoretical principles etc., mechanism to adjust for possible confounders
3. Nature of outcome data on effectiveness	Support inclusion where there are quantitative estimates of effect, preferably based on long-term follow-up and with outcomes expressed as final outcomes or clear relationship between measured outcome and final outcome.
4. Capacity to generate cost data	Support inclusion where there is a clear description of resource inputs for program to which unit costs can be applied.
5. Portfolio – primary purpose of the intervention. Is it primarily concerned with health?	Support inclusion where health/harm reduction is the primary purpose of the intervention. Suggestion exclusion otherwise, for instance where the intervention is primarily about employment, industry policy, transport policy, fiscal (budgetary) policy etc. A simple economic analysis around the health is then not appropriate as other considerations will dominate. (For instance a higher tax on alcohol or cigarettes might be desirable but impact on health is not the primary issue, and it simply is not possible to analyse such policies in the context of a constrained study on risk factor modification.)
6. Suitability for marginal analysis	Support for inclusion where the assumption of ‘ceterus parabus’ or all else unchanged can be taken as valid. That is the intervention operates at the margin – the scope of impacts is contained, not system wide. For instance, this would exclude interventions designed to change the pattern of urban development. This criteria tends to reinforce/be consistent with 4 above.

7. Role of intervention in functioning of the market – issue of market failure	Support for inclusion where the intervention is the provision of a direct service. Suggest exclusion where the intervention is primarily designed to improve the functioning of the market/address market failure, eg to support effective dialogue between consumers and producers. Such interventions, eg the provision of information to consumers and quality assurance programs are required by virtue of market failure to support an empowered and effective consumer. The issue is that such interventions are warranted by virtue of the theory of the market. Support for such interventions is thus fundamental. Their role is not at the margin but designed to influence the whole functioning of the health care market. They do not lend themselves to a simple cost-effectiveness analysis.
8. Health delivery setting	Specific health delivery settings identified by the DHA as of particular interest, notably primary care and specifically general practice. Interventions that fit the priority areas are favoured for inclusion.
9. Population target	Some groups have been identified as important targets, notably those that are seen to be at particularly high risk. There is seen to be an imperative to explore strategies targeted at these groups for their effectiveness and cost-effectiveness. Target groups include indigenous Australians across all risk factors, teenagers for tobacco and alcohol, and pregnant women for alcohol, tobacco and nutrition.

8.2 Recommended Interventions for Cost-Utility Analyses

Tables 8.1 – 8.3 list key interventions that are available to address the issues of poor nutrition, physical inactivity, alcohol misuse and smoking in Australia. The interventions are marked according to whether we recommend their inclusion in the current proposed cost-utility analysis, or whether they should be considered for future analyses. It is apparent that some of these interventions for the different risk factors would naturally operate together whilst others represent distinct management approaches targeting different groups of people. Thus mass media programs promoting healthy lifestyle choices could be designed to cover all of the four risk factors being considered here. On the other hand, interventions designed specifically for people with alcohol problems need to be precisely targeted to those affected.

We have endeavoured to identify between 7 and 10 interventions (although some could take on a variety of formats), for current analysis of performance, in recognition that it will be possible to analyse only a limited number of interventions. Generally we have focused on interventions within the health sector. The results of the literature search highlight gaps in the evidence. Prominent amongst these gaps is the lack of evidence for effective interventions in Australia's indigenous population and other disadvantaged groups. Thus our list of priority interventions contains an inadequate representation of programs targeted at these groups. The interventions selected for economic evaluation are described below under each of the four risk factors. They are again summarised in Chapter 9 but there a multi-risk factor category is defined. In this chapter all interventions, including multi-risk factor are classified (some-what arbitrarily) under an individual risk factor.

8.3 Interventions Concerning Physical Activity

Interventions to address sedentary life-style behaviours, selected as suitable for economic analysis cover both community based programs and individual interventions.

1 Health promotion interventions selected for economic evaluation are:

1. Community coordinated programs involving also mass media, healthy eating programs including the workplace setting and physical activity programs.

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- *Rationale for selection:* There is considerable interest in the use of media combined with community-based activities. There is also uncertainty about the cost-effectiveness of these programs.
 - II. School based programs – such as health education programs to develop student self-efficacy/self-control, development of a range of physical activity programs.
 - *Rationale for selection:* by influencing attitudes and behaviour when young, lifetime benefits might accrue. The studies describe discrete, presumably reproducible interventions. However, benefits from such interventions may take decades to be realised. Evaluations of programs of this type highlight the importance of the choice of discount rate.⁴ This will complement research for the Department of Health and Aging into the cost-effectiveness of interventions for childhood obesity.

2. Individual advice

- III. General Practitioner lead health promotion in general practice and primary care through generic self-help materials covering physical inactivity and nutrition, and specific physical activity advice typified by the Active Script program;
- IV. General Practitioner lead health promotion for formal CHD and other chronic disease risk factor clinics.
 - *Rationale for selection:* Evidence from behaviour change interventions delivered in primary care settings shows reduced mortality and morbidity can be delivered where advice is personalised to the individual client. Benefits should be observable within months or a small number of years. As the 'gateway' to the health system, general practitioners are a logical target for intervention. This category provides an opportunity to analyse sub-categories, particularly through the targeting of people with known increased disease risk;
- V. *Information technology advice-delivery systems.*
 - *Rationale for selection:* IT delivery systems represent alternative mechanisms for delivery of skills and knowledge to primary care settings, allowing integration with general practitioner high-risk prevention services, or geographically-isolated healthcare settings. Centralised production of such products would be most cost-effective when widely used (fixed production costs spread over the largest possible number of clients), and would allow the primary care provider to concentrate on personalisation of the individual counselling situations.

⁴ For example, the convention of applying discount rates of between 3-5% to accrued benefits is such that a year of life gained 30 to 40 years into the future has a net present value of between only 0.14 to 0.23 years, if discounted at an annual rate of 5%.

Table 8.1: INACTIVITY (note overlap with ‘Nutrition’)

Modality	Article/s	Description / Outcome Measures / Results	Assessment Against Criteria	Quality of evidence	Recommendation
PRIMARY PREVENTION					
Infrastructure modification			Does not meet criteria (6)		Reject
Media	Wimbush et al 1998	Scottish study of impact of program comprising TV advertisements, telephone helpline and support booklets. Outcomes measured campaign awareness and attitudinal changes. No change in activity detected	Outcomes cannot be extrapolated to QALYs (3). No difference in outcomes between groups.		Reject
School based programs	Robinson 1999	School-based programs: Intervention aimed to change adiposity, physical activity and dietary intake via reduced TV, video and computer game viewing. Comprised 18 classroom lessons over 6-months. Outcomes BMI, height, weight, triceps SKF, waist and hip circumferences, cardiorespiratory fitness, self-reported media use, physical activity, dietary behaviours; parental report of child and family behaviours. Findings- Intervention children had significant relative decreases in BMI (intervention vs control change: 18.38 to 18.67 kg/m ² vs 18.10 to 18.81 kg/m ² respectively.	Primary prevention in 1 population of school age children. May be able to use BMI to model morbidity and mortality. Although extrapolation of results to long term problematic.	4	Subject to review
	Gortmaker et al 1998	Interdisciplinary intervention. ‘Planet Health’ sessions incorporated in curricula in 4 subjects. Aim: decrease television viewing, high-fat foods; increase fruit/vegetable intake, moderate/vigorous physical activity. Measured using BMI, triceps SKF. Findings: Less obesity among intervention girls vs controls, controlling for baseline obesity (OR 0.47). No diff in boys. Greater remission of obesity among intervention girls vs. controls (OR 2.16). For girls, each hour redn in TV viewing predicted reduced obesity prevalence (OR 0.85).	As above	4	Subject to review
	Manios et al 1999	School-based intervention plus parent seminars to improve diet, fitness and physical activity of primary school age children. Primary outcome: health knowledge, diet, fitness, and physical activity. Other: anthropometric, and biochemical indices Assessed at baseline and after 3 years of program. Findings – Greater positive serum lipid level changes, health knowledge, physical activity and fitness levels. BMI increased less in intervention group than for controls	Reservations apply as above, however additional reservation as to the relevance of the cultural context to an Australian population.		Reject

Modality	Article/s	Description / Outcome Measures / Results	Assessment Against Criteria	Quality of evidence	Recommendation
Workplace policy	Emmons et al The healthy working project: A worksite health-promotion trial targeting physical activity, diet, and smoking. <i>J. Occ & Env Medicine</i> 1999; 41: 545.	Multiple risk factor approach (smoking, nutrition, and physical activity). 2055 individuals from 26 manufacturing worksites completed three health-behaviour assessments. Findings- At both the mid-study and final assessments, intervention participants significantly increased their exercise behaviour, compared with the controls. Also increased consumption of fruit, vegetables and fibre in intervention condition at final assessment, compared with controls.	Outcome measures may be difficult to extrapolate to QALYs. (3)		Reject
	Egger et al Effectiveness of an abdominal obesity reduction program in men: the GutBuster 'waist loss' program. <i>Int J Obesity</i> 1996; 20: 227-31.	GutBusters. A workplace based which is a self-help program conducted in the workplace by allied health professionals for a moderate risk cohort of the general, overweight male population	Multifactorial program with good evidence that can probably be linked to QALYs	444	Accept
INTERVENTION FOR THOSE WITH RISK FACTOR					
Large-scale community	Calfas et al Preliminary evaluation of a multicomponent program for nutrition and physical activity change in primary care: PACE+ for adults. <i>Preventive Medicine</i> 2002; 34: 153-61.	Information technology advice systems. 4-month intervention All patients completed computerized assessment then made a tailored "action plans" to change a physical activity and a nutrition behaviour. Discussed with provider. Subsequent intervention arms: control; mail; infrequent phone and mail; frequent phone and mail. Primary outcomes: moderate and vigorous physical activity stage of change, dietary fat, fruit/vegetable intake, and overeating behaviours Assessment baseline and 4 months. Findings- All conditions improved on all behaviours over time. No benefit from mode or intensity of subsequent intervention.	Outcome measures cannot be extrapolated to QALYs. (3)	4	Subject to review
Small-scale community	Sevick et al Cost-effectiveness of lifestyle and structured exercise interventions in sedentary adults: results of project ACTIVE. <i>American Journal of Preventive Medicine</i> 2000; 19: 1-8.	Community coordinated intervention comparing lifestyle (centre-based behavioural skills training) vs. structured exercise (supervised, centre-based) program. Primary outcomes: cost, cardio-respiratory fitness, physical activity. Findings – Both interventions increased activity and fitness. At 6 months, costs were \$46.53 and \$190.24 per participant/ month respectively. At 24 months, costs were \$17.15 and \$49.31 per participant/ month respectively. At both time points, lifestyle intervention was more cost-effective than the structured intervention for most outcomes measures.	Community based program for general population of at risk adults. Cost-effectiveness data contained in results but based upon estimates already provided (USA).	4	Subject to review
	White et al 1997	Looma healthy lifestyles program targeting morbidity reduction in Indigenous patients with diabetes.	High priority for evaluation being an indigenous population, however may not satisfy criteria (2), (3) and (4).	4	Subject to review

Modality	Article/s	Description / Outcome Measures / Results	Assessment Against Criteria	Quality of evidence	Recommendation
	Munro et al 2000	A 2-year program in the UK for over 65's to attend free supervised exercise sessions in community. Outcomes all-cause and exercise related mortality, service use, health status. Findings 26% attended 1 or more session (women, younger, least sedentary). 50% at least 28 sessions. No significant differences in mortality rates or survival times. Trend for fewer declines in health status (SF36) in intervention group. Cost £70k/yr or average session cost £5. Cost per QALY gain £9807.	Community program targetting specific population (over 65 years). No difference in mortality but important differences reported in quality of life (SF36).	444	Accept
Advice from clinicians	Taylor et al RCT to examine effects of GP exercise referral program in East Sussex, on modifiable CHD risk factors. J of Epidemiology & Community Health 1998; 52: 595-601.	Prescribed 20 exercise sessions at leisure centre (half price) over 10 weeks. Moderate/vigorous aerobic activity, semi supervised. Outcomes: Adherence, BP, sum skinfolds (SSKF). Most used the 'script', Obese and non smokers attended more. Assessed at 8,16,26 and 37 weeks	Life-years gained and QALYs could be derived from reduction in blood pressure and other clinical parameters, to capture benefits of the intervention).	44	Accept
	King et al 1998a Activity Counselling Research Group, 2001	US Activity counselling trial comparing 3-4 minutes advice from a GP to advice from a trained health educator. At 2-year follow-up, there were no differences in cardiorespiratory fitness or reported physical activity.	King et al., would be reviewed for supportive and long-term evidence in respect of evaluation of clinician advice.	4	accept
Advice from other health professionals	Halbert et al 1999	An Australian study comprising counselling by exercise specialist, reinforced at 3 and 6 months. One year follow-up. Outcomes: Physical activity, BP, weight, blood lipids, quality of life. Findings - Intervention group increased physical activity more than controls. No differences on clinical measures	Similar to proposed 'evaluation of advice of clinicians' but with greater capture of benefits in blood pressure, weight and lipid measures. Also quality of life measures provided.	44	Accept
Psychosocial screening					
Healthy lifestyle programs in separate facilities					

Modality	Article/s	Description / Outcome Measures / Results	Assessment Against Criteria	Quality of evidence	Recommendation
WITH RISK FACTOR AND MORBIDITY					
	van Baar et al Effectiveness of exercise therapy in patients with OA of the hip or knee: a systematic review of randomised clinical trials. <i>Arthritis Rheum</i> 1999; 42: 1361-9.	201 patients with osteoarthritis were randomised to either a physiotherapist managed exercise program in a primary care setting or to standard GP treatment. A mean of 16 × 30min sessions for person in the exercise group over 12 weeks. Results included a VAS.			accept

8.4 Nutrition - Interventions for Evaluation

A healthy diet and dietary change in those with a poor diet has been demonstrated to reduce ill-health and death. Interventions can assist people to make those changes. Trials have been undertaken to estimate the magnitude of the benefits of the interventions, and the results can be used to perform cost-effectiveness analyses. Given the overlap between interventions for nutrition and inactivity, a similar categorisation is recommended, although with the addition of a sixth category of screening and lifestyle advice. These interventions cover three dominant modalities and a range of target groups:

Health promotion interventions selected are:

- I. Community coordinated programs with mass media, healthy eating programs including the workplace setting, and physical activity programs.
 - *Rationale for selection:* These interventions may have a capacity to address some of the “drivers” of adverse nutrition such as loss of nutrition/cooking skills, commercial advantage of selling low-quality food. There is also considerable interest in adopting community-based programs;
- II. School based programs – such as health education programs to develop student self-efficacy, and development of food and cooking skills.
 - *Rationale for selection:* by influencing attitudes and behaviour when young, lifetime benefits might accrue, but benefits may take decades to realise. Studies describe discrete interventions that could be replicated. The work will complement the study by Swinburne and others commissioned by the Department of Health and Ageing into interventions to address childhood obesity.

Community individual advice interventions selected are:

- III. Physician lead: health promotion in general practice and primary care through generic self-help materials covering physical inactivity and nutrition;
- IV. Formal CHD and other chronic disease risk factor clinics in general practice;
 - *Rationale for selection:* evidence suggests behaviour change interventions delivered in existing healthcare settings, with personalised (relatively) relevance to the individual clients, potential for reduced mortality and serious morbidity and with benefits realisable within months or a small number of years. Interventions can be integrated informally (III) or formally (IV) with high-risk strategies, by the selection of people with known increased disease risk for more intensive medical investigation and treatment;
- V. Information technology advice-delivery systems.
 - *Rationale for selection:* IT provides an alternative mechanisms for delivery of information into primary care settings, or directly to consumers, allowing integration with general practitioner high-risk prevention services, or geographically-isolated healthcare settings.

Individual medical management combined with risk factor advice

- VI. To address risk factors and associated harm. Pertinent interventions include; lipid screening and lipid-lowering medications plus life style advice.
 - *Rationale for selection:* this represents the default medical-model management intervention with strong professional backing. It tends to be the dominant model, and may divert resources from other possible approaches. It is important that its relative cost-effectiveness is established.

Table 8.2: NUTRITION (overlaps with Inactivity – refer Table 5.1)

Modality	Article/s	Description / Outcome Measures / Results	Assessment Criteria	Against	Quality of Evidence	Accept / Reject for Evaluation
PRIMARY PREVENTION						
Infrastructure modification			Does not meet criteria (6)			Reject
Mass media	Miles 2001	A 7 week program on BBC radio, called 'Fighting Fit Fighting Fat'. Supported by website, materials, and telephone support. Targeted the obese. Survey of registrants found mean weight loss of 1.5kg/m ² .	Results can be extrapolated to life-years and QALYs		4	Accept
Retailing			Does not meet criteria (5)			Reject
Catering			Does not meet criteria (5)			Reject
School-based program	Killen et al Cardiovascular disease risk reduction for tenth graders. A multiple-factor school-based approach. JAMA 1988; 260: 1728-33.	All 1447 tenth graders in four senior high schools from two school districts participated in a cardiovascular disease risk-reduction trial. Within each district, one school was assigned at random to receive a special 20-session risk-reduction intervention and one school served as a control. Almost twice as many baseline experimental smokers in the treatment group reported quitting at 2mth follow-up, while only 5.6% of baseline experimental smokers in the treatment group graduated to regular smoking compared with 10.3% in the control group. Beneficial treatment effects were observed for resting heart rate, body mass index, triceps skin fold thickness, and subscapular skin fold thickness.	Results can only be extrapolated to QALYs by making assumptions concerning long-term disease trends (3).		444	Subject to review
	Harrell et al Effects of a school-based intervention to reduce cardiovascular disease risk factors in elementary-school children: the Cardiovascular Health in Children (CHIC) study. Journal of Pediatrics 1996; 128: 797-805.	Randomized, controlled field trial: the intervention, taught by regular classroom and physical education teachers, provided all children an 8-week exercise program and 8 weeks of classes on nutrition and smoking. Children in the intervention group had significantly greater knowledge (7.9% more correct) and a significant increase in self-reported physical activity than children in the control group. Trends for the intervention group were a reduction in total cholesterol level (-5.27 mg/dl), an increase in aerobic power, a reduction in body fat, and smaller rise in diastolic blood pressure than control children.	Results cannot be extrapolated to QALYs without major assumption concerning long-term disease trends (3).		44	Subject to review

Modality	Article/s	Description / Outcome Measures / Results	Assessment Criteria	Against	Quality of Evidence	Accept / Reject for Evaluation
Work place	"European collaborative trial of multifactorial prevention of coronary heart disease: final report on the 6-year results. World Health Organisation European Collaborative Group." Lancet 1986; 1: 869-72.	60 881 men employed in 80 factories in Belgium, Italy, Poland, and the UK. multifactorial prevention of coronary heart disease (CHD). Intervention was associated with reductions of 10.2% in total CHD, 6.9% in fatal CHD, 14.8% in non-fatal myocardial infarction, and 5.3% in total deaths, with a neutral result for non-CHD deaths. The observed reduction in total CHD was 62% of that predicted by means of a multiple logistic function summary of risk factor changes.	Detailed information, with moderate duration follow-up, and mortality and morbidity outcomes. Data at least 25 years old.	intervention	444	Accept
INTERVENTIONS FOR THOSE WITH RISK FACTOR						
Large scale community	Farquhar et al Effects of community wide education on cardiovascular disease risk factors. The Stanford Five-City Project. JAMA 1990; 264: 359-65.	Two treatment cities (N = 122,800): a 5 yr media/community based healthy life style program using social learning theory, community organization principles and social marketing methods with ~26 hrs exposure to multi-channel multi-factor education. Two comparison cities (N=197,500). Observations knowledge of risk factors, blood pressure, cholesterol, smoking rate, body weight, resting pulse. Results; after 30-64 months, sign. net reduction in mean plasma cholesterol level (2%), blood pressure(4%), resting pulse rate (3%), and smoking rate (13%) in intervention cohort sample. These risk factor changes resulted in decreases in composite total mortality risk scores of 15% and CHD risk scores of 16%.	Subject to review for Criteria 3. Requires extrapolation from risk scores to QALYs		44	subject to review
	Puska et al The community-based strategy to prevent coronary heart disease: conclusions from the ten years of the North Karelia Project. Annual Review of Public Health 1985; 6: 147-93.	Comprehensive community programs to control CVD in North Karelia (Finland). The effect of the program during 1972-82 was evaluated by examining random population samples at outset 1972 and five (1977) and 10 (1982) years later in the program and matched reference area. Main outcome measures: included total mortality, CHD event rate and mortality. There was a 20% decline in CHD mortality rates in both populations, attributable to either physiological or lifestyle risk factor change in the first 5 years.	Provides direct expression of results in terms of mortality and CHD event, but Study results outdated (2)		4	Accept
Small scale community						

Modality	Article/s	Description / Outcome Measures / Results	Assessment Criteria	Against	Quality of Evidence	Accept / Reject for Evaluation
Advice from clinicians	Pritchard et al Nutritional counselling in general practice: a cost effective analysis. Journal of Epidemiology & Community Health 1999; 53: 311-6.	6 counselling sessions led by either <u>GP or dietician</u> for 'at risk' patients. Both intervention groups reduced weight and blood pressure compared with the control group. Patients in the doctor/dietitian group were more likely to complete the 12 month program than those in the dietitian group. Patients in the doctor/dietitian group lost an average of 6.7 kg at a cost of \$A9.76 per kilogram, while the dietitian group lost 5.6 kg at a cost of \$A7.30 per kilogram	Recent study providing data for costs in Australian dollars, and outcomes expressed in biometric units from which it should be possible to estimate possible life-year gains.		44	Accept
	Lindholm et al The impact of health care advice given in primary care on cardiovascular risk. CELL Study Group. BMJ 1995; 310: 1105-9.	Patients with at least two cardiovascular risk factors in addition to moderately high lipid concentrations received "intensive" health care advice through six group sessions, compared with the advice usually offered to subjects with multiple risk factors for cardiovascular disease lasting 18 months. Outcomes- Percentage reduction in total cholesterol concentration (target 15%); In the group receiving intensive health care advice total cholesterol concentration decreased by 0.15 mmol/l more (95% confidence interval 0.04 to 0.26) than in the group receiving usual advice. The overall Framingham risk dropped by 0.068 more (0.014 to 0.095) in the group receiving intensive advice, and most of the risk factors showed a greater change in a favourable direction in this group than in the group receiving usual advice, but the differences were seldom significant.	Supportive evidence to that derived from Pritchard et al., 1999 (above).		444	
	de Lorgeril et al Mediterranean diet, traditional risk factors, and the rate of cardiovascular complications after myocardial infarction: final report of the Lyon Diet Heart Study. Circulation 1999; 99: 779-85.	RCT: A single 1-hr dietary advice session from a cardiologist and dietitian advising a Mediterranean-type diet (with a mean of 46 months per patient). In the Mediterranean diet group, CO 1 was reduced (14 events versus 44 in the prudent Western-type diet group, P=0.0001), as were CO 2 (27 events versus 90, P=0.0001) and CO 3 (95 events versus 180, P=0.0002). Adjusted risk ratios ranged from 0.28 to 0.53. During a follow-up of 4 years, there were a total of 38 deaths (24 in controls vs 14 in the experimental group), including 25 cardiac deaths (19 vs 6) and 7 cancer deaths (4 vs 3), and 24 cancers (17 vs 7).	Recent study of simple intervention with widespread applicability leading to very large beneficial effect. Mortality, morbidity and some service use data available.		44	
Psychosocial screening						

Modality	Article/s	Description / Outcome Measures / Results	Assessment Criteria	Against	Quality of Evidence	Accept / Reject for Evaluation
Advice from other health professionals	Swinburn et al (5-year) effects of a reduced-fat diet intervention in individuals with glucose intolerance. Diabetes Care 2001; 24: 619-24	Long-term A 5-year follow-up of a 1-year randomized controlled trial of a reduced-fat ad libitum diet versus a usual diet. The intervention group participated in monthly small-group education sessions on reduced-fat eating for 1 year with follow-up at 2 years (n = 104), 3 years (n = 99), and 5 years (n = 103). Compared with the control group, weight decreased in the reduced-fat-diet group (P < 0.0001); the greatest difference was noted at 1 year (-3.3 kg), diminished at subsequent follow-up (-3.2 kg at 2 years and -1.6 kg at 3 years), and was no longer present by 5 years (1.1 kg). A lower proportion had type 2 diabetes or impaired glucose tolerance at 1 year (47 vs. 67%, P < 0.05), but in subsequent years, there were no differences between groups. However, the more compliant 50% of the intervention group maintained lower fasting and 2-h glucose at 5 years (P = 0.041 and P = 0.026 respectively) compared with control subjects.	Long-term results showing diminishing effect of intervention over time. Further study may highlight whether funding support is warranted when gains only relate to the medium term.		444	Accept
	Steptoe et al Behavioural counselling in general practice for the promotion of healthy behaviour among adults at increased risk of coronary heart disease: randomised trial. BMJ 1999; 319: 943-7	Brief behavioural counselling, on the basis of the stage of change model, carried out by <u>practice nurses</u> to reduce smoking and dietary fat intake and to increase regular physical activity. Main Outcome Measures: Questionnaire measures of diet, exercise, and smoking habits, and BP, serum total cholesterol, weight, BMI, and smoking cessation at 4 and 12 months. Favourable differences were recorded in the intervention group for dietary fat intake, regular exercise, and cigarettes smoked per day at 4 and 12 months. Systolic blood pressure was reduced to a greater extent in the intervention group at 4 but not at 12 months. No differences were found between groups in changes in total serum cholesterol, weight, BMI, diastolic BP, or smoking cessation	Mixed results amongst outcomes which makes it difficult to interpret impact upon survival. No change in key parameters for modelling of BMI, cholesterol and BP.		444	Reject

Modality	Article/s	Description / Outcome Measures / Results	Assessment Criteria	Against	Quality of Evidence	of	Accept / Reject for Evaluation
	Group ICRFOS. Effectiveness of health checks conducted by nurses in primary care: final results of the OXCHECK study. BMJ 1995; 310: 1099-104.	Health checks, performed by nurses in primary care, in reducing risk factors for cardiovascular disease and cancer. Outcome measures: Serum total cholesterol concentration, blood pressure, body mass index, and smoking prevalence (with biochemical validation of cessation); self reported dietary, exercise, and alcohol habits. Mean serum total cholesterol was 3.1% lower in the intervention group than controls (difference 0.19 mmol/l (95% confidence interval 0.12 to 0.26)); in women it was 4.5% lower (P < 0.0001) and in men 1.6% (P < 0.05), a significant difference between the sexes (P < 0.01).	It may be possible to model from clinical outcomes to QALYs. More likely that the study will provide supportive evidence to that of Eriksson et al., and Swinburn et al.		444		Subject to review
Social support							
Pharmacological		Numerous studies of pharmacological products. Literature not yet reviewed.			444		Discuss with DHA
WITH RISK FACTOR AND MORBIDITY							
Management following cardiac procedures	Mahler et al Effects of a videotape information intervention at discharge on diet and exercise compliance after coronary bypass surgery. Journal of Cardiopulmonary Rehabilitation 1999; 19: 170-7.	Patients were randomised to either one or two videotapes before discharge from the hospital, or to receive only the standard discharge preparation provided by the hospital. Outcome measures: anxiety and self-efficacy at discharge, 1 month and 3 months after discharge; dietary fat consumption and activity level 1 and 3 months after discharge. Relative to controls, patients who viewed either of the videotapes before hospital release reported higher self-efficacy for adhering to the recommended low-fat diet both at discharge and 1 month after surgery. Patients who viewed the tape that portrayed the recovery period as consisting of ups and downs also reported significantly more frequent moderate exercise at 1 month and more frequent strenuous exercise 3 months after discharge.	Outcome measures cannot be extrapolated to QALYs. (3)				Reject

Modality	Article/s	Description / Outcome Measures / Results	Assessment Criteria	Against	Quality of Evidence	Accept / Reject for Evaluation
Management of obesity	Eriksson et al Prevention of Type II diabetes in subjects with impaired glucose tolerance: the Diabetes Prevention Study (DPS) in Finland. Study design and 1-year interim report on the feasibility of the lifestyle intervention programme. Diabetologia 1999; 42: 793-801.	523 overweight subjects with impaired glucose tolerance received general information about the lifestyle changes necessary to prevent diabetes and about annual follow-up visits. The intervention subjects had seven sessions with a <u>nutritionist</u> during the first year and a visit every 3 months thereafter aimed at reducing weight, the intake of saturated fat and increasing the intake of dietary fibre. Intervention subjects also guided to increase their physical activity. During the first year, weight loss in the first 212 study subjects was 4.7 +/- 5.5 vs 0.9 +/- 4.1 kg in the intervention and control group, respectively (p < 0.001). The plasma glucose concentrations (fasting: 5.9 +/- 0.7 vs 6.4 +/- 0.8 mmol/l, p < 0.001; and 2-h 7.8 +/- 1.8 vs 8.5 +/- 2.3 mmol/l, p < 0.05) were significantly lower in the intervention group after the first year of intervention.	Large, recent study in a high risk group but without manifest disease. Biometric outcomes should enable quantification of life-years and conversion to QALYs.		444	Accept
Clinician advice using information technology	Delichatsios et al 2001b. Randomized trial of a "talking computer" to improve adults' eating habits. American Journal of Health Promotion 2001; 15: 215-24.	RCT. Weekly communication for 6 months via a totally automated, computer-based voice system. Among intervention group subjects, the system monitored dietary habits and provided educational feedback, advice, and behavioural counselling. Control group subjects received physical activity promotion counselling. Compared with the control group, the intervention raised fruit intake a mean of 1.1 servings per day and also raised dietary fiber intake 4.0 g/d and decreased saturated fat, as a proportion of energy intake, by 1.7%.	Outcome measures cannot be directly extrapolated to QALYs, but can be interpreted as supportive intervention with Lyon Heart Study.		4	Accept

8.5 Smoking: An Overview of Interventions for Evaluation

Based on an assessment against the specified criteria, five categories of interventions were identified from the Smoking literature:

1. School-based programs. Studies indicate that anti-smoking education programs in schools, on their own and in the limited form in which they are invariably applied outside of initial pilot programs, are generally ineffective. “Even programs that have initially reduced uptake of smoking appear to have only a temporary effect; they can somewhat delay initiation of smoking but not prevent it” Jha and Chaloupka 1999; p 49. However, given the pressure to support funding of such programs, evaluation of their possible cost-effectiveness is supported.
2. Legislation mandating smoke-free policies in pubs and clubs nationally and small businesses in Australian states without comprehensive legislation. The evidence suggests that totally smoke-free workplaces are associated with modest reductions in smoking prevalence and fewer cigarettes smoked per day per continuing smoker. However, legislative based smoke-free interventions are relatively costless and may therefore be cost-effective. Furthermore, smoke-free workplaces were found to protect non-smokers from passive smoking.
3. United Kingdom and New Zealand approaches to subsidising NRT, compared to the proposal to de-schedule most nicotine replacement therapies. Relatively good data are available for most pharmacological therapies and devices for smoking cessation, and which suggest these therapies can be reasonably effective for some populations. These therapies are also a central element to the smoking cessation campaigns in most countries.

Contracts with manufacturers of all major electronic prescribing packages to include modules to enable smoker identification and referral to the Quitline and other services. As was noted in the main review of the smoking literature, although brief physician advice has been shown to be effective, an issue has been the disappointing rate at which GPs identify and counsel their smoking patients. Recent methods to increase the rate of smoker identification may be cost-effective.

1. Enabling all callers to the Quitline to be offered call back counselling.

Physician advice to quit smoking is potentially an important population based approach to smoking cessation because most smokers see their physicians once a year. Inclusion of this type of intervention as a sixth category has not been recommended for pragmatic reasons. However, as the cost-effectiveness of this approach is believed to have already been studied, subject to verification that the methods used were satisfactory, it would be appropriate to include the results of this earlier work in the Stage II report, rather than duplicate the evaluation.

Table 8.3: SMOKING (refer Table 6.1).

Modality	Article/s	Description / Outcome Measures / Results	Assessment Criteria	Against	Quality of Evidence	of	Accept / Reject for Evaluation
PRIMARY PREVENTION							
Mass Media	<p>Bauer et al Changes in youth cigarette use and intentions following implementation of a tobacco control program: findings from the Florida Youth Tobacco Survey, 1998-2000. Journal of the American Medical Association 2000;284: 723-8.</p> <p>Beiner et al Impact of the Massachusetts tobacco control programme: population based trend analysis. British Medical Journal 2000;321; Aug: 351-4.</p>	<p>Mass media aimed at children. Current cigarette use dropped from 18.5% to 11.1% ($P<.001$) among middle school students and from 27.4% to 22.6% ($P = .01$) among high school students. Prevalence of never use increased from 56.4% to 69.3% ($P<.001$) and from 31.9% to 43.1% ($P = .001$) among middle school and high school students, respectively. Prevalence of experimenting decreased among middle school and high school students from 21.4% to 16.2% ($P<.001$) and from 32.8% to 28.2% ($P<.001$), respectively..</p> <p>Mass Media aimed at the entire population. The TV component of the largely health-focussed Massachusetts anti-smoking campaign, the largest to that date anywhere in the world, significantly reduced the rate of establishment of smoking among young Massachusetts adolescents compared to the rest of the US. Among younger adolescents (aged 12 to 13 years at baseline), those reporting baseline exposure to television antismoking advertisements were significantly less likely to progress to established smoking (odds ratio = 0.49, 95% confidence interval = 0.26, 0.93).. From 1992 the prevalence of adult smoking in Massachusetts has declined annually by 0.43% (95% confidence interval 0.21% to 0.66%) compared with an increase of 0.03% (-0.06% to 0.12%) in the comparison states ($P<0.001$).</p>	<p>Evidence about influencing children's behaviour is mixed, however the benefits should a program be successful would be considerable. Further review is warranted for this type of intervention..</p> <p>Supportive evidence to Bauer et al. of the impact of mass media upon adolescent smoking uptake. Also addresses adult cessation rates.</p>	4	444		Subject to review

Modality	Article/s	Description / Outcome Measures / Results	Assessment Criteria	Against Quality of Evidence	Accept / Reject for Evaluation
School-based programs	Peterson et al Smoking Prevention Project: LT Randomized Trial in School-Based Tobacco Use Prevention—Results on Smoking. J. National Cancer Institute 2000; 92: 1979-91	Program to reduce the uptake of smoking amongst secondary school children. Reduction in uptake appeared to reflect rather a delay in uptake.	Evidence for effective school based programs is weak. Considered unlikely to be effective in Australia.		Reject
Taxation			Does not meet criteria (5)		Reject
Work-place policy	Fichtenberg and Glantz Association of the California Tobacco Control Program with Declines in Cigarette Consumption and Mortality from Heart Disease. N Engl J Med 2000;343: 1772-7.	Universal adoption of smoke-free work place bans. Totally smoke-free workplaces are associated with reductions in smoking prevalence of 3.8% (95% confidence interval 2.8% to 4.7%) and 3.1 (2.4 to 3.8) fewer cigarettes smoked per day per continuing smoker.	Does not meet criteria (5)		Reject
Tobacco Regulation			Does not meet criteria (5) or (6)		
INTERVENTIONS FOR THOSE WITH RISK FACTOR					
Large scale community	Wakefield and Miller Evaluation of the National Quitline Service. In: <i>Commonwealth Department of Health and Aged Care. Australia's National Tobacco Campaign: Evaluation Report Volume 1.</i> Canberra: CDHAC, Commonwealth of Australia, 1999.	Evaluation of the National Tobacco Campaign (NTC) – a major initiative launched in 1997 and aimed primarily at assisting smokers aged 18–40 along the road to quitting. As a mass-media led campaign, the NTC is the most intense and longest running anti-tobacco campaign ever seen in Australia. The campaign sought to help smokers move through the process, that is, out of pre-contemplation into contemplation and preparation. Cessation rates and intentions reported.	Comprehensive report available at: www.health.gov.au/pubhlt/publicat/document/meta_data/tobccamp.htm	44	Accept
Small-scale community	Marcy et al A smoking cessation telephone resource: feasibility and preliminary evidence on the effect on health care provider adherence to smoking cessation guidelines. Tob Control 2002;11: 84.	A pilot study of Physician referral to counselling was conducted to assess the feasibility of a central telephone smoking cessation service that would proactively call smokers who gave their provider consent for the referral. Over the four month duration of the study there was a significant increase in those who had follow-up arranged, 17% at baseline compared to 34% post implementation, $p < 0.02$	Outcome measures not suitable for modelling to QALYs (3).		Reject

Modality	Article/s	Description / Outcome Measures / Results	Assessment Criteria	Against	Quality of Evidence	of	Accept / Reject for Evaluation
Advice from clinicians	Silagy and Stead Physician advice for smoking cessation (Cochrane Review). In: The Cochrane Library, Issue 2. Oxford: Update Software; 2002	Brief advice versus no advice (or usual care) from a doctor produced a small but significant increase in the odds of quitting at six months or more (OR 1.69, 95% CI 1.45 ,1.98)	By modelling cessation to increased survival and QALYs, impact of brief counselling could be assessed. Important given role of GPs in Aust. primary care system.		444		Accept
Advice from other health professionals							
Multi-factorial							
Behavioural	Baille et al Meta- analytic review of the efficacy of smoking cessation interventions. Drug and Alcohol Review 1994;13: 157-70	Behavioural intervention + Nicotine Replacement Therapy (NRT) Adding NRT to any psychological (behavioural) intervention provides a net beneficial effect (OR 1.69 CI 1.0,2.7). Similarly, adding a behavioural intervention to NRT provides a net beneficial effect (OR 1.78, CI 1.0, 3.1)	Ideally should be evaluated as C-E of behavioural therapy, and the incremental cost-effectiveness of NRT.		444		Accept
Pharmacological	Zhu S et al Telephone counselling as adjuvant treatment for nicotine replacement therapy in a "Real World" setting. Prev Med 2000;31: 357-63.	Repeated telephone support + NRT. With NRT for maintaining cessation for 12 months 25.5% v 16%	Results of Zhu et al., provide some supportive evidence for long-term modelling. Review against criteria (8)		444		Accept subject to discussion with DHA
	Silagy et al Nicotine replacement therapy for smoking cessation (Cochrane Review). In: The Cochrane Library. Oxford: Software Update; 2002.	Meta-analysis of 4 trials of the use of Nicotine Inhalers. OR 2.08, 95% CI 1.43, 3.04 effect size 8%	Provided the interventions are similar in nature and cost, meta-analyses provide greater confidence in effectiveness. Review against criteria (8)		444		Accept subject to discussion with DHA

Modality	Article/s	Description / Outcome Measures / Results	Assessment Criteria	Against	Quality of Evidence	Accept / Reject for Evaluation
	Curry et al Use and cost effectiveness of smoking-cessation services under four insurance plans in a health maintenance organization. N Engl J Med 1998;339: 673-9	Reducing out of pockets costs for Nicotine Replacement Therapy (NRT). Est. annual rates of use of smoking-cessation services ranged from 2.4% (among smokers with reduced coverage) to 10% (among those with full coverage). Smoking-cessation rates ranged from 28% (among users with full coverage) to 38% (among those with standard coverage). The est. % of smokers who would quit per year as a result of NRT ranged from 0.7% (with reduced coverage) to 2.8% (with full coverage). Rate of smoking cessation among the benefit users with full coverage was lower than the rates among users with plans requiring co-payments, the effect on the overall prevalence of smoking was greater with full coverage than with the cost-sharing plans.	As a supplementary analysis to the cost-effectiveness of NRT, the impact of subsidies upon the uptake of NRT can be analysed.		44	
	Fiore et al Treating Tobacco Use and Dependence. Clinical Practice Guideline. Rockville MD: US Dept Health and Human Services. Public Health Service 2000.	Use of bupropion SR approximately doubles cessation rate compared to placebo 30.5%, (95% CI 23.2, 37.8) versus 17.3%. The odds ratio for sustained abstinence at five months or more 2.1(95% CI 1.5, 3.0)	A PBS listed drug. Evaluation enables a benchmark of 'value for money' supported by the government.		444	Accept
	Hughes et al Antidepressants for smoking cessation (Cochrane Review). Cochrane Library, Issue 2,. Oxford: Update Software; 2002	The odds ratio for sustained abstinence at 12 months using bupropion compared to placebo was estimated at 2.73 (95% CI 1.90, 3.94)	Supportive data to Fiore et al., as to the long-term outcomes from bupropion.		444	Accept
Alternative therapy			Literature not assessed at this stage.			
Clinic Systems	Fiore et al <i>Treating Tobacco Use and Dependence</i> . Clinical Practice Guideline. Rockville MD: US Department of Health and Human Services. Public Health Service 2000	Implementing clinic systems designed to increase the assessment and documentation of tobacco use. Estimated intervention rate by clinicians without a screening system to identify smoking status was 38.5% compared to 65.6% with a screening system (95% CI 58.3, 72.6), OR 3.1 (95% CI 2.2, 4.2)	As a novel approach to smoking evaluation would be helpful. However, end-points do not support economic evaluation (3).		44	Reject

8.6 Alcohol: An Overview of Interventions for Evaluation

Interventions can be generally positioned along a continuum of strategies from community-wide prevention to specialised clinical treatment. Within the framework of such a continuum, interventions can be categorised into at least three broad, overlapping groups: primary; secondary; and, tertiary.

Primary prevention: Interventions aimed at ensuring problem drinking, high alcohol dependence, alcohol-related problems or the processes that culminate in any of these, will not occur. These primary prevention initiatives refer to various educational campaigns conducted through the mass media and the secondary school education system, as well as to broader structural and legislative approaches, such as the enforcement of drink driving and liquor licensing laws and modifications in the taxation, advertising and packaging of alcohol. Arguably the greatest benefits to the community as a whole may result from primary prevention initiatives, since these aim to prevent the occurrence of problematic alcohol use.

Secondary interventions: Those aimed at identifying and terminating, or modifying for the better, problem drinking, alcohol dependence, alcohol-related problems or the processes which culminate in any of these, at the earliest possible moment. These secondary interventions generally target problem drinkers who are unlikely to be highly alcohol dependent. Secondary interventions have been implemented in a range of settings likely to be accessed by low-dependence problem drinkers, including general practice, specialised drug and alcohol clinics within general hospital settings, other general hospital departments, general health screening programmes in the community, community-based health centre, workplaces and tertiary education centres.

Tertiary interventions: Interventions aimed at stopping or retarding the progress and sequelae of problem drinking, alcohol dependence, alcohol-related problems or the processes which culminate in any of these, even though the basic condition persists. These tertiary interventions tend to target highly dependent drinkers and are more likely to promote abstinence as the desirable goal of treatment, as compared to secondary interventions. There is a considerable body of research supporting the efficacy of some tertiary interventions for alcohol dependence (e.g. various forms of cognitive behavioural therapy, motivational enhancement therapy, behavioural couples therapy, and pharmacotherapies). Tertiary interventions have been implemented in a range of settings, including general practice, specialist drug and alcohol services, hospitals, and dual diagnosis services.

Given time constraints and the scope of the tender to identify cost-effective interventions, the purpose of this section is to provide a brief overview of the key interventions identified in Table 7.1. As such, the review of the literature is not exhaustive and does not claim to be comprehensive, rather it is aimed at providing a basis from which to ascertain interventions for evaluation.

To date, no formal attempt to compare the many forms of interventions across the continuum of primary, secondary and tertiary interventions has been published. Evidence exists to suggest that some alcohol treatments the more effective alcohol treatments were brief motivational counselling (vs education lectures and films). It was also noted that some treatments were less significantly less costly to implement than others (for instance, brief motivational counselling compared to pharmacotherapy treatments). Treatments that were both more effective and less costly to implement included brief motivational counselling (compared to aversion therapy).

Table 8.4: ALCOHOL

Modality	Article/s	Description / Outcome Measures / Assessment Against Criteria	Quality of Evidence	Accept / Reject for Evaluation
PRIMARY PREVENTION				
Mass media	Holder and Treno Media advocacy in community prevention: news as a means to advance policy change. <i>Addiction</i> 1997; 92(Suppl. 2): S189-S199.	US Community Trials project where media advocacy was focussed upon community awareness and support of local policy as well as specific community variables aimed to impact on individual behaviour.	The evidence shows that media campaigns alone have no impact. Only when conducted with community based approaches is there an impact. Need to confirm quantifiable outcomes (3).	4 Subject to review
Taxation	Leung and Phelps "My kingdom for a drink...?" A review of estimates of the price sensitivity of demand for alcoholic beverages, in <i>Economics and the Prevention of Alcohol-related Problems</i> . Research Monograph No. 25., B.G. Hilton MH, Editor. 1993, National Institute on Alcohol Abuse and Alcoholism: Rockville, MD. p. NIH Pub. No. 93-513 (pp.1-32).	Review of 15 studies that analysed the impact of taxation upon alcohol consumption. Found a 10% increase in the price of alcohol was associated with a 3% decrease in consumption	Problem with criteria (5)	Reject
Advertising laws			Problem with criteria (5)	
Packaging			Problem with criteria 5	
Random Breath Testing			Problem with criteria (5)	Reject
Secondary schools Indigenous population			Problem with criteria 5 No RCTs in indigenous populations were identified despite the pressing need for effective primary care.	
INTERVENTIONS FOR THOSE WITH RISK FACTOR				
Counselling by GP (brief intervention)	Moyer et al Brief interventions for alcohol problems: a meta-analytic review of controlled investigations in treatment -seeking and non-treatment seeking populations. <i>Addiction</i> 2002; 97: 279-292.	Meta-analysis of 34 studies. Distinguished between treatment seeking from non-treatment seeking populations. Results consistent with findings elsewhere. Effect size ranged from 0.129 to 0.669.	Outcome measurement units and results need to be reviewed (3)	44 Subject to review

Modality	Article/s	Description / Outcome Measures / Results	Assessment Against Criteria	Quality of Evidence	Accept / Reject for Evaluation
	WHO Brief Intervention Study Group, A cross-national trial of brief interventions with heavy drinkers. WHO Brief Intervention Study Group. American Journal of Public Health 1996; 86(7): 948-955.	Study of over 1500 subjects (in 8 countries) considered at risk of alcohol-related problems but with no history of dependence. Consistency of results was observed with 17% decrease in consumption and 10% reduction in intensity.	The feasibility of being able to extrapolate outcome measures to health / utility gains needs to be explored.	44	Subject to review
Workplace programs			No evidence of effectiveness		Reject
Community outreach	Heather et al Assisted natural recovery from alcohol problems: Effects of a self-help manual with and without supplementary telephone contact. British Journal of Addiction 1990; 85: 1177-1185.	RCT of 107 subjects comparing a control group to (1) self-help manual based upon self-help principles (2) general information booklet, (3) a behaviourally-based self-help manual and (4) an opportunity to report to a telephone answering service. Control group showed higher proportion of drinking (not quantified by NDARC)	As the trial asks many questions, the power of the study may be too low.		Reject
Cognitive and behavioural therapy (CBT)	Heather et al A randomised controlled trial of Moderation-Oriented Cue Exposure. Journal of Studies on Alcohol 2000; 61(4): 561-570. Sellman et al A Randomized Controlled Trial of Motivational Enhancement Therapy (MET) for Mild to Moderate Alcohol Dependence. Journal of Studies on Alcohol 2001; 62: 389-396	Significant decrease in drinks per day and in number of days abstinent. Motivational interviewing (similar to CBT) compared to no counselling and non-directive reflective listening) for 122 patients with mild to moderate alcohol dependence. 42% were drinking heavily ≥6 times in 6 months compared to 62% in the no counselling group.	Outcome measurement units and results need to be reviewed (3) A variation of CBT but with successful outcomes. Outcome measurement units and results need to be reviewed (3)	4 4	Subject to review Subject to review
	McCrary et al Maintaining change after conjoint behavioral alcohol treatment for men: outcomes at 6 months. Addiction 1999; 94(9): 1381-1396	Behavioural Couples therapy for 99 alcohol dependent males with partner / spouse comprising BCT + AA or BCT + relapse prevention	Best analysed as incremental to CBT. Outcome measurement units and results need to be reviewed (3)	4	Subject to review
Self help	Hester et al Behavioral self-control program for Windows: results of a controlled clinical trial. Journal of Consulting and Clinical Psychology 1997; 65(4): 686-693.	Computer-based version of behavioural self-control given immediately or 10 weeks after treatment. Program was effective if given immediately following treatment. Results maintained at 12 months.	Outcome measurement units and results need to be reviewed (3). Also, the feasibility of being able to extrapolate outcome measures to health / utility gains needs to be explored	4	Subject to review

Modality	Article/s	Description / Outcome Measures / Assessment Against Criteria Results	Quality of Evidence	Accept / Reject for Evaluation
RISK FACTOR & MORBIDITY				
Pharmaco-therapies	Streeton et al Naltrexone, a relapse prevention maintenance treatment of alcohol dependence: A meta-analysis of randomized controlled trials. Alcohol and Alcoholism 2001; 36(6): 544-552.	Naltrexone (NTX) for patients over 18 yrs, diagnosis of alcohol dependence or abuse, NTX vs placebo or another active drug licensed in Australia. 12 weeks NTX vs placebo or other active drug. All patients received some form of psychosocial treatment in addition to the medication. Trials measured relapse rates, abstinence rates and percentage of patients discontinuing due to adverse events/% of patients with at least 1 adverse event.	44	Accept subject to discussion with DHA.
Inpatient	Winters et al The effectiveness of the Minnesota Model approach in the treatment of adolescent drug abusers. Addiction 2000; 95(4): 601-012.	An uncontrolled, descriptive study, examining the effectiveness of the 12-step Minnesota model in adolescents. The treatment group had better outcomes than the non-treatment group.	Poor evidence (2) and unclear outcomes (3).	Reject
	Sellman et al A Randomized Controlled Trial of Motivational Enhancement Therapy (MET) for Mild to Moderate Alcohol Dependence. Journal of Studies on Alcohol 2001; 62: 389-396.	Meta-Analysis of 21 studies comparing inpatient vs. outpatient treatment for alcohol abuse or inpatient treatment versus detoxification. Inpatient treatment was superior to outpatient treatment in five studies. Day hospital treatment was superior to inpatient treatment in two studies. In the remaining seven studies, no significant differences were found in drinking related outcomes.	No significant differences	Reject
Outreach				

CHAPTER 9: Work Plan for Stage 2

9.1 Background

The overall aim of the risk factor study is to determine how best to reduce the burden of harm on the Australian community from the four risk factors of physical inactivity, poor nutrition, alcohol misuse and tobacco smoking. The purpose of Stage 1 was to gain a sufficient understanding of the literature to select a number of interventions for economic analysis. The interventions that have through, this process, been selected for economic analysis are listed in Table 1. Stage 2 will compare the performance of the selected interventions, to establish how the harm associated with each of the four risk factors can be most effectively and efficiently reduced.

9.2 Interventions Selected for Cost-Effectiveness Analysis

A total of 28 interventions that are consistent with the selection criteria developed in Stage 1 have been identified and selected for economic analysis. These interventions cover all four risk factors and also include a number of multiple risk factor interventions. They have been selected to provide reasonably comprehensive coverage of modalities, but also to reflect the quality of available evidence, and the Department's priorities. The selection is itemised in Table 1 below, covering the risk factor targeted, modality/type of intervention and seminal trial to be used as the source of evidence on effectiveness. A summary of each of these seminal trials is contained in Chapter 8 Stage 1 Report.

Table 9.1: Interventions selected for Economic Analysis

	Program type and modality	Brief description - Seminal Trial
Multi-factorial: Nutrition + Physical activity +/- alcohol +/- smoking		
1	Large scale media + community	FFFF A 7 week program on BBC radio, called 'Fighting Fit Fighting Fat'. Supported by website, materials, and telephone support. Targeted the obese. Survey of registrants found mean weight loss of 1.5kg/m ² . Miles 2001, p 247
2	5 yr media/ community-wide education for CVD risk factors. The Stanford Five-City Project."	Two treatment cities (N = 122,800): 5 yr media/community based healthy life style program using social learning theory, community organization principles and social marketing methods. 26 hr exposure to multi-channel multi-factor education. Two comparison cities (N=197,500). Results: after 30-64 months, sign. net reduction in mean cholesterol, blood pressure, resting pulse rate, and smoking in intervention cohort sample → 15% redn in total mortality risk and 16% redn. In CHD risk. Farquhar et al 1990
	Or Community-based strategy to prevent CHD - the North Karelia Project." (a)	Comprehensive community programs to control CVD in North Karelia (Finland). Effect of the program during 1972-82 was evaluated by examining random population samples at outset 1972, 1977 and 1982, in program area and matched reference area. Findings 20% decline in CHD mortality rates in both populations (no net gain from intervention). Puska et al 1985

3	School-based	Intervention aimed to change adiposity, physical activity and dietary intake via reduced TV, video and computer game viewing. 18 classroom lessons over 6-months. Outcomes BMI, height, weight, triceps SKF, waist/hip circumference, cardiorespiratory fitness, self-reported media use, physical activity, dietary behaviour; parental report of child and family behaviour. Robinson et al 1999, p 241
4	School-based - class room lessons on exercise, nutrition and smoking	RCT field trial: Intervention, teaching by regular classroom and physical education teachers, to all children 8-week exercise program, 8 weeks of classes on nutrition and smoking. Findings - Children in intervention sign. greater knowledge and significant increase in physical activity. Trend for reduction in total cholesterol, increase in aerobic power, reduction in body fat, and smaller rise in blood pressure than control children. Harrell et al 1996
	Or 20-session school based- risk-reduction education	All 1447 tenth graders in four senior high schools from two school districts participated in a cardiovascular disease risk-reduction trial. 'matched control school'. Findings: almost twice as many baseline experimental smokers in the treatment group quit at 2mth, 5.6% of baseline experimental smokers became regular smokers cf 10.3% in control. Beneficial treatment effects observed in resting heart rate, BMI. Killen et al 1988
5	Workplace/ community	GutBusters: Self-help group program conducted in the workplace, or the wider community through self help tapes/booklet and /or group sessions moderated by allied health professionals for a moderate risk cohort of the general, overweight male population. Outcomes, weight, waist measurement Egger et al 1996
6(b)	Workplace - European collaborative trial multifactorial prevention of CHD.	60 881 men in 80 factories in Belgium, Italy, Poland, UK. Multifactorial prevention of CHD. Findings: 10.2% ↓ in total CHD, 6.9%↓ in fatal CHD, 14.8% ↓ in non-fatal MI, and 5.3% ↓ in total deaths. Observed redn in CHD 62% of that predicted by multiple logistic function of risk factor changes. WHO European Collaborative Group Lancet 1986; 1: 869-72
7	Primary care: health checks by practice nurse. The OXCHECK study	Health checks, performed by nurses in primary care, to improve life style behaviours and reduce risk factors for CVD and cancer. Outcome measures: Cholesterol, blood pressure, BMI, smoking, diet, exercise, alcohol use. Group ICRFOS, BMJ 1995
Physical activity		
8	GP active script – Australia	GP script for increased activity levels by persons considered sedentary. Program on-going supported by VicFit. Nacerrella and Huang 2001
9	GP + active script +/- access to supervised exercise, UK	Primary care -based exercise. Prescribed 20 exercise sessions at leisure centre (half price) over 10 weeks. Moderate/vigorous aerobic activity, semi supervised. Outcomes: Adherence, BP, sum skinfolds (SSKF). Most used the 'script', Obese and non smokers attended more. Assessed at 8,16,26 and 37 weeks Taylor et al 1998
10	Targeted community: Access to free community based exercise programs for the elderly	A 2-year program in the UK for over 65's to attend free supervised exercise sessions in community. Outcomes all-cause and exercise related mortality, service use, health status. Findings 26% attended 1 or more session (women, younger, least sedentary), 50% at least 28 sessions. No significant differences in mortality rates or survival times. Trend for fewer declines in health status (SF36) in intervention group. Cost £70k/yr or average session cost £5. Cost per QALY gain £9807. Munro et al 2000

11	Allied health in primary care setting	Counselling by exercise specialist – Australian study initial sessions, reinforced at 3, 6 months. 12 month follow-up. Outcomes physical activity and clinical parameters. Halbert et al 1999, p 245
Nutrition		
12	Primary care, Dietician +/- GP counselling re nutrition	Australian study. 6 counselling sessions re nutrition by GP + dietician, or dietician alone. Target at risk patients. Findings: redn. in weight and blood pressure cf control, Patients in the doctor/dietitian group more likely to complete 12 month program, lost mean 6.7 kg, dietitian group lost mean 5.6 kg. Pritchard et al 1999
13	Specialist care Nutrition counselling to persons with CVD risk factors by a cardiologist and dietitian	RCT: 1-hr dietary advice session from a cardiologist and dietitian advising Mediterranean-type diet. Findings after 4 yrs: In Mediterranean diet group, CVD events sign reduced, versus prudent Western-type diet group; adjusted risk ratios 0.28 to 0.53. Deaths 24 controls vs 14 in the experimental group, (cardiac deaths 19 vs 6). de Lorgeril et al 1999
14	Group session lead by health professional. Monthly small-group education sessions on reduced-fat eating for 1 year.	A 5-year follow-up of a 1-year RCT of a reduced-fat ad libitum diet versus usual diet. Intervention group participated in monthly small-group education sessions on reduced-fat eating for 1 year. Findings: cf control group, weight ↓ in reduced-fat-diet group, ↓ rate of type 2 diabetes or IGT. Swinburn et al 2001
15	Pharmacotherapy (orlistat) for obesity +/- diet	RCT involving 688 patients (743 recruited) randomly assigned to either Orlistat 3 times/day arm or placebo + low calorie diet, for one year. In the second year patients were reassigned to either the Orlistat group or placebo with a weight maintenance diet group. Findings indicated that, over a 2 year period, Orlistat taken with an appropriate diet promoted clinically significant weight loss and reduced the amount of weight regained in obese patients. Sjostrom et al 2000
16	Consultations with nutritionist to improve nutrition (and increase activity). Targeted at persons with IGT.	523 overweight subjects with IGT received information about lifestyle change to prevent diabetes. Annual follow-up visits. Intervention subjects 7 sessions with nutritionist during yr 1, + 3 monthly visit thereafter to ↓ weight, ↓ saturated fat, ↑ dietary fibre. Intervention subjects guided to increase physical activity. Findings: sign weight loss, lower blood glucose in intervention cf control. Eriksson et al 1999 (check also for other arms of the study)
17	Clinician advice using information technology	RCT. Weekly communication for 6 months via a totally automated, computer-based voice system. In intervention group system monitored dietary habits and provided educational feedback, advice, and behavioural counselling. Control group subjects received physical activity promotion counselling. Findings: intervention group ↑ fruit intake and dietary fibre and ↓ saturated fat rel to controls. Delichatsios et al 2001b
Smoking		
18	Mass media aimed at entire population	TV components of Massachusetts anti-smoking campaign, significantly reduced the rate of establishment of smoking among young adolescents compared to rest of US. Younger adolescents (12-13 years at baseline), reporting exposure to TV anti-smoking advertisements were significantly less likely to progress to established smoking (OR 0.49, 95%CI 0.26,0.93), From 1992 the prevalence of adult smoking in Massachusetts has declined 0.43% annually (95% CI 0.21%,0.66%) compared to increase of 0.03% (95% CI -0.06%, 0.12) in comparison states (P<0.001). Beiner et al 2000

19	Mass media campaign aimed primarily at smokers aged 18-40 years	Australian National Tobacco Campaign (NTC) aimed at assisting smokers to quit. It sought to help smokers move through the process of quitting (ie out of pre-contemplation into contemplation and preparation). Cessation rates and intentions reported. Wakefield and Miller 1999
20	Advice from clinicians regarding smoking cessation	Brief advice versus no advice (or usual care) from a doctor produced a small but significant increase in the odds of quitting at 6 months or more (OR 1.69, 95% CI 1.45, 1.98) Silagy et al 2002
21	Behavioural and nicotine replacement therapy (NRT)	Indicated that adding NRT to behavioural intervention provided intervention added a net beneficial effect (OR 1.69, 95%CI 1.0, 2.7) and adding a behavioural intervention to NRT also added a net beneficial effect (OR 1.78, 95% CI 1.0, 3.1) Baille et al 1994
22	Telephone counselling and NRT, aimed at people who had quit	Telephone support with NRT compared to NRT only for 12 months aimed at maintaining cessation of smoking (25.5% v 16%). Zhu et al 2003
	Four HMO insurance plans with different co-payments	Comparison of smoking-cessation rates: which ranged from 28% (users with full coverage) to 38% (users with std coverage). Est % of smokers who would quit per yr as a result of NRT ranged from 0.7% (reduced coverage) to 2.8% (full coverage). Consider as supportive evidence re NRT. Curry et al 1998
23	Pharmacotherapy, bupropion SR	Use of bupropion SR approximately doubled cessation rate compared to placebo (30.5% v 17.3%). OR for sustained abstinence at 5 months or more 2.1 (95% CI 1.5, 3.0) Fiore et al 2000
Alcohol		
24	Mass media, aimed at entire population	US Community Trials project, media advocacy focussed upon community awareness and support of local policy plus specific community variables to impact on behaviour. Evidence showed that media campaigns alone have no impact, but when conducted with community based approach there is an impact. Need to confirm quantifiable outcomes. Holder and Treno 1997
25	GP counselling, aimed at those with alcohol problems OR	Meta-analysis of 34 studies. Distinguished between treatment seeking and non-treatment seeking populations. Results consistent with findings reported elsewhere. Effect size ranged from 0.129 to 0.669. Moyer et al 2002
	Brief interventions, aimed at heavy drinkers	Study of >1500 subjects (in 8 countries) considered at risk of alcohol-related problems but with no history of dependency. Consistency observed in results with 17% decrease in consumption and 10% reduction in intensity. WHO Brief Intervention Study Group, 1996
26	Cognitive and behavioural therapy (CBT)	Significant decrease in drinks per day and in number of days abstinent. Heather et al 2000
27	CBT vs no counselling and non-directive reflective listening.	Motivational interviewing (similar to CBT) compared to no counselling and non-directive reflective listening) for 122 patients with mild to moderate alcohol dependence. 42% were drinking heavily ≥ 6 times in 6 months compared to 62% in the no counselling group. Sellman et al 2001
28	Pharmacotherapy, Naltrexone (NTX) and psychosocial therapy	Australian RCT, comparing 12 weeks of NXT with placebo or another active drug licensed in Australia involving patients >18 years with diagnosis of alcohol dependence or abuse. Trials measured relapse rates, abstinence rate and % of patients discontinuing due to adverse event and % of patients with at least 1 adverse event. Streeton et al 2001

9.3 Research Method for Stage 2

Overview

The 28 interventions identified are to be subject to economic evaluation of performance. The aim is to conduct cost-utility analyses, to determine performance in terms of cost/QALY. In this way all interventions will be comparable with each other, as well as with other interventions for which cost/QALY estimates are published. We are confident that this will prove possible for the majority of interventions; drawing on clinical trial evidence, and utilising modelling that reflects known epidemiology (relating risk factor behaviour to morbidity and mortality) and employing other techniques to translate morbidity onto QALYs. Specifically this approach should be possible in relation to multiple risk factor interventions, and interventions designed to address poor nutrition, physical inactivity and smoking. This confidence reflects in part the location of seminal trials in these fields that provide outcome data, in a form that should be translatable into morbidity and mortality. We are however less confident that it will prove possible to conduct cost-utility analyses in relation to alcohol use. Rather it may only be possible to undertake cost-effectiveness analyses, with performance expressed in terms of cost per intermediate outcome, such as change in drinking behaviour, as it may not be possible to translate intermediate outcomes – such as behaviour change into morbidity or mortality and QALYs. The approach to estimating benefits and costs is described further below. It was also described in some detail in the proposal for Stage 1 of this project

Once the individual economic analyses are complete, the relative cost-effectiveness of all 28 interventions will be compared and conclusions drawn concerning their performance relative to each other and to society norms. This will provide the basis of recommendations concerning interventions to be expanded, and others that may warrant contraction, in order to reduce the burden of harm from the subject risk factors.

Benefits

A literature review has been completed to gather relevant clinical trial data from which to establish the effectiveness of interventions. From this a selection of seminal trials has been made as listed in Table 1. These have been chosen to reflect high quality evidence, ideally RCT, adequate follow-up period, acceptable drop out rates, outcomes expressed in 'final' outcomes such as mortality, or intermediate outcomes with a known relationship with morbidity and mortality. In reality the published evidence falls short of this ideal. This means that even using the best available evidence, the reported effect of interventions will need to be modelled to translate short-term intermediate outcomes into longer term effect on health and wellbeing. This modelling will in part be based on observational data. Ideally benefits will encompass not just the individual, but also the family and the wider community where relevant - for instance, this is likely to be important in relation to alcohol misuse. It is also desirable to incorporate benefits beyond individual health - such as access, health inequalities, patient or citizen empowerment/autonomy; however in the absence of society standards this will not be possible.

In short benefits will be derived directly from the results of the seminal trials, and translated into final outcomes employing suitable modelling based on the epidemiology. Downstream impacts on both health status and use of health care resources will be modelled.

In order to compare across interventions it will be desirable to develop/adopt a single common outcome measure that can be applied across interventions, regardless of modality or type of impact. Based on other experience with priority setting, either the DALY⁵ or the QALY (Quality adjusted life year) are the logical candidates to adopt as a single outcome measure. They both are designed to combine impact on morbidity or quality of life and mortality, and both are widely used. However, recent experience in

⁵ A DALY is the sum of years of life lost (YLL) and years lived with a disability (YLD), see for instance Mathers et al 1999 and Vos & Begg 1999.

priority setting with osteoarthritis, suggests the QALY as the preferred measure. In addition a robust technique for translating disease specific outcomes into utility scores has been developed (the Transfer to Utility technique), will be employed if relevant. Although because many of these interventions will be directed at reducing disease incidence the DALY may well prove appropriate. The single common outcome measure to be used will be determined in consultation with the Department.

Costs/resource use

The cost of interventions will be calculated using one of two methods;

- i) documenting a precise description of the intervention to establish resource inputs and the application of published unit costs to each input, or
- ii) the use of published costs of an intervention. This latter method is only applicable where current cost data is reported for an Australian program.

Each intervention will clearly state which costing method (as above) has been used.

Costs will include the effect of any change in downstream health service costs. Depending on the intervention these might derive from a change in disease incidence or rate of disease progression and associated costs, a change in other costs applied to address harm or to side-effects (harmful or positive) attributable to the intervention. AIHW estimates of disease costs, developed through the disease costing program will, where suitable, be utilised to calculate cost savings from reduction in disease incidence.

A limited societal perspective will be taken, which includes government costs and private copayments. Private costs that do not go through the market such as waiting time, transport, carer costs and productivity costs will not be covered. Methodologies for estimation of these latter costs are insufficiently developed to provide reliable estimates. Furthermore, they are not typically included in economic evaluation of health programs. Cost impacts will be established from a specific perspective, such as the Federal Government, if useful.

Comparison of performance of interventions and development of recommendations

Comparison across interventions will be facilitated by the use of a consistent evaluation methods and associated assumptions. Normally in a priority setting exercise a conventional approach to economic evaluation is employed with the aim of producing a league table of interventions, ranked by cost-effectiveness or cost utility ratios. This is not to suggest a simple hierarchy of interventions, but rather to determine when best practice/optimal clinical practice also represents a cost-effective use of societies resources to justify funding. A priority setting process is designed to find that suit of interventions that all warrant funding to a level consistent with best practice care and also those interventions from which funding should be withdrawn. A simple hierarchy of interventions would only make sense where all interventions are substitutes for each other, where all interventions address the same population and where distributional issues are unimportant. In reality none of these conditions apply, particularly in application of priority setting to reduce the harm attributable to physical inactivity, alcohol abuse, tobacco smoking and poor nutrition. Certainly many interventions will be complementary rather than substitutes and will apply to quite distinct populations, and issues of disadvantage are likely to be important. There will thus be difficulties in applying a simple priority setting model, which will need to be the subject of consideration during the conduct of Stage 2 and will be determined in consultation with the Department. Some initial thoughts are outlined below

Other conceptual and empirical issues - Choice of Outcome Measure

Comparison of performance across all interventions requires outcomes to be expressed in a uniform way. Given a diversity of health states and intervention options to be compared, QALYs gained or DALYs averted, (or life-years gained where the dominant impact is mortality) are the primary options for expressing incremental health gains in a common unit. Where an intervention has an effect on both quality of life and mortality it can also be informative to separately calculate and report impact on life-years and quality of life. However, whether all reported outcomes can be translated into QALYs or

DALYs is yet to be demonstrated. A recent priority setting exercise into osteoarthritis, (Segal et al 2002), suggests this might be possible. That research also suggests the QALY might be the preferred measure, as it can readily be calculated as a continuous variable. This is most important in relation to interventions that have a major impact on quality of life, where quality of life can vary at a given disease stage and/or disease stages are difficult to define. This will often be the case.

The DALY as used in the Australian and Victorian Burden of Disease studies, has only limited potential application to priority setting. This is because DALYs are based on only a very limited number of disability weights for each health condition (typically 2 to 4). However, the DALY may be applicable in relation to many interventions to modify life style behaviours. This is because the DALY is useful where the primary impact of the intervention is to reduce disease incidence and/or rate of disease progression, and where there are clearly defined stages with a narrow range of health status experiences at each stage.

The budget allows for consideration of the preferred outcome measure as a task for Stage 2. As noted, it is not certain it will be possible to adopt a single outcome across all risk factors.

Quantification of the Relationship between intervention, risk factor and disease harm and quality of life and mortality.

Each risk factor is linked to a number of diseases and health problems and types of harm. They may also directly impact on quality of life and sense of wellbeing. The relative risk of selected diseases attributed to particular behaviours is generally known - defined by the relationship between the incidence of the condition among those with the risk factor and of those not so exposed (or with differing levels of risk), the association across all potential sources of harm may be poorly understood. We will draw on the work of Boyd Swinburne and colleagues from Deakin University for this task. Attributing any change in behaviours and thus health outcome to a specific intervention is complicated where the causal pathway is indirect. The complementarity of interventions and potential synergistic relationships is a further matter to be considered.

Role for marginal analysis

In general, in evaluating the impact of a health intervention, such as a new drug or a weight loss program, the reasonable presumption is that everything else remains unchanged (*ceterus parabus*). However certain interventions seeking to change risking life style behaviours, involve radical changes to infrastructure or legislation, with potential for wide-ranging impacts. These have largely been excluded from the selected list of interventions. Thus the assumption of *ceterus parabus* is probably reasonable.

Discounting

In conformity with convention in economic evaluations, discounting is applied to costs, at a rate of 5% pa, consistent with government policy. Rates of 3% and 7% will be included in a sensitivity analysis. Discounting of benefits is more contentious. Discounting of benefits in effect involves an equity weighting in favour of benefits today compared with benefits in the future, which inherently involves different individuals. That this reflects community values has not been established. Both very high rates of discounting of future benefits as well as positive weighting to future benefits (that is preferring benefits in the future) can be seen in individual and societal behaviours⁶. For this reasons sensitivity analyses will be conducted, employing discount rates on benefits of 0%, 3% and 7%. The appropriate 'central case' is to be agreed with the Department. In the UK for health sector evaluation a higher rate of discount is applied to costs than to benefits.

⁶ For instance the action of parents in reducing their own consumption to leave an inheritance for their children, or societal concerns to retain environmental diversity for future generations, suggests a negative discount rate on future benefits, whilst high risk life style behaviours involve a high rate of discount on future benefits (albeit confounded by attitudes to risk).

Optimal mix of Interventions – Consideration of uncertainty in estimates

The literature is characterised by considerable uncertainty in relation to the impact of interventions on behaviours and of this upon disease burden and associated harms. Uncertainty applies particularly to physical inactivity, poor nutrition and alcohol misuse. The data on tobacco smoking is more precise, it has been extensively studied, description of the risk factor is simple and clear and the relationship between the risk factor (smoking) and health is extreme. The definition of what constitutes risk and how to describe it is straight-forward for tobacco smoking, but exceedingly complex in relation to the other three risk factors.

Various means will be adopted for handling uncertainty, these include:

- careful analysis of information to understand the nature of the parameters and possible values;
- conduct sensitivity analysis – for instance taking advantage of available soft-wear (such as ‘at risk’) for this purpose;
- the use more sophisticated modelling designed to determine an optimal portfolio of interventions. For instance the stochastic league table approach, developed by WHO, which is especially relevant to priority setting in the context of multiple interventions. This comprises a two-step approach:
 1. Monte Carlo simulations from the estimated distributions of costs and effects for each intervention under study,
 2. Identification of the optimal mix of interventions – with particular attention to the level of each intervention. The most cost-effective intervention (compared with a ‘do nothing’ approach) is identified and the incremental cost-effectiveness of remaining interventions determined. This step is repeated approximately 10,000 times to generate a probability distributions for each that intervention for a given budget constraint.
 3. By repeating this process for different budget constraints, an expansion path can be developed. WHO have developed the software for this analysis, to which the consulting team has access. The feasibility of applying this approach in the current context will be established.

Conclusion

There is a substantial literature and sufficiently well developed techniques for a valuable study into the comparative performance of various interventions for the reduction in harm from the risk factors of alcohol misuse, poor nutrition, physical inactivity and tobacco smoking. This research will provide a useful input into the policy response to reduce harm from these life style behaviours.

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