Health Technology Board for Scotland

Health Technology Assessment of Prevention of Relapse in Alcohol Dependence

Consultation Assessment Report

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With significant contributions from a broad range of Scottish and UK experts (see Appendix 1)

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CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

GLOSSARY AND ABBREVIATIONS

1 EXECUTIVE SUMMARY

1.1 Background

1. The 1998 Scottish Health Survey included questions to estimate the scale of alcohol dependence in Scotland. It recorded that 10% of male drinkers and 3-4% of female drinkers replied affirmatively to one or more of three questions designed to identify alcohol dependence. All three questions were answered affirmatively by 1% of male drinkers but less than 0.5% of female drinkers.

2. Untreated alcohol dependence results in levels of drinking, which substantially increase the risk of stroke, cirrhosis of the liver, brain damage and several forms of cancer and are associated with substantially increased mortality.

3. Following initial detoxification a longer term programme of treatment is required to prevent relapse into heavy drinking and dependence. A number of different psychosocial and pharmacological interventions are available to prevent relapse. These are the focus of this HTA.

4. The Plan for Action on Alcohol Problems was published in January 2002 (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002) and covers a wide range of social, economic and clinical aspects of the misuse of alcohol in Scotland including chronic heavy drinking. This Health Technology Assessment provides policy makers, planners and those working in the field of relapse prevention in alcohol dependence with a part of the information required to implement the Plan.

5. People with established alcohol dependence are likely to require treatment **mainly** within Tier 3 **(Specialist Alcohol Problem Services)** or Tier 4 **(Regional Specialist Services)** of the Scottish Executive's Draft Alcohol Problems Support and Treatment Framework. Thus this HTA will be of primary interest to those concerned with these specialist tiers. **However aspects of relapse prevention may happen in Tier 1 (Local Services) or Tier 2 (Specialist Support).**

6. There is no agreed definition of alcohol dependence. When possible the pragmatic criterion that a process of detoxification has been undergone has been preferred. However, a range of criteria are used by investigators in clinical trials and exclusive use of any single criterion would force many studies to be discarded.

1.2 Objectives of this Health Technology Assessment

The objectives of this Health Technology Assessment were to answer the following questions:

1. Which approach or combination of approaches (pharmacological and psychosocial) will yield the maximum maintenance of recovery amongst the

population of those with alcohol dependence who have undergone detoxification?

2. What is the most effective and efficient approach to delivering the individual interventions (or combination of interventions) taking into account the different risk groups, locations, durations of treatment, etc?

1.3 Health Technology Assessment Evidence

1. This Health Technology Assessment used systematic literature searching to identify evidence published in scientific literature. It also used evidence submitted by professional groups, patient groups, manufacturers, other interested parties and experts and undertook primary research with patients to elicit their views and preferences.

2. For clinical effectiveness, a number of comprehensive reviews of treatment for alcohol problems were consulted and also reviews of specific interventions. Studies particularly relevant to patients with alcohol dependence were extracted from these reviews. Additional relevant studies were identified and an analysis was carried out to estimate the effects of treatment in a form suitable for input to the HTBS economic model.

3. The patient issues component used published scientific literature, materials from Alcoholics Anonymous, and a qualitative study of patient attitudes commissioned by HTBS.

4. The economic evaluation critically appraised the economic models contained in the literature. HTBS developed a simple, transparent model to combine the clinical effectiveness and epidemiology data with the costs of therapies and diseases to inform on the cost-effectiveness of five psychosocial and three pharmacological therapies to prevent relapse in people who are alcohol dependent. The main source of cost data was Information Services Division (ISD), part of Common Services Agency (CSA), itself part of Scottish Executive Health department (SEHD).

5. The current provision of services for prevention of relapse in alcohol dependence in Scotland was assessed by two postal surveys. One of these was targeted at NHS specialist services and the other at non-NHS providers.

1.4 Clinical Effectiveness

1. A number of psychosocial interventions were found to be of value in preventing relapse in alcohol dependence. The total combined success rates, in terms of abstinence or controlled drinking at the trial end (varying between 6 months and beyond one year), in trials of those psychosocial treatments judged effective, was 43% for patients in the intervention groups and 28% for those receiving control treatments. In common with clinical trials in many

other areas of medicine, these may overestimate the absolute benefits attainable in clinical practice.

2. The HTBS meta-analysis suggested similar, statistically significant, beneficial effect sizes for four types of psychosocial treatment. The odds ratios for abstinence or controlled drinking at the end of the clinical trial compared with patients offered control treatments were: Behavioural Self-Control Training (OR=1.86 [95%CI 1.03,3.36]); Motivational Enhancement Therapy (OR=2.19 [95%CI 1.20,3.98]); Family Therapy (OR=1.81 [95%CI 1.26,2.61]); and Coping/Communication Skills Training (OR=2.33 [95%CI 1.44,3.76]).

3. Behavioural Self Control Training showed benefit when compared to ineffective controls. However, the only trial, which focused on the unique defining features of BSCT and included the more general features in both treatment groups did not show a benefit. Thus there is no proof of superiority over other CBT based approaches.

4. Motivational Enhancement Therapy (MET) has mixed evidence. It shows efficacy over ineffective controls. However, it was slightly less effective than AA based treatment in outpatients in Project MATCH. This may be due to the short course of treatment given. It is suggested that MET form an important initial element in a course of psychosocial treatment but should not be the sole intervention available.

5. Although marital/relationship therapy has shown a beneficial effect it should be recognized that this approach is only usually feasible in those with relatives willing to invest substantial effort in the treatment and with the consent of the patient. Thus it is an option for treatment of only some patients. An exception to this is the Community Reinforcement Approach, which has been shown to be effective when a contractual element with non-family members has been tested.

6. Brief Interventions appear to be of unproven efficacy in patients with established alcohol dependence and the current evidence does not suggest that this is a promising approach. The 'Relapse Prevention' model of treatment is also unproven.

7. Acamprosate and naltrexone are pharmacological treatments intended to reduce relapse. They are sometimes described as anti-craving agents. Both were found to be effective, the combined success rates, in terms of abstinence or controlled drinking at the trial end (varying between 3 months and one year), in trials of these treatments was 36% for treated patients and 26% for those receiving placebo treatments. These may overestimate absolute benefits attainable in clinical practice.

8. Disulfiram, which causes illness when taken with alcohol, was found to be ineffective if taken without supervision to ensure compliance. One good clinical trial and some supporting evidence supports the use of disulfiram with supervision.

9. All the evidence for effectiveness of pharmacological treatments is obtained from studies in which they were adjunctive to psychosocial treatments. Thus the psychosocial treatment should preferably be organised prior to starting medication.

10. Within a specialist unit protocols should be available for all treatment options to ensure standardized and consistent treatment. These protocols should be closely based on methods that have been proven effective in clinical trials.

11. Evidence suggests that practical help with problems such as housing, debt, and claiming benefits is likely to contribute to control of alcohol problems. Thus close liaison with Local Authority services such as Social Work and Housing and groups able to deliver such help is essential.

12. Encouragement to attend AA meetings has been shown to have benefit. Explanation of the aims and philosophy of AA during treatment will allow patients to make an informed choice. As with other psychosocial treatment approaches, cooperation with, rather than coercion into, AA treatment appears essential for benefit to be obtained.

13. The effectiveness of relapse prevention interventions delivered by the Councils on Alcohol has not been tested in clinical studies. Where counsellors are practising treatments, which have been shown to be effective in other settings there is likely to be benefit.

1.5 Patient issues

1. In reply to the HTBS survey only 36% of NHS specialist services carrying out psychosocial interventions indicated that they had patient information sheets or leaflets for any of these interventions. It is recommended that such information should be available for all interventions.

2. A qualitative study is being undertaken for HTBS, to explore patients' treatment preferences and also to elicit factors, which, are felt to prevent relapse to drinking. The aim is to describe the experiences and preferences of individuals for pharmacological or psychosocial interventions, or a combination of both, for the treatment for alcohol dependence. This will be achieved by undertaking in-depth one-to-one interviews with 45 patients in 3 NHSScotland Trusts.

3. Data have, so far, been analysed from interviews with 32 people and this Interim Report presents the results of the preliminary analysis. Of the 32 interviews analysed so far, twenty were with men and twelve with women. Their ages range from thirty to seventy-two years. Four people were still drinking in a harmful way, and the longest period of abstinence at the time of interview was two years.

4. Issues to emerge include:

   - Participation in residential or day case relapse services may currently depend on the way services are structured locally, rather than patient choice
   - Lack of understanding of terms such as cognitive behaviour therapy and motivational enhancement need to recognised in patient literature
   - Participants valued activities such as anger management, stress/anxiety management and relaxation exercises, coping skills, assertiveness training and rehearsing difficult situations within a safe environment
   - Women who had experienced 'women only' group work had a preference for women only groups, but conversely men may have a preference for mixed sex group work
   - Individual therapy sessions may be valued for the depth of work they enable
   - Flexibility of times and venues was valued
   - All participants recognised that AA works well for many people, but most of them felt that it was not suitable for them.
   - Awareness of services other than Alcoholics Anonymous may be low and may require better promotion.

5. It is clear from the results of clinical studies that all interventions are of limited effectiveness. It is thus worth providing a range of options of proven efficacy. Treatment should be individualised taking account of patients' expectations, needs and wishes with the understanding that these needs may change and the treatment plan may need to adapt to this.

1.6 Economic Evaluation

1. The economic evaluation compared the costs and consequences of eight therapies in comparison to a standard care package. The relevant outcomes were disease endpoints being alcohol dependence, alcoholic psychosis (including alcohol-related brain damage), liver cirrhosis, epilepsy, chronic pancreatitis, cancer, strokes and death.

2. For each therapy, the costs and consequences for 1,000 patients complying with the therapy are modelled and compared to the costs and consequences for 1,000 patients receiving a standard care package. This involves:

   - defining and costing each intervention
   - applying the clinical effectiveness odds ratio for the intervention to the epidemiology for the cohort to calculate the number of patients likely to be in the various disease endpoints
   - calculating the costs to NHSScotland of the disease endpoints; and
   - calculating an incremental cost or saving per additional abstinent patient.

3. The results show that four of the five psychosocial interventions (Coping Skills, Behavioural Self Control Training, Motivational Interviewing and Marital and Family Therapy) produce net *savings* per incremental abstinent patient. That is the cost of the treatment is less than the savings available to

NHSScotland. These savings arise because the improved abstinence rate results in a lower incidence of diseases, thereby saving inpatient hospital stays and other disease related costs.

4. Acamprosate is less cost effective than these psychosocial interventions but more cost effective than naltrexone and disulfiram. Sensitivity analysis shows that the ranking of therapies is robust

5. A serious limitation of the model is the absence of data on relapse rates beyond the relatively short trial periods. There are also concerns about generalising from trials to treating patients in a Scottish setting. Further research and evidence is thus needed to give more definitive estimates of the long-term effectiveness of all the therapies in a Scottish setting.

1.7 Organisational Issues

1. Randomised controlled trials testing matters related to the organisation of specialist alcohol services are scarce. Thus recommendations with regard to organisational issues are based on clinical expert judgement.

2. Alcohol services are highly suited to 'joint working', as recommended by the Joint Futures Group, involving specialist mental health and social work addiction services and non statutory agencies with joint resourcing and management of community care services.

3. Treatment should be individualised taking account of patients' expectations, needs and wishes with the understanding that these needs may change and the treatment plan may need to adapt to this.

4. Certain subgroups such as young people, the homeless, those with co-morbid mental health problems, have special service needs and providers should ensure that the service is responsive and accessible to all.

5. Specialist services must make themselves aware of mutual help (AA) and non-statutory agencies operating in their area and co-ordinate their approach, making this information available to individuals within their care. Informing patients about AA and non-statutory agencies should be part of the overall relapse prevention strategy.

6. Controlled use of alcohol may be an appropriate treatment goal for those with less severe alcohol problems. However, as will usually be the case in the specialist setting, abstinence should be the goal for severe dependence, where controlled use is rarely sustainable and especially when there is evidence of alcohol related organ damage. If controlled use / harm minimisation is the considered preferred goal of the individual there must still be options for intervention e.g. referral to a non-statutory agency or outpatient motivational sessions.

7. An improved information collection system is required. (ISD are currently changing the way in which information is collected, for instance from GP contacts).

8. A regularly updated comprehensive directory of alcohol services including residential treatment would be beneficial. This should be useable by all participating agencies and provide accurate outcome data (as recorded and analysed) as well as a greater understanding of progress through the treatment system.

9. It is essential to have a longer term measurement of quality and effectiveness. Future measurements of outcome should cover longer periods post intervention e.g. up to 5 years.

10. More research and evidence are needed regarding the benefits of different settings for psychosocial interventions e.g. group vs. individual, inpatient vs. outpatient vs. day unit, intensity and length and frequency of sessions etc.

1.8 Draft Recommendations

1. Patients value group and one-to-one psychosocial therapies. Certain subgroups such as young people, the homeless and those with co-morbid mental health problems, have special service needs and providers should ensure services are responsive and accessible to all.

2. Coping Skills, Behavioural Self Control Training, Motivational Interviewing and Marital/Family Therapy have been proven to be clinically and cost effective in this HTA and are recommended treatment options. They should be administered by appropriately trained and competent professionals using standardized protocols. Other psychosocial therapies were less effective and are not recommended. In particular, Brief Interventions are not effective in this population of patients with established alcohol dependence.

3. Alcoholics Anonymous provide group therapies using the 12-step approach in hundreds of groups across Scotland. This service is free to the NHS and the 12-step approach has been shown to be effective. Consequently NHS service providers should be aware of local AA groups and offer this as an alternative treatment. However, pressure to attend AA groups is not recommended.

4. People with alcohol dependence have a high chance of relapse in the longer term. Non-statutory agencies can be a responsive source of long term support and information. Specialist agencies should ensure that clients are aware of locally available services.

5. Disulfiram given under supervision and acamprosate are recommended as options for treatment in addition to psychosocial therapies, with acamprosate being the most cost effective. The treatments have different mechanisms of action and associated side effects and so choice of treatment should be considered carefully on an individual patient basis.

6. Naltrexone does not have Marketing Authorisation in the UK for prevention of relapse in alcohol dependence and is less cost effective than acamprosate, so it is not recommended for use in NHSScotland.

7. Specialist unit protocols should be available for all treatment options to ensure standardised and consistent treatment. Clear patient information leaflets should be available for each intervention.

8. For all therapies, both psychosocial and pharmacological, evidence of effectiveness is only available over short time periods of 3-12 months and in trial settings. Collection of longer-term audit data, evaluating patient outcome and resource consequences of alcohol relapse, in various Scottish settings, is required to refine further these recommendations. Improved information on the numbers of Scots who are alcohol dependent and who would benefit from such services, and the availability of resources to meet these demands, is also required.

1.9 Consultation

1. This HTA is currently at the stage of open consultation and comments on this Consultation Assessment Report should be submitted to Ms Susan Quinn, Medical Writer, **by 17 September 2002** (see section 2.3 for further details).

2 INTRODUCTION AND OBJECTIVES

2.1 Introduction

The Scottish Health Plan (Scottish Executive Health Department, 2001) made a clear commitment relating to alcohol misuse. In particular it stated that *we will develop a plan for action on alcohol misuse, bringing together what needs to be done by all concerned, including the Executive. Prevention and services for people with alcohol problems will lie at the heart of the plan.*

This Plan for Action on Alcohol Problems was published in January 2002 (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002) and covers a wide range of social, economic and clinical aspects of the misuse of alcohol in Scotland. The Plan notes that *"Two current exercises will add in the next year or two to our understanding of how best to address the whole range of alcohol problems, including chronic heavy drinking. These are work by the Scottish Intercollegiate Guidelines Network (SIGN) on the management of alcohol problems by primary care professionals and by the Health Technology Board for Scotland (HTBS) on relapse prevention"*. This report fulfils the second of these commitments.

This HTBS Health Technology Assessment will consider interventions to prevent relapse in those who are alcohol dependent and have undergone detoxification. It will link in closely to the SEHD initiative, particularly in terms of organisation of services.

The relapse prevention therapies studied in this HTBS assessment are mainly given in secondary care settings and so this assessment will complement the SIGN guideline on management of alcohol dependence in primary care (due to be completed early in 2003 – see Appendix 2).

The Health Technology Board for Scotland (HTBS) uses the internationally recognised definition of Health Technology Assessment (HTA) (INAHTA, 2000) which describes HTA as a multidisciplinary field of policy analysis that studies the medical, social, ethical and economic implications of the development, diffusion and use of health technology.

The HTA considers four components as identified in Figure 2 - 1 Health Technology Assessment (HTA) process: clinical effectiveness, economic aspects, patient issues and organisational considerations. The assessment report presents the evidence relating to each of these sections and a final discussion and recommendations bring together the key aspects from each section.

This HTA follows the process published by HTBS (Health Technology Board for Scotland (HTBS), 2001) This involves the submission of evidence from a wide variety of sources, expert staff to undertake the analyses, a multidisciplinary expert Topic Specific Group (TSG) to collect and critique evidence and analyses, quality assurance (QA) by the HTBS Governance Board and wide-ranging open consultation and expert review.

In this HTA, national and international evidence is critically appraised, taking account of Scottish circumstances, so that clear, practical recommendations can be made to the National Health Service in Scotland (NHSScotland). This detailed, scientific assessment report will be updated after the open consultation period, to become the final Health Technology Assessment Report. At the final stage, two other summary documents will be produced. The *Advice to NHSScotland* will be aimed at policy makers, NHS Board decision makers and healthcare professionals. An *Understanding HTBS Advice* document will also be published explaining to patients, carers and the public how the evidence was reviewed and the reasons for the HTBS recommendations.

2.2 Objectives

The objective of this Health Technology assessment is to answer the following questions:

1. Which approach or combination of approaches will yield the maximum maintenance of recovery amongst the population of those with alcohol dependence who have undergone detoxification?

2. What is the most effective and efficient approach to delivering the individual interventions (or combination of interventions) taking into account the different risk groups, locations, duration of treatment, etc?

The health interventions considered fall into two categories, pharmacological and psychosocial. This latter category covers a wide range from the purely psychological to those that attempt to intervene practically in many areas of social welfare and functioning.

A number of subsidiary questions were identified by our expert advisers, during the planning phase of this HTA. These were used to focus on the selection of literature and the review process. These questions are included as Appendix 3.

2.3 Current stage of assessment: Open consultation

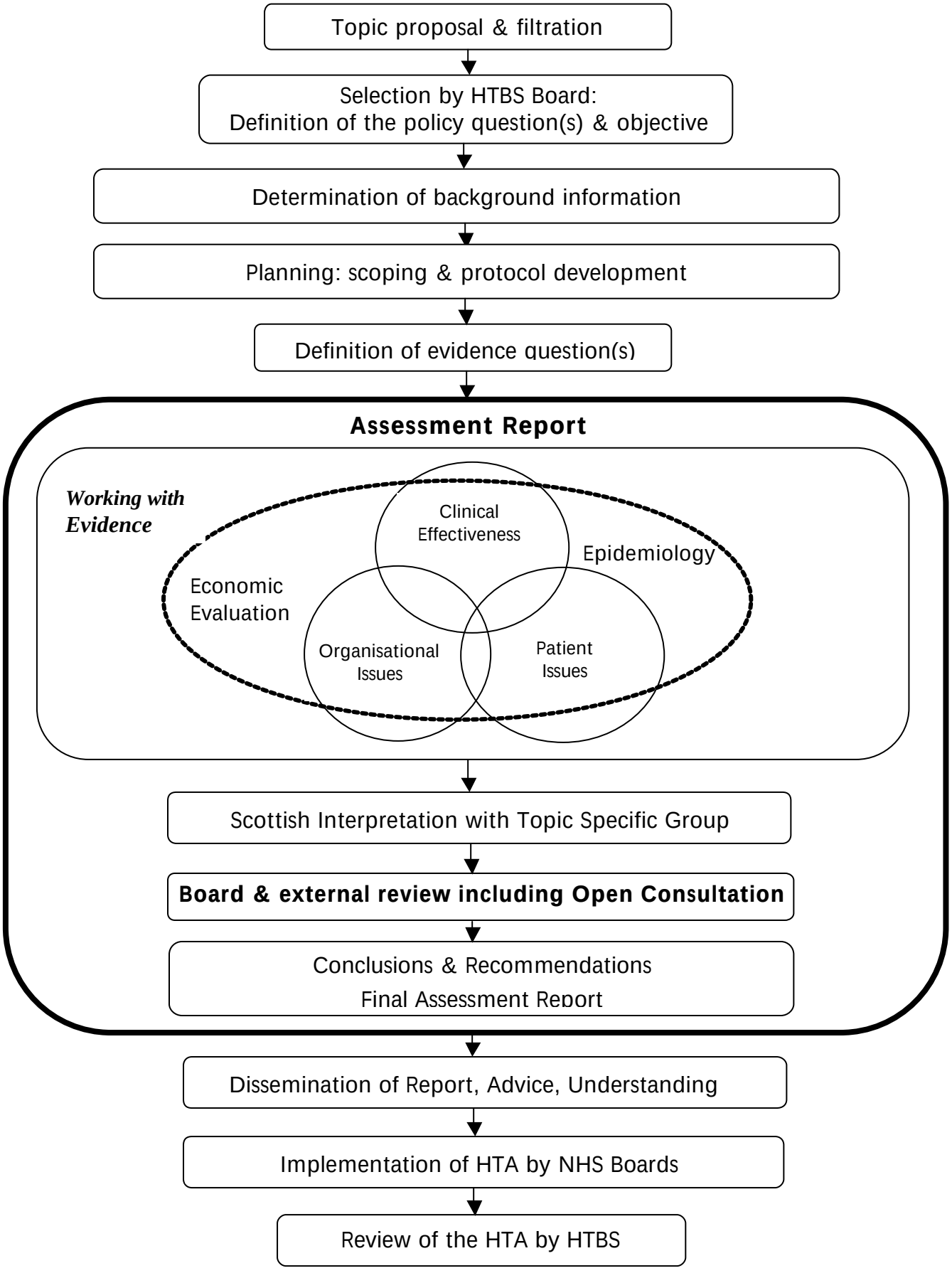
This Health Technology Assessment is currently at the stage of open consultation and comments on this Consultation Assessment Report should be submitted by **17 September 2002** to Ms Susan Quinn.

Electronic files in plain text or in MS Office packages are preferred, but paper copies will be accepted. Comments may be sent via email to squinn@htbs.org.uk or posted to the Health Technology Board for Scotland, Delta House, 50 West Nile Street, Glasgow G1 2NP. Fax +44 (0)141 248 3778.

In the month following consultation, all comments will be posted on the HTBS website (www.htbs.co..uk). **Please indicate if you do not wish your comment to be posted on the world wide web. Also, please mark any confidential information, so that this can be removed before uploading to the web.**

Consultation comments will be incorporated into the Final Assessment Report, as considered appropriate by the HTBS team. Individual replies to comments will not be made, unless specifically requested.

Figure 2 - 1 Health Technology Assessment (HTA) process



3 BACKGROUND

3.1 Alcohol misuse in Scotland

Scotland has a significant alcohol misuse problem. This has been highlighted in the Scottish Executive's Plan for Action on Alcohol Problems (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002). Planning services for treatment of alcohol problems requires an understanding of the existing treatment services and a prediction of the volume of service required, in addition to knowledge of the clinical and cost effectiveness of treatments. This Health Technology Assessment addresses the particular problems of relapse prevention in that subgroup of drinkers who are alcohol dependent. Service planning for these patients is complicated by the difficulty of defining the group of patients who want, or would benefit from, relapse prevention interventions.

The misuse of alcohol can lead to a wide range of physical, psychological and social problems and places a significant burden on the workload of the NHS. This burden results from damage not only to the harmful or problem drinker but also to other third parties affected by the excessive drinking. The Plan for Action estimates that alcohol problems cost Scotland at least £1 billion each year. Much of this is accounted for by reduced productivity and human costs. The direct costs of alcohol problems (£449M annually) to health, social work and criminal justice systems incur more than drug misuse (£382M), Alzheimer's disease (£155M), schizophrenia (£121M) and stroke (£118M). Alcohol problems therefore impose a substantial financial burden on Scottish society, the considerable costs to statutory agencies draining resources from other priorities.

There is no single culture surrounding drinking in Scotland. It extends across age groups, genders, ethnic and religious groups, urban and rural areas. This heterogeneity must be borne in mind when planning services and interpreting clinical and cost effectiveness reviews. In addition, problems, such as access to appropriate and sensitive services, that may be experienced by groups including homeless people, older people, users of illegal drugs, minority ethnic groups, disabled people and people in rural areas must be identified and addressed.

The association between alcohol and drug misuse should be recognised both in treatment approaches and overall service planning. The similarities and differences between alcohol and drug problems are discussed in the Plan for Action, with some approaches to treatment being noted to be applicable to both. There has been concern that alcohol has run a poor second to drugs in terms of service development in recent years. Redressing this imbalance will be an important issue in the Plan for Action service recommendations.

The links between severe problem drinking, homelessness and imprisonment are also well known and important factors in assessment of relapse prevention services.

The Plan for Action on Alcohol Problems (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002) has highlighted concerning trends in alcohol use in Scotland

against which the current initiatives are set. The following are statistics taken from the Plan for Action.

- 44% of all men and 26% of all women are drinking more than twice the recommended daily benchmarks (>8 units for men; >6 units for women) on their heaviest drinking day

- Alcohol related death rates for women have doubled in the last decade (from 13.4/100 000 in 1990 to 31.2/100 000 in 2000)

- In 1990 alcohol related deaths accounted for 1 in 100 deaths in Scotland. By 1999 this had risen to 1 in 40. These figures might in part reflect altered recording although there is evidence for liver deaths that this is not the explanation. More than 2/3rds of alcohol related deaths are of men.

3.2 Treatment strategy and settings

Treatment for alcohol dependence may be considered to have two distinct but interrelated arms. Firstly, helping the individual to stop or reduce alcohol use. This may require supervised detoxification. The second arm of treatment is to help the individual live a life of abstinence or controlled drinking depending on the goal of treatment, the ethos of the service and the individual's preference. This understanding that detoxification is only the start of the story in the treatment of alcohol dependence is of major importance to all agencies involved in healthcare. Long-term benefit relies on the development of life skills and methods that enable individuals to maintain the desired changes in their use of alcohol. It is this second arm of treatment under the title of Relapse Prevention that will be focused on in this assessment.

Detoxification and relapse prevention, although distinct processes, have an important relationship in terms of timing (Stages of Change, Prochaska and Di Clemente 1992). Detoxification may only improve long-term outcome if the individual has reached a crucial point in their attitude toward drinking. The early transition from detoxification, whether inpatient or outpatient, to adapting to life without alcohol may be a crucial period for long-term outcome. This may be the point where pharmacological interventions have a role.

Relapse prevention may involve psychosocial (a combination of psychological and social) and pharmacological interventions. They are characteristically most intensely carried out in the few weeks immediately following detoxification, and may also be part of a longer-term intervention aimed at reducing overall harm caused by alcohol. The main aims are to support, motivate and encourage effective coping skills. Introduction to other agencies in the treatment 'system' can be part of the overall relapse prevention strategy.

Agencies carrying out relapse prevention interventions will be described later in this section of the report. However, it should be mentioned here that the interventions described are, for the most part, carried out by specialist alcohol services. Generalist interventions (e.g. as carried out by GPs, general medical and even general psychiatric wards) are usually limited to 'opportunistic' interventions. These latter interventions

involve screening for alcohol problems, identifying hazardous or harmful drinkers and offering minimal (brief) interventions, aimed at reducing drinking to low risk levels. More seriously impaired or dependent individuals may be referred on to specialist services although some generalists feel more able to offer intensive treatments. Other interventions, which are currently usually commenced in a specialist service, eg. Acamprosate, may be best continued in a generalist setting with ongoing monitoring by the specialist service. This 'shared care' is a current area of development in substance misuse managements generally. The NHS Executive (1995) defines shared care as '*the joint participation of specialists and GPs (and other agencies as appropriate) in the planned delivery of care for patients with a drug (alcohol) misuse problem, informed by an enhanced information exchange beyond routine discharge and referral letters. It may involve the day-to-day management by the GP of the patients medical needs in relation to his or her drug (alcohol) misuse. Such arrangements would make explicit which clinician was responsible for different aspects of the patients treatment and care.*'

3.3 Health Consequences of High Levels of Drinking

The health consequences of drinking beyond the levels that have been shown to be safe are many and varied. Harmful alcohol use often persists over many years, although some drinkers may have intermittent periods of prolonged sobriety. Those with a pattern of harmful alcohol use may present as dependent seeking help, intoxicated, in withdrawal, with physical or psychiatric co-morbidity, in the wake of an accident, with social problems or having infringed the law.

Prolonged harmful alcohol use often leads to serious health disorders affecting the nervous system (Korsakoff's Syndrome, alcoholic dementia, peripheral neuropathy), the liver (cirrhosis, alcoholic hepatitis), the gastrointestinal system (oropharangeal cancer, gastritis, upper gastrointestinal bleeding, pancreatitis), the cardiovascular system (cardiomyopathy, hypertension), the respiratory system (laryngeal cancer), and the haematological system (anaemia, bleeding disorders). In addition, the risk to the foetus in a pregnant alcohol misuser is well recognised.

A recent study of the incidence of Korsakoff's Syndrome in East Glasgow (Jauhar & Ramaya) highlighted a sharp increase in this presentation in recent years, amongst the highest incidence reported anywhere in the world.

Harmful alcohol use is commonly associated with psychiatric illness. Harmful drinking may be a response to underlying depressive illness or may itself precipitate depression. It can cause, or sometimes develops alongside, anxiety disorders. Alcohol is associated with a high proportion of completed and attempted suicides. Harmful drinkers can present with erectile impotence and decreased libido. Dependent drinkers in withdrawal may develop delirium tremens. Alcoholic hallucinosis / psychosis may occur secondary to prolonged heavy alcohol use.

A quantitative discussion of the long-term health expectations of heavy drinkers is given in section 3.20.

3.4 Social and Economic Consequences of Problem Drinking

Alcohol dependence often leads to severe social and economic consequences for individuals and their families. Harmful alcohol use is associated with violence (domestic and otherwise), family stress, problems at work (including loss of job), financial strain and social isolation. The social exclusion that may result from problem drinking may lead to homelessness and offending behaviour. There is an association with theft and other crimes (including homicide) committed under the influence of alcohol. Alcohol contributes to road accidents due to intoxicated pedestrians as well as intoxicated drivers.

3.5 The Prevalence of Alcohol Dependence

Standard definitions of dependence are given in full in Appendix 4. The definition commonly used, and upon which hospital discharge data and mortality data are coded, uses the International Classification of Disease (ICD-10) (World Health Organisation, 1992) diagnostic categories. This requires the presence of three or more of the following for a diagnosis of dependence:

1. a strong desire or sense of compulsion to take alcohol
2. impaired capacity to control alcohol taking behaviour
3. a physiological withdrawal state
4. evidence of tolerance to the effects of alcohol
5. preoccupation with alcohol use (to the detriment of alternative pleasures or interests)
6. persistent alcohol use despite clear evidence of harmful consequences

The true prevalence of alcohol dependence, according to this definition, is difficult to estimate. This is because dependent individuals will not necessarily present for medical treatment. However, various estimates have been made from concomitant evidence.

A high proportion of the Scottish population currently drinks. Only 7% of men and 12% of women aged 16-74 said that they did not currently drink. At mid 2000 there were estimated to be 1,972,394 men and 2,141,658 women of age 16 or over in Scotland. This suggests a population of about 1.8 million male and 1.9 million female drinkers.

The Scottish Health Survey 1995 estimated that the numbers of Scottish adults exceeding the weekly-recommended limits of 21 units for men and 14 units for women were 33% of men and 13% of women. In the same year 8% of men were drinking above 50 units per week and 1% of women were drinking above 35 units per week. These levels are known to have a harmful effect on the drinkers' health. In absolute terms they represent about 160,000 men and 19,000 women drinking at harmful levels.

Drinking at a harmful level does not necessarily mean the drinker is alcohol dependent. The Scottish Health Survey 1998 contained three statements designed to assess dependence: 'There have been occasions when I felt unable to stop drinking'; 'I

have had a drink first thing in the morning to steady my nerves or get rid of a hangover'; and 'I have found that my hands were shaking in the morning after drinking the previous night'.

Looking at the three items on physical dependence, 90% of current male drinkers said none of the three items applied to them, 7% said one applied, 2% two items and 1% all three items. Among current female drinkers, the corresponding figures were 96% none, 3% one item. Precise figures are not given for two and three items but they are noted as being less than 0.5%: An average 'dependence score' of 0.05 is given for women which would suggest that about 0.3% answered three items affirmatively[*]. The likelihood of agreeing with one or more of these three items was highest among 16-24 year olds in both sexes, and then decreased with age. These figures suggest that 180,000 men and 34,000 women might answer one or more items affirmatively. However,18,000 men and 5,700 women would answer all three of these dependence items affirmatively.

Self reported information on drinking must always be interpreted with caution. Cross-sectional surveys have been found to underestimate per-capita consumption judged from alcohol sales figures. However, the figures given above would appear to give reasonable bounds on the size of patient group that might benefit from specialist alcohol services. If we assume that it includes all those who would answer affirmatively to the three dependence items but will not exceed the numbers drinking harmfully, the number of men lies between 18,000 and 160,000 and the number of women between 5,700 and 19,000.

The number who might use services will not necessarily equal the number who might benefit. Some measure of current usage of inpatient services can be gauged from ISD hospital discharge figures for 1999/0, which show 3,268 discharges from psychiatric hospitals and 4,398 discharges from non-psychiatric hospitals with a diagnostic code of F10.2, alcohol dependence syndrome (not necessarily as primary diagnosis). This total of 7,666, of course, does not include the numbers undergoing detoxification in the community and receiving other treatments not involving hospital admission. These may constitute significant numbers.

The Plan for Action on Alcohol Problems (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002) gives the following rates:

- In 1999, 1 in 40 (or 1,595) deaths were reported as alcohol related (the majority of these have a diagnosis of alcohol dependence and alcoholic liver disease: 51% alcoholic liver disease; 44% alcohol dependence; 13% acute intoxication; 1% alcoholic psychosis). (It is believed that alcohol is often omitted as a factor on the death certificate in deaths where alcohol was only a contributing factor, such as deaths from haemorrhagic stroke, cancer of the head and neck, suicide, burns, drowning or injuries – see below).

- An estimated 0.7% (107, 685) of all GP consultations in Scotland were for alcohol related diagnoses in 2000; of these, 69% were due to alcohol

[*] If we assume the highest value for two items (0.5%) we have 0.03x1+0.005x2+Yx3=0.05 and hence Y=0.0033.

dependence, 21% due to alcohol intoxication, 5% due to physical / organ damage (including alcohol liver disease), 3% due to alcohol psychosis and 2% due to unspecified problem drinking / excess consumption.

- 3 in 100 of acute hospital inpatient admissions had an alcohol related diagnosis; of which 28.5% were diagnosed as acute intoxication, 26.2% (8,618) as alcohol dependence, 24.7% as alcohol problems, 17.1% as organ damage (including liver), 11% as alcohol poisoning (many of which were linked to overdoses) and 1% as alcoholic psychosis.

- 15% (4,432) of all psychiatric hospital admissions had an alcohol related diagnosis; over 2/3rds of these had a diagnosis of alcohol dependence (71.4% (3,164) alcohol dependence, 20% (885) alcohol problems, 7.5% (332) alcoholic psychosis, (including alcohol-related brain damage), 2.6% (113) acute intoxication, 0.9% (40) other, 0.2% (9) organ damage including liver, 0.02% (1) alcohol poisoning).

- Men are twice as likely as women to be admitted to an acute or psychiatric hospital for alcohol related problems

3.6 Special Subgroups

A number of subgroups within the alcohol dependent population may present special problems in treatment. These include those with comorbid mental illness, those with a dual alcohol and substance misuse problem, those presenting through the Criminal Justice System, homeless alcohol misusers and those people, often quite young, whose memory and judgement are impaired as a result of brain damage. In addition, slightly different presentations may exist in different ethnic groups.

3.6.1 Comorbidity

Surveys show that about a third of acute psychiatric inpatients with severe and enduring mental health problems also have an alcohol problem. Such a 'dual diagnosis' adds to an individual's difficulties, complicates their treatment and may well delay their recovery (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002). The Greater Glasgow Alcohol Strategy (Greater Glasgow Health Board, 2000) notes that consultant psychiatrists from all parts of Glasgow report an increase in the proportion of patients in psychiatric hospitals where schizophrenia or depressive illness are complicated by alcohol misuse.

3.6.2 Dual Substance Dependence

There is growing evidence of people misusing alcohol along with other drugs, both street-purchased and prescribed such as benzodiazepines or methadone with unpredictable short and long-term consequences. The Plan for Action notes that in 1999 / 2000, 1 in 10 of those attending drug services reported use of alcohol as a problem in addition to their drug problem (Scottish Drug Misuse Database ISD 2001).

3.6.3 Alcohol Problems in Offenders

Over 50% of male prisoners in the UK were drinking hazardously in the year before coming into prison (Psychiatric Morbidity Among Prisoners ONS 1997). In a survey of 50% of all untried prisoners in Scotland in 1993, 22% of the prisoners had alcohol related problems (Greater Glasgow Health Board, 2000). In a review of the medical history of all 906 men admitted to Barlinnie Prison during January 1998, 10% were suffering from serious withdrawal symptoms on admission.

The Scottish Prison Service (SPS) assesses all prisoners on admission for addictions using a general screening questionnaire, and for those screened positive, using its Common Addictions Assessment Tool (CAART). Thereafter a treatment and care plan is developed for each prisoner. Although a significant proportion of prisoners on admission have alcohol problems, there is no access to alcohol in prison and hence there is no use of acamprosate, disulfiram or naltrexone. Treatment includes detoxification and psychosocial interventions including the 12 step programme. AA has a presence in 11 out of 16 SPS establishments, with structured 12 step programmes in 3 establishments.

3.6.4 Homelessness and Alcohol Problems

Scotland has over 5,000 homeless people. Studies among 'rough sleepers' show that 50% are alcohol dependent. More than half of a sample of homeless people in Greater Glasgow in 1999 were drinking hazardously, increasing from 37% of 16-24 year olds to 63% of those aged 55 and over; men (60%) more than women (16%) (Kershaw *et al.*, 2000).

In Greater Glasgow a multidisciplinary Homelessness Addiction Team with representation from social work, housing and Greater Glasgow Primary Care Trust (Glasgow Problem Drug Service and the Alcohol and Drug Directorate) has been formed. Particular problems that they have identified in dealing with the homeless include:

- a proportion of people who do not wish any help
- limited access to services and a lack of facilities specifically for the homeless
- ensuring referrals are appropriate
- considerable co-morbidity.

3.6.5 Alcohol vs Drug Misuse

The Plan for Action points out the similarities and differences between drug and alcohol problems. Links noted are the influence on both by a wide range of overlapping social and cultural factors, the fact that many children who drink or smoke also try illegal drugs and that many adult drug users also have alcohol problems. However, the numbers of people both using and misusing alcohol in Scotland far exceeds the number using illegal drugs. In 1997 there were 82 drug related deaths recorded by the Registrar General in Greater Glasgow compared with 351 alcohol related deaths, although both are likely to be under reported. From 1991 to 1995 there were 3,857 drug related emergency hospital admissions compared with 19,296 alcohol related emergency hospital admissions. Alcohol continues to have a

much greater negative impact on health than misuse of illegal drugs (Greater Glasgow Health Board, 2000). Although there are probably neurochemical and psychological overlaps between dependence on all psychoactive substances, and there are many similarities between the psychological 'first-line' treatments, the range of problems experienced by people who misuse alcohol differ in many respects from those experienced by drug misusers, as do the effects on society and on their families. People with drug and alcohol problems may need different types of services.

3.7 Organisation of NHSScotland

The National Health Service in Scotland (NHSScotland), like the NHS in other parts of the UK, provides comprehensive health care for its citizens, and is free at the point of use. It is funded mainly by direct taxation in the form of income tax and National Insurance Contributions, with a small proportion of funding coming from patient charges such as for dental care and prescriptions. A key advantage of the UK's funding system is its fairness, providing maximum separation between an individual's financial contributions and their use of health care. After social security payments, health is the biggest single component of public expenditure.

Total mortality and morbidity rates are higher in Scotland than in England, reflecting differences in their populations, environmental and socio-economic factors. NHSScotland has core aims of improving the health of the population and reducing inequalities in health. There are five clinical priorities: coronary heart disease, cancer, mental health, children and young people, and older people.

In the UK, 83% of health spending is publicly funded (with the figure for Scotland higher still) compared to the European Union (EU) average of 75%. NHSScotland has around 132,000 staff, including more than 63,000 nurses, midwives and health visitors and over 8,500 doctors. There are also more than 7,000 family practitioners, including doctors, dentists, opticians and community pharmacists, who are independent contractors providing a range of services within the NHS in return for various fees and allowances.

The Scottish Executive Health Department (SEHD) leads the central management of NHSScotland. It oversees the work of 15 NHS boards responsible for planning health services for people in their area and, through the boards, the activities of the 28 acute and primary care NHS Trusts responsible for providing services to patients and the community. Primary Care Trusts, which include specialist mental health services, have been developing Local Health Care Co-operatives (LHCCs), which initially involved only general practitioners but are now evolving into multi-professional organisations. The aim of LHCCs is to allow local decision-making (with involvement of local communities) to improve health and health care.

A number of special Health Boards also exist which have Scotland-wide remits for specific functions. For example, NHS Education for Scotland commissions education and training for some NHS staff and HTBS provides advice on the clinical and cost-effectiveness of new and existing technologies.
More information about the health service in Scotland can be obtained from www.show.scot.nhs.uk and www.scotland.gov.uk/publications/recent.asp.

3.8 Structure and aims of current services

NHS specialist services engaging in relapse prevention for alcohol dependence are incorporated in Primary Care Trusts. The other statutory services focusing particularly on relapse prevention interventions are those provided by Social Work services through Local Authorities. In addition non statutory services provide considerable assistance to people with severe alcohol problems and their families, to the extent that the statutory services could not cope in their absence. For example, in Glasgow they make an indispensable contribution to the overall provision of services (Greater Glasgow Health Board, 2000).

There has been progress in the treatment of alcohol problems over the years with improvement in the range of options available for relapse prevention. This is probably secondary to positive changes in the attitudes of the medical profession and increased recognition of the harm caused by alcohol related problems in the UK. However, local service development in Scotland has been extremely varied probably as a result of local funding policies rather than on the basis of objective needs assessment. Development of training and research resources has also been patchy and generally limited.

It is clear that no one agency can meet all the needs of people experiencing alcohol problems. A combined and co-ordinated treatment 'system' (so termed by Heather, 1995) is required recognising the contribution of statutory and non-statutory services and guiding individuals appropriately through the care pathway. The Treatment Framework of the Plan for Action on Alcohol Problems should guide local agencies on strategic development. Attention should be paid to adequate services at all tiers of service and to avoiding duplication of effort between agencies and diversion of scarce resources from vital areas of care. For example, it is important that the development of the primary care based tier does not reduce the number of trained staff available in specialist tiers delivering relapse prevention to those with established alcohol dependence. Joint planning across Social Work, Health and non statutory sectors should take account of such possibilities.

Specialist agencies may be able to increase efficiency by focusing their efforts on delivering existing treatments of proven efficacy and attempting to minimise duplication and overlap with programmes offered by other agencies involved in the same individual's care. Relapse prevention should not be seen as a treatment in isolation but should be a component part of all treatment programmes (Raistrick & Heather, 1998). As indicated in Section 3.5, in addition to using specialist agencies, problem drinkers seek the services of a range of other NHS facilities.

Non specialist NHS services, therefore, also need to remain aware that detoxification or treating the presenting alcohol related physical disease is only one part of the process of treating alcohol dependence and clear understanding of how to access the care pathway (treatment system) for alcohol dependence is necessary. This understanding of the care pathway integrating specialist and non specialist, statutory and non statutory agencies is relevant to all agencies within and accessing the treatment system.

With respect to specific treatment options there is a need for a balanced response to alcohol misuse. Those at risk of becoming dependent on alcohol but not yet experiencing serious problems may respond well to minimal interventions (Scottish Intercollegiate Guidelines Network (SIGN), 2002). Those with established dependence on alcohol require a more intensive approach.

Details of the nature and extent of services for treatment of alcohol dependence in Scotland were collected by HTBS in two surveys in 2001. Results of these surveys are given in section 3.18

3.8.1 Defining Success

Establishing reliable processes to obtain outcome measures for the effectiveness of available treatments is a problem. Laboratory investigations, corroborative histories and self-reporting questionnaires are currently used patchily throughout Scotland with no standardised approach. Definition of relapse is a key issue in outcome measurement. The consumption of 8 units for a man or 6 units for a woman in a single day is a commonly agreed research definition of relapse for someone in treatment for alcohol dependence. Different considerations would apply to those not meeting the criteria for dependence, where the treatment goal may be harm-free drinking.

3.9 The Draft Alcohol Problems Support and Treatment Services Framework

New proposals for the structure of alcohol services in Scotland are currently under consideration. The Draft Alcohol Problems Support and Treatment Frameworks's aim is "to provide equitable, accessible and inclusive services to address the needs of those who experience problems with alcohol and those affected by others' alcohol problems" (Scottish Executive Health Department, 2002). The Framework proposes a tiered approach to provide services with interaction between the tiers for integrated and comprehensive service provision. The tiers are:

- community based tier – local approaches to alcohol problems with the promotion of positive health through community plans, and information from a variety of media.
- Tier 1 Local services – meets the support and treatment needs of the majority of people with alcohol problems and operates at the level of primary care teams, social work teams and Alcohol Action Teams, with support from NHS24.
- Tier 2 Specialist support – provided by staff who give advice, training and support to those providing local services and provide a link to specialist alcohol problem services.
- Tier 3 Specialist alcohol problem services – operating from within a Primary Care Trust, usually in conjunction with local general mental health services, and provide a range of specialist services.
- Tier 4 Regional specialist services – may be based in a research or academic unit to provide particular expertise, as part of a managed clinical network.

Within tier 1 the Framework identifies a number of groups who have difficulties accessing mainstream services and who should be identified locally. These groups

include young people (including vulnerable groups such as looked after children, homeless, offenders), women who are experiencing or have experienced domestic abuse, people in areas of social exclusion, people in rural areas, disabled people, ethnic minorities, homeless people, older people, and gay and transgender people. Within tier 2 there is a need for services for people with mental health problems, criminal justice services, and support for prisoners. Within tier 3 there should be specialist alcohol problem services, specialist services for young people, people with co-morbidity (alcohol +/- substance misuse +/- mental illness. Tier 4 is envisaged as dealing with complex alcohol problems and would include relapse prevention in patients with alcohol-related neuropsychiatric problems or brain damage, and those with sever co-morbidity.

3.10 HTBS surveys of Scottish services

In order to evaluate the nature and range of services for prevention of relapse provided in Scotland two postal surveys were carried out. The first of these addressed the services within NHSScotland and was sent to all major specialist alcohol units. Twenty-seven questionnaires were sent out of which four questionnaires were mistakenly sent to different individuals within the same service and the number of questionnaires expected to be returned was therefore reduced to 23. Of these, 22 were completed and returned including at least one from each NHS Board. Limited data on the one service, which did not complete the questionnaire was obtained via telephone contact The questionnaire is shown in Appendix 5 and narrative and tabular results are in Appendices 7 and 8.

The second survey attempted to assess the provision of relapse prevention services by non-NHSScotland care providers. This was a briefer questionnaire and is shown in Appendix 6. One hundred and twenty-three (123) questionnaires were sent out and 43 returned. Compiling a full listing of such providers is not an easy task and it was decided to risk inappropriate, or possibly multiple, contacts with some providers in order to maximize appropriate contacts. Thus it is difficult to interpret these response rates in terms of coverage of services.

The figures given for Scottish service provision in the following sections are based on the data obtained from these surveys.

3.11 Psychosocial Interventions

Psychosocial interventions for relapse prevention are based around 'talking therapies', which can involve one to one, couple, family or group approaches and encourage self-help as part of the treatment and support options. These interventions are numerous, having more than 40 different 'brand names', although certain ingredients are common to almost all (e.g. the therapeutic alliance) and they can broadly be grouped into four main categories. These are – therapies aimed at:

1. Building motivation
2. Cognitive restructuring

3. Behavioural and coping skills training
4. Implementing the Twelve Step Model based on the Alcoholics Anonymous approach

Definitions of individual psychosocial interventions are provided in Appendix 9.

Effective motivation building in alcohol dependent patients is based on Motivational Enhancement Therapy (MET**)** or Motivational Interviewing.

Motivational Interviewing / Enhancement Therapy focuses on eliciting the individual's intrinsic motivation for change (Miller & Rollinick, 1991) and contains certain therapeutic strategies. These include expressing empathy, avoiding argument, detecting and 'rolling with' resistance, highlighting discrepancies in the history and drawing out the individual's own discomfort about the behaviour.

This approach, utilising the individual's own skills and resources, is shared generally by client centred approaches e.g. Solution Focused Therapy (Berg & Miller, 1992).

Therapies aimed at cognitive restructuring include Cognitive Behavioural Therapy (CBT**)** and elements of Relapse Prevention Therapy and Coping Skills Training (as opposed to behavioural coping strategies). In Relapse Prevention Therapy individuals unlearn the patterns of drinking behaviour, implement substitute behaviours and rehearse healthier approaches to dealing with situations that previously triggered thoughts of drinking. Relapse Prevention Therapy models include that of Marlatt (Marlatt & Gordon, 1985), which also encompasses social skills training and behavioural coping strategies, and Gorski's CENAPS (Early Warning Signs) approach (Gorski & Miller, 1982). This approach involves a series of procedures to help the drinker to become aware of their habitual warning signs of relapse, develop and implement plans for coping with each sign and develop a lifestyle to prevent the occurrence of the sequence of changes leading to a lapse.

Therapies aimed at behavioural and coping skills often focus on general skills (such as communication and assertion skills) rather than on specific skills for avoiding substance use. They include Social Skills Training, Coping Skills Training, Stress Management, the Community Reinforcement Approach (Azrin *et al*., 1982), where emphasis is placed on changing the individual's social environment by developing rewarding employment, leisure activities and relationships that do not involve alcohol, Behavioural Self Control Training (using simple self contracted goals and self rewards for their achievement) and Behavioural Marital / Couples Therapy (with the aim of increasing the level of positive reinforcement exchanged by the couple).

Therapies involving families or couples are usually in this last category of behavioural / coping skills. Other marital or family therapy approaches draw on systems theory in both formulating the hypothesis about distress and planning interventions.
Group therapy is a commonly used procedure but often poorly defined. Groups can be run according to various psychotherapeutic principles and, in some cases, according to no clear principles at all.

Twelve Step Programmes are based on the Alcoholics Anonymous (AA) model referring to the stages of growth through which the individual must progress in order

to achieve and maintain sobriety. The individual is expected to acknowledge the need for help and aim for complete abstinence.

3.12 Psychosocial Interventions within NHSScotland

Psychosocial interventions used in NHS specialist services in Scotland, based on the HTBS survey, are shown by Health Board in Table 3 - 1 Psychosocial Interventions in NHS Secondary Care. One or more of these is offered formally in 90% of specialist services.

Table 3 - 1 Psychosocial Interventions in NHS Secondary Care

NHS Board/PCT	Motivational Interviewing	Cognitive Behavioural Therapy	Brief Intervention	Twelve Steps	Behavioural Marital/ Couples TheranyT	Community Reinforcement Approach	Social Skills	Coping Skills	Stress Management	Couples Therapy	Family Therapy	Relapse.Managementg.	Relapse Prevention .gp.
Lomond & Argyll	●	●				●	●	●	●			●	●
Renfrewshire & Inverclyde	●	●	●				●	●	●				●
Ayrshire & Arran.	●	●	●		●	●	●	●	●	●	●	●	
Borders.													
Dumfries & Galloway	●	●	●				●	●	●	●			
Fife	●	●	●				●	●	●	●	●		
Forth Valley	●	●	●				●	●	●				
Grampian	●	●	●	●				●	●				
Greater Glasgow	●	●	●		●	●	●	●	●	●			●
Highland	●	●	●		●	●	●	●	●	●	●	●	●
Lanarkshire	●		●				●	●		●			
Lothian	●	●	●	●	●		●	●	●				●
Orkney	●	●	●				●	●	●			●	
Shetland*													
Tayside	●	●	●					●	●			●	●
Western Isles	●	●	●		●	●	●	●	●	●	●		

* No specialist services in Shetland

In the NHS, among specialist services offering psychosocial interventions for alcohol problems, Motivational Interviewing and Coping Skills Training appear to be universally used.

For Motivational Interviewing (MI) the number of sessions offered ranged from 2-10, or up to 3 weeks depending on the service and the individual. About 20% of services using the therapy acknowledged having protocols for this. MI was usually carried out on a one to one basis and in a non-residential setting. Very few services attempted to audit the intervention. Staff carrying out the therapy were most often internally

trained but external training has occurred in the past. Only in a few cases was it declared that staff had no training in the technique.

For Coping Skills (CS) Training the number of sessions offered ranged from 4-10 or up to 4 weeks, with over half of the services noting that this varied depending on the individual. About 15% of the services carrying out this therapy reported having protocols. CS was carried out in one to one and group settings, usually non-residentially. Very few services attempted to audit the intervention. Staff are most often internally trained but external training did occur.

Stress Management was used in 95% of specialist services offering psychosocial interventions. The number of sessions, setting and training of staff were as for Coping Skills Training. About 10% of the services carrying out this therapy acknowledged having protocols.

Brief Interventions (BI) were used in 89% of services offering psychosocial interventions. The number of sessions ranged from 1-10, with over half of the services noting that this varied depending on the individual. Over 1/3 of services carrying out this therapy reported having protocols. Although this intervention may have been expected to be carried out entirely on a one to one basis, some services noted using the technique in a group setting. Although mostly carried out non residentially there was some use of BI in residential settings which may suggest an 'opportunistic' application (eg. by specialist staff liasing to general wards). Only one service appeared to audit interventions of this sort. Both internal and external training took place.

CBT was used in 84% of specialist services offering psychosocial interventions. The number of sessions ranged from 4-10, or up to 4 weeks, but was noted to be variable in over half of the services. About 20% of the services carrying out this therapy acknowledged having protocols. CBT was most commonly carried out on a one to one basis and usually in a non-residential setting. Very few services attempted to audit the intervention. Most staff training was external but additional in-house training did occur.

Social Skills (SS) Training was used in 79% of specialist services offering psychosocial interventions. The number of sessions, setting and training of staff were as for Coping Skills Training. About 20% of services carrying out this therapy reported having protocols.

Other less common interventions included:

- Community Reinforcement Therapy (acknowledged by 40% of the specialist services offering psychosocial interventions);
- Couples Therapy (35%);
- Behavioural Marital / Couples Therapy (25%);
- Family Therapy (20%);
- 'Relapse Management'(20%);
- Twelve Step Facilitation Approach (10%, or 2 services).

Non-specific counselling was noted to take place in 36.8% of these NHS services.

Relapse Prevention Groups were acknowledged in 40% of services offering psychosocial interventions. Some, if not all, have written protocols. Greater Glasgow NHS Board, for instance, uses a standardised protocol based on the Marlatt model (Larimer *et al*., 1999) throughout its 4 centres.

Various other psychosocial interventions were acknowledged including Anger Management, Assertiveness Training, Solution Focussed Therapy, Anxiety Management, Alcohol Education Groups, Supportive Counselling and 'Relaxation and Exercise' Groups.

A number of services offered tailored groups e.g. Women's Groups.

For each of these interventions a number of outcome measures are cited as being used, these varying from service to service, presumably in terms of frequency as well as form. Outcome measures used included laboratory investigations (Gamma GT, Mean Cell Volume, Liver Function Tests), diaries, self-report, rating scales and questionnaires (self-report and therapist), timeline follow back and collateral information. The rating scales and questionnaires cited were Drug-Taking Confidence Questionnaire 8, Readiness to Change questionnaires, the Christo Inventory, the Alcohol Related Problems Questionnaire, client satisfaction questionnaires and CBT rating scales.

Eleven percent (11%) of NHS specialist services carrying out psychosocial interventions did not use routine outcome measures.

Only 36% of NHS specialist services carrying out psychosocial interventions indicated that they had patient information sheets or leaflets for any of these interventions. These are included as Appendix 10**.**

3.13 Psychosocial Interventions in Non NHS Services

In the non NHS day services which we surveyed, of those responding to the questionnaire 42% carried out non-specific counselling, 25% used Person-Centred Counselling, 21% used Social Skills Training, 21% offered support and advice, 17% used Motivational Interviewing and 17% used some form of Group Therapy. Other interventions included psychodynamic counselling, Stress Management, Assertiveness Training, Solution Focussed Therapy, Complementary Therapy, Couples Therapy and Family Therapy.
Although counsellors from the Councils on Alcohol are usually centrally trained by Alcohol Focus Scotland using a CBT based approach, the Councils on Alcohol responding to the survey acknowledged a range of approaches: a CBT based approach (47%), non-specific / eclectic counselling (41%), Person Centred Counselling (23%), Social Skills Training (18%), Motivational Interviewing (19%), Stress Management (6%) as well as support and advice, Couples, Family and Group work.

Social Work services responding to the questionnaire were few in number. The information obtained from those responding would suggest that a range of validated psychosocial interventions might be offered including CBT, Motivational Interviewing and Social Skills Training as well as non-specific counselling.

Of non NHS residential rehabilitation services surveyed the returned information suggests that a range of interventions are being offered including non-specific counselling, CBT based counselling, Person Centred Counselling, Task Centred Counselling, Positive Modelling, Social Learning Theory, Anger Management and Group Work.

Of non-NHS residential homeless services surveyed only 46% acknowledged offering psychosocial interventions for alcohol dependence. Interventions most commonly offered included support and advice, non-specific counselling, Twelve Step Facilitation and Social Skills Training. Less frequently offered interventions included CBT based interventions, Brief Interventions, Motivational Interviewing, Work Theory, Health Education, Problem Solving, Group Therapy and Vocational Training.

Private care facilities (e.g. Priory and Castle Craig) were not sent the survey questionnaire. The Priory (Langside) offers a service which includes detoxification as an inpatient or outpatient aimed at achieving abstinence, CBT, problem solving, family therapy, couple therapy, post treatment planning, continuing weekly aftercare and self-help group meetings within the hospital. Castle Craig adopts a 12 step approach in a residential setting and aims for abstinence.

3.13.1 Alcoholics Anonymous

Founded in 1935, Alcoholics Anonymous (AA) has a long history of providing confidential support and advice to those with alcohol problems.

Alcoholics Anonymous is organised by and for people with a drinking problem. The only requirement for membership is a desire to stop drinking. There are numerous local groups throughout Scotland who may be contacted directly.

HTBS did not survey Alcoholics Anonymous facilities / meetings. However, a large quantity of information was submitted from AA as evidence.

The trustees of the AA General Service Board decided in 1968 to begin conducting anonymous surveys of the membership. These surveys are repeated at three yearly intervals and provide a continuing view of the demographic changes in alcohol related problems over the last 34 years.

The 1968 survey clarified the need for AA to work more closely with professionals in the field, and culminated in the formation of a Professional Relations Committee (now Cooperation With the Professional Community). Succeeding surveys have underlined the importance of outside help in pointing dependent people toward AA and in providing additional help during sobriety. In 1998, 34% of members were introduced to AA through treatment facilities, 11% by court order, and 17% by a counselling agency or health care provider. Before coming to AA, 60% of members received some type of treatment or counselling, and 75% of those members said it played an important part in directing them to AA. After coming to AA, 62% of members received some type of treatment or counselling, and 83% of those believe it was important to their recovery. As in the past several surveys, 75% report that their doctors know they are in AA.

There are numerous branches of AA in Scotland. There are 228 weekly meetings in Glasgow alone and 934 over the whole of Scotland.

The philosophy and approach of AA is well documented in numerous publications. In particular, AA consider that alcohol dependence, once established, is a permanent condition which can only be controlled by complete abstinence. The 12 step facilitation is designed to help achieve this objective (Appendix 11).

3.14 Pharmacological Interventions

Pharmacological interventions used in alcohol dependence for prevention of relapse include deterrent medication, such as disulfiram (Antabuse), which induces illness if the individual consumes alcohol, acamprosate (Campral), an NMDA receptor modulator, specifically designed to prevent alcoholic relapse, and naltrexone (Revia), an opioid antagonist currently unlicensed for this indication in the UK.

3.14.1 Disulfiram

Disulfiram is indicated as an adjuvant in the treatment of carefully selected and cooperative patients with drinking problems. It should be combined with appropriate supportive treatment. It is supplied as 200mg tablets and the manufacturers recommend an initial dose of four tablets, which is reduced by one tablet daily to a maintenance dose of one or half a tablet continuing for up to six months. The individual taking disulfiram regularly in sufficient dose will, on consuming alcohol, experience an unpleasant reaction (flushing of the face and upper body, throbbing headache, palpitation, dyspnoea, tachycardia, nausea, vomiting and with large doses of alcohol, arrhythmias, hypotension and collapse). The reaction occurs about 10 minutes after ingestion of alcohol and may last several hours. The severity of this reaction shows a great deal of individual variation and, rarely, the reaction can be life threatening. Conversely some individuals have no or mild reactions on standard doses and higher doses may be required. Even small amounts of alcohol can lead to unpleasant systemic reactions and therefore care must be taken when using other medicinal products and toiletries. It is advisable for patients to carry a card warning of the danger of administration of alcohol. The patient is told the nature of the reaction prior to prescription of the drug.

There are several contraindications to using disulfiram including cardiac failure, coronary artery disease, previous history of cerebrovascular accident, hypertension, pregnancy, breast feeding, severe personality disorder, suicidal risk or psychosis (which is thought may be exacerbated by disulfiram's action on dopamine β-hydroxylase). Additional caution is required in renal failure, hepatic or respiratory disease, diabetes mellitus, epilepsy and the concurrent use of anti-convulsant, anti-coagulant and anti-hypertensive medication.

The medication is recommended to be administered daily, but can also be given twice or thrice weekly (at 3-4 day intervals) as the action lasts for about 7 days after the last dose. This may be of practical importance if administration is supervised e.g. at a day hospital, by a workplace nurse, community psychiatric nurse or practice nurse. As with all medications there are problems with compliance, perhaps related to the

individual's prior understanding that a lapse is imminent, perhaps related to side effects which include lethargy and loss of libido.

Disulfiram is described as an adjunct to psychosocial intervention (not specified) and is not, for instance, intended for use as a monthly repeat prescription with minimal doctor / patient interaction.

3.14.2 Acamprosate

Acamprosate, has been licensed in the UK since 1995 for abstinence maintenance therapy for up to 1 year in motivated alcohol dependent patients. Its chemical structure is similar to the naturally occurring amino acid neuromediators, taurine and gamma aminobutyric acid (GABA) and it is believed that it may act by binding to NMDA receptors in the brain, modulating the up-regulation of NMDA receptors which occurs on alcohol withdrawal, enhancing GABA inhibitory neurotransmission and antagonising glutamate excitation, thus suppressing putative biochemically based craving in response to learned cues (e.g. feeling stressed, passing a bar or being in the company of others drinking alcohol). It is possible also that its action reduces the likelihood of reinstatement of dependence symptoms if a lapse occurs. For this reason acamprosate should continue to be prescribed despite occasional lapses, if there is evidence that those lapses are significantly less severe than previously. However, there is no point in continuing the medication if significant relapses occur.

The recommended dosage is 2x333mg tablets three times per day over a 1 year treatment period. The dosage is reduced to 4 tablets per day (2 morning, 1 midday, 1 night) in those weighing less than 60 kg. It is licensed only for patients between 18 and 65 years of age.

Pharmacokinetic studies showed very large inter-subject variations in bioavailability. Mean bioavailability was reduced by about 20% when tablets were taken with food. It appears to be excreted primarily via the kidneys and is contraindicated in renal dysfunction (serum creatinine over 120 micromols/l). Other contraindications are hypersensitivity, severe hepatic failure (Childs Pugh Classification C), pregnancy and breast feeding. Adverse effects are usually mild and transient and are predominantly gastrointestinal (diarrhoea, nausea, vomiting, abdominal pain) and dermatological (pruritis, occasional maculopapular rash and rare cases of bullous skin reactions have been reported).

As it takes 5-7 days to reach therapeutic levels (elimination half-life 18 hours) Acamprosate should be started soon after detoxification.

As with disulfiram, acamprosate, is currently recommended to be combined with counselling.

3.14.3 Naltrexone

Naltrexone, an opioid antagonist, is not licensed in the UK for use in alcohol dependence. It has been licensed for this use in the Republic of Ireland and several other EC countries since 1996, as part of a comprehensive treatment programme for alcohol dependence to reduce the risk of relapse to heavy drinking, support abstinence

and reduce alcohol craving. It may act by breaking the desire for the next drink by blocking the pleasure or 'high' which would normally result from sampling alcohol. It is reviewed in this assessment because it is used off-licence in 5 Scottish NHS Boards Table 3 - 2 Pharmacological Treatments in NHS Secondary Care.

The recommended dosage is one 50 mg tablet per day. An initial treatment period of three months is suggested but longer-term treatment can be considered.

Serious side effects of naltrexone are rare but the most commonly reported side effects include nausea (9.8%), headache (6.6%), dizziness (4.4%), nervousness (3.8%), fatigue (3.6%), difficulty sleeping (3.0%), vomiting (2.6%), anxiety (2.0%), and somnolence (2.0%). The incidences were estimated over 12 weeks by Croop et al (1997).

Contraindications are acute hepatitis, liver failure, current dependence on opiates, current use of opioid containing medication and hypersensitivity.

3.15 Pharmacological Interventions in NHS Specialist Services in Scotland

The Greater Glasgow 'Shared Care' protocol for the use of acamprosate and the Lothian protocol for the use of naltrexone can be found in Appendix 12 and Appendix 13

In our survey of NHS specialist alcohol services all used acamprosate and disulfiram. In addition 5 services used named patient / off licence prescribing of naltrexone (see Table 3 - 2 Pharmacological Treatments in NHS Secondary Care). No other medications are routinely used in Scotland for relapse prevention in alcohol dependence. Combinations of acamprosate and disulfiram are used in 57% of services. Combinations of naltrexone and disulfiram are used in one service. There was no noted use of combinations of naltrexone and acamprosate.

Table 3 - 2 Pharmacological Treatments in NHS Secondary Care

NHS Board/PCT	acamprosate	disulfiram	naltrexone
Lomond & Argyll	●	●	
Renfrewshire & Inverclyde	●	●	●
Ayrshire & Arran.	●	●	●
Borders.	●	●	
Dumfries & Galloway	●	●	
Fife	●	●	
Forth Valley	●	●	
Grampian	●	●	●
Greater Glasgow	●	●	●
Highland	●	●	
Lanarkshire	●	●	
Lothian	●	●	●
Orkney	●	●	
Shetland*			
Tayside	●	●	
Western Isles	●	●	

* No specialist services in Shetland

In the majority of NHS specialist services medical staff of all grades (SHO to Consultant) prescribed acamprosate and disulfiram. In the services without medical staff, as well as many of those with medical staff, GPs would prescribe these medications on the advice of the team or in co-ordination with the team, if local NHS Board prescribing arrangements permit.

In services prescribing naltrexone this was always done by consultant medical staff attached to the specialist team.

3.15.1 Disulfiram

Fifty-two percent (52%) of specialist services used supervised administration if required. Supervision may be by CPN / Practice Nurse / Alcohol Unit Nursing staff or relatives (18% of services using supervision acknowledged this method – see Appendix 14 for useful information for the patient, partner / supervising person and supervising doctor (Lothian NHS Board)), place of work or the community pharmacy.

Most of the services commence disulfiram in both inpatient and outpatient settings with initial proposed duration between services varying from 1 month to 1 year (41% of services considered the proposed duration to be variable / indefinite depending on factors such as patient response).

Protocols exist for the use of disulfiram in 9% of services.

All services noted that psychosocial interventions were used in combination with disulfiram but, for instance, one service commented that this was simply the 'normal

clinic regime'. The most commonly acknowledged interventions to be used in combination with disulfiram were CBT and Motivational Interviewing. Also noted were Relapse Prevention Groups, 'Group Work', 'Counselling', 'Abstinence Maintenance' and 'Specific Antabuse adjunctives'.

The goal of treatment was abstinence in 76.2% of services, with 14.3% citing the goal as either abstinence or reduced consumption / controlled drinking and 4.8% citing the goal as reduced consumption.

The outcome measures most commonly used were derived from laboratory tests (28.6% of services), self-report (19% of services) and diaries (14.3% of services) with cumulative abstinence duration (CADs), collateral information and alcometer readings also used. One service used no outcome measures.

Only one service (Forth Valley) noted auditing the use of disulfiram.

3.15.2 Acamprosate

Nine percent (9%) of services acknowledged enlisting a third party to supervise administration of the medication.

Most services commenced the use of acamprosate on both an inpatient and outpatient basis.

The initial proposed duration of treatment varied between services from 1 month to 1 year (47% of services answering the question cited 1 year).

Protocols exist for the use of acamprosate in 48% of services (see Appendix 12 for shared care protocol from Greater Glasgow).

All NHS specialist services used psychosocial interventions in combination with acamprosate, the most commonly acknowledged being Motivational Interviewing, Relapse Prevention Therapy, CBT and Group Work. Also noted were 'counselling', Social Skills Training, Abstinence Maintenance, 'specific acamprosate adjunctives' and 1 service noted using the 'normal clinic regime'.

Fifty-seven percent (57%) of services cited abstinence as the goal of treatment, 29% of services cited either abstinence or controlled drinking as the goal, and 19% of services cited controlled drinking as the goal.

The most commonly used outcome measures were laboratory investigations (38% of services), including gamma GT, MCV, LFTs, self-report (19%), diaries (14%) and CADs (14%).

Twenty-eight percent (28%) of services audited the use of acamprosate.

3.15.3 Naltrexone

Of the 5 services using naltrexone, 2 services set no special condition for administration, 1 service insisted on regular consultant review, and 2 services used some form of supervision of treatment.

Four out of the five services commenced naltrexone on both an outpatient and inpatient basis. One service commenced naltrexone on an outpatient basis only.

The initial proposed duration was reported as six months to one year in one service, one year in one service, indefinite in two services.

Lothian has a protocol for prescribing naltrexone for alcohol dependence (Appendix 13).

All services prescribing naltrexone used psychosocial interventions in combination with the medication although the type of intervention was not specified.

Two services cited abstinence as the goal of treatment. One service cited either abstinence or controlled drinking as the goal of treatment.

The outcome measures used were laboratory tests (4 services), self-report (2 services) and diaries (1 service).

The use of naltrexone is not audited by these services.

3.16 The Care Pathway

For the psychosocial and pharmacological interventions described above it should be noted that in most services these are not carried out in isolation but as part of an ongoing relationship with individuals in contact with the service. Examples of care pathways were provided by a number of services. Those for Forth Valley and Dykebar (Renfrewshire & Inverclyde Health Board) have been included in Appendix 15 and perhaps illustrate more similarities than differences in the care of individuals from the moment of their referral to the alcohol problems service. The use of non-statutory agencies in the treatment system is well illustrated.

The minimum aftercare package offered to most individuals on discharge from hospital following alcohol detoxification varies from service to service, with one service suggesting that there may be no aftercare package, and others offering a follow up appointment by the keyworker (CPN, Day hospital nursing staff, Community Addiction Team, medical staff) at the base alcohol unit or at home depending on geographical factors. Others offer an increasingly intense aftercare package with outpatient clinic appointments and CPN visits, immediate (next day) follow-up by the home detox team and regular follow-up thereafter for several weeks (eg. every 2 days for 6 weeks), Day Hospital attendance for a relapse prevention programme or referral to the waiting list for the Relapse Prevention Group, 1 to 1 psychological intervention, periodic Motivational Interviewing sessions (eg. 8-10

weekly), on-going drop-in facility, referral to other agencies eg. Social Work, if requested, and consideration of anti-relapse agents eg. acamprosate.

The Argyll and Bute service offers respite admissions as well as the availability of 24-hour contact with the unit and outreach clinic appointments if geographically suitable. Areas without NHS statutory alcohol services will advise individuals to utilise local voluntary services e.g. counselling / befriending services, Social Work Alcohol Support Groups, AA and Councils on Alcohol.

There seems to be no standardised approach to aftercare with many of the above elements / options being employed in various combinations presumably tailored to the need of the individual and local resources.

The external agencies most frequently used by NHS specialist services when arranging aftercare are AA, Social Work day services and Councils on Alcohol with non statutory residential rehabilitation services being used more moderately and the least used agencies being residential homeless services and private care.

3.17 Default, non-adherence and recurrent relapse

One issue worth considering is that of default or non-adherence with interventions offered. About 25% of services report that their approach to this may include discharge back to GP care. Other reports involve various degrees of assertive outreach including offering 1-2 follow-up appointments or contacting the patient by letter to ascertain their desire for further contact, perhaps individuals with more severe problems having more aggressive follow-up.

In the case of recurrent relapse, almost all services reported either continued contact or at least no restriction on re-referral.

Miller (1985) notes that a simple hand-written note or telephone call after the first visit, or after a missed visit, can double or triple the likelihood that a client will return. This 'active' interest in the individual with alcohol problems appears to be reflected in most of the services surveyed.

3.18 Services available for alcohol related problems

The provision of services for individuals with alcohol related problems can be categorised into non-specialised (General Practitioners and other Primary Care staff, A & E Departments, General hospitals, General Psychiatric services, Social services and Criminal Justice services and employment-related schemes) and specialised (statutory (NHS and Social Work), voluntary and private). Non-specialised workers are routinely encountering individuals with alcohol problems in their day-to-day work with perhaps only the most seriously affected being referred on to specialist services. Statutory NHS specialist alcohol services may range from a single CPN with an alcohol remit to a fully integrated residential and community based addiction service.

3.18.1 NHS Specialist Services

The Plan for Action on Alcohol Problems (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002) states that 'the general perception is that service coverage in Scotland is patchy and fragmented and there is disparity in support and treatment available across Scotland'. The HTBS survey of specialist services confirms that some gaps in the service exist. There is also an apparent deficit in formal staff training and accreditation. The variability in service provision may reflect historical factors and the enthusiasms of individual consultants and other service developers rather than regional differences in morbidity.

In recent years the emphasis has shifted from inpatient to outpatient treatment. Inpatient services continue to exist, sometimes with dedicated beds for alcohol / addiction problems, sometimes using general adult psychiatry beds and occasionally using general medical beds. Inpatient care may be restricted to the more complex cases, for instance those with a lack of social support, the homeless, those with co-morbid psychiatric or severe physical illness, those at risk of suicide and those with a dual dependence.

As shown in the HTBS survey, there is wide regional variation in NHS specialist service provision with areas such as Shetland offering no specialist NHS alcohol services and areas such as Greater Glasgow, Ayrshire and Arran and Lanarkshire having a relatively large service, though these need to be seen in the context of local needs.

At the most specialised end of the spectrum (referred to as 'tier 4' in the Plan for Action Services Framework) there is an assumption that the individuals with the most complex needs are seen. Most people with alcohol problems are not in this category and will be seen at lower tiers of service, with GPs often being the first and only source of advice for a substantial proportion of those with alcohol problems. It is estimated that 'less than one in ten individuals with alcohol related problems are in contact with a specialist agency' (Unnithan *et al*., 1994).

3.18.2 Inpatient services

Only certain areas provide specialist inpatient-based services. From the survey those areas with no acknowledged specialist inpatient beds at all were Grampian, parts of Lanarkshire covered by Hairmyres Hospital and Shetland. Forth Valley, Fife and Orkney will use a very limited number of general adult psychiatry, or general medical beds (Orkney – 1 bed) for alcohol problems if necessary. South Glasgow and Western Isles have no dedicated beds for alcohol problems but provide inpatient care using general adult psychiatry beds. All other areas have dedicated beds for patients with alcohol problems (61% of all services surveyed).

From the survey the number of inpatient beds specifically dedicated to alcohol problems in NHS specialist services in Scotland is about 100 beds. Table 3 - 3 Breakdown of NHS Bed Usage per NHS Board.

Of these services with dedicated alcohol beds 50% have nursing staff specifically trained in alcohol / substance misuse care to cover these beds.
61% of services use adult psychiatric acute admission beds for alcohol problems, including 63% of the services, which did not acknowledge any form of inpatient based service, and 53% of the services, which were considered to have inpatient based alcohol services (inc. South Glasgow and W. Isles as noted above).

From the survey the number of general adult psychiatry acute admission beds in Scotland used specifically for care of patients with alcohol problems at any one time is estimated to be about 30 beds. (Table 3 - 3 Breakdown of NHS Bed Usage per NHS Board.)

Table 3 - 3 Breakdown of NHS Bed Usage per NHS Board

NHS BOARD	DEDICATED ALCOHOL BEDS	GEN. ADULT PSYCH. BEDS (in use at one time)	TOTAL BEDS (in use at one time)	POPULATION	BEDS per 100 000
Borders	1.5	0.8	2.3	106,389	2.16
Dumfries & Galloway	4*	2	6	147,280	4.07
Lothian	12	0	12	774,528	1.55
Ayrshire & Arran	6(+6)**	0	18	374,545	4.81
G. Glasgow	19-21	6	25-27	897,053	2.90
Renfrewshire & Inverclyde	11***	4	15***	290,000	5.17(some beds daytime only)
Lomond & Argyll	14	0	14	136,046	10.30
Lanarkshire	7	8	15	559,150	2.68
Forth Valley	0	2	2	275,806	0.76
Tayside	12	0****	12	391,397	3.07
Fife	0	4.4	4.4	348,214	1.26
Grampian	0	0	0	532,110	0
Highlands	6	0	6	210,418	2.85
W. Isles	0	1-2 (probably)	1-2	28,476	3.51(only used for alc. problems if needed)
Orkney	0	1	1	19,794	5.05(as above)
Shetland	0	0	0	22,855	0

General Adult Psychiatry (GAP) beds recorded are those used specifically by the Specialist team for their patients for treatment of alcohol problems

* Dumfries and Galloway has 4 dedicated beds for either alcohol or substance misuse
** Ayrshire and Arran has '6 beds for alcohol detoxification and 12 beds for residential dual diagnosis services which at any one time are used by approximately 50% alcohol users (and also drug users)' (C.Lind,Consultant Psychiatrist, Personal Communication, 13 March 2002)
*** Renfrewshire and Inverclyde have 11 dedicated beds but those in Inverclyde (7 beds) are in daytime use only with severely unwell patients, including those at risk of seizures, being admitted to general adult psychiatric beds

**** There are approximately 300 alcohol related admissions/year to General Adult Psychiatry beds in Tayside. An average length of stay of 12 days would lead to 10 GAP beds in use for primary alcohol problems at any one time.

3.18.3 Outpatient services

These can be divided into community, day hospital and outpatient based services.

22% of services surveyed have no community based alcohol service.
22% of services surveyed have no out patient based alcohol service.
61% of services surveyed have no day patient based services.
17% of services are solely community based – Borders, Orkney, parts of Fife and Lanarkshire.

There are no services which are solely inpatient based

The staffing of these services varies widely. Table 3 - 4 Staff Numbers per NHS Board Area (whole time equivalent posts)

74% of services have a Consultant Psychiatrist in or leading the team.
26% of services do not have any medical staff.
33% of services have psychology staff of some kind.
33% of services have Occupational Therapy staff.
14% of services have additional Social Work staff.

Table 3 - 4 Staff Numbers per NHS Board Area (whole time equivalent posts)

AREA	CONSULTANT PSYCHIATRISTS	OTHER MEDICAL STAFF	NURSING STAFF	PSYCHOLOGY STAFF	OCCUPATIONAL THERAPY STAFF	SOCIAL WORK STAFF
Lomond & Argyll	0.2	0.4	9.25	0	0	0
Renfrewshire. & Inverclyde	0.5	1.3	8.2	0.1	0	0
Ayrshire & Arran	1.2	1.0	27.0	0	1.0	0
Borders	0	0	2.0	0	0	0.5
Dumfries& Galloway	1.0	1.0	9.0	0	1.0	0
Fife	0	0	3.0	0	0	0
Forth Valley	0.2	0	6.0	0	0	0
Grampian	0.5	1.0	2.5	0	0	0
G.Glasgow	4.4	7.6	53.3	2.4	4.0	
Highland	0.2	1.6	36.2	0	0	1.0
Lanarkshire	2.0	2.2	22.0	1.7	2.0	0
Lothian	1.6	1.66	21.5	0.5	1.5	0.5
Orkney	0	0	1	0	0	0
Shetland	0	0	0	0	0	0
Tayside	1.0	2.0	18.5	0	0	0
W.Isles	0.0	0	2.0	0	0	0

3.18.4 NHS Generalist Services

Specialist services are resourced to meet the needs of only the small percentage of those most severely affected by alcohol related problems. Generalist services provide the bulk of treatment and preventative work. They may be divided into Primary Care and Non-Specialist Hospital care. These two components interact through, for example, specialist staff offering clinics in primary care; joint work systems such as home detoxification; or delivery of training programmes for Primary Care staff.

The Plan for Action notes 'GPs are often the first source of advice about alcohol problems. They play a vital role in identifying and tackling such problems and referring patients for appropriate help'. The GGHB Alcohol Strategy Consultation document (Greater Glasgow Health Board, 2000), notes that in a randomised survey of 227 GGHB GPs, many GPs had large numbers of patients with serious alcohol related problems. Very few of these GPs had a special interest in alcohol problems. Seventy percent (70%) of GPs said they employed brief intervention techniques, almost 90% employed home detoxification and over 60% employed some form of counselling technique (not specified). Few had access to nursing or counselling staff trained in the management of alcohol related problems. Current work reviewed later in this report shows that effective specialist psychosocial and pharmacological treatments are available for alcohol dependent patients and that brief intervention is not sufficient for those with established alcohol dependence. Thus clear evidence based decision processes for referral to specialist services and greater accessibility of these services would allow GPs to offer a more complete service.

The HTBS survey did not assess the capacity of generalist services for treating alcohol problems, but in the case of this HTA, it could be assumed that the bulk of generalist intervention (not including input from Councils on Alcohol to GP surgeries) is brief intervention, 'support and advice' and the prescribing of medication (eg. benzodiazepines for detoxification; acamprosate for relapse prevention).

Accident & Emergency Departments have a role in recognising alcohol related problems and can be appropriate settings in which to offer help, for instance through the use of brief intervention techniques for less severe cases or by referral on to an appropriate agency within the 'treatment system'.

Significant numbers of admissions to General Hospital medical wards have current alcohol related problems. 'There is little evidence that most problem drinkers entering hospital are having their drinking problem recognised, assessed and appropriate action then taken' (Greater Glasgow Health Board, 2000). Intervention may be limited to the immediate management of alcohol withdrawal. There may be, however, the opportunity for some psychosocial intervention on medical wards, perhaps more so than in the primary care setting, given the lengthier period of time in contact with the individual. It is not clear to what extent this may be occurring.

The Liaison Psychiatrist can advise and educate not only on the immediate management of alcohol withdrawal but also on appropriate subsequent referral to specialist agencies.

Specialist Alcohol Liaison Nurses are few in number but may provide useful support to general hospital wards in terms of both the management of alcohol related problems and the education and training of generalist health care professionals. Lothian and East Glasgow currently provide this Alcohol Liaison Nurse service.

General Psychiatric Services see a large proportion of the alcohol misusers referred to the psychiatric services overall, including the specialist addiction services. Many problem drinkers are admitted to acute psychiatric beds with few of the supervising consultants or nursing staff having a specialist addiction training.

3.18.5 Non NHS Services

Table 3 - 5 Non-NHS Services Distribution (and returned survey numbers in bold) shows the distribution of non-NHS services which have at least some role in the care of individuals with alcohol problems. This does not take into account the numerous AA meetings, which occur throughout Scotland on a daily basis (Section 6).

Table 3 - 5 Non-NHS Services Distribution (and returned survey numbers in bold)

	Lomond &Argyll	Renfrewshire &Inverclyde	Ayrshire &Arran	Borders	Dumfries&Galloway	Fife	Forth Valley	Grampian	G.Glasgow	Highland	Lanarkshire	Lothian	Orkney	Shetland	Tayside	W. Isles.
Day and Counselling facilities																
Council On Alcohol	7 (***3***)	6 (***2***)	5 (***1***)	1 (***1***)	2 (***1***)	1	4 (***1***)	2	9 (***1***)	12 (***4***)	2 (***1***)	9 (***1***)	1 (***1***)		2	
Social Work	1	5	1			1		2	12 (***2***)		3 (***1***)	1			3	
City Council			1			1		1	1							
Church of Scotland									1 (***1***)			1				1
Salvation Army								1								
Other Voluntary		1	1	1		1		3	5 (***1***)			4 (***1***)		2 (***1***)	1	1
Residential Rehabilitation Facilities																
Social Work											1					
City Council																
Church of Scotland	1							1 (***1***)	1	1		1				
Salvation Army		1							1							
Other Voluntary								2	2 (***1***)			2 (***1***)				
Residential homelessness facilities																
Social									1							

Work																
City Council									4			2				
C. of Scotland												1 (***1***)				
Salvation Army												1 (***1***)				
Other non-Statutory		3 (***2***)						2 (***2***)	10 (***3***)			5 (***1***)			7 (***2***)	
TOTAL	**9**	**16**	**8**	**2**	**2**	**4**	**4**	**14**	**47**	**13**	**6**	**27**	**1**	**2**	**13**	**2**
Number per 10^5	**7**	**6**	**2**	**2**	**1**	**1**	**2**	**3**	**5**	**6**	**1**	**4**	**5**	**9**	**3**	**7**

Areas with 5 or more services per 100,000 of population are Greater Glasgow, Lomond and Argyll, Renfrewshire and Inverclyde, Highland, Orkney, Shetland, and Western Isles. Areas with 2 or less are Ayrshire and Arran, Borders, Dumfries and Galloway, Fife, Forth Valley, and Lanarkshire. These figures do not take account of differences in demand or difficulties in accessing the services.

Day Facilities (which, in this report, include all non-residential facilities irrespective of hours of opening, intensity of workload, type of intervention etc.) make up the bulk (71%) of non-NHS services (even excluding AA from these statistics) – largely through the numerous facilities provided by Councils on Alcohol (52% of day facilities); Social Work services make up the next largest group (24%) of facilities (Community Alcohol Teams are not included in these figures).

Residential Homeless services provide 21% of non-NHS facilities identified (excluding AA) through various charitable organisations including Cyrenians (19% of residential homeless facilities) and, in Glasgow, the Talbot Association (16%), as well as city councils (16%).

Many of the homeless facilities identified do not have a special remit for dealing with alcohol problems and over 50% of facilities returning the questionnaire did not offer any psychosocial interventions to deal with these problems. Nonetheless, people with alcohol problems seem to account for a significant proportion of individuals using those facilities.

Greater Glasgow has most in the way of residential homeless facilities (42%), with Edinburgh and Lothian (25%), Tayside (19%), Renfrewshire and Inverclyde (8%) and Grampian (6%) making up the rest of identified facilities of this nature.

A large proportion of homeless people have evidence of severe alcohol related problems. There is an apparent lack of availability of specialist addictions services for homeless people with alcohol problems, although the Rough Sleepers Initiative (RSI) and in Glasgow the development of the Homeless Addictions Team is a step towards tackling this issue. The GGHB Alcohol Strategy Consultation Document (Greater Glasgow Health Board, 2000) recognised that liaison between statutory addiction services and hostels was poor. Glasgow Council on Alcohol hold regular weekly surgeries at Glasgow City Council Hostels.

Residential Rehabilitation facilities are few in number (14 facilities, 9-10% of identified non-NHS facilities). Five (36%) are provided by the Church of Scotland, with two (14%) provided by the Salvation Army and only one (7%) provided by Social Work services.

The facilities are in Greater Glasgow, four (29%), Edinburgh & Lothian, three (21%), Grampian, three (21%), and one (7%) each in Highland, Renfrewshire and Inverclyde, Lomond & Argyll and Lanarkshire.

3.18.6 Social Work Services

The social services are in an ideal position to recognise and assess individuals with alcohol problems through their contact with many 'at risk' groups as part of the work of child and family teams, community care teams and prison social work teams. In addition the specialist addiction Social Work services provide intervention in terms of advice, information, 'counselling', advocacy, support and care planning. They are also involved in purchasing services such as rehabilitation.

The development of Community Addiction Teams (CATs) may create a greater resource for outpatient care though there is also concern that this expanding tier 3 service could result in redistribution of staff from NHS specialist 'tier 4' services.

The survey of existing non-NHS alcohol facilities included 14 Social Work facilities making up 13% of non-NHS facilities surveyed. A further 17 facilities were identified post survey from SACAM information taking the total to 31 facilities identified (18% of the total non-NHS facilities eventually identified). Ninety-three percent (93%) of these were day facilities with 1 residential rehabilitation facility and one residential homeless facility. The Social Work facilities are mostly to be found in Greater Glasgow (42%), with other facilities located in Lanarkshire, Grampian, Tayside, Lomond and Argyll, Renfrewshire and Inverclyde, Lothian, Fife and Ayrshire and Arran.

It appears that a range of validated psychosocial interventions (E.g. Motivational Interviewing, Social Skills Training) may be offered by social work services.

3.18.7 Non-statutory facilities

Non-statutory services may have charitable or independent status. The Plan for Action (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002) points to the 'strong contribution already made by voluntary organisations in providing prevention, education, treatment and support services' and notes their good value for money. Non-statutory services may better meet the needs of marginalized subgroups and communities than statutory services.

The contribution of Alcoholics Anonymous to non-statutory services in Scotland was not assessed in the survey but they are discussed separately later in this report (Section 0).

Eighty-seven (87) non-statutory facilities were surveyed. An additional 32 Council on Alcohol sub offices and 10 other facilities identified post survey from SACAM

information were not surveyed. The total number of non-statutory facilities (not AA) identified was therefore 129.

Sixty-seven percent (67%) are day facilities, mostly Councils on Alcohol (72%), 10% are residential rehabilitation facilities, largely Church of Scotland (38%), and 23% are residential homeless facilities.

The Scottish Executive provides core funding for Alcohol Focus Scotland (AFS), which, in turn, has the function of supporting local Councils on Alcohol. Councils on Alcohol appear to be the largest non-NHS service in the field of alcohol problems identified in the survey, with a rigorous selection and training process resulting in counsellor accreditation. The psychosocial intervention termed 'alcohol counselling' by many of the facilities is a CBT based approach. The average number of clients engaged or re-engaged in a month per facility is 24. Clients remain engaged in the service for a variable period of time taking individual needs into account but the average length of treatment / contact is probably about 3-4 months.

Church of Scotland Board of Social Responsibility services may vary from facility to facility. The Board has five residential rehabilitation facilities plus a day service centre responding to a range of alcohol related challenges. The 'counselling' methods used are person-centred, along similar lines to Motivational Interviewing with psychodynamic approaches also employed. (Victoria View is a residential rehabilitation facility in Glasgow with seven staff, where 12-16 beds are provided for alcohol problems. The mean length of stay is 26 weeks. Psychosocial interventions include intensive group therapy, family therapy and individual counselling. Funding is through social work and local authority. Ronachan House is a residential rehabilitation facility in Lomond and Argyll area, with eight staff, offering 6-8 month stays (depending on need) for up to 20 residents. Psychosocial Interventions include work programme, group work, individual counselling, educational input and leisure activities. Malta House is a rehabilitation unit in Edinburgh, with nine staff, offering 6 month programmes for up to 15 residents with drug / alcohol dependence. Psychosocial interventions include group work, counselling, physical work and activities. Deeford House is a rehabilitation unit in Grampian region with seven full time and two part time staff, offering an average stay of approximately 12 weeks for up to 17 clients (four in a satellite house). Psychosocial interventions include group meetings, one to one counselling and anger management. Beechwood House is a rehabilitation unit in the Highland area, with 22 staff, providing a 4 week intensive assessment and intervention programme with optional access to a further 10 week programme for individuals seeking support in re-establishing a pattern of alcohol free living. Funding for these interventions is through social work. The Health Board funds supported accommodation for those attending the local NHS day service – information gathered from SACAM survey and independent sources).

3.18.8 Private Care

Private care facilities (e.g. The Langside Priory and Castle Craig) were not sent the survey questionnaire. The Langside Priory offers a service which includes detoxification as an in- or outpatient aimed at achieving abstinence, CBT, problem solving, family therapy, couple therapy, post treatment planning, continuing weekly aftercare and self-help group meetings within the hospital (aftercare is provided free

of charge for as long as required). Castle Craig adopts a 12 step approach in a residential setting and aims for abstinence. The treatment program includes group therapy, individual therapy, didactic lectures, video films, individual readings and written assignments. Funding e.g. in Glasgow is via social work and subcontracted with GGHB; in Highland region, health board funding occurs for the first 6 week intensive period and thereafter social work funding is required). There is a similar smaller facility in Aberdeen.

3.18.9 Services for Alcohol Dependent Offenders

Prison services have not been addressed although the SACAM survey identified a number of prison liaison facilities involving collaboration between social work or Councils on Alcohol and the Scottish Prison Service.

3.19 Demand vs Service Distribution

In the consultation process prior to publication of the Plan for Action 'patchiness' in service provision throughout Scotland was noted. This perception was borne out by the HTBS survey of specialist alcohol services (Section 3.10). Services appear fragmented, perhaps leaving some without access to what should be minimum care. This is particularly noticeable in certain rural areas. It may also be that different populations have different needs and, for instance, rural communities may face specific circumstances and difficulties when providing treatment for alcohol problems: distance, geographical location, lack of social support, fear of stigma etc. may constitute barriers to treatment and complicate rehabilitation and follow up procedures.

Some services appear to be comparatively well provisioned but may, nonetheless, be working beyond their capacity, with pressure on resources and long waiting lists. For instance, 84% of the most deprived people in Scotland live in Greater Glasgow area. The rates of general hospital and psychiatric admissions for alcohol related diagnoses are 10 times greater for people in the most deprived, compared to the most affluent areas. The greater levels of socio-economic deprivation in Glasgow mean that for some alcohol related problems the area probably has higher rates than any other health authority in the UK (Greater Glasgow Health Board, 2000). The Plan for Action (2002) notes that men living in the most deprived areas of Scotland are 7 times more likely to die an alcohol related death than those in the least deprived areas.

3.20 Long-term health expectation in alcohol dependence

3.20.1 Effects of chronic and acute exposure to alcohol

The economic evaluation of relapse prevention interventions in this assessment relates the costs of the interventions to the benefits obtained from a reduction in the adverse effects of alcohol on health. In order to do this it is necessary to evaluate the impact of alcohol on the health of alcohol dependent patients.

Drinking large amounts of alcohol alters the chance of developing many diseases and is also associated with increased risks of accidents and suicide. Some of these effects appear to be related to chronic heavy drinking whilst other may be related to acute intoxication. However, whether the nature of these effects is different in alcohol dependent individuals from those who drink similar quantities without developing dependence is unclear. For the purposes of this assessment it seems reasonable to assume that the risks of diseases associated with chronic drinking are similar whether or not dependence is present and also that alcohol dependent individuals are likely to be drinking in quantities which carry a risk similar to the highest levels of risk seen in the population in general. However, whether dependent drinkers account for a high proportion of events associated with acute intoxication is less clear. This is because many such events may be experienced by occasional heavy drinkers. For this reason it seems reasonable to restrict the consideration within the economic model to illness associated with chronic drinking. However, it must be recognized that any benefit of treatment will only reflect a part of the potential benefit to the health service of treatment of alcohol dependence since alcohol dependent drinkers will also experience the heightened risks associated with acute intoxication, for example accidents. The possible extent of this underestimation can be roughly gauged from the following discussion of the Australian National Alcohol Indicators Project (NAIP).

3.20.2 The Australian National Alcohol Indicators Project

The Australian National Drug Research Institute published a report on alcohol-caused deaths and hospitalisations as part of the NAIP. The report used relative risks of disease comparing high alcohol intake with low or moderate drawn from a paper by English (1995), subsequently updated by Gutjahr (Gutjahr *et al*., 2001). From these, combined with information on the drinking levels in Australia and the total disease burden, the amount of disease attributable to drinking was calculated. These figures are of considerable relevance because they show which of the many diseases affected by alcohol are likely to have the biggest clinical and economic impact. The report identifies 19 events/conditions associated with acute intoxication and 15 conditions associated with chronic drinking as partially or wholly attributable to high-risk alcohol consumptions. An additional two conditions, stroke and suicide, are classified as 'mixed' since they are associated with both acute and chronic drinking. The relative impacts of these classes of health events can be judged from the total alcohol-caused deaths, life-years lost, hospitalisations and bed-days associated with them.

Table 3 - 6 Impact on health of acute and chronic drinking (Australia)

	Acute intoxication	**Chronic drinking**	**Mixed**
Males			
Deaths	695	1061	540
Person-years lost	22743	15675	10076
Hospitalisations	31366	14670	3463
Bed-days	156476	95049	25115
Females			
Deaths	218	328	449
Person-years lost	6246	5309	2933
Hospitalisations	13517	6165	3122

Bed-days	60865	41052	25238

From this it can be seen that the adverse health effects of acute intoxication represent a considerable burden to the health service. Just over 50% of total bed-days attributable to alcohol were taken up by such events. Hence it is conceivable that health service benefits from effective treatments could be twice as large as we estimate from our model. However, this would only be under the unlikely circumstance that almost all of the acute drinking events were in alcohol dependent people.

The impact of each chronic and 'mixed' event can be judged from the table below which shows them in descending order of total bed-days in the NAIP report.

Table 3 - 7 Total bed-days from diseases associated with chronic or 'mixed' drinking patterns (Australia)

Condition[c]	Deaths	PYLL[d]	Hosp.	Bed-days
Alcohol dependence	257	4335	13043	85294
Stroke	726	4019	4716	43247
Alc. Liver cirrhosis	683	11108	3222	25654
Chronic pancreatitis	13	151	1516	8377
Suicide	264	8985	1868	7105
Epilepsy	31	794	1730	6453
Oropharyn.cancer	55	637	395	3708
Hypertension	38	216	417	1836
Female breast cancer	51	715	371	1810
Oesophageal cancer	54	532	225	1670
Laryngeal cancer	31	300	182	1485
Oesophageal varices	2	28	473	1205
Liver cancer	65	659	161	1158
Alc. Cardiomyopathy	109	1481	146	873
Alc. poly neuropathy	0	0	32	240
Psoriasis	0	0	40	122
Cholelithiasis*	-1	-6	-1118	-3784
Sub-total	**2,378**	**33,954**	**27,419**	**186,453**

* Alcohol is protective for cholelithiasis

The only beneficial effect of very heavy drinking appears to be an effect on gall bladder stones (cholethiasis). The risk at the highest levels of consumption appear to about half that at low levels. Clinically this is not a benefit comparable to the harm since cholethiasis is almost never a fatal condition. However, the NAIP report shows a saving in hospital bed-days, which may be economically important. Ignoring adverse effects of alcohol will tend to undervalue treatment for dependence whilst ignoring benefits will do the opposite. Thus the decision to ignore this effect should be carefully considered. However, there are several potential adverse effects, which we have already disregarded due to the unavailability of satisfactory information about the relationship between them and the specific type of drinking we are discussing. Furthermore, there are several small but proven adverse associations which can be reasonably disregarded as minor effects but which roughly counter-

balance the bed-days gained through any protective effect on cholelithiasis. Of these we have chosen to disregard hypertension, oesophageal varices, and psoriasis.

3.20.3 Categorisation of drinking by associated risk

In the study by Gutjahr (Gutjahr *et al*., 2001) the relative risks for each disease are estimated from meta-analysis of published studies. Three levels of drinking are considered relative to abstinence. These are described as low, hazardous, and harmful but definitions of these are not given in the report. The UK Medical Council on Alcohol (http://www.medicouncilalcol.demon.co.uk/handbook/glossary.htm) defines these terms as follows.

- **Low risk** Intake unlikely to be associated with the development of alcohol-related harm if taken over 7 days (males $\leq$ 21 units/week, females $\leq$ 14 units/week)
- **Hazardous drinking** Intake likely to increase the risk of developing alcohol-related harm (males 22-50 units/week females 15-35 units/week)
- **Harmful drinking** A pattern of drinking associated with the development of alcohol-related harm (males > 50 units/week females> 35 units/week)

One unit corresponds approximately to 8g of pure ethanol and hence these figures translate to

- **Low risk** (males $\leq$ 24 g/day, females $\leq$ 16 g/day)
- **Hazardous drinking** (males 25-57 g/day, females 17-40 g/day)
- **Harmful drinking** (males > 57 g/day, females> 40 g/day)

3.20.4 Concordance between epidemiological studies

The risk ratios calculated by Gutjahr (Gutjahr *et al*., 2001) between harmful and low risk drinking for the diseases partially explained by chronic drinking are compared in the following table with those quoted by other meta-analytic reports. These other reports are discussed below.

Table 3 - 8 Comparison of reported risk ratios for harmful drinking from three sources. (95% CI in brackets)

Condition[c]	Gutjahr 2001	Bagnardi 2001	Mazzaglia 2001
Stroke	7.72f 1.79m		3.0 Haemorrhagic 2.3 Ischaemic
Chronic pancreatitis	*		
Epilepsy	7.52f 6.83m		
Oropharyn.cancer	5.39	6.01 (5.5,6.6)	
Hypertension	1.79f 2.05m		
Female breast cancer	1.66f	2.71 (2.3,3.1)	
Oesophageal cancer	4.36	4.23 (3.9,4.6)	
Laryngeal cancer	4.93	3.95 (3.4,4.6)	
Oesophageal varices	9.54		
Liver cancer	3.60	1.86 (1.5,2.3)	

- Risk Ratios are not given for chronic pancreatitis but the attributable fraction is estimated as 0.84.

F=female, M=male

Bagnardi's (Bagnardi *et al*., 2001) figures are for alcohol consumption greater than 100g/day. There are appreciable differences between the two sources in estimates for female breast cancer and for liver cancer. Bagnardi also identifies five additional cancers as increased by alcohol intake greater than 100g/day. These are Stomach (RR=1.32 95% CI 1.2,1.5), Colon and Rectum (RR=1.38 95% CI 1.3,1.5), Lung (RR=1.08 95% CI 1.0,1.2), Ovary (RR=1.53 95% CI 1.0,2.3), and Prostate (RR=1.19 95% CI 1.0,1.4). Alcohol increases the risk of each of these rather less than the cancers included in the NAIP report. However, the contribution that each cancer makes to the total burden of alcohol related morbidity will depend on the relative risk, the proportion of heavy drinkers, and on the absolute risk. The Scottish Health Statistics (1999) give numbers of registration for 1996 which can be used to assess this impact. This is a rough calculation and has been done for a population of which 8% are heavy drinkers. It also ignores the raised risks at intermediate levels of alcohol consumption. However, the relative impact of these cancers for men or women is insensitive to these assumptions.

Table 3 - 9 Estimates of Scottish cancers attributable annually to heavy drinking

	RR - Bagnardi	N (1996)	Attributable
Oropharyn.cancer	6.01 (5.5,6.6)	24	7
Female breast cancer	2.71 (2.3,3.1)	3,295	397
Oesophageal cancer	4.23 (3.9,4.6)	840	172
Laryngeal cancer	3.95 (3.4,4.6)	351	67
Liver cancer	1.86 (1.5,2.3)	252	16
Stomach cancer	1.32 (1.2,1.5)	993	25
Colon and rectum	1.38 (1.3,1.5)	3,567	105
Lung	1.08 (1.0,1.2)	4,806	31
Ovary	1.53 (1.0,2.3)	615	25
Prostate	1.19 (1.0,1.4)	2,027	30

From this simple calculation it appears that the five additional cancers identified by Bagnardi each add more to the disease burden than either liver or oropharyngeal cancer. They also add 216 attributable cases to the 659 from the other cancers. Hence we have included all ten cancers when calculating the economic impact of alcohol.

Mazzaglia defined heavy drinking to be more than 40 g/day when calculating estimates of the risk of stroke (Mazzaglia *et al*., 2001) with alcohol. The report included one cross-sectional study, 15 case-control and nine cohort studies in the investigation of chronic drinking and stroke incidence. The report does not attempt to meta-analyse the results and hence is difficult to interpret. There is inconsistent evidence concerning ischaemic stroke. All seven case-control studies for which odds ratios are reported found raised risks, which were between 2.4 and 15.3. Three studies yielded values around 2.9. However, three prospective cohort studies yielded relative risks of 0.4, 0.8 and 2.0, the former being significantly less than one and the latter significantly greater. Random effects inverse variance weighted mean results

(HTBS calculation) for these figures gives an OR of 2.3 (95% CI 0.8,6.75). Thus the effect is not statistically significant but suggests some increase in incidence. By contrast, all but one of ten studies (4 case-control, 6 cohort) gave significantly raised risks for haemorrhagic stroke. The inverse variance weighted mean odds ratio was 3.0 (95%CI 1.1,8.6). There was considerable heterogeneity between studies for both ischaemic and haemorrhagic stroke. In the latter case this was almost entirely due to a single study (Berger *et al*., 1999) which found a reduction in stroke. The finding of a marked difference in additional risk between men and women (NAIP) is not supported in this study, most studies in only men returning relative risks close to the mean. The NAIP report included the large, anomalous study by Berger, which was in male US physicians and it is likely that this will have strongly skewed the comparison of males and females. The NAIP authors note that the position with respect to alcohol and stroke is currently being reviewed in Australia – which suggests some uncertainty about the results used in the report. Thus we have preferred the evidence from Mazzaglia as presented above.

3.20.5 Suicide

Relative risks for suicide are difficult to determine. There is a good discussion of this in the International Guide for Monitoring Alcohol Consumption and Harm http://www.who.int/substance_abuse/PDFfiles/guidemontr_alcohlconsum.pdf in which it is recommended that *Relative Risk estimates be based upon well-conducted studies from, ideally, the country to which they are to be applied, or at least from culturally and economically similar countries.* This WHO publication includes suicide as an effect of acute drinking rather than 'mixed' and for the economic modelling in this report we will not include suicide but note that this may be an additional conservative element in our analysis.

3.20.6 Alcoholic cardiomyopathy and polyneuropathy

As shown in the NAIP report, alcoholic cardiomyopathy and polyneuropathy – although specifically associated with alcohol – are not major contributors to clinical costs. Cardiomyopathy contributes to alcohol associated mortality and hence would be of interest in an analysis which costed lost life-years. Alcoholic polyneuropathy is a rare condition. Hence neither is explicitly accounted in the economic analysis for this report.

3.20.7 Alcoholic psychosis

Alcoholic psychosis, which was one of the main outcomes considered in the report on which our economic model is based (Schadlich & Brecht, 2000) was classified by NAIP to be primarily a result of acute episodes of heavy drinking and hence does not appear in Table 3 - 7 Total bed-days from diseases associated with chronic or 'mixed' drinking patterns (Australia)However, this is potentially misleading as it appears to be a result of amalgamating several different conditions including ICD-10 F10.0 (Acute intoxication) F10.4 (Withdrawal state with delirium) F10.5 (psychotic disorder) F10.6 (Amnesic syndrome) and F10.7 (Residual and late-onset psychotic disorder). The latter categories are predominantly associated with chronic drinking and are included in this HTBS assessment.

Specific risk ratios were not found for these conditions but their impact was estimated using Scottish data on hospital episodes (Scottish Health Statistics) compared with hospital episodes for cirrhosis. This is a fairly crude procedure for accounting a complex mixture of psychological diseases and we note that a subgroup of patients will have chronic debilitating mental problems that have substantial clinical and economic costs and are not acknowledged in our model.

3.20.8 Alcohol associated diseases accounted in the HTBS model

Thus the total disease impact of chronic drinking, which we consider in this report includes the following:

- Alcohol dependence
- Stroke
- Alcoholic Liver cirrhosis
- Cancer
    - Oropharyngeal
    - Female breast
    - Oesophageal
    - Laryngeal
    - Liver
    - Stomach
    - Colon and rectum
    - Lung
    - Ovary
    - Prostate
- Chronic pancreatitis
- Epilepsy
- Alcoholic psychosis including organic brain damage

These conditions fall into two categories, which are handled differently in our analysis. Cancer, stroke and cirrhosis are major events likely to be fatal or, if survived, have appreciable downstream effects upon the patients. For these we calculate the proportion of patients likely to suffer a first event of each type. Chronic pancreatitis, epilepsy and alcoholic psychosis are likely to cause ongoing problems and we calculate the likely burden of each illness in a patient up till the occurrence of one of the severe events considered above or death.

3.20.9 Disease incidence

To calculate the probability that a person develops any one of the partially attributable conditions when exposed to a hazardous level of alcohol exposure it is necessary to know the probability of doing so at low alcohol exposure and the relative risks as discussed above. If the proportion of cases attributable to alcohol is not great the population incidence may be taken as reflecting the baseline risk with only second order errors in calculation of risk to hazardous drinkers. If this assumption is not credible then a correction based on the prevalence of hazardous drinking should be used.

3.20.9.1 Cancer

Incidence figures for all forms of cancer are routinely collected but other, non-notifiable, disease incidences must be estimated from other sources. The cancer incidences for the Scottish population have been taken from the Scottish Health Statistics 1999. They are based on observations made in 1996.

3.20.9.2 Stroke

Warlow *et al*. (1996) quoted eleven different studies of stroke incidence. The averaged age specific incidences per 100,000 were as follows:

Table 3 - 10 Estimates of the age specific incidence of stroke

Age	0-44	45-54	55-64	65-74	75-84	85+
Incidence	13	96	278	664	1409	2089

These figures include ischaemic stroke, primary intracerebral haemorrhage, and subarachnoid haemorrhage. The same source reports that in seven incidence studies of first ever stroke about 80% of strokes were ischaemic, 10% were primary intracerebral haemorrhage, 5% were subarachnoid haemorrhage and 5% were of unknown aetiology. For the purpose of this assessment we will assume that the unclassified strokes were predominantly ischaemic and that the age distribution was roughly similar for ischaemic and haemorrhagic strokes.

Hart *et al*. (2000) followed a cohort of Scottish residents aged between 45 and 64 for twenty years and estimated stroke incidence. They found strokes in 472 (6.7%) of 7052 men and in 557 (6.7%) of 8354 women. This can be roughly compared with the figures from Warlow *et al*.,(1996). Over twenty years the chance of stroke in a 55 year old would be $[1-(1-278/100,000)^{10}x\ (1-664/100000)^{10}\ ]x100\% = 9\%$. This is somewhat higher than the 6.7% observed by Hart, however it is strongly dependent on age, the chance in a 45 year old can be calculated to be 3.7% whilst that in a 65 year old would be 18.2% (ignoring competing mortality). Thus it appears that the two sources of data give similar results.

The very simple model of disease being used in our economic assessment requires some mean stroke risk and a time horizon to be chosen. We have used a 20 year horizon and used baseline risks for people aged 45 at the start of this period.

3.20.9.3 Liver disease and cirrhosis

Becker *et al*. (1996) followed 13285 subjects age 30 to 79 over 12 years in Copenhagen. Self-reported drinking levels, which were not independently verified, were compared with the incidence of liver disease and cirrhosis

A very steep increase in both liver disease and cirrhosis was found with alcohol intake in both sexes. The base-line risk was that in the lowest, non-abstinent, group (12-72 g/week of ethanol). Relative to this group men and women who fulfilled the 'harmful drinking' criterion had greater than 7 times the risk of cirrhosis and 4 times the risk of any alcohol-related liver disease. The highest levels of drinking observed (>120 g/d

for men and between 48 and 70 g/d for women) carried relative risks of around 17 for cirrhosis and 8 for any liver disease.

The baseline risks can be roughly estimated from the figures given in the paper as:

Table 3 - 11 Estimates of population base-line risks of liver disease

Men	Any alcohol-related liver disease	1.5 per 1000 per year
	Cirrhosis	0.52 per 1000 per year
Women	Any alcohol-related liver disease	0.76 per 1000 per year
	Cirrhosis	0.23 per 1000 per year

Any age variation in these rates could not be calculated from the information supplied.

The very large variation in risk with alcohol intake complicates the use of these figures in predicting rates for an alcohol dependent population. In the population from the Copenhagen City Heart Study discussed in this paper the mean relative risk for the 5% of the population with the highest drinking rate was 16.5 in men whilst the relative risk of any liver disease was 8.1. These figures were not calculable for women but the similarity of relative risks in men and women at their respective levels of 'harmful' drinking suggests using the same relative risks in each group. In the absence of information based on a Scottish population, we have used these figures in the present calculations.

3.20.10 Mortality in harmful drinkers

In order to calculate the expected pattern of alcohol related disease in a cohort of harmful drinkers it is necessary to have some information about the likelihood of dying without developing such a disease. Some studies of heavy drinkers have suggested that this is much higher than in the population in general.

Chen *et al*. (2001) followed up 418 alcohol dependent patients detoxified within a psychiatric hospital in Taiwan. The mean age of the patients was 39.4 years and 91% were male. The total follow-up was 1268 person years during which 83 deaths were observed. Life table estimates suggested that only 50% survived for 10 years (mean survival 9.9 years). Sixty three deaths were non-violent and of these 34% were gastrointestinal (predominantly liver disease) and 18% were cardiovascular.

Table 3 - 12 The numbers and causes of death (Chen et al., 2001)

Violent deaths	**20**
Accident	16
Suicide	2
Homicide	2
Non violent deaths	**63**
Cancer	6
Cardiovascular	15
Gastrointestinal	28
Respiratory	2
Others/unknown	12

Denison *et al*. (1995) followed up 1123 male alcoholics in Sweden for one year following detoxification in a psychiatric hospital. The mean age was 46.5 years. Ninety-seven (8.6%) of these patients died – this compares with 6% in the first year of the Taiwan study, possibly reflecting the older age.

Table 3 - 13 The numbers and causes of death Denison et al. (1995)

Violent deaths	**23**
Trauma	10
Intoxication	13
Non violent deaths	**74**
Cancer	5
Cardiovascular (IHD)	20
Liver cirrhosis	6
Cerebrovascular disease	5
Epilepsy	5
Others/unknown	33

The authors note that ethanol was the sole agent in 8 of the 13 intoxication deaths and was involved in 3 others. One of these three and the two cases not involving ethanol appear to have been suicide.

An interesting finding in both these studies is the rather low proportion of deaths, which were attributed to somatic diseases, which are accepted as frequently alcohol-related. In the Swedish study only 16% of deaths were due to cirrhosis, malignancy or stroke. The proportion in the Taiwanese study may have been higher – up to 37% - however, all liver disease was amalgamated and hence it cannot be determined exactly. From the point of view of this HTA it is important to know this proportion as, in calculating the incidence of these conditions, all other deaths are taken as 'censoring' events. For our calculation we have taken 20%.
In calculating the burden of these alcohol related diseases in men we have assumed a mortality rate amounting to 50% over 10 years. Of course, this information does not define the entire relationship of mortality to age. Thus we have assumed a proportional hazards model based on the empirical hazards from Scottish life tables and calculated the hazard ratio, which gives a 50% chance of dying from any cause over 10 years to a 45 year old man. This gives a rather startling relative hazard of death for an alcohol dependent man compared with the general population of 12.1.

Very little information concerning mortality in alcohol dependent women is contained in the two studies discussed above. The study in Taiwan included 9% of women and who accounted for 3 of the 83 deaths. Thus the relative risk for a woman compared to a man was (3/9)/(80/91) = 0.38. However, no information is given about the age distribution in the male and female groups. In this study we have assumed that the relative risk of death for an alcohol dependent woman compared to an alcohol dependent man would be the same as that for a non-alcohol dependent woman compared to a non-alcohol dependent man. This is also calculated from Scottish life table data.

3.21 Mortality in the Scottish population

The health consequence attributable to harmful drinking can only be seen in comparison with the incidences of the same diseases in a non-alcohol-dependent population. These can be calculated in a similar fashion but require an estimate of the (much lower) mortality rate in moderate drinkers. This is because the lower risk of disease is partially compensated by the higher life expectancy allowing more time for disease to develop. We have used 1998 age and sex specific death rates for Scotland as reported in Scottish Health statistics 1999. In this, predominantly non-alcohol-dependent, group we assume that the proportion of mortality due to alcohol related diseases may be ignored.

3.21.1 Calculation of life-time probabilities of severe alcohol related disease.

3.21.1.1 Method

The health prospects of a typical non-alcohol dependent person are assumed to be reflected in the official Scottish health statistics. We initially calculate the probability of developing one of the alcohol-related cancers, stroke or liver cirrhosis using age and sex specific cancer and mortality rates from Scottish Health Statistics 1999 and stroke and cirrhosis rates as described above. For these major events we only calculate first occurrences. Thus each event is considered as censoring for all others. We calculated events in each five years period and then added them to get the total events in this period – i.e. assuming non-overlapping disease groups. The disease-free survivors for the following period was then calculated as the initial group minus the total events.

The same calculation was done for the alcohol-dependent group with two differences. Firstly the incidence rates for each disease were the rates used above multiplied by the appropriate risk ratio from the epidemiological studies. Secondly not all death was considered censoring. This was because a larger proportion of deaths in these patients might be expected to be causally related to the alcohol-related events and death itself is much more common in alcohol-dependent patients. Hence this second order effect could not be ignored.

Rates of hospitalisation for less serious events were then calculated using proportions relative to cirrhosis. These were derived either from Scottish Health Statistics 1999 or, failing this, from the Australian NAIP report. An important potential source of underestimation in this calculation is that each case of cirrhosis was taken as a single hospitalisation. Thus we believe that these estimates are conservative.

For inclusion in the economic analysis all events were discounted at 6%. Because no timings could be estimated for hospitalisations, the discounting was approximated using the same factor as the cirrhosis.

3.21.1.2 Men

We take a base case of a 45 year old man and compare this with the health profile of the general male population. During twenty years our model predicts the following major events in 1000 individuals (figures in brackets are discounted at 6% p.a.):

Table 3 - 14 Expectations of stroke, cancer, or cirrhosis in men

	Alcohol dependent	**Non-alcohol dependent**
Death	936	318
Stroke (all types)	43 (26)	33 (18)
Cancer*	88 (53)	97 (50)
Cirrhosis	102 (72)	10 (6)

*As listed above

In addition we would expect the following hospitalisations:

Table 3 - 15 Expectations of hospitalisation for other disease in men

	Alcohol dependent
Alcoholic psychoses[1]	571 (403)
Chronic pancreatitis[2]	44 (31)
Epilepsy[2]	41 (29)
Alcohol dependence[1]	814 (575)

[1]These figures are based on the recorded ratios of these events compared with hospitalisations for cirrhosis in the Scottish Health Statistics. Thus the hospitalisations for alcohol dependence may be rather lower than might be expected if many patients are treated only as outpatients.
[2]These figures are based on the ratio of events to hospitalisations for cirrhosis quoted in the NAIP report.

3.21.1.3 Women

We take a base case of a 45 year old woman and compare this with the health profile of the general female population. During twenty years our model predicts the following major events in 1000 individuals (figures in brackets are discounted at 6% p.a.):

Table 3 - 16 Expectations of stroke, cancer, or cirrhosis in women

	Alcohol dependent	**Non-alcohol dependent**
Death	785	268
Stroke (all types)	53 (31)	33 (18)
Cancer*	146 (93)	125 (73)
Cirrhosis	52 (35)	4 (3)

* As listed above

In addition we would expect the following hospitalisations:

Table 3 - 17 Expectations of hospitalisation for other disease in women

	Alcohol dependent	
Alcoholic psychoses[1]	160	(107)
Chronic pancreatitis[2]	32	(22)
Epilepsy[2]	50	(34)
Alcohol dependence[1]	260	(175)

[1]These figures are based on the recorded ratios of these events compared with hospitalisations for cirrhosis in the Scottish Health Statistics. Thus the hospitalisations for alcohol dependence may be rather lower than might be expected if many patients are treated only as outpatients.
[2]These figures are based on the ratio of events to hospitalisations for cirrhosis quoted in the NAIP report.

There is also calculated to be an additional burden of non-cirrhotic liver disease, which we estimate to be an extra 24 cases (18 discounted at 6% p.a.) per 1000 alcohol-dependent population for men and 22 (16 discounted at 6% p.a) for women.

4 SOURCES OF EVIDENCE

The Health Technology Assessments undertaken by the HTBS use international evidence from a range of sources: published literature, grey literature (e.g. academic and government reports, website publications, conference abstracts) and information submitted from a variety of interested parties.

The following interested parties were invited to submit evidence for the Assessment (those marked * did not reply and those marked + did not have anything additional to contribute):

Professional / Specialist Groups
Church of Scotland Board of Social Responsibility
Centre for Alcohol & Drug Studies, University of Paisley (*/+)
Scottish Association of Health Councils
Royal College of Physicians Edinburgh
Royal College of Physicians London
Strathclyde University (*/+)
Royal College of Nursing Scottish HQ (+)
Royal College of Physicians & Surgeons Glasgow (+)
Centre for Drug Misuse Research, University of Glasgow (+)
Fife Alcohol Advisory Service (*/+)
British Psychological Society (Scottish Branch) (*/+)
The Medical Council on Alcoholism
Association of Directors of Social Work
Royal College of General Practitioners (+)
Community Psychiatric Nurses Association (*/+)
Royal College of Psychiatrists Scottish Division (+)
Intercollegiate Group on Alcohol Problems (*/+)
Royal Free and University College Medical School
Scottish Executive Health Department

Patient Groups
Alcoholics Anonymous
Alcohol Concern (+)
Beechwood House (*/+)
Phoenix House (*/+)
Alcohol Focus Scotland
Renewal Clinics Ltd
The Priory Hospital Glasgow (*/+)

Manufacturers
Alpharma AS
Merck Pharmaceuticals
DuPont Pharmaceuticals Ltd

Literature searches for systematic reviews, for randomised controlled trials of effectiveness and for previous cost-effectiveness studies were carried out and are

detailed in the appropriate sections. All searches will be updated during the consultation period.

Two surveys of Scottish service provision have been undertaken by HTBS.

Researchers at Caledonian University have undertaken a qualitative study of patient attitudes and concerns relating to relapse prevention.

Alcoholic Anonymous have provided a wide variety of information on the role of their own organization and given a patient-centred view of many other issues.

5 CLINICAL EFFECTIVENESS

5.1 Summary

Psychosocial and pharmacological interventions were evaluated using published reviews and information supplied by pharmaceutical manufacturers. Following this a meta-analysis was carried out to estimate the proportion of patients who had achieved abstinence or controlled drinking at the end of the study when treated with various pharmacological or psychosocial interventions for prevention of relapse in alcohol dependence. In the following section all treatment effects are expressed as the odds of one of these successful outcomes compared to patients treated with control treatments. Control treatments were often judged to have only placebo effects.

The population to whom these results apply is difficult to define precisely. Almost all trials of pharmacological treatment enrolled patients who had undergone detoxification. However, trials of psychosocial treatments are generally less proscriptive. Studies were selected when patients were described as dependent or alcoholic. They were not selected if patients were described as problem drinkers or were obtained through population screening.

The aim of treatment may be abstinence or controlled drinking and will be decided by agreement between the clinician and the patient. Effective treatment packages should be available for either of these aims.

The following points relate to psychosocial treatments.

- The meta-analysis suggested similar, statistically significant, beneficial effect sizes for Behavioural Self-Control Training (OR=1.86 [95%CI 1.03,3.36]), Motivational Enhancement Therapy (OR=2.19 [95%CI 1.20,3.98]), Family Therapy (OR=1.81 [95%CI 1.26,2.61]) and Coping/Communication Skills Training (OR=2.33 [95%CI 1.44,3.76]). Treatment of control groups varied and, since some control treatments may have been effective, these estimates may be conservative.

- Behavioural Self Control Training (BSCT) appears to show benefit when compared to ineffective controls. However, the only trial that focused on the unique defining features of BSCT and included the more general features in both patient groups did not show a benefit.

- Motivational Enhancement Therapy (MET) shows efficacy over ineffective controls. However, it was slightly less effective than Alcoholics Anonymous (AA) based treatment in outpatients in Project MATCH. This may be due to the short course of treatment given. It is suggested that MET form an important initial element in a course of psychosocial treatment but should not be the sole intervention.

- Marital/relationship therapy has shown a beneficial effect. However, it is only usually feasible in those with relatives willing to invest substantial effort in the treatment and with the consent of the patient. Thus it can only form an option for treatment of some patients. An exception to this is the

Community Reinforcement Approach in which the contractual element with non-family members has been tested.

- Brief Interventions appear to be of unproven efficacy in alcohol dependent patients and the current evidence does not suggest that this is a promising approach. The 'Relapse Prevention' model of treatment is also unproven. However, this model is quite loosely defined and some currently used implementations involve Coping Skills training, which is effective.

- Lack of standardization of psychosocial treatments in clinical trials often leaves doubt as to how a treatment shown to be effective in a meta-analysis should be delivered in clinical practice. A pragmatic approach is to adopt a protocol as detailed in a report from a trial included in the meta-analysis and with a larger than average effect size.

- Encouragement to attend AA meetings has been shown to have benefit, but as noted in the patient issues section, patients should not be forced to attend. Explanation of the aims and philosophy of AA during treatment will allow patients to make an informed choice. As with other psychosocial treatment approaches, agreement upon rather than pressure to enrol in AA treatment appears essential for benefit to be obtained.

- Therapists will need to be able to give informed and dispassionate advice regarding AA and other non-NHS services. This ability may be facilitated by regular liaison between NHS staff and the other services.

- Within a specialist unit, protocols should be available for all available treatment options to ensure standardized and consistent treatment. These protocols should be closely based on methods that have been proven effective in clinical trials.

- Practical help with problems such as housing, debt, and claiming benefits also appears likely to contribute to control of alcohol problems. Thus close liaison with Social Work services and groups able to deliver such help is essential.

The following points relate to pharmacological treatment.

- Pharmacological treatments have been tested and licensed as additional to psychosocial treatment, not as alternative therapy.

- Both acamprosate and naltrexone have extensive clinical trial data, which show that, used according to the clinical trial procedures, they can add value to a programme of psychosocial treatment.

- Trials of both acamprosate and naltrexone show statistically significant unexplained heterogeneity in effect sizes. Some large pragmatic trials have not shown an effect. This suggests that differences in the method of use may

materially affect the effectiveness. Further studies are needed to ensure that the full benefits of these treatments are achieved in practice.

- The effect size estimated for naltrexone is smaller than that for acamprosate. There are major differences in the way these products were evaluated which make a direct comparison difficult but this fact, in combination with the unlicensed status of naltrexone, would suggest that acamprosate should be the current preferred choice between these two medicines.

- No strong evidence exists for the use of unsupervised disulfiram.

- Much of the evidence for supervised use of disulfiram arises from observational studies and is hence potentially biased. Most of the evidence from randomised controlled trials confounds supervised disulfiram with other interventions. However, one randomised unconfounded study has found a benefit and it seems likely that supervised disulfiram can contribute beneficially to a relapse prevention programme.

The following points relate to delivery of treatment

- Although a clear benefit for inpatient compared with outpatient treatment has not been demonstrated the literature suggests, and clinical opinion supports, the existence of groups of patients who require residential or inpatient treatment. These include those with few social resources and/or environments that are serious impediments to recovery and those with serious medical/psychiatric conditions.

- An increased rate of failure to attend associated with delay between referral and start of treatment has been demonstrated. This underlines the importance of minimising such delays.

5.2 Literature search

A scoping search was undertaken to gauge the quantity and quality of the existing literature, with particular attention being paid to finding studies by other HTA organisations, systematic reviews and research in progress. Following this, the decision was made to undertake a systematic literature review. Given the large quantities of literature on this topic, this was restricted to material published after 1990 and to randomised controlled trials. The list of databases searched is given in Appendix 16. No language restrictions were applied.

To cover all aspects of the topic, the search was carried out in four parts. The first two parts looked at the population in question, in combination with either pharmacological or psychosocial interventions. A third part looked at the population again but this time in combination with general terms for the intervention, hence retrieving records concerning interventions which might not have been specified in the previous two parts of the search. Finally a fourth part combined the population with the outcome of treatment, thereby retrieving records where the individual recovered without treatment and also relevant records not retrieved in the previous

three parts of the search. The searches were performed using the available subject headings (e.g. MeSH, EMTREE) and free text terms. Members of the Topic Specific Group provided assistance in identifying interventions and their synonyms. Use was also made of the National Institute on Alcohol Abuse and Alcoholism thesaurus.

A copy of the strategy used to search the Medline database is given in Appendix 17 This strategy was adapted to search the other databases. A complete listing of all strategies can be obtained by contacting HTBS. Also contained with Appendix 17 is a flow chart showing the number of studies identified as potentially suitable for meta-analysis and then included in each stage of the process.

Additional studies, in particular grey literature, were identified by the TSG, or were submitted to HTBS as evidence.

5.3 Issues related to assessment of relapse prevention interventions

Therapists helping patients to overcome alcohol dependence have two quite different sets of clinical interventions open to them. First there are the psychosocial methods and second the pharmacological treatments. In addition to these measures, it may also be necessary or desirable to have purely social facilities available, such as accommodation or advice and practical help with other aspects of the client's life which may have been disrupted by alcohol or contribute to continued use of alcohol. All these aspects of a comprehensive alcohol service have been tested in clinical trials.

The psychosocial interventions present very special difficulties for health technology assessment. The literature obtained from the searches described above contained randomised clinical trials of more than forty nominally distinguishable psychosocial methods each of which generally included several different components whose precise application would require a detailed written protocol. This apparent diversity of interventions is handled by specialists through classification into broad categories based both on the underlying conceptual model of alcohol dependence and on familiarity with the practical details of the way interventions are delivered. Appropriate use of such classifications requires considerable in-depth knowledge and hence it is necessary to rely on expert judgments as exercised in published reviews of individual treatment models. We have been guided in selecting which treatment trials to group by the decisions made in previous treatment specific reviews. Thus, this clinical effectiveness discussion is organised according to a hierarchy of evidence ordered by comprehensiveness. First we review major extensive reviews then the reviews of specific treatment models, and lastly, when additional information is required, the individual clinical studies.

Although we have chosen to rely on published expert reviews for decisions about grouping of clinical trials, we note that other approaches are possible. The conceptual models, whilst providing a useful framework for presentation of a treatment programme, may not be the best basis for systematic statistical analysis of psychosocial treatments. The component parts of an intervention, for example 'an analysis of factors which characterise high-risk situations for relapse' or 'practising responsible drinking skills', may form elements in many different treatment

approaches and may cut across the boundaries between conceptual models. Furthermore, even treatments grouped within one conceptual model may contain some quite striking differences in terms of their component parts. Thus analysis based on multiple regressions using such component parts as explanatory variables might prove informative. However, this does assume that some independent effect is attributable to these parts – i.e. that primary effects due to components tend to outweigh those due to interactions between components. To our knowledge, this approach has not been tried even within such dedicated alcohol research facilities as the Mesa Grande project.

Clinical trials of some treatment attributes have been undertaken. For instance there have been investigations of particular interventions delivered to groups or to individuals, as outpatient or as inpatient treatment, or with abstinence as a chosen objective compared to controlled drinking.

In this Health Technology Assessment we have had to be selective. Tested treatments for alcohol include many not judged likely to form part of a conventional NHS service. Examples of these are LSD, electric shocks, acupuncture and intercessory prayer. More conventional pharmacological interventions, such as antidepressants, have also been excluded since we considered only products aimed at reduction of alcohol intake, not at comorbid conditions, which may be associated with alcohol problems.

The population to whom these results apply is difficult to define precisely. Almost all trials of pharmacological treatment enrolled patients who had undergone detoxification. Thus this corresponds with the population stated in our primary HTA questions, section 2.2. However, trials of psychosocial treatments are generally less proscriptive. Studies were selected when patients were described as dependent or "alcoholic". They were not selected if patients were described as problem drinkers only or were obtained through population screening. It was hoped in this way to select trials of patients at the more severe end of the spectrum of alcohol problems. The setting of many of these studies within specialist centres for treatment of alcohol problems may itself add a pragmatic element to the patient selection. The patients in these studies will be those who are referred to specialist centres and hence a fortiori appropriate to this assessment.

A primary objective of some recent studies has been to investigate 'matching' in treating alcohol dependence. In other words the intention was to evaluate differences in effectiveness of treatments between subgroup of patients. Studies aimed at investigating such questions are still designed as randomised controlled trials but one or more patient characteristics are prespecified and the primary hypothesis is concerned with the interaction between the characteristics and treatment rather than with the difference in the effect of treatment between randomised groups. In general the success of this approach has been questionable. Review of recent studies suggests that it adds still another layer of complexity to an already labrynthine area and the methodological difficulties have not been adequately appreciated. Several reports have not reported main effects and the interaction effects, which are the declared focus of the study, are presented purely as statistical measures of interaction without any clear clinical meaning. A statistical point, which does not seem to have been generally understood by the designers of such studies, is that a trial aimed at

characterising an interaction will require at least twice as many patients as a trial investigating a main effect. It is also likely that interactions may be smaller than main effects and obscured by misclassifications of patients, hence the sample size required may be even greater. Matching hypotheses will not be addressed in this review and it may be doubted whether sufficient high quality research exists for a systematic review of the questions posed.

By contrast with psychosocial interventions, the investigation of pharmacological interventions is relatively straightforward. Acamprosate and naltrexone, have been extensively tested in conventional clinical trials over the last few years. The clinical position regarding disulfiram is more complex. This drug has been used for more than forty years and many of the effectiveness studies come from an earlier era of clinical research when a lower standard of proof of efficacy was required for pharmaceutical licensing. Furthermore, the use of social contracts between the patient and a partner to reinforce taking of disulfiram has been incorporated as an element into several psychosocial treatment programmes. Thus, studies that test disulfiram taken under conditions where treatment compliance is most likely tend to confound its effects with other components of a treatment programme.

A major purpose of the clinical effectiveness analysis within a health technology assessment is to provide input to the cost-effectiveness analysis. The most appropriate clinical outcome measure for assessing the impact of treatment on future health appears to be the success rates by patient in achieving lives free of alcohol problems, in other words in which drinking alcohol is either controlled and safe or avoided. Not all studies and no reviews have presented this outcome in a manner, which allows estimates to be applied to economic models. Thus, for this outcome only, it was necessary to extract data from studies and perform a meta-analysis. Rather than include this essentially separate analysis under reviews of specific interventions, it is included as a self-contained section.

5.4 Previous Health Technology Assessments and Comprehensive Reviews

5.4.1 The Mesa Grande Project

The Mesa Grande project (Miller & Heather, 1998); (Miller & Wilbourne, 2002) is a long-term and ongoing systematic review of the randomized controlled trials in treatments for alcohol problems. The results of ranking 87 alternative treatments on the basis of 361 separate studies have been presented. Each study was given an overall score based on methodological quality and the number of studies supporting a beneficial effect compared with the number not doing so.

A criticism of this method of ranking is that interventions are given weight on the basis of a positive benefit relative to a comparator irrespective of the nature of the comparator or the size of the benefit. A more sophisticated model might give more weight to a positive result relative to a comparator which itself had been shown to be effective.

The major strength of the Mesa Grande Project is the immense effort that has been put into identifying and interpreting randomised controlled trials in interventions for

alcohol problems. Its methodology leads directly to a ranking of these interventions and hence it forms a natural starting point for any investigation of relative effectiveness. It provides a good basis for differentiating promising interventions from unpromising ones and hence for focusing further research and reviews of specific comparisons. It also reveals the wide range of interventions, which have been studied for alcohol problems. Thus it is worth presenting the ranking of interventions on the basis of the Mesa Grande scoring system in full (see Appendix 18).
From the point of view of the present review there are some difficulties in interpreting the Mesa Grande results. Notably, the database covers studies across a much wider range of patients and problems than is the remit of this assessment and the ranking table does not include information concerning the type of patient in each study. Hence studies in severely dependent patients may be ranked alongside those studying drinkers with less severe problems. A particular example of this is the primacy of place achieved by brief interventions in the ranking when others have found it ineffective in alcohol dependent patients (see section 5.5.1.3). The outcome measure is also not uniform across studies and thus the nature of the effect of each treatment is unclear. Hence for clinical applications targeting particular types of patient and with clinically relevant estimates of treatment effect it is necessary to seek more focused reviews.

5.4.2 Raistrick and Heather

A UK review of effectiveness of interventions in alcohol dependence has been produced by Duncan Raistrick and Nick Heather (Raistrick & Heather, 1998). Both authors were members of the Alcohol Commissioning Guidance Steering Group.

Estimates of the extent of alcohol problems in England are presented. Eight per cent of English males and 4% of females are estimated to have definite problems and moderate dependence whilst 1.5% of the population may have definite problems and severe dependence.

This report includes many recommendations for organisation of a comprehensive UK service for treatment of alcohol problems. Some of these are based on evidence and some are based on logistical or clinical considerations. A summary of those which are of particular relevance to this HTA is included in Appendix 18.

Discussion is also made of initial assessment of the patient, training of therapists, dealing with psychiatric co-morbidity, measurement of outcomes in clinical practice,

A chapter is devoted to intensive alcohol focused interventions. Social Skills Training, Community Reinforcement, Behaviour Contracting, Aversion Therapy, Cognitive-Behavioural Marital Therapy, and Behavioural Self-control Training are discussed on the grounds that all get good ratings in the Mesa Grande assessment. Relapse Prevention is also discussed. It is noted that two-thirds of clients will relapse within 6 months (Marlatt & Gordon, 1985). Aftercare is discussed and a number of reasons for it are listed. Some evidence for efficacy of aftercare is noted.

The authors note that all the treatments, which, they found to be effective are based on a cognitive behavioural approach. They note that drinking is a learned response,

which can be modified by learning through rehearsal of new behaviours. There is also a social element to most of the interventions.

The final chapter presents the authors' view of a comprehensive service for treatment of alcohol problems. Much of the discussion is very general but specific suggestions are made (Raistrick & Heather, 1998), table 14.1) about the treatment programmes that a health district might need. A 'stepped care' model of treatment is discussed. The need for training is highlighted and general proposals made for research and development.

5.4.3 Swedish (SBU) Health Technology Assessment

In 2001 the Swedish national health technology assessment agency (SBU) published a two-volume report covering the treatment of alcohol and drug abuse (Andreasson *et al*., 2001). The full report has not yet been translated into English but the conclusions of the report have been reviewed.

The report was compiled by a panel of 11 experts and it is noted that the Medline search found 23000 studies on alcohol problems from between 1950 and 2000. 641 relevant studies, mostly RCTs, were selected (presumably this is alcohol and other drugs).

The main questions addressed include assessment of both absolute (compared to no treatment) and relative efficacy. Subgroup effects, setting (inpatient or outpatient), and concomitant mental illness are mentioned. Cost-effectiveness is also an area of investigation.

Three subjects relating to alcohol are covered: detection of hazardous drinking before dependence develops, treatment of alcohol dependence, and alcohol withdrawal. One hundred and thirty-nine (139) studies in psychosocial treatment of alcohol dependence were found 14 of which compared with no treatment. One hundred and twenty (120) randomised controlled trials in medications for alcohol dependence were found.

This report covers a much wider area than this Health Technology assessment and it has not been able to review the evidence base as the report is in the process of translation but conclusions are listed in Appendix 18.

5.5 Treatment specific reviews and clinical studies

In addition to the ongoing work of the Mesa Grande project (Miller & Wilbourne, 2002) the comprehensive review by Raistrick & Heather (1998) and the HTA by the Swedish agency (SBU), there have been a number of reviews focused on specific interventions for relapse prevention. These reviews generally cover a range of severity of alcohol problems. The approach in this HTA has been to review these sources of evidence and ask how well they apply to the group of alcohol dependent patients which is the concern of this assessment and also whether additional evidence can be added to the reviews or subsets abstracted appropriate to the primary HTA question.

5.5.1 Psychosocial treatments

A fairly large number of treatment strategies exist which might be classed as psychosocial therapies. Most of these are based on conceptual models of addiction, which involve several components, each of which is addressed by a facet of the strategy. Different models frequently contain common themes and hence common elements to the treatment. Thus, a challenge in summarising the evidence for the effectiveness of these treatments is deciding when two treatments are substantially the same and should be combined, or have important differences and should not be combined. The following sections report reviews by other authors of a number of interventions commonly used in Scotland.

5.5.1.1 Behavioural Self Control Training (BSCT)

Walters (2000)[i](Walters, 2000) reviewed trials of behavioural self-control training for problem drinkers. The author investigated the subgroup of patients judged to be alcohol dependent. The inclusion of a trial in group required that three quarters of the study population met one of the criteria: DSM-III-R/IV diagnosis of dependence, traditional classification of gamma alcoholism (Jellinek, 1960), significant alcohol withdrawal symptoms, or hospitalisation for alcoholism.

The technique of BSCT aims at controlled drinking rather than abstinence. This is achieved by teaching clients to drink more slowly and increase intervals between drinks and choose less alcoholic drinks. They are also taught to recognise high-risk situations and to set personal goals.

The literature search identified English language studies from the PsycLIT database between 1984 and 1997 and was extended from reference sections of study reports. This found 17 randomised controlled trials. Seven studies were of alcohol dependent clients.

Several comparisons were made. BSCT was compared with controls receiving no intervention, with alternative non-abstinent controls and with abstinent controls.

A fixed effects meta-analysis was performed on standardised measures of outcome differences between groups in the studies. This gave a highly significant positive treatment effect. However, these results combined trials in patients judged to be alcohol dependent with those classed as problem drinkers. Table 5-1 presents the results from this paper restricted to studies of alcohol dependent patients.

A wide range of outcome measures were found in the studies and hence the analysis combined disparate effects.

Table 5 - 1 Randomized Control Studies on Behavioural Self-control Training for Dependent Drinking: Continuous Outcome Measures (Walters, 2000)

				Mean Scores		Effect size	
Study	**Sample**	**Outcome Measure**	**Length of Follow-Up**	**BSCT**	**Control**	***d***	**SE**
Sobell & Sobell (1976)	20 Alcoholics receiving BSCT 19 Alcoholics trained in abstinence	% days functioning well	24 mo	83.1	40.7	+1.28	.35
Caddy *et al*.(1978)	13 Alcoholics receiving BSCT 14 Alcoholics trained in abstinence	% days functioning well	36 mo	94.8	74.9	+0.32	.39
Baker *et al*.(1975)	29 Alcoholics receiving BSCT 9 Alcoholics receiving standard program	% days sober	6mo	56.7	47.3	+0.48	.39
Volger *et al*. (1975)	23 Alcoholics receiving BSCT 19 Alcoholics receiving standard program	Monthly consumption	6 mo	37.0	78.9	+0.95	.34
			12mo	38.7	68.8	+0.68	.33
Stimmel et al. (1983)	17 Alcoholics receiving BSCT 2 16 Alcoholics trained in abstinence 2	2- Day alcohol consumption 3	2.5 yr	-1.5	+1.6	+0.32	.35
	17 Alcoholics receiving BSCT2 36 Alcoholics receiving standards program	2-Day alcohol consumption 3	2.5 yr	-1.5	-4.4	-0.30	.30
Foy *et al*. (1983)	30 Alcohol receiving BSCT 32 Alcoholics receiving standard program	% days functioning well	12mo	72.4	83.6	-0.51	.26

When combined these results give a non-significant trend in favour of BSCT (effect size=0.21, p=0.09). The heterogeneity is highly significant $X^2(6)=22.6$, $p<0.001$. The major contributor to this is clearly the marginally significant adverse effect noted in the study by Foy.

Table 5 - 2 Randomized Control Studies on Behavioural Self-control Training for Dependent Drinking: Discrete Outcome Measures (Walters, 2000)

			Length of	Mean Scores		Effect size	
Study	**Sample**	**Outcome Measure**	**Follow-Up**	**BSCT**	**Control**	***d***	**SE**
Sobell & Sobell (1976)	20 Alcoholics receiving BSCT 19 alcoholics trained in abstinence	Rates improved by collateral	24 mo	85.0	42.1	+1.13	.39
Caddy *et al*. (1978)	13 Alcoholics receiving BSCT 14 alcoholics trained in abstinence	Continuous drunk days	36 mo	38.5	71.4	+.76	.46
Volger (1975)	23 Alcoholics receiving BSCT 19 Alcoholics receiving standard program	Abstinent/control drinking	12mo.	65.2	57.9	+.17	.24
Pomerleau *et al*. (1978)	18 Alcoholics receiving BSCT 14 Alcoholics trained in abstinence	Abstinent/improved	12mo.	72.0	50.0	+.52	.41
Stimmel (1983)	42 alcoholics receiving BSCT 42 Alcoholics trained in abstinence	Undesirable departure	2.5 yr	26.2	33.3	+.19	.26
	42 Alcoholics receiving BSCT 43 Alcoholics receiving standards program	Undesirable departure	2.5 yr	26.2	37.2	+.28	.26

When combined these results give a significant result in favour of BSCT (effect size=0.40, $p<0.005$). The heterogeneity is not significant. Note that the study by Foy, which was negative for the continuous outcomes in the preceding table, did not contribute to this analysis

It is worth commenting that the one trial which gave significant negative results for BSCT (Foy *et al*., 1984) tested simply those parts of the strategy aimed at controlled drinking; blood alcohol discrimination, responsible drinking skills and social drinking practice sessions. Both arms received broad-spectrum behavioural treatment. Furthermore, there was a major imbalance between treatment arms with the pre-treatment abusive days being 22% higher in the BSCT group (201.6) compared to the control group (164.6). When corrected for this imbalance, the change in abusive days over 12 months was identical in the two treatment arms. Thus it seems likely that this trial suggests that the three element listed above may add little to the overall programme but does not suggest that BSCT has a net negative effect.

This review generally appears to support the effectiveness of the BSCT approach in promoting controlled drinking.

5.5.1.2 Cognitive Behaviour Therapy in alcohol dependence

Cognitive Behaviour Therapy provides a conceptual model, which has been widely adapted to treatment of drug and alcohol abuse. Many of the interventions discussed in this report borrow ideas from it. However, this very ubiquity makes it difficult to identify any clear set of therapies, which should contribute to a meta-analysis of CBT in alcohol therapy. The Mesa Grande Project (Miller & Heather, 1998) a comprehensive assessment of alcohol interventions, does not allot a unique category to CBT. By contrast, Project MATCH, possibly the largest clinical trial of alcohol treatments, includes a treatment option labelled CBT.

CBT in Project MATCH was designed to help patients understand their thoughts and feelings and how these trigger behaviours. The goal was to provide clients with coping skills in high-risk situations that could contribute to relapse. This included management of anger, depression and interpersonal difficulties. A similar approach has been classified by others (Wolwer, 2001) as Coping Skills Training.

Morgenstern & Longabaugh (2000) reviewed CBT for alcohol dependence with the specific objective of investigating its hypothesized mechanism of action. CBT is described as care packages which *use a standard set of skills that include identification of specific situations where coping inadequacies occur, and the use of instruction, modelling, role plays and behavioural rehearsal.* These authors considered CBT to be similar in nature to Social Skills Training. They included interventions labelled as relapse prevention, social skills training or cognitive-behavioural approaches.

Interestingly, the authors of this study conclude that, although CBT clearly is effective, the studies provide no evidence to support its hypothesized mechanism.

The conclusion we draw from the discussion on CBT in the studies mentioned above is that it does not, for the purposes of systematic review, constitute a single intervention. Rather it is a model underlying many of the psychosocial interventions.

5.5.1.3 Brief Intervention

Wilk et al. (1997) undertook a review of studies of brief intervention (BI) in heavy alcohol drinkers. These BIs were less than one hour in duration.

The literature search of Medline and PsychLIT covered 1966 to 1995 and did not exclude dependence. Thus studies relevant to this HTA should have been identified. However, most of the trials had 'dependence' as a specific exclusion criterion.

The odds ratio for moderation of drinking with BI compared to no intervention was estimated to be 1.95 (1.66, 2.30). However, the authors note that *generalizability of our results must be limited to less severely affected drinkers who exhibit little or no alcohol dependence.*

A further meta-analysis of BI was carried out by Poikalainen (1999). Two additional studies (Fleming *et al*., 1997); (Nilssen, 1991) were identified and three, included in Wilk, were excluded (Babor & Grant, 1992); (Chick *et al*., 1985); (Antti-Poika *et al*., 1988) on the basis that they included some hospital patients.

Oddly, since the excluded studies would seem likely to contain more severely affected patients, Poikolainen (1999) estimated smaller treatment effects than Wilk et al. (1997). He noted only that BI decreased alcohol consumption in women.

These studies seem to provide no evidence for or against the use of very brief interventions in dependent patients.

Currently the most comprehensive review of brief interventions (Moyer *et al*., 2002) identified a total of 56 studies including all those in the Wilk et al. (1997) and Poikolainen (1999). Thirty-four (34) studies were in non-treatment seeking and 22 in treatment-seeking patients. Of the 22 studies in treatment-seeking subjects, 20 compared to a more extensive intervention and 10 of these did not exclude alcohol dependent patients.

The distinction between non-treatment-seeking and treatment-seeking patients is important because the latter group is likely to contain those with severe alcohol problems.

The authors' primary finding in respect of these groups is stated as *Brief interventions were effective compared to control conditions in studies where more severely affected individuals were excluded; brief interventions were not more effective than control conditions in studies where more severely affected persons were not excluded. This finding suggests that, at least during this period in the post-treatment course (3-6 months), such interventions – which usually consist of a single session of advice, often accompanied by feedback and delivered in a health-care setting – are useful only for patients with less severe drinking problems.*

Almost all studies in treatment seeking subjects compared brief interventions with the longer interventions. Thus this is a more severe test than the no-treatment comparisons often made in less severely affected subjects. However, there is a suggestion that brief interventions were less effective than these longer interventions.

The alcohol consumption was significantly higher in the brief intervention group after 3-6 months of follow-up ($p<0.01$) and a composite drinking-related outcome showed an adverse trend ($p=0.072$). These are the only outcomes reported.

This study added appreciably to the previous reviews in that it showed not only that brief intervention is unsupported in treatment of alcohol dependent patients, but that it may be less effective than other measures.

5.5.1.4 Motivational Interviewing (MI)

Dunn *et al*. (2001) investigated the MI method described by Rollnick & Miller (1995). This analysis was not restricted to alcohol dependence but 17 studies were in substance abuse and 7 of these included dependent patients and measured an alcohol related outcome. Only four studies included only dependent patients. Although very brief interventions were included, there appears to be no overlap with the studies in the reviews of BI by (Wilk *et al*., 1997) and (Poikolainen, 1999).

The literature search used Medline, PsychInfo and Dissertation Abstracts International from 1983 to 1999 and looked for 'motivational intervention', 'motivational interviewing', 'motivational counselling', and 'brief intervention'.

The authors recorded both the time taken to deliver MI and, when available, the time taken to train staff to deliver MI. The latter averaged 15 hours.

Table 5 - 3 Drinking Related Outcomes in studies of Motivational Interviewing (Dunn et al., 2001)

Study	Time	Outcomes	Control	Effect size (95% CI)
ALL DEPENDENT PATIENTS				
Bien (1993) N=31	3 months	Drinks per week	Inactive	0.72 (-0.07, 1.52)
		Percentage of days abstinent	Inactive	0.30 (-0.47, 1.08)
		Composite index	Inactive	**0.83 (0.03, 1.63)**
	6 months	Drinks per week	Inactive	0.35 (0.43, 1.12)
		Days abstinent (%)	Inactive	-0.20 (-0.97, 0.58)
		Composite index	Inactive	0.14 (-0.63, 0.91)
Project MATCH (1997a) N=1726	9-month (o/p arm)	Drinking consequences	CBT	-0.09 (-0.28, 0.11)
		Drinking consequences	TSF	**-0.30 (-0.49, -0.12)**
	15-month (o/p arm)	Drinking consequences	CBT	-0.01 (-0.20, 0.19)
		Drinking consequences	TSF	-0.18 (-0.37, 0.01)
	9-month (aftercare)	Drinking consequences	CBT	-0.02 (-0.23, 0.20)
		Drinking consequences	TSF	-0.02 (-0.24, 0.19)
	15-month (aftercare)	Drinking consequences	CBT	0.09 (-0.13, 0.31)
		Drinking consequences	TSF	0.16 (-0.05, 0.38)
Wertz (1994) N=42	1-Month	Days in treatment	Inactive	-0.08 (-0.68, 0.53)
		Number standard drinks	Inactive	0.43 (-0.44, 1.30)
SOME DEPENDENT PATIENTS				
Gentilello (1999) N=762	6 month	Drinks per week	Inactive	-0.08 (-0.26, 0.11)
	12-month	Drinks per week	Inactive	0.09 (-0.12,0.31)
Handmaker (1999) N=42	2-month	Total alcohol consumption	Inactive	0.03 (-0.64, 0.71)
		Abstinent days	Inactive	0.38 (-0.30, 1.05)
Heather (1996) N=174	6 month	Drinks per week	Inactive	0.16 (-0.29, 0.60)
		Drinks per week	SG	0.35 9-0.07, 0.76)
Schneider (1999) N=89	3-month	Alcohol Addiction Severity Index	Inactive	0.24 (-0.17, 0.66)
		Standard drinks past 30 days	Inactive	-0.09 (-0.51, 0.31)
	9-month	Alc Addiction Sev. Ind	Inactive	**0.42 (0.00, 0.84)**
		Standard drinks in 30 days	Inactive	-0.01 (-0.43, 0.41)

Statistically significant results are in bold type

The authors note that the best evidence for MI effectiveness found by this review was when it was used as an enhancement to more intensive substance abuse treatment.

In the context of the present assessment, in which we are interested in the effects for alcohol dependent patients, it may be appropriate to be cautious. Only two statistically significant effects were observed in trials that included a substantial majority of such patients. A study of 42 patients found a benefit in terms of a composite drinking index (Bien *et al*., 1993) and Project MATCH found a significant adverse effect in outpatients on 'drinking consequences' at 9 months relative to a 12 steps approach. The outpatient group in Project MATCH included 952 persons and the p value for differences between the treatment arms in drinking consequences at 9 months was 0.006.

This review and our own meta-analysis (see section 5.6) supports MI as an effective part of more extensive psychosocial treatment. However the results of Project MATCH suggest that it should not be used as a short stand-alone treatment in the manner of that study (4 sessions).

5.5.1.5 Family Therapy

O'Farrell (2001) reviewed trials with family involvement in the treatment of alcoholism.

Twenty-two relevant studies were identified. The literature search methods are not reported but it is noted that studies were included if spouses and/or other family members were involved in the treatment of an alcoholic adult. This term appears to imply alcohol dependence. Trials were divided into those in which the alcoholic adults were unwilling to seek treatment and those in which they had sought help. In the former the outcome measures were either family coping or initiation of change, in the latter they were generally measures of reduction in drinking. All trials included a randomised control group, which was either 'wait-list', i.e. deferred treatment, or another intervention without family involvement.

The review combines the results of the studies in a meta-analysis. Outcome measures, although differing in nature between studies, were grouped by underlying theme (see Table 5-4). Statistically significant benefits of family involvement compared with wait-list controls or individual therapy are reported in each outcome.

Table 5 - 4 Effect of Family Involvement in Treatment (O'Farrell, 2001)

Outcome	No. Studies	Subjects	Median r	p value
Alcohol Use	16	692	0.30	$2x10^{-10}$
Treatment attendance	3	106	0.32	0.007
Couple/family adjustment	11	413	0.17	0.035
Patient adjustment	10	309	0.21	$2x10^{-5}$
Spouse/family member adj.	6	348	0.26	$2x10^{-5}$

The use of Pearson's r as an outcome measure and the absence of data from individual studies tend to obscure the clinical meaning of these results. The authors give a rule of thumb (r=0.1 is small, r=0.3 medium, r=0.5 large) however this appears quite arbitrary. They also note that the effect size in the Physicians Health Study of aspirin was only r=0.03.

A number of different interventions are included under the portmanteau term family therapy. The paper also examined the efficacy with respect to persuading reluctant patients to seek treatment. The authors note that the only form of family therapy that does not appear to increase engagement in treatment programmes is the Johnson Institute Intervention, which involves training family members to confront the patient. This may be because the family member will often decide against the planned confrontation.

There are a number of difficulties with respect to O'Farrell's analysis. Although overall results are presented, there is only a narrative discussion of the individual studies and the measures used as input for the meta-analysis are not presented. Furthermore, it is clear that the very wide inclusion criteria resulted in the combination of qualitatively different interventions varying from the highly intensive Community Reinforcement Approach to the simple addition of a disulfiram contract to individual therapy.

Whilst there appears to be some support for inclusion of family members in treatment the nature of their involvement and the clinical significance of any benefit is left unresolved.

O'Farrell's own study of couples relapse prevention is of particular interest because it studied long-term effects. Couples were started on the treatment after an initial 5 months of BCT. The results suggested that useful treatment effects were sustained at 18 months. Thus long-term treatment may be an important aspect of relapse prevention.

5.5.1.6 Classical Relapse Prevention

It is important to distinguish the general theme of 'prevention of relapse' from the conceptual model underlying a number of interventions – confusingly referred to as 'relapse prevention'. This section addresses interventions based on this conceptual model, which is founded on the belief (Marlatt & Gordon, 1985) that there is a common mechanism underlying the process of relapse – whether in alcohol dependence, smoking, gambling or any other dependence. Thus therapy may target many areas not obviously related to alcohol intake. In this model relapse is viewed as a natural part of a process of change rather than as a failure. From a pragmatic point of view, many of the component parts of the interventions labelled as relapse prevention will be similar to other psychosocial methods, for example, identification of high risk situations and coping skills training. However, the distinguishing mark of this approach is the emphasis on learning to respond to and learn from lapses.

Irvin (1999) examined the efficacy of Relapse Prevention and undertook a meta-analysis. This meta-analysis examined the efficacy of relapse prevention in a range of addictive behaviours. However, ten of the 26 studies examined the use of this technique in alcohol and hence are potentially relevant to the present HTA.

All outcome measures were converted to weighted average correlation coefficients. The effect size estimated for alcohol treatment was r=0.37 (95% CI 0.28 to 0.45). This effect size represents a statistically significant benefit but is not easily interpretable in terms of clinical effects.

The quality of this review is in some doubt. For instance a positive effect of Relapse Prevention is attributed to one factorial trial of coping skills/relapse prevention against supportive therapy and naltrexone against placebo (O'Malley *et al*., 1992). In fact there appears to be a trend for coping skills/RP to give worse results than supportive therapy in terms of the proportion without relapse and very similar results in other outcomes. The test of significance from which the review result is derived appears to be a test of interaction between naltrexone and the psychosocial treatment for interviewer ratings of psychological problems.

Two of the publications reviewed (Maisto *et al*., 1995); (O'Farrell *et al*., 1993) are different reports of the same study. A subset of the patients is examined in Maisto *et al*. Moreover, the subset is restricted to those patients who suffered a relapse, hence it no longer represents a randomised comparison.

On inspection it is clear that the majority of 'treatment effects' quoted in this report are not relative to no treatment or a control treatment but are assessed on the basis of pre and post intervention results or compared with 'discussion controls'. The authors state that they are 'somewhat perplexed' by the fact that the only study comparing relapse prevention with no-additional-treatment found only a weak effect. A possible reason for this is that the majority of their results are confounded with placebo effects, which are known to be quite powerful in this therapeutic area.

An article not included in the review is that by Allsop and Saunders (1997) that reports a study carried out in Scotland in which 60 patients with a diagnosis of alcohol dependence were 'randomised' to Relapse Prevention (RP) or to a relapse discussion treatment or to no additional treatment. Allocation was in fact not random but alternated in pairs.

The RP therapy consisted of eight 1-hour sessions intended to (1) develop, enhance and sustain commitment to change (2) identify individual relapse precipitants (3) develop coping skills (4) increase self-efficacy (5) encourage recognition that strategies are available to prevent relapse in case of lapse.

The discussion group used the same exercises as RP for enhancing commitment but otherwise shared the patients' personal strategies for avoiding relapse.

Outcome was assessed immediately post treatment, at 6 months and at 1 year. Number of weeks abstinent, drinking moderately, drinking heavily or functioning poorly ($\geq$ 1 day in prison or hospital) was assessed at 6 months and 1 year. Time to first drink and time to first heavy drinking session (relapse) were also examined. It was assumed that patients who could not be contacted had relapsed.

The median times to relapse for the RP, discussion and no treatment groups were 189, 51.5 and 26.5 days. This was a statistically significant difference between survival curves (Log rank $p<0.03$).

Table 5 - 5 Drinking Behaviour at 6-month Follow-up (Allsop & Saunders, 1997)

	Relapse Prevention	**Discussion group**	**Control group**
Contacted for Interview (n)	18	20	19
Totally abstinent over follow-up (n)	8	1	1
	Mean values		
Alcohol consumed in 7 days prior to interview	29.2	50.6	68.7
Weeks abstinent (n)	16.0	9.8	8.4
Weeks moderate drinking (n)	4.0	5.2	1.0
Weeks heavy drinking (n)	5.6	10.6	13.4
Weeks functioning well (n)	19.4	14.9	9.4

Table 5 - 6 Drinking Behaviour at 12-month Follow-up (Allsop & Saunders, 1997)

	Relapse Prevention	Discussion group	Control group
Contacted for interview (n)	15	20	14
Totally abstinent over follow-up (n)	4	1	0
	Mean values		
Alcohol consumed in 7 days prior to interview	59.9	52.0	21.4
Weeks abstinent (n)	10.1	8.2	9.0
Weeks moderate drinking (n)	4.0	3.3	3.3
Weeks heavy drinking (n)	7.8	14.2	11.2
Weeks functioning well (n)	14.1	11.5	12.3

Thirty six (90%) of 40 patients in the two control arms relapsed over 1 year. This compares with 14 (70%) of 20 in the RP group. This is not a statistically significant difference.

5.5.1.7 Intensive case management

Many interventions combine psychological interventions with practical help in other areas of the subjects lifestyle. For instance the Community Reinforcement Approach may involve helping the client find a job, find a home and also to achieve a more rewarding social life. The literature suggests that some interest surrounds the question of the extent to which alcohol dependence behaviour can be modified purely by altering the physical circumstances of the people affected .

Cox *et al*. (1998) examined the effect of an 'intensive case management (CM)' strategy for people with an extensive history of alcohol abuse and treatment failures. This involved practical social support focused on improving welfare. The aims were to stabilize the patients financial condition and housing status and to encourage reduction of substance use. One hundred and fifty (150) subject were randomised to CM and 148 to control.

Follow-up was at 6 month intervals for 2 years. The primary analysis was based on repeated measures and required complete follow-up data. This limited the analysable group to 193 (65%) out of the randomised 298.

Statistically significant improvements between groups were noted in the three primary variables (Public income p=0.043, Own residence p=0.04, Days of drinking p=0.009). There were also changes over time in own residence and days of drinking which suggest a gradual improvement.

Table 5 - 7 Group Means for Dependent Variables for Subjects who had 6-, 12- and 18-month Follow-ups (Cox et al., 1998)

	N	Baseline	6-month	12-month	18-month
		PRIMARY DEPENDENT VARIABLES			
Public Income in last 30 days (dollars)					
Control	84	218	198	262	269
CM	105	238	343	303	358
Difference		20	45	41	89
Nights in own residence in last 60 days					
Control	83	7.1	10.3	17.8	21.7
CM	108	9.5	19.4	24.0	25.4
Difference		2.4	9.1	6.2	3.7
Days of drinking (any alcohol use) in last 30 days					
Control	85	23.8	17.8	14.8	15.3
CM	108	23.6	14.6	12.3	11.3
Difference		-0.2	-3.2	-2.5	-4.0
		SECONDARY DEPENDENT VARIABLES			
Days using alcohol since last interview					
Control	83	NA	123	97	99
CM	105	NA	102	78	70
Difference			-21	-19	-29
Detox admissions in prior 6 months					
Control	85	8.1	11.5	5.7	5.1
CM	107	8.8	9.1	3.6	2.4
Difference		0.7	-2.4	-2.1	-2.7
Days alcohol problems in last 30 days					
Control	80	22.6	15.8	16.3	16.3
CM	105	22.4	15.3	14.8	12.7
Difference		-0.2	-0.5	-1.5	-3.6
Troubled or bothered by alcohol problems					
Control	85	2.9	2.4	2.1	2.1
CM	107	2.7	2.2	2.0	1.6
Difference		-0.2	-0.2	-0.1	-0.5

The imbalance in numbers followed up is clear from Table 5 - 7 Group Means for Dependent Variables for Subjects who had 6-, 12- and 18-month Follow-ups (Cox et al., 1998). This is a weakness of the analysis.
The authors note that their intervention is expensive – one case manager was assigned to each 15 patients – but also appears effective.

Far simpler case management techniques have also been tested (Hilton *et al*., 2001). Stout *et al*. tested a low-cost, long-term procedure for maintaining contact with dependent people during periods when they are at elevated risk for relapse. The intervention involved telephone contacts on a tapering schedule for 2 years. Three hundred and forty two patients were randomised and the follow-up rate was 80%. Follow-up data and health cost data were collected for 3 years. There was a statistically significant ($p < 0.05$) treatment effect on percentage of days of heavy drinking during the third year. The frequency of heavy drinking was twice as high in the controls (mean = 24%) than the case-monitored subjects (mean = 12%).

Whilst these studies only constitute limited evidence, they suggest that practical social interventions, whether to keep clients housed and aid with appropriate use of the welfare system or simple contact over time, may have a beneficial effect on alcohol intake. Some supporting evidence for this is supplied by the good performance of the Community Reinforcement Approach, ranked seventh in the Mesa Grande table of interventions (Section 5.4.1), which has substantial elements of social intervention.

5.5.1.8 Conclusions on psychosocial imterventions

In the preceeding sections a number of psychosocial interventions were found to be of value in preventing relapse in alcohol dependence. These included Motivational Interviewing, Family/Relationship therapy, Behavioural Self Control Training and Coping/Communications Skills training.

Many different outcomes are used in trials of these therapies and meta-analyses identified in the literature have used generalised outcome measures without clear clinical interpretation. A meta-analysis of success rates – either abstinence or controlled drinking – at the end of study shows no clear differences in effect size between these treatments. See section 5.6.

Even effective treatments will fail in around half the patients. The total combined success rates, in terms of abstinence or controlled drinking at the trial end (varying between 6 months and beyond one year), in trials of those psychosocial treatments judged effective was 43% for treated patients and 28% for those receiving control treatments.

No support was found for the efficacy of Brief interventions or classical Relapse Prevention therapy in dependent patients.

The efficacy of purely social interventions has some support, which suggests that this may form an important component of a comprehensive service.

5.5.2 Pharmacological Interventions

The commonly accepted view of the role of pharmacological interventions in the prevention of relapse into alcohol dependence is that they are subsidiary to the psychosocial interventions. Thus they should not be considered as alternative therapies and any treatment programme will contain a psychosocial element but may have an additional pharmacological component. The question, which needs to be addressed in assessing the pharmacological intervention, is whether, for the targeted group of patients, additional net benefit is obtained above that from the psychosocial treatment.

This HTA covers only those pharmacological products, which are currently in widespread use for the specific indication of 'relapse prevention'. This includes two products with UK Marketing Authorisations, acamprosate and disulfiram, but also naltrexone about which there is an extensive literature and which has marketing authorisations both in the US and in some EU member states.

Much of the work to demonstrate the effectiveness of pharmacological interventions comes from clinical trials aimed at providing information for Marketing Authorisation (licensing) applications and has been either designed or sponsored by manufacturers. Thus each manufacturer was given the opportunity to submit evidence regarding their products.

5.5.2.1 Acamprosate

Medication with acamprosate appears to decrease craving and counter the reinforcing properties of alcohol. Although sometimes referred to as a GABA agonist, the mechanism by which it affects the use of alcohol is not known. The manufacturer's Summary of Product Characteristics is reproduced as Appendix 19.

5.5.2.1.1 Information submitted by Merck Pharmaceuticals

An expert report previously supplied to UK regulatory authorities and dated 1994 was supplied (Sass, 1994). The author, Professor Sass, was the principal investigator in a clinical trial of acamprosate, the PRAMA study.

The expert report provided lists 2 phase II and 10 phase III double-blind, placebo controlled trials of acamprosate. In these trials 1839 patients were allocated campral at the licensed dosage for treatment periods between 90 and 360 days. 1601 patients were allocated placebo. All patients entering the studies had undergone a detoxification programme. Patients in these studies generally received psychosocial interventions in addition to the randomised treatment. It is not clear which psychosocial interventions were used.

A number of measures of relapse were collected for assessment of efficacy. These included total abstinence at each visit, time to irrevocable failure, and cumulative abstinence. In three studies (PRAMA, BENELUX, Pelc II) outcome data were confirmed by breathalyzer, urine analysis or evidence from relatives.

High drop-out rates were a problem in all studies. At 90 days 64% of the patients randomised to placebo were followed up and 67% of those randomised to acamprosate. By 180 days the figures had fallen to 49% and 56%. Intention to Treat (ITT) analyses, which assumed failure in non-attenders were carried out.

Failure to attend for follow-up is a problem in most studies of alcohol dependent subjects. If all patients who do not attend for assessment are taken as having relapsed it is impossible to tell the difference between a relapse preventing agent and one, which increases the probability of presenting. Any treatment, which had a benefit – say an antidepressant effect – might increase the probability of presenting. Thus it is important that analysis of attenders should agree qualitatively with the ITT analysis. The assumption that DNA (Did Not Attend) was equivalent to relapse should also be checked.

In addition to the expert report some reports of individual studies were also supplied. A brief description is given below but results of these studies are presented in the HTBS analysis.

The PRAMA study (Schadlich & Brecht, 1998) enrolled 272 newly detoxified (14-28 days) alcohol dependent patients in Germany. They were randomized to 48 weeks of either acamprosate or placebo and then followed up for a further 48 weeks. Patient with psychiatric problems were excluded. All patients received weekly counselling or psychotherapy for a mean period of 18 weeks and then met in fortnightly contact groups. Dosage was 1998mg/d (2x333mg t.i.d) with a 2/3 dose for those with body weight less than 60kg. Assessment was every 4 weeks for 12 weeks and then every 12 weeks. Drinking status was checked by breath testing and GGT. The primary outcome was abstinence. Primary analysis was ITT but per-protocol (PP) was also done. The drop-out rate was high, 134 (49.3%) of patients remained in the study at 1 year. The drop-outs were not balanced between treatments: 57 acamprosate, 81 placebo.

An uncontrolled study of 614 Belgian patients on acamprosate was also supplied to describe the demography and concomitant treatments used over 24 months (Ansoms *et al*., 2000). Measures of outcome were also recorded and drinking episodes were classified as lapse, binge or relapse. Patients included had no other major illness and were actively drinking within the 7 days before study inclusion. Only 517/614 (84%) eventually fulfilled the study inclusion criteria. A further 174 dropped out over the study period.

It is difficult to extrapolate the data from this study. Many patients in clinical practice would not satisfy the entry criteria. However, rough estimates of drinking behaviour can be obtained from the paper.

A brief digest of evidence concerning acamprosate from the British J of Clinical Governance (Earl-Slater, 1999) was also supplied. Effectiveness data are based on three randomised controlled trials (Paille *et al*., 1995); (Whitworth & Fischer, 1996); (Sass, 1996). This is not a meta-analysis but a checklist of issues related to the use of acamprosate in alcohol dependence.

The Lancet report of a study by Whitworth et al was also supplied. Data from this and PRAMA have been extracted and are included in the main effectiveness analysis for the economic model inputs.

A review of the pharmacological treatment of alcohol dependence by Garbutt et al. (1999) covers acamprosate, naltrexone and disulfiram in addition to SSRIs, lithium, buspirone and ondansetron. Randomized controlled trials in alcohol dependent patients were included but so were other forms of controlled study and review articles. Nine studies of acamprosate, 9 of disulfiram (4 oral, 5 implanted), and 3 of naltrexone are assessed. Meta-analysis or other modeling to combine trial results is not attempted. The reviewers consider that acamprosate and naltrexone had consistent proof of efficacy compared to placebo from sufficient data. Disulfiram had inconsistent evidence from sufficient data. This was based on positive evidence that disulfiram reduced the number of drinking days but mixed results for other outcomes. The total drop-out rates in the trials are tabulated but the way that drop-outs are accounted in the analysis is not reported. Relative drop-out rates are not reported. The time period for the naltrexone trials was only 12 weeks and longer-term evidence would have been desirable.

Another review by Mason & Ownby (2000) assesses only trials of acamprosate. It includes all the trials reviewed by Garbutt et al. (1999) with the exception of a small, four week study by Gerra (1992). Six additional placebo controlled trials are included and a trial of acamprosate combined with disulfiram. It is noted that a large US study was still to report and data could not be included. The statement of interest notes that Dr Mason is a consultant to the manufacturer of acamprosate. In these studies missed visits were counted as non-abstinence and biological markers and collateral reports were preferred to self-reports in the case of discrepancies. A meta-analysis of 15 European RCTs is referred to but not described or the results reported. The summary notes that 14 of 16 placebo controlled RCTs found positive treatment effects for acamprosate. (exceptions were Roussaux et al. (1996); Chick et al. (2000)). The authors suggest that delays in initiating treatment following detoxification in the study by Chick may have contributed to the lack of treatment effect.

A further review by Mason was published in 2001. This collated but did not meta-analyse all the available European trials of acamprosate. It is noted that only 2 of 15 trials failed to show a significant effect on primary outcome (Roussaux *et al*., 1996); (Chick *et al*., 2000). A new US study in which Dr Mason is involved is mentioned but not reported.

A summary, an abstract and a report by Soyka describe an observational study (Integral) of various psychosocial interventions with acamprosate. Patients given individual psychotherapy (242), group psychotherapy (183), CBT/coping strategy (122) and brief intervention (204) were found to have almost identical results for complete abstinence – about 55% at 24 weeks. Per protocol cumulative abstinent days were also the same for each intervention – about 127 days. ITT days to first relapse was 74.5. Conflicting results for PP time to first relapse are provided, a graph shows about 128 days but the abstract gives 159 days.

These data do not contain comparative information on acamprosate but provide estimates for effects under conditions closer to clinical practice than those in a clinical trial. The quality of reporting was judged to be poor.

5.5.2.1.2 Evidence from literature search

There appear to be 18 controlled trials of acamprosate in alcohol dependence for which results are currently available. The large US multicentre study of acamprosate has finished and some results were released in abstract form in 2001 but the manufacturers do not wish to release the detailed by-treatment results until 2003.

HTBS effectiveness calculations are reported in section 5.6.

5.5.2.2 Disulfiram

Disulfiram is an antidipsotropic agent. In other words it induces adverse reactions when alcohol is taken. The manufacturer's (Alpharma) Summary of Product Characteristics is included as Appendix 20.

5.5.2.2.1 Submission from Alpharma

Alpharma has supplied some general commentary and literature on the efficacy of disulfiram. They note that, in general, modern controlled trials are not available.

A literature review by Brewer (1992) discusses several studies often of an uncontrolled nature. It is concluded that supervised disulfiram can be effective but that unsupervised disulfiram is of no proven benefit.

One controlled study discussed by Brewer is that by Fuller *et al*. (1986) This was a three arm study in which 605 men received either 250mg of disulfiram (202), 1mg of disulfiram (204), or no disulfiram (199) for one year. The patients were unblinded to whether they received disulfiram but did not know that they might receive an ineffective dose. Single patients were excluded, as social support was considered important for the trial. Follow-up was for one year. No differences in total abstinence or time to first drink were found. However, among those who did drink a reduced frequency of drinking was noted in the 250mg disulfiram group.

A paper by Besson *et al*. (1998) reported a placebo controlled randomized trial of acamprosate in which the (unrandomised) use of disulfiram was also recorded. It was concluded that the concomitant use of disulfiram improved the effectiveness of acamprosate. Results from a single unrandomised study would not generally be considered sufficiently convincing to warrant arecommendation about clinical practice.

5.5.2.2.2 Evidence from literature search

A discussion of the use of disulfiram is given by O'Farrell *et al*. (1995). These authors remark that various methods have been used to reinforce compliance with a disulfiram regimen. They note that disulfiram implants have not been found to be effective because of inadequate levels of disulfiram release and adverse effects. Various incentives to persevere with disulfiram have also been tried and generally found, to some extent, to work. However, the most common and extensively researched method has been a formally and publicly agreed contract, between the patient and a significant other – usual the wife or husband. Such contracts have also been tried within the context of a Community Reinforcement Approach (CRA) (Hunt & Azrin, 1973). This has been tested in Azrin (1976) and Azrin et al. (1982). This latter study suggested that, for married subjects, the contract alone is as good as the contract with CRA. However, CRA appeared to be important for single patients. The authors conclude by noting that previous research has failed to differentiate the effect of recommending disulfiram from the effect of reinforcing compliance through contracts and they recommend further research which includes a double-blind factorial trial of disulfiram (clinical versus nominal dose) and compliance enhancement (present versus absent).

It is difficult to see how compliance enhancement could be double-blind and it is not clear that blinded use of disulfiram is appropriate since the treatment effect appears to be due to fear of an adverse reaction from drinking. This fear will still be present if the subjects think themselves to be taking disulfiram and hence the appropriate clinical effect can be measured only in an open treatment trial. Any effect found in a

blinded trial can only be due to un-blinding caused by exposure to alcohol or some other uncontrolled effect of the drug.

The HTBS analysis of effectiveness is reported in section 5.6

5.5.2.3 Naltrexone

Naltrexone is an opioid antagonist, which is administered to reduce drinking and craving. It is not currently licensed in the UK for this indication but the manufacturer's Summary of Product Characteristics for the Republic of Ireland is included as Appendix 21. In the Republic of Ireland it is licensed for use within a comprehensive treatment programme for alcohol dependence to reduce risk of relapse, support abstinence and reduce alcohol craving.

5.5.2.3.1 Submission from Dupont Pharma

Naltrexone was initially developed for use in opioid addiction but then found to reduce alcohol craving. As a consequence of its effect on opioid receptors current dependence on opioids must be ruled out before use in alcohol dependence.

The product summary discusses two 12 week randomized placebo controlled trials (Volpicelli *et al*., 1992); (O'Malley *et al*., 1992). A combined analysis of the two efficacy trials authored by O'Malley, Volpicelli and three employees of Dupont (O'Malley *et al*., 1995) is included in the submission. The combined results showed statistically significant benefits in favour of naltrexone in time to first drink ($p=0.002$) and time to first episode of heavy drinking ($p<0.001$). During 12 weeks 75% of naltrexone and 48% of placebo treated patients did not have an episode of heavy drinking. Fifty-four percent (54%) of naltrexone and 31% of placebo treated patients were abstinent. An interesting finding of these studies was that patients who were non-abstinent were at significantly lower risk of heavy drinking when on naltrexone. This was not a prespecified hypothesis of either study. Both the percentage of drinking days and craving scores also showed significant benefit in favour of naltrexone.

These were fairly small (combined n=186) and short-term studies. However, they are well reported and appear well conducted.

5.5.2.3.2 Evidence from literature

There has been considerable recent interest in testing naltrexone for alcohol dependence and there appear to be 24 published and one unpublished clinical trial.

Analysis of data from the trials is reported in section 5.6

5.5.2.4 Comparison of acamprosate and naltrexone

A meta-analysis by Kranzler and Van Kirk (2001) was motivated by the absence of direct comparative studies of naltrexone and acamprosate. They thus attempted to collate and contrast the evidence from placebo-controlled trials of each treatment.

Nine naltrexone and 11 acamprosate studies were included. All outcome measures were assessed in intention-to-treat analyses. Two further acamprosate studies, Lhuintre *et al*. (1985) and Lhuintre *et al*. (1990), were omitted because of methodological concerns.

The measures combined across studies were differences in proportions of successes between groups. When continuous measures were reported the standardized mean difference was used.

Comparisons were made of the percentage of patients abstinent at the end of the study, the cumulative abstinent days, and the percentage retention. These comparisons did not show differences between the performance measured in the acamprosate studies and that measured in the naltrexone studies. Both treatments had highly statistically significant benefits in these measures relative to placebo.

Heterogeneity was noted in the estimates of the effect of naltrexone on the percentage of drinking days and the effect of acamprosate on cumulative abstinent days. These effects were found to be significantly correlated with recency of study for naltrexone – effects fell with time - and proportion of males for acamprosate – the effect was greater in females.

The authors conclude that both treatments have small but significant benefits in alcohol dependence.

This study appears to be a systematic and comprehensive assessment of the published RCTs for acamprosate and naltrexone. The comparison between acamprosate and naltrexone is, of course, not randomised. Furthermore, absence of a statistically significant difference does not imply absence of a difference – confidence intervals would be useful rather than p values. A difficulty, which is not addressed, is that the length of follow-up in each study is not reported and our own work (see Appendix 21) shows that it varies systematically between trials of acamprosate and of naltrexone. Thus differences in effectiveness are confounded with differences in trial procedures.

Table 5 - 8 Outcome Measures and Mean Effect Sizes for Naltrexone and Acamprosate (Kranzler & Van Kirk, 2001)

Measure	K	N	Effect size R_w (SD)	Effect p-value	Heterogeneity p-value
Naltrexone outcomes					
% Subjects abstinent	8	781	**0.122 (0.066)**	<0.001	0.88
% Drinking days	8	650	**-0.191 (0.195)**	<0.001	< 0.001
Drinks/drinking day	5	439	**-0.067, (0.126)**	0.081	0.14
% Relapse to heavy drinking	7	549	**-0.161 (0.107)**	<0.001	0.36
Retention (%)	7	529	**0.005 (0.132)**	0.45	0.10
Acamprosate outcomes					
% Subjects abstinent	11	3204	**0.114 (0.073)**	<0.001	0.06
Cumulative abstinent days	10	3077	**0.129 (0.088)**	<0.001	0.003)
Retention (%)	10	3077	**0.074 (0.071)**	<0.001	0.08

Positive effect sizes indicate higher means for active medication group; negative effects sizes indicate higher means for placebo group;
K = number of studies contributing effect sizes;
N = total number of subjects contributing to R_w;

5.5.2.5 Conclusions on pharmacological interventions

Acamprosate and naltrexone were both found to be effective as treatments adjunctive to psychosocial interventions. The combined success rates, in terms of abstinence or controlled drinking at the trial end (varying between 3 months and one year), in trials of these treatments was 36% for treated patients and 26% for those receiving placebo treatments.

Use of unsupervised disulfiram was not supported by evidence but limited evidence suggests that supervised disulfiram may be an effective treatment for prevention of relapse.

5.6 Calculation of effectiveness for input to economic analysis

The economic model used in the cost-effectiveness section of this report compares costs of treatment with the long-term health consequences of any treatment-related changes in drinking behaviour. Only limited information is available on the epidemiology of drinking related disease and, in particular, on the relationship between different patterns and quantities of alcohol consumption and risk of disease. Thus a very simple assumption is made that, following treatment, a subject will either be in a controlled (possibly abstinent) state in which disease risks are reduced to that of the general population or will be in an uncontrolled state with high risk of alcohol related disease.

The nature of the model requires that information be available from clinical studies regarding the proportion of patients in each treatment group who are considered treatment successes – i.e. controlled – and those who are failures. Unfortunately, many studies do not make this distinction on a patient by patient basis but report other drinking outcomes, for instance percentage of heavy drinking days. In particular, none of the systematic reviews of psychosocial treatments have reported success rates in this fashion. Consequently the individual studies have been reviewed and these data extracted when possible.

Some difficulties are inherent in extracting this type of information. Different points in time are chosen for outcome measurements in different studies. The choice of success measure may also vary with some studies reporting only abstinence others only controlled drinking and with different definitions of controlled drinking. Studies where subjects are given the choice of aiming for either an abstinent or controlled state may simply report a combined success rate. In analysis we have generally tried to choose outcome measures around one year after treatment but, if these were not available, the closest time point was used. Absolute success rates are likely to vary considerably with time, so analyses are carried out in terms of odds ratios for success between treated and untreated groups. A further complication is the drop-out rate during follow-up in these studies. We adhere to the view that the most reasonable assumption is that those lost to follow-up are likely to be treatment failures and

intention-to-treat calculations have been used when sufficient information is available. However, we also recognise that interventions of very different intensity or duration may induce different drop-out rates for reasons unrelated to treatment failure and that this methodological difficulty introduces an element of uncertainty into our calculations which will not be reflected in confidence intervals.

The method of analysis used is the simple meta-analysis procedure of (DerSimonian & Laird, 1986). Fixed effects estimates are used reflecting concerns about the quality of some smaller studies.

The choice of interventions, which we have analysed, has been guided by the preceding effectiveness discussion. In particular, interventions, which do not seem effective in dependent patients on the basis of more extensive reviews, have been excluded.

A combination of coping skills training and communication skills training has been advocated by Monti and tested in three clinical trials. No formal review of these was revealed by our literature search but they have been reviewed in the HTBS meta-analysis as they form a well-defined group not covered by the other analyses. In Table 5 - 9 Results of meta-analysis for rates of abstinence or controlled drinking (See Appendix 21) they are referred to as Coping Skills studies.

The results of these calculations and further discussion are presented in the economic section of this report and more details of the calculations, including variations in follow-up period and treatment of missing data, are given in Appendix 21. However, for ease of comparison with the other effectiveness results, the main results are reproduced in the following table.[†]

Table 5 - 9 Results of meta-analysis for rates of abstinence or controlled drinking (See Appendix 21)

Intervention	Treated Total N	Control Total N	Odds Ratio (95%CI)	Heterogeneity p-value
Pharmacotherapy				
Acamprosate	2094	1925	**1.82 (1.55,2.14)**	<0.005
Naltrexone	1176	939	**1.40 (1.16,1.69)**	<0.005
Disulfiram	245	241	1.31 (0.81,2.10)	NS
Psychosocial				
Coping Skills	139	146	**2.33 (1.44,3.76)**	NS
Relapse Prevention*	159	174	1.14 (0.70,1.84)	NS
Behavioural Self Control Training	141	135	**1.86 (1.03,3.36)**	NS
Motivational Interviewing	78	118	**2.19 (1.20,3.98)**	NS
Marital/Family Therapy	360	380	**1.81 (1.26,2.61)**	<0.01

[†] Note that there are small differences between these estimates and those presented in the economic section of this report at the consultation phase. These are due to (1) some late arriving data (2) changing from a one-step approximation to the odds ratio to the maximum likelihood estimate (3) an adjustment to the acamprosate effectiveness in the economic analysis to allow for the US study. They make no qualitative differences to any report conclusion.

* Following 'classical' or 'Marlatt' model.

5.7 Safety of relapse prevention interventions

There does not appear to be any literature on adverse effects associated with psychosocial interventions. If any exist they are only reflected in this assessment in so far as they impinge on the effectiveness of treatment.

Use of acamprosate, disulfiram and naltrexone carries some associated risk of adverse effects. Those, which, have been observed in clinical trials or identified by national spontaneous reporting systems are documented in the SPCs for the products. A clinically relevant discussion is given in the International Handbook of Alcohol Dependence and Problems (Heather *et al.*, 2001). The commonest adverse effect of acamprosate (around 10%) is diarrhoea and abdominal discomfort. Clinical trials of naltrexone have consistently revealed higher level of nausea when compared with placebo treated patients and headache, dizziness and weight loss may also be experienced. Disulfiram may cause drowsiness, headache, bad breath or skin rashes. Very rare serious adverse reactions such as liver hypersensitivity (1/25,000) and psychosis have been reported.

5.8 Other Issues

5.8.1 Effectiveness of Alcoholics Anonymous

AA is a self funding organisation outwith the NHS and, as such, not an easy treatment option to test in clinical trials. However, the limited evidence which does exist has been reviewed by other researchers (Kownacki & Shadish, 1999).

This review included both randomised and unrandomised studies comparing AA treatment with either active or inactive control treatments. The nature of the active control treatments is unclear. Treatments were compared in terms of a standardized mean difference to allow combination over different outcome measures. All outcome measures were alcohol related.

Ten randomised studies were identified which fell into three groups. Three studies randomised to AA meetings, two examined inpatient treatment based on AA principles, and five examined only selected facets of the AA approach. The comparisons in these groups gave different results. The comparison of AA meetings with either active or inactive control treatments estimated a statistically significant adverse effect of AA meetings. The comparison of AA based inpatient treatment with other inpatient treatments suggested no difference between the two. However, the individual facets examined (Communication skills to do AA steps vs discussion, Recovered alcoholics as counsellors vs non-alcoholic counsellors, Senior abstinent patient-led group vs therapist-led group, Honest inventory milieu vs hypnotherapy) gave an overall significant benefit for the treatments based on AA principles.

The authors note that the three studies, which gave the adverse estimate of AA meeting efficacy only enrolled subjects who were coerced into treatment. They argue

that AA meetings, compared with other forms of treatment, may provoke more negative responses in those forced to attend them. Thus the correct interpretation of these trials is that patients should not be coerced into attending AA.

An argument is strongly put for more and better quality randomised trials of AA.

The paucity of data concerning the actual effects of AA as an organisation does not extend to the effectiveness of the AA treatment philosophy. This formed one of the three arms of the Project MATCH study (Project MATCH Research Group, 1993) and was, perhaps, the most successful of the treatment arms. As already noted Project MATCH found a significant beneficial effect for the 12 Steps approach in outpatients on 'drinking consequences' at 9 months relative to motivational interviewing. The outpatient group in Project MATCH included 952 persons and the p value for differences between the treatment arms in drinking consequences at 9 months was 0.006. The effects of the 12 Step approach were found to be similar to the CBT approach used in the third arm. Although this was not a direct test of AA itself it is worth noting that the overall goal of the TSF programme in Project MATCH was to promote the active participation in 'traditional fellowship activities of AA'. To this end the intervention emphasised the beliefs of AA that alcoholism is a chronic and progressive illness without cure for which total abstinence is the only solution. Hence the trial was a direct test of the acceptability and effectiveness of the AA model of alcohol dependence. A further finding of Project MATCH was that TSF was more effective than CBT in patients 'without support for abstinence in their environment'.

5.8.2 Treating drug and alcohol dependent patients together

Beidler (1991) randomised 450 people with either primary drug (206) or alcohol (244) problems to either be treated together or in segregated groups. Subgroups of subjects were examined to try to find any in whom these strategies might be particularly good or particularly poor. Treatment consisted of a number of coordinated psychosocial approaches. Follow-up was for 8 months.

Of those assigned to combined treatment (212) 53 (25%) had problems with both alcohol and drugs. In the separate treatment group (238) only 29 (12.2%) had problems with both. This is an odd and highly statistically significant ($p<0.001$) imbalance.

No differences in changes in dependence levels, criminality, suicidal tendencies or employment levels were seen for either those with primary alcohol or primary drug problems between the two treatment options.

This study is broadly supportive of combined treatment as an option. However, the power to detect problems for particular subgroups is not discussed and the imbalance in multiple abuse may suggest problems with randomisation.

5.8.3 Minimising pre-treatment drop-out.

Stasiewicz & Stalker (1999) report a randomized controlled trial of measures to minimize failure to attend for first appointments at substance abuse clinics. They compared a group given appointments within 48 hours with groups given

appointments after 48 hours but with (a) a reminder call 24 hours before the appointment or (b) an appointment card and clinic brochure in the post or (c) no additional reminder. They found that those given appointments within 48 hours were substantially more likely to keep the appointment than those in the other groups.

Table 5 - 10 Patients Attending for First Appointment

Group	
Intake within 48 hours	23/32 (72%)
Phone call	16/32 (50%)
Appointment card/brochure	16/32 (50%)
No contact	17/32 (53%)

This suggests that a prompt response to requests for help with alcohol related problems is important. Minimising the delay in obtaining treatment has also been picked out as a matter of concern to patients by the SIGN patient focus groups (SIGN, draft, 2002).

5.8.4 Inpatient and outpatient care

Rychtarik *et al*. (2000) randomised 192 individuals with a score of 9 or more on the Alcohol Use Disorders Identification Test (Babor *et al.*,1989) to (a) a residential, abstinence oriented, alcoholism treatment facility or (b) a specialist outpatient clinic with intensive treatment or (c) a specialist outpatient clinic with standard treatment. The intention of the study was to test treatment-matching hypotheses with respect to drinking problem severity and to social support for drinking. Patients with high levels of either variable were expected to benefit from inpatient or intensive outpatient treatment.

Drinking outcomes were obtained in each month following treatment by the timeline follow-back method, which reconstructs daily drinking via a calendar. The primary outcomes were the percentage of voluntarily abstinent days and the number of drinks per drinking day.

There was no overall difference between the groups in primary outcomes over 18 months of follow-up. However, a relationship was found between drinking problem severity and the treatment allocation. This did not follow the hypothesized pattern in that, although highly involved patients benefited more from inpatient treatment, there seemed to be a negative association with intensive outpatient treatment and no significant association with standard outpatient treatment.

Although this relationship was not as expected, and hence might be regarded as hypothesis generating, it suggests that inpatient care may be important for those with more severe alcohol problems.

No interaction was found with social support for drinking.

Several evaluations of the benefits of inpatient and outpatient care are reviewed by Finney & Moos (1998). The evidence concerning effectiveness for all patients does not show clear superiority for either option. However, the authors note that there is a

group of patients with few social resources and/or environments that are serious impediments to recovery for whom residential options should be available and that inpatient treatment options should be available for those with serious medical/psychiatric conditions.

5.8.5 Matching of treatment to patient

Litt *et al*.(1992) examined data from 79 male patients who had been previously allocated (randomized?) to either coping skills therapy or interactional group psychotherapy (Kadden *et al*., 1992). The patients were divided into two subtypes (A and B) using methods of Babor *et al*. (1992) Thirty-three female patients were not used in the study.

It is unclear why a cluster analysis was used to sort patients into type A and type B. An algorithm for doing this should already have been available from the Babor study. Thus this study cannot be considered as a validation of the earlier work.

A classification of the patients based on data, which appear to have been collected prior to starting treatment showed a significant interaction with treatment ($p<0.05$). In other words, the relative treatment effects for coping skills therapy and psychotherapy was different for type A and type B patients.

A prospective classification of the patients would have been more convincing since it is difficult to be sure about the timing of assessments after the study has ended. It is also unclear why the female patients were not used in the study – there does not seem to be any particular reason for supposing that the classification of males and females needed to be carried out separately.

The most extensive and rigorous test of matching hypotheses was that provided by the clinical trial in Project MATCH (Project MATCH Research Group, 1993). In this study 952 outpatients and 774 inpatients were randomised to, either, a cognitive-behavioural treatment (CBT), a 12 steps approach (TSF) or motivational enhancement (MET). A number of patient characteristics were measured at baseline and 10 a priori primary client-treatment matching hypotheses were pre-specified. These failed to find any interaction effects that had an impact on drinking throughout the treatment phase. Despite the size of this trial no convincing subgroup differences in treatment effects were discovered.

6 PATIENT ISSUES

6.1 Summary

The patient issues reported have been identified primarily by the early findings of a qualitative study commissioned by HTBS to explore patients' treatment preferences, patient information leaflets, and a study entitled *'Attitudes Towards Alcohol: Views of the General Public, Problem Drinkers, Alcohol Service Users and their Families and Friends'* (Lancaster B & Dudleston A, 2002).

The qualitative study aims to collect data from 45 participants. Data have, so far, been analysed from interviews with 32 people and this Interim Report presents the results of the preliminary analysis. Of the 32 interviews analysed so far, twenty were with men and twelve with women. Their ages range from thirty to seventy-two years. Four people were still drinking in a harmful way, and the longest period of abstinence at the time of interview was two years.

Issues to emerge include:

- Participation in residential or day case relapse services may currently depend on the way services are structured locally, rather than patient choice
- Lack of understanding of terms such as cognitive behaviour therapy and motivational enhancement need to be recognised in patient literature
- Participants valued activities such as anger management, stress/anxiety management and relaxation exercises, coping skills, assertiveness training and rehearsing difficult situations within a safe environment
- Women who had experienced 'women only' group work had a preference for women only groups, but conversely men may have a preference for mixed sex group work
- Individual therapy sessions may be valued for the depth of work they enable
- Flexibility of times and venues was valued
- All participants recognised that AA works well for many people, but most of them felt that it was not suitable for them.
- Awareness of services other than Alcoholics Anonymous may be low and may require better promotion.

6.2 Introduction

Perhaps more than any other field of medicine, the treatment of addiction involves the risk of important differences between the goals of the patient and the aims perceived as desirable by the doctor. Thus it is very important for both parties to understand and agree the purpose of treatment.

The intention of the patient issues section of a Health Technology Assessment is to ensure that needs and preferences of patients are taken into consideration when developing treatment services and also to identify issues which may only affect a minority of patients but, in those few cases, may profoundly impinge on the benefit which an individual can derive from the service.

Obtaining accurate information about patient concerns regarding alcohol treatment services can present major difficulties. Several methods have been used by HTBS. A limited MedLine search has been carried out to identify published literature on patient preferences. HTBS has commissioned a qualitative study focused on the patients within the Scottish relapse prevention services. HTBS also contacted certain organizations that interact with subgroups of patients, in particular the criminal justice system.

The Topic Specific Group included a representative from the Council on Alcohol and the organization of Alcoholic Anonymous in Glasgow generously gave time to explain its views on a number of issues.

6.3 Literature search

A search of Medline from 1990 to the present was undertaken to ascertain the usefulness of searching for general patient issues and concerns in relation to this topic. Approximately 500 abstracts were retrieved, the majority of which were found not to address the specific area of interest. It was therefore decided not to continue searching in other databases. Instead small-scale searches were carried out in response to specific issues that were identified.

Part of the evidence presented in support of the Scottish Executive's Plan for Action on Alcohol problems (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002) was a study entitled '*Attitudes Towards Alcohol: Views of the General Public, Problem Drinkers, Alcohol Service Users and their Families and Friends'* (Lancaster B & Dudleston A, 2002). The study included an analysis of the perceptions of service provision by current and past problem drinkers of their needs and the extent to which they were being met. As a consequence of recruitment problems, which were outwith the control of the researchers, the participants were mainly derived from urban areas. The report primarily focuses on alcohol misuse rather than dependence.

6.4 Design and conduct of the qualitative patient issues study commissioned by HTBS

The design of this study involved interviews with clients of the Scottish relapse prevention services in three Trusts. This was not a formal questionnaire based interview but was intended to explore patients' treatment preferences and to elicit factors, which prevent relapse to drinking. The full protocol for this study is included as Appendix 22.

This project seeks the experiences of individuals who have received treatment for alcohol dependence. The study aimed to identify people's preferences for psychosocial or pharmaceutical interventions, or a combination of both, according to their own particular experiences. A qualitative approach was adopted using in-depth, one-to-one interviews with a sample of individuals from urban, rural and semi-urban areas in Scotland who have had relevant personal experience. The study also sought to elicit factors, which, in the participants' views, precipitated or prevented relapse to drinking.

6.5 Method and analysis

Approval was granted by each of the three Local Research Ethics Committees, which govern research within the participating Trusts. Consultants responsible for the care of the participating patients also gave approval for access. On recruitment to the study all participants were assured that their confidentiality would be respected. The conditions of the Data Protection Act (1998) are being observed.

The sample was recruited and comprised individuals who had used the alcohol treatment services of three geographically distinct areas in Scotland within the past year. Posters were displayed in prominent positions within treatment facilities and information about the study was made available to anyone who expressed interest in participating. In addition, nurse managers wrote to a random sample of patients who had attended for treatment during the past year, seeking volunteers for the study and suggesting that those interested should contact the researcher. In this way the anonymity of patients was protected until they agreed to volunteer. Moreover, since the study involved an element of service evaluation, the process of randomising the sample recruited via the nurse managers ensured that bias in the selection was minimised.

There were no exclusions with regard to gender, age, social class or employment status.

The findings of this study are not representative of the entire population of Scottish drinkers in statistical terms. Rather, as qualitative research, the results can be considered to be transferable if readers can judge, from the information given, that the findings are applicable to cases for whom, circumstances are similar (Guba and Lincoln 1985).

One-to-one in-depth interviews were conducted during which the participants were asked to recount their experiences of treatment and their preferences for pharmacological and psychosocial interventions. They were also asked to discuss the factors, which they perceived as contributing to the experience being either positive or negative, and to reflect on the reasons for their preferences. The interview guide, which, was used to ensure that all relevant topics were addressed is appended. Prompts were used for clarification when necessary, and to encourage further disclosure. The interviews were conducted at a variety of locations to meet the preferences of the participants and to minimise inconvenience incurred by them. The venues included the researcher's office, patients' own homes, health service facilities and accommodation within the premises of one of the Councils on Alcohol.

The duration of the interviews ranged from 30 minutes to one and three quarter hours. All except one were audio-tape recorded. The reason for the exception was that the participant was reluctant to be recorded, so hand-written notes were taken instead.

The interviews were transcribed prior to analysis. Burnard's framework for thematic analysis of qualitative data was used to search for themes and patterns in the data (Burnard 1991). As a means of ensuring rigour in the process, a sample of the transcriptions are being analysed independently by a colleague of the researcher with experience of undertaking qualitative research. Points of divergence are discussed

and agreement reached for the final analysis. The participants will be invited to comment on a summary of the findings as part of the validation process for qualitative research (Sandalowski 1993, Whittemore et al 2001).

6.6 Interim findings of patient issues study

It is stressed that these are the interim findings of research, which is not yet complete.

The gender distribution and age range of participants are shown in Table 6-1, and Table 6-2 shows the number of participants who had, at some time in their lives, experienced some form of psychosocial or pharmacological treatment for alcohol dependence.

Table 6- 1 Gender distribution and age range of participants

	Gender		Age range
	Male	Female	
Trust 1 (n=15)	9	6	31 - 52 yrs
Trust 2 (n=15)	10	5	30 - 71 yrs
Trust 3 (n=2) (Data collection ongoing)	1	1	56 - 72 yrs

Table 6- 2 Treatment experiences

	NHS individual therapy	NHS group therapy	Disulfiram	Acamprosate	Councils on Alcohol	AA
Trust 1	15	15	5	6	4	9
Trust 2	15	15	5	4	8	11
Trust 3	2	1	-	-	1	1

The following section summarises the views of the participants as regards their preferences for different treatment modalities for alcohol dependence and the prevention of relapse to drinking. As a consequence of the recruitment process, which was through NHS alcohol services, all participants had been referred for treatment within the NHS. Most had attended Alcoholics Anonymous for varying lengths of time. A minority had experience of the Councils on Alcohol. The sample included a small number of people who had defaulted from NHS treatment, and several had done so in the past but had returned to treatment.

6.6.1 Organisation of care within the three participating areas

6.6.1.1 Trust 1

This Trust serves a rural and semi-urban area.

The participants' descriptions of their treatment indicated services available to those attending one of the Trusts included a three week in-patient stay during which time detoxification was available, followed by a structured programme of group work, led by members of the nursing staff, and individual therapy. After-care provision included the opportunity to attend a group on a weekly or twice-weekly basis. The opportunity exists for these patients to attend as and when they feel necessary and appropriate, rather than as obligatory attendance on each occasion that the group meets. This group is therefore open to some extent. One of the options within this service is for a 'women's only' group, which has led, by default, to the formation of a men's group. Some people in this area also talked of having been referred to an organisation, which offered aspects of community reinforcement in the form of training and support in seeking employment.

6.6.1.2 Trust 2

This Trust also serves a rural and semi-urban area.

Those individuals who attended one of the other Trusts described an initial episode of 4 weeks duration as an in-patient. This stay comprised detoxification, a structured programme of group work, and individual therapy with members of the nursing team. Following completion of the programme a phased aftercare programme of one week's in-patient stay was offered, with the interval between episodes lengthening over a two-year period. Patients who live in one geographic area within this Trust's catchment area are offered follow-up out-patient appointments in satellite clinics. Those who live within the same Trust area, but who live outwith the specified area, have no such opportunity. The view was expressed that this represented unequal provision.

6.6.1.3 Trust 3

This Trust serves an urban area.

Data are still currently being collected from patients in the third Trust. The picture emerging is that different patterns of care are available to patients who live in different areas within the Trust's catchment area. For example, in one area a four-week structured day programme is offered and, in another, an in-patient stay of approximately 2 weeks is available with periodic follow-up out-patient appointments arranged on discharge from hospital. However, more data are required to verify the situation, and it may be that differences in service provision reflect differences in local need.

6.6.2 Residential versus day-patient care

For most patients there was no choice. The decision about whether treatment would be offered on an in-patient, day-patient, or out-patient basis was generally made by the consultant and appeared to depend on the basis of how care delivery was organised. An additional factor, in one area in particular, was that the geographic distance from the communities where the majority of patients lived made residential treatment essential.

Most patients valued the sense of asylum, which this brought. However most recognised the fact that, as in-patients, they were protected from the environmental stressors, which they normally experienced. They talked of feeling '*cocooned'*, and '*in a bubble'*. In one Trust they were required to return home from the unit at weekends and this was generally felt to be a useful time for preparing for discharge and practising new skills learned. This sense of trepidation about leaving the relative safety of the hospital was also reported by Lancaster and Dudleston (2002), whose study of current and past drinkers' perceptions of service provision in Scotland formed part of the evidence presented in support of the Scottish Executive's Plan for Action on Alcohol problems (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002).

Several participants, at the Trust where the residential programme seemed to be most structured, found the combined effect of group work, individual therapy, paper-and-pencil exercised in the evenings and over the weekends, tiring, but the majority found it very worthwhile. This level of activity contrasts with reports of residential care in which the users of the services complained of boredom and a lack of structured activity in another area in Scotland (Lancaster B & Dudleston A, 2002). This could reflect variation in the philosophy of care in the two areas, or perhaps in the level of resources available.

6.6.3 Psychosocial interventions

All participants had experienced psychosocial interventions as both individual and group therapies. None were able to identify what was meant by the terms 'cognitive behaviour therapy' or 'motivational enhancement', although one patient who had recently completed a psychology course was able to identify retrospectively different approaches, which he had experienced.

"Now I've done the psychology course, I can recognise that the doctors take the biological approach, and the cognitive approach, and you can see the client-centred approach in the one-to-ones. I didn't see it while I was there, obviously." (Interview 17, male, Trust 2)

Others described the content of the psychosocial interventions as including the following range of activities:

"*… relapse prevention, talking about the cues and triggers, you know, as well as all the educational information. I don't know if that would fit into what ye're asking aboot* [Motivational Enhancement, Cognitive Behavioural Therapy, Relapse Prevention] *You know it's very informative. There was role play, and you know, a lot of group work"*. (Interview 7, female, Trust 1)

'Like, you do the cost/benefits, and how to avoid risky situations, and the high risk situations. Well, we talk about voluntary work and other things to get you into, to try and pass your time. I mean, it's not the cure all and be all, but it does give you the tools and the help to put you on the road and you can say well if this person can do it, then so can I. (Interview 2, female, Trust 1)

In general psychosocial interventions were described as being very helpful. It was acknowledged that all such interventions could be delivered in either a group or an individual formats.

6.6.3.1 Group work within NHS facilities

Activities highlighted as beneficial by several participants included anger management, stress / anxiety management and relaxation exercises, coping skills, assertiveness training and rehearsing difficult situations within a safe environment.

The majority of those who had experience of group work described it as being of value for some of the following reasons:

"I would say that for me, coming here [to the open group] *is the key. It's hard to say how they work, but they do work for me. It's good to come along and see the same people. And you get benefit from other people, knowing that other people have been through the same thing."* (Interview 6, male, Trust 1)

"How does it help? Well I don't know – but we're a' the same. Emm, you can get things off yer chest, and if you relapse or whatever, and yer heed sterts [starts], *and ye get things blown up out of all proportion, and at least coming to meetings you get a chance to air it, and you might not get an answer – often you don't, but it does work, and ye go awa' hame the calmer."* (Interview 7, female, Trust 1)

"I don't come every week, I used to, but I come about once a month now. I come because <u>they</u> know what it's like. I've got other people I could speak to - I've got very good family, but they don't understand – they can't understand. It's not their fault, but they don't understand. Unless you've been there, you don't 'have the tee-shirt', but here everyone does. Even staff don't know, despite all their qualifications, and all the training, unless you've been there, you don't know." (Interview 4, female, Trust 1)

For one individual, attending groups was the preferred treatment of choice, although he did recognise the value of individual sessions too, but felt that the approach may become more directive within the individual situation.

"*I think the groups can be more empowering* [than one-to-one sessions]. *Probably if I think about it, Dr X did say "do this" or "don't do that", and cracks the whip!*" (Interview 1, male, Trust 1)

All but one of the minority of patients who were still drinking, found the groups difficult. One described discharging himself from treatment because he said that he was on the brink of having a fight with one of the group members. During another episode of care the same patient discharged himself again because he found the attitude of a staff member objectionable. He described how, on this occasion, the staff member had instructed him to attend the group and then interrupted him as he was about to speak and told him to be quiet. He could not give a reason for this. Two of the other participants expressed resentment as they described incidents where they felt that the staff had treated them like children in the groups.

Several of the women who were interviewed made the point that one of the weekly groups, which they attended, was for women only. The majority of the women who had experienced these groups valued this, expressing the view that they felt less inhibited in such an environment. One person said that she could discuss issues, which seemed trivial but were sources of irritation, which could have developed into a trigger for drinking. These findings echo those of Lancaster & Dudleston (2002) but are at odds with the recommendations of an expert seminar on women and alcohol, published by the Health Education Board for Scotland, which advocates the provision of '*gender sensitive'*, rather than '*gender specific'* services on the grounds of current limited resources (Plant and Hawe 2000). In the study reported here, those women who had no experience of women's only groups had no strong feelings. However, all of the men felt that mixed groups were preferable.

6.6.3.2 Individual therapy sessions within NHS facilities

This was also found to be helpful by most participants, and most people expressed the view that they enabled problem-solving approaches to be addressed at greater depth. They were also regarded as important for discussing issues which people felt were too personal to discuss within the groups. Other views included:

"The one-to-ones are good, because there's some things that, eh…, there can be so many people speaking at the one time in the groups, that you can't explain, whereas in the one-to-one, although you have a set time for the one-to-one, they'll always make time for you, day or night." (Interview 17, male, Trust 2)

"And the one-to-ones, even though they were total strangers, you could just talk away to them no problem just as though you'd known them all your life. You were a bit strange to begin with, but that might have been the alcohol still working, and all the lies you tell when you're on heavy drinking, like. But after the first couple and I'd done my detox and all that, it was just brilliant. You could talk about everything, whatever troubles you've got, or if you're doing well, even. Just whatever <u>you</u> want to talk about." (Interview 25, male, Trust 2)

"It's directed to your own individual circumstances, it only works if you are honest with them and you are honest with yourself." (Interview 15, male, Trust 2)

"The one-to-ones were more beneficial for me because I could let go more and I could tell more than I could in a group. There's a lot of underlying reasons that you wouldn't share with a group but you need the one-to-ones to open up about them. (Interview 20, male, Trust 2)

One participant felt that he could not cope with individual sessions since he was, *"Too paranoid to benefit – not ready"* (Interview 11, male, Trust 1)

6.6.3.3 Couples therapy

None of the participants had experienced formal couples therapy, although a few said that spouses/partners had attended joint consultations in the early stages of treatment.

6.6.4 Alcoholics Anonymous

Most participants had attended at least one meeting of Alcoholics Anonymous (AA). All said that they recognised that AA works well for many people, but most of them felt that it was not suitable for them. This may, however, have been an artefact of the recruitment strategy. Those who found it beneficial, although in a minority, seemed to gain considerable support. The flexibility of the times and venues of meetings was valued for a range of reasons, as illustrated by the following quotations:

"It doesn't matter how often you come and go, you're always welcome – more than welcome. People are rooting for you and they want you to do well. There's always a meeting while she's [daughter] *at school."* (Interview 7, female, Trust 1)

Some participants found the experience intimidating.

"I was really nervous at the AA because you had to stand up in front of people and it's just the way it's done. I know it works for a lot of people you know, but I found when I went it wasn't right for me at that time. I'll maybe give it another go some time…." (Interview 13, female, Trust 2)

A few people expressed concern about the potential for confidentiality to be breached at AA meetings and were reluctant to disclose their own drinking experiences for this reason. In contrast they appeared to get a feeling of security from the professional code of practice of staff and commitment to confidentiality made by group members in the NHS facilities of which they had experience.

Some people felt that members of AA tended to replace their dependence on alcohol with a dependence on involvement with AA, which they thought represented limited progress towards achieving a fulfilled life. A few participants suggested that some AA members continued to drink while attending meetings. Although they recognised that lapses can occur for people who attend NHS groups, AA appeared to be more tolerant of the latter.

No-one had completed the 12-step programme, the closest reached was one person who had completed nine of the steps. One participant had asked for a sponsor to work through the programme with her, but it had not been possible to find anyone who had completed the programme themselves. However, another had made two attempts to work through the programme and had found both of his sponsors to be very good. However, he felt that it was a mistake to rely too much on the sponsor because, as he said, *"It's nothing to do with sponsorship, it's all to do with me, you know."* (Interview 16, male, Trust 2)

6.6.5 Councils on Alcohol

Fewer of the participants had experienced the services offered by the Council on Alcohol. Some valued the opportunity for one-to-one counselling and for complementary therapies, such as aromatherapy. Others felt that the philosophy of the Councils was that controlled drinking was a feasible option, which many of the participants felt was inappropriate for their own situation.

Some participants said that they felt that they had attended the Council at an inappropriate time in their drinking careers. For example:

"I used to go and see, it was Mary [a pseudonym]. *But I think when I first went to see her, I was still very resistant to change, you know. I was still a bit in denial*." (Interview 12, male, Trust 1)

The availability of the service was important to one participant who described a recent incident when she felt close to drinking.

"A couple of weeks ago I was really desperate for a drink, it was really severe craving, and I thought to myself, 'I can go down to the shop and get a carry out,' and then I thought, 'No I'm going to talk to somebody'. So I went down to the Council on Alcohol and spoke to somebody and stayed there for a couple of hours, and was speaking to other people that have been there and had the cravings, you know, that you're going through, kind of thing and it really helped me. I've found like even just going down to the Council on Alcohol and speaking to people, it was just an informal chat basically, you know, but that helped settle me down and you get a game of cards and stuff." (Interview 13, female, Trust 2))

6.6.6 Pharmaceutical interventions

Participants were asked about their experiences of taking pharmaceutical preparations as prevention of relapse to drinking. The particular preparations of interest were disulfiram, acamprosate, and naltrexone.

6.6.6.1 Disulfiram

All participants had heard of disulfiram as Antabuse and approximately one third had experience of taking it. One person had experienced a skin rash without having been drinking, and one said that she had experienced a reaction to perfume, which she was wearing. This had precipitated a bout of drinking because her family accused her of drinking and she claimed that, having been falsely accused, decided that she might as well have a drink.

A few people described the very unpleasant effects they had experienced as a result of drinking while taking disulfiram.

"Yes , but I actually drank on it and was very ill, and even that didn't deter me. I even drank on it again, knowing how ill I'd be." (Interview 7, female, Trust 1)

Despite knowing about these effects, this person said he was unable to resist alcohol. Another explained his feelings at the time as follows,

"I ended up in A&E one time. It was quite strange, because I'd got to the point where I'd got to the stage that I didn't really care. I knew I wasn't safe to be taking drink but I had a whole bottle of single malt in the house, and I thought, well, it doesn't really matter what happens. For a day there was really no reaction at all, and then, it just massively hit. Apparently it must have been some sort of heart problem, because

when I was in the hospital I was on a heart monitor all the time." (Interview 6, male, Trust 1)

Of those who had no experience of taking disulfiram, most said that this was because they would not trust themselves not to drink while taking it.

"I wouldn't trust myself on Antabuse. I've heard a lot of horror stories about antabuse. I think there's a good possibility that I would drink while I was on it and I wouldn't like to risk it." (Interview 20, male, Trust 2)

Some of the participants said that they took disulfiram but were concerned that this should only provide support until they were able to manage without it, for example:

"I wouldn't be learning how to cope with it [abstinence]. *You know I'd never feel the sense of accomplishing something if I kept on it."* (Interview 16, male, Trust 2)

However, for some others taking disulfiram was an important supplement to other forms of treatment.

"For me it is the backbone – it just strengthens my resolve." (Interview 27, male, Trust 2)

"I had seen these leaflets about Antabuse, so I said, 'I want to go on it', and he said, 'Well are you sure?' And I said, 'Yes it's the only way, I cannot go back out there [home at Christmas and New Year] *and say I won't drink'. So they started me on it and I haven't had a drink since* [December 2000] *actually*." (Interview 21, female, Trust 2)

Later this participant explained that she used disulfiram to reinforce the effects of the psychosocial support she had received while in hospital, in combination with ongoing support she received from a CPN. Indeed, all who had found disulfiram of benefit felt that it was the combination of interventions, which was effective for them.

6.6.6.2 Acamprosate

Approximately half of the participants had taken acamprosate with reports of varying success. Some people noticed no reduction in craving and felt that it was of no benefit, whereas others felt unable to discern whether a reduced sense of craving had resulted from their improved coping skills, the medication, or a combination of both.

"I did try that once but it didn't work for me. I'm not very good at taking tablets anyway, and that's 3 times a day dose and they're quite big tablets, and it didn't seem to affect my desire to drink. I have to take a lot of tablets anyway because of other health problems." (Interview 6, male, Trust 1)

On the other hand, a minority of individuals did report that they were finding that taking acamprosate was effective in that, although they still experienced a craving for alcohol, that it was less severe and this they attributed to the drug.

"I've got my wee job noo and I've been doing alright since, and I'm back on the campral, so I'm quite okay. The campral makes the craving go away, and with me working I've got no time on my hands." (Interview 22, female, Trust 3)

One participant, who had not been prescribed either disulfiram or acamprosate felt that NHS staff should provide more information about these drugs so that they could reach an informed choice about what treatments could be available to them.

6.6.6.3 Naltrexone

None of the participants had been prescribed naltrexone.

6.6.7 Community reinforcement

Only a few people had experience of attending organisations, which offered support regarding training and continuing education, or assistance with housing, but those who did valued the opportunities, which this afforded in terms of building self-esteem and life skills.

"I've done my higher psychology and I'm going to do a computing course next year. I've thoroughly enjoyed the experience and I've met so many people. It's opened so many doors I don't have time to think about drink". (Interview 17, male, Trust 2)

"Once you have been sober for a while, they do a 3 month training programme to try and get you into work or a college" (Interview 3, male, Trust 1)

"I'm with an organisation called Rehab Scotland. It actually helps people with mental illness – with depression and all that, and I'm finding that a great deal of support, and they can pull all the strings for you for to get you back into employment." (Interview 20, male, Trust 2)

6.6.8 Relapse

Participants reported a range of factors, which had contributed to their relapsing. These most often involved stressors. Stressors included moving house, family problems, disappointment related to failed job applications and emotional anniversaries. However, some could not explain why they had relapsed, and others described circumstances such as receiving relatively large sums of money, which was quickly spent on alcohol. A few talked of continuing to use alcohol as a reward for periods of abstinence and described how it took several relapses to realise the irony of such actions. High-risk precipitating factors therefore, for this sample, appear to include both *interpersonal* and *intrapersonal* determinants as described by Cummings et al. (1980)

Those who were experiencing the longest periods of sobriety reflected that the 'time had been right'. When pressed to describe what was different about the 'time' and how they knew this, explanations were elusive. Further analysis of the data pertaining to this aspect of the study has still to be undertaken and will be presented within the final report. These preliminary findings are in keeping with those of Isenhart (1997) whose study of the relationship between pre-treatment stages of change and outcome

indicated that patients who experience less ambivalence about their drinking are more likely to acknowledge the existence of a problem and become more willing to take action to address the problem. Similar findings were reported by Hu et al. (1997)

Patients described several courses of action, which they had taken to prevent relapse. Several had used the Helpline, which the NHS service had made available, and some had contacted AA or the Council on Alcohol. Others said that they rehearsed the exercises which they had learned, such as relaxation techniques, or found some meaningful way of occupying their time, such as tackling some chore or going for a walk, cycle run, or work-out.

Others talked about continuing efforts to maintain sobriety so that relapse was less likely, as this person described:

"Well what I'm doing now, going to xx [nurse therapist] *every 2 weeks and coming here* [NHS group] *every Thursday and just making the effort to come. Keeping it going and it's far, far too easy to get lapsed and, you know and coming here especially is a great reminder that I can't do it, can't go down that road*." (Interview 11, male, Trust 1)

Some people talked about using AA meetings in this way, whereas others valued the chance to return for a week's in-patient stay, for example:

"*I think that respite for me was terribly important. I think I could have fell off the rails if I hadn't had that. I would say you learn something different every time.*" (Interview 17, male, Trust 2)

However, after care, although available in the longer term, was not always timely, as described here:

"You need follow-up. 'I was in [as an in-patient in hospital] *for 4 weeks, then waited 5 weeks for an appointment with my follow-up worker. That's a long time, and you could undo all the good that'd been done".* (Interview 32, male, Trust 3)

The view was also expressed that some facilities served too wide an area, and the suggestion was made that satellite resources should be available. Some participants also felt that some GPs were unsympathetic and lacked understanding and knowledge of alcohol problems. In discussing his experience of using acamprosate, one participant recounted the following:

"It's the GP I got it [acamprosate] *from but it was part of my set up. I actually went to see, actually because I had been sober for six weeks he said, 'Well if you have managed six weeks I think eh. …..' I said, 'Well I managed six weeks, but the six weeks have been sheer hell, its been dragging minute by minute, I have heard of this* [acamprosate] *and I want to give it a try. …. So he didn't give me them but eventually after much persuasion I went to another doctor. It was like dragging teeth to get them but at least I have got them now and I would say I have had a few lapses but I have managed nine weeks, lapsed for a week, then managed seven weeks and the drinking only lasted occasional days. So I at least coming along here, I am on the right road now. They do help."* (Interview 3, male, Trust 1)

6.7 Range of treatment options

It is clear from the clinical studies that all interventions are of limited effectiveness. It is thus worth providing a range of options of proven efficacy. Treatment should be individualised taking account of patients' expectations, needs and wishes with the understanding that these needs may change and the treatment plan may need to adapt to this. Flexibility is important in retaining engagement in the treatment system.

Improving the engagement of the individual in the treatment process is likely to lead to better completion rates and outcomes and can be facilitated by involving individuals in planning their own treatment programme and making treatment plans clear and explicit. Other factors such as engendering a positive relationship with the therapist and practical measures such as provision of transport to those who would otherwise not attend may improve engagement, although evidence is lacking in this area.

6.8 Patient information

In reply to the HTBS survey only 36% of NHS specialist services carrying out psychosocial interventions indicated that they had patient information sheets or leaflets for any of these interventions. It is recommended that such information should be available for all interventions.

Alcohol Focus Scotland publish a variety of information leaflets for people concerned about their drinking and their family and friends, as well as a drink diary and self help guide. The leaflets are distributed through the Councils on Alcohol and do not discriminate between dependence and misuse. They provide information to help people understand sensible drinking, identify if they have a problem or their drinking is harmful, and promote sources of support and advice. Issues addressed include: women and alcohol; alcohol and older people; what children can do if they feel their parents drink too much; dual diagnosis; stress, and how alcohol affects behaviour and the body. Examples are included in Appendix 10.

Alcoholics Anonymous also has numerous leaflets explaining their purpose and philosophy. Some of these are aimed at specific subgroups such as young people, prisoners and armed forces.

6.9 Awareness of alcohol-related services

There may be a lack of awareness of the range of services for people with alcohol-related problems in Scotland. Lancaster & Dudleston (2002) found there were low levels of awareness of organisations that provide help or advice for people with alcohol-related problems and even lower awareness of services for the families and friends of drinkers. They found that in most cases awareness and knowledge improved once contact had been made with the service.

This lack of awareness resulted in the local GP being most commonly named as a source of help and advice, and referral to counselling and psychologists.

Additionally, they found most people were aware of Alcoholics Anonymous, although their knowledge of its aims and the type of service it provided was limited. Only a few people were aware of other specific services.

Lancaster and Dudleston also reported a perception among the public in Scotland that there were more services for drug misuse than services for alcohol problems and that the drug misuse services were better promoted.

7 ECONOMIC EVALUATION

Summary

- The cost effectiveness of eight therapies (three pharmacological and five psychosocial) to prevent relapse in people who are alcohol dependent has been modelled.

- The economic evaluation compares the costs and consequences of each therapy in comparison to a standard care package. The relevant outcomes are the disease endpoints which alcohol dependence affects the likelihood of developing: alcoholic psychosis (including organic brain damage), liver cirrhosis, epilepsy, chronic pancreatitis, cancer, stroke and death.

- The economic evaluation for each therapy models a cohort of 1000 patients and involves:

    - defining and costing each therapy
    - applying the clinical effectiveness odds ratio of the therapy to the epidemiology for the cohort to calculate the number of patients likely to be in the various disease endpoints
    - calculating the costs to NHSScotland of the disease endpoints; and
    - calculating an incremental cost or saving per additional abstinent patient.

- The results show that four of the five psychosocial therapies (Coping Skills, Behavioural Self Control Training, Motivational Interviewing and Marital and Family Therapy) have net *savings* per incremental abstinent patient. This means that the cost of the treatment is less than the savings available to NHSScotland as a result of adopting the therapy. These savings arise because the improved abstinence rate results in a lower incidence of diseases, thereby saving inpatient hospital stays and other disease related costs.

- Acamprosate is less cost effective than these psychosocial therapies but dominates naltrexone and disulfiram. Sensitivity analysis shows that the ranking of therapies is robust.

- A serious limitation of the model is the absence of data on relapse rates beyond the period of the clinical trials (3-12 months). There are also concerns about generalising from trials to treating patients in a Scottish setting. Further research is needed to give more definitive estimates of the long term effectiveness of all the therapies in a Scottish setting.

- The costing of the disease end points is limited because Scottish disease related costs are not available.

7.1 Framework for an economic evaluation

Several guidelines for economic evaluations of health technologies are available, for example, ECHTA (2001), Drummond *et al*. (1997) and Gold *et al*. (1996). HTBS has reviewed these and produced its own draft 'Guidance to Manufacturers' (Health Technology Board of Scotland, 2002) that highlights the main methodological issues to be addressed in the economic evaluations performed within the HTBS Health Technology Assessment (HTA) framework. HTBS has consulted on the Guidance and will revise the draft shortly in light of comments received.

Best practice recommends that economic evaluations adopt a societal perspective (Drummond & McGuire, 2001). Adopting a societal perspective means all changes in resource use, that is all changes to costs and outcomes, should be included in the economic evaluation.

In October 2001, Scottish Executive published a comprehensive report prepared by Catalyst Health Economics Consultants Ltd (Catalyst Health Economics Consultants Ltd, 2001) that estimated the total societal costs associated with alcohol misuse in Scotland to be £1071m, of which £96m are health-care costs. These costs are discussed in section 7.4.1.

The target population for this HTA is people with alcohol dependence who have undergone detoxification. This group will give rise to some of the societal costs estimated in the Catalyst report. However, HTBS cannot quantify the societal costs identified in that report attributable to this sub-group. Rather, the economic evaluation will model future health care costs only, whilst noting that these costs are considerably lower than the costs to society.

7.2 Objectives

The objectives of the economic evaluation are to:

- review the existing literature on economic evaluations of individual therapies, or combination of therapies, that have the aim of reducing relapse in alcohol dependent patients;
- extract from the literature, data from studies that inform on possible economic models and the costs and outcomes of therapies;
- develop a simple model that is valid for the Scottish population and healthcare system and to populate that model with Scottish cost and outcome data;
- run the model to inform on the cost-effectiveness of different therapies;
- make due allowance for uncertainty in the data variables and in the structure of the model by adopting sensitivity analysis; and
- interpret the results, to include the outcomes from the sensitivity analysis in the context of answering the original HTA question.

7.3 Literature search

7.3.1 Search strategy

In 2001, the Centre for Reviews and Dissemination in York undertook a search of electronic databases for the period 1990 to 2000 for cost-effectiveness literature. All economic evaluations were included and all identified studies were quality assessed using a standard checklist. The literature search was used to inform the section on the cost-effectiveness of relapse prevention in 'Cost-effective Measures to Reduce Alcohol Misuse in Scotland.'(Ludbrook *et al*., 2001)

HTBS updated the CRD York database by searching the same range of databases and, where possible, starting from entries added to the databases from January 2000. To date, only one additional paper has been identified, (Palmer *et al*., 2000) a modelling study reviewed below.

The list of databases is shown in Appendix 23. It includes the NHS Economic Evaluation (NHS EED), Health Economic Evaluations Database (HEED) and the web sites of leading health economics units.

A copy of the strategy used to search the Medline database is given in Appendix 24. This strategy was adapted to search the other databases. A complete listing of all strategies can be obtained by contacting HTBS.

7.3.2 Criteria for inclusion and exclusion of studies

The following exclusion criteria were applied when reviewing the economic literature search results:

- review articles not containing data on costs, outcomes nor models;
- studies not carried out in a population that might be broadly relevant to Scotland; and
- studies where it is not possible to disaggregate results of alcohol treatment from other addiction treatments.

7.3.3 Data extraction

Two main types of economic studies were identified in the review. First, some studies have attempted to collect data on costs and effectiveness concurrently. These studies have focussed on short-term economic consequences such as changes in health care costs before and after treatment. In this first category most studies fail even a minimum quality criterion (Ludbrook *et al*., 2001) and are not considered further in this report. The second type of economic study has used modelling techniques drawing data from a number of sources to estimate the longer term consequences of alcohol related problems, for example, the development of liver cirrhosis.

The three key studies used in the economic modelling are of this second type and are described overleaf, with formal data extractions for each set out in Appendix 25.

7.4 Economic model of relapse prevention for alcohol patients

7.4.1 Overview of the economics of relapse prevention

There is substantial evidence that alcohol related ill-health gives rise to considerable costs to the NHS (Mckenna *et al.*, 1996). Moreover, considerably greater costs fall on society as a result of alcohol misuse. In October 2001, Catalyst Health Economics Consultants Ltd quantified the annual societal cost of alcohol misuse in Scotland to be over £1, 070m (Catalyst Health Economics Consultants Ltd, 2001).

This sum comprised costs to NHSScotland (£96m), costs to the social work services and associated organisations (£86m), costs to the criminal justice system and emergency services (£268m), wider economic costs from absenteeism and premature mortality but not reduced productivity in the workplace (£404m) and premature mortality in the non-working population (£217m). Thus healthcare costs are estimated to form only some 9 % of the costs to society arising from alcohol misuse.

Table 7-1 reproduces the analysis of health service resource use in Scotland and is reproduced from the Catalyst document (Catalyst Health Economics Consultants Ltd, 2001).

Table 7 - 1 Annual NHSScotland costs of Alcohol Misuse at 2001/02 prices.

(Catalyst Health Economics Consultants Limited)

Health service resource use associated with:	**Annual resource use**	**Annual cost (£ million)**
GP consultations	211,516	3.6
GP-prescribed drugs	6% of drugs prescribed by GPs for substance dependence	0.2
Consultations with practice & district nurses and health visitors	No information currently recorded. Unable to quantify	
Laboratory tests	147,256	1.8
Hospitalisation days	275,775	54.3
Accident and emergency attendances	187,951	9.6
Outpatient visits	93,999	8.1
Day hospital attendances	44,800	3.1
Community psychiatric team visits	8% of total community psychiatric team expenditure	4.0
Ambulance journeys	64,382	9.1
Health promotion/prevention by Health Education Board for Scotland (HEBS)	HEBS, Drinkwise, Alcohol Development Officers	1.2
Health board expenditure to alcohol-related voluntary organisations	Funding to 25 organisations	0.6
Total for NHSScotland		95.6

In summary, the Catalyst report showed that 57% of the NHSScotland costs of alcohol misuse arise from the occupation of hospital beds to treat alcohol related

diseases, with a further 20% arising from ambulance journeys and attendance at accident and emergency units.

A similar view of the cost of alcohol misuse for the health service is provided in the July 2000 Greater Glasgow Health Board consultation document on its alcohol strategy (Greater Glasgow Health Board, 2000). This document noted that alcohol misuse accounts for probably 8 to 15% of attendances at accident and emergency units and about 13% of acute psychiatric admissions. This document also noted that alcohol-related admission rates to general hospitals had risen by 278% between 1981 and 1997.

A study of the economic costs of alcohol misuse in the Lanarkshire Health Board area in 1999 (Brown *et al*., 2001) identified, measured and where possible valued the cost of alcohol misuse in Lanarkshire. The results indicated that in 1999 between 128 and 200 alcohol specific deaths occurred and that the total cost of alcohol misuse in Lanarkshire was between £31m and £49m. This study concluded health costs formed some 16 to 20% of total societal costs, rather higher than the 9% reported in the Catalyst study. Note about 11% of the Scottish population live in Lanarkshire.

International studies have shown that other countries including Germany, Sweden and USA also face considerable costs to their societies from abuse of alcohol. (National Institute on Drug Abuse & National Institute on Alcohol Abuse and Alcoholism, 1998); (Brecht *et al*., 1996); (Andreasson *et al*., 2001). For example the National Institute on Drug Abuse in the USA undertook a major review of the economic costs of alcohol and drug use in the States in 1992 (National Institute on Drug Abuse & National Institute on Alcohol Abuse and Alcoholism, 1998). This study concluded that in 1992 the costs of treatment for health problems attributable to alcohol abuse were $13.2 billion, rising to $18.8 billion with the inclusion of treatment costs, some 13% of the economic costs to society from alcohol abuse.

These studies also show that the benefits in terms of future costs avoided from successful alcohol treatment extend beyond the initial improvements in health and quality of life for patients.

Successfully treated patients have also been shown to reduce their utilisation of health care resources (Parthasarathy *et al*., 2001). This study reviewed existing published studies and noted that these estimated a reduction in the use of health care resources, following treatment of patients with alcohol disorders, ranging from 26% to 69%, with a median of 40%. The reduction in health care costs ranged from $0.41 to $1.10 for every dollar spent on treatment. The paper also noted that the research informing these results had several limitations, including that most research was conducted prior to the widespread change from inpatient to outpatient treatment.

The Parthasarathy *et al*. (2001) study analysed the use that 1011 patients made of outpatient and inpatient health care services 18 months before and 18 months after entering the Chemical Dependency Recovery Programme at the Sacramento Kaiser Permanente facility. Costs for the provision of the services were mainly from an internal accounting system.

The results of the analysis were that, following treatment, there was a 26% reduction in total medical costs, with a 35% and 39% reduction in inpatient and emergency unit costs respectively.

Other older studies are summarised in Ludbrook *et al*. (2001).

7.4.2 Economic evaluation technique

Economic evaluation has been defined as *' the comparative analysis of alternative courses of action in terms of both their costs and consequences*' (Drummond & McGuire, 2001). An economic evaluation thus requires the identification, measurement, valuation and comparison of the costs and outcomes of the alternatives being considered, from a stated perspective and over a relevant time horizon. In what follows, costs are evaluated from the perspective of the relevant health care system, while benefits are evaluated from the patient perspective.

The outcome under review is relapse prevention, measured in terms of patients who are abstinent or have controlled drinking, consistent with the definition applied for clinical-effectiveness.

The cost consequences of improving the effectiveness of relapse prevention which are within the perspective of our model are the immediate costs of treatment, coupled with any reduced demand for health interventions that are directly related to alcohol abuse (for example, alcoholic psychoses, alcoholic dependence syndrome, acute alcoholic hepatitis and liver cirrhosis).

If satisfactory preference based, non-monetary units such as quality adjusted life years (QALYs) are available to use as outcomes before and after treatment for alcohol abuse then it may be possible to express the results of the analysis in terms of cost per QALY. The resultant cost per QALY can then be compared to the cost per QALY of alternative health care treatments and be of assistance to health care decision makers when they are prioritising the use of scarce resources.

7.4.3 Published and submitted economic models

The literature search revealed that two forms of economic model have been used to model the cost effectiveness of alcohol relapse prevention strategies. The first form is a static decision tree model as adopted by Schadlich & Brecht (1998). This model is based on a cohort of patients entering treatment and then experiencing a range of endpoints with different probabilities. Those who were successfully abstinent at the end of treatment were assumed to be free of alcohol related diseases. Those unsuccessful at the end of treatment were assumed to have a fixed probability of various alcohol related disease endpoints.

The second form of model is a dynamic Markov model, used by Annesmans et al. (2000). In this model patients move between different alcohol related treatment regimes across time in a fashion determined by transition probabilities.

The identified studies are reviewed below in terms of their model structure and the data employed.

7.4.4 Schadlich & Brecht Model

The original Schadlich & Brecht model investigated the incremental costs per additional abstinent alcoholic from taking acamprosate compared to a standard care baseline. The economic evaluation was a cost-effectiveness analysis from the perspective of the German healthcare system, concentrating on the disease costs incurred by the population based on major disease classifications. Only direct costs were included, with accidents and productivity costs excluded.

The clinical effectiveness data came from a randomised controlled trial, the Prevention of Relapse with Acamprosate in the Management of Alcoholism (PRAMA) study of patients at 12 outpatient centres in Germany. All patients in the trial met at least five of the Diagnostic and Statistical Manual criteria for alcohol dependence and had to be completely abstinent from any alcohol consumption for 14 to 28 days before entry into the trial. In the trial patients received acamprosate or a placebo for 48 weeks in addition to routine counselling. The patients were followed-up for a further 48 weeks without medication.

The measured health outcome was abstinence in the 48-week follow-up period but there was no reported definition of abstinence. The analysis stated that at the end of the 48-week medication free period 39.9% of the 136 acamprosate-treated patients and 17.3% of the placebo patients had remained abstinent.

The model included epidemiology data, to include frequency of disease events per person, obtained from records of the disease course of patients with alcohol dependence in West Germany and expert opinion. The medical and rehabilitation inpatient days and associated costs were obtained from official sources.

The model used a three-stage decision-tree analysis and is reproduced at Figure 7.1 for a sample of 1,000 patients. The first step was to model the relapse and abstinent rates for two cohorts of patients, one group having had acamprosate in conjunction with the standard care and the second group having the standard care only. The second stage of the model was to calculate the disease events for patients in each of the two cohorts. Five disease states were considered: alcoholic psychoses, alcoholic dependence syndrome, alcohol fatty liver, acute alcoholic hepatitis and liver cirrhosis. The third stage of the model was to cost the treatments for each cohort, to include the cost of acamprosate and to compare the costs of the two cohorts to derive the incremental costs avoided from using acamprosate.

The results, based on 1,000 hypothetical patients are set out in Table 7-2.

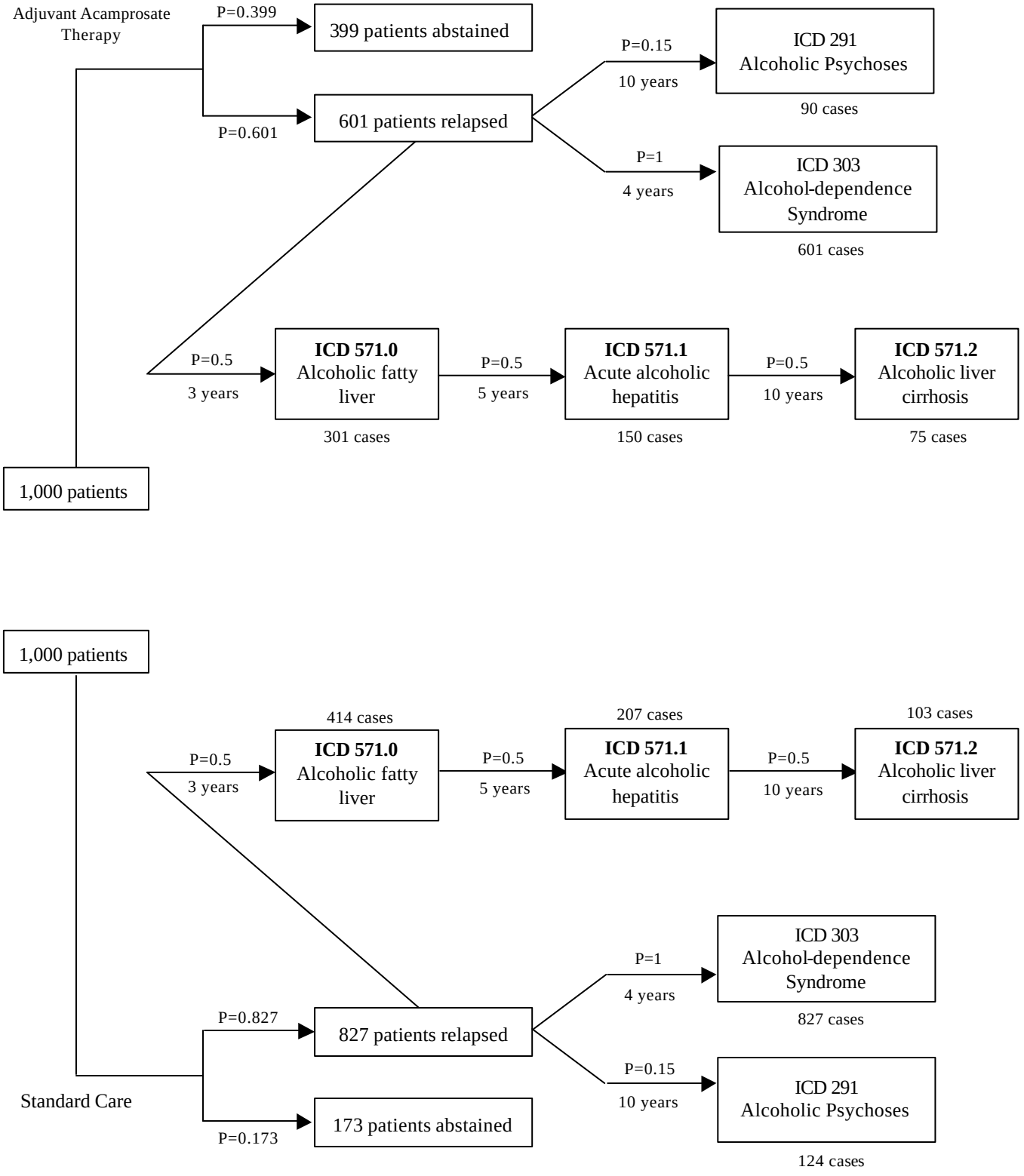
Table 7 - 2 Cost savings of acamprosate (per 1,000 patients)

	DM 000s	£000s
Treatment cost for acamprosate group*	7,333	2,317
Treatment cost for placebo group	10,090	3,188
Cost of acamprosate	2,170	685
Cost saving of acamprosate	587	186
Cost saving per marginal abstinent patient	2.6	0.823

*Number of additional abstinent patients in acamprosate group = 226

The total cost avoided per additional abstinent patient in the acamprosate group (obtained by dividing the cost savings from using acamprosate (£186,000) by the number of additional abstinent patients (226)) was £823.

Figure 7 - 1 Decision tree for evaluation of acamprosate



7.4.5 Palmer Model

Palmer et al. (2000) developed the Schadlich and Brecht model to include both a wider range of disease states and also mortality from these diseases. The model consisted of a number of sub-models to model the disease costs and the mortality from the different diseases. The model tested whether using acamprosate, in conjunction with standard counselling therapy, would reduce the incidence and progression of diseases arising from alcoholism and be cost-effective in comparison to the standard care treatment Palmer et al. (2000)

The Palmer et al. (2000) model applied incremental cost-effectiveness analysis for a German male cohort with an average age of 41. The model assumed that 80% of the cohort presented with fatty liver, 15% with cirrhosis, 22% with pancreatisis and 1% with liver cardiomyopathy when entering the model. Disease progression was modelled using a Markov chain with probabilities of progression/regression between the states being derived from a literature search. Only direct medical costs were considered.

Palmer *et al.* developed a separate Markov model for each significant disease state (liver disease, gastrointestinal, alcoholic cardiomyopathy and other complications to include suicide and accidental death). The results in Table 7.3 showed lifetime costs per patient of £15,244 for the acamprosate group, saving £524 per patient in comparison to the placebo group.

Table 7 - 3 Lifetime costs per patient

	DEM	**£**
Group with acamprosate	48,245	15,244
Placebo group	49,907	15,768
Difference	1,662	524

From a baseline of 41 years, life expectancy increased from 14.70 to 15.90 years with acamprosate, a life year gain of 1.2 years, equivalent to a gain of 0.52 years when discounted at 5% per annum.

7.4.6 Annemans et al. model

Annemans et al. (2000) used a Markov model to investigate flows of patients through different alcohol related treatments, and compared the cost-effectiveness of acamprosate in preventing alcohol relapse, in comparison to no pharmacological treatment, over a 24-month period and from the Belgian health care perspective. Only direct medical costs were used and these were sourced from official statistics and a survey of GPs.

A Markov model was developed to model the movement of patients between six different health states. The six states were:

- Community follow-up after detoxification
- Community detoxification
- Hospital detoxification
- Hospital follow-up after detoxification
- Lost to follow-up
- Death.

Relapse rates were taken from a placebo controlled prospective trial of 448 patients in Belgium, whilst details of treatment following relapse were taken from an unpublished Belgian study. Effectiveness of inpatient and outpatient detoxification was taken from Hayashida (1989) who compared 87 outpatient and 77 inpatient detoxifications, which showed a 66% success rate for outpatients compared with 81% for inpatients.

The data were entered into the Markov model and the costs of treatment and future health care costs applied. The model then predicted how the average patient would progress through the time window of 24 months.

In the Annemans model the expected cost of the acamprosate strategy, to include drug costs, was 211,986 BEF (£3,193) compared to 233,287 BEF (£3,514) for the placebo. Although the cost of acamprosate treatment over the 24 month period was 34,712 BEF (£522) compared to no cost for the placebo population, cost savings through a lower rate of acute hospitalisation, lower long term hospitalisation and fewer liver complications resulted in a net cost saving from treatment of around 213,100 BEF (£320) per patient.

The sensitivity analysis included adjusting several of the unit costs. The authors reported that the cost of acute hospitalisation would need to be 50% lower than in the model before the acamprosate treatment ceased to be cost saving.

The authors conclude that if 30% of patients reporting to their GPs with an alcohol problem were to be detoxified and started on acamprosate the total net saving would be 220 m BEF (£3,314,139) over two years.

7.4.7 Merck model

PH Consulting developed a hybrid of the Schadlich & Brecht and Annemans *et al*. models to investigate the effectiveness of managing alcohol abuse through acamprosate. Dr A Walker added Scottish cost data to the PH Consulting model. The new model, 'the Merck model' and its results formed the main submission by Merck Lipha to HTBS as part of the HTA process (Walker, 2001).

The Merck model (Walker, 2001)adapted some of the data inputs applied in the Schadlich & Brecht model for Scottish conditions. For example, Scottish hospital bed costs were applied to German hospital bed stay days for the four diseases of alcoholic psychoses, alcoholic dependence syndrome, acute alcoholic hepatitis and liver cirrhosis. The Merck model removed any resource costs for in-patient rehabilitation because, according to the author, a Scottish patient care pathway seldom makes provision for such care. The author also noted that he used German epidemiological data because no Scottish epidemiological data were available.

The Merck model applied abstinence rate data from one German and one Austrian study (Sass, 1996)[‡](Whitworth & Fischer, 1996). The abstinence rates applied are set out in Table 7-4.

Table 7 - 4 Abstinence rates after 24 months

	Acamprosate	Placebo
Sass (n=104)[‡]	39%	17%
Whitworth (n=148)	11.9%	4.9%

The Merck model did not include data from the UK trial on acamprosate undertaken by Chick *et al*. (2000). The Merck report stated that this study was not included because the trial placed patients on acamprosate with some delay following detoxification, which is inconsistent with the protocol. The latter specifies that the drug should be used as soon as possible after detoxification. The Chick *et al*. trial did not find any difference in abstinence rates following the use of acamprosate in comparison to the standard baseline treatment.

The Merck model allowed for short-term savings from reduced community and hospital follow-up and reduced detoxification costs adapting the different care pathways from the Annemans *et al.* study of a Belgian trial of 448 patients (Annemans *et al*., 2000).

The results of the Merck model are set out in Table 7-5.

Table 7 - 5 Mean cost-effectiveness of acamprosate (1,000 patients)

	£000
Cost of acamprosate	373.7
Short-term savings from reduced detoxification	(186.6)
Long-term savings from avoided disease conditions	(537.0)
Net cost saving	(349.9)
Cost saving per marginal abstinent patient*	1.841

*Number of additional abstinent patients = 190

The Merck model concluded that, under the base case assumptions, to include the clinical effectiveness of acamprosate, there would be cost savings to the NHS of using the drug. These cost savings, resulting from avoided repeat detoxifications and fewer incidences of liver and mental health diseases exceeded the initial cost of prescribing the drug.

[‡] This study is also used by Schadlich and Brecht in their model

7.5 Summary of Results

The results of the four models are summarised in Table 7-6 below.

Table 7 - 6 Summary of results from economic models

Study	Cost saving per patient from acamprosate £
Schadlich & Brecht	823
Merck	1,841
Annemans	320
Palmer	524

The Merck model realised the greatest savings because it aggregated the effects found by Schadlich & Brecht and Annemans and assumed all the benefits could be attributed to one application of the drug.

7.6 Model Limitations

Models can be validated by considering how well each model performs in respect of three major groups of attributes; these being structure, data and validation (ISPOR, 2001). ISPOR set out 13 attributes concerning model structure, 17 concerning data identification, data modelling and data incorporation and six validation attributes. This economic evaluation has not rigorously examined each model for each key attribute. Rather the limitations notified by the original authors and by others critiquing the studies, for example in the Scottish Executive report on alcohol misuse (Ludbrook *et al.*, 2001), have been noted.

The limitations that apply to all the above models include:

- The assumption that abstinence rates are maintained at the value observed at the end of the trial period
- Lack of clarity about the definition of the abstinence outcome
- The exclusion of benefits relating to an end point of controlled drinking (which itself will reduce morbidity and mortality)
- The model specification of 'lost to follow-up' and incomplete disease states
- The use of average costs determined for insurance or administration purposes
- The absence of opportunity costs and non-medical costs relating to crime, accidents, productivity etc.
- The absence of good incidence data for disease states and death
- The application of data from different sources and often different countries into the same model with no correction for these differences
- The absence of observed probability distributions around costs and epidemiology data

- The exclusion of trial data that shows no significant difference in the abstinence rates following the adoption of acamprosate (Chick *et al*., 2000) and Roussaux (1996) and
- The absence of any revealed preference data.

More research is needed in particular to provide:

- more definitive estimates of the long-term effectiveness of the acamprosate therapies;
- on the incidence and prevalence of alcohol related diseases and
- on the relevant Scottish costs of these diseases.

7.7 Proposed Economic Model

This economic evaluation adopts the Schadlich & Brecht model, which provides a simple but useful approach to structure the evidence on clinical and economic outcomes.

Currently the Schadlich & Brecht model only seeks to measure the marginal costs and outcomes of adopting acamprosate as an adjunct to conventional psychosocial therapy in comparison to adopting only the conventional therapy. This economic evaluation will extend the analysis to consider the changes to costs and outcomes following the adoption of other pharmacological and psychosocial therapies including:

- Naltrexone
- Disulfiram
- Coping Skills
- Classical Relapse Prevention
- Behavioural Self Control Training
- Motivational Interviewing
- Marital/family therapy

The proposed model will have many of the limitations identified above. The implications of these limitations are addressed in the Discussion section of this chapter.

In particular the costings will be from an NHSScotland viewpoint rather than a societal perspective. This limitation has, in part, been addressed by the quantification of the societal costs from the Catalyst Economics report for the Scottish Executive (Catalyst Health Economics Consultants Ltd, 2001). However the assumption will result in an understatement of costs, omitting to capture costs incurred in private sector hospitals and rehabilitation services.

Most costs in the economic model are average costs collected for administrative purposes and thus include non-marginal components such as overheads. However, given the long-term perspective of the economic evaluation, this may be a reasonable approximation to long run marginal costs (see next section).

No revealed preference data is available to enable the model to be enhanced to measure outcomes in terms of QALYs. A study by Patience *et al.* (1997) did report data from a study of 212 patients who had contacted an alcohol problem clinic at the Royal Edinburgh Hospital 12 months previously. The report explained that the results of an Alcohol Related Problem Questionnaire could be used to map drinking behaviour onto a quality of life score (SF-36) and act as an indicator of resource costs. (In essence, the lower the score, the higher the resource cost and the lower the quality of life.) The study concluded that the questionnaire could be used in a clinical setting to predict future costs and act as a marker for quality of life.

The Merck submission noted that a literature search found no utility or QALY measurements for alcohol related health states (Walker, 2001). The author used the SF-36 data obtained from the study by Patience *et al.* and used the SF-36 scores as utility scores. This approach has significant shortcomings including the fact that the SF-36 measures do not explicitly incorporate preferences.

One report of a potential technique to move from observed SF-36 scores to utility scores has recently been published. Brazier *et al*. (2002) simplified the SF-36 scoring system into 249 health states and then asked 836 members of the public to rank and value states. The resultant preferences were incorporated into a least squares regression model and various data transformations applied. The results indicated that the approach adopted by Brazier *et al.* may offer a method of analysing existing quality of life scores, for example SF-36 scores, to generate QALYs. However, as the paper notes, this research is at a very early stage.

The research by Brazier (2002) offers a potentially promising methodology to estimate preference weights from health related outcomes. However, the methodology is not proven and further work is needed before it may be possible to transform SF-36 scores to a preference based utility measure. Thus, in the absence of observed or estimated data on utilities, it will not be possible to include utility measures or QALYs within this economic evaluation.

7.8 Costings for the economic model

Costing for economic evaluations should identify, measure and value all resource changes that occur as a certain health intervention is carried out. The categories of costs identified by Brouwer, Rutten and Koomanschap in Chapter 4 of the book by Drummond & McGuire, (2001) are:

Due to the perspective adopted, a subset of the cost groups identified in Brouwer, Rutten and Koomanschap in Chapter 4 of the book by Drummond and McGuire 2001 need to be quantified:

- Medical resources directly needed for the intervention
- Future medical costs that are a consequence of the intervention

Brouwer *et al.* explain that the decision on whether to use marginal or average cost depends on the research question. They note that when longer-term cost consequences are being considered then average costs may be more appropriate

because many cost items that are fixed in the short-term may become variable in the long term. The authors also state that, in general, the resources used should be valued at their opportunity costs, being the value of their best alternative use. This will usually be the observed price where there are competitive markets but in health care there is often no market price that reflects the opportunity cost.

This economic model requires two major categories of costs, namely the costs of the alcohol relapse prevention therapies and the disease related costs. This section explains the method used to estimate each category.

7.8.1 Cost of pharmacological therapies

Patient pathways for the treatment programmes of acamprosate and disulfiram are set out in Figure 7-2 and Figure 7-3 were provided by a TSG member (Ms C Keogh, Consultant Clinical Psychologist, Personal communication, 17 April 2002). No naltrexone patient pathway has been found. Following discussions with Board Members (Board Meeting, 27 May 2002) it is assumed to be the same as Disulfiram but excluding supervisory requirements.

The resource units, unit costs and total costs of the three drug treatment programmes are contained in Tables 7-7 and Table 7-8 and summarised in Table 7-9. The resources used are derived from the patient pathways. All patients receiving acamprosate are assumed to have a 30 minute consultation with a consultant level alcohol counsellor. This assumption may not fit in with some parts of the Scottish service pattern where initial visits are not with a consultant level counsellor. Sensitivity tests assume a lower grade staff member conducts the initial interview.

Table 7 - 7 Resource uses and costs: Acamprosate 12 months treatment per patient May 2002 prices

Resource	Unit cost £	Total costs £	Source of costings
15 min GP consultation	15.33	15.33	NHSScotland
30 min consultant alcohol counsellor	8.72	8.72	Keyworker £25.59k + 20% & 1760 hours p.a (NHSScotland)
1st appointment	52.50	52.50	NHSScotland
2nd & 3rd appointment	15.33	76.65	As above
Monthly appts CPU then Dr			
90% at 6 tablets per day 10% at 4 tablets a day			

Table 7 - 8 Resource uses and costs: Disulfiram and Naltrexone 6 months treatment per patient May 2002 prices

Resource	Unit cost £	Total costs £	Source of costings
15 min GP consultation	15.33	15.33	NHSScotland
30 min keyworker	8.72	8.72	Keyworker £25.59k + 20% & 1760 hours p.a (NHSScotland)
Medical & bloods	52.50	52.50	NHSScotland
5 monthly GP visits	15.33	76.65	As above
Week 1 visits to APTU	4.36	30.52	As above
6*15min per month keyworker	4.36	26.17	As above
Blood test +check-up month 1	30+14.6	46.83	NHSScotland
25 weeks @ 3 per week 10 min supervision[§]	1.36 per dose	107.39	
Disulfiram tablets			
25 weeks @ 6 tablets per week + 1 week at 8 tablets	18.38 for 50	55.53	BNF 43[*] March 2002 + 5% dispensing on-costs
Naltrexone tablets			
Naltrexone daily dose 50 mg	42.51 for 28	290.14	BNF 43[*] March 2002 + 5% dispensing on-costs

Table 7 - 9 Total costs for three drug treatments per patient

	Total Costs £		
	Mean	**Low**	**High**
Acamprosate 12 month treatment period	538	419	645
Disulfiram 6 month treatment period	337[(a)]	315	425
Naltrexone 6 month treatment period	547	525	630

Resource	Unit cost £	Total costs £	Source of costings
15 min GP consultation	15.33	15.33	NHSScotland
30 min consultant alcohol counsellor	22.96	22.96	Av salary £67.34k +20% payroll costs:1760 hrs (NHSScotland)
1st appointment	19.69	19.69	Keyworker £25.59k + 20% & 1760 hours p.a (NHSScotland)
2nd & 3rd appointment	14.58	29.16	As above
Monthly appts CPU then Dr	4.36:15.33	67.80	As above
90% at 6 tablets per day 10 % at 4 tablets a day	£28.92 for 168	382.65	BNF 43 March 2002 + 5% dispensing on-costs
Total Costs Acamprosate		537.59	

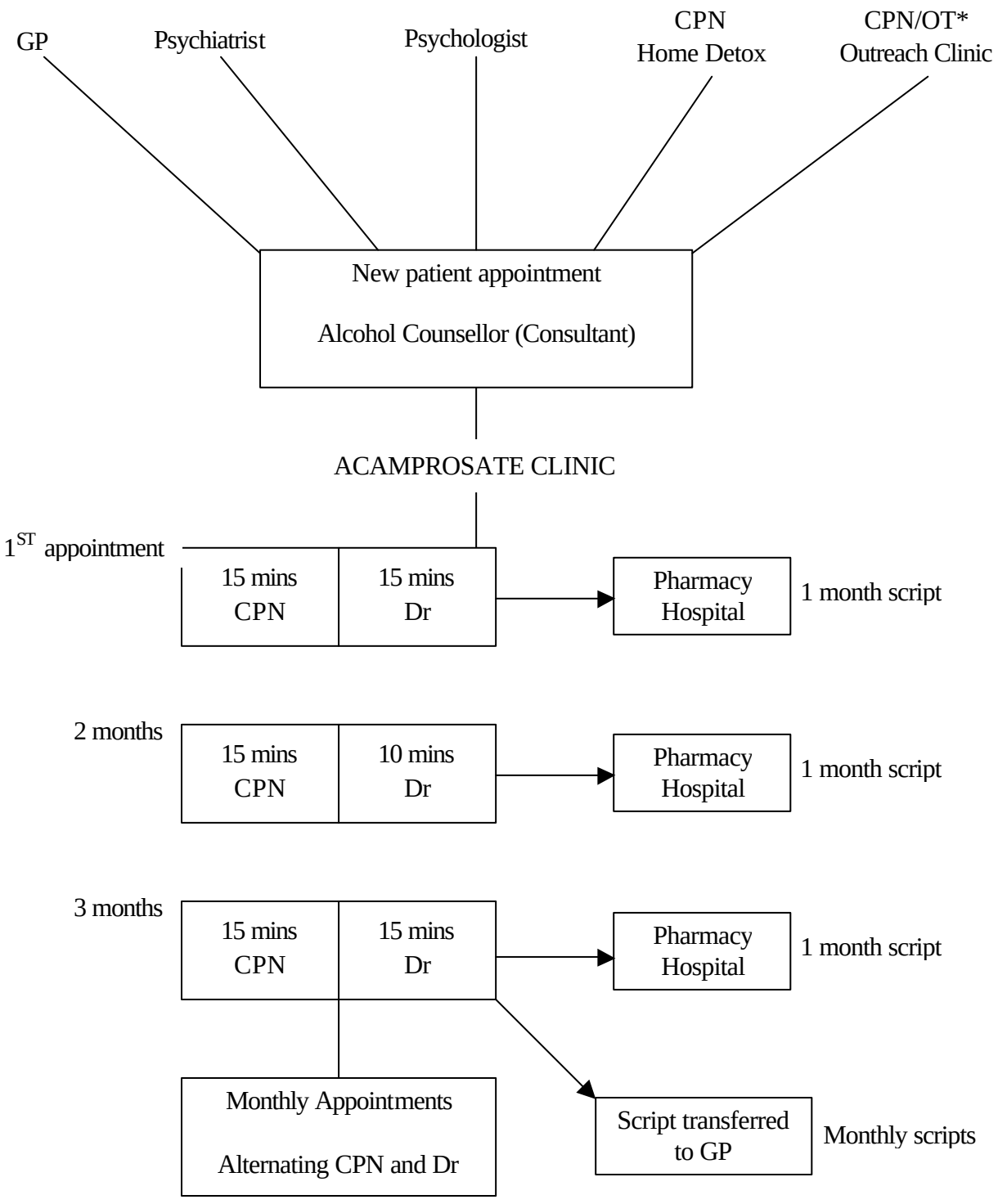
The high and low costs are used in the sensitivity analysis.

[§] Assume supervision at home or at APTU has same cost based on opportunity cost of £12,000 pa

[*] (British Medical Association (BMA) & Royal Pharmaceutical Society of Great Britian (RPSGB), 2002)

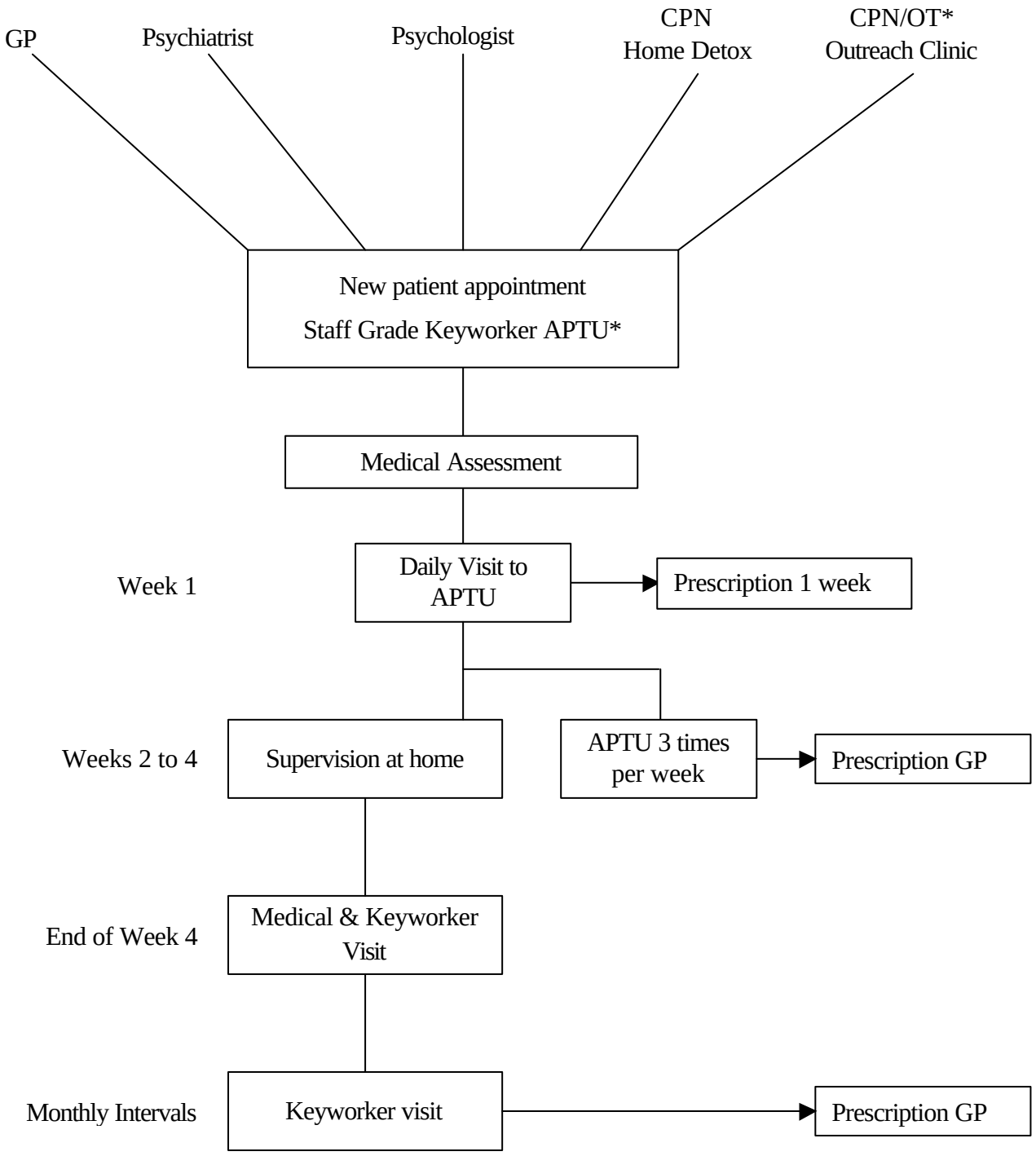
[(a)] if 80% supervision at home with nil cost

Figure 7 - 2 Patient Pathway: Acamprosate - 12 month Treatment Programme



*OT	Occupational Therapist
*CPN	Community Psychiatric Nurse

Figure 7 - 3 Patient Pathway: Disulfiram - 6 month Treatment Programme



*OT	Occupational Therapist
*CPN	Community Psychiatric Nurse
*APTU	Alcohol Problems Treatment Unit

+In addition to the NHSScotland costs, there may be patient costs to include travel and incidental costs of supervision for disulfiram users. Such costs have been excluded in the base case but are modelled in the sensitivity analysis.

7.8.2 Cost of psychosocial therapies

Following discussions with a TSG member (Ms C Keogh, Consultant Clinical Psychologist, Personal communication, 17 April 2002) and Ms M O'Sullivan, (Day Hospital Manager, Alcohol and Drug Directorate, Parkhead Hospital, Personal communication, 13 May 2002) it was decided that the costs of delivering a training programme for psychosocial therapies vary with the structure and duration of the course, rather than course content.

Costings for psychosocial therapies have thus been developed for three different, but commonly used, training courses being:

(a) a six week course of 1 two-hour session per week, with follow up at 3 and 6 months;
(b) a daily course for four weeks with each session of one and a half hours duration; and
(c) ten hourly one-to-one sessions.

An allowance for supervision is included in the costings for all the courses since such a function is regarded as essential to ensure standards are maintained and the course complies with 'best practice' as defined for that location.

The first course format is used in several parts of Scotland and is based on a programme devised by Annis *et al*. (1996). This course is delivered at weekly two-hour sessions (one and a half hour's group work + 30 minutes for one to one work), for groups of 8-12, for some six weeks, with three month and six month follow up. Initially invitations go to some 16 potential participants.

The costed staff input is: one psychologist (although other parts of Scotland use different levels of professional input), one CPN and one trainee/student for three hours on a weekly basis. The costs assume 1 hour for set up, travel time, administration and a supervisory element per session. The accommodation costs are assumed to be £15 per session to hire a community hall for 3 hours plus £5 administration costs.

The second course costed is over 4 weeks, providing one and a half hours group work plus a half-hour set-up, admin and supervision time (ie two hours) per day, five days a week, with two further follow-ups of the same duration. This course is delivered to groups of 8-12 by a mix of staff to include F and E grade nurses, a senior occupational therapist, together with consultant level support. It is assumed initial invitations are issued to 16 with some 12 attending the first session. The accommodation costs of £550 per course are calculated by applying the relevant rates from 'Scottish Health Service Costs' to an area of 100 m^2.

The third option costed is one-to-one training for ten hours, (15 hours if including preparation, administration time and some supervisory element) with a grade G nurse.

No marginal accommodation costs are included for this option because it is assumed accommodation provided for other purposes will be usable at nil additional cost.

All course materials are assumed to cost £10,000 to produce and to be used for 5 years. This has been annualised using the 6% financial discount rate, to yield a cost per person is £5. Admin costs are assumed to be £10 per invited attendee.

The costs per course for the three models are summarised in Table 7-10.

Table 7 - 10 Costs of psychosocial courses

	Model a £	**Model b £**	**Model c £**
Staff	1,778	1,688	262
Accommodation (non-residential)	160	550	0
Admin & manual	303	305	15
Total	2,241	2,543	277
Cost per attendee	£187 to £280 (8 or 12 attendees)	£212 to £318 (8 or 12 attendees)	277

These costs are all reasonably similar with the main determinant being number of attendees and the drop out rate. To avoid spurious accuracy all the psychosocial courses have been assumed to have a mean cost of £250 per person, with sensitivity analysis assuming a high and low cost of £150 and £350 per person.

7.8.3 Costs of disease

The epidemiology of alcohol dependent patients and the resultant incremental disease cases, in comparison to the general population, has been discussed in Section 3.20. This section predicted disease cases over 20 years in a base case of 45-year-old men and women who are alcohol dependent, in comparison to the general male and female population. The results are tabulated in tables 7.11 (a) and (b).

Table 7 - 11 (a) Estimated Disease Cases - Men

	Alcohol Dependent	Non-alcohol dependent
Death to include suicide	936	318
Stroke	43 (26)	33 (18)
Cancer	88 (53)	97 (50)
Cirrhosis	102 (72)	10 (6)
Alcoholic psychoses	571 (403)	-
Chronic pancreatitis	44 (31)	-
Epilepsy	41 (29)	-
Alcohol dependence syndrome	814 (575)	-

(discounted at 6% p.a.)

Table 7 - 11 (b) Estimated Disease Cases 2

	Alcohol Dependent	Non-alcohol dependent
Death	785	268
Stroke	53 (31)	33 (18)
Cancer	146 (93)	125 (73)
Cirrhosis	52 (35)	4 (3)
Alcoholic psychoses	160 (107)	-
Chronic pancreatitis	32 (22)	-
Epilepsy	50 (34)	-
Alcohol dependence syndrome	260 (175)	-

(discounted at 6% p.a.)

The economic evaluation uses these diseases as end points for the economic model. The model attributes costs to each of the end points except death. However it is important to note that avoidance of death is the major benefit from preventing relapse.

The cost of each disease other than stroke has been estimated using data extracted from the Scottish medical records held by ISD. This Division provided:

- mean treatment inpatient days in Scottish non-psychiatric hospitals, mental illness hospitals and psychiatric units for each relevant disease
- mean cost per inpatient day in the following speciality groups:
  - general psychiatry
  - medical
  - general practice
  - radiotherapy.

Each disease other than stroke was mapped to a speciality for costing purposes; for example all liver related diseases were mapped to the medical group. The ISD data showed that some patients with diseases such as alcohol dependence had episodes in general psychiatric and non-psychiatric units. The costings used a weighted average of the costs for these units with the weights being relevant in-patient episodes. All patients were assumed to have six GP appointments, thereby adding some £90 to the disease costs.

No rehabilitation costs are included in the disease costs. The same assumption was used in the Merck model because in Scotland there is little provision for such rehabilitation services (Dr PJ Jauhar, Clinical Director, Greater Glasgow Primary Care Trust. Personal communication).

The cost of stroke was obtained from a study of Scottish Borders stroke patients (Syme *et al*., 2002). The mean value of £5,000 is some 3% lower than the average number of inpatient days costed at a medical unit mean cost of £257 per day. The lower figure may be more appropriate since some of the stay will be in rehabilitation wards at a lower unit cost.

The uncertainty around the costs is expressed in a sensitivity analysis. High and low costs for each disease were obtained using semi-interquartile values of the hospital related costs.

Table 7-12 gives the average inpatient days and mean, high and low cost per hospital day for each relevant disease group.

Table 7 - 12 Average in-patient days and costs by disease

Disease	In-patient days	Costs £		
		Low	Mean	High
Alcoholic dependence syndrome	16.31	2,571	2,897	3,219
Alcoholic psychosis	44.37	7,216	8,131	8,893
Liver cirrhosis	11.97	2,807	3,165	3,517
Epilepsy	3.70	651	726	798
Chronic pancreatitis	5.00	1,223	1,373	1,520
Cancer weighted average; Men	8.56	2,819	3,301	3,696
Cancer weighted average; Women	7.32	2,425	2,836	3,172
Stroke	20.90	4,500	5,000	7,000

The cohort used in the modelling assumes a ratio of four males to every one female in the population. This ratio was observed in the Copenhagen City Heart Study discussed in section 3.20.9.3.

As explained in section 3.20.7, alcoholic psychosis aggregates several separate conditions to include withdrawal, psychotic disorder and amnesic syndrome due to the use of alcohol (ICD codes F103 to F107). Two codes, F106 alcoholic amnesic syndrome, to include Korsakov's syndrome and F107 residual and late onset psychotic disorder, to include alcoholic dementia and chronic alcoholic brain syndrome, account for just over one third of the number of patients discharged in this group but some 90% of the related inpatient stays.

Indeed in 2000/01 the mean stay for patients coded to F106 as a primary diagnosis was over 572 days. Assuming a cost per inpatient week for general psychiatry care of £1,210, (the 2000/01 level updated by 5 %){Scottish Health Service Costs 2000/01} then the cost per inpatient with such a disorder is almost £100,000.

7.9 Discounting

Individuals and society exhibit behaviour that indicates they have a positive rate of time preference (Drummond *et al.*, 1997). Thus most people prefer to have benefits today rather than at a later date and to defer costs for as long as possible. It is important in economic evaluation to adjust the cash flows associated with costs and benefits over time to take account of this time preference effect. This enables decision makers to compare alternative treatments over any time horizon.

In line with HTBS's Guidance to Manufacturers (Health Technology Board of Scotland, 2002) costs will be discounted according to the UK Treasury discount rate (currently 6.0%).

7.10 Effectiveness

Analysis of the cost-effectiveness of therapies for prevention of relapse in alcohol requires estimates of the proportion of patients in whom treatments will be effective. The estimates of the effectiveness of the therapies are taken from sections 5.5 to 5.6 of this report. That section explained that the effectiveness of the pharmacological treatments are based on placebo controlled or no-treatment controlled trials but the evaluations of psychosocial therapies are based on a more heterogeneous selection of trials. Most of these included a treatment arm in which the therapy was thought likely to have little or no effect and this is used as the comparator arm when available. However, other trials included therapies thought likely to be less effective but not necessarily ineffective. These have also been included and thus it may be that psychosocial therapies effects will be somewhat underestimated. Psychosocial therapies are also poorly standardized in content and duration and cannot be blinded which allows the possibility of many other sources of heterogeneity and bias.

The proportion of patients in whom treatment is successful may be expressed either as those in a controlled drinking state or as those totally abstinent. Furthermore, these figures are reported at different time points in different studies. Thus combining these outcomes can be difficult. The strategy used has been to extract figures for controlled drinking where presented and figures for abstinence otherwise. The analysis used works in terms of odds ratios – in the hope that these will vary less than absolute values over time – and chooses times of follow-up as close to 1 year as possible. However, due to limited duration of many trials, follow-up may often be only three months.

In order to make valid comparisons of treatments it is necessary to choose a single baseline value of the probability of success when no treatment is given and refer all the treatment effects to this value. The observed proportions of successes in placebo or no-treatment arms varied widely over the therapies examined. Figures between 15.5% and 37% were found. The following figures are referred to an intermediate figure of 25%.

Table 7 - 13 Effectiveness estimates using odds ratios

Therapies	Odds Ratio	Success per 1000	Failed per 1000	Success per 1000	
				(low estimate)	(high estimate)
Standard treatment	1.0	250	750		
Pharmacotherapy					
Acamprosate	1.74 (1.48,2.04)	367	633	331	405
Naltrexone	1.41 (1.18,1.69)	320	680	283	361
Disulfiram	1.31 (0.82,2.09)	304	696	215	411
Psychosocial					
Coping Skills	2.29 (1.44,3.64)	433	567	325	548
Classical Relapse Prevention	1.10 (0.69,1.76)	268	732	188	370
Behavioural self control training	1.84 (1.04,3.25)	380	620	258	520
Motivational Interviewing	2.16 (1.20,3.88)	419	581	286	564
Marital/family therapy	1.87 (1.33,2.64)	384	616	307	468

The low and high estimates are obtained from the upper and lower limits of the 95% confidence interval.

Various other therapies were considered in the clinical effectiveness analysis but treatment effects were not included. These include:

Brief Therapies. Strong evidence suggests that brief therapies do not work in the class of alcohol dependent patients considered in this HTA. This contrasts strongly with the results in alcohol abusing patients where such measures appear effective.

Cognitive Behavioural Therapy. This does not appear to be a single well defined therapy in treatment of alcohol problems.

Anxiety Management. Some evidence suggests that this is a useful therapy in alcohol dependent patients with anxiety. However, its effect is to reduce anxiety and appears unrelated to reduction of alcohol intake.

Alcoholics Anonymous. Section 5.8.1 explains that there is some evidence to suggest that the treatment philosophy of the AA is successful but that more high quality randomised trials are required. For an economic evaluation conducted from the NHSScotland perspective, the use of AA should be encouraged. Such therapies are costless to NHSScotland at point of delivery and could be cost saving in the longer term through the associated reduction in the incidence of diseases.

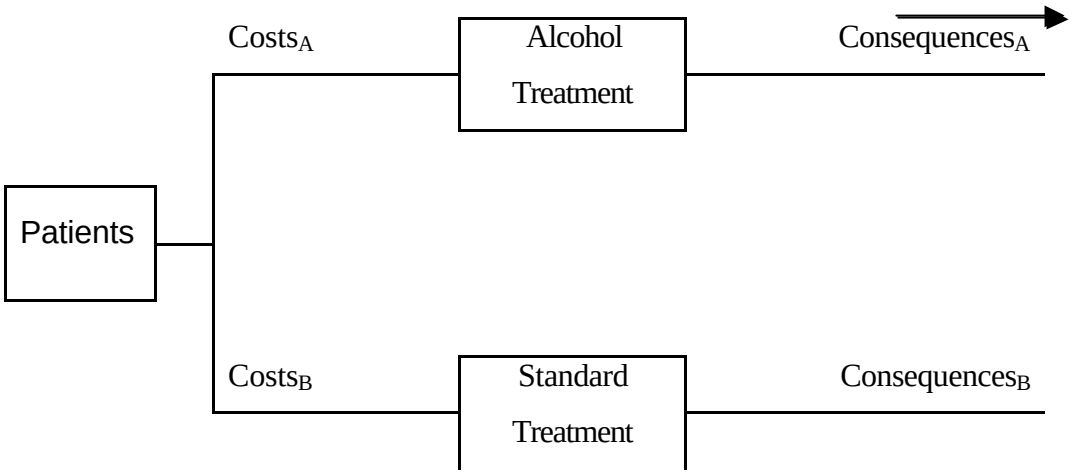
Some points that should be borne in mind in applying the effectiveness figures are:

1. The figures for disulfiram are obtained from studies of oral disulfiram only.
2. It has been noted that the effectiveness of disulfiram may depend strongly on the degree of supervision exercised over those taking it. This has not been incorporated into the analysis.
3. In most studies of pharmacotherapy, patients in both arms of the trial received some psychosocial therapy.
4. Psychosocial and pharmacological therapies should not be treated as competing. The design of the trials of pharmacotherapy gives every reason to believe that some additional effect can be obtained by adding pharmacy to psychotherapy.
5. Family/Marital therapy is only occasionally feasible as the consent of the patient and the availability and cooperation of family are required. Thus it should not be regarded as a competitor treatment to the other psychosocial therapies but as an occasional addition.
6. 'Classical Relapse Prevention' is included despite rather poor performance in trials as it is an option that many experts consider viable and hence should be evaluated. It may be that the available trials underestimate its effectiveness as many use comparators, which may themselves be effective. However, experimental justification of its use appears somewhat lacking at present.
7. The effectiveness of acamprosate currently requires review as a large US trial, as yet unpublished, has recently reported disappointing results. Some adjustment for this fact has been made in the estimates in this report. It is hoped exact results will be available before the final report is published.

7.11 Economic model

The economic model is a simple treatment model constructed in Microsoft Excel. A cohort of 1000 patients is assumed to enter each of the eight therapies: three pharmacological therapies and five psychosocial programmes. Figure 7-4 shows how the range of treatments is compared to the standard care package, with costs and consequences associated with each.

Figure 7 - 4 A basic economic evaluation



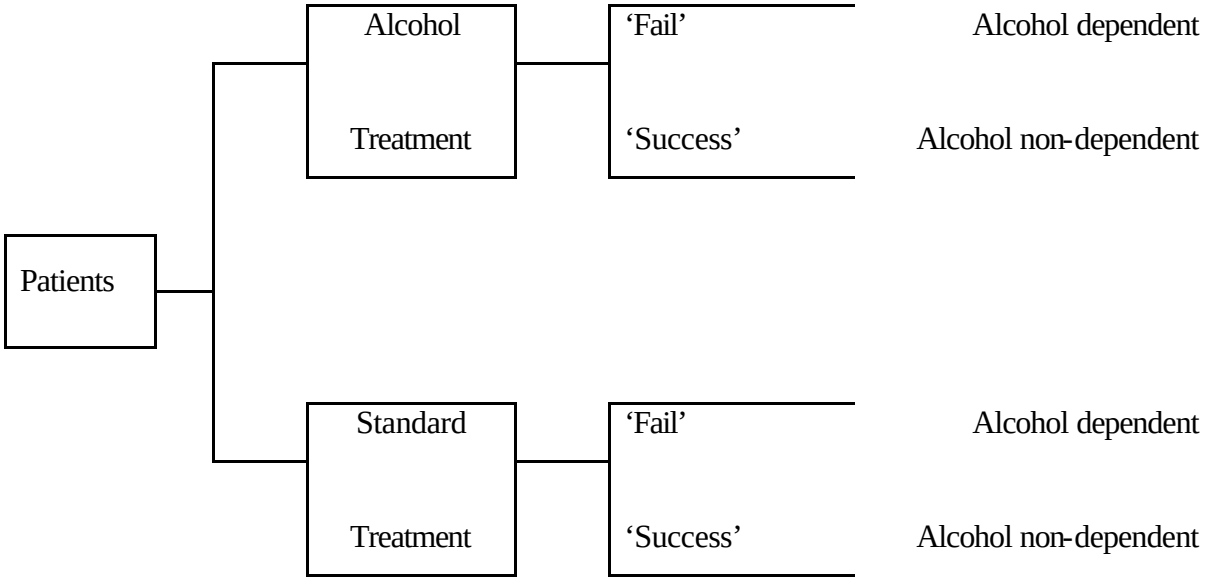
The results are presented as an incremental cost effectiveness analysis of the treatment over and above the 'standard treatment' scenario. The pharmacological therapies used in the model are provided as an adjunct to the standard treatment, for example acamprosate is provided in addition to a standard care package.

The incremental cost effectiveness ratio is calculated as follows:

$$\text{ICER} = \frac{\text{Costs}_A - \text{Costs}_B}{\text{Consequences}_A - \text{Consequences}_B}$$

Patients are assumed to enter one of two arms of a basic decision tree following compliance with the treatment programme. The 'successes' become non-alcohol dependent whilst the 'failures' continue as alcohol dependent. This is shown in Figure 7.5.

Figure 7 - 5 Alcohol dependent and non-dependent outcomes in the model



Patients then experience a range of disease endpoints being death, stroke, cancer, cirrhosis, alcoholic psychoses, chronic pancreatitis, epilepsy and alcohol dependence syndrome.

7.12 Results

The effectiveness of standard treatment is taken as 250 successes and 750 failures per 1000 patients, and therefore the effectiveness of each therapy is calculated by examining the number of successes over and above that of standard treatment.

For each therapy, the number of disease endpoints is multiplied through by the disease costs per case for both the therapy and the standard treatment package. The change in disease costs over and above standard care are calculated and presented both discounted at 6% and also undiscounted for a range of therapies in Table 7.14. The Table also presents the net change in health care costs when the cost of the therapy is deducted.

An estimate of the additional patients abstinent when each treatment is assessed in comparison to standard care is combined with these estimated costs to calculate the cost per additional abstinent patient. Estimates of the number of deaths averted are presented in addition to the cost per change. It should be noted from the Table that a negative cost represents a cost *saving*.

When discounted at 6%, four of the five psychosocial therapies (Coping Skills, Behavioural Self Control Training, Motivational Interviewing and Marital and Family Therapy) demonstrate net health care cost savings ranging from £584,824 (coping skills) to £343,044 (Behavioural Self Control Training).

For the pharmacological therapies there is a net economic cost associated with a cohort using acamprosate of £4,260 rising to £227,668 for naltrexone. Acamprosate is the most cost-effective of the pharmacological therapies.

Also presented are the net health care costs per death averted. Using the discounted results, the range is from -£5635 (a net saving per death averted) for Coping Skills to £15,262 for Relapse Prevention. Assuming that each death averted only saved one life year (a very conservative assumption) these costs per life year saved are lower than the equivalent rates for many of the recent products approved by NICE. Indeed four of the psychosocial therapies actually show a net saving per life year gained.

Table 7 - 14 Results summary for 1,000 patients

	Acamprosate	Disulfiram	Naltrexone	Coping Skills	Relapse prevention	BSCT	Motivational interviewing	Family Therapy
Total Therapy Cost	£538,000	£337,000	£547,000	£250,000	£250,000	£250,000	£250,000	£250,000
Change in Health Care costs (discounted)	-£533,740	-£246,341	-£319,332	-£834,824	-£82,114	-£593,044	-£770,958	-£611,292
Change in Health Care costs (undiscounted)	-£752,054	-£347,102	-£449,947	-£1,176,290	-£115,701	-£835,616	-£1,086,301	-£861,327
Net Health care cost over and above standard treatment (discounted)	£4,260	£90,659	£227,668	-£584,824	£167,886	-£343,044	-£520,958	-£361,292
Net Health care cost over and above standard treatment (undiscounted)	-£214,054	-£10,102	£97,053	-£926,290	£134,299	-£585,616	-£836,301	-£611,327
Additional patients abstinent over and above standard	117	54	70	183	18	130	169	134
Reduction in deaths over and above standard	70	32	42	109	11	78	101	80
Net Health care cost per death averted (discounted)	*£61*	*£2,833*	*£5,421*	*-£5,365*	*£15,262*	*-£4,398*	*-£5,158*	*-£4,516*
Net Health care cost per death averted (undiscounted)	-£3,058	-£316	£2,311	-£8,498	£12,209	-£7,508	-£8,280	-£7,642
Cost per additional abstinent patient (discounted)	*£36*	*£1,679*	*£3,252*	*-£3,196*	*£9,327*	*-£2,639*	*-£3,083*	*-£2,696*
Cost per additional abstinent patient (undiscounted)	-£1,830	-£187	£1,386	-£5,062	£7,461	-£4,505	-£4,949	-£4,562

Note: Discount rate = 6%

7.13 Sensitivity Analysis

The impact of uncertainty in any kind of economic analysis should always be explored to assess how the results change when different values for the input parameters are observed. For the individual cost variables, measures of dispersion around the central case value are not available and hence it is not possible to provide probability distributions. The cost variables have been expressed as mean, high and low values only.

The following analysis is based on incremental discounted cost per additional abstinent patient, with the increment being the costs and consequences over and above standard care. The model used consists of three main variables: the cost of treatment, the effectiveness of treatment and the disease cost consequences.

Table 7.15 shows two extreme scenarios. Scenario 1 is a 'worst case' scenario based upon the highest therapy cost, lowest therapy effectiveness and the lowest costs for averted diseases. The incremental discounted cost per additional abstinent patient ranges from £617 for Coping Skills to £39,700 for Behavioural Self Control Training. The disulfiram and Classical Relapse Prevention programmes are 'dominated', whereby the lower effectiveness estimate is below that of standard case, whilst the cost exceeds the standard care option.

Scenario 2 represents a 'best case' scenario with the lowest treatment cost, highest treatment effectiveness and also highest cost of averted diseases. In this case the range is -£303 (naltrexone) to -£4,236 (Motivational Interviewing) and there is a net health care cost saving from all of the therapies.

Note that the scenario of delivery treatments in an inpatient setting in a dedicated ATU has not been explored. This may be developed in a later draft.

Table 7 - 15 Incremental cost per additional abstinent patient (extreme scenarios)

Therapies	Incremental cost per additional abstinent patient (discounted) Scenario 1: Based on high therapy cost, lowest effectiveness and lowest disease costs.	Scenario 2: Based on low therapy cost, highest effectiveness and highest disease costs.
Pharmacotherapy		
Acamprosate	£3,913	-£2,329
Naltrexone	£15,041	-£303
Disulfiram	Standard treatment dominates	-£3,076
Psychosocial		
Coping Skills	£617	-£4,194
Classical Relapse Prevention	Standard treatment dominates	-£2,949
Behavioural Self Control Training	£39,700	-£4,107
Motivational Interviewing	£5,672	-£4,236
Marital/family therapy	£2,091	-£3,886

7.13.1 Pair-wise sensitivity analysis

Further sensitivity analysis was performed using a pair-wise approach using the incremental cost per additional abstinent patient over standard treatment (discounted at 6%). The three main variables of treatment cost, disease costs and treatment effectiveness are examined, holding two of the variables constant at the average values and using the extreme values of the third. Negative estimates demonstrate net cost savings for the relevant therapy under the high/low conditions at the top of the column.

The sensitivity analysis results show that under each of the different assumptions, the cost per additional abstinent patient is less than or equal to £2,080 for acamprosate, whilst naltrexone costs range from £366 to £12,014 per additional abstinent patient.

Of the psychosocial therapies both Coping Skills and Marital/Family therapy result in net health care cost savings per additional abstinent patient for all of the possible pair-wise comparisons, indicating these results to be fairly robust. Coping Skills is consistently more cost-effective than Marital/Family therapy. The results for Behavioural Self Control Training show the therapies to be generally cost saving although the results are sensitive to the effectiveness estimates at the lower bound. This is very close to the effectiveness of the standard care treatment. Relapse Prevention shows the most variation in results by both effectiveness and treatment cost, although the high and low estimates of disease cost yield similar figures.

Acamprosate is the most cost-effective of the pharmacological treatments except under the high treatment effectiveness assumption whereby disulfiram yields a greater saving

per abstinent patient. However, under no assumptions were any of the pharmacological therapies more cost-effective than Coping Skills. Naltrexone is generally found to have the lowest cost-effectiveness of the three pharmacological therapies except under the lowest treatment effectiveness assumption where disulfiram is the dominated alternative.

It should be noted that the range of odds ratios for naltrexone and Relapse Prevention include 1.0, and therefore the effectiveness evidence may indicate that these programmes do not have a significant outcome when compared to standard treatment.

The full results of the pair-wise sensitivity analysis are presented in Appendix 26.

7.14 Comparison with alternative approaches to estimating cost-effectiveness

The incremental cost per abstinent patient was also estimated using a decision tree model based on the Schadlich and Brecht study of acamprosate therapy in Germany . The costs of treatment and local disease costs for Scotland, together with treatment efficacy, were substituted into the model. In this case costs were discounted by assuming the German observed latent periods for a range of diseases (alcoholic psychoses, alcohol dependence syndrome, cirrhosis and hepatitis) and again the incremental cost-effectiveness over and above standard care was computed. These estimates ranged from a saving of £1,643 (Coping Skills versus standard care) to a cost of £13,991 (Relapse Prevention versus standard care). The full results are shown in Table 7-16.

These compare with a saving of £3,196 (Coping Skills) to a cost of £9,327 (Relapse Prevention) for the methodology described earlier. The higher savings for the most effective therapies and lower costs for the less effective under the previous methodology can be explained by the inclusion of several more disease categories in the estimates.

The figures follow a very similar ranking in terms of cost-effectiveness and also the estimated disease costs are similar despite being calculated by two very different models.

Table 7 - 16 Results based on German decision tree model

Therapies	Incremental cost per additional abstinent patient (discounted at 6%)
Pharmacotherapy	
Acamprosate	£1,288
Naltrexone	£6,819
Disulfiram	£5,715
Psychosocial	
Coping Skills	-£1,643
Classical Relapse Prevention	£13,991
Behavioural Self Control Training	-£923
Motivational Interviewing	-£1,472
Marital/family therapy	-£960

7.15 Discussion

The economic evaluation raises some interesting issues in two main areas being:

i. the epidemiological and effectiveness assumptions; and
ii. the resources used and the costs applied to each resource.

This section will consider each of these areas and briefly discuss the interpretation of the results.

7.15.1 Epidemiology and effectiveness

Section 3.20 raises several methodological issues concerning the calculation of the health benefits from reducing alcohol relapse in a cohort of people who are alcohol dependent. A significant issue for the economic evaluation is the assumption that a person who does not relapse reverts to having the same health condition as a member of the general public. For example, there may be underlying psychological co-morbidities that would cause this assumption to overstate the beneficial effect of abstinence on a cohort of people with mental disorders and alcohol dependence. Also, if the health of a person recovering from alcohol dependence is adversely affected by a history of heavy drinking then the health benefits used in the economic evaluation will be overstated. However, no evidence or discussion of such aspects has been found from the literature search.

The epidemiology does not provide evidence on how the recurrence of alcoholic episodes, after a period of abstinence following detoxification, affects disease incidence. Such data would enable the economic evaluation to model the cost-effectiveness of therapies for a cohort of patients who are in a cycle of abstinent periods for several years followed by an episode of alcohol dependence. Such modelling may be more representative of observed events in the community than the model presented above.

The economic evaluation has assumed that people who relapse are similar to those who do not relapse other than in respect of this one factor. However, there may be inherited or environmental factors that give rise to alcohol dependence in the first place and these may also affect the effectiveness of the therapies. If so, and the occurrence of these inherited or environmental factors is different in Scotland from their occurrence in the populations from whom the clinical effectiveness evidence in Chapter 5 is derived, then the results may not generalise to the Scottish setting.

The odds ratio for each therapy is the parameter that has the greatest impact on cost effectiveness and the ranking of therapies. The evidence used to calculate the odds ratios has been explained in section 5.6 and is primarily from reported randomised controlled trials. However, the trial setting may differ significantly from the Scottish community setting. For example, the entry criteria to trials could result in a sample that is atypical of the alcohol dependent population in Scotland. Such a bias could affect the effectiveness recorded for the placebo group and the therapies under examination. If so, then the

absolute level of benefits used in the model may be overstated since all the odds ratios will be too high.

The trials may also have a higher treatment compliance rate than is observed in the treated population because trial settings provide incentives to comply that do not exist in the community. This would result in an inflated odds ratio.

Trials may also have fewer 'lost to follow up' than is seen in the community setting where the number of dropouts tends to be high. Again, HTBS would welcome data on compliance and dropout rates in Scotland in order to refine the economic model.

A further problem with trial data is that follow-up stops at 48 weeks or earlier for the pharmacological treatments and six month or earlier for the psychosocial treatments. The effectiveness ratios assume the last observed effectiveness rate is maintained over time. This assumption is likely to overstate the benefits from the therapies since experience suggests that people do relapse after years of not drinking. This is related to the earlier point that patients may cycle between abstinence and dependence and this is a key area where further research is required.

Section 5.6 has explained that different trials have used different definitions of abstinence. Thus it may be that there are some health related benefits from patients moving to controlled drinking but not abstinence that have not been adequately captured in the simple economic model.

7.15.2 Resource uses and costs

The costs of the psychosocial therapies are about £250 when costed on a short-run marginal cost basis. However, if significantly more trained staff require to be recruited to meet the demand for alcohol relapse prevention services then there could be a step change in the level of fixed costs.

The disease costs are calculated using inpatient length of stay in NHSScotland hospitals as the only measure of resource use. This is likely to understate resource use. For example, it does not capture outpatient use, rehabilitation provided in the community, or the use of long stay private homes by psychiatrically damaged patients who are discharged there and paid for by NHSScotland.

The underlying assumption of the economic evaluatio n that patients do not cycle between abstinence and relapse means the resource use and costs of repeated detoxifications and interventions for relapse prevention are omitted from the economic model. Thus the present model only captures longer-term effects. It would be helpful to have estimates of the short-term benefits of preventing alcohol relapse, as measured by avoided community and hospital costs. The data set required is the number of events such as community or inpatient detoxifications and other treatments per patient avoided as a result of permanent prevention of relapse. This could be the next stage of the economic evaluation if data on

the events avoided became available. The cost of detoxification in the community has been estimated as £290.

The inpatient hospital costs used are from ISD who collate and publish cost information by speciality group (for example, by medical, general practice, general psychiatry). There are some 38 codes in total but these do not map easily to diseases. However, the economic evaluation requires cost to treat of diseases. Decision-making would be enhanced if Scottish costs were available by disease group, possibly using the ICD code that is currently used by ISD to record hospital and general practice events,

The costings are also limited to the NHSScotland perspective. They do not capture the patient or societal costs that could be avoided by preventing relapse. The Catalyst report indicated that health care costs are less than 10% of the costs that alcohol imposes on society. Whilst the ratio may be different for this sub-group of people with established alcohol dependence, taking the narrow health care perspective will undoubtedly lead to an understatement of the benefits from reducing relapse.

The model has not sought to value death although the epidemiology indicates that reducing the death rate would be the biggest benefit from reducing alcohol relapse. Other Government Departments, in particular the Department of the Environment and Transport have developed a methodology that values a life at about £800,000. The economic model could be extended to include an annual saving per death avoided based on this capital sum. However, this approach would be inconsistent with adopting the NHSScotland perspective and would raise issues of employment participation rates and the appropriateness of applying such a value to this cohort of the population.

7.15.3 Interpretation of Results

The economic evaluation has ranked therapies in terms of the incremental cost per abstinent patient. This approach assumes the psychosocial therapies can be neatly categorised using the definitions applied within the HTA, which may not always be possible. This approach could also be misinterpreted since it fails to recognise that different people will respond better to different therapies and it is thus important that a range of therapies are offered. For example, not all patients, and possibly very few, can take advantage of a Marital/Family therapy.

The costings did not indicate a systematic difference in the cost per person of providing group or individual training and the effectiveness is assumed to be the same under either approach. However, this should not be interpreted as suggesting the courses are identical in terms of outcomes for individual patients; rather individual preferences will still be important when deciding whether a course should be on a one-to-one basis or in a group setting.

Similarly the costings did not indicate a systematic difference in the cost per person of providing intervention in the community rather than a hospital setting, or as an in-patient rather than an out-patient or day-patient. This is probably not true for all service

provision in Scotland and it will thus be important to review the costs for the decision maker's own circumstances.

7.16 Draft Recommendations

The economic evaluation shows that Coping Skills, Motivational Interviewing, Marital and Family therapy and Behavioural Self Control training all result in positive net economic benefits. That is the cost of treatment is more than offset by the savings in alcohol related disease treatment costs following the programme. In these simulations, these four psychosocial therapies therefore dominate the pharmacological therapies and classical Relapse Prevention (i.e. the four therapies are cheaper *and* more effective).

Of these four dominant therapies, Coping Skills generates the greatest cost savings per abstinent patient, whilst Behavioural Self Control Training has the lowest cost saving. However, the results for the four therapies are similar. Of the pharmacological therapies, acamprosate is provided at the lowest economic cost of £36 per abstinent patient, whilst the most costly is naltrexone at £3,252 per abstinent patient.

The Discussion section suggests that the effectiveness observed from the trials may not be appropriate for adoption in a community setting but no evidence is available to indicate the effect of the change in setting. The Discussion also indicates that the potential savings may be understated. Neither effect alters the ranking of the therapies, only their absolute cost-effectiveness.

Under the worst-case scenario the incremental costs of acamprosate, Coping Skills, Motivational Interviewing and Marital/Family Therapy all have an incremental cost per additional abstinent patients of under £6,000. This indicates that these therapies are likely to be cost effective unless new evidence emerges indicating the effectiveness in a community setting is considerably less than that reported under trials, or new trials report lower rates of effectiveness.

7.17 Potential resource impact for NHSScotland

At present, the analysis does not include costings of the potential resource impact for NHSScotland of implementing the draft recommendations. This section summarises how we may take forward this aspect.

HTBS will seek to establish a baseline of the present Scottish costs incurred to prevent alcohol relapse. For example, ISD records show that the present annual costs for acamprosate and disulfiram are £318,021 and £162,208 respectively. We are seeking data on the costs of psychosocial therapies across Scotland and the short-term costs of detoxification. If obtained, these will form the baseline and the cost of implementing the draft recommendations will be compared to this baseline.

Using the epidemiology, we can estimate the number of people with acute alcohol dependence in Scotland. So far, no evidence has emerged of the number of these who would accept treatment, although there is German evidence to indicate one third of patients with alcohol dependence may accept treatment (Schadlich & Brecht, 1998).

Applying this rate will give the number of people who may be suitable for treatment in Scotland. We will cost providing treatment to this sub-group for a range of therapies.

The clinical effectiveness assumptions will be used to estimate the number of additional abstinent patients following the adoption of the therapy. The epidemiological and cost of disease assumptions will be used to determine the number and cost of disease endpoints avoided. The cost and savings will be presented as a cash flow over time.

8 ORGANISATIONAL ISSUES

8.1 Summary

The following points arise from consideration of the service structure and the requirements for effective service delivery. They are primarily based on expert opinion.

- Alcohol services are highly suited to 'joint working', as recommended by the Joint Futures Group, involving specialist mental health and social work addiction services and non statutory agencies with joint resourcing and management of community care services.

- Certain subgroups such as young people, the homeless, those with co-morbid mental health problems, have special services needs and providers should ensure that the service is accessible to all.

- Specialist services must make themselves aware of mutual help (AA) and non-statutory agencies operating in their area and co-ordinate their approach making this information available to individuals under their care. Introduction to AA and non-statutory agencies should be part of the overall relapse prevention strategy.

- Controlled use of alcohol may be an appropriate treatment goal for those with less severe alcohol problems. However, abstinence should be the goal for severe dependence, where controlled use is rarely sustainable and especially when there is evidence of alcohol related organ damage. If controlled use / harm minimisation is the considered preferred goal of the individual there must still be options for intervention e.g. referral to a voluntary agency or outpatient motivational sessions.

- An improved information collection system is required. (ISD are currently changing the way in which information is collected, for instance from GP contacts).

- A regularly updated comprehensive directory of alcohol services would be beneficial. This should be useable by all participating agencies and provide accurate outcome data (as recorded and analysed) as well as a greater understanding of progress through the treatment system.

- More research and evidence are needed regarding the benefits of different settings for psychosocial interventions e.g. group vs. individual, inpatient vs. outpatient vs. day unit, intensity and length and frequency of sessions etc.

8.2 Introduction

Providers of healthcare services require the clearest evidence available to provide cost-effective specialist alcohol services, equitable with other services throughout Scotland and concentrating resources on improving delivery of treatments of proven efficacy. In providing this service account must be taken of the particular problems involved in treating patients with alcohol dependence and of making best use of the available resources. The main aims of relapse prevention are to support, motivate and encourage effective coping skills – medication is an adjunct to this.

The complex and varied nature of the problems faced by alcohol dependent patients means that many agencies might be involved in their care. A high level of coordinated integration must exist between statutory physical health, mental health and social care services and the voluntary agencies with local collaboration and implementation required to promote development of a logical and effective 'treatment system'. Attempt should be made to avoid overlap in treatment provision (and therefore waste and duplication) as much as possible. Development of clear lines of referral from one service to another will be required.

Bearing this in mind, individuals accessing the 'treatment system' note a desire for continuity in terms of those managing their care and therefore transition through the treatment system should ideally be managed retaining such continuity as far as possible. This may also encourage the avoidance of overlap in information gathering and interventions offered.

In this respect alcohol services are highly suited to 'joint working', as recommended by the Joint Futures Group, involving specialist mental health and social work addiction services and non statutory agencies with joint resourcing and management of community care services.

Shared care guidelines, based on national policy but locally determined, can be developed between specialists and GPs and Social Work teams. These require sufficient flexibility to allow for the needs of a diverse range of patients.

Certain subgroups such as young people, the homeless, those with co-morbid mental health problems, have special services needs and providers should ensure that the service is accessible to all.

NHS specialist alcohol services should ideally be multidisciplinary community (and day hospital) based services with the opportunity of access to specialist inpatient care. They should be made up of a highly skilled team that sees the most severe end of the spectrum of alcohol problems. They should also provide supervision and training to all professionals in less specialised tiers of service.

These specialist services should have the core principals of: confidentiality; accessibility; ongoing contact rather than time limited; holistic care; a supportive / non-judgemental

approach; the ability to tailor this approach to the individual; co-ordination with different agencies involved in helping those with alcohol problems (mental health, general medical, social, forensic); addressing the needs of other family members. The specialist service should create the opportunity for individuals to engage in social and occupational activities.

Services should be able to offer a comprehensive package of help whether through their own actions or integration with other agencies, which deal with employment issues, housing issues etc. (Early liaison with Social Work services, housing services and debt counselling services may help in capitalising on the gains achieved through detoxification).

Services from area to area need to show consistency and equity in the content of treatment offered, with interventions being given to centrally accredited standards and protocols, with equity of accessibility to the heterogeneous group which makes up alcohol users, with training of staff locally to agreed national standards (centrally accredited) and with the use of common assessment tools and outcome measures. Staff should be well trained and closely supervised.

Use of screening tools such as FAST (abbreviated version of AUDIT) in Primary Care settings (as per SIGN guidelines) may not be as appropriate to the specialist setting. Standardised assessment tools may none the less be drawn up for use between agencies.

Outcome measures such as biological markers (e.g. gamma GT and MCV) may be useful, if elevated initially, to use as markers of progress. (However, in 20% of patients there will be no such marker to monitor (Scottish Intercollegiate Guidelines Network (SIGN), 2002). Self-report (e.g. of cumulative abstinence days, CADs) is an acceptable measure of outcome when abstinence is not the goal, then self-reported days when drinking is less than e.g. 8 units may be an appropriate measure, supplemented if possible by corroborative reporting.

Long-term (up to 3 years) monitoring following treatment and discharge back to GP care is useful in reducing the severity of relapses and may facilitate early referral back to specialist services.

Alcohol dependence should be viewed as a relapsing condition and the need for ongoing treatment even after a number of unsuccessful interventions should be recognised. Recurrent relapse should not be a barrier to re-referral (and the HTBS survey of specialist services suggest that this is generally accepted). The condition should be approached like other relapsing medical conditions with long term monitoring and intermittent or continuous treatment (Chick).

Relapse prevention should not be seen as a treatment to be implemented at a specific point in the treatment system but rather as a component part of all stages of treatment with time given to motivational work throughout the individual's transition through the care pathway and with recognition that levels of motivation will fluctuate.

Non-specialist NHS services need to remain aware that detoxification or treating the presenting alcohol related physical disease is only one part of the process of treating alcohol dependence and they should have a clear understanding of how to access the care pathway / treatment system. This awareness can be stimulated by improved liaison between general hospitals and specialist services. Acute hospital staff, identified for developing a special interest in alcohol problems, (.e.g.'alcohol liason nurses') may be able to counsel patients as a preparatory step to specialist care, develop knowledge about locally available non-statutory agencies and link up with liaison psychiatry and specialist alcohol services. Such acute hospital staff with this special interest may be able to educate and increase the knowledge of their co-workers.

Specialist services must make themselves aware of mutual help (AA) and non-statutory agencies operating in their area and co-ordinate their approach making this information available to individuals under their care. Introduction to AA and non-statutory agencies should be part of the overall relapse prevention strategy.

The funded non-statutory agencies, which carry out 'counselling' should be expected to deliver interventions of known efficacy. As it stands, our survey of these services suggests that much of the non-NHS sector appears to offer well-validated and probably efficacious interventions (albeit therapist factors and standardisation of interventions are not accounted for). For instance AA is the origin of the now validated process called Twelve Step Facilitation, the Councils on Alcohol are trained in a CBT / Motivational Interviewing approach through the Alcohol Focus Scotland training scheme which is accredited at Edinburgh University, Social Work services appear to be carrying out Social Skills Therapy, CBT and Motivational Interviewing.

Over 50 % of the homeless facilities that we contacted did not provide psychosocial interventions despite a large proportion of their clientele having alcohol problems. There may be opportunity for training the staff in these facilities in community reinforcement therapy, which has been shown to be effective in this population.

Rural communities may have different needs from the urban population. There may be greater need for inpatient detoxification and relapse prevention due to geographical factors, which prevent effective community interventions. The non-statutory agencies are noted to be a valuable resource in the rural setting.

Controlled use of alcohol may be an appropriate treatment goal for those with less severe alcohol problems. However, as will usually be the case in the specialist setting, abstinence should be the goal for severe dependence, where controlled use is rarely sustainable and especially when there is evidence of alcohol related organ damage. If controlled use / harm minimisation is the considered preferred goal of the individual there must still be options for intervention e.g. referral to a voluntary agency or outpatient motivational sessions.

8.3 Implications of cost effectiveness analysis for service provision for prevention of relapse in alcohol dependence

8.3.1 Psychosocial interventions

An evidence based assessment of the efficacy of psychosocial interventions is included in section 5 of this report. Further discussion of these, including comments on cost-effectiveness, is given in section Table 7 - 10 Costs of psychosocial courses. With respect to the implementation of these methods a number of recommendations are widely accepted on the basis of clinical considerations or hypothesis generating studies.

- Shorter less intensive interventions should be offered first, bearing in minds the principles of 'tiered', or 'stepped' care.

- When the patient has not responded to less intense intervention, increasing the intensity is appropriate.

- Disengaged individuals and/or those showing a high degree of anger are probably more likely to benefit from the Motivational Interviewing / Motivational Enhancement Therapy than from other approaches.

- There are common therapist factors and characteristics which appear to be important whatever the intervention used, including; the ability to form a therapeutic alliance; taking a non-judgemental empathic approach; using reflective listening. These factors may be crucial to the successful completion of treatment. Therapist empathy and expertise is as important as experience and in this respect adequate training and audit of therapist competencies is recommended.

- Clear and acceptable guidelines should be used locally, if possible to agreed national standards, for each psychosocial intervention employed.

- Monitoring of adherence to protocols, ensuring that what is delivered under the name of a specific intervention is the intervention as more widely recognised, will be an important factor in auditing the effectiveness of these approaches.

- Another important factor in ensuring that the treatment delivered corresponds to that which has been demonstrated to be effective is continuing clinical supervision of therapists, which will be accompanied by continuing opportunities for skill enhancement.

8.3.2 Pharmacological interventions

Discussion of the clinical effectiveness and cost effectiveness of pharmacological interventions is included in section 5 and section9.2.2. The following points relate to the use of these therapies and are widely accepted.

- Pharmacotherapy should only be used as an adjunct to psychosocial intervention but whether this is structured or relatively non-intensive is not yet established,.

- In using pharmacotherapy note should be taken of individual needs and expectations as well as contraindications, cautions and interactions.

- Shared care protocols (examples of which are provided within Appendix 12) should be drawn up for the use of both acamprosate and disulfiram.

- Acamprosate should be commenced immediately after or shortly before successful completion of alcohol detoxification.

- Compliance with acamprosate should be monitored in the first month and the medication should be discontinued if compliance is poor and/or the clinical result is poor.

- Review of the medication (acamprosate) should take place at 2 weeks, 4 weeks, 8 weeks and 12 weeks at which stage transfer of prescribing to the GP would be appropriate. Ongoing monitoring in shared care with the GP should continue thereafter. Monitoring ideally should include information from the family or other closely involved party, and/or lGGT, MCV, as well as assessment of CADs.

- At present acamprosate is advised to be used for one year, with little evidence available for continued prescription beyond this time period. However, there is no evidence to show that continuing the prescription for 12 months is superior to discontinuing it after, say, 6 months.

- For disulfiram, patients should be told of the nature and dangers of the alcohol reaction prior to prescription of the drug and should carry a card warning of the danger of administration of alcohol.

- Daily, supervised administration of disulfiram is recommended. Twice or thrice weekly administration may be more logistically practical if supervision is by a day hospital, CPN, a practice nurse, or an occupational health worker or deputy.

- Information sheets for the nominated supervising agent (e.g. spouse, family member, Practice Nurse, Workplace Nurse) should be available (an example of such an information sheet can be found in the Appendix 14).

- It is recommended that adherence to disulfiram and ongoing benefit from its use be reviewed on a monthly basis by the specialist service for the first 3 months, and thereafter 2 monthly by a physician alert to rare adverse effects of the drug such as neuropathy, or potential drug interactions.

- Naltrexone is not authorised for treatment of alcohol dependence in the UK and so is not recommended for use.

- Acamprosate and disulfiram have not been studied in combination and so should not be used in this manner.

8.4 High risk groups

Homeless people may have particular problems in accessing specialist services for alcohol dependence. It is thus important to maintain liaison between these services and groups specifically dealing with problems of homelessness in order that referrals can be made when appropriate. As noted in section 3.6.3 the Scottish Prison Service provides a treatment and care plan to those identified as in need of help. However, many of these prisoners might benefit from referral to NHS services during the period of renewed exposure to alcohol immediately after release. Thus agreed procedures for routine referrals between the SPS and NHS services convenient to the prisoner might provide significant benefits.

8.5 Aftercare

Specialist services should make special arrangements for aftercare for each individual.

There has been a dearth of clinical trials comparing different intensities of long-term contact but some evidence suggests that even low-intensity contact may have a beneficial effect (Hilton *et al.*, 2001), see section 5.5.1.7.

If, during aftercare, other psychiatric problems persist e.g. anxiety, depression at 3 weeks post detoxification, these should be treated appropriately e.g. with psychological therapy (CBT) or antidepressant medication (Scottish Intercollegiate Guidelines Network (SIGN), 2002), but without drawing the patient's attention away from the primacy of the drinking goal.

8.6 Data Recording

Greater Glasgow Alcohol and Drug Directorate have developed and are currently piloting a computerised information system specifically developed to enable useful clinical information to be recorded on patients throughout their contact with the directorate. In addition Greater Glasgow Social Work Addiction Services already have an outcome monitoring system for recording information on the progress of clients through their contact with relevant services. However, the information on individuals once they have left these services, through default or completion of a programme, is not collected. Consequently no information can be obtained about the longer-term impact of contact with these services. Such information systems help gain greater understanding of the

demands on and effective organisation of services. Nonetheless, the difficulty in estimating the true prevalence of alcohol problems in Scotland, as noted above, may suggest that further alterations are required in the way that contacts with individuals presenting with alcohol problems are recorded.

8.7 Audit and research

The difficulty highlighted in estimating the prevalence of alcohol dependence suggests that it is important to change the way in which contact with those with alcohol problems is recorded.

An improved information collection system is required. (ISD are currently changing the way in which information is collected, for instance from GP contacts).

ISD and the Scottish Executive are looking at the feasibility of setting up a National Alcohol Information Resource to benefit those who plan and provide services.

A regularly updated comprehensive directory of alcohol services and accommodation would be beneficial. This should be useable by all participating agencies and provide accurate outcome data (as recorded and analysed) as well as a greater understanding of progress through the treatment system.

Attempt should be made to standardise outcome measures so that greater comparison of outcome between services is possible. There is need for ongoing debate about which outcome measures should be used.

There is also the need to collect information routinely on what happens to individuals once they have left the service through default or completion of a programme.
It is essential to have a longer-term measurement of quality and effectiveness. Future measurements of outcome should cover longer periods post intervention e.g. up to 5 years.

There is need for the ongoing monitoring of the performance of the 'treatment system' locally, with the facility to modify the system as the need to change is highlighted.

There should be scope for incorporating any new treatment, with evidence to support its use, into the current system and monitoring its success against current accepted standard treatment.

Local services should liase with ISD regarding methods of recording and collecting information for audit so that local information systems can be co-ordinated with the national information system.
Our survey showed that the current use of audit of psychosocial and pharmacological interventions is minimal, in some areas not occurring at all.

Audit of interventions should include: locally (and nationally) agreed outcome measurements (e.g. % of completed sessions, blood tests, patient self-report, CADs); checking that interventions delivered are done so according to recognised methodology; audit of therapist accreditation and supervision; checking that local protocols are being adhered to etc.

This improvement in recording contact and progress through the service and the long-term outcomes is essential for the longer-term impact of interventions and the organisation of services in the treatment system to be accurately evaluated.

Research and Development is an essential component of any improvement in the current system of care.

More research and evidence are needed regarding the benefits of different settings for psychosocial interventions e.g. group vs. individual, inpatient vs. outpatient vs. day unit, intensity and length and frequency of sessions etc.

National evaluation should be co-ordinated to avoid the 'evaluation overkill' noted by workers in both statutory and non-statutory agencies.

Other published quality standards such as Quality in Alcohol and Drugs Services (QUADS) should be consulted.

8.8 Staff training

Relapse prevention training in Scotland appears to have started with the establishment of the University of Paisley's, Centre for Alcohol and Drug Studies, Scottish Alcohol School training weeks held at Herriot Watt University in the early 1980's. A week-long residential programme allowed a wide range of attendees to review psychosocial interventions for alcohol misusers and in particular relapse prevention techniques. The Centre for Alcohol and Drug Studies maintained these programmes until 1990 when the Scottish Council on Alcohol took over their running.

A research programme to evaluate relapse prevention was undertaken in 1982 (Saunders & Allsop, 1991); (Allsop & Saunders, 1991). The research was conducted in Ravenscraig Hospital, Inverclyde, and the techniques were adopted by the hospital staff as 'standard clinical practice'. The work on relapse prevention and management techniques influenced the residential programme.

In 1998 the Scottish Council on Alcohol changed the residential programme to specific training sessions. The Introduction to Relapse Prevention module is run twice a year and has had 40 attendees.
The Centre for Alcohol and Drug Studies was established in 1979 and provides 6 postgraduate qualifications ranging from a Postgraduate Certificate in Alcohol and Drug Studies to an MSc in Alcohol and Drug Studies with practice. 300 Students have

completed these courses each of which contains educational and skills based sessions on relapse prevention.

The Centre for Alcohol and Drug Studies employed two external National Trainers one for Health and one for Social Care from 1987 to 2001. The educational focus of these trainers posts were brief intervention awareness training for generic and specialist staff. A total of 1,500 staff was trained per year over the 14-year period of the Trainers employment.

Alcohol Focus Scotland, (previously the Scottish Council on Alcohol) runs a national training scheme for volunteer counsellors. This training scheme is run in conjunction with supervision from accredited counsellors. The training scheme has 36 educational units of which two focus on relapse and strategies for relapse prevention. Since 1979 2039 people have completed this training, 356 are still practicing within a Council on Alcohol in Scotland.

STRADA, aims to improve the skills of professional staff addressing drug and alcohol misuse throughout Scotland and will provide training on interventions that are evidence based. The training will consists of: 1 & 2 day Module courses, Certificate in Addictions, Certificate in the Management of Alcohol and Drug Services and a Leadership Programme. Relapse prevention techniques will be a core content of each course.

There are short, undergraduate and postgraduate training courses available that offer the therapeutic concept of relapse prevention techniques to health, social care and voluntary staff in Scotland. There is no evidence of a consistent Scotland wide application of a standardised treatment approach as suggested by the Project Match Manuals, 1995**. The suggestions from Project Match to select, train and supervise therapists to ensure standardised application of therapeutic technique are similarly not presently in evidence.

8.9 Current services

The HTBS survey of NHS specialist services highlighted that availability of treatment is currently unevenly distributed throughout Scotland leaving some without access to what should be minimum core services.

Some areas may appear to be comparatively well serviced but nonetheless are unable to meet the health care needs of their population.
The core minimum services required for one individual with alcohol dependence to be offered a flexible and comprehensive package of care would appear to be:

** There are eight manuals which were published between 1994 and 2001.'They are the result of the collaborative efforts of the Project MATCH investigators and were used as guides by the therapists in the trial.

1. The facility of inpatient / residential detoxification if necessary.
2. At least some members of staff covering this inpatient facility should have a special interest / additional training in alcohol misuse.
3. The facility for outpatient / day patient detoxification (which may be solely a specialist CPN in liaison with the GP who is taking responsibility for the prescription of replacement medication).
4. The GP in liaison with the CPN needs to be able to carry out assessment of need / risk and refer as necessary for inpatient or outpatient detox.
5. The CPN should be able to carry out relapse prevention work including MET, Social Skills Training or another efficacious intervention, and be able to offer ongoing follow-up. Relapse prevention should be available in outpatient, daypatient and inpatient settings.
6. Voluntary agencies should also be able to offer psychosocial interventions of this nature and may take on the bulk of relapse prevention work when the specialist service is small.
7. The voluntary agency may also take on the bulk of individuals seeking controlled drinking.
8. GPs may require to be able to assess for the suitability of prescribing Acamprosate or Disulfiram (supervised e.g. by Practice Nurse, CPN, relative, community pharmacy).
9. The GP will be required, on prescription of such medication, to monitor outcomes, arrange appropriate counselling, and carry out appropriate blood testing etc. The GP might have counselling arranged through his/her Practice, or via a non-statutory agency , or with the locality CPN, if available.
10. A consultant psychiatrist should be accessible for patients with psychiatric symptoms

Areas without core minimum services are therefore:

1. Those with no inpatient facility (unless these routinely go to general medical beds) – Grampian, Shetland.
2. Those without specialist CPNs – Shetland.
3. Those with very minimal community / CPN staffing and a very small voluntary sector – Orkney, Borders, Western Isles (although the Western Isles inpatient unit appears to offer a fairly comprehensive treatment package).

Those areas with a disproportionately small number of beds given morbidity and mortality figures are Grampian and Lothian (and to a lesser extent Greater Glasgow, Forth Valley, Fife and Highland). Fife has no dedicated specialist beds.

Certain areas, Borders and Shetland, might consider offering psychosocial therapies such as motivational interviewing and coping skills training. Many services could add relationship therapies such as the Community Reinforcement Approach (CRA) and Behavioural Marital / Couples Therapy (BMCT) to their repertoire.

Many services would benefit from audit of pharmacological and psychosocial interventions.

In terms of staff complement relative to morbidity and mortality figures, Grampian and Fife are understaffed, as to a lesser extent are Lothian, Argyll and Clyde and Forth Valley.

Fife has no dedicated specialist beds.

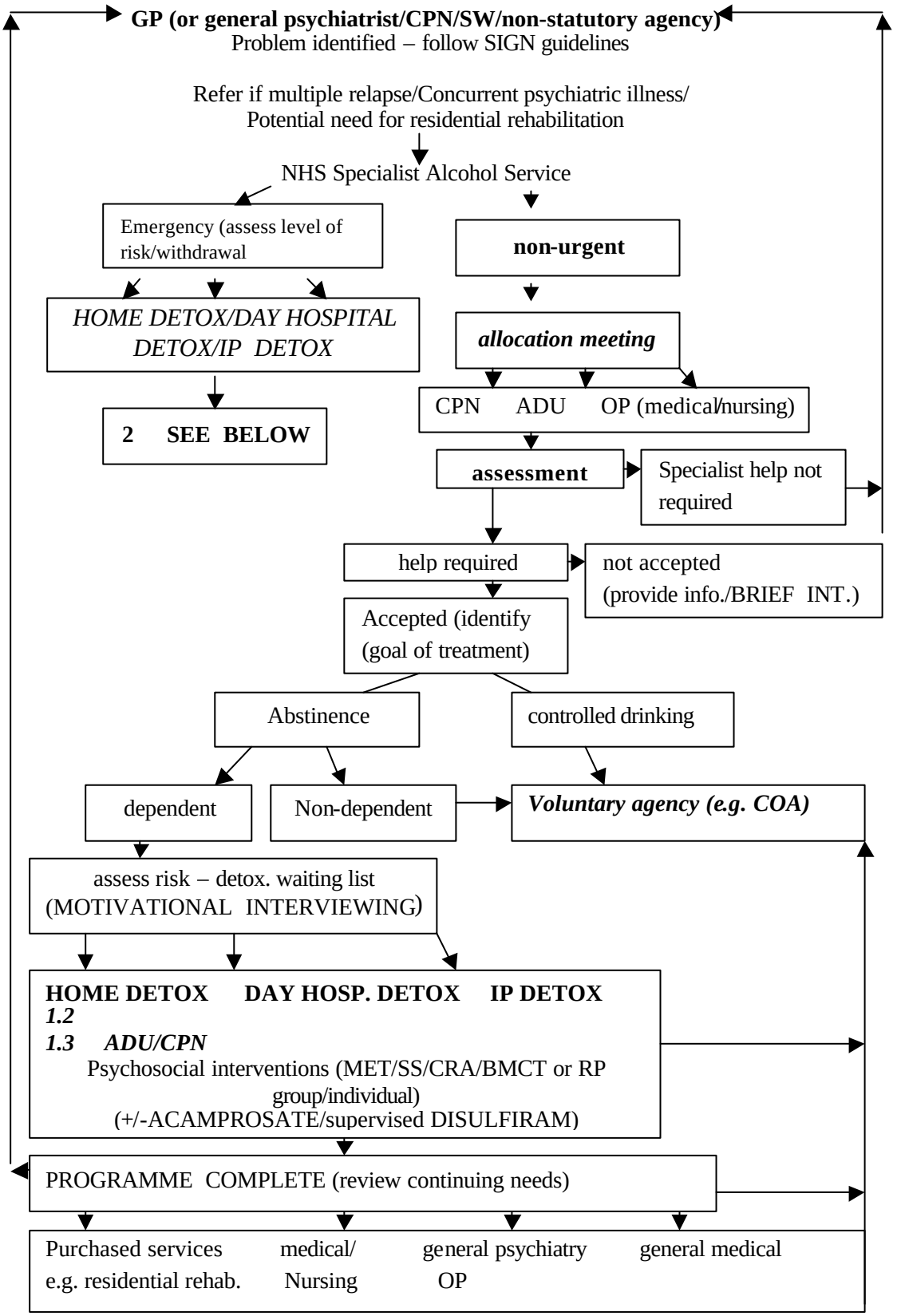
Non-NHS facilities appear to be evenly spread generally (purely in terms of numbers in relation to levels of morbidity and mortality) but Fife and Forth Valley probably have less than their share, as do Lanarkshire and Ayrshire & Arran (although notably this area has a proportionately high specialist staffing level). Lothian and Grampian have proportionately slightly fewer non-NHS services and this is compounded by lower staff and bed numbers, taking account of mortality and morbidity figures.

Overall, areas needing services are Lothian, Grampian, Forth Valley, Fife, Greater Glasgow (beds) and Highland (beds).

8.10 The Care Pathway

A number of care pathways are described in the Scottish specialist care services. The following diagram is a synthesis of these and may provide a useful template for the structure of a local care service.

Figure 8 - 1 Example Care Pathway



9 DISCUSSION

9.1 Nature and scope of this health technology assessment

Inappropriate use of alcohol is a cause of many important problems in Scottish society. A broad picture of these has been given in the Plan for Action on alcohol problems (Scottish Advisory Committee on Alcohol Misuse (SACAM), 2002). The adverse consequences of alcohol are apparent in health, criminal justice, road traffic, employment and productivity. In a substantial part, however, these problems arise through drinking in individuals who are not dependent upon alcohol and may not be considered either by themselves or most others to have an alcohol-related problem.

This report addresses the problems of the relatively small but significant subgroup of people who find themselves, at some stage, unable to control their drinking. This group is qualitatively different from others in the continuity of their exposure to alcohol and the consequent effects it may have on all aspects of their lives and in particular on their health. The profound adverse influence, which high levels of alcohol have on many aspects of morbidity and also on life expectancy, has been investigated in numerous epidemiological studies some of which are reviewed in this report. From these studies HTBS has attempted to construct a profile of the health and life expectations of an untreated alcohol dependent person and contrast it with the expectations of the general population. Such calculations are fraught with difficulties, some of which are described below. However, the general message appeared to be that, whilst the burden of ill health is high in alcohol dependence, the biggest impact of heavy drinking is in raising mortality. Two studies, one in Taiwan (Chen *et al*., 2001) and the other in Sweden (Denison *et al*., 1995), observed death rates which were around 12 times that of the Scottish population. This effect could not be explained by national differences in mortality; the life expectancy at birth in Sweden being slightly higher than in Scotland based on 1997 figures from Statistics Sweden. Furthermore, the majority of the excess mortality did not arise from somatic diseases generally linked with alcohol. Thus it would be unwise to concentrate on too narrow a group of alcohol-associated illnesses and disregard the general message that alcohol dependence should itself be seen as a life-threatening condition.

In this report we have examined four discrete aspects of relapse prevention in alcohol dependence. These are the clinical effectiveness of the interventions, the cost-effectiveness, the patient perspective on treatment and a number of issues related to organisation of treatment services. The intention has been to produce an account which will be useful to those planning and running specialist services for relapse prevention and, with this in mind, it is clear that some interpretive discussion of the report findings is necessary.

9.2 Clinical effectiveness

9.2.1 Psychosocial Interventions

Use of the results of either clinical trials or reviews of research as the basis of a practical effective clinical service is not a trivial undertaking. This is so even with conceptually simple interventions such as medicines that will have been tested according to carefully specified protocols, which should be reflected in the SPC in a way which makes it reasonable to suppose that the efficacy measured in trials will be similar to the effectiveness achieved in clinical practice. For psychosocial interventions the difficulties are much greater. There is rarely a single agreed protocol for delivery of these treatments and the setting, duration and personal qualities of the therapist may all play a part in determining the effectiveness. In addition to this, trials of nominally similar treatments may have involved substantively different procedures. It is generally the responsibility of each service provider to be acquainted with the practical details of what has been proven effective in research and to decide how it can be delivered locally. A pragmatic approach to this problem is to choose treatments which have been shown to perform well in meta-analyses and then to select trials from these meta-analyses of interventions which had estimated treatment effects towards the higher end of the distribution of results – preferably statistically significant in their own right – and examine the nature of the intervention in more detail by consulting original research reports. A good example of this procedure is provided by Finney and Moos (1998) who pick out social skills training, community reinforcement and behavioural marital therapy as examples of effective therapies and discuss the possible elements of a service based on these interventions. The results of the meta-analyses in this report would agree with Finney's general approach.

The results of our analysis also suggest that the combination of Coping Skills Training and Motivational Enhancement Therapy offered by many Scottish specialist care units provides a good foundation for treatment. However, very few of these interventions are delivered according to standardized protocols. This makes it difficult to be certain that the treatments correspond to those proven effective in clinical trials.

There is also common use of Brief Interventions (BI), which is not supported by evidence in alcohol dependent patients. Note that this contrasts strongly with problem drinking among non-dependent people where it has been shown effective. This conclusion may at first seem at odds with much perceived wisdom but the predominance of non-dependent patients in studies of BI and the substantively different nature of the problems faced by dependent drinkers provides a background against which this conclusion appears more compelling. Finney & Moos, (1998) has some comments on the way that BI has been assessed which shed further light on this issue.

The apparent failure of the intervention (confusingly) named classical Relapse Prevention in clinical trials is also worth commenting upon. It is a surprising result because RP includes many of the cognitive-behavioural elements found in effective interventions. It is worth asking whether the failure to show an effect may be explicable in terms of the nature of the clinical trials. O'Farrell(O'Farrell *et al.*, 1993) tested RP with involvement

of a spouse or partner but only following a course of behavioural marital therapy. The intention was to 'develop and cognitively rehearse a relapse prevention plan' and, in addition, to maintain the gains of BMT and deal with emerging marital issues. Thus the only new element was the development of the relapse prevention plan. In a similar way, McCrady (McCrady BS *et al.*, 1999) compared Alcohol Behavioral Couples Therapy with Relapse Prevention plus ABCT. Thus only the specific additional element of RP was assessed. Sandahl (Sandahl C *et al.*, 1998) compared RP with psychodynamically oriented group treatment which appears to have been the primary focus of the study and was not considered by the authors to be an inactive control. Thus a significant result in these three trials would have required RP to show additional benefit over active treatments. The only trial in our meta-analysis to show a marginally significant positive effect was Allsop (Allsop & Saunders, 1997) in which the comparator was inactive. However, the comparator was also inactive in the study by O'Malley(O'Malley *et al.*, 1992)[††] in which no effect was shown. The overall conclusion from these considerations is that no convincing evidence of the efficacy of RP is available. However, from the two trials, which tested the specific relapse prevention paradigm of RP it seems reasonable to draw the stronger conclusion that this particular element has little to add to a cognitive-behavioural based treatment programme.

The psychosocial interventions, which our analysis shows to have empirical support are coping skills training, behavioural self-control training, marital/relationship therapy and motivational enhancement therapy. However, there are some practical limitations in the use of any of these methods and any one treatment is unlikely to suit every situation. These limitations are discussed below.

All the clinical trials of coping skills included in our analysis are based on the work of Monti (2001) who investigated a combination of cue exposure with urge-specific coping skills training (CET), and communication skills training (CST) and compared them with educational discussions and relaxation training. These interventions were delivered as adjuncts to an intensive two-week partial hospital programme involving 6 hours per day of group, individual and marital treatment based on learning principles and 12-step philosophy. This comparison was not randomised, patients being allocated according to month of admission. Each CET/CST session took 90 minutes a day and a total of 5 coping strategies and 8 communication skills were taught. Burtscheidt (2001) used Monti's treatment techniques in an outpatient treatment programme with 26 group sessions of 100 minutes over six months. There were six or less patients per group. The comparator was a standard outpatient programme, also with weekly meetings. The two very different patterns of delivery in these studies do not provide a clear guide to therapists wishing to use these techniques. The greatest estimated treatment effect was in Monti (2001) when CET/CST was used as an adjunct to another therapy.

Behavioural self-control therapy is a complete treatment package. It may be aimed either at controlled drinking or at abstinence. However, the review by Walters (2000) and most of the studies included in it investigate controlled drinking. Some components of the

[††] Note the possibly confusing reference to the psychosocial treatment in this trial as 'coping skills'. It appears to follow the Marlatt model and has thus been classed as Relapse Prevention.

technique, for instance drinking rate control, are only applicable to this aim but other aspects such as goal setting and identification of high-risk situations are applicable to either aim. The meta-analysis we have presented of success rates is based on Walter's selection of studies and restricted to those whom he judged as 'alcoholic' rather than problem drinkers. Consequently it is also restricted to subjects seeking a controlled drinking outcome. It may thus be appropriate to use it in this fashion in clinical practice.

It has already been noted that the brief form of MET used in Project MATCH did not perform as well as the more intensive 12 Steps Approach. This suggests the qualification that it may not be a sufficient stand-alone therapy but should be a precursor to other treatments or, possibly, an early component of a stepped care programme. It is notable that Sellman (Sellman *et al.*, 2001) excluded patients for whom abstinence might be advised or with 'severe dependence' from his study. However, it is not clear whether he considered four sessions of MET inappropriate for such patients or just the 'no further counselling' option. Bien (Bien *et al.*, 1993) used only a single session of MET but as a precursor to standard outpatient treatment, much in the manner recommended in this report.

Many therapies involving spouses, partners or contracts with other individuals have been tested and the twelve trials, which, provided appropriate outcome data for the HTBS analysis are rather diverse. Finney and Moos (Finney JW & Moos RH, 1998) picked out the studies of the Community Reinforcement Approach as figuring prominently in several league tables of effective treatments, and the contribution of CRA (Hunt & Azrin, 1973); (Smith *et al.*, 1998) to increasing the estimated treatment effect of relationship therapies is clear (Appendix 21). It is notable that the trial reported by Smith enrolled homeless patients and, for the most part, the relationship involved a contract with the project nurse for supervision of disulfiram. Other standard elements of CRA such as a job club and social club reinforcing non-drinking recreational activities were also used. Non-CRA relationship interventions generally tended to show positive, if less impressive, results but the only study in which a statistically significant effect was estimated on treatment success rates was that by Corder (Corder *et al.*, 1972). This study involved the wives of patients in an intensive 4-day workshop at the end of a 3-week daily treatment programme. The control group received a four-week daily programme without involvement of wives. Although the intervention appears to have been a successful the result should be regarded with some caution as allocation was unrandomised and confounded by time period – all the control group were recruited first. Combined with the general positive trend in other marital therapies this suggests that involvement of spouses in treatment, when acceptable to both patient and partner, is an option to be considered. However, this acceptability may prove a limiting factor in practice.

A concern with regard to the CRA treatment may be that the social elements involve substantial organisation and time. However, these elements could be run by staff without clinical expertise and the good clinical trial results suggest that such a strategy might be worth serious consideration.

9.2.2 Pharmacological Interventions

Both acamprosate and naltrexone appear to be effective additions to psychosocial treatments. Although the meta-analysis results suggest a slightly larger effect for acamprosate, the confidence intervals overlap by a substantial margin and no firm conclusion can be drawn about the relative efficacy of the treatments. A concern is that there is appreciable heterogeneity between trial results for both acamprosate and naltrexone. This suggests that there are genuine differences in efficacy possibly associated with trial procedures or types of patient. Two large pragmatic studies of acamprosate (Chick *et al.*, 2000) (Mason BJ, 2001) have now produced negative results and this must raise the possibility that the effectiveness may be low in clinical practice. Post-hoc rationalisations of these negative results cannot provide satisfactory guidance on which to base clinical procedures. Hence a large phase IV study using acamprosate according to procedures achievable in clinical practice – which should be recommended by the manufacturer – would do much to strengthen confidence in the treatment. This comment also applies to naltrexone in so much as a very large recent study (Krystal *et al.*, 2001) produced rather disappointing results and a truly pragmatic study with a positive result would do much to increase confidence in the treatment generally.

With regard to Scottish usage of acamprosate and naltrexone it is stressed that only acamprosate currently holds a UK marketing authorisation. A licence to market naltrexone in the UK for prevention of relapse has previously been applied for but refused by the licensing authority on the advice of the Committee on Safety of Medicines. The CSM reviewed full evidence for the efficacy, safety and quality of the product at the time of application. Medicines can be given outwith the provisions of their UK licence but the responsibility for this action lies solely with the prescribing physician. The manufacturers, Dupont, are currently deciding whether to make a further application. Naltrexone is currently marketed in the U.K for the treatment of opioid addiction. It has licences for use as an adjunct treatment in preventing alcohol relapse in a number of countries including the Republic of Ireland and the U.S.A.

The evidence reviewed in this report does not support the unsupervised administration of disulfiram. However, one well-designed clinical trial (Chick *et al.*, 1992) and diverse supporting evidence have suggested that disulfiram is effective when it is appropriately supervised. The single trial did not report long-term success rates in terms of abstinence or controlled drinking and hence it is not possible to express this effect in a manner comparable to the effects for the other treatments we have reviewed.

The studies of pharmacotherapy reviewed in this report have considered the use of acamprosate, naltrexone and disulfiram used in conjunction with psychosocial therapies in centres of expertise. The important issue of how or whether these treatments should be used in other settings has not been addressed.

The prescription of two or more of these medicines for simultaneous use does not appear to have any supporting evidence of effectiveness or safety. However, the HTBS survey

shows that acamprosate and disulfiram are used together in 57% of Scottish services and this is clearly an area for reflection and further study.

9.2.3 Non NHS services

Non-NHS services treating alcohol dependent patients use a wide range of psychosocial techniques. Some of these are not adequately supported by clinical trial evidence. Concentration on a few techniques closely based on those with proven benefits would be likely to increase the effectiveness of these services. Other approaches should be tested in formal randomised trials before being adopted as standard procedures.

9.3 Patient issues

A study involving in-depth one-to-one interviews of 45 alcohol dependent patients attending three NHS Specialist Centres is underway. Interim results show that most patients valued group therapy, which provided an opportunity to share experience with other patients who really understood the situation. Women prefer single sex groups, whereas men did not express a preference. Those still drinking found the group work more difficult. Those coerced into attending AA meetings did not continue with them, but others were positive about AA meetings and valued the flexibility of times and venues available. Most patients also found one-to-one therapy helpful to discuss a wide range of issues in-depth and in a manner direct to meet the individuals' needs. Some interviewees had attended a Council on Alcohol, mainly after being referred by an employer. Some valued the counselling and alternative therapies, but others felt that the 'controlled drinking' philosophy of the Councils was not a feasible approach for them. The availability of the service from the Councils at times of crisis was appreciated.

9.4 Cost effectiveness

Section 7.17 has set out many of the issues emerging from the economic evaluation. These primarily relate to the quality of evidence on the clinical effectives of each therapy and whether it can be generalised to a Scottish setting. These issues have been taken forward in section 9.2 above.

The other issues emerging from the discussion on the economic evaluation included whether the assumptions underlying the epidemiology are robust. Section 3.20 of this document explained that the economic evaluation has included illnesses associated with chronic drinking which may understate the potential benefit to NHSScotland of treating alcohol dependence.

The disease incidences used in the economic evaluation combine probabilities extracted from various international studies with incidences from the Scottish population taken from the Scottish Health Statistics and other sources. These sources are combined to provide a forecast number of disease case for a cohort of alcohol dependent and non-

alcohol dependent men and women. The model is particularly sensitive to the incidence of alcoholic dependence syndrome and alcoholic psychosis, two diseases that were not well covered in the literature. Moreover the model assumes that abstinent patients have the same health as non-alcohol dependents. Evidence on both these points would be beneficial.

The remaining major issue for the economic evaluation is the absence of Scottish disease related costs. These have been approximated by obtaining data from ISD on length of stay by disease and applying the average inpatient cost for a general function. For example, in the case of cirrhosis, ISD advised that the average length of inpatient stay was almost 12 days and we applied a daily cost based on published cost for a 'medical' inpatient day. It is not possible to say whether this average cost overstates or under the costs of managing patients with cirrhosis.

9.5 Current gaps in knowledge

A Health Technology Assessment requires collection of data relating to clinical effectiveness and safety of interventions; a full description of the long-term prognosis for patients and the variation in prognosis with different treatments; and also detailed knowledge of costs of treatments and of disease states. These data come from a variety of sources and it is frequently necessary to combine these sources using a model employing many assumptions. In the process of collecting the data it is often clear that they could be more complete and more directly informative. Thus one of the outputs of an HTA is a set of recommendations concerning how better data might be obtained.

The epidemiology input to the cost effectiveness calculations has relied on many diverse observational studies of disease and mortality among alcohol dependent people. It would be very desirable for this, and many other HTAs, to have access to complete clinical life-event histories collected on a patient-by-patient basis for the Scottish population. This would permit the direct assessment of the interactions between different disease states associated with alcohol and the effects, which current alcohol treatments have on these states. In recent years the linkage of different clinical dataset has allowed the first moves towards making such information available. Access to such data would both speed up and increase the accuracy of HTA assessments.

Data collection in order to assess the long-term clinical course of alcohol dependence following treatment in Scotland is needed. Measurement of simple outcomes such as further detoxification over a period such as five years would provide useful long-term outcome data. Demonstration that a high quality of clinical service is being provided is strongly dependent on the availability of such measures and they also provide a way of assessing potential improvements to the service.

As noted above, large scale pragmatic clinical trials of pharmacological interventions for relapse preventions would increase confidence in the effectiveness of these treatments.

Long-term treatment success rates in terms of abstinence or controlled drinking should be reported.

The quality of trials of psychosocial treatments is generally not high. In this assessment studies which were not randomised have occasionally been included if the treatment allocation appeared to have no element of discretion. However, there is no good reason for not including an element of randomisation – either at the individual or group level – in any clinical trial. Complete blinding is not possible in studies of psychosocial treatments and hence biases due to clinician or patient enthusiasms for particular treatments may be difficult to avoid. Consideration should be given to ensuring treatments are delivered in an unbiased fashion and that outcomes are assessed by clinicians blinded to treatment. The results of Project MATCH may have lessened enthusiasm for performing studies with primary hypotheses expressed in terms of matching patients to treatments. Whether this is so or not, the sample size calculations for such studies should be appropriate to the nature of the hypothesis. In addition the trial results by randomised group (ignoring the matching variables) should be clearly presented.

Finally the availability of Scottish disease related costs would inform the forecast savings to NHSScotland of avoiding relapse in people who are alcohol dependent.

10 ACKNOWLEDGEMENTS

[To be added at completion]

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Appendix 1 Expert Advisers

TOPIC SPECIFIC GROUP MEMBERS

Mr Bill Anderson	Chief Executive	Central Scotland Council on Alcohol 13 Pitt Street,STIRLING
Ms Kay Barton	Head of Substance Misuse Division	SEHD, Public Health Policy Unit
Professor Peter Brunt		ABERDEEN
Dr Jonathan Chick	Consultant Psychiatrist, Alcohol Problems Clinic	Royal Edinburgh Hospital
Dr Ali El-Ghorr	Programme Manager	SIGN Executive
Dr P J Jauhar	Clinical Director/Consultant Psychiatrist	Alcohol & Drug Directorate, Parkhead Hospital
Dr Catherine Keogh	Consultant Clinical Psychologist	Southern General Hospital
Mr Peter Knight	Head of Unit	Information and Statistics Division
Dr John Loudon	Principal Medical Officer	Scottish Executive Health Department
Ms Anna Marie McGregor	Community Pharmacist	Abbey Chemists, GLASGOW
Mr John Reid	Senior Charge Nurse	Lomond & Argyll Primary Care NHS Trust
Dr Peter Rice	Consultant Psychiatrist	Tayside Alcohol Problems Service
Dr Angela Roberts	Secretary	Association of Managers of Alcohol Agencies in Scotland
Ms Thea Stein	Director of Health Service Development	Dumfries & Galloway Health & Social Services
Ms Catherine Tully	Senior Pharmacist	Parkhead Hospital, GLASGOW
Professor Hazel Watson	Professor of Nursing, Nursing Council on Alcohol	Glasgow Caledonian University
Dr Peter S Wiggins	GP	Castlemilk Health Centre, GLASGOW
Mr Stephen Rhodes	Alcohol Services Manager	Parkhead Day Hospital Glasgow

Appendix 2 SIGN Guideline: Key Questions on Alcohol Dependence

Alcohol Dependence Guideline Development Group

SIGN

Key Questions

June 2002

Detection and assessment

1. What evidence is there on the use of CAGE, AUDIT, history taking, liver function tests, and aspects of the physical examination in the detection of harmful drinking and alcohol dependence in A & E and the primary care setting?
2. What evidence is there on the sensitivity and specificity of the above methods?
3. What evidence is there on detection rates of harmful drinking and alcohol dependence by the courts, A & E, schools, homeless services, antenatal services, services for the elderly, police, social workers, new employee assessment, new patient assessment?
4. What evidence is there that training general practitioners, practice nurses, community nurses, social workers, and A & E staff in the detection of harmful drinking or alcohol dependence improves detection rates?

Early Intervention for hazardous and harmful alcoholism

Interventions by general practitioners, practice nurses, community nurses, social workers, and health visitors

5. What evidence is there that advice and information on safe levels of alcohol consumption on one or two occasions (minimum intervention) will (a) reduce hazardous drinking (b) reduce harmful drinking or (c) prevent harmful or hazardous drinking progressing to alcohol dependence?
6. What evidence is there on assessing a patient's readiness to change his or her drinking habits?
7. What evidence is there on how the subject of alcohol consumption should be discussed with patients?
8. What evidence is there on the accuracy of self-assessment of alcohol consumption by counting units of alcohol?
9. What evidence is there on who should be given counselling or who should be referred to specialist addiction wards, or general psychiatric wards, or specialised alcohol services?

Detoxification

10. What evidence is there on the criteria (gender, age, alcohol consumption, associated morbidity such as cardiovascular disease, liver disease, or mental illness) that should be used when considering where detoxification should be carried out (i.e. in-patient versus community, specialist versus primary care)?
11. What evidence is there on the criteria (gender, pregnancy status, age, alcohol consumption, alcohol dependence symptoms, associated morbidity such as cardiovascular disease, liver disease, or mental illness) that should be used when considering whether pharmacological detoxification is required and if so which drugs and with which dosing schedules are appropriate (e.g. chlordiazepoxide, diazepam, variable vs fixed dosage, amount, length of drug treatment)?
12. What evidence is there on how different treatment settings (general psychiatric wards, specialist addiction wards, medical wards, general practice, nurse prescribing, home detoxification services, day units, alcohol clinics, and prisons) affect detoxification

outcome?

13. What evidence is there on the role of vitamin supplements in detoxification?
14. What evidence is there on which is the preferred setting to which the general practitioner should refer (medical ward, psychiatric ward, detoxification unit) a patient with delirium tremens?

Specialist care and relapse prevention in primary care (including treatment for comorbidity)

15. What evidence is there that the AA reduces alcohol dependence or harmful drinking, and how should health care facilitate the patient's utilisation of the AA?
16. What evidence is there that other lay services reduce alcohol dependence, harmful or hazardous drinking, and how should primary care facilitate the patient's utilisation of these services
17. What evidence is there regarding the effectiveness of antidepressants/anxiolytics in alcohol dependence, in relieving depression and anxiety disorders and/or preventing relapse?
18. What evidence is there that alternative therapies help prevent relapse/maintain abstinence? (shaitsu, aromatherapy, relexology, massage)?
19. What evidence is there that involving family members (family therapy, couples therapy, Al-Anon) improves quality of life, drinking habit, and compliance to treatment regime? (Primary care aspects of this question are to be covered by SIGN)
20. What evidence is there on how schizophrenia, learning disability, bipolar disorder and substance abuse affect the management of harmful drinking and alcohol dependence?

Appendix 3 HTBS planning questions

HTBS ASSESSMENT OF PREVENTION OF RELAPSE IN ALCOHOL DEPENDENCE

The HTA questions

1. Which approach or combination of approaches will yield the maximum maintenance of recovery amongst the population of those with alcohol dependence who have undergone detoxification?

2. What is the most clinically and cost effective approach to delivering the individual interventions, or combination of interventions, taking into account the different risk groups, locations, duration of treatment, concomitant medications, etc?

HTBS Evidence Questions

1. Relapse

Q1a. What definitions of relapse are in current use?
Q1b. Are different definitions appropriate to different individuals?
Q1c. Are different definitions comparable?

2. Population

Q2a. How are individuals identified for alcohol relapse prevention?

3. Service capacity and demand

Q3a. What is the current service capacity for inpatient and outpatient care?
Q3b. What is the current service demand for inpatient and outpatient care, as indicated by those presenting for treatment?
Q3c. How is healthcare use distributed between primary vs specialist care?

4. Effectiveness and Delivery of psychosocial interventions – current practice

Q4a. What psychosocial interventions are in current use for relapse prevention?
Q4b. Who is delivering psychosocial therapies?
Q4c. Where are psychosocial therapies being provided?
Q4d For what time period are psychosocial therapies being provided (no. of sessions and length of treatment period).
Q4e. For which of the psychosocial interventions are there protocols/manuals?
Q4f. If a psychosocial intervention has no manual/protocol can it be sufficiently well characterised for an HTA to be performed?
Q4g. Are pharmacological interventions used as a standard adjunct to psychosocial therapies?

5. Effectiveness and Delivery of psychosocial interventions – evidence base

Q5a. What is the evidence base for the effectiveness of each psychosocial method (including objective evaluations of relapse using blood, breath or other formal test)?
Q5b. Who should deliver psychosocial therapy?
Q5c. What evidence exists on the effectiveness of inpatient versus outpatient delivery of treatment?
Q5d. What evidence exists on the optimal duration for the provision of psychosocial therapies?
Q5e. What are the training, competency, accreditation and supervision requirements for the therapists?
Q5f. Are there groups of individuals at whom psychosocial therapies are best targeted (e.g. treatment matching)?
Q5g. Should pharmacological interventions be given with psychosocial therapies?
Q5h. What evidence is there that the AA helps to reduce relapse and how should healthcare services facilitate access of individuals to the AA?

6. Effectiveness and delivery of pharmacological interventions – current practice

Q6a. What pharmacological interventions are in current use for relapse prevention?
Q6b. Who is prescribing and administering these therapies?
Q6c. Where are pharmacological therapies being provided?
Q6d. For what time period are pharmacological therapies being prescribed?
Q6e. Do established protocols exist for delivery of these interventions?
Q6f. What are the safety issues with these pharmacological interventions – particularly interaction issues with Antabuse?

Q6g. What adjunct psychosocial therapies are being given with pharmacological interventions?

7. Effectiveness of pharmacological interventions – evidence base

Q7a. What is the evidence base for the effectiveness of each medication (including objective evaluations of relapse using blood, breath or other formal test)?
Q7b. Who should deliver pharmacological therapy?
Q7c. What evidence exists on the optimal location for the commencement and subsequent provision of pharmacological therapies?
Q7d. What evidence exists on the optimal duration of treatment with pharmacological therapies?
Q7e. Should pharmacological therapies be targeted at groups of individuals?
Q7f. Should adjunct psychosocial therapies be given with pharmacological interventions?

8. Important concomitant substances

Q8a. What other medications do individuals use for the treatment of alcohol or alcohol related problems in addition to those prescribed for relapse prevention?
Q8b. Is the success of either psychosocial or pharmaceutical interventions in relapse prevention affected by the use of other medications?
Q8c. Does the presence of concomitant disease or substance abuse affect the choice of interventions for relapse prevention?

9. Combining treatment

Q9a. Are combinations of psychosocial and pharmacological interventions more effective in relapse prevention than either approach given alone?

10. Patient Issues

Q10a. What are the best methods to support and encourage individuals through the treatment programme?
Q10b. What are the patient preferences for treatment?
Q10c. What are the issues involved in relapse prevention in alcohol dependent individuals who have been involved in the criminal justice system?

11. Healthcare system use

Q11a. Following relapse, what proportion of individuals leave the healthcare system and what proportion remain undergoing further detoxification and relapse prevention?
Q11b. What are the current courses of action when a patient relapses?
Q11c. Is there any evidence for continued repetitions of the detoxification and relapse prevention treatment programme, following failure?

Appendix 4 Definitions of dependence

DSM-IV Criteria for Substance Dependence

The Diagnostic and Statistical Manual (DSM-IV) of the American Psychiatric Association defines substance dependence as:

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

(1) Tolerance, as defined by either of the following:

- (a) a need for markedly increased amounts of the substance to achieve intoxication or desired effect.
- (b) Markedly diminished effect with continued use of the same amount of the substance.

(2) Withdrawal, as manifested by either of the following:

- (a) The characteristic withdrawal syndrome, for the substance (refer to Criteria A and B of the criteria sets for Withdrawal from the specific substances).
- (b) The same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms.

(3) The substance is often taken in large amounts or over a longer period than was intended.

(4) There is a persistent desire or unsuccessful efforts to cut down or control substance use.

(5) A great deal of time is spent in activities necessary to obtain the substance (e.g. visiting multiple doctors or driving long distances) use the substance (e.g. chain-smoking), or recover from its effects.

(6) Important social, occupational, or recreational activities are given up or reduced because of substance use.

(7) The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have caused or exacerbated by the substance (e.g. current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption.

Specify if:

With Physiological Dependence: evidence of tolerance or withdrawal (i.e. either Item 1 or 2 is present).

Without Physiological Dependence: no evidence of tolerance or withdrawal (i.e. neither Item 1 nor 2 is present).

Course specifiers (See text for definitions):

Early Full Remission
Early Partial Remission
Sustained Full Remission
Sustained Partial Remission
On Agonist Therapy
In a Controlled Environment

Table 4 ICD-10 criteria for substance dependence

A diagnosis of dependence should usually be made only if three or more of the following have been experienced or exhibited at some time during the previous year.

(a) A strong desire or sense of compulsion to take the substance.
(b) Difficulties in controlling substance-taking behaviour in terms of its onset, termination, or levels of use.
(c) A physiological withdrawal state when substance use has ceased or been reduced, as evidenced by the characteristic withdrawal syndrome for the substance, or use of the same (or a closely related) substance with the intention of relieving or avoiding withdrawal symptoms.
(d) Evidence of tolerance such that increased doses of the psychoactive substance are required in order to achieve effects originally produced by lower doses.
(e) Progressive neglect of alternative pleasures or interests because of psychoactive substance use, increased amount of time necessary to obtain or take the substance or to recover from its effects.
(f) Persisting with substance use despite clear evidence of overtly harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning; efforts should be made to determine that the user was actually, or could be expected to be, aware of the nature and extent of the harm.

Appendix 5 HTBS survey of NHS secondary care in Scotland - Questionnaire

Health Technology Board for Scotland

NHS SCOTLAND

The Current Provision of Services for Alcohol Relapse Prevention In Secondary Care

Name of Respondent: _____

Occupational Title and Grade: _____

Work Address: _____
_____
_____
_____

Name and Address of Employer: _____
_____
_____
_____

Name / Title of the Service Covered in this Questionnaire:
_____
_____

Geographical Area / Sector Covered by the Service:
_____
_____

Name of the Consultant / Other (Please give designation) in Charge of the Service:
_____

Date of Completion of Questionnaire: _____

May we contact you to clarify details regarding your response to this questionnaire? YES / NO
Telephone no. _____
E-mail address _____

A INVENTORY OF ALCOHOL SERVICES

Delete As Appropriate

1. Do you have any specialist alcohol workers / services? YES / NO

Go to Q.A2 go to Section B

2. Is the service:

Please 'X' all that apply

community based ___
outpatient based ___
day hospital based ___
inpatient based ___
other (please specify) _____

3.With respect to inpatient alcohol services:

Delete As Appropriate No. of beds (If applicable)

do you have dedicated beds for alcohol patients? YES / NO ___

if yes, are the nursing staff covering these beds dedicated to or specifically trained in alcohol / substance misuse nursing? Delete As Appropriate YES / NO

Please give an estimate of

Delete As Appropriate no. in use at any onetime

do you use general adult psychiatric acute admission beds? YES / NO ___

4. Please complete details of the specialist alcohol workers in the **community / outpatient / day hospital** based service as well as **inpatient staff solely dedicated to alcohol/substance misuse services**.

	Please 'X' all that Apply	Permanent Whole Time Equivalent Posts	Temporary Whole Time Equivalent Posts
(Example-staff grade psych.)	X	0	1 x 0.6
Consultant psychiatrist			
Staff grade psychiatrist			
Senior house officer			
Other medical-please specify _____			
Other medical-please specify _____			
Community / staff nurse (I)		*	*
Community / staff nurse (H)		*	*
Community / staff nurse (G)		*	*
Community / staff nurse (F)		*	*
Community / staff nurse (E)		*	*
Community / staff nurse (D)		*	*
Community / staff nurse (C)		*	*
Nursing assistant			
Other nursing staff-please specify_____			
Other nursing staff-please specify_____			
Consultant clinical psychologist			
Clinical psychologist			
Trainee psychologist			
Assistant psychologist			
Occupational therapist			
Other-please specify _____			
Other-please specify _____			

*Please indicate whether nursing staff are RGN or RMN

B ALCOHOL RELAPSE PREVENTION – PSYCHOSOCIAL INTERVENTIONS

1. Does your service offer psychosocial interventions for alcohol relapse prevention?

   Yes ☐ No ☐ (If No go to section C)

2. Which psychosocial intervention does your service provide for relapse prevention?

		Please 'X'
A	Motivational interviewing	
B	Cognitive Behaviour Therapy	
C	Brief intervention	
D	Twelve step facilitation therapy	
E	Behavioural marital/couples therapy	
F	Couples therapy	
G	Family therapy	
H	Community reinforcement approach/therapy	
I	Social skills training	
J	Coping skills training	
K	Stress management	
L	Non-specific counselling (please give details below*)	
M	Other (please specify below*)	

* _____
_____
_____

3. Please give codes (A-M above) of those interventions with written protocols in place.

   _____

   (It would be helpful if copies of protocols could be enclosed with the questionnaire)

4. Please give codes (A-M above) of those interventions with patient information leaflets.

   _____

   (It would be helpful if copies of patient information leaflets could be enclosed)

5. For each of the interventions marked in question 1 above please give the following details

Note: *If there are more than 4 interventions used please photocopy this page and attach to the completed questionnaire.*

Code (A-M above)				
Individual/group (*If applicable*)				
Residential (Y/N)				
Proposed duration/ number of sessions				
Aim of intervention e.g. abstinence, increase in CAD				
Outcome measures used? e.g. timeline follow back, collateral info, diary, laboratory investigations (specify)				
Process audited? (If known give no. seen/year)				
Accredited staff e.g. discipline, grade, no.				
Non-accredited staff carrying out therapy. e.g. discipline, grade, no.				
What training does staff receive? e.g. internal or external and from which body/organisation etc				
Does this result in accreditation?				

C ALCOHOL RELAPSE PREVENTION – PHARMACOLOGICAL INTERVENTIONS

1. Please complete details of the pharmacological interventions offered for relapse prevention

	Acamprosate	Naltrexone	Disulfiram	Other (*specify)
Please 'X' if used				
Start as in/outpatient/both?				
Which staff prescribe this medication?				
Frequency of review?				
Initial proposed duration?				
Are psychological interventions usually used in combination? (Please specify)				
Are special conditions of administration employed? e.g. CPN supervision (Please specify)				
What outcome measures are used? e.g. timeline follow back, collateral info, diaries, lab. Investigations (Please Specify				
What is the goal / aim of the treatme e.g. abstinence inc. in CAD				
Is the process audited? (If possible enter no. seen / yr)				

*_____

2. Are combinations of pharmacological interventions regularly used for relapse prevention? Please specify.

_____

3. For which of the pharmacological interventions are there protocols in place?

_____

(It would be helpful if copies of protocols could be enclosed with the questionnaire)

D APPROACH TO TREATMENT ADHERENCE, DEFAULT, RECURRENT RELAPSE

1. What is your approach to non-adherence / default from psychosocial intervention? _____
_____
_____

2. What is your approach to non-adherence / default from pharmacological intervention? _____
_____
_____

3. What measures would you continue to offer in the case of recurrent relapse if each of the aforementioned interventions has already been used?
_____
_____

E USE OF OTHER AGENCIES

1. Which agencies do you 'make use of' / integrate in the aftercare of patients?

	NEVER	RARELY	OCCASIONALLY	REGULARLY
Social work				
Alcoholics Anonymous				
Alanon (carer / family support)				
Council on Alcohol				
Voluntary hostels				
Private care e.g. Priory, Castle Craig				
Non-statutory rehabilitation units e.g. Church of Scotland				
Other secondary care (e.g. GI clinic – please specify) _____				
Other primary care (e.g. practice nurse – please specify) _____				
Other (please specify) _____ _____				

F OTHER ASPECTS OF CURRENT SERVICE

1. With respect to your service, what is the standard **minimum** aftercare package offered to most individuals on discharge from hospital care following alcohol detoxification? (Please only answer if relevant to your service)

_____
_____
_____
_____

2. Are there other features of your service which are important in relation to relapse prevention which are not covered in this questionnaire? If so please comment.

_____
_____
_____
_____
_____
_____

Appendix 6 HTBS survey of other providers in Scotland - Questionnaire

Health Technology Board for Scotland

SERVICES FOR PREVENTION OF RELAPSE IN ALCOHOL DEPENDENCE IN SCOTLAND

Name of Respondent_____

Designation (Occupational title and grade) _____

Name of Service / Unit _____

Address of Service / Unit _____
_____

Parent Body _____

Date of Questionnaire Completion_____

A.1 Please give the approximate no. of staff in your service. ____

B.1 Do you have dedicated beds for individuals with alcohol dependence/problems? Delete as appropriate YES / NO no. of beds ____

Please add any additional explanatory comments if required _____
_____

B.2 Please describe on what basis these beds are allocated to individuals and the length of time individuals would be expected to occupy these beds. _____
_____
_____
_____

C.1 Does your service offer psychosocial interventions / counselling for alcohol dependency / alcohol relapse prevention? Delete as appropriate YES / NO

C2 Please describe what forms of psychosocial intervention are offered (e.g. CBT, social skills training, non-specific counselling) _____
_____

C.3 Please describe the training that staff receive to carry out these interventions.
_____
_____

C.4 Does the training result in accreditation? Delete as appropriate YES / NO

D.1 Please estimate how many individuals with alcohol problems are newly engaged or re-engaged (e.g. in treatment programs, counselling etc.) with your service in an average month. _____

D.2 On average, what would be the usual proposed length of treatment / ongoing contact with individuals engaged with your service? (Please add any additional comment if required). _____

Appendix 7 Narrative summary of results of surveys by NHS Board

NHS SPECIALIST SERVICES QUESTIONNAIRE
(A specimen questionnaire can be found in Appendix 5)

- 27 survey questionnaires were sent to identified individuals who were either known to be leading NHS specialist alcohol teams or, in the case of NHS Board areas without such teams, individuals who would have information regarding specialist services for the treatment of alcohol problems in their area.

- The questionnaires covered all NHS Board areas.

- Telephone enquiry prior to sending the questionnaires could not identify any further NHS specialist service specifically involved in the treatment of alcohol problems which may have been overlooked.

- After the questionnaires had been sent out, it was clarified that Lanarkshire NHS Board had 3 main centres with base hospitals at Hairmyres, Hartwood and Monklands. 5 questionnaires had been sent to Lanarkshire with a resultant overlap in the services covered. In addition both Lothian Health Board and Western Isles Health Board were sent 2 questionnaires each with only 1 respondent answering for the whole area. The number of questionnaires expected to be returned was therefore reduced to 23.

- Only 1 questionnaire out of the 23 remaining questionnaires was not returned. Additional information was obtained on telephone enquiry from that particular service covering basic staffing and service data.

- The returned questionnaires were almost universally completed to a high standard in terms of quality and detail of information.

- Additional protocols for psychosocial interventions, pharmacological interventions and other aspects of aftercare were submitted by respondents from Orkney, Lothian, East Glasgow, South Glasgow, Lomond and Argyll, Dumfries and Galloway and Renfrewshire & Inverclyde.

- The collated information has been checked for accuracy using written follow-up contact with all respondents.

NON NHS SERVICES QUESTIONNAIRE

(A sample questionnaire can be found in Appendix 6)

- Survey questionnaires were sent out to all voluntary facilities / Social Work facilities that we could identify as having some role in helping individuals with alcohol related problems. We did not send out questionnaires to the AA who have already submitted information to the HTBS. Neither did we send questionnaires to private facilities such as Castle Craig or The Priory who were asked to submit comments during the earlier information gathering process.

- 114 questionnaires were sent to various groups and organisations based throughout Scotland. Of these 2 questionnaires had erroneously been sent to facilities already surveyed. In addition 1 questionnaire was sent to an NHS service, again by mistake. The number of active questionnaires was therefore 111.

- The organizations, which were sent the questionnaire included all identified Councils on Alcohol (31), although the sub offices of the various Councils were not surveyed. The Council on Alcohol appears to have services in all NHS Boards except Western Isles and Shetland. Other non NHS facilities surveyed included the day services of various voluntary, independent, Church of Scotland and Social Work organisations. Residential rehabilitation facilities and residential homeless facilities, again run by various voluntary, independent, Church of Scotland or Social Work organisations were also surveyed.

- 39 (35%) of the questionnaires were returned (44% of which were from Councils on Alcohol).

- 61% of questionnaires returned were from day services (this was 24 out of 62 (39%) of the day services surveyed).

- 8% of questionnaires returned were from residential rehabilitation services (this was 3 out of 13 (23%) of the residential rehabilitation services surveyed)

- 31% of questionnaires returned were from residential homeless services (this was 12 out of 37 (32%) of the residential homeless services surveyed).

- The questionnaires returned represent a reasonably broad distribution of the non-NHS services identified for the survey as can be seen in Table 4 (returned surveys in bold italics).

- 17 Social Work facilities were not identified until after the questionnaires had been returned. Information from these services was available from the SACAM survey of alcohol services carried out for the preparation of the Plan for Action on Alcohol Problems.

- Of non-statutory services, 32 Council on Alcohol sub-offices and 10 other facilities identified post-survey from SACAM information were not surveyed.

- The total number of non-statutory facilities (i.e. not including the Social Work services) identified in Scotland as dealing in some way with people with alcohol related problems was therefore139 (of which 97 were surveyed, 36 (37%) of whom returned completed questionnaires). This figure does

not include the very large number of AA meetings, which take place on a daily basis throughout Scotland.

SERVICES SUMMARY IN BRIEF PER NHS BOARD

ARGYLL & CLYDE

(Population: 426 046)

LOMOND & ARGYLL

(Population: 136 046)

NHS STATUTORY SECONDARY CARE

1 inpatient and outpatient based secondary care service but no community or day hospital service. (Community Addiction Team, CAT, in Dumbarton area)
14 dedicated inpatient beds, no use of general adult psychiatry beds (total: 14 beds)
Staffing compliment includes Consultant Psychiatrist, other medical staff and RMN trained nursing staff.
Uses Acamprosate and Disulfiram.
Psychosocial interventions include Motivational Interviewing (MI), Cognitive Behavioural Therapy (CBT), Community Reinforcement Approach (CRA), Social Skills Training (SS), Coping Skills Training (CS), Stress Management (SM), Non-specific Counselling (NSC), Residential Relapse Prevention Programme and Respite Admissions.

NON NHS SERVICES

In addition to Alcoholics Anonymous (AA), the area has 9 of the non-NHS facilities identified, about 8 of which are day facilities (7 Council on Alcohol and 1 social work facility) and 1 service which is a Church of Scotland residential rehabilitation facility.

REFREWSHIRE & INVERCLYDE

(Population: 290 000)

NHS STATUTORY SECONDARY CARE

2 outpatient and day hospital based services.
11 dedicated inpatient beds and about 4 other general adult psychiatry beds in use for alcohol problems at any one time (total: 15 beds).
Staffing compliment includes Consultant Psychiatrists, other medical staff, RMN trained nursing staff and Clinical Psychology staff.
Uses Acamprosate, Disulfiram and Naltrexone (1 of services).
Psychosocial interventions include MI, CBT, Brief Intervention (BI), SS, CS, SM, Alcohol Education Groups, Solution Focussed Relapse Prevention Groups, Anxiety Management, Anger Management, Relaxation and Exercise Groups, outpatient women's group 'self help'.

NON NHS SERVICES

In addition to AA, the area has 16 of the non nhs facilities identified, about 12 of which are day facilities (mostly Councils on Alcohol and social work facilities), 3 of which are residential homeless facilities (Jericho Society) and 1 facility which is a Salvation Army residential rehabilitation facility.

AYRSHIRE & ARRAN
(Population: 374 545)

NHS STATUTORY SECONDARY CARE

A comprehensive community, outpatient, day hospital and inpatient based service.
6 dedicated alcohol beds and 12 beds for residential dual diagnosis service, which at any time are used by approximately 50% alcohol users (total: 12 beds).
Staffing compliment includes Consultant Psychiatrist, other medical staff, nursing staff (both RGN and RMN trained) and Occupational therapy staff.
Uses Acamprosate, Disulfiram and Naltrexone.
Psychosocial interventions include MI, CBT, BI, Behavioural Marital/ Couples Therapy (BMCT), Couples Therapy, Family Therapy, CRA, SS, CS, SM, NSC, Anger Management, Relapse Management.

NON NHS SERVICES

In addition to AA the area has 8 of the non NHS facilities identified, all of which are day facilities, spread between the Council on Alcohol, social work, Church of Scotland and an independent voluntary facility.

BORDERS
(Population: 106 389)

NHS STATUTORY SECONDARY CARE

A solely community based service.
1.5 dedicated alcohol beds and 0.8 general psychiatry beds in use for alcohol problems at any one time (total: 2.3 beds)
Staffing compliment without a Consultant Psychiatrist or any medical staff, but does have dedicated social work staff as well as nursing staff.
Uses Acamprosate and Disulfiram.
No psychosocial interventions offered.

NON NHS SERVICES

In addition to AA, the area has 2 of the non nhs facilities identified, both of which are day facilities (Council on Alcohol and independent voluntary).

DUMFRIES & GALLOWAY
(Population: 147 280)

NHS STATUTORY SECONDARY CARE

A community, outpatient and inpatient based service with no day hospital service.
4 beds dedicated to either alcohol or substance use disorders and 2 general psychiatry beds in use for alcohol problems (total: 6 beds).
Staffing compliment includes a Consultant Psychiatrist, other medical staff, RMN and RGN trained nursing staff and Occupational Therapy staff.
Uses Acamprosate and Disulfiram.
Psychosocial interventions include MI, CBT, BI, Couples, SS, CS, SM.

NON NHS SERVICES

In addition to AA the area has 2 of the non nhs facilities identified (Councils on Alcohol)

FIFE
(Population: 348 214)

NHS STATUTORY SECONDARY CARE

2 services, a very small outpatient and day hospital based service in West Fife and one solely community based service in Kirkcaldy and related areas.
No dedicated alcohol and up to about 4 general adult psychiatry beds in use at any one time (total: up to 4 beds).
Staffing compliment with no Consultant Psychiatrist or other medical staff.
Uses Acamprosate and Disulfiram.
Only 1 of the 2 services offers psychosocial interventions, which include MI, CBT, BI, Couples, Family, SS, CS, SM.

NON NHS SERVICES

In addition to AA the area has 4 of the non nhs facilities identified, all of which are day facilities equally spread between Council on Alcohol, social work, Church of Scotland and another independent voluntary facility.

FORTH VALLEY
(Population: 275 806)

NHS STATUTORY SECONDARY CARE

A community and outpatient service with no day hospital or specialist inpatient provision.
No dedicated alcohol beds and 2 general adult psychiatry beds in use for alcohol problems (total: 2 beds).
Staffing compliment includes Consultant Psychiatrist and RMN nursing staff.
Uses Acamprosate and Disulfiram.
Psychosocial interventions include MI, CBT, BI, SS, CS, SM.

NON NHS SERVICES

In addition to AA the area has 4 of the non nhs facilities identified (Councils on Alcohol).

GRAMPIAN
(Population: 532 110)

NHS STATUTORY SECONDARY CARE

A community and outpatient service with no day hospital or specialist inpatient provision.
No acknowledged use of beds for alcohol problems, either dedicated or general adult psychiatry (total: 0 beds).
Staffing compliment includes Consultant Psychiatrist, other medical staff and RMN nursing staff.
Uses Acamprosate, Disulfiram and Naltrexone.
Psychosocial interventions include MI, CBT, BI, Twelve Step Facilitation (TSF), CS, SM.

NON NHS SERVICES

In addition to AA the area has 14 of the non nhs facilities identified, 9 of which are day facilities (spread across Councils on Alcohol, social work, Salvation Army, Cyrenians etc.), 2 of which are residential homeless facilities (Cyrenians and independent voluntary) and 3 residential rehabilitation facilities (1 Church of Scotland and 2 independent voluntary facilities). Albyn House Association Ltd. has 14 hostel beds for respite / rehabilitation and 4 designated place beds for sobering up of 'drunk and incapable' persons arrested by Grampian Police.

GREATER GLASGOW
(Population: 897 053)

NHS STATUTORY SECONDARY CARE

4 centres, 3 of which have comprehensive community, outpatient, day hospital and inpatient services, 1 of which has no day hospital service.
19-21 dedicated alcohol beds and 6 general adult psychiatry beds in use at any one time (total: 25-27 beds). Future planning to reorganize as 2x15 bedded units.
Staffing compliment includes Consultant Psychiatrists, other medical staff, nursing staff, Consultant Clinical Psychologists and other clinical psychology staff and Occupational Therapy staff.
Uses Acamprosate, Disulfiram and Naltrexone (1 service).
Psychosocial interventions include MI, CBT, BI, SS, CS, SM, BMCT, Couples, CRA, Anger Management, Relapse Prevention Groups/Programme.

NON NHS SERVICES

In addition to very large AA presence, the area has 47 of the non NHS facilities identified, 28 of which are day facilities (9 Councils on Alcohol, 12 social work, others include Church of Scotland, independent voluntary and City Council facilities), 15 of which are residential homeless facilities (6 Talbot Association, 4 City Council, 3 Simon Community (SW and HB funded), and independent voluntary facilities), 4 of which are residential rehabilitation facilities (1 Church of Scotland, 1 Salvation Army, 1 Turning Point, 1 ind. vol. facilities).

HIGHLAND
(Population: 210 418)

NHS STATUTORY SECONDARY CARE

A comprehensive community, outpatient, day hospital and inpatient based service (also employing a prison liaison nurse and providing liaison to general hospital receiving ward and maternity ward)
6 dedicated alcohol beds and no general adult psychiatry beds used (total: 6 beds).
Staffing compliment includes Consultant Psychiatrist, other medical staff, nursing staff and social work staff.
Uses Acamprosate and Disulfiram.
Psychosocial interventions include MI, CBT, BI, BMCT, SS, CS, SM, Solution Focussed Therapy, Assertiveness Training.

NON NHS SERVICES

In addition to AA the area has 13 of the non NHS facilities identified, 12 of which are Councils on Alcohol with 1 Church of Scotland residential rehabilitatio n facility.

LANARKSHIRE
(Population: 559 150)

NHS STATUTORY SECONDARY CARE

3 services with base hospitals at Monklands, Hairmyres and Hartwood. All are community, outpatient and inpatient services with no day hospital service.
7 dedicated alcohol beds and 8 general adult psychiatry beds in use at any one time (total: 15 beds).
Staffing complement includes Consultant Psychiatrists, RMN trained nursing staff, Consultant Clinical Psychology and other Clinical Psychology staff and Occupational Therapy staff.
Uses Acamprosate and Disulfiram.
Psychosocial interventions include MI, BI, CS, SS, Couples.

NON NHS SERVICES

In addition to AA the area has 6 of the non nhs facilities identified, 5 of which are day facilities (3 social work,2 Councils on Alcohol) with 1 facility which is a social work residential rehabilitation facility.

LOTHIAN
(Population: 774 528)

NHS STATUTORY SECONDARY CARE

A community, outpatient and inpatient based service.
12 dedicated alcohol beds and no use of general adult psychiatric beds (total: 12 Beds).
Staffing compliment includes Consultant Psychiatrists, other medical staff, nursing staff, occupational therapists and a clinical psychologist..
Uses Acamprosate, Disulfiram and Naltrexone.
Psychosocial interventions include MI, CBT, BI, TSF, BMCT, SS, CS, SM, Supportive Counselling, Group Therapy (support and relapse prevention groups).

NON NHS SERVICES

In addition to a large AA presence, the area has 27 of the non nhs facilities identified, 15 of which are day facilities (9 Councils on Alcohol with 1 social work and 1 Church of Scotland facility, the rest being other ind. vol. facilities), 9 of which are residential homeless facilities (3 Cyrenians, 2 City Council, 1 Church of Scotland, 1 Salvation Army, 2 independent vol.) and 3 of which are residential rehabilitation facilities (1 Church of Scotland and 2 independent vol. facilities).

ORKNEY
(Population: 19 794)

NHS STATUTORY SECONDARY CARE

A solely community based service.
1 bed allocated for use in Balfour NHS Hospital (total: 1 bed).
Staffing compliment with nursing staff only.
Uses Acamprosate and Disulfiram.
Psychosocial interventions include MI, CBT, BI, SS, CS, SM, Relapse Prevention.

NON NHS SERVICES

In addition to AA the area has only 1 of the non nhs facilities identified (Council on Alcohol).

SHETLAND
(Population: 22 855)

NHS STATUTORY SECONDARY CARE

No specialist service (total: 0 beds).

NON NHS SERVICES

In addition to AA the area has 2 of the non nhs facilities identified (independent voluntary day facilities).

TAYSIDE
(Population: 391 397)

NHS STATUTORY SECONDARY CARE

A community, outpatient and inpatient service with no day hospital service.
12 dedicated alcohol beds as well as general adult psychiatry beds in use (total: 12 beds).
Staffing compliment includes Consultant Psychiatrist, other medical staff and RMN trained nursing staff.
Uses Acamprosate and Disulfiram.
Psychosocial interventions include MI, CBT, BI, CS, SM, womens' groups,jointly staffed relapse prevention groups (TAPS and OT Dept. in Montrose, and NHS and SW Dept in Angus.

NON NHS SERVICES

In addition to AA the area has 13 of the non nhs facilities identified, 6 of which are day facilities (3 SW, 2 Councils on Alcohol, and 1 independent vol.) and 7 of which are residential homeless facilities (3 Cyrenians, 1 Jericho Society, 3 other independent vol.).

WESTERN ISLES
(Population: 28 476)

NHS STATUTORY SECONDARY CARE

A small but comprehensive community, outpatient, day hospital and inpatient based service.
No dedicated alcohol beds and up to 1 –2 general adult psychiatry beds in use at any one time (total: 1-2 beds).
Staffing compliment includes Consultant Psychiatrist and nursing staff.
Uses Acamprosate and Disulfiram.
Psychosocial interventions include MI, CBT, BI, BMCT, Couples, Family CRA, SS, CS, SM.

NON NHS SERVICES

In addition to AA the area has 2 of the non nhs facilities identified (Church of Scotland day facility and independent vol. day facility)

Additional notes

1) Residential homeless facilities may not have any specific remit for dealing with alcohol problems. This was the case in about 50% of questionnaires returned.

2) Community Addiction Teams (CATs) may not have been included in all cases due to the newness of the service and the fact that they may not have been picked up as NHS statutory facilities, coming under a social work umbrella instead.

Appendix 8 Tabulated summary of results of survey of services

Table 1: Pharmacological and Psychosocial Interventions in NHS Secondary Care

NHS Board/PCT	Acamprosate	Disulfiram	Naltrexone	Motivational Interviewing	Cognitive Behavioural Therapy	Brief Intervention	Twelve Steps	Behavioural Marital/ Couples Therapy	Community Reinforcement Approach	Social Skills	Coping Skills	Stress Management	Couples Therapy	Family Therapy	Relapse.Managementg.	Relapse Prevention .gp.
Lomond & Argyll	●	●		●	●				●	●	●	●			●	●
Renfrewshire & Inverclyde	●	●	●	●	●	●				●	●	●				●
Ayrshire & Arran.	●	●	●	●	●	●		●	●	●	●	●	●	●	●	
Borders.	●	●														
Dumfries & Galloway	●	●		●	●	●				●	●	●	●			
Fife	●	●		●	●	●				●	●	●	●	●		
Forth Valley	●	●		●	●	●				●	●	●				
Grampian	●	●	●	●	●	●	●				●	●				
Greater Glasgow	●	●	●	●	●	●		●	●	●	●	●	●			●
Highland	●	●		●	●	●		●	●	●	●	●	●	●	●	●
Lanarkshire	●	●		●		●				●	●		●			
Lothian	●	●	●	●	●	●	●	●		●	●	●				●
Orkney	●	●		●	●	●				●	●	●			●	
Shetland*																
Tayside	●	●		●	●	●					●	●				●
Western Isles	●	●		●	●	●		●	●	●	●	●	●	●		

* No specialist services

Table 2: Break down of NHS bed usage per health board

NHS BOARD	DEDICATED ALCOHOL BEDS	GEN. ADULT PSYCH. BEDS (in use at one time)	TOTAL BEDS (in use at one time)	POPULATION	BEDS per 100 000
Borders	1.5	0.8	2.3	106,389	2.16
Dumfries & Galloway	4*	2	6	147,280	4.07
Lothian	12	0	12	774,528	1.55
Ayrshire & Arran	6(+6)**	0	18	374,545	4.81
G. Glasgow	19-21	6	25-27	897,053	2.90
Renfrewshire & Inverclyde	11***	4	15***	290,000	5.17(some beds daytime only)
Lomond & Argyll	14	0	14	136,046	10.30
Lanarkshire	7	8	15	559,150	2.68
Forth Valley	0	2	2	275,806	0.76
Tayside	12?	0****	12	391,397	3.07
Fife	0	4.4	4.4	348,214	1.26
Grampian	0	0	0	532,110	0
Highlands	6	0	6	210,418	2.85
W. Isles	0	1-2 (probably)	1-2	28,476	3.51(only used for alc. problems if needed)
Orkney	0	1	1	19,794	5.05(as above)
Shetland	0	0	0	22,855	0

General Adult Psychiatry (GAP) beds recorded are those used specifically by the Specialist team for their patients for treatment of alcohol problems.

* Dumfries and Galloway has 4 dedicated beds for either alcohol or substance misuse
** Ayrshire and Arran has '6 beds for alcohol detoxification and 12 beds for residential dual diagnosis services which at any one time are used by approximately 50% alcohol users (and also drug users)' (C.Lind,Consultant Psychiatrist,13/3/02, Personal Communication)
*** Renfrewshire and Inverclyde have 11 dedicated beds but those in Inverclyde (7 beds) are in daytime use only with severely unwell patients, including those at risk of seizures, being admitted to general adult psychiatric beds
**** Tayside has General Adult Psychiatry beds not exclusively for alcohol use but used by general adult psychiatry for patients whose primary problem is related to alcohol. About 300 alcohol related admissions/year (assuming a stay of 12 days this would be 10 GAP beds in use at any one time) (P.Rice, Consultant Psychiatrist, 16/03/02, Personal Communication)

Table 3: Psychosocial Interventions as used in NHS Secondary Care Alcohol Services

intervention	% of those services which provide psychosocial interventions	written protocols	patient info. leaflets	individual /group	residential / non res.	proposed duration	audited	% using accredited staff	external training
MI	100	few	few	mostly individual, some group	mostly non res., some res.	up to 6 sessions, rarely longer	few	53 - 83.%	some
CBT	84	few	several	mostly individual, some group	mostly non res., some res.	variable	very few	63 – 91%	Most
BI	90	1/3rd	few	mostly individual, some group	non res.	variable/ 1-2 sessions	1 service	53 - 82%	Some
BM/CT	25	none	none	couples	non.res.	? (1-2 sessions in 1 response)	no	20 -100%	some
CRA	33	few	few	individual	mostly non res., some res.	variable	no	43 -100%	some
SS	79	few	few	mostly individual, some group	mostly non res., some res.	variable (up to 10 sessions specified by 25%)	1 service	60 -100%	some
CS	100	few	few	both individual and group	mostly non res., some res.	variable (up to 10 sessions specified by 25 %)	few	53 -100%	some
SM	95	very few	1/3rd	both individual and group	mostly non res., some res.	variable (up to 10 sessions specified by 25%)	very few	56 -100%	some
couples	33	none	none	couples	mostly non res.	variable	no	0%	?
Rel.prev. groups	?25-33	?all	none	group	mostly non res., some res.	variable (6-8 sessions specified in some services)	routinely done	20-100%	?

Key to table: acmp = Acamprosate ; dislf = Disulfiram ; naltx = Naltrexone ; MI = motivational interviewing ; CBT = cognitive behavioural therapy ; BI = brief intervention ; TSF = twelve step facilitation ; BM/CT = behavioural marital / couples therapy ; CRA = community reinforcement approach ; SS = social skills training ; CS = coping skills training ; SM = stress management ; couple = couples therapy ; RP.gp. = relapse prevention group

Table 4: Staff Numbers per Health Board Area – *WHOLE TIME EQUIVALENT* posts

AREA	CONSULTANT PSYCHIATRISTS	OTHER MEDICAL STAFF	NURSING STAFF	PSYCHOLOGY STAFF	OCCUPATIONAL THERAPY STAFF	SOCIAL WORK STAFF
Lomond & Argyll	0.2	0.4	9.25	0	0	0
Renfrewshire. & Inverclyde	0.5	1.3	8.2	0.1	0	0
Ayrshire & Arran	1.2	1.0	27.0	0	1.0	0
Borders	0	0	2.0	0	0	0.5
Dumfries& Galloway	1.0	1.0	9.0	0	1.0	0
Fife	0	0	3.0	0	0	0
Forth Valley	0.2	0	6.0	0	0	0
Grampian	0.5	1.0	2.5	0	0	0
G.Glasgow	4.4	7.6	53.3	2.4	4.0	
Highland	0.2	1.6	36.2	0	0	1.0
Lanarkshire	2.0	2.2	22.0	1.7	2.0	0
Lothian	1.6	1.66	21.5	0.5	1.5	0.5
Orkney	0	0	1	0	0	0
Shetland	0	0	0	0	0	0
Tayside	1.0	2.0	18.5	0	0	0
W.Isles	0.0	0	2.0	0	0	0

Table 5: Non-NHS Services Distribution (and returned survey numbers in *bold*)

	Lomond &Argyll	Renfrewshire	Ayrshire &Arran	Borders	Dumfries &Galloway	Fife	Forth Valley	Grampian	G.Glasgow	Highland	Lanarkshire	Lothian	Orkney	Shetland	Tayside	W. Isles.
Day facilities *																
Council On Alcohol	7 (***3***)	6 (***2***)	5 (***1***)	1 (***1***)	2 (***1***)	1	4 (***1***)	2	9 (***1***)	12 (***4***)	2 (***1***)	9 (***1***)	1 (***1***)		2	
Social Work	1	5	1			1		2	12 (***2***)		3 (***1***)	1			3	
Other LA/ City Council			1			1		1	1							
Church of Scotland									1 (***1***)			1				1
Salvation Army								1								
Other Voluntary		1	1	1		1		3	5 (***1***)			4 (***1***)		2 (***1***)	1	1
Residential Rehabilitation Facilities																
Social Work											1					
Other LA/City Council																
Church of Scotland	1							1 (***1***)	1	1		1				
Salvation Army		1							1							
Other Voluntary								2	2 (***1***)			2 (***1***)				
Residential homelessness facilities																
Social Work									1							
Other LA/ City Council									4			2				
Church of Scotland												1 (***1***)				
Salvation Army												1 (***1***)				
Other Voluntary		3 (***2***)						2 (***2***)	10 (***3***)			5 (***1***)			7 (***2***)	
TOTAL	**9**	**16**	**8**	**2**	**2**	**4**	**4**	**14**	**47**	**13**	**6**	**27**	**1**	**2**	**13**	**2**
Number per 10^5	**7**	**6**	**2**	**2**	**1**	**1**	**2**	**3**	**5**	**6**	**1**	**4**	**5**	**9**	**3**	**7**

* day facilities include all non-residential facilities irrespective of hours of functioning and intensity / time period of intervention

Appendix 9 Definitions of psychosocial interventions

Psychosocial interventions

Psychotherapy: The term frequently used to talking treatment based upon psychodynamic or psychoanalytic principles. In practice, the term is also used to refer to a wide range of psychological interventions.

Psychotherapeutic techniques: A term used to describe the process/skill involved in carrying out the particular psychotherapy or treatment.

Behaviour therapy/modification: A branch of psychotherapy narrowly conceived of as the application of classical and operant conditioning to the amelioration of clinical problems. It is more broadly conceived of as applied experimental psychology.

Behaviour contracting: A procedure involving the client signing a contract that he/she will attend a specified number of continuing care meetings; this is combined with active follow-up if the client fails to meet the conditions of the contract.

Cognitive therapy: Therapy aimed at examining and change cognitions and their underlying assumptions. This involves identifying and challenging negative thoughts, developing alternative more accurate and adaptive thought and promoting cognitive and behavioural responses based on these adaptive thoughts. It is an active, structured and directive therapy.

Cognitive behavioural therapy: This involves the use of behavioural techniques to modify maladaptive cognitions. There are a range of behavioural, activity—oriented interventions or homework exercises that are used e.g. graded task assignments, activity scheduling, and behavioural experiments.

Motivational interviewing/enhancement: A client-centred counselling approach for initiating behaviour change by helping clients to resolve ambivalence about engaging in treatment and stopping alcohol use. This approach uses strategies to evoke rapid and internally motivated change in the client.

Twelve-Step model/Alcoholics Anonymous: A self-help or mutual support group with explicitly religious/spiritual aspects. The philosophy is that alcoholics drink because of a compulsion to do so and that they have lost control over their drinking whether or not they are aware of this.

Psychosocial intervention: Cognitive behavioural therapy, motivational interviewing/enhancement and the twelve-step/Alcoholics Anonymous comprise the three main forms of psychosocial intervention. The best evidence of effectiveness was found in Project March.

Group Therapy: Commonly used procedure but often poorly defined. Groups can be run according to strict psychoanalytical principles, as problem solving groups, experimental groups, support groups, discussion groups and, in some cases, according to no clear principles at all.

Aversion therapy: A behavioural therapy based on the principle of counter-conditioning. This involves pairing incompatible or aversive consequences with specific stimuli associated with the use of alcohol or drugs.

Cover Sensitisation: A form of aversion therapy which uses imagined scenes as aversive events.

Counselling: The task of counselling is to draw out the client and enable him or her to reach a greater level of understanding, or a greater commitment to take action. The process involves enabling clients to realize that alternatives exist, and helping the, to clarify what some of those choices might be.

Relapse Prevention: A treatment package involving a range of strategies to prevent relapse in the field of addictive behaviours. The aim of this approach, within the field of alcohol treatment, is to help the problem drinker develop confidence or self-efficacy in his or her ability to cope with high-risk for drinking situations. The focus of the treatment is to teach the individual coping-skills so that he/she can avoid relapse in the future. Avoidance of high-risk for drinking situations would be encouraged as an early coping strategy, however, during the course of treatment, gradual exposure to progressively more risky situations is encourage.

Techniques such as:
Stress management
Relaxation
Anger management
Assertiveness training

can be delivered as individual treatments but are also incorporated within the relapse prevention treatment package.

Coping skills: as described above, this treatment approach involves teaching clients coping skills for successful living and relationships (such as communications and assertion skills).

Social skills: the focus of social skills training is to help clients increase social support and improve their ability to establish rewarding interpersonal relationships. The content of training will focus on a range of areas including body language, listening skills, assertiveness etc.

Couples/marital/family therapy: behavioural marital or family therapy emphasis the teaching of skills to improve communication and behaviour change negotiation. Other marital and family therapy approaches draw on systems theory in both formulating the hypotheses about distress and planning interventions. Systemic therapists invariably construct a map defining the organisation, roles and rules of the family and couples they treat.

Community reinforcement: in this approach, partners, family and friends are viewed as crucial collaborators in the treatment process. Their roles have included supervising disulfiram, being partners in marital counselling, active agents in re-socialisation and reinforcement programmes, and relapsed or problem detectors.

Brief intervention: this is time-limited intervention focusing on changing an individual's behaviour with respect to alcohol consumption. The precise content of brief interventions vary. They are mainly used to reduce alcohol consumption in people drinking above recommended levels but who are not dependent.

Supportive-expressive psychotherapy: is a time limited, focused psychotherapy. (This approach has been adapted for heroin and cocaine use)

The therapy has two main components:

- Supportive techniques to help patients feel comfortable in discussing their personal experiences.
- Expressive techniques to help patients feel comfortable in discussing their personal experiences.

Special attention is paid to the role of drugs in relation to problem, feelings and behaviours, and how problems may be solved without recourse to drugs.

Appendix 10 Patient Information

REMEMBER

- *Counselling is free at Alcohol and Drugs Support South West Scotland*
- *Whether you drive or walk to a counselling session try to manage your time so that you are free of stress before the session begins.*
- *A cup of tea or a short walk afterwards is often very useful.*
- *Please inform Alcohol and Drugs Support South West Scotland staff if you cannot keep your appointment*

"I've been told I can see a counsellor. I'm not sure...I don't know much about it."

Alcohol and Drugs Support
South West Scotland

82 King Street, Castle Douglas
DG7 1AD

Tel: 01556 503550

Alcohol and Drugs Support
South West Scotland

Counselling?

Been offered counselling and you are not sure?

Who? What? Where? How?.....

There is nothing magical or mysterious about counselling. Quite often it is just an invitation to look at things in a different way perhaps to see if there other options for you.

Alcohol and Drugs Support
South West Scotland

82 King Street, Castle Douglas
DG7 1AD

Tel: 01556 503550

Alcohol and Drugs Support
South West Scotland

What is counselling?

Counselling is a personal, one to one relationship in which you can explore your thoughts and feelings with someone who has the skill to help you. It is not an advice service.

Advice givers, whether friends or professionals, seldom know the real you, but they will tell you what they think is best for you or what has worked for themselves or other people. But as we are all individuals, the advice-giving approach does not always suit everyone.

Counsellors try to find out how you usually approach problems and what you have tried before. What worked or didn't? What do you think might be useful? What is "just not on" for you? As you actually know more about yourself than anyone else does, the counsellor will ask you about you.

MAKES SENSE?

The counsellor may invite you to explore your thoughts in a little more detail. In doing so you may discover thoughts and ideas that you were not aware of before. Those new thoughts can bring the opportunity to make decisions and take the best path for you—without any more help from anyone.

GOODBYE COUNSELLOR

Not everyone walks out of a counselling relationship quickly, however. Some may have several different problems to face at the same time and will need more time than others.

How long and where?

It is practical to meet at a regular time and day each week in a room where you will have privacy. A receptionist will be nearby, but will not be able to hear the conversation. Six sessions, each less than an hour long, is usually a good target. But we can discuss what is best for you at our first meeting.

Judgement of you or your way of life is not a part of the deal and although you may be asked to examine your old habits and consider change, only you can decide when the time is right for you to do so.

With support you will begin to accept how much you already know about yourself and will learn to trust your own experiences and feelings. That is counselling beginning to work. The eventual goal is to help you, the client, manage your life without any counsellor. Your life, your choices, your successes.

A GOOD FEELING!

Who will find out what I say?

Confidentiality usually stays within the agency. Trust is essential and has to be built. There are clear guidelines to protect client and counsellor and those will be discussed in the first counselling session. It's a good time to set the boundaries and find out whether we can work together.

How long do sessions last?

Counsellors are busy people and the counselling session starts on time - with or without you. Sessions are usually no longer than fifty minutes. The session may be shorter if the client wishes.

What if we cannot work together?

One skill in counselling is to recognise when it is not working and to respect your right to quit or perhaps see a counsellor who might suit you better. Usually, however, clients and counsellors work out their difficulties by facing up to them, just like most problems in life have to be faced.

What problems can I bring?

What you want to bring—the time is yours—but counselling is not a cosy chinwag. Honest working sessions may be difficult for client and counsellor alike but are often the most helpful. Facing the problem often brings it down to size.

Will the counsellor have experience of my problem?

Some have personal experience of similar problems, but your experience is much more important. Counselling is not about how a counsellor found answers. It's more about believing in yourself— the real expert.

Depression, alcohol, drugs and family relationships are typical counselling matters. But no matter how ordinary or unusual you think your problem is, the counsellor will listen to you and treat you with respect.

OUR APPROACH TO COUNSELLING

We treat our clients as individuals. We don't seek to persuade people to accept a particular view of alcohol or drugs problems. Instead, we listen to each person to help them understand the cause of their problems, and to find appropriate solutions.

We also offer support and encouragement. We respect each persons' choice, although if we consider the goal to be unrealistic we'll say so.

OUR STANDARDS

We work hard to offer a good standard of service to all of our clients. To do this we ensure that our counsellors:

- receive appropriate training
- receive case supervision
- meet ethical standards
- maintain client confidentiality outside the agency
- respect our clients as individuals

HOW TO CONTACT US

If you need information about alcohol or drugs .....

If you would like advice, assistance or counselling about your own or someone else's alcohol or drugs problem.....

Please do not hesitate to contact us!

- telephone to arrange an individual appointment with a counsellor
- ask your GP, employer, social worker, solicitor, family member or friend to make an appointment

Our office opening hours are:

Monday to Friday:
9.00 am to 1.00pm
2.00pm to 5.00pm

Our address is:

Alcohol and Drugs Support
South West Scotland
82 King Street
Castle Douglas
DG7 1AD

Tel: 01556 503550
Services across Dumfries and Galloway

Alcohol and Drugs Support South West Scotland

ARE YOU WORRIED ABOUT ALCOHOL OR DRUGS?

Alcohol and Drugs Support
South West Scotland

If you need help - We're only a phone call away!

Alcohol and Drugs Support
South West Scotland

82 King Street, Castle Douglas
DG7 1AD
Tel: 01556 503550

Previously known as The Dumfries and Galloway Council on Alcohol, we are a Registered Charity, offering advice, information and counselling to anyone within Dumfries and Galloway on any alcohol or drugs related matter.

We are affiliated to Alcohol Focus Scotland, the country's National Alcohol Charity. If your life is affected in any way by alcohol or drugs, whether it is your own or someone else's problem, we may be able to help.

WHAT CAN WE OFFER YOU?

...We offer a safe and private space away from work or home for you to concentrate on **your** concerns.

...We provide a trained counsellor to help to identify the problems you feel **you** have.

...We can provide information and advice about alcohol and drugs,and about the services available to **you** in the community.

...We have good links with other agencies locally and nationally and can put people in touch with them if it's appropriate.

HOW DO WE DEFINE AN ALCOHOL OR DRUGS PROBLEM?

Alcohol and Drugs Support South West Scotland does not attach "labels" to people with alcohol or drugs problems. We work with anyone who feels they might be in difficulty because of alcohol or drugs problems, their own or someone else's.

Someone in difficulty with alcohol or drugs might :

- *Suffer from health or fitness problems*
- *Find themselves in trouble with employers or the police*
- *Experience difficulties with money*
- *Feel unable to cope without a drink or drugs*
- *Have rows with family and friends*
- *Drink or take drugs to forget difficult problems*
- *Be irritable or upset without a drink or drugs*
- *Face severe medical, legal, marital or employment problems*

WHO USES OUR SERVICE?

We can help anyone who is looking for advice and information about alcohol or drugs, or who is worried about their own or someone else's alcohol or drugs problem. The people who use our service come from all walks of life and contact us for many reasons.

WHAT CAN YOU EXPECT FROM US?

- You can expect honesty without being judged
- You can expect confidentiality within the agency
- You can expect advice, information and one-to-one counselling, independent of any other agency
- You can expect one-to-one communication with a trained counsellor
- You can expect an initial interview followed by a series of appointments if you decide it will help

'Being There' Befriending Service.

Are You Having Problems With Alcohol or Drugs?

Are You Feeling Isolated?

Do You Feel Life Is Getting On Top Of You?

A Befriender May Be Able To Help You Reduce Your Isolation.

'Being There' is funded by the **Community Fund**

COMMUNITY FUND
Lottery money making a difference

'Being There' Befriending Service

'Being There' Befriending Service,
Alcohol And Drug Support
South West Scotland
82, King Street,
CASTLE DOUGLAS
DG7 1AD

Service Manager: Guy Oscroft
Volunteer Development Officers:
Annandale and Eskdale: Carol Greenhow.
Wigtownshire: Glynis Lockhart

Phone: Head office: 01556-502141 (Fax: 01556 503550)
'e'mail: alcohol.info@virgin.net

Volunteer Befriender Recruitment, Training and Support.

'Being There' *Befriending Service*

'Being There' Befriending Service,
Alcohol And Drug Support
South West Scotland
82, King Street,
CASTLE DOUGLAS
DG7 1AD

Tel: 01556—502141

What is the 'Being There' Befriending Service?

'Being There' provides a befriending service for people who have become isolated through their own or someone else's drinking or drug use.

WHAT IS A BEFRIENDER?

A Befriender is a trained volunteer who meet with his/her client in a regular basis—usually weekly. A Befriender can provide company on social outings, such as swimming, the cinema or simply provide on-going support when a client is experiencing difficulties in coping.
After an initial basic training, Befrienders receive monthly supervision, agency training as available, and may also take an SVQ III in Care.

WHO CAN BE BEFRIENDED?

Anyone who is experiencing isolation resulting from an alcohol or drug related problem. Recognising that problems may be experienced by those other than the drinker/drug user, Befriending is also available to friends and families of problem drinkers or drug users, who are finding it difficult to cope.

DO I NEED A BEFRIENDER?

Do you feel isolated, lacking in confidence and wishing to get more out of life? Would you like support in making new friends, renewing old acquaintances, or simply to have someone to talk to? If you find this difficult or impossible because of a personal alcohol or drug problem, or if someone in your family is experiencing a problem with alcohol or drugs and you are unsure how to help -

CALL US NOW

WHAT HAPPENS NEXT?

When you call us we ask for a few personal details so that we can contact you again. This only takes five minutes, although you may tell us more about the problems you are experiencing if you wish.
An appointment will then be sent out for one of our Development Workers to visit you to discuss ways in which befriending may help you. This will usually be within two weeks.
The Development Worker will then try to find a suitable befriending match for you and will make an appointment to introduce you to your befriendee. This can take some time, depending upon which of our volunteers are available.

HOW DO WE MATCH PEOPLE?

We take great care when matching people, aiming to match people with similar interests wherever possible. Once we have identified a suitable Befriender, you will be contacted by us and given the opportunity to meet.

AND THEN??

During your befriending relationship there will be regular reviews of the progress you are making with your Befriender.

WHAT HAPPENS IF WE DON'T GET ON?

If this should happen, you will both be given the support you need to end the relationship without any blame being apportioned to either party: the Service Manager will then endeavour to match you with another Befriender if you wish. If you are unhappy with any aspect of our service there is a Complaints Procedure you can follow.

WHAT ABOUT MY CONFIDENTIALITY?

To assist with the initial matching, the volunteer will be given basic information in order to help with the befriending process. Your Befriender will respect your right to confidentiality at all times.

'Being There' Befriending Service,
Alcohol And Drug Support
South West Scotland
82, King Street,
CASTLE DOUGLAS
DG7 1AD

Service Manager: Guy Oscroft
Volunteer Development Officers:
Annandale and Eskdale: Carol Greenhow,
Wigtownshire: Glynis Lockhart

Phone: Head office: 01556-502141 (Fax: 01556 503550)
'e'mail: alcohol.info@virgin.net
Lochmaben office: 01387-811571
Stranraer office: 01776-700226

Appendix 11 12 steps of Alcoholics Anonymous

TWELVE SUGGESTED STEPS OF ALCOHOLICS ANONYM OUS

1. We admitted we were powerless over alcohol – that our lives had become unmanageable.
2. Came to believe that a Power greater than ourselves could restore us to sanity.
3. Made a decision to turn our will and our lives over to the care of God as we understood Him.
4. Made a searching and fearless moral inventory of ourselves.
5. Admitted to God, to ourselves and to another human being the exact nature of our wrongs.
6. Were entirely ready to have God remove all these defects of character.
7. Humbly asked Him to remove our short-comings.
8. Made a list of all persons we had harmed, and became willing to make amends to them all.
9. Made direct amends to such people wherever possible, except when to do so would injure them or others.
10. Continued to take person inventory and when we were wrong, promptly admitted it.
11. Sought through prayer and meditation to improve our conscious contact with God as we understood Him, praying only for knowledge of His will for us and the power to carry that out.
12. Having had a spiritual awakening as the result of these steps, we tried to carry this message to alcoholics and practice these principles in all our affairs.

Appendix 12 Greater Glasgow shared care protocols for acamprosate

DRAFT FOR APPROVAL

ACAMPROSATE SHARED CARE PROTOCOL

The Area Drug and Therapeutics Committee has approved the use of Acamprosate in the treatment of Alcohol Dependence Syndrome on a shared care basis with Primary Care.

Acamprosate
Acamprosate is indicated for maintenance of abstinence in patients with Alcohol Dependence.

The mechanism of action is believed to be by stimulating GAB ergic inhibitory transmission and by antagonising excitatory amino acids, particularly glutamic acid. It may surpress cravings for alcohol triggered by conditioned response.

A meta analysis of randomised controlled trials demonstrated that six months to one year treatment with Acamprosate doubles abstinence rates in alcoholics.

An evaluation of treatment with Acamprosate over a one year period in Glasgow showed that two thirds of patients assessed suitable for treatment were compliant after one month and they achieved 83% of potential Cumulative Abstinent Days.

Acamprosate does not interact with alcohol or Benzodiazepines. Acamprosate does not impair an individuals ability to drive or operate machinery.

The main side effects are gastrointestinal as well purites and fluctuation in libido.

Inclusion Criteria
Moderate to severe Alcohol Dependence with abstinence goal in conjunction with psychosocial treatments and counselling.

Tendency to anxiety symptoms in post withdrawal phase, not amounting to Generalised Anxiety Disorder or Panic Disorder.

Reported cravings for alcohol, prompting relapse.

Exclusion Criteria
Patients with a history of repeated self harm, Anti-Social Personality Disorder or minimal brain damage.

Patients with significant social problems and lack of support.

Dosage
Acamprosate should be initiated soon after detoxification.

Acamprosate 333 mg tablets.

For adults over 60 kilograms 2 tablets in the morning, one at noon and one at night with meals.

For adults below 60 kilograms 2 tablets in the morning, one at noon and one at night with meals.

Shared Care

Acamprosate will be initiated by Specialist Alcohol Services, as part of therapeutic plan including counselling, relapse prevention or psycho-social support.

Patients would be monitored at least monthly by Specialist Alcohol Services for a three month period. Acamprosate will be dispensed by Hospital Pharmacy during this period.

Specialist Alcohol Services would liase with general practitioners regarding continued prescribing, for a further nine months (total treatment one year).

Continued monitoring by specialist services, while Acamprosate is prescribed by general practitioner.

Treatment Discontinuation and Outcome

Acamprosate should be discontinued following repeated or protracted relapse (relapse is defined as more than five drinks for a five day period) or non compliance.

Outcome will be evaluated by measuring Cumulative Abstinence Days (CADs).

Contact

For further information please contact your local specialist service:-

_____ Tel No: _____

Dr P Jauhar
Clinical Director
December 2001

Appendix 13 Lothian protocol for use on naltrexone

Alcohol Problems Service, Lothian Primary Care NHS Trust

PROTOCOL FOR THE USE OF ORAL NALTREXONE

Naltrexone given to detoxified patients, or non-dependent patients who commence taking Naltrexone when sober, reduces the frequency and severity of relapses into "heavy drinking" (over 8 units a day) (references attached). There is one study where Naltrexone was started in patients of mild severity of dependence who continued to drink; overall drinking in the coming year reduced.

Contraindications

Established liver disease (bilirubin currently about 25 mmols/l, history of varices or ascites); current use of opiates or any opiate-like analgesic.

Indications

Either Has achieved abstinence but has repeatedly relapsed to problem drinking despite previous attempts with Disulfiram, Acamprosate, individual or group therapy or, refusal to consider these therapies.

Or Repeated failure to succeed with an abstinence goal and patient and therapist feel that goal of limited drinking is clinically appropriate.

And History of impaired control within sessions of drinking.

Relative Indications

Theoretically, Naltrexone is most likely to help those for whom drinking has positive rewards e.g. euphoria, rather than for reduction of negative feelings e.g. to reduce anxiety or depression.

Procedure

1. Baseline liver function is checked, and a biological marker, sensitive in that patient (GGT, MCV and /or CDT) is chosen so that outcome can be objectively monitored in the coming months.

2. Patient signs Consent Form having read the information Sheet.

3. Initial prescription for one week at a time.

4. Initial prescription 25 mg (half tablet) for first 2 days, to continue at half a tablet until nausea (if present) diminished, when full tablet 50 mg is taken (with breakfast).

5. Our prescription should be via REH Pharmacy (only if patient unable to attend Pharmacy is the GP asked to prescribe, when he is given full background).

6. Renewed prescriptions only if evidence of reduction of problematic/heavy session drinking e.g. improving blood tests. The patient is breathalysed at each appointment.

7. After 3 months the prescription is changed to "targeted" use only on days when risk of drinking is anticipated and one day before e.g. only taken on Thursday, Friday and Saturday.

LOTHIAN PRIMARY CARE NHS TRUST
ALCOHOL PROBLEMS CLINIC
SUMMARY OF INTERVENTIONS DURING TREATMENT PROGRAMME

Assessment

Brief Interventions used to increase awareness of alcohol and motivation.

Detoxification over two weeks

Day patient detoxification and four motivational sessions on individual basis:

1. Exploring lifestyle issues.
2. Awareness – the good things and less good things.
3. Decisional balance pros/cons of changing and staying the same.
4. Exploring ambivalence and supporting self-efficacy

Education groups

Six sessions over two weeks:

1. Alcohol dependence – withdrawal, importance of detox. – consequences of dependence.
2. What is alcohol, factor affecting consumption, effects of alcohol, how body gets rid of alcohol.
3. Tolerance cravings – domains of dependence.
4. Aids to abstinence Antabuse, Campral and other agencies – AA, RCA.
5. Introduction to cycle of change, process of change, where are we now?
6. Weekend planning / daily planning.
   Structuring time.
   Evaluation questionnaire.

These groups are audited.

Relapse Prevention – solution focused

Six sessions over two weeks:

1. Introduction to principles of solution focused therapy. Exploring confidence/importance of change.
   "The miracle question"
   Lifestyle changes
2. Cycle of change -

Predicting relapse – ABC model – antecedents – behaviour-consequences.
Slips/lapse/relapse.

3. High risk situations.
   High success situations
   Seemingly irrelevant decisions.
4. Craving – Cognitive and behavioural -
   Stop, refocus, breathe technique
5. Decision making – how we make decisions and influences on decision-making.
   Problem solving and success finding.
   Goal setting.
6. Drink refusal skills/re-evaluating importance/confidence.
   Assertiveness – support and follow up.
   Post group questionnaire.

These groups are audited.

Anxiety Management

Six sessions over three weeks –

Individually as required.
Cognitive/behavioural approach.

Anger Management –

Six sessions over six weeks –

Individually cognitive / behavioural approach

Longer term support group

One session per week –

Ongoing support for clients remaining abstinent.
Support of clients using Antabuse and Acamprosate.

Input from other services as required –

Physiotherapy – eight week (16 sessions) fitness/exercise programme.

3 sessions relaxation.

O.T. – one session per week – women's group.
We currently audit all referrals to the Unit as a way to provide statistical data of referrals and treatment outcomes.

Appendix 14 Information on supervised administration of disulfiram

LOTHIAN PRIMARY CARE NHS TRUST

ALCOHOL PROBLEMS SERVICE

ANTABUSE (DISULFIRAM): THE PARTNERSHIP APPROACH

1. A partner is a person who is asked by the patient to observe them taking the Antabuse tablets.

2. So that other tablets cannot be substituted, the genuine Antabuse tablets are marked DUMEX 110 L (Dumex is the manufacturer).

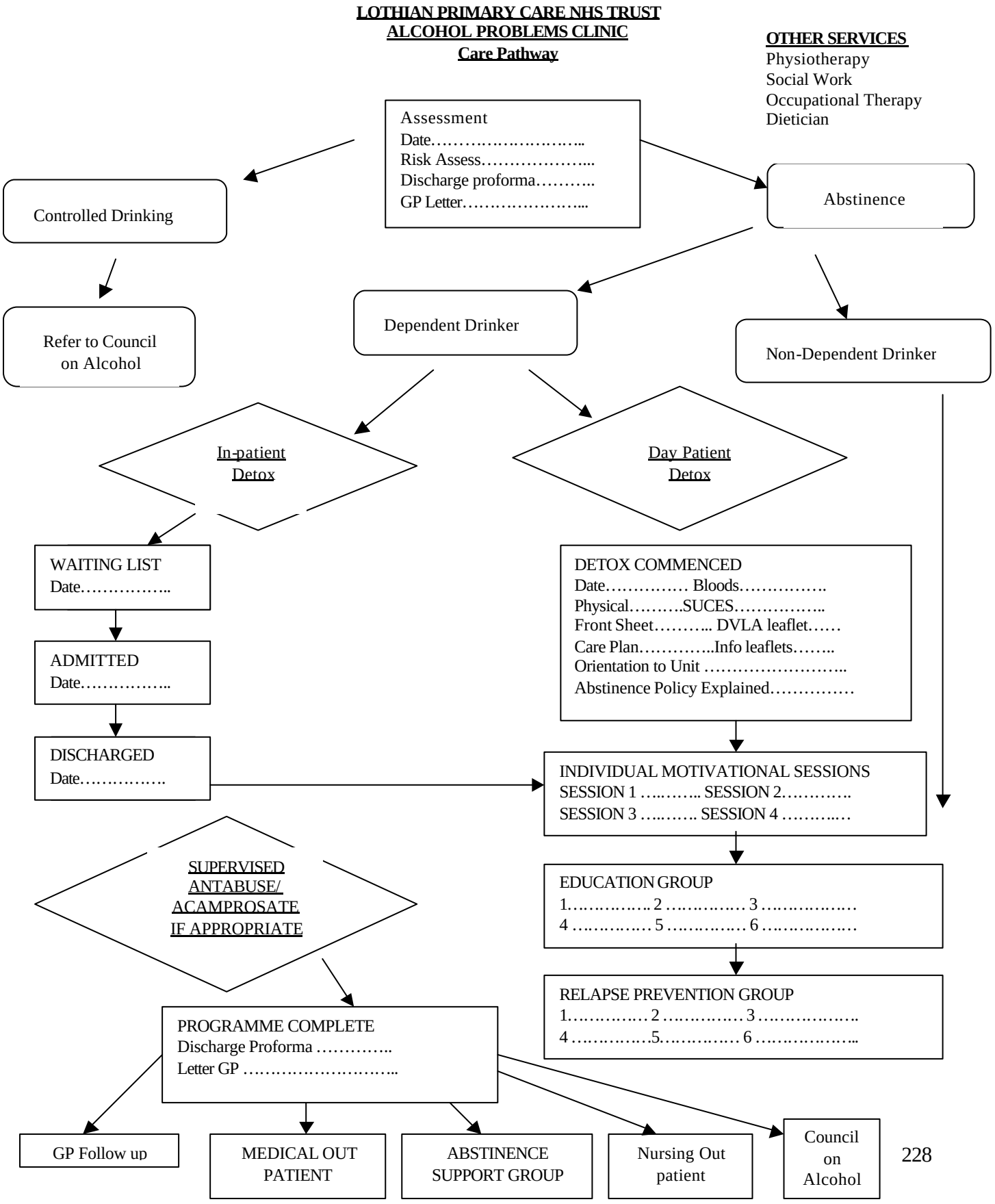
3. To ensure they are not placed under the tongue and removed later, Antabuse tablets should be dissolved in half a glass of water (the tablets break up and disperse and the mixture is tasteless).

4. It does not matter what time of the day the tablet is given. If it is more convenient, it can be given on 3 days per week – instead of one tablet daily it can be taken: 2 on a Monday, 2 on a Wednesday and 3 on a Friday.

5. If it is suspected that the patient has decided to vomit after taking the tablet, the partner can stay with the patient for up to 30 minutes after the tablets are taken (this is rarely necessary).

6. If the patient decides to stop taking the tablets, the patient or the partner should telephone the treating Doctor or a member of nursing staff so that the reason for this may be discussed.

Appendix 15 Examples of care pathways



Appendix 16 Databases searched for clinical effectiveness studies

Databases searched for clinical effectiveness studies

High Level Literature Search - Sources
An initial search was undertaken in August 2001 to identify HTA reports, systematic reviews and other evidence reports, using the following sources:

- Health Technology Assessment Database
  Via the Cochrane Library (CD-ROM, 2001 Issue 2)
- NICE (National Centre for Clinical Effectiveness)
  http://www.nice.org.uk/
- NCCHTA (National Coordinating Centre for Health Technology Assessment)
  http://www.ncchta.org/
- NHS Centre for Reviews and Dissemination, University of York
  http://www.york.ac.uk/inst/crd/
- Birmingham Technology Assessment Group, Department of Public Health and Epidemiology, University of Birmingham
  http://www.publichealth.bham.ac.uk/wmhtag/
- ScHARR, University of Sheffield
  http://www.shef.ac.uk/~scharr/publications.htm
- South and West R&D Directorate, DEC reports
  http://www.doh.gov.uk/research/swro/rd/publicat/dec/
- British Columbia Office of Health Technology Assessment (BCOHTA)
  http://www.chspr.ubc.ca/bcohta/
- Health Services Utilization and Research Commission (HSURC Saskatchewan)
  http://www.hsurc.sk.ca/
- Institute for Clinical and Evaluative Sciences (ICES)
  http://www.ices.on.ca/
- Manitoba Centre for Health Policy (MCHP)
  http://www.umanitoba.ca/centres/mchp/
- ISTAHC (International Society of Technology Assessment in Health Care)
  http://www.istahc.org/
- ECRI
  http://www.ecri.org/
- HSTAT
  http://text.nlm.nih.gov/
- Cochrane Database of Systematic Reviews (CDSR)
  Cochrane Library (CD-ROM, 2001 Issue 2)
- Database of Abstracts of Reviews of Effectiveness (DARE)
  Cochrane Library (CD-ROM, 2001 Issue 2)
- Ongoing Reviews database
  http://www.update-software.com/National/
- SIGN (Scottish Intercollegiate Guidelines Network)
  http://www.sign.ac.uk/
- ARIF (Aggressive Research Intelligence Facility)
  http://www.bham.ac.uk/arif/
- Health Evidence Bulletins Wales

http://hebw.uwcm.ac.uk/

- Centre for Clinical Effectiveness, Monash Institute of Public Health
  http://www.med.monash.edu.au/healthservices/cce/
- TRiP
  http://www.tripdatabase.com/
- Bandolier
  http://www.jr2.ox.ac.uk/bandolier/

Randomised Controlled Trials – Sources

The following sources were searched during December 2001 to identify randomized controlled trials

- Medline (Ovid)
- Premedline (Ovid)
- Embase (Ovid)
- Cochrane Controlled Trials Register (Ovid)
- Psychinfo (Ovid)
- EtOH
  http://etoh.niaaa.nih.gov/
- MRC Funded Research
  http://fundedresearch.cos.com/MRC/
- Current Controlled Trials
  http://www.controlled-trials.com/
- Clinical trials.gov
  http://clinicaltrials.gov/
- NRR
  http://www.update-software.com/National/
- CRISP (Computer Retrieval of Information on Scientific Projects)
  https://www-commons.cit.nih.gov/crisp/

Appendix 17 Search strategy for clinical effectiveness studies

Search Strategy for clinical effectiveness randomized controlled trials in Medline
Database: MEDLINE
Coverage: <1966 to October Week 5 2001>
Host: Ovid
Date searched: 1/12/01

---

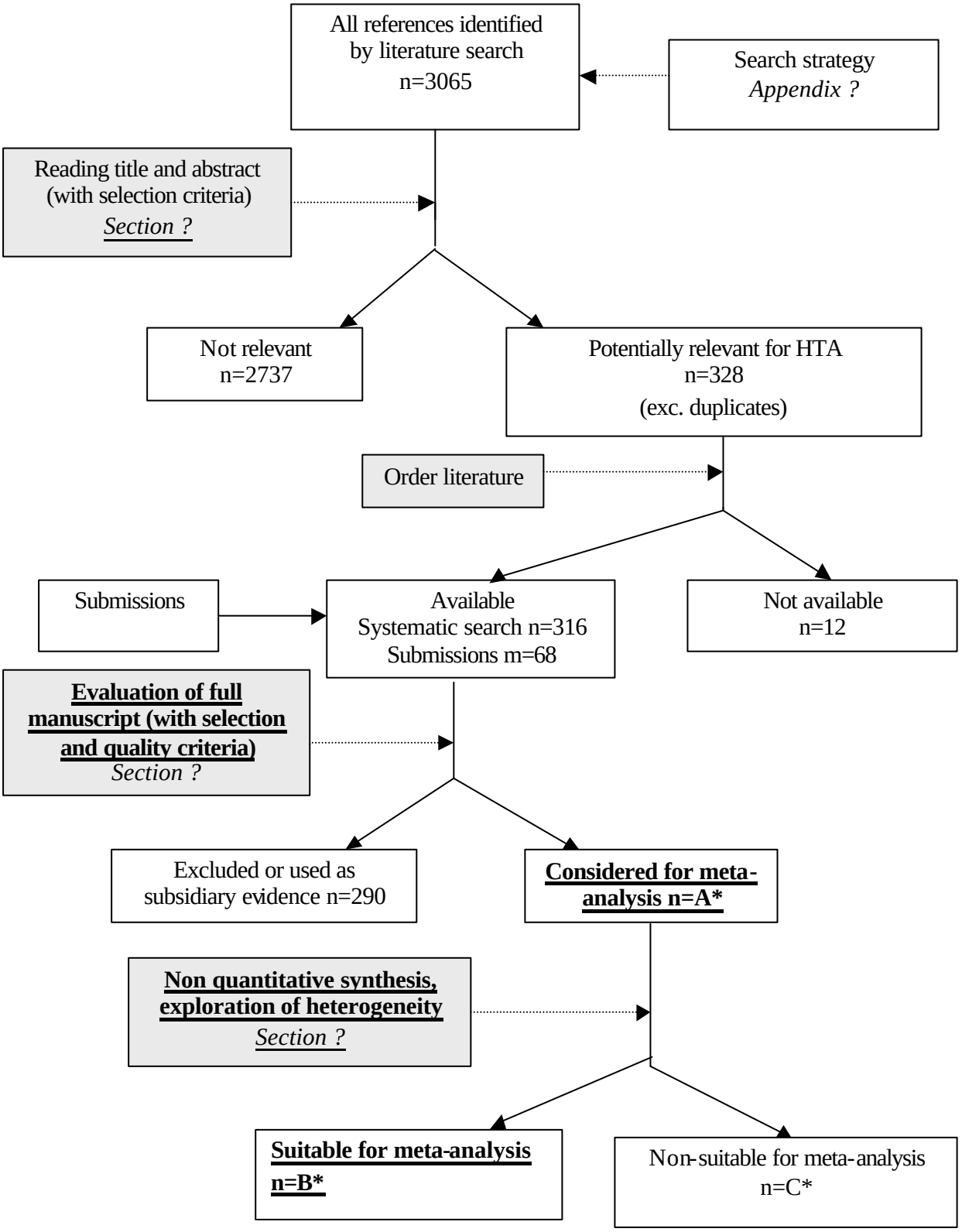
1 alcoholism/
2 alcohol drinking/
3 alcoholic?.tw.
4 alcoholism.tw.
5 (harmful$ adj1 drinking).tw.
6 dipsomania$.tw.
7 (alcohol adj2 (dependen$ or addict$ or abus$ or misus$)).tw.
8 or/1-7
9 intervention studies/
10 intervention$.tw.
11 (relaps$ adj1 prevent$).tw.
12 or/9-11
13 alcohol deterrents/
14 behavior addictive/dt
15 (alcohol adj2 deter$).tw.
16 (alcohol adj1 sensiti$).tw.
17 (alcohol adj2 aversi$).tw.
18 (alcohol adj2 anti?craving).tw.
19 (pharmacolog$ adj1 (intervention$ or treatment$)).tw.
20 taurine/
21 disulfiram/
22 naltrexone/
23 acamprosate.tw.
24 campral.tw.
25 disulfiram.tw.
26 antabuse.tw.
27 naltrexone.tw.
28 trexan.tw.
29 or/13-28
30 psychotherapy/
31 exp behavior therapy/
32 exp psychoanalytic therapy/
33 exp socioenvironmental therapy/
34 exp self concept/
35 psychotherapy brief/
36 alcoholics anonymous/
37 social support/

38 behavior addictive/px
39 psychotherap$.tw.
40 (psychosocial adj2 (care or therap$ or intervention$ or technique$ or treatment$)).tw.
41 (behavio?r$ adj2 (therap$ or treatment$ or modification or contracting)).tw.
42 (assertive$ adj2 (skill$ or training or technique$)).tw.
43 (aversi$ adj2 (therap$ or treatment$)).tw.
44 (cognitive adj2 (therap$ or treatment$)).tw.
45 cbt.tw.
46 (relaxation adj2 (skill$ or training or technique$)).tw.
47 sociotherapy.tw.
48 psychoanaly$.tw.
49 (socioenvironmental adj2 (therap$ or treatment$)).tw.
50 therapeutic community.tw.
51 ((group or marital or couple$ or famil$) adj2 (therap$ or intervention$or technique$ or treatment$)).tw.
52 (community adj2 reinforc$).tw.
53 (motivational adj (interview$ or enhancement)).tw.
54 supportive expressive therap$.tw.
55 counsel?in g.tw.
56 counsel?or?.tw.
57 (cue$ adj1 (therap$ or exposure)).tw.
58 covert sensitization.tw.
59 (self adj1 concept).tw.
60 (self adj (efficacy or esteem or control or care)).tw.
61 (social$ adj1 support).tw.
62 ((coping or life) adj1 skills).tw.
63 social skill$.tw.
64 ((stress or anger) adj2 manag$).tw.
65 supportive treatment$.tw.
66 ((brief or short or minimal) adj2 intervention$).tw.
67 coping behavio?r.tw.
68 stepped care.tw.
69 alcoholics anonymous.tw.
70 aa.tw.
71 twelve step.tw.
72 "12 step".tw.
73 or/30-72
74 temperance/
75 temperance.tw.
76 sobriety.tw.
77 (alcohol adj2 (consum$ or intake) adj2 (reduc$ or control$ or moderat$ or attenuat$ or restrict$ or restrain$)).tw.
78 (abstinence or abstain$).tw.
79 ((control$ or moderat$ or attenuat$ or reduc$ or restrain$ or restrict$) adj2 drinking).tw.
80 (self adj (change or help)).tw.
81 maturing out.tw.

82 or/74-81
83 randomized controlled trial.pt.
84 randomized controlled trials/
85 (random$ adj2 (trial$ or stud$)).tw.
86 random allocation/
87 double blind method/
88 single blind method/
89 or/83-88
90 animal/ not (human/ and animal/)
91 89 not 90
92 8 and 12 and 91
93 limit 92 to yr=1990-2002
94 8 and 29 and 91
95 limit 94 to yr=1990-2002
96 8 and 73 and 91
97 limit 96 to yr=1990-2002
98 8 and 82 and 91
99limit 98 to yr=1990-2002

This search strategy was reviewed by Gill Ritchie, Information Officer, at CRD, University of York. Suggested changes will be incorporated when the strategy is updated during the Consultation period.

Flow chart of literature selection process for meta-analysis



Numbers of studies for each meta-analysis (see preceeding figure)

	A	**B**	**C**
Acamprosate	19	17	2
Naltrexone	21	16	5
Disulfiram	3	2	1
Motivational enhancement	8	3	5
Relapse Prevention	11	5	6
Behavioural self-control training	7	5	2
Coping Skills	3	3	0
Marital/Relationship therapy	22	12	10

Appendix 18 Conclusions from comprehensive reviews of alcohol treatment

In this appendix we present:

1. The ordering of all interventions derived using the Mesa Grande methodology
2. Some recommendations for a comprehensive UK alcohol problems treatment service from the report by Raistrick and Heather
3. Some conclusions from the Swedish health technology agency (SBU) report on management of drug and alcohol problems.

Table 18-1 Mesa Grande Project – Rankings of interventions derived from controlled trials in patients with alcohol problems of any severity

Rank	Treatment modality	N	Rank	Treatment modality	N
1	Brief intervention	31	45	Family therapy	3
2	Motivational enhancement	17	46	'Moral reconation' therapy	1
3	GABA agonist	5	47	Community reinforcement – buddy	1
4	Anti-depressant, non-SSRI	6	48	Recreational therapy	1
5	Opiate antagonist	6	49	Job finding	1
6	Social skills training	25	50	Legally sanctioned probation/rehab.	2
7	Community reinforcement	4	51	Medical monitoring	1
8	Behaviour contracting	5	52	BAC surveillance	1
9	Behavioural marital therapy	8	53	Occupational therapy	1
10	Dopamine antagonist	2	54	Tobacco cessation with nicotine gum	1
11	Sensory deprivation	2	55	Tobacco cessation with exercise	1
12	Biofeedback	2	56	Aversion therapy, electric	20
13	Case management	6	57	Twelve-Step facilitation	3
14	Cue exposure	2	58	Antidepressant, SSRI	15
15	Developmental counselling	1	59	Dopamine agonist	1
16	Anti-convulsant medication	1	60	Dopamine precursor	1
17	Detoxification as treatment	1	61	Serotonin precursor	1
18	Significant other as treatment support	1	62	BAC discrimination training	2
19	Self-monitoring	6	63	Beta blocker	1
20	Transcendal meditation	1	64	Client choice among options	1
21	Assessment as intervention	1	65	Psychotherapy, group process	2
22	Aversion therapy, negative emotion	1	66	Lithium	7
23	Feedback	1	67	Marital therapy, other	8
24	Hypnotic medication	1	68	Electrical stimulation of the head	2
25	Cognitive therapy	10	69	Functional analysis	3
26	Client-centred counselling	7	70	Anti-psychotic mediation	2
27	Disulfiram	24	71	Hypnosis	4
28	Unilateral family therapy	1	72	Psychedelic medication	8
29	Aversion therapy, apnoeic	3	73	Placebo (non-blinded to provider)	2
30	Covert sensitization	8	74	Calcium carbimide	3
31	'Affective contra-attribution' therapy	1	75	Serotonin antagonist	3
32	Problem solving	2	76	Anti-anxiety medication	14
33	Acupuncture	3	77	Relapse prevention	20
34	Aversion therapy, nausea	5	78	Metronidazole	9

35	Tobacco cessation	2	79	Milieu therapy	12
36	Systematic desensitisation	2	80	Alcoholic anonymous	7
37	Self-help	5	81	Video self-confrontation	8
38	'Reminiscence' therapy	1	82	Standard Treatment	15
39	Self-control training	35	83	Relaxation training	18
40	Other medications (3 types)	3	84	Confrontational counselling	11
41	Minnesota model	3	85	Psychotherapy	18
42	Exercise	3	86	General alcoholism counselling	20
43	Stress management	3	87	Educational lectures, films, groups	23
44	Therapeutic community	1			

N denotes the number of studies on which each intervention is ranked. It should be noted that the project authors have concerns about ordering an intervention on the basis of less than three studies and hence split the above list into two section for those with three or more and those with two or less studies.

Summary of recommendations by Raistrick and Heather

1. In-patient and supported residential units might be shared between several health districts.

2. Arrangements should be in place to deal with mentally ill, violent or aggressive patients and those with acute stress reaction.

3. An argument is put for Motivational Enhancement Therapy as a standard of treatment. It may be a self contained treatment or a preparation for more intensive treatment (Brown & Miller, 1993)

4. Pharmacotherapies should be integrated into the treatment model.

5. 'Relapse prevention should not be seen as a treatment in itself but should be a component part of all treatment programmes'.

6. Information on local mutual aid groups should be available through staff.

7. There is a marked diversity of clients and, although Project MATCH did not support the systematic matching of therapies to clients (see section 5.6.4) it is clear that different facilities will be necessary: for instance for homeless or very young people.

8. Disulfiram is considered to have some effect as a sensitising agent. The importance of monitoring compliance is noted.

9. Naltrexone and acamprosate are both considered to have a role in treatment of alcohol problems. Four uses are suggested (1) when sensitizing agents are contraindicated (2) enhancement of abstinence oriented programmes when clients are in the pre-contemplation or contemplations stages of change (3) an enhancement to controlled drinking programmes (for some subgroups not yet determined) (4) an aid to containing relapse.

Conclusions from SBU report

Amongst the conclusions are:

1. The effectiveness of certain 'mini interventions' that are possibly not used as much as they might be.

2. That certain other psychosocial treatments have beneficial effects, which are similar to each other. These include types of CBT (e.g. 12 steps) and motivational programmes. Structured interactional therapy and structured modern therapy with psychodynamic reference frameworks seem similar in effect to CBT. Partner therapy and family intervention show positive effects.

3. Only weak evidence exists on subgroup effects. Inpatient and outpatient results are similar. Important to address problems of mental illness and lifestyle problems concurrently with abuse.

4. Acamprosate, naltrexone and disulfiram are noted to have confirmed effect. Disulfiram only when given under supervision.

Certain areas for research are noted. Of particular interest for the current assessment are:

5. Integration of psychosocial and pharmacological interventions
6. Optimal intensity and duration of different treatment interventions
7. The cost-effectiveness of different treatment methods

SBU Economic analysis

A search of several literature databases found 1200 articles of which 24 studies were economic analyses and 8 were based on RCTs. These included alcohol and drug studies. About half the studies were of poor quality and the remainder covered diverse areas. It was concluded that evidence was weak and contradictory. No conclusions on cost-effectiveness could be drawn.

Appendix 19 Summary of Product Characteristics for Acamprosate

Appendix 20 Summary of Product Characteristics for Naltrexone (Ireland)

Awaiting permission to reprint from Manufacturers

Appendix 21 Meta-analyses of treatment effectiveness for economic model

In this section we present the data extracted from individual studies concerning the numbers of patients in each treatment arm who were considered to have achieved a controlled drinking state at the end of the study follow-up period.

These data are combined using meta-analytic methods in order to give estimates of effectiveness, which can be used as inputs to the cost-effectiveness model.

Trials of pharmacotherapy

The clinical trials of acamprosate and naltrexone generally compare the active drug with a placebo allocated in a random fashion and both the patients and the clinical investigators are unaware of the nature of the intervention received. These are aspects of study design, which are considered important in reducing the likelihood of biased results and, in these respects these trials are of good quality. The major difficulty with these, and indeed almost all, trials of treatments for alcohol dependent subjects is the high incidence of patients being lost to follow-up before the designated end of the trial. Good practice in analysis requires consideration of the influence which such drop-out might have on inferences drawn from the trial and one method of doing this is to analyse all randomized patients using various strategies to estimate what outcomes might have been observed in drop-outs (an Intention To Treat analysis). We have attempted to do this wherever possible using the assumption that drop-outs have relapsed. This is the strategy used in most of the original analyses of acamprosate but not so frequently in analyses of naltrexone where 'last observation carried forward' seems to have been preferred. This means that the state of the patient at the end of the study is assumed to be the same as that at the last actual observation.

A successful outcome may either involve complete abstinence on the part of the patient or drinking at a moderate level, which does not cause acute crises, have a deleterious effect on their lifestyle, or unacceptably increase risk of longer term clinical harm. Either abstinence or controlled drinking may be nominated as the treatment goal and different treatments may be aimed more to one than the other. For instance, acamprosate is licenced for the promotion of abstinence. We have combined trials aimed at abstinence with those aimed at controlled drinking but have identified the outcomes for each trial in the tables.

A further difficulty in making valid comparisons between acamprosate and naltrexone is that the trials tended to report outcomes at very different times. Many acamprosate studies reported after a year of follow-up whilst naltrexone studies often had only 3 months. The time at which our results are extracted is shown in the table. Differences are also present in the time duration over which the outcome was assessed. For instance a twelve-month outcome might only consider abstinence or control over the previous 6 months.

There are fewer trials of disulfiram and they are generally of lower quality. Some of this deficiency is unavoidable, for instance the only intended clinical effect of disulfiram is the unpleasant reaction when alcohol is drunk. Hence an important part of the true effect of disulfiram is the fear of what might happen after drinking. A blinded placebo controlled trial would not

measure this effect since the placebo should cause the similar fear. Hence simple blinded trials are inappropriate – possibly also unethical since the knowledge that they might be receiving a placebo could encourage the patient to take an unnecessary risk.

It has been suggested that the use of disulfiram is only likely to have an effect when it is coupled with some method of increasing compliance. This could involve either a contract with a family member or directly observed administration by clinic staff. Whilst this suggestion appears very reasonable, the evidence to support it is limited. Only one study (Chick et al., 1992) appears to have examined supervised disulfiram in a randomized controlled trial against an inactive comparator without any additional confounding treatment. This study found a statistically significant increase in the number of abstinent days and a reduction in the number of units consumed over six months as assessed by a blinded assessor. The results are not given in terms of abstinence or controlled drinking by patient and hence cannot be used in the economic model.

Trials of psychosocial treatments

The evaluations of psychosocial interventions are based on a fairly heterogeneous selection of trials. Most of these included a treatment arm in which the intervention was thought likely to have little or no effect and this is used as the comparator arm when available. However, other trials included interventions thought likely to be less effective but not necessarily ineffective. These have also been included and thus it may be that psychosocial intervention effects will be somewhat underestimated. Psychosocial interventions are also poorly standardized in content and duration and cannot be blinded which allows the possibility of many other sources of heterogeneity and bias. The difficulties with respect to length of follow-up, high numbers of drop-outs and variety of outcome measures which have already been discussed for trials of pharmacological agents are present in the trials of psychosocial treatments.

The following tables show the calculations performed to combine results across different studies. The methods used are those of DerSimonian and Laird (1986). The dependent variable Y which is combined across studies is the estimated Log(odds ratio) for a successful outcome given the intervention of interest compared with the control intervention. The weight given to each study is the inverse variance estimate for the Log(odds ratio).

Key

N	Number of studies combined	
Y	Dependent variable	
W	Weight for study	
C1	W x Y	
C2	$(Y - ?WY/?W)^2$	
C3	W x $(Y - ?WY/?W)^2$	
Q	SC3	
C4	W x W	
SW2	$(SW^2 – (SW)^2/N)/(N – 1)$	
U	$(SW/N – SW2/SW) \times (N – 1)$	
D	$(Q – N + 1)/U$	
Wc*	$1/(D + 1/W)$	Weight for random effects model

C6 Y x Wc*
Y* SC6/SWc* Random effects estimate
LCB Y* - 1.96 / √(SWc*)
UCB Y* + 1.96 / √(SWc*)

It should be noted that the random effects estimate is not used unless Q is greater than the degrees of freedom (N –1). When this is not the case the fixed effect – the weighted mean of Y – is used and is written in bold to indicate this.

META-ANALYSIS OF TRIALS OF NALTREXONE

Name of trial	NT	NC	XT	XC	Odds ratio	95% CI	Months of fu	Outcome[1]
O'MALLEY 1992/6 (S)	29	25	6	5	1.0435	(0.28,3.89)	9	C
O'MALLEY 1992/6 (C)	23	27	12	4	6.2727	(1.65,17.51)	9	C
VOLPICELLI 1997	48	49	31	23	2.0614	(0.91,4.50)	3	C
KRYSTAL 2001	418	209	235	104	1.2965	(0.93,1.81)	3	C
MORRIS 2001	55	56	19	7	3.6944	(1.41,8.11)	3	C
VOLPICELLI 1992	35	35	27	16	4.0078	(1.42,9.61)	3	C
LEE 2001	35	18	16	7	1.3233	(0.42,4.09)	3	A
CHICK 2000	90	85	32	30	1.0115	(0.55,1.88)	3	C
KNOX 1999	31	32	3	5	0.5786	(0.14,2.57)	6	A
OSLIN 1997	21	23	18	15	3.2000	(0.75,11.23)	3	C
LANDABASO 1999	15	15	11	3	11.0000	(1.94,32.52)	12	C
ANTON 2001	68	63	38	28	1.5833	(0.80,3.12)	6	C
KRANZLER 2000	61	63	35	32	1.3041	(0.64,2.63)	3	C
MONTI 2001	64	64	32	34	0.8824	(0.44,1.76)	12	C
DUPONT-MERCK 393-103[2]	84	87	46	49	1.0652	(0.58,1.94)		
HERSH 1998	31	33	16	18	1.1250	(0.42,2.98)		
JURD 2000	TOTAL PATIENTS=105		NO OUTCOMES REPORTED					
MONTERESSO 2001	121	62	SUCCESS RATES NOT REPORTED					
BALLDIN 1998								
GALARZA 1997								
HEINALA 2001								

1 Outcomes – C = controlled drinking, A = abstinence
2 Data from Streeton & Whelan 2001

TREATED TOTAL 1176 CONTROL TOTAL 939
TREATED EVENTS 605 CONTROL EVENTS 398
OVERALL ODDS RATIO= 1.41 95% CONFIDENCE INTERVAL= (1.16, 1.69)
CHISQUARE FOR HETEROGENEITY= 40.5 DEGREES OF FREEDOM= 16

	N1	N2	X1	X2
O'MALLEY 1992/6 (S)	29	25	6	5
O'MALLEY 1992/6 (C)	23	27	12	4
VOLPICELLI 1997	48	49	31	23
KRYSTAL 2001	418	209	235	104
MORRIS 2001	55	56	19	7
VOLPICELLI 1992	35	35	27	16
LEE 2001	35	18	16	7
CHICK 2000	90	85	32	30
KNOX 1999	31	32	3	5
OSLIN 1997	21	23	18	15
LANDABASO 1999	15	15	11	3
ANTON 2001	68	63	38	28
KRANZLER 2000	61	63	35	32
MONTI 2001	64	64	32	34
DUPONT-MERCK 393-103*	84	87	46	49
HERSH 1998	31	33	16	18
			n=	16

Y	W	C1	C2	C3	C4	Wc*	C6
0.04256	2.173228	0.092492	0.08603	0.186962	4.7229	1.3581	0.057801
1.836211	2.138028	3.925871	2.25103	4.812766	4.5711	1.3442	2.46841
0.723376	5.779632	4.180848	0.150163	0.867885	33.404	2.2262	1.610419
0.259669	34.65124	8.997847	0.005806	0.201196	1200.7	3.2784	0.85131
1.30683	4.103832	5.363012	1.344074	5.515853	16.841	1.9236	2.513917
1.388246	3.607912	5.008668	0.746493	2.69328	13.017	1.8072	2.508882
0.280135	2.866169	0.802914	0.078476	0.224924	8.2149	1.5998	0.448172
0.011429	9.999347	0.114279	1.316736	13.1665	99.986	2.6583	0.030382
-0.54719	1.649935	-0.90283	0.29942	0.494024	2.7222	1.1334	-0.62023
1.163151	1.722488	2.003513	1.35292	2.330388	2.9669	1.1672	1.35768
2.397895	1.32	3.165222	5.749902	7.58987	1.7424	0.9673	2.319632
0.459532	8.068756	3.707854	0.21117	1.703879	65.104	2.4993	1.148548
0.265503	7.660427	2.033865	0.070492	0.539997	58.682	2.4587	0.652815
-0.12516	7.984344	-0.99935	0.015666	0.125081	63.749	2.4912	-0.31181
-0.06318	10.55087	-0.66659	0.003992	0.042115	111.32	2.6958	-0.17032
-0.11778	3.977901	-0.46853	0.013873	0.055185	15.823	1.8955	-0.22326

Totals	9.281218	108.2541	36.35909	Q=	40.5499	1703.5	31.505	14.64235	Random effects
	Mean=	6.765882	0.335868		SW2=	64.743	Y*=	0.464761	**1.59**
	ASE=	0.096112	0.147488		U=	92.517	LCB=	0.115568	1.12
			0.524248		D=	0.2761	UCB=	0.813954	2.26
	Fixed=		**1.41**	1.16	1.69				

META-ANALYSIS OF TRIALS OF ACAMPROSATE

Name of trial	NT	NC	XT	XC	Odds ratio	95% CI	Months of fu	Outcome[1]
LADEWIG 1993[3]	29	32	12	7	2.5210	(0.83, 7.18)	3-6	A
PAILLE 1995	361	177	67	20	1.7889	(1.05, 2.78)	12	A
ROUSSAUX 1996[3]	63	64	18	21	0.8190	(0.39, 1.74)	3	A
SASS 1996	136	136	58	29	2.7436	(1.60, 4.42)	11	A
WHITWORTH 1996	224	224	41	16	2.9126	(1.58, 5.37)	12	A
GEERLINGS 1997	128	134	14	7	2.2281	(0.89, 5.27)	12	A
PELC 1997	63	62	32	16	2.9677	(1.39, 5.85)	3	A
POLDRUGO 1997	122	124	53	37	1.8061	(1.07, 3.01)	12	A
NAMKOONG	72	70	27	25	1.0800	(0.55, 2.13)	2	C
TEMPESTA 2000	164	166	62	48	1.4943	(0.94, 2.35)	9	A
BESSON 1998	55	55	14	3	5.9187	(1.63,12.76)	12	A
GUAL 2001	141	147	49	38	1.5277	(0.92, 2.52)	6	A
CHICK 2000	289	292	19	23	0.8230	(0.44, 1.54)	6	C
LHUINTRE 1985[2]	42	43	26	14	3.366	(1.25, 9.07)	3	
BARRIAS 1997	150	152	59	39	1.879	(1.15, 3.07)	9-12	A
PELC 1992[2]	55	47	13	2	6.964	(1.48,32.71)	12	
LHUINTRE 1990	279	290	Not Reported				3	
MASON 2001	TOTAL N=601				N/A			

1 Outcomes – C = controlled drinking, A = abstinence
2 Data from Mason 2001
3 Data from AHCP report (West et al., 2000)

TREATED TOTAL 2094 CONTROL TOTAL 1925
TREATED EVENTS 564 CONTROL EVENTS 345
OVERALL ODDS RATIO= 1.82 95% CONFIDENCE INTERVAL= (1.55, 2.14)
CHISQUARE FOR HETEROGENEITY= 64.4 DEGREES OF FREEDOM= 15

The US multicentre trial (Mason) has not yet published results and the manufacturers report that it will not do so until 2003, however, it is known to be negative. Despite the size of this trial a negative result would not qualitatively change the results of the meta-analysis. Insertion of a trial with no treatment effect and size N=600 into this analysis would reduce the fixed effects OR ratio to 1.68 (1.45, 1.96)

	N1	N2	X1	X2	N1-X1	N2-X2	Log OR	W
LADEWIG 1993[T]	29	32	12	7	17	25	0.924659	3.07679
PAILLE 1995	361	177	67	20	294	157	0.581626	13.38757
ROUSSAUX 1996[T]	63	64	18	21	45	43	-0.19961	6.727092
SASS 1996	136	136	58	29	78	107	1.009267	13.53355
WHITWORTH 1996	224	224	41	16	183	208	1.069035	10.29205
GEERLINGS 1997	128	134	14	7	114	127	0.801136	4.330285
PELC 1997	63	62	32	16	31	46	1.087801	6.768318
POLDRUGO 1997	122	124	53	37	69	87	0.591176	13.9117
NAMKOONG	72	70	27	25	45	45	0.076961	8.231707
TEMPESTA 2000	164	166	62	48	102	118	0.401645	18.10254
BESSON 1998	55	55	14	3	41	52	1.778117	2.230237
GUAL 2001	141	147	49	38	92	109	0.423793	14.97727
CHICK 2000	289	292	19	23	270	269	-0.19477	9.658941
LHUINTRE 1985*	42	43	26	14	16	29	1.213746	4.833887
BARRIAS 1997	150	152	59	39	91	113	0.630504	16.01826
PELC 1992*	55	47	13	2	42	45	1.940795	1.605253

n= 16

Y	Weight	WeightxY	(Y-Ym)2	xWeight	Weight2	Wc*	Wc*xY
0.924659	3.07679	2.844982	0.106227	0.326837	9.46664	1.450983	1.341664
0.581626	13.38757	7.786563	0.000293	0.003918	179.227	2.278578	1.325281
-0.19961	6.727092	-1.34282	0.637359	4.287572	45.25377	1.949977	-0.38924
1.009267	13.53355	13.65897	0.168537	2.280904	183.157	2.282769	2.303924
1.069035	10.29205	11.00256	0.398897	4.105469	105.9262	2.167616	2.317258
0.801136	4.330285	3.469147	0.001691	0.007321	18.75137	1.680374	1.346208
1.087801	6.768318	7.362586	1.183312	8.009031	45.81013	1.953426	2.124939
0.591176	13.9117	8.224256	0.91696	12.75647	193.5353	2.293284	1.355733
0.076961	8.231707	0.633521	0.005923	0.048756	67.76101	2.059073	0.158468
0.401645	18.10254	7.270798	0.161319	2.920281	327.702	2.384274	0.957632
1.778117	2.230237	3.965621	3.161699	7.051337	4.973955	1.230683	2.188298
0.423793	14.97727	6.34727	0.179601	2.689931	224.3187	2.320499	0.983412
-0.19477	9.658941	-1.88123	0.037934	0.3664	93.29515	2.1381	-0.41643
1.213746	4.833887	5.867112	1.47318	7.121186	23.36646	1.75117	2.125476
0.630504	16.01826	10.09958	0.397535	6.367827	256.5847	2.344101	1.477966
1.940795	1.605253	3.115467	3.766685	6.046482	2.576837	1.013039	1.966101

Totals	12.13588	147.6854	88.42438	Q=	64.38973	1781.706	31.29795	21.16669	Random effects
Mean=	9.23034	0.598735		SW2=	27.90128	Y*=	0.676297	**1.9665**	
ASE=	0.082287	0.437452		U=	135.6213	LCB=	0.32595	1.3853	
		0.760017		D=	0.364174	UCB=	1.026643	2.7916	
Fixed=	**1.819814**	**1.548756**	**2.138313**						

META-ANALYSIS OF TRIALS OF DISULFIRAM

Name of trial	NT	NC	XT	XC	Odds ratio	95% CI	Months of fu	Outcome[1]
FULLER 1979	43	42	9	5	1.9588	(0.61, 5.98)	12	A
FULLER 1986	202	199	38	32	1.2092	(0.72, 2.02)	12	A

1 Outcomes – C = controlled drinking, A = abstinence

TREATED TOTAL 245 CONTROL TOTAL 241
TREATED EVENTS 47 CONTROL EVENTS 37
OVERALL ODDS RATIO= 1.31 95% CONFIDENCE INTERVAL= (0.81, 2.10)
CHISQUARE FOR HETEROGENEITY= 0.532 DEGREES OF FREEDOM= 1

	N1	N2	X1	X2	N1-X1	N2-X2	Log OR	W
FULLER 1979	43	42	9	5	34	37	0.672344	2.720719
FULLER 1986	202	199	38	32	164	167	0.189978	14.35722

n= 2

Y	W	C1	C2	C3	C4	Wc*	C6
0.672344	2.720719	1.829259	0.164446	0.447412	7.402312	3.769489	2.534394
0.189978	14.35722	2.727551	0.005905	0.084785	206.1297	-30.6649	-5.82564

Totals	0.862322	17.07794	4.55681	Q=	0.532197	213.532	-26.8954	-3.29125	Random effects
	Mean=	8.538969	0.266824		SW2=	67.70406	Y*=	0.122372	**1.13**
	ASE=	0.241982	-0.20746		U=	4.574552	LCB=	#NUM!	#NUM!
			0.741108		D=	-0.10226	UCB=	#NUM!	#NUM!
	Fixed=	**1.31**	0.81	2.10					

META-ANALYSIS OF TRIALS OF BEHAVIORAL SELF-CONTROL TRAINING

Name of trial	NT	NC	XT	XC	Odds ratio	95% CI	Months of fu	Outcome[1]
Sobell 1995(?)	35	35	5	2	2.7500	(0.54, 12.05)	12	C
Volger 1975	23	19	15	11	1.3636	(0.39, 4.66)	12	C
Caddy 1978	35	35	10	5	2.4000	(0.74, 7.17)	36	C
Pomerleau 1978	18	14	13	7	2.6000	(0.61, 10.37)	12	C
Foy 1984	30	32	8	7	1.2987	(0.41, 4.10)	12	C

1 Outcomes – C = controlled drinking, A = abstinence

TREATED TOTAL 141 CONTROL TOTAL 135
TREATED EVENTS 51 CONTROL EVENTS 32
OVERALL ODDS RATIO= 1.86 95% CONFIDENCE INTERVAL= (1.03, 3.36)
CHISQUARE FOR HETEROGENEITY= 0.96 DEGREES OF FREEDOM= 4

All trials other than Foy et al. (1984) used a control arm with a dissimilar and possibly ineffective treatment. Foy used the same Broad Spectrum Behavioral approach in both groups which differed only in the addition of blood alcohol discrimination, responsible drinking skills training and social drinking practice to thr BSCT treatment.

An additional study, Harris & Miller (1990), was carried out in problem drinkers rather than dependent drinkers. It is of interest, however, because of some suggestion that the BSCT method can be self administered for a few weeks when specialists are unavailable and may prove a useful interim measure.

	N1	N2	X1	X2	N1-X1	N2-X2	Log OR	W	
	35	35	5	2	30	33	1.011601	1.309524	
	23	19	15	11	8	8	0.310155	2.453532	
	35	35	10	5	25	30	0.875469	2.678571	
	18	14	13	7	5	7	0.955511	1.777344	
	30	32	8	7	22	25	0.261365	2.830362	
			n=	5					
	Y	W	C1	C2	C3	C4	Wc*	C6	
	1.011601	1.309524	1.324715	0.152068	0.199137	1.714853	2.418957	2.447019	
	0.310155	2.453532	0.760975	0.097024	0.238051	6.019817	17.43962	5.408983	
	0.875469	2.678571	2.345006	0.064428	0.172576	7.174745	43.29325	37.90189	
	0.955511	1.777344	1.698272	0.111469	0.198119	3.158951	4.708047	4.498592	
	0.261365	2.830362	0.739757	0.052608	0.1489	8.010949	325.0296	84.95128	
Totals	3.414101	11.04933	6.868725	Q=	0.956783	26.07932	392.8894	135.2078	Random
									effects
	Mean=	2.209867	0.621642		SW2=	0.415441	Y*=	0.344137	**1.41**
	ASE=	0.300838	0.032		U=	8.689071	LCB=	0.245254	1.28
			1.211283		D=	-0.35024	UCB=	0.44302	1.56
	Fixed=	**1.86**	1.03	3.36					

META-ANALYSIS OF TRIALS OF FAMILY/MARITAL THERAPY

Name of trial	NT	NC	XT	XC	Odds ratio	95% CI	Months of fu	Outcome[1]
Hunt 1973	8	8	7	1	49.0000	(2.50,**.**)		C
Hedburg 1974[2]	15	30	11	16	2.4063	(0.65, 7.89)	6	C
O'Farrel 1996	10	12	6	6	1.5000	(0.28, 7.63)	12	A
O'Farrel 1993	30	29	14	10	1.6625	(0.59, 4.60)	12	A
McCrady 1991	31	14	9	4	1.0227	(0.26, 4.05)	18	A
Zweben 1988	79	139	8	13	1.0921	(0.43, 2.78)	18	C
Bowers 1990	8	8	6	4	3.0000	(0.38,19.30)	12	C
McCrady 1982	26	7	16	4	1.2000	(0.22, 6.43)	6	C
Corder 1972[3]	20	20	11	3	6.9259	(1.54,20.03)	6	C
Cadogan 1973[2]	20	20	13	7	3.4490	(0.95,10.96)	6	C
Fichter 1993	49	51	14	16	0.8750	(0.37, 2.05)	18	A
Smith 1998	64	42	22	6	3.1429	(1.16, 6.70)	9	A

1 Outcomes – C = controlled drinking, A = abstinence
2 No clear statement about randomisation
3 Systematic allocation

TREATED TOTAL 360 CONTROL TOTAL 380
TREATED EVENTS 137 CONTROL EVENTS 90
OVERALL ODDS RATIO= 1.81 95% CONFIDENCE INTERVAL= (1.26, 2.61)
CHISQUARE FOR HETEROGENEITY= 25.9 DEGREES OF FREEDOM= 11

	N1	N2	X1	X2	N1-X1	N2-X2	Log OR	W	
	8	8	7	1	1	7	3.89182	0.4375	
	15	30	11	16	4	14	0.87807	2.105983	
	10	12	6	6	4	6	0.405465	1.333333	
	30	29	14	10	16	19	0.508322	3.489669	
	31	14	9	4	22	10	0.022473	1.974078	
	79	139	8	13	71	126	0.088094	4.4654	
	8	8	6	4	2	4	1.098612	0.857143	
	26	7	16	4	10	3	0.182322	1.340782	
	20	20	11	3	9	17	1.935272	1.683	
	20	20	13	7	7	13	1.238078	2.275	
	49	51	14	16	35	35	-0.13353	5.233645	
	64	42	22	6	42	36	1.145132	3.792066	
			n=	12					
	Y	W	C1	C2	C3	C4	Wc*	C6	
	3.89182	0.4375	1.702671	10.87816	4.759194	0.191406	0.349008	1.358275	
	0.87807	2.105983	1.849199	0.080914	0.170404	4.435164	0.948415	0.832774	
	0.405465	1.333333	0.54062	0.0354	0.047201	1.777778	0.752133	0.304964	
	0.508322	3.489669	1.773877	0.007275	0.025387	12.17779	1.154584	0.586901	
	0.022473	1.974078	0.044363	0.042891	0.08467	3.896983	0.92071	0.020691	
	0.088094	4.4654	0.393376	0.756138	3.376457	19.9398	1.24456	0.109639	
	1.098612	0.857143	0.941668	1.206949	1.034528	0.734694	0.572666	0.629138	
	0.182322	1.340782	0.244453	1.157223	1.551584	1.797697	0.754497	0.137561	
	1.935272	1.683	3.257062	3.745277	6.303301	2.832489	0.851985	1.648822	
	1.238078	2.275	2.816628	1.532838	3.487207	5.175625	0.981245	1.214858	
	-0.13353	5.233645	-0.69886	0.017831	0.093319	27.39104	1.297649	-0.17328	
	1.145132	3.792066	4.342417	1.311328	4.972642	14.37976	1.185872	1.35798	
Totals	11.26013	28.9876	17.20748	Q=	25.90589	94.73022	11.01332	8.028325	Random
									effects
	Mean=	2.415633	0.593615		SW2=	2.246074	Y*=	0.728965	**2.07**
	ASE=	0.185735	0.229575		U=	25.71964	LCB=	0.13836	1.15
			0.957656		D=	0.579553	UCB=	1.31957	3.74
	Fixed=	**1.81**	1.26	2.61					

META-ANALYSIS OF TRIALS OF RELAPSE PREVENTION

Name of trial	NT	NC	XT	XC	Odds ratio	95% CI	Months of fu	Outcome[1]
O'Farrell 1993	30	29	14	10	1.6625	(0.59, 4.60)	12	A
O'Malley 1992	54	50	19	17	1.0538	(0.47, 2.35)	12	C
Sandahl 1998	24	25	3	10	0.2143	(0.07, 0.88)	15	C
McCrady 1999	31	30	12	11	1.0909	(0.39, 3.04)	6	C
Allsop 1997	20	40	6	4	3.8571	(0.99,17.19)	12	C

1 Outcomes – C = controlled drinking, A = abstinence

TREATED TOTAL 159 CONTROL TOTAL 174
TREATED EVENTS 54 CONTROL EVENTS 52
OVERALL ODDS RATIO= 1.14 95% CONFIDENCE INTERVAL= (0.71, 1.84)
CHISQUARE FOR HETEROGENEITY= 7.37 DEGREES OF FREEDOM= 4

The effect found by Allsop & Saunders (1997) is larger than that in the other trials and marginally statistically significant. This may be because Allsop used No Treatment and Discussion Only control groups – interventions very likely to be ineffective. Other trials may have used effective controls. McCrady et al. (1999), for instance, added only four sessions of RP to 15 session of behavioral couples therapy. However, the absence of any effect suggests that no additional effect is attributable to the distinctive features of RP.

	N1	N2	X1	X2	N1-X1	N2-X2	Log OR	W	
	30	29	14	10	16	19	0.508322	3.489669	
	54	50	19	17	35	33	0.052385	5.870971	
	24	25	3	10	21	15	-1.54045	1.826087	
	31	30	12	11	19	19	0.087011	3.577746	
	20	40	6	4	14	36	1.349927	1.938462	
			n=	5					
	Y	W	C1	C2	C3	C4	Wc*	C6	
	0.508322	3.489669	1.773877	0.141991	0.495502	12.17779	1.812583	0.921377	
	0.052385	5.870971	0.307552	0.00626	0.036752	34.4683	2.296378	0.120296	
	-1.54045	1.826087	-2.81299	2.795419	5.104677	3.334594	1.230379	-1.89533	
	0.087011	3.577746	0.311305	0.189298	0.677262	12.80027	1.83606	0.159758	
	1.349927	1.938462	2.616781	0.545889	1.058184	3.757633	1.28039	1.728433	
Totals	0.457201	16.70293	2.196528	Q=	7.372377	66.53859	8.45579	1.034533	Random
									effects
	Mean=	3.340587	0.131506		SW2=	2.685245	Y*=	0.122346	**1.13**
	ASE=	0.244683	-0.34807		U=	12.71929	LCB=	-0.55168	0.58
			0.611084		D=	0.265139	UCB=	0.796376	2.22
	Fixed=	**1.14**	0.71	1.84					

META-ANALYSIS OF TRIALS OF MOTIVATIONAL ENHANCEMENT

Name of trial	NT	NC	XT	XC	Odds ratio	95% CI	Months of fu	Outcome[1]
Bien	16	16	9	5	2.8286	(0.68,10.58)	6	
Handmaker	20	22	7	6	1.4359	(0.39, 5.19)		
Sellman	42	80	24	29	2.3448	(1.10, 4.92)	6	

1 Outcomes – C = controlled drinking, A = abstinence

TREATED TOTAL 78 CONTROL TOTAL 118
TREATED EVENTS 40 CONTROL EVENTS 40
OVERALL ODDS RATIO= 2.18 95% CONFIDENCE INTERVAL= (1.20, 3.98)
CHISQUARE FOR HETEROGENEITY= 0.55 DEGREES OF FREEDOM= 2

	N1	N2	X1	X2	N1-X1	N2-X2	Log OR	W	
	16	16	9	5	7	11	1.039772	1.835275	
	20	22	7	6	13	16	0.36179	2.227435	
	42	80	24	29	18	51	0.852212	6.608825	
			n=	3					
	Y	W	C1	C2	C3	C4	Wc*	C6	
	1.039772	1.835275	1.908268	0.066393	0.121849	3.368236	3.396441	3.531523	
	0.36179	2.227435	0.805864	0.176664	0.393507	4.961467	5.0379	1.822662	
	0.852212	6.608825	5.632119	0.004915	0.032483	43.67657	-10.0869	-8.59616	
Totals	2.253774	10.67154	8.346251	Q=	0.547839	52.00627	-1.65254	-3.24197	Random
									effects
	Mean=	3.557179	0.782104		SW2=	7.022858	Y*=	1.961813	**7.11**
	ASE=	0.306116	0.182116		U=	5.798172	LCB=	#NUM!	#NUM!
			1.382092		D=	-0.25045	UCB=	#NUM!	#NUM!
	Fixed=	**2.18**	1.20	3.98					

META-ANALYSIS OF TRIALS OF COPING SKILLS TRAINING

Name of trial	NT	NC	XT	XC	Odds ratio	95% CI	Months of fu	Outcome[1]
Monti 2001[2]	77	88	48	32	2.8966	(1.53,5.17)	12	C
Burtscheidt 2001	40	40	21	15	1.8421	(0.76,4.37)	6	C
Monti 1993	22	18	11	7	1.5714	(0.45,5.33)	6	C

1 Outcomes – C = controlled drinking, A = abstinence
2 Systematic allocation

TREATED TOTAL 139 CONTROL TOTAL 146
TREATED EVENTS 80 CONTROL EVENTS 54
OVERALL ODDS RATIO= 2.33 95% CONFIDENCE INTERVAL= (1.44, 3.76)
CHISQUARE FOR HETEROGENEITY=   1.09 DEGREES OF FREEDOM= 2

	N1	N2	X1	X2	N1-X1	N2-X2	Log OR	W
Monti 2001*	77	88	48	32	29	56	1.063521	9.576413
Burtscheidt 2001	40	40	21	15	19	25	0.610909	4.832849
Monti 1993	22	18	11	7	11	11	0.451985	2.40625

			n=	3					
	Y	W	C1	C2	C3	C4	Wc*	C6	
	1.063521	9.576413	10.18472	0.047346	0.453406	91.70768	97.05058	103.2153	
	0.610909	4.832849	2.952431	0.055235	0.26694	23.35643	8.865408	5.415958	
	0.451985	2.40625	1.087589	0.155192	0.373431	5.790039	3.110758	1.406016	
Totals	2.126415	16.81551	14.22474	Q=	1.093777	120.8541	109.0267	110.0373	Random
									effects
	Mean=	5.605171	0.845929		SW2=	13.30017	Y*=	1.009269	**2.74**
	ASE=	0.243862	0.367959		U=	9.628448	LCB=	0.821558	2.27
			1.3239		D=	-0.09412	UCB=	1.19698	3.31
	Fixed=	**2.33**	1.44	3.76					

Appendix 22 Protocol for patient preference study

Project title
A study of the relapse prevention treatment preferences of individuals[1] who have experienced alcohol dependence.

Names and contact details of investigator
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Brief summary of project
The project aims to describe the experiences and preferences of individuals for pharmaceutical or psychosocial interventions, or a combination of both, for the treatment for alcohol dependence. A qualitative approach will be adopted whereby data will be collected using in-depth, one-to-one interviews with a purposive sample of people who have relevant personal experience. The focus of the study will be to explore patients' treatment preferences and also to elicit factors which prevent relapse to drinking.

1. Background to project

The International Classification of Diseases (ICD), describes alcohol dependence syndrome as a cluster of symptoms which include a subjective compulsion to drink, physiological dependence (tolerance and withdrawal) and rapid reinstatement of symptoms after a period of abstinence. There may be a loss of control over drinking, an increased urgency to drink, and increased priority of alcohol over the person's previous interests and activities. The individual persists with drinking despite evidence of its harmful effects (ICD-10, WHO 1992).

The goals of treatment are to reduce alcohol-related harm. This may be achieved at differing levels, and by a variety of means (Heather 2001). Such goals may range from achievement of controlled drinking at a negotiated level to the achievement and indefinite maintenance of total abstinence. Decisions concerning goals may depend on therapists' philosophies, and patients' preferences are likely to impinge on the treatment approach adopted.

Relapse prevention aims to reduce the impact of cues which precipitate relapse to alcohol (Brown 2001). Because the goals of treatment are so variable, the concept of relapse can be interpreted in a

[1] This term is used to denote a person who has experienced treatment for alcohol dependence syndrome. It encompasses the terms 'patient' and 'client'. Where either of these latter terms is used, the intention is to refer to such an individual.

range of ways. For the purposes of the Health Technology Board for Scotland's (HTBS) Health Technology Assessment (HTA) of alcohol dependence relapse prevention strategies, the following definition was agreed: *"Failure to achieve a pre-determined goal (e.g. complete abstinence, < 5 drinks on one occasion, total number of drinks over a certain time period, or cumulative number of days of complete abstinence)"* see Minutes of Topic Specific Group meeting, 31 May 2001).

People's preferences are closely bound to motivation and, in terms of treatment for an alcohol problem, with adherence with treatment (Donovan 1998). Given that more than two-thirds of clients of alcohol treatment programmes may relapse within six months of treatment (Marlatt and Gordon 1985), it is important to consider the preferences of such clients in order to find ways of improving patient outcomes through corresponding improvements in compliance rates.

In order to develop services, which meet the needs of local populations it is crucial that the views of users are sought (WHO 1996, Coulter 1999). As highlighted in the Plan for Action for the NHS (Scottish Executive 2000), this is particularly true for individuals and groups who are marginalised and whose voices may not be heard for a range of reasons. Those who misuse alcohol constitute just such a group.

A literature search has revealed some case study work on potential causes of relapse but no comparable wide-ranging study exists which attempts to identify and explore patient attitudes to relapse. It is therefore timely that such a study be conducted. This study aims to explore and describe the relapse prevention treatment options from the perspective of individuals who have themselves experienced alcohol dependence.

2. Aim

The project aims to describe the experiences and preferences of individuals with regards pharmaceutical and/or psychosocial interventions for the treatment for alcohol dependence. Furthermore, the study will attempt to elicit factors that prevent relapse to drinking.

3. Methods

A phenomenological approach is the methodology of choice as this can facilitate an understanding of the social world from the standpoint of the of individuals (Wilkes 1991). As a qualitative research method it provides a rigorous, critical and systematic means of investigating complex phenomena which are enmeshed in the life experience of people (Streubert and Carpenter 1995).

Sample

The sample will comprise individuals who have used the alcohol treatment services of three geographically distinct areas in Scotland within the past year. Individuals who have experienced treatment for alcohol dependence from one of three NHS Primary Care Trust, two of which provide services within rural and semi-urban areas, and one whose catchment area is urban, will be invited to participate in the study.

The sample will be recruited in two ways. Firstly, posters will be displayed in prominent positions within treatment facilities and information about the study was made available to anyone who expressed interest in participating. In addition, the nurse managers will write to a random sample of patients who have attended for treatment during the past year, seeking volunteers for the study and suggesting that those interested should contact the researcher. In this way the anonymity of

patients will be protected until they agree to volunteer. Moreover, since the study involves an element of service evaluation, the random process of sample recruitment via the nurse managers will ensure that bias in the selection is minimised.

There will be no exclusions with regard to gender, age, social class or employment status.

In keeping with the tenets of qualitative research, data collection will continue until saturation is reached, (i.e. until no new themes emerge). It is therefore not possible to determine the exact sample size necessary to achieve this at the outset of the study (Polit and Hungler 1997). However, it is anticipated that it will be necessary to undertake approximately forty interviews.

Procedures

One-to-one in-depth interviews will be conducted during which the participants will be asked to recount their experiences of treatment and their preferences of pharmacological and psychosocial interventions (e.g. disulfiram, acamprosate, motivational enhancement therapy, cognitive-behavioural therapy, supportive psychotherapy, group work, counselling, the 12-steps approach). They will be invited to discuss the factors which they perceived as contributing to the experience being either positive or negative, and to reflect on the reasons for their preferences. An interview guide will be used to ensure that all relevant topics are addressed (Appendix 1). Prompts will be used for clarification if necessary, and to encourage further disclosure. Interviews will be conducted at the location of the participants' choice and, with permission, audio-tape recorded. It is anticipated that each interview will last for approximately 1 hour.

Analysis

All tape-recorded interviews will be transcribed verbatim. Burnard's framework for thematic analysis of qualitative data will be used to search for themes and patterns in the data (Burnard 1991). As a means of ensuring rigour in the process, a sample of the transcriptions will be independently analysed by a colleague of the researcher with experience of phenomenology. Points of divergence will be discussed and agreement reached for the final analysis. The participants will be invited to comment on a summary of the findings as part of the validation process for qualitative research (Sandalowski 1993, Whittemore et al 2001).

Plans for ethical approval and access negotiation

Approval of each of the Local Research Ethics Committees of the participating Trusts has been granted. Verbal permission for access has been agreed from the consultant psychiatrists with responsibility for all participating patients.

Full informed consent will be sought in writing from all individuals who are invited to participate. Permission to tape-record the interviews will be sought, and participants will be assured that they may request that recordings cease at any point. All participants will be informed that they can withdraw without penalty at any stage in the project. Those who agree to participate will be guaranteed confidentiality. However, since their identity will need to be known if they are to be contacted to provide verification of the findings full anonymity cannot be assured. If they do not wish to be contacted again their full anonymity can and indeed will be afforded.

The conditions of the Data Protection Act (1998) will be observed.

Existing facilities
The study will be based in the Caledonian Nursing and Midwifery Research Centre. This is located within the Department of Nursing and Community Health and has all the advantages of the modern facilities of the new Faculty of Health building. The researcher has access to a wide range of support systems, such as library and computing advice. Equipment for tape-recording and transcribing the interviews are available, as are computing hardware and the necessary software.

Justification of requirements
Given the sensitivity of the interviews it is important that the data are collected by an individual who has experience both of the research methods and of working with people with problems of alcohol dependence. Since the participants' views of their treatment are being explored, it is preferable that the researcher is not be regarded by the participants as being part of the NHS culture. It is therefore proposed that the data be collected by a member of the academic fraternity whose Curriculum Vitae is appended (Appendix 2). A secretary will be employed on a part-time basis to transcribe the tape-recorded interviews.

4. **Dissemination plans**

The following strategies will be adopted to disseminate the study findings:

1. Copies of the research report will be sent to the Health Technology Board for Scotland from which it will be available to all interested parties.
2. The report will be lodged in the libraries of the participating voluntary organisations and NHS Trusts, and Glasgow Caledonian University.
3. Results will be presented at relevant medical, social science and nursing conferences.
4. Manuscripts will be submitted for publication in appropriate specialist and generic professional journals, such as Addiction, Addiction Research, the Health Bulletin.

5. Research expertise / practice experience

The applicant has research experience in the management of problem drinkers and has investigated aspects of the nurse's role in relation to working with problem drinkers in acute care settings, having undertaken a PhD and published widely in this area.

Key references

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ADDENDUM

A study of the relapse prevention treatment preferences of individuals who have experienced alcohol dependence.

Interview guide

1. Introduction, reiteration of the purpose of the study, and explanation of the processes for data collection, including the use of the tape recorder.

2. Discuss drinking history and treatment history.

3. Explore the form(s) of treatment the patient has experienced, and his/her views of its effectiveness and acceptability. (using layman's terms, cover disulfirum, acamprosate, psychosocial interventions including individual, group and 12-step).

4. If relevant, depending on the answer to item 3, explore patient's preferences for treatments, and reasons for answers.

5. Explore whether some treatments may be more appropriate at different times in one's life/drinking history, and what these might be.

6. If appropriate, ask how important it is that the person's wife/husband/partner is involved in the treatment to help him/her to continue.

7. Ascertain whether the person has relapsed. If so, explore the circumstances; duration of period of abstinence/controlled drinking; the extent of the relapse, and the pattern of relapses.

8. Ask what might have prevented the relapse(s).

9. What aspects of the service does the person perceive to be good, and what is felt to be less good/bad (if not already discussed).

10. To what extent was the person involved in decision-making about the choice of treatment? Does s/he see this as this relevant to relapse prevention?

11. If the patient has defaulted from an appointment, what action did s/he take?

12. How proactive should the service provider be in trying to re-establish contact?

Ask if the patient feels I should know anything else; thank the patient for his/her time; end recording.

Appendix 23 Databases searched for cost effectiveness studies

Databases searched for cost effectiveness studies

Cost Effectiveness Literature Search – sources
The following sources were searched during February 2002 to update the search undertaken by CRD, York during 2000:

- Medline (Ovid)
- Premedline (Ovid)
- Embase (Ovid)
- DARE
  Cochrane Library (CD-ROM, 2001 Issue 4)
- NHS EED
  Cochrane Library (CD-ROM, 2001 Issue 4)
- HTA
  Cochrane Library (CD-ROM, 2001 Issue 4)
- Ongoing Reviews
  http://www.update-software.com/National/
- National Research Register
  http://www.update-software.com/National/
- HEED (CD-ROM, Feb, 2002)
- Econlit (OCLC)
- Social Science Citation Index (Web of Science)
- Science Citation Index (Web of Science)
- Cinahl (Ovid)
- British Nursing Index (SilverPlatter)
- Psychinfo (Ovid)
- AMED (Allied and Complementary Medicine Database) (Ovid)
- PAIS (Public Affairs Information Service) (CSA)
- HMIC (SilverPlatter)
- SIGLE (SilverPlatter)
- ASSIA Plus (Applied Social Sciences Index and Abstracts) (CSA)
- EconBase
  http://www.elsevier.nl/homepage/sae/econworld/menu.htm
- HDA Evidencebase
  http://213.121.184.60/hda/docs/evidence/eb2000/corehtml/intro.htm

In addition, the following web-sites were searched:

- EtOH
  http://etoh.niaaa.nih.gov/
- Health Economics Research Unit, Aberdeen
  www.abdn.ac.uk/heru
- Centre for Health Economics, York
  www.york.ac.uk/inst/che/
- Health Economics Research Centre, Oxford
  www.ihs.ox.ac.uk/herc/

- Health Economics Research Group, Brunel
  http://http1.brunel.ac.uk:8080/departments/herg/home.html
- Health Economics Group (HEG), Newcastle
  www.ncl.ac.uk/deph/hegroup.html
- SCHARR School of Health and Related Research, Sheffield
  www.shef.ac.uk/uni/academic/R-Z/scharr/
- Health Economics Group, East Anglia
  www.uea.ac.uk/menu/acad_depts/hsw/hpp/hegwelc.htm
- Institute of Health Economics IHE, Alberta, Canada
  www.ihe.ab.ca
- LSE London School of Economics and Political Science
  www.lse.ac.uk/
- Southampton University Economics Department
  www.soton.ac.uk/~econweb/
- Centre for Health Economics Research and Development CHERE, University of Sydney and Central Sydney Area Health Service
  www.chere.usyd.edu.au
- Institute of Health Economics (IHE), Alberta, Canada
  www.ihe.ab.ca/
- International Health Economics Association iHEA
  www.healtheconomics.org/cgi-bin/WebObjects/ihea
- Centre for Health Economics and Policy Analysis (CHEPA), McMaster University
  www.chepa.org/
- Centre for Health Program Evaluation (CHPE), University of Melbourne and Monash University, Australia
  chpe.buseco.monash.edu.au/
- NetEc
  http://netec.mcc.ac.uk/NetEc.html
- IDEAS Internet Documents in Economics Access Service
  http://ideas.uqam.ca/

Appendix 24 Search strategy for cost effectiveness studies

Search Strategy for cost effectiveness studies in Medline

Database: Medline
Coverage: <January 2000-January 2002 Week 3>
Host: Ovid
Date Searched: 11/02/02

1. alcoholism/
2. alcohol drinking/
3. alcoholic?.tw.
4. alcoholism.tw.
5. (harmful$ adj1 drinking).tw.
6. dipsomania$.tw.
7. (alcohol adj2 (dependen$ or addict$ or abus$ or misus$)).tw.
8. or/1-7
9. intervention studies/
10. intervention$.tw.
11. (relaps$ adj1 prevent$).tw.
12. or/9-11
13. alcohol deterrents/
14. behavior addictive/dt
15. (alcohol adj2 deter$).tw.
16. (alcohol adj1 sensiti$).tw.
17. (alcohol adj2 aversi$).tw.
18. (alcohol adj2 anti?craving).tw.
19. (pharmacolog$ adj1 (intervention$ or treatment$)).tw.
20. taurine/
21. disulfiram/
22. naltrexone/
23. acamprosate.tw.
24. campral.tw.
25. disulfiram.tw.
26. antabuse.tw.
27. naltrexone.tw.
28. trexan.tw.
29. or/13-28
30. psychotherapy/
31. exp behavior therapy/
32. exp psychoanalytic therapy/
33. exp socioenvironmental therapy/
34. exp self concept/
35. psychotherapy brief/
36. alcoholics anonymous/
37. social support/

38. behavior addictive/px
39. psychotherap$.tw.
40. (psychosocial adj2 (care or therap$ or intervention$ or technique$ or treatment$)).tw.
41. (behavio?r$ adj2 (therap$ or treatment$ or modification or contracting)).tw.
42. (assertive$ adj2 (skill$ or training or technique$)).tw.
43. (aversi$ adj2 (therap$ or treatment$)).tw.
44. (cognitive adj2 (therap$ or treatment$)).tw.
45. cbt.tw.
46. (relaxation adj2 (skill$ or training or technique$)).tw.
47. sociotherapy.tw.
48. psychoanaly$.tw.
49. (socioenvironmental adj2 (therap$ or treatment$)).tw.
50. therapeutic community.tw.
51. ((group or marital or couple$ or famil$) adj2 (therap$ or intervention$ or technique$ or treatment$)).tw.
52. (community adj2 reinforc$).tw.
53. (motivational adj (interview$ or enhancement)).tw.
54. supportive expressive therap$.tw.
55. counsel?ing.tw.
56. counsel?or?.tw.
57. (cue$ adj1 (therap$ or exposure)).tw.
58. covert sensitization.tw.
59. (self adj1 concept).tw.
60. (self adj (efficacy or esteem or control or care)).tw.
61. (social$ adj1 support).tw.
62. ((coping or life) adj1 skills).tw.
63. social skill$.tw.
64. ((stress or anger) adj2 manag$).tw.
65. supportive treatment$.tw.
66. ((brief or short or minimal) adj2 intervention$).tw.
67. coping behavio?r.tw.
68. stepped care.tw.
69. alcoholics anonymous.tw.
70. aa.tw.
71. twelve step.tw.
72. "12 step".tw.
73. or/30-72
74. temperance/
75. temperance.tw.
76. sobriety.tw.
77. (alcohol adj2 (consum$ or intake) adj2 (reduc$ or control$ or moderat$ or attenuat$ or restrict$ or restrain$)).tw.
78. (abstinence or abstain$).tw.
79. ((control$ or moderat$ or attenuat$ or reduc$ or restrain$ or restrict$) adj2 drinking).tw.
80. (self adj (change or help)).tw.
81. maturing out.tw.
82. or/74-81
83. exp economics/
84. exp "quality of life"/

85. (economic$ or cost$).tw.
86. "quality of life".tw.
87. qol$.tw.
88. quality adjusted life year$.tw.
89. qaly$.tw.
90. or/83-89
91. 200$.em.
92. 8 and 12 and 90 and 91
93. 8 and 29 and 90 and 91
94. 8 and 73 and 90 and 91
95. 8 and 82 and 90 and 91
96. or/92-95

This search strategy was reviewed by Gill Ritchie, Information Officer, at CRD, University of York. Suggested changes will be incorporated when the strategy is updated during the Consultation period.

Appendix 25 Economic data extraction

Study Paper	Economic Evaluation of Campral (Acamprosate) Compared to Placebo in Maintaining Abstinence in Alcohol-Dependent Patients
Study Authors	Annemans L., Vanoverbeke N., Tecco J., D'Hooghe D.
Study Perspective	Health care payers in Belgium
Clinical Data Sources	Survey of 129 GPs informed frequency of somatic, psychic and other problems related to alcohol use
Diagnostic Technology	Acamprosate is an anti-craving neuromodulator
Study Population	RCT (n = 448) for relapse rates; RCT (n=582) unpublished trial for type of relapse in second line management and Belgian registry data
Data Sources for Resource Use	Resource savings from sample of GP records. Success of detox from RCT (N = 164). Resource costs and resource use, from official statistics from Ministry of Health
Outcome Measures	Net cost savings per incremental abstinent patient
Method of Analysis	Monte Carlo Markov model
Discounting	No discounting applied; study period 2 years
Assumptions	• % of patients remaining abstinent after 2 years 11.9% for acamprosate and 4.9% for placebo • saving from institutional and ambulatory detoxification, acute and long term hospitalisation and liver complications.
Results	Average net saving per patient over the two year period of 21,301 BEF (528 Euro)
Comments	High lost to follow up and unclear of treatment of this group. • Rate of abstinence under acamprosate has greatest impact on net savings • The model assumes that the abstinence rate after 48 weeks is continued, with no further relapses.

Study Paper	The Cost Effectiveness of Acamprosate in the Treatment of Alcoholism in Germany
Study Authors	Schadlich PK., Brecht JG
Study Perspective	The German healthcare system
Clinical Data Sources	Retrospective analysis of clinical data on the effects of acute alcohol dependency on the incidence of • alcoholic psychosis • alcoholic dependency syndrome • fatty liver • hepatitis and • cirrhosis
Drug Technology	Acamprosate was registered in Germany in 1996 and is an anti-craving neuromodulator
Study Population	Abstinent clients in 12 German psychiatric outpatient clinics
Data Sources for Resource Use	Effectiveness data from a RCT: health resources savings from retrospective German registry data; health savings per resource from insurance and administration sources and expert knowledge
Outcome Measures	Net cost savings per incremental abstinent patient from treatment avoided
Method of Analysis	Decision tree analysis using Monte Carlo simulation
Discounting	5% discount rate
Assumptions	Key assumptions are: • 39.9% of acamprosate treated clients remain abstinent after 48 weeks in comparison to 17.3% of the placebo; and • health care savings from avoiding alcoholic psychosis, alcohol depending syndrome, fatty liver, hepatitis and liver cirrhosis
Results	Net savings in direct medical costs of DEM2600 per additional abstinent alcoholic
Comments	• The rate of abstinence under acamprosate has the greatest impact on the net savings. • The model assumes that the abstinence rate after 48 weeks is continued, with no further relapses.

Study Paper	The Long-Term Cost-Effectiveness of Improving Alcohol Abstinence with Adjuvant Acamprosate
Study Authors	Palmer AJ., Neeser K., Weiss C., Brandt A., Comte S., Fox M
Study Perspective	German health insurance perspective
Clinical Data Sources	Probabilities for clinical events were retrieved from published literature
Drug Technology	Acamprosate was registered in Germany in 1996 and is an anti-craving neuromodulator except registered in Gemany 1996
Study Population	A typical male cohort aged 41, 80% with fatty liver, 15% with cirrhosis, 22% with pancreatitis and 1% with alcoholic cardiomyopathy
Data Sources for Resource Use	• disease incidences and transitional probabilities from literature • disease costs from literature and an expert German health economics company
Outcome Measures	Incremental savings in mean total lifetime costs with acamprosate compared to standard therapy
Method of Analysis	Meta-analysis to inform a series of Markov sub-models
Discounting	5% per annum
Assumptions	• key assumption is description of disease in cohort (see above) • acamprosate assumed to prevent relapse in 40% of the cohort in comparison to 20% for the placebo
Results	Mean expected total lifetime discounted savings per patient of 1662 DEM
Comments	All assumptions are from meta-analysis and no validation of the model and its assumptions

Appendix 26 Sensitivity analysis on economic model

This appendix contains the full results of the pair-wise sensitivity analysis referred to in Chapter 7.

Table A26-1 Acamprosate

	Low estimate	High estimate
Average treatment cost, average disease cost, varying intervention effectiveness	£2,080	-£1,091
Average treatment cost, average intervention effectiveness, varying disease cost	£549	-£434
Average intervention effectiveness, average disease cost, varying treatment cost	-£981	£951

Table A26-2 Naltrexone

	Low estimate	High estimate
Average treatment cost, average disease cost, varying intervention effectiveness	£12,014	£366
Average treatment cost, average intervention effectiveness, varying disease cost	£3,765	£2,782
Average intervention effectiveness, average disease cost, varying treatment cost	£2,938	£4,438

Table A26-3 Disulfiram

	Low estimate	High estimate
Average treatment cost, average disease cost, varying intervention effectiveness	Standard treatment dominates	-£2,469
Average treatment cost, average intervention effectiveness, varying disease cost	£2,191	£1,208
Average intervention effectiveness, average disease cost, varying treatment cost	£1,271	£3,308

Table A26-4 Coping Skills

	Low estimate	High estimate
Average treatment cost, average disease cost, varying intervention effectiveness	-£1,229	-£3,723
Average treatment cost, average intervention effectiveness, varying disease cost	-£2,684	-£3,666
Average intervention effectiveness, average disease cost, varying treatment cost	-£3,742	-£2,649

Table A26-5 Relapse prevention

	Low estimate	High estimate
Average treatment cost, average disease cost, varying intervention effectiveness	Standard treatment dominates	-£2479
Average treatment cost, average intervention effectiveness, varying disease cost	£9,839	£8,856
Average intervention effectiveness, average disease cost, varying treatment cost	£3,771	£14,883

Table A26-6 Behavioural self control training

	Low estimate	High estimate
Average treatment cost, average disease cost, varying intervention effectiveness	£26,688	-£3,636
Average treatment cost, average intervention effectiveness, varying disease cost	-£2,127	-£3,109
Average intervention effectiveness, average disease cost, varying treatment cost	-£3408	-£1870

Table A26-7 Motivational interviewing

	Low estimate	High estimate
Average treatment cost, average disease cost, varying intervention effectiveness	£2,383	-£3,766
Average treatment cost, average intervention effectiveness, varying disease cost	-£2,570	-£3,553
Average intervention effectiveness, average disease cost, varying treatment cost	-£3,674	-£2,491

Table A26-8 Marital and Family Therapy

	Low estimate	High estimate
Average treatment cost, average disease cost, varying intervention effectiveness	-£176	-£3,415
Average treatment cost, average intervention effectiveness, varying disease cost	-£2,184	-£3,167
Average intervention effectiveness, average disease cost, varying treatment cost	-£3,442	-£1,950

GLOSSARY AND ABBREVIATIONS

A&E	Accident and Emergency
AA	Alcoholics Anonymous
ABCT	Alcohol Behavioural Couples Therapy
Acamprosate	A drug that in combination with counselling may be helpful in maintaining abstinence in alcohol dependent patients.
Accreditation	A process, based on a system of external peer review using written standards, designed to ensure the quality of an individual, activity, service or organisation.
ADU	Alcohol Day Unit
AFS	Alcohol Focus Scotland
Alcohol Development Officers	Government-appointed personnel who co-ordinate action programmes to tackle alcohol misuse at a local level in Scotland.
Alcohol Support Groups	Self help groups offering support and advice to people with alcohol problems and their families.
Anger Management	Relapse prevention technique which offers training and support for learning to recognise and manage angry emotions.
Antabuse	Manufacturers' name for disulfiram.
APTU	Alcohol Problems Treatment Unit
Arrhythmias	A condition in which the heart beats with an irregular or abnormal rhythm.
Assertiveness Training	A relapse prevention technique which teaches the individual to express thoughts and emotions in a direct, honest, and appropriate way.
AUDIT	Alcohol Use Disorders Identification Test
Audit	The process of setting or adopting standards and measuring performance against those standards with the aim of identifying both good and bad practice and implementing changes to achieve unmet standards.
Aversion Therapy	A behavioural therapy based on the principle of counter-conditioning. This involves pairing incompatible or aversive consequences with specific stimuli with the use of alcohol or drugs.
BEF	Belgian Francs

Behaviour Contracting	A procedure involving the client signing a contract that he/she will attend a specified number of continuing care meetings; this is combined with active follow-up if the client fails to meet the conditions of the contract.
Behaviour Therapy	A branch of psychotherapy narrowly conceived of as the application of classical and operant conditioning to the amelioration of clinical problems. It is more broadly conceived of as applied experimental psychology.
BENELUX	Belgium, The Netherlands and Luxembourg
BI	Brief Intervention
	This is a time-limited intervention focusing on changing an individual's behaviour with respect to alcohol consumption. The precise content of brief interventions vary. They are mainly used to reduce alcohol consumption in people drinking above recommended levels but who are not dependent.
Blinding	Concealment of intervention in a controlled trial to ensure the absence of subjective bias in evaluation of intervention effects.
BNF	British National Formulary
BSCT	Behavioural Self Control Training
	Aims at controlled drinking rather than abstinence. This is achieved by teaching clients to drink more slowly and increase intervals between drinks and choose less alcoholic drinks. They are also taught to recognise high-risk situations and to set personal goals.
CAART	Common Addictions Assessment Tool
CAD	Cumulative Abstinence Duration/Days
Campral	Trade name for acamprosate.
Capital costs	The cost of investment in items which remain useful beyond the period when costs are incurred.
Carer	A person, paid or unpaid, who regularly helps another person, often a relative or friend with all forms of care as a result of illness or disability. This term incorporates spouses, partners, parents, guardians, paid carers, other relatives, and voluntary carers who are not health professionals.
CAT	Community Addiction Team

	Treatment and rehabilitation – referrals are usually through the family doctor but referrals will be accepted from users and their families.
CBT	Cognitive Behavioural Therapy This involves the use of behavioural techniques to modify maladaptive cognitions. There are a range of behavioural, activity-oriented interventions or homework exercises that are used e.g. graded task assignments activity scheduling, behavioural experiments.
CENAPS	A biopsychosocial approach to recovery and relapse prevention.
CET	Coping Skills Training This treatment approach involves teaching clients coping skills for successful living and relationships, such as communication and assertion skills.
Chronic	Present over a long period of time.
CI	Confidence Interval.
Clinical Effectiveness	The evaluation of benefit: risk in a standard clinical setting using outcomes of importance to the patient.
Clinical Governance	A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. *Source: DEPARTMENT OF HEALTH – NHS WHITE PAPER: A FIRST-CLASS SERVICE (1998).*
Clinical Trial	Research study conducted with patients, usually to evaluate a new treatment or drug. Each trial is designed to answer scientific questions and to find better ways to treat individuals with a specific disease.
CM	Case Management
COA	Councils on Alcohol
Committee on Safety of Medicines (CSM)	An independent advisory committee established under the Medicines Act (Section 4). The CSM advises the UK Licensing Authority (Government Health Ministers) on the quality, efficacy and safety of medicines.
Co-morbidity	The presence of co-existing or additional diseases with reference to either an initial diagnosis or the index

	conditions that is the subject of study. Co-morbidity may affect the ability of affected individuals to function and also their survival; it may be used as a prognostic indicator for length of hospital stay, cost factors, and outcome or survival.
Complementary Therapy	Treatments such as acupuncture and hypnosis.
Contraindication	Any factors related to the patient's condition, medical history or other current treatments which generally or absolutely preclude the use of the treatment in question.
Control	Standard of comparison in a clinical trial or an experiment.
Corroborative	Supported with evidence or authority.
Cost effectiveness	Cost effectiveness is used in its broadest form to encompass all forms of economic analysis.
Cost effectiveness analysis	A form of economic analysis which compares two interventions in terms of both their costs and their effect upon patients, to ascertain whether the additional cost of the more expensive intervention gives rise to sufficient additional patient benefits to warrant the additional cost.
Cost effectiveness ratio	The additional cost of the more expensive intervention as compared with the less expensive intervention divided by the difference in effect or patient outcome between the interventions. This gives a cost per effect, such as the additional cost per true positive from a screening test, or a cost per patient outcomes, such as the cost per QALY.
Counselling	The task of counselling is to draw out the client and enable him or her to reach a greater level of understanding, or a greater commitment to take action. The process involves enabling clients to realise that alternatives exist, and helping them to clarify what some of those choices may be.
Couples/Marital/Family Therapy	Behavioural, marital or family therapy emphasises the teaching of skills to improve communications and behavioural change negotiation. Other marital and family therapy approaches draw on systems theory in both formulating the hypotheses about distress and planning interventions. Systemic therapists invariably construct a map defining the organisation, roles and rules of the family and the couples that they treat.
CPN	Community Psychiatric Nurse

CPU	
CRA	Community Reinforcement Approach In this approach, partners, family and friends are viewed as crucial collaborators in the treatment process. Their roles have included supervising disulfiram, being partners in marital counselling, active agents in re-socialisation and reinforcement programmes and relapse or problems detectors.
CRD	Centre for Reviews and Dissemination
CS	Coping Skills
CSA	Common Services Agency.
CST	Communication Skills Training
Day Facilities	Non-residential facilities. Opening hours and type of intervention may differ.
DEM/DM	Deutchmark
Detoxification	Treatment designed to free an addict from his drug habit.
Discounting	A means of converting the value of future events to their value in the present period. Future costs are converted using a financial discount rate similar to the interest rate, while patient benefits are converted using the reported time preference for health benefits. This reflects society's preference for immediate benefits compared to benefits occurring in the future.
DNA	Did Not Attend
DoH	Department of Health (England).
Drinkwise	A campaign to promote the reappraisal of personal drinking behaviour.
DSM	American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders
EC	European Community
ECHTA	The European Collaboration for Health Technology Assessment
Economic model	This simplifies the patient pathway to a level that describes the essential choices and consequences within treatment options. Linking patient outcomes to resource usage enable different courses of action to be compared from an economic viewpoint. Modeling may also be used to extrapolate from existing data into the longer

	term.
Effect sizes	A measure of the magnitude of a treatment effect commonly used in meta-analyses.
EMTREE	Embase (literature searching database) Subject Headings.
Epidemiology	The medical and scientific study of epidemic diseases.
EU	European Union
Evidence-based	The process of systematically finding, appraising, and using contemporary research findings as the basis for clinical decisions.
FAST	Family Addiction Screening Tool
GABA	?-aminobutyric acid
Gamma GT/GGT	Gamma glutamyltransferase
GGHB	Greater Glasgow Health Board
GP	General Practitioner
Grey Literature	That which is produced on all levels of government, academics, business and industry in print and electronic formats, not controlled by commercial publishers.
Group Therapy/Work	Commonly used procedure but often poorly defined. Groups can be run accordingly to strict psychoanalytical principles, as problem solving groups, and, in some cases, according to no clear principles at all.
HDL	Health Department Letters
Health Board	In Scotland there are 15 area health boards, responsible for commissioning and delivering local health care.
Health Education	Educational strategy designed to improve health knowledge and promote informed decisions conducive to health.
Healthcare Professional	A person qualified in a health discipline.
HEBS	Health Education Board for Scotland
HEED	Health Economics Evaluation Database
HQ	Headquarters
HTA	Health Technology Assessment is a multi-disciplinary field of policy analysis which studies the medical, social, ethical and economic implications of

	development, diffusion and use of health technology.
HTBS	Health Technology Board for Scotland
ICD	International Coding Dictionary
ICER	Incremental Cost Effectiveness Ratio
INAHTA	International Network of Agencies for Health Technology Assessment
Incidence	How often a disease occurs; the number of new cases of a disease among a certain group of people during a specific period of time.
Indication (therapeutic)	The diseases or conditions which a medicine has been authorised (licensed) to treat.
Intervention (health)	An item or service delivered or undertaken primarily to prevent, diagnose or treat a medical condition or to maintain or restore functional ability.
IP	In Patient
ISD	Information and Statistics Division
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
ITT	Intention to treat
LFT	Liver Function Test
LHCC	In Scotland, Local Healthcare Co-operatives are voluntary groupings of GPs and other local health care professionals intended to strengthen and support the primary health care team in delivering local care.
Life Tables	Tabulated mathematical models presenting, for example, the number of individuals who have experienced a certain event by a specified time.
LSD	Lysergic acid diethylamide
Managed Clinical Networks	Linked groups of health professional and organisations from primary, secondary and tertiary care, working in a co-ordinated manner, unconstrained by existing professional and NHS Board boundaries, to ensure equitable provision of high quality clinically effective services throughout Scotland.
MATCH	Matching Alcoholism Treatments to Client Heterogeneity
MCV	Mean Cell Volume
Medication	Drugs prescribed to treat a condition.

MeSH	Medical Subject Headings
MET	Motivational Enhancement Therapy
	*A client-centred counselling approach for initiating behaviour change by helping clients to resolve ambivalence about engaging in treatment and stopping alcohol use. This approach uses strategies to evoke rapid and internally motivated change in the client.
Meta-analysis	Statistical method to combine the outcomes of more than one randomised clinical trial.
MI	Motivational Interviewing
	As *
Morbidity	The frequency (incidence and/or prevalence) of a particular disease or group of diseases.
Mortality rate	The number of deaths in a given population during a specified period of time.
Multidisciplinary	A multidisciplinary team is a group of people from different disciplines (both healthcare and non-healthcare) who work together to provide care for patients with a particular condition. The composition of multi-disciplinary teams will vary according to many factors. These include: the specific condition, the scale of the service being provided and geographical/socio-economic factors in the local area.
NAIP	National Alcohol Indicators Project
Naltrexone	An opioid antagonist, blocks the action of opioids and precipitates withdrawal symptoms in opioid-dependent subjects.
NHS	National Health Service
NHS Boards	The role of the NHS Boards is to ensure the efficient, effective and accountable governance of the local NHS system. There 15 NHS Boards in Scotland.
NHS EED	NHS Economic Evaluation Database
NHS24	NHS24 is a special Health Board of NHSScotland that aims to give people across Scotland equal access to health advice, information and help, when they need it and as far as possible in one phone call.
NHSScotland	National Health Service in Scotland
NICE	National Institute for Clinical Excellence.

NMDA	*N*-methyl-D-aspartate
Odds ratio	The association between a random event, E, and some condition, A, expressed as the odds that E occurs when A is true divided by the odds that E occurs when A is not true.
OP	Out Patient
Opportunity cost	The opportunity cost of selecting a particular health technology is the amount of alternative health technologies that could have been obtained had that selection not been made.
OT	Occupational Therapist
Outcome	The end result of care and treatment. In other words, the change in health, functional ability, symptoms or situation of a person, which can be used to measure the effectiveness of care and treatment. Also referred to as patient impact or patient benefit.
p.a	*Per anum*
Patient	A person who is receiving medical treatment (especially in a hospital). Also, a person who is registered with a doctor, dentist, etc and is treated by him/her when necessary. Sometimes referred to as a user.
PCT	Primary Care Trust
Person-centred counselling	Counselling which focuses on the individual.
Pharmacological	Deals directly with the effectiveness and safety of drugs in humans.
Placebo	Dummy treatment which is given to some of the volunteers participating in a clinical trial. Patients can feel better even when the treatment they are given is a 'sugar pill' or placebo.
Plan for Action	Refers to the SACAM document "The Plan for Action on Alcohol Problems".
Positive Modelling	
PP	Per protocol
PRAMA	Prevention of Relapse with acamprosate in the Management of Alcoholism
Prevalence	The number of existing cases of a disease among a certain group of people, usually at a specified point in time.

Problem Solving (Skills Training)	A systematic method used to approach problems in general.
Prognosis	An assessment of the expected future course and outcome of a person's disease.
Psychosocial Intervention	Cognitive behavioural therapy, motivational interviewing/ enhancement and the twelve-step/Alcoholics Anonymous comprise the three main forms of psychosocial intervention. The best evidence of effectiveness was found in project Match.
Psychotherapeutic Techniques	A term used to describe the process/skill involved in carrying out the particular psychotherapy or treatment.
Psychotherapy	This term is frequently used to refer to talking treatment based upon psychodynamic or psychoanalytic principles. In practice the term is also used to refer to a wide range of psychological interventions.
PYLL	Potential Years of Life Lost
QA	Quality Assurance
	Improving performance and preventing problems through planned and systematic activities including documentation, training and review.
QALY	Quality adjusted life year. A means of adjusting the benefits accruing to patients that takes into account the quality of life of each year.
QUADS	Quality in Alcohol and Drugs Services
r	Pearson's r
	An estimate of the association between two variables.
Randomised	Randomly allocated to one or more than one different choices of treatment.
RCT	Randomised, controlled trial
Risk Factor	A clearly defined occurrence or characteristic that increases the possibility that a person will get a disease.
RP	Relapse Prevention
	A treatment package involving a range of strategies to prevent relapse in the field of addictive behaviours. The aim of this approach within the field of alcohol treatment, is to help the problem drinker develop confidence or **self-efficacy** in his or her ability to cope with **high-risk** for drinking situations. The Focus of treatment is to teach the individual **coping-skills** so that he/she can avoid relapse in the future. **Avoidance** of

	high-risk for drinking situations would be encouraged as an early coping strategy, however, during the course of treatment, gradual exposure to progressively more risky situations is encouraged. Techniques such as: **Stress management** **Relaxation** **Anger management** **Assertiveness training** Can be delivered as individual treatments but are also incorporated within the relapse prevention treatment package.
RR	Risk Ratio
RSI	Rough Sleepers Initiative
SACAM	Scottish Advisory Committee on Alcohol Misuse
SBU	Swedish Council on Technology Assessment in Healthcare
Scottish Executive	The Scottish Executive is the devolved government for Scotland. It is responsible for most of the issues of day-to-day concern to the people of Scotland, including health, education, justice, rural affairs and transport.
SD	Standard Deviation
SEHD	Scottish Executive Health Department
Sensitivity	The probability that a test result is positive given the subject has the disease.
Sensitivity Analysis	An exploration of the impact upon results of changing parameter values within a model.
SF-36	Short Form 36 Health Questionnaire
SHO	Senior House Officer
Side-effect	A side-effect is an unpleasant and unwanted effect of treatment.
SIGN	Scottish Intercollegiate Guideline Network
Social Learning Theory	A cognitive and behavioural intervention focussing on attention, memory and motivation.
Solution Focussed Therapy	Please refer to definition of CBT.
SPC	Summary of Product Characteristics
SPS	Scottish Prison Service

SS	Social Skills The focus of social skills training is to help clients increase social support and improve their ability to establish rewarding interpersonal relationships. The content of training will focus on a range of areas including body language, listening skills, assertiveness etc.
SSRI	Selective Serotonin Reuptake Inhibitor
STRADA	Scottish Training on Drugs and Alcohol
Stress Management	A relapse prevention technique.
Supportive-Expressive Psychotherapy	Is a time limited, focused psychotherapy. (This approach has been adapted for heroin and cocaine use.) The therapy has two main components: • Supportive techniques to help patients feel comfortable in discussing their personal experiences. • Expressive techniques to help patients feel comfortable in discussing their personal experiences. Special Attention is paid to the role of drugs in relation to problem feelings and behaviours and how problems may be solved without recourse to drugs.
SW	Social Worker
Tachycardia	An abnormally rapid heart rate.
Task Centred Counselling	A method of cognitive behavioural therapy.
Trust	There are two types of trust in Scotland: Acute Hospital Trusts and Primary Care Trusts. Acute Hospital Trusts are responsible for a defined set of acute hospital services. Primary Care Trusts have the responsibility for the provision of the full range of primary care, community and mental health services. Both types of trust operate within the geographical boundaries of an individual NHS Board.
TSF	Twelve-Step Facilitation Please see definition of Twelve-Step Model.
TSG	Topic Specific Group.
Twelve-Step Model/Alcohol Anonymous	A self-help or mutual support group with explicitly religious/spiritual aspects. The philosophy is that alcoholics drink because of compulsion to do so and

	that they have lost control over their drinking whether or not they are aware of this.
UK	United Kingdom
US	United States
USA	United States of America
Vocational Training	Focuses on developing skills to enhance employment prospects, often through re-training, further education or government employment initiatives.
WHO	World Health Organisation