

Workbook 7

Outcome Evaluations

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WHO
World Health Organization



UNDCP
United Nations International Drug Control Programme



EMCDDA
European Monitoring Center on Drugs and Drug Addiction

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Overview of workbook series

This workbook is part of a series intended to educate programme planners, managers, staff and other decision-makers about the evaluation of services and systems for the treatment of psychoactive substance use disorders. The objective of this series is to enhance their capacity for carrying out evaluation activities. The broader goal of the workbooks is to enhance treatment efficiency and cost-effectiveness using the information

that comes from these evaluation activities.

This workbook considers outcome evaluation. Outcome evaluations measure the extent to which clients of services, or networks of services for substance use disorders, change following participation in treatment. The workbook offers advice on measuring the changes and attributing change to programme involvement.



Introductory Workbook Framework Workbook



Foundation Workbooks Workbook 1: Planning Evaluations Workbook 2: Implementing Evaluations



Specialised Workbooks Workbook 3: Needs Assessment Evaluations Workbook 4: Process Evaluations Workbook 5: Cost Evaluations Workbook 6: Client Satisfaction Evaluations Workbook 7: Outcome Evaluations Workbook 8: Economic Evaluations

What is an outcome evaluation?

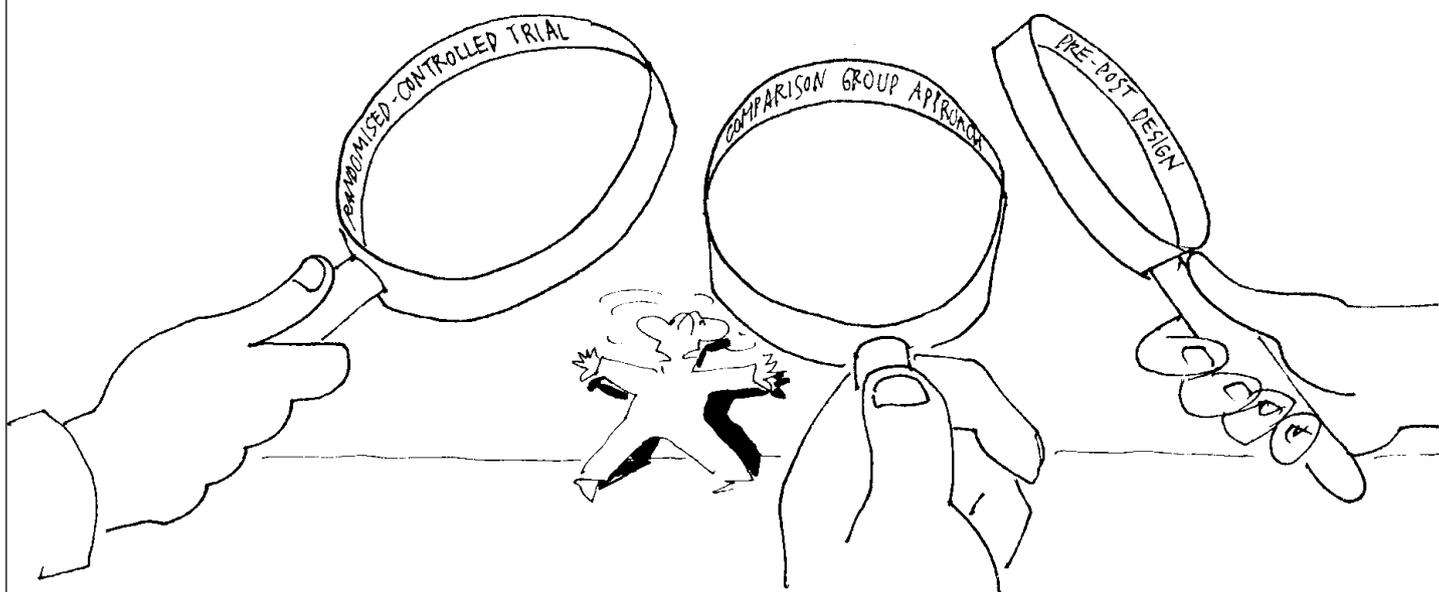
Outcome evaluations provide information on how well your programme is accomplishing its goals.

Outcome evaluations **measure how clients and their circumstances change**, and **whether the treatment experience has been a factor in causing this change**. In other words, outcome evaluations aim to assess **treatment effectiveness**.

Some questions that might be addressed in outcome evaluations include:

- Have clients' quality of life improved following treatment?
- Has there been a reduction in the quantity/frequency of PSU following treatment?
- Is client participation in our treatment programme "responsible" for their improvement?

There are a number of ways to design outcome evaluation and measure these types of changes. The most widely-praised way to measure client improvement and infer causality (i.e., to infer that your programme is responsible for the observed client improvement) is the experimental approach. This is sometimes called a "randomised-controlled trial". Other methods for studying outcome include the "comparison group approach" and the "pre-post design." All these methods are described later in this workbook.





Why do an outcome evaluation?

If clients get better following treatment, it does not necessarily mean that your treatment caused these changes.

If your programme is typical, several groups of people would be interested to know whether your treatments are actually effective.

- Your clients
- Their family members
- Your treatment staff
- Employers of clients
- Criminal justice system
- Health insurers or other “payers” for your treatment services
- Government organisations
- General community members

You may be saying to yourself, “I know that my treatment programme is effective because I have seen many people get better following participation. Why do I need to do an outcome evaluation?” The answer is relatively simple. If clients get better following treatment, it does not necessarily mean that your treatment **caused** these changes. Think about it. People change for many reasons. Improvements in your clients’ PSU may be the result of something completely different from your programme. Common other reasons for improvement, beyond the effects of treatment itself, include:

- **Other things that happened during and after treatment**

Clients may have found or lost an important interpersonal relationship; found or lost a job; moved to a new neighbourhood; or become involved with a self-help group. All of these events could influence their PSU independently of the effects of treatment. Such events can also interact with treatment effects in complex ways. For example, the clients who have done well may be those who experienced other positive life events.

- **Client “maturation”**

Over time, many people grow out of their problems due to age-related changes. This is particularly so for adolescents whose PSU tends to decrease as they reach young adulthood.

- **Natural variation or regression**

Although many clients of services for PSU disorders, lead disruptive lives, they also have periods of relative stability when they cut down or eliminate their PSU. Any changes in the behaviour and circumstances between two periods of time may simply reflect “normal” variations rather than the effects of an intervention. Some of those who enter treatment during a particularly disruptive period can be expected to change for the better without treatment, even if temporarily.

For these reasons, outcome studies go beyond merely describing positive changes in clients. They attempt to demonstrate scientifically whether your treatment process has caused any client changes that occur.





How to do an outcome evaluation?

Your choice of designs should be influenced by the resources you have available.

Outcome evaluation is based on a quantitative approach. It typically uses one of three designs:

- randomised controlled trial
- comparison group
- pre-post comparison

Each of these designs are described below. After reading this workbook, you must make your choice among these design options. In general, pre-post comparison is the least scientifically rigorous design, comparison group designs are “moderate” in their scientific rigour, and randomised controlled trials use the strongest design. However, randomised controlled trials and compar-

ison group designs are more resource-intensive and complicated to conduct than pre-post comparisons. Your choice of designs should be influenced by the resources you have available. After reading this material, you must carefully consider the practical realities of implementing each type of design in your programme setting.

Method 1: Randomised controlled trial design

...clients are randomly assigned (like the flip of a coin) to either the treatment in question or to a plausible alternative.

This design option uses two or more groups of clients who are **randomly assigned** to either the treatment in question or to a plausible alternative. Members of both groups receive the same pre-treatment and post-treatment assessments. Because the randomisation process makes it equally likely that any one client will be assigned to one group or the other, with a sufficient number of participants this design controls for pre-treatment individual differences in clients (e.g., PSU frequency, motivation for treatment) and other events that might happen during treatment.

Randomised controlled trials can compare many things, including different types of treatment, (e.g., pharmacotherapy vs. psychotherapy); different

intensities of the same treatment (e.g. short vs. long-term); different strategies for delivering the same treatment (e.g., group vs. individual); and different settings (e.g., inpatient vs. outpatient). Other comparisons involve people who received no treatment vs. people who receive treatment.

A significant strength of randomised controlled trials is that they can control for most competing explanations for improvement following treatment (e.g., other events that happened during treatment). However, there are many technical and logistical problems to overcome in the proper design and conduct of these evaluations. Consultation with an evaluator experienced with randomised controlled trials is recommended if you are considering this design.

The first case report located at the end of this workbook (by Formigoni and Marques) provides an example of a randomised controlled trial design. In this

evaluation, individual and group cognitive-behavioural treatments were compared using random assignment to treatment conditions.

Method 2: Comparison group designs

The success of the evaluation depends on how similar the two groups are at the beginning of the evaluation.

This design option is similar to the randomised design except the comparison group is deliberately rather than randomly chosen. Comparison groups are chosen so that clients are as similar as possible to those in the treatment service or system being evaluated. Statistical methods are used to control for any remaining differences (e.g., differences in client age). The types of treatment and alternative conditions featured in comparison group evaluations are similar to those noted above in connection with experimental evaluations (i.e., comparisons treatment types or intensity).

The extent to which comparison group studies successfully control for the various competing explanation factors varies with the types of services and client groups involved. The “success” of the evaluation depends on how similar the two groups are at the beginning of the evaluation. For example, different types of clients may have different reasons for their choice of treatment programme. Similar to randomised controlled trials, there are many technical and logistical problems to overcome in the proper design and conduct of these evaluations. Consultation with an evaluator experienced in comparison group evaluations is recommended if you are considering this design.

Method 3: Pre-post design

Pre-post studies assess clients on the same variables, and over the same time intervals, before and after they complete treatment

This design option is not as complex as experimental and comparison group evaluations. It is more realistic for treatment services or systems with limited experience and/or resources. Although pre-post designs are less scientifically rigorous, they can produce useful results for purposes of accountability and programme improvement.

Pre-post studies assess clients on the same variables, and over the same time intervals, before and after they complete treatment. For example, baseline data collected

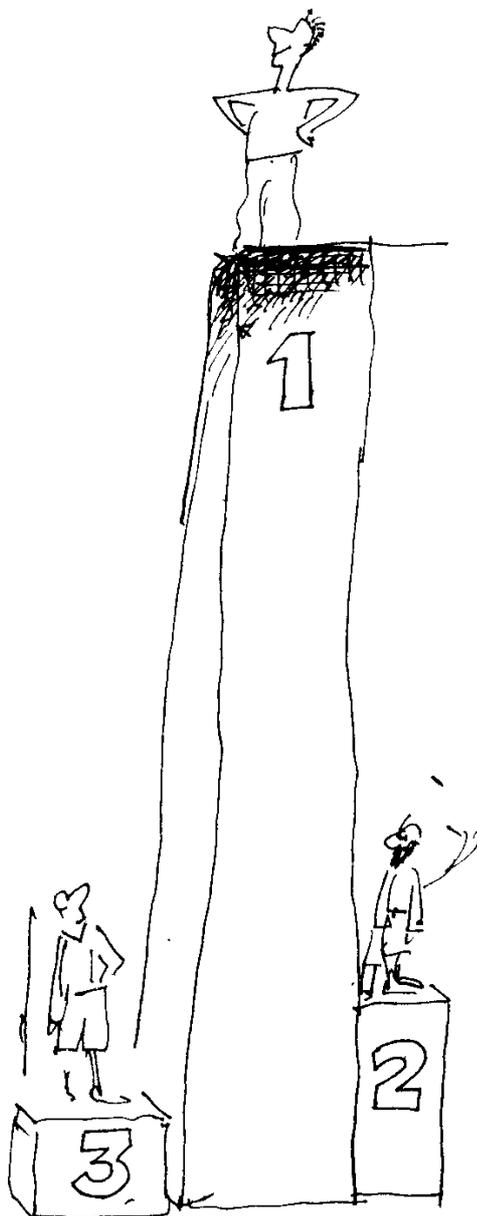
at intake may ask about quantity and frequency of PSU over the past 90 days. Exactly the same questions would be asked of clients six months following discharge. With a pre-post design, clients may be re-contacted on more than one occasion (e.g., six months, 12 months, 18 months, and 24 months). In this case, the evaluation is called a time-series design. While this extended design is especially helpful in showing the stability of outcomes being achieved, an extra effort is required to maintain contact with the sample of clients being followed-up.

Simple pre-post designs have some limitations. They do not control for competing explanations, such as something else that happened during treatment. They also do not show if a treatment service or system is effective **relative to alternative treatments**.

Despite these drawbacks, pre-post evaluations have several strengths. They can determine if treatment objectives are being achieved, and the type of client who improves most or least. They also can show if improvement varies with the amount or type of treatment received. For example, you can show if those attending treatment consistently fare better than those with poor attendance. You also can show if those who attended specific components of the service did better than others. Positive results from a pre-

post study are rewarding for staff and can satisfy accountability requirements of some funding agencies. Positive results from pre-post studies also can lend support for getting the resources to conduct more rigorous randomised controlled trials. If your results seem worse than those reported for similar clients in other programmes, some action to improve your services may be needed. If, on the other hand, the results seem better than expected, a rigorous evaluation may be desirable to be sure your programme can take the credit for these positive outcomes.

The last case report located at the end of this workbook (by Auriacombe and colleagues) provides an example of pre-post design. In this evaluation, clients receiving opiate-substitute treatment were followed over time.



Other methodological issues in outcome evaluation

Beyond choosing the basic design of your evaluation, there are other methodological details to be decided. Workbooks 1 and 2 provide valuable general information in this area; be sure to review them with this workbook. The information in this section is specialised for outcome evaluations and complementary to the more general information provided in the introductory workbooks. The following issues are discussed:

- 1 selecting clients for participation
- 2 sample size
- 3 timing and frequency of follow-up
- 4 preparing and tracing clients for follow-up interviews
- 5 conduct of follow-up interviews
- 6 selection and training of interviewers

1. Selecting clients for participation

¹One could argue that all clients, as opposed to a sample of clients, should be routinely followed up for purposes of accountability. This is not usually feasible given the time and resources required to do so.

The selection of clients for participation in an outcome evaluation should be determined by objectives of the evaluation. If you are interested in general programme effectiveness, random samples of **all** clients who enter treatment in a typical time period should be selected.¹ If, on the other hand, your objectives of evaluation concern particular types of clients (e.g., opiate users), or clients who complete a certain amount of treatment, then random samples should be chosen to represent this subgroup. If there is a desire to compare one service with another, then similar types

of cases should be recruited from each service.

Beyond taking a random sample, there are no steady-state rules about who to enrol. However, the procedures used to select clients should be stated clearly to ensure individuals who read your evaluation report understand the procedures and potential biases. Attention should be drawn to clients who were excluded from participation, such as clients who don't have a telephone, because exclusions can affect your results.

2. Sample size

More cases are required if you want to detect smaller differences between groups.

There are no simple answers to the question, “How many clients do I need to study?” Much depends on the objectives of the study, the kinds of clients involved and the kinds of measures used. Case examples from this workbook report evaluations with as few as 16 participants to greater than 1,000 participants. If the aim is to compare outcomes of two groups of clients (i.e., males or females; two programs), the number to be studied depends on the size of difference you want to detect between the two groups on the outcome measure. A statistician will be able to calculate the required sample size if you provide the following information:

- the relative sizes of the two groups to be compared
- the expected frequency of the behaviour in one group
- the magnitude of the difference that you want to be able to detect, between groups
- the degree of confidence you want to have in the results

To show you how this process works, consider this example. Imagine that you want to find out if males in your programme are more likely to relapse within the first three months than females. Assume that you will have data for an equal number of males and females and that you expect 40% of males to relapse. Assume further that a difference of 20% would be of practical significance, and that

you want to be 95% certain that any such observed differences were not due to chance. In this case, the statistician will likely advise you to collect data on about 180 cases (90 males and 90 females). If, however, you think that a difference of 10% between males and females is likely to be of interest, the statistician will advise you to collect data on 600 cases. More cases are required if you want to detect smaller differences between groups. More cases are also required if more than two groups are to be compared or if the groups are of unequal size.

When planning the number of people to be studied in an outcome evaluation, allowance should be made for clients who cannot be contacted and for whom outcome information will be missing. Remember, your final sample calculations will be based on the number of clients for whom you have complete data. You will have to contact more clients in order to get this many for final calculations. The percentage of clients “lost” to follow-up will vary from situation to situation. It will depend to some extent on the social stability of clients and the ingenuity of follow-up workers. It would be reasonable to expect that up to 30% of cases chosen for follow-up cannot be traced and to, therefore, increase the sample selected for follow-up by 30%. McLellan and colleagues (1996) recommend a 70% follow-up rate as the minimum standard for outcome evaluation.

3. Timing and frequency of follow-up

You have three factors to consider here:

- the point in time at which you start counting weeks/months until the follow-up interval (i.e., 4 weeks after intake and assessment vs. 4 weeks after some period of treatment participation vs. 4 weeks after the last treatment contact or formal discharge)
- the duration of the follow-up interval (e.g., 4 weeks vs. 8 weeks vs. 12 weeks)
- the time period over which PSU and other outcomes are assessed

Start Date

...we recommend that you start the follow-up period at the first face-to-face contact for client assessment.

²Many programmes have a clerical function incorporated into the initial stage of treatment involvement which collects basic demographic information and screens the client for programme eligibility. It is very difficult to collect baseline evaluation data during such a contact with the programme. Thus, the “intention-to-treat” design often means that clients are selected for evaluation at the point of their first **clinical encounter** for assessment and/or treatment.

In selecting the start date for the follow-up period, there are several trade-offs to be made. If you decide to follow-up a random sample of clients who are enrolled at intake and/or assessment, you will obtain the largest sample. Using this method, results can be generalised to all clients who have participated in the programme regardless of the level of service they eventually receive. On the other hand, most clients who drop-out of treatment do so early in the treatment process; many after their first contact. Selecting your sample this early in the process will mean more effort to locate people for follow-up, because early drop-outs will be more difficult to locate.

If you select your follow-up sample from those who complete a certain period of treatment, or who have made a certain number of contacts (e.g., three outpatient visits), you will have a more stable group to re-contact. You will, however, have missed the opportunity to determine outcome for those with fewer contacts. If you contact only those completing treatment, and who are formally discharged, you will probably have a sample heavily biased toward positive outcome.

Given the above considerations, we recommend that you start the follow-up period at the **first** face-to-face contact for client assess-

ment. McLellan and colleagues (1996) refer to this as the “intent-to-treat” design and recommend it as a minimum standard for outcome evaluation.² With this approach, your baseline evaluation information must be collected as early as possible in the intake/assessment process. In many programmes, clinical assessment and treatment planning extends over several contacts. For the period of the evaluation, routine assessment procedures may need to be modified in order to get the pre-treatment evaluation information at the first contact for assessment.

The relationship between standard programme intake/assessment procedures and the collection of the pre-treatment evaluation data requires careful planning. One option is to conduct an evaluation interview **in addition to** the normal assessment protocol. The interview may be conducted by an independent evaluator or by other programme staff. The disadvantage of this approach is that the client may be overburdened by two data collection procedures that ask for similar information in slightly different ways. An alternative is to blend the pre-treatment evaluation questions into the clinical assessment process. This has the advantage of reducing the burden on clients and maximising the use of staff resources if independent evaluators can not be used.

Duration of follow-up period

It is recommended that you select at least a six-month follow-up interval and consider the potential benefits of at least one additional contact in another few months.

Your second major decision is the duration of the follow-up interval. Follow-up studies published in research journals have reported on information obtained at many different points in time after treatment engagement. Some evaluations report on client changes at the time of discharge or after a certain period of outpatient contact. Other evaluations have followed a sample of clients for several years. Most common are reports of outcomes assessed after a three, six, or 12 month interval. Outcome studies to be reported in scientific journals typically require

a one to two year follow-up period. The case examples at the end of the workbook demonstrate this variability. Two evaluations used a 12-month follow-up, whereas the third followed participants for five years.

The timing of your follow-up will have a significant impact on your results and conclusions. Short-term follow-up studies will show better results than longer term ones, because 60%-80% of “relapses” occur in the first three to four months following discharge (McClellan et al., 1993).

It is recommended that you select at least a six-month follow-up interval and consider the potential benefits of at least one additional contact in another few months. However,

there are no hard and fast rules that must be followed, other than that your follow-up periods and intervals should be consistent with the objectives of your evaluation.

Time period for measures

...it is recommended that you select a 90-day period for your outcome measures.

Your third major decision concerns the time period over which outcomes will be assessed. For example, even though you may have decided that your follow-up period will be six months in duration, you still need to decide the time period over which clients will be asked to recall their PSU and its consequences. The same time period must be chosen for both the pre-treatment and post-treatment assessments.

There are trade-offs for any time period you choose. A client's PSU in the 30 days prior to starting treatment may not be representative of longer term PSU. Thus, comparison of

the 30-day pre-treatment period and a 30-day post-treatment period may not yield a reliable and meaningful difference. On the other hand, if the time period is too long (e.g., 4-6 months), clients may not be able to recall important information accurately (e.g., frequency and quantity of PSU; use of health and correctional services).

Based on these concerns, it is recommended that you select a 90-day period for your outcome measures. This time period will need to be stated clearly to clients and reflected in your questionnaires during pre-treatment and post-treatment assessments.

4. Preparing and tracing clients for follow-up interviews

The consent form should indicate the reason you are evaluating clients, the (random) process of selection, assurances of confidentiality, the timing of the follow-up and the types of questions to be asked.

Clients selected for evaluation should be asked to sign a written consent form that explains the purpose and methods of the follow-up procedures. A sample form is shown in Workbook 1, Appendix 2. The consent form should indicate the reason you are evaluating clients, the (random) process of selection, assurances of confidentiality, the timing of the follow-up and the types of questions to be asked. It also should indicate that the client has the right to decline to participate and that their decision will not influence current or future participation in treatment. The form records the client's name, address and telephone number and asks for details of other people who may be contacted to assist in locating the client. It is important to know if follow-up workers can, if necessary, identify themselves to others who may respond to the follow-up contact. In out-

come evaluations, it is common practice to ask all clients to complete the consent form at intake and then take a random sample of those who agree.

For additional information and advice about preparing and using consent form, review Workbook 2 Step 1A, entitled "Manage Ethical Concerns."

Your consent form should accommodate the special circumstances of young clients whose right to consent to treatment and evaluation may need to be endorsed by parents or guardians. The legal requirement to obtain consent from parents or guardians will vary across jurisdictions: Check with your local authorities and/or an ethics board to determine the best way to proceed in your setting.

The process of locating former clients for follow-up can be time consuming and frustrating for follow-up workers. This is especially the case for socially unstable clients and those who may have relapsed. Interviewers

must be tolerant and flexible. Whether face-to-face or telephone interviews are planned, a pre-determined schedule of contact attempts must be followed (e.g., five telephone calls at varying times of day).

5. The conduct of follow-up interviews

Many follow-up studies of clients of PSU services use telephone interviews. There is a general consensus among evaluators that telephone interviews can provide valid outcome data when properly conducted (IOM, 1990). They are a good option for collecting follow-up in settings where most clients have telephones. However, they are inappropriate in situations where few clients have phones, or where phone calls to clients' homes may violate their rights to privacy.

Interviewers should not go to clients' homes or other street addresses except in pairs or with clear backup support. Otherwise, they may place themselves at risk. These are not trivial concerns and the safety of follow-up workers engaged in face-to-face follow-up should be given careful consideration.

If telephone interviews cannot be used, your next best option is to interview cli-



6. Selection and training of interviewers

All data collectors should be trained thoroughly before starting work with clients.

An important standard for outcome evaluation is that all client interviews and data collection be undertaken by people not associated with the provision of the intervention. This is the case for both pre-treatment and follow-up interviews, although practical and resource constraints may make it difficult during the pre-treatment assessment. Resource constraints may require that programme staff assist in the collection of follow-up information. However, they should not do so for clients they have treated. This is important in order to avoid clients “faking good” at follow-up to the clinical staff who have treated them.

All data collectors should be trained thoroughly before starting work with clients. Review Workbook 2 Step 1C, entitled “Develop a Data Management Plan,” for more information about how to do this.

If your follow-up interviews are to be conducted by telephone, the interviewers must have a professional manner and clear voices over the phone. If face-to-face interviews are used, interviewers should be selected and trained such that clients feel they can talk freely. For example, if you are planning face-to-face interviews and the people to be interviewed are young adults with unconven-

tional lifestyles, try to engage young interviewers who have flexible time schedules and who feel comfortable in casual clothes and conversation. Similarly, a face-to-face follow-up of adults or elderly persons would best be done by older, more conventional individuals. The gender of the interviewer may also be important, especially if your programme has objectives specific to female or male issues.

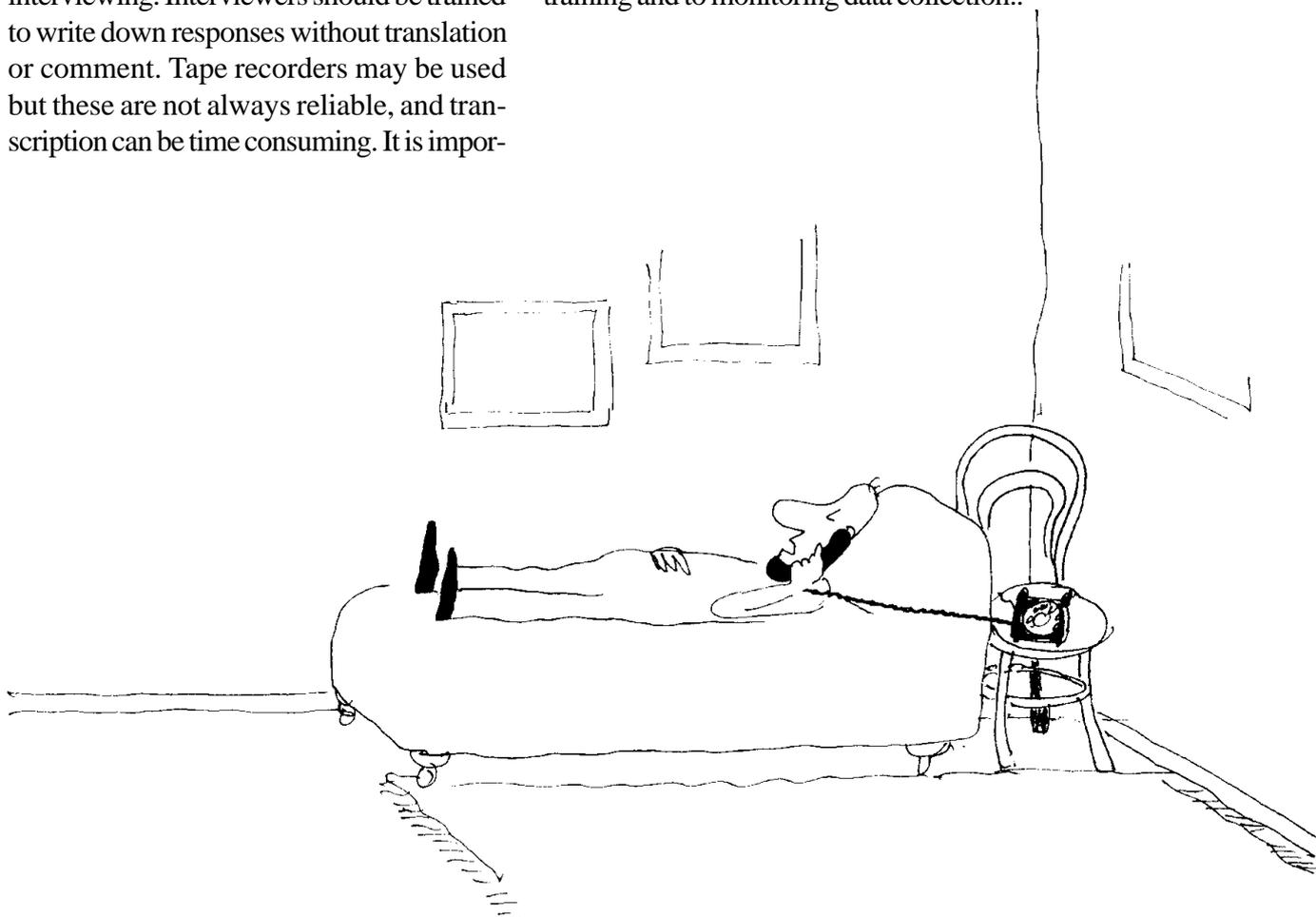
The language in which the follow-up interviews is conducted is of obvious concern. This may be difficult to accommodate in all cases, especially if your programme has a multicultural clientele. Careful attention must be given to the use of outcome measures validated in one culture and developed in particular language, and then translated into another language. Such cross-cultural application may significantly influence the reliability and validity of the measure.

Interviewers should be familiar with the interview schedule and objectives of the evaluation. They should practice before they start interviewing. Interviewers should be trained to write down responses without translation or comment. Tape recorders may be used but these are not always reliable, and transcription can be time consuming. It is impor-

tant that interviewers be well supervised to ensure they stay within the agreed evaluation protocol and act professionally.

Whether you are using face-to-face or telephone interviews, an important issue in the selection and training of interviewers is the extent to which they are allowed to address clinical issues that may arise. It is recommended that a written protocol be developed for interviewers to guide their response to requests for additional treatment or more serious emergencies such as expressed suicidal ideation. While clinical training and experience are usually not required of follow-up workers, they must be capable of responding professionally and ethically to a range of situations that may present themselves.

Some programmes have trained former clients or other volunteers to locate clients and conduct the follow-up interviews. This may be an option for programmes with limited resources for outcome evaluation. In these cases, particular attention should be given to training and to monitoring data collection..



Choosing your outcome measures

Outcome measures can be selected from three broad domains:

- reduction of PSU
- improvement in personal and social function
- reduction in public health and safety risks

A wide range of potential outcome measures in each of these domains may be relevant for the evaluation of your treatment service or system. Your choice of outcome measures is critical to the success of your evaluation. The decisions you make are closely tied to decisions you will have to make regarding data collection procedures. For example, some measures will be appropriate for self-comple-

tion, others by telephone and still others may require a face-to-face interview with particular groups of clients. Most importantly, your choice of measures must be guided by the objectives that your treatment service or system is trying to achieve.

The table below identifies many possible outcome measures within each of these areas:

Domain: PSU

- Workbook 1, Appendix 2 includes a brief format for measuring quantity/frequency of PSU
- Timeline Follow-back Method (Sobell and Sobell, 1992)
- Alcohol and Drug Use Subscales of the Addiction Severity Index (McLellan et al., 1988)
- Quantity/Frequency Measures from Directory of Outcome Measures (Addiction Research Foundation)

Domain: personal and social functioning

- Short Alcohol Dependence Data (Raistrick et al., 1983)
- Drug Abuse Screening Test (Skinner, 1982)

- WHO - CIDI (Witchen, 1994)
- Symptom Checklist-90 (Derogatis, 1977)
- Beck Depression Inventory (Beck et al., 1961)
- Perceived Social Support (Procidano and Heller, 1983)
- Social/Family Subscale of the ASI (McLellan et al., 1988)

Domain: Public Health and safety risks

- Workbook 1, Appendix 2 includes a brief format for measuring HIV-risk behaviours, and health, social, and correctional services
- Legal Sub-scale of the ASI (McLellan et al., 1988)
- the follow-up data collection strategy (i.e., telephone versus face-to-face interviews)
- the resources you have available for data collection, analysis and preparation of reports

In addition to your **outcome** measures, you also need measures that help you explain or **predict** outcome for certain groups of clients. For example, PSU is an outcome measure; while the number of days in treatment is a predictor variable.¹ Information on any given client's participation in treatment needs to be linked with his/her outcomes. Demographic characteristics of clients such as gender, age, and socio-economic status are often used as predictor variables. Other predictor variables could include:

- the objectives of your treatment service
- the client population you serve
- the time you are prepared to invest in your assessment process for the collection of data
- the potential use of a computer to assist in collection of the information (i.e., self-administered questions)
- the time period over which you wish to have clients report PSU
- established reliability and validity data for your culture
- cost to use the instrument if not in public domain
- severity of dependence
- extent of family and social supports
- psychiatric symptoms, in particular the presence of anti-social personality diagnosis

These predictor variables are measured by some of the questionnaires listed in the table above.

¹Scientific jargon refers to these as dependent variables (your outcome) and independent variables (your predictors).

These measures are presented as examples only. You must decide on their appropriateness and availability for your clients and your culture. In making your selection of outcome measures, you should consider:

...ethical considerations prevent collecting data from third parties (e.g., family members) without clear, written permission from clients themselves.

What information source should you use?

You will have to decide whether to collect all of your outcome information from one source (usually the client), or from more than one source. Having additional information to back-up clients' self-reports is recommended (McLellan et al., 1996) (e.g., breathalyser; urine screening tests, and/or collateral

reports). This may not be practical in all situations or if limited resources are available for evaluation.

Do PS users tell the truth? Overall, research indicates that self-reports of PSU, criminal and other behaviours *are reasonably reli-*

able and valid under certain conditions (Sobell et al., 1992). PS users are more likely to give accurate answers when:

- they are sober and PS free at the time of the interview
- confidentiality can be assured and there are no consequences for reporting PSU or illegal behaviours
- the interviewer is skilled and non-judgmental and there is good rapport between the interviewer and the respondent
- questions are clear, direct and easily understood by the respondent

There is additional evidence that PS users are more accurate when they are aware that their answers will be verified against third party reports or official records. Such verification is not always possible, but if family members can be interviewed or police records checked, clients will have less reason to deny their actions to you.

Not every client will tell “the whole truth and nothing but the truth” about every aspect of their lives in treatment outcome studies. Some will be motivated to under- or over-report certain behaviours and many will not remember everything they did, or everything that happened to them. However, if the conditions for the interview are right, few respondents are likely to present distorted accounts of their lives and behaviours over a given follow-up period.

Face-to-face interviews present opportunities to observe former clients and these observations may give clues about their lives and situations. Interviewers can be trained to rate clients with respect to their levels of intoxication, appearance and mood and signs of PSU, for example, smell of alcohol, presence of bottles or syringes and other paraphernalia, or needle marks on the arms.

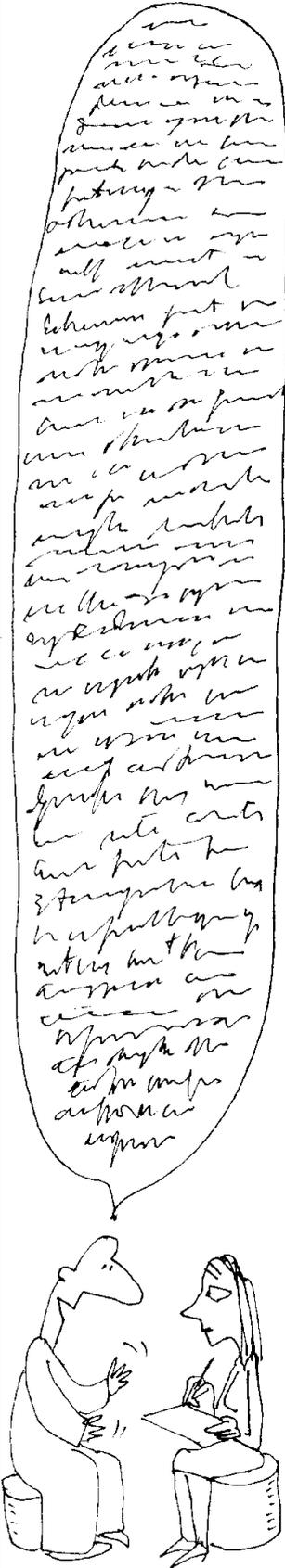
Family members and friends may know about the lives and behaviours of former clients and be willing to report these to evaluators under certain conditions. However, ethical considerations prevent collecting data from third

parties (e.g., family members) without clear, written permission from clients themselves. When this permission has been obtained, third parties approached for an interview should be told why the information is needed and what the consequences will be for the client. Reports from third parties will be most reliable under the same conditions as those identified for client interviews.

A serious limitation to third party interviews is that respondents are often unaware of the behaviours of individual clients. PSU may take place in private or away from family members and friends. Clients may not always tell others what they have been doing. Families and friends may have observed clients in various states of intoxication, however, and be willing to report this to a follow-up worker.

Records kept by police, hospitals, employers, welfare workers and other agencies may indicate contacts with former clients. These records may be accessible if clients have given written permission. The value of these records for treatment outcome studies varies with the type of clients treated. For clients who typically have contacts with criminal justice, health or social agencies records kept by these agencies may show significant changes following treatment. If clients typically have few contacts with these agencies, searches of records may turn up little value. The value of records for outcome measurement depends on their completeness and accessibility. When records are not computerised, or stored alphabetically, a great deal of effort may be needed to abstract relevant information on individual cases.

Recent alcohol use can be detected with a breathalyser or through urine and blood tests. Less recent use of certain psychoactive substances can be detected in urine, blood, and hair samples. Tests of these samples require supplies and equipment for collection of specimens. Access is also needed to properly equipped laboratories. The costs involved may be prohibitive for many programme evaluations.





Outcome evaluation at the system-Level

Recently, more attention has been given to assessing outcomes associated with large networks of treatment programmes. System-level outcome evaluation can involve any of the evaluation designs described above — randomised controlled trial, comparison group, or pre-post test. In practical terms, however, it is difficult to randomly assign clients to one network of services versus another. The most practical design to implement at the system-level is the pre-post design with the same data collected from all programmes in the defined network. Large scale outcome monitoring systems are now operational in the USA and Canada (e.g., Harrison et al., 1996; Policy and Service Consultation Information and Funded Services, 1995). Others are being developed elsewhere. The second case example located in the back of this workbook (by Gossop and colleagues) is a good example of an outcome evaluation at the national system level.

Practical issues are considerably magnified with outcome evaluations at the system-level:

- involvement of a wider range of key groups in the evaluation process and more difficulty achieving consensus on outcomes to be measured
- more involvement of funders and/or payers in developing the evaluation questions.

They may, for example, find it difficult to formulate specific policy questions that they would like addressed

- difficulty identifying relevant outcomes across programmes with widely varying objectives and client populations (e.g., detoxification centres, assessment and referral centres, treatment programmes aftercare programmes, youth programmes, and programmes serving the elderly, the homeless, or multicultural populations)
- more difficulty getting system-wide buy-in to the evaluation process due to fear that the results will be used to restructure the system in dramatic ways and cut programs
- limitations of the pre-post evaluation design in attributing causality to outcomes obtained and fearing that the results will be used inappropriately for policy decisions
- fear among service providers that if outcomes are being measured in a **sample** of agencies the results may not be representative of their program

For these reasons, it is recommended that you consult with an experienced outcome evaluation researcher before attempting a project at the system level.



It's your turn

Put the information from this workbook to use in your own setting or treatment system. Complete these exercises below.

Remember to use the information from Workbooks 1 and 2 to help you complete an evaluation plan. Review that information now, if you have not already done so.

Exercise 1

Think about your treatment programme. List five **general areas** in which you want to know the effectiveness of your programme.

Example: Is our women's programme effective?

1 _____

2 _____

3 _____

4 _____

5 _____

Exercise 2

For each area that you listed above, choose a series of specific questions to ask:.

Example (from above):

- A) Does our women's programme reduce PSU?
- B) Does our women's programme reduce the severity of depressive symptoms?
- C) Among participants, do younger or older women do better?

Now it's your turn. Follow the same procedure for each of the five areas that you listed in Exercise 1.

Exercise 3

Review the questions that you created in Exercise 2. Consider which of these questions are **feasible** to study, and which are **most important** to study in your setting. You should review Workbook 1, Evaluation Planning, for additional information about how to do this. Once you have settled on key ques-

tions, decide how you will measure each of them.

Review potential outcome measures using the appendix in this workbook, other resource manuals, and if possible, consultation with evaluators in the PSU field. Then:

A. Decide which of these data collection methods you will use:

	Yes	No
open-ended items on self-administered questionnaire	<input type="checkbox"/>	<input type="checkbox"/>
one-on-one interviews	<input type="checkbox"/>	<input type="checkbox"/>
focus groups	<input type="checkbox"/>	<input type="checkbox"/>
program documents	<input type="checkbox"/>	<input type="checkbox"/>
clinical observations	<input type="checkbox"/>	<input type="checkbox"/>

B) Decide **how** data will be collected and **by whom**:

Baseline data	Follow-up worker	Follow-up method
blended with clinical assessment	independent evaluator	telephone
separate from clinical assessment	programme staff	face-to-face
but collected by programme staff	volunteer	mail out
collected by external evaluator	flexible depends on client	flexible depends on client

Example (from above):

Data will be collected using self-administered questionnaires and corroborating medical chart data:

a) PSU:

- Questions about frequency, quantity, and type of PSU over the past eight weeks
- Review of medical records for results of intake and discharge toxicology screens

b) Depressive symptoms: The Beck Depression Inventory

c) Age: General demographic questions

All data will be collected by an external evaluator, using face-to-face contact within the clinic building, and separate chart review.

Now it's your turn. Follow the same procedure for each of the questions that you listed in Exercise 2.

Exercise 4

Using the information provided in this workbook about how to design and conduct an outcome evaluation, make the following decisions:

- Choose an evaluation design:
 - experimental
 - comparison group
 - pre-post
- Choose a sampling procedure for choosing clients to survey
- Decide the timing of the evaluation
- Develop a procedure for ensuring clients' confidentiality and promoting their honesty in answering questions.

Example (from above):

- *Given programme resource limitations, a pre-post design will be used.*
- *All clients checking in for their assessment appointment will be asked by staff to meet with an external evaluator while waiting for their appointments. Pre-treatment data will be collected over a three month period of time.*
- *After agreeing to participate, clients will be given the questionnaires, and envelopes in which to place their completed questionnaires before returning them to the evaluator. Clients will be instructed to complete the questionnaires before leaving the clinic that day. The following statement will appear at the top of the questionnaire:*

“Please help us improve our programme by answering some questions about your PSU and related problems. To ensure

your confidentiality, please do not write your name on this form. When you are finished, place the form in the envelope (provided) and seal it closed, then give it to the evaluator in the waiting area.”

- *ID numbers will be used in place of names on all questionnaires. A confidential list will be kept that links these ID numbers with clients' names and contact information. This list will be kept separate from the data, to further ensure client privacy. Three months after discharge from the 8-week programme, the clients will be contacted by the evaluator to schedule a follow-up meeting that is roughly 6 months post-admission. Clients will return to the clinic for this confidential follow-up meeting, where they will complete the same questionnaires and return them to the evaluator.*

Now it's your turn. Follow the same procedure for your evaluation questions.

Exercise 5

You will need to prepare a consent form that explains the purpose of your study. Review Section 1A of Workbook 2, entitled, “Manage Ethical Issues,” for more information about the important topic of participants' rights in evaluation research. Also review Workbook 1, Appendix 2 for an example of an outcome evaluation consent form.

In general, all participants should be asked permission ahead of time before being enrolled in the study. When you do this, you should explain the purpose, nature, and time involved in their participation. No person should be forced or coerced to participate in the study.

The consent form should:

- describe the purpose and methods of the study
- explain what they will need to do if they participate
- explain that participation is voluntary

Now it's your turn. Using the example in Appendix A, and the information provided in Workbook 2, section 1A, write your own consent form.

Exercise 6

Run a pilot test of your evaluation measurement and procedures (including your follow-up interviews) to ensure that everything runs smoothly. Review section 1C of Workbook 2 entitled "Conduct a Pilot Test" for specific information about how to do this. In general, pilot tests assess these questions:

- Do the questions provide useful information?
- Can the questions be administered properly? For example, is it too long or too complicated to be filled out properly?
- Can the information be easily managed by people responsible for compiling the data?
- Does other information need to be collected?

Example (from above):

A pilot test will be run during one clinic day: 3 November. During this day, all patients checking in for an assessment appointment will be asked to complete the questionnaire. Afterwards, their responses will be examined to determine whether they seemed to understand the questions and were answering honestly. All persons involved with dis-

tributing the forms and tallying the data will be interviewed to determine their views on any improvements that could be made in the process and/or to the forms. Follow-up contact procedures and interviews also will be pilot tested.

Now it's your turn. Write down how you will pilot test your evaluation study. Don't forget to review Workbook 2 first!



Conclusion and a practical recommendation

In this workbook, we have outlined the basic principles and practices of outcome evaluation of PSU services and systems. The goals of this type of evaluation are the assessment of change within different dimensions of the client's life and demonstrating that your programme had a role to play in causing these changes. You have learned about the design of outcome evaluations — experimental, comparison group, pre-post — and how your choice of design affects the confidence you have in attributing changes in client's to their participation in your program. You also have learned about other methodological issues important for all types of outcome evaluation.

A word of advice: trade-offs always have to be made to the **rigour** with which you collect and analyse information to answer evaluation questions, and the **amount of resources** available to you. This is especially true for outcome evaluations. Your research goal should be to achieve the best possible information with the expertise and resources available in your setting. Be sure to review your resources carefully before embarking on an outcome evaluation.

After completing your outcome evaluation, you want to ensure that your results are put to practical use. One way is to report your results in written form (described in Workbook 2, Step 4). It is equally important, however, to explore what the results mean for your programme. Do changes need to happen? If so, what is the best way to accomplish this?

Return to the expected user(s) of the research with specific recommendations based on your results. List your recommendations, link them logically to your results, and suggest a period for implementation of changes.

Remember, outcome evaluations provide important information on the effectiveness of your programme. It is important to use the information to improve treatment services. Through careful examination of your results, you can develop helpful recommendations for your programme. In this way, you can take important steps to create a “healthy culture for evaluation” within your organisation.

References

- Addiction Research Foundation. *Directory of Outcome Measures for Addiction Treatment Programs*. Available from Marketing Department, Addiction Research Foundation, 33 Russell Street, Toronto, Ontario, Canada, M5S 2S1, Undated.
- Beck, A.T., Ward, C.H., Mendelson, M., Mock, J., & Erbaugh, J. An inventory for measuring depression. *Archives of General Psychiatry*, 1961, 4:561-571.
- Derogatis, L.R. *SCL-90: Administration, scoring and procedures manual-I for the revised version*. Baltimore: Clinical Psychometrics Research, 1977.
- Harrison, P.A., Beebe, T.J., Fulkerson, J.A., Torgerud, C.R., The development of patient profiles for Minnesota's treatment outcomes monitoring system. *Addiction*, 1996, 91(5): 687-701.
- Institute of Medicine (IOM), Committee for the Study of Treatment and Rehabilitation Services for Alcoholism and Alcohol Abuse. *Broadening the Base of Treatment for Alcohol Problems*, Washington, DC: National Academy Press, 1990.
- McLellan, A.T., Grissom, G., Alterman, A.I., Brill, P., & O'Brien, C.P. (1993). Substance abuse treatment in the private setting: Are some programs more effective than others? *Journal of Substance Abuse Treatment*, 1993, 10:243-254.
- McLellan, A.T., Laborsky, L., Caccida, J., et al. *Guide to the Addiction Severity Index: Background, administration and field testing results*. U.S. Department of Health and Human Services. Rockville, Maryland, 1988.
- McLellan, A.T., Woody, G.E., & Metzger, D. et al. Evaluating the effectiveness of addiction treatments: Reasonable expectations, appropriate comparison. *The Millbank Quarterly*, 1996, 74(1):51-85.
- Policy and Service Monitoring Consultation Information and Funded Services. *Outcome Monitoring System: Outpatient Treatment Procedure Manual*. Edmonton, Alberta: Alberta Alcohol and Drug Abuse Commission, 1995.
- Procidano, M.E., & Heller, K. (1983). Measures of perceived social support from friends and from family: Three validation studies. *American Journal of Community Psychology*, 1983, 11(1):1-24.
- Raistrick, D., Dunbar, G., & Davidson, R. Development of a questionnaire to measure alcohol dependence. *British Journal of Addiction*, 1983, 78:89-95.
- Skinner, H.A. The Drug Abuse Screening Test. *Addictive Behaviors*, 1982, 7:363-371.
- Sobell, L.C., & Sobell, M.B. Time-line followback: A technique for assessing self-reported alcohol consumption. In: R. Litten & J. Allen (Eds.). *Measuring alcohol consumption: Psychosocial and biological methods*. New Jersey: Humana Press, 1992:41-72.
- Sobell, L.C., Toneatto, T., Sobell, M.B., & Shillingford, J. Alcohol problems: Diagnostic Interviewing. In: M. Hersen & S.M. Turner (Eds.). *Diagnostic interviewing* (2nd ed.). New York: Plenum Press, 1992.
- Witcher, H.U. Reliability and validity studies of the WHO-Composite International Diagnostic Interview (CIDI): A critical review. *Psychiatric Research*, 1994, 28: 57-84.

Appendix 2

Outcome measures

Instruments in Appendix 2 are adapted from a data collection protocol for treatment process and outcome monitoring being developed by the Addiction Research Foundation, Ontario, Canada. Information about the instruments can be obtained from: Addiction Research Foundation, 100 Collip Circle, Suite 200, London, Ontario, Canada, N6G 4X8.

These measures are presented as examples only. Reliability and validity data are not available. You must decide on their appropriateness and availability for your clients and your culture. In addition to considering these in-

struments, a review of the ARF Outcome Measures Directory (undated) is highly recommended. This Directory contains many potentially useful instruments for process evaluation and discusses reliability, validity, and practical issues in administration.

Several ARF measures also were adapted for an outcome-monitoring project in Illinois, U.S.A. For more information about these measures, contact Dr. Michael Dennis, Lighthouse Institute, Chestnut Health Systems, 702 West Chestnut, Bloomington, IL, 61701, U.S.A.

Psychoactive substance use

Substance	Average quantity per day of use in past 90 days*	Used in past 12 months (1 = Yes / 2 = No)	Number of days used in past 90 (Days)	Use currently a problem? (1 = Yes / 2 = No)
Alcohol (beer, liquor, wine)				
Cocaine/ crack/ coke				
Amphetamines/ other stimulants				
Cannabis (hash, weed, grass, pot, marijuana)				
Benzodiazepines				
Barbiturates				
Heroin/ opium				
Prescription opioids				
Over-the-counter codeine preparations				
Hallucinogens				
Glue/ other inhalants				
Tobacco				
Other psychoactive substances				

* It may be difficult to quantify the exact amount for certain substances. Indirect estimates can be made from the number of times per day a substance is injected, inhaled, snorted, or smoked.

Risk behaviour

1 Thinking about your use of psychoactive substances, have you:

- Never injected Injected prior to one year ago
 Injected in the last 12 months Unknown

If ever injected, answer the following questions:

i) During the past 90 days, on how many days did you inject any kind of psychoactive substance? days

ii) Have you ever shared a needle, syringe, cooker/spoon or cotton/filter with anyone at any time in your life?

- Yes No No response

If **Yes**, during the past 90 days, on how many days did you share a needle, syringe, cooker/spoon or cotton/filter with anyone? days

During the past 90 days, with how many people have you shared? people

2 How often do you use condoms with your sexual partner or partners?

- Never Sometimes Always

During the past 90 days, how many times have you had unprotected sex? times

3 During the past 90 days, on how many days have you driven a motor vehicle or used a machine at the workplace while under the influence of alcohol or other psychoactive substances? days

Health and correctional service utilisation

1 Thinking about physical health problems, during the past 90 days, how many:

- times have you had to go to the emergency room times
- nights total did you spend in the hospital nights
- times did you have an outpatient surgical procedure times
- times did you see a doctor in an office or outpatient clinic times

2 a) Thinking about mental health problems, during the past 90 days, how many:

- times have you had to go to the emergency room times
- nights total did you spend in the hospital nights
- times did you see a doctor in an office or outpatient clinic times

b) Are you currently in any type of treatment or counselling for mental or emotional problems?

Yes

No

No response

3 Over the last 90 days, how many days have you received alcohol or substance use treatment at the following places?

• a hospital overnight for withdrawal or related problems days

• an inpatient substance use treatment facility (3 -90 days) days

• a long-term (3 to 12 months) residential program or therapeutic community for substance use disorder treatment days

• a methadone or other opioid treatment program days

• an assessment or outpatient substance use treatment facility sessions

• a mental health centre or facility as an outpatient sessions

• an employee assistance program sessions

• a family and/or marital counselling service sessions

• an emergency room days

• a private doctor's office visits

• a prison or jail days

• some other place (please describe _____) days

4 a) How many self-help meetings, (e.g., AA, NA, ACOA) have you attended for your substance use problem in the past 90 days? meetings

b) How many self-help meetings have you attended for issues other than substance use problems in the past 90 days? meetings

5 a) During the past 90 days, how many days have you been on probation or parole or been in jail or custody?

• Probation days

• Parole days

• Jail/prison/closed custody days

• Open custody days

b) During the past 90 days, how many times have you been charged for breaking the law (please do not count minor traffic violations)? times

Were you charged with:	Please check if Yes	# of charges in the last 90 days
• driving while impaired	<input type="checkbox"/>	<input type="checkbox"/>
• drunkenness or other liquor law violation	<input type="checkbox"/>	<input type="checkbox"/>
• possession, distribution, or sale of illegal substances	<input type="checkbox"/>	<input type="checkbox"/>
• sexual assault	<input type="checkbox"/>	<input type="checkbox"/>
• theft (including B&E, theft over and theft under)	<input type="checkbox"/>	<input type="checkbox"/>
• violence against family or others	<input type="checkbox"/>	<input type="checkbox"/>
• major crime	<input type="checkbox"/>	<input type="checkbox"/>
• Other (please describe _____)	<input type="checkbox"/>	<input type="checkbox"/>



Comments about case examples

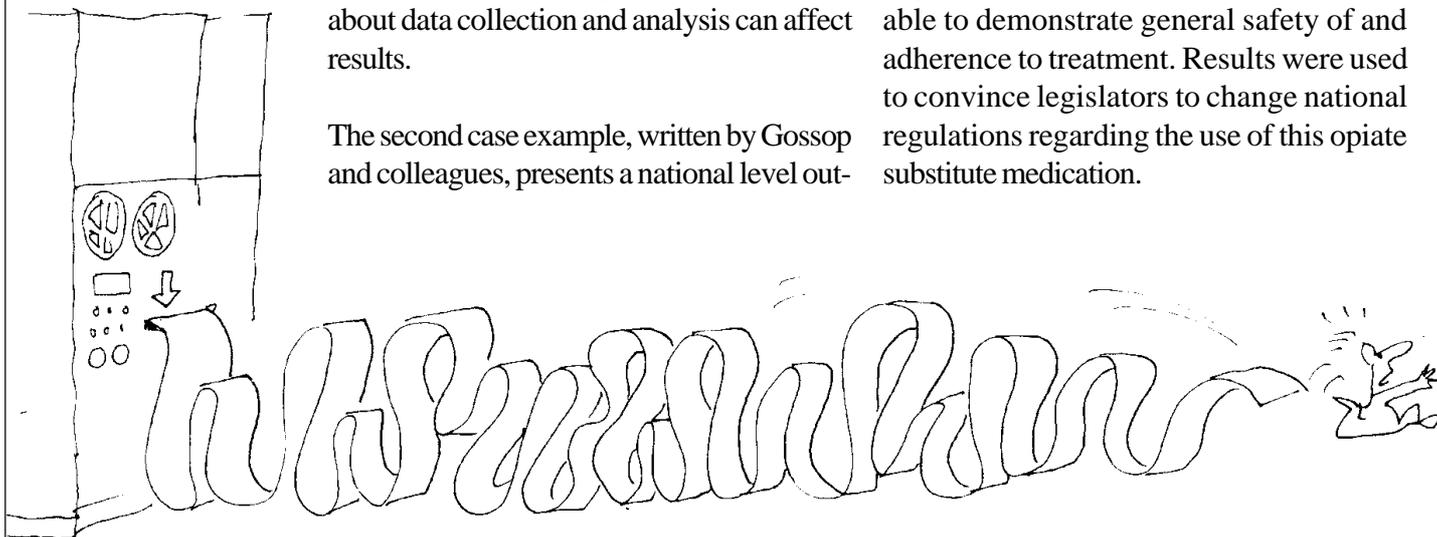
The three following case examples demonstrate different types of outcome evaluations. Each of the evaluations were based on different questions about treatment outcome, and each used different evaluation methods.

The first case example, written by Formigioni and Marques, presents a comparison between group and individual cognitive-behavioural treatment for PS dependence in Brazil. Evaluators used a randomised controlled trial design, a rigorous and technically-challenging type of outcome evaluation. Participants were assessed at their initial intakes, and one year later. Results indicated no significant differences between groups after initial levels of outcome variables were taken into account. Of note, evaluators encouraged all participants to complete follow-up interviews, regardless of whether they finished treatment. They also statistically controlled for initial levels of outcome variables using an ANCOVA technique. Their evaluation decisions, while scientifically rigorous, probably contributed to nonsignificant results. This case underscores the point that decisions about data collection and analysis can affect results.

The second case example, written by Gossop and colleagues, presents a national level out-

come evaluation of four types of PSU treatment in the United Kingdom. The evaluation is large-scale: a total of 54 treatment agencies were selected for inclusion in the evaluation, and over 1,000 clients were recruited for participation. Evaluators chose a naturalistic design: participants were not randomly assigned to treatment groups, but rather, assessed in the context of care that they were already receiving. While naturalistic evaluation designs are considered by many to provide less reliable information about treatment outcome than randomised controlled trials, the authors present a compelling argument for their choice of this design strategy.

The third and final case example, written by Auriacombe and colleagues, describes an outcome evaluation of the use of buprenorphine for people with opiate dependence. Evaluators followed sixteen participants over a one-year period, using a pre-post design. This evaluation strategy has some limitations, such as that it does not control for competing explanations in participants' improvement. Nonetheless, evaluators were able to demonstrate general safety of and adherence to treatment. Results were used to convince legislators to change national regulations regarding the use of this opiate substitute medication.



Case example of outcome evaluation



Comparison between individual and group settings in the cognitive-behavioral therapy for individuals with alcohol and/or drug dependence

The authors alone are responsible for the views expressed in this case example.

by

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Sc.D., researcher from Association of Incentive to Psychopharmacology (AFIP). Financial support from AFIP, a Brazilian non-profit institution.

Who was asking the question(s) and why did they want this information?

The lack of public resources to address health and social problems is a very serious issue in Brazil. Therefore, it is very important to find the most cost-effective solutions for health and social problems, including Addiction treatment. In Brazil,

there is little information available about the effectiveness and cost-effectiveness of Addiction treatment. Traditionally, people who are drug and alcohol dependent are treated either by psychiatrists at private offices/clinics or at public mental health hospitals. Most are based on the Minnesota model, including 28-day to three-month inpatient care, and participation in AA meetings. The less severe cases are usually referred to outpatient intervention, available at private offices (individual setting) or public health units (group setting).

Since 1989, brief interventions have been compared with more traditional models to treat alcohol/drug dependence in Brazil. The Brief Intervention Model proposed in Canada by Sanchez-Craig (1984, 1990) and Sanchez-Craig et al (1984, 1987, 1989) was adapted to Brazilian conditions under the supervision of those authors at the turn of this decade (1989-1991). After that experience, further adaptations were performed in order to fit the needs of Brazilian clients (Formigoni et al., 1992, Formigoni & Neumann, 1993, Sanchez-Craig et al. 1991). After some changes to the treatment model (e.g., increased number of sessions and more comprehensive approach) this technique is now closer to what can be called a brief cognitive-behavioural therapy.

In order to estimate the effectiveness of the adapted treatment model, the co-ordinator and the staff of UDED (Drug Dependence Unit — Department of Psychobiology — Federal University of São Paulo — Brazil) decided to perform an outcome evaluation. They decided to undertake a randomised control group trial to evaluate the effectiveness of the method currently used to treat substance abusers and dependants. The most important factor to be studied was the influence of setting (individual or group sessions) on outcome. Also of interest were the characteristics of the clients who responded to this kind of treatment with a good attendance record. Should the group setting outcome turn out to be similar to the outcome in individual settings, the former would be selected as a “standard”, since the cost per client is significantly lower. Individual setting would only be available to “special” cases.

The main questions to be answered with information from the evaluation process were:

- How effective was the cognitive-behavioural therapy utilised for alcohol and/or drug dependent clients?
- Did clients who completed treatment decrease their alcohol and drug use significantly one year after assessment?
- Did clients who dropped out during treatment differ from those who completed treatment on their initial characteristics (drug abused, dependence level, associated problems)?
- Was outcome better for those who completed treatment than for those who dropped out?
- Was there a difference between individual and group settings on client attendance at treatment or the outcome?
- Did the kind of substance abused influence the attendance rate or the outcome?



What resources were needed to collect and interpret the information?

UDED staff developed the evaluation process, after having received the training to do so. The data were inputted by a secretary on a DbaseIII-Plus datafile, as they were being collected (at assessment, during treatment and at follow-up interviews). The UDED co-ordinator and a post-graduate student spent about 500 hours extracting data, performing all statistical analyses and writing reports in a personal computer.

The UDED team (2 psychiatrists, 2 psychologists and 1 secretary) was supported by the Association of Incentive to Psychopharmacology (AFIP) a NGO non-profit organisation.

How were the data collected?

Design of outcome evaluation

The staff chose a quantitative approach — a randomised control group design — to perform the outcome evaluation.

Sample selection: The study included clients admitted to treatment between 1993 and 1994. Given the characteristics of the program, only clients with no serious physical or psychiatric disorders were admitted, provided they met DSMIII-R criteria (APA, 1987) for alcohol and/or drug abuse or dependence, had at least 4 years of formal education, had a fixed address and agreed to participate in the follow-up evaluation.

Sample size: Previous data showed that about 30% of alcohol/drug dependent individuals admitted to the individual setting treatment were considered “successful” one year after assessment. To assess the influence of setting (group vs. individual), we established that a difference of 15% between settings would be considered of practical significance. We also wanted to be 95% certain that differences observed were not due to chance (alpha error rate = 0.05), and that in the case where groups being considered were similar, the possibility of this happening by chance would not be over 20% (beta error rate of 0.20). With these data, we calculated the sample size utilising the Process Analysis module of the statistical software CSS:Statistica (Statsoft, 1991). The minimum “N” calculated was 58 clients per group. It is important to consider this as the expected sample size for each group at follow-up. Considering a probable 30% dropout rate, it was calculated that the minimums of 75 clients were required per group. The data were collected by each professional in charge of assessment, treatment and follow-up of clients, and recorded in standardised forms.

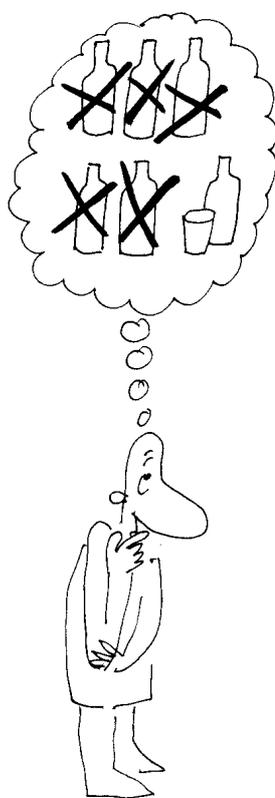
General procedure: After the initial assessment to determine whether clients would be

admitted or referred elsewhere, clients were randomly assigned to one of the two setting modalities (individual vs. group) by a previous lot. A follow-up evaluation was performed approximately one year after assessment.

The initial assessment: The initial assessment data were collected by one of the two psychiatrists trained to do so. The interview included a comprehensive alcohol and drug use history of the client, client’s social and demographic characteristics, drug dependence diagnosis according to DSMIII-R criteria (APA, 1987) plus a clinical and psychological evaluation. The drinking history for the past 90 days, and also a lifetime alcohol and other drugs history were obtained by means of a standardised inventory, adapted from Martin et al. 1991. The drug use was categorised according to an index of drug use severity (Wilkinson & LeBreton, 1986). The SADD (Short Alcohol Dependence Data - Raistrick et al., 1983) was used to evaluate adverse consequences of alcohol use. A standardised medical examination was done including laboratory tests (GGT, ALT, AST and MCV). After the medical interview, clients underwent psychological testing (Rainho, 1962, Weschler, 1987, Moraes et al., 1992) to ensure their adequate cognitive capability, since this is required by the technique. The tests were applied by graduate students of psychology under the supervision of a specialised psychologist. All clients with severe medical or psychiatric problems who needed inpatient care were referred to other specialised services.

During the interview, clients were informed about the main objectives of treatment, that their data would be included in a Research protocol, and their confidentiality would be preserved. They signed a consent form authorising the staff to use their data and agreed to provide blood and urine samples for laboratory tests (hepatic enzymes and drugs/HIV detection). They also provided a name of a collateral person to be contacted at follow-up.

Treatment procedures: The treatment was developed in 17 sessions, over a six-month period. One session per week was held in the first three months. The sessions in the fourth and fifth months were held every two weeks and in the sixth month, one session was held. The first treatment session was in an individual setting for both groups. It included a review of assessment data, a discussion about laboratory results and orientation about changes that could be expected if alcohol/drug use were to be reduced. The clients' concepts about their problems related to substance abuse were discussed, followed by the therapist presentation of key concepts and proposals. This included the concept that excessive drug/alcohol use is considered a learned habit that people could change with some effort. A therapeutic contract was then presented, including some rules about attendance at therapy sessions and homework assignments. After this, clients signed a consent to participate in which they authorised the use of their data having been assured that confidentiality would be preserved.



The therapist pointed out the need for abstinence from alcohol and drugs as the initial goal for the first three months of treatment. For alcohol dependent clients, the possibility of moderation as a long-term goal was discussed when clients expressed desire for reduction and not for total abstinence. This possibility was only to be considered if clients presented normal laboratory tests and no physical/psychological alterations at clinical examination.

After this initial session, half of the sample was randomly assigned to the individual setting and the other half to the group setting. The groups remained open during the first month, receiving up to 10 clients. After this period of time, the group was closed with any number of bigger than three.

The treatment was developed in 17 sessions over a six-month period, divided into two phases: acquisition and maintenance. The first eight sessions were considered the acquisition period, in which the clients should acquire skills to recognise their problems and

to develop strategies to cope with them. It included procedures such as: identification of risk situations (using the Inventory of Drinking Situations - Annis & Graham -1987) and the roles attributed to drug use; self-monitoring of alcohol/drug use utilising a self-monitoring card; identification of possible means of support and strategies for reaching the goal; evaluation of the use and effectiveness of strategies, etc.

After clients were trained to develop effective ways of coping with risk situations, they entered the "maintenance phase". The purpose of this phase was to ensure the maintenance of improvements accomplished by clients and to encourage them to continue using strategies developed in the previous phase.

Treatment attendance data: The attendance at treatment sessions was recorded on special client forms. At each session, the therapist filled out a form in which the following data were considered: level of alcohol/drug consumption; if the goal was being reached; work/school, family, leisure, physical, psychological and legal situations.

Follow-up data: The follow-up evaluation was done by the same professional who had interviewed him/her at assessment but was not involved in treatment. Clients were invited to come to a face-to-face interview similar to that performed at initial assessment (including laboratory tests). If the client refused to come, at least a phone interview was tried.

During the follow-up interview, clients were also asked to make a self-evaluation about their current alcohol/drug problems, in which they considered their current status in relation to assessment, classifying themselves as "successful", "improved" or "unimproved/worse". They were also asked to evaluate the treatment's contribution to their improvement.

A collateral recommended by the client was also interviewed by an independent person, in order to give objective data about the client's alcohol/drug consumption and problems.

How were the data analyzed?

Data base: The data were transferred to a statistical package (CSS/Statistical) after a careful check to prevent missing or out of range data inclusion.

Statistical methods: The comparisons between the two different setting groups were made by the student's "t" test for independent samples, when variables taken into account were measured at least in an interval scale. If the substance being abused was included in the analysis, a two-way ANOVA (Analysis of Variance) was made, followed by post-hoc tests (Duncan's multiple range test). When differences between groups were detected at assessment, the initial values were considered covariate variables in the follow-up comparison.

The Mann Whitney U-test was utilised when variables were measured at an ordinal level or if there was not a normal distribution of values. Comparisons of frequencies between groups were made using the Chi-square (X^2) test. Comparisons between pre- and post-treatment data were made by the t-test for dependent samples (interval measurements), Wilcoxon matched pairs test (ordinal measurements), MacNemar's chi-square test or Cochran q test (nominal measurements). The same kind of procedure was done to compare treatment attenders and non-attenders. In all cases, the level of significance considered was 5%.

Spearman Rank Order coefficients were calculated to explore relationships between assessment and outcome variables in order to look for predictors of success and compliance to treatment.

What did they find out?

Before comparing settings (individual vs. group) at follow-up, samples were compared on their assessment data and treatment attendance. Data collected at follow-up were

then compared with those collected at assessment (intra-group analysis).

Client characteristics: The study included 155 clients admitted to treatment between 1993 and 1994 and evaluated at least one year afterwards. Half of them (77) were treated in an individual setting and the others (78) in a group setting. The two samples were similar in relation to all characteristics at the initial assessment.

Table 1 shows the main social-demographic characteristics of both samples, divided into two groups, according to main substance abused: "alcohol" (only alcohol abuse or dependence) or "drugs" (other drug dependence including alcohol or not). Most clients were men, employed, with 10 years of formal education (varying from 4 to 24 years) and had monthly incomes over US\$500. Drug dependants differed from alcohol clients in age (younger) and marital status (more were single).

Table 2 presents data on social relationships, living arrangement, family and personal substance abuse and a history of psychiatric disorders. Most clients lived with family, had a positive family history of alcohol and/or drug abuse, and had previously participated in other treatments. About 30% presented some kind of psychiatric disorders or had participated in psychiatric treatment in the past. Only three clients from the alcohol group (individual setting) scored below average in the psychological tests. All others presented normal scores.

Table 3 shows dependence levels diagnosed at initial assessment. No differences between settings or drug groups were detected. Proportions of clients with psychological and physical disorders, according to physician's clinical diagnosis, are also presented, as are the mean values (\pm standard deviations) of laboratory tests. It can be observed that many alcohol dependent clients showed altered MCV, GGT, GTO and GTP. Drug dependants presented lower percentage of altered tests and equal or lower mean levels.

Treatment attendance data: Clients were considered “treatment attenders” if they showed up for at least eight sessions (which would correspond to acquisition phase). Clients were considered to be “complete attenders” if they attended on a regular basis until the last session (17th session) and “partial attenders” if they completed at least the acquisition period (first eight sessions) and dropped out during the maintenance phase.

Table 4 shows the main attendance data for both groups, divided according to drug abused. Alcohol dependent clients treated in group setting tended to have higher attendance than those treated individually ($p <$

0.06, Fischer exact p , one-tailed) and also a significantly higher attendance than drug dependants treated in group ($X^2 = 5.9$ $p < 0.05$). However, regarding drug dependants, no significant differences in attendance rates were observed between the settings. The average number of sessions was similar (7 ± 8) for both settings, but it was observed that alcohol clients attended significantly more sessions than drug dependants. This difference was particularly clear in the group setting. Considering only the clients treated in group, if complete attenders are compared with the others (dropouts at acquisition + partial attenders), a significant difference in attendance is de-

TABLE 1: Sociodemographic characteristics of the sample. Percentage of clients.

Setting Substance abused	INDIVIDUAL		GROUP		TOTAL	
	Alcohol	Drugs	Alcohol	Drugs	Alcohol	Drugs
Number of clients	31	46	36	42	67	88
Age (mean \pm sd)	40 \pm 8	26 \pm 8 ^②	41 \pm 8	24 \pm 7 ^②	41 \pm 8	25 \pm 8 ^②
Sex						
male	77.4	84.8	94.4	90.5	94.4	90.5
female	22.6	15.2	5.5	9.5	5.6	9.52
Marital status						
single	19.4	63.0 ^①	5.5	69.0 ^①	19.4	65.9 ^①
married	61.2	30.5	19.5	11.9	59.7	21.5
separated	19.4	6.5	58.3	19.1	20.9	12.5
Employment status						
employed	64.5	60.8	72.2	66.7	68.6	63.6
unemployed	25.8	26.1	16.6	28.5	20.8	27.3
retired	0	0	5.6	0	2.9	0
student or other	9.7	13.1	5.6	4.8	7.4	9.1
Education (years)						
up to 8	35.5	41.3	47.2	45.2	41.8	43.2
9 - 11	22.6	43.5	16.6	33.4	19.4	38.6
college	41.9	15.2	36.2	21.4	38.8	18.2
Income (US\$)						
100 - 499	25.8	39.1	27.8	21.4	26.9	30.7
500 - 999	25.8	13.0	19.4	21.4	22.4	17.0
1000 or +	48.4	47.9	52.8	57.2	50.7	52.3

No differences between settings were detected.

Comparisons between alcohol and drugs in the same setting or total sample:

① $p < 0.05$ comparison by X^2

② $p < 0.05$ comparison by Student's t test for independent samples

tected between alcohol and drug dependants ($X^2 = 4.7$ $p < 0.03$), showing the low complete attendance of drug clients in the group setting (19%).

All subgroups presented similar referral and dropout rates. About 50% of the clients completed at least the acquisition period. Seven percent of the clients dropped out after the first treatment session.

Treatment attenders (partial + complete attenders) and non-attenders (dropouts at acquisition) were compared in relation to sociodemographic data, severity of dependence and associated problems so that possible attendance predictors could be detected. They were compared by the X^2 test or t-test for independent samples according to the level of measurement (categorical or continuous variables). The main findings are summarised in Table 5. Clients who dropped out were slightly younger (31 years old) than

those who completed treatment (36 years old). Although statistically significant ($p < 0.04$) this difference has little relevance. On the other hand, very recent cocaine use and the presence of cocaine related problems were also associated with a low level of treatment attendance. While 74% of clients who reported cocaine use in the last 24-48 hours before the initial assessment dropped out, the dropout rate of those who had not used cocaine during that period was significantly lower (42%) ($X^2 = 7.0$ $p < 0.01$).

When considering all clients dependent on cocaine, it was observed that 40% of those who dropped out had reported very recent cocaine use at the assessment interview; this proportion being lower among those who attended treatment (about 13%). Among the clients dependent on cocaine, those who reported only nasal use presented higher attendance than those who reported only

TABLE 2: Social relationships, living arrangement, family and personal substance abuse and psychiatric disorders history. Percentage of clients.

Setting Substance abused	INDIVIDUAL		GROUP		TOTAL	
	Alcohol	Drugs	Alcohol	Drugs	Alcohol	Drugs
Living arrangement	31	46	36	42	67	88
Sex						
alone	16.1	4.3	13.9	9.5	14.9	6.8
family	80.6	93.5	83.3	88.1	82.1	90.9
friends	3.3	2.2	2.8	2.4	3.0	2.3
Relationship with family or significant others						
good	29.0	23.9	38.9	35.7	34.3	29.5
regular	54.8	60.8	41.7	40.5	47.8	51.1
bad	3.2	10.9	5.5	14.2	4.5	12.5
not applicable	13.2	4.4	13.9	9.6	13.4	6.9
Positive family history of alcohol/drug abuse						
	83.9	93.5	91.7	90.5	88.0	92.0
Positive psychiatric antecedents/treatments						
	29.0	26.1	22.2	33.3	25.4	29.5
Previous treatments for alcohol/drug abuse						
	67.7	43.5 ^①	63.9	38.1 ^①	65.7	40.9 ^①

No differences between settings were detected.

① differs from alcohol group ($X^2 = 9.3$ $p < 0.002$)

TABLE 3: Substance dependence level (according to DSMIII-R criteria) and associated problems according to physician's assessment. Percentage of clients.

Setting	INDIVIDUAL		GROUP		TOTAL	
	Alcohol	Drugs	Alcohol	Drugs	Alcohol	Drugs
Dependence level (DSMIII-R)#						
light dependence	0	2.2	0	7.1	0	4.5
moderate dependence	29.0	30.4	44.4	42.8	37.3	36.4
severe dependence	71.0	67.4	55.6	50.1	62.7	59.1
Psychological disorders						
	54.8	32.6 [Ⓜ]	30.6	21.4	41.8	27.3 [Ⓜ]
Physical disorders						
	71.0	43.5 [Ⓜ]	80.6	51.2 [Ⓜ]	71.6	43.2 [Ⓜ]
Laboratory tests (ML)						
GGT (28UI/l)	116 ± 263	22 ± 16	88 ± 164	18 ± 14	101 ± 214	20 ± 15 [Ⓜ]
% of altered tests	58.1 [Ⓜ]	26.1	63.9 [Ⓜ]	9.5	61.2	18.2
GTO (19UI/l)	35 ± 28	28 ± 45	34 ± 52	17 ± 13	35 ± 43	23 ± 34
% of altered tests	51.6	44.4	58.3 [Ⓜ]	14.3	55.2	29.5
GTP (24 UI/l)	24 ± 18	27 ± 55	27 ± 21	19 ± 25	26 ± 20	23 ± 43
% of altered tests	38.7	22.2	41.7 [Ⓜ]	14.2	40.2	18.2
MCV (95 fl)	99 ± 7	96 ± 11	92 ± 6	95 ± 5	98 ± 7	91 ± 9 [Ⓜ]
% of altered tests	67.8 [Ⓜ]	15.2	55.6 [Ⓜ]	28.6	61.2	21.6

considering the main substance abused

[Ⓜ] X² p<0.001 drug comparison (alcohol vs. drugs) in the same setting

ML= Maximum limit of normality

the means in bold type are out of normal values

[Ⓜ] Student's t-test p<0.05 for drug comparison (alcohol vs. Drugs) in the same setting or in the total sample

TABLE 4: Attendance to treatment - Number and percentage of clients in each category.

Setting	INDIVIDUAL			GROUP			TOTAL		
	Alcohol	Drugs	Total	Alcohol	Drugs	Total	Alcohol	Drugs	Total
Number of clients	31	46	77	36	42	78	67	88	155
Complete attenders	22.6	15.2	18.2	44.5	19.0 [Ⓜ]	30.8	34.3	17.0 [Ⓜ]	24.5
Dropouts at acquisition	54.8	52.2	53.2	33.3	50.0	42.3	43.2	51.1	47.7
Partial attenders (only acquisition)	22.6	32.6	28.6	22.2	31.0	26.9	22.3	31.9	27.7
Attenders (partial + complete attenders)	45.2	47.8	46.8	66.7	50.0	57.7	56.7	48.9	52.2
Referred	16.1	10.9	13.0	11.1	16.7	14.1	13.4	13.6	13.5
Number of sessions (average ± sd)	8 ± 5	6 ± 4	7 ± 4	9 ± 5	6 ± 5 [Ⓜ]	8 ± 5	9 ± 5	6 ± 4 [Ⓜ]	7 ± 5

[Ⓜ] Differs from Alcohol group p<0.002 (X² test)

** Differs from Alcohol group p<0.002 (Student's t-test)

TABLE 5: Clients previous characteristics and drug history as predictors of treatment attendance.

VARIABLES	ATTENDANCE CATEGORY			p level
	Complete attenders	partial attenders	dropouts at acquisition	
Age (years - mean \pm sd)	36 \pm 11	30 \pm 10	31 \pm 11	0.04
Recent cocaine use (48 hours before assessment)	12%	14%	40%	0.06 (n.s.)
Cocaine mode of administration oral or nasalsmoked, injected or more than one	67% 33%	45% 55%	28% 72%	0.03
Previous treatment	66%	49%	46%	n.s.
Substance abuse in the family	24%	28%	48%	0.01
Problems related to cocaine use	67%	72%	91%	0.03
Lived alone	8%	7%	13.5%	n.s.

smoking (“crack”), i.v. use or more than one mode of administration. Although not statistically significant, a higher proportion of treatment attenders reported having had previous treatment when compared to the dropout clients. The clients who dropped out were more likely to have cocaine-related problems and more relatives with drug problems. Although few clients lived alone, the dropout rate was higher among them than among those who lived with family or friends. Among clients who lived alone only 37.5% complete the treatment, while 54% who lived with family or friends did so.

It was observed that the initial level of dependence, the average weekly number of drinks and severity of drug consumption index were not good predictors of treatment attendance. However, clients who were light or moderate dependants on alcohol tended to present with a better attendance rate (68%) than severely dependent ones (50%).

The average number of drinks/week at initial assessment was similar for attenders (35 \pm 31) and non-attenders group (33 \pm 39).

Follow-up data analysis

Follow-up attendance: After analysing the data regarding attendance to treatment, attendance to follow-up was studied. This procedure is very important to prevent wrong conclusions that could be reached if the follow-up attenders’ population was too much different from the initial sample in relation to some characteristics. About 70% of the sample (106 clients) attended follow-up evaluation, as can be seen in Table 6. The follow-up evaluation was scheduled to take place 12 months after assessment. However, just 8% of the clients attended on that occasion. Most of them (68%) were evaluated between 12 and 17 months after assessment. There was no difference between groups in relation to time elapsed between assessment and follow-up interviews (individual setting: 16 \pm 3 months and group setting 15 \pm 3 months).

The average number of effective contacts needed to schedule a follow-up interview was similar (2.5 \pm 1.8 for individual and 3.1 \pm 2.1 for group setting). The number of con-

TABLE 6: Attendance to follow-up. Percentage of the initial sample (155 clients) according to setting and substance abused.

FOLLOW-UP ATTENDERS			
Substance abused (n at follow-up)	Alcohol (n = 52)	Drugs (n = 54)	Total (n = 106)
INDIVIDUAL	74	61	66
GROUP	81	62	70
TOTAL	78	61	68

tacts in which it was not possible to talk directly with clients or their collaterals was not computed. Up to eight contacts were necessary to “convince” some clients to attend the interview. Only 29% of individually treated clients and 31% of group treated ones scheduled the follow-up interview at the first contact.

The data collected on assessment from follow-up attenders and follow-up non-attenders were compared. Follow-up attenders presented with lower level of satisfaction with their physical health and family relationship, reported more previous treatments (mainly AA participation) and were more religious than non-attenders. No significant differences in relation to alcohol or drug use variables were detected. The samples were not comparable in relation to attendance to treatment. The average number of treatment sessions attended were 8 ± 5 for follow-up attenders and 5 ± 4 for follow-up non-attenders. Considering the attendance categories, 61% of follow-up non-attenders were dropouts and just 4% were complete treatment attenders. Among follow-up attenders, 34% had completed the whole treatment and 24% had completed at least the acquisition phase. This analysis allowed us to determine more accurately the kind of clients to whom our conclusions could be extended.

Comparison of samples at follow-up

With regards to the 106 followed-up clients, a comparison of initial data and outcome measures was made between those treated individually and those treated in group. Besides, a pre-post treatment comparison was also made for each group.

The two main broad domains in which changes were supposed to occur determined the selection of outcome measures: reduction of alcohol/drug use and improvement in personal/social function. To evaluate alcohol and drug use, both amount (number of drinks) and frequency (number of days and uses by day of use) were analysed. The evaluation of personal/social function was made by analysing severity of dependence (SADD and DSMIII-R classification), clients' self-evaluation and collaterals' evaluation. The demographic characteristics (such as age and socio-economic status), severity of dependence, number of treatment sessions attended and initial pattern/consumption level of substances abused were analysed as predictor variables of “success”.

Alcohol consumption: All measures referred to a time period of 90 days prior to interview, both at assessment and follow-up. Numbers of drinking days, heavy drinking days, problem drinking days as well as the

TABLE 7: Alcohol consumption at assessment and follow-up. The values are mean \pm standard deviation or percentage of followed-up clients (alcohol and drug dependants).

Alcohol consumption frequency (last 90 days)	ASSESSMENT		FOLLOW-UP		ANOVA ^②		
	INDIVIDUAL	GROUP	INDIVIDUAL	GROUP	F gr	F oc	F interaction
Number of drinking days	47 \pm 36	51 \pm 31	30 \pm 31 #	29 \pm 28 #	0.07	30.4 ^①	0.56
Number of heavy drinking days	29 \pm 34 ^①	40 \pm 32	11 \pm 22 #	20 \pm 26 #	4.62 ^①	29.1 ^①	0.08
Number of problem drinking days	12 \pm 21 ^①	21 \pm 20	4 \pm 12	7 \pm 13 #	3.46	25.3 ^①	2.08
Mean weekly consumption (drinks/week)	30 \pm 36 ^①	43 \pm 33	12 \pm 22 # ^①	19 \pm 22 #	5.12 ^①	33.2 ^①	0.74
Abstinent/moderate rates (%)					X ²	X ²	
only alcohol dependants	17%	3%	85% ^①	50%	1.58	6.7 ^①	
alcohol and other drugs dependants	68%	65%	92%	75%	0.04	2.7	
all clients	45%	33%	89% ^①	62%	1.22	10.0 ^①	

① differs from group treated clients (t-test (means) or X²(rates) p<0.05) at the same occasion

differs from the assessment (“t” test for dependent samples or Wilcoxon matched pairs test p<0.05)

② Between-within ANOVA Fgr = F group (individual x group); Foc = F occasion (assessment x follow-up); Fint = F interaction (group x occasion)

① indicates statistical significance (p<0.05)

Note: If the initial values are considered “covariates” (ANCOVA) no significant differences are detected between individual and group setting in the variables: mean weekly consumption, number of drinking days, problem drinking days and heavy drinking days at the follow-up.

TABLE 8: Laboratory tests according to group (Part A) and drinking categorization (Part B) of followed-up clients at assessment and follow-up.

Alcohol dependants	Part A - Setting categorization				Part B - Drinkers categorization			
	ASSESSMENT		FOLLOW-UP		ASSESSMENT		FOLLOW-UP	
	Individual	Group	Individual	Group	Abstinent/Moderate	Heavy	Abstinent/Moderate	Heavy
MCV (95 fl)	98 \pm 9	97 \pm 6	97 \pm 9	91 \pm 4	24 \pm 47	97 \pm 216 ^③	20 \pm 15	57 \pm 73 ^③
GGT (28UI/l)	87 \pm 119	109 \pm 201	34 \pm 28	43 \pm 60#	25 \pm 47	32 \pm 30	14 \pm 5	27 \pm 28 ^③
GTO (24 UI/l)	38 \pm 37	44 \pm 64	32 \pm 35	16 \pm 10	16 \pm 46	28 \pm 29 ^③	18 \pm 16	35 \pm 41 ^③
GTP (19 UI/l)	20 \pm 15	32 \pm 22	21 \pm 11	22 \pm 13	91 \pm 12	96 \pm 7 ^③	90 \pm 5	93 \pm 7
Drug dependants								
MCV (95 fl)	87 \pm 17	92 \pm 5	90 \pm 5	90 \pm 6				
GGT (28UI/l)	19 \pm 13	20 \pm 15	17 \pm 9	21 \pm 12				
GTO (24 UI/l)	19 \pm 11	20 \pm 19	15 \pm 6	21 \pm 25				
GTP (19 UI/l)	15 \pm 9	22 \pm 32	19 \pm 17	28 \pm 39				

Part A: # differs from itself at assessment (Student’s paired “t” test p<0.05)

Part B: ③ differs from abstinent/moderate drinkers (Student’s “t” test or Mann-Whitney “U” test p<0.05) at the same occasions

mean weekly consumption (drinks/week) were analysed. Based on these measures, a categorisation of alcohol consumption (“abstinent/moderate” vs. “heavy”) was made and used to compare clients treated in group with those that were individually treated. Alcohol dependent clients were considered “abstinent/moderate” drinkers if they didn’t exceed 20 drinks/week, with no more than 10% of heavy drinking days (of 5 + drinks).

Clients exceeding either of these cut-offs were considered “heavy” drinkers. Drinker categorisation was corroborated by laboratory tests, i.e., the clients classified as “heavy” drinkers presented significantly higher levels of hepatic enzymes than those considered “abstinent/moderate” (see Table 8).

Table 7 summarises the main results. Group-treated clients presented slightly higher levels of alcohol consumption, both at assessment and at follow-up. In comparison with individually-treated clients, they showed a significantly higher number of heavy drinking days (at assessment) and mean weekly consumption. However, if assessment levels are considered “covariates” in follow-up data analysis, differences between settings disappear. This statistical procedure allows one to “control” the initial difference in alcohol consumption levels observed between the settings. Significant reductions were observed in both settings when assessment data were compared with follow-up data in the variables: number of drinking days, heavy drinking days and mean weekly consumption. Only group-treated clients presented a significant reduction in the number of problem drinking days, probably due to its higher initial level. At follow-up, both settings were similar.

With regards to client categorisation as “abstinent/moderate” or “heavy” drinkers, significantly higher rates of “abstinent/moderate” were observed in individually treated clients. This could be partially due to the higher initial consumption (heavy drinking days and mean weekly consumption) observed in

group setting clients. If these rates are calculated in relation to the initial sample (155 clients), considering all the follow-up non-attenders as “unsuccessful” cases, the “alcohol consumption success” rate was 45% for individually treated clients and 33% for group treated ones. When considering only the 106 followed-up clients, the alcohol consumption success rates are 89% (individual setting) and 62% (group setting).

Laboratory tests: Although a significant difference was observed between initial and follow-up alcohol consumption, just GGT levels were significantly different, at follow-up, from those observed at assessment. However, if abstinent/moderate GGT, MCV and GTP levels were compared between abstinent/moderate and heavy drinkers, significant differences were detected at both phases (assessment and follow-up) (Table 8), corroborating client categorisation.

Drug consumption: The measures utilised to evaluate drug use were: IDUS (Index of Drug Use Severity) (see Appendix 1) and frequency of use (months per year, days per month and uses on a typical day of use). Table 9 shows IDUS and individual ratings for the most often used drug classes (alcohol, cannabis and cocaine) at assessment and follow-up in both settings. A significant improvement in relation to their initial values was observed in both groups in all variables. Drug dependants were considered “successful” if they showed a maximum IDUS of 0.11 (considering their drug use) or 0.22 (if they just used alcohol). The “success” in relation to drug use was 65% of followed-up clients in the individual setting, and 52% in the group setting.

The outcome measures related to personal/social functioning evaluated were: SADD (Short Alcohol Dependence Data), severity of dependence according to DSMIII-R and mean ratings of satisfaction clients attributed to their physical and emotional health, social relationships, work, leisure, financial and legal situations.

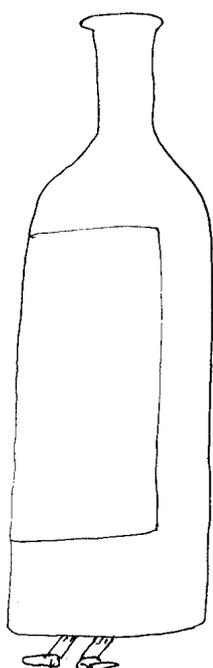


Table 10 shows dependence levels attributed to clients, according to DSMIII-R criteria, for each drug, at assessment and follow-up. Considering the highest level of dependence (for those who were diagnosed as dependent on more than one drug) the “success” (partial or total remission) was similar between settings (50% for individual setting and 45% for group setting). Considering severity of dependence of each class of drug (scoring -2 for total remission, -1 for partial remission, 0 for abuse, 1 for light dependence, 2 for moderate dependence and 3 for severe dependence), it was observed that both groups presented significant improvements when compared to their initial values (Wilcoxon matched pairs test) with regards

to their alcohol and cocaine but not cannabis dependence. This could be due to the small number of cannabis dependants actually evaluated and to their initial low dependence level. Furthermore, no difference was found between group and individual treatment settings. The remission rates of alcohol dependants were similar between settings (41% and 38% for individually and group-treated, respectively) and slightly superior in the individually-treated drug dependants (60% for cannabis and 62% for cocaine) when compared with the group treated ones (50% for cannabis and 54% for cocaine).

The SADD average scores were similar between settings. Significant reductions in rela-

TABLE 9: Drug consumption (during the previous year) at assessment and follow-up. The values are mean — standard deviation or percentage of drug dependent followed-up clients.

Drug consumption	ASSESSMENT		FOLLOW-UP	
	INDIVIDUAL	GROUP	INDIVIDUAL	GROUP
Index of Drug Severity (IDUS)	0.57 ± 0.3	0.60 ± 0.2	0.25 ± 0.2 #	0.30 ± 0.2 #
Alcohol use				
months per year	11 ± 2	11 ± 2	8 ± 5 #	8 ± 5 #
days per month	22 ± 10	19 ± 11	12 ± 11 #	11 ± 9 #
uses per day	9 ± 7 ^①	11 ± 4	4 ± 6 #	7 ± 6 # ^①
alcohol IDUS rating	2.4 ± 1.4 ^①	3.0 ± 1.3	1.2 ± 1.0 #	1.5 ± 1.3 #
Cocaine use				
months per year	11 ± 2	9 ± 4	6 ± 5 # ^①	4 ± 4 #
days per month	21 ± 9 ^①	16 ± 11	9 ± 11 #	8 ± 10 #
uses per day	3 ± 3	3 ± 3	1 ± 1 #	1 ± 2 #
cocaine IDUS rating	1.8 ± 1.9	1.8 ± 1.9	0.9 ± 1.4 #	0.9 ± 1.5 #
Cannabis use daily frequency				
months per year	9 ± 3 ^①	7 ± 4	3 ± 4 #	4 ± 5 #
days per month	12 ± 12	10 ± 11	3 ± 5 #	6 ± 9 #
uses per day	2 ± 2	1 ± 1	0.5 ± 0.8 #	0.9 ± 1 #
cannabis IDUS rating	0.8 ± 1	6 ± 1	0.2 ± 0.5 #	0.3 ± 0.7 #
Alcohol and drug use “success” categorisation (%) (General IDUS ± 0.22)	9%	4%	65% #	54% #

① differs from group treated clients (t-test for independent samples or Mann-Whitney U test p<0.05) at the same occasion

differs from the assessment (t-test for dependent samples, Wilcoxon matched pairs test or Mc Nemar chi-square test p<0.05)

tion to initial levels were observed at follow-up for both groups.

Satisfaction scores: The clients were requested on both occasions to grade their satisfaction levels in the following areas: physical health, emotional health, work/

school, social, familiar, financial and legal situation, giving each item a grade between 0 and 10. The mean values are presented in Table 11. Group-treated clients reported significant improvements in most of the areas but family, social and legal, while individually-treated clients did not present significant

TABLE 10: Severity of dependence measures at assessment and follow-up.

	ASSESSMENT		FOLLOW-UP	
	INDIVIDUAL	GROUP	INDIVIDUAL	GROUP
SADD (mean ± standard deviation)	17 ± 10	17 ± 10	11 ± 8 ^②	15 ± 8 ^②
General dependence severity #				
light dependence	2	4	14	4
moderate dependence	33	40	16	20
severe dependence	65	56	20	31
partial remission	-	-	16	14
total remission	-	-	34	31
Alcohol #				
abuse			-	-
light dependence	12	5	29	5
moderate dependence	3	3	13	30
severe dependence	36	42	16	27
partial remission	48	50	11	25
total remission			30	13
Cocaine #				
abuse				
light dependence			8	12
moderate dependence	4	12	11	11
severe dependence	32	36	19	23
partial remission	64	52	27	8
total remission			35	46
Cannabis				
abuse	22	17	20	-
light dependence	22		-	25
moderate dependence	44	33	20	-
severe dependence			-	25
partial remission	11	17	20	25
total remission		33	40	25

^② differs from their initial values

Ratings between -2 (total remission) and +3 (severe dependence) were attributed to the subsequent levels of dependence. Wilcoxon matched pairs test detected significant differences between assessment and follow-up evaluation for both setting groups.

improvements just in the legal area. It should be taken into account that most of the clients did not present legal problems at assessment.

General success rates: A general classification of clients as “successful” or “unsuccessful” was made based on alcohol and drug consumption data. For alcohol dependent clients, the categorisation of consumption (abstinent/moderate) was used as the “successful” measure. For drug dependent clients, IDUS and alcohol consumption categorisation (in cases of both alcohol and drug dependence) were taken into account. Clients were considered “successful” if they were abstinent/moderate in relation to alcohol and presented an IDUS lower than 0.11 (drug use) or 0.22 (just alcohol use). The rates of “success” are showed in Table 12. The settings presented similar rates in relation to drug use but alcohol dependent clients who were individually treated improved more than group-treated clients did. However, as discussed above, this may be attributable to their high initial alcohol consumption levels.

Clients self-evaluation: Clients rated themselves in relation to assessment as “successful”, “improved” or “unimproved/worse”. Forty-four percent of individually-treated cli-

ents and 24% of group-treated clients considered themselves “successful”. The “improved” category was chosen by 52% of individually-treated and 69% of group-treated clients. The treatment and their personal effort were considered determinant factors in their improvement/success by 75% of individually-treated clients and by 82% of group-treated ones. The correlation between “success” according to client’s self-evaluation and consumption criteria (alcohol categorisation for alcohol dependants and IDUS for drug dependants) was significant in spite of being low (Spearman $r=0.25$ for alcohol and 0.24 for drug dependants). The lack of success was attributable to lack of personal effort by 100% of alcohol dependent clients (in both settings). When considering drug dependent clients 75% of individually-treated and 67% of group-treated clients attributed failure to lack of personal effort.

Collateral evaluation: Most of the collaterals who attended were clients’ spouses, who reported having daily contact with client. According to the information provided by them, the effectiveness of both groups (individual/group) was also considered similar. They classified the client’s improvement after treatment into three categories: “unimproved”, “improved” or “successful”.

TABLE 11: Satisfaction scores attributed by clients to several areas of life at assessment and follow-up.

	ASSESSMENT		FOLLOW-UP	
	INDIVIDUAL	GROUP	INDIVIDUAL	GROUP
Physical health	6 ± 1	6 ± 1	8 ± 1 ^①	7 ± 1 ^①
Emotional health	6 ± 1	5 ± 1	8 ± 2 ^①	7 ± 1 ^①
Family relationship	6 ± 2	6 ± 2	8 ± 2 ^①	8 ± 1
Social relationship	8 ± 2	8 ± 2	8 ± 2	8 ± 2
Work/School	6 ± 2	6 ± 2	8 ± 2 ^①	8 ± 2 ^①
Financial	5 ± 1	5 ± 1	5 ± 2	5 ± 2 ^①
Leisure	4 ± 2#	5 ± 2	6 ± 2 ^①	6 ± 2 ^①
Legal situation	10 ± 0	10 ± 0	10 ± 0	10 ± 0

① differs from their assessment values (Wilcoxon test)

differs from group treated clients at the same occasion (Mann-Whitney test)

Results are presented in Table 12. “Success” rate was slightly higher in the group setting (36%) than in individual setting (29%), although no significant statistical differences were detected. Considering only alcohol dependents, 70% of the collateral’s rating of “success” agreed with the alcohol consumption categorisation. On the other hand, low agreement (32%) was detected regarding drug dependants. The main disagreements were due to clients considered “unimproved” (IDUS rating > 0.22) by the consumption categorisation and “improved” by collaterals.

Predictors of outcome: “Successful” or “improved” clients were compared with the “unimproved” ones in relation to their initial characteristics in attempt to identify predictor variables for “success”. The first variable tested was treatment attendance. Outcomes of treatment attenders were compared with those of treatment non-attenders, in order to evaluate the contribution of attendance to

treatment to the observed outcomes. These data are summarised in Table 13. Outcomes varied depending on the main substance abused. Regarding alcohol dependent clients, it was observed that 96% of followed-up individually treated clients who had completed the treatment were considered “success”/“improved”, while the same was true for 82% of those who dropped out presented the same result. For group-treated clients, the same comparison showed a smaller difference in success between those who completed treatment (68%) and the dropouts (47%). However, the difference in success rate between settings was not statistically significant if the initial values were used as covariates (ANCOVA).

The number of attended sessions, the severity of alcohol consumption, the weekly average alcohol consumption, the heavy drinking days and log of GGT levels showed significant correlations with success at follow up

TABLE 12: Summary of results, according to various success criteria (alcohol and drug consumption, severity of dependence(DSMIII-R), clients’ self-evaluation and collateral’s evaluation. Percentage of the 106 followed-up clients. Between brackets the percentage of the initial sample, being all the not-followed up clients considered “unsuccessful”.

SUBSTANCE ABUSED	ALCOHOL		DRUGS		TOTAL	
	INDIVIDUAL	GROUP	INDIVIDUAL	GROUP	INDIVIDUAL	GROUP
SETTING						
Success criteria						
Alcohol consumption (abstinent/moderate)	85 [Ⓢ]	50	92	75	89 (60) [Ⓢ]	61 (41)
successful	55 [Ⓢ]	44	80	62	69 (47) [Ⓢ]	52 (35)
improved	30 [Ⓢ]	7	12	12	20 (14)	10 (7)
Alcohol and drug consumption (IDUS)	83 [Ⓢ]	57	52	46	65 (43)	52 (36)
Alcohol dependence (remission)	56	41	-	-	40 (27)	37 (25)
Cocaine dependence (remission)	-	-	64	56	64 (44)	56 (38)
Cannabis dependence (remission)	-	-	60	66	60 (40)	66 (45)
Clients’ self-evaluation						
successful	44	24	39	27	42 (29)	25 (17)
improved	52	69	39	65	45 (31)	67 (46)
Collateral evaluation						
successful	30	27	28	43	29 (20)	36 (24)
improved	52	50	50	40	51 (35)	44 (30)

Ⓢ differs from group-treated clients

TABLE 13: Outcomes measures comparison between treatment attenders and non-attenders.

SETTING	ALCOHOL CONSUMPTION (abstinent/moderate %)		DRUG CONSUMPTION (IDUS > 0.22)		REMISSION OF DEPENDENCE (DSMII-R)	
	INDIVIDUAL	GROUP	INDIVIDUAL	GROUP	INDIVIDUAL	GROUP
Treatment attendance						
attenders	96 ^① #	68	78 ^①	60	54	54
non-attenders	82	47	50	37	46	30

① differs from non-attenders

differs from group treated

— the higher the initial alcohol consumption, the lower the success. A logistic regression multivariate analysis showed that the GGT level and the number of sessions were the best predictors of outcome. The smaller the number of sessions attended and the higher the GGT levels log, the lower the success.

Regarding drug dependent clients attendance to treatment and index of drug consumption (IDUS) were considered as predictors of success. The stronger the adherence to treatment and the lower the IDUS, the higher the success.

How were the results used?

The initial questions were answered by the data analysis. With regards to setting influence, an interaction was observed with drug type. Alcohol dependent client treated in group tended to have higher treatment attendance than those treated individually. However, their outcomes were similar when initial levels were controlled. This information should be taken into account when recommending the treatment setting to a client. Considering that attendance is an important predictor of outcome, group setting should be preferably indicated for alcohol dependent cli-

ents. On the other hand, drug dependants hardly attended treatment, independently of setting, and this is a point worthy of attention/intervention: what could be done to increase their compliance to treatment?

Since the results indicated there were no significant differences in relation to “success” between the two settings, both options were maintained. The group format was chosen as the “standard” kind of therapy to be offered. However, the “individual” option was maintained in order to supply specific needs, according to clients’ needs/preferences and the therapist’s diagnosis. It was also decided to allow the drug dependent client to choose the setting.

It was decided to implement a motivational program to increase early compliance to treatment, since it was observed that most dropouts occurred in the very beginning of treatment. Furthermore, since substance abuse in the family was a predictor of non-success, it was decided to include a family-functioning diagnosis in the assessment as a routine and the possibility of family therapy when necessary.

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It's your turn

What are the strengths and the weaknesses of the presented case example? List three positive aspect and three negative aspects:

Strengths of the case study

1 _____

2 _____

3 _____

Weaknesses of the case study

1 _____

2 _____

3 _____

Appendix 1 for case example

The IDUS (Index of Drug Use Severity) was proposed by Wilkinson and LeBreton (1986) and took into account the number of drug classes used and the amounts of each drug used. This was made according to the guidelines proposed by those authors (see chart), using the data obtained by means of the Psychoactive Drug Use History table.

Index of drug use severity (IDUS)

Guidelines for ratings of drug use in past year (Wilkinson and LeBreton, 1986)

	Alcohol	Cannabis	Other drug classes
0 = abstinent	No use of drugs from this class during past year		
1 = low	≤ 20 drinks/week and problem still? = No	≤ 4 joints/week and ≤ 2 joints/day by use and problem still? = No	≤ 1 use/month
2 = intermediate	≤ 10 drinks/day and ≤ 42 drinks/week	< 10 joints/week	> 1 use/month but < 1 use/week
3 = high	> 10 drinks/day or > 42 drinks/week	≥ 10 joints/week	≥ 1 use/week
4 = “outrageous”	Very high level of consumption, even within this sample. At rater’s discretion		

The rating for each of the main substances abused (alcohol, cocaine and cannabis) and the general index (IDUS) were considered in the analysis. The IDUS was obtained by adding scores of eight classes and then dividing the sum by 8, converting it to a *mean rating per drug class* for each client, on a 5-point scale (0 to 4).

References for case example

- Addiction Research Foundation. *Directory of Client Outcome measures for addiction treatment programs*- Addiction Research Foundation, Toronto, Canada, 1993.
- American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*, 3rd ed., Washington, DC, USA, 1987.
- Annis, H.M., Graham, J.M. & Davis, C.S. *Inventory of Drinking Situations (IDS). User's guide*. Addiction Research Foundation, Toronto, Canada, 1987.
- Ashton-Tate Software. *DbaseIII-Plus*, 1990.
- Formigoni, M. L. O. S. (Ed.). *A Intervenção Breve na Dependência de Drogas*, (Ed.) Contexto, São Paulo, Brasil. (Portuguese), 1992.
- Formigoni, M.L.O.S. & Neumann, B. *Treatment of drug and alcohol dependents through brief intervention: The first Brazilian experience*. In M.G. Monteiro and J.A. Inciardi, (Eds.), *Brasil-United States Binational Research*.CEBRID. São Paulo, Brasil, 1993.
- Holder, H., Longabaugh, R., Miller, W.R. & Rubonis, A.V. The cost effectiveness of treatment for alcoholism: A first approximation. *Journal of Studies on Alcohol*, 1991, 52:517-540.
- Moraes, R., Andrade, E.M. & Alves, D.G. *CIA-Teste coletivo de inteligência para adultos - Forma I* - CEPA - Centro Editor de Psicologia Aplicada Ltda, São Paulo, Brazil, 1962.
- Rainho, O. *Bateria CEPA-Testes de aptidões específicas*. CEPA-Centro Editor de Psicologia Aplicada Ltda. São Paulo, Brasil, 1962.
- Raistrick, D., Dunbar, G., & Davidson, R. Development of a questionnaire to measure alcohol dependence. *British Journal of Addiction*, 1983, 78:89-95
- Sanchez-Craig, M., Annes, H.M., Borner, A.R., & McDonald, K.R. Random Assignment to abstinence and controlled drinking: Evaluation problem drinkers. *Journal of Consulting and Clinical Psychology*, 1984, 52(3): 390-403.
- Sanchez-Craig, M. *A Therapists? Manual for secondary prevention Alcohol Problems: procedures for teaching moderate drinking abstinence*. Addiction Research Foundation, Toronto, Canada, 1984.
- Sanchez-Craig, M. Brief didactic treatment for alcohol and drug-related problems: an approach based on client choice. *British Journal Addiction*, 1990, 85:169-177.
- Sanchez-Craig, M., Neumann, B., Souza-Formigoni, M.L.O., & Rieck, L. Brief treatment for alcohol dependence: level of dependence and treatment outcome. *Alcohol and Alcoholism*, 1991, suppl 1:515-518.
- Sanchez-Craig, M., & Wilkinson, D.A. Brief treatments for alcohol and drug problems: practical and methodological issues. In T. Loberg, W. R. Miller, P. E. Nathan, A. Marlatt (Eds.), *Addictive Behavior prevention and early intervention*, Amsterdam, Suvets e Zeillinger, 1989:233-252.
- Sanchez-Craig, M., Wilkinson, D. A., & Walker, K. Theory and Methods for secondary prevention of alcohol problems: a cognitive based approach. In: M. W. Cox (Ed.). *Treatment and Prevention of alcohol problems: A Resource Manual*. (Nova York, Academic Press), 1987:287-331.

- Sanchez-Craig, M., Leigh, G., Spivak, K., & Lei, H. (1989). Superior outcome of females over males after brief treatment for the reduction of heavy drinking. *British Journal of Addiction*, 1989, 84:395-404.
- Statsoft Inc. *CSS (Complete Statistical System): Statistica*, 1991.
- Weschler, D. *Weschler Memory Scale - Revised*. San Antonio: Psychological Corporation, 1987.
- Wilkinson, D. A., & LeBreton, S. Early indications of treatment outcome in multiple drug users. In: Miller, W. and Heather, N. (Eds.). *Treating Addictive Behaviors: process of change*. Plenum Publishing Corporation, pp. 239-261 (New York), 1985.
- Wilkinson, D. A., Leigh, G. M., Cordingley, J., Martin, G. W., & Lei, H. Dimensions of multiple drug use and a typology of drug users. *British Journal of Addiction*, 1987, 82, 259-273.

Case example of an outcome evaluation



The National Treatment Outcome Research Study (NTORS): inception and implementation of a major treatment evaluation study in the UK

The authors alone are responsible for the views expressed in this case example.

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Who was asking the question (s) and why did they want the information?

In 1994, the Department of Health in the UK established a Task Force to review the effectiveness of the national services for drug misusers. Its specific goal was “to conduct a comprehensive survey of clinical, operational

and cost effectiveness of existing services for drug misusers; to review current policy in relation to the principal objective of assisting drug misusers to achieve a drug free state, and the secondary objective of reducing harm caused to themselves and others by those who continue to use drugs; to make recommendations where appropriate and to report to Ministers” (Task Force Report, 1996). The Task Force committed itself to base its deliberations as far as possible upon firm research evidence derived both from within the UK and from other countries.

One of the first actions of the Task Force was to commission the National Treatment Outcome Research Study. NTORS is a large-scale, multi-site, prospective study of treatment outcome conducted with a cohort of more than 1000 people who entered drug misuse treatment services in England during 1995. It was specifically commissioned to provide evidence of the effectiveness of existing national drug misuse treatment services. NTORS is the largest prospective study of treatment outcome for drug abusers ever conducted in the UK. NTORS owes much to other large scale studies of treatment outcome which were conducted in the United States. These include DARP (Simpson and Sells, 1990), TOPS (Hubbard et al., 1989), and the six cities study of methadone maintenance (Ball and Ross, 1991). Such studies have demonstrated that the treatment of drug abuse problems can be effective. However, the problems of generalising from studies carried out in other countries are considerable. The characteristics of American drug abusers could be expected to differ in many respects from those in the UK, as will the types of treatment services and interventions which are provided. The problems associated with drug abuse are complex and the treatment of such problems is difficult. In order to improve the effectiveness of treatment interventions for drug problems, policy planners, service purchasers and providers, and researchers all need a clearer understanding of the many factors that contribute towards the success of treatment.



The significance of NTORS is in part due to the fact that it has been designed and implemented as a *national* study; investigating treatment programmes from all parts of England. Its design is *comprehensive*, looking in detail at the social and psychological characteristics of clients, and at a wide range of treatment operation factors in relation to multiple measures of treatment outcome. For these reasons, the results of NTORS will be of great interest in terms of their contribution to our scientific understanding of treatment outcome. The results will also provide valuable data about the impact of the national

treatment responses upon drug abuse problems and be relevant to the needs of policy planners, purchasers and providers in helping to develop and strengthen drug services and interventions.

The primary purpose of NTORS is to provide empirically derived information about the nature of the existing national treatment responses and about the changes in behaviour which occur among problem drug users who have been treated within those services. More specifically, NTORS has been designed to provide answers to the following questions:

- 1 What are the characteristics of clients entering the national treatment programmes included in the study?
- 2 What are the key structural and operational components of the NTORS treatment programmes and interventions?
- 3 What types of problems are presented by clients in NTORS and how severe are they?
- 4 What sorts of changes occur subsequent to treatment?
- 5 To what extent are these initial changes maintained over time?
- 6 What is the relationship between client characteristics and observed outcome?
- 7 What is the relationship between treatment structure and process variables and observed outcome?

What resources were needed to collect and interpret the information?

The project was run from the National Addiction Centre at The Maudsley Hospital in London. The Project Director was Dr. Gossop. The project was co-ordinated in London by Dr Marsden with two research-

ers and a research administrator. Due to the national scale of the study two further researchers were based in Manchester. A total of 54 agencies were selected for participation in NTORS. These included 16 methadone maintenance programmes, 15 methadone reduction programmes, 15 residential services and 8 in-patient units. During the selection of agencies and after participation in the project had been agreed, NTORS researchers made visits to all of the participating agencies. The purpose of this visit was to conduct training with the MAP interview procedures and to set up necessary administrative procedures to ensure agencies would be in regular contact with the two research bases. Researchers encouraged one person at each agency to take responsibility for the on-site co-ordination of the project. All staff who were involved in conducting the interviews were trained in the use of the instrument and client response cards. Training manuals were also supplied to each agency for guidance about procedures. Sites were provided with specially designed posters and leaflets to advertise the study to clients and to encourage the identification of clinical workers with the project.

Close liaison between the research team and the clinical agencies has been an issue of primary importance in ensuring the success of the project. This issue deserves emphasis as one of the “hidden” factors behind the implementation of NTORS. Without the commitment, active co-operation and assistance of the agencies, it would have been impossible to conduct this study.

How were the data collected?

NTORS monitors the progress of clients who are starting a treatment episode in one of four treatment modalities (specialist inpatient treatment, residential rehabilitation, methadone maintenance, and methadone reduction programmes). In NTORS, the term ‘modal-

ity’ is used to refer to a broad category of treatment intervention. Within this category it is accepted that there may be some, and possibly considerable variation. However, the treatment interventions included within each modality should have general defining characteristics and common features, such as the treatment setting within which the intervention is provided, and/or the goals of treatment, and/or the types of procedures used (e.g. the prescription of substitute drugs).

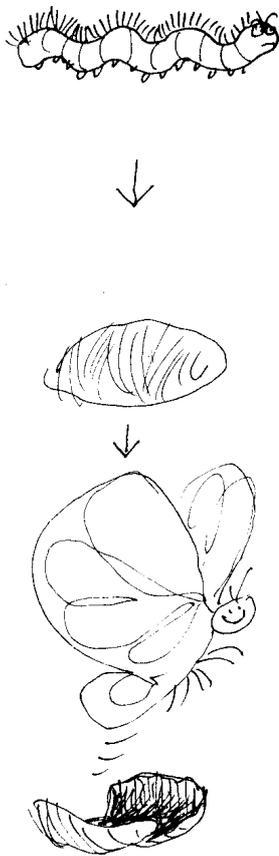
The research design used by NTORS is based on a tradition of programme evaluation and longitudinal outcome research developed in the United States. The study is naturalistic and causal inference will be achieved through measurement of key variables and comparison of treatment samples on the basis of pre- and post-treatment outcome measures. This design was chosen in preference to a randomised control design.

Individual differences among clients seeking drug abuse treatment are often so great that it renders the assembling of matched treatment and control groups untenable; truly random designs are extremely difficult if not impossible to implement in a field setting; withholding treatment from a control group cannot be ethically justified; and client samples based upon random selection will behave differently from clients selected through clinical need and motivation for treatment thus creating an “experiment” which is not relevant to real treatment circumstances. Useful evaluation studies require longitudinal data and, in NTORS, the client’s own baseline measures are used as a control condition to assess change. In a naturalistic or quasi-experimental design such as that used in NTORS, pre-existing differences in client characteristics as well as differences in social and environmental circumstances may explain part of the differences observed in outcome across programmes. NTORS measures such differences precisely so that they can be taken into account in explaining what sorts of factors influenced the observed outcomes.



The conceptual approach underpinning NTORS sees addictive behaviour change as a dynamic process in which multiple influences determine the outcome of any treatment intervention (Gossop, 1992). This approach has guided the overall design of the study and the specific selection of measures. NTORS sees treatment outcome as dependent upon the action and interaction of four types of factors. These are:

- 1 the type and severity of drug use behaviour (including type of drug used, duration of use, route of administration, severity of dependence);
- 2 personal functioning (e.g. readiness for change, attitudes and beliefs, psychological health, personal coping skills);
- 3 treatment effects (e.g.; treatment setting, duration and intensity of treatment, type of intervention, therapist effects);
- 4 social/environmental factors (including social resources, relationships influences and supports).



Services of potential usefulness to NTORS were selected after giving consideration to: the capacity of the agency, and in particular, its ability to recruit a sufficient number of cases to NTORS within the restricted time available for recruitment: capacity was defined in terms of the number of new cases presenting to the services in the last month; the location of the service: NTORS required agencies which were located throughout England but which were also located in areas which were representative of areas in which drug problems and drug treatment services were prevalent.

In general, the former criterion was used to identify agencies which would potentially be able to recruit at least 20 new clients into treatment during the recruitment phase of the project, and the latter, to attempt to recruit agencies from health regions across the country.

The Maudsley Addiction Profile (MAP) is a set of structured research interviews

which were developed specifically for the NTORS project. The MAP profiles the social circumstances, key problems and experiences of drug users at treatment entry and at the follow-up points during and after leaving treatment. MAP interviews were designed to be used by clinical and agency staff without a research training. Efforts were made to balance the information needs of the study against the burden on staff time in interviewing clients. Post-treatment interviews were conducted by trained independent interviewers from the Office for National Statistics.

Development of the MAP proceeded in three stages. First, an initial pool of measures were compiled across three overarching measurement domains: substance use, physical and psychological health, and social functioning and life context. Second, a further set of measures was incorporated which concerned psychological aspects of drug use, motivation for treatment, and coping strategies. These latter items were included to assess their value in understanding the manner in which clients respond to treatment as well as to longer term recovery. Draft versions of the MAP interviews were piloted with samples of drug users in several treatment services. This piloting led to further refinements and improvements in item structure and interview design. Two specific modifications were made. On the basis of experience derived from the feedback from pilot interviews, a response card booklet was prepared to assist interview completion for each of the MAP instruments. Another design modification concerned questions about involvement in criminal activities and with the criminal justice system. Given the sensitivity of this topic, the respondent was given the choice of using a self-completion questionnaire.

A training strategy was implemented by the NTORS team to assist agency staff in the administration of the MAP interviews. Instruction manuals were prepared describing the rationale and structure of the interviews

with detailed notes on the interview procedure and item completion. The research team then conducted on-site training sessions at each agency with staff to ensure familiarity with the interviews. Subsequent feedback from the agencies suggested that this procedure was valuable both as a specific learning exercise and also for enhancing working links between NTORS and treatment staff. A pack of materials was prepared for each participating agency containing information for clients, consent forms, MAP interviews and response cards, and enrolment forms. A single "at-a-glance" information sheet for agency staff was also designed describing the procedure to follow for client enrolment and completion of the MAP-1 interview.

As implemented in NTORS, the MAP-1 is a 62 item structured interview of approximately 45 minutes duration. It comprises 7 sections: 1. background information; 2. drug and alcohol use; 3. change motivation and coping; 4. health; 5. relationships; 6. legal issues; 7. treatment.

Six scales which have been used in previous research were selected and adapted to assess issues 1-6. A full description of the development of these measures is available from the National Addiction Centre (contact Drs Gossop and Marsden). The MAP scales have established validity and reliability and will facilitate comparison of NTORS data with previous research. New items were developed specifically for the study, particularly within the legal and treatment sections. The legal section of the MAP looks in detail at involvement with the criminal justice system and criminal activity. The treatment section records the clients' treatment history and use of hospital, residential and community services for medical, psychological and substance use problems. Successive MAP interviews administered during and after the index treatment episode comprise a core set of repeated measures from the above domains.

NTORS employs a design of time-anchored follow-ups following admission. Data is collected at five interview points: (a) intake; (b) six months; (c) one year; (d) 2-3 years; and (e) 4-5 years from intake. The intake, and for clients still in treatment, six month interviews were conducted by treatment staff at the agencies. Follow-up interviews with clients who had left treatment before six months, and all remaining interviews were carried out by independent researchers from the Office for National Statistics (ONS). At each interview point, clients were asked to provide contact addresses (personal address, family/friends, doctor, etc.) to enable location for future follow-up interviews. Follow-up rates of at least 70% were expected at each point in the study.

Agency staff approached all eligible clients starting treatment at the agency between February 27th and July 31st 1995, and invited their participation into the study. Clients were eligible for an NTORS intake interview providing *all* of the following criteria were met:

- starting a new treatment episode;
- presenting with a drug-related problem (other than alcohol);
- able to provide an address in the UK for follow-up;
- not a previous client of NTORS.

1,110 eligible clients were interviewed over a five-month recruitment period for inclusion in the study. Of these, 35 did not provide sufficient locator information to allow follow-up and a revised sample base of 1075 clients was established. The number of clients recruited to each treatment modality is shown in Table 1.

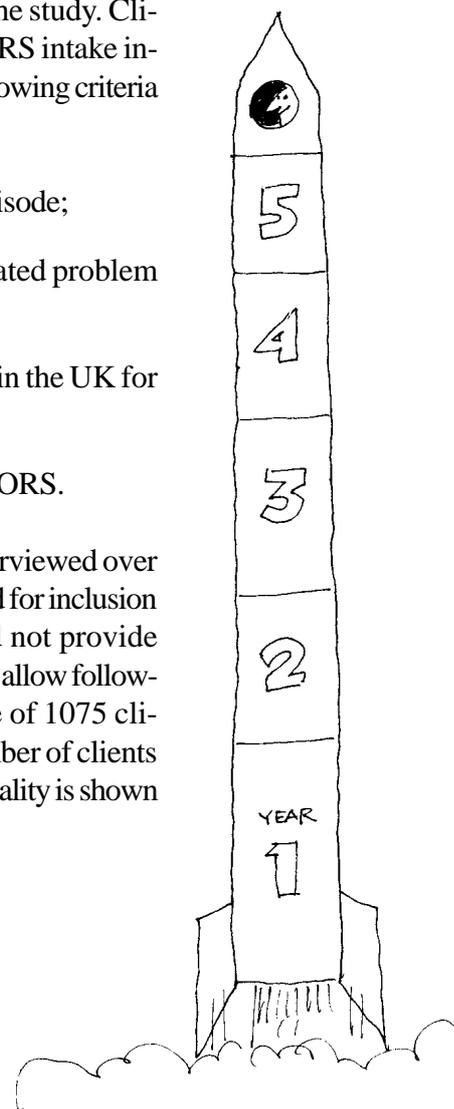


TABLE 1: Clients recruited to NTORS by treatment type

Treatment Type	Number of clients recruited	% of cohort
Inpatient	122	11.3%
Residential Rehabilitation	286	26.6%
Methadone maintenance	458	42.6%
Methadone reduction	209	19.4%

The largest number of clients was recruited from the methadone maintenance programmes. This was mainly due to the inclusion of the eight pilot structured methadone maintenance projects within the NTORS framework. A total of 350 clients were recruited into these methadone maintenance treatment programmes within the NTORS recruitment period. It should be noted that within study resources, verification of self-reported drug use was provided by urinalysis. Urine was collected from clients for screening at 25 programmes (selected on a one-in-two sampling basis), with samples taken at each interview. Initial detection of opiate, methadone, amphetamines and cocaine metabolites were performed with enzyme immunoassays (EMIT), confirmed with thin layer chromatography procedures. Concordance between self-reported drug use and urinalysis were high. For example, at the six month follow-up, concordance was as follows: heroin (92%); cocaine (93%); amphetamines (97%).

How were the data analysed?

At present, the project is still at an early stage. In this paper, the intake-follow-up comparisons are presented as basic rates and proportions, with changes assessed by the McNemar test. More detailed and system-

atic analyses employing multivariate procedures will be utilised in subsequent presentations. NTORS assesses a wide array of client behaviours and other measures which are assessed on a number of different occasions. Various statistical procedures will be employed for the analysis of longitudinal data. For example, the procedure used to assess change over time in each continuous dependent variable is multivariate analysis of covariance with time (i.e. repeated measures) being regarded as a within subjects factor. For this analysis of variance various effects of treatment, time, and treatment x time interactions are estimated.

What did they find out?

A basic demographic profile of the NTORS cohort is shown in Table 2.

Opiates, benzodiazepine and stimulants (notably cocaine and amphetamines) were among the drugs most commonly used by people presenting for treatment in recent years. Individuals approaching UK treatment services most often present with opiate problems (and specifically with heroin dependence), although the misuse of stimulant drugs and benzodiazepine is not uncommon (Strang and Gossop, 1994). However, the classification of drug problems according to the use of single substances can be mislead-

TABLE 2: Personal demographic profile at treatment entry

Characteristic	Inpatient (n = 122)	Residential (n = 286)	Methadone Maintenance (n = 458)	Methadone Reduction (n = 209)
Gender				
% Males	77%	74%	72%	73%
Mean Age	30 yrs.	29 yrs.	30 yrs.	27 yrs.
Race/ethnicity				
% White-UK	94%	88%	90%	93%

ing. Very few drug abusers who require treatment confine themselves to the use of a single substance, and many tend to be heavy and problematic users of more than one drug. The identification of someone as a heroin addict should not be taken to imply that the drug problem is solely that associated with the use of heroin. For example, there has been increased problematic use of cocaine and benzodiazepines by opiate users in the UK in recent years (Strang et al. 1994).

The clients who received treatment within the NTORS agencies were almost all multiple users. Few drug users restricted their behaviour to one drug, though dependence upon heroin was the single most common drug problem. The average length of heroin use for the cohort was 9 years (standard deviation = 5.8 years). The relative *chronicity* of the drug abuse problems experienced by the NTORS clients must be borne in mind when evaluating the impact of treatment.

In the three-month period before starting NTORS treatment, more than half of the cohort reported using benzodiazepines. Benzodiazepines were the second most frequently used type of drugs to heroin and the opiates. While approximately one in five clients were using benzodiazepines every day, a further one in six were using them regularly each week and a further 17% on an occasional basis. There may be significant direct

harm associated with the use of these drugs, particularly when they are used by intravenous injection. For instance, a good deal of national concern has been linked to the injection of temazepam preparations.

TABLE 3: Illicit Drug Use

Drug	%
Heroin	87
Illicit methadone	49
Benzodiazepines	54
Cocaine powder	18
Crack cocaine	35
Amphetamines	24

Stimulant drugs were used by many NTORS clients. More than one third of the clients reported using crack cocaine in the period prior to starting the NTORS treatment episode. Almost a quarter reported using amphetamine sulphate. The frequency of crack cocaine use was *higher* than cocaine powder. Forty-nine clients used crack cocaine every day in the 3 months before intake; a further 130 (12%) clients were regular weekly users of crack and 199 reported using the drug though on a less than weekly basis. It was comparatively rare for the NTORS cohort to be daily users



of cocaine powder; only 1% used daily, although 17% used it on an occasional or weekly basis. There is considerable concern about the prognosis for drug misusers with serious stimulant problems, and future analyses of the NTORS data will permit investigation of different patterns of drug use in relation to treatment outcome.

Overall, 62% of the cohort reported that they had injected a drug in the three months prior to treatment. There were no statistically significant differences between men and women, nor differences across treatment modality. The usual route of administration was intravenous for 59% of the clients who had used heroin three months prior to treatment, 40% of the heroin users smoked the drug. Cocaine powder and amphetamines were also frequently injected, approximately half of the clients who had used these drugs in the previous three months had injected them.

Injecting drug users are at risk of HIV and other infections, including the hepatitis infections B, C and D, through the sharing of injecting equipment as well as through unsafe sexual behaviours. During the three months prior to treatment, 156 clients (15%) reported using a needle or syringe after someone else had used it. There was a higher rate of pre-treatment needle and syringe sharing amongst female drug users where proportionately more females than males reported using a needle or syringe after somebody else had already used it. This pattern of needle sharing has been observed in clinical populations and may be sharing between partners. Sharing rates also differed significantly across treatment modality. Clients in residential treatment were more likely to report having used a needle or syringe after somebody else had used it.

In the three months prior to intake, the majority of the cohort reported a range of general health problems. Specific symptoms included sleep disturbance (81%); weight loss (68%); injection-related abscesses and infections (15%); chest pains (38%); and peripheral nervous system disorders (37%). Dental

problems (frequently involving pain) were reported by more than half of the entire cohort. Similarly, many clients reported a range of psychological problems before intake. During the three months before treatment, about two thirds reported depressed mood or anxiety, and more than 300 clients reported thoughts of suicide. These problems of depressed mood and suicidal thinking were surprisingly common within the cohort. It is a matter for concern, and indicative of the considerable distress of the NTORS clients that such a large proportion of them were thinking of ending their lives.

The rates of criminal activity among the cohort was high. More than 70,000 separate criminal acts were reported by the NTORS clients during the three months prior to treatment. Shoplifting was the most commonly reported illegal activity with more than one third of the cohort having committed at least one such offence before intake. Crimes of fraud and burglary were also quite common, and more than a quarter of the cohort reported crimes of selling drugs. Almost three quarters of the full cohort had been arrested in the two years before intake (again, most commonly for shoplifting offences). About one third had been arrested for a drug offence. There were differences in profiles of criminal activity between clients entering the different treatment modalities. The highest rate of theft offences, for instance, was reported by the clients who entered the residential rehabilitation services. Similarly, the highest rate of imprisonment during the three months prior to recruitment was also reported by the rehabilitation clients.

Similar differences were found for previous contact with addiction and other health care services. The addiction treatment histories of drug users typically reveal multiple help seeking from different drug treatment services. The service use history that each drug user brings to addiction treatment may have an important bearing on the impact of the current treatment. Rates of previous psychiatric treatment were highest among residential and inpatient clients. A higher proportion of drug users



entering the inpatient and residential modalities had received past hospital psychiatric treatment when compared to the community methadone programmes (inpatient = 14%; residential = 15%; methadone maintenance = 8%; methadone reduction = 6%). Clients of residential programmes were also more likely to have received community psychiatric treatment (21%); and also to report receiving treatment from an Accident and Emergency department (64%). Overall, about half of all the NTORS clients had been in contact with an Accident and Emergency department. This latter finding deserves some attention. We are surprised at the extent to which the NTORS clients in general and the rehabilitation clients in particular had been in contact with hospital A & E services. This finding alone draws attention to the considerable demands which clients with serious substance use problems make upon health care resources other than the specialist addiction treatment services.

Impact of Treatment at Six Months

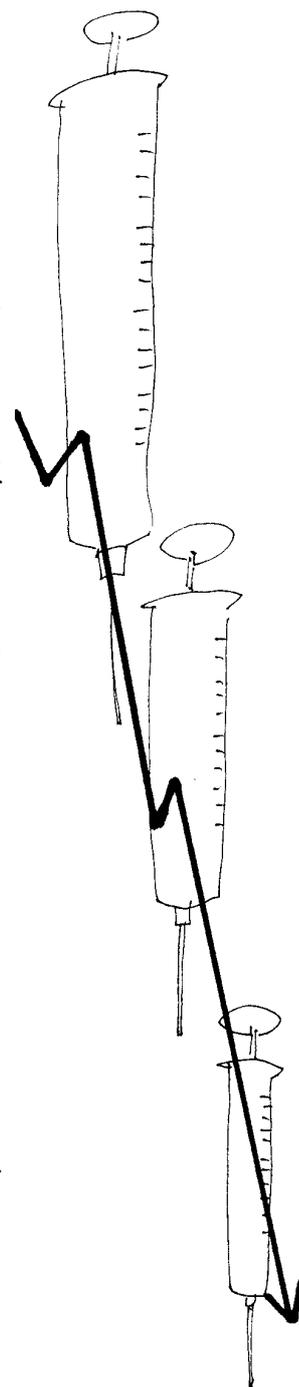
NTORS is a prospective study which will provide follow up information on the clients during a five year period after entering the target treatment. During the full five-year follow-up period, presentations of the data will be made at various points. The results will show the immediate impact of treatment upon substance use and other problems, continuing benefits at one year follow-up, and longer-term gains throughout the five-year period. At present, the project is still at an early stage. In this paper, outcome data are presented as basic rates and proportions. More detailed and systematic analyses employing bivariate and multivariate procedures will be utilised in subsequent presentations. 809 clients were interviewed approximately 6 months after treatment intake (75.3% of the cohort).

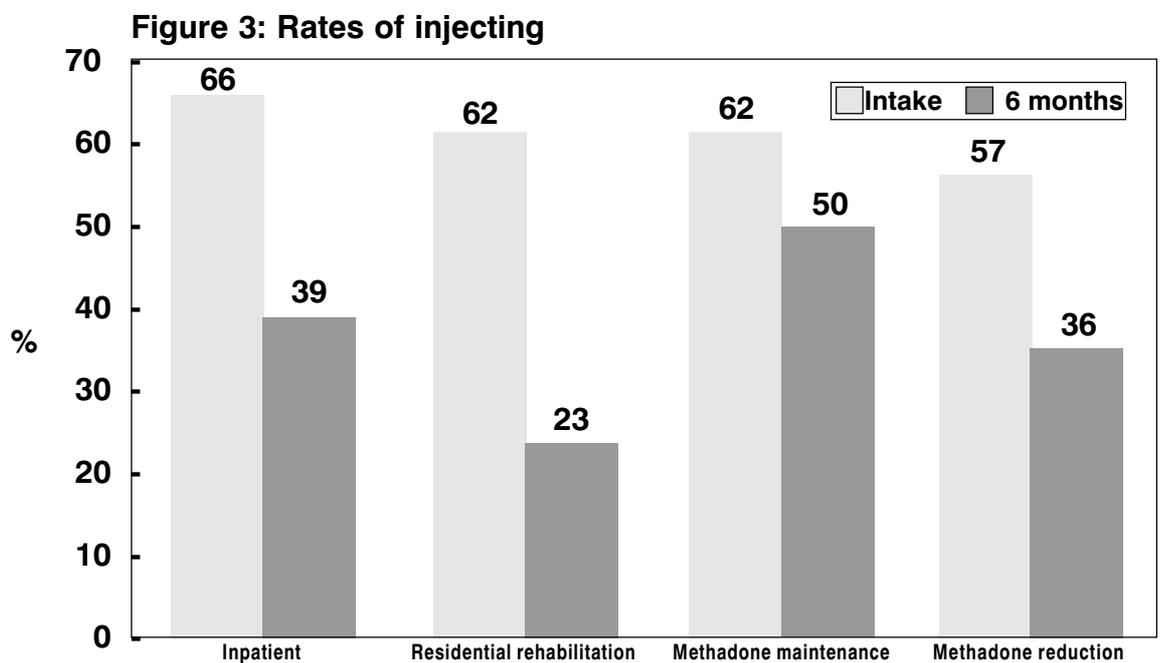
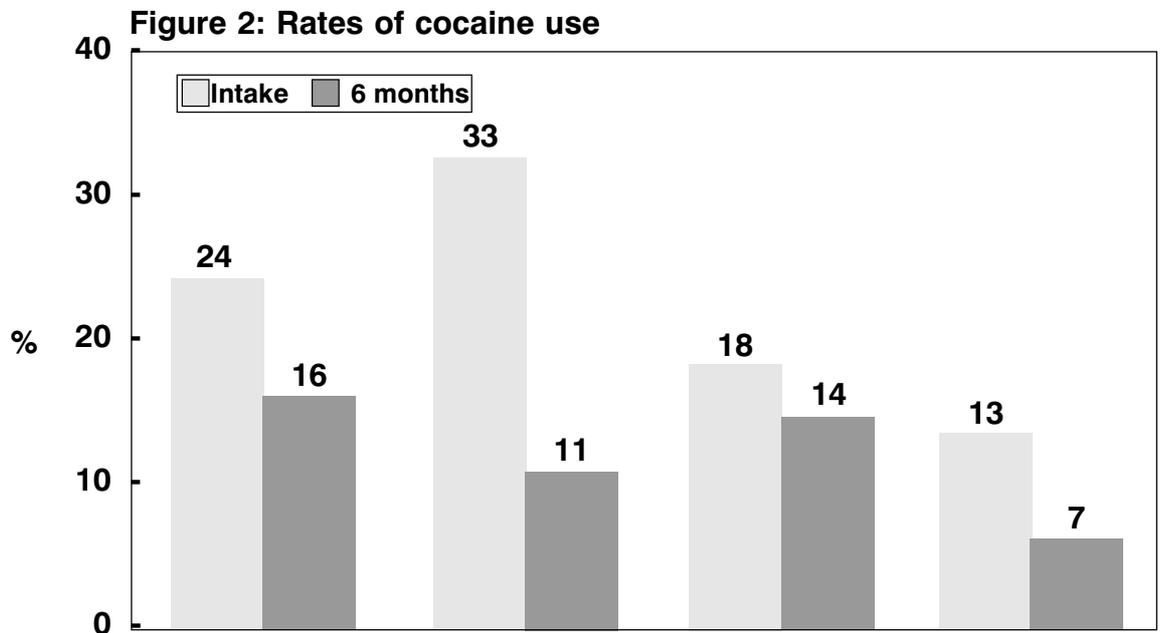
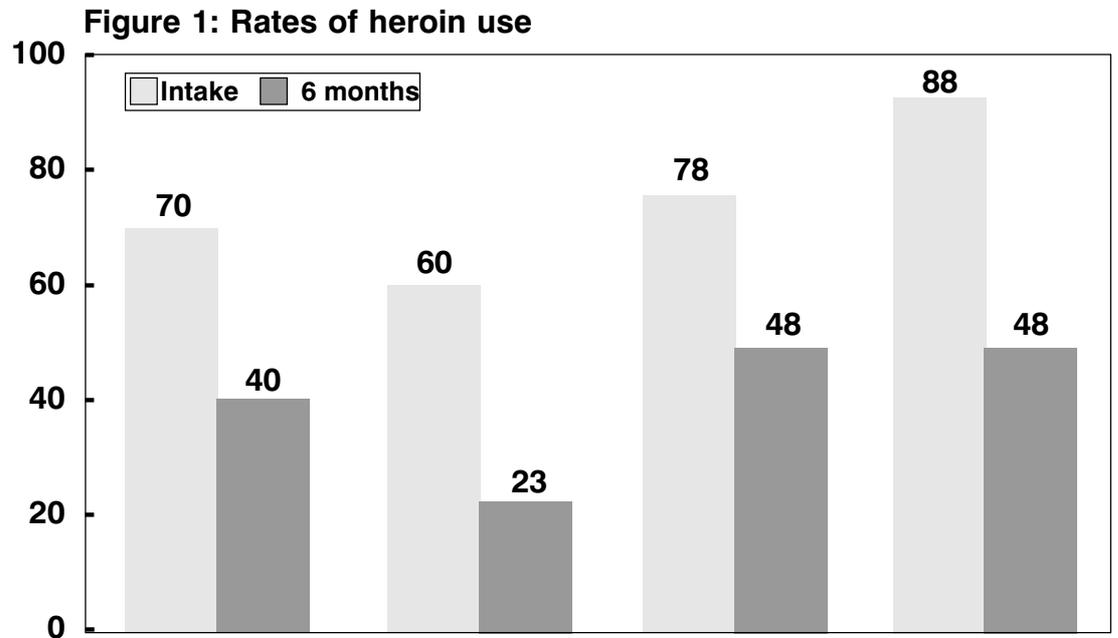
We have avoided making any direct comparisons between modalities in terms of their outcomes. We would caution the reader against attempting any such relative comparisons. The

important differences that are known to exist between clients at intake provide one compelling reason to avoid simple comparisons of outcomes across modalities.

Following implementation of NTORS, the UK Government Task Force was informed of initial improvements after treatment entry for available data in a report submitted to the Department of Health in October 1995. A summary of these results is in the public domain (Gossop et al., 1996). There were significant increases in the number of clients who were drug-free and who had been abstinent for at least the previous 30 days. At the cohort level, abstinence rates for heroin improved from 15% at intake to 42% at follow-up; for crack-cocaine from 65% to 78.5%; for non-prescribed methadone from 52% to 80%; and from 32% to 41% for alcohol. In many respects, the use of heroin or other opiates is frequently a focus of treatment interventions and it is encouraging that the use of these drugs showed substantial reductions at follow-up. Marked reductions in heroin use were found among clients in all modalities at six-month follow-up. As a further illustration of changes in the pattern of drug consumption, regular use of heroin and cocaine (in this case, operationally defined as weekly or more frequently), reductions from intake to six months by treatment modality, are presented in Figures 1 and 2 (reproduced from Gossop et al., 1997).

The importance of injecting behaviours in general, and the sharing of injecting equipment in particular, have been clearly specified as priority drug problem behaviours in the UK. The NTORS findings regarding these behaviours are, therefore, of considerable importance. For the full cohort, there were significant reductions both in injecting rates and in the sharing of injecting equipment. The rate of injecting fell from 61% (n = 497) to 39% (n = 314). The sharing of injecting equipment fell from 14.5% (n = 117) to 5% (n = 41) at six-month follow-up. Among those who were injecting drugs at intake, sharing fell from 23.5% to 7%. Significant improvements were observed among clients who were treated in all four of the NTORS modalities. Figures 3 and 4 show





rates of injecting and sharing needles and syringes respectively at the two interview points. The reductions in needle sharing behaviours can clearly be seen in Figure 4.

At admission, many of the cohort were regularly drinking excessive amounts of alcohol. Among regular drinkers, average daily alcohol consumption on a typical day fell from 17 units at intake to 8 units at follow-up. For daily drinkers, average consumption fell from 24 to 12 units. The percentage of daily drinkers who were drinking 10 units or more fell from 75% to 41%.

For the health domains, there were also marked improvements in the prevalence of physical and psychological health symptoms (anxiety and depression). For example, the percentage of clients who reported feeling hopeless about the future fell from 62.5% to 44%; clients having suicidal thoughts fell from 29% to 16%, and clients who were extremely troubled by suicidal thoughts fell from 10% to 4%. There were also reductions in criminal activity at follow-up. Rates of criminal activity, excluding drug selling, are shown in Figure 5.

Figure 4: Rates of sharing

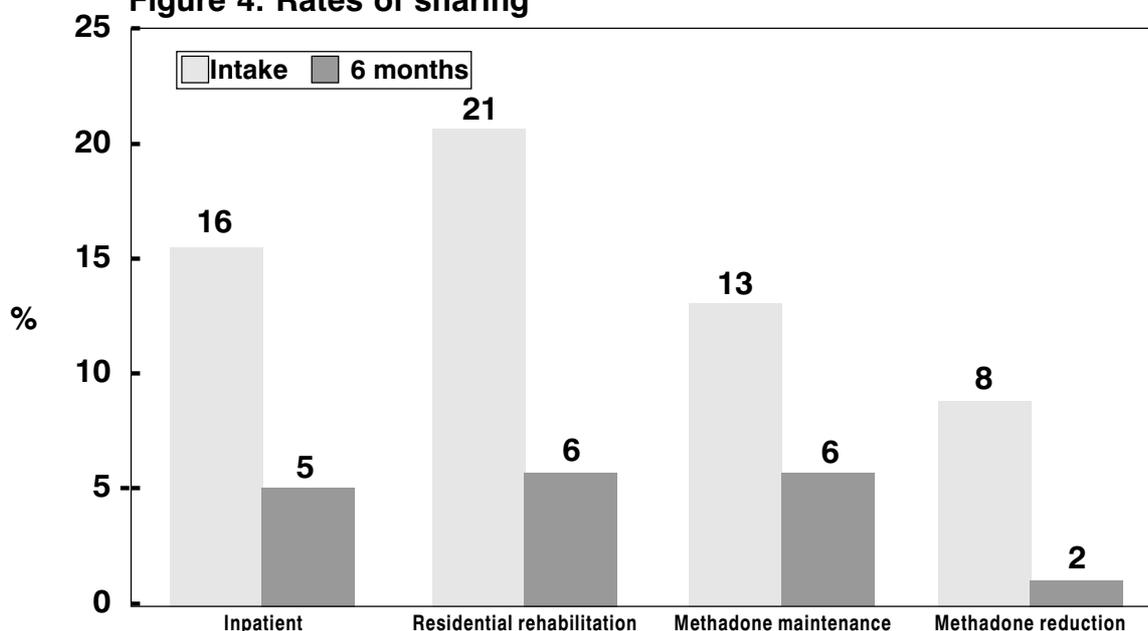
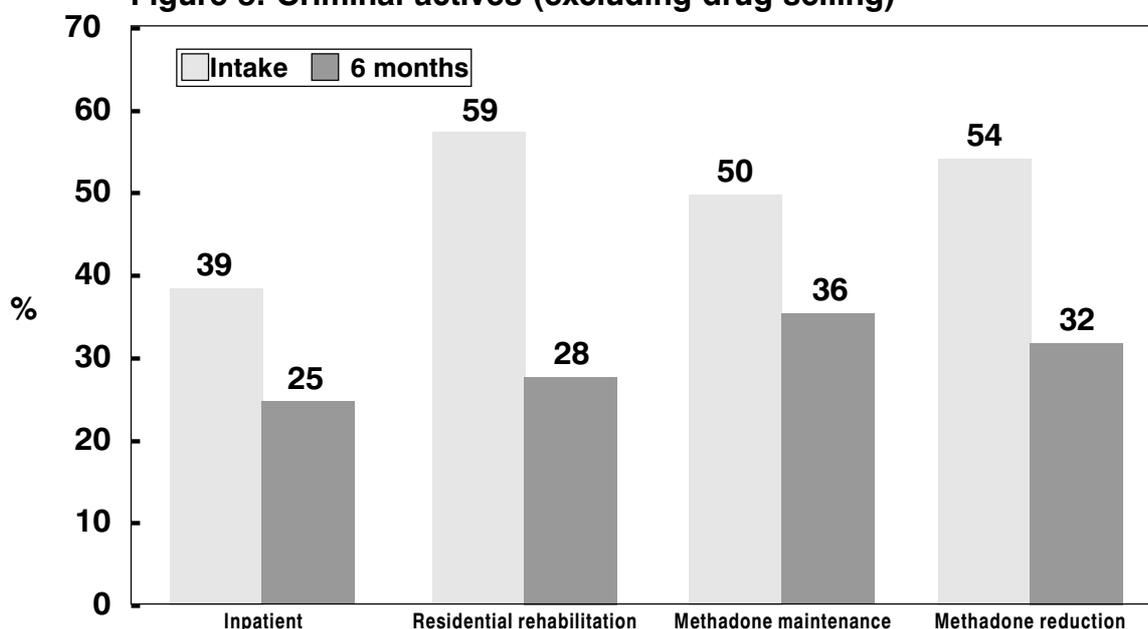


Figure 5: Criminal actives (excluding drug selling)



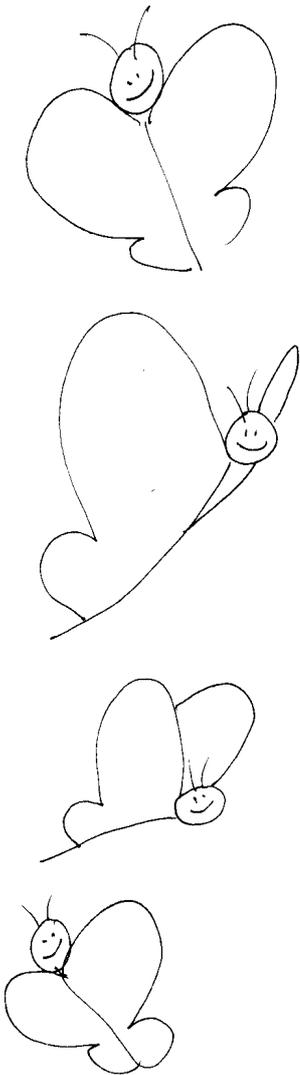
How did they use the information?

NTORS is still at a comparatively early stage. Data have now been collected on clients at the 6 month and 12 month follow-up points. Detailed analyses of these data are being conducted and full reports on the outcomes observed at these points are currently in preparation. The initial results from NTORS point to substantial improvements in all target problem behaviours immediately after starting treatment. Data presented in this paper show that the NTORS cohort reported marked improvements in terms of increased abstinence rates for opiates (specifically for heroin and illicit methadone). The results also show considerable reductions in the use of illicit opiates including heroin, cocaine and amphetamines, as well reductions in rates of injecting and sharing needles and syringes. Measures of physical and psychological health and of criminal activity showed further improvements. Detailed analyses of these six month follow-up data are now in progress and will be published in peer-reviewed journals in the near future. Follow-up data at 12 months from intake are now being processed, and additional funding for NTORS has been made available to allow continued follow-up of the clients up to the beginning of the year 2001.

NTORS provides evidence about the possibilities for recovery among problem drug users who seek treatment. Some traditional views of drug addiction have taken a pessimistic position on the question of outcome. It has often been suggested that people who become dependent upon drugs seldom give up and that treatment has little effect. In the first edition of the *International Journal of the Addictions*, the editor stated that there is no relationship between treatment and outcome, the end result is that "the great majority of addicts simply resume drug use" (Einstein, 1966). Similarly, in a review of treatment evaluation studies, Callahan (1980) noted that "the treatment of heroin addiction has been singularly unsuccessful."

Such views are not consistent with the available evidence. The large-scale treatment outcome studies in the United States provide some of the most compelling evidence for the possibility of recovery (Hubbard et al., 1989; Simpson and Sells, 1990; Ball and Ross, 1991) and there is no longer any doubt that many addicts go on to become abstinent or to achieve important improvements in their problem behaviours. In a review of longitudinal studies of addiction careers, Thorley (1981) concluded that there is a gradual and steady trend towards abstinence. In a ten-year follow-up study of a group of heroin addicts who approached London drug clinics in 1969, Stimson and Oppenheimer (1982) estimated that 38% of their sample had become abstinent. There was considerable evidence for the stability of abstinence. Among the clients who had maintained abstinence for nine months or more at the seven year follow-up, the likelihood of relapse to heroin use was rare up to the tenth year. It was also clear that those who became abstinent from heroin had not, for the most part, transferred their dependence to other substances.

These first results from NTORS provide further support for the view that substantial change, including abstinence, is a real possibility for many people with serious drug problems. The NTORS clients presented with a range of extremely serious, long-standing problems. Most were physically dependent upon one or more drugs and had been for many years. They were experiencing a range of physical and mental health problems and half of them had experienced some sort of medical emergency requiring attendance at a general hospital Accident and Emergency Department during the period immediately before recruitment to NTORS. Almost one in three of the entire cohort reported suicidal thoughts prior to starting treatment. Many were regularly involved in criminal behaviours and many had previously been in prison. It is encouraging, therefore, to be able to report such substantial improvements in key outcome measures.



References for case example

- Ball, J. & Ross, A. *The effectiveness of methadone maintenance treatment*. New York: Springer, 1991.
- Callahan, E. Alternative strategies in the treatment of narcotic addiction. In: W. Miller (Ed.). *The Addictive Behaviours*. Pergamon, Oxford, 1980.
- Einstein, S. The narcotics dilemma: who is listening to what? *International Journal of the Addictions*, 1966, 1:1-6.
- Gossop, M. Addiction: treatment and outcome. *Journal of the Royal Society of Medicine*, 1992, 85: 469-472.
- Gossop, M., Green, L., Phillips, G., & Bradley, B. Lapse, relapse and survival among opiate addicts after treatment. *British Journal of Psychiatry*, 1989, 154:348-353.
- Gossop, M., Marsden, J., Edwards, C., Wilson, A., Segar, G., Stewart, D., & Lehmann, P. *The National Treatment Outcome Research Study. Summary of the project, the clients, and preliminary findings*. London: Department of Health, 1996.
- Gossop, M., Marsden, J., Stewart, D., Lehmann, P., Edwards, C., Wilson, A. & Segar, G. *The National Treatment Outcome Research Study*. Improvements in substance use problems at six months follow-up. London: Department of Health, 1997.
- Hubbard, R.L., Marsden, M.E., Rachal, J.V., Harwood, H., Cavanaugh, E & Ginsburg, H. *Drug abuse treatment: A national study of effectiveness*. Chapel Hill: University of North Carolina Press, 1989.
- Marsden, J. *Treating alcohol and drug problems: A review of assessment domains, outcome measures and instruments*. London: Department of Health, 1994.
- Simpson, D.D. & Sells, S.B. *Opioid addiction and treatment: A 12-year follow-up*. Malabar: Kreiger, 1990.
- Strang, J., & Gossop, M. *Heroin addiction and drug policy: The British system*. Oxford University Press, Oxford, 1994.
- Strang, J., Griffiths, P., Abbey, J., & Gossop, M. Survey of the use of injected benzodiazepines among drug users in Britain. *British Medical Journal*, 1994, 308:1082.

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Case example of an outcome evaluation



Use of buprenorphine for the treatment of opiate dependent subjects: impact on quality of life

The authors alone are responsible for the views expressed in this case example.

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Who's asking the question(s) and what did they want to know?

Opiate substitution treatment for heroin dependence has been considered as inappropriate, and less than 50 subjects were treated by methadone up to 1993 in France. Codeine, available as an over-the-counter-

medication, was the only medication available for most heroin dependent subjects, without medical or psychological support and in a somewhat illegal status as the indication for codeine is cough. In 1988, after an initial experience with opium tincture (2) our group, at the Victor Segalen University of Bordeaux started using buprenorphine for substitution of heroin dependent subjects seeking treatment in Bayonne (6). In 1990, a retrospective evaluation of those subjects first treated

with buprenorphine was carried out (3). This study was extremely controversial, since the idea of using substitution therapy was considered irrelevant by both regulatory bodies and substance abuse therapists. Data from the evaluation disputed this attitude, however, this study was retrospective. This resulted in further studies being performed involving buprenorphine on a prospective basis. Preliminary results of this ongoing prospective research are given here.

In addition to urinalysis, a large amount of analysis was carried out on quality of life (QOL) issues and psychopathology to specifically attempt to address the general impact of treatment and not only drug intake. The ultimate goal for treatment of substance abuse is to enable the patients to become abstinent from their primary substance of abuse, which in France is usually heroin for opiate dependent subjects.



How were the data collected?

All patients that began buprenorphine treatment at our clinic in Bordeaux were given the opportunity to receive a research-oriented assessment before treatment; three and 6 months after treatment and every 6 months thereafter (post-admission assessment: at 3, 6, 12, 18, 24 months and so on). This assessment was integrated into the clinical intake procedure. It involved a two hour face-to-face paper and pencil semi-structured interview using hetero- and auto-administered questionnaires. The instruments used are presented in TABLE II.

These evaluations are part of a more comprehensive long term follow-up study of a cohort of methadone and buprenorphine maintenance treated group of opiate dependent subjects looking for long term impact of treatment and dependent predictive variables of outcome (7).

All patients were treated according to a pre-determined protocol. Each subject was seen

on an individual basis once a week by a psychiatrist specifically trained for treatment of opioid dependent subjects with substitution therapy. Weekly visits were psychotherapy-oriented towards inducing behavioural changes in patients, based on the cognitive model and extensive collaboration with the patient. Buprenorphine was available as sublingual 2 mg tablets. Dose was adjusted according to patients' use of problematic opiate (heroin, codeine, morphine,...), reporting of withdrawal symptoms and craving. Delivery of treatment was done by a private practice pharmacist, within a non specific pharmacy. Pharmacists received a brief training and information on the nature and goal of the treatment. Each patient selected the pharmacist of his choice depending on proximity to home or workplace, and on quality of rapport with the pharmacist. Pharmacists delivered treatment on a daily basis, 6 days out of 7. This schedule was not changed until patient presented with three months consecutive opiate free urine.

How were the data analysed?

All data was treated through a data management unit. Statistics were done with SAS software package.

What did they find out?

Results are reported on a group of 16 subjects that had completed 12 months treatment in the fall of 1995. The average buprenorphine dose at that time was 6 mg and, due to the low dose strength of the available sublingual tablets (0.2 mg), absorption of the medication took approximately 30 min/visit. Mean age in years at admission was 33, of which 66% were males.

This group of subjects had started treatment between the beginning of 1993 and end of 1994. During that time 19 sub-

jects were started on buprenorphine treatment. This results in an 84 % one year study retention. Of the 3 subjects that had dropped from the study, one was deceased, one had stopped treatment at the clinic and one was still in treatment but had moved to another city. Overall this results in a 95 % retention.

At baseline 42 % of those started on treatment (8/19) were HIV positive. Within the

group that completed 12 months treatment, 50 % were HIV positive at baseline (8/16). None of those that were negative at baseline and completed 12 months treatment seroconverted for HIV during that time.

The primary outcome measure assessed was urinalysis for opiates. Abstinence was classed as less than one opiate-positive urine sample per month in random weekly urinalysis. Considering this group of subjects who completed

TABLE I

Instrument	Reference
DSM III-R	APA, 1987 (1)
ASI (Addiction Severity Index)	McLellan, 1985 (13); Grabot, 1993 (8); Martin, 1996 (12)
TEAQV (Tableau d'évaluation assisté de la qualité de vie)	Grabot, 1996 (9, 10)
BDI (Beck Depression Inventory)	Beck, 1961 (4)
STAI (Stait & Trait Anxiety Inventory)	Spielberger, 1970 (14); Bergeron, 1976 (5)
NHP (Nottingham Health Profile)	Hunt, 1980 (11)
Urine Toxicology	

TABLE II

	ASI Severity Score							BDI	NHP
	psych	med	fam	empl	legal	alcohol	drug		
Baseline	4,07	1,5	2,29	2,21	1,21	1,29	6,57	21	15
HIV positive	4,29	1	3,29	1,86	0,86	1,43	6,71	17	17
HIV negative	3,86	2	1,29	2,57	1,57	1,14	6,43	24	13
12 month follow-up	2,79	1,79	1,93	1,43	0,71	0,5	1,5	14	8
HIV positive	2,86	2,86	1,71	1,57	0,86	0,43	1,43	16	10
HIV negative	2,71	0,71	2,14	1,29	0,57	0,57	1,57	12	8

12 months' buprenorphine treatment, 78% were abstinent at three months and 93% at 12 months.

Preliminary results from the ASI, BDI, and NHP are presented in TABLE I. Results from the TEAQV are not yet available on that group of subjects. Results show that subjects improve in most areas. This is true for both HIV positive and negative patients.

Because the goal of treatment should not only be to reduce symptoms, measures of quality of life was extensive. Data from the Addiction Severity Index (8, 12, 13) clearly showed that the severity scores, measured on a scale of 1-9 and including objective measurable data (verifiable), subjective self-report data (patient) and subjective report data (interviewer), were lower after three months and twelve months admission to buprenorphine treatment as compared to before treatment. Patients generally improved in all areas measured: psychological health, medical, family, employment, legal, alcohol and illegal drug use. Interestingly, patients did not switch from heroin to alcohol, as was expected by some, but their overall alcohol consumption actually decreased. Legal problems increased after three months, and this was due to the effective treatment promoting a return to 'normal' life: finding a permanent home and registering with local authorities, resulted in them becoming traceable for their previous offences and/or tax evasion. Quality of Life is a global multifaceted concept that can not be measured by only one instrument. It is made of objective and subjective aspects, in physical, psychological and environmental areas. This is why we used a combination of different instruments already available in addition to an instrument that we specifically designed. In addition to reduction of drug use, improvements in the more specific areas of psychopathology — depression, anxiety and general health — were also noted after 12 months.

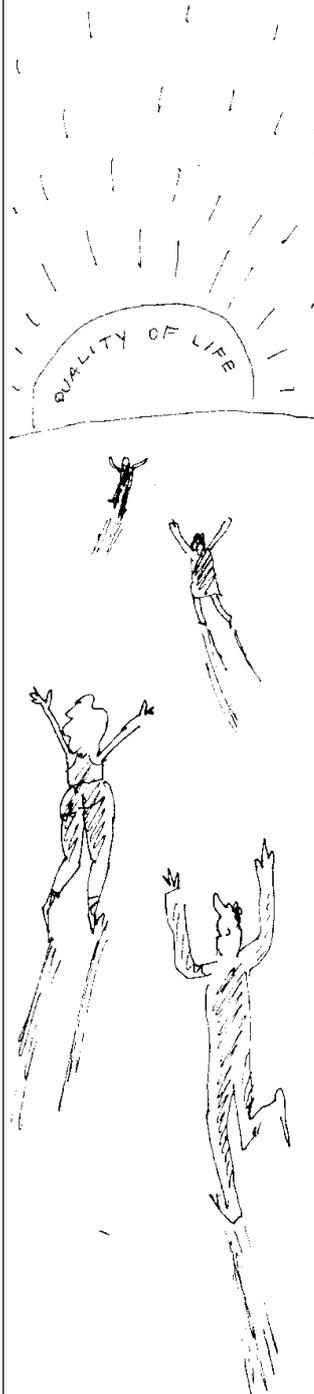
The TEAQV (9, 10) (Tableau d'Evaluation Assistée de la Qualité de Vie) is an instrument designed to standardise the collection

of quality of life data among patients with chronic psychiatric or somatic diseases. This instrument is a two part, 7 point scale (0=extremely bad; 7=excellent), self-rated quantitative evaluation of quality of life at different time points in 4 areas (physical and psychological well-being, family relationships, professional activity). The first part is a one-time retrospective lifetime evaluation whereas the second part is a current state evaluation that can be prospectively repeated. Time points are determined by important periods during the illness or treatment course.

This instrument is administrated by a trained interviewer in 5 to 10 minutes. The TEAQV has been used in different populations. Our early results with the TEAQV, suggest that it is an easy to use and beneficial instrument for making quality of life assessments.

Although many patients in our studies have been shown to improve significantly in several areas with buprenorphine treatment, studies elsewhere have shown that many still do not reduce their heroin intake or improve in other areas of health. This is thought to be due to insufficient dosing or the environment in which treatment is given, since it is well-known that complementary counselling programs are also imperative for successful rehabilitation. The conditions for treatment efficacy also vary quite widely and can, therefore, be difficult to compare. Within our institution treatment protocols were strictly standardised which is not the case elsewhere. Patients are counselled initially and advised that the treatment program is specifically for the reduction of their addiction problem. Treatment delivery is supervised daily by pharmacists, since 90% of the French population lives within 15 minutes walk from a pharmacy. This enables the treatment of addicts to occur in a controlled yet unstigmatized environment, preventing diversion of the drug to the intravenous route and integrating the patients into their local community.

Our feeling is that treatment outcome is dependent of its control — as seen with other treatments in psychiatry or medicine at



large. Our group advocates that this treatment should be controlled by three methods: I) extensive collaboration with the patient, ii) use of urinalysis and iii) supervision of drug delivery by the local pharmacist. Problems with patient compliance and poor behaviour are generally not seen with this protocol due to the time spent in consultation with the patient, the responsibility given to the patient for their rehabilitation and their integration into the community by daily pharmacy visits.

Results from patients treated previously demonstrate the high retention in treatment programs and high percentage of clean urine. Studies considering QOL indicate that buprenorphine treatment has more benefit to the patient than simply switching them from an illegal street heroin addiction to a legal buprenorphine addiction. Psychological problems, concurrent drug use and alcohol consumption are greatly reduced; in addition, health, social and employment situations are improved. Patients are not constantly seeking prescriptions from several clinicians, as has been the case in the past, and the current treatment program is gaining credibility with the general public.

How did they use the information?

In France, buprenorphine was not considered by many people in the field to be an effective treatment. Indeed, in certain areas it was considered to be one of the primary drugs of abuse. Buprenorphine treatment was considered as maintaining subjects in addiction: switching from heroin to buprenorphine was denied to be a therapeutic action.

Following on from our studies, and others, there was a change in French regulations for treatment of substance abuse and dependence and in February 1996, 0.4, 2 and 8 mg sublingual buprenorphine tablets were registered in France specifically for use in the treatment of opiate dependent subjects.



It's your turn

What are the strengths and the weaknesses of the presented case example? List three positive aspect and three negative aspects:

Strengths of the case study

1 _____

2 _____

3 _____

Weaknesses of the case study

1 _____

2 _____

3 _____

References

- American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. Third Edition Revised. Washington: APA, 1987
- Auriacombe M, Grabot D, Daulouède JP, Vergnolle JP, O'Brien CP, Tignol J. Alternatives to methadone maintenance: laudanum, buprenorphine. In: Harris H (ed.). 54th., *Annual Scientific Meeting, College on Problems of Drug Dependence*. Keystone CO: National Institute on Drug Abuse Research Monograph, 1992: 308
- Auriacombe M, Grabot D, Daulouède JP, Vergnolle JP, O'Brien CP, Tignol J. A Naturalistic Follow-up Study of French Speaking Opiate Maintained Heroin Addicts. Effect on Biopsychosocial Status. *Journal of Substance Abuse Treatment*, 1994, 11:565-568.
- Beck AT, Ward C, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. *Archives of General Psychiatry*, 1961,42:667-675.
- Bergeron J, Landry M, Belanger D. The development and validation of a french form of the state trait anxiety inventory. In: Spielberger C, Diazguerrero R (ed.). *Cross Cultural Anxiety*. Washington: 1976: 41-50.
- Daulouède JP, Tignol J. *L'expérience d'utilisation de la buprénorphine à Bayonne*. Colloque Toxicomanies, Hépatites, SIDA, Saint-Tropez, 1993.
- Franques P, Auriacombe M, Martin C, Grabot D, Cornish J, Tignol J. Predicting which patients do well on methadone maintenance. *National Institute on Drug Abuse Research Monograph*, 1996, 162:168.
- Grabot D, Auriacombe M, Martin C, Landry M, McLellan AT, Bergeron J, O'Brien CP, Tignol J. L'Addiction Severity Index: Un outil d'évaluation fiable et valide des comportements de dépendance. In: Leger JM (ed.). *Comptes Rendus du Congrès de Psychiatrie et Neurologie de Langue Française*. 1993: 213-219.
- Grabot D, Martin C, Auriacombe M, Tignol J. A new method for quality of life assessment: le Tableau d'Evaluation Assistée de la Qualité de Vie (TEAQV). In: NN (ed.). *American Psychiatric Association Annual Meeting*. Miami: American Psychiatric Association, 1995.
- Grabot D, Martin C, Auriacombe M, Tignol J. Tableau d'Evaluation Assistée de la Qualité de Vie (TEAQV). *Encéphale*, 1996, 22:181-185.
- Hunt SM, McEven J. The development of a subjective health indicator. *Social health and illness*, 1980, 2:231-246.
- Martin C, Grabot D, Auriacombe M, Brisseau S, Daulouède JP, Tignol J. Données descriptives issues de l'utilisation de l'Addiction Severity Index en France. *Encéphale*, 1996, 22:359-363.
- McLellan AT, Luborsky L, Cacciola J, Griffith J, Evans F, Barr HL, O'Brien CP. New data from the Addiction Severity Index: reliability and validity in three centers. *Journal of Nervous and Mental Disease*, 1985, 173:412-423.
- Spielberger C, Gorsuch R, Lushene R. The state trait anxiety inventory. In: *Stai manual for the state trait anxiety inventory*. Palo Alto: Consulting psychologists Press, 1970, 3-8.