SECTION 1: COMPLIANCE

Compliance: significance

Unsuspected non-compliance can hinder evaluation of drug efficacy and lead to premature changes in drug treatment of chronic illness, unnecessary laboratory investigations and avoidable hospital admissions.

Asthma can be a chronic disorder in which poor compliance may hinder good management. The goal of treatment is to enable the patient with asthma to lead as near a normal life as possible (Mellis 1980). If the symptoms are persistent, it is appropriate to give symptomatic and preventative medication. Although drug therapy may not alter the natural history of asthma, it can improve the functioning of asthmatic patients (Williams and Phelan 1977). Recent studies have suggested that many asthma admissions to hospital and asthma deaths were due to factors which could have been prevented through correct education and self-management practices (Leeder et al. 1981, Sutherland 1984). It is reasonable to conclude that medication compliance is a key element in the overall management of asthma in children.

Compliance: prevalence

It is difficult to make comparisons between the numerous studies of compliance because of variations in study design, the population observed, and the measures and definition of
compliance. Nonetheless, reviews of the literature on compliance indicate that from 15% to 93% of patients do not take their medication in accordance with their physicians' directions (Sackett and Snow 1979, Shope 1981). Poor compliance is a significant problem in both short- and long-term courses of therapy (Sackett and Snow 1979). In paediatric practice compliant behaviour implies co-operation from two parties - parent and child.

Most of the studies investigating medication compliance in those with asthma have been conducted in North America, where the mainstay of treatment is oral theophylline. However, a small number of studies are emerging, particularly from Australia, New Zealand and the United Kingdom which focus on compliance in patients who are prescribed in the first instance inhaled medications for their asthma, with oral theophylline added to the regimen as required (see Table 1.1). Overall, studies where compliance with oral theophylline was measured by serum theophylline levels showed optimum levels (indicating good compliance) in one-third or less of the patients. Compliance determined for aerosolised medications or for an unspecified combination of medications to treat asthma was generally higher. In many instances, though, the methods used to assess compliance (patient reports, diaries, tablet counts) may not have been as accurate as serum assays in determining medication intake.
### Table 1.1: Studies of medication compliance in asthma

**Chryssanthopoulos et al. 1983:**

| Sample                          | 22 males, 11 females  
<table>
<thead>
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<tr>
<td></td>
<td>Outpatient Clinic</td>
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<tr>
<td></td>
<td>Age: mean 8.9y; range 1.5y-18y</td>
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<tr>
<td>Prescribed Medications</td>
<td>Theophylline</td>
</tr>
<tr>
<td>Compliance Measures</td>
<td>Plasma theophylline measures</td>
</tr>
<tr>
<td>Outcome</td>
<td>25%: optimum levels</td>
</tr>
<tr>
<td></td>
<td>22%: suboptimum levels</td>
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<td>53%: unacceptably low levels</td>
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**Chryssidis et al. 1981:**

<table>
<thead>
<tr>
<th>Sample</th>
<th>67 males, 47 females</th>
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<tr>
<td></td>
<td>Outpatient Clinic</td>
</tr>
<tr>
<td></td>
<td>Age: mean 53.5y; range 17y-77y</td>
</tr>
<tr>
<td>Prescribed Medications</td>
<td>Inhaled salbutamol and/or beclomethasone</td>
</tr>
<tr>
<td>Compliance Measures</td>
<td>Pre-weighed aerosols</td>
</tr>
<tr>
<td>Outcome</td>
<td>Mean compliance:</td>
</tr>
<tr>
<td></td>
<td>Beclomethasone 93.1% (1st month)</td>
</tr>
<tr>
<td></td>
<td>103.1% (2nd month)</td>
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<tr>
<td></td>
<td>Salbutamol 103.9% (1st month)</td>
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<td>118.0% (2nd month)</td>
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</tbody>
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**Cluss et al. 1984:**

<table>
<thead>
<tr>
<th>Sample</th>
<th>11 males, 11 females</th>
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<tr>
<td></td>
<td>Outpatient Clinic</td>
</tr>
<tr>
<td></td>
<td>Age: mean 9.8y; range 7y-12y</td>
</tr>
<tr>
<td>Prescribed Medications</td>
<td>Theophylline</td>
</tr>
</tbody>
</table>
Compliance Measures: Riboflavin tracer

Outcome: Mean positive urine results: 77% (range 50%-100%)

Enev and Goldstein 1976:
Sample: 43 children
Outpatient Clinic
Age range: 3y-16y

Prescribed Medications: Theophylline

Compliance Measures: Serum theophylline levels

Outcome: 11%: optimum levels
65%: sub-optimum levels
23%: no detectable levels

Glanz et al. 1984:
Sample: 91 patients
Emergency Department
Age range: 15y-45y

Prescribed Medications: Oral corticosteroids (n=42)
Oral placebo (n=49)

Compliance Measures: Interview and blood corticosteroid levels

Outcome: Corticosteroid: 81% patients complied
Placebo: 86% patients complied

Hilton et al. 1982:
Sample: 28 males, 22 females
Private practice
Age: mean 31.5y; range 6y-64y

Prescribed Medications: Unspecified antiasthmatic drugs

Compliance Measures: Questionnaire

Outcome: 89% subjects compliant
James et al. 1985:
Sample: 22 children with severe asthma
Summer Camp
Age range: 8y-10y
Prescribed Medications: Beta-2-adrenergics, cromoglycate, beclomethasone, theophylline
Compliance Measures: Questionnaire
Outcome: 60% children used medications inappropriately

Kinsman et al. 1980:
Sample: 25 males, 60 females
Hospitalised
Age: mean 39.9y; range 24y-56y
Prescribed Medications: Inhaled beta-2-adrenergics when required
Compliance Measures: Observation
Outcome: 33%: appropriate usage
20%: over-usage
20%: under-usage
27%: erratic usage

Macfarlane and Lane 1980:
Sample: 56 males, 44 females
Outpatient Clinic
Mean age: 50y
Prescribed Medications: Inhaled beta-2-adrenergics, cromoglycate and beclomethasone
Compliance Measures: Questionnaire
Outcome: 47%: inappropriate use

Mecoy and Laby 1980:
Sample: 54 patients
University trial
Age range: 6y-62y
Prescribed Medications
Inhaled beta-2-adrenergics and cromoglycate, theophylline plus:
(a) beclomethasone twice daily, or
(b) beclomethasone 3 or 4 times daily

Compliance Measures
(i) aerosol count
(ii) interview

Outcome
(i) all subjects took >90% doses
(ii) 26 subjects took >90% doses

Radius et al. 1978:
Sample
111 children
Emergency Department
Age: mean 7.7y; range 0.75y-17y

Prescribed Medications
Theophylline

Compliance Measures
(i) interview (n=111)
(ii) serum theophylline levels (n=80)

Outcome
(ii) 66.3% children compliant

Sheen and Sly 1978:
Sample
19 males, 6 females
Outpatient Clinic
Age range: 0.8y-14y

Prescribed Medications
Theophylline

Compliance Measures
Serum theophylline levels

Outcome
10 children had zero or trace levels
Smith et al. 1984:

Sample
126 males, 64 females
Outpatient Clinic
Age: mean 8.2y; range 1.5y-17.3y

Prescribed Medications
Beta-2-adrenergics, cromoglycate, theophylline, beclomethasone, prednisone

Compliance Measures
(i) pre-weighed aerosols (n=19)
(ii) interview (n=190)
(iii) serum theophylline levels (n=37)

Outcome
(i) weighed aerosols: 86.9% doses taken
(73.1% doses stated to have been taken)
(ii) 67.9% doses taken
(iii) 22% levels less than predicted

Spector et al. 1986a:

Sample
13 males, 6 females
Private practice
Age range: 18y-65y

Prescribed Medications
Theophylline, beclomethasone, idoxamide (cromoglycate-like drug)

Compliance Measures
(i) nebuliser chronolog
(ii) diaries

Outcome
(i) patients complied on 47.1% of days
(ii) patients complied on 90.4% of days

Sublett et al. 1979:

Sample
33 males, 17 females
Emergency Department
Age: 5.1y; range 0.7y-14.0y

Prescribed Medications
Theophylline

Compliance Measures
(i) interview
(ii) serum theophylline levels (n=37)

Outcome
(i) inadequate doses prescribed for 12 patients
(ii) 5 patients: sub-optimum levels
32 patients: zero or trace levels
Tabachnik et al. 1982:

**Sample**
- 24 males, 16 females
- Outpatient Clinic
- Mean age: 9.3y

**Prescribed Medications**
- Sustained-release theophylline (SRT),
- Short-acting theophylline (SAT), beta-2-adrenergics, cromoglycate, beclomethasone

**Compliance Measures**
- (i) serum theophylline levels
- (ii) tablet count
- (iii) interview

**Outcome**
- (ii) SRT: 96.6% compliant
- SAT: 94.3% compliant
- (iii) SRT: 6 patients non-compliant
- SAT: 29 patients compliant

Taylor et al. 1984:

**Sample**
- 36 males, 27 females
- Private practice home visits
- Age: mean 66.9y; range 24y-86y

**Prescribed Medications**
- Theophylline

**Compliance Measures**
- (i) plasma theophylline levels (n=45)
- (ii) interview (n=63)
- (iii) tablet count (n=63)

**Outcome**
- Number of patients (Day 1/Day 15):
  - (i) toxic levels (1/1)
    - optimum levels (10/10)
    - sub-optimum levels (20/22)
    - zero levels (14/12)
  - (ii) non-compliant (16/2)
  - (iii) non-compliant (-/2)

Tinkelman et al. 1980:

**Sample**
- 8 males, 12 females
- Outpatient Clinic
- Age range: 11y-18y

**Prescribed Medications**
- Sustained-release theophylline (SRT)
- Short-acting theophylline (SAT)

**Compliance Measures**
- Tablet count
Outcome

SRT: 3.4% doses omitted
SAT: 6.6% doses omitted

Trembath and Marty 1981:

Sample
46 adults
Outpatient Clinic

Prescribed Medications
Theophylline

Compliance Measures
(i) plasma theophylline levels
(ii) interview

Outcome
(i) optimum levels: 8 patients
sub-optimum levels: 21 patients
zero levels: 4 patients
(ii) all subjects claimed they had
taken the morning dose
Correct inhalation technique is essential if the treatment is to be effective, as only about 10% of the released dose is deposited in the lung (McEvoy 1975). Many studies have shown that from 8% to 75% of the patients were unable to use conventional metered dose aerosols efficiently, even after careful tuition (Banias and Hurley 1986, Lee 1983, Crehek et al. 1976, Paterson and Crompton 1976). In a study by Frew and Macfarlane (1982), while 75% of 79 patients had correct inhalation technique, only 28% of 101 physicians and 17% of 18 hospital pharmacists performed all the necessary manoeuvres correctly.

The very young, the very old, arthritis sufferers and those experiencing difficulties with comprehension or co-ordination have particular problems in using aerosols correctly. Alternative inhaled modes include the use of attachments to contain the aerosol spray cloud prior to inhalation, and powders and nebuliser solutions for inhalation - all obviating the need to co-ordinate inhalation with activation of the canister (Levison et al. 1985, Van Asperen et al. 1981). Intuitively, those who belong to this category of patients who are unable to use aerosols correctly face additional barriers to complying, although no formal studies have evaluated this as an aspect of non-compliance. It could be expected that medications inhaled incorrectly would be perceived by patients as being ineffective, thus decreasing their motivation to continue with the treatment.
Compliance: Many techniques of measurement

There are many techniques which have been applied to the measurement of compliance. However, reliable and informative estimates of compliance are confounded by using methods that produce data which is frequently inaccurate and derived from a diverse array of measurement techniques. Some of these difficulties may be minimised by augmenting indirect measures (e.g. patient interviews, tablet count) with direct methods of measurement (e.g. biological measures).

Direct measures

(a) Appointment keeping and prescription filling

Keeping the appointment and filling the prescription are initial steps in complying. Both attendance at appointments and the relationship between appointment keeping and compliance are self-evident, as is the result if the prescription is not filled. It is wrong to assume, however, that simply keeping the appointment and filling the prescription implies compliance. To complicate the issue, studies such as those by Mattar and co-workers (1975a) have shown that there can be a 15% incidence of prescription underfilling, whereby patients are dispensed less than the prescribed amount of medication.
(b) Biological measures

The presence of drugs, metabolites and biological markers (e.g. medications containing radioactive tracer materials, riboflavin or dyes) may be detected in body fluids. Such methods can be costly in terms of time and resources, but generally provide reliable results and are simple to perform.

In asthma, the most commonly monitored medication is theophylline. Many studies have examined the pharmacokinetics of theophylline in serum and saliva (Ginchansky and Weinberger 1977, Kelly et al. 1981) and the monitoring of theophylline has been used to measure compliance (see Table 1.1). Theophylline levels depend not only upon obvious factors such as the dose, dose interval and time between the last dose and sampling, but also upon variables such as age, sex, diet, bioavailability, liver function, smoking status, diurnal variation and clearance rates (Hendeles and Weinberger 1980). Thus, sub-therapeutic levels may not always indicate poor compliance. The technique of measuring plasma and saliva drug concentrations are not generally applicable to aerosols because of minimal absorption of the aerosolised medications.

(c) Direct observation

Direct observation of the patient's behaviour provides both qualitative and quantitative information, but is time-consuming and labour-intensive. In addition, there are opportunities for bias to occur in the patients, who often alter their behaviours
whilst under scrutiny, and in the observer, who may be selective in what is observed (Dunbar 1979).

**Indirect measures**

**(a) Monitors and tablet counts**

These methods are based on the assumption that all the medication leaving its container enters the patient correctly; the remaining medication being taken as an index of compliance. The assumption is frequently unjustified, since the tablet count fails to identify medications that are consumed in an erratic manner, discarded, shared, or incorrectly administered (Dunbar 1979).

Devices for regular monitoring of compliance provide a greater degree of sophistication than tablet counts. A recently developed example of such a device is the Chronolog Nebulizer (Spector et al. 1986a) which measures not only the number of doses which have been fired from the aerosol canister but also produces a print-out showing the actual pattern of usage. This method is expensive and is prone to bias as patients are aware that they are being monitored. The latter concern did not, however, appear to be a problem in the study by Spector and colleagues (1986a). The authors gave only the minimum required information concerning the monitoring procedure to patients, and few patients asked about the Chronolog device. The poor compliance observed did not suggest that participants became "model patients" whilst under observation.
Clinical outcome

certain cases, such as in antimicrobial therapy, the clinical response to treatment is a useful measure of compliance. For many other types of therapy, however, this type of dose-response relationship is tenuous, and the effects of other modifying factors (e.g. additional health care practices, altered ironment) should be considered (Gordis 1979).

relationship between compliance and preventative medications. The overall control of asthma has not been clarified. There evidence that some of the medications to treat asthma when on a regular basis can dampen the bronchial hyperreactivity (an et al. 1985). On a long-term basis this should lead to less violent and less severe attacks of asthma because the ocation concentration of histamine has been shown to relate with clinical severity of asthma (Juniper et al. 1979, no 1966).

Physician's estimate

es conducted in a variety of settings have shown that the ian's estimate of patient compliance is only of limited e (Caron 1985). Roth and co-workers (1969), using a bottle check for comparison, asked 27 war residents to estimate their 'ents' compliance with antacid therapy. The median patient iance (bottle check) was 41% while the median physician or in estimating compliance was almost the same (32%). Even patients about whom they felt more confident, the physicians
could not identify "good" or "bad" compliers any better than could be achieved by chance. Similarly, Charney and colleagues (1967) found that physicians could successfully differentiate compliers and non-compliers (identified on the basis of urine analysis results) by using an adjective check-list which described the mothers' personal characteristics. They could not, however, make independent predictions as to which mothers would comply.

Much of the problem lies in the doctor-patient relationship where inadequate communication skills on the part of the physician leads to incomplete and inaccurate information obtained from the patient (Pendleton 1983). In a study of 100 asthmatics, Kleiger and Dirks (1979) suggested that physicians tend to avoid the problem of non-compliance simply by not asking patients about medication usage. Only 27% of the physicians studied inquired routinely about compliance, yet over 54% of their patients admitted quite readily to misusing medications when questioned by the investigators.

(d) Interviewing

Merely asking the patient about compliance can produce reliable information about compliance. The major disadvantage of this procedure is the reliance placed upon the accuracy and truthfulness of the patients' statements. Numerous studies have assessed how closely patients' reports of compliance correlate with actual compliance determined by direct measures (Boyd et al. 1974, Francis et al. 1969, Gordis et al. 1969, Radius et al.)
1978). The results have been conflicting; nonetheless the following points are generally agreed upon:
(1) In each study, whenever a discrepancy occurred between compliance estimates obtained from direct measurements and estimates obtained through interviews, overstatement of compliance always occurred in the latter.
(2) When patients admit to non-compliance they are almost certainly telling the truth.
(3) Interviews enable a more intensive investigation of the types of errors made and the reasons for the errors.
(4) Interviewing the patient is most effective when it is used in conjunction with a direct method of validating responses.

While researchers such as Caron (1985) contend that the interview as a measure of compliance is unreliable and inaccurate, Boyd and co-workers (1974) have justified their use of interviews to assess compliance provided that the following aspects of interview format and procedures were met:
(1) questions were asked at a level understood by the patient
(2) questions were open-ended to elicit spontaneous and complete responses
(3) phrasing of questions and attitude of the interviewer were non-judgemental and non-threatening
(4) the investigators were experienced in interviewing the type of population studied.

Unfortunately, only meagre information was supplied concerning the interview procedures adopted by many of the other studies cited above. It may well be that those studies reporting
significant discrepancies between reported compliance and compliance measured directly did not follow those procedures outlined by Boyd et al. (1974). It is pertinent, though, to recall Hippocrates' dictum, 
"...the physician) should keep aware of the fact that patients lie when they state that they have taken their medications".

**Compliance: associated factors**

In their annotated bibliography (1979), Haynes and colleagues listed more than 200 factors studied in relation to compliance. Although the results of these studies do not show consistent associations between various factors and compliant behaviour, some general findings have emerged.

*Demographic factors*

Demographic features such as occupation, social status, family size and sex are of little use as determinants of compliant behaviour. As Porter (1969) concluded, "It has not proved possible to identify an unco-operative type. Every patient is a potential defaulter, compliance can never be assumed". One factor which can affect compliance is age. Compliance is generally poorest at extremes of age: more than half of the elderly patients studied were non-compliant (Boyd et al. 1974, Latiolais and Berry 1969); while paediatric compliance implies additional barriers to overcome such as sleeping times, multiple caretakers and poor co-ordination when using aerosols in the case

* The illness

Compliance is likely to be poor when the illness is chronic, the patient does not perceive the illness as life-threatening and the consequences of stopping therapy are delayed (Blackwell 1979, McKercher and Rucker 1977, Shope 1981).

The type of disease, the severity of illness, or increasing symptoms do not seem to be important determinants of compliance (Charney et al. 1967, Hulka et al. 1976). However, the patient's perceptions of the illness do not necessarily coincide with those by the physician, and those patients who perceive that the illness is serious, and that they are susceptible to illness are more likely to comply (Becker 1979, Becker et al. 1979, Becker and Rosenstock 1984).

* The medications

A number of features associated with the treatment are determinants of compliance. Beginning with the formulation itself, Jellett (1975) noted that previously established regimens, unpalatable medications, child-proof closures, unsatisfactory labelling, tablet similarity and concurrent medicating with non-prescribed drugs could adversely affect compliance. At the dispensing phase, Mattar et al. (1975a) found a 15% incidence of underfilling of prescriptions from retail pharmacies.
As mentioned previously, poor compliance is more commonly associated with chronic rather than acute treatments. It seems that forgetfulness, complacency, boredom and inadequate supervision are major contributing factors (Blackwell 1979; Mattar et al. 1975b).

It is well-established that a complicated regimen (i.e. greater number of medications and frequency of doses) correlates with poor compliance (Clinite and Kabat 1976, Malahy 1966). Latiolais and Berry (1969) in a pharmacy-based controlled study of 180 out-patients, found a prescription:patient ratio of 2.7 for non-compliers as against 1.8 for compliers; while Francis et al. (1969) showed compliance to decrease significantly when three or more medications were prescribed.

Measurements of serum theophylline level in patients with asthma have suggested that sustained-release preparations (prescribed at 12 hour intervals) should be taken more regularly than conventional preparations (prescribed at 6 hour intervals) because the doses would be taken less frequently each day. This was evaluated by Tinkelman et al. (1980) and others (Jones and Sears 1980, Mitchell and Liang 1980), who showed that sustained-release formulations prescribed as a twice-daily regimen had significantly better compliance than conventional preparations which were to be taken four times a day.

There is controversy concerning the significance of side-effects as a reason for patients to discontinue therapy. Putten (1974)
reported that side-effects considered by the investigators to be relatively minor became a major determinant of non-compliance in out-patient schizophrenics. Latiolais and Berry (1969) and Kincey et al. (1975) did not find any strong correlations between adverse effects from medications and poor compliance, and a review by Ley (1982a) concluded that there is little evidence to support any such association.

In Australia, aerosolised medications form the basis of treatment for asthma in children, and thus a good inhalation technique is mandatory in achieving optimal benefit from the therapy (MoEvoy 1975). Apart from the obvious difficulties in co-ordinating the various inhalation manoeuvres, the patient is often presented with confusing or conflicting recommendations concerning the "correct" technique for administering aerosol therapy (Harper and Strunk 1981, Newman et al. 1980).

* Doctor-patient interaction*

The doctor-patient interaction is unquestionably an integral component in the compliance process, and encompasses variables which are complex and difficult to define, measure and quantify (Hulka et al. 1975, Pendleton 1983).

When considering the organisational aspects of the consultation, few associations were found between compliance and appointment-keeping patterns, distance to the clinic and time since the last appointment (Becker et al. 1972, Gordis et al. 1969, Mattar et al. 1975a,b, Mattar and Yaffe 1974). In her
review Shope (1981) found that compliance is higher in patients attending private practices rather than patients attending hospital clinics.

While demographic features such as level of education, social status, sex and occupation do not distinguish compliers from non-compliers, personal attributes of the patient may be useful in this regard. Davis (1968) found obstructive and authoritative patients to be less compliant, and Charney et al. (1967) used an adjective check-list to successfully identify compliers ("responsible" "mature" "organised") and non-compliers ("unreliable").

The patient holds certain expectations of the physician and the consultation, and if these are not met then compliance is less likely to ensue (Francis et al. 1969, Hulka et al. 1975, Ley 1978). Conversely, Radius et al. (1978) found that mothers of children with asthma were more likely to comply if they were sceptical of the physicians' abilities.

Another variable found to correlate frequently with compliance is satisfaction with the consultation or some particular aspect thereof (Ley et al. 1976a, Ley 1982b, Ley 1986). Patients' satisfaction with the physician, communication and aspects of the doctor-patient interaction is an important determinant of good compliance (Francis et al. 1969, Hulka 1979, Korsch et al. 1968). In his review Ley (1985) found that one-third of patients were dissatisfied with communications during the consultation. Efforts by the physicians to better their communications with patients
had led to improved patient compliance, satisfaction and comprehension (Ley et al. 1976a). However, in Roter's study (1977), after assessing what information each patient wanted, she rehearsed patients in asking the physicians questions. The manoeuvre of increased question-asking by the patients resulted in decreased satisfaction, although the appointment-keeping rate improved. Medication compliance had not been assessed.

The physician's personal characteristics and communication style have significant bearing on the outcome of the consultation. Compliance is greater if a familiar rather than a different physician is seen by the patient (Leistyna and Macauley 1966), and if the patient perceives the doctor as "friendly", "understanding patient concerns" and "believing in efficacy of therapy" (Francis et al. 1969).

How the actual information is transmitted, received, understood and remembered is a complicated process that is not always successful. Using doctor-patient pairs Hulka et al. (1976) assessed the communication variable to find significant discordance between what the patient thought he was supposed to be doing and what the doctor thought the patient was doing.

In his review (1982a) Ley states that:

"(1) patients do not seem to receive as much information as they desire, or as professionals judge adequate;

(2) the information provided to patients is often not understood by them, and patients frequently forget what they are told;

(3) the provision of information does not lead to the adverse
consequences often feared by clinicians;

(4) it is possible to improve communications, often with beneficial effects on compliance and recovery". He feels that non-compliance occurs largely because patients don't understand what they are told, can't recall directions and are diffident in seeking further explanations.

Bartlett et al. (1984) examined the effects of physician interpersonal skills and teaching statements on patients' satisfaction, recall and compliance. They found that physician communications did not directly affect compliance but instead mediated their effects through patient satisfaction and/or recall.

It is particularly important that people with chronic illnesses are well-informed about their disease and treatment. Surveys of people with asthma, their relatives and concerned others have revealed that basic misconceptions concerning asthma and its treatment are common (Buchanan and Van Asperen 1985, Ellis and Friend 1985, Gunnell et al. 1987, Imbeau and Williams 1981, Reddihough et al. 1977, Van Asperen et al. 1986). A British survey by Macfarlane and Lane (1980) showed that 47 of the 100 adults with asthma studied used preventative aerosols (i.e. beclomethasone and cromoglycate) in a variable, symptom-related manner, rather than on a regular basis as prescribed. Instructions were recalled incorrectly by less than 5% of compliers, compared with 28.6% of non-compliers.

Certainly part of the difficulty lies in the manner in which the
information is conveyed and the receptiveness of the patient. However, a reason for poor comprehension and hence poor compliance which is sometimes overlooked is difficulty with the language. In their survey of 257 non-English speaking out-patients Shaw et al. (1977a) found that 35% had poor comprehension of their treatments and that there was a deficiency of trained interpreters available. In a second study (Shaw et al. 1977b) of comprehension in English and non-English speakers, they found that the latter had twice the error rate of the former. Twentyfive per cent of English and 40% of non-English speakers were unaware of precautionary labels on their medications while a further 5% and 12% respectively could not recall the messages on the labels.

Nor should literacy competence be overlooked. On testing 225 mothers attending a paediatric casualty department Wingert et al. (1969) found that 45% were reading at a 6th Grade primary school level or below. The use of medical jargon and technical terms also creates problems, and surveys have demonstrated that patients do not know, or hold incorrect interpretations of, many of the supposedly common medical terms (Boyle 1970). It should be remembered, though, that while knowledge and comprehension are prerequisites for compliance, it does not always follow that possessing the necessary knowledge will ensure that the patient will comply.
*The Health Belief Model*

The Health Belief Model (HBM) (Becker et al. 1979) is based on a theory which argues that the likelihood of a patient's complying with a recommended preventative health action is dependent on that patient's perceptions of (a) susceptibility to the illness (b) seriousness of the illness (c) benefits of preventative actions (d) barriers to preventative action. A cue to action is needed to trigger the appropriate behaviour. The Model accommodates compliance in children by including (a) general health motivations (b) resusceptibility to illness (c) general faith in physicians and health care (d) the doctor-patient interaction.

The HBM has been used both as an explanatory and predictive model for compliance (Becker et al. 1978, Becker et al. 1979). There is considerable evidence that the variables involved in the HBM, such as the subject's perception of vulnerability, seriousness of the illness, effectiveness of the treatment, and costs and barriers in following the treatment regimen, correlate with compliance (Becker 1979, Becker and Rosenstock 1984).

Janz and Becker (1984) conducted a comprehensive review of 46 HBM studies (18 prospective, 28 retrospective). The studies addressed preventive health behaviours (24), sick-role behaviours (19) and clinic utilisation (3), and were conducted in diverse settings using a variety of methods to assess health beliefs and behaviours. They found that in both retrospective and prospective studies there was substantial empirical evidence showing HBM
variables to be important contributors to the explanation and prediction of subjects' health-related behaviours. "Perceived barriers" was found to be the most important variable across all of the studies. "Perceived susceptibility" contributed strongly to preventive health behaviours, while sick-role behaviours were explained by "perceived benefits" and "perceived severity". Janz and Becker concluded that although the HBM variables were predictive despite the variety of situations in which it was used, there remained a need to standardise the means of measuring HBM variables, and to develop intervention strategies directed at altering health beliefs.
SECTION 2: INTERVENTION

Intervention: general principles

By identifying the features associated with dissatisfaction, poor comprehension and inadequate knowledge and non-compliance it is possible to select strategies suited to the problem in question. There are some general principles which can be gleaned from the literature (Bartlett 1984, Dunbar et al. 1979, Green 1979, Haynes 1979, Ley 1982a and 1986):

* organisational strategies may alter structural barriers to compliance
* educational strategies can provide essential information that enables the patient to perform particular skills critical to compliant behaviour
* increasing knowledge alone is insufficient to ensure good compliance
* compliance implies a change in behaviour, hence behavioural strategies are required
* the causes of non-compliance are multi-factorial, hence a multiple intervention is more effective than is any strategy applied singly
* individualisation, where there is opportunity in group sessions to tailor information to meet an individual's needs, is important
* a personalised rather than a mediated (e.g. videotapes) approach is better
Intervention: strategies

Spector et al. (1986b) discussed practical methods for improving compliance with respect to asthma clinical drug trials. These methods are relevant to the treatment situation and included the provision of appropriate information, cues and reminders, rewards, re-inforcement, monitoring and feedback of drug levels and comprehensive asthma self-management programmes. The following discussion will outline some particular strategies and their specific effects on compliance and, in some instances, morbidity, patients' perceptions of the illness, the treatment and the health care professionals involved.

(1) Appointment reminders

Simple strategies such as post-cards, telephone calls and home visits can increase attendances at appointments but will not necessarily produce any other benefits such as better compliance or improved satisfaction with their health care (Anderson et al. 1982).

(2) Information

A number of studies and reviews by Ley and his co-workers (1976b and 1982a) have established that providing relevant information to patients in an appropriate manner can have beneficial effects on the patient's satisfaction, understanding and compliance. The types of educational strategies can span a broad spectrum, from the simple provision of information on medication labels to the
more elaborate techniques involved in doctor-patient interactions and self-management programmes.

Even the most motivated patients cannot comply unless they know how and when to take their medications. Stewart and Cluff (1972) remarked that "Better instructions are provided when purchasing a new camera or car than when a patient receives a life-saving antibiotic or cardiac drug". Medication labels are subject to misinterpretation (Mazzullo et al. 1974, Rothel et al. 1981) and ancillary advisory labels often go unnoticed or are misunderstood (Shaw et al. 1977a,b). The pharmacist should provide labels which specify unambiguously when and how to take the medications, plus any special precautions to be observed while doing so.

Written information is an inexpensive and time-efficient strategy for providing information to patients, and is usually the strategy of first choice unless the consequences of poor compliance are serious and costly (Ley 1986). Tone (the emphasis placed upon the risks of a treatment, for example), readability and format can be manipulated by applying psychological principles to the design of the leaflets. Particular forms of language and lay-out can improve the chances for certain pieces of information to be remembered (Dolinsky et al. 1983, Kanouse et al. 1981, Morris and Groft 1982). Ley (1975 and 1982a) has shown that that readability of leaflets is a powerful influencing factor in comprehension and recall. Since many leaflets issued to patients are too difficult to read, he advises that routine readability tests of written information be made. In a recent review (1986) Ley suggests ways for improving the technical aspects of both the vehicle carrying
the written information and its contents. In the same article, he discusses the possibilities for providing behavioural strategies in the written form, and for using behavioural manipulations to ensure that written materials are read and acted upon.

There is a belief amongst some physicians that providing patients with full information about the medications, in particular advice about adverse drug reactions, will lead to unwanted consequences such as non-compliance and side-effects. These fears have been shown to be unwarranted (Kanouse et al. 1981, Ley 1982a).

Improving knowledge alone does not ensure good compliance. This was demonstrated in a randomised control trial of a passive instructional programme applied to hypertensive men at their worksite (Sackett et al. 1975). At the follow-up assessment 6 months after receiving the programme, there were found no changes in either compliance or blood pressure control. In their review, Morris and Halperin (1979) summarised the status of written information as an educational strategy as follows:

"The provision of written information increases a patient's knowledge about medications and disease management and can improve compliance with short-term therapy. However, when used alone this particular strategy is insufficient to effect good compliance with chronic medication regimens".

Clinite and Kabat (1976) showed written information to be "counterproductive" unless it was reinforced with verbal instructions; and Morris (1978) concurred, demonstrating that "patient package inserts" were ineffective unless accompanied by
verbal explanations. Pharmacists have been encouraged to extend their responsibilities to include counselling patients about their medications (Mattar et al. 1975a,b, Weintraub 1975).

Counselling allows specific areas such as problems with compliance to be addressed, and has been shown to be effective in improving compliance (Cole and Emmanuel 1971, Madden 1973, Woroniecki et al. 1982). In an extensive study of 757 patients over four years Kellaway and McCrae (1979) found that counselling by the pharmacist reduced non-compliance significantly by 40%. However, studies by Latiolais and Berry (1969) and Malahy (1966) did not demonstrate such a correlation.

Mazzucco (1982) used meta-analysis to compare the effects on compliance and clinical course of chronic disease by educational and informational strategies with behavioural methods of counselling. He found that while patient education improved compliance, the behaviourally-oriented programmes were much more successful in improving both compliance and the clinical outcome of the disease involved. Ley (1986) used Mazzucco's figures to estimate that approximately 66% of those exposed to educational and informational strategies would be expected to be compliant, while a complementary compliance estimate for those receiving behaviourally-based interventions would be 76%.

The physician is in an ideal position to enhance satisfaction, comprehension and compliance in patients through the application of effective communication skills. Patients are less likely to comply if their expectations of the consultation are not met, yet
diffident in telling physicians what information they want to give (Ley 1982b and 1985).

Various methods for achieving satisfactory communications between patients and doctors have been described. These include training physicians in interviewing skills (Ley 1972, Ley et al. 1973, Ley et al. 1976), teaching patients to be more assertive in demanding information (Rotter, 1977) and increasing the understandability of information presented (Ley et al. 1973).

(1982a) has shown that much of the information given to patients is forgotten soon after leaving the consulting room, and tests that the following techniques can be used by physicians to reduce this phenomenon:

1. explicit categorisation, where related information is grouped into categories and then presented to the patient category by category
2. simplification
3. repetition by the physician
4. repetition by the patient
5. using specific rather than general advice statements

Information that is essential, understandable, and enables patients to perform skills relating to compliant behaviour is a significant determinant of compliance. Using a combination of educational strategies such as written and oral information is most effective, and both the pharmacist and the physician can play key roles in this area.
(3) Reduced workload

Schemes that reduce the patient's workload (i.e. remembering which doses need to be taken or have been taken, administration of the doses) should be quite successful in effecting compliance (Graham and Suppree 1979).

A variety of memory aids such as pill calendars, pill-wheels, special blister packaging and reminder labels (e.g. clock stickers) have been useful in aiding compliance with short-term regimens (Graham and Suppree 1979, Liberman 1972, Limia et al. 1976). Similarly, tailoring the dose regimen so that doses are linked with the patient's daily routine can assist in remembering dose times (Blackwell 1979).

Modifying the dose form can also be effective. Sustained-release, high-dose and combination formulations can reduce the complexity of the regimen. Where the actual administration technique is prone to potential errors, such as the conventional metered dose aerosols for asthma, alternatives may be necessary - e.g. in the case of aerosols. inhaled powders, spacer devices and nebuliser pumps may be appropriate (Levison et al. 1985).

(4) Monitoring

Increased supervision of patients by monitoring their drug administration and their clinical outcome can have positive effects on compliance.
Eney and Goldstein (1976) found that when serum and saliva theophylline levels were measured in a group of children with asthma who were informed that they were being monitored for compliance, therapeutic levels were achieved by 42% of the sample as against 11% of a similar, but uninformed, group of children.

Some investigators suggest that self-monitoring, where the patients record their own compliance and/or symptoms, can promote good compliance (Kellaway and McCrae 1979, Weinstein 1981). Care is needed in interpreting the results of such studies, as the onus is on the patients to collect the data, and this recorded information may be missing or inaccurate (Hetzel et al. 1979, Norman et al. 1982). Linkewich et al. (1974) found that 88% of patients who used drug calendars were more compliant than their counterparts who were not issued with the cards. However, such strategies are not universally successful because of difficulties as seen in this study where 60% of all those issued initially with the drug calendars chose to discard them.

Still, self-monitoring is valuable to patients who misperceive their drug intake (e.g. through erratic compliance patterns) or who are truly forgetful (Dunbar et al. 1979). Hore (1982) emphasised the value of peak flow monitoring by patients with asthma since it aided patient education (understanding the nature of asthma, predicting exacerbations) and facilitated the physician-patient interaction through improved communication and patient co-operation.
(5) Contracts

In North America in particular, contracting has attracted interest as a method for altering health behaviours (Dunbar et al. 1979). In contracting the usual pattern is as follows: if the behaviour occurs, then $X$ consequence ensues, if the behaviour doesn't occur then $Y$ consequence and not $X$ follows. Contracts may involve rewarding good compliance with monetary credits, tokens, inexpensive treats etc.

Becker and Maiman (1980) reviewed several studies that used provider-client contracts to establish compliant behaviour. They concluded that the method is effective, and that it offers the following advantages:
* provides a written plan of behavioural expectations
* involves the patient in planning the regimen and provides the opportunity to discuss potential problems in complying
* elicits a formal commitment
* establishes an incentive through the reward and reinforcement component

**Intervention: professional non-compliance**

Professional non-compliance is neither a new phenomenon nor an infrequent one. In his review Ley (1981) described instances where 12% to 95% (median 80%) of health care professionals failed to issue advice to patients. He also reported that 51% to 100% (median 65%) of patients did not receive appropriate medications or information about their treatments. Health professionals
should be actively interested in their patients' compliance, yet a study by Kleiger and Dirks (1979) revealed that only 27% of physicians in the sample enquired about compliance.

In another aspect of professional non-compliance, Banias and Hurley (1986) found that only 32.5% of patients surveyed had had their metered aerosol inhalation technique checked since they were first prescribed for these patients, and that pharmacist involvement in educating patients about correct inhaler use was minimal.
SECTION 3 - ASTHMA

Asthma: Prevalence and natural history

Asthma can occur at any age and approximately 20% of children in Australia will experience asthma during childhood (Britton et al. 1984). Of these children, about two thirds will have only mild episodic asthma, a further 25% will experience frequent episodic asthma, and the remaining 5% to 10% will have chronic persistent asthma. Most wheezy children, particularly those with mild episodic asthma will appear to "grow out of it" but will retain evidence of bronchial hyperreactivity (Van Asperen 1985).

Asthma: Causes

The fundamental abnormality in asthma is bronchial hyperreactivity, defined as exquisite sensitivity of the airways to physical, chemical and pharmacological stimuli (Boushey et al. 1980). However, the underlying cause of bronchial hyperreactivity is unknown. There appears to be a genetic component in that there is clustering within families. Superimposed upon this genetic predisposition are unknown factors which induce a state of bronchial hyperreactivity. Individual episodes of airway narrowing can be triggered by numerous factors such as the following:

* exercise
* cold, dry air
* water loss from the airways
* irritants e.g. smoke, dust, fumes
* viruses
* allergens - inhaled (e.g. dustmite, moulds), ingested (e.g. some food additives), occupational (e.g. red cedar dust)
* medications (e.g. beta adrenoeceptor antagonists, aspirin)
* emotional stress

**Asthma: Assessment**

Generally, the severity of asthma symptoms are not perceived accurately by the patient (Couriel et al. 1986, Rubinfeld and Pain 1976), so an objective measurement is needed. Pulmonary function tests, such as the peak expiratory flow rate (PEFR) or the forced expiratory volume in one second (FEV₁) are simple, convenient and reliable measures of airway narrowing (Light et al. 1977, Prior and Cochrane 1980). In 1977, Murray et al. compared PEFR readings with blood gas measurements in children, and concluded that PEFR monitoring was a useful aid in assessing the severity of asthma. There is recent evidence showing correlations between PEFR, bronchial hyperreactivity as defined by the provocative dose of histamine or methacholine to produce a 20% fall in FEV₁, and clinical severity of asthma (Juniper et al. 1981, Ryan et al. 1982, 1985).

Makino (1966) found correlations between asthma symptom scores and airway hyperresponsiveness. A variety of indices and assessment scores have been developed to provide a summary of the clinical severity of asthma, both during during an attack and in the intervals between attacks (Busse et al. 1986, Landau 1979).
Asthma: Significance

Asthma, being a common illness in childhood, is one of the major reasons for school absenteeism (Landau 1979). While asthma is not a frequent cause of death in children, it does cause significant morbidity and exerts considerable emotional and financial strain on the family (Creer 1986). Schwam (1987) recognised the particular difficulties experienced by families of children with a chronic disease, and discussed the various strategies that the physician might employ to help parents cope more effectively with childhood asthma in the following situations:
* disciplining the child
* attending school
* participating in exercise
* the child's peer relationships
* parental conflicts over asthma management
* social support systems for the parents
* behavioural aspects of medical management (e.g. compliance).

Asthma: Treatment

Asthma can often be unrecognised or, if diagnosed, remain under-treated (Speight et al. 1983). Thus the first step in managing asthma is correct diagnosis, followed by prescribing the appropriate treatment. The medications used for the treatment of asthma are outlined below, increasing in number in accordance with increasing severity of symptoms:
* episodic bronchodilators (inhaled beta-agonists, oral
theophylline)

* regular bronchodilators
* regular bronchodilators and regular cromoglycate
* regular bronchodilators and inhaled corticosteroids
* regular bronchodilators, inhaled corticosteroids and low doses of oral corticosteroids.

Where possible, inhaled medications are preferred to oral alternatives, since the inhaled route offers a number of advantages such as:

* lower dose needed to produce the equivalent effect of an oral dose
* minimal absorption into the systemic circulation
* fewer side-effects
* in some cases, rapid onset of action and greater protection afforded from induced asthma.

An integral part of asthma management is patient education, an observation that has been made in a number of reviews on aspects of preventing asthma morbidity and mortality (Leeder et al. 1981, Sutherland 1984). The treatment of asthma can be quite complicated, involving a variety of medications and routes of administration. The concept of preventative treatment as against treatment to relieve symptoms can be difficult for patients to comprehend. Moreover, many patients forget the instructions and advice they receive during the consultation (Ley 1982c).

Sutherland (1984) advocates the use of diaries in which "at risk"
patients record symptoms and PEFR so that they can more accurately perceive the severity of their symptoms. He also believes that these patients should be provided with a written crisis plan which bears specific instructions on the following items:
* recognising a crisis
* emergency treatment
* gauging the effectiveness of treatment
* action if the treatment fails
* action if the treatment works.

**Asthma: Medication compliance**

Since medications provide the mainstay of asthma management, it is essential that they are taken correctly. Most surveys of medication compliance in those with asthma have shown that more than half of the population under scrutiny do not take their medications as the physicians had recommended (See Table 1.1).

In addition to taking the right dose at the right time, patients prescribed aerosolised medications need to develop correct inhalation techniques (Lee, 1983).

There are numerous myths and misconceptions about asthma and its treatment (Buchanan and Van Asperen 1985, Ellis and Friend 1985, Gunnell et al. 1987, Imbeau 1981, Reddihough et al. 1977, Van Asperen et al. 1986), the effect of which is to create further barriers to complying with the prescribed treatment. Some of the
more common misconceptions are listed below:

* asthma is caused by "nerves" or psychological stress; children with asthma are "nervous" children; asthma is "all in the mind"
* milk and milk products increase mucus production and so make asthma worse; diet is a strong factor in causing asthma
* a tolerance develops if the medications are not regularly taken
* the medications are addictive
* exercise is "bad" for people with asthma
* antibiotics, antihistamines and cough syrups are useful in treating asthma
* children do not get asthma but "wheezy bronchitis".

Asthma: Intervention: strategies

Table 3.1 illustrates the diverse array of strategies that have been applied to adults and children with asthma. Usually, these interventions were intended to increase the patient's knowledge of asthma and its treatment, and to improve asthma self-management practices. Most of the strategies comprised a combination of educational and behavioural components, and many of them were "Asthma Self-Management" programmes where the emphasis was on the patient learning and practising asthma self-management skills taught in group sessions held over a few weeks.

To evaluate the interventions all of the studies used the patients' reports and a few studies employed additional measures
such as asthma diaries and monitoring plasma theophylline levels. Some of the studies adopted a design where subjects were randomly allocated to test groups (who received the intervention) or to control groups (who did not receive the intervention) and all evaluations were conducted at Pre-Intervention and Follow-up.

In general, these interventions led to better knowledge of asthma and its treatment, improved asthma self-management behaviours, decreased visits to the casualty department and admissions to hospital for asthma and, in the case of children, improved school attendance and adjustment. However few of these studies made specific assessments of changes in medication compliance and overall very little information was given concerning the severity of asthma and the treatment that was prescribed. The effects of intervention on medication compliance and on the clinical course of asthma, and the relationship between them, are areas which require further detailed study.
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<th><strong>Table 3.1 Studies evaluating interventions in children and adults with asthma</strong></th>
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Clark et al. 1986 and 1987:

**Intervention**  "Open Airways/Respiro Abierto" asthma self-management programme
1 hour/session for 6 sessions
Group work:
* information
* self-monitoring
* self-assertiveness
* life-style and using the government system
* Newsletter
* "Asthma Hotline" (telephone information line)

**Evaluation Design**
Randomised to Test (receive the programme) or to Control (do not receive the programme) groups.
Pre-Course and 12-month follow-up assessments

**Evaluation Measures**
* Interview using questionnaire
* Interview the physician
* Medical record
* School record
* Spirometry

**Sample**
Children; age 4y to 17y; Test (n=203), Control (n=107)
Outpatient Clinic; mostly poor and Hispanic

**Outcome**
Improved: self-management behaviours
  school adjustment
  relaxation exercises
Decreased: casualty and physician visits

Cree 1986:

**Intervention**  "Living With Asthma" asthma self-management programme
80 minutes/session for 8 sessions
Group work:
* knowledge
* medications, compliance
* social learning principles; applying these to asthma-related situations
* antecedent conditions, symptoms
* concurrent conditions, "responsibility" for asthma, family conflict
* general problem solving

**Evaluation Design**
Controlled-waiting list procedure
Evaluations at Pre- and Post-Course, 6 months, 1 year and 5 year follow-up
Evaluation Measures
* Interview using standardised questionnaire
* Asthma diary
* Episode report
* Spirometry
* Pen and paper attitude measures
* Social and economic data
* School records

Sample
Children (age range 5y - 17y; n=123) and their parents
Referred to the programme

Outcome
(a) at 1 year
Improved: spirometry readings
school attendance
child's self-esteem
knowledge of asthma and its treatment
child better able to cope with asthma-related difficulties
Decreased: family expenditure on asthma
average number of attacks/month
(b) at 5 years
Improved: quality of life measures
positive attitude about the programme

Darr et al. 1981:

Intervention
Audiovisual information about bronchodilators
Two-part slide-tape programme of 15 minutes duration:
* use, rationale and effects of bronchodilators

Evaluation Design
Pre-Course, Post-Course and 1- to 6- month follow-up
using a randomised sequence of questionnaires

Evaluation Measures
*Questionnaires

Sample
Adults; age range 15y to 69y; n=30
Outpatient Clinic

Outcome
Improved: short-term (not long-term) knowledge
**Feren et al. 1986:**

**Intervention**  
Asthma education seminar  
One day of lectures to a single large group

**Evaluation Design**  
Pre-Course, Post-Course and 5-month follow-up

**Evaluation Measures**  
*Questionnaire

**Sample**  
Adults  
Test group (n=60; self-referred to programme, from the community)  
Control group (n=135; did not receive the programme; attending hospital)

**Outcome**  
Improved knowledge at 5-month follow-up

**Hilton et al. 1985:**

**Intervention**  
Asthma education programmes in general practice  
Maximum programme:  
* asthma booklet  
* treatment card  
* physician interview  
* audiostreamer  
Limited programme:  
* asthma booklet  
* treatment card

**Evaluation Design**  
Randomised to one of three groups  
Pre-Course and 12-month follow-up

**Evaluation Measures**  
*Interview using questionnaire

**Sample**  
Adults  
Maximum programme group (n=86)  
Limited programme group (n=88)  
Control group (n=100)  
Private practice

**Outcome**  
Improved: knowledge (Maximum programme only)  
satisfaction with understanding of asthma  
(Maximum and Limited programmes)
**Hindi-Alexander and Cropp 1984:**

**Intervention**
"Family Asthma Programme".
Sessions: 2 hours/week for 6 weeks
Group work; 15-20 families per group:
* medical, physiological and allergic aspects
* social, psychological and behavioural aspects

**Evaluation Design**
Pre-Course and Post-Course testing; follow-up at 3- and 12- months

**Evaluation Measures**
* Interview
* Questionnaire
* Daily diary

**Sample**
Children; age range 6y to 14y; n=92
Self-referred or referred by others to programme

**Outcome**
Improved: knowledge (short-term)
"internal control" scores (at 3 months)
physical activity reports (long-term)
school attendance record (long-term)
Decreased: casualty visits

**LeBaron et al. 1985:**

**Intervention**
Education programme about cromolyn
Individual sessions
1 session per month for 4 months:
* use, rationale and effects of cromolyn

**Evaluation Design**
Randomised to Test (receive the programme) or to Control (do not receive the programme) groups
Knowledge tested Pre-Course and Post-Course
Compliance and morbidity assessed at each session

**Evaluation Measures**
* Questionnaire
* Interview
* Cromolyn urine analysis
* Spirometry
* PEFR home-monitoring
* Physician's independent morbidity scores

**Sample**
Children; age range 6y to 17y; Test (n=15), Control (n=16)
Referred from Private practices

**Outcome**
Improved: knowledge compliance
Lewis et al. 1984:

**Intervention**  
"Asthma Care Training (A.C.T.) for Kids"  
Sessions: 1 hour/week for 6 weeks  
Group work; 5-7 families per group:  
* "Driver's Seat" and "Traffic Light" analogies  
* information about asthma and the medications  
* self-monitoring  
* self-assertiveness  
* lifestyle

**Evaluation Design**  
Randomised to Tread (receive the programme) or to Control (do not receive the programme) groups  
Interviews at Pre-Course, 3-, 6- and 12-month follow-up  
Records reviewed at Pre-Course and 12-month follow-up

**Evaluation Measures**  
* Interview  
* Questionnaire  
* Medical records

**Sample**  
Children, mean age 10y; Test (n=4); Control (n=28)  
Referred from Private practices

**Outcome**  
Improved: compliance behaviours  
Decreased: child's dependency on adults  
child's trouble with asthma  
casualty visits  
days of hospitalisation  
institutional costs of $180/child/year

Mainan et al. 1979:

**Intervention**  
Educational and motivational strategies  
Individual sessions; patients receive various combinations of three of the following strategies:  
* Nurse interview by a Nurse who was  
  - asthmatic and self-identified  
  - asthmatic and not self-identified  
  - non-asthmatic  
* Booklet which was or was not provided  
* Telephone follow-up

**Evaluation Design**  
Randomised to 6 intervention groups  
Interviews at Pre-Course and 6-week follow-up  
Casualty visits monitored for intervals prior to interview, telephone follow-up and 6-week follow-up

**Evaluation Measures**  
* Interview  
* Medical records

**Sample**  
Adults; n=245  
Attending Casualty
Outcome: Decreased visits to Casualty when:
- Nurse was asthmatic
- Booklet was provided (except for non-asthmatic Nurse)

Modell et al. 1983:

Intervention: Management plan for asthma in general practice
"Spontaneous" physician consultations during 12 months:
- discussion and information about asthma and the medications
- PEFR home-monitoring
- self-management plan
- special consultation for asthmatic if no "spontaneous" consultation is required

Evaluation Design: Pre-Course and Post-Course interviews

Evaluation Measures: * Interview
* Medical record

Sample: Children and adults; n=92
Private practice

Outcome: Improved PEFR readings

Moldofsky et al. 1979:

Intervention: "Living with your asthma"
Videotape of 55 minutes duration; non-technical language; dialogue between a physician and a sports star with asthma:
- physiology
- managing asthma using self-care and medications
- common asthma-related problems

Evaluation Design: Randomised to Test (receive the programme) or to Control (do not receive the programme) groups
Questionnaire and clinical assessment Post-Course and 16-month follow-up

Evaluation Measures: * Questionnaire
* Medical record
Sample  
Adults Test (n=31, mean age 46y); Control (n=31, mean age 46y)  
Outpatient Clinic

Outcome  
Improved knowledge at short-term but not long-term assessment

Richards et al. 1981:

Intervention  
Self-help programme at:  
(a) hospital  
* slide-tape about asthma  
* discussions with the physician  
* printed information  
* discussion groups  
* quizzes and reinforcement  
* individual medication storage boxes  
* child self-administers medication under Nurse supervision  
(b) home  
* programme continued under parental supervision

Evaluation Design  
Evaluated over 9 months  
Questionnaire and clinical assessment Pre-Course and Post-Course

Evaluation Measures  
* Questionnaire  
* Medical record

Sample  
Children; age range 6y to 13y; n=23

Outcome  
Improved: control of asthma  
self-management (initial and sustained)

Robinson 1985:

Intervention  
Asthma Summer Camp self-management programme  
45 minutes/session for 6 sessions  
Group work (15-20 children/group):  
* audiovisual information  
* hands-on demonstrations  
* asthma-related games and discussions  
* reinforcement

Evaluation Design  
Children: Pre-Course, Post-Course and 3-month follow-up assessments  
Parents: Pre-Course and 3-month follow-up assessments

Evaluation Measures  
* Questionnaire
Sample: Children; age range 10y to 14y; n=74

Outcome: Improved: knowledge
ability of child to remember medication
ability of child to take medications unsupervised
attitude of child toward asthma
ability of child to manage own asthma

Rubin et al. 1986:

Intervention: "Asthma Command" - an asthma-specific computer game
Individual; 45 minutes duration per game session for six sessions over a year:
* medication use
* using the physician's office and casualty
* attending school
* recognising signs and symptoms of asthma

Evaluation Design: Randomisation to Test (receive the programme) or to Control (do not receive the programme) groups
Pre-Course and Post-Course (12-month follow-up) assessments

Evaluation Measures:
* Questionnaire
* Medical record
* Interview
* School record

Sample: Children; age range 7y to 12y; Test (n=32), Control (n=33)
Outpatient Clinic

Outcome: Improved: asthma management behaviours
knowledge of asthma in general
knowledge of "Asthma Command" information
Selner and Staudenmayer 1980:

| Intervention | "CASH-IN" (Child's Asthma Self-Help) Sessions: 0.5-2 hours/session/week for 8 weeks Group work (15-20 children/group): * short lessons, group discussions, swimming classes * self-responsibility and self-care * physiology, medications * breathing and relaxation exercises * smoking * psychosocial aspects |
| Evaluation Design | Pre-Course, Post-Course, 2- and 4- month follow-up assessments |
| Evaluation Measures | * Questionnaire |
| Sample | Children; age range 6y to 17y; n=56 Referred from Private practice |
| Outcome | Improved: exercise tolerance and participation school attendance compliance (30% of sample) asthma self-management behaviours |

Sly 1975:

| Intervention | Slide-tape about asthma and allergen control 14 minutes duration, shown at Clinic visit |
| Evaluation Design | Alternate assignation to Test (receive the programme) or to Control (do not receive the programme, receive a personal interview) Pre-Course, Post-Course and 6-week follow-up at home assessments |
| Evaluation Measures | * Questionnaire * Interview * Observation |
| Sample | Children; Test (n=16), Control (n=16) Outpatient Clinic |
| Outcome | As effective as a personal interview in achieving better knowledge and compliance with allergen avoidance measures |
Van Asperen et al. 1986:

Intervention

(a) initial session with nurse educator:
* general information (oral and written) about asthma
(b) 3 hour seminar:
* pathogenesis and treatment of asthma
(c) 1 hour follow-up session with respiratory physician:
  * answering participants' questions

Evaluation Design

Knowledge questionnaire Pre-Course and at 1- and
3- month follow-up
Morbidity questionnaire Pre-Course and 3-month follow-up
Diary card over 3-months Post-Course

Evaluation Measures

* Knowledge questionnaire
* Morbidity questionnaire
* Diary card

Sample

Parents of children (age 12 month - 12y)
Test (received the programme; n=29; 14
completed the study); Control (did not receive the
intervention; n=14; 10 completed the study)
Children admitted to hospital or attended the
Outpatient Clinic

Outcome

Both groups showed improved knowledge at 1- and 3- month
follow-up
Test group showed significantly better knowledge than the
Control group

Weinstein and Cusky 1985:

Intervention

Behavioural strategies
At each office visit (every month or 2 weeks)
over 6 months:
* telephone reminders
* serum theophylline levels
* parental encouragement
* increased supervision of medication
* contracts
* exercise challenge
* stop daily medications if necessary

Evaluation Design

At least a monthly consultation if serum
theophylline levels are low
Serum theophylline levels taken at initial visit,
thereafter on a random basis
Assessments at each visit
<table>
<thead>
<tr>
<th>Evaluation Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Questionnaire</td>
</tr>
<tr>
<td>* Medical record</td>
</tr>
<tr>
<td>* Serum theophylline levels</td>
</tr>
<tr>
<td>* PEFR readings</td>
</tr>
<tr>
<td>* Asthma diaries</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children; age range 1y to 18y; n=39</td>
</tr>
<tr>
<td>Referred from Private practice and Outpatient Clinics</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved: compliance with theophylline</td>
</tr>
<tr>
<td>control of asthma</td>
</tr>
<tr>
<td>PEFR readings</td>
</tr>
<tr>
<td>appropriate use of medications</td>
</tr>
</tbody>
</table>
SECTION 4 - INTRODUCTION AND AIMS: INTERVENTION STUDY

Asthma can be a chronic illness in which preventative medications, taken on a regular basis, are needed if persistent symptoms are to be controlled. Medication compliance is therefore an important factor in the management of asthma.

Our previous study (Smith et al. 1984) and studies by others (Cluss et al. 1984, Eney and Goldstein 1976, Radius et al. 1978, Sublett et al. 1979) have shown that children prescribed daily medications for the treatment of asthma were not taking their medications as regularly as had been recommended by their physicians. Consequently, we instituted some measures designed to improve the medication compliance of the children attending the Asthma Clinics at the Children's Hospital, Camperdown.

It has been well established that applying a range of interventions is more likely to improve medication compliance than is the use of any single strategy (Epstein and Cluss 1982, Haynes 1979). In a preliminary study (Smith 1981) we improved the compliance in children with persistent asthma by implementing an intervention comprising educational and behavioural strategies, and this formed the basis for the intervention used in the present study.

The aims of the present study were to determine:

(1) the reasons given by parents and children for omitting prescribed medications
(ii) the factors, such as health beliefs and characteristics of the subjects and the regimen, which were important correlates of compliant behaviour

(iii) the effects on compliance of an intervention designed to improve poor compliance.
SECTION 5 - METHODS: INTERVENTION STUDY

1. Patient selection

The study population comprised children and parents attending the Asthma and Immunology or the Asthma and Chest Clinics at the Children's Hospital, Camperdown, N.S.W. For entry into the study, recruits met the following criteria. They:

(i) were prescribed continuous medication for the treatment of asthma

(ii) spoke English, or an interpreter was available

(iii) were returning to the Clinic for a follow-up appointment.

The protocol for the study is detailed in Figure 5.1. Subjects were assessed twice: during the initial visit to the Clinic, and again at the follow-up appointment. During the patient's first visit to the Clinic the physicians were assigned randomly to see either Control patients (i.e. receiving no intervention) or Test patients (i.e. receiving the intervention). Thus, at each Clinic session a physician would see a variable number of children (between 1 and 8), either all as Control or all as Test subjects, according to allocation of random numbers applied to the physician. With this method, 102 and 115 children were recruited to the Test and to the Control groups respectively. The subjects were further classified as "New" (i.e. attending the Clinic for the first time) or as "Old" (i.e. attended the Clinic previously). Following the consultation with the physician, the subjects were interviewed by the observer (NAS) before they
visited the hospital pharmacy. During interviews conducted at both initial and follow-up visits to the Clinic, information about asthma, the medications, satisfaction and health beliefs was obtained. However, questions pertaining to medication compliance were asked only during the follow-up interview, to avoid alerting the subjects that compliance would be under scrutiny.

All children were prescribed two or more medications. The range of medications prescribed at the Clinics is shown in Table 5.1.
Figure 5.1 Protocol for Intervention Study

Initial visit
New & Old subjects

Attach Assessment Sheets to Medical Record

See Physician

Prescribed continuous treatment.

Prescribed intermittent treatment.

Subjects at follow-up visit

TEST Receive intervention. Assessed by Physician.

CONTROL Receive no intervention. Assessed by Physician.

Exclude from Study

See Interviewer

Prescriptions designated by Interviewer as "Test" or "Control"

See Pharmacy

TEST Receive intervention

CONTROL Receive no intervention
<table>
<thead>
<tr>
<th>DRUG GROUP</th>
<th>MEDICATION</th>
<th>DOSE FORM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta-2-adrenoceptor</td>
<td>Salbutamol</td>
<td>Tablet</td>
</tr>
<tr>
<td>agonist</td>
<td></td>
<td>Syrup</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rotacap</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aerosol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nebuliser solution</td>
</tr>
<tr>
<td></td>
<td>Terbutaline</td>
<td>Tablet</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Syrup</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Misthalar</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aerosol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nebuliser solution</td>
</tr>
<tr>
<td></td>
<td>Orciprenaline</td>
<td>Tablet</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Syrup</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aerosol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nebuliser solution</td>
</tr>
<tr>
<td></td>
<td>Fenoterol</td>
<td>Tablet</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Elixir</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aerosol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nebuliser solution</td>
</tr>
<tr>
<td></td>
<td>Theophylline</td>
<td>Conventional release</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tablet</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Syrup</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Elixir</td>
</tr>
<tr>
<td></td>
<td>Sustained</td>
<td>Tablet</td>
</tr>
<tr>
<td></td>
<td>release</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anticholinergic</td>
<td>Ipratropium bromide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aerosol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nebuliser solution</td>
</tr>
<tr>
<td></td>
<td>Cromolyn</td>
<td>Disodium cromoglycate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spinhaler</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Halermatic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nebuliser solution</td>
</tr>
<tr>
<td></td>
<td>Inhaled steroids</td>
<td>Beclomethasone dipropionate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rotahaler</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aerosol</td>
</tr>
<tr>
<td></td>
<td>Oral steroids</td>
<td>Prednisone, Prednisolone</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tablet</td>
</tr>
</tbody>
</table>
2. Obtaining the data - the questionnaire

At each visit subjects were interviewed by the one observer (NAS), who was described as a pharmacy student from the University and thus attached to the Clinic but not part of it. The study was introduced to parents as a "survey on asthma, on the medicines used to treat asthma, and on your visit to the Clinic". The initial and follow-up questionnaires (see Appendix 1) were based on a questionnaire used previously and found to be reliable: good correlation had been found between reported aerosol usage (as stated at interview) and actual usage (as determined by the change in weight of the aerosol canisters), and there was close agreement between actual and predicted plasma theophylline levels (Smith et al. 1984). Both the attitude of the observer, and the phrasing of the questions were non-judgemental and non-threatening to encourage truthful responses. Confidentiality of responses was stressed. The interviews, which lasted 15 to 20 minutes, were conducted while patients were waiting to see the doctor or to have lung function tests. The answers to the questions were noted on the questionnaire forms by the interviewer. Data concerning compliance, asthma, the medications, satisfaction and health beliefs were elicited. Generally, only the accompanying adult was interviewed, but where appropriate (i.e. the child was responsible for remembering the medications) the child was included in the questioning. The final sections of the questionnaires consisted of Likert-type 5-point scales measuring subjects' health beliefs and satisfaction, and these were completed by the participants. Scoring was done in such a way that for each scale high scores were given to answers
theoretically likely to increase compliance. In addition, composite scores for satisfaction and health beliefs were obtained by summing the individual scores.

3. Calculating compliance

Compliance figures were calculated as follows:

\[
\% \text{ compliance} = \frac{\text{number of doses taken per week}}{\text{number of doses prescribed per week}} \times 100\%
\]

For further analyses, the sample was divided into four compliance groups. These four groups were considered by the attending physicians to constitute a clinically useful categorisation of the extent of patients' compliance with medications.

<table>
<thead>
<tr>
<th>Group</th>
<th>% Compliance</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0 - 50</td>
<td>poor compliers</td>
</tr>
<tr>
<td>2</td>
<td>51 - 70</td>
<td>omitting 1 or 2 doses (on average) of medications prescribed 3 or 4 times a day respectively</td>
</tr>
<tr>
<td>3</td>
<td>71 - 90</td>
<td>taking at least 3 out of 4 doses prescribed a day</td>
</tr>
<tr>
<td>4</td>
<td>91 - 100</td>
<td>optimum compliance</td>
</tr>
</tbody>
</table>

4. Reproducibility

To assess reproducibility, 17 subjects in the Test group and 26 subjects in the Control group were interviewed a third time at
their regular follow-up visits to the Clinic. All the questions asked during the second interview were asked again, and compliance was assessed as before.

5. Physicians' Assessments

Attached to the child's medical record was one of four Assessment Sheets (see Appendix 2). For the Test group the sheet had a checklist of information to be conveyed by the physician to the patient during the consultation, a space for the physician to record his assessment of the patient's compliance (on a 4-point scale), another space for the physician to describe the adequacy of aerosol inhalation technique, and an assessment of severity of asthma (on a 4-point scale). This global assessment of severity was based on consideration of the child's spirometric readings (expressed as per cent of the predicted normal values) and the acute response to inhaled bronchodilator, the frequency of symptoms and current drug requirements. For the Control group the physician received an Assessment Sheet which asked the same questions but did not contain a checklist of information to be conveyed to the patient.

6. Medical Record

The physician's global assessment sheet, a carbon copy of the prescription written during the consultation, and the results of any serum theophylline and pulmonary function tests were retained in the child's medical record. This information and relevant demographic data were extracted from the record at a later date.
7. Analyses

Information from the questionnaires was coded and transferred to tapes held at the University Computing Centre. The results were analysed using the Statistical Package for the Social Sciences (Nie et al. 1975).

8. Intervention

The intervention included educational and behavioural components.

(a) Educational component

Leaflets conveying the details of the rationale and the effects of the medications (see Appendix 3) were prepared for distribution to patients. The leaflets were structured in simple language, and the Flesch Scores (Flesch 1974) for reading ease are shown in Table 5.2. The Flesch Score bases the level of reading ease on the length of words and sentences used as follows:

\[
\text{Reading ease} = 206.84 - 0.85W - 1.02S
\]

where \( W \) = number of syllables per 100 words

\( S \) = average sentence length in words
A "Reading Ease" chart is used to interpret the Flesch Scores in terms of the graded reading ability required to understand the material and the estimated percentage of the American population who would fall into these categories of reading ease.
<table>
<thead>
<tr>
<th>Leaflet</th>
<th>Average Sentence Length in words</th>
<th>Syllables per 100 words</th>
<th>Flesch Score</th>
<th>Style</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventolin (A)</td>
<td>6.9</td>
<td>147.7</td>
<td>75</td>
<td>Fairly Easy</td>
</tr>
<tr>
<td>Ventolin (B)</td>
<td>9.0</td>
<td>159.5</td>
<td>63</td>
<td>Standard</td>
</tr>
<tr>
<td>Intal (A)</td>
<td>6.3</td>
<td>142.1</td>
<td>81</td>
<td>Easy</td>
</tr>
<tr>
<td>Intal (B)</td>
<td>8.4</td>
<td>153.6</td>
<td>69</td>
<td>Standard</td>
</tr>
<tr>
<td>Nuelin (A)</td>
<td>6.6</td>
<td>155.9</td>
<td>69</td>
<td>Standard</td>
</tr>
<tr>
<td>Nuelin (B)</td>
<td>9.2</td>
<td>165.8</td>
<td>58</td>
<td>Fairly Difficult</td>
</tr>
<tr>
<td>Becotide (A)</td>
<td>6.6</td>
<td>147.4</td>
<td>75</td>
<td>Fairly Easy</td>
</tr>
<tr>
<td>Becotide (B)</td>
<td>8.9</td>
<td>158.7</td>
<td>64</td>
<td>Standard</td>
</tr>
<tr>
<td>Atrovent (A)</td>
<td>7.0</td>
<td>148.2</td>
<td>75</td>
<td>Fairly Easy</td>
</tr>
<tr>
<td>Atrovent (B)</td>
<td>9.1</td>
<td>164.4</td>
<td>62</td>
<td>Fairly Difficult</td>
</tr>
<tr>
<td>Prednisone (short course)</td>
<td>7.3</td>
<td>149.0</td>
<td>74</td>
<td>Fairly Easy</td>
</tr>
<tr>
<td>Prednisone (long course)</td>
<td>7.7</td>
<td>148.1</td>
<td>74</td>
<td>Fairly Easy</td>
</tr>
</tbody>
</table>
Leaflets were prepared for each of the following seven medications:

* Salbutamol and equivalent bronchodilators
* Theophylline
* Cromoglycate
* Beclomethasone
* Ipratropium bromide
* Prednisone taken as a "long course"
* Prednisone taken as a "short course"

Except for both Prednisone leaflets, two leaflets in English were available; one in easily readable language for subjects with comprehension and/or reading problems (leaflet "A"), the other being a less simple version for literate subjects with good comprehension (leaflet "B"). Since not all of the patients attending the Clinic were fluent in English, both of the Prednisone leaflets and all of the "A" leaflets were translated into ten languages (Greek, Italian, Arabic, Chinese, Macedonian, Croatian, Serbian, Vietnamese, Spanish and Polish) by Mrs T. Cheshers of the Translations Services, N.S.W. Health Department.

When the patients presented to the Pharmacy Department to have their prescriptions filled, they were given the appropriate leaflets together with additional medication counselling provided by the pharmacist.
(b) Behavioural component

Behavioural strategies, detailed in the check-list attached to the medical record showing information to be conveyed to the patient, were effected by the physicians and involved the following:

(i) tailoring the drug regimen so that dose times were cued to the subject's daily routine activities
(ii) providing written instructions about the drug regimen (see Appendix 4)
(iii) stressing and reinforcing the importance of compliance with continuous medication
(iv) increasing the supervision of compliance by inquiring about compliance, problems with taking the medications and time taken to use up a canister, and measuring serum theophylline levels when the physician felt it was appropriate.

Thus, physicians were provided with different assessment sheets for the two groups of patients, identical in the information which the physician was to complete but differing in the aide memoire role of a checklist of strategies for improving compliance and suggestions for tailoring medication.

9. Physician's Compliance

Medical students who sat in on the consultations with patients were able to covertly observe the physicians' compliance with the protocol. Their reports indicated that the physicians were adhering to the protocol. When presented with a Test assessment sheet the physician emphasised the compliance improving
strategies and followed the checklist. With the Control assessment sheet the physicians varied considerably in their approach. If they thought that the patient had major compliance problems they spent some time discussing possible strategies but if they felt certain that the patient was under control they frequently omitted discussing compliance.