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Compliance Aids – Do They Work?

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Summary

The decision to use a compliance aid will depend on the motivation of the patient, their specific medication regimen, and their physical and cognitive ability. The administration of oral medicines may be facilitated through the appropriate use of 'organisers' which act as aides memoire. 'Medidos' and 'Dosett' are the most frequently studied compliance aids and both have been shown to be beneficial to the elderly and to community-based psychiatric patients. Adherence to a medication regimen may be improved without the use of proprietary compliance aids by ensuring that the most appropriate traditional container is used and by paying attention to the highest standard of labelling on the medicine container. Gadgets that are designed to improve physical dexterity can be useful when applying topical preparations, administering insulin injections, operating pressurised inhalers or administering eyedrops. The accurate administration of eyedrops is particularly important when treating glaucoma and may be facilitated by using devices that are designed to help with aiming of the eyedrops ('Easidrop', 'Mumford Auto-drop', 'Opticare'). If squeezing the eyedrop container is a problem the 'Opticare' device may be particularly suitable.

There may be value in the use of the compliance aids to provide assistance to carers who become involved with preparing medication for patients. Selection of an appropriate compliance aid is not likely to be the total solution to inadequate adherence and most patients will require a combination of strategies to facilitate adherence to treatment with medicines.

If patients do not comply with prescribed medication they risk the possibility of reduced therapeutic benefit and associated increase in morbidity (Leppik 1988; Morrow et al. 1988; Pullar & Feely 1990). Inadequate compliance, or rather *adherence* which is a more neutral and useful term (Cooper et al. 1982), also has economic implications since the benefits from treatment will be reduced but costs will remain the same. Significantly, there is growing evidence that lack of adherence in clinical trials may have a profound effect on the outcome of their results (Savage 1991). A re-examination of results from a trial of β -blockers in the management of myocardial infarction showed an association between adherence to therapy, certain psychosocial features and an increase in mortality (Horwitz et al. 1990). Although a direct link between adherence and mortality was not established, this study serves to heighten awareness of the importance of adherence in improving the effectiveness of prescribed medication. Hence, there is a need for strategies to improve adherence to therapy. There are several possible solutions at the disposal of the physician or pharmacist, one of which is to offer the patient a compliance aid. The evaluation of such appliances, both independently and in conjunction with other adherence improving strategies, is the subject of this review.

Before discussing the relative merits of various compliance aids it is necessary to consider the relevant reasons for inadequate adherence. These have been categorised as: (a) patients do not understand their treatment; (b) patients forget to take their medication; and (c) patients decide not to take their medication (Pullar & Feely 1990). Contributory factors are numerous, and include complex therapeutic regimens with respect to the type and number of medicines, frequency of dosage schedules, poor instructions, unsuitable packaging of the drug and inadequate advice about the importance of adherence. When medicines are not taken, it is arguable that patients are more likely to have made a conscious decision to this effect. For example, a study in the United States found over 70% of elderly people who were not adhering to their medication regimen were doing so intentionally (Cooper

et al. 1982). Factors that have a bearing on deliberate nonadherence include unacceptable size of tablet, or undesirable appearance or route of administration (Cowderoy & Coker 1987).

Alternatively, the patient might be fearful of, or have actually experienced, adverse effects from medicines and may prefer not to discuss these problems with the doctor or pharmacist (Pullar & Feely 1990). The physical and mental frailty of the patient also has an important bearing on the outcome of adherence, especially with regard to failing memory or poor sight (Cowderoy & Coker 1987). Many of these factors are likely to affect the level of adherence of elderly people because they generally receive more prescribed medicines, use more nonprescribed medicines, and are more likely to have cognitive or physical impairment. Relatively few studies have demonstrated a consistent relationship between medication adherence and age. In fact, there is evidence to suggest that the elderly may adhere well to their prescribed treatment (Stewart 1991). The vulnerability of certain people of advancing age is, therefore, more likely to be associated with the medication regimen itself, together with an individual's personal beliefs and level of fitness.

The most appropriate strategies to improve adherence depend on establishing the cause for each individual, and tailoring the method to the perceived cause (Fincham 1988). For instance, if comprehension is a problem, language will need to be matched to the level of intellect and explanations will need to be repeated until they are understood. The use of charts or written instructions in nonspecialist terms may be helpful, as can the adaptation of timing of dosage intervals to patients' daily schedules. Fincham (1988) points out that misleading conclusions can be drawn when examining only the rates of adherence between short- and long-acting agents which have the same active ingredient. For example, assuming the same level of nonadherence, a short-acting preparation that is to be administered 4 times a day may be more effective than the same drug in a long-acting preparation administered once a day since, if the occasional dose is missed, some drug from the 4-times-daily

regimen is more likely to reach the blood stream than if a once-daily dosage is omitted.

After an assessment of the cause of inadequate adherence, it may be appropriate to offer a compliance aid. The decision should be made after the prescription has been scrutinised and amended where appropriate in order to maximise adherence. The aim should be to keep the number of drugs prescribed to an absolute minimum, and the dose and frequency of administration should be chosen carefully and reviewed frequently (Royal College of Physicians 1984). Great efforts should be taken to communicate with the patient to ensure that he/she understands the purpose of the medication and the way it is to be administered. It is important to be aware that adverse effects or toxicity could be responsible for deliberate nonadherence, so steps that are taken to improve adherence in these circumstances may in fact be detrimental to the patient.

1. Types of Compliance Aids

Compliance aids have been designed to assist patients with a variety of different types of medication. They may be categorised as: (a) organisers, i.e. those that help to organise doses according to the time of administration and function as aides memoire; and (b) appliances that facilitate the physical administration of a drug or selection of the correct dose. The latter group includes such appliances as a gauge to help blind diabetics administer accurate insulin doses (Editorial 1984). A 'button infuser' device has been designed so that diabetics who would normally need 4 injections daily can reduce the frequency of injection to once every 3 or 4 days (Editorial 1984). A range of other appliances is available, including a gadget to help apply topical preparations to awkward parts of the body and various products that facilitate grip and coordination of pressurised inhalers. These products have been described in detail elsewhere (Roberts 1987). Patients who find it difficult to swallow tablets may find a tablet-splitting or tablet-crushing device helpful if no liquid or dispersible formulation is available (Pritchard & Senders 1989). Care

should be taken to ensure that patients do not crush specially formulated tablets such as slow release preparations unless a pharmacist or physician has advised that this would be the best course of action.

There are comprehensive reviews in the literature that describe the range and application of compliance aids (Cowderoy & Coker 1987; Pritchard & Senders 1989; Roberts 1987), but there is a paucity of studies that report on their effectiveness in improving adherence. Evaluations of compliance aids have concentrated primarily on 2 of the most popular appliances for oral medication, the 'Medidos' and the 'Dosett'.¹ Studies have also been conducted to assess the value of devices to assist in the administration of eyedrops.

1.1 Administration of Oral Medication (Fig. 1)

In a study of 10 psychiatric patients from 2 large hospitals, a subjective evaluation of the 'Medidos' was made (Feetam & Kelly 1982). Nine male patients (age range 18 to 55 years) and one female (aged 68 years), with diagnoses that included schizophrenia, manic depression, paranoid psychoses, personality disorders and subnormal intelligence, were included in the study. Although a quantitative assessment of compliance was not reported, several advantages of the 'Medidos' were claimed on the basis of a subjective assessment of the case histories. The device was considered to be valuable as a simple memory aid in patients who were motivated to take their therapy, but who were forgetful. There were benefits for long-stay psychiatric patients because the 'Medidos' has been found to be a valuable teaching aid during rehabilitation programmes designed to prepare hospitalised patients for life in the community. Interestingly, use of 'Medidos' improved the confidence that some patients had in the value of their medication because they could link the correct taking of medication with an improvement in well-being. How-

¹ The 'Dosett' is licensed for sale in North America under the name 'Mediset'.

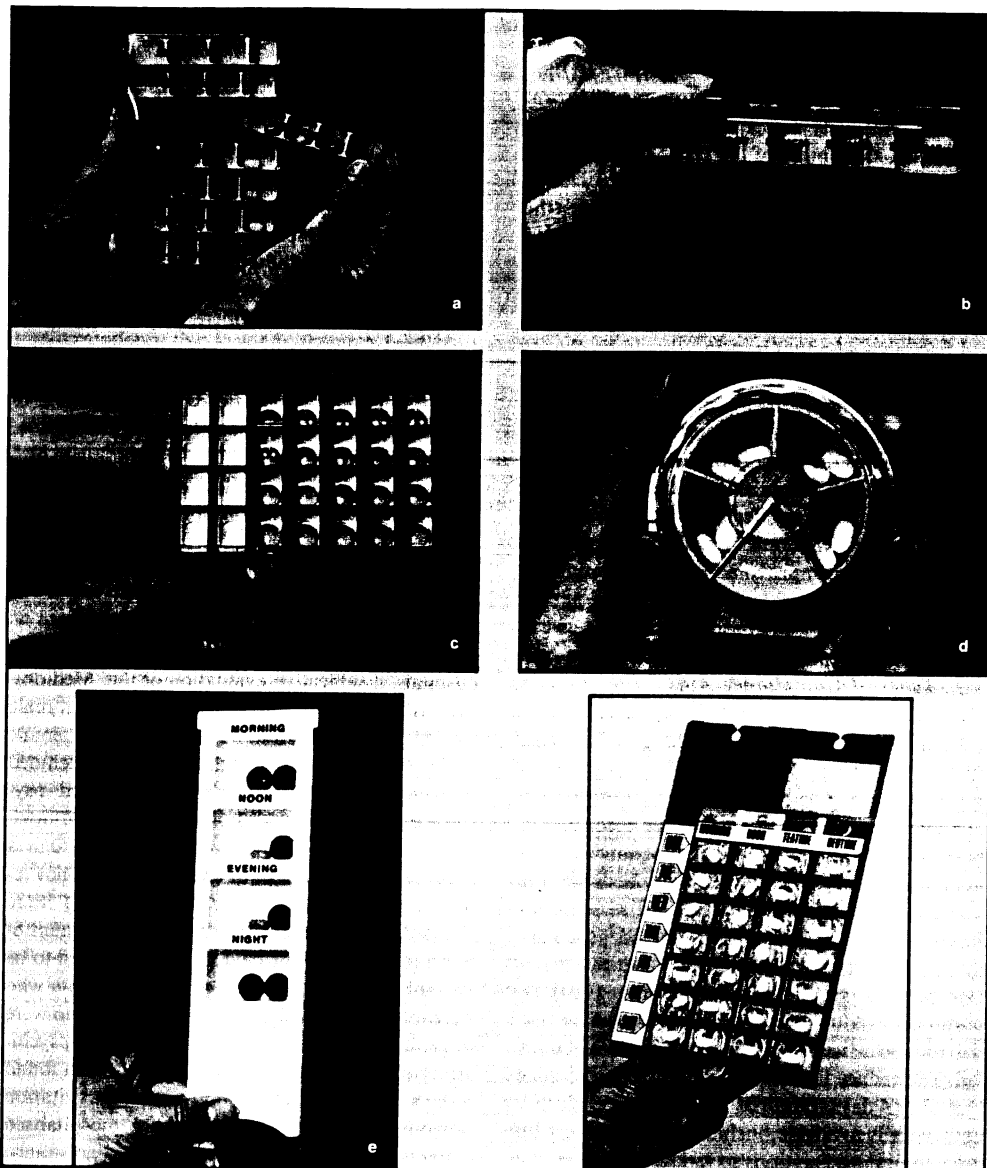


Fig. 1. Solid oral dose organisers: (a) 'Medidos' - will hold up to 1 week's supply in daily containers with retractable sliding lids ('Redidose' is very similar). (b) Close-up of 'Medidos' daily container showing adjustable dosage compartments for breakfast, lunch, dinner and bedtime; (c) 'Dosett' - a single box which will hold up to 1 week's supply in rigid compartments. Days of the week and dosage times are printed in relief to assist those with poor sight. The days are also labelled in Braille; (d) 'Medi-Wheel' - The circular knurled lid is twisted to provide an opening to release doses. May be used singly and loaded 1 day at a time or a week-pack can be prepared; (e) 'Patient Medication Tray' (with retractable translucent sliding lid) - designed for daily use but could be prepared for a week's supply; (f) 'Complipak' - a weekly bubble-pack that requires preparation by the dispensing pharmacist.

ever, it was recognised that these patients probably improved partly because of the additional attention that was being paid to them quite independently of the compliance aid. In this respect, it is difficult to determine with certainty whether or not the design of the 'Medidos' contributed to the improvements reported.

In another study, 222 patients of mean age 69 (± 9) years were recruited from an outpatient clinic and were invited to participate in a comparative study of 7 compliance aids - 'Medidos', 'Redidose', 'Pill Mill', 'Medi-Wheel', 'Dosett', 'Dispensatab' and 'Med-system' (Walker et al. 1990). Patients were asked to perform a dexterity test which involved removing a single tablet from each of these devices. On completion of the test the patients were asked to rank each in order of preference. The results indicated that the 'Medidos' was subjectively preferred by the majority of patients, with the 'Medsystem', 'Pill Mill' and 'Medi-Wheel' least popular, and the 'Pill Mill' causing dexterity problems for the majority of patients. Paradoxically, dexterity problems also occurred when patients tried to remove tablets from the 'Medidos'. Although the authors did not discuss this aspect of their results, the conflicting data seem to suggest that, although patients preferred the 'Medidos', they had not necessarily accounted for the way the device would actually be operated. One should not, therefore, necessarily rely on patients' initial subjective assessment to determine whether devices like these will be beneficial.

In recognition of this problem an attempt has been made to investigate the factors which influence the desire of patients to continue using a compliance aid (Walker 1991). From a total sample of 222 patients, 125 elected to receive a free 'organiser' compliance aid and, thus, agreed to participate in the study. Over the 6-month study period 16 patients were lost at follow-up due to death or leaving the area and 34 had withdrawn due to medication changes or lack of perceived benefit of the device. Of the 109 surviving patients available at follow-up, 75 (69%) wished to continue using their compliance aid on the basis that it facilitated adherence to their treatment programme. It is worth

bearing in mind that there may be some risk attached to the use of a compliance aid. For example, in one instance, a 'Medidos' led to obvious signs of overdosage, indicating that review of treatment was required (Feetam & Kelly 1982).

Whilst it is relevant to consider the preferences of patients with regard to the type of compliance aids that are available, it is equally important to determine whether patients would actually use one. In published studies, most compliance aids have been offered to patients free of charge. Whether a patient would actually want a device enough to pay for it is an entirely different issue. This question was raised when a survey was conducted with 52 patients, the majority of whom experienced partial or complex-partial epileptic seizures and were attending a neurological outpatients clinic (Wildin & Skellern 1989). Respondents in the survey were each shown a 'Medidos' and a 'Dosett' and were asked to state their preference whether they would use an appliance if given one and if they would be prepared to buy one. 18 of the 52 patients said they would use a compliance aid, but 17 said that they would not; only 8 patients indicated that they would be prepared to buy an appliance. 58% said that they preferred the 'Medidos' to the 'Dosett', while 20% had no preference. Reasons for their choice were the greater portability of 'Medidos' and also its facility to provide adjustable sections for day or weekend use. One person used the 'Dosett' at home as a storage device and the 'Medidos' when she went out.

The 'Dosett' was the subject of study in 12 psychiatric patients who were recognised as having a real or potential problem with adherence (Bazire 1984). Criteria for the successful use of the 'Dosett' were defined as 'no tablets remaining in the box at the end of the week on ≥ 4 successive occasions, coupled with full patient acceptance. Ten successful outcomes and 2 failures were reported. Patients with successful outcomes were more likely to be anxious and had less stable moods than the failed outcomes, who had markedly impaired cognitive function. It is difficult to interpret associations between anxiety and the value of the 'Dosett'. Perhaps, if a patient's anxiety interferes with memory

and the ability to concentrate on taking medication correctly, a compliance aid may assist by removing a substantial element of this worry.

Although data have been produced to support the value of compliance aids such as 'Medidos' and 'Dosett' some workers have found that one intervention on its own, such as counselling or special medication containers, have not improved adherence to medication therapy (Crome et al. 1980; Sackett et al. 1975). This acted as a stimulus for a randomised trial where a combination of strategies was offered to patients in order to improve adherence (Peterson et al. 1984). 53 adult and teenage epileptic outpatients were studied in a controlled longitudinal study in which patients in the intervention group received a combined strategy to improve compliance, including counselling, provision of a 'Dosett' container and medication seizure diary. Patients were asked to check their 'Dosett' and to ensure that all the medication for that day had been taken. They were then required to record this check in the diary along with records of any seizures. Reminder cards were sent if the patient did not return to obtain medication at a specific interval. Results from the study showed that the combination of strategies resulted in a statistically significant improvement in adherence as measured by plasma anticonvulsant concentrations and medication refil frequencies. Most importantly, a 50% reduction in seizure rate correlated with changes in plasma anticonvulsant concentration, implying that the improved adherence was linked to an improved therapeutic outcome.

Adherence to prescribed oral medication need not necessarily require a purpose-built compliance aid. The repackaging of medication provided in 'unfriendly' containers such as strip or blister packs into traditional tablet bottles, may be the main requirement. This was the case when a self-medication scheme on a rheumatology ward was introduced in one study (Owen et al. 1987). It is also possible to improve adherence by designing label instructions that enable patients to readily construct a simple mental model of how to take their medication. This can be achieved by using computer software to design pictorial and annotated la-

bels (Morrow et al. 1988). The use of graphic aids has also been advocated in order to improve adherence in the treatment of diabetes mellitus (Wedman & Kahan 1987). Attention also needs to be paid to the difficulties posed by child-resistant containers to patients with arthritis or who, for some reason, cannot apply sufficient grip to enable them to open a container. Here, an aid to adherence may simply be to issue a medication card which requests pharmacists not to supply child-resistant containers or blister packages to the patient (Owen 1987).

1.2 Administration of Eyedrops (*Fig. 2*)

The administration of eyedrops can be difficult even for those individuals who are fully dexterous, so people with physical handicap or poor coordination may have severe problems in this respect. Lack of adherence to medication instructions has been demonstrated among a sample of elderly patients (mean age = 73 years; range = 56 to 90) who were selected from an outpatient glaucoma clinic (Norrell & Granstrom 1980). They used a special medication monitor and fluorescein technique to assess the ability of patients to self-administer their eyedrops: 71% of the patients were found to have missed 6 or more doses during the 20-day study period. Similarly, over half of the patients in a US study missed 20% of their prescribed doses (Kass et al. 1986). In a Canadian study, as many as 70% of patients could not hit the eye with an eyedrop dispensed in conventional bottles (Brown et al. 1984), and difficulty in administration was reported by 21% of patients who were questioned about the level of assistance they required to administer eyedrops (Winfield et al. 1990). This difficulty was explained by the force that patients were able to apply to the eyedrop bottle. When the force reaches the limit of the patient's capability the hand becomes unsteady. This may result in failure to apply the drops, administration of more than 1 drop, or the need for a second person to administer the drops on behalf of the patient. In older patients, difficulties were experienced in raising their arm, tilting the head, squeezing the

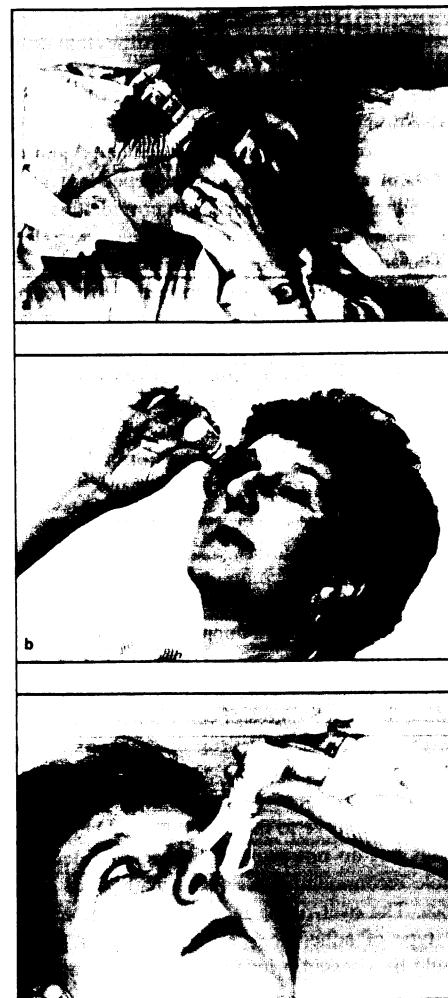


Fig. 2. Appliances to assist the administration of eyedrops: (a) 'Opticare' – assists locating the eye, aiming and squeezing; (b) 'Mumford Auto-drop' – assists locating the eye and aiming; (c) 'Easidrop' – assists locating the eye and aiming.

eyedrop bottle and opening the tamperproof seal on the new bottle (Winfield et al. 1990). Such data have led to the development of appliances to assist in the administration of eyedrops, such as 'Opti-

care' (fig. 2a), which is designed to help with the aiming of drops and squeezing the bottle. The 'Easidrop' (fig. 2c) and 'Mumford Auto-drop' devices (fig. 2b) assist with aiming eyedrops. The effectiveness of the 'Easidrop' was measured by Winfield and co-workers (1990) who found that the number of people who could instil a drop unaided first time increased from 20 to 87% after using this appliance. The authors suggested that an aid for the administration of eyedrops should ideally help in aiming and squeezing the container, physically reaching the eye, gripping the bottle, preventing blinking and finally giving confidence to the patient.

2. Choosing a Compliance Aid

2.1 Patient Considerations

When making decisions about the possibility of using a compliance aid for oral medication and of the type to use, it is important to consider factors that relate to the specific person in question. People who are most likely to benefit are those who are motivated to take their medication, but have difficulty in remembering to take it. Alternatively, if carers such as home helps, district nurses, friends or neighbours are involved in reminding patients to take their medication, a compliance aid could be a valuable asset (Parish et al. 1983). The successful use of a compliance aid in these circumstances will reduce the burden on carers, who might not need to visit the patient so often just to supervise the administration of medicines. Use of a compliance aid can also assist in the monitoring of medication by carers because the appliance can be inspected to see whether or not specific doses have been removed.

Psychiatric patients are likely to respond well to a compliance aid if poor memory or being muddled or anxious is contributing to their lack of therapeutic adherence. Patients who are unlikely to benefit from these appliances are those who, for whatever reason, have decided not to take their medication. If a significant degree of mental confusion is present, success is also less likely. The choice of compliance aid will depend on the physical and mental characteristics of the patient as well

as personal preferences. However, a superficial assessment of the patient should not take precedence over more relevant criteria for assessment of the dexterity of the patient.

2.2 Appliance Features

Attributes of the 'Medidos' include its portability and flexibility in terms of being able to separate each day's medication (fig. 1a,b). Disadvantages are its lack of robustness and unsuitability for those who lack dexterity, such as arthritic patients or those with conditions which impair motor coordination, such as Parkinson's disease. The 'Dosett' is more robust but is constructed as a single box which cannot be split into separate days of the week and is, therefore, more bulky (fig. 1c). The sliding lid is better than that of the 'Medidos' because it has 'click' stops that enable the user to feel when the lid has been moved to the correct position before the doses are tipped out. The times of the day printed on the 'Medidos' may not be appropriate for some patients. For example 'dinner' means a midday meal to some but an evening meal to others. However, if a patient is motivated to use a compliance aid, this sort of difficulty can be overcome by relabelling. If a patient or carer prefers to prepare medication on a daily basis, the larger and very easy-to-handle 'Patient Medication Tray' may be a good choice (fig. 1e). If necessary, 7 trays could be prepared for a week's supply. However, there is no formally documented evidence of its effectiveness and the larger size inevitably reduces portability.

Among some newer products, the 'Medi-Wheel' is designed to be easy to manipulate and gives a satisfying 'clunk' when each dose is brought in line to dispense (fig. 1d). Like the 'Patient Medication Tray', each appliance will hold only 1 day's medication. For a week's supply, the individual 'Medi-Wheels' can be stacked vertically in a 'week-pack'. Finally a large format bubble-pack, known as 'Complipak' in Canada, contains up to 1 week's supply of solid oral medication and is designed to be supplied ready-filled by a pharmacist (fig. 1f). Each bubble contains all the medication for 1 dose

for a specific time of day. Large pictorial labels indicate the day of the week and the times that doses should be taken. This method eliminates the need for the patient or carer to redispense and label the medication in separate compliance aids. 'Complipak' has not yet been formally evaluated and its successful application would be dependent upon the willingness of pharmacists to provide this kind of service.

The administration of eyedrops can be greatly assisted by using a compliance aid. Most benefit will be derived by those who need to use eyedrops regularly, such as in the treatment of glaucoma or for the symptomatic treatment of dry eye. These appliances will be particularly valuable where a patient is striving to maintain independence or to reduce the burden of a carer who normally administers the eyedrops.

3. Conclusion

This overview of common types of compliance aid is not comprehensive, but serves to provide an insight into the variety of appliances that are available and their relative merits. From the literature, it is not possible to draw definite conclusions regarding the effectiveness of compliance aids in improving adherence with drug therapy. This is because many data are anecdotal, and subjective assessments are made without adequate controls. Such studies serve to indicate potential benefits or pitfalls but do not provide sufficient evidence to enable recommendations to be made with confidence. The over-riding message is, therefore, that the type of adherence problem for each patient should be assessed prior to implementing any corrective strategy. If a compliance aid seems appropriate, it should be backed up by verbal encouragement, appropriate instructions, and review. Support may also be required in the form of well presented information on the medication to be taken.

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