

## Review article

## Helping patients to face the challenges of renal failure. Opportunities to improve compliance

Ziroyannis P N, Vamvakari P

*Nephrology Department, General Hospital of Athens, Athens, Greece*

**Abstract:** *Opportunities to improve compliance* It is well known that efficacy of a specific treatment may be evaluated only when there is compliance with the treatment. The term compliance is customarily used to refer to the degree to which patients follow the therapeutic recommendations of a health care provider. Recently there has been renewed interest in this area due to technical advances and a new appreciation of its importance as assessed by outcomes research. In fact, research has shown that the rates of non-compliance are often high, ranging from 30 to 60 percent for all types of medical therapies - even among those patients who are seriously ill. Despite the lack of uniform criteria for measuring compliance in the interpretation of reported rates, there is little doubt that overall compliance with prescribed regimens is suboptimal. Noncompliance among ESRD patients undergoing renal replacement therapy is a clinical challenge. Studies have reported noncompliance rates as high as 86% with ESRD patients' full regimen, including medications, fluid restrictions, dietary restrictions and consistency in returning/staying for treatments. To evaluate adherence to treatment, it should be possible to measure it simply and repeatedly. Outcomes researchers have rediscovered the importance of compliance, and have been able to demonstrate in long-term studies, including the Beta-Blocker Heart Attack Trial, the Medical Research Council Trial in the Elderly, and the Acute Infarction Ramipril Efficacy Study, that compliance with therapy is a major determinant of a beneficial outcome. The study of compliance has been improved by the implantation-based memory chips that are inserted into the caps of medication containers, which "remember" the times and dates when the container is opened, presumably to dispense a pill. This has provided a new gold standard for the estimation of compliance, which formerly was based on pill counting or other less accurate measures. *Hippokratia* 2006; 10(2): 51-59

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**Corresponding author:** Ziroyannis P, Taigetou 3D, Vrillissia 15235, Athens, Greece, e-mail: pziroyan@otenet.gr

### Introduction

Over one million individuals all over the world were on a form of chronic dialysis in 2003 and about 80.000 kidney transplants were performed<sup>1</sup>. End-stage renal disease (ESRD) patients on chronic dialysis or those with a functioning transplant are required to perform a group of behaviors daily which may be restrictive and unpleasant. These vary from dietary restrictions to performance of dialysis sessions and to taking immunosuppressive medications. Thus, the patient with ESRD who is on chronic replacement of kidney function (hemodialysis, continuous ambulatory peritoneal dialysis) or has received a transplant lives with the agony of today and the hope or fear of the future. Recently, there has been a rekindling of interest in the confrontation of the challenges of ESRD and the methods of treatment with a goal towards complete restoration of a normal way of life. This reappraisal comes from a twenty - year period of unfulfilled expectations for the improvement in the physical health of patients with ESRD<sup>2</sup>. In many cases, traditional methods of treatment have been replaced by a new method, which takes into account all the functions of the patient based on the holistic theory of the individual.

Therefore, the treatment and method of dealing with a problem does not aim solely at an improvement

in results. This is so because an increase in the outcomes of the patient does not constitute the only acceptable factor as an expression of quality or normal lifestyle. On the contrary, attention has turned to the rehabilitation of disturbed organ function and to adaptation in ways dealing with disabilities with new criteria.

The new challenges have been confirmed and many of them have undergone clinical tests after the widening of the definition of physical health<sup>3</sup>. The way of life of patients on hemodialysis is changing. The reasons for this change and the conditions affecting it are many. The disease and consequently its treatment influence the mental and physical function of the patient to a greater or lesser degree, reducing his physical activity and restricting his ability to work. Hemodialysis changes the normal way of life because it obliges the patient to adapt to a way of life, which brings him into contact with an artificial kidney machine for 12 to 14 hours weekly. There are very few therapeutic interventions, which cause such a huge disturbance of a normal lifestyle. At the same time the patient is instructed to take a lot of medicine and to undergo a special therapy to which he is forced to adapt for many years<sup>4</sup>.

Compliance with the instructions is one of the main characteristics of a patient in the establishment of a balance between the challenges stemming from the

disease and the kind of treatment he is on. Compliance with dietary instructions, consumption of fluids and medication are critically important factors in the maintenance of the quality of life of patients undergoing chronic hemodialysis<sup>4,6</sup>. The term compliance expresses the degree to which the patient follows instructions given by a member of the medical or nursing team who is treating him<sup>7,8</sup>.

Compliance influences personal habits on a long-term basis and changes the way of patient's life. Restrictions on food and fluid intake create marked psychological stress and take quite an important part away from quality of life. In many patients, intake of certain foods becomes an obsession, which influences their quality of life to a certain degree. There are patients showing great adherence to dietary instructions while others hide behind some excuse and consume large quantities of fluid and food, which in turn results in putting their lives in immediate danger.

Chronic hemodialysis comprises the ideal method of studying compliance or non-compliance problems with medical instructions. Firstly, treatment is long-term and contact with the patient is frequent. The patient cannot easily change treatment or go to another doctor. Problems arise when the patient is being advised by 3 or more doctors and receives many and various instructions which create confusion and put him in the position of being unable to comply with any of these<sup>9</sup>. Even though patients' studies have failed to prove the presence of a high level of compliance, it is claimed that Health Care Providers insist on enforcing instructions or expect a high level of compliance<sup>10</sup>.

Frequency of compliance in hemodialysis patients is small, fluctuating to below 25%<sup>11</sup>. The compliance in patients with high blood pressure fluctuates between 30%-50%<sup>12,13</sup>. Frequency of non-compliance fluctuates between 30-86% in patients with ESRD for all types of treatment including medication, restrictions on fluid and food<sup>5,14-16</sup> even among patients who are serious sufferers<sup>17</sup>.

Despite the lack of consistent criteria for the definition of compliance which makes the interpretation of the results of various studies difficult, there is no doubt that the level of compliance to treatment forms is low<sup>5,14</sup>. Undoubtedly, non-compliance of patients with ESRD who are undergoing methods of substitution of renal function represent a constant challenge to medical practice<sup>15</sup>. Non-compliance of the patient creates a situation with particular psychological repercussions for the medical and nursing staff as well as for the families of patients because it upsets all their expectations<sup>11</sup>. However, the level of compliance with pharmaceutical treatment in relation to compliance with food and fluid intake is different. Many studies have focused their interest on treatment with medication and have claimed that non-compliance with pharmaceutical treatment is greater<sup>5,14,15,18-20</sup>. It has been shown that more than 50% of patients in hemodialysis were taking a higher or lower

dose of medication or did not take their antihypertensive agents or their phosphate binders. It has been claimed that to obtain success and the desired outcome from high blood pressure treatment, compliance must be > 80%<sup>21,22</sup>. It has been calculated that only 52% of hemodialysis patients showed the expected clinical outcome from antihypertensive medication<sup>20</sup>. Attempts to show demographic characteristics of patients who are undergoing hemodialysis and show an increased danger of non-compliance with some or a part of their treatment has been unsuccessful<sup>15</sup>. It has been shown that older patients show higher levels of compliance<sup>5,14,21,23</sup>.

### Characteristic elements and predictors of compliance

It is not easy to find a model patient with ESRD presenting all the clinical and laboratory elements of compliance even if he is well-informed, logical and comfortably off. Even in this case we expect the patient to comply with: a diet with minimum quantities of fluid, a large quantity of medication taken at different times of the day on an empty stomach, during meals again with minimal quantities of fluid, a programme of hemodialysis which obliges him to be at the hospital three times a week despite any personal, professional or social obligations, a therapy which suddenly sends him to the hospital because an infection or arteriovenous anastomosis, a dialysis programme in which he sees many co-sufferers losing the battle of life every year, when he knows that the morbidity and mortality is not what one would wish and the opportunity for transplant is not the best possible<sup>24</sup>.

In the past the belief that compliance was related to how much the patient knew about the disease and the treatment held firm despite the contradictory data from various studies. However, a relationship has been shown between understanding the meaning of the limitations of the treatment and compliance. Informing the patient about the disease and the importance of adopting a steady therapy is necessary for compliance but this is not always adequate.

Length of treatment affects compliance, sometimes positively and sometimes negatively, there are fluctuations in compliance but in general the longer the treatment the lower the degree of compliance<sup>25</sup>. Patients undergoing hemodialysis show a greater degree of compliance in all areas of treatment<sup>23</sup> compared to other diseases. A patient may comply with some of the instructions in a certain length of time and at the same time diverge from others.

Side-effects of the treatment do not influence compliance. It has been shown<sup>26</sup> that non-compliance is not related to the severity of the disease, the amount of inconvenience, which it causes, disability or threat to life. Non-compliance is greater when the disease is without symptoms or psychiatric in its nature. Studies have shown that there is no relation between severity of the illness before admittance to hospital or before definition diagnosis<sup>25-27</sup>.

Patients who present serious problems have a tendency to show a high level of compliance. However, these problems create difficulties in compliance because of the limitations which the disease creates and feelings of disappointment in the patient from previous unsuccessful methods of treatment. The fact that the disease is serious and even life-threatening does not always go together with a high level of compliance<sup>26</sup>. Patients with a low level of social support show a low degree of compliance. Individuals who live alone show lower degree of compliance in comparison to those who live with adults and children (cohabitation). Marriage increases patient's compliance. It has been proved that unskilled workers show a lesser degree of compliance than skilled (profession). Families with a low socio-economic and educational level present a high frequency of non-compliance<sup>28</sup>. This observation is rooted in the fact that for those with a low income, medical care and therapy do not constitute their first priority. Since their aim is to ensure food and survival, this priority is far more important than a diet low or high in K<sup>+</sup> or Na<sup>+</sup>, which is necessary for the maintenance of physical health<sup>28</sup>. The level of education influences compliance to dietary treatment in patients with ESRD to a small degree, while it is related to other aspects of lifestyle such as physical health<sup>9</sup>. In patients with chronic disease self-esteem plays an important role in compliance. Patients with a high degree of non-compliance have a tendency to show a progressively positive attitude in order to affirm their self-esteem. This comes about despite incomplete procedures which let them down<sup>11</sup>. Attitude towards the illness: High level of acceptance of the disease is linked to greater levels of compliance related with the patients' belief that their health will improve if they follow the instructions<sup>22,23</sup>. The patient who accepts the illness and takes responsibility for its care, in consequence, will show a high degree of compliance. Patient with non-compliance see the disease as an enemy or a burden and have a tendency to take a defensive attitude. These patients have a strong sense of negativity which contributes to non-compliance with treatment forms<sup>11</sup>.

### Theories and models of compliance

There are models and theories aiming to describe and define the meaning of compliance. There are three main models of compliance who help us to understand the factors which may possibly lead to non-compliance. These are the Locus of Control Theory (LOC), the Health-Belief Model through which compliance is approached from psychological aspect and Piaget's Theory, in which cognitive development makes up the basis for the understanding in differences in learning abilities among people and supplies the necessary instructions to individuals. The above mentioned models make up the basis for the creation of a more contemporary theory of compliance. A better understanding of the meaning facilitates the necessary changes from the traditional relationship between patient and provider

to a type of partnership which will significantly improve the patient's outcomes.

The control center theory was set down in 1966 by Rotter<sup>29</sup> and makes up a small part of his social learning theory. Rotter suggested that the outcome of his disease as the result of chance or skilled handling can be foreseen. In 1978 Wallston et al<sup>30</sup> presented the multi-dimensional Health Locus of Control Scale for use in the prediction of compliance in patients with health problems. This theory claims that compliance can be predicted if we determine the degree of control which the patient exerts over his actions during his life. Those who believe that the outcome is a result of their efforts and skills are said to have an internal control center. Examples are patients, who take an active role in their diet and are able to describe clearly the limitations of the diet. Individuals who have an external control center believe that the outcome is a question of luck, opportunity or various other factors. Patients who complain about high level of K or blood phosphorous and blame their wives who prepared the wrong food or the nurse who gave too much fluid during hemodialysis can be placed in this category. Those who cannot be definitely placed in one or the other category can usually be found closest to one end of the scale<sup>30</sup>. The theory of control center has been the object of great research effort in recent years. In one study a comparison between compliance and non-compliance was made between overweight individuals and people suffering from diabetes mellitus type II, to determine the control and to facilitate understanding of the disease. In these individuals compliance was determined by loss of weight. Loss > 10% of the original weight per year for 3 years and random sugar level < 195 mg/dl made up the elements of compliance. The non-compliance group could not achieve the weight loss criteria, which were presented by the compliant group and in a random sample the level of sugar was > 250 mg/dl. The compliant group showed that it had a tendency towards internal control centers<sup>31</sup>. It has been claimed that patients with an internal control center have greater possibilities of showing positive behavior in illness, for example, taking responsibility for their medication. Their attitude towards the disease ensures greater success, regarding the attainment and maintenance of changes in behavior. Patients with an external control center are more suspicious, dogmatic and are influenced by people in high position. In this case, the doctor can play a role in forming the patient's attitude. This is also true for all the other health professionals. The findings of Lowry and Cette<sup>32</sup> contradict those of Alogna<sup>31</sup> who studied the differences in sugar control between two groups of patients who presented internal and external control centers. It is claimed that patients with internal control centers become disappointed when their tactics which are a result of knowledge and correct information do not result in complete control. This leads them to non-compliance with instructions<sup>32</sup>. These findings seem to

support the idea that health care providers need to provide more support for internally centered patients. Frequently, communication with patients tends to be of bad quality because of the limited time available for analysis of their problems. In order to succeed in activating a patient with a chronic disease, efforts need to be focused on sensitising and kindling the positive elements which determine the outcome of the illness.

Maiman and Becker<sup>33</sup> presented the Health-Belief Model (HBM) as a tool in the description and prediction of non-compliance. In this model non-compliance is described in relation to character indications, social situation and activating factors which prevent patients from following a model of therapy. The basis for this model rests on the fact that compliance can be predicted if we determine the way in which the patient perceives his illness<sup>34</sup>. Basic factors being studied include the patient's perception as regards sensitivity towards the disease, its severity, the outstanding or threatening symptoms and the advantages in comparison to the difficulties that are inherent to the application of therapy. HBM questionnaires were given out to 29 chronic hemodialysis patients in order to study their knowledge and behavior towards the disease. At the same time compliance with diet, limitation of liquids and taking of medication were determined in those patients. It was shown that total perception of the illness and its complication were the factors of least importance in prediction of compliance. Generally speaking, there was an significant relationship between patients' prescription and subsequent difficulties which follow recommended treatment and compliance<sup>35</sup>. The study showed the importance of confirmation and recognition of the problems and the behavior of patient towards the factors which come about as a result of recommended treatment.

Piaget's theory of cognitive development deals with the ways in which man gains his knowledge. He describes four separate stages in the learning function that man uses consecutively from the more simple to the more complicated ways of organizing and forming his information. The first two stages are referred to very young individuals. In the sensory-motor phase infants receive information from the world from sense stimulation and bodily movement. During this development phase children learn about the world mainly through activity<sup>36</sup>. In other words infants and young children learn from what is happening in the world around them. In the two final stages of the learning function, conscious functions are developed (Concrete Operations, CO) and formal operations and logical thoughts appear. These functions refer to the ability of the individual to carry out intellectual functions. These last two stages are of great importance when they operate in adults.

### **Confrontation of non-compliance**

The main question from a clinical point of view in the procedure of compliance is focused on non-compliant

patients. How does the Health Care Professional operate under these circumstances<sup>25</sup>? They often wish to know to what extent they are responsible for the non-compliance of their patients<sup>37</sup>. Undoubtedly, the patient has two choices - compliance or non-compliance. These attitudes are derived from the patient's wrights and his family to be well-informed of everything relevant to his treatment, even what could happen if he did not correctly follow instructions. When Health Care Providers have been convinced that the reasons for non-compliance are not ignorance or inadequate information, the responsibility is transferred to the patient. There are even cases where the patient gives the doctor all the facts which led him to the decision to follow the way of non-compliance<sup>37</sup>. In these cases Health Care Providers have great problems, indeed, because from the moment that they know of and accept the facts there is very little room for them to help because no one can persuade the patient to comply with instructions that he does not believe in. In these cases the patient who does not comply with instructions should not be made an outcast, should not be ignored but all possibilities should be exhausted and the support towards him continued within the boundaries which reality always places.

### **Ways of improving compliance**

Each change in the behavior of patients develops according to the following four stages: exposure, understanding, change in attitude and action<sup>38</sup>. In each case we accept that patients are in a position to respond to the instructions of the Health Care Providers. Understanding follows the ascertainment of the problem which may lead to a positive or a negative attitude. A positive leads to the formation of a complete picture of the disease which will be exhibited clinically through compliance to instruction. A fact which will determine the degree of compliance is every-day behavior, which in most people is up to the patient and the patient alone.

### **Compliance of a patient may be improved by:**

**Securing compliance:** This is gained when the treatment is carried out by the nurse eg. in hospital. It is also possible for the taking of medication by the patient, if it is carried out in the presence of another person who is caring for him.

**Limiting factors which make compliance difficult:** Ensuring a pleasant taste makes the intake of medication easier e.g. adding banana flavor improves the taste of antibiotics and facilitates the taking of medication in children. Substitution by syrup, or replacing medication which causes unpleasant side-effects with another of the same properties brings about an improvement in compliance. The implementation of dated pills which clearly indicates the day on which they should be taken helps the patient to take medication at correct intervals (Figure 1).

**Simplification of treatment form:** This demands reduction in the number of pills and the frequency with which they are taken. Reduction of the number can be gained





**Figure 1.** Calendar packs remind patients when to take their medicines.

by avoiding or discontinuing medication which is not completely necessary or by the use of combination of pills. The major difficulty with combination medication is that of adapting the dose for each patient (Table 1).

**Table 1.** Examples of the useful combination of drugs.

Iron and folic acid during pregnancy
Rifampicin with isoniazid in tuberculosis
A thiazide with potassium-sparing diuretic in cardiac disfunction

A reduction in the frequency of medication can be gained by the use of medication with long-lasting effects. Examples of the use of combination medication can be seen in Table 1.

**Educating patients:** Each individual has his own relationship with food which is influenced by sex, social position, work, nationality and age. This relationship obtains greater importance for a patient with ESRD because following special diet rules is a problem which follows him for the rest of his life. During 60's a reduced albumin diet aimed at the reduction of uremic symptoms. In 1970, with the introduction of hemodialysis and transplants, diet began to take second place at the scale of clinical interest. In 1980, the introduction of Brenner's hyperfiltration hypothesis renewed the importance of diet of renal failure. It is well known that compliance with long-term medication and diet is related to interest presented, simplicity of administration, lack of unpleasant side-effect and long-term appearance of beneficial results. For many years the educational level was considered to be the main method for improvement of compliance. Despite this fact, some claim that this is inadequate for the attainment of the desired result. In every level of education the patient aims at an increase in the extent of compliance until it reaches an acceptable level (> 85%)<sup>39</sup>. Today, acceptable conclusions about compliance education are summarized in the following:

a) Education, independently of whether it is received, from the doctor or the pharmacist<sup>40</sup> or any other person on the medical team<sup>41-43</sup>, gives far better results in comparison to patients who do not receive education.

b) Education did not increase the frequency of compliance to the desired level<sup>44,45</sup>. Recently new improvement interventions have been suggested which aim at giving the patient a greater understanding of the importance of compliance. These are: leaflets<sup>46</sup>, mailings<sup>39</sup>, videotapes (for home or office)<sup>47</sup>, information from the media<sup>48</sup>. Finally, special efforts are made to improve

the physician's understanding of the patients problem by using an analysis of the social and cultural dimensions of his character<sup>49</sup>.

**Increasing autonomy:** Much interest has been generated recently in increasing patient autonomy, ie, "patient empowerment". Some supporters of this suggest that if physicians involve patients in important decisions, eg, choice of drug therapy, frequency of follow-up, and so on, patients will be more likely to achieve compliance and adherence.








**Reminders:** Telephone and mail reminders improve compliance<sup>44</sup>. Such research was supported by the pharmaceutical industry (which gains financially when patients refill their prescriptions). On a more practical level, many patients have integrated a seven-day pill container into their daily lives, which serves as a reminder that certain pills need to be taken each day and shows which pills have not yet been administered. Although no studies of this intervention have been yet reported in the literature, such pill containers are widely available, inexpensive, and have been distributed by certain pharmaceutical companies. A somewhat more intrusive device is the recently developed pill container with an intrinsic alarm that sounds when the patient is to take another dose (Figure 2). Although very likely to be



**Figure 2.** The prescription Time Cap.

helpful, such devices have not been tested rigorously to see whether they improve compliance. A recent advance, the computerized pill schedule, has been tested in small numbers of patients given medications with a small therapeutic-to-toxic ratio on discharge from the hospital; this schedule has been shown to improve compliance rates<sup>50</sup>. Although the software and hardware for this intervention are not yet widely available, the concept of drawing up a similar schedule (Figure 3) seems relatively simple to implement. Anecdotal information suggests that taping a pill next to the scheduled dosing times makes it easier to recognize which pill is to be taken at the time indicated.

**A written list of medication:** In this way, patients can be taught to take greater responsibility towards their problems<sup>51</sup>. The consecutive steps which play a role in encouraging the patient to follow the suggested treatment form are the following<sup>26</sup>: To promote compliance a detailed description of the illness, methods of dealing with it and participation in therapy must be made clear to the patient. Although it is useful, presenting information by itself does not always help towards compliance. Regarding the nurse to ensure that the patient has

Medicine	Shape	Dose, mg	Time of day			
			7 AM	Noon	6 PM	Bedtime
Hydrochlorothiazide		25	X			
Atenolol		100	X			
Hydralazine		50	X		X	
Ampicillin		500	X	X	X	X
Lovastatin		40			X	
Warfarin		5				X
Cimetidine		800				X

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**Figure 3.** A sample computer generated patient reminder chart for medication administration. The recognition of pills shown in the second column may be enhanced by taping an appropriate pill over the outline shown.

understood he must encourage and repeat the main parts of the programme . For treatment forms which demand basic changes in behaviour (as for example diet), it is recommended that information be given step by step. During visits, taking into consideration individual behavior patterns, compliance should be encouraged in stages and new information added in subsequent visits<sup>52</sup>. At each visit, the nurse may check that medication is being taken appropriately (Table 2a and 2b).

**Terminology of noncompliance in ESRD patients**

Wolcott et al<sup>6</sup> proposed a multidimensional categorization of noncompliance behavior in ESRD patients to include the following parameters of noncompliance: duration, specific regimen behaviors, “primary” versus “secondary” (see below), “endogenous” versus “reactive” (see below), and “continuous”, “mixed”, or “episodic” (Table 2).

**Table 2a.** Interventions to increase compliance in dialysis patients.

Intervention	Resource cost	Effectiveness
Education	low	high at dialysis onset. variable later
Situational assessment/ intervention	low	high for specific problems low for others (e.g. cravings)
Health belief change	variable	often high early in dialysis difficult later
behavioral problems	medium	very high for specific problems, may need long-term reinforcement
Individual Psychotherapy	high	high for acute depression low to medium for other variables
Staff-patient Patient-family	low to medium medium to high	high for acute problems uncertain

Noncompliant behavior lasting less than 3 months is considered short-term, with noncompliance of longer duration categorized as long-term. The specific regimen behaviors need to be specified (e.g. fluid restriction in HD patients, sterile exchange in technique in CAPD

patients, immunosuppressant ingestion in transplant patients). Noncompliance may refer to a single parameter (e.g. fluid restriction noncompliance) or be multibehavioral (e.g. fluid restriction and PBM noncompliance). Noncompliance beginning with the onset of the treatment modality is considered “primary”, while “secondary” noncompliance is that which begins after a compliant interval of at least 6 weeks. “Endogenous” noncompliance is that not associated with any known factor such as underlying psychiatric syndrome or health beliefs, while “reactive” noncompliance is associated with one of these factors. “Continuous” noncompliance is a stable

**Table 2b.** Types of dialysis noncompliance.

Short-term (less than 3 months) versus long-term (longer than 3 months)
Specific regimen behavior(s) for which the patient is noncompliant.
“Primary” (continuous since modality onset) versus “secondary” (onset after a compliant interval for that regimen behavior)
“Endogenous” (no known associated medical or psychosocial factor) versus “reactive” (known associated medical or psychosocial factor)
“Continuous” (noncompliant at least 70% of the time for an interval) versus “mixed” (noncompliant less than 30% of the time for an interval)

pattern of noncompliance behavior (more than 70% of measurements). “Mixed” noncompliance is when 30-70% of measurements indicate noncompliance to a specific behavior required by the regimen. “Episodic” noncompliance is diagnosed when less than 30% of measurements indicate noncompliance.

**Ways of defining compliance**

Doctors believe that as soon as they give a prescription to a patient he will closely follow the instruction. Unfortunately, patients do not always take their medication, especially in cases where there is no direct result from treatment. Inevitably, inadequate compliance follows. Even Hippocrates had observed that patients often lie about compliance with medication. Rates of compliance fluctuate between 10-90% and depend on many factors which have been referred above<sup>53,54</sup>. There is no way that doctors can predict rates of compliance with precision<sup>55</sup>. Therefore, for the same definition of compliance the following special methods have to be used. They are:

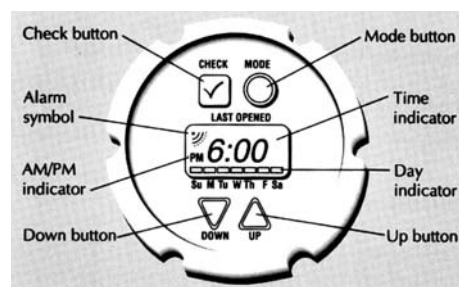
- a. The use of special methods which record the number and frequency of pill taking
- b. The use of special methods which record the number and frequency of pill taking
- c. Accumulation of the medication in body fluid
- d. Placement of special indicator substances in the medication
- e. Measuring the action of the medication

The simplest way of determining compliance is to ask the patient whether he is taking the medication or

**Table 3. Factors associated with noncompliance in dialysis patients\*.**

<i>Situational</i>
Food/H <sub>2</sub> O craving
Special meal preparation away from home
Forgetting medication
Out of medication
PBM regimen complexity
<i>Socio-demographic</i>
Adolescent/young adult
Single
Male
Living alone
Unemployed
<i>Knowledge of regimen and regimen rationale</i> (Knowledge may be variably important in different compliance behaviors)
<i>Family relationship</i>
More family problems
Less spouse assistance
Less family communication
More negative illness impact on family
<i>Patients-staff relationships</i>
Staff dislike-negative evaluation
Unrealistic staff expectations of patient rehabilitation
<i>Psychological factors</i>
“External locus of control”
Less highly motivated to feel well-preserved life
Less general life satisfaction
Compliance level based on physical symptoms, not objective factors
Depression
Fear of complications
Low frustration tolerance
Anger/hostility
Psychological gains from illness and risk role
<i>Health beliefs</i>
Less concerned about the effect of noncompliance
Less belief that the treatment is beneficial
Effects of noncompliance are less serious
Report more difficulties in following the treatment regimen
<i>History of noncompliance with previous medical regimens</i>
Grief loss of kidney transplant
* Each factor identified in at least one methodologically adequate study. A lack of relationship with compliance may also have been reported in one or more other studies <sup>6</sup> .

not. Even through the patient's answer may be yes, it has recently been shown that this may not be true<sup>56,57</sup>.

**Figure 4. The medication Event Monitoring System.**

In other circumstances it is possible to get this information from another individual who is assisting the patient. In clinical practice this second opinion gains special meaning in the analysis of quality of life but this has not been studied regarding the determination of compliance. New microchip technology has played a part in control and monitoring of medication treatment. The medication Event Monitoring System (Figure 4) records the time and date when the cap of the pill container has been opened.

This method is used in research, especially in clinical studies of a new medication which desires a reliable estimate of compliance<sup>58-60</sup>. Undoubtedly, the safest indication of compliance is to determine the level of medication in urine and serum.

### Complications

Every patient suffering from a serious illness has a basic obligation and responsibility to take care of his health<sup>61</sup>. When Health Care Professionals present an educational programme without first determining what has priority for the patient his communication will end in failure<sup>62</sup>. Patients who do not comply with the treatment present a huge threat to its outcome. A treatment intervention ignoring the multi-dimensional nature of the problem is impossible to be accompanied by long-term patient compliance<sup>52</sup>. The reason why some patients adapt themselves very well to the restriction of treatment is very difficult to answer. The answer to this question would help to ascertain the risk which cause limited outcome and would thus allow the application of premature clinical intervention which would reduce the danger and also throw light on the human capability to confront other types of chronic disease.

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