Confidence in Compliance

Tassilo Korab at the HCPC Europe discusses strategies in managing patients' adherence to medicinal therapies

Patient adherence to medicinal therapy is the prerequisite of any successful treatment. Furthermore, it is the prerequisite for an economical and efficient way of curing illnesses, or improving the general level of human health. Despite this, compliance is not the rule, but the exception. Non-compliance is an issue for individuals whose condition may worsen, or who may even die if they fail to take medication correctly. It is, however, just as much a concern for the public, as non-compliance leads to losses in productivity and increased expenses for modern medication, for better and more efficient drugs. The subsequent cost of non-compliance is not only that of the wasted medicines, but also the cost of emergency and acute intervention when medication is not taken.

The US National Council on Patient Information and Education (NCPIE) states: "Perhaps it is no surprise that one of the most common examples of patients not following their prescription regimen involves antibiotic therapy, usually when they stop taking their medicine prematurely. This can cause a recurrence of the condition that the antibiotics were originally prescribed to treat" (1). What is even more problematic in this instance is that non-compliance can cause the bacteria to become resistant to the initially applied antibiotics.

All studies investigating the subject conclude that insufficient compliance or non-compliance lead to worsening health conditions, hospitalisations, acute interventions, increased morbidity and mortality. Yet, non-adherence to medical treatment remains a persistent and still underestimated problem. "In spite of many advances made in adherence research, non-adherence rates have remained nearly unchanged in the last decades" (2). Statements like this suggest that efforts to improve patients' adherence have been insufficient or ineffective. This seems even more surprising, given that the benefits of compliance in drug therapy are obvious and manifold.

Non-compliance is especially problematic in chronic diseases that are not associated with any symptoms and in diseases in which the symptoms occur erratically (3). The WHO report, Adherence to Long-term Therapies Evidence for Action, states that "despite the availability of effective treatment, over half the patients being treated for hypertension drop out of care entirely within a year of diagnosis, and of those who remain under medical supervision, only about 50 per cent take at least 80 per cent of their prescribed medications" (4).

With regard to asthma patients, the report says: "When patients were aware that they were being monitored (for proper use of inhaled corticosteroids), 60 per cent of the patients were fully adherent, 20 per cent were partially adherent (taking just 70 per cent of the prescribed dose) and 20 per cent were totally unadherent. When patients were unaware of the monitoring, six out of eleven took between 30 and 51 per cent of the prescribed doses."

Non-compliance is in most cases related to one of the following four factors:

Type, Seriousness and Duration of the Illness

Figure 1 shows the compliance ratio versus the seriousness of the disease (5). Figure 2 shows that the duration of the treatment has strong influence on the compliance rate (6).

The Complexity of the Therapeutic Regimen

"Compliance is inversely related to the number of prescribed medications", but the frequency of the daily intake of medication also reduces the rate of compliance (7). Ideally, the medication is taken once a day in the morning. A twice daily intake causes deterioration, and an intake of four times or more a day provokes a sharp decline in the compliance rate (8).

Information About the Health Condition and Trust Between the Patient and Healthcare Provider

Compliance depends largely on information about the health condition and the trust between the patient and the health care provider. On average, practitioners spend less than 60 seconds per prescription for conveying compliance-related information to their

Figure 1: Compliance ratio versus seriousness of disease

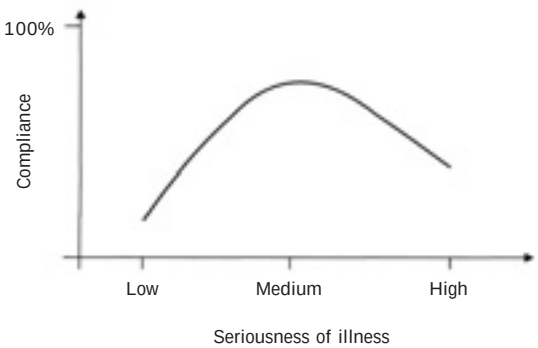
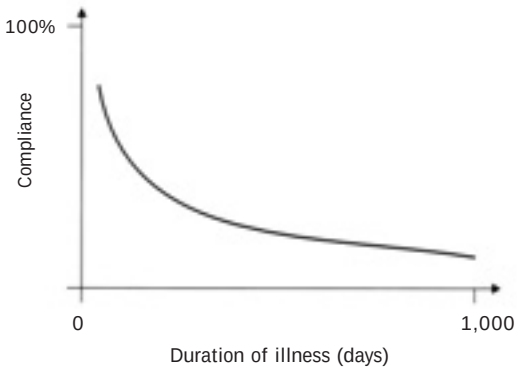


Figure 2: Compliance ratio versus duration of illness



patients. Consultations usually end with a prescription, and most patients are left alone with their questions and concerns regarding therapy, benefits and risks of the medication, interaction with other drugs and side effects (6). The information about the health condition, the medicine and the necessity of medicinal treatment play the most important role.

The Health Belief Model

The lay patient's perception of a treatment's degree of necessity can differ completely from the diagnosis and recommendations of the healthcare provider. The key question in this context is whether the patient sees their condition as a threat, and indeed whether they accept the existence of the illness at all. Fears regarding the treatment and the possible side effects will influence or determine the patients' behaviour.

To summarise, we can say that most patients will be non-compliant some of the time, and there are various patterns of compliance (or rather non-compliance) according to which the likely reasons and causes can be linked.

- Omissions of doses are mostly linked with forgetfulness or with the complexity of the therapy
- Underdosing is mostly caused by fears of side effects
- Overdosing frequently happens when the desired effect of the medication does not happen within the expected time frame
- Medication holidays are mostly the result of temporary improvement of the condition (less apparent symptoms) and happen particularly frequently with anti-hypertensives
- Incorrect timing is likely to be caused by forgetfulness

Consequently, attempts to make changes and to increase the level of compliance with the prescribed regimen will have to address technical, behavioural and educational aspects (or a combination of all of them), and monitoring will have to be an essential part of all measures. Adherence interventions have to be based on data about the patient's drug intake. These data can be collected in various ways; for example, by objective, biochemical, subjective and clinical methods. Direct methods, such as tests of metabolic levels of a drug in blood or urine, and indirect methods, such as pill counts and patients' reports, are used to monitor adherence levels. For practical and financial reasons, the direct method remains limited to clinical trials.

Interventions have proven to be effective in increasing the level of patients' adherence to their therapies (9). Interventions can, however, restrict the autonomy and privacy of the patients. Patients often want to stay in control of their healthcare and, while acknowledging the benefits of interventions, not all patients will always welcome all forms of them. In particular, interventions by call centres will have to remain limited to specific patient groups and disease areas.

One aspect of non-compliance, the accessibility of medicines, in particular the role of drug packaging and the effect it has on patients and their ability and willingness to comply with their therapy, has received little attention. There is, however, evidence that packaging contributes to improving compliance. In their report about infectious diseases, published in 1999, the World Health Organization states: "User-friendly packaging of drugs is

a low-cost way of increasing compliance with antimalarial drug therapy. Studies in Ghana show that over 80 per cent of patients given a course of anti-malarial drugs packaged in a numbered blister pack finished the course of treatment. Of those receiving loose, unpackaged drugs – the way they are usually dispensed in developing countries – only 65 per cent completed the treatment. A simple packet of fast acting drugs made widely available to parents – together with training to recognise malaria symptoms – could save the lives of many children with severe malaria" (10).

What this report says about the treatment of malaria is just as true for most other diseases and is not restricted to the developing world. Appropriate drug packaging increases compliance. Healthcare is delivered in many different contexts, and patients' sensory, physical and mental capabilities vary greatly. Design solutions have to address these factors (11).

Heneghan, Glasziou and Perera, in their study of the role of packaging with regard to long-term medicinal treatment, found that: "People often miss taking prescribed medication because of forgetfulness, changing medication schedules or busy lifestyles. It is estimated that between 40 and 60 per cent of people do not take medication as prescribed, which can lead to worse health outcomes. Packaging of medications with reminder systems for the day or time of the week is an attempt to help people take long-term medications." And they concluded: "Reminder packing for certain individuals may represent a simple method for improving the taking of medications" (12).

But modern packaging technology goes far beyond simple calendar packs, however valuable they are. Patient-centred design takes into account that there is no ideal solution and that drug packaging has to serve many needs. Newly developed wallets, which have proven to get better patient acceptance than traditional drug pack forms, include the patient information leaflet (PIL), making sure that the blister remains well protected and the PIL is always available for convenient reference.

About the author

Starting his career as an international Sales Manager, Tassilo Korab has been in the packaging industry for more than 20 years. A recognised expert in flexible packaging, he holds an MSc in Healthcare Economics, and has written several publications on patient compliance, standards and regulations for child resistant packaging and the war against counterfeits. Tassilo is currently Managing Director of TKM Handels GmbH, Vienna, a consulting company in the sector of flexible packaging for the pharmaceutical and healthcare industries. He was one of the co-founders of HCPC-Europe, the Healthcare Compliance Packaging Council, a not-for-profit organisation uniting the pharmaceutical industry, packaging materials suppliers, packaging machine manufacturers and patient organisations in their common endeavour to improve drug packaging design in the interest of the patients. He has been Executive Director since September 2005. Email: ???

Since about 80 per cent of all self-administered solid form drugs are taken by people aged 60 years and over, and since multi-morbidity rises with age, tailor-made solutions providing all medication for the individual patient are largely compliance-enhancing. Individualised blisters incorporate a detailed, easy-to-read description as to how and when to take the tablets, with one system even offering the possibility to include liquid forms of drugs. They are designed to hold a week's medication with the option to break off the dose needed for a day which can easily be put in a handbag.

Radio frequency identification (RFID) and printed electronics embedded in either plastic containers designed to hold blister cards, in the folding carton, or even in the patient information leaflet, can record data about the time of drug intake and remind the patient by means of a beeper. Alternatively, the pack or leaflet can communicate with either a server to store the data or a mobile phone, which in turn will act as an electronic diary and send SMS reminders.

Modern packaging technology allows the monitoring of a patient's compliance pattern, and can send a reminder when a dose is missed. It further allows the care giver, if the patient wishes, to look into these data and to convene on external interventions.

Managing patients' adherence starts and ends with the patient themself. The better patients can keep control of their medication, the better compliance with the prescribed regimen will be. Packaging can make a large contribution, while maintaining the patients' privacy and autonomy.

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