

Compliance Monitor

Information Mediary Corporation

Do Your Patients Report Accurately?

Medication Non-compliance causes:

*\$100 billion annual U.S. health care system costs

*Over 100,000 patient deaths

*Over 1 million hospital admissions

*Antibiotic resistance

*Erroneous efficacy data from clinical trial studies

By Allan Wilson, MD, Ph.D.

The problem of clinical trials involving patient-determined dosing is widely recognized. If data obtained in clinical trials where patients take medication once or twice a day are known to be inaccurate, it follows that data from patients taking medication intermittently over

longer intervals will be even less accurate.

The researcher studying such medications is generally reliant upon the patient recording the date and time of self-medication.

One commonly used procedure for such clinical trials is unit dose packaged medication with a place to record the date and time of dosing beside each blister.

“Are patients likely to remember to record the date and time they took the tablet?”

Probably not.”

The package might be 6 inches by 9 inches in size and does not come with a pen attached. Is it likely that a patient will carry around a blister package and pen for several months when only the occasional tablet will be required? It is more likely the patient will take one or two tablets out of the package and put them away in a purse or pocket.

Are patients likely to remember to record the date and time they took

the tablet? Probably not.

It should come as no surprise that very little is known about how patients self-administer such medications, and that at least two such medication categories – opiate analgesics and hypnotic sedatives – are widely abused by patients.

Unfortunately the methodology for obtaining accurate medication compliance data has fallen behind clinical

research methodologies, research ethics, and the ability of pharmaceutical companies to develop new drugs. Compliance data is currently the weakest link in the process.

One area within clinical pharmaceutical trials where patient compliance data are especially problematic is in studies of medications designed to be titrated by the patient against signs or symptoms

of disorders, such as:

- Chronic pain syndrome
- Angina pectoris
- Asthma
- COPD
- Environmental allergies
- GERD/dyspepsia
- Gout
- Migraine headache
- Other medication side effects

It should come as no surprise that very little is known about how patients self-administer such medications.

In clinical pharmacy applications, the situation is complicated by the fact that two categories of medica-

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Med-ic[®] ECM[™] eliminates guesswork

Compliance monitoring has been viewed increasingly as a problem in clinical research and clinical pharmacy over the past decade. Prior to the Med-ic[®] ECM[™] (Electronic Compliance Monitoring) Package there was no user friendly, seamless, and accurate solution to the problem.

In our last newsletter I talked about the advantages to be gained from accurate patient compliance data in clinical trials. We have had overwhelming interest since we debuted the Med-ic[®] ECM[™] Package at Interphex 2002.

It is widely accepted that patient compliance with prescribed medication imposes an enormous burden on the health care system, to the tune of over \$100 billion annually in the United States alone.

In our White Paper report presented at Interphex 2002, we discussed how non-compliance with medication regimens during clinical trials of new pharmaceuticals can have protean and insidious negative implications for pharmacotherapy and health care in general.

At Issue: Patient Reporting

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tion that are widely prescribed (in many cases inappropriately) in this way are also the largest sources of prescription drug abuse and dependence. Hypnotic sedatives, especially benzodiazepines, are often prescribed to be taken as required (*prn*) for the management of anxious symptomatology or to induce sleep.

It is well known that a significant number of such patients abuse their medication by taking more than is prescribed, taking it more often

than is recommended, using it to cope with interpersonal stresses, or combining it with alcohol to augment its effects. Abusers who are genetically predisposed are at high risk to progress to benzodiazepine dependence.

At the abuse stage the problem can be corrected in many patients without difficulty. Unfortunately, abusive patterns of benzodiazepine taking are often impossible to detect.

Monitoring the compliance of pa-

tients prescribed hypnotic sedatives on a *prn* basis would reduce the likelihood of dependence by indicating to their prescribing physician or pharmacist that a problem is developing before the patient reaches the dependence stage.

The same dynamics also apply to the development of dependence on prescribed opiate analgesics.



The Med-ic® ECM™ provides effective compliance data using existing standard blister packaging

Med-ic® ECM™ means no more guesswork

Inaccurate compliance data can:

- result in an effective new drug being abandoned, and
- lengthen the approval process by undermining consensual validity.

The financial consequences of inaccurate data are only the tip of the iceberg. No one wants research to be based on poor data – not the researcher, not the regulatory body, not the pharmaceutical company and, most of all, not the patient.

Unfortunately the methodology for obtaining accurate medication compliance data has fallen far behind clinical research methodologies, research ethics, and the ability of pharmaceutical companies to develop new drugs.

Compliance data is currently the weakest link in the process.

The use of a Med-ic® ECM™, integrated seamlessly in a standard blister package is the solution to this problem. It obviates the requirement for a space to write the date and time the medication was taken, making it easier for the patient to carry the medication in its proper container.

In addition to this application we are currently working on a number of custom applications in the pharmaceutical packaging field.

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About Us

Information Mediary Corporation is dedicated to the convergence of medicine, logistics, high-technology, pharmacology, wireless, e-business and anthroponomy.

IMC's recent flagship Med-ic® and Log-ic™ ECM™ product development efforts underscore this commitment by recognizing and solving important issues.

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