DEBLISTERING AND COMPLIANCE

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Health care providers have long known that patients are poorly compliant with recommended treatment, but the extent of non-compliance has only become apparent during the last two decades. An extensive literature now demonstrates that non-compliance is a problem in every area of health care.

Non-compliance has an enormous impact on clinical trials. Poorly compliant subjects introduce error variance into statistical analyses, increasing the possibility of erroneous conclusions regarding the efficacy or lack thereof of the drug of interest. Poor compliance can also complicate tolerability or dose-response studies leading to long-term safety and other issues once a drug has been approved.

Most non-compliance in clinical trials is due to forgetfulness or inconvenience. If a subject has signed up to participate in a trial he or she is likely motivated. The exception to this is logic is the professional subject who is paid to participate in a Phase II trial.

The general thesis regarding non-compliance is that making medication taking more convenient will correct the problem. With the new generation of electronic compliance monitors (ECMs) it is now possible to obtain accurate data regarding a subject's medication-taking behaviour.

Use of the Med-ic ECM in a recent clinical trial gave an interesting revelation. Forty percent of the subjects deblistered their blister-packaged medication at least once, and half of those did it more than once. Why go to the trouble of blister packaging the medication in the first place if subjects are going to take the medication doses out of the package at the onset of the treatment interval? And why do patients deblister at all?

A quick look at the format of the blister packages gives the answer. They measure 8in x 11in x ½ in and have a formidably utilitarian look. On closer examination, the blisters were not scaled to the size of their contents. Historically, the move to blister packaging was driven by the belief that this format would be user-friendly and thus increase compliance. Unfortunately, the use of enormous package formats simply defeats the purpose. How does a subject carry around a package that barely fits into a briefcase or large purse. In the interest of privacy subjects are going to deblister. Where the contents end up is anyone's guess, but it is unlikely the improvised format will enhance compliance.

If we are serious about patient compliance during clinical trials, and there are many compelling reasons to be so, we need to make trials packaging as attractive as that of cosmetics. Blisters need to be scaled as closely as possible to the size of the contents to allow for minimizing the package dimensions. If a package won't fit in a pocket it is a candidate for deblistering. The process may initially be more costly (until there is a bank of custom-designed formats that can accommodate variously-sized medications) but the benefits will be well worth the effort.

Given a reasonably attractive, compact blister package equipped with an electronic compliance monitor, and good subject education, compliance can be changed from a liability to an asset with enormous return on investment.

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