

Cognitive Factors and the Use of Over-the-Counter Medication Organizers by Arthritis Patients

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The present study investigated the ability of 45 arthritis patients, all using three or more prescription medications, to correctly load their medications into three types of over-the-counter medication organizers. The results indicated that use of a seven-day organizer with compartments for different times resulted in fewer errors than did an hour-by-hour wheel organizer or a seven-day organizer with only one compartment for each day. It was concluded that the seven-day organizer with compartments for different times appears to have the potential to improve compliance behaviors, but the usefulness of the other two organizers in promoting compliance is uncertain. Data analyses also indicated that age was not related to comprehension or loading accuracy of the organizers but that individuals using seven or more prescribed medications were particularly likely to make comprehension errors.

INTRODUCTION

A substantial body of literature suggests that a major problem in the therapeutic effectiveness of prescribed medication may be caused by noncompliance—that is, patients take too little or too much of the drug, take it at the wrong time, fail to follow special instructions, or do not take the drug at all. There have been many estimates of noncompliance, ranging from 25% to 59% (Stewart and Cluff, 1972). Some evidence suggests that noncompliance rates are particularly high

among patients with chronic diseases, such as hypertension and arthritis, which typically require lifetime drug therapy (Zola, 1986).

As Morrell, Park, and Poon (1989, 1990) have pointed out, a major cause of noncompliance may be cognitive, particularly in older adults. Older adults may have difficulty understanding what they are to do with their medication or, if they do understand, remembering what to do with it. Because arthritis patients are typically older adults, cognitive factors may play an important role in affecting their compliance and use of medication, an issue addressed in the present study. In fact, it has been suggested that one major reason arthritis patients sometimes appear not

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to respond to specific drugs may be related more to poor compliance than to drug efficacy per se (Belcon, Haynes, and Tugwell, 1984). Studies using blood and urine measures have indicated that noncompliance rates for arthritis patients range from 35% to 50% (Joyce, 1962; Mason, Barnardo, Fox, and Weatherall, 1967; Nugent, Ward, and MacDairmid, 1965). Deyo (1982), using a careful measure of compliance based on prescription refills, reported an overall compliance rate of 64% for arthritis patients. Other researchers have specifically implicated comprehension as a major cause of noncompliance in arthritis patients, suggesting that they have difficulty in understanding how and when to take their arthritis medications (Blechman, 1984; Mason and Florence, 1982).

The primary purpose of this project, in addition to studying comprehension of drug regimens in arthritis patients, was to determine whether over-the-counter organizers, which are allegedly designed to facilitate compliance behaviors, actually have the potential to improve compliance. Although we did not measure actual compliance behaviors in the present study, we were interested in whether patients could correctly load their own medications into different types of organizers, as this would appear to be required for compliance to occur. The patients' comprehension of their personal medication regimen was also examined.

The motivation for studying these over-the-counter organizers came from two divergent lines of research: one applied and one theoretical. First, there is some evidence in the applied literature on drug compliance that providing patients with special packaging improves compliance. For example, blister-packaged unit doses of medications (Linkewich, Catalano, and Flack, 1973; Wong and Norman, 1987) or drug charts and organizers loaded by pharmacists (Rehder, McCoy, Blackwell, Whitehead, and Robinson,

1980) facilitated patients' compliance with a drug regimen relative to a control condition in which patients received standard pill bottles. Such findings might suggest that patients on complex drug regimens would profit from the use of over-the-counter organizers. However, such an extrapolation presupposes that patients can comprehend their medication instructions sufficiently well to load the organizers correctly. A second issue has to do with the amount of cognitive processing or effort subjects must engage in for the organizers to be used effectively. Most of the organizers are designed so that the patient must not only comprehend what to do with the medication but also be able to integrate or organize the instructions from a number of different medications across a one-day or one-week time frame.

Considerable evidence from the cognitive aging literature indicates that older adults have difficulty with organizational skills in classification problem-solving tasks (Cicirelli, 1976; Denney and Lennon, 1972) as well as with forming correct inferences when required (Cohen, 1979, 1981). Findings such as these suggest that the organizational and inferential requirements to correctly use medications and organizational devices may pose a particular problem for older adult patients, particularly those who use multiple pharmacies. Moreover, the different types of devices available for loading medication vary in terms of their complexity, the period of time for which medication is loaded (typically one day vs. one week), and the amount of information provided by the device (e.g., some have separate compartments for the different times medication is to be taken, whereas others do not). The present study addresses the usefulness of over-the-counter medication repackaging devices by assessing whether arthritis patients can correctly load three different types of devices with their own medications. The devices are displayed in

Figure 1 and consisted of (a) a seven-day organizer that had separate compartments for different times of the day (7-day/times), (b) a seven-day organizer that had only a single general compartment for medication for each day (7-day/no times), and (c) a one-day wheel organizer with separate compartments for each time of day (1-day/wheel).

METHOD

Subjects

The subjects were 45 arthritis patients recruited from two local rheumatologists in Athens, Georgia, and from advertisements placed in local newspapers. All subjects recruited met the following requirements: they were more than 35 years old, they were taking three or more different medications daily, they maintained their own drug regimen without the assistance of others, and they were diagnosed as having osteoarthritis, rheumatoid arthritis, or both. Assignment to the three experimental conditions was random, with the exception that only rheumatoid arthritis subjects were assigned to the 7-day/times condition. This occurred because these subjects were to participate in a later study that involved monitoring their medication-taking behaviors over a lengthy period using the 7-day/times organizer.

Detailed information regarding the characteristics of subjects assigned to different conditions appears in Table 1. These data indicate that there were no significant differences in the number of drugs or dosages subjects were taking across the three groups, the years that they had been diagnosed as having arthritis, their self-reported health, or their comprehension of their medication regimen. The only significant difference that emerged was that subjects in the 7-day/times condition were significantly younger than subjects in the other two conditions. The difference in

verbal ability across groups had a significance level of 0.07. The effects of both age and verbal ability on performance measures are addressed in subsequent statistical analyses.

Stimulus Materials and Apparatus

All subjects were asked to load their medications into one of three types of over-the-counter medication organizers commonly available in most local drugstores. Fifteen subjects were assigned to each type. The three organizers selected were judged as prototypical of the range of styles commonly available. The 7-day/no times organizer had seven compartments, one for each day of the week, in which subjects placed their weekly supply of pills. The use of this organizer required subjects to remember the identity of individual pills, when they were to take them, and any special instructions associated with the pills, as all of this information was unavailable once the pills were loaded into the organizer. The 1-day/wheel organizer was a 24-hour organizer with an individual slot for each of 12 hourly times. The use of this organizer required subjects to load it daily and to remember special instructions associated with the pills. The third (7 day/times) was a weekly organizer with four partitions for different times of the day, providing subjects with more detailed information about what medicines were to be taken at specific times but no information regarding special instructions or pill identity.

Procedure

All subjects were tested individually in a quiet room at a local rheumatologist's office. Each subject was instructed to bring to the session all medications that he or she was currently taking. These were placed on the table, and the experimenter recorded the information from each prescription signature so that an accurate record of the subject's medication regimen was obtained. Following

7-Day with Times Organizer

SUN	•	MON	•	TUE	•	WED	•	THU	•	FRI	•	SAT
MORN		MORN		MORN		MORN		MORN		MORN		MORN
NOON		NOON		NOON		NOON		NOON		NOON		NOON
EVE		EVE		EVE		EVE		EVE		EVE		EVE
BED		BED		BED		BED		BED		BED		BED

7-Day without Times Organizer

S	M	T	W	T	F	S
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Wheel Organizer

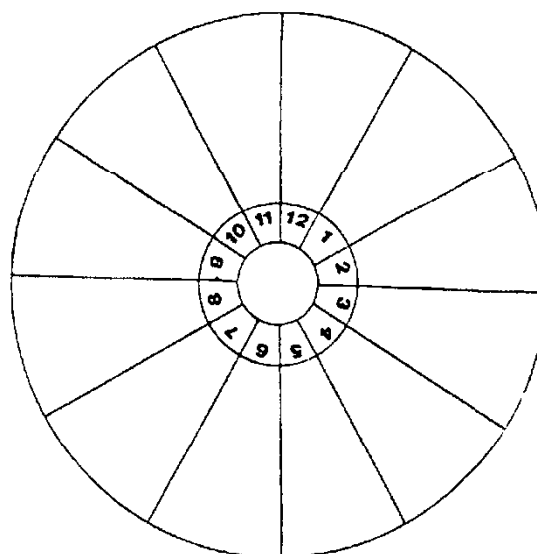


Figure 1. Schematic representation of the three types of organizers used in the study.

TABLE 1

Subject Characteristics as a Function of Condition

Variable	Condition			P Value*
	7-Day/Times	1-Day Wheel	7-Day/No Times	
Number drugs/day	5.80	4.20	5.07	0.24
Number doses/day	8.93	7.46	9.93	0.35
Years diagnosed	14.13	15.60	14.00	0.09
Age	52.47	63.93	63.73	0.009
Self-reported health ^a	3.00	2.40	2.73	0.109
Verbal ability ^b	13.33	16.93	10.73	0.07
Comprehension ^c	0.045	0.190	0.164	0.279
Type of disease	15 RA 0 Osteo	5 RA 10 Osteo	10 RA 5 Osteo	

Note. RA = rheumatoid arthritis; Osteo = osteoarthritis.

^a Self-perceived health on a scale of 1–5 with 1 signifying *health much better than others same age* and 5 signifying *health much worse than others same age*. ^b As measured by the Gardner and Monge (1977) 30-point Word Familiarity Survey. ^c Comprehension errors in medication regimen as measured in present study.

* Results of a one-way analysis of variance.

this, the subject was given a medication comprehension sheet to complete, as used in Morrell et al. (1989, 1990). On this sheet subjects recorded all details of how they understood that they were to take their medications in a 24-hour period so that the experimenters could determine the overall level of comprehension subjects had for their medication regimen. Subjects wrote exactly what medication(s) they would take on an hour-by-hour basis for a 24-hour period as well as the quantity of the medication and any special instructions they were to follow (e.g., take with meals). Subjects had unlimited time to complete this information, and they also had access to their medication bottles, as this was a measure of comprehension rather than memory.

After they completed this record, subjects were asked to load their actual medications into one of the three organizers illustrated in Figure 1. Subjects in the 1-day/wheel organizer condition were given two organizers: one marked for the a.m. hours and one marked for the p.m. hours. Subjects had unlimited time to complete this task. After this, subjects were given a questionnaire to com-

plete about their health, and they were also administered the Gardner and Monge (1977) Word Familiarity Survey (a measure of verbal intelligence).

RESULTS

The data were scored in terms of the number of errors subjects made in completing the comprehension sheet or in loading the medication organizer. The types of potential errors were categorized as follows: (a) *time errors*, in which the subjects indicated that a pill would be taken more than two hours away from the appropriate time; (b) *quantity errors*, in which subjects recorded or loaded the wrong number of pills (either too many or too few); (c) *omission errors*, in which a dose was excluded from the schedule; (d) *commission errors*, in which an extra dose was included; and (e) *total errors*, a proportion created by dividing the sum of the errors made in the foregoing categories by the total number of dosages.

The subjects' performance on the medication comprehension sheets was a measure of their comprehension of their own drug regimen. Their performance on loading the organizers could be considered a measure of how

effectively the different types of organizers could be utilized by arthritis patients at home to help them to remember to take their medications with no outside instruction or supervision.

Knowledge and Comprehension of Drug Regimen

The first set of analyses was conducted on the number and types of errors subjects made when completing the medication comprehension sheets. A multiple analysis of variance (MANOVA) with organizer condition as the independent variable was conducted with omission, commission, quantity, and time errors as dependent variables. It yielded no significant effects, indicating that the groups had equal knowledge about their drug regimen at the beginning of the study. A univariate ANOVA on total comprehension scores, shown in Table 1, was not significant ($p = 0.27$).

A second set of analyses was conducted, with age rather than organizer as the independent variable on the comprehension data,

in order to determine if age affected the types of errors subjects made in recording their medication information. Although the data suggested that subjects in the middle age group (56–65 years) made the most errors (24.62%, compared with 6.53% for the young and 11.24% for the old), neither the MANOVA nor the ANOVA was significant. Perhaps of most interest was the finding that the oldest subjects (above age 65), who had an overall error rate of only 11%, were not more likely to make errors in the comprehension of their drug regimen, as has typically been suggested in the literature.

A third analysis was conducted on these comprehension data using the number of medications that subjects were taking as the independent variable. The MANOVA yielded a significance value of 0.08, Wilks' lambda = 0.650, $F(10,76) = 1.78$, $p = 0.078$. Follow-up univariate analyses were significant only for omission, $F(2,42) = 7.49$, $p = 0.003$; and total errors, analyzed separately, was also significant $F(2,42) = 4.85$, $p = 0.013$. These data are displayed in Figure 2, which shows that sub-

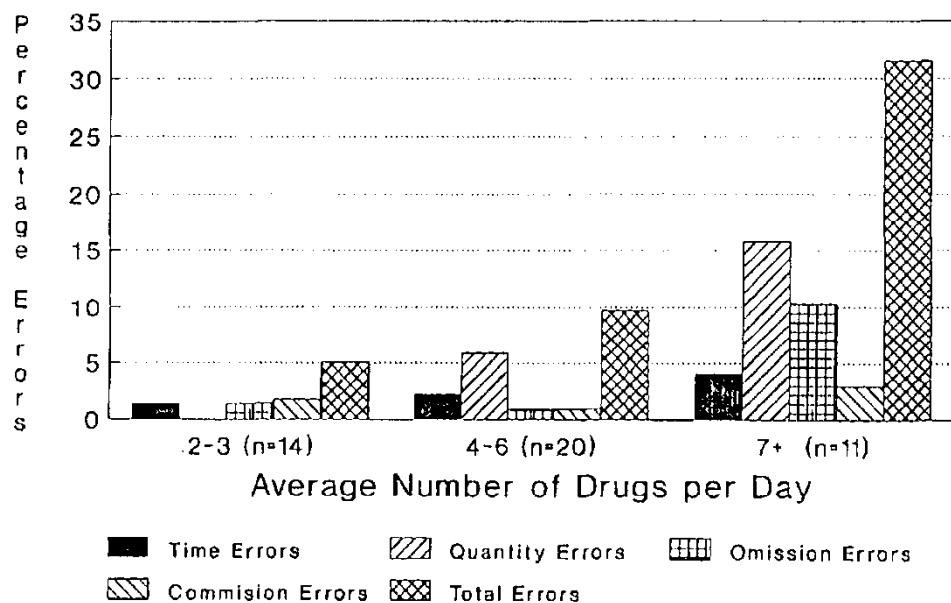


Figure 2. Mean percentage of dosage errors on preliminary medication chart as a function of mean number of drugs per day in regimen.

jects who were taking seven or more medications made more errors in completing the medication sheets than did subjects taking fewer medications. The total error rate for the former group of subjects exceeded 30%, which is extremely high when one considers that they were working with their own medications, were under no time constraints, and did not have to remember anything (that is, they were free to look at their medication bottles as often as they liked to assist them in completing the sheets). It is also important to keep in mind that these numbers are percentages; that is, subjects taking a lot of medications did not make more errors simply because they gave more responses. Rather, the percentage of their responses in error was higher, which corrects for the differences in numbers. Their absolute rate of error was dramatically higher than that of subjects taking fewer medications.

Errors in Loading the Organizers

Analyses similar to those conducted on the comprehension data were conducted on the

errors subjects made in loading the three different types of organizers. The MANOVA examined time to load the organizer, omission errors, and commission errors (it was not possible to examine time errors for the 7-day/no times organizer, so this was omitted). Figure 3 portrays these data, as well as percentage of total errors, as a function of organizer type. The MANOVA was significant, Wilks' lambda = 0.708, $F(6,80) = 2.510$, $p = 0.028$, as was the univariate for omission errors ($p = 0.036$) and time to load the organizer ($p = 0.047$). As can be seen in Figure 3, the significant effects occurred because fewer errors were made in loading the 7-day/times organizer than with the other two. It is interesting that the 7-day/no times organizer was the simplest of the three but had the highest error rate. In addition, the fewest errors were made with the 7-day/times organizer, but it took the longest to load: 536 s compared with 150 s for the 1-day/wheel organizer (a one-day plan) and 275 s for the 7-day/no times. Figure 3 also reveals that the absolute rate of error was relatively low, ranging from less than 2%

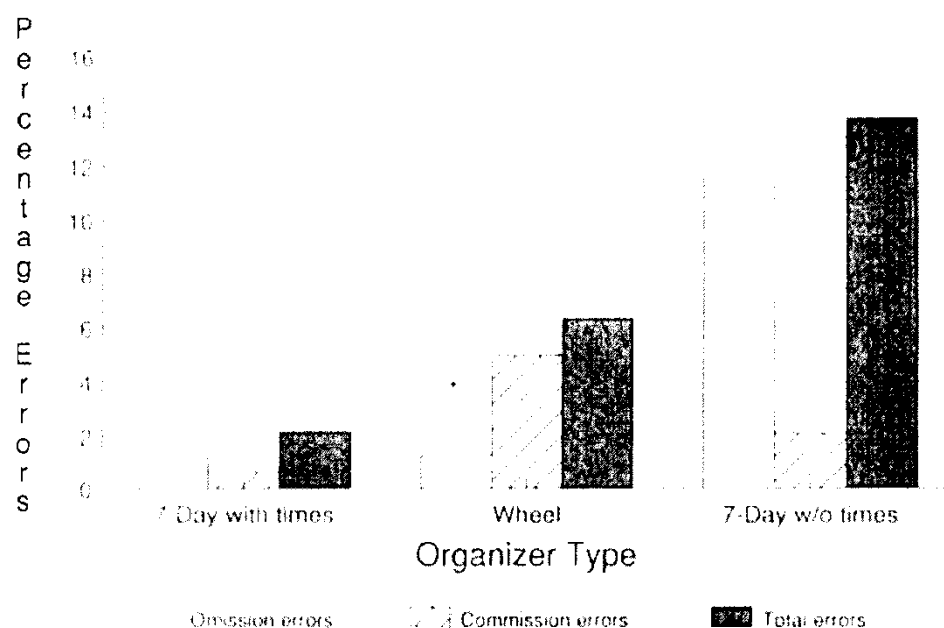


Figure 3. Mean percentage of errors loading organizer as a function of type of organizer.

for the 7-day/times organizer up to nearly 14% for the 7-day/no times organizer. From these data it appears that the error rate was so low with the 7-day/times organizer that at least the subjects who volunteered for this experiment could safely load it at home without assistance.

Further analysis of the data used comprehension of medication regimen as a covariate in each of the univariate analyses in order to test the hypothesis that differences in errors in loading the organizers could be primarily accounted for by original comprehension rates. This was of particular interest because there were comprehension differences (albeit nonsignificant) among the three groups. Inclusion of comprehension as a covariate in the univariate analyses did not change the significance of any of the results, and further analysis revealed that the correlation between comprehension and errors in loading was 0.118. Thus initial differences in comprehension rates could not account for the findings.

As indicated in Table 1, the groups differed in age and may have differed in verbal ability. As a result, these two measures were used individually as covariates in the univariate analyses. Inclusion of age as a covariate did not change the outcome of the analyses. The inclusion of verbal ability scores as a covariate in the analysis of omission errors, however, did result in the significant effect of condition ($p = 0.036$) being changed to a marginally significant effect ($p = 0.084$). The adjusted means for the effect were changed slightly from the original, with values for the 7-day/times, 1-day/wheel, and 7-day/no times organizers at 1.5%, 1.3%, and 11.5%, respectively. Thus the relatively large difference in omission errors remained between the two types of seven-day organizers, even after adjusting for verbal ability. Because the covariate altered the significance level, however, it might be most conservative to conclude that

low verbal ability may have contributed to a higher error rate on the 7-day/no times organizer. The overall correlation between errors and verbal ability was 0.251, accounting for only 6.3% of variance.

Examination of the number of subjects who made errors reveals that the majority of subjects were able to use the organizers correctly. In the 7-day/times condition, only four subjects made errors, and all of those errors were of a very small magnitude. In the 1-day/wheel condition, only three subjects made errors, but one error was of a large magnitude: a subject put in twice as much medication as needed for nearly every dose. Seven of 15 subjects made errors in the 7-day/times condition. Thus nearly half of the subjects who used this device made errors.

Further analysis using age as an independent variable indicated that there was no effect of age on errors in loading any of the organizers, as in the comprehension analysis. Perhaps no age effects are evident in the data set because the age of subjects was sufficiently homogeneous to preclude their emergence. If a group of young adults (under 35) had been included, differences in age might have emerged. There was also no evidence that correct loading of the organizer was related to the number of medications subjects were taking per day. The overall MANOVA was significant for these data, Wilks' lambda = 0.724, $F(6,80) = 2.341$, $p = 0.039$. However, the only significant univariate analysis result was for time to load the organizer. Not surprisingly, subjects who had more pills to put in the organizer took longer to load it. Subjects with more pills did not appear to make more errors when loading the organizer.

Overall the data suggest that subjects were extremely careful when loading the organizers and made few errors when they used the 7-day/times organizer. The errors made with the 1-day/wheel organizer were intermediate,

whereas those that occurred with the 7-day/no times organizer were sufficiently greater than zero to indicate that the use of this organizer may be a cause for concern.

DISCUSSION

The results of this study suggest the following. Arthritis patients have a relatively good comprehension of their drug regimen, and comprehension is not related to age (at least in subjects over 35). Not surprisingly, subjects who were taking many drugs (seven or more) did show more difficulties comprehending what they were to do with a relatively complex drug regimen relative to subjects using fewer medications. Subjects made more errors loading the 7-day/no times organizer relative to the 7-day/times organizer. Age and comprehension of drug regimen were not related to accuracy in loading the organizer, whereas there was a modest relationship between verbal ability and loading the organizer.

The overall level of comprehension errors in this study (prior to the use of any organizer) was relatively low (about 13.5% overall). Morrell et al. (1989) reported a comprehension error rate of 21% in older adults for an unfamiliar drug regimen, so this somewhat lower figure for a personal medication regimen appears to be in line with their findings. Unlike the present study, Morrell et al. (1989) reported age differences in comprehension, but they compared college students with older adults; in the present study the age distribution was less extreme. Moreover, the fact the drug regimen was familiar in this study (unlike in Morrell et al., 1989) may have minimized age effects, as it is in keeping with the notion that older adults manage well on cognitive tasks that are ecologically valid and familiar to them (Poon, 1985).

Perhaps the most puzzling finding was that comprehension did not predict errors in loading the organizer. Two alternative explanations

are offered. The first is that the measures of comprehension collected represent a performance deficit rather than a competence deficit, and that fatigue, difficulty in understanding the form, or a lack of motivation affected performance on the task. It is not clear from this explanation why giving subjects the organizers to load (which occurred after they had completed the comprehension form) would have increased motivation or relieved fatigue, though the novelty of the task could conceivably have had such an effect. The alternative explanation is that the presence of the organizer acted to structure subjects' behavior and actually facilitated their comprehension of the drug regimen, resulting in correct loading of the organizer despite errors on the comprehension task. Given that the absolute error rate for loading the organizers is lower than that for comprehension, this argument has some merit. These findings suggest that further work on instrumentation for the measurement of comprehension of a medication regimen is required and that paper-and-pencil measures may not adequately capture what subjects know about their medication regimen. Of course, the important question ultimately is, which of these measures is a better predictor of compliance with a medication regimen outside of the laboratory? This issue can be resolved only with further research.

With respect to the actual loading of the organizers, relatively low error rates were associated with the use of the 7-day/times organizer, which provided subjects with detailed information about days and times that medication should be taken. In addition, few subjects made errors with the 1-day/wheel organizer, but one subject made a very serious error (loading twice as much medication as needed) and two others made small commission errors. Thus it is difficult to conclude whether this organizer can be recommended without further investigation, but the data

suggest that its confusing design may increase commission errors, a particularly dangerous type of error. Perhaps the confusing design made it difficult for subjects to keep track of what had been loaded, increasing commission errors. This conclusion is tentative, however, pending additional research with larger samples which could confirm the reliability of the commission error finding.

With respect to the 7-days/no times organizer, the data suggest that it led to a substantial number of errors in loading, though this condition did have a disproportionate number of subjects with low verbal ability. At the least, the data suggest that this organizer leads to errors for subjects with low verbal ability. Moreover, the covariate analysis suggested that a higher rate of errors remains when corrections are made for differences in verbal ability. This organizer is cause for particular concern because, even if it is correctly loaded, it is also likely to enhance errors in timing of medication, as there is no information about what time different pills should be taken, unlike the other two organizers. Subjects merely have a pile of pills that they are to take sometime during the day but no information about when to take them or how many they should take at a given time. The potential for perceptual confusion of tablets is also greatest with this organizer. It would appear from these data that any device that would aid the comprehension of a drug regimen should include information about the day, time, and quantity of the drug to be taken.

In summary, the organizational data suggest that only one of the three over-the-counter organizers examined appears to have the clear potential to help subjects remember to take medications. The low error rate associated with loading the 7-day/times organizer suggests that loading errors are not likely to contribute to compliance problems, though a systematic manipulation of low versus high

verbal ability subjects may be needed to ascertain whether this finding generalizes to adults with low verbal ability. The 1-day/wheel organizer, although not characterized by many errors, was associated with a large error. Further study is required to determine the organizer's safety. The 7-day/no times organizer appears to have the potential to increase medication errors in subjects, particularly because once the organizers are incorrectly loaded, forgetting a dose and confusing one medication with another in the same bin are additional barriers to compliance. Caution should also be exercised in concluding that the 7-day/times organizer is safe for independent use by patients. The patients who participated in the experiment were highly motivated volunteers and may not be representative of the range of arthritis patients in the community. However, the low rate of absolute error that subjects demonstrated when they loaded this organizer suggests that the design of the organizer may actually have facilitated subjects' organization of their drug regimen. Of the four subjects assigned to this condition who made comprehension errors, none made errors loading the organizer. It also needs to be recognized that the present data provide no indication of whether subjects remember what to do with their medication (long-term memory for medication information) or of whether the organizers actually facilitate the prospective memory task of remembering to take medication at the appropriate time, compared with control subjects who do not use organizers.

Given our lack of knowledge about these devices, it might be prudent to recommend that any individual who chooses to use such an organizer should have a relative or health professional check the loaded device for errors. Because the probability of making a compliance error appears to be high once the organizers are incorrectly loaded, it is important to determine which factors contribute to

correct use of the devices. Moreover, the organizers are marketed presumably as devices to enhance medication compliance, but little work directly linking such organizers to improved compliance exists. Future research should focus not only on factors that influence the correct use of the organizers but also on whether or not these organizers ultimately improve compliance.

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