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COMPREHENSION AND READABILITY OF DRUG INFORMATION: A COMPARATIVE STUDY AT DIFFERENT LEVELS OF READING ABILITY

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Comprehension and Readability of Drug Information: A Comparative Study at Different Levels of Reading Ability by Timothy Patrick Stratton

A Dissertation Submitted to the Faculty of the DEPARTMENT OF PHARMACY PRACTICE In Partial Fulfillment of the Requirements For the Degree of DOCTOR OF PHILOSOPHY In the Graduate College THE UNIVERSITY OF ARIZONA 1986
As members of the Final Examination Committee, we certify that we have read
the dissertation prepared by Timothy Patrick Stratton
entitled Comprehension and Readability of Drug Information: A Comparative
Study at Different Levels of Reading Ability

and recommend that it be accepted as fulfilling the dissertation requirement
for the Degree of Doctor of Philosophy

Final approval and acceptance of this dissertation is contingent upon the
candidate's submission of the final copy of the dissertation to the Graduate
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DEDICATION

To Nadine, with my eternal love and devotion.
"Have you ever considered going for your Ph.D.?” asked his wife. "Once," he answered. This seemingly innocuous exchange five years ago initiated a journey, the final leg of which is represented by this paper.

Certainly any endeavor of the magnitude of a dissertation is not undertaken without considerable assistance and moral support. It is with this consideration in mind that I gratefully acknowledge the contributions of the following people.

I cannot even begin to describe the gratitude due my wife Nadine. Her constant love and support (and occasional prodding) continue to encourage me to perform at levels far exceeding what I thought possible.

I am indebted to Peter D. Hurd, Ph.D., my advisor, who helped me to maintain a realistic perspective throughout my journey. His invaluable suggestions during the dissertation process saved immense amounts of time and effort and certainly helped to improve the finished product.

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Policy. Their emphasis on scholarly excellence helped to shape me as a researcher and will serve as my standard of practice in the future.

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My heartfelt thanks go to Mrs. Ruth Siers, the ubiquitous Departmental Secretary, and Ms. Daina Wasson, WOPO extraordinaire, who were there throughout my academic career at the University of Arizona. Their efforts to keep me out of mischief and their willingness to lend a sympathetic ear are greatly appreciated.

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Finally, I would be remiss if I failed to acknowledge my closest companion during this journey. He has been there from start to finish, enabling me to accomplish in days what would have otherwise taken months (and megabucks for a typist). He was there from writing up the initial proposal, to generating (and revising) test instruments, to entering data, to crunching numbers, to writing and rewriting (and rewriting again) the final dissertation. He accompanied me to Scottsdale, Coolidge and Eloy, and commuted with me innumerable times between home and office. He was there to start work at 5:30 in the morning and was there when I finished at three the next morning, and was eager to do it all over again two hours later. He stuck with me faithfully through back-to-back, ten-hour marathon sessions, and never cried, never complained, and most importantly, NEVER CRASHED. Thanks, KAYPRO.
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ABSTRACT

Ley's Partial Model of Compliance suggests that patients who understand information given to them are more likely to remember the information and are more likely to be satisfied with the information. The model then suggests that these components will lead to greater patient compliance with medication regimens.

To test the model, Patient Package Inserts (PPIs) describing thiazide diuretics from the American Association of Retired Persons, the American Medical Association, the Canadian Pharmaceutical Association, the Food and Drug Administration, the National Association of Retail Druggists, the United States Pharmacopoeial Convention and a Test PPI written by the Principal Investigator were used. The SMOG Readability Formula was used to determine the grade levels at which PPIs were written.

One hundred thirty-six adults enrolled in GED classes in Tucson and other communities and 107 adults enrolled in remedial reading classes at Tucson's Pima Community College were administered the Zip Scale reading placement test and blocked by their reading abilities. Within each of the three blocks, subjects randomly received one of the seven information sheets or no sheet. Subjects took a multiple-choice test based upon information common to all of the PPIs, a cloze comprehension test based upon the PPI which they read, and completed a satisfaction survey which asked subjects to
rate the PPI which they read. Subjects also read five vignettes describing fictitious patients taking thiazides who were confronted with different barriers to compliance. Subjects indicated how likely the fictitious patients were to overcome the barriers to compliance.

Among this sample of remedial-reading adults, the Test PPI emerged as clearly superior to the others for any of the variables measured. This result would behoove providers of PPIs to rewrite PPIs, reducing the difficulty of these documents as much as possible.

Ley's Partial Model of Compliance did not accurately describe the associations between Understanding, Memory, Satisfaction and Compliance for this sample. A New Model emerged describing different associations between these components and between subject reading ability and PPI readability.
CHAPTER 1

INTRODUCTION

Consumer demand for information about prescription drugs has increased in recent years. A 1973 poll (Morris, Mazis and Gordon 1977) revealed that 49% of the respondents desired additional information about prescription medicines, particularly written information which could be easily understood by the lay person. Several consumer groups petitioned the United States Food and Drug Administration (FDA) in 1975, requesting that written patient information be dispensed along with prescription medicines (Oneck, Greenberger and Ensminger 1975). Public pressure led to the introduction of the Drug Regulation Reform Act of 1978, mandating enhanced labeling for a wide variety of prescription medicines (Morris and Halperin 1979). This "enhanced labeling" emerged as the "Patient Package Insert," or PPI, a detailed drug information sheet intended for the consumer.

Trends in Federal Government policy favoring deregulation led to the 1982 suspension of the proposed rules requiring PPIs (Federal Register 1982). The regulations requiring PPIs were tabled with the understanding that the FDA reserved the right to require PPIs once again should the need arise (Federal Register 1982). To address the challenge of providing patients with written drug information, professional organizations such as the American Medical Association
(AMA), the United States Pharmacopeial Convention (USP) and the National Association of Retail Druggists (NARD) have developed patient-oriented drug information sheets to be voluntarily distributed to patients by health care providers.

The voluntary PPI program has not been very successful. An issue of the American Pharmacy Association Newsletter (American Pharmacy Association 1984) carried the headline, "AMA discouraged at use of PMIs." This concern is reinforced by the research literature. Morris, et al. (1984) conducted a nationwide telephone survey among 1104 adults who had received new prescriptions within the four weeks prior to the survey; only five percent of the respondents reported receiving some form of written information from their physician. Sixteen percent claimed to have received some form of written drug information from the pharmacist. Meanwhile, consumer demand for written information about their drugs continues to increase, based upon the results of several surveys (Morris and Olins 1984; Pequet, Wegner and Brown 1984).

Were the public needs for prescription drug information being met by the private sector, a concern would remain that many patients may be unable to understand the information provided to them (Mohammed 1964; Wingert, Grubbs and Freidman 1969 and Stratton, Bradley and Hurd 1985). This lack of understanding has been found to negatively impact patient compliance with medication-taking regimens as explained in Ley's Partial Model of Compliance in Figure 1 (Ley 1980).
Based upon empirical findings (Ley, Jain and Skilbeck 1976), this model suggests that patients who can understand written drug information are more likely to remember the information. Understanding and remembering the written information will lead to patient satisfaction with the information, resulting in increased compliance with medication regimens by the patient. Ley concedes that there exist many determinants of compliance which have greater impact than improved information. Ley stresses, however, that increases in understanding and memory are worth the effort to increase the probability that consumers of health communications will be able to make decisions and take actions with knowledge rather than in relative ignorance (Ley 1980).

Statement of Problem

Patients continue to request information about their prescription drugs written in language easily understood by the lay
person. Health professionals have been charged with voluntarily providing this information; however, patients are not receiving the information despite its availability from a variety of sources.

The PPIs now available are written at several different reading grade levels; however, research demonstrates that there exist many patients who are unable to understand information written beyond elementary school level (Mohammed 1964; Wingert, et. al. 1969; Stratton, Bradley and Hurd 1985). The concern is that among patients who do not read well, many of these information sheets may be of little value.

In the event that the dissemination of written drug information to patients is once again mandated, it is very likely that one of the PPIs now in use would be selected to serve as a model. The question as to which of these PPIs will be most readily understood by the greatest number of people remains unanswered.

**Purpose and Objectives**

The impact of adult reading abilities on the comprehension of patient medication information sheets (patient package inserts or PPIs) will be explored. The goal of this project is to determine the appropriateness of the PPIs tested to serve as models for future PPIs, based solely on the ability of subjects to comprehend the PPIs. The specific objectives of the study are to: (1) Have adults of different reading abilities read PPIs from the American Association of Retired Persons, the American Medical Association, the Canadian Pharmaceutical
Association, the United States Food and Drug Administration, the National Association of Retail Druggists, the United States Pharmacopeial Convention, or a PPI written by the Principal Investigator; (2) Test subject understanding of the PPIs using a multiple-choice test with questions based upon medication-taking scenarios; (3) Test subject memory of the information contained in these PPIs using modified random, standard blank, exact cloze reading comprehension tests developed for each PPI; (4) Determine how satisfied subjects are with different aspects of each of the information sheets; (5) Determine the correlation coefficients between the components of Ley's Partial Model of Compliance; (6) Using the SMOG readability formula (McLaughlin 1969), determine the readabilities of PPIs from the suppliers listed above describing drugs or drug classes other than the thiazides in an attempt to arrive at a more generalized statement regarding the readability of PPIs.

Study Significance

Many patients are unable to understand written drug information developed for patient use (Mohammed 1964; Wingert, et al. 1969; Stratton, et al. 1985). This problem has arisen as a result of the assumption that the majority of Americans read at a ninth grade level, a standard adopted for the General Educations Development (GED) tests administered nationwide (Sonnenblick 1982). The inability or unwillingness of publishers of patient drug information to develop easily readable materials has also contributed to this problem. In an
earlier study, Stratton, Barreuther and Schondelmeyer (1984) found only two of fourteen consumer drug information books to be written below high school level.

Why be concerned about whether or not people understand written drug information? One reason involves the right and desire of the public to be informed about factors affecting their health, including their medications (Oneck, et al. 1975; Morris, et al. 1977; Pequet, Wegner and Brown 1984). This has assumed greater importance as a function of the trend towards greater patient participation in decisions affecting their health (Pequet, et al. 1984).

A second reason concerns the importance of patients understanding medication instructions to improve compliance with drug therapy regimens (Colcher and Bass 1972; Sharpe and Mikeal 1974; Mattar, Markello and Yaffe 1975; Ley, et al. 1976). The phenomenon of noncompliance with medication regimens has reached epidemic proportions (Haynes, Taylor and Sackett 1979). The contribution of written drug information towards overcoming barriers to compliance will be examined in this study.

**Hypotheses**

Understanding of PPIs

The "understanding" component of Ley's Partial Model of Compliance will be measured using a multiple-choice test. The construction and validation of this test are detailed in later chapters.
Initial testing of the multiple-choice test among Tucson GED students suggested that students reading the Test PPI (written at fifth grade level) scored higher than subjects receiving the USP PPI (written at eleventh grade level), although this difference was not significant due to the small sample size. The results of these pilot tests lead to the following hypothesis:

H(1): Subjects receiving a PPI written at or below their reading ability will score significantly higher on the multiple-choice test than will subjects receiving PPIs written above their reading abilities. All groups receiving PPIs will score significantly better on the tests than will controls who receive no PPI.

Retention of PPI Information

Ley, Jain and Skilbeck (1976) found that patients receiving drug information sheets which they could not understand committed medication errors more frequently than persons receiving drug information sheets which were easily understood. Essentially, this served as a measure of comprehension, although patients were not stratified by reading ability. Stratton and colleagues (1985) found that persons reading at ninth grade level performed better on ninth grade cloze comprehension test materials than did persons reading at fifth grade level and receiving the same ninth grade material.

H(2): Subjects receiving a PPI written at or below their reading abilities will have significantly higher cloze comprehension
scores than will subjects receiving PPIs written at levels exceeding their reading abilities.

Satisfaction with PPIs

Ley's Partial Model of Compliance (Ley 1980) suggests that if subjects can understand written information, they are more likely to be satisfied with the information. This proposition is supported by data collected by Kahn (1978) which revealed that college students given easy-to-read pamphlets on drug abuse claimed to be more likely to recommend the pamphlets to friends than students receiving difficult-to-read pamphlets.

H(3): Subjects receiving a PPI written at or below their reading level will claim to be more satisfied with the PPI than subjects receiving PPIs written at levels exceeding their reading abilities.

Likelihood of Compliance

Ley's Partial Model of Compliance (1980) suggests that if patients understand information about a therapeutic regimen, they are likely to remember the information, be satisfied with the information, and hence, be more likely to adhere to the prescribed therapeutic regimen. Ley, Jain and Skilbeck (1976) demonstrated that a relationship between understanding and compliance among psychiatric outpatients as described previously in this paper.

Compliance will not be measured directly in the present study. Rather, subjects will be presented with a fictitious third
party who is faced with several of the barriers to compliance proposed by Becker and Maiman (1975). The subject will be asked to indicate on a seven-point Likert-type scale how likely they feel that the person in the story is to comply with the physician's instructions regarding the person's thiazide diuretic. The development and validation of this instrument are described later in this chapter.

H(4): Subjects receiving a PPI written at or below their reading ability will say that a fictitious patient will be more likely to comply with a medication regimen than will subjects receiving PPIs written at levels exceeding their reading abilities.

Testing the Partial Model of Compliance

Ley (1980) suggests that understanding, memory, satisfaction and compliance are related (Figure 1). Measures have been described for each of the components which make up Ley's Partial Model of Compliance (Ley 1980).

H(5): Within each treatment cell, beta weights between the components of Ley's Partial Model of Compliance will be significant.

Definition of Terms

Cloze test: A reading comprehension test, the cloze test is derived from the "closure" concept of Gestalt psychology, the phenomenon by which a human will see a not-quite-complete circle as a whole circle by mentally "closing" the gap and making the image conform to a familiar shape. Likewise, it seems that humans try to
complete a mutilated sentence by filling in those words that make the finished pattern of letters fit the apparent meaning.

Compliance: Compliance will not be measured directly in the present study. Rather, the contribution of written drug information towards overcoming some of the barriers to compliance outlined in the Health Belief Model as modified by Becker and Maiman (1975) will be examined. Subjects will be presented with a fictitious patient confronting several barriers to compliance. Based upon the information sheets they read, subjects will be asked to indicate how likely they feel the patient is to overcome the barriers and comply with a prescribed medication regimen.

Currently available or Commercial PPI: Patient medication instruction sheets which may be ordered from the AMA, USP, NARD, American Association of Retired Persons (AARP), or the Canadian Pharmaceutical Association (CPhA).

Drug Information: Any statements made about specific drugs or pharmacologic or therapeutic classes of drugs, including instructions for the proper use of drugs.

FDA PPI: A patient package insert proposed by the United States Food and Drug Administration to serve as a model for future PPIs but never marketed.

Frustration reading level: Based upon a subject score of 65 percent or less at a particular grade level on the Zip Scale reading placement test, this is the point at which the subject is completely unable to cope with the general vocabulary of reading materials.
GED: An abbreviation for General Education Development, also known as a High School Equivalency Certificate. The GED is a certificate awarded to persons who have not completed high school but who have performed satisfactorily at high school level on a battery of tests in reading, mathematics, social science and natural science. In Arizona, State-supported classes are offered to prepare persons sixteen years of age or older for the battery of tests.

Independent reading level: Based upon a subject score of 80 percent or more for a particular grade level on the Zip Scale reading placement test, this is the point at which the subject functions solely upon his or her own abilities and does a satisfactory job of handling the general vocabulary of printed materials.

Instructional reading level: Based upon a subject score of 66-79 percent for a particular grade level on the Zip Scale reading placement test, this is the point at which the subject can profit from specific reading instruction by reading specialists.

PPI: Patient Package Insert. The consumer version of the professional literature included with each package of medication purchased by a physician or pharmacist, PPIs are fact sheets intended for the lay person which provide detailed information about the uses, side effects, drug interactions and cautions of prescription drugs. PPIs are currently supplied by a variety of professional or consumer organizations and are available for more than eighty drugs or drug classes. Most, but not all, PPIs are based upon the USP's Dispensing Information, Volume II (Advice for the Patient).
Readability: The ease with which a piece of writing will be understood by the audience for whom it was intended. Readability is usually considered in terms of vocabulary complexity (based upon the number of syllables in the piece of writing) and grammatical complexity (based upon the number and length of sentences in the piece of writing).

SMOG Readability Formula: Developed by McLaughlin (1969), this readability formula estimates the grade level at which a piece is written by using counts of polysyllabic words (those with more than three syllables) from samples of prose. Demonstrated to be reliable and valid, this formula has been adopted by the National Cancer Institute to determine the readability of NCI patient education materials.

Test PPI: A patient package insert written by the investigator, based upon Long's Essential Guide to Prescription Drugs, 4th edition (1985). This PPI is in no way a modification of existing PPIs, although the format used may be similar to that found in existing PPIs.

Thiazides: Analogs of 1,2,4-benzothiadiazine-1,1-dioxide, thiazides are a class of diuretics ("water pills") commonly used in the management of edema secondary to chronic cardiac decompensation (congestive heart failure) and in the treatment of hypertension (high blood pressure).

Zip Scale: Short title for the Zip Scale for Determining Independent Reading Level, a word recognition test
used for reading placement for grades 1-12. The test consists of sections on reading comprehension, listening comprehension and word recognition.

**Scope and Delimitations**

With at least five major suppliers producing PPIs covering over eighty drugs or drug classes, it would be difficult, if not impossible, to test each and every PPI available today. Simply using two PPIs in actual subject testing would cause the sample size to become unmanageable given the limited resources available for this study. For these reasons, PPIs covering one drug or drug class were selected for use in the patient testing. To arrive at inferences regarding how well patients might understand PPIs covering drugs other than the thiazides, additional PPIs from one supplier were evaluated using the SMOG readability formula.

The ideal study would include monitoring actual patient medication-taking behavior to directly measure the impact of written drug information on patient compliance. Unfortunately, an undertaking of this complexity would far exceed the resources available for conducting this project, and was not attempted in the present study.
CHAPTER 2

REVIEW OF THE LITERATURE

A large body of knowledge has been accumulated in the areas of reading, testing of reading comprehension, and the readability of written information; however, in the area of consumer drug information, the collection of literature is less voluminous. In this chapter a review of the literature relevant to the present study is presented. Topics to be covered include reading theory, testing of reading comprehension, readability theory, a review of readability formulas, and the use of the readability concept as it has been applied to patient education materials.

Reading Theory

The exact mechanism by which one reads remains a mystery. Vast amounts of research continue to be done in an effort to better describe the reading process, and to attempt to describe how the reading process differs for "good" readers and "poor" readers. While many theories have evolved to explain the processes involved in the act of reading, each of these theories have explained a slightly different segment of the reading process rather than offer competing mechanisms (Lueers 1983).

Two major schools of thought exist in explaining the reading process (Richgels 1982). The schema theory from psychology suggests
that there exists a knowledge structure or framework which interrelates all of one's knowledge about a given topic. Prior knowledge, organized into schemata, influence the form and content of new knowledge. Schemata are thought to serve as organizers for input; without them, new experiences would be incomprehensible.

Linguistic theorists comprise the other camp. The sentence is seen as the surface level manifestation of a more fundamental level or "base component" of language production. This base component relates sentence parts syntactically and possibly semantically. For example, the relationship between the noun phrase and the verb is responsible for much of that sentence's meaning.

A synthesis of the schema and linguistic theories gives rise to a third possible explanation for the reading process. Miller and Kintsch (1980) suggest that as a reader works through a text, only a fraction of the already-read text is held in short term (working) memory. If a segment of text is read which does not relate to the current contents of the working memory, long-term memory is searched to locate a part of text that can interrelate what has already been read with current input. This aspect of Miller and Kintsch's model draws upon schema theory.

The linguistic school is incorporated into this theory in Miller and Kintsch's discussion of the contribution of propositions to the comprehension process. Introduced in an earlier effort to explain a person reads (Kintsch and van Dijk 1978), propositions are composed of a relational concept (subject of sentence or paragraph for example)
and a series of one or more arguments (verbs describing what the subject did). When faced with a new concept, the reader will process through layers of propositions, attempting to establish a relationship between the new concept and existing concepts. When no such interrelation can be surmised, the reader will resort to a bridging inference. Consider the example:

Sam left his phonograph record inside the hot car.
Sam's phonograph record was ruined.

No interrelation can be made between the two sentences based upon the relational concept of phonograph record. The reader must infer the relationship that somehow leaving the phonograph record in the hot car caused it to become ruined.

Summers (1984) takes a different approach to explaining the reading process. He lists three major components of reading: decoding, assessing the meaning of individual words, and obtaining meaning from longer passages. He posits that word knowledge is the key to reading comprehension, serving as a linkage between longer passage; words themselves convey concepts and eventually flow together as ideas.

Summers suggests that a student's vocabulary is very important in determining how well the student will read. A reader's "sight-recognition vocabulary" consists of that collection of printed words which can be quickly associated with the spoken form. The effective reader samples text sparingly, automatically processing high frequency
words; common words are automatically coded into a visual word code which then quickly excites the meaning code if the reader has a sufficient repertoire of meaning for such words. Infrequently occurring words or words which are not readily matched to a reader's vocabulary set require more reader concentration.

Summers suggests that "good readers" do not concentrate upon every word, but concentrate only on those words which are unfamiliar. Good readers therefore have more capacity for higher level comprehension processes. Another explanation for this process was offered by Sahu and Devi (1984), who rely upon the concept of selective concentration to differentiate between good and poor readers. Using ninety Indian fifth-graders, these researchers discovered that good readers use a simultaneous process in reading as opposed to poor readers who use a sequential process. To use a computer analogy, good readers send written information to the processing centers of the computer (brain) over a parallel cable, different packets of information passing through the cable's various wires simultaneously. Poor readers must send this information over a serial cable, packets of information following one another in sequence. The information is completely transferred in both cases; poor readers simply require more time, and have to exert considerably more mental effort to arrive at the same conclusions as good readers.

The idea of "parallel" processing in reading is also used by Le (1984) who suggests that reading allows the reader to generate new ideas at the same time the reader is processing the ideas of the
Rather than a cognitive process, Le posits that the generation of new thoughts occurs as a result of a creative interaction between conscious and subconscious, "meditation."

Danemom (1982) states that most theories of reading comprehension are based upon storage capacity of the reader as well as the reader's information manipulating processes. As in the theories of Miller and Kintsch (1980) and Summers (1984), Danemom suggests that the poor reader is at a disadvantage because the encoding and word retrieval processes are executed more slowly than for good readers. These slower processes "tie up" the brain's comprehension centers, and do not permit the execution of higher level processes; moreover, the extra time required would allow important information to decay from working memory, making subsequent comprehension more difficult.

Danemom (1982) uses three measures of a person's reading comprehension ability. The reader's "reading span measure" is tested by having the person read several sentences aloud and then recite the last word from each sentence. "Pronominal reference ability" is measured by having a person read a passage in which several people are mentioned and then identify the person to whom a pronoun in the passage refers. The ability to monitor and revise comprehension errors is also measured. For example, in the sentence, "The dentist used the drill which he found useful for mastering the Latin and Greek verbs," the reader is tested to determine whether or not he or she realizes that the "drill" used in this sentence is not a dental instrument. Danemom's research has demonstrated that readers with larger memory
capacity perform better on these tests than persons without this capacity.

Two of the most recent theories reported in the literature serve to bring together this myriad of different approaches to explaining the reading process. These are the explanation offered by Curtis and Glaser (1983), and Lueers' Short-Circuit Model (1984). These theories represent the most comprehensive explanations of the reading comprehension process, and as a result, they are exceedingly complex.

Based on reviews of the reading literature, Curtis and Glaser (1983) suggest a four step model: word recoding, assessing semantic word information, sentence processing and discourse analysis. Word recoding is based upon information available from properties of the word itself and information derived from the semantic constraints the previous context imposes on the possibilities for the next word. "Poor" readers are slower at tasks involving the recognition of isolated words and must rely more on the context in which the word is found than do good readers. This process requires more "internal memory" than does simple word recognition, so higher level comprehension becomes resource-limited. As decoding skills are developed, the attention required to maintain these skills is decreased, allowing more effort to be directed toward understanding what is being read.

Higher level processes used to assess semantic word information appear to be influenced by several factors. The accuracy
of a word is one of these factors, the reader automatically determining whether or not he or she has any appropriate semantic knowledge in memory associated with a word. The richness or depth of knowledge about a word's meaning, flexibility, also impacts these higher level processes. Fluency, the speed with which a person accesses the meaning of a word, is the third of the influential factors. Curtis and Glaser cite studies which show that increasing accuracy (vocabulary) does not increase comprehension significantly, although increasing flexibility and fluency does positively impact comprehension.

Comprehension requires integration of each incoming sentence into the memory structure that exists for what has already been read. Curtis and Glaser call this sentence processing. Incoming sentences are checked to determine if any portion of them matches the contents of working memory. If no exact match is found, the next step involves searching the incoming sentence for pronomial or explicit references to a concept mentioned in previous sentences; new information is connected to that already stored in working memory. Should these first two steps fail to link the incoming sentence to information already "on board," the reader attempts to relate the new information to existing information through inferential processes, bridging inferences. Should inferential processes not make the link necessary for comprehension, the reader will draw upon his or her long-term memory, signaled by cues in the incoming sentence such as repetition of a concept presented earlier. Integration in this case is achieved
by reactivating passage content that has been stored previously and was not in current use.

Discourse analysis represents the last step in Curtis and Glaser's model of reading comprehension. This step involves the interaction between the ease with which the first three steps are executed by the reader and the individual's familiarity with the theme of the overall passage.

Curtis and Glaser's model incorporates portions of earlier models. Lueers' Short-Circuit Model (Lueers 1984) takes this one step further, incorporating entire models into her "super-model." Lueers posits that comprehension occurs as long as this complex model functions intact. When a "short-circuiting factor" is introduced, however, the meaning which the author intends becomes lessened or misaligned with the meaning the reader receives from the printed page. Examples of short-circuiting factors include linguistic factors, sociocultural factors, attitudinal and motivational factors, neurological factors, perceptual factors and cognitive factors. In short, just about every variable ever found to influence reading comprehension is included in this model, and is capable of causing the model to "short-circuit."

The reading process is indeed complex, and no simple test exists which will tap all of the subprocesses which occur in reading comprehension. At best one can hope to develop a test which examines the interaction between reader and text, the purpose of the comprehension test.
Testing of Reading Comprehension

Standardized reading comprehension tests such as the McCall-Crabbs Standard Test Lessons, California Achievement Test, the Stanford Diagnostic Reading Test or the Nelson-Denny Test tend to be atheoretical and pragmatic; these tests do not really contribute to our understanding of text processing or text structure (Danemom 1982). Using the multiple-choice format, each of these standardized reading tests is highly reliable, if not entirely valid.

The cloze test was developed as an alternative to multiple-choice comprehension tests, and is considered to yield more accurate results than the multiple-choice test (Miller 1974). Miller (1974) has compared the characteristics of the McCall-Crabbs comprehension test to those of the cloze test, finding the cloze test superior based upon the following arguments:

1. In a cloze comprehension test, reader-examinees guess and fill in deleted words (usually every fifth word) in a passage as they read the passage; in multiple-choice tests (such as McCall-Crabbs), reader-examinees read a passage and then answer multiple-choice questions about that passage.

2. A cloze test measures the difficulty of a passage, not the difficulty of the questions about the passage; in the multiple-choice test, questions may be easier or more difficult to understand than the passage itself, questions may fail to sample passage material adequately, etc.

3. A cloze test measures what the reader actually brings to the passage in terms of content knowledge. In a multiple-choice test, questions about the passage make it difficult to determine how much an examinee knew about the passage content before he read it of how much he learned from the passage after he read it.
4. A cloze test measures the difficulty of every word, phrase or sentence in a passage (if all cloze versions of that passage are used). In a multiple-choice test, questions cannot be as precise in measuring intrasentence meanings and relationships.

McKenna (1979) offers some insight into the processes which occur when a reader is confronted with a cloze test. Coming upon a blank, the reader infers which word should fill the blank. Among the inferential constraints with which the reader must work are syntactic restraints, semantic restraints, subordinate constraints, and coordinate constraints. Syntactic restraints arise based on the part of speech the missing word represents. Semantic restraints are a result of limitations put upon the meaning of the missing word. Subordinate restraints occur when possible substitute words are combined by the subject because the combination is thought of in a singular sense. For example, in the sentence, "The ____ hurt one of its four legs," the blank could be filled with almost any word describing an animal with four legs. Coordinate constraints arise when conclusions about the missing word are combined logically, but not thought of together. In the sentence, "His mother named him ____ because she liked monosyllabic names," the reader knows that the missing word must be (1) a male name and (2) one syllable.

Accepted constraints are combined to arrive at a single set of possible replacement words which have common attributes from several categories of constraints, each category having a single constraint. The more constraints a possible substitution meets, the
greater the chance of success. This is the process of concept building which occurs during a cloze exercise.

The cloze comprehension test has been validated in a variety of studies since its inception (Buros 1978). Results from cloze tests have been found to correlate from 0.54 to 0.96 with the results of multiple-choice tests over the same material (Bormuth 1968 and 1967; Rankin and Culhane 1969). Deno (1982) compared the results of cloze tests to the results from oral reading tests, word recognition tests, words-in-context tests and performance on the Stanford Diagnostic Reading Test among children with learning disabilities. All comprehension tests were found to correlate well with the Stanford Test.

A cloze score of approximately 60% has been determined to correspond to a score of 90% on a comparable multiple-choice comprehension test (Bormuth 1968; Rankin and Culhane 1969). Duffelmeyer (1978) questions this performance criterion, however, finding that performance on cloze tests is directly proportional to a student's reading ability. Fifth grade readers who are rated as "good" readers were found to do no better on fifth grade cloze material than did tenth grade readers rated as "poor" on tenth grade cloze material. Similar results were obtained by Stratton, et al. (1985) in the pilot study to the present project. Among Veteran's Administration outpatients and GED students, subjects reading at grade levels 3-5 did not perform as well on a fourth grade cloze test as did subjects reading at 6th-12th grade who received cloze tests written at
these levels. Duffelmeyer (1978) suggests at the upper grade levels, the 60% criterion may not be sufficient to indicate adequate comprehension of the reading material.

Although grade level appears to impact student performance on the cloze test, no relationship between subject age and performance has been found to exist. Holcomb (1979) utilized the cloze procedure to measure the comprehension of hypertension information among eighty-four adults ranging in age from sixty-one to ninety-three years. Holcomb investigated the relationship between cloze test scores, patient age and formal years of schooling. She found that for all three test forms used (covering three different sources information sources about hypertension), patient age was not significantly correlated with test score. Similar results were obtained by Stratton, et al. (1985).

There exists some debate over the most valid method by which to construct a cloze comprehension test. Generally cloze comprehension tests are developed using an every nth-word deletion pattern. A concern with this deletion pattern is that systematic error may be introduced because some sets of deleted words may be easier to figure out than other patterns over the same material.

Henk (1981) developed different cloze tests based on a single passage from the Graduate Record Examination (GRE) Aptitude Test. Design variations were: Every fifth word deletion or random deletion; Deleted words were replaced either with blanks of a standard length or with blanks which had spaces corresponding to the number of letters in
the missing words (cued blanks); and Verbatim responses (exact words) only were counted as correct replacements for missing words or synonyms for the missing words were accepted as correct. Every fifth-word deletions produced higher scores than a total random deletion pattern and synonymic responses yielded more correct responses than did the verbatim method. Cueing responses did not differ significantly with test scores from non-cued responses.

Although an every-fifth-word deletion pattern yielded higher test scores than a totally random deletion pattern, use of every-nth-word deletion patterns necessitates the construction of n different cloze versions over the same material. Using an every-fifth-word deletion pattern for example would require one version to delete the first, sixth, eleventh, sixteenth words, the second version to delete the second, seventh, twelfth and seventeenth words, the third version would delete the third, eighth, thirteenth and eighteenth words and so forth. The problem results when one or more versions are either more or less difficult than other versions. Most investigators administer multiple versions of the cloze test and average the results to determine the difficulty of a passage.

A much more logical approach statistically would be to delete words at random, providing each word in the passage an equal chance of being deleted. If the words deleted in such a version were more difficult than the words deleted in another version, the resulting error would represent random error rather than systematic error, and
should yield a more accurate estimate of the difficulty of the passage.

A potential problem with a totally random deletion pattern arises in the event that two or more consecutive words could be selected for deletion. In one instance during the pilot study (Stratton et al. 1985), five consecutive words were marked for deletion as a result of random selection. The cloze procedure is dependent upon the ability of the reader to make guesses based on the grammatical, syntactic and semantic relationships of the missing word to the remaining words, an impossibility when four or five consecutive words are deleted. Henk found that context differences (the distances between blanks) had no effect on cloze test scores. Meredith and Vaughan (1981), however, found that if more than two consecutive words were deleted, subjects did not perform as well. Their recommendation is to use a "modified" random deletion pattern. In the event that three or more consecutive words are to be deleted, delete the first two words, skip the third, fourth and fifth words, then continue the deletions with the sixth word (Meredith, personal communication 1984).

Verbatim replacement scoring yielded higher scores than did synonymic scoring (accepting synonyms as correct responses). Henk found an overall correlation of 0.75 between scores from the verbatim and synonymic response versions. A great amount of effort must be expended to decide whether or not a synonym is a grammatically, syntactically and semantically correct replacement for the missing
word. Again referring to the pilot study, one line of the cloze passage read, "you may ___ to take this drug for the rest of your life." The word "have" is the logical and correct response for this blank; however, many subjects inserted the word "want" in this blank (After all, the word fit and almost made sense.). Simply referring to a thesaurus is not adequate to determine whether or not a word should be a permissible replacement.

Considering the high correlation between the verbatim and synonymic versions, and in light of the great lengths to which one must go to determine whether or not a word is a correct synonymic replacement, Henk concludes that, "There seems to be no overt advantage in giving credit for synonyms." This recommendation is further supported by the results from a study conducted by Brown (1980) who found little, if any, advantage in permitting synonymic responses over exact responses.

With microcomputers increasingly available to teachers, construction of cloze tests is no longer the onerous task that it once was (Montgomery 1984). Word processing programs make it a simple matter to generate several copies of a passage and quickly delete words in different patterns. Klare's concerns over the difficulty in constructing cloze comprehension tests (Klage 1974-1975) are less well founded today in light of present technology. Only time will tell if cloze tests increase in usage among the Nation's schoolteachers.

A third type of comprehension test which has been used is the Informal Reading Inventory (IRI) described by Blanchard, et al.
(1983). The teacher quizzes the student verbally immediately after the student has finished reading a passage. This is felt to also yield more accurate results than multiple-choice questions because the cueing of the multiple-choice format is felt to result in overestimation of a student's reading ability. Obtaining correct responses through guessing is all but eliminated. On the other hand, because students tend to answer only 52-62% of the IRI questions correctly, Blanchard suggests that the IRI may be more useful at determining frustration reading level than either instructional or independent reading levels.

**Readability Theory**

Many definitions for readability have been developed over the years, the concept being described by Herbert Spencer as early as 1852 (Harris and Jacobsen 1979). Without actually coining the term, Spencer expressed readability as "economy of the reader's attention," and "least possible mental effort." Spencer defined "economy" as, "efficiency of effort to improve understanding," and, "variety of presentation (stylistic variety) to achieve interest and delight." A century later, Smith (1961) offered a refined definition of readability, proposing that the concept referred to the, "quality of a piece of reading matter that makes it interesting and understandable to those for whom it was written."

Spencer and Smith both describe the concept of readability in terms of "understanding" and "interest" without specifying what they
mean by these terms. Ligouri (1978) proposes that "understanding" may be thought of in terms of structural elements such as vocabulary, sentence length and grammatical complexity. Ligouri further proposes that "interest" is composed of those characteristics of writing which do not greatly contribute to actual understanding (Fry 1969), the "design" elements of readability such as page and type size, line spacing, margins, contrast, color, illustrations and graphics. Ligouri posits that the function of design is to enhance the readability of the primary structural elements. Indeed, researchers at the University of Colorado are currently investigating the impact of design elements on patient satisfaction with the PPI produced by the United States Pharmacopeial Convention (United States Pharmacopeial Convention 1984). Others propose that the function of design is to sell more books (Fry 1969).

Klare, acclaimed as a widely recognized bibliographer of readability studies (Fry 1977), suggests that the readability concept is important because a problem in mass communication is how to determine whether a particular piece of writing is likely to be understood by a particular group of readers. Klare proposes three solutions to this dilemma, "guessing," administering comprehension tests based upon the material, or application of readability formulas (Klare 1974-1975).

By guessing Klare means judgements made by experts in reading. Klare finds this a useful technique; however, questions of reliability, validity and of time and effort become more serious as
the task becomes more complex. Comprehension tests can overcome the validity and reliability problems encountered when using judges. Gains in these areas must however be weighed against the time and precision required in constructing such tests, as mentioned previously. Because of the practical difficulties encountered in formulating comprehension tests, most writers and teachers are likely to choose a formula with which to estimate the readability of a written piece (Klare 1974-1975). These formulas have been devised statistically and are used to "predict" comprehension test scores; no actual reader participation is needed (Klare 1974-1975).

Readability—Theoretical Foundations for the Formulas

By using counts of language variables (usually sentence length and word length) in a piece of writing, readability formulas provide an index of probable difficulty for readers (Klare 1974-1975). Sentence length is considered to provide a good measure of grammatical complexity, while word length, determined by the number of syllables, provides a fair index of vocabulary difficulty (Fry 1969). Although most readability formulas use both sentence length and word length, Spadaro, et al. (1980) have found that syllable counts (word length) correlate more directly with reading difficulty than does sentence length. Few readability formulas have emerged which make use of the findings of Spadaro and his colleagues.

Validation of readability formulas is usually accomplished by comparing the grade level assignment from a formula to scores from
comprehension tests on the same piece of writing. Most frequently, the test lessons developed by McCall and Crabbs (Klare 1974-1975) have been used to validate the results of readability formulas. Klare finds these lessons useful statistically because 100 or so passages covering a wide range of difficulty have been developed, and almost sixty years of use have provided detailed grade scores. The test lessons were revised in 1950; however, Powers, Sumner and Kearl (1958) point out that the range of difficulty of the revised lessons was restricted by omitting some of the more difficult passages from the revision. These researchers prefer the original 1926 version for developing readability formulas.

Miller (1974) compared the predictive capabilities of the Dale-Chall readability formula, a formula validated using McCall-Crabbs test lessons, and the Bormuth formula, validated using the cloze comprehension test. Miller compared results from the readability formulas to the results obtained from both a multiple-choice comprehension test and a cloze comprehension test for a specific passage. When the results from each of the readability formulas were compared to the results of the comprehension tests, no significant differences in the predictive powers of the two readability formulas were found. Miller concludes that formula selection remains a matter of personal preference rather than a matter of statistical validity.
A plethora of readability formulas have been developed since the 1920's. Among the older formulas, only a few remain in widespread use (Klare 1974-1975). For a more complete review of the various readability formulas which have been developed over the last sixty years, the reader is referred to Klare's reviews (Klare 1963 and 1974-1975).

Lorge Formula

Proposed in 1939, the Lorge formula was perhaps the first of the modern, easy-to-use formulas (Klare 1974-1975). The Lorge formula, designed to measure the readability of materials for grades 3-12, was modified over the next thirty years and evolved to its present form:

\[
\text{Grade level} = 10 \left( \frac{\text{ratio of hard words}}{\text{average sentence length}} \right) + 0.7
\]

where a "hard word" is defined as a word not appearing on the Dale list of 769 words.

The original Lorge formula was found to correlate by a factor of 0.77 with the McCall-Crabbs test lessons.

Dale-Chall Formula

The Dale-Chall readability formula was developed in 1948 and is cited by Klare and others as being the most accurate (valid) of the formulas intended for adult materials (Dale and Chall 1948a, Powers, et al. 1958 and Klare 1963). Dale and Chall (1948a) propose a
rather complex formula involving word counts and determinations whether or not words appear on a list of 3000 "common" words. Many different rules must be followed in determining which forms of a word (plural, participle, inflection, etc.) are considered to be "included" on the list (Dale and Chall 1948b). The words appearing on the list of 3000 "common" words are those selected by eighty percent of the fourth grade students as being familiar words. The authors do not tell the reader how words were originally selected for testing, nor the number of words selected for testing. It further cannot be ascertained how many students participated in the testing, what demographics characterized the fourth graders involved, nor over how many years this data was collected. Researchers today must also keep in mind that words familiar to today's fourth graders (e.g., "computer" or "television") may not have been unknown forty years ago.

Despite its shortcomings, the Dale-Chall formula has evolved into one of the two most widely used readability formulas (Klare 1974–1975). The formula is provided below (Dale and Chall 1948a; Klare 1974–1975):

\[ X_{c50} = 0.1579x_1 + 0.0496x_2 + 3.6365 \]

where:

- \( X_{c50} \) = reading grade score of a reader who could receive a score of 50% on a McCall-Crabbs test.
- \( X_1 \) = Dale score (percentage of words outside the list of 3000 words).
- \( X_2 \) = average sentence length in words.
To validate the formula, Dale and Chall constructed several experiments to compare formula predictions with the judgements of experienced teachers, a group of "experts" in readability and actual comprehension test scores of readers on passages (Dale and Chall 1948a). On fifty-five passages of health education materials, formula predictions correlated by a factor of 0.92 with the experts and by 0.90 with the reading grade levels of children and adults who were able to answer three to four questions asked on each of thirty passages. Again, the authors fail to provide the reader with some useful information such as how many "children and adults," and whether or not the "experts" used were experts in readability or experts in health education.

On seventy-eight passages on foreign affairs from magazines, governmental pamphlets and newspapers, the correlation between formula predictions and judgements by expert teachers in social studies was 0.90. No comprehension tests were apparently given on the materials evaluated, nor were readability experts apparently utilized in this phase of the validation procedure.

Fortunately, Dale and Chall did not rely solely upon the results of their own tests to establish the validity of their formula. Comparing the results of their formula to the results obtained from the McCall-Crabbs test lessons, Dale and Chall (1948a) report a correlation of 0.6883. They compared this to a correlation of 0.66 between the McCall-Crabbs test lessons and both the Lorge and Flesch
formulas, but fail to indicate if their test was found to have a statistically higher correlation than these latter formulas.

A correlation of 0.69 between the Dale-Chall formula and the McCall-Crabbs test lessons is far from perfect; however, Klare points out that Dale-Chall has consistently proven more accurate than other formulas (Klare 1963). This claim has been supported by the work of Powers, et al. (1958) who revalidated several formulas, including Dale-Chall, using the revised McCall-Crabbs test lessons from 1950.

Flesch Formula

The most accurate formula is the Dale-Chall formula; however, it is not the most widely used formula. According to Klare (1963), this honor goes to the Flesch Reading Ease Formula. Because of its widespread use, more research data has been collected on this formula than on any other (Klare 1963). This popularity is sometimes the only reason provided by researchers to justify their selection of the Flesch formula (Ligouri 1978; Spodaro, et al. 1980; Holcomb 1981). The Flesch Reading Ease Formula is as follows (Flesch 1950; Klare 1974-1975):

\[
RE = 206.835 - 0.846w1 - 1.015s1
\]

where \(w1\) = number of syllables per 100 words
and \(s1\) = number of words (average) per sentence

The Flesch Reading Ease Formula provides ratings from zero (almost unreadable) to 100 (very readable). The formula has been
found to correlate between 0.66 and 0.70 with the McCall-Crabbs lessons (Dale and Chall 1948a; Klare 1974-1975).

The original Flesch formula was simplified soon after its release by Farr, Jenkins and Paterson (1951):

New Reading Ease Index = 1.59nosw - 1.015sl - 31.517

where nosw = number of one-syllable words per 100 words and sl= sentence length.

Farr and his coworkers found that it is much easier to count the number of one-syllable words in a 100 word passage than to count all of the syllables in that passage. This formula correlated 0.93 and 0.95 with the original Flesch formula over two different passages.

The Farr-Jenkins-Paterson version of the Flesch formula would seem to be preferable over the original Flesch formula because of its greater ease of application. Further validation studies will be necessary, however, before the Farr-Jenkins-Paterson formula gains the acceptance accorded the original Flesch Reading Ease Formula.

Devereux Formula

Developed by Smith (1961) and named in honor of the institute for which he worked, the Devereux formula purports to be faster than using a word list and simpler than using syllable counts. This formula, shown below, involves a count of the average number of character spaces (letters, numbers and punctuation marks):
Grade placement = 1.56wl + 0.19sl - 6.49

or

Readability Index = 8WL + SL

When the Readability Index is used, the predicted value is located on a table developed by Smith which yields a corresponding grade level.

The Devereux formula is unique in that it was not validated against either the McCall-Crabbs test lessons nor the cloze comprehension test. Rather, it was validated against booklets in the Reading for Meaning series, which "experience had indicated were accurately graded," for grades 4-12 (Smith 1961). Smith found that his Readability Index correlated well (rho = 1.00) with the recommended reading levels proposed by the publisher of the Reading for Meaning series. One must wonder why no authors of readability tests before or since Smith have used this set of books as a criterion. Klare fails even to mention that the Reading for Meaning series has ever been used as a validating instrument, and no evaluations of text readability which have appeared in the literature since introduction of the Devereux formula have used the instrument.

Fry Readability Graph

Investigators continued to improve upon readability formulas and instruments, one such improvement being the Fry Readability Graph (Fry 1968). The Readability Graph was originally developed in Uganda and was first used mostly by British readers. The version presented
by Fry in the *Journal of Reading* (1968) was developed for use in the American educational system.

Fry did not base the construction of his graph upon any statistical theories (e.g., regression) nor upon any previously-developed formulas. Rather, "Grade level designations were determined by plotting lots of books which publishers said were third grade readers, fifth grade readers, etc.," looking for clusters and then smoothing the resulting curve. The grade level areas were then adjusted after some use and correlational studies.

Fry's less-than-scientific method of constructing the graph gives one cause for concern over the validity of the results obtained from the graph. One of Fry's graduate students selected ten books used in his tenth grade English classes and constructed comprehension tests (true-false, multiple-choice and short answer essay). This student determined the correlation coefficients between the comprehension test results and the Readability Graph, the Dale-Chall formula, the Flesch formula and two other formulas. Correlations between the Fry Graph and the Dale-Chall readability formula was 0.94; for the Flesch test the correlation was 0.96. Results from the Fry Graph correlated to the results from the student comprehension tests by a coefficient of 0.93. More recently, Longo (1982) validated the Fry Graph to Grade Level 17, finding agreement between the Fry Graph, the Dale-Chall formula, the Flesch formula and the Farr-Jenkins-Paterson formulas twenty out of twenty-one times.
SMOG Formula

McLaughlin (1969) named his SMOG formula partly to comment on the air quality of his native London and partly to make fun of the name Gunning (1968) selected for his formula (the Fog Index). McLaughlin validated his instrument against multiple-choice comprehension tests and against judgements by reading experts. Carver (1976) validated the SMOG formula against the Flesch and Dale-Chall formulas and against the Fry Graph, and found correlations ranging from 0.86 to 0.97. When compared to the results from a cloze test, a correlation of 0.79 was obtained.

The formula is much faster to use than formulas based on word lists and is less cumbersome to use than the older formulas. The SMOG formula has been selected by the National Cancer Institute as the readability formula of choice for evaluating NCI patient education materials (DHEW 1979).

Other Formulas

Gunning's Fog Index. Gunning's Fog Index (Gunning 1968; Klare 1974-1975) is a simplified formula involving average sentence length and syllable counts as do so many other formulas:

\[
\text{Reading grade level} = 0.4(\text{average sentence length} + \text{percentage of words with 3 or more syllables}).
\]

The formula's name was derived from Gunning's pleadings with writers to clear the "fog" from their work by writing simply and clearly.
The Caylor Formulas. Two formulas which make use only of syllable counts have been developed by Caylor, et al. (Klare 1974–1975). The first formula, developed for evaluating military training manuals, takes the following form:

\[ RGL(\text{Reading Grade Level}) = 20.43 - 0.11(\text{number of one-syllable words}). \]

The formula was simplified, the easier version becoming known as the FORCAST formula:

\[ \text{FORCAST} = 20 - \frac{\text{number of one-syllable words}}{10}. \]

Caylor and his coworkers report that the simplified version is less precise than the parent version, and they recommend that the first version be used whenever possible. Stratton, Barreuther and Schondelmeyer (1984) found the Caylor formula to be particularly useful in analyzing the readability of consumer drug information books. Many of these texts were not written in sentence form; rather, phrases and lists of words were provided. This format rendered useless those formulas which rely upon sentence counts.

Lix and Rix Formulas. The Lix readability formula was developed in Sweden and has been validated on twenty-four textbooks from fifteen countries (Anderson 1983). Lix, which is an acronym for "readability index" in Swedish, was found to correlate 0.85 against cloze tests and recall tests, and 0.89 when compared to judges rankings of text. The Rix formula is a modification of the Lix
formula for use specifically with English-language texts, and has only recently become available.

The Rix formula takes the form:

\[
Rix = \frac{\text{number of long words}}{\text{number of sentences}}
\]

where a long word is any word with more than six letters.

Rix ratings range from 20 (very easy) to 60 (very difficult).

4.WSF Formula. The Wiener Sachbuchformel, or Fourth Viennese formula for nonfiction, is another of the recent readability formulas to come from European researchers (Bamberger and Rabin 1984). This formula follows:

\[
\text{Grade level} = 0.2656S_1 + 0.2744MS - 1.6939
\]

where \( S_1 \) = sentence length and \( MS \) = number of multisyllabic words

\( S_1 \) = the average sentence length in a series of 10-sentence passages.

Limitations of Readability Formulas

Formulas are far from being a panacea in determining the readability of written material. Dale and Chall (1948a) remind the researcher that a readability formula is nothing more than a statistical device which is based upon the presumption that overall, longer sentences and use of unfamiliar words make material more difficult to understand. Many other factors which cannot be measured by a formula influence a reader's ability to easily understand a piece of writing.
Organization, word order, format and imagery in writing are stylistic components of writing which are beyond the capacity of formulas to measure (Klare 1963). Syntactic complexity is not taken into account by formulas, and sentence length is not felt to be an adequate predictor of syntactic complexity (Harber 1979).

The difficulty or lack of difficulty in a piece of writing depends a great deal upon the reader (Danemom 1982). Factors such as what an author expects the reader to gain from a piece of writing and reader motivation cannot be accounted for by formulas (Dale and Chall 1948a; Klare 1963).

Fry (1977) offers additional cautions about the limitations of instruments used to determine readability, specifically his Readability Graph. He stresses that readability scores are merely estimates which deviate about a mean score. "Readability formulas are not strong in reporting either reliability or validity," Fry says; however, "it can be assumed that formulas have at least a moderate amount of reliability because they consistently correlate fairly well with each other."

Alternatives to Readability Formulas

Several new methods for determining the readability of written materials have emerged in recent years. These methods use none of the methods suggested by Klare for determining readability (Klare 1974-1975). One of the methods uses persons who "qualify" as experts through a testing procedure; these "experts" making subsequent
judgements. The other two methods are actually competency-based determinations made by the actual audience for whom the written material is intended.

Rauding Scale

Carver (1976) created the Rauding Scale of Prose Difficulty, a method which utilizes judgements by "qualified" experts. The word, "Rauding," is derived by contracting "reading" and "understanding." "Experts" become qualified as such by reading several "anchor" passages somehow written to represent grade levels 2, 5, 8, 11, 14 and 17. Persons who correctly rate the passages after reading them are designated as being "expert." Anchor passages are then used as the basis by which test passages are rated. A passage rated by a judge to be more difficult than the anchor passage at grade level five but slightly easier than the anchor passage at grade level eight would be assigned a grade level of seven. Carver claims that this method is superior to the Dale-Chall or Flesch formulas because it reflects the difficulty of ideas or concepts in a passage, characteristics which cannot be measured by readability formulas.

Carver does nothing to validate his instrument beyond performing inter-rater reliability studies (correlation of 0.97). The reader has no idea how grade levels are assigned to anchor passages, and the shortcomings of using judges presented earlier (Fry 1969; Klare 1974-1975) are not addressed. Kirby (1975) develops additional arguments questioning the accuracy of the Rauding Scale, including the
point that Carver never defines the "idea or concept difficulty" which he claims to measure.

Competency-based Methods

Estes and Wetmore (1983) suggest that readers should assess text for comprehensibility rather than for readability. This is accomplished by examining the unity, coherence and emphasis of a piece of writing. Unity is defined as the number of ideas which are raised within a given section of the piece. If many unrelated ideas are presented within a section, the piece is said to have low comprehensibility. Coherence describes how well one topic builds on the next. Emphasis determines whether or not key points are emphasized by the author. These investigators provide a nine-step approach to testing for comprehensibility.

Funkhouser (1983) recommends that researchers look not at readability, nor even comprehensibility. Rather, Funkhouser suggests that usability is the criterion by which written pieces should be judged. In the case of patient package inserts, he argues that instead of including large amounts of technical information, the patient should be told how to safely use the drug and when to contact the physician for advice or information. When developing patient package inserts, Funkhouser recommends the following questions be asked:

1. Do patients immediately understand the information and remember key facts through the course of their therapy?
2. Does the PPI result in patients making more informed decisions about the use of their drugs?

3. Do patients follow the regimens of dosage more closely?

4. Is there an increase in useful feedback from patients to physicians?

Funkhouser's recommendations are best put to use in a longitudinal compliance study in which patients are followed for a period of weeks or months after reading a PPI. Such a study has yet to be conducted, and is certainly beyond the scope of the present project.

**Readability of Patient-Oriented Materials**

Readability has been of great concern for years to those in the education field. Readability in the area of patient education, however, is a relatively new topic of interest. Readability first emerged into the health care spotlight as a result of the mandate requiring patient written patient information be dispensed with certain prescription medications (Morris and Halperin 1979).

The concept of readability appears to have been introduced into the health care literature out of a concern for teaching the diabetic patient. Lanese and Thrush (1963) acquired a sampling of literature for diabetic patients from twenty-one teaching hospitals from across the country. Using the Dale-Chall formula, these researchers found the average reading level of the materials to be approximately ninth grade. Based upon census data available at the time, Lanese and Thrush determined that fully fifty percent of the diabetic patients over the age of forty-five years had not completed
the ninth grade (the average education being 6.9 years). Despite reservations about using the Dale-Chall formula to evaluate technical material (Brown 1965), Lanese and Thrush are able to make a point. Writers of health materials for patients must keep their audiences (and the reading ability of that audience) in mind, possibly using a word list such as Dale's to construct such materials.

Mohammed (1964) used a different approach to address the readability question as it applied to diabetic teaching materials. Using the Dale-Chall formula, Mohammed constructed five 100-word passages at the fourth, sixth and eighth grade levels. Each paragraph was followed by four questions whose answers were clearly stated in the paragraph. She then administered this comprehension test to 300 diabetic patients, of which almost one-third were unable to complete the answer sheets. She then used the Dale-Chall formula to rate a diabetic teaching handbook and found it to be written at approximately eighth grade. Comparing this result with the results of her comprehension test, this handbook would be comprehensible by only twenty-two percent of her diabetic population. Fully forty percent of the patients studied would be unable to profit from any form of written information.

Several years after being published, Mohammed's instrument was resurrected by Wingert, Grubbs and Friedman (1969). These investigators modified Mohammed's instrument so that it dealt with pediatric problems rather than general adult medicine situations. Administering this test to 255 indigent mothers who registered their
children at the Pediatric Emergency Room of the Los Angeles County-University of Southern California (LAC-USC) Medical Center, they found that thirty-seven percent of the high school graduates and twenty-seven percent of those who had attended college did not read beyond the sixth grade level.

Wingert and his colleagues proceeded to evaluate two patient-oriented publications, including Dr. Spock's Baby and Child Care (1957). They found parts of Spock's book to be written at ninth or tenth grade levels. Their final recommendations were that patient information pamphlets be written at the sixth grade or below. Even at this level, fifteen percent of the mothers in the LAC-USC study could not have read and understood the written material.

Much of the work in the area of readability of patient-oriented materials has been published only within the last six years. Pyrczak and Roth (1976) evaluated the statements of "Warning" and "Caution" that appeared in the directions of ten aspirin-containing over-the-counter (OTC) products. Using the Dale-Chall formula, these investigators determined that, on the average, the warning statements could be read and understood only by consumers with eleventh to twelfth grade reading abilities. It was further determined that the presence of the words "accidental," "overdose," "contact," "physician," and "immediately" were the main source of difficulty. Recalling the criticisms of using the Dale-Chall formula presented in the preceding sections, it can be assumed that the statements were not as difficult as they were made out to be.
Pyrczak and Roth's work would have been of little value had they simply rated the statements; however, they took their work one step further. Using the 3000-word Dale list, they rewrote the cautionary statements: "If someone takes too much by accident, talk to a doctor right away." The grade level of this passage: IV or below.

Kahn (1978) evaluated a sixty-five page booklet and four 3-5 page pamphlets addressing the problem of drug abuse. Using the Flesch formula, Kahn found that three of the sources were rated at college level. College students who received the more difficult pamphlets were reluctant to recommend that the material be distributed to other students. Those who received the less difficult material, however, were enthusiastic about distributing the literature to other students.

Ross, Metts and Parrish (1981) utilized both Gunning's Fog Index and Fry's Readability Graph to evaluate the readability of poison prevention materials. In the first part of the study, these investigators evaluated a single passage from one pamphlet and averaged the results from each instrument and predicted the readability grade level at eleventh grade. The validity of this technique to make a statement about readability is questionable; however, the authors use the technique for demonstration only. Using this averaging technique to evaluate, rewrite and then reevaluate this particular passage, these researchers were able to reduce the readability grade level to sixth grade through the rewriting process.
The second part of this study involved the review of eighteen poison prevention pamphlets from various governmental and private sources. Using the Fry Graph, the pamphlets were found to range in readability from fourth grade through college level. Results from the Fog Index were similar, resulting in a range of readability levels from the sixth through sixteenth grades.

The Flesch formula has proven useful in evaluating patient-oriented brochures dealing with general health topics. Spadaro, et al. (1980) evaluated 111 patient brochures and pamphlets describing various disease states. These information sources were found to be written at the eighth grade level or below only fifty percent of the time.

Holcomb (1981) randomly selected fifteen patient information brochures produced and used by the Kaiser Foundation Hospitals of Oregon. Only one publication was rated as fairly easy (6th grade level), six tested as standard (7th-8th grades), six tested as fairly difficult to difficult (high school to college) and two tested as being understandable only to college graduates. The one pharmacy publication selected, "Department of Pharmacy Instruction Sheet: To Patients on Coumadin (Warfarin) Therapy," was rated as standard difficulty. The single most difficult publication was entitled, Health Plan Member's Handbook.

Holcomb concludes that to reach a mass audience, the writer of patient materials must aim roughly at the seventh to eighth grade level. This estimate may still be too high as evidenced by the
studies cited previously in this paper. Holcomb's is a perfect setting in which to test patient reading abilities and then design patient information targeted for these reading abilities.

**Readability of Patient Drug Information**

While others in health care were evaluating patient-oriented materials of a more general nature, pharmacy researchers were busy reckoning with a relatively new source of patient-oriented literature, the patient package insert (PPI). Using the Flesch formula, Ligouri (1978) evaluated four PPIs (Tables 1 and 2). He found that the PPIs in use at the time of the study, those required for oral contraceptives (OCs) and estrogens, were rated at grade levels 10-12 and 8-9, respectively. Ligouri also found that the newer PPIs which had been proposed for methyldopa and the thiazides were both written at grade level six. This suggests that the reading ability of the target population had been taken into account when the more recent PPIs were written.

Morris, Myers and Thilman (1980), unlike previous health researchers, used a variety of readability formulas to evaluate the readability of a PPI. These investigators prepared four different versions of a patient labeling document (PPI) for ValiumR. Each version contained the same basic information about the drug's uses, side effects and potential for producing dependency, but differed in vocabulary and complexity of sentence structure.
### TABLE 1
Results of Flesch Analysis of Required PPIs

<table>
<thead>
<tr>
<th>PPI Required by FDA</th>
<th>Reading Ease Score</th>
<th>Interpretation</th>
<th>Grade Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Contraceptives</td>
<td>55</td>
<td>Fairly Difficult</td>
<td>10-12</td>
</tr>
<tr>
<td>Estrogens</td>
<td>60</td>
<td>Standard</td>
<td>8-9</td>
</tr>
</tbody>
</table>

From Ligouri (1978)

### TABLE 2
Results of Flesch Analysis of Proposed PPIs

<table>
<thead>
<tr>
<th>PPI Under Study</th>
<th>Reading Ease Score</th>
<th>Interpretation</th>
<th>Grade Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyldopa</td>
<td>81</td>
<td>Easy</td>
<td>6</td>
</tr>
<tr>
<td>Thiazides</td>
<td>81</td>
<td>Easy</td>
<td>6</td>
</tr>
</tbody>
</table>

From Ligouri (1978)
One hundred ninety-nine persons either currently enrolled in college or who had completed at least one year of college were asked to read an excerpt from one of the four versions and complete a questionnaire about the document. The questionnaires included questions about interest value, positive evaluation and adult readability; however, they were not comprehension tests.

Morris and his colleagues then proceeded to evaluate the four versions of the PPI using fourteen different instruments with which to measure readability. They found a great deal of variability in predicted reading grade levels, ranging from grade levels of 1.9 to 9.8. They conclude that readability formulas are of little value because of reliability problems from test to test.

Morris and his colleagues caution that, "the blind application of readability formulas easily could lead to incorrect conclusions about text difficulty." They certainly appear to have "blindly" applied many of these readability formulas! Using the results from the Dale-Chall formula as a point of reference (grade level assignment of 8.0), an analysis of the application of the readability formulas reveals several concerns with Morris' conclusions.

The Spache formula is intended for reading material written at grade levels one through three (Klare 1963); yet, all four documents were rated by the Dale-Chall instrument at grade level five or above. Most readability formulas recommend that several passages be used because of text variability from passage to passage found in
most books (Spadaro, et al. 1980; Fry 1977). Some of the documents evaluated were so short that it is highly doubtful that more than one passage could be sampled. Moreover, only the SMOG formula provides contingencies for dealing with very short passages (less than thirty sentences), so the validity of applying many of the other formulas at all is subject to question.

The authors also miss some very important trends in the data. Previous studies have established very high correlations between the results of several formulas, such as between the Dale-Chall and Flesch formulas. Stratton (1982) conducted inter-formula correlations using the results of Morris and his coworkers. Correlations between the Dale-Chall, Flesch, Farr-Jenkins-Paterson and the two Caylor formulas ranged from 0.97 to 0.99. Morris' conclusion that the formulas lack reliability can certainly be questioned in light of Stratton's findings.

Once the proposed rule mandating the distribution of PPIs was rescinded (Fed Regist. 1982), research into the readability of these documents tapered off. At the same time, in response to the FDA's call for the private sector to continue to provide patients with written drug information, many drug information books for consumers began to appear on the market. In addition to other characteristics of these books, namely completeness and accuracy, Stratton, Barreuther and Schondelmeyer (1984) evaluated the readability of fourteen consumer drug information books, using the formula proposed by Caylor, et al. (Klare 1974-1975).
Introductory text and the text from ten drug monographs were evaluated from each book. Stratton and his coworkers found that the books ranged in readability from ninth grade to fourteenth grade. The lowest reading grade level assigned to a particular passage in a book was 8.0; the highest found was 16.0. These researchers concluded that all of the consumer drug information books available were written at levels too difficult for many consumers to understand. They recommend that authors pay more attention to the reading ability of the audience when writing such texts.

In the studies cited thus far, we have seen how many researchers have applied readability formulas to written patient information. Most have used the formulas simply to estimate the reading ability required for patients to understand the material. Some have used the readability formulas to rewrite existing text in an attempt to simplify the materials. Still others have used the formulas to construct reading comprehension tests to determine patient reading ability. Only one study to date has combined all of these elements, the pilot study to this project conducted by Stratton, et al. (1985).

**Readability, Reading Ability and Patient Comprehension**

Based upon the American Medical Association's **Patient Medication Instruction** sheet (PMI) describing thiazides, Stratton, et al. (1985) used the SMOG formula to construct PPIs at grade levels four, seven, ten and thirteen. Each PPI was identical in appearance
to the AMA PMI; only vocabulary differed. The readabilities of the modified PPIs were cross-validated using the Dale-Chall and Flesch formulas, and the Fry Graph. A high degree of agreement was found among the different instruments (Stratton and Bradley 1985).

Eighty-nine patients from the Tucson Veteran's Administration Medical Center (TVAMC) and forty-four adults enrolled in Tucson General Education Development (GED) classes were administered a standard reading placement test (Cramer and Dorsey 1979) and categorized by reading ability. Within each classification block (3-4-5, 6-7-8, 9-10-11 or 12 and above), subjects were randomly assigned to read either the AMA PMI or a modified version of the PMI written at the subject's reading ability.

After reading the drug information sheets, subjects were administered a short multiple-choice comprehension test which presented situations describing medication-taking behavior, and a cloze test based upon the particular version of AMA PMI received by a particular subject. Only two significant differences emerged. In responding to one of the multiple-choice questions, subjects who had received a modified PMI selected the correct answer more frequently than subjects receiving the AMA PMI.

The other significant findings were based upon subject reading ability. Subjects reading at below sixth grade level performed significantly poorer on the cloze comprehension tests than subjects reading at or above this level. Within each block, no significant difference based upon information sheet read was seen.
It is most likely that no treatment effects were seen because the modified PMIs were so similar to the AMA document. Only vocabulary was changed, and a SMOG rating of fourth grade for a modified version of the PMI did not necessarily mean that the document was syntactically written at the fourth grade level. Many of the reading instructors involved with the study indicated that no fourth grade reader could be expected to grasp the volume of information presented in the supposedly fourth grade version of the PMI. The authors conclude that it is inappropriate to use readability formulas to rewrite text.

Readability formulas have been applied to PPIs in an attempt to discover whether or not patients could understand the information contained therein. Some researchers (Morris, et al. 1980) have even gone so far as to ask patients to assign ratings of satisfaction to the PPIs. Funkhouser (1983) recommends that the true test of the usefulness of written information is reader performance based upon the instructions found in the reading. Several studies in health care have investigated this relationship, specifically the relationship between provision of written instructions and patient compliance with medical regimens.

Written Drug Information and Compliance

Paulson, et al. (1976) provided questionnaires to 1500 college students the day after they had received prescriptions at a university student health center. The first group of 741 students
received only verbal instructions at the time the prescription was dispensed. The 759 students comprising the other group received the verbal counseling and a written medication data sheet (essentially a PPI). Significant improvement in answering the questionnaire was seen among students receiving the written information in the areas of course of action to follow if a dose was missed, what foods or drinks to avoid, and refill information.

Paulson and his coworkers do not actually measure compliance, although Ley's Partial Model of Compliance (Ley 1980) presented in the Introduction suggests that greater understanding and increased knowledge about the medical regimen should lead to increased compliance. It is unfortunate that no effort was made to measure actual compliance in this relatively "captive" population.

Colcher and Bass (1972) studied 200 children who had been prescribed phenoxyethyl penicillin (penicillin V) for treatment of streptococcal pharyngitis. The drug regimen for all patients was the same, one 250mg tablet three times per day for ten days. One hundred of the patients were randomly assigned to receive written information about the penicillin along with counseling from the pharmacist. For remaining patients, the pharmacist was permitted to answer specific questions, but was not permitted to offer any unsolicited counseling. Among patients receiving the verbal and written reinforcement, there were eight relapses and ten treatment failures for a total compliance rate of eighty percent. Among controls, there occurred twenty-four relapses and twenty-five treatment failures for a
total compliance rate of fifty-eight percent. The rate of compliance was significantly different using Fisher's Exact Test ($p < 0.001$).

It is difficult to attribute the improved compliance of the treatment group solely to the written information provided. It is most likely that improved compliance resulted from an interaction between the written information, the verbal counseling, and some confound, possibly a Hawthorne effect. The latter may have arisen as a result of the children's parents wanting to comply simply because they felt that the pharmacist was truly concerned for their child's well-being.

Sharpe and Mikeal (1974) also studied the effect of providing written information on antibiotic compliance. Eighty adults receiving prescriptions for ten day regimens of either ampicillin, phenoxyethyl penicillin potassium (penicillin VK) or tetracycline were randomly assigned to receive either the usual prescription label only or the usual prescription label plus an auxiliary label instructing the patient to take the medication until finished and an information sheet describing the importance that the entire course of therapy be completed. Compliance was monitored using pill counts at days three, six or nine. Among persons receiving only the usual prescription label, 63% were found to be compliant versus 84.7% of the patients in the treatment group. This difference was statistically significant ($p < 0.05$).

As in the previous study, it is unfortunate that the investigators insisted upon combining all treatments without testing
each treatment separately as well. This makes it impossible to conclude exactly what contributed to the increased compliance seen in the treatment group.

Mattar, et al. (1975) monitored the compliance of 200 children who received an antibiotic suspension from a community pharmacy for treatment of otitis media. Compliance was measured by having parents bring in the remaining suspension during the course of therapy and measuring this remaining amount. Compliance among this group of patients was judged to be 8.5%.

Thirty-three different children receiving an antibiotic for the treatment of otitis were sent to the hospital pharmacy to have their prescriptions filled. The hospital pharmacist gave these patients written and verbal instructions at the time the prescription was dispensed, and the compliance rate for this group was found to be 51%. Once again, it is very possible that increased compliance resulted as an interaction between the written instructions, the verbal counseling, and a Hawthorne effect resulting from the parent feeling "special" because he or she was asked to go see the hospital pharmacist instead of to the usual pharmacist at the usual drugstore.

Ley, Jain and Skilbeck (1976) evaluated three leaflets about antidepressants and three about tranquilizers for use in the psychiatric outpatient setting. Using the Flesch formula, readability scores were determined and correlated to the number of medication errors committed by patients. Sixty patients on each drug were given one of the three leaflets about their drug and then were monitored for
compliance using pill counts. The results of the study (Table 3) reveal that patients with "easy" leaflets committed significantly fewer medication errors than did the group with difficult-to-understand leaflets ($p < 0.05$). This final group committed about the same number of medication errors as the control group who had no leaflets (difference not significant).

**TABLE 3**

Mean Percentage of Medication Errors Committed by Patients Receiving Patient Package Inserts of Variable Difficulty\(^a\)

<table>
<thead>
<tr>
<th>Flesch Formula Rating</th>
<th>No Pamphlet</th>
<th>Easy Pamphlet</th>
<th>Moderate Pamphlet</th>
<th>Difficult Pamphlet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antidepressant</td>
<td>16.17</td>
<td>2.66</td>
<td>8.13</td>
<td>14.54</td>
</tr>
<tr>
<td>Tranquilizer</td>
<td>14.65</td>
<td>5.83</td>
<td>7.83</td>
<td>14.86</td>
</tr>
</tbody>
</table>

Easy < Moderate < Difficult = No pamphlet ($p < 0.05$)

\(^a\)Ley, Jain and Skilbeck (1976)

**Compliance: The Health Belief Model**

A large body of research literature has emerged in the area of patient compliance with health and medical care regimens, including drug therapy (Haynes, Sackett and Taylor 1979). As evidenced by the
variety of outcome measures used in the studies cited in the previous section, many operational definitions for "compliance" exist.

Becker and Maiman (1975) reviewed a large portion of the compliance literature, and evolved a socio-behavioral adaptation of the Health Belief Model. This model (Figure 2) uses a patient's perceptions of susceptibility to a particular disease, to explain patient compliance and non-compliance with preventive health measures.

Patient Education: Alternatives to Written Patient Information

Two recent studies report comparisons of the impact which written drug information and other methods of transferring drug information have on patient drug knowledge. Mullen and Green (1984) looked at effect size in reviewing 102 studies published since 1977 reporting on the impact of different educational strategies on patient knowledge and use of prescription drugs. In the four studies involving patient package inserts as the sole educational intervention, almost no impact on patient knowledge or compliance was found, whereas interventions including counseling, behavior modification, group education and memory aids alone or in combination improved patient knowledge and use 32-45%. The authors suggest that PPIs were ineffective because PPIs could not increase the amount of information already received from health professionals, or because the information contained in the PPIs was of too general a nature to impact specific medication-taking situations.
FIGURE 2

The Health Belief Model

INDIVIDUAL PERCEPTIONS

Perceived Susceptibility of Disease "X"
Perceived Seriousness (Severity) of Disease "X"

MODIFYING FACTORS

Demographic Variables
Sociopsychological variables (personality, social class, peer and reference group pressure)
Structural variables (knowledge about the disease, prior contact with the disease, etc.)

Perceived Threat of Disease "X"

LIKELIHOOD OF ACTION

Perceived benefits of action minus Perceived barriers to action
Likelihood of taking recommended preventive health action

Cues to Action
- Mass media campaign
- Advice from others
- Reminder postcard from physician or dentist
- Illness of family member of friend
- Newspaper or magazine article

Olsen and DuBe (1985) compared the impact of written drug information and an audio-visual (AV) slide-tape program on patient knowledge of steroid therapy among sixteen adult patients receiving steroid therapy. These researchers claim to have found that both methods increased patients' short-term knowledge, and that the AV program had significantly greater impact on patient knowledge than did the written information. Unfortunately this study suffers from several major shortcomings.

The investigators imply that their written materials were rewritten until an eighth-grade level was achieved using the Fry Graph. Stratton, Bradley and Hurd (1985) have shown that this is an inappropriate way in which to use readability "formulas," in that other components of the reading process are not taken into account by these instruments (Lueers 1984). Additionally, Stratton, et al. (1985) found a correlation of less than 0.50 between education level and reading ability among subjects with greater than a seventh-grade education. The assumption that similar educations guaranteed similar reading abilities was unfounded.

The investigators cite earlier studies which suggest that educational programs can increase short-term knowledge; yet, without explanation they hypothesize that no significant increases will be found in their patient sample.

No pretesting of the 20-item multiple-choice test is reported, so the researchers cannot make any claims as to the validity of their testing instrument. Likewise, no reliability analyses of the
test instrument were undertaken. The authors imply that their two treatment groups are equivalent. If this is so, how do they explain the difference in pre-intervention scores? Possibly, the lack of pretesting of the testing instrument resulted in these differential pre-intervention scores between the two groups.

Knowledge increases are reported to have occurred, the authors attributing this change to the intervention. Their lack of a control group weakens this conclusion as the authors were unable to account for any change resulting from test-retest effects, history effects or differential maturation (Cook and Campbell 1979, Chapter 2).

Knowledge measurements were transformed to percentage change; however, these investigators analyze the data using a Student's t test. Because of the differential growth rates of the two groups (the AV group having lower pretest scores than the written information group, but higher post-test scores) an analysis of covariance (ANCOVA) could not have been used on the non-transformed raw data (Cook and Campbell 1979, pp. 170). It therefore appears appropriate to transform the data to percentage change, in which case a chi square test would have been the most appropriate test to use.

The application of newer technologies to the reading area is an exciting area which will surely be investigated extensively in the future. It is unfortunate that the shortcomings in Olsen and DuBe's research design preclude them from making a strong statement regarding the impact of audiovisual materials on reading comprehension.
Summary

Several of the theories which attempt to explain the process by which a person reads have been presented. The application of the readability concept to patient information materials has also been presented. Although most reading theorists point to the inadequacy of standardized reading tests and tests of readability in contributing to our knowledge of the reading process, it appears that the cloze comprehension test may actually tap some of the reading processes which occur.

In the present study, the cloze test will be used in an attempt to determine which of several drug information sheets are most readily understood by adults of below-average reading ability. The chapter which follows offers a detailed description of the materials and methods to be used in undertaking this project.
CHAPTER 3

MATERIALS AND METHODS

At least five commercial suppliers of patient package inserts publish PPIs covering over 80 drugs or classes of drugs. These PPIs are provided to patients whose educational levels and reading abilities range from below first grade through college-level. In the present study, PPIs from seven different sources covering the thiazide diuretics were read by English-speaking persons aged sixteen years or older who were neither enrolled in high school of the study nor had received a high school diploma at the time of the study.

In this chapter, a detailed description of the testing instruments and methods is provided, including justifications for the population of interest, the reading placement test used, and the formula selected to estimate the readabilities of the various PPIs. Studies validating the reading placement test and the readability formula are reviewed. Instruments for measuring each of the component's of Ley's Partial Model of Compliance are also described and validated.

Study Design

The proposed study was of a randomized blocks design. As mentioned previously, there were four grade level blocks, grades 3–4–5, 6–7–8, 9–10–11 and 12 and over. There were seven treatments and a
<table>
<thead>
<tr>
<th>Zip Scale Grade Level</th>
<th>3-4-5</th>
<th>6-7-8</th>
<th>9-10-11</th>
<th>≥ 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>AARP MILS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMA PMI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPhA SIM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDA PPI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NARD PIL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEST PPI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USP PPI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Understanding  
Memory  
Satisfaction  
Likelihood of Compliance

FIGURE 3
Diagram of Treatment Design
control group within each block (Figure 3). Subjects within a reading grade block were assigned to treatments in a stratified random fashion, preventing the possibility of any one treatment being over-represented at a particular testing site as a result of purely random assignment. This also helped to insure that treatments were equally represented despite terminating data collection prior to testing the planned eighty subjects per cell.

**Pilot Study Population**

The pilot study preceding the present project utilized ambulatory outpatients from the Tucson Veteran's Administration Medical Center (TVAMC). The staff of TVAMC report that the mean education level of patients patronizing VA outpatient clinics nationwide is fourth grade, although the staff were unable to produce any documentation to their claim. Nonetheless, this population was selected based upon the assumption that a subpopulation of poor readers would be more readily accessible than that existing in the general population.

During the pilot study (Stratton, et al. 1985), almost ninety VA patients were screened; fewer than one-half of the needed subjects read below ninth grade. Several possible explanations exist for this disparity. Patients who were poor readers were disproportionately represented among persons declining to participate, or outpatients at the Tucson VAMC are not representative of VA
outpatients nationwide, or subjects in this population read much better than anticipated.

It was impossible to test the first explanation; once a patient declined to enter the study that person's reading ability could not be accurately determined. The second possibility is the most likely explanation. Although no formal survey was conducted, many patients who participated in the study were asked why they sought care at the VAMC. Among older patients, a common response was that they had retired to Tucson from other parts of the country, and because they were now on fixed incomes and eligible for free care at VA facilities, it was economically more feasible to receive care at the VAMC. It may be assumed that persons who could afford to retire to Arizona would also be better educated (and hence, probably better readers) than persons who could not afford such a move, although no tests of this assumption were made.

Younger patients frequently cited current unemployment as the reason they turned to the VAMC for care. Many of these younger patients were attending college classes at the time of their participation in the study; almost all such persons read at least at ninth grade level, and usually higher. This group certainly reads better than the "average" VA patient.

The possibility that patients at the Tucson VAMC population read better than anticipated merits consideration. We had assumed that the Tucson VAMC would provide us with "average" VA outpatients. While it is still likely that the reading ability of the "typical" VA
outpatient is not much above the fourth grade level, it appears that
the outpatient population at the Tucson VAMC is not representative of
the VA outpatient population as a whole. Prior to conducting the
initial study we had no reason to expect that outpatients at Tucson
VAMC might differ from the VA outpatients elsewhere.

To identify persons reading at lower levels, students from
Tucson's County-sponsored adult reading program were recruited. The
adults enrolled in the County reading program were all found to read
below third grade level; the vast majority did not read above the
first grade level. Only two of the nine people screened from this
program were able to attempt the reading comprehension tests. It was
concluded that this population of adults would be unsuitable for
further participation in the study because of their extremely low
reading abilities.

Adults enrolled in one of Tucson's State-sponsored General
Education Development (GED) classes were next recruited in the hope
that the reading ability of this population was somewhere between that
of the TVAMC patients and the students in the Pima County Adult
Education Program. Of the twenty-five subjects tested from the GED
class, only two read above the eighth-grade level. Additionally, only
two students declined to participate, as compared to a refusal rate of
nearly 50% at the VAMC. This population was therefore selected as the
population of interest for the present study.
Population of Present Study

The study population was comprised of students enrolled either in GED classes or in community college remedial reading classes in Tucson and in towns throughout central Arizona. In Tucson, five different GED classes across three sites participated in the study. GED students in Casa Grande, Coolidge, Stanfield, Scottsdale and Eloy also took part in the study. Six classes of students enrolled in remedial reading at Tucson's Pima Community College Eastside campus and three classes from the Pima Westside campus served as subjects. The remainder of the junior college participants were enrolled at Central Arizona College in Coolidge.

The study subjects were not representative of the general public, nor were they intended to be. The assumption was made that adults lacking a high school diploma would not read as well as adults possessing such a document, an assumption supported by findings in the pilot study. Adults who do read at twelfth grade level or above probably can read any of the PPIs with little difficulty, and would be expected to comprehend any of the PPIs equally well. Certainly, this also was borne out in the pilot study conducted earlier (Stratton, et al. 1985). Because it has been established that adults with good reading abilities exhibit similar levels of comprehension regardless of PPI received, they were not actively sought for this project, although students enrolled in the above programs who were found to read at higher levels were included in the study.
Students included in the study spoke English as their first language. This stipulation was made because of the large Hispanic population found in Arizona; not being able to read English may have little to do with a person's ability to read other languages (and several of the PPIs are available in the Spanish language).

The pilot study revealed no significant correlations between subject age and reading ability, nor between age and performance on comprehension tests. Similar results were obtained by Holcomb (1979) among elderly patients, there being no significant correlation between subject age and performance on the cloze comprehension test.

Age sixteen years is the minimum age at which students may be admitted to the GED programs. Although not legally considered to be adults, persons in this age group may have cause to use medications from time to time, and are certainly old enough to take responsibility for their own medication-taking behavior. For these reasons, no age limits were established for participants.

Measuring Reading Abilities

All subjects consenting to participate in the study were administered a standard reading placement test, the Zip Scale for Independent Reading Level (Appendix). The Zip Scale is a word recognition test used for reading placement which can be used to test reading abilities ranging from grades one through twelve.

Word recognition has been shown to be a valid method by which to test reading ability. Researchers in the late 1960's determined
that word recognition accounts for over 90 percent of the variability in reading comprehension (Davis 1968 and 1972; Thorndike 1973).

The Zip Scale has been demonstrated to be highly reliable. A correlation of 0.97 was achieved using the test-retest technique involving 360 students (Cramer and Dorsey 1979). The Zip Scale has been validated against several different criterion measures (Cramer and Dorsey 1979). Twelve reading specialists, and twelve high school teachers certified in language arts, English and literature determined the independent levels of 1,811 seventh to twelfth grade students using both standardized test data and actual reading performance. The high school instructors then administered the Zip Scale to the same students. Using the Chi square test with the Yates correction, 1,723 of student scores on the Zip Scale were found to agree with the assessments by the reading specialists (Chi square = 1096.206, p < 0.001). A correlation of 0.96 was found between Zip Scale results and the results obtained on Levels 1-5 of the California Achievement Test.

The Zip Scale was further validated against readability formulas and the cloze comprehension test used in the pilot study (Stratton, et al. 1985). Cloze comprehension tests were prepared from PPIs with SMOG formula ratings ranging from fourth to thirteenth grades. An overall correlation of 0.73 (p < 0.001) was attained between student Zip Scale scores and cloze comprehension test scores. Within grade blocks, this correlation was much higher.

The Zip Scale has three parts, a reading comprehension survey, a listening comprehension survey and a word recognition
survey. Only the reading comprehension test was used. The listening survey is used to establish the level at which the student can understand materials read aloud (Cramer and Dorsey 1979, p. 4). Physicians and pharmacists rarely read a PPI to a patient; rather, the information sheet is handed to the patient to be read later at the patient's convenience. Moreover, the listening comprehension survey generally yields a higher reading grade level than does the reading comprehension survey. Cramer and Dorsey suggest that a student's listening comprehension score may be more indicative of the level at which the student should be reading in contrast to the level at which he or she is reading (Cramer and Dorsey, p. 4).

The word recognition survey is used to group students for special vocabulary building instruction (Cramer and Dorsey 1979, p. 4). Such a purpose was beyond the scope of the present study, so this survey was not used.

In taking the reading placement test, subjects were given a list of twenty test words at a particular grade level. There were twelve grade levels in the survey. Along with each test word are four additional words, one of which was an approximate antonym of the test word. The remaining three words had no particular relationship to the test word. The student was asked to identify the approximate antonym for each test word. The student's independent reading level was that grade level at which the student was no longer able to correctly identify 80% of the approximate antonyms to the test words. In other words, the independent reading level was the final level at
which the student correctly identified sixteen out of twenty words. Words for which no antonym was indicated were counted as incorrect.

Subjects at each of the testing sites were provided with a verbal explanation of the project by the principal investigator and were given the option of declining to participate in the study. The Zip Scale was administered by the principal investigator, and graded by the principal investigator and his assistant. Subjects were not told their reading levels until after they were finished with the study. Subjects wishing to know their scores were asked to place their names on the top of the test forms which permitted reporting of their Zip Scale scores to their GED instructors. Students then received their scores from their instructors, enabling the instructors to discuss the scores with the students, and put the results in perspective for the students.

Subjects were placed into one of four reading grade blocks based upon their Zip Scale scores. Because cloze test scores have been found to vary as a function of educational level (Duffelmeyer 1978; Stratton, et. al., 1985), it was inappropriate to pool the data of all subjects to conduct statistical analyses.

Subjects placing at third, fourth or fifth grade reading abilities were placed in the first block. The second block had subjects who read at grade levels six, seven, or eight. Ninth, tenth and eleventh grade readers were placed in the next block; those reading at twelfth grade made up the final block. Subjects reading below the third grade did not have their data included in the study.
The selection of grade-level groupings was based upon the precision of the readability formula being used to estimate the readability of the PPIs. The precision of the SMOG readability formula has been found to be ± one grade level. A PPI written at the eighth grade level based upon the SMOG formula may indeed be written at seventh or ninth grades.

**PPI Assignments**

Once placed in a reading grade block, subjects were assigned in a stratified random fashion to receive either no PPI, a PPI describing thiazides written at the lowest possible grade level by the principal investigator in collaboration with reading experts, an American Medical Association *Patient Medication Instruction* sheet (AMA PMI) on thiazides, a United States Pharmacopeial Convention thiazide PPI (USP PPI), a National Association of Retail Druggists thiazide *Patient Information Leaflet* (NARD PIL), the *Medication Information Leaflet for Seniors* produced by the American Association of Retired Persons describing thiazides (AARP MILS) the Canadian Pharmaceutical Association's *Supplementary Information Material* (CPhA SIM) or a copy of the thiazide PPI proposed by the United States Food and Drug Administration, the FDA PPI (Ligouri 1978).

The AARP MILS was based upon the American Society of Hospital Pharmacists' *Medication Teaching Manual*. The origin of the FDA PPI is unknown. All other PPIs in the study were based upon the USP's *USP Dispensing Information*. Despite so many of the PPIs being based
upon the same reference, it was not possible to collapse this collection of PPIs into one group because each sponsoring organization has seen fit to include slightly different information in its version of the PPI. Despite this variation, the PPIs were found to be written at similar levels of difficulty, within the accuracy of the SMOG formula (Table 4).

The physical layout of the PPIs did differ, and format of written material has been found to influence readability (Dolinsky, et al. 1983), although the methodology used to make this determination is questionable (Stratton 1984). Because the text of four of the PPIs (AMA, NARD, CPhA and USP) were so similar, it had the effect of holding text constant while varying format. This provided the opportunity to test for the impact of format in a manner different from that used by Dolinsky and her coworkers.

The Principal Investigator's PPI (Test PPI) was based upon the fourth edition of Long's *The Essential Guide to Prescription Drugs* (Long 1985). This text was selected because the third edition of Long's book ranked second only to the USP's *About Your Medicines* in terms of readability, completeness and accuracy (Stratton 1982).

**Sample Size Determination**

Sample size was based upon a power analysis utilizing cloze comprehension test scores from subjects participating in the pilot study (Stratton, Bradley and Hurd 1985). A summary of the data used in the calculations is provided in Table 5. The value for phi, the
TABLE 4
SMOG Reading Grade Levels of Study PPIs

<table>
<thead>
<tr>
<th>Thiazide PPI Supplier&lt;sup&gt;a&lt;/sup&gt;</th>
<th>SMOG&lt;sup&gt;b&lt;/sup&gt; Reading Grade Levels of PPIs</th>
<th>SMOG Reading Grade Levels of Cloze Comprehension Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Judge 1</td>
<td>Judge 2</td>
</tr>
<tr>
<td>AARP</td>
<td>9.95</td>
<td>10.14</td>
</tr>
<tr>
<td>AMA</td>
<td>10.75</td>
<td>11.12</td>
</tr>
<tr>
<td>CPhA</td>
<td>11.20</td>
<td>11.57</td>
</tr>
<tr>
<td>FDA</td>
<td>8.60</td>
<td>8.50</td>
</tr>
<tr>
<td>NARD</td>
<td>11.00</td>
<td>12.36</td>
</tr>
<tr>
<td>Test</td>
<td>5.69</td>
<td>5.64</td>
</tr>
<tr>
<td>USP</td>
<td>11.20</td>
<td>12.36</td>
</tr>
</tbody>
</table>

Pearson's r for PPIs = 0.984.

<sup>a</sup> AARP = American Association of Retired Persons
AMA = American Medical Association
CPhA = Canadian Pharmaceutical Association
FDA = United States Food and Drug Administration
NARD = National Association of Retail Druggists
Test = Principal Investigator
USP = United States Pharmacopeial Convention

<sup>b</sup> McLaughlin, G. Harry. *J Reading*, 1969; readabilities are ± one reading grade level.
### TABLE 5
Cloze Comprehension Test Data
Used in Power Analysis

<table>
<thead>
<tr>
<th>Reading Grade Level</th>
<th>Grades 3-4-5</th>
<th>&gt; 9th grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>7</td>
<td>12</td>
</tr>
<tr>
<td>Range</td>
<td>6-40</td>
<td>35-48</td>
</tr>
<tr>
<td>Mean</td>
<td>23.86</td>
<td>40.33</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>10.84</td>
<td>3.87</td>
</tr>
<tr>
<td>Pooled standard deviation</td>
<td></td>
<td>10.72</td>
</tr>
</tbody>
</table>

\[ \phi = 2.28^c \]

---

\[ ^a \text{Data from Stratton, Bradley and Hurd, 1985.} \]

\[ ^b \text{Maximum score of 50 points possible.} \]

\[ ^c \text{Neter, Wasserman and Kutner, 1985.} \]
The noncentrality parameter used in the power analysis, was calculated from the formula provided in Neter, Wasserman and Kutner (1985, page 547). Phi is a measure of how unequal the mean scores of each group are.

The standard deviation used for the phi calculations was calculated from the pooled data of pilot study subjects reading at the fourth grade level and the ninth grade level who had received the AMA PMI (written at ninth grade level). The raw score means from these two groups of subjects were likewise used in the calculations.

It appears to be valid to use these groups in performing sample size estimations for this study. Use of these two groups approximates the outcome which would be expected within a single grade level block where one group received a PPI written at their grade level while the second group received a totally different PPI written at a level exceeding their reading ability. Using two pilot study groups from within the same grade block to make this estimation was inappropriate because of the inability to account for any effects on readability which may have arisen from differences in syntactic format (Stratton, et al. 1985). That is, in the pilot study the two information sheets used at the fourth grade level were so similar syntactically and in physical appearance that it is not surprising that no differences were found among subjects receiving the different PPIs within this block. By using two groups where a difference was found (fourth grade readers scoring much lower with the AMA PMI than did ninth grade readers), the expected effects from using truly
different PPIs among readers of similar abilities was better approximated.

An alpha level of 0.05 and a beta level of 0.2 were selected (providing a power of 0.8). A power of 0.9 may fail to detect a small difference which has practical importance. While a difference of two reading grade levels may be statistically small, it may determine whether a person will understand written material. A beta level of 0.2 is more likely to detect this smaller difference if it existed.

The method described above for calculating phi prime may overestimate actual treatment differences. This is suggested by the additional pilot data presented in Table 6. If the actual treatment difference is smaller than described above, then a larger sample size would be required to detect a difference at a beta level of 0.1. The beta level of 0.2 requires a smaller sample size to detect this same difference, negating the need to increase sample size given a smaller difference between treatments.

The power tables found in Neter, Wasserman and Kutner (1985, pp. 1089-94) are good only to six treatments. In the present study, there are seven treatments and a control group. Review of the sample sizes calculated from Neter and Wasserman's power tables for two through six treatments reveals that at worst, using the power tables for six treatments provides a conservative estimate of the sample size required for the number of treatments in the present study.

Based upon a values for alpha of 0.05, a beta value of 0.2, and upon the estimated phi prime value of 1.0, a sample size of ten
TABLE 6
Multiple-Choice Test Results Among Tucson GED Students

<table>
<thead>
<tr>
<th>Reading Ability</th>
<th>Grades 3–5</th>
<th>Grades 6–12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test PPI</td>
<td>USP PPI</td>
</tr>
<tr>
<td>n</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Range&lt;sup&gt;a&lt;/sup&gt;</td>
<td>5–7</td>
<td>5–7</td>
</tr>
<tr>
<td>Mean</td>
<td>6.20</td>
<td>5.60</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>2.05</td>
<td>0.89</td>
</tr>
<tr>
<td>KR20 Reliability</td>
<td>0.60</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>Possible score of 10.00.
subjects will be needed in each treatment within each grade level block. In this four by eight factorial study, ten persons will be needed in each of seven treatment groups and a control group within four reading grade blocks; a total sample of 320 will be necessary.

**Assessing PPI Readability**

The readability of each thiazide PPI as well as the cloze test developed from each thiazide PPI was assessed by the principal investigator and one other judge using McLaughlin's SMOG readability formula (McLaughlin 1969). Inter-rater reliability was tested using Pearson's correlation, selected over Kendall's Coefficient of Concordance (Siegel 1956) because the latter is used to compare rankings by judges. In the present study judges actually generated interval-scale values for the readability of each PPI and corresponding cloze test.

The SMOG readability formula has been found to correlate highly with the results of multiple-choice comprehension tests and with the reading difficulty levels assigned to passages by reading experts (McLaughlin 1969). The formula is much faster to use than formulas based upon word lists (such as Dale-Chall) and is less cumbersome to use than the older formulas based on word counts (such as Flesch). The SMOG formula has the additional advantage of retaining its validity when being used to evaluate short documents, such as patient information leaflets. For all of these reasons, the SMOG formula has been selected by the National Cancer Institute as the
readability formula of choice for evaluating NCI patient education materials (DHEW 1979), and for the same reasons it was selected for use in the present study.

Instructions for using the SMOG formula follow (McLaughlin 1969):

1. Count off ten consecutive sentences near the beginning, in the middle and near the end of the text.

2. From this sample of thirty sentences, circle all of the words containing three or more syllables (polysyllabic), including repetitions of the same word, and total the number of words circled.

3. Determine the square root of the total number of polysyllabic words counted.

4. Finally, add a constant of three to the square root. This number gives the SMOG grade, or the reading level that a person must have reached if he or she is to fully understand the text being assessed.

Additional guidelines:

1. A sentence is defined as a string of words punctuated with a period (.), an exclamation point (!) or a question mark (?).

2. Hyphenated words are considered as one word.

3. Numbers which are written out should also be considered, and if in the numeric form in the text, should be pronounced to determine if they are polysyllabic.

To test a text that has fewer than thirty sentences:

1. Count all of the polysyllabic words in the text.

2. Count the number of sentences.

3. Find the average number of polysyllabic words per sentence.
4. Multiply the average by the number of sentences short of thirty.

5. Add that figure on to the total number of polysyllabic words.

6. Find the square root and add the constant of three.

The SMOG reading grade levels for all PPIs and corresponding cloze tests used in the study are presented in Table 4. The Principal Investigator and one other judge independently assessed the readabilities of the documents using the SMOG formula. The scores for the NARD PIL and the USP PPI differ by more than one grade level because each judge chose to include different sentences in the word counts. All other scores are within one-half of a grade level of one another. The overall Pearson correlation of the judges' scores for the PPIs is 0.97. The correlation between judges' scores for corresponding cloze tests is essentially 1.00.

The suppliers of the thiazide PPIs were asked to provide the principal investigator with PPIs describing the penicillins, the benzodiazepines and the digitalis glycosides. These drug classes were selected because of their widespread use and because every PPI supplier has information sheets describing these drug classes. In an attempt to arrive at more general conclusions about the readability of PPIs, these additional PPIs were subjected to the same SMOG readability analysis as the thiazide PPI. The results of this analysis are provided in the next chapter.
Testing Understanding of PPIs

Ley cites three methods to test patient understanding: self-report; direct questioning; and readability measurement (Ley 1980). Ley does not provide theoretical or operational definitions of the understanding which he sets out to measure. In the present study, understanding was measured using a multiple-choice test.

One multiple-choice test was developed from general concepts common to all of the PPIs in the study and was used by all subjects regardless of which PPI was read. Every effort was made to write this test at the lowest possible grade level.

The multiple-choice test consisted of ten short vignettes describing medication-taking situations which a subject might have encountered in real life. The intent here was to determine how well subjects understood the material contained in the PPIs they read. This tested for the understanding aspect of Ley's Partial Model of Compliance (Ley 1980).

Each vignette was followed by four possible courses of action which the patient in the story might have taken. In each case, one of these responses was, "The patient should call the doctor or the pharmacist," and another response was, "The correct answer is not given." In the pilot study, the response, "The patient should call the doctor or pharmacist," was the correct answer two of four times. Subjects admitted to selecting this answer when they did not know what else to do, so it cannot be said with any degree of certainty that subjects derived this information from the PPI which they read. In
the present study, the response suggesting that the patient contact the doctor or pharmacist served as a distractor response as often as possible.

Validation of the Multiple-Choice Test

The multiple-choice test was administered to seventeen college students enrolled in a consumer-oriented course on medications. One student was a senior Nursing major; remaining students were either enrolled in pre-professional programs or were majoring in areas unrelated to the health professions. Prior to taking the test, the students read the Test PPI prepared by the principal investigator. This class of students generated a mean score of 8.7 (out of a possible 10.0), with a standard deviation of 1.05. Scores ranged from 7 to 10 (Table 6).

The reliability of the multiple-choice comprehension test was analyzed using the KR20 formula, as described for the cloze test (Grussing 1977). The KR20 formula is selected over the KR21 formula, because of the uncertainty that the difficulty among the test items is homogeneous. The Kuder-Richardson formulas are selected over Cronbach's alpha because the latter is more applicable when responses to individual test items cannot be coded dichotomously. In the present study, each response was either correct or incorrect; Kuder-Richardson was the appropriate test of reliability to use. The Kuder-Richardson (KR20) reliability score was 0.55 for this group.
The multiple-choice test was then administered to thirty-one college seniors enrolled in a class on drug, alcohol and tobacco abuse. These students were not permitted to read any information about thiazides before taking the test, so in effect served as a control group. A mean of 6.61 ± 1.23 was obtained for this group, which was statistically different from the first group (t = 5.92, df = 46, p < 0.01). This suggests that the multiple choice test successfully differentiated between persons who had no knowledge of thiazides and those who had gained such knowledge.
The next step was to pilot test the multiple-choice instrument using students enrolled in a GED class. The results of this testing is given in Table 6. As a result of item analyses conducted for all pilot test groups, three of the questions were modified. In each of these questions, the correct answer called for the patient to consult with the physician. Subjects tended to get these questions correct whether they had read no PPI, the Test PPI or the USP PPI. These questions were modified so that consulting the physician was no longer the correct response.

Testing Memory: Development of Cloze Tests

"Memory" in Ley's model was measured by administering cloze comprehension tests to treatment group subjects after they had read a particular PPI. Cloze comprehension tests were constructed for each PPI. Subjects assigned to the control group within each grade level block were assigned randomly to complete one of these cloze tests without previously reading a PPI. Graves, Cooke and Laberge (1983) suggest that controls should not perform as well as subjects who first "preview" the contents of cloze tests by first reading a PPI.

In the present study, no performance criterion was specified, because cloze scores for each PPI were compared within each reading grade block. The debate over a satisfactory criterion (Bormuth 1968; Rankin and Culhane 1969; Duffelmeyer 1978) therefore did not affect the outcome of the study.
Based upon the findings of Henk (1981), Meredith and Vaughan (1981) and Brown (1980), cloze tests used in this study were constructed utilizing a modified random deletion pattern, accepted only verbatim responses as correct, and made use of blanks of standard length (ten character spaces).

Only material contained in a PPI which appeared in sentence format was used to develop the cloze test for each PPI. Lists of words or phrases were excluded. Sentences containing drug trade names, names of disease states, or those containing specific instructions were avoided as much as possible.

Each cloze test had an opening and a closing sentence which remained unchanged. Between these sentences, passages of at least 250 words were constructed from sentences taken verbatim from the PPI of interest. Words within this passage were then deleted based upon the schedule of computer-generated random numbers. Subjects were awarded scores ranging from zero to fifty, one point for each correct response.

Reliability of the cloze tests was evaluated using the Kuder-Richardson formula 20 (KR20) as described by Grussing (1977). The KR20 formula represents the average correlation from all possible split-half combinations and estimates. The KR20 was selected over the KR21 because of the varying difficulties found among individual items in each cloze test. Copies of each instrument are included in the Appendix.
Pilot testing of two of the cloze tests to be used was conducted among a sample of Tucson GED students. Only seven of seventeen students were able to complete the cloze test; the results reported are based upon this group. Scores among three students reading at grades 3-5 who completed the test ranged from 16-26 out of a possible score of fifty. For four students reading above fifth grade level, the scores ranged from 23-34. Because of the small number of students completing this portion of the testing, it was inappropriate to analyze the results based upon PPI received.

Assessing Subject Satisfaction with PPIs

As in the pilot study (Stratton, et al. 1985), subject satisfaction with the PPI read was assessed by having subjects respond to several questions constructed on a seven-point Likert-type scale. The first question asked how much the subject feels that he or she learned from reading the PPI. Anchor responses varied from, "Nothing at all," to, "I learned very much."

The second satisfaction question asked how likely the subject would have been to use the sheet, given that the person had to take the drug. Anchor responses were, "I would not use the sheet," at the low end of the scale to, "I am sure that I would use the sheet," at the upper end.

One question inquired as to how much diagrams either did help or would have helped the subject to understand the material. Responses
ranged from, "Not at all," to, "Helped (or would have helped) very much."

Another question asked about the size of the print. Responses were anchored with, "Too small to read easily," on one end, and, "Larger than I needed," on the other.

Information overload was examined in one question. "Too much information," anchored the low end of the scale, and, "Not enough information," anchored the high end.

In one question, subjects were asked to give a global assessment of their PPIs. Anchor responses ranged from, "I did not like it at all," to, "I liked it very much."

The final question asked how likely the subject would be to recommend the PPI to a friend taking thiazides. "Not at all likely," was the response at the low end of the scale, and, "Very likely," anchored the high end of the scale.

Scores were assigned to this instrument by summing a subject's ratings. A high score indicated that the subject was generally pleased with the PPI. A low score suggested that the subject was dissatisfied with the PPI. Responses were checked for internal consistency using Cronbach's Alpha (Grussing 1977).

The satisfaction scale was pilot tested in a Tucson GED class (Table 8). Several of the standard deviations are notably large. The overall satisfaction rating among third to fifth grade readers receiving the Test PPI was 33.6; the standard deviation of the summed
satisfaction ratings for this group was 6.2. Examination of the data revealed an outlier. One person gave an overall rating of "7" to the Test PPI while three of the remaining four gave it a rating of "4". The person who awarded the PPI the high overall rating had a summed rating score of 43 while the remaining scores in this group ranged from 27 to 36. The value for Cronbach's alpha among the poorer readers is also influenced by the large standard deviation, the value being 0.49 among persons reading below sixth grade.

The summed satisfaction ratings for persons reading from sixth to eighth grade who received the Test PPI was 37.2. The relatively large standard deviation seen here (3.6) can also be explained by an outlier; one person had a summed rating score of 32 while remaining scores in this group ranged from 36 to 41.

Among the poorest readers, the USP PPI received a significantly higher overall rating than the Test PPI, when the outlier is discounted (t = 4.06, df = 8, p < 0.01). Two possibilities exist for this finding.

The Test PPI consisted of no more than text on white paper. The USP PPI was professionally rendered. It may be that subjects perceived the Test PPI as being less legitimate than the USP PPI. The Test PPI was rewritten by varying typefaces of the print and including the logo of the University of Arizona College of Pharmacy on the front of the PPI.
TABLE 8
Mean (Standard Deviation) PPI Satisfaction Ratings Among GED Students<sup>a</sup>

<table>
<thead>
<tr>
<th>Reading Ability</th>
<th>Grades 3-5</th>
<th>Grades 6-12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test PPI</td>
<td>USP PPI</td>
</tr>
<tr>
<td>n</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>How much did you learn?</td>
<td>5.4 (1.3)</td>
<td>5.8 (1.1)</td>
</tr>
<tr>
<td>Would you use PPI?</td>
<td>5.8 (1.6)</td>
<td>7.0 (0.0)</td>
</tr>
<tr>
<td>Did pictures help (or would they have helped)?</td>
<td>5.8 (1.6)</td>
<td>3.8 (1.5)</td>
</tr>
<tr>
<td>Was print size appropriate?</td>
<td>4.6 (1.3)</td>
<td>4.6 (1.3)</td>
</tr>
<tr>
<td>How much information was given?</td>
<td>4.0 (0.0)</td>
<td>4.2 (0.4)</td>
</tr>
<tr>
<td>Liked overall?</td>
<td>4.4 (2.3)</td>
<td>5.8 (1.3)</td>
</tr>
<tr>
<td>Suggest to friend?</td>
<td>4.4 (1.5)</td>
<td>6.2 (1.3)</td>
</tr>
<tr>
<td>Satisfaction rating</td>
<td>33.6 (6.2)</td>
<td>38.8 (2.0)</td>
</tr>
<tr>
<td>Cronbach's alpha</td>
<td>0.49</td>
<td>0.94</td>
</tr>
</tbody>
</table>

<sup>a</sup>From Stratton, Bradley and Hurd, 1985. Each aspect of the satisfaction scale was measured on a 7-point Likert-type scale with "1" representing a low rating and "7" representing a high rating.
The second possible explanation for the higher rating given the USP PPI might have been that subjects receiving this PPI found it to be difficult to understand. It is possible that persons were afraid to admit that they did not like the PPI because they did not understand it, and so claimed to like it overall and would recommend it to a friend taking the drug. This would be consistent with findings from the study conducted earlier (Stratton, Bradley and Hurd 1985). In that study, the only subjects to claim that the fourth grade PPI was too easy were persons reading at fourth grade level; subjects reading at higher levels claimed that the fourth grade PPI was written at just the right level for them.

Measuring "Compliance": Development of Likelihood Scales

In the ideal situation, this portion of Ley's Partial Model of Compliance (Ley 1980) would have been measured by actually monitoring the medication-taking behavior of subjects for a period of time after they had read their PPIs. To cope with the less-than-ideal, other researchers have turned to the concept of "intent to comply," (Stergachis, Johnson and Bootman 1980; Edmundson 1981). A variation, "likelihood of compliance," was used in this study.

Subjects were asked to read a series of paragraphs describing a fictitious patient's health situation. In each situation, the patient was taking a thiazide diuretic, but extenuating circumstances were present which might have inhibited the patient from taking his medication as instructed. The subject was asked to indicate on a
seven-point Likert-type scale how likely the patient would have been to comply with his medication regimen.

The "extenuating circumstances" were based upon the Health Belief Model as modified by Becker and Maiman (1975). The first circumstance dealt with perceived risks of hypertension versus perceived risks of the thiazides. One circumstance involved perceived susceptibility of the patient to the complications of hypertension interacting with the patient's perception of the severity of the hypertension (The patient knows of the complications which can result from hypertension but feels fine.). Another circumstance dealt with the patient having a family member who had hypertension, but never suffered complications despite noncompliance with medication. Cost of medication as a barrier to compliance was explored in another paragraph. The subject was asked how likely a patient with a limited income was to purchase expensive medication, given that the patient knew the importance of keeping hypertension under control. The final circumstance involved the "risk" of losing sleep from constant nocturnal urination versus the risk from uncontrolled hypertension.

Scores were again assigned by summing the responses given by a subject. A high score implied a high likelihood of compliance. A low score suggested little likelihood of complying. Responses were checked for internal consistency using Cronbach's Alpha (Grussing 1977).

As with the other proposed scales and tests, this attitude scale was pretested among Tucson GED students. The results of the
pilot testing are provided in Table 9. The reliability coefficients are relatively high, especially among better readers (Cronbach's alpha = 0.88). The coefficients were far enough from 1.0, however, to suggest that respondents did not try to, "Tell the investigator what he wanted to hear," as has plagued other researchers (Edmundson 1981). It is quite possible that these variances were attained by involving a fictitious third party as the patient confronted with the barriers to compliance, rather than by asking the subject what he or she would have done personally in each situation.

Analysis of Data

The independent variable was the PPI received. The dependent variables were the scores on the multiple-choice test, the cloze comprehension test, the satisfaction scales and the likelihood of compliance scales. Subject reading ability functioned as the blocking variable.

The distribution of scores from the multiple-choice test, cloze test, satisfaction scales and likelihood of compliance scales were evaluated using the Stem and Leaf Display (Velleman and Hoaglin 1981, Chapter 1).

The stem-and-leaf analyses were followed by analysis using Tukey's Box and Whisker Diagram, known more simply as boxplots (Velleman and Hoaglin 1981, Chapter 3).
TABLE 9

Results of Pilot Test: Likelihood of Compliance According to GED Students

<table>
<thead>
<tr>
<th>Reading Ability</th>
<th>Grades 3-5</th>
<th>Grades 6-12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test PPI</td>
<td>USP PPI</td>
</tr>
<tr>
<td>n</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Range&lt;sup&gt;a&lt;/sup&gt;</td>
<td>17-30</td>
<td>14-30</td>
</tr>
<tr>
<td>Mean</td>
<td>22.4</td>
<td>22.8</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>5.4</td>
<td>7.1</td>
</tr>
<tr>
<td>Cronbach's alpha</td>
<td>0.63</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>Set up on a 7-point Likert-type scale. 1 = Not likely to comply; 7 = Very likely to comply. A score of 35 represents a perfectly compliant patient.
Exploratory data analyses were conducted using the BASIC programs provided in Velleman and Hoaglin (1981). These programs were loaded and tested during the pilot study. Although Tukey's stem and leaf display and boxplots are available in the SPSS program, the output provided by Velleman and Hoaglin was superior.

After testing for and dealing with any outliers, normality of the data was tested by constructing a normal probability plot of residuals as described by Neter, Wasserman and Kutner (1985, pp. 118–19).

Homogeneity of variances among the different treatment groups was analyzed using the Bartlett-Box Test (Neter, Wasserman and Kutner 1985 pp. 618–22).

The efficiency of the blocking variable was determined using the method described by Neter Wasserman, and Kutner (1985, pp. 924–926). Using this method, efficiency was expressed as the ratio between the variance attained from the randomized block design and the variance which would have been obtained had the study been completely randomized.

The four tests were analyzed using two factor analysis of variance (Neter and Wasserman 1974, pp. 722–758). An alpha level of 0.05 was selected to detect significance differences. The ANOVA program available with SPSS was used to conduct the analyses.

Where the ANOVA yielded a significant F ratio, the Scheffe' multiple-comparison procedure (Neter and Wasserman 1974, pp. 477–80)
was used to identify significant contrasts. The ANOVAs and posteriori tests were conducted using the SPSS program (Nie, et al. 1975, 1981).

In analyzing the relationship between the components of Leys' Partial Model of Compliance, standardized regression coefficients (beta coefficients) were calculated between each component rather than using non-parametric measures of association because all components were measured on an interval scale (Klugh 1974). An alpha level of significance of 0.05 was selected to detect significant correlations.
The ability of adults enrolled in remedial reading classes to read and understand seven PPIs was evaluated in this study, using four different measures. The four dependent variables, understanding, memory, satisfaction and compliance, are all components of Ley's Partial Model of Compliance (Ley 1980).

In this chapter, results of the data analysis are presented. The demographic characteristics of the sample will be summarized, subjects who did not complete the study will be accounted for, followed by analyses for each separate variable in Ley's Partial Model of Compliance. This will involve analyses both across reading grade blocks and within blocks. The inter-relationships among the various components of Ley's Model will also be examined. Finally, results of SMOG readability evaluations of PPIs from AARP, NARD, the AMA and the Canadian Pharmaceutical Association which describe the benzodiazepines, digoxin and the penicillins will be presented.

**Subject Demographics**

Subjects were asked several demographic questions, the results from 215 subjects completing the study being summarized in Table 10. Eighty males and 135 females completed the study. The mean education level of subjects was eleventh grade with a range of from 102
TABLE 10
Subject Demographics

<table>
<thead>
<tr>
<th>Education Level</th>
<th>Reading Ability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Grade Attained</td>
<td>Mean Grade Level</td>
</tr>
<tr>
<td>11.31</td>
<td>5.97</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>2.06</td>
<td>2.90</td>
</tr>
<tr>
<td>Range</td>
<td>Range</td>
</tr>
<tr>
<td>3-College</td>
<td>1-12</td>
</tr>
<tr>
<td>n</td>
<td>n</td>
</tr>
<tr>
<td>210</td>
<td>243</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>Percentage</td>
</tr>
<tr>
<td>Caucasian</td>
<td>27.4</td>
</tr>
<tr>
<td>Hispanic</td>
<td>39.4</td>
</tr>
<tr>
<td>Black</td>
<td>15.9</td>
</tr>
<tr>
<td>American Indian</td>
<td>12.5</td>
</tr>
<tr>
<td>Asian</td>
<td>3.4</td>
</tr>
<tr>
<td>Other</td>
<td>1.4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>n</td>
</tr>
<tr>
<td>28.01</td>
<td></td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>Male</td>
</tr>
<tr>
<td>10.72</td>
<td>80</td>
</tr>
<tr>
<td>Range</td>
<td>Female</td>
</tr>
<tr>
<td>16-67</td>
<td>135</td>
</tr>
<tr>
<td>n</td>
<td></td>
</tr>
<tr>
<td>208</td>
<td></td>
</tr>
</tbody>
</table>

*"n" varies as this reflects the number of subjects responding to the question in each category.
third grade to college level. The mean reading ability was sixth grade level, ranging from less than first grade to twelfth grade. No subject who read at less than first grade level spoke English as their primary language.

The categories for race were Caucasian, Hispanic, Black, American Indian, and Asian. The most frequently represented category, Hispanic, comprised 33.7% of all subjects. Three subjects described themselves as fitting into none of the above categories. The races indicated by these persons included Eritrean, Filipino, and Turkish.

Students are not eligible to enroll in the GED program until they have reached sixteen years of age; there is no upper limit on the age at which a student may enroll. The ages of subjects enrolled in the study ranged from sixteen to sixty-seven, with a mean of twenty-eight years and a mode of nineteen years. Thirty-six of the subjects indicated that they were forty years of age or older (Several subjects who failed to indicate their age appeared also to fall into this age group.).

Subject Mortality

Approximately fifteen students from among all sites declined to participate in the project. The sites provided a total sample size of 243 subjects.

Six subjects left the study after completing the Zip Scale reading placement test because of time constraints. There did not appear to be a preponderance of drop-outs at any particular reading
level. Among these subjects, one each read at the third, fourth, fifth and eighth grade levels, and the remaining two subjects read at seventh grade level. Nineteen additional subjects were dropped from the study because they failed to meet inclusion criteria, their Zip Scale reading placement scores being less than third grade level. The majority of persons in this latter group did not speak English as their primary language.

Combining High School-Level Readers

At the outset of this study, subjects were to be placed into one of four blocks depending upon their reading ability. Persons reading at grade levels three, four or five were placed into the first block, those reading at levels six, seven or eight were placed into the second block, persons reading at grade levels nine, ten or eleven comprised the third block, and persons reading at twelfth grade level made up the final block. As the study progressed, it became apparent that few persons enrolled in GED classes read at eighth grade level, let alone at twelfth grade level. Upon completion of data collection on 243 subjects, only eighteen persons were found to read at the twelfth grade level, and one third of these subjects were instructors or instructor aides who requested to participate in the study. Retaining the block at the high end of the scale yielded no more than two subjects in each treatment block; therefore, the data from these persons are included with the data from persons reading at the ninth-tenth-eleventh grade levels.
Collapsing the two upper blocks is justified on the grounds that a two-way analysis of variance (ANOVA) across the two blocks and the seven PPIs revealed no significant difference across blocks between the two groups (Table 11). This finding is also consistent with the results from the pilot study (Stratton, Bradley and Hurd 1985) which revealed that persons reading above the ninth grade level performed at a similar level on the various tests.

**Analysis of Variable "Understanding"**

Descriptive statistics for the variable "Understanding" are given for each reading grade block in Table 12. Means ranged from 3.75 for subjects in the lowest grade block who served as controls to 8.86 among persons receiving the Test PPI in the 9-12 grade block. The smallest and greatest ranges of scores, two points and seven points, respectively, were seen among persons receiving the NARD PIL. The two-point range was seen among persons reading at the highest grade levels, the seven-point range was found among subjects in the lowest block. In general, the ranges seen in the highest reading grade block were much more restricted than those seen in the other two reading grade blocks, especially in the lowest block.

Across PPIs, understanding scores attained by subjects in the lowest reading grade block are lower than the scores attained by subjects attained in the remaining blocks. The scores for the AARP Medication Information Leaflet for Seniors is a notable exception, the scores across all three reading grade blocks being quite similar.
### TABLE 11

ANOVA Table for Subjects Reading at Grade Levels 9-10-11 and at 12 or Above

**Variable "Understanding"**

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>Sum of Squares</th>
<th>Degrees of Freedom</th>
<th>Mean Square</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within cells</td>
<td>21.42</td>
<td>26</td>
<td>0.8237</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Block</td>
<td>0.34</td>
<td>1</td>
<td>0.3375</td>
<td>0.41</td>
<td>NS</td>
</tr>
<tr>
<td>PPI</td>
<td>13.50</td>
<td>6</td>
<td>2.2501</td>
<td>2.73</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Block by PPI</td>
<td>1.52</td>
<td>6</td>
<td>0.2534</td>
<td>0.31</td>
<td>NS</td>
</tr>
</tbody>
</table>

**Variable "Memory"**

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>Sum of Squares</th>
<th>Degrees of Freedom</th>
<th>Mean Square</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within cells</td>
<td>888.21</td>
<td>26</td>
<td>34.16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Block</td>
<td>74.96</td>
<td>1</td>
<td>74.96</td>
<td>2.19</td>
<td>NS</td>
</tr>
<tr>
<td>PPI</td>
<td>228.37</td>
<td>6</td>
<td>38.06</td>
<td>1.11</td>
<td>NS</td>
</tr>
<tr>
<td>Block by PPI</td>
<td>137.69</td>
<td>6</td>
<td>22.95</td>
<td>0.67</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS = Not significant (p > 0.05).
**TABLE 11—Continued**

ANOVA Table for Subjects Reading at Grade Levels 9-10-11 and at 12 or Above

**Variable "Satisfaction"**

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>Sum of Squares</th>
<th>Degrees of Freedom</th>
<th>Mean Square</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within cells</td>
<td>553.08</td>
<td>26</td>
<td>21.27</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Block</td>
<td>49.50</td>
<td>1</td>
<td>49.50</td>
<td>2.33</td>
<td>NS</td>
</tr>
<tr>
<td>PPI</td>
<td>115.69</td>
<td>6</td>
<td>19.28</td>
<td>0.91</td>
<td>NS</td>
</tr>
<tr>
<td>Block by PPI</td>
<td>93.50</td>
<td>6</td>
<td>15.58</td>
<td>0.73</td>
<td>NS</td>
</tr>
</tbody>
</table>

**Variable "Compliance"**

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>Sum of Squares</th>
<th>Degrees of Freedom</th>
<th>Mean Square</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within cells</td>
<td>899.50</td>
<td>26</td>
<td>34.60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Block</td>
<td>8.44</td>
<td>1</td>
<td>8.44</td>
<td>0.24</td>
<td>NS</td>
</tr>
<tr>
<td>PPI</td>
<td>193.93</td>
<td>6</td>
<td>32.32</td>
<td>0.93</td>
<td>NS</td>
</tr>
<tr>
<td>Block by PPI</td>
<td>82.13</td>
<td>6</td>
<td>13.69</td>
<td>0.40</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS = Not significant (p > 0.05).
TABLE 12

Descriptive Statistics for Variable "Understanding" Across Reading Grade Blocks

<table>
<thead>
<tr>
<th>PPI Source</th>
<th>Reading Grade Block</th>
<th>3-4-5</th>
<th>6-7-8</th>
<th>9-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>AARP(^c)</td>
<td>Mean</td>
<td>8.11</td>
<td>8.08</td>
<td>8.20</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation(^b)</td>
<td>1.45</td>
<td>0.95</td>
<td>0.84</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>5-9(9)</td>
<td>6-9(13)</td>
<td>7-9(5)</td>
</tr>
<tr>
<td>AMA(^d)</td>
<td>Mean</td>
<td>6.56</td>
<td>7.64</td>
<td>7.33</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation(^b)</td>
<td>1.13</td>
<td>0.81</td>
<td>0.52</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>5-8(9)</td>
<td>6-9(11)</td>
<td>7-8(6)</td>
</tr>
<tr>
<td>CPhA(^d)</td>
<td>Mean</td>
<td>6.14</td>
<td>7.08</td>
<td>7.00</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation(^b)</td>
<td>1.77</td>
<td>1.26</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>4-8(7)</td>
<td>5-8(13)</td>
<td>6-8(5)</td>
</tr>
<tr>
<td>FDA</td>
<td>Mean</td>
<td>5.90</td>
<td>7.59</td>
<td>7.86</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation(^b)</td>
<td>1.62</td>
<td>1.00</td>
<td>0.69</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>3-9(9)</td>
<td>6-9(12)</td>
<td>7-9(7)</td>
</tr>
<tr>
<td>NARD(^d)</td>
<td>Mean</td>
<td>6.00</td>
<td>7.27</td>
<td>8.20</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation(^b)</td>
<td>2.31</td>
<td>1.42</td>
<td>0.45</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>2-9(7)</td>
<td>5-9(11)</td>
<td>8-9(5)</td>
</tr>
<tr>
<td>Test</td>
<td>Mean</td>
<td>6.64</td>
<td>7.73</td>
<td>8.86</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation(^b)</td>
<td>1.96</td>
<td>0.79</td>
<td>1.07</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>4-10(11)</td>
<td>6-9(11)</td>
<td>7-10(7)</td>
</tr>
<tr>
<td>USP(^d)</td>
<td>Mean</td>
<td>6.80</td>
<td>7.73</td>
<td>7.80</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation(^b)</td>
<td>2.10</td>
<td>1.19</td>
<td>1.10</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>3-9(10)</td>
<td>6-10(11)</td>
<td>6-9(5)</td>
</tr>
<tr>
<td>Control</td>
<td>Mean</td>
<td>3.75</td>
<td>5.93</td>
<td>7.67</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation(^b)</td>
<td>2.72</td>
<td>3.16</td>
<td>1.51</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>0-7(16)</td>
<td>0-10(15)</td>
<td>6-9(6)</td>
</tr>
</tbody>
</table>

\(^a\)A score of ten on multiple-choice test means subject answered all questions correctly.

\(^b\)Variances are homogeneous by Bartlett-Box Test (F = 1.17; \(p > 0.05\)).

\(^c\)AARP=American Association of Retired Persons; AMA=American Medical Association; CPhA=Canadian Pharmaceutical Association; FDA=Food and Drug Administration; NARD=National Association of Retail Druggists; Test=Experimental PPI; USP=United States Pharmacopeial Convention.

\(^d\)Based upon the United States Pharmacopeial Convention's Dispensing Information (USPDI).
Stem and Leaf displays were undertaken to look for clustering in the data and to roughly estimate the shape of the data's distribution curve. Stem and Leaf displays are similar to histograms, but have the advantage of retaining each of the original data values. For example, if we are looking at subject test scores and have an interval of five units, say, from fifteen to twenty, our histogram will only indicate the total number of values between fifteen and twenty which lie in the interval. We have no way of knowing how many persons scored sixteen within this interval. With a Stem and Leaf display, however, we would know exactly how many subjects scored sixteen within the interval.

A basic introduction to interpreting a Stem and Leaf display will be provided here; the reader is referred to the Velleman and Hoaglin (1981) reference for a more thorough discussion of this topic. The numeral immediately to the left of the decimal point is called the stem. Stems are used to sort the data, by ones in Figure 4 (1.0, 2.0, 3.0, etc.). To the right of the decimal points are the individual data points within a stem, or the "leaves." Each display includes a header indicating the units for the display. Each header uses $1.2 = 0.12, 12, 120, \text{etc.}$, depending upon the units used in that particular display. If the header states that $1.2 = 12$, then a stem and leaf like 3.44445555 would be interpreted as five values of 34 and four values of 35. Likewise, if the header indicates that $1.2 = 120$, then a stem and leaf of 3.44445555 would be interpreted as representing five values of 340 and 4 values of 350. In Figure 4, the header...
Units = 1.0
1.2 = 1.2

Reading Levels 3-4-5

1 2.0
3 3.00
10 4.0000000
23 5.0000000000000000
(15) 6.0000000000000000
35 7.0000000000000000
22 8.0000000000000000
12 9.0000000000000000
1 10.0

Reading Levels 6-7-8

1 4.0
7 5.0000000000000000
19 6.0000000000000000
42 7.0000000000000000
(34) 8.0000000000000000
14 9.0000000000000000
2 10.00

Reading Levels 9-12

5 6.0000000000000000
15 7.0000000000000000
(18) 8.0000000000000000
11 9.0000000000000000
2 10.00

FIGURE 4

Stem and Leaf Displays
for Variable "Understanding"\textsuperscript{a,b,c}

\textsuperscript{a}Understanding measured with a ten-item multiple choice test based upon information common to all PPIs tested. A score of ten would mean that the subject answered all questions correctly.

\textsuperscript{b}Values in parentheses indicate location of median values.

\textsuperscript{c}A more thorough discussion of Stem and Leaf displays is provided in Velleman and Hoaglin (1981), Chapter 1.
indicates that $1.2 = 1.2$; therefore, $4.0000000$ represents seven subjects who had scores of 4.0.

The numbers to the left of the stems represent the depths, and represent a count of the number of leaves present for any given stem added to the number of leaves present for all stems closer to the end of the data batch. In Figure 4, for Reading Levels 3-4-5, one subject had a score on the multiple choice test of 2.0; hence, the depth is listed as 1. The next stem is for the score 3.0, two subjects having scores of 3.0. Rather than the depth of this stem being 2, to represent the two subjects having this score, the depth is 3, taking into account the two subjects with a score of 3.0, and the one subject closer to the low end of the data batch who had a score of 2.0. Similarly, seven subjects had a score of 4.0; however, the depth is indicated as 10, adding the depths for scores 4.0 (7), 3.0 (2) and 2.0 (1). The depth values eliminate the need for the researcher to count the number of leaves present in any particular interval, and are used to help locate the median value of the data set. Depth values within parentheses are located at that stem containing the median data value; for the stem containing the median value, only the leaves present in this stem are counted in calculating the depth. Stem and leaf displays for the various grade blocks revealed only unimodal distributions (Figure 4) for the variable "Understanding". In each reading grade block the depth values of the stem and leaf displays indicate that the tails of the data curves are of unequal lengths, suggesting that the data are skewed rather than normally distributed.
Boxplots, another type of exploratory data analysis described by Velleman and Hoaglin (1981), are used to check conformance of the data to a normal distribution by detecting outlying data points. In a "normal" boxplot (Figure 5), the median is centered, each whisker is approximately the same length as the box, and no data points lie beyond the whiskers.

**FIGURE 5**  
THE "NORMAL" BOXPLOT

Boxplots are based upon median values and inter-quartile ranges from those median values. The ends of each box represent the data points which are located one quartile above (Q3) and below (Q1) the median. The inter-quartile range (IQR) is the difference between the values of the data points at Q1 and Q3. The inner fences are calculated by taking 1.5 times the IQR, which we will call "k," and then adding this to Q3 and subtracting it from Q1. The ends of the "whiskers" are the "adjacent values," the largest value inside the upper fence and the smallest value inside the
lower fence. "Outliers" are data points which lie beyond the inner fences. Highlighting outliers permits the researcher to concentrate more on extreme data values without being distracted by values clustered close to the median.

Outlying points may indicate an error in the collection, recording or entry of data. Alternatively, outliers may indeed represent true data points which resulted from some unusual circumstance. Regardless of their origin, outlier points call for special attention by the researcher, as such points may influence subsequent data analyses disproportionate to their contribution to the total data set.

Boxplots for the variable "Understanding" (Figures 6 to 8) revealed outliers in each block and more decided departures from what one would expect for a normal distribution. All were checked to insure that they did not result from errors in data entry. Data points verified as accurate, those which represent true "outliers," were included in the data set for subsequent analyses for this variable.

The Bartlett-Box test yielded a nonsignificant value (F = 1.40; p > 0.05). This suggests that the variance blocks for this variable are homogeneous, permitting use of parametric statistical analyses.

For the variable "Understanding", the assumptions necessary to use analysis of variance with the randomized block design were met. Homogeneity of variance has been demonstrated both within blocks and across blocks as a result of the nonsignificant Bartlett-Box Tests.
Neither were significant block-treatment interactions identified. The data is therefore analyzed using the program MANOVA available in the Statistical Package for the Social Sciences, Version 9.0.

Table 13 shows the analysis of variance for the variable "Understanding." Considering all three blocks, a significant difference was found to exist across blocks ($F = 20.34; \text{df} = 2; \ p < 0.05$). Likewise, a significant difference was found to exist among the various PPIs ($F = 9.06; \text{df} = 7; \ p < 0.05$). The interaction between reading grade block and PPI was not significant.

The Scheffe test for significant contrasts revealed that for all subjects, the confidence interval for the variable understanding among Controls was significantly different from the family confidence interval for subjects reading any of the patient information leaflets (Figure 9).

A detailed examination of the differences within blocks reveals differing patterns of significance. Within the block which includes subjects reading at grade levels three, four or five, the family confidence interval for subjects receiving the AARP MILS, the AMA PMI, the Test PPI or the PPI produced by the USP represents a significantly higher multiple-choice test score than the confidence interval for controls.

Among subjects reading at grade levels six, seven or eight, the family confidence interval composed of persons receiving the AARP, AMA, Test or USP information sheets is significantly higher than that of the controls.
E = Outlier beyond third quartile from median.

AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopoeial Convention PPI.

FIGURE 6
Boxplots of Variable "Understanding"
Across Treatments for Reading Levels 3-4-5
O = Outlier beyond second quartile from median.
E = Extreme outlier beyond third quartile from median.

AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopoeial Convention PPI.

FIGURE 7
Boxplots of Variable "Understanding"
Across Treatments for Reading Levels 6-7-8
E = Extreme outlier beyond third quartile from median.

AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopoeial Convention PPI.

FIGURE 8
Boxplots of Variable "Understanding" Across Treatments for Reading Levels 9-12
TABLE 13
ANOVA Table for Variable "Understanding"
Among All Subjects

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>Sum of Squares</th>
<th>Degrees of Freedom</th>
<th>Mean Square</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within cells</td>
<td>549.97</td>
<td>197</td>
<td>2.79</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Block</td>
<td>113.56</td>
<td>2</td>
<td>56.78</td>
<td>20.34</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>PPI</td>
<td>177.09</td>
<td>7</td>
<td>25.30</td>
<td>9.06</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Block-PPI Interactions</td>
<td>43.82</td>
<td>14</td>
<td>3.13</td>
<td>1.12</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS = Not significant (p > 0.05).
Reading grade levels 9-12

3 2874 15 6
+

Reading grade levels 6-7-8
8 35 42671
+

Reading grade levels 3-4-5
8 453 267 1
+

Overall
8 354276 1
+

Multiple-Choice Test Score

1 = AARP; 2 = AMA; 3 = CPhA; 4 = FDA; 5 = NARD; 6 = TEST; 7 = USP; 8 = CONTROL

FIGURE 9

Scheffe Families of Significant Contrasts for Variable "Understanding"
(Level of significance = 0.2)
In the block made up of subjects of the highest reading abilities, the only significant contrast occurred between subjects reading the CPhA SIM and those reading the Test PPI. Subjects receiving the Test PPI prepared by the Principal Investigator performed significantly better on the multiple-choice test than did persons receiving the Canadian document.

The efficiency of the blocking variable was determined using the method described by Neter, Wasserman and Kutner (1985, pp. 924-26). For the variable "Understanding," blocking resulted in an efficiency index of 3.4. This suggests that had the study been completely randomized, three and one-half times more replications would have been necessary to achieve the same variance attained in this randomized block study.

Analysis of Variable "Memory"

Descriptive statistics for the variable "Memory" across all three grade level blocks are provided in Table 14. Mean cloze comprehension test scores varied proportionately to reading grade block, increasing from a low of 13.50 among subjects in the lowest reading grade block receiving the USP PPI to a high of 36.17 among people reading at or above the ninth grade level who received the test PPI. Within grade blocks, scores on the AMA PMI, the CPhA SIM, the NARD PIL and the USP PPI, all based upon the USP'S Dispensing Information (USPDI), were lower than scores for the remaining PPIs.
### TABLE 14

Descriptive Statistics for Variable "Memory" Across Reading Grade Blocks^a^

<table>
<thead>
<tr>
<th>Source</th>
<th>Reading Grade Block</th>
<th>3-4-5</th>
<th>6-7-8</th>
<th>9-12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
<td>Standard Deviation</td>
<td>Range(n)</td>
</tr>
<tr>
<td>AARP^c</td>
<td>Mean</td>
<td>22.81</td>
<td>9.66</td>
<td>1-33(9)</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>4.18</td>
<td>3.88</td>
<td>4-37(13)</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>27-35(5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMA^d</td>
<td>Mean</td>
<td>16.67</td>
<td>5.64</td>
<td>7-24(9)</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>7.10</td>
<td>5.31</td>
<td>12-36(11)</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>21-36(6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPhA^d</td>
<td>Mean</td>
<td>15.60</td>
<td>3.00</td>
<td>10-19(7)</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>21.51</td>
<td>9.31</td>
<td>4-34(13)</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>28.57</td>
<td>11.25</td>
<td>13-39(5)</td>
</tr>
<tr>
<td>FDA</td>
<td>Mean</td>
<td>26.42</td>
<td>8.07</td>
<td>11-40(9)</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>28.06</td>
<td>5.37</td>
<td>14-44(12)</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>31.63</td>
<td>5.37</td>
<td>21-37(7)</td>
</tr>
<tr>
<td>NARD^d</td>
<td>Mean</td>
<td>20.86</td>
<td>8.78</td>
<td>8-36(7)</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>26.91</td>
<td>9.17</td>
<td>5-39(11)</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>30.80</td>
<td>2.95</td>
<td>28-35(5)</td>
</tr>
<tr>
<td>Test</td>
<td>Mean</td>
<td>24.28</td>
<td>5.86</td>
<td>14-33(11)</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>31.92</td>
<td>5.17</td>
<td>24-40(11)</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>36.17</td>
<td>4.99</td>
<td>26-40(7)</td>
</tr>
<tr>
<td>USP^d</td>
<td>Mean</td>
<td>13.50</td>
<td>11.78</td>
<td>2-35(10)</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>25.18</td>
<td>9.21</td>
<td>11-40(11)</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>32.80</td>
<td>2.59</td>
<td>92-36(5)</td>
</tr>
<tr>
<td>Controls</td>
<td>Mean</td>
<td>9.62</td>
<td>10.16</td>
<td>0-25(16)</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>17.40</td>
<td>11.24</td>
<td>0-30(15)</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>24.83</td>
<td>9.28</td>
<td>7-32(6)</td>
</tr>
</tbody>
</table>

^aA score of fifty on the cloze comprehension test means subject answered all questions correctly.

^bVariances not homogeneous by Bartlett-Box Test (F = 1.74; p < 0.05).

^cAARP=American Association of Retired Persons; AMA=American Medical Association; CPhA=Canadian Pharmaceutical Association; FDA=Food and Drug Administration; NARD=National Association of Retail Druggists; Test=Experimental PPI; USP=United States Pharmacopeial Convention.

^dBased upon the United States Pharmacopeial Convention's Dispensing Information (USPDI).
Among persons reading at grade levels three, four and five, the mean cloze comprehension test score of 26.42 for subjects receiving the FDA PPI was almost twice the mean of 13.50 attained by subjects reading the USP PPI. There appears to be a clear line of demarcation between those PPIs based upon the USP Dispensing Information (those from the AMA, CPhA, NARD and the USP) and the PPIs based upon sources other than the USPDI (AARP, FDA and Test). The exception to this pattern is the NARD PIL, the only USPDI-based PPI with a mean cloze comprehension score in excess of twenty.

Control subjects, those who did not receive a PPI, were assigned in a random fashion to receive either the cloze comprehension test based upon the AARP MILS, the AMA PMI, the FDA PPI, or the Test PPI. Because of the similarity of the AMA PMI to CPhA SIM, NARD PIL and the USP PPI in terms of their SMOG readability formula scores, the cloze tests from these latter PPIs were not assigned to controls.

The Bartlett-Box F test for homogeneity of variance across all reading grade blocks and across all PPIs is significant ($F = 1.74$; $p = 0.015$) suggesting unequal variances across blocks. The greatest range in standard deviations for any one PPI occurred with the USP PPI, from 2.59 for the ninth to twelfth grade block to 11.78 for the 3-4-5 block.

The Bartlett-Box test is very susceptible to deviations from normality, much more so than is the $F$ test. The values for the kurtosis of the data distributions for the three grade levels are
-0.640, 0.958 and 2.78, respectively. The skewness of the three distributions are -0.216, -0.957 and -1.114, suggesting that the data distribution for persons reading at grade levels nine through twelve deviates quite a bit from a normal distribution. The significant Bartlett-Box test may therefore be no more than a function of the non-normality of the skewed data distributions rather than a result of the unequal variances. Because the F value is highly significant, however (p = 0.015), this data will be treated as if a true difference in the homogeneity of variances exists despite the non-normality of the data distribution for the third reading grade block.

The assumptions for the randomized block model include equality of variances across blocks, and lack of block-treatment interactions. Based on the analyses described above, it appears that the first of these assumptions has been violated for the variable "Memory." The presence of unequal variances across blocks is not likely to affect the F test, however, because of this test's robustness against unequal variances when roughly equal cells sizes are involved as in this study. The randomized block format was therefore retained for the analysis of this variable.

The Stem and Leaf displays for the variable "Memory" are given in Figure 10. All displays are unimodal. The deviation for the displays from a normal distribution is evident, and is most pronounced with the display of the data from the block for reading grade levels nine to twelve.
Units: 10.0
1.2 = 12

Reading Levels 3–4–5

<table>
<thead>
<tr>
<th>Value</th>
<th>Stem and Leaf Displays</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>0.012222</td>
</tr>
<tr>
<td>12</td>
<td>0.557789</td>
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<tr>
<td>21</td>
<td>1.0112334444</td>
</tr>
<tr>
<td>34</td>
<td>1.55578889999999</td>
</tr>
<tr>
<td>(19)</td>
<td>2.0000001122223334444</td>
</tr>
<tr>
<td>20</td>
<td>2.5677778999</td>
</tr>
<tr>
<td>10</td>
<td>3.012233</td>
</tr>
<tr>
<td>4</td>
<td>3.556</td>
</tr>
<tr>
<td>1</td>
<td>4.0</td>
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</tbody>
</table>

Reading Levels 6–7–8

<table>
<thead>
<tr>
<th>Value</th>
<th>Stem and Leaf Displays</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0.14</td>
</tr>
<tr>
<td>4</td>
<td>0.56</td>
</tr>
<tr>
<td>10</td>
<td>1.123344</td>
</tr>
<tr>
<td>18</td>
<td>1.56779</td>
</tr>
<tr>
<td>36</td>
<td>2.0001112223334444444</td>
</tr>
<tr>
<td>(28)</td>
<td>2.5556667777777888888999999</td>
</tr>
<tr>
<td>32</td>
<td>3.000111112223333344444</td>
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<tr>
<td>11</td>
<td>3.55566789</td>
</tr>
<tr>
<td>3</td>
<td>4.004</td>
</tr>
</tbody>
</table>

Reading Levels 9–12

<table>
<thead>
<tr>
<th>Value</th>
<th>Stem and Leaf Displays</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.7</td>
</tr>
<tr>
<td>2</td>
<td>1.3</td>
</tr>
<tr>
<td>2</td>
<td>1.</td>
</tr>
<tr>
<td>6</td>
<td>2.0113</td>
</tr>
<tr>
<td>17</td>
<td>2.677788888889</td>
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<tr>
<td>(15)</td>
<td>3.11122223333344444</td>
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<tr>
<td>14</td>
<td>3.55566677788889999999</td>
</tr>
<tr>
<td>1</td>
<td>4.00</td>
</tr>
</tbody>
</table>

FIGURE 10

Stem and Leaf Displays for Variable "Memory"a,b

Memory measured with a fifty-item, modified random exact cloze comprehension test based upon each PPI.

Values in parentheses represent median values.
Boxplots for the different treatment groups within the first reading grade category are shown in Figure 11. Many data points were found to lie beyond the second quartile from the median within treatments. Additional points were found to lie beyond the third quartile from treatment medians. In each case, the accuracy of these data points were checked for errors which may have occurred during the data entry process. In those situations where the data points were found to be legitimate, they were retained in the data set for the analyses to follow.

Trends in the data among persons reading at grade levels six through eight for the variable "Memory" are similar to those reported for the previous reading grade block. Again, mean scores tended to be higher for PPIs which were developed from sources other than the USPDI. The demarcation between USPDI-based PPIs and the other PPIs is less striking, however, than it is among persons reading at grade levels three, four or five.

As reported in Table 14, mean cloze comprehension test scores ranged from 17.40 among Controls to 31.92 among subjects in the 6-7-8 block who read the Test PPI developed by the investigator. The Boxplots (Figure 12) again revealed several outlier data points which were examined for accuracy and found to be actual data points.

Cloze comprehension test data from subjects reading at ninth grade level or above are also summarized in Table 14. Mean cloze comprehension test scores range from 24.83 for Controls to 36.17 for
O = Outlier beyond second quartile from median.
E = Extreme outlier beyond third quartile from median.

AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopoeial Convention PPI.

FIGURE 11
Boxplots of Variable "Memory"
Across Treatments for Reading Levels 3-4-5
FIGURE 12

Boxplots of Variable "Memory"
Across Treatments for Reading Levels 6-7-8

O = Outlier beyond second quartile from median.
E = Extreme outlier beyond third quartile from median.

AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopoeial Convention PPI.
persons receiving the Test PPI. This reading block fails to exhibit the trend for mean scores on USPDI-based PPIs to be lower than mean scores of the remaining PPIs. Persons receiving the USP PPI attained a higher mean score than did persons receiving the AARP MILS or the FDA PPI. This was not seen at lower reading abilities.

The Bartlett-Box test for homogeneity of variance was significant ($F = 2.04; p = 0.48$). As discussed previously, the Bartlett-Box test is highly susceptible to deviations from normality. As demonstrated in Figure 13, the data appears to deviate from normal. This is verified by further analysis, the data set having a skewness of -1.14 and a kurtosis of 2.78. Because the $F$ value in this particular instance just barely exceeds the level of significance, it is most likely that this finding is an artifact resulting from the deviations in normality. In subsequent data analyses, this block was treated as if the data have equal variances across treatments.

The ANOVA for the variable memory was significant (Table 15). The Scheffe test (Figure 14) indicated that overall, subjects receiving any of the patient package inserts performed better on the cloze comprehension tests than did control subjects who received no information sheet. A second finding was that subjects receiving the Test information leaflet performed significantly better on the comprehension test than did subjects receiving the Canadian document.
0 = Outlier beyond second quartile from median.
E = Extreme outlier beyond third quartile from median.

AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopoeial Convention PPI.

FIGURE 13
Boxplots of Variable "Memory"
Across Treatments for Reading Levels 9-12
<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>Sum of Squares</th>
<th>Degrees of Freedom</th>
<th>Mean Square</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between Treatments</td>
<td>10373.5</td>
<td>23</td>
<td>451.02</td>
<td>6.9</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Within Treatments</td>
<td>12864.6</td>
<td>197</td>
<td>65.30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>23238.1</td>
<td>220</td>
<td></td>
<td></td>
<td></td>
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</table>
Reading grade levels 9-12

<table>
<thead>
<tr>
<th></th>
<th>8</th>
<th>325147</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+</td>
<td>++++++</td>
<td>+</td>
</tr>
</tbody>
</table>

Reading grade levels 6-7-8

<table>
<thead>
<tr>
<th></th>
<th>8</th>
<th>3 2 75 4 1 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+</td>
<td>++ ++ ++ +</td>
</tr>
</tbody>
</table>

Reading grade levels 3-4-5

<table>
<thead>
<tr>
<th></th>
<th>8 7 3 2 5 1 6 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+ + + + + + +</td>
</tr>
</tbody>
</table>

Overall

<table>
<thead>
<tr>
<th></th>
<th>8</th>
<th>3 72 5 14 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+</td>
<td>++ + ++ +</td>
</tr>
</tbody>
</table>

---|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
|    | 5  | 10 | 15 | 20 | 25 | 30 | 35 | 40 | 45 | 50 |

Cloze Comprehension Test Score

1 = AARP; 2 = AMA; 3 = CPhA; 4 = FDA; 5 = NARD; 6 = TEST; 7 = USP; 8 = CONTROL

FIGURE 14

Scheffe Families of Significant Contrasts for Variable "Memory"
(Level of significance = 0.20)
Within reading grade blocks, subjects with reading abilities of third, fourth or fifth grade who served as controls or read the AMA, CPhA, NARD or USP documents comprised one family of contrasts, while subjects in this reading group receiving the AARP, FDA or Test leaflets made up a different family. It was also found that subjects reading at grade levels 3-4-5 who read the AARP PIL were in a statistically different family than were subjects in this reading grade block who read the USP document.

For subjects reading at grade levels 6-7-8, two statistically distinct families of contrasts were found. Persons receiving the AARP, FDA or Test leaflets performed better than persons in this reading grade block who received any of the other PPIs. This latter group performed no better than did control subjects who received no patient information sheet before taking the cloze comprehension test.

Among subjects reading at the highest grade levels, no significant contrasts were found to exist; people performed equally well on the cloze comprehension test irrespective of whether or not they first received a PPI or which PPI they received.

**Analysis of Variable "Satisfaction"**

A seven-item, seven-point Likert-type scale was used to measure how satisfied subjects were with the PPIs which they read. Ratings for individual items were summed for each individual, a total greater than the median score of 28 indicating overall satisfaction
with the PPI, and a total less than this score suggesting dissatisfaction with the PPI. Subjects who served as controls did not read any of the patient information sheets; therefore, they were not asked to participate in this segment of the study.

Descriptive statistics for the variable "Satisfaction" across all grade blocks are presented in Table 16. The mean satisfaction scores ranged from 32.40 among subjects in the highest reading block who received the NARD document to 39.92 in the 6-7-8 reading grade block for persons who read the AARP MILS. This is a rather small range of scores, and actually is surprising in that the AARP document is written at an lower (easier-to-read) grade level than is the NARD leaflet.

The variances are equal across the blocks per the Bartlett-box test ($F = 1.55; p > 0.05$). No block-treatment interactions were detected. Further data analyses using randomized block ANOVA techniques are justified provided the assumptions for the ANOVA model are met within blocks as well.

Internal reliabilities were measured using Cronbach's alpha. The reliability of the instrument among persons with reading placement scores of three, four or five was 0.74. In the 6-7-8 block and the 9-12 block, the reliabilities were 0.96 and 0.93, respectively.

The stem and leaf display for the variable "satisfaction" is presented in Figure 15. The plots for the reading grade blocks 3-4-5 and 9-12 are unimodal and appear to be skewed.
TABLE 16

Descriptive Statistics for Variable "Satisfaction" Across Reading Grade Blocks

<table>
<thead>
<tr>
<th>Source</th>
<th>Reading Grade Blocks</th>
<th>3-4-5</th>
<th>6-7-8</th>
<th>9-12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AARP</td>
<td>37.44</td>
<td>39.92</td>
<td>34.40</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>2.74</td>
<td>2.96</td>
<td>2.79</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>34-42(9)</td>
<td>36-45(13)</td>
<td>32-39(5)</td>
</tr>
<tr>
<td>AMA</td>
<td>36.67</td>
<td>36.00</td>
<td>35.83</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>4.15</td>
<td>4.47</td>
<td>3.43</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>29-43(9)</td>
<td>10-31(11)</td>
<td>30-40(6)</td>
</tr>
<tr>
<td>CPhA</td>
<td>37.29</td>
<td>36.69</td>
<td>35.60</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>4.46</td>
<td>3.45</td>
<td>3.36</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>29-44(7)</td>
<td>32-43(13)</td>
<td>32-40(5)</td>
</tr>
<tr>
<td>FDA</td>
<td>33.33</td>
<td>36.67</td>
<td>34.29</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>4.58</td>
<td>3.42</td>
<td>4.57</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>28-41(9)</td>
<td>30-42(12)</td>
<td>27-41(7)</td>
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<tr>
<td>NARD</td>
<td>34.00</td>
<td>36.09</td>
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<tr>
<td></td>
<td>Standard Deviation</td>
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<td>7.80</td>
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<tr>
<td></td>
<td>Range(n)</td>
<td>28-40(7)</td>
<td>27-42(11)</td>
<td>19-39(5)</td>
</tr>
<tr>
<td>Test</td>
<td>34.73</td>
<td>37.73</td>
<td>37.86</td>
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<td></td>
<td>Standard Deviation</td>
<td>5.42</td>
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<td>4.52</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>34-45(11)</td>
<td>29-43(11)</td>
<td>32-45(7)</td>
</tr>
<tr>
<td>USP</td>
<td>34.70</td>
<td>35.54</td>
<td>37.00</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Range(n)</td>
<td>27-43(10)</td>
<td>28-42(11)</td>
<td>33-42(5)</td>
</tr>
</tbody>
</table>

aA score of 28 on seven-item, seven-point Likert-type scale indicates neutral opinion; > 28 = satisfaction; < 28 = dissatisfaction. Controls did not read any PPI so were not asked their opinions in this section.

bVariances homogeneous by Bartlett-Box Test (F = 1.55; p > 0.05).

cAARP=American Association of Retired Persons; AMA=American Medical Association; CPhA=Canadian Pharmaceutical Association; FDA=Food and Drug Administration; NARD=National Association of Retail Druggists; Test=Experimental PPI; USP=United States Pharmacopeial Convention.

dBased upon the United States Pharmacopeial Convention's Dispensing Information (USPDI).
Units: 10.0
1.2 = 12

Reading Levels 3-4-5       Reading Levels 6-7-8
1   2.5                  1   2.7
2   2.7                  5   2.8889
8   2.888899             9   3.0011
13  3.00111              14  3.22233
19  3.22333              29  3.444444455555555
29  3.4444444455          38  3.666667777
(12) 3.66666777777777    (26) 3.888888888888889999999999
21  3.88888899           20  4.00000111
13  4.00000001           12  4.22222333
  5   4.233               3   4.555
  2   4.45

Reading Levels 9-12

LOW = 19

1   2.7
1   2.
2   3.0
12  3.222223333
(9) 3.444455555
18  3.66777
13  3.88899
  8   4.000111
  2   4.2
  1   4.5

FIGURE 15
Stem and Leaf Displays
for Variable "Satisfaction"a,b

aSatisfaction measured with a seven-item, seven point Likert-type scale asking subjects to assess specific aspects of the PPI which they read. Scores greater than 28 indicate overall satisfaction with the PPI read; those less than 28 indicate overall dissatisfaction.
bValues in parentheses represent median values.
The plot for persons reading at grade levels 6-7-8 is bimodal, suggesting that within this category, an additional blocking variable may be identified. Re-examination of the data reveals that among the fifteen persons awarding satisfaction ratings of 34 or 35 to the PPIs (accounting for the small peak seen in the display for this reading grade), twelve of the respondents were female, and all but two subjects had at least completed high school. Females and high school graduates are over-represented by these percentages when compared to the demographics of the overall sample (Table 10). This suggests that within this block, sex and/or educational level may be appropriate additional categorical variables.

The stem and leaf display for this block also identifies an outlying value of 19.0, suggesting that this value will reappear as an extreme outlier in the boxplots for this block.

The mean satisfaction scores among subjects reading at grade levels 3-4-5 represent a narrow range of values, from 33.33 for the FDA PPI to 37.44 for the AARP MILS. The variances across treatments are equal, resulting in a nonsignificant the Bartlett-Box test \( F = 1.92; p > 0.05 \).

Figure 16 displays the Boxplots for the variable "Satisfaction" within the reading grade block 3-4-5. The scores for the CPhA SIM and the FDA PPI are clustered about the median, and extreme outliers, beyond the third quartile from the median, are present for these two treatments. These points were checked for accuracy and were found to be actual data points.
FIGURE 16
Boxplots of Variable "Satisfaction"
Across Treatments for Reading Levels 3-4-5
Boxplots in Figures 16-18 reflect the very small variances apparent in some treatments. "Boxes" which appear very flattened do so because data tends to be clustered about the median, probably as a result of the relatively small numbers of subjects in these treatments cells.

Satisfaction ratings from among persons reading at grade levels six through eight are presented in Table 16. As with the lower reading grade block, mean scores across treatments (PPIs) vary within a narrow range. All PPIs were scored at 35 or above, indicating that subjects claimed to quite satisfied with each of the PPIs. The scores ranged from 35.54 for the USP PPI to 39.92 for the AARP MILS.

The Bartlett-Box test for homogeneity of variance was nonsignificant (F = 1.92; p > 0.05). This suggests that the variances are equal across treatments, meeting the assumption for the ANOVA model.

An examination of the Boxplots for the variable "Satisfaction" within the 6-7-8 reading grade block (Figure 15) reveals a pattern very similar to that seen in the 3-4-5 reading grade block. The Boxplot for the FDA PPI in particular, is very similar in both of the reading grade block, most of the values being clustered around the median and giving a very flat "box." No extreme outliers, data points beyond the third quartile from the median, are present.
O = Outlier beyond second quartile from median.
E = Extreme outlier beyond third quartile from median.

AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopoeial Convention PPI.

FIGURE 17
Boxplots of Variable "Satisfaction"
Across Treatments for Reading Levels 6-7-8
O = Outlier beyond second quartile from median.
E = Extreme outlier beyond third quartile from median.

AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopoeial Convention PPI.

FIGURE 18
Boxplots of Variable "Satisfaction"
Across Treatments for Reading Levels 9-12
The trend which shows subjects being satisfied overall with all of the PPIs continues among persons reading at grade levels nine to twelve. Scores range from 32.40 for the NARD PIL to a high of 37.86 for the Test PPI. Standard deviations ranged from a low of 2.79 to a high of 7.80 among persons receiving the NARD sheet. The Bartlett-Box test, however, determined the variances to be homogeneous across treatments. Within this grade block, a score of 19.0, the lowest satisfaction rating given any PPI at any reading grade level, was assigned to the NARD PIL by one subject.

The Boxplots for the various PPIs in the 9-12 reading grade block are shown in Figure 18. Many of the boxes are quite narrow, reflecting the small ranges in satisfaction scores seen in this block. The lone outlier, 19.0, is beyond the third quartile from the median score awarded the NARD sheet. The data point is retained after being verified as correct.

The results of the several Bartlett-Box tests suggest that the experimental variances are equal across classification blocks and across treatments within blocks. The nonsignificant interaction terms suggest the absence of any block-treatment interactions. The assumptions necessary for the randomized blocks ANOVA model appear to have been met, and so this procedure will be used to conduct subsequent analyses for this variable.
The analysis of variance for the variable "Satisfaction" is summarized in Table 17. Controls were omitted from the ANOVA, because it was illogical to ask these subjects their opinions of PPIs which they did not read. The F statistic for the ANOVA was nonsignificant; no differences in the mean satisfaction ratings were detected. Because of the nonsignificance of the F test, no Scheffe comparison was conducted.

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>Sum of Squares</th>
<th>Degrees of Freedom</th>
<th>Mean Square</th>
<th>F·p</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within cells</td>
<td>2587.53</td>
<td>147</td>
<td>17.60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Block</td>
<td>91.40</td>
<td>2</td>
<td>45.70</td>
<td>2.60</td>
<td>NS</td>
</tr>
<tr>
<td>PPI</td>
<td>196.03</td>
<td>6</td>
<td>32.67</td>
<td>1.86</td>
<td>NS</td>
</tr>
<tr>
<td>Block by PPI</td>
<td>227.76</td>
<td>14</td>
<td>16.27</td>
<td>1.06</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS = Not significant (p > 0.05).

Although in a statistical sense it is inappropriate to go "snooping" in the data because of the nonsignificant F test, it may be useful to look at some overall trends in the individual areas which subjects were asked to rate. The first question asked how much
subjects felt that they learned from the PPIs. Almost 65% of subjects rated the amount of knowledge gained from reading their PPIs at six or seven on the seven-point Likert-type scale.

Over 56% of the subjects responded that they would be certain to use the PPI in the event they were required to take a thiazide diuretic, these subjects responding with a rating of seven to this question.

The third question asked subjects whose PPIs contained pictures (the AARP MILS and the FDA PPI) to rate how helpful these persons found the pictures to be. Alternatively, those persons whose PPIs lacked diagrams or pictures were asked to rate how much they felt such aids would have helped them to understand the information. Such persons were unsure as to the pictures' contributions, the mean, median and modal scores all being four on the seven-point scale.

The fourth question asked about the size of the print used in the PPIs. Almost 83% of the subjects responded with a rating of four, indicating the print size was just the right size. One quarter of respondents, however, indicated that overall the print size used was too small. Seventeen percent of persons indicated that the print size used was actually larger than what they needed.

Fewer than ten percent of the respondents indicated that too much information was given in the PPIs, while more than 46% answered that not enough information was given. This is interesting in that anecdotal comments from many of the GED instructors indicated that too
much information was contained for students to be expected to understand and retain it.

The sixth question asked subjects to provide a global satisfaction rating for the PPIs which they read. Over 80% of respondents rated the PPIs five, six or seven, indicating that they were satisfied to very satisfied with the PPIs.

The final question asked subjects to indicate how likely they were to recommend the information sheet which they read to a friend who was taking thiazide drugs. This question was intended to serve as a check on subject responses to the questions regarding whether or not subjects would use the PPIs themselves and the overall satisfaction ratings. Again, eighty percent of the subjects responded to this question with a six or seven, indicating that they were highly likely to recommend the information sheet to a friend.

Blocking subjects by reading ability does appear to have had some effect on the variance for the variable "Satisfaction." The efficiency calculations resulted in an index of 1.23. A completely randomized design would have required 23% more replications to attain the same variance attained through blocking.

Analysis of Variable "Compliance"

Compliance, the final variable in Ley's Partial Model of Compliance (Ley 1980), is defined in this study as a subject's perceived likelihood that a fictitious patient would overcome barriers
to compliance (Becker and Maiman 1975) based upon the information contained in the PPI which the subject read.

The descriptive statistics for the variable "Compliance" across reading grade blocks are presented in Table 18. Mean scores ranged from 16.20 among persons reading at the highest levels who received the CPhA SIM to 24.00 among persons reading at the third, fourth or fifth grade levels who read the Test PPI. No clear pattern in mean scores emerged between USPDI-based PPIs and the remaining PPIs. A neutral score is 20.00, and many of the mean compliance scores across blocks are very near this score, suggesting that subjects were essentially unable to determine whether the patient would be likely to comply with his medication regimen or not.

The standard deviations of scores are between 4.0 and 5.0 for the most part, the lone exception being the persons reading at grade levels nine through twelve who read the USP PPI (SD = 1.14). The Bartlett-Box test yielded an F value of 0.259, which is nonsignificant (p > 0.05), suggesting that variances across blocks are homogeneous, verifying a necessary assumption for the randomized blocks ANOVA model.

The stem and leaf displays for the variable "Compliance" are presented in Figure 19. Although ragged, there are no sizable gaps to suggest non-homogeneity. Nonetheless, the data were re-examined in a search for an explanation for some of the notable peaks. The ragged pattern suggests that additional blocking variables may be of interest within these blocks.
TABLE 18

Descriptive Statistics for Variable "Compliance" Across Reading Grade Blocks

<table>
<thead>
<tr>
<th>PPI Source</th>
<th>3-4-5</th>
<th>6-7-8</th>
<th>9-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>AARP</td>
<td>Mean</td>
<td>21.22</td>
<td>20.69</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>4.18</td>
<td>7.13</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>15-28(9)</td>
<td>10-35(13)</td>
</tr>
<tr>
<td>AMA</td>
<td>Mean</td>
<td>18.90</td>
<td>20.36</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>4.76</td>
<td>6.44</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>13-27(9)</td>
<td>10-31(11)</td>
</tr>
<tr>
<td>CPhA</td>
<td>Mean</td>
<td>20.14</td>
<td>18.34</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>6.09</td>
<td>3.84</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>11-26(7)</td>
<td>12-25(13)</td>
</tr>
<tr>
<td>FDA</td>
<td>Mean</td>
<td>17.90</td>
<td>21.17</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>4.94</td>
<td>6.24</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>11-26(9)</td>
<td>10-29(12)</td>
</tr>
<tr>
<td>NARD</td>
<td>Mean</td>
<td>20.29</td>
<td>19.82</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>2.36</td>
<td>4.71</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>16-23(7)</td>
<td>12-27(11)</td>
</tr>
<tr>
<td>Test</td>
<td>Mean</td>
<td>24.00</td>
<td>22.82</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>5.10</td>
<td>5.15</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>14-32(11)</td>
<td>16-30(11)</td>
</tr>
<tr>
<td>USP</td>
<td>Mean</td>
<td>21.20</td>
<td>21.46</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>4.83</td>
<td>4.20</td>
</tr>
<tr>
<td></td>
<td>Range(n)</td>
<td>16-32(10)</td>
<td>13-29(11)</td>
</tr>
<tr>
<td>Controls</td>
<td>Mean</td>
<td>18.73</td>
<td>20.00</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>7.60</td>
<td>5.54</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>9-35(11)</td>
<td>11-25(12)</td>
</tr>
</tbody>
</table>

* A score of 20 on five-item, seven-point Likert-type scale indicates neutral opinion; > 20 = compliance; < 20 = noncompliance.

Variances homogeneous by Bartlett-Box Test ($F = 0.259; p > 0.05$).  

*CPhA=American Association of Retired Persons; AMA=American Medical Association; CPhA=Canadian Pharmaceutical Association; FDA=Food and Drug Administration; NARD=National Association of Retail Druggists; Test=Experimental PPI; USP=United States Pharmacopeial Convention.

Based upon the United States Pharmacopeial Convention’s Dispensing Information (USPDI).
Units: 10.0  
1.2 = 12

Reading Levels 3-4-5
1 0.9  
4 1.111  
10 1.233333  
13 1.455  
24 1.6666777777  
29 1.89999  
(16) 2.000000000001111
30 2.2222333333
21 2.4444555555
11 2.66667
5 2.8  
4 3.1  
3 3.22  
1 3.5

Reading Levels 6-7-8
1 1.0001  
4 1.2233  
9 1.4444455  
17 1.666667777777  
29 1.889999999999  
40 2.0000000000001111
39 2.222223333333
27 2.4444555555
18 2.66667
12 2.8899999
5 3.0011
1 3.
1 3.

Reading Levels 9-12
1 0.9  
2 1.0  
5 1.233  
12 1.4444445  
14 1.67
(10) 1.8888888999  
22 2.000111
16 2.2233  
12 2.44455  
7 2.6677
3 2.89
1 3.
1 3.
1 3.

FIGURE 19
Stem and Leaf Displays
for Variable "Compliance"a,b

aCompliance measured with a five-item, seven point Likert-type scale with questions based upon barriers to compliance from Becker and Maiman's Health Belief Model (1975). Scores greater than 20 indicate that the subject feels that the fictitious patient will take his medication as prescribed. Scores less than 20 indicate that the subject feels that the fictitious patient will fail to take his medication as prescribed.

bValues in parentheses represent median values.
Reexamination of the data from block 3-4-5 reveals that of the nine subjects with a compliance score of 16 or 17 (the scores which represent the smaller peak in the stem and leaf display), eight of the subjects were female, and none of the subjects was Hispanic. Females and non-Hispanics are quite over-represented in this cluster of scores when compared to the demographics of this subsample as a whole (Table 10). This would suggest that within this reading grade block, compliance scores may vary by sex, race or some other variable which was not measured in this study.

For the 9-12 reading grade block, the data was re-examined to determine why a peak is seen in the stem and leaf display at scores of fourteen and fifteen. No discernible pattern in subject demographics is apparent which might explain this cluster. These scores are almost evenly distributed between males and females, whites and blacks, Pima Community College East and Pima Community College West, ages, and treatment groups within the block. The scores in this reading grade block may vary by some demographic variable which was not measured in the study, or may reflect an underlying anomaly in the data.

Mean compliance scores among persons in the lowest reading grade block (Table 18) range from 17.90 for persons reading the FDA PPI to 24.00 for persons reading the Test PPI prepared by the principal investigator. Scores greater than 20.00 indicate that the subject felt that the fictitious patient would comply with his medication regimen, while those less than 20.00 indicated a
noncompliance. There appears to be no pattern of differences in mean scores arising from the different sources from which each PPI was derived, suggesting that whether the PPI was USPDI-based or developed from some other reference source, the impact on the subjects' perceptions of compliance was the same.

The variances across treatments are homogeneous as evidenced by the nonsignificant Bartlett-Box test ($F = 0.24; p > 0.05$). This homogeneity permits use of the randomized block ANOVA model.

The Boxplots for the variable "Compliance" are for subjects in this reading grade block presented in Figure 20. No outlying points are found beyond the third quartile from the median, although three data points lie beyond the second quartile. These outliers were verified for accuracy and then included in subsequent analyses.

The mean scores and other statistics for the compliance scales for persons reading in the 6-7-8 block (Table 18) reveal that the range of mean scores is narrower than seen in the previous reading grade block. Mean scores ranged from 18.54 for the Canadian Pharmaceutical Association's information sheet to 22.82 for the Test PPI. Once again, mean scores were very close to 20.00, indicating that subjects were unsure whether or not the fictitious patient would comply with his medication regimen. As in the previous block, the homogeneity of variance test was nonsignificant for scores in this block (Bartlett-Box $F = 0.98; p > 0.05$).

The Boxplots in Figure 21 reflect the expanded range of compliance scores seen in the 6-7-8 block. Two data points fell
O = Outlier beyond second quartile from median.
E = Extreme outlier beyond third quartile from median.

AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopeial Convention PPI.

**FIGURE 20**

Boxplots of Variable "Compliance"\(^a\) Across Treatments for Reading Levels 3-4-5

\(^a\)Compliance measured with a five-item, seven point Likert-type scale with questions based upon barriers to compliance from Becker and Maiman’s Health Belief Model (1975). Scores greater than 20 indicate that the subject feels that the fictitious patient will take his medication as prescribed. Scores less than 20 indicate that the subject feels that the fictitious patient will fail to take his medication as prescribed.
O = Outlier beyond second quartile from median.
E = Extreme outlier beyond third quartile from median.

AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopeial Convention PPI.

FIGURE 21
Boxplots of Variable "Compliance" Across Treatments for Reading Levels 6-7-8

Compliance measured with a five-item, seven point Likert-type scale with questions based upon barriers to compliance from Becker and Maiman's Health Belief Model (1975). Scores greater than 20 indicate that the subject feels that the fictitious patient will take his medication as prescribed. Scores less than 20 indicate that the subject feels that the fictitious patient will fail to take his medication as prescribed.
beyond the outer fence, and these points were verified and included with the rest of the data set.

As in the previous two reading grade blocks, persons reading at grade levels nine through twelve who received the Test PPI awarded the fictitious patient the highest compliance score (Table 18). The mean scores ranged from a low of 16.20 for the CPhA SIM to a high of 23.14 for the Test PPI. Again, the variances across treatments were equal by the Bartlett-Box test ($F = 0.162; p > 0.05$).

The Boxplots for the variable "Compliance" are displayed in Figure 22. One data point lies beyond the outermost fence for the FDA PPI; this data point resulted from one subject awarding the only score of thirty-five to the fictitious patient, meaning that this person felt that the patient would overcome each of the barriers to compliance with which he was faced.

This subject's data were re-examined to determine whether the subject had also indicated all seven's on the satisfaction scale. Had this been the case, it may have been that this subject simply selected sevens "straight down the list" rather than thinking about each question before answering. This would have justified discarding the data point. This subject's satisfaction scale did show variation from seven for several questions; therefore, it is unlikely that the compliance score of thirty-five is spurious.

The analysis of variance yielded a nonsignificant $F$ value for the interaction between treatments and grade blocks. Analyzing across
AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopeial Convention PPI.

FIGURE 22

Boxplots of Variable "Compliance"
Across Treatments for Reading Levels 9-12

Compliance measured with a five-item, seven point Likert-type scale with questions based upon barriers to compliance from Becker and Maiman's Health Belief Model (1975). Scores greater than 20 indicate that the subject feels that the fictitious patient will take his medication as prescribed. Scores less than 20 indicate that the subject feels that the fictitious patient will fail to take his medication as prescribed.
cells and within cells, the Bartlett-Box Test for equal variances was conducted and was nonsignificant in each case. The lack of treatment-box interactions and the presence of equal variances clears the way to analyze the data using the randomized block ANOVA model.

The analysis of variance of the variable "Compliance" is presented in Table 19. No significant differences in compliance scale scores were detected across blocks. Between PPIs, however, a significant F value was obtained ($F = 4.07; \text{df} = (7,197); p < 0.05$).

The Scheffe procedure (Figure 23) detected that persons reading at grade levels three, four or five who received the Test PPI awarded a significantly higher compliance score to the fictitious patient than did persons in this block who served as controls. Overall, the compliance scores awarded the fictitious patient by persons receiving any of the patient information leaflets comprised one family of contrasts, while controls constituted a statistically separate family.

Blocking for the variable "Compliance" was actually just slightly less efficient than would have been a completely randomized design, the calculated efficiency index being 0.93. Failing to classify subjects into blocks would have resulted in requiring no more replications than there were in the present study to attain variances similar to those attained in the present study.
TABLE 19

ANOVA Table for Variable "Compliance"* Among All Subjects Receiving PPIs

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>Sum of Squares</th>
<th>Degrees of Freedom</th>
<th>Mean Square</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within cells</td>
<td>7771.42</td>
<td>197</td>
<td>39.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Block</td>
<td>33.60</td>
<td>2</td>
<td>16.8</td>
<td>0.42</td>
<td>0.65(NS)</td>
</tr>
<tr>
<td>PPI</td>
<td>1126.60</td>
<td>7</td>
<td>160.94</td>
<td>4.07</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Block by PPI</td>
<td>1632.60</td>
<td>14</td>
<td>33.74</td>
<td>0.86</td>
<td>0.61(NS)</td>
</tr>
</tbody>
</table>

NS = Not significant (p > 0.05).

*aCompliance measured with a five-item, seven point Likert-type scale with questions based upon barriers to compliance from Becker and Maiman's Health Belief Model (1975).
Reading grade levels 9-12

31 75248 6
++ ++++ +

Reading grade levels 6-7-8

3582147 6
+++++++ +

Reading grade levels 3-4-5

8 4 2 35 71 6
+ + ++ ++ +

Overall

8 324157 6
+ ++++++ +

FIGURE 23

Scheffe Families of Significant Contrasts for Variable "Compliance"
(Level of significance = 0.20)

1 = AARP; 2 = AMA; 3 = CPhA; 4 = FDA; 5 = NARD; 6 = TEST;
7 = USP; 8 = CONTROL
Rankings of PPIs

Tables 20 to 22 show rankings of the various PPIs across variables within each reading grade block. The probabilities that the Test PPI developed by the investigator would be ranked in the first or second positions were determined. Across reading grade blocks, the probabilities that the Test PPI would be ranked first or second were calculated to be \((2/7)^2\) or 0.08 for grade levels 3-4-5, and \((2/7)^4\) or 0.007 for grade levels 6-7-8. The probability that the Test PPI would be ranked first for all four variables for reading grade levels 9-12 was calculated to be \((1/7)^4\) or 0.0004. Based upon the calculated probabilities, therefore, it is unlikely that the Test PPI received consistently high rankings purely by chance, although the calculated probability for the lowest reading grade block is not significant.

Associations Between Components of Ley's Partial Model of Compliance

Using data from all subjects completing the study, the associations between the Zip Scale reading placement score, PPI readability, as measured by the SMOG Readability Formula (McLaughlin 1969) and each of the four variables which serve as components of the Partial Model of Compliance proposed by Ley (1980) were examined. Components of the Ley's model, with subject reading ability and PPI readability introduced as additional components, were entered into a series of simple multiple regression equations. Each component served as the dependent variable in one of the equations, with the remaining components entered as predictors. Those components of the model which
## TABLE 20

Rankings\(^a\) Across Variables\(^b\) and PPIs\(^c\)
for Reading Grade Levels 3-4-5

<table>
<thead>
<tr>
<th></th>
<th>Understanding</th>
<th>Memory</th>
<th>Satisfaction</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH SCORES</td>
<td>AARP</td>
<td>FDA</td>
<td>AARP</td>
<td>TEST</td>
</tr>
<tr>
<td></td>
<td>FDA</td>
<td>TEST</td>
<td>CPhA</td>
<td>AARP</td>
</tr>
<tr>
<td></td>
<td>USP</td>
<td>AARP</td>
<td>AMA</td>
<td>USP</td>
</tr>
<tr>
<td></td>
<td>TEST</td>
<td>NARD</td>
<td>TEST</td>
<td>NARD</td>
</tr>
<tr>
<td></td>
<td>AMA</td>
<td>AMA</td>
<td>USP</td>
<td>CPhA</td>
</tr>
<tr>
<td>LOW SCORES</td>
<td>NARD</td>
<td>USP</td>
<td>FDA</td>
<td>FDA</td>
</tr>
</tbody>
</table>

\(^a\)Rankings made without consideration to statistical differences between PPIs.

\(^b\)Understanding measured with a ten-item multiple choice test based upon information common to all PPIs tested.

\(^b\)Memory measured with a fifty-item cloze comprehension test developed for each PPI tested.

\(^b\)Satisfaction measured with a seven-item, seven point Likert-type scale.

\(^b\)Compliance measured with a five-item, seven point Likert-type scale with questions based upon barriers to compliance from Becker and Maiman's Health Belief Model (1975).

\(^c\)AARP = American Association of Retired Persons  Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopeial Convention PPI.
TABLE 21
Rankings\textsuperscript{a} Across Variables\textsuperscript{b} and PPIs\textsuperscript{c} for Reading Grade Levels 6-7-8

<table>
<thead>
<tr>
<th></th>
<th>Understanding</th>
<th>Memory</th>
<th>Satisfaction</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH SCORES</td>
<td>AARP</td>
<td>TEST</td>
<td>AARP</td>
<td>TEST</td>
</tr>
<tr>
<td></td>
<td>TEST</td>
<td>AARP</td>
<td>TEST</td>
<td>USP</td>
</tr>
<tr>
<td></td>
<td>USP</td>
<td>FDA</td>
<td>CPhA</td>
<td>FDA</td>
</tr>
<tr>
<td></td>
<td>AMA</td>
<td>NARD</td>
<td>FDA</td>
<td>AARP</td>
</tr>
<tr>
<td></td>
<td>FDA</td>
<td>USP</td>
<td>NARD</td>
<td>AMA</td>
</tr>
<tr>
<td>LOW SCORES</td>
<td>CPhA</td>
<td>CPhA</td>
<td>USP</td>
<td>CPhA</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Rankings made without consideration to statistical differences between PPIs.

\textsuperscript{b}Understanding measured with a ten-item multiple choice test based upon information common to all PPIs tested.

\textsuperscript{b}Memory measured with a fifty-item cloze comprehension test developed for each PPI tested.

\textsuperscript{b}Satisfaction measured with a seven-item, seven point Likert-type scale.

\textsuperscript{b}Compliance measured with a five-item, seven point Likert-type scale with questions based upon barriers to compliance from Becker and Maiman's Health Belief Model (1975).

\textsuperscript{c}AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.

AMA = American Medical Association Patient Medication Information.

CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.

FDA = United States Food and Drug Administration PPI.

NARD = National Association of Retail Druggists Patient Information Leaflet.

Test = PPI developed by Investigator.

USP = United States Pharmacopeial Convention PPI.

upon information common to all PPIs tested.
TABLE 22

Rankings Across Variables\textsuperscript{a} and PPIs\textsuperscript{b} for Reading Grade Levels 9-12

<table>
<thead>
<tr>
<th>Understanding</th>
<th>Memory</th>
<th>Satisfaction</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIGH SCORES</strong></td>
<td>TEST</td>
<td>TEST</td>
<td>TEST</td>
</tr>
<tr>
<td>NARD</td>
<td>USP</td>
<td>USP</td>
<td>FDA</td>
</tr>
<tr>
<td>AARP</td>
<td>FDA</td>
<td>AMA</td>
<td>AMA</td>
</tr>
<tr>
<td>FDA</td>
<td>AMA</td>
<td>CPhA</td>
<td>USP</td>
</tr>
<tr>
<td>USP</td>
<td>NARD</td>
<td>AARP</td>
<td>NARD</td>
</tr>
<tr>
<td>AMA</td>
<td>AMA</td>
<td>FDA</td>
<td>AARP</td>
</tr>
<tr>
<td><strong>LOW SCORES</strong></td>
<td>CPhA</td>
<td>CPhA</td>
<td>NARD</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Rankings made without consideration to statistical differences between PPIs.

\textsuperscript{b}Understanding measured with a ten-item multiple choice test based upon information common to all PPIs tested.

\textsuperscript{b}Memory measured with a fifty-item cloze comprehension test developed for each PPI tested.

\textsuperscript{b}Satisfaction measured with a seven-item, seven point Likert-type scale.

\textsuperscript{b}Compliance measured with a five-item, seven point Likert-type scale with questions based upon barriers to compliance from Becker and Maiman's Health Belief Model (1975).

\textsuperscript{c}AARP = American Association of Retired Persons Medication Information Leaflet for Seniors.
AMA = American Medical Association Patient Medication Information.
CPhA = Canadian Pharmaceutical Association Supplementary Information on Medications.
FDA = United States Food and Drug Administration PPI.
NARD = National Association of Retail Druggists Patient Information Leaflet.
Test = PPI developed by Investigator.
USP = United States Pharmacopeial Convention PPI.
were found to have significant standardized regression coefficients between a predictor variable and the dependent variable are included in the model shown in Figure 24. This figure includes all of the components of Ley's Model (Figure 1), although Figure 24 differs markedly in its shape from the original model, and many of the relationships suggested by Ley's model are not present in the experimental model.

Figure 25 is the model resulting from the set of multiple regression equations using the data from grade levels three, four and five. Memory and Satisfaction remain correlated to Understanding as in Ley's original model. Memory did not predict Satisfaction as suggested by Ley, however, and Compliance was predicted by PPI Readability, a component absent from Ley's model. Memory predicted Compliance in a direction opposite that suggested by Ley.

At grade levels six, seven and eight, Memory, Understanding and Compliance remain in the model (Figure 26). This model consists of two segments, with no common component linking the segments. One segment consists of Memory predicting Understanding Ley predicts the opposite relationship), and the other segment has PPI Readability predicting Compliance.

At the highest level of reading ability (Figure 27), Memory predicts Understanding (opposite of Ley's model) and Compliance (in a direction opposite that suggested by Ley). PPI Readability, absent from Ley's Model, predicts Compliance, and Satisfaction fails to appear in the model at this reading grade level.
FIGURE 24

Standardized Regression Coefficients Between Components of Ley's Partial Model of Compliance (Ley 1980), PPI Readability and Subject Reading Ability for All Subjects (All coefficients significant at the 0.05 level)
FIGURE 25

Standardized Regression Coefficients Between Components of Ley's Partial Model of Compliance (Ley 1980), PPI Readability and Subject Reading Ability for Reading Grade Block 3-4-5 (All coefficients significant at the 0.05 level)
MEMORY — 0.280 — UNDERSTANDING

PPI READABILITY — -0.247 — COMPLIANCE

FIGURE 26

Standardized Regression Coefficients Between Components of Ley's Partial Model of Compliance (Ley 1980), PPI Readability and Subject Reading Ability for Reading Grade Levels 6-7-8
(All coefficients significant at the 0.05 level)

PPI READABILITY

-0.351

COMPLIANCE

-0.412

MEMORY

0.395

UNDERSTANDING

FIGURE 27

Standardized Regression Coefficients Between Components of Ley's Partial Model of Compliance (Ley 1980), PPI Readability and Subject Reading Ability for Reading Grade Levels 9-12
(All coefficients significant at the 0.05 level)
Table 23 lists the results of SMOG Readability Formula evaluations conducted on PPIs covering the benzodiazepines, digoxin and the penicillins. These PPIs were supplied by the American Associations of Retired Persons, the American Medical Association, the Canadian Pharmaceutical Association and the National Association of Retail Druggists. Additional PPIs from the United States Pharmacopeial Convention were unavailable, and actually unnecessary because the text of each USP PPI is identical to that found in the corresponding NARD PILs.

The FDA PPI was a prototype which was published in 1978. PPIs covering the additional drug classes were unavailable from this source. The Test PPI describing the thiazide diuretics was constructed by the Principal Investigator for the sole purpose of the present study. No additional PPIs were developed for any other drug class.

Two judges independently assessed the PPIs from the AARP, AMA, and USP. The additional SIMs from the Canadian Pharmaceutical Association were not available to the second judge. The overall Pearson correlation among those PPIs evaluated by both judges is 0.876.

Readability of the PPIs varied both by PPI and by source. The PPIs from AARP, based on the American Society of Hospital Pharmacists' Medication Teaching Manual, tended to have lower SMOG
### TABLE 23

SMOG Readability Formula$^a$
Grade Level Scores for Various PPIs
from Different Sources

<table>
<thead>
<tr>
<th>Drug</th>
<th>Benzodiazepines</th>
<th>Digoxin</th>
<th>Penicillins</th>
<th>Thiazides</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Judge 1</td>
<td>Judge 2</td>
<td>Judge 1</td>
<td>Judge 2</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>10.21</td>
<td>10.00</td>
<td>9.08</td>
<td>8.83</td>
</tr>
<tr>
<td>AARP</td>
<td>12.00</td>
<td>12.02</td>
<td>11.68</td>
<td>11.27</td>
</tr>
<tr>
<td>AMA</td>
<td>11.71</td>
<td>11.31</td>
<td>11.21</td>
<td>12.59</td>
</tr>
<tr>
<td>CPhA</td>
<td>12.47</td>
<td>12.42</td>
<td>12.35</td>
<td>12.74</td>
</tr>
</tbody>
</table>

Pearson correlation between judges = 0.876.

$^a$McLaughlin 1969.

$^b$AARP = American Association of Retired Persons
AMA = American Medical Association
CPhA = Canadian Pharmaceutical Association
NARD = National Association of Retail Druggists
scores overall than did the PPIs from the remaining sources, all based upon the United States Pharmacopeial Convention's USPDI. Although PPI readabilities also varied from drug to drug, no clear pattern in scores emerged across drugs.
CHAPTER 5

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

This project was undertaken to accomplish two objectives: Determine which of seven Patient Package Inserts (PPIs) was the easiest for poor-reading adults to understand, and determine whether Ley's Partial Model of Compliance (Ley 1980) was applicable to this sample of poor-reading adults. In this chapter, study results are discussed with respect to the hypotheses which arose as a result of the study's major objectives.

Generalizability of Study Findings

Data was collected from a variety of sites in Arizona. Towns with a wide range of populations were used, including unincorporated towns (Stanfield), small towns (Coolidge, Eloy), large towns (Casa Grande), small cities (Scottsdale) and large metropolitan areas (Tucson). These sites were distributed throughout Central and Southeastern Arizona. Within Tucson, multiple GED sites were used, and almost all classes (morning, afternoon and evening) at these sites were utilized. Even within Pima Community College, two different campuses were used, and approximately 90% of the remedial reading classes held at these two sites were accessed. Study findings are therefore more than a local phenomenon and are somewhat more generalizable to adults enrolled in GED or remedial reading courses.
throughout the state than they would have been had only the Tucson area been utilized.

Subject Understanding of Thiazide PPIs

It was hypothesized that subjects receiving a PPI written at or below their reading grade ability would better understand the material (as measured by a multiple-choice test) than would subjects receiving PPIs written at levels which exceed their reading abilities. The only significant differences found for the understanding scores, however, occurred between reading grade blocks.

One possible explanation for this inter-level variability is that while the Test PPI developed by the Principal Investigator was rated at less than sixth grade level using the SMOG readability formula, most of the remaining PPIs were rated at grade nine or above. Therefore, subjects who read at grade levels nine through twelve were more likely to receive a PPI written at or below their reading abilities than were subjects in the 4-5-6 block, and so would be expected to outperform subjects in the lower reading grade blocks based upon the hypothesis.

A second possibility is that the multiple-choice questions used to measure understanding were too difficult to be understood by persons reading at the lowest grade levels; however, every attempt was made to write these questions at the lowest grade level possible. If this second scenario were indeed true, the differences seen would
be the result of this artifact rather than as a result of reading more difficult PPIs.

One would not have expected to find differences between PPIs in the 9-12 reading grade block because all PPIs are written at or below the reading abilities persons in this block; however, this is the only block where intra-group differences were found to exist. Persons receiving the Test PPI written by the Principal Investigator scored significantly higher on the multiple-choice test than did subjects receiving the Canadian Pharmaceutical Association's Supplemental Information on Medications.

A possible explanation for this finding is suggested by the model of reading proposed by Curtis and Glaser (1983). This model predicts that if the amount of information provided in the PPIs overwhelmed poorer readers, these persons would have had difficulty processing what they read, regardless of the level at which the PPIs were written. Because good readers are hypothesized by the model to expend less effort in understanding the meaning of the words they read than do poor readers, they have a greater capacity for higher level processes, such as integrating ideas. It would follow that only among good readers is it possible to detect differences in understanding between PPIs, because among this group vast amounts of information pose less of a barrier to understanding of the material.

The second part of this hypothesis proposed that subjects receiving any of the PPIs would exhibit better understanding by scoring significantly higher on the multiple-choice test than would
control subjects receiving no PPI; however, this was only partially supported. In no block did the Canadian PPI nor the Patient Information Leaflet produced by the National Association of Retail Druggists significantly impact subject performance on the multiple-choice test compared to controls. Only in the 6-7-8 block did the scores from persons receiving the FDA PPI differ from controls. In the highest reading grade block, persons who read no PPI actually scored higher on the multiple-choice test than did persons who read the Canadian PPI or the American Medical Association's PMI, although these differences were not significant.

In the lower reading grade blocks, learning appears to have occurred with most of the PPIs, which would explain why persons who read PPIs performed better on the test of understanding than did controls who read no PPI before testing. In the highest reading grade block, controls performed as well as subjects who received a PPI. It might be expected that adults who are better readers read more in general and more about health in particular. Control subjects in the highest reading grade block may have had enough prior knowledge about hypertension and its treatment that no learning appears to have occurred by reading the PPIs. It is also possible that the testing instrument used was not sensitive enough to detect differences which may have occurred.

Among persons reading at grade levels three, four or five the PPIs produced by the Principal Investigator (TEST), the American Association of Retired Persons (AARP), the American Medical
Association (AMA), the United States Pharmacopeial Convention (USP) improved understanding of thiazides over subjects who received no PPI. This same pattern is repeated for the 6-7-8 grade block, but in this block, the FDA PPI also improved understanding. The FDA PPI is written at two to three grade levels lower than the AMA and USP documents; therefore it is a rather surprising finding to see these latter PPIs have more of an impact on reading performance than the FDA leaflet at the 3-4-5 level. Possibly among the poorest readers, the diagrams present in the FDA PPI actually served to distract persons from the textual content of the information sheet. The AARP MILS, which improved subject performance significantly over that of controls, also contains diagrams; however, there is much less verbage present in the AARP document than in the FDA PPI. This suggests that for the poorest readers, a combination of minimal text combined with diagrams may be easier to understand than a copious amount of written information combined with diagrams.

Conclusion 1: Among adults reading below high school level, the hypothesis that PPIs would increase patient understanding of thiazide diuretics is only conditionally accepted, particular PPIs resulting in improved performance on a multiple-choice test and others having no impact. Among Arizona adults reading at high school level or above, a PPI written at the 5th-6th grade level improves understanding of thiazides over a PPI written at 10th-11th grade level.
Memory of Drug Information

Subject retention of the information about thiazides was measured using the cloze comprehension test. Subject performance on these tests was hypothesized to improve for persons receiving PPIs written at or below their reading abilities. Moreover, it was predicted that subjects receiving any PPI would be perform better on the cloze test than controls who received no PPI.

The Scheffe analysis reveals several patterns which differ from block to block. Among those persons reading at the highest level, none of the PPIs resulted in higher cloze test scores than the others. Persons reading at grade levels 6-7-8 and receiving one of the PPIs written at the ninth grade level or below (AARP, FDA or Test) performed better on the cloze comprehension test than did subjects in this block receiving any of the other PPIs. For subjects reading at the lowest level, subjects receiving the test PPI performed statistically better than those receiving the CPhA SIM (written at above 10th grade level).

As in the case of the variable, "understanding," the findings for memory of the information is readily explained in terms of Curtis and Glaser's (1983) model. Poor readers struggling with material which they find to be difficult are unable to make use of higher thought processes necessary for committing the information to memory. Persons of higher reading ability, however, are able to store information as they read it, expending less effort to understand the information as they read.
Duffelmeyer (1978) and Stratton, Bradley and Hurd (1985) found that good readers performed better on the cloze comprehension test than did poor readers. This confounds any differences found between groups who read at different levels; that is, it would not be possible to attribute differences in cloze scores across reading grade levels solely to differences in PPI difficulty. In the present study, however, differences across reading abilities were not detected.

Conclusion 2: For Arizona adults enrolled in either GED classes or remedial reading classes, those receiving a PPI written far below their reading abilities retain significantly more information than do persons receiving a PPI written at a level far exceeding their reading abilities.

**Subject Satisfaction With PPIs**

Subjects were asked to rate the PPIs which they read on a variety of facets. It was hypothesized that persons receiving PPIs written at or below their reading abilities would give such documents higher satisfaction ratings than would persons receiving PPIs which exceeded their reading abilities. This hypothesis was not supported by the data, the overall satisfaction ratings did not differ significantly from PPI to PPI or from reading grade block to reading grade block. These results are consistent with the findings from the pilot study, where no differences were found in patient satisfaction with the AMA PMI or with PPIs adapted to patient reading abilities (Stratton, Bradley and Hurd 1985).
There are two plausible explanations for no differences being found between PPIs or groups. First, subjects receiving PPIs which exceeded their reading abilities may have been reluctant to admit that they really did not understand the information contained in the PPIs and hence did not care for the documents all that much. In other words, indicating a disliking for the documents may have been construed by subjects to constitute an admission of lack of understanding of the documents.

The other possibility for the lack of a significance difference may have to do with the social desirability of the PPI concept rather than liking the specific PPIs read. Subjects who were found to read at less than third grade level were provided a copy of the Test PPI and then orally interviewed by the Principal Investigator in regards to their impressions of the PPI concept. Most individuals responded unprompted that they felt the concept was a good idea, even though they themselves might not use the documents because they were so difficult to read. (One notable exception to this trend was an individual from Mexico who tested out at first grade level. This person, a physician enrolled in the English as a Second Language (ESL) program, did not feel that patients needed the type of information provided by the PPI. He further indicated that he would not want his patients to receive such a document.) It is possible then that subjects who received PPIs were subconsciously evaluating the concept of PPIs rather than evaluating the PPIs which they received.
Conclusion 3: Arizona adults enrolled in either GED or remedial reading courses claim to be equally satisfied with any PPI which they receive.

Application of PPI Information to Medication-Taking Situations

One of the most important questions to be answered in any evaluation of patient education is whether or not patients are able to apply to actual situations the information they gained from the educational intervention. It was beyond the scope of the present study to have subjects actually take thiazide diuretics and monitor their compliance for a period of time after reading the information sheets. An alternative method is to present subjects with simulated situations and monitor how patients react to these situations based upon the information with which they were provided. This method has been used by others (Edmundson, et al. 1981 and Dolinsky, et al. 1984).

A problem can arise in these simulations because subjects who are asked to indicate how they would react to given situations tend to give responses which are "socially desirable." Certainly, this may have occurred in this study for those Satisfaction Scale questions which asked whether subjects would use the PPIs or recommend them to others. In an attempt to circumvent this problem with the Compliance Scales, subjects were provided with vignettes which involved fictitious third persons who were confronted with different barriers to compliance as described by Becker and Maiman (1975).
It was hypothesized that persons receiving PPIs which were at or below their reading abilities were more likely to indicate that the fictitious patient would overcome the barriers to compliance than would subjects receiving PPIs which exceeded their reading abilities, and those receiving any PPI would award higher scores than would persons reading no PPI. The ANOVA for the variable "Compliance" indicates a significant difference in compliance scale scores between treatment groups. The Scheffe procedure revealed significant contrasts occurred between Controls and persons receiving any of the PPIs. An additional significant contrast was detected in the 3-4-5 block, between control subjects and persons in this block who received the Test PPI. Learning appears to have occurred as a result of reading the PPIs, and the hypothesis is therefore conditionally accepted.

Providing subjects with a third person resulted in a great deal of variability in responses from question to question. The median responses varied from 2.83 for the question involving family experience with hypertension to 5.69 for the question weighing the risks of hypertension against the risks of thiazide side effects. For whatever reason, therefore, subjects appeared to feel that the fictitious patient was more likely to overcome the barrier to compliance created by the possibility of side effects than the barrier created by previous experience of a family member.

For four of the five questions, the overall mean scores indicated that subjects felt that the fictitious patient was somewhat
likely to overcome the barriers to compliance. For the question involving the patient having to get up numerous times during the night to urinate, however, more than one-half of all subjects indicated that the patient was more likely than not to stop taking his medications. This outcome is particularly suggestive that subjects did not apply the information which they read to this situation. Virtually all of the PPIs informed the reader that more frequent urination should be expected initially, and instructed readers not to stop the drug should this occur.

Previous studies have shown that written drug information alone has only marginal, if any, impact upon patient compliance (Haynes, Taylor and Sackett 1979). If the vignettes used in the present study can be extrapolated to actual patient behavior, then the findings here are in agreement with the results of previous studies, suggesting that the learning which occurred through reading written drug information might have a small, but significant positive impact on patient behavior.

Conclusion 4: Among Arizona adults enrolled in either GED or remedial courses, reading a PPI improves the likelihood that these persons will overcome barriers to compliance with which they are confronted in simulated medication-taking situations when compared to persons of similar reading ability who do not read any PPI.
Readability Differences Attributable to Format

Most definitions of readability include two components, semantics, syntax and vocabulary, and style or format. It was possible in this study to test for the effects of format on readability, because the PPIs from the AMA, CPhA, NARD and the USP, all based upon the USPDI, are so similar in textual content that they are essentially identical. These PPIs are, however, markedly different in format. It would be possible, therefore, to attribute differences in subject performance to differences in format.

For the variable Satisfaction, persons rated the Test PPI significantly higher than persons rated the Canadian Pharmaceutical Association's SIM. No differences in scores were seen between the Test PPI and the other USPDI-based PPIs; therefore, the difference involving the CPhA SIM probably resulted from the different format used for the CPhA SIM. Several subjects complained that the print used in the SIM was too small to read easily (the print is indeed smaller than that used in the other USPDI-based PPIs). In addition, there is very little "wasted" space in SIM on thiazide diuretics—almost all of the space is filled with text. The PPIs which are similar to the CPhA PPI all make judicious use of "white space".

For the variable "Memory," PPIs from the NARD and the USP resulted in significantly higher cloze comprehension test scores than those obtained by Controls. The AMA PMI and the CPhA SIM, almost identical in textual content to the NARD and USP PPIs, were not
significantly different from Controls. Again, differences in format are most likely responsible for the differences in performance on the cloze comprehension tests.

Conclusion 5: The format of a PPI impacts the comprehension of that PPI by Arizona adults enrolled in either GED or remedial reading courses. Small print, limited use of white space, and interspersion of diagrams within a large amount of text may all contribute to reduce comprehension of the PPIs.

Validity of the Partial Model of Compliance

Few compliance studies have tested Ley's Partial Model of Compliance (Figure 1) since its publication in 1980. In this study, such an evaluation was undertaken for written information, measuring all of the components of Ley's model and then testing the associations among these measurements. Readability of the PPIs and subject reading ability were introduced as additional components to Ley's original model. The resulting model will be referred to as the "New Model" throughout the remainder of the chapter.

Across all study subjects, all components of Ley's original model are included, although not all are associated as Ley predicts (Figure 23). In the new model from the present study, compliance is not significantly associated to understanding nor to satisfaction as Ley predicts. Memory is associated with compliance, but in a direction opposite that suggested by Ley. In addition, multiple regression reveals that memory is a better predictor of understanding,
as measured in this study, than understanding predicts memory. Memory is not significantly associated with satisfaction, although this relationship does appear to be mediated through understanding.

The negative association between memory and compliance suggests that the more patients remember about the negative aspects of their medications, the less likely they would be to overcome barriers to compliance with which they were confronted. This could be tested by having subjects read a PPI and then list all of the facts which they could remember from the information sheet.

It should also be noted that although some components of Ley's model are significantly associated with one another in the present study, many of the relationships are weak, at best. Among the components of Ley's original model, only the associations between understanding and memory is even moderately high, the standardized regression coefficient being 0.306.

Ley's original model is intended to explain the relationships between components as they apply to all forms of patient information, verbal as well as written. In looking specifically at written patient information, two components, PPI readability and subject reading ability, are added to the model as a result of the present study. Patient reading ability and memory actually account for the strongest association between any two components of the New Model (b = 0.427). Again, this relationship is to be expected when considered in terms of the Curtis and Glaser model (Curtis and Glaser 1983). Better readers spend less effort on understanding words as they are read and can
concentrate on the higher-order processes necessary to commit the material being read to memory.

A detailed examination of the relationships between the components of Ley's models within reading grade blocks reveals the reshaping and gradual disintegration of both Ley's original model and the New Model resulting from the present study. At level 3–4–5, the model retains the shape seen in the overall model; however, the associations between components are weaker than in the model for all subjects. The negative association between PPI readability and compliance suggests that persons receiving easier PPIs indicating that the fictitious patient was more likely to overcome the barriers to compliance with which he was confronted.

Within reading grade blocks, it was expected that reading ability would drop out of the model, subjects being blocked by reading grade ability; however, this failed to occur in the 3–4–5 block, suggesting reading abilities should have been grouped differently. Reading ability also appears in the model for the 6–7–8 block, with a weak negative association to compliance. The remainder of the model in the 6–7–8 block consists of memory and understanding, associated to each other, but neither to reading ability nor compliance, giving the model a disjointed appearance (Figure 25).

The negative association between compliance and reading ability may again have resulted from the selective application of the negative aspects of the mediation to the vignettes. A more likely explanation for the unexpected directionality between reading ability
and compliance in the 6-7-8 block may be that persons in this group predicted the fictitious patient's behavior based upon preconceived notions about patient behavior which were not changed by the acquisition of new knowledge. This is theory is supported by the finding that compliance scores from persons reading any PPI were not significantly different from scores of Controls who read no PPI.

Many of the components of the New Model drop out completely for grade blocks 9-12. Only PPI readability, understanding and memory and compliance remain in the model (Figure 26). All relationships are in the expected directions, with the exception of the association between memory and compliance.

At this highest level, objective assessments of PPI difficulty, a readability formula rating, the multiple-choice comprehension test for understanding and the cloze comprehension test for memory are included in the model. The only subjective assessment present in this model is compliance. Subject reading ability is the only objective measurement not to appear in this model. The pilot study (Stratton, Bradley and Hurd 1985) demonstrated that for persons reading at the high school grade levels, people understand written materials equally well regardless of their absolute reading abilities. That is, for persons reading at high school level, there appears to be no association between subject reading ability and performance on the multiple-choice test or on the cloze comprehension tests used in this study.
The subjective rating of satisfaction was not associated with the remaining components of the model. This is consistent with the nonsignificant results of the ANOVA obtained for this variable in the 9-12 reading grade block. Roughly equal satisfaction ratings were awarded all PPIs, so there would be no correlation between components which remain in the model and satisfaction.

Conclusion 6: Ley's original Partial Model of Compliance is not confirmed among Arizona adults enrolled in GED or remedial reading courses. Although all of the components of Ley's original model, understanding, memory, satisfaction and compliance, are included in the New Model which resulted from this study, several of these components are not significantly associated to one another as Ley's model would suggest. Subject reading ability and PPI readability are found to be significantly associated with some elements of Ley's original model, and so appear in the New Model.

Convergent Validity of Difficulty of PPIs

In this study, five separate measures of PPI difficulty were made. Direct measures included the readability formula assessment, the multiple-choice test and the cloze comprehension test. Indirect measures included the satisfaction and compliance scales, which were related to the direct measures of PPI difficulty through the various models described in the previous section.

Convergent validity occurred as one PPI was overall significantly different from the others (either easier or more
difficult) across all variables. Tables 20 to 22 present the rankings of the PPIs across the variables. The Test PPI appears to be easier to read based on the probabilities presented in Chapter 4. For grade levels 3–5, where the Test PPI was not ranked first or second to a significant extent, the AARP MILD was ranked first or second across three of the four variables. The probability of this occurring purely by chance is \((2/7)^3\), or 0.02. With the exception of the rankings in this grade block, the rankings suggest that the Test PPI has convergent validity.

The Test PPI developed by the Principal Investigator consistently received the highest rankings across all variables in two of the three reading level blocks (Tables 20–22). For this PPI, convergent validity could be demonstrated. Likewise, the PPI from the Canadian Pharmaceutical Association would have had convergent validity, receiving the lowest rankings across variables. The rankings of the remaining PPIs vary across variables, so lack this convergent validity. The convergent validity seen for the Test PPI and the CPhA STM becomes less clear in the 3–4–5 grade block.

**Readability Evaluations of Additional PPIs**

Because PPI readability appears as a significantly correlated component in the New Model, it was worthwhile to evaluate PPIs covering drugs or drug classes in addition to the thiazide diuretics. The New Model predicts that the grade level at which a PPI is written will be inversely related to memory and compliance.
The AARP various MILS' were consistently written at the lowest levels, and the NARD PILs were consistently written at the most difficult levels. The CPhA SIMs and the AMA PMI's were between these two extremes. Based upon the New Model, therefore, patients receiving an AARP MILS would be expected to perform better on the various tests given in this study than persons receiving the corresponding NARD PIL.

Incomplete Treatment Cells

Adults reading at less than high school level were intentionally sought out for the purpose of this study. The pilot study (Stratton, Bradley and Hurd 1985) revealed that persons reading above ninth grade level understood written materials regardless of their reading ability and regardless of the difficulty of the material given them. In the GED program, the reading comprehension test is written at ninth grade level (Sonnenblick 1982), so there was no reason to expect persons enrolled in GED classes to be reading at ninth grade or higher. Likewise, most of the persons enrolled in the remedial reading classes at the Community College level would be expected to read at a lower level than most college students (eleventh and twelfth grade in the pilot study).

When considering the population with which this study dealt, it is not surprising that the upper reading grade blocks were not filled. Although among the twenty-five GED students used in the pilot study, only two students read above eighth grade level, an insufficient number of GED students participated in the pilot to
predict this similar outcome with a ten-fold sample size. Statistically speaking, continued data collection among this population of poor adult readers would not yield many additional persons reading above the eighth grade.

**Limitations**

A problem pervasive in the construction of cloze tests is the possibility that one version of a particular cloze passage will be more or less difficult than another version of the same cloze passage. One remedy to this dilemma is to construct and use a number of cloze versions of the same passage corresponding to the number of words in the deletion pattern. That is, if an every fifth word deletion pattern is used, five cloze versions of the same passage would be constructed.

Another alternative is to construct a cloze version using a random deletion pattern. Use of this latter method should help insure that any differences between cloze versions result from random error rather than from systematic error resulting because one set pattern of words is intrinsically more or less difficult than another set pattern.

Use of a random deletion pattern still does not insure that variance seen in cloze scores among different PPIs is not a result of more or less difficult words being deleted from one PPI compared to another. This is more of a concern when two different passages are of similar difficulty. Where two passages differ markedly in difficulty
because most of the words used in one PPI are easy and most of the words in the second PPI are difficult (as evidenced by different readability formula scores for example), then random deletion of words should reflect this difference as well.

Subjects were asked to indicate how likely a fictitious patient would comply with his medication regimen in light of numerous barriers to compliance confronting the patient. By having subjects predict what a third party might do instead of having subjects predict what they themselves would do, it was hoped that greater variance in responses would result. Indeed, a greater variation in responses was seen in the present study than was seen among subjects in the study by Edmundson, et al. (1981), which used self-reporting by subjects. The question remains, however, whether or not the subjects would have made similar estimations had the vignettes required the subjects to indicate how they would act in the situations. An even more difficult question to answer is whether or not subjects would actually behave in a fashion consistent with their responses.

The mean age of study subjects was far below the age commonly encountered when dealing with hypertensive patients. Many subjects admitted that they did not read the PPIs as carefully as they could have, because they were not actively involved with the drug. Subjects who either were themselves hypertensive or who had relatives with hypertension claimed to be very interested in the information presented. In the pilot study, however, prior knowledge/experience with thiazides failed to have a significant impact on subject
satisfaction with the information sheets. Nonetheless, testing instruments used in the present study may have lacked the sensitivity necessary to detect subtle differences in the dependent variables which arose as a result of different levels of interest in the thiazides.

**Future Research**

The impact of written drug information on actual patient medication-taking behavior remains ambiguous. An extension of the present study would be to modify the patient sample to use poor-reading adults who are actually taking antihypertensive medication and monitor their actual compliance in a longitudinal fashion after reading a PPI about their medication. This design could be repeated for patients requiring acute drug therapy (e.g., short-term home antibiotic therapy) to determine if there exists a differential impact of written drug information on short-term and long-term compliance.

Another interesting prospect would be to investigate the impact of different informational media on the components of Ley's Model. In addition to PPIs, slide-tape presentations, videotape presentations, computer-interactive learning programs and group-discussion sessions could be used and compared.

In future research based upon Becker and Maiman's health Belief Model, it would be interesting to incorporate the New Model which resulted from this project to study its impact as one of the "modifying factors" or "cues to action" in the Becker-Maiman model. The New Model at least appears to be related to modifying factors.
including demographics variables and structural variables such as knowledge about the disease. As a cue to action, written information may encourage a patient to make appropriate decisions about medication-taking based upon the content of the PPIs.

**Summary**

Among adults enrolled in high school continuation classes, in Arizona, none of the seven PPIs emerged from the study as clearly superior to the others. When statistical differences did occur, the Test PPI constructed by the Principal Investigator was the only PPI consistently among the easiest to understand. None of the PPIs was clearly the most difficult for this sample of poor readers to understand.

Contrary to the findings of previous studies, written drug information alone did appear to significantly impact patient decisions among poor-reading adults facing medication-taking situations, although the clinical significance of the small difference found is questionable. Moreover, whether or not this form of patient reporting can be extrapolated to actual medication-taking behaviors remains to be tested.

For the sample of adults who participated in the study, many of whom read at less than high school level, all PPIs appear to be equally well understood based upon the results of the multiple-choice tests, cloze comprehension tests and satisfaction and compliance scales used in this study. This finding suggests that for health
professionals whose patient populations include a group of poor readers, provision of any of the commercially-available PPIs to this group should result in similar levels of understanding, information retention, satisfaction and impact on patient behavior.

It appears unnecessary to write special PPIs for this population, although every effort should be made to reconstruct existing PPIs so as to lower the grade levels at which they are written. The fact that the Test PPI was written at three to seven grade levels lower than the commercially-available PPIs, yet compared favorably to these latter documents, demonstrates that these information sheets can be reduced in difficulty while retaining full meaning.
APPENDIX 1

ZIP SCALE FOR DETERMINING INDEPENDENT READING LEVEL
WITH SCORING KEY

| APPENDIX 1 |
| ZIP SCALE FOR DETERMINING INDEPENDENT READING LEVEL          |
| WITH SCORING KEY | |

### Reading Comprehension

<table>
<thead>
<tr>
<th>Level I</th>
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</thead>
<tbody>
<tr>
<td>Reading Answer</td>
<td>Listening Answer</td>
<td></td>
</tr>
<tr>
<td>1. came (a) boy, (b) get, (c) went, (d) jump</td>
<td>1.</td>
<td></td>
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<tr>
<td>2. more (a) less, (b) and, (c) oh, (d) this</td>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3. their (a) have, (b) come, (c) see, (d) our</td>
<td>3.</td>
<td></td>
</tr>
<tr>
<td>4. from (a) too, (b) to, (c) want, (d) two</td>
<td>4.</td>
<td></td>
</tr>
<tr>
<td>5. new (a) old, (b) yes, (c) good, (d) another</td>
<td>5.</td>
<td></td>
</tr>
<tr>
<td>6. happy (a) did, (b) look, (c) sad, (d) green</td>
<td>6.</td>
<td></td>
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<tr>
<td>7. dark (a) are, (b) body, (c) not, (d) light</td>
<td>7.</td>
<td></td>
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<tr>
<td>8. before (a) behind, (b) make, (c) lives, (d) paint</td>
<td>8.</td>
<td></td>
</tr>
<tr>
<td>9. could (a) find, (b) house, (c) can't, (d) will</td>
<td>9.</td>
<td></td>
</tr>
<tr>
<td>10. many (a) that, (b) few, (c) no, (d) made</td>
<td>10.</td>
<td></td>
</tr>
<tr>
<td>11. night (a) day, (b) out, (c) street, (d) farm</td>
<td>11.</td>
<td></td>
</tr>
<tr>
<td>12. back (a) bed, (b) out, (c) dress (d) front</td>
<td>12.</td>
<td></td>
</tr>
<tr>
<td>13. gave (a) in, (b) run, (c) took, (d) years</td>
<td>13.</td>
<td></td>
</tr>
<tr>
<td>14. then (a) now, (b) run, (c) where, (d) eat</td>
<td>14.</td>
<td></td>
</tr>
<tr>
<td>15. first (a) little, (b) last, (c) called, (d) on</td>
<td>15.</td>
<td></td>
</tr>
<tr>
<td>16. these (a) surprise, (b) farm, (c) long, (d) those</td>
<td>16.</td>
<td></td>
</tr>
<tr>
<td>17. something (a) ball, (b) the, (c) nothing, (d) strong</td>
<td>17.</td>
<td></td>
</tr>
<tr>
<td>18. told (a) heard, (b) fast, (c) other, (d) birds</td>
<td>18.</td>
<td></td>
</tr>
<tr>
<td>19. cold (a) some, (b) next, (c) than, (d) warm</td>
<td>19.</td>
<td></td>
</tr>
<tr>
<td>20. there (a) is, (b) here, (c) sleep, (d) hot</td>
<td>20.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reading Score</th>
<th>Listening Score</th>
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<tbody>
<tr>
<td>%</td>
<td>%</td>
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</tbody>
</table>

193
ZIP SCALE SCORING KEY

LEVEL 1

C 1.
A 2.
D 3.
B 4.
A 5.
C 6.
D 7.
A 8.
C 9.
B 10.
A 11.
D 12.
C 13.
A 14.
B 15.
D 16.
C 17.
A 18.
D 19.
B 20.
1. throw  (a) warm, (b) catch, (c) shout, (d) tricks
2. beautiful  (a) really, (b) voice, (c) ugly, (d) felt
3. leave  (a) queer, (b) come, (c) door, (d) keep
4. cover  (a) open, (b) straight, (c) happened, (d) sorry
5. most  (a) mountain, (b) ever, (c) least, (d) city
6. begin  (a) wagon, (b) dance, (c) until, (d) finish
7. ahead  (a) gray, (b) behind, (c) angry, (d) seemed
8. mean  (a) people, (b) else, (c) kind, (d) only
9. enough  (a) need, (b) track, (c) interesting, (d) believe
10. carry  (a) strange, (b) use, (c) place, (d) bank
11. quiet  (a) dressed, (b) seen, (c) large, (d) noise
12. alone  (a) while, (b) together, (c) dollars, (d) bridge
13. sudden  (a) glass, (b) care, (c) slow, (d) act
14. follow  (a) lead, (b) hole, (c) popped, (d) herself
15. different  (a) frighten, (b) kind, (c) almost, (d) same
16. teach  (a) learn, (b) fairy, (c) garage, (d) tied
17. always  (a) suddenly, (b) never, (c) wrong, (d) even
18. young  (a) quickly, (b) because, (c) telephone, (d) old
19. every  (a) none, (b) friend, (c) tired, (d) answered
20. short  (a) wrote, (b) tall, (c) birthday, (d) knock

Reading Score ________%
Listening Score ________%
LEVEL II

B 1.
C 2.
B 3.
A 4.
C 5.
D 6.
B 7.
C 8.
A 9.
C 10.
D 11.
B 12.
C 13.
A 14.
D 15.
A 16.
B 17.
D 18.
A 19.
B 20.
Reading Comprehension

Level III

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<th></th>
<th>Reading Answer</th>
<th>Listening Answer</th>
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<tbody>
<tr>
<td>1. dangerous</td>
<td>(a) weather, (b) harbor, (c) safe, (d) instead</td>
<td>1.</td>
</tr>
<tr>
<td>2. narrow</td>
<td>(a) driving, (b) easier, (c) women, (d) wide</td>
<td>2.</td>
</tr>
<tr>
<td>3. farther</td>
<td>(a) notice, (b) near, (c) worse, (d) signal</td>
<td>3.</td>
</tr>
<tr>
<td>4. neither</td>
<td>(a) language, (b) angry, (c) either, (d) written</td>
<td>4.</td>
</tr>
<tr>
<td>5. awake</td>
<td>(a) promise, (b) sleep, (c) choose, (d) locomotive</td>
<td>5.</td>
</tr>
<tr>
<td>6. enemy</td>
<td>(a) friend, (b) busy, (c) curiosity, (d) fresh</td>
<td>6.</td>
</tr>
<tr>
<td>7. customer</td>
<td>(a) interesting, (b) dangerous, (c) food, (d) seller</td>
<td>7.</td>
</tr>
<tr>
<td>8. question</td>
<td>(a) carried, (b) nodded, (c) reply, (d) festival</td>
<td>8.</td>
</tr>
<tr>
<td>9. seize</td>
<td>(a) understood, (b) return, (c) visit, (d) group</td>
<td>9.</td>
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<tr>
<td>10. cruel</td>
<td>(a) dining, (b) feathers, (c) kind, (d) raised</td>
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<tr>
<td>11. cheerful</td>
<td>(a) sad, (b) engine, (c) lifted, (d) cracked</td>
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<tr>
<td>12. suppose</td>
<td>(a) quietly, (b) terribly, (c) deliver, (d) know</td>
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<td>13. found</td>
<td>(a) countries, (b) possible, (c) lost, (d) usual</td>
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<tr>
<td>14. attack</td>
<td>(a) defend, (b) patched, (c) above, (d) shock</td>
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<td>15. continue</td>
<td>(a) mirror, (b) complete, (c) tasted, (d) statues</td>
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<tr>
<td>16. repaired</td>
<td>(a) ocean, (b) edge, (c) broken, (d) wild</td>
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<tr>
<td>17. tight</td>
<td>(a) traveler, (b) loose, (c) problem, (d) special</td>
<td>17.</td>
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<td>18. bundle</td>
<td>(a) favorite, (b) moment, (c) appeared, (d) piece</td>
<td>18.</td>
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<tr>
<td>19. beat</td>
<td>(a) built, (b) protect, (c) excited, (d) finally</td>
<td>19.</td>
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<tr>
<td>20. against</td>
<td>(a) several, (b) pasture, (c) agree, (d) beautiful</td>
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</table>

Reading Score ____ %
Listening Score ____ %
LEVEL III

C 1.
D 2.
B 3.
C 4.
B 5.
A 6.
D 7.
C 8.
B 9.
C 10.
A 11.
D 12.
C 13.
A 14.
B 15.
C 16.
B 17.
D 18.
B 19.
C 20.
Level IV

1. rough  (a) fear, (b) even, (c) string, (d) shrill
2. charge (a) figure, (b) after, (c) remember, (d) retreat
3. work  (a) pain, (b) every, (c) relax, (d) spinning
4. thickest (a) courage, (b) lawn, (c) trash, (d) paid
5. watchful (a) careless, (b) reason, (c) yours, (d) cruel
6. chummy (a) foolish, (b) lose, (c) expert, (d) huge
7. blame  (a) shrewd, (b) praise, (c) tribe, (d) force
8. adult  (a) labor, (b) train, (c) couple, (d) youth
9. action  (a) narrow, (b) avoid, (c) stable, (d) alert
10. strength (a) smart, (b) rude, (c) weakness, (d) sigh
11. bunch  (a) ability, (b) separate, (c) capable, (d) harmony
12. noise  (a) emperor, (b) absence, (c) length, (d) calm
13. polished (a) rough, (b) evidently, (c) graduate, (d) mission
14. native  (a) garment, (b) mortal, (c) foreign, (d) needle
15. original (a) educate, (b) copy, (c) absolute, (d) honestly
16. glance  (a) canal, (b) frequent, (c) imply, (d) glare
17. dull  (a) sharp, (b) doctrine, (c) abundance, (d) mixture
18. hollow (a) accuse, (b) collection, (c) solid, (d) beggar
19. actual  (a) daughter, (b) imaginary, (c) noisyly, (d) blanket
20. motion (a) afraid, (b) vacation, (c) chiefly, (d) pause

Reading Score  __________%
Listening Score  __________%
Reading Comprehension

Level V

1. beckon (a) inclusive, (b) pursue, (c) beach, (d) tackle
   Reading Answer

2. tourist (a) chapel, (b) revolt, (c) prospect, (d) resident
   Listening Answer

3. conquer (a) lunges, (b) died, (c) defeat, (d) haze

4. miserable (a) withdraw, (b) replace, (c) origin, (d) glorious

5. motionless (a) movement, (b) flung, (c) sack, (d) selfish

6. consent (a) society, (b) deny, (c) license, (d) ornament

7. confuse (a) canopy, (b) wrong, (c) connect, (d) explain

8. dismiss (a) character, (b) rarity, (c) hire, (d) protection

9. rigid (a) accept, (b) plastic, (c) nephew, (d) casual

10. generous (a) guard, (b) bright, (c) injury, (d) miserly

11. twilight (a) dawn, (b) romance, (c) quiet, (d) multitude

12. similar (a) liquid, (b) portrait, (c) different, (d) greedy

13. proceed (a) chute, (b) occupied, (c) return, (d) muscle

14. shrewd (a) proclaim, (b) distant, (c) resistance, (d) dense

15. public (a) individual, (b) cured, (c) weak, (d) mercy

16. support (a) sparkle, (b) republic, (c) wreck, (d) idle

17. request (a) occupation, (b) demand, (c) luster, (d) plus

18. burden (a) faint, (b) spite, (c) previous, (d) lighten

19. ridiculous (a) sensible, (b) answer, (c) ounce, (d) research

20. severe (a) mysterious, (b) confident, (c) mild, (d) fierce

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Reading Score _____%
Listening Score _____%
## Reading Comprehension

### Level V

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<td>20.</td>
<td>20. __</td>
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### Vocabulary

- **beckon**: (a) inclusive, (b) pursue, (c) beach, (d) tackle
- **tourist**: (a) chapel, (b) revolt, (c) prospect, (d) resident
- **conquer**: (a) lunge, (b) died, (c) defeat, (d) haze
- **miserable**: (a) withdraw, (b) replace, (c) origin, (d) glorious
- **motionless**: (a) movement, (b) flung, (c) sack, (d) selfish
- **consent**: (a) society, (b) deny, (c) license, (d) ornament
- **confuse**: (a) canopy, (b) wrong, (c) connect, (d) explain
- **dismiss**: (a) character, (b) rarely, (c) hire, (d) protection
- **rigid**: (a) accept, (b) plastic, (c) nephew, (d) casual
- **generous**: (a) guard, (b) bright, (c) injury, (d) miserly
- **twilight**: (a) dawn, (b) romance, (c) quiet, (d) multitude
- **similar**: (a) liquid, (b) portage, (c) different, (d) greedy
- **proceed**: (a) chute, (b) occupied, (c) return, (d) muscle
- **shrewd**: (a) proclaim, (b) darken, (c) resistance, (d) dense
- **public**: (a) individual, (b) cured, (c) weak, (d) mercy
- **support**: (a) spartak, (b) republic, (c) wreck, (d) idle
- **request**: (a) occupation, (b) demand, (c) luster, (d) plus
- **burden**: (a) faint, (b) spice, (c) previous, (d) lighten
- **ridiculous**: (a) sensible, (b) answer, (c) ounce, (d) research
- **severe**: (a) mysterious, (b) confident, (c) mild, (d) fierce

### Reading Score ___

### Listening Score ___
LEVEL V

B 1.
D 2.
C 3.
D 4.
A 5.
B 6.
D 7.
C 8.
B 9.
D 10.
A 11.
C 12.
C 13.
D 14.
A 15.
C 16.
B 17.
D 18.
A 19.
C 20.
### Level VI

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<th>Reading</th>
<th>Answer</th>
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<th>Answer</th>
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<tbody>
<tr>
<td>1. annual</td>
<td>(a) fruitful, (b) charm, (c) daily, (d) terror</td>
<td>1. ___</td>
<td>1. ___</td>
</tr>
<tr>
<td>2. miniature</td>
<td>(a) fatal, (b) immense, (c) knotted, (d) harmony</td>
<td>2. ___</td>
<td>2. ___</td>
</tr>
<tr>
<td>3. flourish</td>
<td>(a) anxiety, (b) mingle, (c) whether, (d) fade</td>
<td>3. ___</td>
<td>3. ___</td>
</tr>
<tr>
<td>4. ally</td>
<td>(a) enemy, (b) squawk, (c) continent, (d) accident</td>
<td>4. ___</td>
<td>4. ___</td>
</tr>
<tr>
<td>5. acquire</td>
<td>(a) sirens, (b) humidity, (c) dispose, (d) brace</td>
<td>5. ___</td>
<td>5. ___</td>
</tr>
<tr>
<td>6. amateur</td>
<td>(a) professional, (b) arid, (c) dwell, (d) quarter</td>
<td>6. ___</td>
<td>6. ___</td>
</tr>
<tr>
<td>7. horizontal</td>
<td>(a) devotion, (b) ignorant, (c) lecture, (d) vertical</td>
<td>7. ___</td>
<td>7. ___</td>
</tr>
<tr>
<td>8. sparse</td>
<td>(a) fetch, (b) meer, (c) dense, (d) flick</td>
<td>8. ___</td>
<td>8. ___</td>
</tr>
<tr>
<td>9. departure</td>
<td>(a) essential, (b) arrival, (c) legislature, (d) marvel</td>
<td>9. ___</td>
<td>9. ___</td>
</tr>
<tr>
<td>10. idle</td>
<td>(a) period, (b) solve, (c) engaged, (d) ancestor</td>
<td>10. ___</td>
<td>10. ___</td>
</tr>
<tr>
<td>11. differ</td>
<td>(a) immense, (b) agree, (c) liberal, (d) heir</td>
<td>11. ___</td>
<td>11. ___</td>
</tr>
<tr>
<td>12. luxury</td>
<td>(a) indigo, (b) welcome, (c) ranger, (d) poverty</td>
<td>12. ___</td>
<td>12. ___</td>
</tr>
<tr>
<td>13. manual</td>
<td>(a) automatic, (b) evident, (c) build, (d) diet</td>
<td>13. ___</td>
<td>13. ___</td>
</tr>
<tr>
<td>14. contaminate</td>
<td>(a) wrenched, (b) perfection, (c) urge, (d) purify</td>
<td>14. ___</td>
<td>14. ___</td>
</tr>
<tr>
<td>15. abolish</td>
<td>(a) gallery, (b) impress, (c) establish, (d) elevation</td>
<td>15. ___</td>
<td>15. ___</td>
</tr>
<tr>
<td>16. conclude</td>
<td>(a) dignified, (b) initiate, (c) neatly, (d) digest</td>
<td>16. ___</td>
<td>16. ___</td>
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<tr>
<td>17. insulate</td>
<td>(a) expose, (b) gratitude, (c) basement, (d) jealous</td>
<td>17. ___</td>
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<td>18. acknowledge</td>
<td>(a) conquest, (b) hint, (c) refuse, (d) yonder</td>
<td>18. ___</td>
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<tr>
<td>19. create</td>
<td>(a) destroy, (b) proceeding, (c) behave, (d) stow</td>
<td>19. ___</td>
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<td>20. applaud</td>
<td>(a) powder, (b) gesture, (c) exceed, (d) denounce</td>
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**Reading Score** ___

**Listening Score** ___
C 1.
B 2.
D 3.
A 4.
C 5.
A 6.
D 7.
C 8.
B 9.
C 10.
B 11.
D 12.
A 13.
D 14.
C 15.
B 16.
A 17.
C 18.
A 19.
D 20.
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<tr>
<td>1. <strong>simplify</strong></td>
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<td>2. <strong>destructive</strong></td>
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<td>4. <strong>specify</strong></td>
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<td>5. <strong>barbarous</strong></td>
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<td>6. <strong>scrawny</strong></td>
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<td>7. <strong>approximate</strong></td>
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<td>8. <strong>precisely</strong></td>
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<td>9. <strong>cherish</strong></td>
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<td>10. <strong>detached</strong></td>
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<td>11. <strong>nourish</strong></td>
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<td>12. <strong>attentive</strong></td>
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<td>13. <strong>modest</strong></td>
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<td>14. <strong>camouflage</strong></td>
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<td>15. <strong>suspend</strong></td>
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<td>16. <strong>beneficiary</strong></td>
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<td>17. <strong>definition</strong></td>
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<td>18. <strong>upright</strong></td>
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<td>19. <strong>flatter</strong></td>
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<td>20. <strong>browse</strong></td>
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Reading Score: ___%
Listening Score: ___%
LEVEL VII

A 1.
B 2.
C 3.
D 4.
A 5.
B 6.
D 7.
C 8.
B 9.
D 10.
D 11.
C 12.
A 13.
B 14.
D 15.
B 16.
C 17.
A 18.
C 19.
B 20.
| 1. absolute | (a) instinct, (b) incomplete, (c) lyre, (d) diagonal | 1. | 1. |
| 2. delicacy | (a) vulgarity, (b) wriggle, (c) cuss, (d) stammer | 2. | 2. |
| 3. liable | (a) squeak, (b) recline, (c) meridian, (d) exempt | 3. | 3. |
| 4. vast | (a) ignite, (b) confined, (c) esquire, (d) deceit | 4. | 4. |
| 5. determined | (a) wavering, (b) calamity, (c) jewel, (d) offend | 5. | 5. |
| 6. absurdity | (a) canopy, (b) artistry, (c) certainty, (d) interest | 6. | 6. |
| 7. continuance | (a) wrench, (b) arrest, (c) tundra, (d) solemn | 7. | 7. |
| 8. vouch | (a) stub, (b) racial, (c) meek, (d) contradict | 8. | 8. |
| 9. liberate | (a) ingot, (b) restrain, (c) heathe, (d) drool | 9. | 9. |
| 10. vague | (a) conscious, (b) beacon, (c) alibi, (d) definite | 10. | 10. |
| 11. apparent | (a) shed, (b) principle, (c) doubtful, (d) impulsive | 11. | 11. |
| 12. crop | (a) heifer, (b) lengthen, (c) elegance, (d) theory | 12. | 12. |
| 13. forlorn | (a) secure, (b) delighted, (c) tidal, (d) journal | 13. | 13. |
| 14. appropriate | (a) give, (b) train, (c) suede, (d) readily | 14. | 14. |
| 15. unity | (a) plot, (b) odorous, (c) immortal, (d) diversity | 15. | 15. |
| 16. reluctant | (a) voluntary, (b) endear, (c) egotist, (d) lair | 16. | 16. |
| 17. imply | (a) leash, (b) gush, (c) describe, (d) neutral | 17. | 17. |
| 18. transact | (a) lapel, (b) function, (c) activity, (d) impede | 18. | 18. |
| 19. revive | (a) abide, (b) wither, (c) appraise, (d) infidel | 19. | 19. |
| 20. cease | (a) jest, (b) lofty, (c) militia, (d) institute | 20. | 20. |

Reading Score _____%  
Listening Score _____%
### Reading Comprehension

#### Level IX

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<td>(a) adorn, (b) accept, (c) chaste, (d) topaz</td>
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<td>2. defame</td>
<td>(a) exult, (b) tendon, (c) viewpoint, (d) turbine</td>
<td>2. 2.</td>
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<td>3. particular</td>
<td>(a) tension, (b) sphere, (c) rally, (d) infinite</td>
<td>3. 3.</td>
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<td>4. sensation</td>
<td>(a) paralysis, (b) refine, (c) crater, (d) latter</td>
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<td>5. intolerant</td>
<td>(a) incision, (b) fruitless, (c) consoling, (d) fabulous</td>
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<td>6. reluctance</td>
<td>(a) fantasy, (b) enthusiasm, (c) eligible, (d) crimson</td>
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<td>7. celestial</td>
<td>(a) confusa, (b) bustle, (c) valiant, (d) earthly</td>
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<tr>
<td>8. apprehend</td>
<td>(a) petition, (b) release, (c) tracer, (d) soluble</td>
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<td>9. invigorate</td>
<td>(a) reside, (b) obligation, (c) impair, (d) jovial</td>
<td>9. 9.</td>
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<tr>
<td>10. scanty</td>
<td>(a) irk, (b) hormone, (c) express, (d) ample</td>
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<td>11. delusion</td>
<td>(a) actuality, (b) demote, (c) conflict, (d) acuse</td>
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<td>12. authentic</td>
<td>(a) venom, (b) turmoil, (c) spurious, (d) unravel</td>
<td>12. 12.</td>
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<td>13. discord</td>
<td>(a) trod, (b) agreement, (c) plough, (d) initial</td>
<td>13. 13.</td>
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<td>14. nomad</td>
<td>(a) resident, (b) galleon, (c) fraternal, (d) gauge</td>
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<td>15. ravishing</td>
<td>(a) disgusting, (b) emerging, (c) discount, (d) outlying</td>
<td>15. 15.</td>
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<td>16. ruthless</td>
<td>(a) concept, (b) access, (c) merciful, (d) suitor</td>
<td>16. 16.</td>
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<td>17. censor</td>
<td>(a) strand, (b) propel, (c) instead, (d) laud</td>
<td>17. 17.</td>
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<tr>
<td>18. articulate</td>
<td>(a) mute, (b) jurist, (c) foul, (d) garb</td>
<td>18. 18.</td>
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<td>19. reimburse</td>
<td>(a) buffet, (b) dignify, (c) embezzle, (d) carees</td>
<td>19. 19.</td>
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<td>20. hesitant</td>
<td>(a) casual, (b) fluent, (c) antics, (d) emotion</td>
<td>20. 20.</td>
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</table>

### Reading Score %

### Listening Score %
LEVEL IX

B 1.
A 2.
D 3.
A 4.
C 5.
B 6.
D 7.
B 8.
C 9.
D 10.
A 11.
C 12.
B 13.
A 14.
A 15.
C 16.
D 17.
A 18.
C 19.
B 20.
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<th>1. abdicate</th>
<th>(a) rue, (b) lass, (c) retain, (d) knob</th>
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<td>2. adequate</td>
<td>(a) wistful, (b) superb, (c) unsuited, (d) lea</td>
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<td>3. harass</td>
<td>(a) havoc, (b) aid, (c) valor, (d) psychological</td>
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<td>4. deficiency</td>
<td>(a) subside, (b) surplus, (c) motto, (d) rehearsal</td>
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<td>5. tonic</td>
<td>(a) respite, (b) depressant, (c) frisk, (d) retainer</td>
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<td>6. recede</td>
<td>(a) sponsor, (b) abrupt, (c) ensemble, (d) progress</td>
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<td>7. tolerant</td>
<td>(a) enclosure, (b) prejudiced, (c) weak, (d) stockade</td>
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<td>8. prominent</td>
<td>(a) mastery, (b) chaos, (c) obscure, (d) gnat</td>
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<td>9. salutation</td>
<td>(a) vista, (b) oblivious, (c) inject, (d) conclusion</td>
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<td>10. initial</td>
<td>(a) promulge, (b) destitute, (c) incidental, (d) terminal</td>
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<td>11. facsimile</td>
<td>(a) envoy, (b) equator, (c) variance, (d) enhance</td>
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<td>12. prelude</td>
<td>(a) completion, (b) motif, (c) halter, (d) indent</td>
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<td>13. resurrection</td>
<td>(a) lap, (b) cringe, (c) dictation, (d) demise</td>
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<td>14. acclamation</td>
<td>(a) battle, (b) citation, (c) disapproval, (d) undue</td>
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<td>15. befit</td>
<td>(a) unsuitable, (b) chide, (c) prodigy, (d) onyx</td>
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<td>16. compulsion</td>
<td>(a) oracle, (b) gait, (c) liberty, (d) discord</td>
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<td>(a) fungus, (b) mellow, (c) rogue, (d) careless</td>
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<td>18. elude</td>
<td>(a) solicit, (b) digest, (c) confide, (d) gavel</td>
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<td>19. comply</td>
<td>(a) mark, (b) reject, (c) humus, (d) officiate</td>
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<td>20. garnish</td>
<td>(a) galley, (b) divine, (c) inert, (d) obliterate</td>
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LEVEL X

C 1.
C 2.
B 3.
B 4.
B 5.
D 6.
B 7.
C 8.
D 9.
D 10.
C 11.
A 12.
D 13.
C 14.
A 15.
C 16.
D 17.
A 18.
B 19.
D 20.
### Reading Comprehension

#### Level XI

| 1. abhor | (a) virtually, (b) trait, (c) slight, (d) esteem | Reading Answer | 1. ___ |
| 2. compensation | (a) penalty, (b) potion, (c) futile, (d) distort | 2. ___ |
| 3. daunt | (a) chase, (b) unstable, (c) encourage, (d) squall | 3. ___ |
| 4. elation | (a) notary, (b) misery, (c) litter, (d) gala | 4. ___ |
| 5. fabricate | (a) durable, (b) conduct, (c) affirm, (d) disintegrate | 5. ___ |
| 6. garrulous | (a) reserved, (b) warp, (c) slung, (d) ordain | 6. ___ |
| 7. sanction | (a) vigorous, (b) format, (c) censure, (d) docile | 7. ___ |
| 8. impartial | (a) chamois, (b) biased, (c) agitate, (d) metric | 8. ___ |
| 9. justify | (a) tweak, (b) snare, (c) prone, (d) incriminate | 9. ___ |
| 10. latitude | (a) vigor, (b) petite, (c) muffle, (d) equip | 10. ___ |
| 11. malice | (a) scald, (b) canter, (c) sympathy, (d) effigy | 11. ___ |
| 12. obverse | (a) file, (b) evolve, (c) genial, (d) lanky | 12. ___ |
| 13. relish | (a) husk, (b) distaste, (c) incisor, (d) jasmine | 13. ___ |
| 14. perverse | (a) yielding, (b) whence, (c) lunar, (d) penance | 14. ___ |
| 15. lenient | (a) kinetic, (b) inquest, (c) exacting, (d) wretched | 15. ___ |
| 16. naïve | (a) sophisticated, (b) villa, (c) surmise, (d) trivial | 16. ___ |
| 17. obscure | (a) warily, (b) stamina, (c) undisputed, (d) ovation | 17. ___ |
| 18. martial | (a) impudence, (b) medley, (c) meek, (d) disaud | 18. ___ |
| 19. nautical | (a) curtail, (b) refract, (c) neutral, (d) ambulatory | 19. ___ |
| 20. lunacy | (a) rationality, (b) prowess, (c) leaven, (d) transcend | 20. ___ |

**Reading Score** ___
**Listening Score** ___

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**Notes:**

- Words are paired with their antonyms to test understanding of word meaning.
- Students are asked to choose the correct antonym from the options provided.
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<td>A 20</td>
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Level XII

1. concede (a) dispute, (b) historical, (c) breed, (d) roam
2. suppress (a) newly, (b) forge, (c) advertise, (d) dove
3. rise (a) fortunately, (b) informally, (c) wrong, (d) nominate
4. traverse (a) hearth, (b) irregular, (c) remain, (d) crude
5. requisite (a) wove, (b) offender, (c) tweed, (d) unnecessary
6. vivacious (a) sailed, (b) utter, (c) polarize, (d) justice
7. prudent (a) label, (b) excessive, (c) impetuous, (d) rheumatic
8. resolve (a) irritate, (b) vacancy, (c) ominous, (d) task
9. haggard (a) exuberant, (b) oppress, (c) lease, (d) reason
10. provincial (a) lawful, (b) national, (c) judicial, (d) oaken
11. dispersal (a) upwards, (b) obedient, (c) windy, (d) collective
12. yore (a) prosecute, (b) bedlam, (c) futurity, (d) mortar
13. willful (a) summary, (b) accidental, (c) defile, (d) moral
14. wane (a) bleak, (b) augment, (c) groovy, (d) observance
15. wince (a) luckily, (b) novelize, (c) gorge, (d) smile
16. heresy (a) numb, (b) abnormal, (c) belief, (d) diffuse
17. illicit (a) abyss, (b) legitimate, (c) feud, (d) liability
18. incautious (a) deliberate, (b) ode, (c) grange, (d) impel
19. latent (a) chilly, (b) feeder, (c) blur, (d) obvious
20. prolific (a) juror, (b) footage, (c) singular, (d) epic

Reading Comprehension

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<th>Listening Answer</th>
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Reading Score ______%  
Listening Score ______%
LEVEL XII

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B 3.
C 4.
D 5.
A 6.
C 7.
C 8.
A 9.
B 10.
D 11.
C 12.
B 13.
B 14.
D 15.
C 16.
B 17.
A 18.
D 19.
C 20.
APPENDIX 2

RANDOM PPI ASSIGNMENT SCHEME USED WITHIN EACH READING GRADE BLOCK

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APPENDIX 3

THIAZIDE PATIENT PACKAGE INSERTS
USED IN STUDY

American Association of Retired Persons'
Medication Information Leaflet for Seniors

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Information your Doctor needs:

Do you have or have you ever had:
- An allergy reaction to thiazides or "sulfur" drugs?
- Diabetes, kidney or liver disease?
- Gout?
- Lupus or rheumatoid arthritis?

Are you taking:
- Heart medicines (Digoxin, Digibid)?
- Lithium carbonate or phenobarbital?
- Medicines for diabetes?
- Narcotic pain medications?
- Alcohol?

Possible side effects:

These can be bothersome at times. But do not stop taking Thiazides unless your doctor tells you.

---

Important Information about You and your Medication...

Thiazide and Related Drugs

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Name of your medication:
Thiazide and Related Drugs

Other names:
Hydrochlorothiazide (Hydrdiuril, Esidrix)
Chlorothiazide (Diuuril), Chlorthalidone (Hygroton)

What is it?
They are diuretics or water pills.

What is it for?
• They are used to lower high blood pressure.
• Thiazide drugs help the body get rid of extra salt and water due to heart, liver or kidney disease

How long will you have to take it?
• Probably for the rest of your life
• This medicine cannot cure high blood pressure, but it taken as directed, can help control it

How should you take this medication?
• Take as directed, preferably in the morning after breakfast.
• Try to take every day at the same time.
• If you take two doses a day, take the second one in the evening before dinner
• Do not take two doses at the same time.
• If you forget to take the first dose, take only your usual second dose.
• Do not take after dinner. It may interrupt your sleep and cause you to urinate (pass water)
• Do NOT stop taking if you feel better.

Things to remember:
• Do not rise quickly after lying down or sitting. You may feel dizzy or lightheaded.

Check yourself:
• If you feel dizzy, sit up slowly, put legs over the side of the bed, and stay there for a few minutes.
• Some people think because Thiazides are taken to remove fluids from the body, they must restrict fluid or water intake. This is wrong. Continue to drink normal amounts of fluid.
• When you first take Thiazide drugs, you may urinate more often. If this is very inconvenient, do NOT stop taking the drug. Call your doctor. Perhaps they can be taken at a different time.
• Thiazide drugs may cause your body to lose salt and water. Your doctor may recommend foods rich in potassium such as bananas or oranges, or you may be given a prescription for a potassium drug. Do not take potassium supplements unless prescribed by your doctor.
• Thiazides may make you more likely to sunburn. Avoid too much heat, sunlight, saunas, or hot baths.

• If you have shortness of breath or swelling of hands or feet, call your doctor.
American Medical Association's
Patient Medication Instruction Sheet

Thiazide Diuretics

Patient Medication Instruction Sheet

For: ____________________________

Drug Prescribed: ____________________________

Directions for Use: ____________________________

Special Instructions: ____________________________

Please Read This Information Carefully

This sheet tells you about the medicine your doctor has just prescribed for you. If any of this information causes you special concern, check with your doctor. Keep this and all other medicines out of the reach of children.

Uses of This Medicine
This medicine is commonly used to treat high blood pressure. It also is used in heart and kidney problems to help reduce the amount of salt and water in the body by increasing the flow of urine. Thiazide diuretics also may be prescribed for other conditions as determined by your doctor. Take this medicine only as directed by your doctor.

Before Using This Medicine
BE SURE TO TELL YOUR DOCTOR IF YOU...

- are allergic to this medicine or to sulfa drugs,
- are pregnant or intent to become pregnant while using this medicine,
- are breast-feeding,
- are taking any other prescription or nonprescription medication, or have any other medical problems.

Proper Use of This Medicine

DIRECTLY
When you begin to take this medicine, you may notice an increase in the amount of urine and in your frequency of urination. In order to keep the increase in urine from affecting your nighttime sleep, follow this regimen:
- If you take one dose a day, take it in the morning after breakfast.
- If you take one dose a day, take it in the morning after breakfast.
- If you are taking more than one dose a day, take the last dose no later than 8 p.m. unless otherwise directed by your doctor.

If you miss a dose of this medicine, take it as soon as possible unless it is almost time for your next dose. In this case, do not take the missed dose at all and do not double the next one. Instead, go back to your regular dosing schedule.
FOR HIGH BLOOD PRESSURE

It is high blood pressure is not treated, it can cause serious problems such as heart failure, stroke, blood vessel disease, stroke, or kidney disease. Remember that this medicine will not cure your high blood pressure, but it does help control it. Therefore, you must continue to take the medicine as directed—even if you feel well—if you expect to keep your blood pressure down.

Precautions While Using This Medicine

This medicine may cause a loss of potassium from your body. To help prevent this, your doctor may want you to:
- eat or drink foods that have a high potassium content (for example, orange or other citrus fruit juice); or
- take a potassium supplement; or
- take another medicine to help prevent the loss of potassium in the first place; or
- reduce your salt intake and/or use a salt substitute.

Be sure to check with your doctor, however, before changing your diet on your own. Loss of appetite, vomiting, or diarrhea may cause a further loss of potassium and you should inform your doctor if these events occur.

Do not take other medicines unless they have been discussed with your doctor. This especially includes over-the-counter (OTC) or nonprescription medicines for appetite control, asthma, colds, cough, hay fever, or sinus, since they may tend to increase your blood pressure.

Side Effects of This Medicine

SIDE EFFECTS THAT SHOULD BE REPORTED TO YOUR DOCTOR

- Increased sensitivity of skin to sunlight
- Nausea and vomiting
- Unusual redness or weakness
- Unexplained sore throat
- Loss of appetite
- Irregular heartbeat
- Skin rash or hives

SIDE EFFECTS THAT MAY NOT REQUIRE IMMEDIATE MEDICAL ATTENTION BUT SHOULD BE REPORTED TO YOUR DOCTOR IF THEY PERSIST MORE THAN 1 DAY OR TWO

- Diarrhea
- Decrease in sexual ability
- Diarrhea or light-headedness
- Headache
- When getting up
- Lightheadedness
- Pain
- When getting up
- Rash
- Skin rash or hives
- Sensitivity
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**THIAZIDE DIURETICS**
(Systemic—Oral)
Supplementary Information on Medication

This medicine may cause you to have an unusual feeling of tiredness when you begin to take it. You may also notice an increase in the amount of urine or in your frequency of urination. After taking the medicine for a while, these effects should lessen. In order to keep the increase in urine from affecting your nighttime sleep:
- If you are to take a single dose a day, take it in the morning after breakfast.
- If you are to take more than one dose a day, take the last dose no later than 6 p.m., unless otherwise directed by your doctor.

However, it is best to plan your dose or doses according to a schedule that will least affect your personal activities and sleep. Ask your doctor, nurse, or pharmacist to help you plan the best time to take this medicine.

If you miss a dose of this medicine, take it as soon as possible. If it is almost time for your next dose, do not take the missed dose at all and do not double the next one. Instead, go back to your regular dosing schedule. If you have any questions about this, check with your doctor or pharmacist.
This medicine may cause a loss of potassium from your body. To help prevent this, or to bring the body potassium back to normal, your doctor may want you to:

- eat or drink foods that have a high potassium content (for example, orange or other citrus fruit juices), or
- take a potassium supplement, or
- take another medicine to help prevent the loss of potassium.

It is very important to follow these directions. Also, it is very important not to change your diet on your own. This is more important if you are already on a special diet (as for diabetes), or if you are taking a potassium supplement or a medicine to reduce potassium loss. Extra potassium may not be necessary and, in some cases, too much potassium could be harmful.

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects appear very often, when they do occur they may require medical attention. Check with your doctor if any of the following side effects occur:

- severe stomach pain with nausea and vomiting
- skin rash or hives
- unexplained sore throat and fever
- dryness of mouth
- increased thirst
- irregular heartbeats

ALWAYS REMEMBER:

+ Tell any other doctor, dentist, or pharmacist that you see that you are taking this medicine.
+ In order to decide on the best treatment for your medical problem, your doctor should be told if you are allergic to this medicine. If you are pregnant or if you intend to become pregnant while using this medicine, if you are breast-feeding an infant, if you are taking any other medicine, or if you have any other medical problems.

Developed by the Canadian Pharmaceutical Association in co-operation with the Health Protection Branch, Health & Welfare Canada, the medical profession, and medication users. Adapted from the USP DI. 1981, USP Convention. April 1982
Thiazide Diuretics

About Your Medicine
Thiazide diuretics are commonly used to treat high blood pressure. They are used also to help reduce the amount of water in the body by increasing the flow of urine. Thiazide diuretics may also be used for other conditions as determined by your doctor.

If any of the information in this leaflet causes you special concern or if you want additional information about your medicine and its use, check with your doctor or pharmacist. Remember, keep this and all other medicines out of the reach of children and never share your medicines with others.

Before Using This Medicine
Tell your doctor and pharmacist if you...
• are allergic to any medicine, particularly sulfa medicine;
• are pregnant or intend to become pregnant while using this medicine;
• are breast-feeding an infant;
• are taking any other prescription or nonprescription (OTC) medicine, especially corticosteroids (corticosteroid-like medicines); digoxin glycosides (heart medicine); lithium; or medicines for acne, control, asthma, colds, cough, hay fever, or sinus;
• have any other medical problems, especially kidney disease.

Proper Use of This Medicine
Thiazide diuretics may cause you to have an unusual feeling of tiredness when you begin to take them. You may also notice an increase in the amount of urine or in your frequency of urination. After taking the medicine for awhile, these effects should lessen. In order to keep the increase in urine from affecting your nighttime sleep:
• if you are to take a single dose a day, take it in the morning after breakfast;
• if you are to take more than one dose a day, take the last dose no later than 6 p.m.
If you are taking this medicine for high blood pressure, remember that it will not cure your high blood pressure but it does help control it. Therefore, you must continue to take it as directed if you expect to keep your blood pressure down. You may have to take medicine for the rest of your life.

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, do not take the missed dose at all and do not double the next one. Instead, go back to your regular daily schedule.

**Precautions While Using This Medicine**

This medicine may cause a loss of potassium from your body. To help prevent this, your doctor may want you to:

* eat or drink foods that have a high potassium content, or
* take a potassium supplement, or
* take another medicine to help prevent the loss of the potassium in the first place. It is very important to follow these directions. Also, it is important not to change your diet on your own and to check with your doctor if you become sick and have severe or continuing vomiting or diarrhea.

**Side Effects of This Medicine**

**Side Effects Which Should Be Reported To Your Doctor**

- Flank or stomach pain
- Severe stomach pain
- Unusual bleeding or bruising
- Joint pain
- with nausea and vomiting
- Sore throat and fever
- Skin rash or hives
- Yellowing of eyes or skin

**Signs of Too Much Potassium Loss**

- Dryness of mouth
- Mood changes
- Unusual tiredness or weakness
- Increased thirst
- Muscle cramps or pain
- Nausea or vomiting
- Weak pulse

**Side Effects Which Usually Do Not Require Medical Attention**

These possible side effects may go away during treatment however, if they continue or are bothersome, check with your doctor or pharmacist:

- Dizziness or light-headedness when standing up
- Increased sensitivity
- Diarrhea
- Sore throat
- Headache
- Loss of appetite

Other side effects not listed above may also occur in some patients. If you notice any other side effects, check with your doctor or pharmacist.

The information above has been selectively abstracted from the United States Pharmacopeia (USP) database for use as an educational aid only. It is not intended as individualized advice. It does not cover all possible uses, actions, precautions, side effects, contraindications, or interactions of this medicine. All medicines should be taken properly and with care. Consult your pharmacist or doctor should you have questions concerning any medication you are taking.

(1983 The United States Pharmacopeia Convention, Inc., which is solely responsible for its content. This leaflet is provided as a service of your pharmacist and the National Association of Retail Druggists.)
Test Patient Package Insert (PPI)

UNIVERSITY OF ARIZONA
COLLEGE OF PHARMACY
PATIENT DRUG INFORMATION SHEET

Patient Name
Instructions

TRIAZIDES

Triazides are also known as "water pills." These drugs are used to treat high blood pressure. They work by causing your body to get rid of water and salt, which lowers blood pressure. These drugs cannot cure high blood pressure, but they can help to keep your blood pressure under control. You may have to take these drugs for the rest of your life.

BEFORE USING THESE DRUGS, TELL YOUR DOCTOR IF

* Sulfa drugs cause you to have a rash, fever, sore throat, breathing problems or bruises.
* You are pregnant and your doctor does not know it.
* You have had kidney disease or liver disease, or have had problems with your kidneys or liver.
* You or your family have any long-term illness.
* You are taking any other drugs.
* You plan to have surgery in the near future.
* You are taking any other drugs ordered by a doctor or which you can buy without a doctor's order.

HOW LONG BEFORE THE DRUG WORKS?

You should begin going to the bathroom more often 2 hours after taking the drug. This effect should peak 4 to 6 hours after you take the drug, and should wear off 8 to 12 hours after you take the drug. If you are going to the bathroom so often that it becomes a problem, do not stop taking the drug. Check with your doctor to see if there is a better time for you to take the drug. You will have to use the drug each day for about 2 to 3 weeks before your blood pressure begins to go down.
COMMON SIDE-EFFECTS

*You may become dizzy when you get up from sitting or lying down. Get up more slowly the first few days until your body gets used to the drug.

*If you have diabetes, these drugs may cause your blood sugar may go up. Check with your doctor.

*If you have gout, these drugs may cause you to have gout attacks. Check with your doctor.

*These drugs make your body lose potassium along with the water and the salt. You may feel very weak, very tired or have muscle cramps from a loss of potassium. Your doctor may want you to eat foods which are high in potassium like bananas, dates, figs, peaches, prunes or raisins.

LESS-COMMON SIDE-EFFECTS

The side effects listed below should clear up by themselves within a few days. If they last more than one week, call your doctor.

*You may not feel like eating as much.

*You may get an upset stomach or you may vomit.

*You may get diarrhea.

*You may get headaches or become dizzy.

*Your vision may blur or things may appear yellow.

DANGEROUS SIDE-EFFECTS

If any of the side effects in the next list occur, stop the drug right away and call your doctor.

*If you get a fever which you cannot explain.

*If you get a skin rash or hives.

*If you notice that your skin or the whites of your eyes turn yellow.

*If you have a severe asthma attack or a sudden problem breathing.

*If you get severe stomach pains that will not go away.

*If you feel very weak, vomit all the time or get a heartbeat that does not feel normal.

*If you get a sore throat, or if you bleed or bruise for no reason.
CAUTION

Do not take more of these drugs than your doctor says. Too much drug can cause you to lose too much salt and potassium. This can cause you to have a severe upset stomach, to vomit a lot, to feel weak, to feel tired or to be confused. Taking too much drug can make you become very sick or even die if you are also taking drugs for your heart like digitalis or digoxin.

WHEN TO TAKE THESE DRUGS

If you take only one dose of these drugs each day, take the dose in the morning with breakfast. If you take more than one dose of these drugs each day, take the last dose no later than 6 o'clock at night. This will keep you from going to the bathroom all night. If you forget to take a dose, DO NOT TAKE TWO TABLETS FOR THE NEXT DOSE! Simply take the right dose the next time and get back onto your normal schedule.

USE DURING PREGNANCY AND NURSING

These drugs should not be used if you are pregnant or planning to become pregnant because it may affect the unborn child. These drugs are also known to be present in breast milk. Check with your doctor before using these drugs if you want to breast-feed your baby.

USE OTHER DRUGS WITH CAUTION

*Other blood pressure drugs taken with water pills may cause your blood pressure to become too low.

*Drugs for your heart like digitalis or digoxin taken with water pills may cause problems with your heartbeat.

*Drugs used to treat dour may not work as well while you are taking water pills.

*Steroids taken with water pills may cause you to lose too much potassium.

*Drugs used to treat pain which are taken with water pills may cause your blood pressure to become too low.

*Drugs for hay fever may cause your blood pressure to go up, so water pills will not work as well.

This sheet does not include all of the possible side effects or problems which can arise while taking these drugs. It is meant to provide you with the things you will need to know to take these drugs properly. If you have more questions, ask your doctor or druggist.

This information sheet was prepared by Tim Stratton, M.S., R.Ph., College of Pharmacy, University of Arizona. 1985.
United States Pharmacopeial Conventions' PPI

Thiazide Diuretics (Oral)
Incluing Benidrometramide USP, Cefazolin USP, Chlorothiazide USP, Chlorothiazide USP, Cimetidine USP, Hydrochlorothiazide USP, Hydrochlorothiazide USP, Methyldopa USP, Metolazone USP, Nifedipine USP, and Triamterene USP C.

Patient: ___________________ Rx No: ___________________
Other Drug Name: ___________________ Date: ___________________

Take:
☐ At the time(s) shown below
☐ Only when needed but not more than
☐ 1 hr. before or 2 hrs. after food
☐ With or immediately after food
☐ At bedtime only

About Your Medicine
Thiazide diuretics are commonly used to treat high blood pressure. They are used also to help reduce the amount of water in the body by increasing the flow of urine. Thiazide diuretics may also be used for other conditions as determined by your doctor.

If any of the information in this leaflet causes you special concern or if you want additional information about your medicine and its use, check with your doctor, pharmacist, or nurse. Remember, keep this and all other medicines out of the reach of children and never share your medicines with others.

Before Using This Medicine
Tell your doctor and pharmacist if you:
• are allergic to any medicines, particularly sulfa medicine;
• are pregnant or intend to become pregnant while using this medicine;
• are breast-feeding an infant;
• are taking any other prescription or nonprescription (OTC) medicine, especially corticosteroids (corticosteroid medicines), digoxin (heart medicine), lithium, or medicines for appetite control, asthma, colds, cough, hay fever, or sinus;
• have any other medical problems, especially kidney disease.
Proper Use of This Medicine

Thiazide diuretics may cause you to have an unusual feeling of tiredness when you begin to take them. You may also notice an increase in the amount of urine or in your frequency of urination. After taking the medicine for awhile, these effects should lessen. In order to keep the increase in urine from affecting your nighttime sleep:

* If you are to take a single dose a day, take it in the morning after breakfast.
* If you are to take more than one dose a day, take the last dose no later than 6 p.m.

If you are taking this medicine for high blood pressure, remember that it will not cure your high blood pressure but it does help control it. Therefore, you must continue to take it as directed if you expect to keep your blood pressure down. You may have to take medicine for the rest of your life.

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, do not take the missed dose at all and do not double the next one. Instead, go back to your regular dosing schedule.

Precautions While Using This Medicine

This medicine may cause a loss of potassium from your body. To help prevent this, your doctor may want you to:
* eat or drink foods that have a high potassium content, or
* take a potassium supplement, or
* take another medicine to help prevent the loss of the potassium in the first place.

It is very important to follow these directions. Also, it is important not to change your diet on your own and to check with your doctor if you become sick and have severe or continuing vomiting or diarrhea.

Side Effects of This Medicine

Side Effects Which Should Be Reported To Your Doctor

* Pain or stomach pain
* Joint pain
* Skin rash or hives
* Sore throat and fever

Signs of Too Much Potassium Loss

* Dryness of mouth
* Mood changes
* Increased thirst
* Irregular heartbeat
* Nausea or vomiting
* Weak pulse

Side Effects Which Usually Do Not Require Medical Attention

These possible side effects may go away during treatment; however, if they continue or are bothersome, check with your doctor or pharmacist:
* Dizziness or light-headedness when standing up
* Nausea or vomiting
* Diarrhea
* Headache
* Skin rash

Other side effects not listed above may also occur in some patients. If you notice any other side effects, check with your doctor or pharmacist.

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APPENDIX 4

MULTIPLE-CHOICE TEST TO TEST UNDERSTANDING

INSTRUCTIONS FOR MULTIPLE CHOICE TEST

You will meet ten people who are taking thiazide diuretics (water pills). Each person also has some health problem. You are asked to decide what each person should do.

Please read each story. After each story you will find four actions that the person in the story could follow. You might want the person in the story to do something that is not listed. In this case, mark answer D, "The correct answer is not given." Circle the ONE ANSWER which best describes what you think that the person in the story should do.

TURN THE PAGE...
1. The doctor says that Mr. Smith needs a thiazide drug. Mr. Smith has had bad reactions to other drugs in the past, like sulfa drugs. Mr. Smith should:

A. Not tell the doctor about the bad reactions because the doctor is not giving him a sulfa drug.

B. Not tell the doctor about the bad reactions he has had to sulfa drugs, because they are not important.

C. Tell the doctor about the bad reactions only if the doctor asks.

D. The right answer is not given.

2. Fred Jones is seeing a new doctor who wants to give Fred a thiazide drug for Fred's high blood pressure. Fred had hepatitis, a liver disease, thirty years ago. Fred should:

A. Not tell the doctor about the liver disease because liver disease has nothing to do with high blood pressure.

B. Not bother the doctor about the liver disease because it was so long ago.

C. Not forget to tell the doctor about the liver disease even if the doctor does not ask.

D. The right answer is not given.

3. Mary Jones is seeing the doctor for a refill of her thiazide drug. Last week Mary had a tooth pulled and is taking aspirin when her mouth hurts. Mary should:

A. Not tell her doctor that she is taking aspirin because it she can get it without a doctor's order.

B. Not tell the doctor about the aspirin because there is no problem between aspirin and thiazide drugs.

C. Not bother the doctor about the aspirin because it was given to her by her dentist.

D. The right answer is not given.
4. Jane Doe has just begun taking a thiazide drug for high blood pressure. She thinks that the drug has been causing her to go to the bathroom once each hour during the night. Jane should:
A. Not stop the drug, but check with her doctor.
B. Stop taking the drug because she feels okay anyway.
C. Take the drug only when she feels her blood pressure is high.
D. The right answer is not given.

5. James West has been taking a thiazide drug for a couple of days. When he gets out of bed in the morning, he feels dizzy. James should:
A. Call his doctor immediately.
B. Stop taking the drug because it is making him feel dizzy.
C. Sit up slowly and dangle his legs over the side of the bed a few minutes before getting up.
D. The right answer is not given.

6. Sandy Smith is taking a thiazide drug for high blood pressure. She knows that the drug makes her lose salt and potassium. During the hot summer when she loses even more salt and potassium from sweating, Sandy should:
A. Eat foods like bananas and oranges.
B. Put more salt on her food to prevent salt loss.
C. Drink a glass of water with a teaspoon of salt in it each day.
D. The right answer is not given.

7. Mary Jones has been taking a thiazide drug for 3 days. Mary has had some diarrhea for the last day, but it seems to be getting better. Mary thinks that her medicine may be causing her problems. Mary should:
A. Call her doctor right away because her medicine may be causing her problems.
B. Stop taking her medicine.
C. Not bother the doctor. Even though her medicine may be causing the diarrhea, it should go away.
D. The right answer is not given.
8. Bill Doe takes his thiazide drug once each morning and once each evening. This morning Bill forgot to take his medicine, and in two hours it will be time for his evening dose. Bill should:

A. Take his morning dose now and his evening dose in two hours.
B. Take only his evening dose and skip today's morning dose.
C. Check with his doctor or pharmacist to find out what to do.
D. The right answer is not given.

9. Jane O. Public is taking a thiazide drug for high blood pressure. Every year she gets a runny nose and watery eyes from olive tree pollen. Jane bought some hay fever medicine before the doctor told Jane that she had high blood pressure. Jane thinks that it would be okay to take the hay fever medicine because she already has it. Jane should:

A. Use the hay fever medicine because she has used it before without any problems.
B. Use the hay fever medicine only one or two days because this will not make her blood pressure go any higher.
C. Use the hay fever medicine and check with her doctor or pharmacist only if she wants to buy a different allergy medicine.
D. The right answer is not given.

10. Joe Smith has been taking a thiazide drug. For a week, Joe has noticed that he has been weaker and more tired than usual and he has felt sick to his stomach and has been throwing up. Joe's wife had the flu just last week, and Joe thinks that he has the flu now. Joe should:

A. Not bother the doctor. Joe's right, he probably has the flu.
B. Not bother the doctor. Joe's problems may be from his medicine, but they should go away.
C. Call his doctor right away. His problems may be from his medicine.
D. The right answer is not given.
APPENDIX 5

SATISFACTION SCALES

INSTRUCTIONS FOR SATISFACTION SCALES

This set of questions asks you to tell us how you liked the information sheet you read. You are asked to circle the number which best describes the way you feel about the statement. A sample question follows:

A. How much did you like the information sheet you read?

I did not like it at all. I am not sure if I liked it or not. I liked it a lot.

<p>| | | | | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
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<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

In the sample, the person sort of liked the information sheet, so circled "5."
Circle the number which best describes your feelings about each of the following questions.

1) How much do you think that the information sheet helped you learn about this drug?

<table>
<thead>
<tr>
<th>I did not learn anything at all.</th>
<th>I am not sure how much I learned.</th>
<th>I learned a lot.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>3</td>
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<tr>
<td>4</td>
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<td>6</td>
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<tr>
<td>7</td>
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</tbody>
</table>

2) If you had to take this drug, how likely would you be to use the information sheet?

<table>
<thead>
<tr>
<th>I would not use the sheet.</th>
<th>I am not sure if I would use the sheet.</th>
<th>I would use the sheet.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
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<tr>
<td>4</td>
<td>5</td>
<td>6</td>
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<td>7</td>
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</tbody>
</table>

3a) If your information sheet had pictures, how much did they help you to understand the information? (If your sheet did not have pictures, go to next question.)

<table>
<thead>
<tr>
<th>The pictures did not help at all.</th>
<th>I do not know if the pictures helped or not.</th>
<th>The pictures helped a lot.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
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<tr>
<td>4</td>
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</tbody>
</table>

3b) If your information sheet did not have pictures, do you think that pictures would have helped you to better understand the information sheet? (If your sheet had pictures, do not answer this question.)

<table>
<thead>
<tr>
<th>Pictures would not have helped at all.</th>
<th>I do not know if pictures would have helped.</th>
<th>Pictures would have helped a lot.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>4</td>
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<td>7</td>
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</tbody>
</table>

4) What did you think about the size of the print used on your information sheet?

<table>
<thead>
<tr>
<th>The print was much too small to read easily.</th>
<th>The print was just the right size.</th>
<th>The print was larger than I needed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
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</tbody>
</table>
5) What do you think about the amount of information found in your sheet?

<table>
<thead>
<tr>
<th>Far too much information given.</th>
<th>Just the right amount of information given.</th>
<th>Not enough information was given.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
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<tr>
<td>4</td>
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<td>6</td>
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<tr>
<td>7</td>
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</tbody>
</table>

6) Overall, how much did you like the information sheet?

<table>
<thead>
<tr>
<th>I did not like it</th>
<th>I do not know if I liked it</th>
<th>I liked it very much.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2</td>
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<tr>
<td>7</td>
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</tbody>
</table>

7) If you had a friend who used this drug, how likely would you be to suggest he or she use the information sheet you read?

<table>
<thead>
<tr>
<th>Not at all likely.</th>
<th>I do not know if I would suggest it or not.</th>
<th>I'm sure I'd suggest it.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>1</td>
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</tbody>
</table>
This last set of questions asks about you. The information about you is very important to us. Please answer each question as best you can.

1) What is the highest grade in school which you finished? (Circle answer.)
   3rd 4th 5th 6th 7th 8th 9th 10th 11th 12th attended college

2) What is your gender?
   Male          Female

3) Do you consider yourself to be (Circle best answer.):
   a) Caucasian (white)
   b) Hispanic
   c) Black
   d) American Indian
   e) Asian
   f) Other (If so, what? ________________________________)

4) How old were you at your last birthday? _____
INSTRUCTIONS FOR COMPLIANCE SCALES

You know some of the problems from high blood pressure. You will read some short stories about persons who have high blood pressure. These people are each taking medicine for their high blood pressure. Each person also has a reason not to take the medicine. You are asked to tell us how likely you think each person is to take their medicine. A sample question follows:

A. Fred Derf has high blood pressure. He knows that high blood pressure can cause bad problems with his heart and kidneys. He also knows that his medicine might make his right ear fall off. How likely do you think Fred is to take his medicine?

Not at all likely. I do not know if he would take it or not. I'm sure he would take it.

1 2 3 4 5 6 7

In the sample, the person answering the question thinks that Fred is not very likely to take his medicine, so "2" is circled.
1. Barney Smith has just been told that he has high blood pressure. His doctor told Barney about all the problems which could result from high blood pressure. Barney has also been told about all of the side effects which he could have with thiazide blood pressure drugs. How likely do you think that Barney is to take his thiazide drugs as his doctor tells him?

Not very likely at all. I don't know if he'll take them or not. He is very likely to take them.

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

2. Barney Smith has been told that he must take his thiazide blood pressure drugs for the rest of his life. Barney feels as healthy as could be, but he has been told about the problems from high blood pressure. How likely is it that Barney will forget to take his drugs every day?

It's very likely he will forget to take them. I'm not sure whether he'll take them or not. He's not very likely to forget to take them.

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
3. Barney Smith knows that he has high blood pressure and he knows the problems which can result from high blood pressure. He is about to run out of his thiazide blood pressure drug. He does not have much money this month, and his blood pressure drugs cost a lot of money. How likely is Barney to have his prescription refilled this month?

<table>
<thead>
<tr>
<th>He's not very likely to get a refill.</th>
<th>I do not know if he will get a refill or not.</th>
<th>He's very likely to get a refill.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Barney Smith's wife had high blood pressure for years, and she would forget to take her blood pressure drugs from time to time. She never had any problems with her heart or blood vessels or kidneys. Now Barney has high blood pressure. How likely is Barney to skip taking his thiazide drugs now and then?

<table>
<thead>
<tr>
<th>It's very likely he will skip some doses.</th>
<th>I'm not sure whether he'll skip some or not.</th>
<th>He's not very likely to skip taking them.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5. Barney Smith has began taking thiazide water pills for his high blood pressure three days ago. He has been getting up six times a night to go to the bathroom since he has started his drug, and he is not getting any sleep. How likely is Barney to stop taking blood pressure pills?

<table>
<thead>
<tr>
<th>He's very likely to stop taking the pills.</th>
<th>I'm not sure if he'll stop taking his pills or not.</th>
<th>He is not very likely to stop taking his pills.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
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APPENDIX 7

CLOZE COMPREHENSION TESTS FOR
INDIVIDUAL PATIENT PACKAGE INSERTS

Instructions Common to All Cloze Tests

AARP MILS

INSTRUCTIONS FOR READING TEST

To complete this reading test:

1. Note that the blanks are of different lengths. The lengths of
   the blanks are the same as the number of letters in the right
   words.

2. Write only one word in each blank.

3. Fill in every blank, if you can. Guess if you do not know.

4. Skip hard blanks and come back to them later if you have to.

5. Write down a word even if are not sure how to spell it.

6. Most of the blanks can be answered with normal words, but a
   few may be:

   *numbers like 3,427 or 512 or 1954;
   *words like can't or won't (contractions);
   *abbreviations like Mrs. or U.S.A.; or
   *parts of a hyphenated word like "self" in the word
   "self-made."

Try this short example before turning to the next page.

Mary had a little _________. Its _________ was white
________ snow. Everywhere that _________ ________, the
lamb was sure _______ go.

TURN THE PAGE...
These drugs are diuretics or water pills. They are to lower high pressure. Thiazide drugs help the to get rid of extra salt and water due to heart, liver or kidney disease. will probably have take this drug the rest of your life. This medicine cannot cure blood pressure, but if directed, can help control it.

should be as directed, preferably in the morning every day at the same time. you take doses a day, take the second one in evening before dinner. Do not take doses at the time. If you forget the first dose, take only your dose. Do not take it after dinner. It interrupt your sleep you to urinate (pass water). Do not stop taking it if you .

Do not rise quickly after lying down . You may feel or lightheaded. If dizzy, sit up slowly, put your legs the side of the bed, and there for few minutes. people think because Thiazides are taken to remove fluids from , they restrict fluid or intake. This is wrong. Continue to drink normal amounts of fluid.

When you take Thiazide drugs, you have to urinate more often. this is inconvenient, do not stop taking the drug. Call your doctor. Perhaps they can be taken at a different time. If you want more information about this drug, ask your doctor for a more technical leaflet.
This medicine is commonly used to treat high blood pressure. It is sometimes used in heart or kidney problems to help reduce the amount of salt and water in the body by increasing the flow of urine. Thiazide diuretics may also be used for other conditions determined by your doctor. Take this medicine only as directed by your doctor.

When to take this medicine, you may increase the amount of urine or in the amount of urination. Keep the amount of urine affecting your sleep. Follow a regimen. If you are to take a single dose a day, take in the morning breakfast. If you are taking more than one dose a day, take the last dose no later than 6 p.m. unless directed by your doctor.

If you miss a dose of this medicine, take it as soon as possible. It is almost time for your next dose. This case, do not take the missed dose all and do not double the next dose. Instead, go back to your regular schedule.

If blood pressure is not treated, it can cause serious problems such as heart, vessel, stroke or kidney problems. Remember that this medicine will not cure your high blood pressure, but it will help control it. Therefore, you should continue to take the medicine as directed— if you feel well—if you expect to keep your blood pressure down.

Do not take other medicines unless they have been discussed with your doctor. This especially includes over-the-counter (OTC) or nonprescription medicines for appetite control, asthma, colds, cough, hay fever, or sinus, since they may tend to increase your blood pressure.
Thiazide Diuretics

Thiazide diuretics are commonly used to treat high blood pressure. They are _______ used to help _______ the amount of water in _______ body by increasing the flow of urine.

This medicine may cause you to have an _______ feeling of tiredness _______ you begin to _______ it. You may also notice an increase in the _______ of urine or in _______ _______ of urination. After taking the _______ _______ a while, _______ effects should lessen. In order to _______ _______ increase in _______ _______ affecting your nighttime _______: If you _______ to take _______ single dose _______ day, take it in the _______ after breakfast; If you are to _______ more than one _______ a day, take the _______ _______ no later than 6 p.m., unless _______ _______ by your doctor. However, it is best to _______ your dose or _______ _______ to a schedule that will least affect your personal activities and sleep. _______ _______ doctor, nurse or pharmacist to help you _______ _______ best time to _______ this medicine.

If _______ _______ a dose of this medicine, take it _______ soon as possible. If it is _______ time for _______ next dose, _______ not take the missed dose at all and do not _______ _______ next _______. Instead, go back _______ your regular dosing schedule. If you have any questions about this, check with _______ doctor or pharmacist.

In order _______ decide on the best _______ for your _______ problem, be sure to tell the doctor if you are allergic to this medicine or if you have other medical problems. Tell any other doctor, dentist or pharmacist that you see that you are taking this medicine.
The drug prescribed for you is a Thiazide drug. Thiazide drugs are made by several companies. Each company has its own name for the drug it manufactures. It is important to know the name of the drug you are now taking. You should also know the dose you should be taking, how often, and what times, so you can take the drug the way that works best for you.

Any drug can help reduce the body's job. You may need to urinate more often than usual. Thiazide drugs help the body get rid of excess salt and water. They can also get dizzy or have a headache. This is because there is less salt and water getting into blood. If you feel faint, rest for a while. Do not get up and move suddenly...move slowly so the body can adjust. Each morning, sit at the side of the bed for a few minutes before getting up. If the faint feeling ever lasts more than a few minutes, ask the staff for advice.

Thiazide drugs reduce high blood pressure and keep it under control. High blood pressure is a pressure inside your blood vessels that you cannot feel. High blood pressure puts an extra burden on your heart. The aim of treatment is to reduce the blood pressure to normal. Proper treatment usually can control blood pressure and prevent trouble.
Thiazide diuretics are commonly used to treat high blood pressure. They are also used to help the amount of water in the body by increasing the flow of urine. Thiazide diuretics may also be used for other as determined by the doctor.

If any the information causes you special concern or if you additional information about your its use, check with your pharmacist. Remember, share your medicines with others.

Thiazide cause you an unusual feeling tiredness when begin to them. You also notice an increase in amount of urine or in your of urination. After the medicine for awhile, should lessen. order to keep in urine from affecting your nighttime sleep: If are to take a day, take it in the morning after breakfast: If you take more than one dose a day, last dose no than 6 p.m.

are taking this medicine for high blood, remember that it will not cure high blood but it help to control it. Therefore, you must continue to take directed directed you expect to your blood pressure down. You may have to take this medicine for the of your life.

If you a dose of this , take it soon as possible. However, if it is almost time for your next dose, do not take the missed dose at all and do not double the next one. Instead, go back to your regular dosing schedule.
Thiazides are also known as water pills. These drugs are used to treat blood pressure. They work by your body to get rid of water and salt, which lowers blood pressure. These drugs cure high blood pressure, but they can keep your blood pressure under control. You have to take these for the rest of your life.

Begin going the bathroom more often a few taking these, you are going the bathroom often that becomes a , do not stop taking the. Check with your doctor to see there is a better time for you to drug. You have to use each day for 2 to 3 weeks before blood pressure begins down.

If you take only one dose of these drugs each day, dose in the morning with breakfast. If more than one of these drugs , take the last dose no later than o'clock at night. This will keep from going to the bathroom night. If you forget to take a dose, do not tablets the next dose. take the right dose at the next time and get back on your schedule.

These drugs should not used if you are or are to become pregnant because it may effect the unborn child. This drug is also known to be present in breast milk. Check with your doctor before using this drug if you want to breast-feed your baby.
Thiazide diuretics are commonly used to treat high blood pressure. They are also to help the amount of water in body by increasing the flow of urine. Thiazide diuretics may also be used for other as determined by doctor.

If any the information causes you special concern or if you additional information about your its use, check with your pharmacist. Remember, share your medicines with others.

Thiazide cause you an unusual feeling tiredness when begin to them. You also notice an increase in amount of urine in your of urination. After the medicine for awhile, should lessen. order to keep in urine from affecting your nighttime sleep: If are to take dose a day, take it in the morning after breakfast; If take more than one dose a day, last dose no than 6 p.m.

are taking this medicine for high blood , remember that it will not cure high blood but it help to control it. Therefore, you must continue to take directed you expect to your blood pressure down. You may have to take this medicine for the of your life.

If you a dose of this , take it soon as possible. However, if it is almost time for your next dose, do not take the missed dose at all and do not double the next one. Instead, go back to your regular dosing schedule.
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