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This report is produced by the Office of Evaluation and Inspections (OEI), one of the three major offices within the OIG. The other two are the Office of Audit Services and the Office of Investigations. Inspections are conducted in accordance with professional standards developed by OEI. These inspections are typically short-term studies designed to determine program effectiveness, efficiency, and vulnerabilities to fraud or abuse.

Entitled “Medication Regimens: Causes of Noncompliance” this report identifies why elderly people have difficulty following instructions for prescription medication use.

The study was carried out under the direction of Linda Herzog, Regional Inspector General, Office of Evaluation and Inspections, Atlanta Region. Participating in the project were the following people:

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MEDICATION REGIMENS: CAUSES OF NONCOMPLIANCE

Richard P. Kusserow
INSPECTOR GENERAL
EXECUTIVE SUMMARY

PURPOSE

The purpose of this inspection is to determine why elderly people fail to follow prescription medication regimens.

BACKGROUND

Failure to adhere to medication instructions, either willful or inadvertent, has been termed noncompliance with medication regimens. Instances of noncompliance can include failing to initially fill a prescription, taking either more or fewer doses than instructed, and taking medications that have been prescribed for someone else.

Current research indicates that 55 percent of the elderly do not follow the medication regimens prescribed by their physicians.

METHODS

This inspection examines and summarizes extensive prior research in the area of noncompliance with medication regimens. It also draws on congressional testimony, reports issued by consumer groups involved with medication issues, and reports of government agencies concerned about the elderly, medications, and medical compliance.

FINDINGS

The consequences of noncompliance are serious and costly.

Noncompliance with medication regimens can result in the increased use of medical resources such as nursing homes, hospitals, physician visits, and unnecessary treatment. Noncompliance with medication regimens may also result in therapeutic failure. For example, missed doses of cardiac anti-arrhythmics can lead to arrhythmia and cardiac arrest.

There are many inter-related reasons for noncompliance.

Reasons why elderly people fail to comply with medication regimens fall into four main categories:

Physiological factors: Loss of vision or hearing can impede an elderly person's ability to read important information about his prescription or to hear instructions about his regimen. Mobility limits, type of disease, the presence of symptoms, memory loss, depression, and cognitive impairment are other physiological variables that can negatively affect compliance.
Behavioral factors: These include social isolation, social and health beliefs, and economic condition. Many elderly people live alone. Studies have shown that people who live alone more often fail to comply with medication regimens. For those elderly on fixed, minimal incomes, the ability to purchase expensive medications may also be a factor in noncompliance.

Treatment factors: These include the duration and complexity of the medication regimen. Compliance rates decrease when the treatment is long-term and when the regimen includes many different medications that must be taken concurrently. Other treatment factors include the type of medication prescribed, and the patient’s perception of the medication.

Health Care Provider/Patient Interaction factors: These include how well the physician, the pharmacist, and the patient communicate with each other. The quality and content of a physician’s instructions, the content of a pharmacist’s label, and the ability of a patient to ask questions can all affect compliance.

*Education is the key to improving compliance.*

Strategies to improve compliance include physicians and pharmacists better educating patients about their medication regimens. Effective counseling by the physician and pharmacist may be the single best intervention for patients with compliance problems. Public education groups are also currently involved in informing and educating elderly citizens about medication issues. Compliance aids such as medication reminder charts may be useful tools for patients with memory impairments, or patients on complex medication regimens.

Attempts to improve compliance through educational and other behavioral strategies do work, as long as they are matched to the individual patient’s needs. There is evidence to suggest that with the proper education and support the elderly can overcome compliance difficulties.
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INTRODUCTION

PURPOSE

Research has shown that a significant proportion of elderly people do not correctly follow their physicians' instructions for taking prescribed medications. The purpose of this study is to determine why elderly people may fail to follow prescription medication regimens.

BACKGROUND

In April 1989, the Office of Inspector General issued a report entitled "Medicare Drug Utilization Review" (OAI-01-88-00980). The report describes patterns of mismedication among elderly adults, identifies components of the drug delivery system that contribute to the problem, and describes drug utilization review (DUR) interventions that appear most promising to Medicare.

This inspection is related to that April report. Its focus is noncompliance among the elderly with medication regimens. Willful and inadvertent noncompliance contribute significantly to the problem of mismedication.

Appendix A lists additional studies related to medication and the elderly which have been completed, are underway or are planned by the Office of Inspector General.

DEFINITIONS

Mismedication occurs when a patient fails to take medication as prescribed by his physician. This failure, either willful or inadvertent, is termed noncompliance. Noncompliance can include:

- failing to initially fill a prescription;
- failing to refill a prescription as directed;
- omitting a dose(s);
- over dosing;
- prematurely discontinuing medication;
- taking a dose at the wrong time;
- taking a medication prescribed for someone else;
- taking a dose with prohibited foods, liquids, and other medications;
taking outdated medications;
• taking damaged medications;
• storing medications improperly; and
• improperly using medication administration devices (e.g. inhalers.)

METHODS

This report is based on the findings of numerous researchers in the field of medical compliance. The number of original studies on compliance is itself extensive. The number of reviews of the literature now exceeds the number of original studies. This inspection draws on both the original research and the reviews for many of its findings. The literature ranges from small, narrowly focused studies on aspects of noncompliance, to books which extensively discuss the elderly and their medication problems, including noncompliance. In addition, various authors of the literature were contacted for information and clarification of issues. This report also draws on congressional testimony, reports issued by consumer groups involved with medication issues, and reports issued by government agencies which are concerned about the elderly, medications, and compliance. See Appendix C for a list of compliance-related literature reviewed for this inspection.
MANY ELDERLY DO NOT COMPLY WITH MEDICATION REGIMENS; THE CONSEQUENCES OF THEIR NONCOMPLIANCE ARE SERIOUS.

Extent of Prescription Medication Use By the Elderly
Adults aged 65 and over comprise approximately 12 percent of the United States population, but they consume 30 percent of all prescription medications dispensed. By the year 2030, the proportion of elderly to the total population is expected to reach 23 percent. It is likely that their consumption of prescription medications will also rise, as more and more elderly come to rely on medications for management of chronic disease. Eighty-six percent of the elderly have at least one chronic disease requiring medication. The following table shows that those over 65 have a greater incidence of chronic disease which commonly requires medication therapy.

<table>
<thead>
<tr>
<th>Extent of Chronic Disease</th>
<th>Commonly Treated with Medication by Age Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthritis</td>
<td>Under 45</td>
</tr>
<tr>
<td></td>
<td>3%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>4%</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>3%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>.8%</td>
</tr>
</tbody>
</table>

Adapted from: National Center for Health Statistics, C.A. Shoenborn and M. Marano, 1988
Vital and Health Statistics Series 10, No. (PHS) 88-1594, Public Health Service. Washington:

There is heightened concern in the health care field about patients with chronic conditions. Their use of prescription medication shifts the mode of their treatment from direct medical care to continuous patient self-management. Ninety-five percent of the elderly live outside of institutions and are responsible for their own medications.

One researcher found that 25 percent of elderly patients discharged from a hospital received six or more prescriptions.

A community-based sample showed that 25 percent of the elderly use four or more prescriptions regularly.
The types of prescription medications most used by the elderly are:

- cardiovascular;
- diuretic;
- anti-infective; and
- psychotropic.\(^9\)

The American Association of Retired Persons (AARP) has estimated that the total amount spent by elderly persons for medications (including over-the-counter preparations) in a single year is over $9 billion.\(^{10}\)

**Frequency of Noncompliance Among the Elderly**

Prior research indicates that 55 percent of the elderly fail to comply in some way with their medication regimens.\(^{11}\) Podell and Gary have suggested that one-third of the elderly always comply, one-third sometimes comply, and one-third never comply with their medication regimens.\(^{12}\)

An American Association of Retired Persons (AARP) survey of ambulatory elderly found that 33 percent said they had prematurely discontinued a prescribed medication, and 14 percent failed to initially fill a prescription at least once.\(^{13}\)

Noncompliance with medication regimens is a problem not only among the elderly. Forty-three percent of the general population made errors in self-administration of their medications according to one study. However, the same study showed that 58 percent of the elderly made errors when taking their medications.\(^{14}\) In one of the early studies done on the subject of noncompliance, 26 percent of the elderly studied made errors which had potentially serious consequences as judged by the patients' primary physicians.\(^{15}\)

Rates of medication compliance are difficult to generalize. An individual patient's compliance behavior may not be consistent. A patient may comply with one medication but not another.\(^{16}\) Compliance behavior may change over time due to the patient's perceptions of efficacy of treatment and other factors.\(^{17}\)

Methodological difficulties associated with conducting compliance studies may lead to an underestimation of the extent of the compliance problem.\(^{18}\) The development of electronic compliance monitoring devices may help researchers, clinical trial investigators, and practicing physicians better track noncompliance in their patients.
Consequences of Noncompliance

Of all age groups the elderly benefit the most from taking medications and risk the most from failing to take them properly. The consequences are more serious, less easily detected, and less easily resolved than in younger age groups.19

Noncompliance with medication orders can increase the use of medical resources.

- Across the general population it has been estimated that noncompliance with treatment for cardiovascular disease results in an excess of 125,000 deaths and several thousand hospitalizations per year. (Six of the ten most frequently used drugs for patients 75 years and older are cardiovascular.)20
- Up to 23 percent of nursing home admissions may be due to elderly patients’ inability to self-administer medications.21
- About 10 percent of hospital admissions may be due to poor patient compliance with medication orders.22
- Over a two-month period, researchers at a large teaching hospital found that drug-noncompliance-related hospital admissions for 23 patients accounted for 590 hospital days and approximately $60,000 in avoidable costs.23
- Emergency care may be required if patients fail to take their medications properly.
- Increased physician visits may be required if, because of medication noncompliance, the patient’s condition does not improve. If the physician is not aware of the noncompliance, higher doses or additional medications might be prescribed which are unnecessary and possibly dangerous.24
- Additional diagnostic tests may be ordered if, because of medication noncompliance, the patient’s condition does not improve or worsens.
- Additional or unnecessary alternative treatments may be prescribed as a result of noncompliance.

There is documentation that medication noncompliance is directly related to therapeutic failure. For instance:

- Missed doses of anti-glaucoma medications lead to optic nerve damage and blindness.
- Missed doses of cardiac anti-arrhythmics lead to arrhythmia and cardiac arrest.
- Missed doses of anti-hypertensives lead to rebound hypertension (sometimes worse than if no medication had been taken in the first place).
- Missed doses of antibiotics lead to recurrent infection and also to the emergence of resistant micro-organisms.25
The foregoing section described the adverse consequences of patients’ failure to take medication as prescribed. However, there is another side to the story. Noncompliance can reveal when a medication has been unnecessarily prescribed. The patient who has been prescribed an unnecessary medication may be better off if he/she does not comply, provided that the physician is aware of the noncompliance. Otherwise the physician may keep prescribing the unnecessary medication.

**There are many inter-related reasons for noncompliance.**

One group of researchers identified over 200 variables that have been examined in relation to compliance with medical regimens. This report by the Office of Inspector General identifies those variables that have the most bearing on reasons why the elderly may fail to comply with their medication regimens. These variables fall into four main categories:

- physiological factors
- behavioral factors
- treatment factors
- health care provider/patient interaction.

Despite the fact that the variables are discussed as separate classes, in practice they overlap substantially. They should not be viewed as independent.

It is also important to keep in mind that age by itself is not a determining factor in noncompliance. Rather, the many factors discussed below may combine to render the elderly less able to comply with their medication regimens.

Finally, there is evidence to suggest that with the proper motivation, education, and support, the elderly can overcome compliance difficulties.

**Physiological Factors**

Sensory Impairment: Well over a million older adults have impaired vision - a critical factor in compliance with prescription medication regimens. Loss of vision can impair reading and understanding of prescription labels and other printed instructions handed out by the physician or pharmacist.

- Fifty-four percent of partially sighted persons are estimated to be at least 65 years old. (Most partially sighted persons are unable to read newspaper column type at normal reading distances even with the help of eyeglasses, and have difficulty recognizing faces even when they are close.)
- Forty-six percent of the functionally blind group are 65 years or older.
Critical communication with the physician or pharmacist can be missed by the patient with a hearing deficit. At least 30 percent of individuals 65 and older have significant impairment of hearing in the frequencies associated with normal speech.

**Mobility Limits:** Decreased mobility and dexterity can limit a person’s ability to have prescriptions filled, and to open and close childproof containers. Almost half of all noninstitutionalized elderly are limited in mobility because of chronic conditions.

**Type of Disease:** Studies of patients with chronic conditions show that compliance is worse when:

- the medicine is taken preventively;
- the disease is without symptoms; and
- there are no immediate negative consequences of noncompliance.

**Presence of Symptoms:** An illness with easily recognized and unpleasant symptoms that are relieved by the use of medication is more likely to promote compliance with medication regimens. However, Haynes claims that it is the degree of disability brought about by symptoms that promotes good compliance. He speculates that compliance improves because the disability results in closer supervision of the patient.

Some symptoms may fail to stimulate the commitment to follow medication orders. The elderly in particular may adapt to a steady state of symptomatic discomfort, or resign to “feeling pretty good for my age.” Some of these elderly may prefer to live with minor symptoms than deal with the inconvenience of a medication regimen.

Some patients use symptoms as barometers to determine when they should discontinue taking medication. Such decisions to discontinue medication are based on the mistaken assumption that the abatement of symptoms indicates recovery. In a study of a group of hypertensives, some patients reported that they only took their medication(s) when they knew their blood pressure was high. Their assessments of blood pressure levels were based on symptoms such as headaches and stress, although research shows that hypertension is a disease without symptoms.
Memory Loss: Memory loss is a critical problem for many elderly trying to recall a physician's or pharmacist's instruction for medication use.

- Memory loss can be caused by prescribed medications.
- Memory loss may indicate senile dementia, a condition difficult to recognize in its earliest stages. The prevalence of dementia in the noninstitutionalized elderly population is about five percent.

Depression: Depression is one of the most important psychological disorders of late age. A community-based sample estimated the prevalence of depressive symptoms among the elderly to be approximately 15 percent. The older adult with depression can present serious problems to the health care provider who depends on the patient's cooperation to achieve compliance with a medication regimen. Some depressive symptoms include:

- sadness;
- loss of gratification;
- constant fatigue;
- apathy;
- psychomotor retardation;
- diminished social interaction; and
- insomnia.

Cognitive Impairment: According to Lamy, approximately 15 percent of the noninstitutionalized elderly have significant cognitive impairments likely to affect their ability to give an accurate medical history as well as to follow physicians' instructions.

Some older persons do not seem to process new information as thoroughly as younger persons and may need more time to learn new information. Distractions and information presented at a fast pace can seriously disrupt learning.

Trying to learn a great deal of information in a short period of time (such as learning a complex medication regimen), can create a state of information overload. People deal with information overload by:

- omission - failing to process information;
- error - processing information incorrectly;
- delay - processing information at a later time;
- filtering - fitting input into existing belief;
• approximation - processing only a part of the information; and
• avoidance - ignoring information.

**Behavioral Factors**

Social Isolation: People who live alone more frequently fail to comply with medication regimens. This suggests that for those not living alone, the spouse, companion, or associate assumes a role in ensuring that medications are taken as prescribed.

• Approximately 35 percent of individuals over 65 live alone (the large majority of whom are women).

The effects of social isolation include:

• rusty social skills, including difficulty asking and answering questions; and
• cognitive impairment, including difficulty understanding directions.
• Even regular contact with children may not compensate for the loss of a spouse or a dwindling social network.

Social and Health Beliefs: Patients hold many beliefs about their health and about the potential efficacy of any proposed treatment action. Patients’ beliefs can be based on:

• misconceptions;
• faulty information; and/or
• cultural conditioning.

For example, some elderly people may believe:

• "You need to give your body some rest from medicine once in awhile or else your body becomes dependent on it or immune to it," or
• "You only take medicine when you are ill and not when you feel better," or
• "If one dose is good, two must be better."

These beliefs and feelings may be shared and supported by significant others in the patient’s life.

Economic Condition: Elderly people on minimal fixed incomes may be unable to afford necessary medications. Overall, the elderly pay 14 percent more per prescription than the nonelderly because of the mix of medications and the number of doses, which is often greater due to long-term therapy. Furthermore, the elderly pay a larger percentage of their prescription medication costs out of pocket.
Since 1980 prescription medication prices have increased two to three times faster than all consumer prices, while real income has remained relatively static. Social Security payments have increased at about the same rate as general inflation, but medication price inflation has far exceeded general inflation.

About 14 percent of the noninstitutionalized elderly live below the poverty level. An additional 25 percent live just above the poverty line. Some of these patients may need to make choices between medications and food. A survey conducted for the American Association of Retired Persons (AARP) in 1986 found cost the second most frequently cited reason for not getting a prescription filled.

*Treatment Factors*

**Side Effects of Medications:** Although some researchers think that side effects of medications contribute to noncompliance, the research evidence is inconclusive.

- Two controlled studies found no difference in the frequency of side effects between persons who comply with medication regimens and those who do not.
- In thirteen studies in which patients were asked their reasons for not taking medication as directed, side effects were mentioned by only five to ten percent.
- In an anti-hypertensive drug trial, seven percent of the actually treated group complained of symptoms that may or may not have been medicine related; the placebo group had the same frequency and distribution of complaints.

The AARP has drawn a different conclusion about the relationship between side effects and noncompliance. In a survey of people 45 and older, 40 percent of the respondents stated they had experienced some form of side effect during medication use. Of this 40 percent, 59 percent responded that they stopped taking the medication as a result of the side effect. Of the 65 and older respondents, only 47 percent informed their physicians of the discontinuation.

Furthermore, the elderly may be more prone to side effects, because their metabolic response to doses of medications tested on younger people may be different.

Finally, for diseases (such as hypertension) which have no unpleasant symptoms, a medication that causes unpleasant effects may well increase the likelihood of noncompliance.

**Medication Class:** There is evidence to suggest that compliance will vary with the type of medication. Researchers have observed:

- 89 percent compliance rate with cardiac medicines;
- 78 percent compliance rate with insulin and anti-diabetic medicines;
- 72 percent compliance rate with diuretic medicines;
a 61 percent compliance rate with anti-hypertensive medicines;

- a 41 percent compliance rate with sedatives;

Research in this area is not complete. Researchers do not offer conclusive reasons for their findings.

Perception of Medication: Researchers have found that the size, form, and color of medication affect compliance.

- Capsules are viewed as significantly stronger than pills.
- Larger preparations are equated with greater strength.
- Capsule or pill colors can elicit expectations of medication action. Green is associated with tranquilizing effects, and yellow is associated with energizing effects.

A patient may decide to discontinue or alter medication use because the pill or capsule simply looks like it will have an effect that the patient does not want to experience.

Some elderly patients with vision or cognitive deficits may be confused by similarly shaped and colored medications.

The nature of the dosage form, such as the size of the pill or a liquid preparation, can negatively affect compliance if it is inconvenient to take or unpalatable.

Duration of Treatment: A consistent finding in the research on medication compliance is that compliance rates decrease over time. This is significant for the elderly because of the higher frequency of chronic conditions which require long-term or permanent medication therapy.

Complexity of Treatment: The number of medications taken can negatively affect compliance. The more medications taken, the worse the compliance.

It has not conclusively been shown that the frequency of dosing (how often medications are taken during the day) affects compliance, but differing concurrent dosage schedules can be inconvenient, confusing, and easy to forget. Furthermore, the number of medications prescribed can affect the frequency of dosing.
Health Care Provider/Patient Interaction

Role of the Physician: Although most research focuses on the issue of compliance as a patient problem, compliance is the physician's responsibility as well as the patient's.75

Physicians generally underestimate the levels of noncompliance among their own patients.76 They have also been shown to be unreliable predictors of whether or not individual patients will comply.77

Physicians' beliefs about and attitudes toward elderly patients can affect their interaction and communication with them.

Studies have shown that many physicians have an overall negative attitude toward treating elderly patients.78 Gerontological studies suggest that while people form impressions of younger persons on a wide variety of characteristics (sex, occupation, ethnicity), these distinctive categories are ignored when forming impressions of older adults, and the stereotypes (mental weakness, contrariness, physical frailty) associated with age tend to dominate.79 One study of physician attitude noted that 67 percent of physicians interviewed attributed noncompliance primarily to the patient's uncooperative personality.80

The physician-patient encounter is a situation in which patients must learn a very specific role and set of expectations about:
- the purpose of the medication;
- which medication should be taken;
- how long each medication should be taken; and
- the dosage schedule that should be followed.81

In Svarstaad's study on physician-patient interaction it was evident that physicians frequently did not discuss their expectations in an explicit manner. Of the 347 medications prescribed during the course of that study:
- Seventeen percent were never discussed at all.
- In only ten percent of the cases were patients told how long to take the medication.
- Dosage schedules were discussed ambiguously—"Take two capsules every four hours"—without specifying how many should be taken in a twenty-four hour period.
- Patients were not always given printed or written instructions for proper use of medications.
During the patient interviews of this same study, many misconceptions were discovered. Fifty-two percent of the patients made at least one error when describing the physician’s expectations. For example, patients who had been prescribed anti-hypertension medication sometimes thought the medication was for the relief of other ailments such as low back pain or asthma.

The traditional physician-patient encounter is ill-suited for learning to take place.

- The encounter is perhaps the most anxiety-laden of all lay-expert consultations.
- Too much information is often transmitted in too short a time.
- A potentially upsetting diagnosis and advice may disrupt learning.
- Traditional learning tools, such as note-taking, are not used.
- The patient’s ability to learn can also be hampered by the physician’s use of technical language.

Older patients are often reticent to ask questions of their physicians perhaps because of:

- respect for professional authority;
- fear of looking unintelligent or unsophisticated; or
- anxiety about the medical condition.

Furthermore, physicians rarely invite questions from patients regarding proposed medication therapy.

A Food and Drug Administration survey of physicians discovered that 79 percent feel they spend the right amount of time discussing medication therapy with their patients, and 32 percent feel their patients are very well informed about prescribed medications. An additional 56 percent feel their patients are adequately informed.

Seventy-two percent of the physicians feel that patients frequently discontinue taking medication. However, only seven percent of physicians surveyed who prescribe antibiotics tell their patients to finish the medication.

Twenty percent of the physicians surveyed said that sharing of medications is a problem, but only three percent of the physicians who prescribe tranquilizers tell their patients not to share the medication.

No physicians who prescribe thiazides (anti-hypertension medication) report that they tell their patients the therapy is long-term or permanent.
The small percentage of physicians in the survey who feel that they don’t spend enough time discussing medications with their patients cite practice demands and limited time. Physicians see an average of three patients per hour. Physicians who are high prescribers are more likely to use supplemental education materials such as brochures or pamphlets to explain medications.\textsuperscript{66}

Role of the Pharmacist: One study discovered discrepancies between what the physician wanted on the label and the information the pharmacist actually printed on the label in 20 percent of 179 prescriptions studied. Types of discrepancies most commonly found were:

- The condition or symptom(s) to be treated were either omitted or incorrect.
- The label omitted the physician’s individualized instructions for frequency or amount of dose.
- The label did not include a language translation for foreign speaking patients.\textsuperscript{67}

In regard to patient interaction, pharmacists who were surveyed indicated that:

- Seventy-nine percent would like to have more time for patient consultation.
- Limited time and practice demands are responsible for the lack of patient consultation. Pharmacists dispense seven to nine prescriptions per hour.
- Forty-five percent of pharmacists say patient questions interrupt their work not at all, and an additional 26 percent say patient questions interrupt their work just a little. So, while pharmacists do not often offer information voluntarily, they do not seem to feel that patients’ questions are an imposition on their time.
- Ninety-six percent report that they provide auxiliary labels on prescriptions and 69 percent provide pamphlets for certain medications.\textsuperscript{68}

Patient Expectations and Attitude: The AARP survey of Americans over 45 years of age discovered that 69 percent of respondents go first to their physicians when they have questions about prescription medications.\textsuperscript{69} However, the FDA survey of physicians found that 38 percent of physicians screen out most or all calls about medications.\textsuperscript{70}

Twenty-five percent of respondents to the AARP survey turn to their pharmacists for information, and a small percent use books or other reference materials to get their information about medications.\textsuperscript{91}
Forty-nine percent of the over-65 age group report that they never ask their doctors or pharmacists questions about medications. Respondents in general, and especially the over-65 age group, report dissatisfaction about the information they receive from both their physicians and pharmacists about:

- the name and purpose of the medication;
- how and when to take the medication;
- whether adverse effects are a possibility;
- whether side effects are a possibility;
- what the storage requirements are;
- how many refills are required; and
- whether there are alternative therapies for the condition.92

Finally, over 45 percent of the above-65 respondents report that their physicians and pharmacists do not ask them what prescription and nonprescription medications they are taking before writing or filling a prescription.93

**EDUCATION IS THE BEST WAY TO IMPROVE COMPLIANCE.**

The complex nature of the medication compliance issue suggests that there are not likely to be any quick or simple remedies for this problem.94 A number of suggestions have been offered by various researchers. Haynes has pointed out that any efforts to improve compliance should target only treatments for which there is reasonable evidence of therapeutic efficacy.95

**Educating Patients and Health Care Providers**

Physician/Pharmacist Level: Patient education has been suggested as a primary means of improving patient compliance, and has been shown to be successful in many cases. However, as Falvo has pointed out, patient education is not simply repeating directions or handing out printed materials. It is a process involving skill in data gathering; individualization of instructions; prompting and support; and evaluation and follow-up of the patient's success in implementing the treatment regimen.96 Furthermore, the patient must be involved in designing any intervention to improve his compliance. Only when the patient has been allowed to express his or her point of view can the health care provider best decide what strategies will be most appropriate to improve compliance.

Meichenbaum has suggested that when health professionals view patient education as a process rather than a single intervention, they may fear that the process will become too time consuming. However, the process of patient education, if incorporated into the daily interactions of each patient encounter, can actually save time by increasing patient
compliance. Fewer calls or visits to the physician or pharmacist, as well as other benefits of compliance such as avoiding hospitalization, may result if proper educational techniques are employed early in the therapy. Studies have shown that compliance-improving programs have cost/benefit ratios as high as 1:14.

Public Education Programs: There are currently many programs for informing and educating elderly patients about medication issues. Some of the better known programs are:

- The Elder-Ed and Elder Health Programs conducted by the University of Maryland's School of Pharmacy: In the Elder-Ed program retired pharmacists are teamed with pharmacy students to provide counseling to senior citizens in group settings. Within the Elder-Health Program, pharmacy students are required to form a relationship with an elderly patient. The student visits the elderly patient periodically to help educate the patient about medications. In this way the student learns first-hand some of the problems elderly people face with medication regimens.

- The San Francisco SRx (Senior Medication Program): Sponsored in part by the San Francisco Department of Health, SRx involves pharmacies in community outreach programs to inform and educate elderly people about their medication regimens.

- The National Institute of Drug Abuse (NIDA): The Institute developed a film and a booklet about the elderly and medication issues. These are distributed to State agencies involved in prevention of medication abuse.

- The American Association of Retired Persons (AARP): Among other activities, AARP developed, with the help of the FDA, patient package inserts known as MILS (medication information leaflets for seniors) which contain information about medications and their proper use. The MILS are distributed with over 90 percent of medications dispensed through the AARP's mail-order pharmacy service.

- The National Council on Patient Information and Education (NCPIE): The Council employs public service announcements, education campaigns, and special events such as the "Talk About Prescription Month" to raise public awareness about problems associated with prescription medications.

Using Compliance Aids

It has been suggested that various electronic and mechanical devices called "compliance aids" might help to improve compliance. There are a wide range of compliance aids available, from simple charts to record and remind patients of medication use, to sophisticated micro-electronic bottle caps that have alarms and flashing indicators to alert a patient when a
dose is due. Compliance aids can range in price from a few cents for a chart to fifteen dollars for a micro-electronic cap. Such aids may be useful for patients with memory impairments or patients on a complex medication regimen.

Other strategies and mechanisms proposed to improve patient compliance include:

- providing reminder cards for refills;
- providing written or printed information that is easy to read (large type);
- keeping medication histories;
- using large type and specifying instructions on prescription labels; never writing "take as directed;"
- simplifying the regimen as much as possible;
- involving family members in support and/or supervisory roles; and
- demonstrating the proper technique for using a medication application apparatus.

**Compliance Can Be Improved**

Green et al. conducted a quantitative review of 10 experimental studies specifically addressing the elderly with education and behavioral interventions designed to improve medication compliance. They discovered that all methods, with the exception of written materials used alone, were effective in significantly and substantially improving knowledge of medication use, and decreasing the incidence of error.101

However, strategies employed to improve patient compliance have been shown to be effective only insofar as they are matched to individual patient needs.102
## APPENDIX A

**Office of Inspector General Studies of Elderly Medication Issues**

<table>
<thead>
<tr>
<th>Studies Completed</th>
<th>Request Report Number</th>
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</thead>
<tbody>
<tr>
<td>Medicare Drug Utilization Review</td>
<td>01-88-00980</td>
</tr>
<tr>
<td>Physician Drug Dispensing</td>
<td>01-88-00590</td>
</tr>
<tr>
<td>Implications of the Medicare Prescription Drug Benefit's Electric Claims Processing System</td>
<td>01-89-89170</td>
</tr>
<tr>
<td>State Discipline of Pharmacists</td>
<td>01-89-89020</td>
</tr>
<tr>
<td>The Clinical Role of the Community Pharmacist</td>
<td>01-89-89160</td>
</tr>
<tr>
<td>The Clinical Role of the Community Pharmacist: Case Studies</td>
<td>01-89-89161</td>
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</tbody>
</table>

**Studies Underway**

Adverse Drug Reaction Reporting System                                               | 12-90-01000           |

**Studies Planned**

Prescription Drug Advertising                                                        | 01-90-00480           |
APPENDIX B

ENDNOTES


16 Donald Meichenbaum and Dennis Turk, Facilitating Treatment Adherence.


27. Meichenbaum, *Facilitating Treatment Adherence*.


32. Ibid.

33. Amaral, "The Special Case of Compliance."

35Helene Levens Lipton, Statement on "Drug Misuse Among the Elderly and Its Impact on Community Based Care," before the U. S. House of Representatives, Subcommittee on Human Services, Select Committee on Aging, April 19, 1989.

36Ibid.


38Meichenbaum and Turk, *Facilitating Treatment Adherence*.


40Meichenbaum, *Facilitating Treatment Adherence*.

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43Helene Levens Lipton, Statement on "Drug Misuse Among the Elderly and Its Impact on Community Based Care," before the U. S. House of Representatives, April 19, 1989.

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54 Helene Levens Lipton, "Elderly Patients and Their Pills: The Role of Compliance in Safe and Effective Drug Use."

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61 R. Brian Haynes, "Determinants of Compliance."

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71. Meichenbaum, Facilitating Treatment Adherence.


75. Irving Kenneth Zola, "Taking Your Medication – Problem for Doctor or Patient?" in Barofsky, Medication Compliance.


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87 Svarstaad, "Physician-Patient Communication."

88 FDA, "Patient Information and Prescription Drugs."


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92 Ibid.

93 Ibid.

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96 Falvo, Effective Patient Education.

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101 Green, Mullen and Stainbrook, "Programs to Reduce Drug Errors in the Elderly."

102 Amaral, "The Special Case of Compliance."
APPENDIX C

COMPLIANCE ISSUES
Selected Bibliography


- Statement on "Drug Misuse Among the Elderly and Its Impact on Community-Based Care." Presented by Dr. Monroe Gilmour before the U.S. House of Representatives Select Committee on Aging, Subcommittee on Human Services. April 19, 1989.


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Statement on "Drug Misuse Among the Elderly and Its Impact on Community Based Care." before the U.S. House of Representatives Select Committee on Aging, Subcommittee on Human Services. April 19, 1989.


