

REDUCING THE USE OF CHEMICAL RESTRAINTS IN NURSING HOMES

WORKSHOP

BEFORE THE

SPECIAL COMMITTEE ON AGING UNITED STATES SENATE

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PREFACE

On July 22, 1991, the U.S. Senate Special Committee on Aging held a forum entitled "Reducing the Use of Chemical Restraints in Nursing Homes." It was held as a follow-up to the December 1989 symposium on the use of physical restraints in nursing homes. The overwhelming interest in that symposium and in the issue of restraints in general demonstrated to the Committee the need for a second forum on the use of drugs as a means of restraint for nursing home patients.

With the October 1990 implementation of OBRA 1987 nursing home reforms, the appropriate use of these drugs—usually antipsychotics—has become the focus of growing attention on the part of health care professionals and the general public alike. The December 1989 symposium was successful in informing providers and the public about the effects of physical restraints as well as alternatives to their use, and it is the Committee's hope that the forum on the use of chemical restraints will yield similar results.

Unlike physical restraints, which in most instances are detrimental to the patient, these drugs can truly benefit the patient—if used properly. Unfortunately, these drugs are all too often inappropriately prescribed, and are used to sedate and restrain a patient, rather than treat the condition for which they are medically intended. Clearly, there is a significant need to educate health professionals on the appropriate use of these medications—and the dangers of their misuse.

The Aging Committee is pleased to release this print, which contains the proceedings of the forum, as well as related materials on the use and misuse of chemical restraints. We would also like to express our appreciation to everyone who made this event possible.

DAVID PRYOR,
Chairman.

WILLIAM COHEN,
Ranking Member.

REDUCING THE USE OF CHEMICAL RESTRAINTS IN NURSING HOMES

MONDAY, JULY 22, 1991

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, in the Dirksen Office Building.

Staff present: Portia Porter Mittelman, staff director; Holly Bode, professional staff; and Mary Berry Gerwin, minority staff director/chief counsel.

WELCOME BY PORTIA PORTER MITTELMAN, STAFF DIRECTOR, SENATE SPECIAL COMMITTEE ON AGING

Ms. MITTELMAN. Good morning, everyone. I know we're packed in here like sardines, but we're really delighted to have all of you join us this morning.

My name is Portia Mittelman and I'm staff director for the Senate Aging Committee. We are really delighted to have you here for the second in our series of issues regarding restraint use nursing homes. This forum is a follow-up to our 1989 forum on physical restraints. We will be discussing the whole realm of chemical restraints in long-term care facilities.

Before I turn it over to our moderator, I would like to make a few recognitions. First of all, my colleague Holly Bode, has been the driving force behind this forum, and I really would like to give her a round of applause, if you will. [Applause.]

Ms. MITTELMAN. None of you would be here and none of this would be happening without Holly's work, so I really appreciate her.

I would also like to recognize one other person that the aging community needs to know, and that's Mary Berry Gerwin. Mary is the staff director for Senator Cohen, who is the ranking member of the Aging Committee, and is new to some of these issues. So we should all welcome her.

Let me introduce our moderator, so we can get started. Our moderator is Mr. David Sherman. Mr. Sherman is the founder and President of Health Care Visions, Inc., of Greenbrae, CA. Health Care Visions is a nonprofit consulting and educational foundation. He has had over 15 years of experience in long-term care pharmacy consulting and education. He has also authored many articles in professional journals and is a widely traveled lecturer.

Prior to his work with Health Care Visions, Mr. Sherman was a research associate and geriatric pharmacotherapy specialist in the Department of Social Medicine and Health Policy in the Division on Aging at the Harvard Medical School. So you can see he is uniquely suited to moderate our session this morning, and I would now like to turn it over to David.

**OPENING REMARKS BY DAVID S. SHERMAN, R.PH., FASCP,
PRESIDENT, HEALTH CARE VISIONS, INC., GREENBRAE, CA**

Mr. SHERMAN. Thank you, Portia. Good morning, everybody. I am very happy to be here today. Over the last number of years I have been involved in long-term care, the focus of my clinical practice and research has been this area. So it feels really great to have the opportunity to talk in a forum like this. I want to express my gratefulness to the Senate Special Committee on Aging for bringing something like this together.

First of all, I would like to congratulate each of you for taking the time out of your busy schedules to attend the symposium. Clearly, you are here because you care enough to want to learn more about how you can reduce the suffering of nursing home residents who are medicated inappropriately.

It was not too long ago that we routinely warehoused mentally ill people in facilities that came to be known as snake pits. In these places, meals were shoved under the doors, and electroshock was administered as punishment for lack of cooperation with institutional rules. Today, we look back at those times with disdain and even disbelief that we could have treated our fellow human beings in this way.

I think that at some time in the not too distant future we will similarly look back at this time, the routine drugging of our elders, as an equally barbaric form of treatment.

This is not to discount the fact that sometimes use of antipsychotic medications may be necessary, or even be considered compassionate in certain circumstances. Unfortunately, the statistical evidence of antipsychotic drug use patterns in our Nation's nursing homes demonstrates a continued lack of awareness in our medical, nursing, and pharmacy communities that use of these drugs is not only not helpful in many of the circumstances they are currently used, but downright dangerous.

The factors that contribute to our Nation's "other" drug problem are complex and sometimes quite insidious. I hope to touch on some of these factors over the next 20 minutes. There are currently pharmacists, physicians, nurses, administrators, regulators, policy-makers that are doing something about this issue now. And you will be hearing from some of them today during this program.

I think the easiest way to get to the heart of this matter is to consider this: If your mother or your father, your brother or sister, one of your loved ones, was in a nursing home, and they were about to receive a medication that potentially had some pretty serious adverse effects, wouldn't you want to know that there had been some pretty well-designed research that showed this medication actually worked for the condition it would be used for on your loved one?

And then, since we are all individuals and each of us respond differently to medications, wouldn't we want to know that in that particular nursing home there was some particular mechanism in place, some monitoring approach, that would show whether the medication actually helped, or maybe even hurt, our loved one?

It's only commonsense that the people that are caring for our loved ones would need this information in order to make more educated therapeutic decisions. But the sad fact is that in most nursing homes across the country, this still isn't happening. Often, the decision of whether to start, increase, decrease or discontinue an antipsychotic medication is based on not much more than a guess, a shot in the dark. Because the prescriber has no reliable data base of monitoring information on which to base his or her decision.

To require the gathering of this information was the intent of the new Health Care Financing Administration antipsychotic drug requirement. We have the author of that requirement in the back, Sam Kidder. And also the subsequent interpretive guidelines were intended to help surveyors assess whether these medications were being used correctly in our Nation's nursing homes.

Since this is a forum about inappropriate chemical restraints, I would like to briefly mention my concern about the potential watering-down of the interpretive guidelines that are occurring as a result of the resistance of California to implement those interpretive guidelines. As I have spoken to groups of surveyors around the country, consistently what I've heard, time after time, is surveyors saying "We need these interpretive guidelines, because we need to have some guidelines so that nursing home staff and administrators are not saying it's just your opinion." I am concerned that this impact might be diffused somewhat because of the potential changes that could occur in the preamble of the interpretive guidelines.

One of the grandfathers of American medicine, William Osler, once said that the desire to take medicine is one of the principal factors that distinguishes man from animals. We could also change this a little bit and say one of the principal factors that distinguishes health care professionals from other people is the desire to give medication. We have all learned in our particular health care profession that medications can be very useful tools. So we believe in their use, and for a good reason, because they can be lifesaving in some cases.

But unfortunately in some cases, they really don't work. When we are talking about antipsychotic drugs, and about how much they don't work, it's important to remember that medications are only tools. They are just as good as they are used and monitored.

Sometimes antipsychotic drugs may be useful, even in demented individuals, for very specific circumstances. If someone is severely paranoid, if they are experiencing frightening delusions or hallucinations. By the way, it is commonly thought that people have visual hallucinations, when they have a dementing illness. But they actually are not that common. It is usually auditory hallucinations that are more common in people who are demented. Visual hallucinations are more indicative of a state of delirium, which may be drug-induced.

Violent behavior that is nonresponsive to nondrug approaches, mutilating behavior, any of these things, these severe kinds of situations that are occurring, it's worth trying these medications if the nondrug approaches are not working, to see if they might help.

But we don't know if they are working unless we monitor and assess the therapy to see what's going on, and we have some baseline to work from. And that's what the folks on our panel are going to be talking about today, how we can do that in our Nation's nursing homes.

These drugs cause a lot of pretty serious side effects, one of the worst if not the worst is something called tardive dyskinesia. Tardive dyskinesia is something that may start out just with seeing the tip of someone's tongue, like this, and they are just walking around with the tip of their tongue sticking out. They might progress to sucking and smacking motions. Often people who have dementing illnesses will make these motions anyway. So it's always important to differentiate.

And whenever we are talking about abnormal involuntary movements, again we need to have a baseline. Were these people making these movements prior to being on medication? Movements of the jaw from side to side—sometimes these things can get pretty extreme, people just walking around with their tongues looking swollen or hanging out.

Thrusting or fly-catching movements of the tongue I will leave to your imagination. This disorder can cause other parts of the body to make strange movements as well. As a matter of fact, it often goes unnoticed, because people often think it only happens in the facial region.

These drugs also cause other adverse effects, like Parkinson's symptoms. People have tremor, rigidity, difficulty ambulating. They become oversedated. Tardive dyskinesia actually is secondary only to oversedation. People think tardive dyskinesia is uncommon. But according to a task force report the American Psychiatric Association put out in 1979, at least 40 percent of elderly people that are placed on these medications are likely to develop some form of tardive dyskinesia. And it is frequently irreversible.

Oversedation can lead to other problems, such as falls. What happens when fragile elderly bones hit the linoleum? You get fractured hips. There was a study in the *New England Journal of Medicine* about 5 years ago that found that elderly nursing home residents on antipsychotic drugs are two to three times more likely to experience a fractured hip.

Oversedation also may lead to urinary incontinence. I am going to be talking a little bit about the economic consequences of that later, as a model for how we can open up more time in our nursing homes to help people. Because oftentimes we hear the complaint that we just don't have the time in nursing homes to do the things we would like to do, more humanistically interactive kinds of things for people.

With all these things, what happens is that people have a reduction in their self-care abilities. I refer to it as the illusion of the easier to care for residents. There is a tacit belief in the medical, nursing, and pharmacy communities that these medications make people easier to take care of. But actually, they make people

harder to take care of. It takes more staff time. And I will show you more about that later.

Not only do these drugs cause a lot of bad side effects, but most studies that have been done have found that these drugs don't even work for most of the behavioral problems that occur in people who have dementing illness. And these are the folks that the medications generally are used for in our nursing homes.

You might ask, if this is the case, and the drugs don't really seem to work, then why is it they continue to be used? Well, first of all, we are in this business to help people. We want to help people, we believe that medications work. We are taught in our medical, nursing, and pharmacy schools that medications work. If they didn't work, why would doctors prescribe them, pharmacists dispense them, and nurses administer them?

We routinely underestimate the toxicity of these drugs. We commonly view behavioral symptoms as a problem, judging people instead of just assessing what's going on. We often see these medications used for environmental control. They are sometimes used because families get concerned, and feel guilty because they have their family member in a nursing home, and they hear mom or dad going "Gaa, gaa, gaa." They think they should get medication for that, when maybe what they need is an anti-gaa drug, which doesn't exist.

Also, nursing staff stress is a very big factor in nursing homes. Nurses who work in long-term care are second only to nurses who work in trauma units or emergency care units in the incidence of substance abuse. That's quite a strong indication of stress. Some of the people who work in nursing homes are some of the most unheralded individuals in our country, particularly nursing assistants. It's sort of the case of the disenfranchised taking care of the disenfranchised.

Also inadequate training is a reason why these medications get misused. As a matter of fact, I go through these reasons in much more detail in an article—I have a few articles that were out on the table there that go into this information and what I'm talking about in greater detail.

Another factor that influences the use of these drugs is the advertising that comes from the drug manufacturers that occurs with these medications. Years ago, drug advertising looked something like this: "Dr. Williams' Electric Medicated Pad, it's good for the cure of malaria, chills, biliousness, nervousness * * *" I don't know why they took this off the market, it worked for everything. You had to be a little wealthy to use it though, because it used electricity.

Well, thank God we have the Federal Trade Commission and the Food and Drug Administration so that this kind of thing doesn't happen in advertising today. Well, actually, because we as consumers have become much more sophisticated, so have the people who advertise.

Here we have a guy who is leaving the psychotic symptoms of organic brain syndrome behind. This guy who couldn't find his way from his bedroom to his bathroom last night, now that he has taken this medication, he is taking his grandson fishing. Of course what

you don't see in the next panel here is that he is throwing his grandson into the water.

It's important that when we look at these advertisements that we remember the purpose of advertising is not to intellectually convince. Physicians, nurses, pharmacists—we're not stupid. We don't look at it and say "Gee, that's great." It's a subtle influence. The purpose of advertising is to plant a seed in the unconscious for later harvesting.

So later, at 2 o'clock or 3 o'clock in the morning when a physician gets a call from some upset nurse at a nursing home, they will remember this subliminal message of this peaceful scene, and they prescribe this medication.

I don't mean to say this is why doctors prescribe these medications at all. It's another influence, and if it wasn't useful, you can be sure drug companies would not spend \$3 billion a year doing this.

"I made a flower today." Isn't that sweet? Actually, this lady is only 32 years old and heavily made up. On the other part of the ad it says "Helps make nursing home residents less disruptive." The idea was—this little asterisk you probably can't see—at the bottom of the other page, there was a statement saying "Now she can get to activities." The idea was, she made this flower in activities. But at the bottom, next to the asterisk, it says "Not a real nursing home resident and not a real flower made by a nursing home in a real activity." This is a paid actress.

So these are some examples. If I had some more time I would show you some more of these advertisements. They are really quite humorous. So what are we going to do? Side effects are really a problem with these medications. They don't seem to work for what we wish they would work for. These are influences on the prescribing that we wish weren't there.

Well, I think probably what we need to do is look at why people get agitated, if we're going to try and help them. And it's very important to remember, it's much easier to prevent agitation than it is to treat it. That's what we need to do, look at how we are going to prevent people from getting agitated, and by looking at why they get agitated.

Side effects of drug therapy—there is a member of the health care team named a consultant pharmacist. There are 4,000 members of an organization called the American Society of Consultant Pharmacists that are mandated by Federal law to be in nursing homes to monitor medications and to give people information about medications.

So people who work in nursing homes can turn to consultant pharmacists, and we have a consultant pharmacist on the panel today, as a matter of fact, who will talk about some research that she has been doing in her organization about this subject.

Undiagnosed medical problems—I'm sure Dr. Elon will be covering those kinds of things today as well, so I will not go through them. Frustration at being unable to express their needs—people who are demented know that something is wrong, but they can't tell you what it is. That gets them very frustrated and eventually angry.

People get afraid, they misperceive environmental stimuli. Those of us that are in this room know that when I go like that, it's the pointer going down on the podium. To someone who has a dementing illness, they may think that's a bomb going off. So they react in exaggerated ways.

Feelings of isolation—probably everybody in this room at one time or another, probably more than one time, has felt rejected, unloved. It's not a good feeling. People who have dementing illness also have these feelings, but they don't have the emotional and intellectual capabilities to integrate and process that kind of feeling. So they just sit with that pain. They feel unloved and alone. As a result, they get angry and they want to strike out at people.

Unexpected actions of caregivers—I think the best example of this is to think about it. I would say to people, have you ever looked in the mirror when you are having a particularly difficult day? If you do, you look something like this, with some version of a grimace on your face.

Now imagine being 80 years old and demented, and having somebody walk up to you with a look like that on your face, they are bigger than you, they can move faster than you, and they want you to do something that you don't want to do. How would you respond?

You can understand why people are trying to strike out. They are just trying to defend what they think they are supposed to be doing.

The message is that we have to change our behavior. We can't change the behavior of demented people. We need to change the environment, we need to change how it is we approach these people. That's really the key to this. In doing this, we need to try and find out what's wrong, we need to document each time something happens. One of my articles I co-wrote with Nancy Mace goes into this slide in much greater detail. It does not work just to have a checklist of certain kinds of behavioral symptoms and just be checking those symptoms off. That does not justify the use or non-use of medications.

But that information can be very useful if it is analyzed appropriately, maybe even if it's presented in a graph so you can identify patterns that occur. That's when this information is effective, not just as a checklist to apparently satisfy a regulation. That's not what the intent of this regulation has been.

We want to find out why this stuff is going on, and how we can approach it. Medication should not be a sole approach. It should be an adjunct to a total care plan. Finding out whether the behavior is occurring when someone is active or not active, how long it lasts. I know of many cases I could tell you about that we found out what was going on with somebody just because we did this.

There was one guy who was getting crazy sporadically. We couldn't figure out what was going on, then we finally narrowed it down to this one nursing assistant. Then we narrowed it down to it only being when she wore a red smock. It turns out the guy didn't like the color red very much. She didn't wear the red smock any more, he didn't get agitated any more. Sometimes it's not that simple, but sometimes it really is. It's that simple, just common sense.

But when you are in the thick of it, you can't see that. That's why we need to create a monitoring record to help us separate the forest from the trees. And I'm sure this is going to be discussed by other members of the panel in greater detail.

Really what works best for many residents is reassurance. That's the main message I would like to leave with you today, that connecting at the heart level is what really prevents behavioral symptoms. People feel more secure, more loved, that's how we prevent agitation from occurring. If we do it on a consistent basis, just stopping and saying "hi" to somebody, taking 15 seconds to do that, using appropriate body language, bending down to their level so that you are not towering over them in some imposing figure. Those are the things that really work for these folks.

What I would like to do in the last few minutes is share with you something that I call the hidden costs of psychoactive drug misuse in long-term care. I have been talking about this subject for many, many years, and I think it's really important, if we want to effect change in this area, that we be very pragmatic about how we do that.

We need to understand that the long-term care industry is a business. Although it's a business to help people and to take care of people, it is a business and there is a bottom line that needs to be attended to. We can't be too naive and think that isn't the case.

So thing it's important to look at the cost effectiveness of decreasing drug therapy, not just in the costs of drugs, but in terms of the indirect costs of drugs. When we look at the costs involved in urinary incontinence in the nursing home setting, for example, there is labor from the nursing assistant, supervising time for nurses, the housekeeping costs, the cost of labor for that.

We are talking about the costs from laundry, from depreciation of washing equipment, detergent costs, cost of electricity—and where I come from in California, water is every expensive—supplies, disposable bedpans, briefs, catheters, skin products. Some of these things are a cost to the nursing home, some of these things are costs to the Government. In any case, it's a lot of money.

If we look at the daily cost of this, using information from an article in the *Clinics and Geriatric Medicine* from 1986 by a person name Hu, at that time it cost about \$6 a day to take care of a person with urinary incontinence in a nursing home setting.

I do a monthly column for a magazine that goes to all nursing homes in the country called "Contemporary Long-Term Care." Jim Bowe, the editor of this journal, tells me that it now costs \$12 a day to take care of a person with urinary incontinence in the nursing home setting. I know that this does not come as a surprise to those of us who work in long-term care, or does the fact that study after study has shown that over half of nursing assistant's time is spent on incontinence related issues.

Sixty percent of the cost is labor, 24 percent laundry, 16 percent is supplies. Now, if we take a hypothetical nursing home, "Tranquility Lane," a 100-bed nursing facility, and I apologize if anyone is from a facility called Tranquility Lane. I don't think one exists. You never know with a name like that, it's a catchy name, right?

Let's say, according to the national average, and this goes back to 1976 data that was collected in a survey by the Department of

Health, Education, and Welfare. This data was duplicated by my former colleagues and I in a study that we did from Harvard Medical School that was in the Journal of the American Medical Association in 1988 looking at facilities in Massachusetts. About half the people in nursing homes were on some kind of psychoactive medication.

So, if half, or 50 of the residents in "Tranquility Lane" are on psychoactive medication, of those half, let's say 20 people are incontinent of urine due to a psychoactive drug. Let's say of those 20 people, we can get 10 of them off the medications, and they are no longer incontinent of urine. For those 10 people, that's \$120 a day, \$3,600 a month, \$43,000 a year. That ain't hay.

Now let's say—remember, 60 percent of the cost was labor—let's say we don't do anything to change the cost associated with labor. So let's say we only save \$18,000. Let's be even more conservative and say \$15,000. Let's say \$10,000. What nursing home administrator would not want to add \$10,000 to their bottom line? It's a very pragmatic approach to this kind of thing.

And the nice thing about this approach is not only do we have an improved quality of life for our residents at this nursing home that does this, we certainly are going to be saving money on incontinence related costs. And I'm not talking about any other costs, the time it takes to feed people who are on these medications, who are much more likely to choke by the way, because these drugs actually paralyze the gag reflex. Or the time it takes to dress people, or ambulate people, or all these things that are necessary because people are oversedated.

That all takes staff time, and not only does it take staff time, it takes staff energy, and people are more likely to get burned out as well. So if we can shift staffing patterns around in positive ways, so people can interact with people in these more humanistic ways, not only is it going to help the residents, but it's going to help the staff as well, because they are going to feel better about what they're doing.

They are not going to be physically exhausted from what they need to do each day, with the physical care of these people. They will be able to sit and talk with them for a few seconds here, or a few seconds there. It does not have to be sitting with them for half an hour and taking their life story. It can just be for 15 or 30 seconds, a minute, and that will be fine.

If that's done frequently throughout the day, people will reconnect. Remember that half the nursing assistant's time is spent on incontinence related issues. They can use this extra time that is broken away by people being off the medications that are causing the incontinence to do these kinds of activities. This is what they are currently complaining about, and rightfully so, that they don't have the time to do a lot of things they really want to. People know what they need to do. They see the effect of what they want to do. They want to do these things.

I don't believe what I see in the newspapers, that people in long-term care are these ogres that are torturing people and tying people up in closets. Sure, this happens on occasion, and sure, it happens through ignorance. But for the most part, this does not happen through malintent. It happens because people feel they are

between a rock and a hard place, and they don't know what else to do. They need to be educated on what else to do.

We are certainly going to be complying with Health Care Financing Administration regulations in doing this. And there is also an opportunity for good public relations for the nursing home. Imagine the headline—"Tranquility Lane starts new program to reduce unnecessary tranquilizers." I'm sure people would flock to their nursing home.

Now, in closing, you are going to hear a lot of information today, information I hope you will find practically oriented and useful in your work. But to me, the most important part of today is for all of us to be in touch with the fact that this is not just another medical topic. Ultimately, this subject is very much a matter of heart. Changes in regulations are useful tools. And learning new and effective techniques for the assessment and monitoring of behavioral symptoms are very important.

But the true seeds of change lay waiting in our hearts. For us to stop the drugging of our elderly—this requires that we, who are more aware of this problem, to help others to become aware, not in a judgmental or accusatory manner. We can't allow our judgment of what has occurred in the past to cloud our vision for the future.

We need to help every one of our colleagues feel the pain that occurs when our fellow human beings are treated inhumanely. This is what will encourage the development of new policies that are not only cost-effective, but also people effective.

Then we need to be ever vigilant, that when such policies, regulations, and guidelines are developed, that they aren't watered down by those who are not sensitive to the enormity of this problem. How do we do this? By example, not by placing blame. By offering alternatives, not by condemning others' therapeutic choices. By carrying our message with an urgency and passion that will move others to do the same.

Because true and lasting change will occur not through regulations alone, but through a change in attitude, by an increased awareness of the consequences of our actions, by helping others bring to consciousness that which they wish to deny, that as painful as it is to realize, when we inappropriately administer antipsychotic drugs, we are doing something that causes more harm than good for the people we have dedicated ourselves to serve.

As the educator Herbert Spencer once said, the great aim of education is not knowledge, but action. I want to thank you all today for your kind attention, and I look forward with you all to a symposium filled with ideas that will help us carry this message to our colleagues. Thank you very much.

For our first speaker on the panel today, we are going to have Zofia Long. Zofia Long has been an administrator for 9 years, and is licensed in both New Hampshire and Massachusetts. She ran the first restraint-free nursing home in New Hampshire, and she is now at the Highlands Long-Term Care Center, in Fitchberg, MA.

I had the great pleasure of visiting her nursing home in Massachusetts, and I was incredibly impressed with what I saw there. She has been leading efforts in Massachusetts to reduce restraint use. She has taught workshops throughout the country and to Massachusetts State surveyors. And she has participated on a Massa-

chusetts committee which is responsible for the publication of a national manual on restraint reduction.

Zofia.

**STATEMENT OF ZOFIA LONG, ADMINISTRATOR, THE HIGHLANDS
LONG-TERM CARE CENTER, FITCHBERG, MA**

Ms. LONG. Thank you very much for that nice introduction.

I would like to start off by saying I am very proud and honored to have this opportunity to come and speak to you here in Washington. Out of all the workshops I have taught in the past, I think a total of nearly 75, I am by far the most nervous at this one.

I want to begin by telling you that everything I will mention today is only the tip of the iceberg. I have 20 minutes, and I am going to give out some theories and ideas that can take as long as a day to understand and comprehend. But I am excited about having this opportunity to share with you the ideas we have been using at The Highlands, and we have been using them very successfully.

I would like to start off by reading to you a little statement written by my medical director, Henry Wieman, who is a geriatrician. He wrote this paragraph, trying to describe what dementia is like. I would like you to just listen to this for a minute:

Try to imagine yourself in the middle of the night. You are in bed, sleeping, you might have had a few cocktails before going to bed. All of a sudden you have been aroused by an alarming noise. You can't remember exactly what it was. Figuring out what awakened you seems very important. But the harder you try, the more elusive it becomes. In your half dream, half awake state, you mistake a shadow in the room for an intruder. Maybe it's the monster you saw in the movie the night before.

Now try to imagine that that state never ends. You can never awaken completely, and you can't go back to sleep again. You are just suspended in midair. Objects are hard to identify. Sounds are frightening. You can't tell the voices on the radio from voices in the room. Your hands seem like they belong to someone else. You do things backwards. You catch yourself trying to open a can with a pair of scissors.

All this makes you embarrassed, but most of all angry. Someone is doing this to you. It's not fair, and you're going to get them. You start to cry out, and once you start, you can't stop.

If this happened to you, how would you want to be treated? What usually happens to people in this state—and add to that physical problems that might make this problem worse.

I hope that kind of gave you an idea of what dementia might be like. I hope none of you ever experience it, I certainly hope I never do. Unfortunately, at this point it seems inevitable that at least 50 percent of us in this room might reach that stage sometime.

Now, I would like to make a few comments before I begin on my interventions. In defense of the industry that I have been working in for the past 9 years, I would like to state that I don't believe the nursing home industry ever used chemical restraints strictly as a convenience or discipline in caring for the elderly. They used it for two main reasons: frustration—not knowing what to do with these people and how to cope with these behaviors, and two, we continue a standard of practice that is currently in existence in the acute care industry.

The hospital industry has always been the mecca as far as health care, and the long-term care industry has been the second class citizen. Right now, the nursing home industry is faced with many

new challenges and I sincerely hope that the hospital industry will quickly follow suit.

One of the ways we have dealt with this frustration in trying to deal with behaviors at The Highlands Long-Term Care Center is through behavior logging. Behavior logging is step number one in trying to reduce chemical restraints. What I mean by that is, you take a log and describe a particular behavior, describe the exact time of the behavior, and you monitor for 24 hours a day, 7 days a week.

You do this with all your staff. You make them aware you are doing this behavior log on a particular resident. For instance, if the resident has had 13 outbursts of aggressive language in one 24-hour time period, what you need to do is understand the time it occurred, and what preceded the incident.

What this does is develop a pattern for you to determine what might be causing the behavior. In the majority of our residents, we have been able to determine what causes the behavior by using simple behavior logging techniques. Once you know what causes the behavior, you have to determine what the proper intervention is.

The interventions we use fall into three basic categories. Number one is simple distraction techniques. That's by far the easiest, and the quickest to use. The second technique is agenda behavior, which I credit to Joann Rader, who has developed that. The third is validation theory, and I credit Naomi Feil for writing and studying these behaviors for a number of years, and then finally teaching and doing a lot of education across the country on how to validate people's behaviors.

I am going to give you some basic examples of each type of behavior and each type of intervention. Hopefully this will give you some insight on how to cope with these behaviors without the use of chemical restraints. Some simple distraction techniques include food, a calm approach, reminiscing groups, programming, tapes such as relaxation tapes, a different environment, and family. Those are just some very basic ideas, and I will tell you how this worked on one of our residents, that I will call Peggy.

Peggy is about 85 years old and weighs 250 pounds, and has Alzheimer's disease. Every day at around 2:30, Peggy would come off our unit and try to get outside the front door to catch the bus. Now, of course, in front of my facility, the city bus does stop, so it made my life even more difficult. So every single day we noticed, we did the behavior log, it was 2:30 she's coming downstairs again. Why does she have to do this? What's causing her to do this? She would be very aggravated if you tried to stop her.

What we found out was she wanted to go home to make supper for her family. She felt she had to leave this place to get home, because her family wouldn't be able to eat. When I first arrived at The Highlands 2 years ago, I noticed the way they tried to get her back into the building. In those days, they brought the geri chair down, and three or four aides came to try to get this 250-pound woman into the geri chair and bring her back up.

I said that's just not right. There has to be a better way to deal with this person's behavior. She is very, very strong. So you can imagine all the fighting that could take place when this occurred.

What we did was talk to her daughter and said "Look, every day she is trying to go home to cook supper for her family. I would like you to be available on the phone at this time to talk to your mother when she goes outside." So what we did was, every time she goes out the front door, we would follow her and say, "Peggy, your daughter is on the phone. Would you like to take the call, or would you like us to take a message?" She would always say "I want to talk to my daughter."

So she would come right back into the building. Of course, the staff was upstairs frantically calling her daughter. She would get on the phone and her daughter would say "Hi, Mom, I love you. I won't be home for supper tonight. Don't worry about dinner." And then Peggy would say "Oh, isn't that nice."

So this is a very simple distractive technique. If the daughter isn't there, by chance, and we don't get hold of her, we say to Peggy, "Peggy, we're sorry, your daughter had to hang up. She says she loves you very much and she misses you." And Peggy then says "What a nice message. My daughter is a good girl." And that is 100 percent better than trying to get her back into the facility through the use of a geri chair, with three or four aides coming at her from different directions.

So that's a basic distraction technique that we used at The Highlands.

Another intervention is the agenda behavior. What this basically means, in the simplest of terms, is trying to meet the resident where they are at. Every behavior has a purpose. People don't just become agitated for no reason. Anxiety leads to agitation, which then leads to aggression. So you have to understand the escalation process. When you see a person start to become anxious, you need to intervene immediately.

An example of agenda behavior that I want to share with you is a gentleman called Levi. Every day at around 4 o'clock, Levi would get very angry, very aggravated. He would almost pace like a caged animal up on our special care unit. He would strike out at others, he would swear. He was not very pleasant to be around. We couldn't figure out what was causing this behavior.

We did the behavior log, and all we could determine was the time. There seemed to be nothing in particular that preceded the incident. We didn't know what we could do to prevent this from occurring.

So at 4 o'clock every day, we at least knew we were going to have to have some sort of intervention. What we did, however, was call in his wife and have a more in-depth discussion with her about his past. We had known that Levi was a factory worker his whole life, but we never knew what shift. He always worked 4 o'clock to midnight. So, at 4 o'clock, Levi wanted to go to work.

So we had to deal with that. How did Levi know what time it was? Surprisingly enough, Levi had his big clock in this room. You know in reality orientation, we always wanted to orient our people, time and place? Big mistake.

We took the clock out of his room, and I know some of you might think that's cruel, now the poor gentleman doesn't know what time of day it is, but now at 4 o'clock, he does not get agitated. He doesn't realize it's 4 o'clock. He doesn't think he has to go to work.

So that's a very simple case of agenda behavior. It often occurs—agenda behavior is often a good intervention at bathing time. If some of you have been in nursing homes and you realize people with Alzheimer's or related dementias often hate to bathe, and when you go to bring them into the whirlpool or the shower, a lot of screaming, yelling, and swearing takes place.

That's because the resident's agenda is different than yours. We are forever bathing these people, dressing, and cleaning them. These people, prior to the nursing homes, might have bathed once a week. That generation often did, or even less frequently. They might have had sponge baths their whole life. And here we are, trying to put them in this thing that looks like a jacuzzi, which they have never seen before.

So what you have to do is try to meet the resident where they are, try to reach them at their agenda. When you do that, they will not be as disruptive and agitated and angry when you do. Something as simple as bathing at night versus bathing in the morning, or vice versa, often will help.

The last intervention I am going to mention is called validation theory. This is the most complicated of the three interventions. Validation theory, in simplest terms, means to validate the person's feelings. That's the only way I can describe to allow you to remember that.

A good example of that occurred—we have a resident named John—every day he would come downstairs looking for the social worker. He always wore a suit, jacket, and tie. In his pocket, he always carried a certificate. It looked like stocks, like a stock certificate. But it really wasn't. I'm not quite sure what it was, but it was not anything of value.

Every day John was very frightened he was going to lose this. So every day, he would come looking for the social worker, because he thought she ran the bank, or the office downstairs. So he would come to see her, and he would pull out this paper every day, he could not communicate at all, but you could see his anxiety. He would start shaking and take the piece of paper—he can't read it, he doesn't know what to do with it—but he would be trying to hand it to her. So what she had to do was try to figure out what that behavior was. It was insecurity.

This gentleman handled the finances of this family prior to coming into the facility and he felt he either had to pay his bills or keep his money safe. So what we did was take the certificate from him and put it in our safe. We showed him where the safe was. Every day he would come down; the social worker would take it out and show him it was safe, and he would go back upstairs. So we validated his feeling of insecurity by doing this.

Because of this technique, his agitation level was greatly reduced. And we developed all this through the behavior log. We didn't know this just by looking at this gentleman. We had to study it, and decide what patterns were taking place. So that's a simple example of validation.

Another one is people that are very disoriented, the very old, old. These people often are uncommunicative. They won't respond, they won't talk to you, they often walk straight, with tunnel-like vision.

They often can't see peripherally, they are often crying or showing a grimace on their faces.

We have one woman, her name is Susie. She walks constantly, pacing, and always like this with her hands, very scared. Her eyes are never looking at anybody or anything, just straight. She will trip over everything; she does not see a thing when she's walking. It's zombie-like.

No one had ever been able to communicate with her. It was very frustrating for her daughters to come to visit. All she does is cry. She cries a lot for no reason. What we tried to do is see how we can communicate with her. I learned that this symbol is the symbol for mother, the hand becomes a symbol for mother. She was looking for her mother, as many of our elderly people who are disoriented and are in this old, old category will do.

So what I did one day was go up to Susie and I started talking to her, I got nowhere. Here I think I'm so smart, I'm going to validate her feelings. Well, she wasn't responding at all to me. Then one day I decided to use touch. I went up to her and gave her the symbol for mother, which is this, on the cheek.

She looked at me, right in my eyes, grabbed my hand and walked with me. That was a big step. It sounds like nothing, but that was a tremendous step for this woman. So when she sees me now, I do this to her cheek, the motherly symbol, and she will grab me. We trained all the staff to do this, and now when they see her, they go up to her and touch her face gently, and then she is receptive to either her care or the person she's with.

So that was another simple way of validating this woman's feeling that she is missing her mother.

Basically, that's all I wanted to talk to you about. Again, this is the tip of the iceberg. I see that my time is up, and I want to thank you for your attention. I hope that I didn't oversimplify this, and you think I'm crazy. There is a lot of in-depth information that goes along with these three basic techniques.

And I can honestly say, since I run a 168-bed nursing home, with an overall 10 percentage of psychotropic drugs use at this point, I think I can honestly say these techniques really work.

Thank you.

Mr. SHERMAN. Thank you Zofia, for that excellent presentation. Zofia is very modest about what she does. But what she does is a model for what nursing home administrators can do across the country to improve care for residents in nursing homes.

Our next speaker is Dr. Elon. Dr. Elon is the Medical Director of the Washington Home, which is a 180-bed nursing facility in the District of Columbia. As an assistant professor of geriatric medicine at George Washington University Medical Center, she was responsible for teaching medical students, residents, fellows, nurse practitioners, and physicians assistants about medical care in the nursing home.

At the end of this summer, she will be joining the medical school faculty at Johns Hopkins University. It is a great pleasure to introduce Dr. Elon.

STATEMENT OF DR. REBECCA ELON, M.D., MEDICAL DIRECTOR,
THE WASHINGTON HOME, WASHINGTON, DC

Dr. ELON. It is a great pleasure for me to be here and address all of you this morning. I would like to review a few things about the medications we are talking about, and expand on the comments David already made. I want to talk about the scope of the problem, the regulations, and then discuss what are the controversial elements of the implementation of the regulations from the physician's viewpoint.

I think I will be speaking for the minority opinion here this morning. The overview of the controversial elements includes the responsibility of the nursing facility regarding medical practice in the facility and the role of the regulations in determining medical practice. I would like to touch upon what I view as a failure of medical education in properly equipping physicians to deal with this population.

I would like to talk about residents' rights versus facilities' rights, and also the rights of physicians. Then I would like you to think with me a little bit about the battered woman syndrome. This is an analogy that can perhaps help us to understand the relationship between nursing homes and physicians, as they have historically been.

I would like to end on a positive note and talk about the future.

We are talking specifically about neuroleptic medications this morning, the major tranquilizers, also known as the antipsychotics, although in medical practice, they have a number of uses other than treating people with psychotic symptoms. The most common secondary use is to treat people with nausea and vomiting, as antiemetic medications.

The three major drugs in this category are haloperidol, or Haldol (sometimes the medical residents call this Vitamin H), Mellaril, or thioridazine and chlorpromazine, or Thorazine. These drugs have been commonly called chemical restraints. My own preference is to avoid that phrase, because in clinical practice I have seen these medications when they are appropriately used actually facilitate, enable, or enhance an individual's functioning.

In our own nursing home, as we went through dose reductions and drug holidays, we found several cases of individuals whose function actually decreased as their medication was withdrawn. For example, an elderly demented woman who hallucinated that she and others were on fire. When we couldn't understand why she was throwing water at other people, it was because she was having visual hallucinations that they were on fire. Small doses of these medications controlled that symptom for her.

Another woman became very paranoid when her medication was withdrawn such that she felt the sustenance she was receiving through her gastrostomy tube was actually poison. Her function improved when her medication was resumed. And another individual has hallucinations which were so distracting to her that she could not attend to the process of eating, because she was so distracted by what she was seeing around her.

So although I would be the first to acknowledge that this class of medication has been overused and inadequately monitored in the

nursing home setting, my own preference is to use a more neutral language and talk about the use and misuse, the appropriate use and the inappropriate use, adequate monitoring for efficacy and side effects, and inadequate monitoring for efficacy and side effects of this class of medications.

Why is this particular class, and this particular class alone, at this moment targeted for heightened regulatory scrutiny? I think that David outlined some of these issues. These are very potent drugs. The vast majority of people living in nursing homes who are receiving these drugs do not suffer from psychosis. But in fact they are elderly individuals with dementia.

There was a recent article in JAMA which is called a meta-analysis, where they take all the reasonable studies on the efficacy of these particular drugs and try to come up with a conclusion based on all the different data. The conclusion of the meta-analysis of the literature was that in people with dementia, neuroleptic medications are only moderately effective in improving target behaviors, about 20 percent of the time.¹

Well, with most medical interventions, if it's only effective 20 percent of the time, you wouldn't use it if you had something more effective to use. But when you don't know what to do, you do what you know. And unfortunately, physicians have been trained in the acute care model and have carried what has been taught to them as standard of practice in the acute care hospital into the nursing home. We will discuss this more in a moment.

Another reason why this potent class of medications has been specifically targeted is what David alluded to earlier, and that is, they can have irreversible, severe, side effects in this group of frail elderly people (eg., tardive dyskinesia).

My biggest praise for OBRA 1987 is that OBRA 1987 has really brought long-term care into a leadership role in geriatrics that I don't think it had prior to the implementation of OBRA 1987. That is, previously this discussion of drug therapy and physicians' use of drugs in the nursing home was a medical issue—or at least doctors thought so—and it was a private issue. With OBRA 1987 this has become a public issue, a public idea, something that is debated openly. And I think that is one of the greatest things OBRA has done.

So what was the scope of the problem before the implementation of OBRA 1987? Studies reveal that somewhere between 20 and 45 percent of residents in nursing homes were being given these medications.¹ In our own facility, we had about 15 percent of our residents taking neuroleptic medications before OBRA. Now we are down to about 7 percent. Currently, I believe that these 7 percent of our residents who are taking these medications have good medical indications for them.

In a study published in the Journal of the American Medical Association in January 1991,¹ it was stated that about half of the residents in nursing homes on neuroleptic did not have documentation of a diagnosis or a specific condition to justify their use. Therefore about half of the neuroleptics use would be considered ineligible for

¹ See p. 149.

use, based on the new regulations, simply due to lack of documentation. Now, if the physicians go in and do all the documentation, that does not necessarily improve practice. But you can't judge practice until you have documentation for why the drug is being used in the first place.

Now, instead of reviewing the drug therapy regulations, I am going to assume that most of you here know what the regulations are. I am just going to highlight certain points. Perhaps the biggest one, and for physicians, the most pivotal and controversial element of the drug therapy regulations, is that nursing homes are now held responsible and are subject to sanctions for some things that previously they did not have direct control over. That is, physician behavior and prescribing practices in the nursing home.

Currently, the facility must ensure that residents being given these drugs meet Federal criteria. However, facilities don't prescribe. Physicians prescribe. Physicians have the legal authority, the responsibility, the liability, hopefully the education and training, for prescribing medications for individual residents.

In hospital practice and in outpatient practice, physicians are subject to peer review, which is often informal. That's an internal sort of review. Physicians are subject to review by State licensing boards, county or State medical societies, and more recently, physicians are subject to external peer review organizations in scrutinizing their practice. Physicians typically have not had scrutiny of their practice in the nursing home setting.

Being a medical educator, I repeatedly ask myself this question: How have we come to this position where the Federal Government is telling physicians how they can and cannot practice, how they can and cannot prescribe this class of medication in the nursing home. And the answer I have to give myself is that medical education has failed physicians in this realm, I believe.

In my own training, I entered medical school in 1977. There was not a single course offering at that particular time in geriatrics or long-term care. Throughout my entire training in internal medicine and even in my geriatric fellowship training, I did not get formal education about long-term care and taking care of this class of residents. Now, I believe there is an increasing cadre of people really interested in this area and trying to make a change and educate physicians about medical practice in nursing homes.

But I believe that the reason we are at this juncture as physicians with the Federal Government dictating the details of our medical practice is because institutions of medical education have not been particularly interested in the needs of the nursing home population.

There is a question I would like to pose to all of you, and it's a difficult one for me to ask. It's a difficult one, I think, to answer. But the question is, is there a parallel to be drawn between the recent Supreme Court decision in which physicians working in clinics receiving Federal dollars cannot counsel their patients about the option of abortion (*Rust v. Sullivan*) and OBRA 1987 telling doctors under what conditions they may or may not prescribe medications?

Personally, I believe that the drug therapy guidelines outlined in the regulations and the interpretive guidelines generally reflect

good medical practice, and I endorse them and I support them. And I teach them. However, when I ask myself about the parallels between the Federal Government telling doctors what they can and cannot do in clinical practice, I have to answer myself that yes, I think there is a parallel there.

In medical practice, there is an imbalance of power. Before I became medical director of the Washington Home, I was medical director of an Alzheimers day treatment center. I worked with an excellent nurse. She used many techniques similar to what Zofia was telling you about earlier in dealing with problematic behaviors that would arise during the day with a large number of demented elderly people.

She was really an expert at recognizing side effects of neuroleptic medications. She would often counsel the families to go back and take mom or dad or grandpa back to the doctor and tell them about these things. They can't get up out of the chair, they are drooling, shaking, having trouble swallowing, can't stay awake. She would tell the families to ask the doctor if it could be the medications and whether the dose of the medications could be lowered.

As medical director, I supported her in this practice. And most of the time the physicians she worked with were very amenable to getting feedback about efficacy and side effects, and lowering the dosages. However, there was one doctor that wrote her licensing board and said "This nurse is practicing medicine without a license" because she was making a clinical judgment about side effects of medication. There is a power imbalance that exists.

However, there are also an increasing number of physicians who will support nurses and others in trying to do what's best for the patient.

One public policy avenue which may help improve physician education in long-term care is the reauthorization of the Graduate Medical Education Act. Some of you may be aware that Medicare dollars, in fairly significant amounts, go to support residence training of physicians who are practicing in the hospital. This Act has done a lot to fund post-graduate medical education. But the backside of this is that residency programs don't get paid per capita dollars when residents are not in the hospital.

So residency program directors don't like to send their trainees out to nursing homes. If they can't show that the bodies are in the hospital, they can't get the dollars. Perhaps there are some of you here here who would have the ability to see if perhaps the Graduate Medical Education Act could do something to fund medical education in the nursing home, because it is sorely needed.

Nursing homes—and I believe this is thought the guidance of OBRA—are currently taking the leadership role in decreasing physical restraints and eliminating the inappropriate use of anti-psychotic medications for older people. As I try to think about how these devices and these drugs became so widely used in nursing homes historically, I believe it is because physicians and nurses were always trained in the hospitals, they learned how to do things a certain way, and then they went out to the nursing homes and did what they always had done in the hospitals.

I believe through the leadership of OBRA, it's time for the nursing homes to turn around and start teaching the hospitals. I would like to tell you two stories, which illustrate this point.

My mother's neighbor is 91 years old. She lives in a small town south of Chicago. She and her elderly husband would often have to call in the local police in this town of Kankakee, because they would both fall, or some other bad thing would happen and the local cop on the block would come and help them out.

She had to have surgery. She was transferred to a tertiary care teaching hospital in Chicago. After surgery, she was tied down in her bed. She is very alert and cognitively intact. And she was able to reach the phone. She called the police in Kankakee and said "I am being tied down against my will. Come up here and do something about it." Well, Kankakee is about 50 miles south of Chicago, and they didn't make the drive.

But they did call the Chicago police department and the Chicago police department sent an officer to a surgical ward in a tertiary care hospital and went to talk to this woman, and got the nurses in there, and basically told the nurses they were violating her civil rights. She was untied.

One of my own patients from the Washington Home was admitted within the last couple of weeks to an acute care hospital for the treatment of a heart attack, an acute myocardial infarction. When I went in to make rounds, she had a POSY restraint on, she had both of her wrists tied down, and she was very agitated. I said "What's the matter?" She was an old medical surgical nurse herself, 89 years old, she retired at the age of 75.

She said "Look at this. This is horrible. They have tied me down." So I untied her. The nurse came in saying "What are you doing?" In looking over the orders, the resident had been giving her 5 milligrams of Haldol intravenously all night long. We had a real education session that morning.

Another issue under OBRA 87 is that residents have the right to choose a physician. I endorse this right. But the resident's right to choose a physician has to be exercised within the facility's right to make sure that physicians know the rules of the game, and that the nursing home has the authority to enforce the rules of the game.

Physicians also have rights, and physicians have rights to due process. If a physician is cited for being out of compliance with the regulations, the physician should also have the right to defend his or her medical practice in the nursing home.

In the past, I have heard nursing home administrators, medical directors, directors of nursing say: "We cannot hold our doctors to all these standards, because if we make them angry or upset, they will leave, and we don't have anyone to replace them."

This is where the analogy to the battered woman syndrome comes into place. You can't live with them, and you can't live without them. For an abused woman to break the battered woman cycle, she must examine her own needs and dependencies, develop the insight and courage to leave an abusive situation, break old patterns of interaction and realize that she is a worthy person deserving of something better. Then she has to know there is something better out there.

Nursing homes need to realize that their residents deserve the best medical care. It's a vicious cycle, when the nursing home says "I can't enforce these standards, because my doctors will leave." On the other hand, if they don't enforce high standards to begin with, they are not going to get good doctors in there to practice.

In medical education, we are trying to equip a cadre of people interested in long-term care, trained in geriatrics, to fulfill these roles and provide good medical leadership within the nursing home setting. The American Medical Directors Association, AMDA, which now has 1,400 members, is taking a leadership role in certifying medical directors, and providing educational programs for administrative, management, and leadership skills for physicians already in practice as nursing home medical directors.

Nursing homes should not be afraid to set high standards and should work with physicians through strong, positive medical direction, to realize that they can break the patterns of negative interaction between physicians in nursing homes and move forward with quality medical leadership to implement the guidelines of OBRA 1987.

Thank you.

Mr. SHERMAN. Thank you, Rebecca, for your comments. Very well said. I wish we had more doctors in our nursing homes like Dr. Elon.

Our next speaker is Jeanine Mount, who has a Ph.D. in sociology. She is both a sociologist and pharmacist on the faculty of the Social and Behavioral Pharmacy program at the University of Wisconsin-Madison. Her research interests focus on how service organizations and professionals working within them provide care to persons with complex physical, psychological, and social needs.

And important for this particular forum, I think, she has been involved for the past 6 years in a project called the Wisconsin Nursing Home Use Project, a large field study describing the patterns and analyzing factors influencing psychotropic drug use and quality of care of elderly nursing home residents.

Dr. Mount.

STATEMENT OF JEANINE MOUNT, PH.D., UNIVERSITY OF WISCONSIN SCHOOL OF PHARMACY, MADISON, WI

Dr. MOUNT. I would like to begin by recognizing two important sources of support for the work that I will discuss today. One is the collaboration of my colleagues at the University of Wisconsin School of Pharmacy, particularly Dr. Bonnie Svarstad, also Dr. C.A. Bond and Ms. Elizabeth Tesdahl. Each of them has been highly involved in development of the Wisconsin psychotropic screening protocol (WPSP), the instrument I will be discussing. Second, I would like to recognize that this work has been facilitated by funding from the National Institute on Aging and the National Institute of Mental Health.

My comments today focus on using screening criteria to assess the appropriateness or quality of antipsychotic use among nursing home residents. My objectives are: (1) to analyze various types of criteria we might use to assess appropriateness of antipsychotic use; (2) to discuss the notion of "screening criteria"; (3) to identify

strengths and weaknesses associated with use of screening criteria; and (4) to discuss how screening criteria can be developed, adapted, and applied within ongoing quality assurance systems.

In the last few years, we have been forced to come to grips with two difficult realities in contemporary nursing home care. One is that nursing home staff members, nursing home residents, policy-makers, and funders alike are being confronted with numerous serious concerns; inappropriate use of psychotropic medications is one of these concerns. The second is that budgetary and personnel constraints are likely to continue to influence nursing home operations. It is unrealistic to assume that nursing home care will experience a substantial infusion of new funds or a tremendous increase in the availability of essential personnel.

ASSESSING QUALITY OF ANTIPSYCHOTIC DRUG USE

In this context, inappropriate use of antipsychotic medications, particularly their use as chemical restraints, has developed as a serious cause for concern. Many researchers have provided us with documentation of the high quantity and wide variations in antipsychotic use in nursing homes.

Our focus currently is changing, however. Rather than looking at aggregate patterns describing the quantity of antipsychotic medications used, we now are interested in indicators of the quality or appropriateness of antipsychotic use and we are interested in evaluating this at the level of the individual resident.

Unfortunately, assessing quality on an individual resident basis has two substantial problems: it is expensive to perform and it frequently is difficult for care providers to agree on what constitutes appropriate use. Each of these factors has the potential to limit the effectiveness of efforts to improve antipsychotic use.

Use of screening criteria and screening procedures—also known as case-finding procedures—offers a helpful tool for efficiently and reliably identifying individual residents who are at greater risk of inappropriate care.

What are screening criteria and how can they be used? Simply, a criterion is a standard or rule that one can use to make some judgment. We can distinguish among several different types of criteria that have been applied within health care. The first type, clinical criteria, evaluate appropriateness of care on the basis of treatment outcomes as observed in individual residents. Because they utilize such highly particularized bases for determining appropriateness, clinical criteria often are viewed as providing definitive evaluations. Their reliance upon expert knowledge and in-depth assessments make systematic application of clinical criteria both difficult and expensive, however.

A second type of criteria, what might be referred to as legalistic criteria, have been developed to address difficulties inherent in clinical criteria. Legalistic criteria offer the advantages of efficient and reliable application. Their scope, however, historically has been limited to examination of inputs into the care process or the processes employed in care provision. It frequently is argued that these lack direct connection to individual residents' quality of care outcomes or quality of life.

A third type of criteria, normative criteria, are pattern-oriented criteria based upon factors that generally are associated with positive resident outcomes. This type of criteria serves as the basis for the Wisconsin psychotropic screening protocol. Specifically, we have focused on the model psychopharmacologic screening criteria that have been developed by the American Psychiatric Association and endorsed by numerous medical associations in the United States. These criteria are supplemented with psychotropic drug use recommendations that have been accepted by the U.S. Pharmacopeial Convention and/or the U.S. Food and Drug Administration. This approach offers the advantages of providing valid, up-to-date criteria. In general, these criteria are indicators of appropriate psychotropic drug use and are associated with positive resident outcomes. Formalizing them into explicit protocols offers the additional advantages of reliability and efficiency.

There are, of course, alternate sets of criteria that might be used in evaluating the quality of antipsychotic drug use. While we focus on the APA-developed criteria, criteria associated with OBRA 87 are a second set. Guidelines developed by the American Society of Consultant Pharmacists reflect yet a third. Although they differ in specific details, these sets of criteria have many common elements and any could be adapted for use in a screening protocol to review antipsychotic use among nursing home residents.

THE WISCONSIN PSYCHOTROPIC SCREENING PROTOCOL

Screening, then, refers to a systematic evaluation of individual residents' care. The purpose of such examination is to identify those cases that do not conform to target criteria. Of interest here is the systematic evaluation of residents' antipsychotic drug orders and determination of whether they are in conformance with criteria that we have identified as relevant.

Thus, screening protocols focus on identifying deviations or instances where practices do not conform to professionally recognized norms. It is important to recognize that such instances may or may not represent real problems in medication use. Rather, application of screening or case finding procedures results in identification of cases where there is an increased likelihood that a given practice—such as antipsychotic use by a particular nursing home resident—is inappropriate. Cases with deviations warrant further in-depth examination to determine their clinical correctness. Other speakers in this forum have commented on the importance of such assessments.

The Wisconsin psychotropic screening protocol is an instrument for screening nursing home residents' antipsychotic, antidepressant, antianxiety, and hypnotic drug orders. The preface and antipsychotic sections of the protocol are included here; a complete copy of the WPSP is available from the authors.

Several important characteristics of the WPSP should be noted. First, the WPSP is a screening tool specifically designed to identify potential psychotropic drug therapy problems. As discussed earlier, cases identified through its application are those failing to conform to some professionally recognized criterion and may or may not re-

flect actual drug use problems. Cases that are identified warrant more in-depth examination.

Second, from the antipsychotic portion of the protocol, it is obvious that it does not include all potential criteria for evaluating drug use. Rather, we have selected for inclusion those criteria that can be ascertained reliably from generally available information sources. This recognizes the fact that certain types of information may be unavailable, difficult to ascertain, or unreliably recorded. For example, in the WPSP we do not evaluate whether critical adjunctive services—such as laboratory monitoring—are being provided or whether critical adverse developments—such as medication side effects—are present in a particular resident's case. While such information is quite important, its collection requires additional effort and may be more appropriately considered during subsequent in-depth assessments.

Finally, the WPSP utilizes consensus criteria. Such criteria have been examined closely by expert review groups and a consensus has been reached that they are appropriate criteria for use in reviewing drug use.

In the antipsychotic portion of the Protocol, you see the content and diversity of criteria relevant to screening antipsychotic drug orders. (Note that these criteria are for use only in evaluating antipsychotic medications that are being used for the purpose of addressing a resident's mental health problems.) The first, most fundamental question asked is whether the resident has an appropriate diagnosis or indication substantiating antipsychotic use. Obviously, this criterion may not be met if a documentation problem exists or if there simply is no appropriate reason for use. The next two criteria are related to duration of antipsychotic use, whether too short or too long. Criteria 4, 5, and 6 relate to inappropriate concomitant drug use. Remaining criteria evaluate the presence of any contraindications for use and whether the dosage falls within the recommended age- and diagnosis-specific range. Note that under- and overdosage are considered parallel concerns.

The structure of this set of criteria enables efficient, reliable reviews to be conducted by anyone who has received basic instruction in its use. Familiarity with drug terminology and medical records is necessary. Once training is completed and the records for individual residents have been assembled, reviewers require on average only 10 minutes to screen each resident's psychotropic drug orders. In other words, all antipsychotic, antidepressant, antianxiety, and hypnotic drug orders, the bulk of all psychotropic medications one might wish to evaluate, can be evaluated in a brief period of time by any trained reviewer.

It is important to recognize that screening protocols have two potential weaknesses. First, as is the case in any type of screening instrument, there is the possibility of false positive results. For example, we may identify cases that deviate from screening criteria where subsequent application of clinical criteria leads to the conclusion that observed drug use is entirely appropriate. Such overspecification of potential problems is seen fairly commonly. Alternatively, false negative review results are likely if we focus on a very small number of criteria or if an extremely wide range of

practices is recognized as acceptable. Either situation can result in underidentification of cases where real problems exist.

Estimating and attempting to control the rate of false positive and false negative results are other challenges presented to facilities that choose to employ screening procedures. Involved staff members must assess the validity and reliability of their protocols, based upon their experiences with application in specific facilities.

DEVELOPING AND APPLYING A SCREENING PROTOCOL

What might nursing home staff members with an interest in using an antipsychotic screening protocol need to consider? First, selection of sound criteria and incorporation of the most-up-to-date standards for drug use insure that the reviews are relevant and timely. Second, involvement of nursing, medicine, pharmacy, social work, and other appropriate staff members in efforts to develop and/or adapt a protocol can promote the type of collaborative relationships that are essential for reducing use of chemical restraints and address other complex resident care problems. Third, because different nursing homes experience different concerns and different opportunities, the protocol should be tailored to the individual facility's circumstances. For example, data availability and medical information systems differ across facilities and permit reviews of varying depth or complexity. Some facilities may be able to marshal additional pieces of information that allow more complete assessment of the appropriateness of antipsychotic use. Some may have that ability to computerize review procedures.

Once a protocol is finalized, its application often can be carried out by staff members with modest skill levels. Expert knowledge, as one might expect the medical director, physicians, the nursing director or the consultant pharmacist to possess, is not required. Consequently, we are able to involve a larger number of staff members in the process.

This has the potential disadvantage of complicating the system, although it has two clear advantages: It spreads the workload over a larger number of individuals and it can involve those staff members who are most directly responsible for providing care to the specific resident whose drug orders are reviewed.

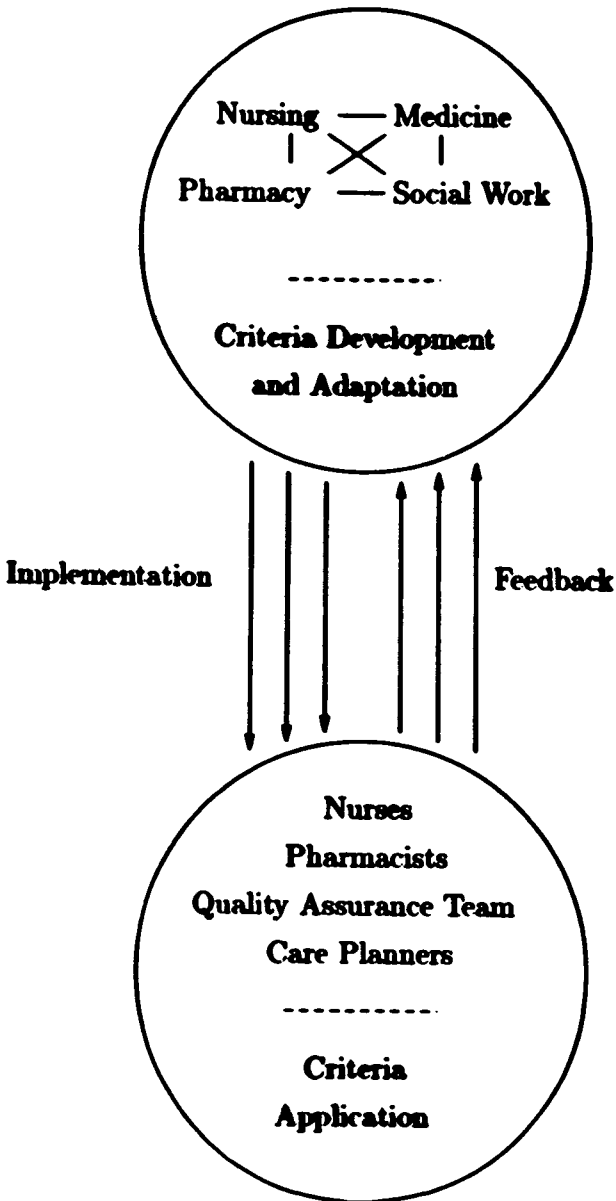


Figure 1:

Use of Screening Procedures in a Multidisciplinary Context

Dr. MOUNT. Overall, as shown in Figure 1, such a system reflects a true multidisciplinary effort in the development of the protocol, implementation of the review system, and feedback regarding review results. It recognizes and builds upon the social system of the nursing home, rather than imposing an artificial structure. Further, application of screening protocols can move beyond identifying individual residents whose care requires closer evaluation. It can be incorporated into an ongoing quality assurance system and used, for example, during quarterly care planning meetings or annual resident assessments.

No set of drug use criteria or guidelines should be universally adopted or indiscriminately applied to any nursing home; variations in personnel, data availability and access simply argue against this. Consequently, one must continually evaluate (1) the appropriateness of review criteria and associated practices, and (2) how productively they are being applied within a given nursing home.

Persons who have contact with several nursing homes (e.g., administrators working in multifacility organizations, pharmacists working in long-term care pharmacies) should recognize that these kinds of screening procedures can be applied across nursing homes, to identify where causes for concern exist. This moves us beyond examining care of individual residents and permits analysis of the quality of antipsychotic use patterns within particular nursing units, particular nursing homes, groups of residents with particular diagnoses, and so on.

EMPIRICAL FINDINGS

Description of the appropriateness of antipsychotic use and analysis of factors associated with observed variation in appropriateness of use are two goals of the Wisconsin Nursing Home Study. This is a study of about 2,000 residents in 18 randomly selected skilled nursing homes in the State of Wisconsin. Information describing this sample is presented in Table 1.

In addition to analyzing all residents included in this sample, we have used case-mix referencing procedures to identify several groups of residents who warrant particular concern. These are residents who have diagnosed: (1) affect disorders, (2) psychotic disorders, or (3) dementia in addition to (1) or (2).

Results presented in Table 2 address the question: What characteristics of nursing homes (as organizations) predict that a higher quantity of antipsychotic medications will be used in the facility? (Quantity is measured here as the average number of doses of antipsychotics administered during a 30-day audit period.)

Several patterns are clear. First, when use among all nursing home residents is analyzed, a wide variety of characteristics are significant predictors of the quantity of antipsychotic medication used. Significant predictors of higher antipsychotic use include: lower per diem rates for Medicaid residents, higher percentage of Medicaid-paid residents in the facility, and lower percentage of residents who can be described as frail elderly residents.

Second, when we control for differences in facility case-mix by focusing on our three more diagnostically homogeneous resident

groups, most observed correlations are reduced and become statistically nonsignificant. In other words, differences observed across facilities in the quantity of antipsychotic medication used generally appear to be due to systematic differences in resident case-mix. There are a few exceptions to this pattern and each is related to operation of the Medicaid program. Most notable is the finding that among residents with affect disorders, residing in a facility with lower Medicaid per diem rates is strongly related to administration of a higher quantity of antipsychotic medications (Pearson $r = -0.75$). (It is not clear why these residents with affect disorders are receiving antipsychotics; this might be an indication of chemical restraint use.)

A substantially different pattern emerges when we analyze predictors of the quality of antipsychotic use, as measured by the presence of polymedicine (i.e., concomitant use of ≥ 2 antipsychotics and/or use of ≥ 2 psychotropic medications in addition to an antipsychotic medication). When the total sample of residents is analyzed, a wide variety of facility characteristics again are significantly related to the quality of antipsychotic use.

Analysis of the subgroups of residents with diagnosed mental illnesses reveals quite a different story from that above. When the group of residents with psychotic disorders is considered, none of the selected facility characteristics appears to be related to the quality of antipsychotic use. However, among residents with affect disorders and those with dementia in combination with another severe mental illness, we see that multiple facility characteristics remain significantly correlated with the quality of antipsychotic use. A facility's source and amount of financial resources, administrative stability, nurse staffing, size and resident mix characteristics are statistically significant—or marginally significant—predictors of the quality of antipsychotic use within these facilities.

Recall that in these analyses, our goal is not to identify factors that place individual residents at higher risk of high quantity or poor quality antipsychotic use. Rather, we are identifying factors that place entire facilities and their residents at increased risk.

I would like to end here on a positive note. Unfortunately, the empirical results of our research make that difficult as they suggest that certain characteristics inherent in the structuring of long-term care place certain types of facilities—and persons residing within them—at increased risk of poor quality antipsychotic use. And many of these factors appear to be very difficult to modify so as to modify that risk.

Mr. SHERMAN. Thank you, Dr. Mount. It was very interesting to see the final results of that research project.

Our next speaker is Judith Welty, who is a consultant pharmacist with an organization called GPS Health Care out of Harrisburg, PA. Judy is a consultant coordinator who is responsible for the development and implementation of consultant pharmacist programs for long-term care facilities in Pennsylvania and New Jersey.

She coordinates and supervises the activities of consultant pharmacists in her group. Judy is one of those consultant pharmacists I was talking about earlier, who represents many of the consultant

pharmacists in the country who are doing some really good things that we are going to hear more about now.

Judy.

STATEMENT OF JUDY WELTY, CONSULTANT PHARMACIST, GPS HEALTH CARE PHARMACY SERVICES, HARRISBURG, PA; ACCOMPANIED BY JANET STEIN, RN, CONESTOGA VIEW NURSING FACILITY, LANCASTER COUNTY, PA

Ms. WELTY. Good morning. It's very exciting for me to be here today to address you and to represent consultant pharmacists all over the country.

I think if we wanted to briefly subtitle this program, we could maybe call it "OBRA From the Trenches." I have to be honest with you, though, this is my first trip to Washington, D.C., and when you're a native of a place called Puzzetown, PA, the Nation's Capital is a bit intimidating, so I am going to try to tough this out.

I would like to say a few words about GPS Health Care, our company. We are a full service, long-term care pharmacy company: We offer what we call the core business—tablets and capsules, and we provide i.v. therapy. We have a nursing branch that provides consultation to long-term care facilities and we have a respiratory therapy branch. We service approximately 12,000 beds in Pennsylvania and most recently in New Jersey.

About a year ago, GPS developed what we call an antipsychotic monitoring program for the facilities we serve. It consists of three parts: two formalized in-services and many informal in-services along the way, a behavior monitoring form which the nurses use to track behavior problems and medication side effects. The third part of the program is a monthly report which we generate, with comments from the pharmacists and from our medical director, relative to the quality of drug therapy.

We currently have about 20 facilities that participate in this program. Many of them will be the facilities I talk to you about today.

At this time I would also like to introduce, camouflaged behind the screen here, my colleague Janet Stein. Janet is a registered nurse and also a nursing home administrator in Pennsylvania. She currently is Director of Utilization Review and Quality Assurance at Conestoga View Nursing Facility, which is the county home of Lancaster County, PA.

Conestoga View is a 450-bed home and it is the county home. They have approximately 300 nursing personnel there, a staff of three full-time physicians who are in the building every day and who make rounds daily on the residents. Our company, GPS, maintains an in-house pharmacy there, and that is our connection with Conestoga.

In June 1990, GPS and Conestoga jointly entered into a pilot program to see how many Conestoga View residents we would be able to get off antipsychotic drugs, or doses we could decrease. Since a lot of the data and the residents I will talk to you about today are from Janet's facility, I thought it would be appropriate for her to be here to present some information to you, and also to be available for questions during the question period.

I would like to present to you Janet Stein.

Ms. STEIN. I have the pleasure of telling you a few stories, and Judy gets to present the dirty data from the study.

Imagine that you are an 85-year-old gentleman. You have been married for 60 years. You have been living in the same house for 50 of those years, slept in the same bed, eaten breakfast in the same space by the garden window almost daily for those 50 years.

Your wife died a few years ago. Since then, you've been running the house yourself. You've been doing the laundry, the cleaning, the gardening, and the finances. You have even managed to cook for yourself.

Lately, though, you've been experiencing a few medical problems. You don't really feel you want to continue to run this large house by yourself. You decide, after talking to your daughter, to admit yourself to a nursing home.

On the day of admission, you and your daughter work in the morning to close the house. By the time you get to the nursing home and through the admission process, you are tired. So the nurse on the unit offers to bring you a dinner tray to your room. Tomorrow you will begin eating in the dining room with the rest of the residents.

You wonder where it is and how to get there. But you assume that one of the staff will probably escort you to the dining room. The first night passes, and you sleep well in spite of the totally new environment. The next morning you are hungry. You are really ready for breakfast. Since no one seems to be available, you follow a group of residents, and something that smells like breakfast, to the dining room.

After breakfast, you leave the dining room, and you aren't quite sure which way to turn—right or left? You wish now you had paid more attention to the directions coming down, than to your hunger pains. You make a choice. You turn left. Nothing looks familiar to you, but you see a door at the end of the hallway, and you decide, if I can just get outside and look at the building, I can orient myself to the facility and find my way back to my nursing unit.

But before you reach the door, someone comes into the hallway and takes you by the arm. She reads your i.d. bracelet and leads you back to your nursing unit. She doesn't say anything to you, but you hear her tell a nurse "This gentleman was confused." Label number 1. "And wandering in the hallway." Label number 2. "I caught him before he got out the side door."

The nurse, fearing you might try to leave again when no one was watching you, calls the physician. You hear her tell another nurse that she is getting something for you called a restraint. You don't know what that is, you haven't been in a nursing home before. But four people approach you without explanation. They begin to tie you into a wheelchair with a band around your waist.

You try to talk to these people. You try to reason with them. You try to explain to them an innocent wrong turn, but no one listens. They are all intent on tying you into your chair. You feel helpless and frightened and then you get very angry.

You begin shouting and struggling against the restraint. You believe that perhaps that will get their attention. It didn't. You kick and hit at the staff and that gets their attention. You then hear a nurse say, "He's really combative." That's label number 3. "I'll call

the doctor for something." That's good, you think. Maybe the doctor will come and put a stop to all this foolishness.

The doctor is busy on another unit. He hears that you kicked a nursing assistant. He is comfortable with the competence of his nurses. And they are competent. They always seem to know their patients, he thinks. So the doctor does order something for you, Haldol, 2 milligrams, i.m.—immediately. And four times a day if necessary.

In a few days, your spirit is broken. The very thing you needed to survive and thrive in this new home is gone. You no longer fight the restraint or the staff, and they seem to like you better that way. They compliment you on your good behavior.

The charting progression in this case, though, tells a different story. Within 3 weeks, the gentleman in question was a total care resident. He was fed, bathed, could no longer walk independently, and couldn't even marshal enough spirit to communicate coherently. Unfortunately, the story is not unique. It occurs all over the Nation in nursing homes and has been occurring for some time. This is why I, like David, support the intent of the regulation Sam Kidder has written.

This story, and some others, were addressed by the study we did at Conestoga View in 1990. In supporting something David said about changing nursing approaches, I have another little story.

One resident on the 11 to 7 shift had a dose of Thorazine before he went to bed, because he was combative at nighttime. He kicked and pinched and hit the staff at 2 a.m. when they did his care. They needed some help with this resident, so they called me. I met with them and the first thing I asked them to do was describe to me how they gave his care. And boy did they describe it.

"Well, we go into the room, we turn on the lights, we pull down his covers, we roll him over, we change his wet bed, we cover him up, turn the light off and leave the room."

Yes, they did. They described it to me. That's what I asked for. I asked them to try something different. And when I described what I wanted them to do, they didn't give it a prayer of working, but they agreed to try it. And he said, and others have said, the simplest things sometimes work the best. Enter the room quietly, turn on the bathroom light instead of an overhead light, approach the man quietly, touch him gently on the shoulder. Talk to him while you are doing his care, very softly.

It was amazing how a little gentleness and consideration changed the patient's behavior, all because of a little change in the staff's approach.

The third and final story I want to tell you is about a gentleman who was not in the study, but was admitted after the study occurred. I really liked this old fellow, he was about 87 years old. I would see him probably three or four times a week. He has a wonderful sense of humor.

One day I was wearing a bright red suit jacket at work, sitting at the nursing unit, studying a chart. He rolled himself over, and remembered this is a man who was both physically and chemically restrained at one point in his admission. He rolled himself over in the wheelchair and he said to me "You know, you shouldn't wear

that color." I looked at him and said "What are you talking about?"

He said "It's bright red, you'll get a reputation." I looked at him and said "Ah, I'm too long married and too old to get one of those." The sense of humor they have is tremendous, if you listen to them. They have much to tell us, many stories we can use to improve their care. We need to listen to that.

Thank you.

Ms. WELTY. Janet's first story was pretty frightening, wasn't it? We like to use that story with our in-service programs for two reasons. First of all, we feel it does help to emphasize some of the problems, the devastating effects that these types of medications can have on elderly residents when they are not used properly.

The other thing I would like to have you think about, and we will revisit the people in the story in a few minutes, is some of the stereotyped thinking that went on among those people. If you think about it, none of them did anything overtly terrible to the resident. But nobody stopped to examine that person on an individual basis, and to evaluate that particular situation.

In a few minutes, when we talk about some of the educational needs in long-term care facilities, I would like to return to those people.

Time is ticking away here very quickly. I have a habit of talking fast, and I think I'll take advantage of that. What I would like to do for a few minutes is present to you some data, some experiences that GPS Health Care has had with our monitoring program. Some of the data will be numbers, some of it will be percentages. But a large part of it will be anecdotal. There will be stories of some of the residents' lives that we have touched, and certainly a lot of residents who have touched our lives.

At the end of the program, via videotape, I would like to introduce you to a resident named John Allen. John is an 87-year-old man, he lives in Reading, Pa. He has been antipsychotic free for 5 months, and he is very pleased to tell people how good he feels off the medication.

We had requested that John make a videotape with us, and he was so excited that he was up at 6 o'clock and dressed on the morning of the filming and asking the nurses "Where are the girls with the camera?" In a few minutes I will introduce you to John.

As I go through some of my experiences here, several of them involve John, and I think by the time we see him, you will feel like he's an old friend of yours.

One of the things I noticed as we began to do monitoring—we had Conestoga View and we added other facilities to our program—was many similarities that seemed to occur, regardless of the size of the facility. The Conestoga Views, the large county homes seemed to have many of the same preconceived notions about antipsychotics, many of the same monitoring problems that the small 60-bed facilities had who were private pay.

With your indulgence I have created a list of what I call the three great truths of antipsychotic monitoring. I would like to go over with you at this time.

These are the three great truths of monitoring. There is a strong need to monitor behavior episodes in residents receiving antipsy-

chotics. I might add, before I go on, I think you will hear some recurring themes here that you have heard from some of the other speakers. But I hope that just helps to validate their importance to you.

The second great truth of monitoring is you don't need a sophisticated monitoring system to begin to make an impact in residents' lives. The third great truth is education is vitally important before any program begins, and constantly, day after day, thereafter.

Let's examine each of these quickly. Number one, there is a need to keep a record of all problem behavior incidents in residents receiving antipsychotics. You might wonder why. Well, quite simply, once you start to track episodes, you may find out that there are not any episodes, that the medication is not really needed. That's not to say that it was not needed at some time. But currently, whatever the problem was that caused the medicine to be prescribed, the problem has resolved on its own. This is very commonly in elderly residents. We had a woman in one of our facilities who had been on Mellaril, 15 milligrams twice a day for 20 years. When we looked back through the record, we discovered that her son had died very unexpectedly 20 years ago. And she was a behavior problem for a short period of time. After that, there was nothing ever charted relative to behavior problems. No one in the facility ever bothered to reevaluate her.

It is quite common for me, as I go into facilities to do in-services, to have nurses, as I present examples and cases say "Well, you might have cut antipsychotics in other facilities, but don't expect to do any here. Every resident we have in here needs the medication, and we can prove it to you." So we go in, after a 3-month trial, and we do find people that we recommend for dose reductions, because they simply do not have behavior problems.

And I want to say quickly here, please do not feel I am saying that nurses want residents to receive medication, or that they are not careful about monitoring residents. Rather, I think the problem is that when you do not monitor on a daily basis, you start to rely on the nurse's memory, when she cares for many, many patients over weeks and weeks, sits down at the end of the month to do her charting, she is not going to remember any patient specifically. And that is why I say I think it's very, very important that you monitor behavior on a daily basis.

I personally applaud HCFA's idea—and they have it written in the regulations "quantitative" number of episodes. I think that's an excellent thing. If you think about it logically, if you have a resident who has hypertension, a resident who has low potassium, and you are giving these people therapy, you monitor their need for the drug based on a number. With antipsychotic drugs, through the years we have always said "Yes, this resident's better; no, that resident got worse this month." We have never had any type of numeric evaluation.

If you have a monitoring form, you are able to chart episodes on a daily basis, you now have numbers, you have a way to tell numerically, quantitatively, whether or not the behavior is better or worse. That's the end of the first great truth.

Let me show you some examples of what can happen when you do monitor behavior. You have a handout, out in the front there is

a blue folder, "People with Solutions," which is our company motto. I won't have time today to discuss all the data in there, I will just present a little bit of it to you.

The study was broken down beyond just the medications that were reduced. We talk about the physician responses, which medications were involved, some of the types of diagnoses we have dealt with and so on. So just let me briefly tell you the final results of the study in Janet's facility.

We ran the pilot project from July 1 until September 1. During that period, we were able to discontinue 44 percent of the antipsychotic medications in the residents we dealt with. We decreased doses in another 21 percent. So we thought that was a pretty nice impact.

Also in your folder, is some current data from some of the other facilities that we are doing. You will notice these numbers are not quite as dramatic. I have to give some credit here to my colleague Janet. I think any time you have a monitoring program in a facility, you need a believer in there. You need someone with a real commitment to making the study be successful. Janet was that person for the pilot project. As you can see, we still are able to decrease drugs, but we have not had quite as dramatic an effect in the other facilities.

We have 27 to 12 here, 25 to 20, and 11 to 7. Incidentally, these things are all ongoing. We are still working at this.

Beyond the numbers we generate, I think it is important to talk about quality of resident life. That is what we are all here to show. I would like to show you a slide now, these are actual physician's progress notes, of one of the residents in Janet's facility.

In August 1990, he received 400 milligrams of Mellaril a day. If you are not familiar with drugs, that's a lot of Mellaril for anybody. At that time, the physician had charted he must be fed, he is continent only at times, he is out of bed in a geri chair only, his ambulation is essentially negative.

In January 1991, when the Mellaril was down to 50 milligrams a day, he had decreased agitation with less Mellaril, he is now continent, he is no longer restrained, he ambulates with a walker and one assist. He is going to PT for strengthening and he is aiming for independent ambulation. He also feeds himself, and probably even better than all that for himself, the nurses began to like him. They said "You know, he's really a nice old man." Unfortunately, this story has rather a sad ending. This particular resident developed a fever as part of a urinary tract infection, tried to stand up, fell and broke his hip. The subsequent hospitalization, surgery, and anesthesia set his progress back a little bit. He still does feed himself, still is continent, but walking probably is not realistic for him any more.

Another resident I want to tell you about briefly is Mr. Allen, the man we will see in the videotape. Once he was off his antipsychotic medication, he was able to verbalize a problem he had with his dentures for nearly 4 months. He told our consultant pharmacist that he had problems in his mouth, and he thought he knew it was his teeth, but he really didn't know how to verbalize to the staff that his teeth were bothering him. Once he was off the medi-

cation and was able to understand it, he called the dentist himself and made his own dental appointment.

Let's move on to great truth number two. You don't need a sophisticated monitoring program to make an impact on resident quality of life. I don't want to say that you don't ever need to do that. But I do think in the beginning as facilities are starting out, they should be aware of the value of close observation and common sense. I would like to give you some examples of this.

First, there's Mr. Allen again. He was taken off his antipsychotic drugs because a pharmacist noticed during the monthly review that the nurses had been charting he was deteriorating, he was increasingly confused, and the family was concerned about his well-being.

Based on that, this is a sample of a letter that was written to the director of nurses with the monthly antipsychotic report. "In reviewing John Allen, who is receiving Serentil, we see he is increasingly confused, and generally deteriorating. We need to be sure the Serentil is really necessary—since he does not possess an appropriate diagnosis—and that it's not contributing to his deterioration."

Based on this request, the director of nurses talked to the physician, the Serentil was tapered, now John is drug-free.

A few other quick examples. When we go into facilities, we like to talk to the nurses about behavior programming. I am sure you are aware in the regulations they talk about behavior programming—changing the staff's approach to the resident or the resident's physical environment. In one facility, after we had done this in-service, one of the charge nurses reviewed a resident who was in the wheelchair every day. They had taken him to the activities room on a daily basis because they felt even though he was not able to participate, he was better for being there with the other residents.

Unfortunately, when they put him there, they sat him in the doorway where there was a tremendous amount of traffic, a lot of people in and out. He began slapping and hitting at the staff, the other residents, even sometimes family members. He was given Mellaril first to control this—it didn't work. He was given Haldol. That also did not work.

Fortunately, this particular nursing supervisor had an excellent idea. Perhaps if he was at the other end of the room, he could still be a participant, but he would not be in this heavy traffic area. The staff moved him to the other end of the room; he is fine. He slaps no one and he takes no medication.

A third example—Ann Martin, one of our consultant pharmacists in the front row here today, was presenting, to an Alzheimer's family support group some information about OBRA, about the regulations, things that needed to be done. She mentioned in there something we have heard mentioned before, many times to understand a resident's current behavior, you need to do a little investigation into the past, to see some of the things they did when they were younger.

One resident's daughter-in-law spoke up and said "I believe my father-in-law is receiving medication at bedtime to help him sleep." That was checked out and yes, he was getting 4 milligrams of Navane every night at bedtime. She said "For 45 years, this man

worked 11 to 7. I can tell you before he came into the facility, when he lived with me and my family, he never slept more than 5 p.m. to 10 p.m. any night. He is never going to sleep any more than that."

The nurse took this information to the physician; the Navane was cut; and the third shift staff found a way to keep him busy at night so that he was not disruptive to other residents. He is medication free.

Another example from that same evening, a daughter spoke up and said "You know, my mother goes to activities every day, I believe she enjoys the activities, but I know she receives medication because she is very disruptive at activities." When we checked that out, we found that it was true. The daughter went on to say "For her entire life, my mother was afraid to leave our house. Many times when she was required to go to a new situation, she would become physically ill after she went outside. It went so far that she did all her shopping by catalog, because she was terrified of new experiences."

The people in the facility were able to think about this, to bring the activities into the department. The woman does not have to leave her room. She happily participates, and she is medication free.

Those are some examples of easy, common sense, "getting involved with the resident ways," of getting people off medication.

The third great truth of monitoring has to do with education. Education is vitally important on an ongoing basis. It needs to start the day you start any kind of a program, and it needs to continue. Think about the people in the story Janet told you.

As I said before, no one there did anything overtly bad to that resident, but they all had a preconceived idea. One said he was confused, one said he was a wanderer, another person said he was combative. Had they decided to look at the resident personally and evaluate that situation, perhaps that terrible thing with the Haldol would not have happened.

I have a quote here to show you. You may wonder what are some of the reasons we need to educate people. First of all, these patients are very, very difficult to care for. One of the consultants found this and brought it to me, and I think it's excellent. It says "The healthy can endure invalids only when the latter are quiet and motionless. But let them cough or scratch and sympathy flies out the window." And when you are dealing with antipsychotic patients, we are talking about the scratchers of the world, trust me.

But I think it's important to educate all the staff to understand why these people scratch. And I won't spend a lot of time on this, David talked about it, but they need to understand what cognitive impairment is, what it's like not to be able to see, not to be able to hear, not to be able to remember. The staff needs to understand that sometimes when the resident does strike at them physically, that is not to be interpreted in the way you would normally interpret it.

I also think staff needs to be educated to approach residents and not expect them to react as their co-workers would react. I will tell you a real quick story. I witnessed a terrible confrontation in a nursing facility one day that did not need to happen. An elderly

resident wheeled herself to the desk and said to the nurse's aide, "I didn't have any lunch today." The aide said "Yes, you did, you had ham, and so on." This happened four different times—the resident wheeled herself out and said "I had no lunch." On the fifth time, the aide said to her "Are you calling me a liar? I told you that you had lunch."

Well, the tone of voice or whatever she said got the resident angry, and she said "Don't you yell at me." And this thing just escalated and got worse and worse. The point of the thing is, if the aide had known how to approach this person, the ugly confrontation would not have occurred.

I would like to show you two books that I recommend, "Understanding Difficult Behavior" and also "Care of the Alzheimer's Patient." These are books which tell staff how to deal with particular situations, people who repeat questions, people who get into other people's belongings, a lot of the common problems you have in the nursing home.

Families need to be educated also—During an inservice at a Harrisburg facility, the nursing staff commented on one female receiving Haldol 1 mg tid. "We had her off the medication, but her family called the doctor and requested to have it restarted."

Apparently the pattern was this, the family took this resident home every Sunday for dinner, she ate, took a nap, and was returned to the facility. With the resident off the Haldol, she was refusing the afternoon nap, opting instead to walk through the house, refamiliarize herself with her old home, and wanting to visit with the neighbors. The family could not deal with this new activity and requested the medication be restarted.

Finally I would like to leave you with a positive example of how valuable an educated, enlightened nurse is to a facility and to residents. Re: John Allen of Reading again—shortly after the Serentil was discontinued, he had a bad dream in the early morning where he thought his wife, who is deceased, was in the facility. For several hours he was quite a behavior problem to the staff and in many facilities would have been returned to the antipsychotic medication immediately. Enter Betsy Mathias, LPN on the daylight shift. She took John "under her wing" and began to encourage him to vent his feelings to her. I will share with you two separate entries from nurses' notes. The Serentil was discontinued on February 9, 1991.

2-11-91—10:00 "Resident alert, oriented to person, place, and time. Verbalized to nurse problem on 2-9-91. Verbalized "I was out of control" with details of being in geri-chair, biting and kicking. Resident verbalized, "If my teeth had been in, I would have bit them harder." Verbalized that he heard his wife's voice and was trying to find her, and that someone said she was in a room here. Verbalized he is aware his wife is not living, is aware his medication has been decreased, and will try and work with the facility. Social service made aware."

3-23-91—10:30" * * *. Resident verbalizes how well he feels, how proud he feels not to be taking any antipsychotic medication. Nurse verbalized how proud she was of resident, encouraged him to verbalize to staff any problems or frustrations he may have and we can work them out together.

I want you to look at John Allen here for a few minutes, and I thank you for your attention. [Video shown.] [Applause.]

Mr. SHERMAN. I'd like to thank Judith Welty and Janet Stein for their presentations. That's an interesting video.

We would like to take the next 10 minutes, and if any of you in the audience have any questions for myself or any of the members of the panel, please feel free to bring that up now. Yes, Bill Cavish.

STATEMENT OF BILL CAVISH, PHILADELPHIA GERIATRIC CENTER

Mr. CAVISH. My name is William Cavish. I am the Medical Director of the Philadelphia Geriatric Center. I know it's really late, I wanted to respond to some of the things that my colleague, Rebecca Elon, said. We are both members of the American Medical Directors Association, and interested in the same directions of the use of psychotropic drugs.

But I did want to comment on a couple of things that were said about the physician's role. First, nursing homes have always been responsible for physicians' behavior. In fact, one of the biggest complaints I used to get when I lived in Massachusetts from the people at the Massachusetts Federation of Nursing Homes was that almost all the deficiencies they got in their surveys were because physicians were not coming in and signing the things they were supposed to sign, and doing some of the other things they were supposed to do.

On the question of whether OBRA is an unreasonable intrusion, I don't think so. I do disagree with my friend Sam Kidder about attempts to regulate certain things around drug dosages and the use of medications like Coumadin and other medications that I think it is very hard for surveyors to respond to appropriately.

But I think dealing with behavioral issues is a very different matter than prescribing an antibiotic for an infection. We are really talking about depriving people of their humanity, not simply treating a physical symptom. We are also talking not about adding drugs, but about removing drugs and substituting nursing interventions, which I also think is very different.

I definitely don't think that this is like the Supreme Court telling doctors what they can say or not say to their patients to help them make health care decisions for their benefit. What OBRA 1987 does is prod physicians to offer their patients a range of options. What the Supreme Court did was restrict options.

Finally, 15 years ago the predecessor agency to the Department of Health and Human Services responded to people on this Committee, Senator Moss and his colleagues who really began to get out to the public that there was a problem with contemporary nursing home care.

In that response, the Department of Health, Education, and Welfare recommended education for physicians to reduce excess of psychotropic drug use in nursing homes. And there are lots of examples of peer review and education efforts directed toward physicians that were tried, and failed throughout this period.

Education is valuable only when the environment is suitable for education to have an impact. There have been more positive educa-

tional activities directed at doctors in the years since OBRA 1987 went into effect than for the 15 years before that.

Thank you.

Dr. ELON. Thank you for those comments. In considering the nursing home's responsibility for medical practice, prior to OBRA 1987, the nursing home was not specifically responsible for physician prescribing habits in the nursing home. And although I applaud what is written in the interpretative guidelines for drug therapy for physicians' practice habits, in looking at those guidelines, it's a little bit like expecting a farmer to get his grains to market without the infrastructure of roads.

What I'm saying is that the way the interpretive guidelines first came down, you had surveyors judging physician practice, and citing negative findings without giving physicians the right to due process and without giving physicians the right defend their practices within the nursing home.

I think that medical practice in nursing homes and the review of medical practice in nursing homes is quite variable State to State. If you take a State like Massachusetts, and a State like Minnesota or California, the nursing home medical practice might be much more sophisticated than if you take a State like Texas, Oklahoma, or Mississippi. My own hope is that OBRA will be the impetus for getting more physician peer review on a local level within nursing homes and really helping support the infrastructure, the education and the physician based monitoring of physician care.

I really support Jeanine's concept of using the interpretative guidelines as screening criteria, and I think they are excellent when they are used as screening criteria. However, my own opinion is that physician peer review needs to be the methodology for final judgment as to whether a physician's practice is reasonable or not.

As far as intrusion into the medical practice, I think there needs to be more "intrusion" into the way that physicians are dealing with the majority of our elderly population. My own preference would be that this comes out of education, out of the academic centers, not out of Federal or State micromanagement of medical practice.

Unfortunately, the academic centers have lagged behind. So for that reason, I applaud the leadership that OBRA provides. And I think it would be good to continue this discussion, I don't think we really disagree on substantive issues.

Mr. SHERMAN. Thank you, Dr. Elon. Any other questions?

Thank you very much. We are stopping now, just about at 12:30. We would like everyone back here at quarter after 1 o'clock.

AFTERNOON SESSION—1:28 P.M.

Mr. SHERMAN. Welcome back, everybody. I hope everybody had a pleasant lunch. This afternoon we are going to have a panel discussion on regulatory and implementation issues, and for this panel, we have assembled a number of people I am sure you will be happy to hear from, and draw upon a variety of experiences.

The first person we will be hearing from today is Dr. Barry William Rovner. Dr. Rovner is an Associate Professor of the Depart-

ment of Psychiatry and Human Behavior, as well as Director of the Division of Geriatric Psychiatry at Thomas Jefferson University and Jefferson Medical College in Philadelphia, PA. He is also Medical Director of the Wills Eye Hospital in the Geriatric Psychiatric Unit in Philadelphia.

**STATEMENT OF DR. BARRY ROVNER, WILLS EYE HOSPITAL,
GERIATRIC PSYCHIATRY, PHILADELPHIA, PA**

Dr. ROVNER. Thank you. Good afternoon. What I would like to do today is describe a number of important trends that have occurred over the past few years in nursing home research.

The first trend will be the prevalence of psychiatric disorders in nursing homes. The second trend will be evidence of the misuse of psychotropic drugs in nursing homes. The trend will be the effectiveness of the OBRA implementation so far, in terms of antipsychotic drugs.

And finally, I will be talking about some alternative treatments in nursing homes that might fill the gap between what drugs were doing before, though inadequately and improperly, and what might be possible for nursing home patients.

The first thing we should notice, though, is that over the past 10 years there are two trends that have been evidenced in the nursing home research. The first trend is that these drugs, antipsychotic drugs, are widely used and perhaps uncritically. Numerous studies point that out.

The second point is that the prevalence of psychiatric disorders in nursing homes is very high. Many of these disorders are potentially treatable. But right now, the first trend, that is the use of antipsychotic drugs, is wrongly applied, and second, a lot of patients need psychotropic drugs. The balance is to find a linkage between appropriate use of the medicines, and making correct diagnoses.

These are comments I have been working on along with Dr. Ira Katz, at Philadelphia Geriatric Center along with the HCFA effort. Let's start with the first slide.

Much of our knowledge needs to come from research, not just from intuitions and clinical impressions. What I will be describing first off, very briefly, is a study of the prevalence of psychiatric disorders in nursing homes. This is a National Institute of Aging Research Project called the Impact of Mental Morbidity on Nursing Home Experience. The principal investigator was Pearl German, of Johns Hopkins University School of Public Health and Hygiene, and myself. At that time I was in Baltimore.

Essentially what we did was study 454 new admissions to eight Baltimore nursing homes, 454 was our sample. Just to see whether our results would be generalizable to other nursing home patients in the United States, we compared their age, race, and sex to data from the 1985 National Nursing Home Survey, of 1.5 million nursing home patients. Basically it shows that with regard to the demographic variables, the sample of patients we studied represents other nursing home patients.

The first question was, for these new admissions to nursing homes, what was the prevalence of dementia? What we did differ-

ently in this study, compared to previous studies, was the psychiatrist examined each and every one of the new admissions upon admission, to make a DSM-III-R psychiatric diagnosis.

The figure I will draw your attention to right at the bottom is that 306, or 67.4 percent, of these new admissions, were demented. That is twice the number that is generally recorded in many medical reviews and chart reviews and that sort of thing. You see the most common dementing condition was Alzheimer's disease, primary degenerative dementia, in about 38 percent of the patients.

That's followed by dementia due to stroke, in 17.8 percent, then dementia from other causes in a smaller percent. Then a combination of delirium and dementia, which is another smaller percentage. But overall, over two-thirds of these new admissions to nursing homes were demented. And over half of these were not recognized as such.

Ms. LUCERO. Are you talking a diagnosis of a primary degenerative dementia, or organic dementia, or are you talking about being demented in the sense of the clinical characteristics?

Dr. ROVNER. I'm not sure what the difference is. These are people who met DSM-III-R diagnostic criteria—

Ms. LUCERO. I'm talking about—you can have a person who is diagnosed as having a dementing illness who is not yet demented, in that they have aphasia and apraxias, but they are still able to survive without assistance.

Dr. ROVNER. But you say they have already started to have a dementing illness. So they are demented.

Ms. LUCERO. Not in my mind.

Dr. ROVNER. Well, we can talk more about it as we go along.

The next question would be, what are the psychiatric disorders besides dementia in this new admission cohort. What we found was an additional 12.8 percent of the patients, 58 people, had other psychiatric disorders, the first of which most commonly was depression, affective disorders, in about 10 percent of the nondemented nursing home patients.

Then there were less common conditions, like schizophrenia, in about 2.4 percent.

If you add up the first two slides together, for all psychiatric disorders, that is the demented plus the nondemented, with other psychiatric disorders, you see that 364, or 80 percent of these new admissions, have a psychiatric diagnosis. There are only 90, about 20 percent of these new admissions, that did not have a psychiatric diagnosis. That leads many of us who work in the field to believe that nursing homes really are mental institutions, because the majority of the patients have mental disorders.

Another point, of course, is that if they are mental institutions by the fact that most patients have mental disorders, we also notice that psychiatric kinds of treatments are very common in nursing homes, particularly neuroleptics, the kinds of medicines you might expect to see in a psychiatric facility, neuroleptics or antipsychotic medications. What this slide shows is a bar graph of four different diagnostic groups, and the proportion of patients who are receiving antipsychotic drugs.

The first group is dementia plus. These are patients with dementia plus depression or delusions. Demented patients do develop

these non-cognitive psychiatric problems such as depression and delusions. That is the dementia plus group. Then there are people with dementia only. That is, they are demented, they have memory impairments and so forth, but they don't have the other, non-cognitive psychiatric problems, like depression and delusions.

Then there is the group of people I have already told you about, the other psychiatric disorders group, 90 percent of whom were depressed. Then there is a small group of patients with no psychiatric diagnosis at all.

So this is the whole sample of 454. But what this slide shows you is what proportion of these patients by diagnostic group were receiving neuroleptic drugs. This slide will talk to you about the inappropriate use of these medications. What it shows you is regardless of the kind of dementia you have, that is complicated or uncomplicated, you see that between 30 and 40 percent—this was in 1988—30 to 40 percent were receiving antipsychotic drugs.

Now maybe we could argue that antipsychotic drugs would be useful in the demented patients with delusions, because that's really what those drugs are proposed for. But clearly what you see here, though, is that they are used independent of the diagnosis, and about 30 to 40 percent of all demented patients were receiving these drugs.

Regarding the inappropriate use, I will draw your attention to where it says "Other Psychiatric Diagnosis," there we see that about 30 percent of these patients were receiving neuroleptics. That is different than, and in contrast to, the fact that these patients were depressed. Neuroleptic medications are not the appropriate treatment for depression, by and large, yet many of these patients were receiving those medications. This is the inappropriate use of neuroleptic medications for a condition of depression.

Finally, peculiarly, people with no psychiatric diagnosis, about 10 percent of these patients were receiving neuroleptics. Clearly that was a disassociation between diagnosis and treatment.

Another point I want to make is that these drugs are used to treat behavior disorders. That is why they are used. They are not used for the diagnosis, even though they should be. Behavior disorders emerge from a lot of different conditions, with different treatment implications. This is just a look at the people whom the nursing staff said were uncooperative. About 17 percent of the sample were thought by nurses to be uncooperative.

What I have on this pie chart is broken down by those four diagnostic groups. The point is that patients can be uncooperative for a variety of different reasons. In the patient with dementia complicated, he or she might be uncooperative because of delusions. So the nurse is asking them to get into the shower and they think the nurse is trying to kill them because they are delusional, and they might be uncooperative.

That is a totally different treatment implication than somebody with dementia only. Somebody with dementia only who is uncooperative might be because of their aphasia not comprehending what a nurse is asking, so they seem to be uncooperative, because they don't truly understand what is being asked of them. That has a different treatment implication than the first one I described.

And about 15 percent of the people were depressed. Well, a depressed person might be uncooperative because they have no will to live, because they are not interested in doing anything, because they are apathetic and depressed, and that's why they would be uncooperative. That has a totally different treatment implication. Such a person requires a treatment for depression.

Then, people can be uncooperative and not have any diagnosis at all. But my point to you is that all these patients are treated the same way. In the past, they have all been treated with neuroleptic medications, which is probably only appropriate in a small group of patients.

I have been working with Dr. Kidder at HCFA to develop an approach for surveyors to begin to try to sort out when to use these drugs and when not to use these drugs. We have laid out five sorts of conditions to begin to understand where behavior disorders come from, to assist surveyors in being able to sort out whether a drug is appropriately used or not.

The first were the cognitive symptoms. As I said, most nursing home patients do have a cognitive disorder, about two-thirds of the new admission cohort do. A patient can be uncooperative because, as I said, of a cognitive problem, that is aphasia. Aphasia is when they don't understand what somebody is saying, it is the incomprehensibility of language.

Sometimes a behavior disorder emerges because the nursing staff does not appreciate that the person really does not understand the words that are being used. And a person might become agitated about that. So the way to approach that is to teach the nursing staff about what those cognitive symptoms are, and to show what a patient can and can't do, according to their abilities, and not so much that a patient is doing it intentionally, or willfully. So many behavior disorders emerge themselves from the cognitive problems.

Then there is the catastrophic reaction. This directly relates to the cognitive symptoms. Imagine what it is like when you are half asleep, and somebody is asking you to do something, like get into a shower, get undressed or something like that. If you feel like your cognitive capacities are overwhelmed, you don't understand what's happening, the only sort of response you might have is to become agitated or combative.

If somebody is pushing you and you can't quite see properly, you are not awake, what happens in such a circumstance that there is a behavioral outburst. That has a different treatment implication. That means the approach of the staff has to be entirely different for such a patient. The agitation is occurring through a catastrophic reaction, rather than some other cause, which is totally different from the next condition, namely non-cognitive symptoms.

Somebody can become agitated because they are delusional, or because they are depressed. In such a case, these symptoms usually respond to antipsychotic or antidepressant medications, which is a totally different kind of treatment implication.

Physical illnesses, such as unrecognized urinary tract infections, can lead to agitation and combativeness. And drug toxicity can as well. So the approach is to be able to dissect behavior disorders, using this sort of differential diagnosis, where the behavior is identified. Then there is some effort followed after to sort out what the

cause of that behavior disorder might be with these principles in mind.

This is just one approach. There may be very many others, but this is the one we have come up with for now.

The next point is the fact that from our study we showed that most nursing home patients, particularly those with any kind of a psychiatric problem, are not participating in activity programs in nursing homes. What this slide shows is that for the three groups with the psychiatric disorder, who comprise 80 percent of the sample, only between 25 and 35 or 40 percent of these patients are participating in any kind of an ongoing activity.

In contrast, you see amongst the patients with no psychiatric diagnosis a much higher level of participation in activities. Of course, they are the substantial minority in nursing homes. The point is that as they are currently structured, most nursing homes don't provide adequate activity for patients in the nursing home, particularly for the demented.

The consequence is that you have a lot of people looking like this in a nursing home. That is predominantly women, sitting outside their doors, looking blank, doing nothing. That's why OBRA was important, these antipsychotic drug regulations were important. Many of these patients, because they had nothing to do, were wandering and agitated and so forth, were prescribed medications.

This slide is an attempt to show you that in the 3 months preceding and the 3 months following, October 1990, you see changes in psychotropic drug practices. These are from 18 nursing homes in the State of Maryland.

What you see in red are the antipsychotic drugs. It shows you that about 26 percent of patients were on antipsychotic drugs in July 1990. Then you go over to December, the last column, and you see a reduction. This is about 16 percent of the patients who are now on antipsychotic drugs. So in anticipation of October, we have seen a 37 percent decline in the use of these medications for these particular nursing homes in Maryland.

One of our concerns, though, was an increased rate of use of other psychotropic medications, like benzodiazepines, or antidepressants, perhaps, or barbiturates. But basically there has been no change in this time period, no increase in other kinds of medications for these patients.

But what is a place to do, if a place has many agitated patients, who are wandering and have nothing to do, and you can no longer restrain them, or give them medications to quiet them down? I think that's the dilemma that most nursing homes face today. We have been involved in developing a care program, to test it in a rigorously controlled manner, to develop an effective way to take care of patients that is reasonable in nursing homes, that I will describe now.

I have one more. This is from Dr. Kidder. What it shows is that for this particular researcher in Georgia, it's showing that there has been a reduction in the use of antipsychotic medications as well. Before the OBRA implication, you see 31.5 percent were receiving antipsychotic drugs. But by sometime afterwards, I'm not sure when, about 20 percent were on the medications, which constituted a 38 percent reduction in antipsychotic drugs.

There is also over this time period a 60-percent reduction in falls and also a substantial reduction in doses in patients who were receiving antipsychotic drugs. The point I want to make here from these two slides is simply that OBRA works in some way. That is, we recognize that drugs were overused in the nursing home, and now in response to this law, we see that they are not used as much.

Seeing as the majority of the usage was probably inappropriate, from a public health perspective this is a good thing.

I want to describe the alternatives. This is a randomized trial of what we are calling dementia care in nursing homes. In one particular nursing home with 250 patients, we identified 40 behaviorally disturbed, demented patients. We randomly assigned half of them to what we called a psychiatric intervention program. The other half was to be followed as controls, receiving usual nursing home care.

Now, many of you know about Alzheimer's care units. They are wonderful ways to take care of patients, for the most part. By and large, though, they are unavailable for most nursing home patients, because of the added expenses in taking care of such patients. What we tried to do in this particular nursing home was to design an intervention that could be easily implemented by other nursing homes, using a few basic principles.

Basically what we did was follow the sample for 6 months, to see if there was a greater reduction in behavior disorders in the people who received the treatment compared to the controls. This is what the treatment was. First, it was weekly clinical rounds where the staff who took care of the patients met and talked about the behavior problems the patients were having and whether they were emerging from physical illnesses, medications, delusions, depressions or cognitive symptoms, the same approach I described earlier.

We also defined certain psychotropic drug protocols, when we would use an antipsychotic medication, in which dosage, how it would be increased, what would be the indications, to lay out a standard that might be effective.

Finally, and most importantly, what this intervention did was gather these 20 patients who lived throughout the nursing home and brought them to an activities room, a room that was just being used before for nursing reports, where the patients spent the remainder of the day. They got there first thing in the morning and stayed there until about 3 o'clock or 4 o'clock in the afternoon, and they participated in activities.

From our previous research, this was a needed intervention, because most of these patients were not doing anything before this intervention started.

This is just a picture. It shows you rather severely demented patients being able to do something. Most of these patients would normally not be doing anything in a nursing home, because as it is currently constructed, many activity staffs feel there is nothing you can do for this severely demented kind of patient.

Besides looking at whether this kind of program of activities, and rounds, and psychotropic drugs, when used in a prescribed fashion, is effective in reduction behavior disorders, we are also looking at decreases in use of restraints, changes in cognition, functional capacity, nursing staff job satisfaction, family satisfaction, and also

the incremental cost of having an activity program for these kinds of patients.

Our goal is to have patients look better than that blank sort of appearance that I showed you before. Thank you.

Mr. SHERMAN. Thank you very much, Dr. Rovner.

Our next speaker is Beth Klitch, who is Chief of the Division of Health Facilities Regulation, from the Ohio Department of Health.

Beth directs, plans, and administers State licensure and Federal Medicare/Medicare certifications programs for 22 health care facilities, providers and suppliers, including nursing homes, rest homes, adult care facilities, hospitals, home health agencies, hospices, and laboratories. She also administers the Board of Examiners of Nursing Home Administrators.

Beth A. Klitch.

STATEMENT OF BETH A. KLITCH, CHIEF, DIVISION OF HEALTH FACILITIES REGULATION, OHIO DEPARTMENT OF HEALTH, COLUMBUS, OH

Ms. KLITCH. Good afternoon; I should also let some of you know, I see some familiar faces out here, I am also the Vice President of the National Association of Health Facility Survey Agencies. So I get an opportunity every now and then to come to Washington and meet with providers and advocates and my fellow survey agency heads.

I want to express a special thanks to the Senate Committee on Aging for their continuing efforts to examine and publicize quality issues in long-term care. As many of you are aware, past forums on the use and reduction of physical restraints have proven enormously successful across the Nation, and I am pleased to participate in today's discussion of the use and misuse of chemical restraints.

To give you a little bit of background, the Ohio Department of Health licenses and certifies more than 1,000 nursing facilities for participation in the Medicare and Medicaid programs. These facilities, like many other States, range from large multi-facility chains all the way to small "mom and pop" operations. We employ more than 300 surveyors to inspect nursing homes as well as well as 20 others types of health care providers.

We perform an average of one annual survey with our licensure and certification visits combined, about 1.5 followup surveys, and two complaint investigations for each nursing home, for an approximate total of four or five visits per facility per year.

In addition, for the 30 to 40 nursing homes that present an immediate and serious threat to their residents each year, we employ and sometimes round the clock monitoring to assure the residents' well-being.

Ohio is also fortunate to have a highly respected nursing home ombudsman program, aggressive in resolving more than 8,000 nursing home resident rights complaints each year. We actively share information and jointly pursue enforcement action with them when necessary.

Today I am going to share information with you that illuminates both, unfortunately statistically, and also anecdotally, the extent of the use and misuse of chemical restraints in Ohio's long-term care

facilities. I also will describe a few "best practices" as observed by Ohio surveyors and propose a four-point plan for reducing the inappropriate use of these drugs in nursing homes.

Let me start by describing the primary regulations under which State survey agencies look for evidence of inappropriate psychoactive drug use, and for those of you for whom this is repetitive, I apologize. But it kind of occurred to me that we ought to make sure we know what regulations we are talking about here.

First, for the more compulsive among us, CFR 483.13(a) or what we call Tag F204, states that the resident has the right to be free from any psychoactive drug administered for purposes of discipline or convenience, and that is not required to treat the resident's medical symptoms. The accompanying guidance to surveyors defines psychoactive drugs as "drugs prescribed to control mood, mental status, or behavior."

Discipline is defined as "any action taken by the facility for the express purpose of punishing or penalizing residents" and convenience is defined as "any action taken by the facility to control resident behavior, or maintain residents with the least amount of effort by the facility and not in the resident's best interests."

Interestingly, however, nearly all the survey procedures and probes for this regulation direct surveyors to the examination of physical restraints, not psychoactive drugs. Since October 1, 1990, Ohio surveyors have cited F204 out of compliance in 10 facilities out of 632 surveys, or a percentage of only about 1.6 percent.

Nationally, 550 facilities of out 9,626 surveyed have been cited out of compliance, for a total of 5.7 percent. Incidentally, all national comparative data derives from the Federal OSCAR system, the Online Survey and Certification Automated Reporting system.

The second applicable regulation, CFR 483.25(1)(2)(i), or Tag F308, addresses the use specifically of antipsychotic drugs. It says "Based on a comprehensive assessment of a resident, the facility must ensure that residents who have not used antipsychotic drugs are not given these drugs, unless antipsychotic drug therapy is necessary to treat a specific condition."

The interpretive guidelines, which as many of you know States have been instructed only to use as guidance, not additional requirements beyond those stated in the regulation, lists examples of commonly used antipsychotic drugs, it lists examples of specific conditions that must be documented in the resident's clinical record, and lists indications for which antipsychotics should not be used if they are the only indication.

I would like to put a quick overhead up here, just to give you an idea. If you look at this list of indications, you have probably all heard both this morning and tonight, these kinds of behaviors described as some of the primary behaviors that are most troubling to nursing homes facilities. Ohio has cited 7 facilities out of 632 since October 1, or only 1.11 percent. Nationally, 2.2 percent, of 214 of those 9,626 facilities surveyed were found out of compliance with this requirement.

The third applicable regulation specific to the use of antipsychotic drugs is CFR 483.25(1)(2)(i), or TAG F309, which states that residents who use antipsychotic drugs receive gradual dose reductions,

drug holidays, or behavioral program, unless clinically contra-indicated, in an effort to discontinue these drugs.

The interpretive guidelines define behavioral programming as modification of the resident's behavior and/or the resident's environment, including staff approaches to care to the largest degree possible to accommodate the resident's behavioral disturbance.

Ohio has cited 11 facilities for failure to comply with this requirement since October 1, 1990, or 1.74 percent, and nationally, 156 facilities have been cited for a percentage of 1.62 percent.

The Ohio Health Care Association, which is an American Health Care Association affiliate, provided some additional information to me, comparing residents who have received antipsychotic medications from January 1990 to March 1991. I would like to put a second overhead up.

Of 2,377 nursing facility residents compared over this period, approximately 17 percent had routine orders for these drugs in January 1990, and fewer than 13 percent in March 1991. The PRN, or "as-needed" orders, decreased by nearly half, from 6.9 percent to 3.6 percent in March 1991.

Then I have some examples of a smaller sampling of residents that was also conducted, 176 residents compared from March 1990 to March 1991—I think you will find this interesting. While 49 percent of antipsychotic medicines were discontinued or reduced in dosage, 51 percent of these orders remained unchanged or increased. I think it is evident that as a philosophy, OBRA and these regulations have had some impact. But I think clearly we have a lot of work yet to do.

Let's shift the focus for a minute from statistics to people. Ohio surveyors recently had occasion to monitor a nursing home presenting a serious and immediate threat for nearly 3 weeks. During our daily monitoring sessions, we observed three residents, and I wanted to share their stories with you, because I thought they were good indications of both the bad and the good we can find.

Resident number one was a female resident admitted from her home, diagnosed with organic brain syndrome. The nursing assessment upon admission stated that she was oriented to person and disoriented to place and time. She was seen by the physician 5 hours after the admission. During those 5 hours, in the words of the facility staff, she displayed behavior indicating that she was not adjusting to the nursing home, in 5 hours.

Due to a history of falls, she was physically restrained, and when the physician saw her, he also ordered a chemical restraint, due to restlessness. Within 1 week the resident removed the physical restraint and fell, striking her head. She was seen in the emergency room and received sutures. During the ongoing monitoring of this facility, we watched the staff eliminate both the physical and the chemical restraints.

This resident began adjusting well to the facility, and although she was unable to walk without assistance, she was able to spend her day in a wheelchair without a restraint by the time we had concluded our monitoring.

Resident number two was a male resident admitted during our survey with a diagnosis of organic brain syndrome with dementia. The nursing staff assessed him to be disoriented to person, place,

and time. Social services assessed him to be oriented to person, and at times to place and time. The survey staff found him oriented to person and place on 2 of the 4 days of the survey.

The resident was found on the day of the admission wandering outside the facility. Since the physician was in, he ordered Thorazine, 25 milligrams, i.m., which was given. The resident left the facility twice more over the next 24 hours. Nursing interventions included continued use of Thorazine and a geri chair.

At the end of our monitoring, 3 weeks later, this resident was without chemical and physical restraints, and had adjusted well to the facility. He was an active participant in most activities and had not left the facility since the restraints were discontinued.

Both of these residents were admitted from their homes with incomplete assessments. Nursing staff did not use any interventions to help these residents adjust to the major change of admission to a nursing home, and both were physically and chemically restrained shortly after admission, contributing, no doubt, to their adjustment difficulties.

After our intensive monitoring, this facility completely changed their resident interventions and were very pleased.

Let me tell you the story of resident number three. He was a male resident admitted during the time of the survey, in our monitoring sessions. His record and facility staff interviews indicated that he kept wandering out of the facility to the dumpster.

Past practice of the facility would have been to restrain and/or medicate him for wandering. However, since this was a problem area identified by our surveyors, the facility completed a more comprehensive assessment and found that he had worked for many years as a garbage collector.

So the facility included in his daily activities the task of emptying trash cans at the nurse's station. This occupied him and completely stopped his wandering behavior.

Because of the survey agency's constant presence during this facility's crisis, surveyors were able to observe, question, and document physical and chemical restraint use, as well as subsequent and more effective staff interventions. Some of the best practices that our surveyors report in observing staff approaches and other interventions include the following.

One, short walks, both inside and outside the facility, several times a day, individually and in groups, advantages are that it diverts attention and burns excess energy. Two, short-term activities in as few as 15-minute sessions, three to four times a day, playing catch with a ball, bowling, memory association games, folding and distributing linens.

Three, frequent small snacks, such as pudding, ice cream, fruit, small sandwiches or other nutritious foods, has both a calming effect and prevents weight loss. Four, a calm atmosphere, having the staff lower their voices and less use of the intercom and paging systems.

Five, a fenced-in area outdoors, a small controlled area that allows residents access to the out of doors without the fear of loss of security. Six, bed mattresses on the floor to prevent residents who would otherwise need to be restrained from falling out of bed. Seven, furniture groupings, small groupings of furniture placed up

and down the hallway to allow residents who pace or wander an area to meet or rest with other residents.

We believe that a four-point plan will help eliminate the inappropriate use of chemical restraints in nursing facilities. Step one is leadership. The Congress, the Health Care Financing Administration, State survey agencies, and State ombudsman programs must exert strong philosophical leadership about the undesirability of chemical restraints.

We must share that philosophy with nursing facility owners and operators and we must use the visibility of our organizations to communicate and promote alternatives. In other words, we must create a powerful new culture of humane alternatives to the use of chemical restraints in nursing homes.

Step two is research. We must advocate, participate in and fund clinical research into the development and application of alternative approaches, to help residents manage their own behaviors. Step three is education. We must target continuing education requirements to all health professionals working with nursing home residents, especially physicians, pharmacists, nurses, social workers, and nursing assistants.

Additional training must include side effects of these drugs, coping with difficult resident behaviors, comprehensive assessments, and multidisciplinary care planning. We must not forget to involve residents' families and friends, so that they will understand and gain confidence in alternative approaches. Remember, the loved ones of nursing home residents have been told for many years that the only way to keep their mom safe was to tie her down. They are not going to change their minds overnight.

Step four is enforcement. HCFA, State survey agencies and State ombudsman programs must vigorously enforce State licensure and Federal regulations prohibiting the inappropriate use of chemical restraints. We must be visible, active, and determined in our efforts to detect and eliminate violations of these requirements.

Thank you for the chance to share Ohio's survey agency experiences in eliminating inappropriate restraints, and to propose this action plan for the future. We look forward to joining our partners in long-term care—Congress, HCFA, the nursing home provider community—in creating this new culture of human alternatives.

Thank you.

Mr. SHERMAN. Thank you very much, Beth. Our next speaker is Susan Acker, who has a background as a surveyor and as a director of nursing. She has a masters in nursing administration from the University of Florida, and a Ph.D. in administration from the University of Florida.

She currently supervises the central office operations for the 31 facility types that are certified and licensed by the Florida Office of Licensure and Certification.

Dr. Acker.

STATEMENT OF SUSAN ACKER, R.N., PH.D., HEALTH SERVICES AND FACILITIES CONSULTANT SUPERVISOR, OFFICE OF LICENSURE AND CERTIFICATION, TALLAHASSEE, FL

Ms. ACKER. Good afternoon. I would like to thank you for the opportunity, some of you more than others, for joining you all here in Washington today. Those of you that are familiar with State government know that it almost took an act of Congress to get anyone out of the State of Florida to participate in this seminar. So I would like to extend a special thanks to the committee staff members who assisted me with that.

As you all know, although I sound like I originally come from New Jersey, which I do, I am here representing the State of Florida, which has 570 long-term-care facilities, 40 of which are licensed only. Those of you that are statistically inclined know that then means that 530 of them are dually licensed and certified.

So they must sustain surveys or inspections under the State of Florida, Florida Statute 400 and the rules thereof, 10D-29, as well as the certification standards, OBRA of 1987. We have 69,000 long-term-care beds in Florida, of which 91 percent are occupied on any given day.

People think of Florida as Miami Vice, lots of turquoise and flamingos and no socks. But you must remember that the distance from Key West to Pensacola is the same as the distance from Pensacola to Chicago. So when long-term-care surveyors take to the road in Florida, they really take to the air in an attempt to survey those facilities.

We have facilities that are extremely urban in nature—downtown Miami, Tampa, Orlando, Jacksonville. But we also have facilities that are extremely rural, that make Plains, GA, look like a metropolis, where the nursing home is the primary employer, and the residents are related to all the caregivers.

In Florida we have a very diverse population. When you look at the HCFA guidelines for second language, in Florida you find that on the southeast coast the second language is as you expect, Spanish. But if you go to the southwest coast of Florida, the second language is Greek. If you go to central Florida, just slightly north of Orlando, the second most commonly spoken language is Slavic. And if you go to the Panhandle of Florida, the second most commonly spoken language is Vietnamese.

So you have some idea of what is happening in the facilities that you would think of as being just a short distance from Disneyworld.

The only thing you probably know about Florida is that when you get to the border, the children want to know "Are we there yet?" And as you know, no matter what border you cross, you have at least a 5-hour drive to get where you're going. In some cases you have between a 8-hour and 10-hour drive.

The residents of long-term care facilities are as diverse and anxious to get things on the road as your children going to Disneyworld. They want their lives taken care of, and we in the regulatory agency of the State of Florida consider that our mission. We are very righteous in the State of Florida. We take our mission very seriously, as do they all over the Nation.

The thing we realized our residents have in common is their humanity, our respect, and the protection of OBRA 1987. But long before OBRA 1987, the Florida Statute 400 listed resident rights. With your permission, I will read to you the part of this statute in Florida that has protected residents' rights from physical and chemical restraints for over a decade. That is "the right to be free from mental and physical abuse, and from physical and chemical restraints, except those restraints authorized in writing by a physician for a specific and limited period of time, or as are necessary by an emergency." Then the statute goes on to define an emergency.

The second part of that phrase that you will find interesting is that they then add a sentence that says "Restraints may not be used in lieu of staff supervision, or merely for staff convenience, for punishment or for other reasons other than resident protection or safety." In Florida, we have been doing this for over a decade. And so when we hear the rumblings out of the West that the interpretive guidelines are going to be modified, we stand tough and we stand tall.

In the past 3 years, Florida has reduced the incidence of physical restraints from 37 percent to 18 percent, 37 percent to 18 percent. At 69,000 beds, that's almost 15,000 residents who are no longer tied down.

When you think of 15,000 people who have been released from physical restraints, your antenna should go up, for those of you that are surveyors, the fur on the back of your neck should start to twitch. Because that means that they probably—and you know who "they" are—are probably watching them wander out of the facility? No. Are they probably getting programming to them in those facilities? Maybe—hopefully.

What is really probably happening, and what we thought might be happening is that we had better start checking on the relationship between physical restraint reduction with a corresponding chemical restraint increase. So we began to turn over the pages in the medical record. Essentially, chemical restraint, we have found, or the use of the antipsychotic drug, is invisible and aesthetic. You don't see it. It's very invisible and very aesthetic. There aren't any people tied down with things, or wearing things, or strapped in with things.

It's very benign to the average person. You give them medication, everybody takes something, even those of us on normal diets take our vitamins every day. And last but not least, one of the best things about chemical restraints is that, best in a sardonic, sarcastic way, is that it is attributable to the physician. When you walk into a nursing facility, and you see someone with a chemical restraint, an anti-psychotic drug, for an inappropriate diagnosis, it can always be said "The doctor made me do it."

In the State of Florida we began to look at this. And we looked at it from those three categories and cited accordingly. As I said, in Florida we have been tough on this for a long time. Under the invisible and aesthetic, let me tell you a little anecdotal story about a 160-bed facility in a moderately rural area. This facility was surveyed by yours truly, 4 years ago, before OBRA.

The nicest thing that happened when I walked in the door at 9—in Florida we start when the business day starts on the first day of

the survey, although our surveys are unannounced, they don't really start at the change of shifts, they start around 9—I walked into the over 160-bed facility, at 9 o'clock in the morning, started my tour, and it was quiet.

Those of you that have ever been in a long-term care facility at 9 o'clock in the morning, with only 60 residents, let alone 160 beds, know right away that one of the strangest and most bizarre things is to walk into a 160-bed facility at 9 o'clock in the morning and find it quiet.

No one was in the hall, no one was hollering about going to the shower, no one was fussing about the fact that they wanted corn flakes instead of oatmeal. No one was anywhere. They weren't anywhere!

The residents were semi-somnolent in two huge day rooms, approximately 35 residents in each, and all the rest of the folks were tucked in their wee little beds, somnolent. When we asked why, after the tour, and they were able to run a computer record for us, 98 of the 160 residents were receiving—well, they were receiving psychoactive drugs, most of them antipsychotics, some of them tranquilizers.

On that survey, we took out State and Federal standards at that time, State standards of course. But do you want to know who we cited besides nursing care? We took the consultant pharmacist. When he rushed in to appeal and say "The doctor made me do it," I said "That's fine. Is this the practice of the consultant pharmacist?"

By the time he left that building, all the PRN orders had been discontinued, because the residents had not been receiving them anyway. Most of the drugs for noncategorized dementia, such as wandering, and other issues of that nature, had been discontinued. And a lot of the people that were on the heavy-hitting antipsychotics were on stepdown programs. So we felt fairly justified.

At the follow-up 45 days later, there were no more "Stepford" residents. Everyone was out in the hall fussing, refusing to take a shower, talking about the corn flakes, just like a normal day.

So that's how to deal with invisible and aesthetically pleasing antipsychotics, you cite them. Let's take a look at benign, how benign these antipsychotics are. As I left the office on Thursday, I got a telephone call from one of our area offices. Florida is divided into 11 districts or areas. A young woman who is in charge in southwest Florida had been in the nursing facility with 86 residents. She wished to place a moratorium, which is a State sanction, under our scope and severity rule.

The reason she wished to place this was of the 86 residents, 3 of them had lost over 30 pounds in a 1-month period of time. Of those folks, all 3 of them were on at least one antipsychotic medication. Two of them were on three or more antipsychotic medications. And, these people had started to break down and develop incontinence, and one had been hospitalized during the course of the survey.

So we placed a moratorium on admission, which is a very severe State sanction in our area, and took two of the Level A's. More to come.

Under the issue of physician attributable, I happened to talk with Dr. Kidder on the telephone on occasion—with him giving me the pep talk, to hang in there—and he was telling me that really it's the nurses attitudes in long-term care that change behavior regarding the administration of antipsychotic drugs, because it is the nurses who request them.

He can cite the studies for you that say the nurses are the ones that call in and say Susan Acker wandered out the door, or Susan Acker is being belligerent, which would not be unlike Susan Acker and that medication is required. But it's very important that you understand the physician oftentimes is acting at the request or behest of the primary caregiver who is the nurse.

I told you the story of a nursing facility in Florida where we took out the standard for 98 residents. Now I will tell you where we took it out for just one. Another rural facility, 120 beds, this resident was physically restrained because he liked to touch female residents.

Now, this was a very rural facility, and he had been a "rounder"—that's what they say in Florida for "party animal," I guess—he had been a rounder all his life in that town. Everybody knew him. And of course, as he aged—you don't become nice little old ladies if you weren't nice little young ladies, and you don't become nice little old men if you weren't nice little young men * * *.

Anyway, to make a long story short, he had been a rounder and liked to touch the ladies his entire life. However, in the nursing home this was no longer acceptable. They physically restrained him.

When the physical restraint initiative went into effect, they decided to untie him and chemically restrain him. He fell three times in the course of 1 week on massive doses of Haldol, I'm sure that would have fundered the average horse, and was admitted to the local hospital. When his family complained, they threatened to preemptively discharge him.

For some strange reason, most of this was documented in the medical record. You know, surveyors do get lucky every once in a while. So based on that one incident, the fact that he was being punished, and the fact that this was being used in lieu of staffing and for staff convenience, we are able to go after them on just one person.

I have a feeling that even were it not in the medical record, with this team they would have gone just for that single individual.

I have two or three issues in closing that I just can't speak before a Senate Special Committee hearing, or seminar, and let go by. I don't think there is a health caregiver in the United States that does not believe that the antipsychotics have beneficial effects when there are clinical indications. We are all committed to just that, the appropriate use of them.

But when they are not clinically indicated, we do consider them to be chemical restraints. It's not only a matter of morality, it's not only a matter of ethics. As you have heard speaker after speaker say today, it's a matter of cost. It's not only economic costs, but human costs. You lose not only the dignity, but eventually appetite, continence, you get pressure sores, weight loss, and things that start off as being fairly innocent become cumulative.

In the elderly, institutionalized elderly in particular, inappropriate use of psychotropics usually result in increasing acuity of need and eventually may, as in the case of one of the residents in the facility where we took the standard on three, the Level A's on three, eventually in the death of that resident.

Increasing staffing needs can be viewed not only on the staff needed to care for the resident if he or she wanders. But we need to take a look at what staffing needs are deferred, based upon the reduced acuity, because they have not been psychotroped into the next century.

I think that in regulation and enforcement we would like to respectfully request that those of you with influence attempt to use that with your legislators and those of you in the legislative body continue to provide us with statutory authority and continue to support those individuals at HCFA and everywhere who write the regulations to support them as written, to allow us to serve and to protect the residents of the long-term care facility.

Mr. SHERMAN. Thank you, Dr. Acker, for the eloquent summation.

Our next speaker is Larry Price, who is Senior Pharmacist of the Office of Long-Term Care. Mr. Price has been with this agency in Arkansas for 9 years, and surveys nursing homes and intermediate care facilities for the mentally retarded. He is also in charge of training nurses and other staff on pharmacy regulations, and reviews the work of other field surveyors as well as handling all pharmacy office correspondence.

Mr. Price will speak to the current status of the regulations as they relate to one State, the State of Arkansas.

STATEMENT OF LARRY PRICE, SENIOR PHARMACIST, OFFICE OF LONG-TERM CARE, ARKANSAS DEPARTMENT OF HUMAN SERVICES, LITTLE ROCK, AR

Mr. PRICE. Thank you very much. What I would like to do today is just speak to one State, what we are doing in the State of Arkansas, what our results are, and what we have found. As it relates to other States, it is probably on-line, but I couldn't exactly say that, so I do want to keep my comments just strictly to Arkansas, and what we are doing.

Since October 1, 1990, up to the present date, approximately 60 percent of the residents who receive antipsychotics have received gradual dose reductions. Basically the dose reductions have come about in three different ways by the physicians. One is some physicians will reduce the dose every month by around 10 percent, almost on a monthly basis. Other physicians will do a dose reduction and wait 4 to 6 months before trying again. And others wait longer than 6 months. Those seem to be the three ways it's being done.

We do have one facility in the State that has basically met the condition of clinically contraindicative, which is that the residents have received the gradual dose reductions, they are on the lowest dose possible, and they have a correct diagnosis. But to my knowledge, only one facility so far has met 100 percent of the residents who use antipsychotics.

What we try to do when we survey a nursing home, or what we have been trying to do since October, and will continue for a while longer, is we look for a trend in a facility. For instance, when we go into a nursing home, we pick a case mix. And it may be a case mix of 20 individuals, and maybe 5 of those individuals take anti-psychotics. It may be as we look through the clinical record we find that they all have been on them for extended periods of time and the clinical records does not show a risk where these individuals would not benefit from a dose reduction.

So what we try to do is find out how many residents are on anti-psychotics in the facility and also how many dosage reductions have occurred. Because they may have 50 residents in the facility, and 45 of them may have had dose reductions, and the 5 that we happen to pick on our case mix may be the 5 that have not yet received, and are due to. So we try to be fair in enforcing the regulation, we do look at the overall status of the facility, and not just a particular set of individuals at this point.

Also, approximately 25 percent of the residents in Arkansas have had at least two or more dosage reductions at this time. Approximately 95 percent of the residents who have received reductions have not required an increase in dosage at a later date. I am going to read that again, because I think that's a very important statement. Approximately 95 percent of the residents who have received reductions in dosage have not required an increase in the dosage at a later date.

One thing we note is that drug holidays are not being used. I think possibly that's due to definition, which is basically a gradual lowering of the dose, and a subsequent discontinuance of the drug, to test for its continued need. I think it's the wording of "subsequent discontinuance" that a lot of physicians and facilities would rather go the dosage reduction route than the drug holiday route. I think I have seen one individual in the State of Arkansas that has been on a drug holiday at this point.

Approximately 50 percent of the facilities in Arkansas, of which there are a little over 260, I think 262, use an outside resource as a behavioral management tool. And this is growing at a very rapid rate, because in October 1990, it was probably less than 10 percent. Now it is up to 50 percent. The main firm that seems to be used in Arkansas is called Clinical Service Inc. I have some of their material available which I will leave out on the desk if anyone would like to look through it.

Basically, when they do their consultations, a small percentage of physicians give CSI complete control of the psychotropic portion of the patients' drug regimen. But by and large, the majority of physicians keep control of the psychotropic drugs and allow CSI to make suggestions.

Approximately 40 percent of Arkansas residents on antipsychotics have an organic mental syndrome diagnosis. Facilities, as least as we note by surveys, are doing a relatively poor job of documenting the episodes of danger, either to the other residents, to the staff or show some interference with the staff's ability to provide care.

Also, to document these episodes, a lot of homes are using form sheets, which I also have some examples available. But by and large most nursing homes use nurses' notes to document this.

Also, surveyors are required to use professional judgment. Every time we survey in this particular area of regulations, and I will give you two examples of the last survey I did, I was looking at this gentleman who lived with his wife in a nursing facility. He had a diagnosis of senile dementia. As I looked at his chart, I could see nothing in the clinical record that would indicate that this individual would have a need for the drug. There was just nothing to indicate a reason for the episodes, as we mentioned, being noted at all.

But as I looked at the incident and accident reports of the facility, over half of the incidents and accidents were on this particular gentleman. What he was doing was, instead of using the call light or getting a nurse's aide assistant to lift his wife from the bed to the wheelchair, he was trying to do it himself. And he had dropped her many times, he had bruised her, she had never had any broken hips or anything like that. But looking back, I would say probably instead of using an antipsychotic on this individual, perhaps some behavioral modification would have been in order for this gentleman.

Another resident in the same home I was looking at was on Haldol, 10 milligrams at bedtime. His primary diagnosis was epilepsy. The diagnosis for the use of the Haldol was restlessness. As I looked through his clinical chart, I really couldn't see anything that would justify it, plus the fact that it's not a correct diagnosis in the first place.

But as I talked to the charge nurse, she informed me that the resident did not sleep well at night, and that the drug had been to help him sleep. Sure enough, he was sleeping very well, I might add. But the point is, the gentleman had been on the drug since 1984 at the same dose every night, 10 milligrams of Haldol. And there are other interventions that could have been used.

First of all, he is certainly a candidate for a dose reduction. There is nothing in the clinical record that suggests otherwise. There are also other drugs on the market that could be used in place—and I'm not necessarily talking about sedative hypnotics—drugs like perhaps Benadryl, or Periactin or something like that may be of more benefit. And it may be, as they do the dose reduction, they may find that the gentleman sleeps very well, anyway.

Another area we run into where we have a problem is the diagnoses that are not indicated for the use of an antipsychotic, such as the restlessness, the anxiety, insomnia, this sort of thing. I would say approximately 15 percent of the residents have this diagnosis. Now, obviously, this is changing. The regulations have certainly had an effect on the way the diagnoses are being tended to.

Also, one of the more major changes that I have seen as a surveyor is the use of PRN antipsychotics. Right now, the regulations read that if you sue a PRN antipsychotic more than five times in a 7-day period, the physician should be notified and acknowledged. But we're finding out is a lot of the consultant's are recommending the discontinuance of PRNs and the use of PRN antipsychotics has gone down greatly in the nursing homes we survey.

One thing we also find—and this has really happened in the last 3 months, I would say—is that the physicians are more adequately documenting clinical risks for a resident. Because as surveyors, we are taught that if we find problems in the antipsychotic drug area

that we are to give the facility a chance to explain things to us, including talking to the physician, whatever evidence they would like to present that would show a need for the drug.

So we are finding that physicians document the risk factors much better than they did before. And that's really been in the last 3 months that I have noticed an increased effort in that area.

One thing we have not used is the regulation F170. I am sure we will use it in the future. Basically, our intention has been to give the facilities a chance to adjust to the regulations, give the surveyors a chance to adjust to the regulations, and go forth with them, and show improvement in each area both by the way we survey with it, and with the way the facilities do it.

But F170 basically says that a resident has the right to choose a physician, but if that physician will not allow the facility to meet certain requirements, and it specifically indicates unnecessary drugs and antipsychotic drugs, then the facility may, after informing the resident, choose a physician that will allow the facility to meet these requirements.

So that is going to be a regulation that I think in the future is going to make nursing facilities more attuned to discussing these problems with the physicians and getting things done.

As far as the side effects of antipsychotics, what we find mostly is that these are treated by form sheets, but not necessarily monitored in the facility. A lot of homes use standardized sheets to put down what the side effects of the drugs are going to be, and this is placed away somewhere, usually in the care plan or something like that, not necessarily used. The sheet is only good if the monitoring is in effect.

So I think that's one area that nursing facilities need to be doing a better job in, monitoring the side effects, not simply just writing them down, but actually having some kind of monitoring system, an ongoing program.

As for the consultant pharmacists' involvement with the new regulations, I find it is true that the independent pharmacist, or the pharmacist that strictly consults for a living, rather than consults in the retail setting, that they do a much better job of informing the facility of these regulations and what needs to be done.

Sometimes, especially in Arkansas, which is a rural State by nature, you might have a town with one or more pharmacies in it, and the pharmacy is both provider as well as consultant for the home. Sometimes they can be reluctant to tell the home the advice or give them the correct status of the facility at a particular moment.

But Federal guideline indicators have included most of the antipsychotic drug regulations as part of the indicators. So this gives the consultant pharmacist another tool to work with in their efforts to meet the requirements of the regulations.

Basically, one thing I do know, in the Federal guideline indicators it says that the pharmacist should comment on residents who are not at clinical risk, that have not had dosage reductions in 6 months. That's one thing I think we need to work on, is what is a proper standard, what's an extended period of use.

But the indicators do give us a 6-month criteria as a consulting tool in this particular case. Part of that regulation, the 6-month

criteria and the 25 percent maximum dose, has been taken out of part of the Federal regulations. But I did note that it is in the Federal guideline indicators.

That's really about all I have to say at this time. I just wanted to give you kind of a status report from a surveyor's point of view as to what was going on and how these regulations are being enforced at this time. I thank you very much.

Mr. SHERMAN. Thank you, Larry, for that very practically oriented presentation.

At this time we would like to welcome any questions for members of the panel. Does anybody have any questions they would like to address to anyone?

[Question from audience.]

Mr. SHERMAN. Is your question addressing the PRN use of antipsychotic medications? Sam, do you want to address that?

Dr. KIDDER. I'm Dr. Sam Kidder with the Health Care Financing Administration, my original thinking was, an antipsychotic drug takes about 10 days to build up its antipsychotic effects, as Dr. Rovner was saying, to have an effect on hallucinations and delusions. When it is used on a PRN basis, it is used for its immediate sedative effect. So we didn't think that was a reasonable use of the drug.

However, a number of people convinced us that there were certain circumstances where they needed that effect, principally in catastrophic reactions, as Dr. Rovner talked about. But we tried to circumscribe that use, by saying five doses in a 7-day period, there should be a physician looking at that resident, because they have something going wrong, there is a lot of stress there, and somebody ought to look at it.

We don't want to be taking that tool away from the physicians, because it was necessary in certain circumstances.

Mr. SHERMAN. Thank you, Dr. Kidder. Any other questions? Yes, ma'am.

STATEMENT OF MARIE SAUNDERS, WISCONSIN NURSE CONSULTANT

Ms. SAUNDERS. I am Marie Saunders. I'm a nurse consultant from Wisconsin. I practice in several other States. One of my great concerns with psychoactive drugs is the target behavior monitoring. I am finding very little good information coming into the medical record. I am finding the target behavior sheets with lots of little squares on them, with checks or slashes or numbers. And I am finding surveyors who are counting the boxes, and the number of empty boxes, and citing on the number of empty boxes.

I don't find that to be useful to anyone. I am finding my clients are very vulnerable to cites that are not meaningful in terms of regulation. I am wondering if anyone has any ideas or suggestions in terms of what might be some meaningful monitoring.

Mr. PRICE. One thing I would suggest to you is to have in-service to the nurse's aides. Because they are the primary caregivers in the facility, the bathing, toileting, eating. A lot of the incidents that happen will be happening to the aides. If they don't tell you

about it, then it doesn't get done. Episodes have to be documented quantitatively and qualitatively.

I would also suggest to you that you get away from using words like combative and aggressive, and be more specific as to why the episode happened. But you need to get your reporting mechanism in place, and that is that the aides, and all the facility personnel, know that these things are to be reported as to what happened, so it can be put down and show a clinical record.

STATEMENT OF NANCY WILBURN, NATIONAL COUNSELING ASSOCIATION

Ms. WILBURN. I'm Nancy Wilburn, an executive with the National Counseling Association. We have gerontological counselors, rehab counselors, all kinds. But I am also speaking from another perspective.

For about 11 years now, I have been grieving over the loss of my mother in a nursing home in the State of Maryland. If I had echoes of that experience, I heard them all here, every one, with some of the anecdotes.

My deep concern is, though, we are talking about drugs and their administration and dosage. We are perhaps avoiding—I think I have only heard two people today speak to the tremendous need of some of our caregivers in our society for docile, quiet places, docile, quiet people. Some of our caregivers and I talk about nurses aides, I talk about nurses, doctors, whatever, counselors included, require this. The need is tremendous for total re-education.

I am ashamed of any part any one of us play, since 50 percent of us will leave this earth from one of those places, possibly, that we admire and respect the conforming, docile person. This is what has developed the industry of medication. It has put down the creative interventions that were described so well today, the alternative interventions.

I am not anti-medication, but I think we have been so absolutely enraptured by them, because they are such a quick fix in many cases. I do feel deeply about this, and I came here with a bias that I had to share.

There are a lot of caregivers out there who are ready to work, and yet are not named as potential providers. We are not talking about people who administer medication, but counselors, social workers, others in the community who could come in and work with people in nursing homes.

The nursing home where my mother died was one of those big franchise operations, there are a million of them all over the country, same name, different location. Again, I know other people in this room have had comparable experiences with their loved ones, sisters or brothers.

But I would urge all of you to look at the real target, and that is the tremendous need of our society to keep things calm and flat. All these industries develop because of that need. So unless we change and educate ourselves, I think we are going to continue to have this problem.

Mr. SHERMAN. Thank you very much. Yes, sir?

[Question from audience.]

Mr. SHERMAN. I can speak to that, or would anyone else like to?

I don't think that it has been done in a large enough way yet, or the information has been presented, at least in a way that people in the Government agencies responsible for reimbursement have really heard that. I also feel that it is a very difficult area to evaluate. So that just as this woman expressed, she comes here with a bias, I think we all come here with a bias. I don't think there's anything wrong with that, as long as we are aware that this occurs, and acknowledge it as we are talking to each other.

But I think that those individuals who do these kinds, these pieces of research, that examine these kinds of things, oftentimes they are done anecdotally and not designed in a way that really stands up to what might be considered well-designed methodology from a public health perspective. I think there are a number of those projects in the works now, but it is a very complicated area. It is a multi-variant area, so it's a difficult kind of study to analyze.

Yes?

STATEMENT OF DAVID ZIMMERMAN, UNIVERSITY OF WISCONSIN

Mr. ZIMMERMAN. I am David Zimmerman, from the University of Wisconsin Center for Health Systems Research and Analysis. I think the issue of the relationship between psychotropic drug use, and for that matter physical restraints and resource use, has been one, unfortunately, that has been the subject of a lot of convoluted thinking, and not very good empirical work.

Many people have said that one of the problems is that if we reduce our use of psychotropic drugs or physical restraints that we are going to see an increase in RN time, in nurse's aide time, etc. In fact, there will be an article coming rather shortly that shows with respect to physical restraint use, quite the opposite is true, across many data bases.

In fact, I think of the four or five data bases on which some analysis was done, the authors have found that only in one case was there an increase in use, and in the other cases there was in fact decreased use with the removal of physical restraints.

Some of our work in the area of resource use and psychotropic drugs, analyzing data from Texas, suggests that there is really not any major effect one way or the other in terms of resource use, when you reduce the use of psychotropic drugs. In that regard, I think there is going to be a golden opportunity in the next 3 or 4 years to do some work in this area from another product of OBRA, which is the implementation on a universal basis of the minimum data set.

We are putting together a set of quality indicators now for four States that are participating in a case mix demonstration. But all States will have—I suspect in 2 or 3 years—available data from that data set, on all nursing home residents. One of the things I think can be done with this information, not only do you have wonderful information on the use of psychotropic drugs, in particular antipsychotic medications, but you also have information that can be used to serve as predictors of psychotropic drug use, antipsychotics in particular.

And you also have information that, short of hospital admissions, etc., can be used to take a look at outcomes that might result from this use. So I think that this information can be used in a regulatory context, which is what we have been talking about this afternoon.

But it also can be used in an internal quality assurance context, by some of these same nursing homes, whether or not they be franchises or whatever the word is that you use, to develop internal quality assurance systems.

So I think we will learn a lot more about that issue, as well as some of the other outcomes, in the next couple of years.

Mr. SHERMAN. Thank you very much for your input, David.
Ted.

STATEMENT OF TED COLLINS, UNIVERSITY OF WISCONSIN

Mr. COLLINS. I'm Ted Collins, I'm also from the Center for Health Systems Research at the University of Wisconsin. You mentioned earlier this morning the study done by Wayne Ray in which he has shown that the use of antipsychotics, and for that matter, most psychotropics, nearly all psychotropics, cause an increase in the incidence of hip fractures. So certainly there is a potential for reduction in that sort of thing.

I think as it relates to reductions in Medicaid payments for drugs, I think the savings is going to be somewhat modest, partly because most of the antipsychotics are now available generically, and the cost to Medicaid is nowhere near what it used to be. But certainly there is some potential there.

Mr. SHERMAN. Thank you, Ted. I think the important point that most of us make is that the cost, the moneys that are to be saved are not from the drugs themselves, but from the drug-induced illness that results, the indirect costs of the drug. I agree that it is an area that is worthy of more exploration of well-designed work, and I look forward to the project you were just describing, David.

Any other questions? Yes, sir?

STATEMENT OF STEVE BALL, MARYLAND DISABILITY LOSS CENTER

Mr. BALL. I'm Steve Ball, Maryland Disability Loss Center, Baltimore. Dr. Rovner, I was interested in the study you cited, the 1988 Study in Baltimore, with the nursing homes. Would that be available? Is that published in a journal?

Dr. ROVNER. It's published in a journal. I can give you a reference.

Mr. BALL. Thanks, I would appreciate that.

Mr. SHERMAN. Any other questions? Please feel free.
Yes, ma'am?

STATEMENT OF MARY LUCERO, GERIATRIC RESOURCES

Ms. LUCERO. My name is Mary Lucero, and I have a company called Geriatric Resources that develops sensory stimulation products for dementia people. I was very interested in Dr. Rovner's study. But what I wanted to mention, which I have not heard much about today, was remembering—well, after Dr. Rovner shared with

us about who the people are who are the prime targets for antipsychotic drugs, and what are the behaviors staff are perceiving as necessary to control, he identified that as uncooperativeness.

I think we also need to be really careful that we remember what else OBRA tells us, and that is that people, no matter what their mental status, have the right to refuse treatment. That means that someone who is cognitively impaired, even severely, who chooses not to go willingly to a bath, it tell us that we do not have the right to force that, and to ask for an antipsychotic medication to enable that.

That means that we need to take a really hard look at our caregiving practices and priorities, especially when we are looking at cognitively impaired people, and to remember and maybe update our perceptions, that these people are terminally ill people. They have fatal, irreversible illnesses. And to look at what is our long-term goal in caregiving to them, which is palliative care, which means comfort, dignity, supporting remaining capabilities, and compensating for losses.

When we are looking at uncooperativeness and resisting we also need to remember that that is part of the dementing process, those behaviors, as Dr. Rovner shared with us, about the language problems that occur, we really need to take a hard look.

Mr. Price talked about educating nursing assistants. I also think we need to maybe look at educating nursing home administrators as well as people who are in power, directors of nurses and so on. Maybe we need to change practices. Who made us boss and said that someone has to have a bath three times a week, and that someone has to sleep in their pajamas, if they are severely impaired and they don't understand?

I think we also are charged with looking at what our priorities are with demented people, and looking at the care practices we have put in place, using an acute care model.

Mr. SHERMAN. Thank you.

Dr. ROVNER. I certainly support many of the sentiments you expressed. One issue about the antipsychotic drugs and the ability to refuse or not refuse those medications is an important issue. Many facilities are now requiring that a patient or guardian sign an informed consent document if such a drug is to be used. The benefit of that is, of course, that somebody makes a knowledgeable decision about whether this medicine is appropriate or not. It also weighs against the side effects, namely tardive dyskinesia, which is a long-term complication of the drug.

So as with other medical procedures, it makes perfect sense to have a patient and/or family member comment on the appropriateness of the medication, whether it is desirable or not. Most of the patients for whom these drugs are used are incompetent, they cannot make these decisions on their own. That does not mean somebody should not make them for them, either through previous indications, or through family, legal guardians, and that sort of thing.

Mr. SHERMAN. One of the best quotes I have heard that sums that feeling is from the late Supreme Court Justice Louis Brandeis. He once said that "one of our most cherished rights is the right to be left alone."

I would like to introduce Holly Bode, a member of the professional staff of the Senate Committee on Aging, who will provide closing remarks today.

Thank you very much for your kind attention today.

**STATEMENT OF HOLLY BODE, PROFESSIONAL STAFF, SENATE
SPECIAL COMMITTEE ON AGING**

Ms. BODE. My closing remarks will be extremely brief, and consist mostly of my thanking everyone for coming today. I want to mention to you that we will have a printed record of this event today. It should be available within the next couple of months. I encourage you to contact us and let people in your communities know it will be available.

I again want to thank everyone for coming today. I was very pleased with the turnout today, and with all of our speakers. I thank all of them for coming, some of them from very long distances. Thank you. [Applause.]

[Whereupon, at 2:58 p.m., the forum was adjourned.]

APPENDIX

Item 1

PUBLIC LAW 100-203—DEC. 22, 1987

101 STAT. 1330-165

“(C) maintain clinical records on all residents, which records include the plans of care (described in paragraph (2)) and the residents’ assessments (described in paragraph (3)).

“(7) REQUIRED SOCIAL SERVICES.—In the case of a skilled nursing facility with more than 120 beds, the facility must have at least one social worker (with at least a bachelor’s degree in social work or similar professional qualifications) employed full-time to provide or assure the provision of social services.

“(c) REQUIREMENTS RELATING TO RESIDENTS’ RIGHTS.—

“(1) GENERAL RIGHTS.—

“(A) SPECIFIED RIGHTS.—A skilled nursing facility must protect and promote the rights of each resident, including each of the following rights:

“(i) FREE CHOICE.—The right to choose a personal attending physician, to be fully informed in advance about care and treatment, to be fully informed in advance of any changes in care or treatment that may affect the resident’s well-being, and (except with respect to a resident adjudged incompetent) to participate in planning care and treatment or changes in care and treatment.

“(ii) FREE FROM RESTRAINTS.—The right to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident’s medical symptoms. Restraints may only be imposed—

“(I) to ensure the physical safety of the resident or other residents, and

“(II) only upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used (except in emergency circumstances specified by the Secretary) until such an order could reasonably be obtained.

“(iii) PRIVACY.—The right to privacy with regard to accommodations, medical treatment, written and telephonic communications, visits, and meetings of family and of resident groups.

“(iv) CONFIDENTIALITY.—The right to confidentiality of personal and clinical records.

“(v) ACCOMMODATION OF NEEDS.—The right—

“(I) to reside and receive services with reasonable accommodations of individual needs and preferences, except where the health or safety of the individual or other residents would be endangered, and

“(II) to receive notice before the room or roommate of the resident in the facility is changed.

“(vi) GRIEVANCES.—The right to voice grievances

Original Contributions

Evaluation of Neuroleptic Drug Use by Nursing Home Elderly Under Proposed Medicare and Medicaid Regulations

Judith Garrard, PhD; Lukas Makris; Trudy Dunham, MS; Leonard L. Heston, MD; Susan Cooper, MS; Edward R. Ratner, MD; Daniel Zeltzman, PhD; Robert L. Kane, MD

Federal regulations for use of neuroleptic drugs in Medicare- and Medicaid-certified nursing homes throughout the United States were implemented October 1, 1990. These regulations constitute the first time that prescription drugs are required, by law, to be justified by indications documented in the medical chart. This study used extant data to estimate ineligible neuroleptic use at the individual and nursing home levels had these regulations been in effect in 1976 through 1985. Subjects, randomly sampled admissions (N=5752) and residents (N=3191), were followed up for up to 24 months in 60 nursing homes. One half of neuroleptic use in each cohort could be considered ineligible under the regulations; all but one of the nursing homes had one or more individuals who were treated with the ineligible use of neuroleptics. Improvements in documentation and/or prescription of neuroleptic drugs for nursing home elderly will be needed to ensure compliance with these new regulations.

(JAMA. 1991;265:463-467)

CONCERN has been raised by the public (*New York Times*, March 13, 1989:1), legislative bodies,¹ and the scientific community² about possible misuse of

From the Division of Health Services Research and Policy, School of Public Health (Dr Garrard and Kane), the Department of Applied Statistics, School of Statistics (Dr Makris), the Department of Educational Psychology, College of Education (Ms Dunham), the Department of Pharmacy Practice, College of Pharmacy, and the Department of Clinical Pharmacy, St Paul-Ramsey Medical Center, St Paul, Minn (Mr Cooper), the Abbott Northwestern Hospital, Minneapolis, Minn (Dr Ratner), and the Division of Biostatistics, School of Public Health (Dr Zeltzman), University of Minnesota, Minneapolis; and The Washington Institute for Mental Illness Training and Research, University of Washington, Seattle (Dr Heston).

Dr Makris is now affiliated with Merck Sharp & Dohme Research Laboratories, West Point, Pa.

The statements contained in this report are solely those of the authors and do not necessarily reflect the views or policies of the Health Care Financing Administration. The authors assume responsibility for the accuracy and completeness of the information contained in this report.

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drugs in nursing homes. Neuroleptic drugs in particular have been identified as being potentially overused, exposing nursing home residents to the undue risks of adverse reactions.³ Federal legislation that requires regulation of neuroleptic drug use in Medicare- and Med-

icaid-certified nursing homes was passed in 1987 as part of the Omnibus Budget Reconciliation Act. The Health Care Financing Administration (HCFA) has developed guidelines, to be implemented on a nationwide basis that began October 1, 1990, to guide surveyors in evaluating nursing homes.⁴ The HCFA guidelines include a section on antipsychotic drug use that consists of four components: (1) documentation of a specific condition, including psychiatric diagnoses that warrant neuroleptic use; (2) prohibition of neuroleptics if certain behaviors are the only justification; (3) prohibition of neuroleptic use on an as-needed basis; and (4) gradual dose reductions coupled with attempts at behavioral programming, including environmental modification. There is also a more general section on unnecessary drugs (not limited to neuroleptics) defined as those that are given in excessive doses, for excessive periods of time, either without adequate monitoring, or without a diagnosis or behavioral justification. If the HCFA surveyor determines that one nursing home resident who is receiving neuroleptic drugs is found in violation of either section, the HCFA guidelines stipulate that a negative finding can be recorded for the nursing home. Multiple incidences of negative findings could result in the issuance of a citation to the nursing home for violation of HCFA rules.

Neuroleptic drug use in nursing homes has been examined in a limited number of studies,⁵⁻⁸ but none have used these HCFA guidelines as criteria for judging inappropriateness or included estimates of neuroleptic use across multiple time points over the duration of a nursing home stay. Residents who have lived in the facilities have been the subjects of these studies, and they are also the group that a survey team evaluates in reviewing nursing homes for compliance with HCFA regulations. An understanding of how problems develop, however, depends on a longitudinal assessment of an admissions cohort, a subject group not used in previous research.

For editorial comment see p 502.

icaid-certified nursing homes was passed in 1987 as part of the Omnibus Budget Reconciliation Act. The Health Care Financing Administration (HCFA) has developed guidelines, to be implemented on a nationwide basis that began October 1, 1990, to guide surveyors in evaluating nursing homes.⁴

The HCFA guidelines include a section on antipsychotic drug use that consists of four components: (1) documentation of a specific condition, including psychiatric diagnoses that warrant neu-

The purpose of this study was to apply the HCFA guidelines to an existing set of data about medication use in nursing homes to estimate the potential impact of the new regulations.

SUBJECTS AND METHODS

Subjects

The data were collected in a previous study, and the methods used have been described in detail elsewhere.¹² Briefly, patient records in 60 nursing homes located in eight western states were abstracted on the basis of a standardized record review form by nurse abstractors who were not affiliated with the nursing homes. The nursing home records included physicians' and nurses' notes, medication records, logs or passbooks, business office forms, and hospital discharge summaries for patients who were admitted or returned to the nursing home.

Thirty study nursing homes were selected as a convenience sample of 102 Medicare- and Medicaid-certified skilled nursing and intermediate care facilities that participated in the Mountain States Health Corporation program¹³ to train geriatric nurse practitioners (GNPs). The nursing homes were recruited as matched pairs that consisted of a study nursing home and a control nursing home. A control nursing home (without GNPs) was matched to each study nursing home on the basis of number of beds, type of ownership, affiliation, and rural/urban location. No nursing home was a facility for the mentally ill or mentally retarded. Information about staffing levels within the nursing home, physicians' characteristics, or prescribing patterns was not collected as part of the original study. Preliminary analyses showed no differences between GNP and non-GNP facilities in psychotropic drug use by subjects in this study.

Within each nursing home, separate random samples were drawn of admissions ($N=5752$) and residents ($N=3191$). Subject selection was limited to individuals whose length of stay was 6 weeks or more; there was no restriction by age, source of admission, or source of payment. For purposes of the present study, only data from individuals who were 65 years of age or older were analyzed.

An admission was defined as any individual who was admitted to the nursing home during a 12-month enrollment period. This definition included individuals who had not previously lived in a nursing home, as well as readmissions from this or other nursing homes. Only the individual's first admission during the study period was considered. No

subject was used more than once, and there was no subject replacement on discharge within either cohort. To generate a sufficient sample size from each nursing home, three random samples of admissions were drawn from each nursing home, one for each of 3 years. A nonproportionate, simple random sampling design was used, and the sampling frame consisted of all admissions over each 12-month period who met the subject criteria.

A resident was defined as any individual who lived in the nursing home on the first day of the study period. Similar to the sampling of admissions, three random samples of residents were drawn within each nursing home. The sampling frame for each of these 3 years consisted of all residents who met the subject criteria and were living in the nursing home on a given day.

The start of the 3-year study period varied between 1976 through 1983 across these 60 facilities. Subjects were observed (in the records) from admission to the nursing home (admissions cohort) or the beginning of the study period (residents cohort) until either discharge or the end of the study, whichever occurred first. Follow-up varied from 6 weeks to 24 months for admissions depending on enrollment date and either 12 months (subjects sampled in years 1 and 3) or 24 months (those subjects sampled in year 2) for residents. Discharge was due to death, discharge alive to community, transfer to another facility, or hospitalization with no return to the nursing home.

Up to 12 current diagnoses were abstracted from the medical record on admission or the beginning of the study and at discharge or the end of the study. Each diagnosis was assigned the first three digits of its corresponding *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code*,¹⁴ and all diagnoses were included in the analysis. Mental status (alert and oriented, occasionally confused, usually confused, and comatose) and behavior (no problems, occasionally disruptive, usually disruptive, and comatose) were rated by the nurse abstractor based on information in the nursing home record that was recorded during the same 2-week periods that neuroleptic drug use was assessed. Information about sex and marital status had been inadvertently omitted from the data form in the original study.

Neuroleptic Drugs

Information about neuroleptic use was obtained from the nursing home chart, including the medication record, which is the same source used by HCFA

surveyors in establishing compliance with the documentation part of the regulations. The nurse abstractor recorded a maximum of 10 drugs used throughout each of two 2-week periods: at admission (admissions) or beginning of the study (residents) and the first 2 weeks of the month prior to either discharge or the end of the study. The three neuroleptic agents most commonly used in nursing homes were recorded in standard dose equivalents¹⁵ and treated as a single variable: 25 mg of thioridazine equals 25 mg of chlorpromazine equals 0.5 mg of haloperidol. Because the emphasis in the original study was on dosage levels rather than type of use, scheduled and as-needed use were not differentiated in the coding.

Based on the antipsychotic drugs section of the HCFA guidelines,¹⁴ we defined antipsychotic or neuroleptic drug use as "ineligible" if used without a documented diagnosis of psychotic mood disorder (*ICD-9-CM codes 296 and 298*), schizophrenia (*ICD-9-CM code 295*), and Tourette's syndrome or other conditions (*ICD-9-CM code 307*). The HCFA guidelines specify that organic mental syndrome (OMS), including dementia (*ICD-9-CM codes 290 to 294, 310, and 331*), must be accompanied by documentation of associated psychotic and/or agitated features to justify use of neuroleptics. We used the nurse abstractor's assessments of mental status (usually or occasionally confused), behavior problems (usually or occasionally disruptive), or both as surrogate measures.

Statistical Methods

Descriptive data are presented in the form of a tree diagram. Multiple linear regression analysis was used to model percent of neuroleptic use and, separately, percent of ineligible use at the nursing home level. Logistic regression was used to model ineligible neuroleptic use at the individual level; χ^2 tests were used with categorical variables, including the Yates' correction when $d.f.=1$. A $P<.05$ level was used for statistical significance.

RESULTS

Cohort Characteristics

Admissions had a mean age of 83.3 years (SD, 7.8 years), 99% were white, 28% were Medicaid recipients on admission, and 60% entered from the hospital and 21% from the community. By the end of the study, 19% had died, 15% were discharged to the community, 7% were discharged to the hospital with no further information, and 59% remained alive in the nursing home. Residents had a mean age of 85.4 years (SD, 8.1

years), 99% were white, and by the end of the study, 28% had died, 4% were discharged to the community, 6% had been transferred to the hospital, and 62% remained alive in the nursing home.

Organic mental syndrome, including dementia, was recorded for 21% of the admissions and 26% of the residents; other HCFA-eligible diagnoses were recorded for about 13% within both groups. Of those individuals who had OMS, 80% to 85% of both groups had confused mental status, behavior problems, or both. Of those without OMS, approximately 27% had confused mental status problems only, 5% had behavior problems only, and 24% had both types of problems.

Use of Neuroleptic Drugs

Within each cohort, the same proportion of people who were taking neuroleptic drugs was found at the beginning and ending points of the study; however, these were *not* the same individuals. On admission to the nursing home, 17% (N = 996) of the individuals were taking neuroleptics. By discharge or the end of the study, one third (N = 345) of these individuals who were taking neuroleptics had discontinued use; however, approximately the same number (N = 349) of individuals who were not taking neuroleptic drugs at admission had initiated such use at the end point. Of the 3191 residents, 21% (N = 657) were taking a neuroleptic drug at the time of initial evaluation. By the end of follow-up, half of the 657 individuals who were taking neuroleptics had discontinued use, but an additional 326 residents had initiated neuroleptic use.

Neuroleptic use did not differ by either source of admission (community vs hospital) or payment source (Medicaid vs private pay) for the admissions cohort. The rate of those individuals who were taking neuroleptic drugs among those who entered the nursing home from the hospital was 16%; from the community, 18%; and from another nursing home, 21%. By source of payment, 18% of the Medicaid recipients (N = 1580) were taking neuroleptics, compared with 18% of those individuals who paid privately (N = 2829) and 14% of the Medicare recipients (N = 1322). Neuroleptic use declined with age, a finding more pronounced for residents than admissions. Thirty-one percent of residents aged 65 to 74 years were taking these drugs, as were 23% of those aged 75 to 84 years and 17% of those aged 85 years or older; the corresponding rates for admissions were 20%, 20%, and 14%, respectively.

Physical restraints were applied to

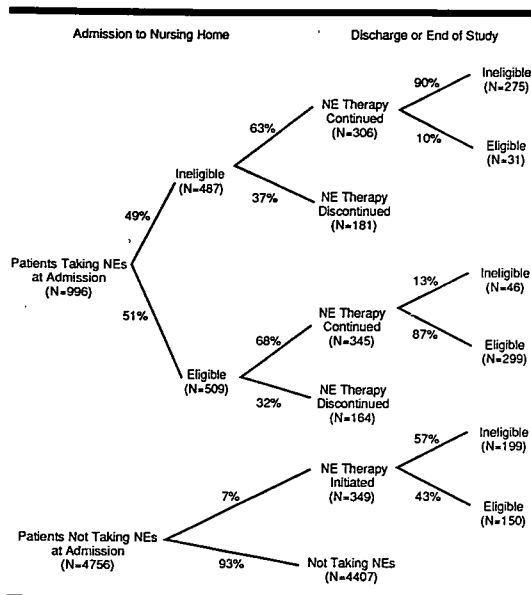


Fig 1.—Eligible and ineligible use of neuroleptic (NE) therapy by 5752 patients at admission to nursing homes and at discharge or the end of the study.

55% of the residents who were taking neuroleptics at the initial evaluation compared with 39% of all residents. Rates were similar for admissions during their first 2 weeks in the nursing home: 60% of the individuals who were taking neuroleptics were restrained vs 39% of the total cohort. The duration and extent of restraint use during the 2-week period of assessment were not clear from the data available.

Ineligible Use of Neuroleptics

In each cohort, half of the neuroleptic use would not have met the HCFA criteria as defined in this study. As shown in Fig 1, ineligible neuroleptic use by the admissions cohort was 49% of the 996 individuals who were taking neuroleptics at admission and 52% of the 1000 individuals who were taking neuroleptics at discharge or the end of the study. Among those who were receiving ineligible neuroleptic therapy at admission who were still receiving neuroleptics at

the end of the study, only 10% had documentation that made such use HCFA-eligible. Neuroleptic use initiated after admission was associated with a 57% rate of ineligibility.

Findings were similar within the residents cohort: 46% were ineligible at initial evaluation and 53% at discharge or the end of the study. By discharge or the end of the study, only 11% of the individuals who were initially ineligible for neuroleptic therapy had become eligible.

In subsequent analyses of alternative explanations for these rates, ineligible use of neuroleptic therapy within the admissions cohort could not be explained by the treatment of developmentally disabled persons who had behavior problems,^{11a} by the presence of OMS without documentation of mental or behavioral problems, by study characteristics such as GNP effect, by missing data, or by variations by calendar year in which the data were collected.

Predictive Probabilities of Ineligible Neuroleptic Use Based on Characteristics of 996 Individuals Who Were in the Admissions Cohort*

Age, y	Presence of Other Mental Disorders	Source of Admission		
		Nursing Home (SE)	Community (SE)	Hospital (SE)
65-74	No	.31 (.04)	.31 (.04)	.39 (.03)
	Yes	.49 (.05)	.49 (.05)	.58 (.04)
75-84	No	.36 (.03)	.37 (.03)	.44 (.02)
	Yes	.55 (.04)	.56 (.04)	.63 (.03)
≥85	No	.43 (.04)	.44 (.04)	.53 (.03)
	Yes	.62 (.05)	.63 (.05)	.70 (.04)

*Individuals who were taking neuroleptics at nursing home admission.
 †Other mental disorders and corresponding International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes included neurotic disorders, code 300; alcohol and/or other drug abuse or dependence, codes 303 to 305; depression, not psychosis, code 311; brain cancer, codes 225 and 239; encephalitis, code 323; strokes and cerebral vascular diagnoses, codes 434 to 437; and other syndromes, including parkinsonism, epilepsy, and Huntington's chorea, codes 326, 332, and 333.

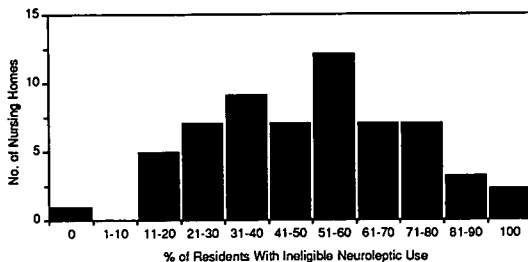


Fig 2.—Distribution of the percentage of residents who were ineligible for neuroleptic therapy across 60 nursing homes.

Residents' ineligible use of neuroleptics could also not be explained by these factors, with the exception that the data generated in 1977 through 1978 show a higher rate of ineligible use (70% to 80%) than in later years (50%).

Characteristics of Ineligible Users

Five individual characteristics were considered in modeling eligible and ineligible neuroleptic use by admissions on entrance to the nursing home: (1) presence or absence of other mental disorders, (2) source of admission, (3) age, (4) source of payment, and (5) number (0 through 6) of activities of daily living dependencies. Other mental disorders, listed in the Table, were identified by our study team as possible explanatory conditions for neuroleptic use, although such use is not necessarily recommended, nor were these conditions included in the HCFA guidelines. The six activities of daily living were ambulation, transferring, feeding, toileting of

urine and feces, and dressing.

The first three of the five predictor variables were found to be statistically associated with ineligible use; none of the interactions were statistically significant. The β coefficients, their SEs, and the odds ratios (ORs) for the three predictor variables were as follows: presence of other mental disorders ($\beta = 0.75$, SE = 0.14, OR = 2.12); source of admission coded as two dummy variables with "other nursing home" as the comparison variable: community ($\beta = 0.03$, SE = 0.20, OR = 1.03) and hospital ($\beta = 0.34$, SE = 0.17, OR = 1.40); age used as a continuous variable ($\beta = 0.02$, SE = 0.009, OR = 1.02); and the constant ($\beta = -2.48$, SE = 0.73).

To maximize the use of these findings, the results are summarized in the Table as predictive probabilities based on the β coefficients. For example, there is a 70% probability that use of neuroleptics will not meet the HCFA guidelines, as

defined in this study, if the individual is aged 85 years or older, has one or more of the other mental disorders, and was admitted from the hospital; whereas, the probability is 31% if the individual who takes a neuroleptic drug is aged 65 to 74 years, does not have one of the other mental disorders, and entered the nursing home from the community.

Nursing Home Rates

At the nursing home level, use of neuroleptics varied from 2% to 35% within each cohort, and ineligible use varied from 0% to 100%. As shown in Fig 2, only one of the 60 nursing homes had no ineligible use by residents. Based on regression analyses, none of the nursing home characteristics (number of beds, ownership, affiliation, or rural or urban location) predicted either the overall rate of neuroleptic use or that of ineligible use within either cohort.

COMMENT

The 21% rate of neuroleptic use by residents in this study is comparable with that found in other studies.^{8,11} Higher rates, 39% to 44%, have been reported in previous research, which included individuals who were living in rest homes,⁸ many of whom were former psychiatric patients and therefore likely to have greater use of neuroleptics, and studies¹¹ based on Medicaid claims files in which all neuroleptic use over a 1-year period was assessed. Considering the amount of discontinuation and initiation of neuroleptics found in our study, such rates over an extended period would be expected to be higher. Furthermore, data from claims files tend to overestimate actual use.⁸ Alternatively, our estimates may be lower because we included only three of the 15 or more neuroleptic agents on the market, although these three agents accounted for 78% of all neuroleptic use in a nationwide survey of nursing homes.⁸

Approximately one half of admissions and residents did not have documentation of a diagnosis or specific condition to support neuroleptic use based on the HCFA guidelines. Characteristics of individuals who took neuroleptics associated with ineligible use included the presence of one of the other mental disorders not included in the HCFA guidelines, advanced age, and admission to the nursing home from the hospital. Virtually all nursing homes had at least one individual who was considered ineligible for neuroleptic use, which could result in a negative finding under the HCFA guidelines.

These results are even more disturbing when we consider that rates of ineligible neuroleptic use in this study may

underestimate those that currently exist throughout the country for several reasons: our criteria for defining ineligible neuroleptic use were a subset of those in the guidelines; we were not able to examine as-needed use; our measures of mental status and behavior problems are probably more lenient than the HCFA's requirement of "psychotic and/or agitated features"; and the nursing homes in this study were probably above average because they were willing to participate in a study that required complete access to all records.

The high rate of ineligible use of neuroleptics can be attributed to either poor documentation or inappropriate clinical use of the drug. Since the data in this and other published studies¹⁸ depend on some form of record review, it is not possible for us, the previous researchers, or HCFA-affiliated surveyors to determine which of these reasons, alone or in combination, best explains the evidence (hence our choice of the term *ineligible* rather than *inappropriate*). In implementing these regulations, however, HCFA surveyors will have the advantage of being able to augment record information through interviews with patients and staff, although the requirement regarding documentation will nonetheless require reliance on nursing home records.

The strengths of this study include sufficiently large numbers of subjects and nursing homes, data that are based on actual use rather than prescription

orders or claims files, assessment of mental and behavioral status in the same time periods as drug use, and follow-up data of an admissions as well as a residents cohort.

If the results are attributable solely to poor documentation in nursing home records, better record keeping will not guarantee a concomitant improvement in quality of care. However, until the reason for the use of the drug and its effects on each individual have been recorded, there will be no systematic way to determine whether the medication was clinically justified.

Alternatively, we might speculate that compliance with the requirement for documentation could result in possibly negative outcomes for patients, such as substitution of other less specifically regulated psychoactive drugs, eg, benzodiazepines; increased staff time and effort spent on improvement of documentation at the expense of direct patient care activities; compliance with regulations by recording OMS, which might discourage complete diagnostic assessments; increased use of physical restraints to control disruptive behavior; and a shift from an as-needed use to regular use of the same medication.

The legislative intent of the nursing home provision of the 1987 Omnibus Budget Reconciliation Act was to improve the quality of care in nursing homes, and the HCFA guidelines constitute a regulatory vehicle for accomplishing that intent. If compliance with

these guidelines extends beyond simple documentation, resulting in a closer examination of why neuroleptic drugs are being used, the spirit of the law, as well as the letter of the law, may very well be accomplished. Ideally, only the patients who need these medications will receive them at the lowest effective dosage levels and with ongoing monitoring. Such efforts should result in a reduced likelihood of adverse risks,¹ such as tardive dyskinesia, reduced confusion, and possibly the ability to function with less risk to physical safety.¹⁹

The HCFA guidelines on antipsychotic, ie, neuroleptic, drugs constitute an unprecedented regulatory approach to the management of drug use by nursing home elderly. In spite of the fact that the data available for this study were gathered prior to implementation of the regulations, the results of this study suggest that justification of the use of these prescription drugs by the physician and at the facility level will constitute a major endeavor if current practices in long-term care facilities are similar to those in the recent past.

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Item 3

Matrix of Problematic Behaviors and Alternatives to Restraint Use*

Types of Alternatives	Problematic Behaviors		
	Fall Risk	Treatment Interference	Disruptive Behavior
Physiologic	Positioning Evaluate drugs Regular toileting	Comfort Pain relief Regular toileting Change in treatment (e.g. remove IV/NG tubes, catheters)	<u>Agitation/restlessness:</u> Comfort, pain relief Correction of underlying problem, eg. dehydration Positioning Toileting Sensory aids <u>Wandering:</u> Attention to toileting, massage <u>Other disturbing behavior:</u> Comfort, sensory aids, pain relief, adequate hydration
Psychosocial	Supervision Authorization of "no restraint" from resident/family	Companionship and supervision Authorization of "no restraint" from resident/family Reassurance	<u>Agitation/restlessness:</u> Companionship, therapeutic touch, active listening, provision of sense of safety and security <u>Wandering:</u> Supervision; behavioral modification; promotion of trust and sense of mastery; attention to resident's agenda. <u>Other disturbing behavior:</u> Remotivation, reality orientation; therapeutic touch, active listening; attention to feelings, concerns, social ties and need gratification; behavior modification; facilitating resident control over activities of daily living

Matrix of Problematic
Behaviors and Alternatives
to Restraint Use, cont.

Types of Alternatives	Problematic Behaviors		
	Fall Risk	Treatment Interference	Disruptive Behavior
Activities	Daily physical therapy/ambulation Gait training	Distraction Television, radio, music Something to hold	<p><u>Agitation/restlessness:</u> Distraction, planned recreation, exercise, PT/OT, social activity, outlets for arduous behavior</p> <p><u>Wandering:</u> Distraction, planned recreation, exercise, ADL training, PT/OT, social activity, nighttime activities pm, redirection toward nursing home unit</p> <p><u>Other disturbing behavior:</u> Distraction, planned recreation, exercise, ADL training, PT/OT, social activity</p>
Environmental	Chairs that slant or fit body contours Wedge cushions Low beds, or mattress on floor Mobility aids Body props Bedside table placed in front Alarm signal system Bedside commode Bedrails down Accessible call light Fall-safe environment	Locate near nursing station Accessible call light Camouflaged or padded treatment site	<p><u>Agitation/restlessness:</u> Decreased use of intercom; decreased/increased light as appropriate, quiet room or soothing background music, personalized area</p> <p><u>Wandering:</u> Camouflaged doors, exits, elevators; floor tape or planters to signal end of hall; "baffle" locks, alarm systems, velcro "doors"; contained areas that are safe and interesting; broad-based rockers and footstools; music; familiar objects; special clothing, variety of seating and furniture; controlled lighting, sound, noise reduction</p> <p><u>Other disturbing behavior:</u> Quiet room or soothing background music; personal space</p>

*Adapted from

Evans, L.K. & Strumpf, N.E., & Williams, C.C. (in press). Redefining a standard of care for frail older people: Alternatives to routine physical restraint. In R. Kane, P. Katz, & M. Mezey (eds.), *Advances in Long Term Care*, Vol 1. New York: Springer.

Item 4

SECTION 46.6 PSYCHIATRIC PROBLEMS OF THE MEDICALLY ILL GERIATRIC PATIENT 2049

46.6

**PSYCHIATRIC PROBLEMS OF THE
MEDICALLY ILL GERIATRIC PATIENT**

GARY W. SMALL, M.D.

INTRODUCTION

Medical, technological, and socioeconomic changes of the twentieth century have managed to keep more persons alive to ages unprecedented in human history. A woman born at the turn of the century expected to live an average of 49 years; a man, 47 years. By 1980, life expectancy had jumped to nearly 78 years for women and 71 years for men.

Despite these advances, those persons who survive to old age face the likelihood of physical illness. Most elderly persons suffer from one or more chronic illnesses, such as arthritis, hypertension, hearing impairment, and heart disease, which also disable 1 out of 5 people age 65 or older. For those between 75 and 84 years of age, 1 in 10 requires assistance in such activities of daily living as walking, bathing, dressing, using the toilet, transferring from the bed to a chair, eating, or going outdoors. In the 85-plus age group, the number of people requiring basic assistance is 1 in 3. These

chronic conditions lead to more frequent visits to the physician and to a greater number of days in the hospital. Persons between 65 and 74 years of age average 6.3 doctor visits per year, compared with 4.5 for the 45-through-54 age group.

Psychiatric illness, too, is common in the elderly. An estimated 10 to 15 percent of people age 65 and older suffer from anxious and depressive symptoms; at least another 5 percent are cognitively impaired; and it is conservatively estimated that an additional 5 percent are afflicted with personality and other psychiatric disorders. The precise frequency of concomitant physical and psychiatric illness in the elderly is unknown, but estimates of the prevalence of psychiatric disorders in elderly medical and surgical inpatients range from 40 to 50 percent.

Fewer psychiatric consultations are requested for geriatric inpatients than for younger ones. Medicare coverage for outpatient geropsychiatric care has only recently increased from the \$250 annual limit that was set at the program's inception. Not long ago, cognitive decline in the aged was considered normal senility and not a disease process. Though attitudes and socioeconomic incentives may improve, ageism seems to persist in society, further complicating the delivery of optimal care.

The assessment and treatment of psychiatric illness in the medically ill elderly is, thus, a common and a complex clinical task. These patients rarely fit into neat, diagnostic categories, with the classic symptom clusters one seeks in making Axis I diagnoses based on the revised third edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R)*. Rather, the clinician is faced with multiple, overlapping problems and is forced to infer causal relationships from associational ones. Is the patient depressed because of the illness, or is the illness causing the depression? Or are both phenomena at work? These kinds of questions are further muddled by subtle drug-disease and drug-drug interactions, pharmacokinetic changes associated with aging, and possible ageist attitudes among caregivers. Despite these roadblocks, the psychiatric problems of medically ill geriatric patients can be sorted out and treated. A systematic approach that takes into consideration each potential obstacle is the suggested strategy.

**MEDICAL ILLNESS THAT PRESENTS AS
PSYCHOPATHOLOGY**

Significant mental symptoms in any patient generally warrant a diagnostic evaluation aimed at identifying underlying physical causes. The cause and effect relationship is not always absolute; it is often inferred and tested retrospectively by treatment of the physical disorder. If the mental symptoms improve, the causal relationship is presumed. Many psychiatric disorders remain diagnoses of exclusion.

Studies performed on psychiatric patients of all ages in a variety of settings routinely identify unrecognized physical illnesses. One prospective study of 100 psychiatric inpatients found that 46 percent had a psychiatric illness associated with a physical illness, even though these patients were screened before admission to rule out physical illnesses. Other studies of psychiatric patients have found frequencies ranging from 10 to 30 percent in both inpatient and outpatient settings. Similar studies on elderly patients have focused on specific psychiatric syndromes, particularly dementia and depression. These findings, too, are based on relatively small samples; large-scale epidemiological data are unavailable.

DEMENTIA SYNDROME Dementia, which afflicts an estimated 5 percent of people age 65 years and older, is characterized by global deterioration of intellect, cognition, behavior, and emotion. Surveys performed on patients with cognitive impairment that suggests a dementia syndrome generally identify from 10 to 30 percent as suffering from some secondary illness that may be impairing cognition. Half of these patients have depression; the other half suffer from a variety of physical conditions, such as thyroid disease or drug toxicity. Although investigators are searching for a positive diagnostic marker for Alzheimer's disease, to date the clinical diagnosis of the illness remains one of exclusion. Concurrent medical illness or depression can worsen cognitive function and exacerbate symptoms of primary degenerative dementia of the Alzheimer type.

DELIRIUM From 10 to 40 percent of hospitalized elderly patients develop delirium, defined as clouding of consciousness (reduced clarity of awareness of the environment), perceptual disturbance, incoherent speech, impaired sleep-wake cycle, psychomotor disturbance, memory impairment, disorientation, and relatively acute onset (hours to days), with fluctuation of symptoms over the course of the day. Although DSM-III-R specifies the need for evidence of a specific organic factor judged to be etiologically related to the disturbance, some surveys indicate that a specific cause is never discovered in up to 20 percent of cases. Many medical illnesses can cause delirium, but medications may be the most important cause in elderly patients, given the brain sensitivity to drug effects and the altered pharmacokinetics associated with aging. Many drugs that cause dementia may also cause delirium. Once delirium is diagnosed, it is imperative to search for a cause, to avoid further mental incapacity and possibly death.

MOOD DISORDERS Physical illnesses that cause delirium or dementia may also create a depression syndrome or secondary depression. DSM-III-R defines the term "organic mood syndrome" as "a prominent and persistent depressed, elevated, or expansive mood, resembling either a manic episode or a major depressive episode, that is due to a specific organic factor." The exact frequency of secondary depression is unknown; commonly cited causes include drugs, endocrine disorders, and structural brain lesions. Antihypertensive agents and central nervous system (CNS) depressant medications are frequently implicated. Disorders of the thyroid and parathyroid glands may present as a depressive syndrome, and carcinoma of the pancreas is an often cited example of a malignancy that causes depression. Space-occupying supratentorial lesions have also been reported as causes of depression, as has cerebral infarction, particularly of the left hemisphere. Depressed geriatric patients often emphasize somatic and cognitive complaints, which may obscure the diagnosis.

OTHER PSYCHIATRIC CONDITIONS Physical illness may mimic nearly any psychiatric syndrome. Such drugs as caffeine and amphetamines can cause panic disorders and other states of anxiety. Brain tumors, Alzheimer's disease, Cushing's disease, and multiple sclerosis each have the capacity to cause organic personality syndromes. Intracranial conditions specific for local cerebral regions may produce characteristic personality profiles (e.g., lesions of the orbital surface of the frontal lobes have been associated with poor impulse control, bizarre social behavior, and angry outbursts). By

contrast, lesions of the prefrontal convexities may produce apathy and psychomotor retardation. A variety of physical illnesses and drugs, particularly alcohol, may result in organic delusional syndrome or organic hallucinosis.

PSYCHIATRIC SYMPTOMS IN PATIENTS WITH PHYSICAL DISEASES

In recent years, investigators have studied the frequency of psychiatric illness in medically ill patients; the frequencies vary among studies, depending on numerous variables, including specific diagnostic criteria. Because of the difficulty of carrying out large epidemiological studies, estimates are made instead from smaller samples derived from patients receiving psychiatric consultation. Among medically ill geriatric inpatients receiving psychiatric consultation, the most frequent general diagnostic categories are organic mental disorder (37 to 54 percent), mood disorder (19 to 38 percent), and adjustment disorder (9 to 22 percent). The high frequency of organic mental disorder is thought to result in low rates of diagnosis of anxiety and personality disorders in hospitalized geriatric patients.

Other studies have explored the rates of psychiatric illness (usually depression) in elderly patients who attend medical clinics. Rates of depression in such settings range from 10 to 20 percent, and elderly patients with a greater number of depressive symptoms appear to visit physicians more often than less depressed patients. Depressed geriatric outpatients also have more medical diagnoses than those without depression. These findings are in line with studies of younger medical outpatients in whom, depending on the criteria, depressive symptoms are present in 12 to 36 percent. The following discussion reviews psychiatric symptoms in some physical illnesses commonly seen in geriatric patients.

CARDIOVASCULAR DISEASE One of the most prevalent physical illnesses in the elderly, cardiovascular disease, may affect a patient's mental state by a variety of pathophysiological mechanisms. Severe congestive heart failure may directly cause mental changes through inadequate cerebral blood flow and oxygenation. Secondary complications of cardiovascular disease include cerebral thromboembolic events, infection, hypertension, electrolyte and acid-base disturbances, as well as the effects of drug treatment. Patients with hypoxia associated with heart failure develop confusion, impaired concentration and judgment, psychomotor retardation, anxiety, irritability, or depression. Acute hypoxia may cause severe anxiety, agitation, or delirium. Prolonged hypoxia may result in dementia, amnesic syndrome, stupor, or coma.

Hypertensive encephalopathy is characterized by severe blood pressure elevations (diastolic >120 mmHg) associated with headache, nausea, vomiting, seizures, visual disturbances, delirium, and coma. The etiology of encephalopathic changes is unclear but may be due to microinfarcts from small-vessel damage.

Acid-base disturbances from congestive heart failure may cause such symptoms as apathy, confusion, impaired level of consciousness, and stupor. Hyponatremia may result from cardiac failure, alone or in combination with diuretic use. The acuteness and severity of the hyponatremia will determine which specific mental symptoms will result. With rapid decreases in serum sodium, the patient develops headache, nausea, vomiting, myoclonus, seizure, and coma—symptoms

that are probably related to cerebral edema. More gradual onset may result in symptoms of lethargy, weakness, confusion, and headache. Disturbances in potassium concentration, hypokalemia or hyperkalemia, may result in lethargy and confusion.

CEREBROVASCULAR DISEASE The most common form of cerebrovascular disease is stroke, defined as the sudden onset of focal, nonconvulsive neurological or behavioral deficit. Acute stroke, especially subcortical or brain stem lesions, may produce delirium, while lesions to other areas, such as the undersurface of the temporal and occipital lobes, have been reported to cause restlessness and distraction. Alterations in consciousness from acute stroke have been attributed to mass effect, metabolic disturbances, or secondary medication effects.

DSM-III-R defines multi-infarct dementia (MID) as a dementia syndrome associated with neurological deficits and incremental cognitive decline. The illness is thought to result from multiple infarctions in small vessels throughout the brain. The concept of MID, however, has not been convincingly validated, even by neuropathological studies.

Many clinicians have presumed that depression following stroke is a reaction to disability, but studies comparing orthopedic and stroke patients with comparable physical disabilities have demonstrated higher rates of depression in stroke patients, which suggests a mechanism involving direct brain injury. Approximately half of acute stroke patients develop clinically significant depression and one-fourth of that group have vegetative symptoms as well. Some studies suggest that right-hemisphere stroke results in a syndrome of irritability, loss of interest, impaired concentration, and depression. Impaired communication, impaired self-awareness, or both, may lead clinicians to overlook depression associated with right-hemisphere infarction. Most studies, however, have found more frequent and severe depression with left-hemisphere lesions. Mania, too, has been associated with stroke, particularly focal lesions in the diencephalic structures or adjacent areas.

Amnesic syndrome will result from infarction in the diencephalic and medial temporal structures of the brain. Ischemia in the medial temporal structures may also cause transient global amnesia, an inability to record ongoing information without an alteration in level of alertness. Recurrence is uncommon, although occasional patients have multiple attacks.

Other psychiatric symptoms that can result directly from stroke include delusional syndromes, hallucinations, organic personality disorders, and psychosexual disorders. In psychosexual disorders, injury to the frontal lobes may cause sexual disinhibition.

PARKINSON'S DISEASE In the United States, the prevalence of Parkinson's disease is approximately 250 per 100,000 and it usually begins after age 50. Symptoms gradually worsen as the patient ages; the early subtle symptoms of slowness, loss of agility, and tremulousness progress to the characteristic rhythmic tremor, rigidity, and accompanying disability. Dementia has been reported to occur in 20 to 90 percent of Parkinson's patients, the wide range reflecting the varying study methodologies and samples. The prevalence of severe intellectual impairment is probably closer to 30 percent. Both cortical and subcortical dementias have been described, the former possibly due to concurrent Alzheimer's and Parkinson's disease. Subcortical dementia, characterized by apathy, absence of cortical signs of aphasia, agnosia, or

apraxia, psychomotor retardation, involuntary movements, and forgetfulness with inability to learn new material, is thought to result directly from the neuropathological damage of the Parkinson's disease process.

Depressive symptoms are observed in 40 to 90 percent of patients with Parkinson's disease. Major depression has been reported in nearly one-third of patients, and depressive episodes may antedate the movement disorder. Other psychiatric symptoms associated with Parkinson's disease include psychosis and confusion.

PULMONARY DISEASE Pulmonary illnesses in geriatric patients may result in varied psychiatric symptoms. Chronic obstructive pulmonary disease (COPD), for example, may be associated with anxiety, depression, or both. Cognitive impairment has also been reported in COPD patients with hypoxemia; these changes may be reversed with supplemental oxygen.

The rate of development of hypoxia to some extent affects the intensity and form of mental symptoms. Chronic hypoxia may cause few changes; abrupt onset may result in delirium. Hypercarbia, too, causes mental confusion, particularly when onset is acute. Patients with COPD are prone to delirium from exacerbations of their illness owing to infection or other causes. Elevated $p\text{CO}_2$ in these patients causes confusion, headache, and lethargy.

Some patients develop neuropsychiatric symptoms, including delirium and dementia, due to lung carcinoma that has not metastasized, and symptoms may persist even after tumor resection. Lung carcinoma can also metastasize to the brain and cause mental changes directly. Pulmonary embolism is another condition that may cause delirium, anxiety, and other mental symptoms by directly affecting cerebral blood flow.

OTHER DISEASES Physical illness in nearly every organ system can result in psychiatric symptoms in the geriatric patient. Hepatic encephalopathy is characterized by personality changes, disturbances in consciousness, cognitive deficits, mood changes, and psychotic symptoms. Moreover, diseases of the liver and kidney impair clearance of drugs, leading to toxicity and the possibility of mental symptoms. Renal disease may also result in anemia, hyperglycemia, and electrolyte disturbance, all of which may contribute to mental symptoms. Sensory impairment, a common problem for geriatric patients, sometimes contributes to symptoms of paranoia, depression, and apparent cognitive deficits.

EFFECTS OF MEDICAL DISEASE ON DRUG ACTIONS IN ELDERLY PERSONS

Both age-related physiological changes and physical illnesses common in old age will alter drug absorption, distribution, metabolism, and excretion. Altered absorption may be the least important age-related change, though gastrointestinal (GI) edema from congestive heart failure may decrease absorption. Such changes in body composition as increased fat, decreased extracellular fluid, and lean body mass may alter the kinetics of drugs and their volume of distribution. Decline in serum albumin, the major binding protein, can increase free drug availability for pharmacokinetic action. Declines in hepatic blood flow and first-pass extraction may decrease drug metabolism, and age-related decline in glomerular filtration rate diminishes excretion. Receptor sensitivity to specific agents also may change with age.

SIDE EFFECTS OF PSYCHOTROPIC DRUGS Physical illnesses often increase the geriatric patient's sensitivity to psychotropic drug side effects. For example, patients with cardiac disease are at increased risk for heart block and anticholinergic or hypotensive effects of tricyclic antidepressants (TCAs). Patients with Parkinson's disease cannot tolerate the extrapyramidal effects of antipsychotics. Patients with impaired renal function who need lithium must have the dosage adjusted to avoid toxicity, as must some of those with neurological disease.

DRUGS THAT CAUSE PSYCHIATRIC SYMPTOMS

The many drugs used to treat geriatric physical illnesses may cause psychiatric symptoms (Table 46.6-1). Digitalis toxicity, reported in approximately 20 percent of general hospital patients, may result in arrhythmias, GI and visual effects, and confusion. Antihypertensive drugs may cause secondary depression, the worst offenders being reserpine, α -methyl dopa (Aldomet), and such β -blockers as propranolol (Inderal). A relatively new class of drugs used to treat arrhythmias and angina pectoris, calcium-channel blockers, may cause dizziness, headache, and fatigue. Other antiarrhythmics, such as lidocaine (Xylocaine) and procainamide (Pronestyl), have been reported to cause a variety of mental symptoms, ranging from confusion to mania. Cimetidine (Tagamet) and related compounds, almost routinely prescribed in general hospital settings, may also cause delirium.

DRUG-DRUG INTERACTIONS When multiple illnesses are being treated with several medications, the potential for drug-drug interactions is a serious concern. These interactions are numerous and may be within or between classes of compounds. The effects may alter absorption, distribution, protein binding, metabolism, excretion, or receptor sensitivity. Table 46.6-2 lists some examples of potential interactions from drugs commonly used in geriatric patients.

TABLE 46.6-1
Some Commonly Prescribed Drugs Reported to Cause Psychiatric Symptoms in Geriatric Patients

Antihypertensive agents	Hypoglycemic agents
Reserpine	Psychotropic agents
Methyl dopa (Aldomet)	Sedatives
Propranolol (Inderal)	Barbiturates
Clonidine (Catapres)	Meprobamate (Miltown)
Hydralazine (Apresoline)	Phenothiazines
Guanethidine (Ismelin)	Butyrophenones
Analgesics	Chloral hydrate
Narcotic	Benzodiazepines
Morphine	Others
Codine	Cimetidine (Tagamet)
Meperidine (Demerol)	Cancer chemotherapeutic agents
Pentazocine (Talwin)	Alcohol
Propoxyphene (Darvon)	Over-the-counter cold preparations
Nonnarcotic	Corticosteroids
Indomethacin (Indocin)	Estrogens
Antiparkinsonian drugs	
Levodopa (Dopar, Larodopa)	
Antimicrobials	
Sulfonamides	
Isoniazid	
Cardiovascular drugs	
Digitalis	
Diuretics	
Lidocaine (Xylocaine)	
Phenytoin (Dilantin)	

TABLE 46.6-2
Some Examples of Possible Drug-Drug Interactions in Geriatric Patients

Psychotropic Drug	Second Drug	E ^{ffect}
Tricyclic antidepressants	Anticholinergic agents	Increase anticholinergic effect
	Anticoagulants	Increase anticoagulant effect
	Class I cardiac depressants (e.g., quinidine)	Increase quinidine effect
Antipsychotic agents	Levodopa	May decrease levodopa absorption
	CNS depressants	Sedation, confusion
	Anticonvulsants	Decrease anticonvulsant effect
Lithium salts	Thiazide diuretics	Increase hypotension
	β -adrenergic blockers (e.g., propranolol)	Increase hypotension
	CNS depressants	Sedation, confusion
	Thiazide diuretics	Increase plasma lithium level
	Nonsteroidal anti-inflammatory drugs	Increase plasma lithium level
	Low-potency antipsychotics	May increase plasma lithium level

A 74-year-old hypertensive woman presented with a 6-month history of weight loss, insomnia, and tearfulness. The symptoms improved after a TCA was prescribed, and though she experienced light-headedness and syncope, adjustment of diuretic dosage reduced these side effects. She remained in remission, and her antidepressants were discontinued after a year. Two years later, however, she was admitted to the hospital with agitation, weight loss, paranoid symptoms, and confusion. A computed tomographic (CT) scan revealed multiple white-matter lucencies, and more extensive history from collateral sources uncovered a step-wise intellectual decline, as well as a relatively sudden onset of memory loss 8 months earlier. She was thought to have MID in addition to recurrent unipolar depression. An antipsychotic drug was added to her antidepressant, but it caused severe cogwheel rigidity and akinesia. Neurological consultation uncovered underlying Parkinson's disease, which responded well to carbidopa-levodopa (Sinemet).

Though the patient had continued patchy cognitive deficits, her depression and Parkinson's disease were well controlled over the following year. Eventually, however, she developed more severe confusion from the anticholinergic effects of the antidepressant, perhaps because of increased sensitivity following additional small cerebral infarcts. Future recurrent depressions were treated with electroconvulsive therapy (ECT), which also improved the Parkinson's symptoms. Maintenance ECT was used for another 6-month period but was eventually stopped because of increasing amnesic effects.

APPROACH TO PATIENTS

Given the complex interactions of diseases and drugs, as well as the numerous possible clinical presentations, a systematic, comprehensive approach to the evaluation and treatment of the medically ill geriatric patient with psychiatric symptoms is essential (Table 46.6-3). Selected laboratory tests in geropsychiatric patients yield higher rates of abnormal results than unselected tests. A missed abnormal result, however, may have greater clinical consequence than carrying out unnecessary tests.

Although familiarity with physical illnesses and drugs is crucial, the psychiatrist must also know when to turn to medical consultants for their expertise. Ongoing communication

TABLE 46-3

General Recommendations for Psychiatric Evaluation and Treatment of Medically Ill Geriatric Patients

- Evaluate patient for previously undiagnosed medical illness that may be causing psychiatric symptoms.
- Remember that most causal relationships are inferred from associational ones, taking into consideration onset, severity, and rates of change, as well as the likelihood of a given condition causing a specific symptom.
- Be sure that medical illnesses are treated properly so that medication does not cause or exacerbate psychiatric symptoms.
- Maintain ongoing communication with medical consultants, other health care personnel, family members, and caregivers.
- Obtain a detailed drug history, including over-the-counter drugs and alcohol. Have patients bring in all medications currently being used.
- Manage conditions without drugs, if possible.
- When starting a medication, begin at a low dose and increase the dose gradually.
- For patients on multiple medications, try to change only one medication at a time, so that each drug effect can be assessed individually.
- Psychosocial factors need careful consideration. They may exacerbate medical and psychiatric illness (i.e., a psychological reaction rather than an organic disturbance of the brain may be causing symptoms).
- Environmental amendments, such as night lights and familiar objects brought from home, may improve functioning of confused patients who are hospitalized.

with consultants optimizes patient care and allows the psychiatrist to treat more physically ill patient. Because many geriatric patients rely on family members or other caregivers for help with activities of daily living, the psychiatrist needs to obtain comprehensive histories from these sources and maintain close communication with them. These communications, however, should not replace the direct doctor-patient relationship and should demonstrate respect for the patient's sense of independence and self-worth.

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Psychiatric Problems in the Nursing Home St. Louis University Geriatric Grand Rounds

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George T. Grossberg At the present time, Americans over the age of 65 constitute approximately 13% of the population, with those over the age of 85 growing at the most rapid pace. Although only about 6% of the nation's elderly reside in nursing homes, these numbers are expected to grow as our population ages. The prevalence of psychiatric behavioral disorders in nursing homes has been estimated to range from 68% to 94%.¹⁻³

Rovner and Rabins⁴ have divided psychiatric disorders seen in the nursing home into three major groups: (1) cognitive disorders, e.g., delirium and dementias; (2) depression; and (3) behavioral disorders. Other issues of special concern in the nursing home include disorders of anxiety and sleep, the appropriate use of medications (particularly psychotropics), family issues, as well as surrogate decision making for nursing home residents. The multiplicity of psychiatric disturbances in the nursing home has resulted in the comment by Libow and Starer that "expert and readily available psychiatric consultation is a hallmark of the best nursing homes."⁵ It should be stressed at the outset that there are major limitations in the available existing research in nursing homes. For this reason, the authors will present information from their clinical experience, which we believe is useful but which requires empirical studies and clinical trials for validation.

CASE REPORT

B. R. S. Nakra R. B., a 72-year-old, white married female, was living with her husband and had worked as a volunteer at a hospital gift shop. She was admitted to a nursing home on October 22, 1988, with a diagnosis of Senile Dementia Alzheimer's Type, from a hospital where she had been admitted a month earlier with com-

plaints of change in personality, restlessness, early morning insomnia, loss of memory, poor concentration, difficulty in swallowing, and loss of interest in usual activities. These symptoms had gradually become worse over a period of 2 months, necessitating her admission to the hospital. In the hospital, she continued to complain of poor memory and stayed in her room, afraid that if she left her room she would get lost. Her physical examination, neurological examination, and laboratory work-up were within normal limits. Because of her presenting complaints of memory difficulty and her inability to function independently, her family asked to place her in the nursing home. A week after her admission to the nursing home, a neuropsychiatric evaluation was done and suggested that she was suffering from major depression with panic disorder. She was started on desipramine 30 mg/d, which was gradually increased to 75 mg/d, and alprazolam 0.25 mg in the morning and 0.5 mg at bedtime. After 4 weeks of therapy she started to show improvement. She became more independent, started to participate in group activities and activity therapy, and stopped complaining about poor memory. Evaluation of her cognitive functioning showed that she was oriented, and she scored 28/30 on the Folstein Mini-Mental Status. She continued to improve and a month later was given a pass to go home. Her family was surprised at her improvement.

DELIRIUM AND DEMENTIA

G. T. Grossberg Deliria, or acute confusional states, are not uncommon among nursing home residents and may account for upwards of 6% of psychiatric diagnoses.³ However, deliria are often unrecognized.⁴ This is unfortunate because delirium needs to be considered reversible until proven otherwise.

According to Lipowski, the clinical features of delirium include a global disorder of cognition and attention, a decreased level of consciousness, increased or decreased psychomotor activity, and a disturbance in the sleep-wake cycle. An acute onset, often at night, is common. There is a tendency for the symptoms to fluctuate

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in severity and to peak at night.⁷ Delirium may be particularly common among elderly in nursing homes and, in particular, among those with multiple medical problems who are taking a variety of medications.

Two subtypes of delirium are seen in the nursing home: agitated or noisy delirium with increased psychomotor activity, and quiet or apathetic delirium. The latter is more difficult to recognize and presents as disorientation, apathy, withdrawal, and often lethargy of an acute onset in the nursing home resident who may have previously been quite active. It is also important to keep in mind that delirium and dementia can coexist. Although the dementing disorder may not be curable, recognition and aggressive treatment of superimposed delirium is important in improving quality of life and manageability of patients in the nursing home environment.

Common Causes of Delirium in the Nursing Home Table 1 lists some of the more common causes of delirium in the elderly in nursing homes.

Treatment of Delirium The key to appropriate treatment of delirium in the nursing home is a thorough work-up aimed at identifying the underlying cause or causes.⁸ Once this is established, treatment can be fo-

cused and the patient restored as closely as possible to his or her previous level of functioning. Acute behavioral problems, such as agitation or psychosis, may require immediate management. A quiet, structured, well-lit environment with an open, nonthreatening approach may be calming for the agitated patient with delirium. Occasionally the acutely agitated, assaultive, or psychotic patient may need rapid pharmacologic control to avoid danger to self and/or others. In these instances, the use of high potency antipsychotics such as haloperidol or thiothixene is recommended. These agents are relatively safe, with almost no autonomic, cardiac, and anticholinergic effects. Once control is achieved, doses of these drugs need to be tapered rapidly to prevent toxicity secondary to cumulative effects. Physical restraints should be avoided because they may exacerbate agitation and other symptoms of delirium.

ANXIETY DISORDERS

R. Hassan Anxiety disorders of late life have not been intensively investigated.⁹ In nursing home residents, anxiety is a common problem and a common cause for psychiatric consultation. Himmelfarb and Murrell in 1984 demonstrated that 17% of men and 22% of women above the age of 60 years had anxiety of a degree that warranted treatment with the prevalence increasing with advancing age.

Various factors play a role in causing anxiety states in the elderly, especially in a nursing home setting:

1. *Psychosocial Stressors.* Loss of control over one's immediate environment, loss of independence, failing health, decrease in intellectual functioning, loss of friends and loved ones, feelings of helplessness and hopelessness, and especially fear of death and dying (which can sometimes be precipitated by a roommate dying in bed¹⁰) play a role. Studies are not available to delineate the role of the abuse of older people in the pathogenesis of anxiety in the nursing home situation. Anxiety has been reported to be the most common psychological manifestation of the abuse of older people.¹¹ This can either be physical or verbal abuse, but is more typically related to neglect. All of the above are causes of a type of psychogenic anxiety in the elderly, an anxiety that is typically acute, dramatic, and highly treatable.¹²

2. *Medical Disorders.* Anxiety symptoms are frequently associated with various medical disorders.¹³ Differential diagnosis is extremely important. The common medical causes of anxiety-like symptoms are given in Table 2.

3. *Dementia and Delirium.* The early stages of Alzheimer's disease and other dementias often present with anxiety-like symptoms such as restlessness and agitation. Appropriate diagnosis may often be missed if memory and intellectual functioning are not thoroughly evaluated.¹³ Delirium can also present similar features in nursing home patients.

TABLE 1. COMMON CAUSES OF DELIRIUM IN THE NURSING HOME

Medications
Anticholinergics
Long half-life benzodiazepines
Digoxin
Diuretics
Psychotropics
Cerebrovascular disorders
Cerebrovascular accidents
Transient ischemic attacks
Post-ictal confusion
Cardiovascular disease
Congestive heart failure
Myocardial infarction
Abrupt arrhythmia
Infections
Urinary tract infection
Upper respiratory infection
Pneumonia
Metabolic disorders
Dehydration
Water intoxication
Electrolyte imbalance
Diabetes mellitus
Hypoglycemia
Fecal impaction
Urinary obstruction

Adapted from: Grossberg GT, Nakra BRS: *Psychiatry in the nursing home*, in Bienenfeld D (ed): *Adrian Verwoerdt's Clinical Geropsychiatry*, Baltimore, Williams & Wilkins, 1990.

TABLE 2. MEDICAL DISORDERS FREQUENTLY ASSOCIATED WITH ANXIETY SYMPTOMS¹²

Cardiovascular	Angina, cardiac arrhythmias, hypertension
Endocrine	Hyperthyroidism, pheochromocytoma, parathyroid disease, hypoglycemia, carcinoid syndrome
Hematologic/immune	Anemia, lupus erythematosus
Neurologic	Essential tremors, seizure disorders, vertigo, brain tumors
Nutritional	Caffeinism, vitamin deficiencies, food additives, e.g., monosodium glutamate
Respiratory	Chronic obstructive pulmonary disease, asthma
Drug-induced	Anticholinergic drugs, amphetamines, thyroid supplement, akathisia due to neuroleptics, ritalin, paradoxical reactions to benzodiazepines

To begin the evaluation of anxiety, a thorough history and physical examination must be carried out. For patients with impaired mental functioning in nursing homes, nursing staff and family often must serve as a source of information.

Common signs and symptoms of anxiety include both physiological and psychological reactions, i.e., tachycardia, tremulousness, dyspnea, hyperventilation, gastrointestinal complaints, motor restlessness, and insomnia, as well as confusion, fears, and feelings of helplessness and hopelessness. Hypochondriasis is also a common presentation of anxiety disorders in the elderly. Stress, such as a nursing home admission, may be associated with vasopressin hypersecretion leading to hyponatremia in association with an anxiety-like syndrome.¹⁴ Agitated depression can mimic anxiety. Not infrequently, there seems to be an overlap of anxiety and depression in the elderly. Careful questioning may elicit anhedonia, guilt, self-reproach, and suicidal ideations. Individual or family history of depression and suicide attempts may aid in the diagnosis of major depression.

Successful treatment in nursing home residents depends on careful diagnosis to determine whether the patient's anxiety is organic in origin. If so, treatment should begin with correction of underlying problems. Acute adjustment reactions may respond well to crisis intervention, supportive psychotherapy, and environmental manipulations. For patients who are cognitively intact, behavioral modification techniques including biofeedback and relaxation training may be helpful.

If such approaches fail to reduce anxiety, anti-anxiety agents can be helpful. For a limited time, shorter-acting benzodiazepines without active metabolites should be used, e.g., lorazepam (Ativan), oxazepam (Serax), and

alprazolam (Xanax). The half-lives of these drugs tend to be slightly increased in the elderly (9 to 17 hours) compared with younger individuals (9 to 14 hours).¹⁴ For this reason, dosage should be one half to one third the usual adult dose.¹¹ Placebo-controlled trials have demonstrated that, after the acute anxiety state is resolved, patients can often be weaned off the benzodiazepines and continued on supportive therapy. Buspirone is a nonbenzodiazepine anxiolytic that may produce less sedation than the benzodiazepines. A small trial in a group of elderly (mean age, 72.4 years) suggested buspirone may produce significant anxiety reduction.¹⁴

Anxiety and agitation in response to acute mental status changes/delirium can be treated with a low dose of a high-potency neuroleptic such as 0.5 mg/d of haloperidol. However, these are potentially dangerous drugs when used inappropriately in the elderly and should only be considered when all other therapeutic modalities have been exhausted. Anxiety and, in particular, panic anxiety in a patient with a primary depressive disorder is best treated with antidepressants, such as imipramine or monoamine oxidase inhibitors.

DEPRESSION IN NURSING HOME PATIENTS

B. R. S. Nakra Depression in nursing home patients is often undiagnosed or misdiagnosed, and is often not treated vigorously. Undiagnosed depression occurs in about 40% of nursing home patients.^{15,16} Depression in these patients is not recognized because of the presence of other medical and neurological illnesses common to this age group. The patient we reported above illustrates very well the possibility for diagnosing dementia when the true diagnosis is depression.

Recognizing depression in nursing home patients requires a high index of suspicion. It is necessary to pay closer attention when communicating with these patients because symptoms and signs of depression in some patients are subtle. Some nursing home residents are at particularly high risk of developing depression; they are the following:

1. Those with a past history of depression, family history of depression, and/or suicide attempts
2. Those with a history of cerebrovascular accidents, especially those with a stroke involving the frontal lobe of the dominant hemisphere
3. Those admitted to the nursing home for rehabilitation following fracture, stroke, or major medical and surgical problems
4. Those admitted to the nursing home against their wishes
5. Those receiving multiple medications for multiple medical problems
6. Those with a history of recent loss of a relative or close friend

Although elderly depressed patients usually present

with the well-known symptomatology of feelings of sadness, hopelessness, discouragement, and worry,¹⁷ many nursing home patients present with "atypical" forms such as the following:

1. Severe malnutrition
2. Decrease in verbal and physical ability
3. Persistent complaint of lack of energy and increase in time spent in bed
4. Severe regression requiring care of basic activities of daily life
5. Cognitive deficits
6. Increased preoccupation with death and dying, and persistent guilt feelings
7. Refusal to take regular medications

Patients presenting with any of the above symptoms should be suspected of depression and carefully watched for other symptoms, such as sleep disturbance, tearfulness, loss of weight, apathy, and loss of interest in nursing home activities.

Owing to their frequent occurrence during late life, there are at least three forms of depression that deserve special attention: masked depression, pseudodementia, and delusional depression.

Nursing home patients may be more likely to mask their depression by denying being depressed or dysphoric. Instead, they often complain of chronic pain, gastrointestinal upsets, decreased energy, and drive, or of memory and concentration disturbance. Such "depressive equivalents" serve to mask or distort the underlying depression and make diagnosis difficult.^{17,18} Depression may also be masked by cognitive difficulties such as forgetfulness or difficulty in remembering. Indeed, one of the most difficult tasks in making the diagnosis of depression in nursing home patients may be its differentiation from senile dementia. Both conditions are common, and patients often present with combinations of cognitive and effective dysfunction, but as prognosis and treatment are so vastly different, making the correct diagnosis and instituting appropriate treatment may be a matter of life and death.

Suspiciousness of others, ideas of reference, and even delusional beliefs are seen with greater frequency in depression in the elderly than in any other age group. Paranoid thinking may be a prominent part of depressive symptomatology and may necessitate administration of antipsychotic drugs along with antidepressants. High-potency neuroleptics such as haloperidol or trifluoperazine should be preferred over low-potency but highly sedating neuroleptics like chlorpromazine and thioridazine. Sometimes, it may be necessary to administer electroconvulsive therapy; when used, it is usually effective.

Depression in nursing home patients responds to the same modes of therapy as depression in other geriatric and adult patients.¹⁹ The first principle in the treatment

of depression is to do a complete evaluation, including chart review, latest laboratory data, current medications, and environmental and social stressors. For some patients with mild depressive symptoms, supportive psychotherapy, rearranging the environment, or encouraging activities may be all that is necessary to alleviate depression. In more severely depressed patients, antidepressant medications may be necessary. Patients with psychotic symptoms, malnutrition, or suicidal ideation may require electroconvulsive therapy.¹⁸

Because of their vulnerability to adverse effects of antidepressants, elderly depressed patients should be treated with much lower doses than younger patients.^{18,20} Doses as low as 10 mg desipramine or nortriptyline or 50 mg trazodone daily may be appropriate to initiate therapy. Increases in dosing should be done carefully and gradually, monitoring side effects and changes in heart rate and blood pressure. In most cases, the therapeutic dose will be one third to one half that used in younger patients. Tertiary amine antidepressants like amitriptyline and imipramine should not be used because of their potent cardiovascular and anticholinergic effects. Drugs with the least sedative, hypotensive, anticholinergic, and cardiovascular side effects should be selected. Monoamine oxidase inhibitors (MAOI) and psychostimulants have also been used successfully. If the patient responds favorably, treatment should continue for 6 to 9 months. Electroconvulsive therapy may be considered in patients who fail to respond to antidepressant medications, whose medical condition contraindicates use of antidepressants, or whose depression is accompanied by delusions or is life-threatening.

Psychotherapy and behavior therapy should be recommended to stimulate outside interests. Love and compassion from family members, friends, and nursing home staff often help to reinforce the view that life should be enjoyed.

CASE REPORT

J. E. Morley An 82-year-old man was admitted to a nursing home unit to allow his wife a period of respite. The patient was mildly disoriented and expressed a desire to go and walk in the garden. He was told he could not go outside in view of construction activities. On three occasions he attempted to walk outside. The physician then ordered 2 mg haloperidol for the patient's "safety." Two hours later the patient began to scream loudly and a further 2 mg haloperidol was administered. The patient was, in fact, having a reaction to haloperidol and further administration should have been avoided. After a brief period of sleep, the patient became more aggressive and abusive and was given a further 2 mg haloperidol and restrained to his bed. At no time was the wife contacted to obtain informed consent for the use of physical or chemical restraints.

This case represents a typical example of how an understaffed institution will use inappropriate chemical and physical restraints for the so-called safety of a patient. The next section of this Grand Rounds will discuss appropriate approaches to the management of behavior disorders and wandering with the use of medications in nursing homes.

BEHAVIOR DISORDERS

P. A. Szabo A recent study in a community nursing home suggested that 76% of residents had at least one behavioral problem.²¹ Behavior disorders of the elderly in long-term care situations present a confusing and complex problem for care providers. Behavior disorder implies that one is troubled or presents with symptoms that are hard to manage. These disorders include the acting-out of impulsive and antisocial behaviors that challenge the capacity of the long-term care staff (and the residents' families) to respond appropriately.

The causes for these behaviors are varied. The institutionalized elderly person presents with a multiplicity of interrelated and overlapping problems—physical, psychological, cognitive, social, familial, environmental, and economic.

To understand better the cause of behavior problems, one needs to consider the impact of aging on some individuals. This may result in uneasiness and distaste for growing old and becoming more infirm and possibly disabled. Fears of powerlessness, uselessness, and death may result in exacerbation of previously inappropriate personality traits or personal care issues, and lead to behavior disorders.

Elderly individuals in long-term care are often ill, frail, and confused, and often exhibit regressive behaviors. Some may become stubborn and irritable, and may lose previous levels of functioning and abilities to cope with their world, as their dignity and independence are threatened and eroded. Their coping abilities may no longer be adequate to deal with stress factors, such as the aging process, life-long personality disorders, illness, chronic psychiatric problems, and new or acute psychiatric problems.

The Aging Process Individuals may have difficulty accepting growing old, and they may fight this process by turning their anger and frustrations inward. Alternatively, some individuals may lash out at others, causing friends, family, and staff members to avoid them. Anger and frustration turned inside can also cause persons to neglect their own physical care and appearance and refuse assistance when it is apparently needed.

Life-Long Personality Disorder Older adults may have developed inappropriate ways of handling stress throughout their lives. For example, individuals with a dependent personality have been taken care of by others all their lives. Now that they are alone, they may

become demanding of care and attention from others. The dependent person may mishandle living situations and decision making. He or she is apt to seek constant reassurance and direction. On the other hand, people with an inadequate personality are intellectually capable of caring for themselves but let things slide. The stresses of aging, illness, or loss cause additional deterioration in their ability to manage daily needs.

Illness The older adults' ability to function independently may be limited by chronic health problems. Undergoing treatment for the illness may require so much energy that it is easier to give up than carry on an ongoing struggle with diminishing abilities, supports, and resources.

Chronic Psychiatric Problems Older adults who have struggled throughout their lives with intermittent hospitalizations and periods of instability may no longer be able to cope with their own care. They may lack initiative in providing for themselves due to the chronic nature of their illness. These individuals do well in a supervised setting that encourages their functioning at the best of their abilities but can be a challenge to caregivers because their needs are different from the more traditional nursing home resident who is frail and physically ill. Their psychiatric symptoms may isolate them from the more typical nursing home resident.

New or Acute Psychiatric Problems Over half of the elderly in long-term care facilities have been estimated to have mental health symptoms.²² These symptoms may be exhibited as behaviors that are difficult to manage. These various behaviors are troubling because they disturb, disrupt, and upset other patients, the environment, and the staff. They fall into four general categories:

1. Disruptive: noisy, screaming, pacing, rummaging, repetitive speech, and wandering
2. Demanding: dependent and seeking attention and reassurance
3. Distressful: agitated, labile, hitting, crying, and suspicious
4. Disgusting: verbally abusive, engaging in self-exposure, poor feeding behavior, and other inappropriate behaviors²²

Treatable causes for disruptive behavior should be carefully investigated. Examples are infection, functional disorders, and new or exacerbated previous mental disorders. Progression of the dementing illness or deterioration of chronic illness may manifest itself in increasing behavior problems, and management plans that may require constant revision as a result. There may be particular events or tasks, such as bathing, that trigger disruptive behaviors, so simple changes in daily care plans may be useful.

Neuroleptics have consistently been shown to decrease agitation in demented or psychotic older subjects.²³ However, on the whole, their effectiveness is modest and, in many cases, little better than placebo. There is no one class of neuroleptics that appears to be superior to another for the treatment of agitation. Older subjects are particularly liable to develop sedation, orthostatic hypotension, and involuntary movements when given neuroleptics. For these reasons the clinician should always begin by attempting to control disruptive behaviors with behavioral methods. If not sufficient, these methods can then be combined with psychopharmacologic options. One of these is to use short-acting benzodiazepines, which have been reported to be effective in some cases.²⁴ Propranolol, in doses from 60 to 560 mg/d, has been reported to improve aggressive and disruptive behavior in a number of studies.²⁵⁻²⁷ Meanwhile, problem-solving is a part of the treatment—trying to understand why it is occurring, what are the factors involved, and what can be changed. It is important to recognize elements in the environment, the medical and psychiatric situation, and problems in communication that may be contributing to the problem. The education of nursing assistants to optimize their ability to deal with behavior disorders is an important part of the management.

WANDERING

J. E. Morley Wandering represents a major problem in the nursing home. The 1977 National Nursing Home Survey found that 11.4% of nursing home residents were considered wanderers by the staff.²⁸ Zimmer et al²⁹ reported that 5% of nursing home residents showed "dangerous ambulation," and 4% showed "inappropriate ambulation" (i.e., wandering into rooms belonging to other residents).

Wandering is most often seen in patients with dementia. It is rare in depressed patients. In a survey of nursing home directors, Hiatt³⁰ found the following to be considered the most likely reasons for wandering: dementia (54%), restlessness (40%), disorientation as to place (32%), a sense of being "shut in" (27%), desire to return home (25%), and newness to facility (20%). Environmental stressors, such as noise, may be particularly liable to trigger wandering behavior. Dawson and Reid³¹ found that patients who were rated by nurses as being both hyperactive and cognitively impaired were most likely to be wanderers, whereas agitated and aggressive behavior did not identify potential wanderers.

Wandering has both positive and negative sides. On the positive side the wanderer is obtaining exercise and perhaps some decrease in tension. The wanderer is also asserting some independence. However, these effects are counterbalanced by the risk of being lost and/or sustaining injury. The wanderer may typically enter other resident's rooms and rummage through their

drawers. From the point of view of the long-term care staff, wanderers create a highly stressful situation that requires an increase in time spent watching the individual. Not only does the wanderer lead the caretaker to worry about the potential harm that can occur to the wanderer, but the staff in nursing homes has to constantly worry about being censured by nursing home administration if the wanderer falls or escapes. Further, many states impose financial penalties on nursing homes if residents are found wandering away from their facilities. These external stressors often lead the caregiver staff to make inappropriate management decisions, such as the use of physical or chemical restraints. Fennelly³² has calculated that a wanderer costs a nursing home \$2,500 per year extra in staff time.

The management of wandering requires both staff intervention and environmental modifications. Restraints should *never* be a response to the management of the wandering patient. Use of restraints represents a failure of the institution to provide either adequate staff time or to carry out appropriate environmental modification. Restraints represent curtailment of the patient's individual liberties and in fact may well lead to increased injuries and confusion. Chemical restraints often lead to confusion and malnutrition.³³ Successful staff responses to wandering include seeing that the patient is obtaining adequate exercise during the day and distracting the patient when he or she is seen to be attempting to escape from the facility. Organized group activities represent a relatively cost-effective and therapeutic manner in which to watch the potential wanderer. A recent report of the development of a wanderer's lounge represents an innovative approach to the problem.³⁴ It is also important that the staff examine potential stressors that may be triggering the wandering behavior. As wandering may represent a "search for home," it is important that new patients have recognizable personal items in their room. All wanderers should wear a Medic-Alert bracelet with a contact phone number on it. This is often forgotten in institutionalized patients.

The major approach to successful management of the wanderer is the development of an environment that allows limited wandering without danger to the resident or intrusion on other residents' privacy. The first need is to make sure that the nursing home is adequately signposted so that the residents can find the bathroom, dining room, and, most important, their own room. Placing a Polaroid picture of the resident at the entrance to the room can be most useful in this regard.

For the disruptive wanderer, the use of "Dutch doors" (half doors) permits restraint to a room or a set area while allowing visual access to the rest of the world. Wanderers can also be housed in the same corridor with a "Dutch door" barring access to the rest of the nursing home. In many areas this sensible approach is inhibited

by fire codes. In addition, it is essential that wanderers are allowed access to the outside. This requires at minimum the construction of a "wandering garden" where the person can wander without restriction. The tendency to build high-rise nursing homes is an architectural abomination. When space dictates this approach, fenced roof gardens and balcony gardens are an essential part of good nursing home design.

The advent of high technology in the nursing home has led to the development of a number of sophisticated monitoring systems. The most commonly used are the door-monitoring systems, where the patients wears a bracelet that activates a detector unit in the doorway leading to the sounding of an alarm. Other units, such as the Kiddie or Kare Alert system from Cortex Electronics Inc., allow the wanderer to wear a transmitter that will set off an alarm in a receiver when a preselected perimeter distance is exceeded. Door-locking devices work on a code that is known only to the staff. Johnson Engineering Corporation has developed a personnel locator system that displays individual locations on a microcomputer screen. Full details of potential individual monitoring devices are given in a report prepared by the Research Triangle Institute.²³

Wandering in institutionalized patients is a complex problem. However, as we enter the 1990s, we have the tools to provide the potential wanderer with limited freedom, while maintaining a safe environment. It is sad to record that the use of physical restraints for wandering has not been banned in the United States. This is an unacceptable situation. The excuse that environmental modification is too expensive should not be accepted by those caring for the older person. In addition, many of the problems associated with wandering could be solved by adequate staffing ratios in nursing homes. Approaches to the management of wanderers are summarized in Table 3.

ISSUES IN THE USE OF MEDICATIONS IN NURSING HOMES

K. Solomon The appropriate use of medications in nursing homes may be quite challenging. The requirement for multiple oral medications or any parenteral medication is a risk factor for institutionalization of the elderly patient. Several studies have demonstrated the widespread use of psychoactive medications in nursing home patients.^{34,37} This review will briefly discuss issues of drug-illness interactions, overmedication, and undermedication.

Drug-Illness Interactions Drug-illness interactions are quite common in the elderly. Many nursing home patients have cardiac arrhythmias, ulcer disease, chronic constipation, or prostatic hypertrophy. The addition of a psychotropic medication to the drug regimen of these patients might precipitate symptoms of these

TABLE 3. APPROACHES TO THE MANAGEMENT OF THE WANDERING BEHAVIOR

Staff interventions
1. Adequate and repeated orientation of residents
2. Exercise
3. Planned group activities
4. Distracting techniques
5. Elimination of stressors that trigger wandering
6. Having pictures and items from home in resident's room
7. Behavior modification
8. Picture of resident outside room
9. Medic-Alert bracelet with contact phone number
Environmental modifications
1. Clear signposting
2. Dutch doors
3. Wandering garden
4. Door-monitoring systems
5. Perimeter-monitoring systems
6. Door-locking devices
7. Electronic locator system
Administrative interventions
1. Environmental design and space allocation
2. Staff training: nursing and activity
3. Staff support
4. Adequate staffing ratios

disorders. A thorough review of the side effects of psychotropic medications in the elderly, including drug-illness interactions, has been published by Levenson.³⁸

Overmedication Symptoms of psychotropic overmedication in the elderly usually present as falls or oversedation, or result in physiologic changes such as constipation, urinary retention, or electrocardiographic abnormalities. More subtle symptoms of overmedication may be missed. Psychotropic drugs are capable of producing psychiatric side effects that frequently mimic the very disorders they are designed to treat. For example, depressed mood, apathy, and vegetative symptoms of depression may be side effects of antidepressants. Delusions, hallucinations, and agitation may be secondary to an antipsychotic. Anxiety and agitation may be side effects of benzodiazepines in elderly patients. These drugs may also cause subtle shifts of mood and cognitive functioning, so that a psychotic patient may start to develop symptoms of depression as a side effect of antipsychotics; or the depressed patient may develop delusions, paranoid ideation, or hallucinations as a side effect of antidepressants; or the cognitive functioning of a demented patient may become worse after administration of an antipsychotic designed to limit agitation. All these drugs are capable of producing delirium. The physician must be extremely alert to subtle shifts of mood, behavior, and cognitive functioning in order to consider the possibility of an untoward psychotropic drug reaction.

Undermedication Many physicians are too cautious in prescribing psychotropic medications. Lithium is often not prescribed for the elderly patient with an affective disorder because of an undeserved reputation that it is too dangerous to use. Therapeutic dosages of psychotropics are often prescribed for too short a time for there to be a clinical benefit. This is often true if the patient is quite agitated and disruptive or physically threatens harm to self or others. Nursing home staff and administrators must be patient with the difficult-to-manage resident and allow psychotropic medications to be administered in a high enough dose and for a long enough time for them to have an effect.

Physiologically, the elderly comprise an extremely heterogeneous population. Some elderly patients may not only require the usual and customary adult doses of psychotropic medications but may also require higher than customary doses. There is a paucity of research regarding the correlation of antidepressant levels and clinical response in the elderly. In the case of lithium, serum levels may be helpful in treating mania or depression in the elderly. Blood levels required are similar to younger patients, between 0.7 and 1.2 mEq/L. Side effects of large doses of medications can often be reduced by giving antidepressants and antipsychotics in a once-a-day dose (at bedtime) to make use of the sedative properties of some of these drugs and to improve compliance.³⁹

NURSING HOME SUPPORT FOR RESIDENTS' FAMILIES

C. W. Bretscher Family members commonly experience considerable stress in adjusting to the nursing home placement of a loved one. Nursing home personnel who understand this stress and respond to it in a supportive manner can have a positive impact on the well-being of family members and residents alike, as well as on the working relationship between families and the facility's staff.

The need for such support is clear. In most cases, the placement of a relative in a nursing home has been preceded by a prolonged, physically demanding, and psychologically traumatic period of caregiving in the home. This "family burden," particularly as it pertains to family members of the cognitively impaired, has been amply documented.⁴⁰⁻⁴³

In addition, for most families the mere decision to institutionalize a loved one is exceedingly difficult.⁴⁴⁻⁴⁹ A decision no one really wants, it is usually fraught with intense feelings of inadequacy and failure, fear and uncertainty, anger and resentment, sadness and unrelenting guilt.

The emotional pain does not promptly evaporate once the nursing home decision has been implemented. The guilt goes on, often for months and even years, mixed feelings persevere, and "second thoughts" about

the placement rob the caregiver of sleep and serenity. Feelings of deepening sadness, loneliness, helplessness, loss, and lostness continue to overwhelm and demoralize, as family members grope to establish their identity and role in the new situation.

Any viable nursing home response to families' need of support must originate at the institutional level, starting with the underlying philosophy and policies of the facility itself. First and foremost, there needs to be a clear and conscious determination to treat residents as members of a family rather than as isolated individuals.^{47,50} It then has to be communicated to staff that time spent in a supportive posture with family members is an integral part of its caregiving responsibilities. Training sessions also need to be planned to sensitize staff members to the family's overall experience, especially its psychological dimensions, and to teach the fundamentals of providing emotional support.

Out of the same orientation would flow an assortment of facility-sponsored, family-targeted programs such as time-limited or ongoing family support groups^{44,48,51,52} or workshops on more effective communication with institutionalized loved ones.⁵³ Nursing homes with special "dementia units" could help families make their involvement with their impaired relatives more rewarding through programs to recruit family members to supplement the formal activities provided by staff.⁵⁴

Most important of all, support of stressed and emotionally traumatized families becomes a matter of the one-to-one interactions between family members and individual staff persons. In the final analysis, it is staff alone that will or will not put into operation the facility's philosophy of and commitment to the inclusion of family care as an institutional goal.

What might staff persons (nurses, nursing aides, social workers, etc.) do, and be trained to do, in support of distressed family members? First, as already stated, they are the ones who will communicate to families the nursing home's concern for their well-being. They will do so less by words than by their demeanor and demonstrated interest in families and their willingness to spend time with them. They will, thus, be conveying by action that family support is pivotal, an extension rather than a disruption of their caregiving role.

Second, nursing home staff members can be trained to listen in an empathic and nonjudgmental way. This includes assuming a posture that signals to family members that the staff person is comfortable with their sharing some of their experiences, feelings, and struggles. Comments like "That must have been a terribly hard decision" or "You must feel awfully alone and lost at times" not only express understanding but also gently invite family members to say more if they have the need. It is vital in this connection that staff members develop the skill to "hear" what the family member is not saying, to listen to what lies behind the words. The best re-

sponse, for example, to a wife's question, "Do you think I could take my husband home and care for him there?" may be no direct answer at all, but rather the kindly observation "It hurts to have him here," or "You feel sorry for him in an unfamiliar setting," or "You feel uncomfortable, or perhaps guilty, not caring for him yourself."

Third, families gain support when they observe a caring and respectful attitude on the part of the caregiving staff toward their own loved one and the other residents. Staff convey this both by the way they talk about and deal with the residents, and can be trained in the kinds of specific verbal responses and behaviors that potentially are and are not supportive.

Fourth, it is supportive to families to be clearly identified as a desired and valued component of the caregiving team.^{47,51,55,56} Staff need to relate to families in a manner that forcefully urges them to continue to play a useful and needed role in the care of their loved ones. Crucial in this regard is an openness to learn from family members about the unique aspects of their relative's life, his or her personal preferences, as well as strategies the family may have developed to provide care more effectively. Staff can, furthermore, actively enlist and guide families in the kinds of caregiving tasks they can perform to supplement those of the professional personnel, thus enhancing not only the quality of care for the resident but also the family members' sense of usefulness and self-worth.

Finally, staff can support family members by giving them practical tips as to how to make their visits more fulfilling. They can teach by example how the resident can most effectively be communicated with, verbally and nonverbally. They can offer clues as to how to respond to things their relative repeatedly says or does. They can teach the value and techniques of reminiscing with the resident. If the family's own loved one is so impaired as to render impossible any meaningful interaction, staff can encourage involvement with other residents who may be more intact, but who lack caring family members to come and visit.

In summary, family members of relatives in long-term care facilities have emotional and practical needs that nursing homes are in a unique position to meet. Both at the level of institutional policy-making and programming and at the level of individual staff-family encounters, opportunities for providing needed and helpful family support are abundant. Efforts expended in this direction can substantially benefit all concerned: the families themselves, the loved ones they care about, the caregiving staff, and the institution as a whole.

SURROGATE DECISION MAKING FOR NURSING HOME RESIDENTS

G. H. Zimny Mental disorders of nursing home residents, like their physical disorders, can result in partial

or complete impairment of their cognitive functioning and, therefore, of their competence at making decisions. Incompetence in decision making is a matter of vital concern when it involves medical matters such as residents' taking or changing medications, visiting a physician, being hospitalized, and undergoing surgery. Weinstock described the following case:

A 68-year-old depressed woman refused antibiotics for a respiratory infection because she was discouraged, did not want needles, and did not care if she died since everything was empty and hopeless anyway. She did not actively wish to kill herself but was merely refusing treatment because she did not want painful needles. She intellectually understood the risks and benefits and could repeat them, but she did not appreciate the situation because of her depression. Her hopelessness reached delusional proportions and interfered with her ability to reason, so she did not even meet that test. Her husband died 2 months ago and she had vegetative signs of decreased appetite and early morning awakening. She was willing to take antidepressants since they helped in a similar episode ten years earlier, so she was not refusing psychiatric treatment and was willing to be a voluntary psychiatric patient. However, she should in my opinion, be considered as incompetent to refuse her medical treatment.⁵⁷

In this and similar cases in nursing homes, the practical and legal question arises as to who will make decisions for the presumably incompetent resident. This question must be answered by the family of the resident, the physician, and the nursing home. From a practical point of view, decisions benefitting the incompetent resident, although not endangering the parties involved, might well be made through discussions among the three parties. This apparently is what is ordinarily done.⁵⁸

From a legal point of view, it is important that the parties recognize that a family member or the responsible party who signed the nursing home admission form does not necessarily constitute a legal substitute in decision making for an incompetent resident. Areen,⁵⁹ an attorney, states that "there is no basis in common law for relying on a family member as a proxy decision-maker unless he has been appointed the patient's legal guardian." Kapp,⁶⁰ an attorney, states that "the naming of a 'responsible party' in an admission agreement, by itself, has absolutely no legal effect on the distribution of decisionmaking power for that resident" (p. 24).

Legal responsibility for surrogate decision making can be provided for or by nursing home residents through the establishment of one or more surrogate management arrangements (SMAs). An SMA is any written agreement whereby one person (or persons) or an institution functions as a substitute for a person to carry out

designated responsibilities of that person. Surrogate management arrangements include guardianship, conservatorship, power of attorney, and trust funds. The number and type of SMAs vary among states. Some SMAs, such as power of attorney and trusts, can be set up by the resident before incompetence, whereas others, such as guardianship, are established after incompetence. A frequently utilized SMA is the durable power of attorney, which is established before incompetency but, unlike the power of attorney, remains in effect if the resident becomes incompetent.

The choice of one or more SMAs for a resident involves obtaining sufficient substitute decision making to provide the necessary protection for the resident while also maximizing the resident's autonomy and independence. If limited guardianship provides the needed protection for the resident, then it is preferable to full guardianship, which severely restricts the rights of the resident.⁴⁰ Arranging for surrogate decision making for nursing home residents requires careful consideration and full discussion among the parties involved.

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Pharmacy

EVALUATING PSYCHOTROPIC DRUG USE IN THE NURSING HOME

Jean Johnson

Psychotropic drug use in the institutionalized elderly has been a major concern for over a decade. The mental picture of putting Grandma in the nursing home and then drugging her up so that she is not a bother, is a common image in the public mind. A comprehensive study by the Office of Long Term Care in 1976 indicated that there was significant misuse of drugs in nursing homes; nearly 50 percent of residents were prescribed antipsychotic drugs or minor tranquilizers. Subsequent studies describe similar rates of drug prescribing. In a recent study of 12 intermediate care facilities in Massachusetts, over half of all residents were administered psychoactive drugs.

The concern over prescribing practices has less to do with the fact that psychotropic drugs are widely prescribed in nursing homes as with the concern about the lack of documentation of signs or diagnosis to support the use, as well as the selection of psychotropic drugs that are known to be highly hazardous to the frail elderly.

The lack of documentation has been interpreted to suggest that there is no need for psychotropic drugs. However, it could indicate that there is a need, but that need is simply not well documented. The inappropriate dose and type of drug selected for treatment may be related to drug treatment being prescribed to populations many physicians have not had specialized training to treat.

The inappropriate use of psychotropic drugs has prompted the Health Care Financing Administration to promulgate detailed regulations concerning their use.

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"A major reason for the use of psychotropic drugs in nursing homes is to treat behavior disorders that often accompany dementia."

The approach taken to regulate psychotropic drug use is through specific guidelines defining the dosage, duration, and type of psychotropic that can be used for treatment of specific mental disorders.

A Clear Need in Facilities

Those who work in nursing homes know that there is a basis for psychotropic drug use in this population. Estimates of the current prevalence of mental disorders in nursing homes range from 30 to 85 percent of all residents. The deinstitutionalization of patients in psychiatric facilities in the 1970s resulted in shifting many of the older patients to nursing homes. A study done in 1985 indicates that the number of residents in nursing homes increased 100 percent between 1969 and 1983. The substitution of nursing homes for psychiatric hospitals and community-based services has been of concern to many. There has been a fear that nursing homes are not providing the type of "active treatment" that is needed to adequately care for those with mental disorders.

There is currently in place the requirement for prescreening potential nursing home residents in order to assure that those individuals with mental illness (MI)

or mental retardation (MR), who are not in need of nursing home care, are not admitted or at least do not stay very long in the nursing home setting. Ironically, even though this requirement is intended to ensure that the type of treatment needed by those with MR or MI is provided, the incapacity of most states to provide the "active treatment" suggests that those with MR and MI who are not allowed admission to nursing homes may be without services at all.

However, even with the prescreening requirement, there will continue to be residents in nursing homes who receive psychotropic drugs, primarily because individuals with Alzheimer's disease are excluded from those who cannot be admitted. A major reason for the use of psychotropic drugs in nursing homes is to treat behavior disorders that often accompany dementia. Common behaviors include screaming, wandering, sleep disturbances, and combativeness. In addition, there are many residents who experience episodes of depression, anxiety, and paranoia. It is not clear how many individuals with chronic schizophrenia or other psychoses will remain in nursing homes.

Nurses Play Major Role

Caring for residents with a mental disorder is a significant challenge to the nursing staff. The role of nursing is vital to the identification and documentation of mental disorders, as well as to the ongoing monitoring of individuals, whether on psychotropic drugs or not. Nurses should play a major role in the determination of the use of psychotropic medication.

Before discussing the role of the nursing staff, the factors that impact on the ability of staff to provide the type of care required must be acknowledged, otherwise, the nursing role falls within the realm of "fantasy land." Managing psychiatric disorders takes a considerable

amount of expertise and time. Most nurses in long term care, though they have had principles of psychiatric nursing in their basic nursing programs, have not had extensive training. In addition, many nurses in long term care completed their training years ago. Since that time, there have been significant changes to the approach to mental disorders.

Currently, most states have no requirement for continuing education, so that it is possible that many nurses are not aware of the new approaches or new drugs available to treat mental disorders. To further complicate the situation, most licensed nurses in nursing homes have either supervisory responsibility or are responsible for passing medications and doing treatments. There are few hours to spend in direct interactions with residents developing a therapeutic relationship. The nurse assistants, the least well trained of all the staff, are the ones who have the most contact and responsibility for direct resident care. Few facilities have the luxury of having experts in mental health available to all levels of staff to help in assessing and managing the psychiatric problems that are frequently encountered in nursing homes.

"Active Treatment" Not Reimbursable

Even though it has been recognized that a mental health expert could be of immense value in assisting staff to effectively care for residents with mental disorders, this is not recognized as a reimbursable cost. The regulations regarding prescreening for mental retardation and mental illness specifically state that even if a resident is determined to need nursing home care, but also needs "active treatment," the facility will have to provide the active treatment, but will not be reimbursed for the costs of this treatment.

Given these constraints, nursing staff continue to be the cornerstone of care for residents with mental disorders. Critical responsibilities fall in the domains of assessment and management. The nursing staff are best positioned to collect pretreatment data. Pretreatment data must include information about behaviors associated with the mental disorder that causes the resident or other residents discomfort. Precipitating factors, including environmental, interpersonal, and intrapsychic factors, should be identified.

In addition, the time of day, frequency, intensity, and duration of the behaviors, as well as any alleviating factors, should be noted. It is critical to the resident's welfare that alternatives to drug therapy be explored. If the information noted can be collected, alternative or concurrent treatment modalities can be developed.

If a decision is made to prescribe a psychotropic agent, the nursing staff must monitor the effects of the therapy. Evaluation should include targeting specific behaviors and then measuring the absence, presence, or frequency of these behaviors. The nurse must be aware of the potential side effects of drug therapy to be able to detect them, early on, as well as measures to decrease the risk of adverse side effects.

High Risk Factor in Residents

The elderly nursing home resident is at a high risk of developing an adverse reaction. Factors associated with a high rate of risk are polypharmacy, greater severity of disease, low weight, presence of multiple diseases, and hepatic and renal insufficiency. The most common side effects associated with psychotropic drug use include confusion, extapyramidal effects, arrhythmias, sedation, and postural hypotension. In addition, irreversible tardive dyskinesia is more common in the elderly than in younger populations. Also, the risk of falling and fracturing a hip is more likely in a resident taking hypnotic-anxiolytics, tricyclic antidepressants, and antipsychotic drugs.

Nursing's responsibility in managing the resident on psychotropic drugs is also to coordinate the care of physicians, social workers, family, and nursing staff. This entails accurately reflecting in the care plan details of treatment. Information must be communicated among health professionals to ensure the most appropriate care. Coordination of care will also include education. Education will primarily focus on the nurse assistant and family members, as well as on the resident. Licensed nurses will need to be explicit in requesting information concerning the resident's condition and response to treatment. Information about treatment plans will need to be consistently reinforced to the resident, family, and staff.

Care of the nursing home resident with a mental disorder who is receiving psychotropic drugs is challenging to all care providers. Basic principles of drug use, including starting at a minimum dose, monitoring the effects, using the minimal number of drugs, and stopping all unnecessary drugs, will help in delivering effective care to residents with mental disorders. Drug use has as its overall goal alleviation of symptoms and restoration of the resident to optimal functioning. The ultimate goal is to enhance the quality of life as perceived by the resident. ■

References available upon request.

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Improving Medication Prescribing and Utilization in the Nursing Home

Jerry H. Gurwitz, MD,*†‡ Stephen B. Soumerai, ScD,*§ and Jerry Avorn, MD*†‡

There is ample and compelling evidence to suggest that medications are frequently used inappropriately in the nursing home. The occurrence of avoidable adverse drug reactions is the most serious consequence of inappropriate prescribing; economic implications are also of interest. With increasing concern over the quality of care in nursing homes, and with the revision of regulations governing such care by the Health Care Financing Administration, it is important to consider the experience thus far in monitoring and improving drug use in nursing homes. A number of studies have investigated approaches designed to reduce inappropriate prescribing and drug utilization in this setting. In contrast to the wide range of approaches that have been evaluated and implemented in the hospital setting, interventions in the nursing home have centered primarily around consultant-pharmacist

activities. Although these activities are now federally mandated in all nursing homes, there is little evidence from adequately controlled studies to document their impact or cost-effectiveness. By contrast, face-to-face educational interventions directed at physicians ("academic detailing") have been shown to be effective in improving prescribing for some medications. The prominent role played by the nursing staff in the utilization of many medications in the nursing home implies that an educational intervention excluding nursing staff would be insufficient to influence drug utilization positively in many situations (eg, psychoactive medications and laxatives). Future research efforts must pay greater attention to adequate study design considerations as well as to the clinical outcomes of such interventions and their cost-effectiveness. J Am Geriatr Soc 38:542-552, 1990

With the aging of the population and changes in the American family, nursing homes have taken on an increasingly prominent role in the medical care of disabled older people.¹ Since 1966 the proportion of those over 65 residing in nursing homes has risen from 2.5% to 5%.² The number of beds committed to nursing-home care in the United States exceeds the number of acute-care beds.³ Over 1.5 million Americans currently reside in nursing homes, nearly all of them older people.⁴ With the continuing demographic shifts that will take place in the United States over the coming decade, the number of institutionalized older people will rise to 2 million by the year 2000.⁵

Older people consume a larger number of drugs than other segments of the population.⁶ Nursing-home pa-

tients are among the heaviest of medication users⁶ and the utilization of drugs in this setting is coming under increasing scrutiny. With the coming implementation of new Health Care Financing Administration regulations for long-term-care facilities,^{7,8} it is crucial to evaluate the use of medications in the long-term-care population. The purpose of this paper is twofold: (1) to examine several issues surrounding medication use in the nursing home, including the evidence for excessive prescribing, the risks and consequences of adverse drug reactions, and factors contributing to inappropriate prescribing; and (2) to review critically the numerous studies that have investigated approaches for improving drug prescribing and utilization in the nursing home.

THE PROBLEM: OVERUSE, UNDERUSE, INAPPROPRIATE USE

In a review of nursing-home care, Rango noted that overuse of medications was "the most common error of commission."⁹ Polypharmacy is the rule rather than the exception in the nursing home. A 1976 study by the Office of Long Term Care based on a sample of 3,458 nursing-home patients reported an average of 6.1 drugs per patient with some patients receiving over 20 different medications.¹⁰ In a recent one-month audit of patterns of medication use among residents of 12 repre-

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sentative Massachusetts nursing homes, our group reported that the average number of medications prescribed per patient was 8.1.¹¹

Defining what "inappropriate" medication use is in the nursing-home context is not always straightforward. Ideal or acceptable treatment goals are often controversial or poorly understood (eg, in regard to hypercholesterolemia), and what is "appropriate" for a middle-aged patient may be undesirable for the frail older person. Despite these caveats, there is still compelling evidence to suggest that medications are frequently used inappropriately in many nursing homes.

In a 1980 study that reviewed Medicaid patients residing in Tennessee nursing homes, Ray et al¹² reported that 43% received antipsychotic drugs. As nursing-home practice size increased, doctors were found to prescribe more antipsychotic medication per patient. A greater amount of medication was also prescribed per patient in larger nursing homes, suggesting that these drugs were being used excessively as a behavioral management or "crowd control" strategy rather than therapeutically. Similar high levels of psychoactive drug use in nursing homes have been reported in other studies.^{10,11,13,14} An Institute of Medicine report on improving the quality of care in nursing homes likewise concluded that excessive use of tranquilizers and antipsychotic drugs provided evidence of poor quality of care.¹⁵

Problems have also been found for a number of other drug classes. Sherman et al described patterns of cimetidine use in a survey of 3,032 nursing-home patients, reporting that prescribing indications appeared unjustified in 90% of patients receiving this drug.¹⁶ In the case of another widely prescribed medication, the medical literature has suggested that many patients are on maintenance digoxin therapy unnecessarily, and may be withdrawn without detriment.¹⁷⁻²⁴ The Office of Long Term Care study of physicians' drug-prescribing patterns in skilled nursing facilities reported that nearly one quarter of sampled nursing-home patients had a prescription for digoxin,¹⁰ suggesting the possibility that in many cases this drug was being prescribed to nursing-home patients without continuing review or therapeutic benefit.

Antibiotics are another class of medication whose utilization in the long-term-care setting has been evaluated.²⁵ Systemic antibiotics are utilized by 8% to 16% of nursing-home patients at any one time.^{10,26-28} Based upon a review of 2,238 nursing-home patient records, Zimmer et al reported that documentation of the reasons for using an antibiotic was inadequate in 38% of cases,²⁷ and Jones et al reported that 51% of systemic antibiotic use was inappropriate or unjustified over a three-month period of observation in two Portland, Oregon, nursing homes.²⁹ A possible consequence of the excessive use of antibiotics is the development of increasingly virulent

bacterial strains, forcing reliance on potentially more toxic and expensive antibiotic regimens.

Underuse of potentially beneficial medications represents another kind of problem in nursing-home drug use. One example is the undertreatment of hypertension. There is now convincing evidence that the risks of untreated hypertension persist into old age.³⁰ More important, there is also evidence to suggest benefits from pharmacologic treatment of hypertension in older people.³¹ Yet there may be a reluctance on the part of many physicians to treat hypertension in institutionalized older people.

ADVERSE DRUG REACTIONS: RISKS AND CONSEQUENCES

The occurrence of avoidable adverse drug reactions is the most serious consequence of inappropriate drug prescribing in nursing homes. The risk of an adverse drug reaction increases substantially with the number of medications taken³² and probably with advancing age as well.³³ These two factors make the nursing-home patient particularly vulnerable. Supporting this conclusion are various studies that have suggested an association of medication use with a number of disorders prevalent in the institutionalized older population. These include cognitive impairment,³⁴ falls,³⁵⁻⁴¹ hip fractures,^{42,43} depression,^{44,45} and incontinence.^{46,47} Many of these adverse reactions may be unavoidable consequences of medications essential to the care of sick older patients, yet the numerous studies documenting the extent of inappropriate drug prescribing in nursing homes suggest that an important proportion may be due to poor pharmacotherapeutic decision making.

There are several reasons why older patients are particularly at risk for adverse drug reactions. An increase in the sensitivity to many commonly prescribed medications, notably the benzodiazepines, has been noted with increasing patient age.^{48,49} Important pathways of drug metabolism in the liver may be impaired in advanced age.⁵⁰ Due to age-related declines in renal function,⁵¹ drug excretion by the kidney may be considerably prolonged in older people. In addition, an age-related increase in body fat at the expense of muscle leads to a greater volume of distribution and drug half-life for highly lipid-soluble medications, further increasing the potential toxicity of usual drug dosages.⁵² Therefore, dosages of medications in older people often need to be reduced to protect patients from serious drug-induced complications.

A recent study suggests poor physician recognition of these critically important pharmacologic principles. In a study utilizing data obtained from patients filling prescriptions through the American Association of Retired Persons Pharmacy Service, Campion et al⁵³ observed that physicians frequently failed to adjust drug dosage for either advancing age or body weight. Because of the

strong inverse correlation between age and body weight, those patients receiving the highest drug doses, on a mg/kg basis, were also the oldest and at the greatest risk for the hazards of pharmacotherapy.

FACTORS CONTRIBUTING TO INAPPROPRIATE PRESCRIBING

Many factors contribute to inappropriate drug use in the nursing home. Training programs generally do not include formal training or experience in long-term care.⁵⁴ Which physicians provide care in nursing homes and how they provide this care are strongly affected by government reimbursement policies, particularly those of Medicaid. Such reimbursement for services in nursing homes is generally less than the usual and customary charges of physicians, which may impact on the care provided to the nursing-home patient as well as the quality of effort of physicians providing that care.⁵⁵ Physician visits to nursing-home patients tend to be infrequent and brief and are more often the result of regulations than of any specific medical event.⁵⁶ The general lack of organized medical staffs in nursing homes further impairs the ability to institute educational programs or to enforce standards of drug usage in this setting.

Because approximately 50% of all medication orders for nursing-home patients are written by the physician with directions for PRN administration,⁶ the nursing staff by default takes responsibility for a substantial proportion of prescribing decisions. In addition, the bulk of direct care for nursing-home patients is provided by nurses' aides who often have little experience or formal training⁵⁷ and who are subject to high turnover rates. Current federal regulations allow nurses' aides to deliver all resident care in intermediate-care facilities without the supervision of a registered, licensed, or vocational nurse from 3 PM to 7 AM every day.¹³ Prescribing decisions by physicians are by necessity often based on clinical information provided by nurses' aides.

While physicians and nursing staff play key roles in drug prescribing and utilization in the nursing home, the expectations and demands of patients and their families must also be considered. The pressures exerted by patients and family members both for and against the prescribing of many medications can be enormous. Schwartz et al⁵⁸ studied the motivations behind physicians' prescribing decisions that were in contradiction to the scientific literature. They reported that "patient demand" was the most common reason cited by physicians for inappropriate prescribing. In the long-term facility, nurse/aide/family demand would have to be added to this list. A contextual factor of particular importance is the frequent inadequacy of staff, making it more likely that "chemical restraints" will be applied rather than interpersonal, nonpharmacologic solutions.

A number of additional factors may contribute to sub-

optimal medication prescribing to nursing-home patients. These include: failure to review medication orders frequently and critically; poor communication with the nursing staff and the pharmacist; lack of knowledge regarding the principles of geriatric pharmacology; a heavy reliance on pharmaceutical company advertising in therapeutic decision making⁵⁹; and an insulation from cost considerations in drug prescribing due to third-party coverage.

In the face of the many issues described above, a number of studies have investigated approaches designed to improve drug prescribing and utilization in the nursing home. This article critically reviews this literature in terms of the impact of various interventions on the use of medications in this setting.

All published studies of interventions to improve medication use in nursing homes were initially screened for review. The medical, pharmacy, public health, and social science literature was systematically searched with the aid of computer-assisted retrieval services including MEDLINE, the International Pharmaceutical Abstracts, the Health Planning and Administration Database, and Ageline. Only those studies that attempted to document changes in drug prescribing and/or utilization were included. The classifications of Campbell and Stanley⁶⁰ were used to describe the research designs employed in the various studies. Controlled trials, time-series studies, and one-group pretest-posttest studies were included for review. Studies were excluded if they described educational programs but presented no data, or simply reported physician attitudes or satisfaction with programs. Investigations focusing solely on regulatory interventions, such as formulary restrictions, were also excluded. Studies included in this review are summarized in Table 1.

APPROACHES TO IMPROVING DRUG PRESCRIBING AND UTILIZATION IN THE NURSING HOME

Controlled Trials Studies employing these research designs provide the opportunity to control for nonprogram influences in the evaluation of a particular nursing-home intervention. The comparability of the control group critically impacts on the ability to generalize from the results of such studies.

Two studies evaluated the impact on nursing-home prescribing of face-to-face educational visits to physicians by clinical pharmacists ("academic detailing"). In a randomized controlled trial, Soumerai and Avorn⁴¹ were able to track nursing-home drug use by 319 physicians in two states. They found a significant reduction (18%) in nursing-home prescribing of targeted drug categories (propoxyphene, peripheral/cerebral vasodilators, and cephalixin) by a group of physicians receiving two educational visits compared with a control group. This degree of prescribing change was comparable to

TABLE 1. INTERVENTION STUDIES TO IMPROVE MEDICATION PRESCRIBING AND UTILIZATION IN THE NURSING HOME

Investigators	Intervention	Design	Target Medications	Outcome Measures
Soumerai and Avorn ⁶¹	"Academic detailing"	Randomized controlled trial	Propoxyphene; cerebral vasodilators; cephalixin	Medication orders
Ray et al ⁶²	"Academic detailing"	Nonrandomized controlled trial	Antipsychotics	Medication orders
Hood et al ⁶³	Consultant pharmacist	Nonrandomized controlled trial	All	Medication orders
Williamson et al ⁶⁴	Consultant pharmacist	Nonrandomized controlled trial	Antihypertensives	Medication orders; blood pressure
Strandberg et al ⁶⁵	Consultant pharmacist	Time-series	All	Medication orders and doses
Young et al ⁶⁶	Consultant pharmacist	Time-series	All	Medication orders and doses
Cooper and Bagwell ⁶⁷	Consultant pharmacist	Pre-post	All	Medication orders
Cheung and Kayne ⁶⁸	Consultant pharmacist	Pre-post	All	Medication orders
Brodie et al ⁶⁹	Consultant pharmacist	Pre-post	All	Medication orders
Chrymko and Conrad ⁷⁰	Consultant pharmacist	Pre-post	All	Medication orders
Cooper ⁷¹	Consultant pharmacist	Pre-post	All	Medication orders
Elzarian et al ⁷²	In-service education	Pre-post	Laxatives	Medication orders and doses
Pink et al ⁷³	Consultant pharmacist	Pre-post	Digoxin	Medication orders
Cooper and Francisco ⁷⁴	Consultant pharmacist	Pre-post	Psychotropics	Medication orders
Wilcher and Cooper ⁷⁵	Consultant pharmacist	Pre-post	Analgesics	Medication orders
Tsai et al ⁷⁶	Consultant pharmacist	Pre-post	Iron supplements; vitamins	Medication orders

Pre-post, pretest-posttest.

that observed for the office-practice patients of these physicians.

This result is in marked contrast to a similar study reported by Ray et al,⁶² in which the investigators targeted antipsychotic medication prescribing in the nursing home. This study was not randomized by physician; instead, 50 physicians practicing in a single geographic area of Tennessee were compared with 150 control physicians from two other regions of Tennessee with practice settings and case mixes similar to those in the experimental group. The experimental group of physicians was specifically selected because they were the most frequent antipsychotic drug prescribers for Medicaid nursing-home patients. In this case, the face-to-face educational intervention by a "physician counselor" had no impact on the prescribing of antipsychotic medications.

In these two studies, the educational interventions involved direct contact only with the physician prescriber and not with the nursing staff of the nursing home. This suggests an important reason for these conflicting results. In the nursing home, nursing staff and aides play a prominent role in pharmacotherapeutic decision making, particularly in regard to antipsychotic drug use.³⁷ Nursing-staff input regarding the use of a specific analgesic (eg, propoxyphene), cerebral vasodilator, or antibiotic is less likely to be important.

Hood et al⁶³ documented the impact of a consultant-pharmacist on overall drug prescribing in a group of 40 nursing-home patients. The intervention consisted of pharmacist review of medication orders and the provision of recommendations regarding drug therapy to physicians and nurses. A group of 25 patients consisting of patients from another wing of the nursing home was

employed as a control group. Over a two-month period, an 11% reduction in the number of prescribed medications per study patient was observed ($P < 0.01$), whereas there was no observed change in prescribing for the control patients. No demographic or clinical information was presented regarding the comparability of the study and control groups.

Williamson et al⁴⁴ evaluated the impact of consultant pharmacist services on antihypertensive therapy of nursing-home patients in a 100-bed facility. The intervention included drug utilization review and communications to physicians through progress notes or by telephone when pharmacist review indicated inadequate blood pressure control or a potential adverse drug reaction. In the study group of 30 patients, the authors reported a significant increase ($P < .02$) in mean systolic blood pressure relative to preprogram levels (128 to 135 mmHg). In a nonrandom, poorly described control group of patients who were not receiving antihypertensive therapy, no change was noted in this measure. The authors interpreted these results as a positive effect of the program in that the risk for adverse hypotensive effects of antihypertensive therapy had been reduced. This is one of the very few studies to measure a clinical outcome (blood pressure) as part of an intervention to change prescribing practice, but the authors provided no documentation of any change in the frequency of adverse drug reactions following the intervention.

Time-Series Studies The essence of the time-series design is a frequently repeated periodic measurement in a group or individual, with introduction of an intervention into this time series of measurements. Although the studies discussed below do not entirely fulfill the criteria to allow the appropriate analysis of a time-series experiment, they have been categorized as such in light of their use of multiple observations over time to track program effects.

Strandberg et al⁴⁵ documented the effect of comprehensive pharmacist services in three nursing homes over an eight-year period. These services included medication-dispensing functions and clinical activities within the nursing homes. Medication records of a 10% sample of 4,004 patients were reviewed. A unique aspect of this study is its evaluation of the effects on drug prescribing and utilization of two separate interventions implemented in a staggered fashion. An automatic stop-order policy after 30 days was associated with essentially no change in mean number of prescribed drugs per patient, although it did lead to small but statistically significant reductions in number of medication doses administered per patient per month (8%; $P < .003$). The second intervention, involving drug-utilization review of the medication profiles of all patients plus written communications to physicians

and nursing staff, was associated with a 19% decrease in the number of prescription drugs ordered per patient per month and a 32% reduction in nonprescription drugs. In addition, a 15% reduction in prescription drug doses and a 44% reduction in nonprescription drug doses were found.

Young et al⁴⁶ monitored the effects of consultant pharmacist services on 25 randomly selected patients in a 177-bed nursing home. They observed a 30% decrease in the number of medications prescribed per patient and an 18% reduction in number of medication doses administered per patient compared with preintervention levels. These reductions were sustained over a subsequent five-month period of observation. This study was unique in presenting an adequate number of observation points to evaluate the effect of the intervention over time, albeit a relatively brief period of time.

The major strength of these two studies lies in their employment of the most relevant measure of drug utilization in the nursing home, the number of drug doses actually administered to patients.

One-Group Pretest-Posttest Design A number of reviewed studies utilized a simple one-group pretest-posttest design. Conclusions based on the results of such studies are open to question due to the lack of a control group, the limited number of observations, and the associated difficulties in controlling for confounding by factors extraneous to the intervention being studied. For example, in a hypothetical one-group pretest-posttest study designed to test the effectiveness of an educational intervention in reducing medication utilization, a reduction in drug use may reflect seasonal effects such as the end of an influenza epidemic rather than a successful educational program. Although the following studies all suffer from such drawbacks, they serve to provide an appreciation of the limitations of current research efforts.

Cooper and Bagwell⁴⁷ studied the impact of consultant-pharmacist services in a 116-bed nursing home over a one-year period. The program included pharmacist consultation services emphasizing drug utilization reviews and the development of procedures for communication with physicians and nursing staff regarding medication issues. The program was associated with a 34% decrease in the overall number of drugs prescribed per patient compared with preprogram levels (7.2 to 4.8 drugs prescribed per patient). Physician orders for PRN medications, which had accounted for half of all drugs prescribed in the nursing home, were reduced by 46% (3.9 to 2.1), whereas regularly scheduled drugs fell by only 19% (3.3 to 2.7). Unfortunately, the true impact of this program is uncertain due to the concurrent institution of stop-order policies for a variety of drug categories during the period of study. Further, it is not clear how

the reduction in orders for PRN drugs related to changes in medications actually administered, particularly if many "standing" orders were infrequently implemented before the intervention. In two very similar studies, Cheung and Kayne⁶⁸ and Brodie et al⁶⁹ reported reductions in prescriptions of 18% (6.8 to 5.6) and 32% (6.8 to 4.6), respectively, associated with the institution of drug-utilization review services.

In a variation on this theme, Chrymko and Conrad⁷⁰ described the effect of removing consultant-pharmacist services from long-term-care facilities. One year after the termination of the consultant pharmacist of a 21-bed facility, Chrymko and Conrad reported a 19% increase in the number of regularly scheduled medications prescribed per patient (3.7 to 4.4) and a 123% increase in the number of PRN medications prescribed per patient (0.8 to 1.8; $P < .01$). Combining both approaches, Cooper⁷¹ reported on the effect of initiation, termination, and restoration of consultant-pharmacist services in a 72-bed long-term-care facility. (The introduction of pharmacy consultant services at two different points in time was to meet federal regulations and to prevent the facility from being closed by state inspectors.) The termination of consultant-pharmacist services had come as the result of local physician pressure on the facility and resulted in a return to elevated preintervention drug prescribing levels within eight months. With each respective initiation of consultant-pharmacist services, which included stop-order policies, there was at least a 40% decrease in overall drug prescribing per patient (8.9 to 4.8 and 9.6 to 5.5, respectively; $P < .05$). The impact on the prescribing of PRN medications was considerable, with a reduction of at least 60% with each implementation of services (4.1 to 1.6 and 4.8 to 1.6, respectively). Reductions in the prescribing of regularly scheduled medications were more modest, at 19% and 33% (4.8 to 3.9 and 4.8 to 3.2, respectively). However, it is difficult to generalize from this experience to that of nursing homes not facing closure.

A number of the pretest - posttest studies determined the impact of consultant-pharmacist services on the utilization of a specific drug or drug class. Elzarian et al⁷² reported the results of an innovative educational program for nurses and physicians designed to reduce excessive laxative prescribing in a long-term-care facility. Over a 17-week study period, in-service educational programs regarding appropriate laxative use were provided first to nurses, then to physicians. This was followed by a memorandum from the director of nursing that supported and encouraged nursing staff to substitute bran for laxatives. Significant reductions in the prescribing of laxatives were noted in comparison with a preintervention period ($P < .001$), with physician orders to discontinue laxatives about twice as frequent as new laxative orders. At the conclusion of the study, the authors also observed a significant reduction in lax-

ative use and a halving of costs for laxatives per patient-day. These changes reflect nursing decisions as well as physician decisions, because laxatives are frequently prescribed on a PRN basis.

Pink et al⁷³ assessed the impact on digoxin use of drug-utilization review activities by a consultant pharmacist in a nursing home. The consultant pharmacist recommended discontinuation of digoxin if no history of a diagnosis requiring its use could be found or when a patient was asymptomatic while on subtherapeutic doses of digoxin. The authors observed an increase in the number of digoxin discontinuations per patient-month over a two-year period during which consultant-pharmacist services were in place (0.67 per patient-month) relative to a two-year comparison period before the institution of these services (0.29 per patient-month). The authors concluded that the observed increase in digoxin discontinuations relative to a preintervention comparison period implied an improvement in drug utilization and patient care. However, clinical information regarding the cardiac status of patients whose digoxin was discontinued was not presented.

Cooper and Francisco⁷⁴ examined changes in psychotropic drug-prescribing patterns and reported that the percentage of the nursing-home population prescribed psychotropic medications on either a regularly scheduled or PRN basis decreased from 90% to 36% over the study period, and that the average number of prescribed psychotropic medications per patient was reduced by 31% (1.6 to 1.1). Data regarding the actual consumption of medications by patients were not provided. More worrisome results were reported by Wilcher and Cooper,⁷⁵ who observed an overall increase in the prescribing of regularly scheduled and PRN analgesic drugs, including propoxyphene after an intervention designed to encourage aspirin or acetaminophen use in preference to propoxyphene.

One particular study raises concerns about the implementation of interventions designed to improve prescribing where inaccurate information is conveyed to providers. Tsai et al⁷⁶ reported a 42% increase ($P < .02$) in the number of iron supplements and/or vitamins prescribed per nursing-home patient (0.7 to 1.2) resulting from the institution of consultant-pharmacist services. Although the authors suggested clinical improvements resulted from the program as reflected in mean hemoglobin levels, clinical data presented were inadequate to conclude that the reported increase in iron supplement and vitamin use represented any improvement in the quality of patient care. Most important, it appears that the consultant pharmacist recommended iron supplements in clinical settings such as anemia of chronic disease, anemia associated with chronic renal failure, and anemia associated with malignancies, where supplementation with iron is not indicated unless there is an accompanying iron deficiency anemia.

DISCUSSION

Drugs are often indispensable in the medical care of older nursing-home patients; the inappropriate use of drugs in this setting is of great concern, however. Medications can become a substitute for careful diagnostic maneuvers and/or effective nonpharmacologic therapies, thus increasing the risk of serious adverse drug reactions in this already vulnerable population. In an era of cost containment and rising drug costs, the overuse of medications can also divert resources from more important purposes.

In view of the federally mandated consultant-pharmacist requirements in nursing homes,^{77,78} it is not surprising that the vast majority of studies discussed in this review have centered around clinical pharmacist services and drug-utilization review activities, a situation in contrast to the wide range of approaches to improving medication use that have been evaluated and implemented in the hospital setting.⁷⁹ Despite the relatively small size and limited breadth of this literature, it is important to comment on the experience thus far regarding efforts to improve drug utilization and prescribing in the nursing-home setting. Only through such a critical review will more efficient and effective interventions be developed.

Study Design Although it is generally accepted that well-designed clinical trials of pharmacologic interventions should serve as the basis for rational medication prescribing, health-care delivery interventions are rarely subjected to the same quality of evaluation. Of the many research designs employed in the reviewed literature, only one⁸¹ utilized an adequate control group. Because it is frequently impractical or impossible to construct an appropriate control group in such studies, careful collection and analysis of multiple observations at several time periods before and after the initiation of an intervention (the time-series design) can serve as a useful alternative to increase the validity of conclusions about program effects. None of the reviewed studies met the true definition of a time-series design.

Furthermore, the intervention being tested should be implemented in such a way that the influence of extraneous factors on the measured outcomes of interest is minimized. When an educational intervention is employed in the setting of concurrently instituted regulatory policies regarding drug prescribing, it becomes difficult to sort out the influence of each independent of the other. If lessons are to be drawn from studies dealing with nonregulatory approaches to improving drug prescribing and utilization in the nursing-home setting, then this differentiation is crucial.

Finally, the "active ingredient" of the intervention must be clearly defined. For example, the term "drug-utilization review" can mean different things, from a simple review of the physician order book to make cer-

tain that regulatory policies are being enforced, to scheduled face-to-face interactions, using sophisticated educational protocols, with medical and nursing staff.

Until the last few decades, evaluation of clinical interventions was frequently done without the benefit of adequately designed trials. Such approaches gave rise to the widespread use of leeches, gastric freezing, internal mammary artery ligation, and numerous other therapies now known to be useless. Health-services research must make the transition into a more mature mode of investigation if it is not to replicate similar misleading findings.

Measures of Outcome The reviewed studies utilized a variety of outcome measures to evaluate the impact of particular interventions. These included: (1) prescribing by physicians practicing in the nursing home; (2) drug utilization by nursing home patients; (3) economic outcomes; and (4) outcomes involving specific clinical issues.

Drug-Prescribing Behavior Factors involved in prescribing in the nursing home are more complex than in either the acute-care hospital or outpatient settings, where physicians are the predominant decisionmakers. In the nursing home, influence by nurses and nurses' aides regarding pharmacotherapeutic decisions is substantial. The reasons for this include infrequent physician visits to the nursing home, a large number of PRN orders, and the frequent problem of understaffing. In the case of psychoactive drug use, staffing problems have been suggested as encouraging the administration of antipsychotic medications for behavioral problems in preference to personell-intensive interventions.^{12,80}

Three of the reviewed studies reflect the contribution of nursing-staff decision making to drug prescribing and utilization in this setting. Ray et al.⁶² demonstrated that the provision to physicians alone of face-to-face education about antipsychotic medication use was ineffective in reducing prescribing. In contrast, the study by Elzarian et al.,⁷² which specifically addressed nursing practice in addition to physician prescribing of laxatives, resulted in substantial reductions in target drug prescribing and utilization. Soumerai and Avorn⁸¹ reported a reduction in physician prescribing to nursing-home patients of targeted analgesics, antibiotics, and vasodilators using an intervention directed *only* to physicians.

Whereas decisions to employ laxatives for constipation or PRN antipsychotics for behavioral problems in the nursing home involve substantial input from nursing staff, the use of a specific pain medication (propoxyphene) or specific antibiotic (cephalexin) may not. Therefore, the proper targeting of interventions to nurses, physicians, or both is critically dependent on the drug being used and its clinical context. These observations provide one of the most important lessons of this review, which should be considered in the design of any

program targeting inappropriate prescribing and drug utilization in the nursing home.

Drug Utilization A number of studies have focused on changes in the number of medication orders as an assumed measure of actual drug utilization. As pointed out by Roberts,⁶ the interchangeable use of the terms "medication" and "prescription," and the imprecise meaning of the terms "prescribed medication" and "prescription medication" to describe outcomes in studies purporting to investigate changes in drug utilization, only serve to add ambiguity to the interpretation of results. When reported changes in medication "orders" include PRN medications, which many patients never use, any conclusions about the impact on actual drug utilization must be questioned. Reductions in PRN medications are often reported to comprise a large proportion of the favorable effect of an intervention. However, many PRN orders are never administered. In a study of 20 nursing homes in Indiana, Brown and DeSimone⁸¹ observed that 47% of patients did not use any of their prescribed PRN medications, and that an additional 40% used less than 10%. Beers et al reported that in 12 Massachusetts nursing homes, only 20% of PRN orders for psychoactive medications were actually administered.¹¹ Similar results have been reported by other investigators.^{6,10} For these reasons, any study that sets out to evaluate program effects on drug utilization in the nursing-home setting must present outcome data on doses of medication actually administered to patients.

In a recently published review concerning the impact of pharmacist drug-utilization reviews in long-term-care facilities, McGhan et al⁸² concluded that "with a very high degree of certainty, pharmacist drug-regimen reviews do exert a significant effect on drug use in long-term care facilities." The validity of this conclusion must be questioned: very few (3 of 15) of the reviewed studies reported outcomes in terms of medication actually administered to patients. In addition, only two of these studies utilized a control-group design, lending additional uncertainty to this conclusion.

For clinical relevance, the best outcome measure of drug use would be the presentation of data regarding utilization in terms of milligram equivalents of a reference compound to standardize doses across a given therapeutic class, stratifying within the class to describe differing pharmacologic properties. It also should be emphasized that an improvement in drug prescribing might involve a reduction in dose or a switch to a potentially safer medication in the same therapeutic class, rather than a drug discontinuation. For example, it has recently been reported that short elimination half-life benzodiazepines are less likely than long half-life benzodiazepines to increase the risk of falling for older patients.^{82,83} An improvement in drug prescribing represented by a pharmacotherapeutic switch consistent with

these reports might be obscured if data were presented only in terms of numbers of doses of hypnotic administered. Finally, it must be emphasized that utilization could also improve through the *addition* of a medication whose use was appropriate, but which was not being prescribed.

Economic Issues Programs designed to improve drug utilization and prescribing in the nursing home should also be evaluated in economic terms. Criteria for the evaluation of cost studies have been reviewed in depth elsewhere.^{84,85} Such economic evaluation should be comprised of a comparative analysis of at least two alternative programs in terms of both their costs and consequences. For example, a program that reduces the use of one drug but results in an unexpected switch in physician prescribing to a more costly medication must consider the costs resulting from this unanticipated use of an alternate therapy. On the other hand, an improvement in drug therapy that reduces patients' utilization of other more expensive resources (eg, acute hospitals) must also be considered. In ambulatory care, one group has documented that a program of face-to-face educational outreach for physicians regarding drug prescribing can achieve savings that are substantially higher than program costs.⁸⁶ Although more difficult, the completion of such analyses provides powerful evidence for administrators or policymakers who must evaluate such programs against others competing for scarce resources.

Although a recently published review of the literature regarding pharmacist-conducted drug-regimen reviews⁸⁷ suggested an impressive net savings of \$220 million nationwide if drug-regimen reviews were conducted for all Medicare and Medicaid patients in nursing homes, this conclusion cannot be supported by currently available data. The fact that the federally mandated consultant pharmacist often is an employee of the pharmacy or service that sells drugs to the nursing home has been poorly studied. Such potential conflict of interest poses important questions concerning the extent to which such consultants can reduce excessive or unnecessary costly drug use.

Clinical Outcomes Unfortunately, very few studies attempted to address the issue of clinical outcomes resulting from changes in drug utilization in nursing-home patients. Assessment of clinical outcomes is essential for the complete evaluation of any program designed to improve medication prescribing and drug utilization. Examples of important clinical outcomes might include (1) changes in the incidence of adverse drug effects (overall or specific reactions) after the implementation of a drug utilization review program; (2) changes in the cognitive, behavioral, and functional status of nursing-home patients associated with a program to improve prescribing of psychoactive medications; and (3) changes in the use of physical restraints in

association with an intervention designed to reduce sedative use. Such studies are more difficult to design and implement, and the problems of completing clinical research studies in the nursing-home setting have been well documented.^{88,89} Such studies require study populations of adequate size, randomly selected control groups or well-matched concurrent controls, rigorous definitions of the clinical outcomes of interest, and intensive patient assessments going beyond mere record review.

Analysis of Results All the studies reviewed above addressed an issue of health-care provider functioning, namely, the effect of a particular intervention on drug prescribing to nursing-home patients. Whiting-O'Keefe et al⁹⁰ described an analytic error that can arise when patient-related observations (eg, medications per patient per month) are employed as the unit of analysis to form conclusions about health-care provider behavior or outcomes affected by patients as well as by providers. The correct unit of analysis in such an experiment is the provider, and the hypothesis of the study should be constructed in terms of the true focus of the intervention, the provider and not the patient. This can often lead to a striking decrease in statistical power because the number of providers will be substantially less than the number of patients.

This analytic problem was encountered in a study by Thompson et al.⁹¹ These investigators described the results of a program involving clinical pharmacists as direct medication prescribers to nursing-home patients. Under the overall supervision of a physician, two pharmacists prescribed all medications to one half of the patients in a 152-bed nursing home. A control group comprised the remaining patients, who were cared for by a community-based internist. Whereas the outcomes utilized in the analysis were patient-specific ($n = 152$), the actual study population included only two pharmacists and one physician "control." When the correct unit of analysis is appreciated, problems regarding sample size become obvious. With only two exceptions,^{81,82} the reviewed studies focused inappropriately on the patient as the unit of analysis.

Implications for Future Research There are many dimensions to the challenge of improving drug prescribing and utilization in the nursing home. Unfortunately, in this as in many areas in health policy, the federal government has mandated a nationwide program of consultant-pharmacist monitoring of medication use without evidence from adequately designed studies that such a requirement, when put into place universally, can be expected to accomplish its goals. Of particular concern is the issue of clinically irrelevant "paper compliance" to satisfy regulatory requirements, in the absence of genuine improvements in medication prescribing and utilization.

From those few studies that satisfied minimal research design criteria, certain tentative conclusions can be drawn:

1. Although individual pharmacists can be of great value in advising physicians about drug regimens in the nursing home, little evidence currently exists with which to evaluate the effectiveness of the current federally mandated program of drug-utilization review by consultant pharmacists.
2. Face-to-face educational interventions directed at physicians ("academic detailing") are effective in improving prescribing of selected medications to nursing-home patients, specifically those medication categories where nursing input into the pharmacotherapeutic decision is limited.
3. The prominent role played by the nursing staff in the utilization of many medications in this setting suggests that an educational intervention excluding nursing staff would be insufficient to influence drug prescribing and utilization in many situations (eg, psychoactive medications and laxatives).
4. Because of the high frequency of "as needed" orders in nursing homes, many of which are never administered, any study designed to evaluate the true impact of an intervention on drug utilization must provide data concerning doses of medication administered to patients rather than merely "ordered."
5. Greater attention must be paid to the clinical and economic outcomes of such interventions.

New methods for improving drug prescribing and utilization must be developed and tested. For example, computer-assisted feedback of therapeutic decisions has been shown to be effective in improving care in the ambulatory setting.⁹² The technology is readily available to incorporate such a strategy into the nursing-home setting. However, widespread implementation of any new intervention must be preceded by careful evaluation according to rigorous standards of health-services research, particularly in this vulnerable population.

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Managing Behavior Problems in Nursing Homes

This issue of *JAMA* contains two disquieting articles on the use of neuroleptics and mechanical restraints in nursing homes. These articles have a special timeliness because of a growing movement, embodied in recent Health Care Financing Administration (HCFA)' regulations, to transform nursing homes into rehabilitative environments that promote individualized care and the highest practical levels of functioning and independence. A major objective of this movement is to limit the use of medication and mechanical restraints to purposes of medical treatment.

See also pp 463 and 468.

For 15 years, evidence has been accumulating that nursing home residents receive more psychotropic drugs, especially neuroleptics, than is easily explained by good medical practice.^{1,2} Garrard et al³ confirm previous evidence that the prescribing of neuroleptic drugs is widespread (not news) and show that the reasons for such prescribing are poorly documented (a new finding). Specifically, only half of the neuroleptic therapy used in the study of Garrard and colleagues was for management of either a major psychiatric disorder or specific behavioral manifestations of dementia. When neuroleptics are used for purposes other than medical conditions for which they are effective, that use is inappropriate and there is strong reason to suspect that the neuroleptics are being used as chemical restraints rather than as medical treatments.

Garrard et al could not test whether the prescribing of neuroleptics met other HCFA rules, which restrict neuroleptic use on an as-needed basis and require systematic efforts to reduce the dose and to replace neuroleptics with behavioral programming and environmental modification. These latter rules, however, were perceived as being more controversial by those who commented on the draft regulations and therefore seem more likely to be violated.

Prescribing psychotropic drugs without an appropriate psychiatric diagnosis is an established practice not only in nursing homes but also in the offices of primary care physicians, where the majority of psychotropic drugs are prescribed without a recorded diagnosis of mental disorder.⁴ Although some physicians may perceive the discrepancy as a

documentation issue, the nursing home record, like the hospital record, is a medium for communication, and quality of care is likely to suffer if a patient's major illnesses are not recorded.

There are at least four reasons to think that change in clinical practice may also be needed. First, nursing home staffs may induce inappropriate prescribing by asking physicians to control resident behavior such as wandering, combativeness, and the pulling out of intravenous and feeding tubing. There is good reason to fear, therefore, that psychotropic drugs in general, and neuroleptics in particular, may be used to sedate and incapacitate patients rather than as appropriate therapy for diagnosed mental disorders. Second, neuroleptics are not benign drugs and have serious side effects, especially in the disabled or frail elderly. Third, neuroleptics are not the treatment of choice for many conditions (eg, toxic drug effects, depression, loss of memory, and anger) that can produce troublesome behavior in nursing home residents. If an appropriate psychiatric diagnosis is not made, it seems likely that the differential diagnosis has not been adequately considered. Finally, neuroleptics, like other psychotropics, can increase disorientation and confusion when given inappropriately, and increased confusion can lead to a vicious cycle of increasing dosage.

We have already pointed out that unnecessary neuroleptic use suggests that these drugs are incapacitating rather than rehabilitating nursing home residents. Concerns are naturally even more intense regarding mechanical restraints because there are few, if any, medical indications for the persistent use of mechanical restraints. The use of mechanical restraints has serious side effects: they not only cause contractures, decubitus ulcers, incontinence, and all the other consequences of inactivity, but also often increase rather than reduce agitation. There is no real evidence that, on balance, use of restraints either reduces injury or improves behavior.⁵

Tinetti and colleagues⁶ confirm earlier reports (including HCFA data⁷) that use of physical restraints has high prevalence in nursing homes. They further report that restraints are usually applied to active residents for safety and behavioral reasons rather than to treat medical conditions. This pattern of restraint use appears to be in serious conflict both with the principle of maximum independence and with the new law, which establishes the nursing home resident's right to be free from any physical restraints imposed on him or her to reduce staff effort or impose discipline. Not only should restraints be limited to treating a resident's medical symptoms,

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but the treatment plan must carefully consider less restrictive measures and obtain specific informed consent from the resident, a family member, or a legal representative⁷; Tinetti et al provide no information regarding how well the latter criteria were met in the nursing homes they studied.

The HCFA regulations are part of a professional and social movement that seeks better functioning and greater dignity and freedom for nursing home residents. The challenge for attending physicians and nursing home medical directors is to replace mechanical restraints and unnecessary use of medication with social, behavioral, and medical interventions that will support their patients' basic rights. This means that the treatment team—physicians, nurses, and others—must evaluate the medical, social, and environmental causes of the troublesome behavior that leads to the use of restraints and employ less restrictive strategies such as environmental safeguards, increased interpersonal contact, steps to decrease disorientation, and behavioral therapy.

The HCFA regulations fundamentally envision the acceptable nursing home as one that achieves what has already been accomplished in a variety of settings. Over the past 20 years, behavioral treatment and social programming have revolutionized care of mentally retarded and developmentally disabled persons and allowed care in less restrictive settings. Nursing homes in Scotland and Sweden use mechanical restraints far less frequently than do nursing homes in this country.⁸ Psychiatric facilities have virtually eliminated the use of physical restraints except for emergencies. And a growing number of model nursing homes in this country have achieved remarkable changes.⁹ A number of states and nursing home associations are working toward these goals. Although the research base for managing behavior problems in the elderly remains distressingly meager, and further studies are urgently needed, there is a wealth of clinical experience on which to draw.

Physicians should therefore see the new regulations primarily as a mandate to adopt techniques that are available today to improve the care of patients who live in nursing homes. The regulations rest on a clinical reality that is sometimes forgotten: the use of neuroleptics and mechanical restraints is a clinical intervention. Clinical interventions should reflect both an understanding of the problem, expressed in a working diagnosis, and a considered choice among therapeutic alternatives. Attending physicians need to be able to make a clinically complete assessment of the causes of those troublesome behaviors that are currently being managed with inappropriate medication and mechanical restraints. They should also be familiar with the alternatives for managing such behavior. Nursing home medical directors have a special responsibility to ensure that their

staff members have the skills to manage behavior without restraints. Good clinical practice and respect for persons give nursing home residents a right to such care.

Some physicians will be unsure of their ability to reach an explanatory diagnosis for patients with behavioral problems. Some will be unsure of their ability to make the necessary comprehensive assessments. Many will be uncertain of the therapeutic alternatives to the use of restraints in dealing with troublesome behavior. Such uncertainties are natural because few physicians, including psychiatrists, are trained in managing troublesome behavior in the elderly, and the most helpful literature tends to be in journals and texts of nursing, geriatrics, mental retardation, and behavioral therapy. The solution is neither to substitute neuroleptics for physical restraints nor to seek out diagnoses that will justify unnecessary neuroleptic use. Rather, uncertainty is an indication for interdisciplinary planning, consultation, and continuing education. Few physicians would prescribe a cephalosporin or calcium channel blocker without at least a provisional diagnosis and knowledge of the therapeutic options; behavioral interventions deserve the same attention.

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NONPHARMACOLOGIC ALTERNATIVES To Chemical Restraints

THE SCENE IS ALL TOO FAMILIAR:

PATIENTS HARNESSSED TO THEIR WHEELCHAIRS, WRISTS

TETHERED TO BEDRAILS, LEGS AND ARMS STRAPPED TO

SIDE CHAIRS—OR THE EMPTY, EXPRESSIONLESS FACES

AND BLANK STARES OF PATIENTS HEAVILY SEDATED ON

MAJOR TRANQUILIZERS. AND ALL FOR WHAT?

JANICE L. FEINBERG

The dehumanizing treatment—exemplified by the overuse of physical and chemical restraints—once prevalent in the nation's nursing homes and committed in the name of resident safety, staff convenience, and avoidance of liability, have come under increasing scrutiny during the past few years. Finally—primarily through the efforts of watchdog and patient-advocacy groups—things are beginning to change for the better.

On October 1, the long-awaited Health Care Financing Administration (HCFA) nursing home regulations will implement the requirements of the 1987 Omnibus Budget Reconciliation Act (OBRA). The regulations state that the nursing home "resident has the right to be free from any physical

restraints imposed or psychoactive drug administered for purposes of discipline or convenience and not required to treat the resident's medical symptoms."

Antipsychotics are specifically addressed under Section 483.25, which specifies that the resident's drug regimen must be free from unnecessary drugs, and in the interpretive guidelines which sets out specific guidelines for their use (see Appendix I).

The success or failure of a facility in complying with the new requirements will depend, in large part, on how the consultant pharmacist responds to the challenge presented by the regulations. What should consultant pharmacists do to prepare their facilities for compliance with the regulations? What is the consultant pharmacist's role in achieving a re-

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duction in the use of chemical restraints in the facilities he serves?

Most important, are consultant pharmacists ready for the change in attitude and behavior necessary for entry into an area of practice—requiring increased involvement with residents and their behaviors—that they may not be prepared for?

The commitment required of the consultant pharmacist to successfully implement an alternative approach program may be frightening to many. This is one area of practice where answers cannot be readily found in pharmacy textbooks or literature.

Developing a Plan for Reducing Restraints

Many consultant pharmacists have garnered experience in developing programs and participating in identifying alternative approaches to the use of chemical restraints in the facilities they serve. However, many more consultant pharmacists may not currently be involved to the extent required for facilities to successfully comply with the new regulations. For those facilities without a plan to reduce the use of restraints, the work must begin immediately.

Any consultant pharmacist who

thinks that on October 1 he can go into a facility and recommend that a resident's psychotropic drugs be decreased or discontinued without significant negative repercussions is in for a surprise. "Without a cooperative, agreed-upon program, the consultant pharmacist can recommend until he's blue in the face," says Bob Williams of Institutional Pharmacy Consultants (IPAC), Portland, Oregon. "If there are no alternative approaches presented to the use of chemical restraints, the nursing staff will resist the consultant pharmacist's recommendations to decrease or discontinue anti-psychotic medications."

Consultant David Sherman of Health Care Visions, Inc., Westwood, Massachusetts, agrees: "The consultant pharmacist cannot expect the staff to seriously consider a recommendation to reduce a patient's psychotropic medication without also providing alternatives; this approach will backfire on the consultant every time."

The nursing staff may perceive any attempt to reduce the use of restraints as requiring additional nursing time—time not available under current staffing patterns. Overcoming this perception is one of the greatest challenges to any alternative approach program. These programs do not necessarily require additional staff, just a reallocation of staff time. Nursing time is saved if the residents' activities of daily living (ADLs) improve, since the residents are capable of more self-care, and require less assistance with their daily activities.

Where to Start

The IPAC consultant group is one of several that has been involved in reducing or eliminating the use of unnecessary antipsychotics in its facilities. According to Williams, the consultant pharmacist's major task is

to convince the facility staff to buy into a program of discontinuing or decreasing the dose of antipsychotic drugs in selected residents. IPAC consultant pharmacist Karen Rasmussen noted that none of the antipsychotic medication at first; they wanted the patient's behavior to remain under control. Rasmussen found that this resistance could be overcome through education and staff support.

Gamering Support

Any alternative approach program must have the complete support of the facility administrator, director of nursing, and medical director. If necessary, the consultant pharmacist must educate the facility's administration about the risks and problems associated with the inappropriate use of psychotropic drugs and the requirements of the new regulations. Additionally, resource material on alternative approaches to the use of restraints can be provided to get the administration to support a program aimed at reducing restraint use in the facility (see Appendix II).

Educating the Staff

The entire facility staff must be educated as well. In-service programs should be developed to educate the staff about alternative approaches to the use of chemical restraints, the existence of other causes of problem behaviors, and tips for working with demented patients (see Appendix III).

Proper training and emotional support must be provided to enable the staff to tolerate and respond appropriately to a broader range of potential problem behaviors once the use of restraints is reduced or discontinued.

Proper education and support of the physician staff is extremely important to the success of any program. Physicians should be kept abreast of the recent literature on both the prob-

lems associated with the use of psychotropics and alternatives to their use. If necessary, the consultant pharmacist should work one-on-one with resistant physicians to more effectively influence their prescribing behavior. Make sure that recommendations are based on improving patient care, not on the requirements of the regulations.

Developing Assessment Tools

The consultant pharmacist can assist in the development of assessment and monitoring tools for use by the staff to identify target behaviors and the success of different therapies or approaches used. This tool can be used to qualify and quantify a resident's behavior over time so trends can be identified and interventions evaluated.

David Sherman emphasizes the need to collect information—not just to comply with the regulations—but to enable the consultant pharmacist to make better educated decisions about the patient's care and to assess the appropriateness of the patient's therapy. For instance, in an agitated resident, "Specific information is needed about where and when a patient is becoming agitated to determine the cause and possible solutions to the problem behavior," says Sherman. "The consultant pharmacist cannot do this in isolation," he continues. "It must be a team effort involving the entire facility staff."

Sherman recommends using an assessment record that documents what is going on with the resident: when behavior happens and what the behavior is. Is the patient hungry, thirsty, restless, or bored? A log can be used to chart each time the resident has an episode of problem behavior. Does the behavior occur during the day or night? What is its relationship to meals or interactions with the staff or other residents?

"Baseline information on the resident's behavior must be available," says Sherman, "or you cannot know if the approach used is working." Consultant pharmacist-designed forms are already in use that require the nursing staff to document, by shift, each occurrence of specific, targeted behaviors, and any side effects of the drugs prescribed. The importance of this documentation may not be apparent to the nursing staff; it may be seen by nursing as just a lot more unnecessary paperwork. If the consultant pharmacist uses this information effectively to assess the resident's therapy and make the appropriate adjustments, the staff will come to appreciate the benefit of the documentation.

Initiating Dosage Reductions

The interpretive guidelines state that residents on antipsychotic drugs should receive gradual dose reductions, drug holidays, or behavioral programming in an effort to discontinue these medications, unless this course is clinically contraindicated. A step-by-step approach should be implemented to institute dose reduction or drug holiday programs (see Appendix IV).

The consultant pharmacist should not attempt to decrease or discontinue the use of psychotropics in all the residents at once. "There is a potential for consultant pharmacists to precipitate behavior problems by discontinuing antipsychotic medications," cautions Williams. "The nursing staff will ask, 'Now what?': the consultant pharmacist better be prepared to suggest alternative approaches to deal with the problem behaviors."

A systematic approach should be developed to initially select those patients most likely to respond positively to a psychotropic dose reduction or discontinuation. Here, says Rasmussen, the consultant pharmacist

can play a role in targeting which patients are appropriate for a decrease in dose or discontinuation of the drug. Williams adds that patients should be selected carefully: "A positive outcome will help bolster staff confidence in the program."

Whenever possible, the consultant pharmacist should ensure that antipsychotic therapy is not initiated unless clearly indicated. If a patient is admitted on an antipsychotic drug and an appropriate diagnosis is not indicated in the record, the physician should be required to document a diagnosis that justifies the use of the drug, or requested to discontinue the medication. If the attending physician was not the one who initiated psychotropic therapy and there is no apparent indication for its use, he is likely to discontinue the medication.

If a nurse requests that a patient be started on an antipsychotic to control a particular problem behavior, the consultant pharmacist should assess the patient's current therapy, assist in identifying environmental or other causes for the behavior, and participate in identifying alternative solutions to the problem.

The time invested by the consultant pharmacist and nursing staff up front to keep patients off psychotropic medication is less than what is required to monitor a patient once therapy has begun.

Reassure Staff

To help encourage the staff and to bolster confidence in the program, the consultant pharmacist must let the staff see that patient therapy will be individualized by not insisting that antipsychotics be discontinued in all patients. For some patients, appropriate therapy may well be an increase in dose. Williams found that, after assessment, 20 percent of the patients in one facility actually benefited from an increase in antipsychotic dose. In-

dividualized therapy reassures the staff that patients who need and benefit from drug therapy will continue to get it. "That realization helped the staff's comfort level," said Williams. "They felt we were enabling them to treat patients better."

"The consultant pharmacist better prepare the staff for the fact that [dose reduction] doesn't work on everybody," cautions Williams. "However, once the staff begins to see a positive response in a resident, they will buy in; success in a patient is a great staff motivator."

The consultant pharmacist has a lot to gain from his investment in a successful alternative approach program; once the staff has confidence in the program the nurses will be more likely to reinforce the consultant's recommendations with physicians. Without staff confidence and support, a consultant's attempts to decrease or eliminate the use of antipsychotics will be strongly resisted by nursing.

Assessing Problem Behavior

Antipsychotic drugs have frequently been used to treat agitation—a group of behaviors such as screaming, yelling, throwing objects, and resisting nursing care; patients who are verbally or physically abusive, or who exhibit socially inappropriate behavior; and residents who wander and are at risk for leaving the facility grounds, disturbing other residents, or injuring themselves.

The interpretive guidelines do not recognize these behaviors as appropriate indications for antipsychotic drugs (see Appendix V). Many of these behavioral symptoms are found in dementia patients; they may arise from the resident's response to his environment and an awareness of his cognitive defects.

Even in dementia, the causes of these behaviors are frequently identifiable and treatable without the use of

medication. The goal is quite simply to attempt to identify the problem causing the behavior and to eliminate it.

Understanding and Identifying the Source of Behavior

Is there a specific problem causing or triggering the behavior? Difficult behavior may be a manifestation of illness, pain, physical discomfort, confusion, interpersonal conflict, lifestyle, noise, grief, loneliness, fear, and other feelings that the resident may be unable to express in conventional ways.

Frequently what is labeled "problematic" behavior may in fact be caused by the facility's resistance to meeting the individual needs of the resident. Who is this person? What has been his lifetime pattern of living? What are his preferences in sleeping, eating, companions, dressing, and activities? What are the major events or losses in the resident's life? Who are the people most important to the resident? Is it reasonable to expect that all residents can be successfully treated alike? Should all residents be expected to wake up, eat, relax, and sleep at the same time?

Is it surprising that a person who spent his life as a night watchman should be found wandering around the facility during the night shift? Or that an elementary school teacher is heard giving orders to other residents to "sit down," "stop talking," or "go back to your seat"?

An inadequately trained staff can exacerbate behavior problems, especially in the demented resident. "Anything the consultant pharmacist can do to get the facility staff to be more sensitive to the needs of the demented elderly," says Sherman, "will help the process."

The consultant pharmacist can play a role in helping facility personnel to recognize the source of problem behavior instead of thinking that the resident is the problem.

Identifying Alternative Approaches

The consultant pharmacist can participate in the identification of alternative approaches to the use of medication to control problem behaviors. Be prepared for the administration or nursing staff to argue that staffing patterns or shortages do not allow for the development of alternative approaches. Overcoming this resistance may be the most crucial role for staff education. Though the number of staff available may be an impediment to the use of many one-on-one interventions, there are other, less staff-intensive approaches that can be tried.

"In addition to encouraging appropriate antipsychotic drug therapy, one of our responsibilities as consultant pharmacists is to provide direction regarding alternatives to drugs for problem behaviors," says Sherman. "The consultant pharmacist should not feel he is expected or required to come up with all the ideas to solve a problem," he continues. "But he can help facilitate the development of creative ideas among the facility staff."

Behavior Management Programs

With the cooperation and participation of the entire facility staff, an individualized behavior management program can be designed for each resident. What is most important to remember is there is no one right solution for each resident or situation and what works may change over time. It is just as important for the consultant pharmacist to realize that it takes a different approach for each resident.

"The whole process of developing alternative approaches and fostering creativity is so important to the success of a program," says Sherman.

"Consultant pharmacists have a unique perspective that can help the

An alternative program to reduce the use of restraints requires a multidisciplinary team effort to determine the source of problem behavior and identify nondrug alternatives.

long-term care facility staff develop creative ideas to deal with problem behaviors."

The value of ideas of the entire facility staff, including the nonprofessionals, must be recognized. Fostering a climate in which each person's ideas are given consideration will bring forth a wide array of suggestions for the benefit of the patient. "Staff members should not be made to feel that any idea is too radical or stupid," says Sherman. "Consultants can help develop that kind of atmosphere in the facility by working with the administrator and director of nursing to get the entire staff involved."

A successful behavior management program has many advantages over and above those that directly benefit the patient. An alternative approach program can create a more pleasant working and living environment, increase staff satisfaction and morale through improved quality of care and a team approach to problem solving, decrease staff turnover, decrease patient injuries resulting from the use of

psychoactive medication or the improper use of physical restraints, and increase patient morale and attitude.

Making It Work

An alternative program to reduce the use of restraints requires a multidisciplinary team effort to determine the source of problem behavior and identify nondrug alternatives. "The effective consultant pharmacist will lend his expertise in system development, implementation, and monitoring," says Dianne Tobias of HealthCare Network, Tustin, California. "He should assist in the development of an alternative approach program and serve as an educator and provider of resource information." However, Tobias contends that the facility cannot rely on the consultant pharmacist alone: "This cannot be a program that the consultant pharmacist sets up and does; the staff must be involved to carry the ball."

This sentiment is echoed by Sherman: "The consultant pharmacist should not feel he must be the one to develop the program, collect the

"The confused elderly have the right to skillful and thoughtful care. They have the right to be as free from physical and chemical restraints as is humanely possible. The staff that cares for these individuals has the right to supportive policies and helpful education and information. These four approaches provide a comprehensive way to deal with the complex problems of [the] wandering [or agitated resident]. They require a team approach and flexibility. They require staff education and commitment as well."

Radar J. A comprehensive staff approach to problem wandering. *Gerontologist*. 1987;27(6):756-760

data, interpret the results, and formulate solutions; he should act as a catalyst to the process by giving the facility and its staff the tools to do it."

The following examples of alternative approaches to the use of drugs for problem behaviors is most instructive and hopefully will show that staffing is not always an impediment to a successful behavior management program.

Case 1. A gentleman was chemically restrained at the end of every month because he would leave the home in great agitation. He was not restless, wandering, or agitated at any other time. A nurse's aide found that by walking outdoors with him at this time, he would briskly walk a couple of blocks, become fatigued, lose interest, and be willing to return to the facility. No restraints were used. When this was discussed with family members, they remembered that at the end of every month he always paid his bills by walking around the town and paying them in person. This gentleman was simply continuing a lifelong practice.¹

Case 2. A nurse's aide reported that a resident appeared agitated, a change from her usual behavior. A social worker was asked for an assessment and found that an adult child had died at this time of year 10 years

before. Without identifying the cause, that resident might have been restrained for agitation rather than talking out the problem and sharing her grief.²

Case 3. An 85-year-old woman spent most of her time in bed because she chose to do so. She used her cane on anyone who came within her reach. Staff removed the cane, bringing furious outbursts. Chemical restraints were considered. On assessment, a social worker discovered that staff were not respecting this woman's small amount of territory—her bed—and she protected it the only way she knew how. When staff were taught how to ask permission to assist her in her daily activities, the cane was no longer an issue nor were the use of chemical restraints.³

The importance of preserving choice, a sense of control, and autonomy for older people has been well documented.⁴ Efforts should be made to minimize this sense of loss for all residents.

Case 4. An ex-prize fighter entered a nursing home. He was in excellent physical health, but was agitated and suffered from dementia. He was a threat to both staff and residents and was restrained both chemically and physically. The activities professional assessed this individual and arranged

for him to go to a neighboring gym six days a week for a workout. After each workout he was relaxed and fatigued. Staff and residents no longer complained of his pugnacious behavior. Physical restraints were removed and chemical restraints were reduced to a very low level only on Sundays when the gym was closed. Although this is an extreme—but true—example, many nursing home residents are restrained for agitated or wandering behavior when a simple exercise program of walking outdoors often relieves the high energy level and provides satisfaction to the resident.⁵

Case 5. A nursing home resident created problems by his continued wandering into the parking lot. The staff was unable to supervise him adequately and were considering restraints. Only an assessment of a resident's customary and usual habits would reveal that this resident had been a car salesman. Pictures of the kind of car he used to sell were put up around his room; his wandering was then confined to his room where he walked around looking at the cars.⁶

Case 6. A patient was admitted for dementia and was particularly agitated when interacting with the staff. An assessment revealed that he had been a bank executive and was accustomed to being addressed as "Mr." Calling someone by his first name may be interpreted as disrespectful by some residents. Some behavior problems can be diminished if the time is taken to find out how the resident wants to be addressed or what he wants to be called.⁷

¹Source: National Citizens's Coalition for Nursing Home Reform
²Source: David Sherman
³Source: Joanne Hirschfield

⁴Autonomy in long-term care. *The Gerontologist* 1988; 28 (Suppl) 3-96

APPENDIX I**FEDERAL REGULATION AND INTERPRETIVE GUIDELINES APPLYING TO THE USE OF ANTIPSYCHOTIC MEDICATIONS**

Section 483.25 Level A requirement: Quality of care.

(1) Level B requirement: Drug Therapy.

(i) Unnecessary drugs. Each resident's drug regimen must be free from unnecessary drugs.

(2) Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that—

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, drug holidays or behavioral programming, unless clinically contraindicated in an effort to discontinue these drugs.

- Interpretive Guidelines—Guidance to Surveyors
- Psychoactive drugs are drugs prescribed to control mood, mental status, or behavior. Evaluate the use of psychoactive drugs under 483.25 (1), Drug Therapy.

APPENDIX II**ALTERNATIVES TO RESTRAINT USE****Underlying Principles for Reducing Restraint Use**

Resident Assessment. In-depth assessment of resident by interdisciplinary team including nurse; physician;

dietitian; social worker; pharmacist; occupational, physical, and speech therapist; and activities professional. Identification of strengths and weaknesses, including lifelong habits, daily routine, activities of daily living, mood, attitude, memory, communication, disease states, activities, and medications. Assessment is continuous and ongoing throughout the stay.

Individualized Care Plan. Plan based on strengths and deficits identified by assessment. Include resident and/or family or legal representative and nurse's aide in care-planning conference. The care plan must meet individualized resident needs and change as resident needs change.

Teamwork. No one person or discipline has all the answers. Ideas may come from professional or nonprofessional direct caregivers, indirect caregivers, volunteers, family, and other residents.

Options for Action to Avoid Restraint Use—General

- Companionship and supervision including the use of volunteers, family, friends, and other residents
- Physical and diversionary activity such as exercise, outdoor time, activities that resident would like to do, small jobs agreed to by the resident
- Psychosocial interventions including meeting lifelong habits and patterns of daily activity that must be incorporated into the care plan
- Environmental approaches such as alarms or other systems for keeping track of those who need to wander, using ribbon barriers on doors of resident rooms so wandering residents will not come in uninvited; good lighting; reduced glare; mattress on floor to reduce falls; the use of low beds; and individualized seating and furniture placed to aid in ambulation

- Meeting identified physical needs such as hunger, toileting, sleep, thirst, and exercise according to individual routine rather than facility routine
- Modifying staff attitude and training staff to identify resident needs and then meet them on an individualized basis
- Staffing levels high enough to comply with the law, which requires enough staff to meet residents' mental, physical, and psychosocial needs. Use heavier staffing during peak busy periods of the day
- Administrative support so that flexibility in routines is the norm in order to accommodate individual needs

Specific Programs for Reducing Restraint Use

- Restorative care program including walking, bowel and bladder, independent eating, dressing, and bathing
- Wheelchair management program to assure correct size is used and the condition of the chair remains intact
- Individualized seating program for those residents who do not need wheels for mobility. Chairs should be tailored, the same way as wheelchairs, to individual needs
- SERVE program (self-esteem, relaxation, vitality, and exercise), including fun, relaxation, stretching, range of motion, and walking
- Specialized programs for residents with dementia, designed to increase their quality of life during the day
- Video visits—videotaped family visits when families live far away
- Outdoor program every morning and afternoon in nice weather. Two aides assigned to take care of residents using enclosed outdoor area
- Rehabilitation dining room to help residents increase mealtime skills and independence
- Wandering program to allow safe wandering while preserving the rights of others

- Preventive program for calming aggressive behaviors based on knowing the resident, preventing triggering or aggression, and using protective intervention as a last resort
- Enhancement project—a program to improve the quality of residents' lives, run by certified nursing assistants

Implementation of Program for Decreased Restraint Use

- Support of owner/operator Board of Directors to care for residents more humanely
- Support of professional caregiving staff who can be challenged to creatively think of new ways to identify and meet residents' needs
- Education for all staff on each person's role in decreasing restraint usage
- Allaying fears of families who have been taught that residents must be restrained for safety
- Closer involvement of social worker, activities director, pharmacist, various therapists, volunteers, and family
- Flexibility in staff use, including permanent staff assignments
- Remove easiest restraints first to have success

Source: National Citizens Coalition for Nursing Home Reform.
Reprinted with permission.
An informational packet on restraints, describing the above information in more detail, is available for \$20. Contact: NCCNHR, 1424 16th Street, N.W., Washington, DC 20036, 202-797-0657.

APPENDIX III

DEALING WITH DEMENTIA PATIENTS

1. Determine if there is a physiologic cause for the resident's behavior such as hunger, thirst, pain, or discomfort.
2. Evaluate the resident's environment at the time of the problem behavior.

i.e., the placement of his room and its proximity to noise or activity.

3. Train staff to interact and communicate appropriately with demented patients.

- Be patient; do not taunt patient or overreact to problem behavior.
- Talk softly and gently.
- Explain things slowly and clearly.
- Physically interact with the patient at his level; do not tower over him.

- Be conscious of body language.
- Make eye contact when communicating.

- Use nonverbal gestures to communicate if unable to explain things verbally; point or show resident what is being referred to.

- Use simple commands; do not get into a major discussion since it gives the resident the opportunity to argue.

- Do not presume that what is occurring is a problem.

- Do not surprise the resident by approaching suddenly or from the rear.

- Demented persons are easy to distract; change subject or redirect behavior.

- People are more likely to get agitated when they are restless or bored; keep them busy by providing activities such as toys that can be taken apart and reassembled. Remember that it is easier to prevent agitation than treat it.

4. The consultant pharmacist should evaluate if the behavior is induced by the resident's current drug therapy.

5. Use a team approach to identify alternatives to the use of restraints.

APPENDIX IV

APPROACH TO PSYCHOTROPIC DOSAGE REDUCTION

1. Check the resident's medical record for a diagnosis that justifies

the use of the antipsychotic drug.

2. Identify the "targeted" behavior problems that require treatment.
3. Evaluate the resident's current drug therapy as a possible cause of the problem behavior.
4. Determine if drug is having a negative effect on resident's activities of daily living or is associated with unacceptable side effects.
5. Target "as needed" (p.r.n.) drugs for discontinuation.
6. Observe, monitor, and document the frequency and severity of the targeted behaviors and any side effects of the medication.
7. Gradually reduce the dose of the antipsychotic, monitoring for behavior "breakthroughs."
8. Implement nondrug interventions.
9. Adjust drug dose based on patient response.
10. Attempt dose reduction approximately every six months.

APPENDIX V

INAPPROPRIATE INDICATIONS FOR THE USE OF ANTIPSYCHOTICS

The interpretive guidelines state that antipsychotic drugs should not be used if one or more of the following is/are the only indication:

- simple pacing
- wandering
- poor self care
- restlessness
- crying out, yelling, or screaming
- impaired memory
- anxiety
- depression
- insomnia
- unsociability
- indifference to surroundings
- fidgeting
- nervousness
- uncooperativeness
- any indication for which the order is on an "as needed" (PRN) basis.

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Research and Reviews

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The Prevalence and Management of Dementia and Other Psychiatric Disorders in Nursing Homes

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ABSTRACT. The prevalence of psychiatric disorders among new admissions to nursing homes is unknown. Such data are needed to estimate the psychiatric needs of this population. We report the prevalence of specific psychiatric disorders in 454 consecutive new nursing home admissions who were evaluated by psychiatrists and diagnosed according to the Diagnostic and Statistical Manual of Mental Disorders, third edition, revised. Eighty percent had a psychiatric disorder. The commonest were dementia syndromes (67.4%) and affective disorders (10%). Also, 40% of demented patients had additional psychiatric syndromes such as delusions or depression, and these patients constituted a distinct subgroup that predicted frequent use of restraints and neuroleptics, and the greatest consumption of nursing time. These data demonstrate that the majority of nursing home residents have psychiatric disorders on admission, and that their management is often quite restrictive. Research is now needed to determine the best methods of treatment for nursing home patients with mental disorders.

In the United States 1.5 million elderly persons are currently in nursing homes, and their number will double in the next 30 years (Institute of Medicine, 1986). Their need for psychiatric care is uncertain because of insufficient research on the prevalence of psychiatric disorders in this setting (Rovner, Kafonek, Filipp, Lucas, & Folstein, 1986). Few large systematic studies examining patients have been conducted since Goldfarb's report (1962), which found that 87% of nursing home patients had chronic brain syndrome, and that 33% were "psychotic." Recent surveys such as the 1985 National Nursing Home Survey (NNHS, National Center for Health Statistics, 1985) and the NNHS Pretest (Burns et al., 1988) have found that 63% of nursing home patients are cognitively impaired, and that 25% are depressed. Regarding behavior disorders such as agitation and combativeness, Zimmer, Watson, and Treat (1984) found that 64% of nursing home patients were behaviorally disturbed, and that most behaviorally disturbed patients were demented.

Cross-sectional studies such as these cannot reveal whether psychiatric or behavior disorders are the cause or the consequence of institutionalization. Furthermore, these surveys have relied on nonclinicians' reviews of nursing records and interviews with nursing staff rather than on psychiatrists' direct examination of patients; therefore, they have produced diagnoses of unknown reliability and validity. None has used current diagnostic terms such as those specified in the *Diagnostic and Statistical Manual of Mental Disorders*, third edition, revised (DSM-III-R) (American Psychiatric Association, 1987). Thus, no studies have been done on the prevalence of mental disorders among new admissions to nursing homes in which psychiatrists have examined large, systematically ascertained samples and made diagnoses according to modern diagnostic criteria.

Such data are needed because new federal legislation in the United States now requires that patients with mental disorders be excluded from nursing homes (House of Representatives, 1987). Effective January 1, 1989, the Nursing Home Reform provisions of the 1987 Omnibus Budget Reconciliation Act (OBRA) required states to screen nursing home admissions and current nursing home residents for mental disorders and need for psychiatric treatment. Those with mental disorders who need active treatment are to be discharged to mental facilities in the state.

The potential impact of the OBRA regulations is unknown, especially because the definitions of "mental disorder" and "active treatment" are unclear. The diagnosis of dementia, for example, is not considered a mental disorder even though it is classified as such by the DSM-III-R, and is often associated with depression, delusions, and behavioral disorders. In light of the new federal nursing home initiative and the need to determine the impact of mental disorders in nursing homes, we report the prevalence of the commonest psychiatric disorders, including dementia, in a large cohort of consecutive new nursing home admissions who were examined by psychiatrists. We also describe new associations between these disorders and nursing time, the use of restraints and neuroleptic medications, and participation in nursing home activity programs. The findings suggest that, currently, nursing homes function as ill-equipped psychiatric hospitals.

METHODS

The sample was drawn from consecutive new admissions to eight Baltimore-area proprietary nursing homes owned by Meridian Healthcare. Meridian, a private corporation that owns and operates 13 nursing homes in Maryland and 32 nursing homes nationwide, is the largest

nursing home chain in Maryland with more than 2,800 beds. Meridian and the Dementia Research Clinic of the Johns Hopkins Hospital established a collaborative relationship in 1983 allowing researchers at Hopkins to conduct epidemiologic studies and to develop new approaches to psychiatric care in this setting. The current project is a longitudinal study of new admissions to nursing homes examined by psychiatrists to determine the prevalence and incidence of mental disorders, and to evaluate their impact on patient adjustment during one year. This report focuses on the prevalence of mental disorders on admission.

The eight nursing homes were selected because of their proximity to the Johns Hopkins Hospital. All are licensed in Maryland as intermediate/skilled care facilities and range in size from 104 to 250 beds. Patients are admitted from the mainly white (81-94%) and middle-income communities surrounding each nursing home. The average sources of payment for nursing home care are private pay (45%), Medicare (2%), and Medical Assistance (53%). Meridian nurse staffing patterns are comparable to national norms (National Center for Health Statistics, 1985). National data also indicate that 75% of all nursing homes are proprietary, 75% are intermediate or intermediate/skilled, and that sources of payment are similar to Meridian homes (National Center for Health Statistics, 1985). Thus, the Meridian homes resemble other U.S. nursing homes in these characteristics.

From February 1987 until March 1988, 716 consecutive patients were admitted to the eight Meridian nursing homes. Eligible patients were those who had not resided in nursing homes in the preceding six months. This exclusion avoided the effect of recent nursing home exposure on current admission status. One hundred fifty-four cases (22.3%) were ineligible for this reason. They did not differ from eligible patients in age, race, or sex. Informed consent was obtained from both the nursing home resident and a responsible family member. In cognitively impaired residents, informed consent was obtained from the family member. Refusal to participate by either the resident or the family excluded the resident from study. Of the 562 eligible cases, 84 (15%) refused participation, and 24 (4%) were excluded because examinations were not completed at the time of admission. Thus, 454 (81% of the eligible cases) were enrolled. The age and race of patients who refused or were unexamined did not differ from those of enrolled cases, although males were slightly overrepresented among refusers.

Four sources of information were used to evaluate each case: a psychiatric examination conducted by a research psychiatrist; a nursing staff interview and a family interview conducted by a research assistant; and the review of medical records. The interviews with the patient, nursing staff, and family were conducted independently and within two weeks of each other. Demographic information, medical diagnoses, and the use of neuroleptic medications and restraints were obtained from nursing home records. Neuroleptic use referred to daily administration of a drug. Restraint data reflected utilization during the first month and, based on the distribution, was divided into use for more than or less than 15 days.

The psychiatric examination was conducted by one of four research psychiatrists using the Modified Present State Examination (MPSE). This is a semistructured clinical examination whose interrater reliability and validity have previously been demonstrated in patients with stroke and Alzheimer's disease (Robinson, Kubos, Starr, Rao, & Price, 1983; Rovner, Broadhead, Spencer, Carson, & Folstein, 1989). Cognition was measured using the Mini-Mental Status Examination (MMSE) (Folstein, Folstein, & McHugh, 1975). Diagnoses of dementia, delirium, affective disorder, and schizophrenia were made according to DSM-III-R criteria based on the symptoms elicited from the psychiatric examination, available medical

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records, and information from families. The diagnosis of dementia and depression was made in patients who met DSM-III-R criteria for major depression and dementia, and when it was impossible to determine which disorder was primary.

Three psychiatrists conducted the psychiatric examinations from February 1987 until November 1987, and two from November 1987 until March 1988. To assess interrater agreement on psychiatric diagnosis, eight nursing home patients who exhibited a variety of psychopathological symptoms were examined by one of the initial three research psychiatrists using the MPSE and MMSE with the other two psychiatrists present. These three psychiatrists then independently recorded their diagnoses. The generalized kappa was 0.89 (p less than .001) (Bartko & Carpenter, 1976). Interrater agreement was reassessed one year later between the two remaining psychiatrists and the kappa was 1.0.

The nursing staff interview was structured using the Psychogeriatric Dependency Rating Scale (PGDRS) (Wilkinson & Graham-White, 1980). This instrument assesses the orientation, behavior, and functional dependency of elderly institutionalized patients. The behaviors it assesses are disruptiveness, wandering tendencies, verbal aggression, physical aggression, resistance to caretaking efforts, demanding nature, restlessness, and noisiness. The interrater reliability and validity of the PGDRS have been demonstrated previously, and time-and-motion studies indicate that the Pearson correlation between total PGDRS score and nursing time is .90 (Davies & Goldberg, 1982). Thus, the PGDRS score can be used to determine the relative "nursing time requirement" of patients.

A patient's participation in recreational and social activities in the nursing home was assessed by asking nurses, "To the extent the patient is able, does he or she generally take part in group or organized activities that are offered here?" The family interview focused on the patient's past psychiatric and medical history, his or her behavior before admission, and the reason for admission. Possible reasons for admission included "behavior problems," "the primary caregiver was ill," and "need for specialized nursing care."

To test for differences in mean levels of continuous variables (age, MMSE scores, and PGDRS scores) between different diagnostic groups, a one-way analysis of variance was used. When significant differences were found between groups, Duncan's Multiple Range Test was used to test for pairwise differences between the means. To test for differences in proportions regarding categorical variables (sex, neuroleptics, restrained more than 50% of the time), a chi-square test was used. When significant differences between proportions were found, a normal-deviate or Z test was used to test for pairwise differences between the proportions corresponding to each diagnostic group. The level of significance for the multiple comparisons testing of these differences in means and proportions was adjusted using the Bonferroni method.

RESULTS

Table 1 compares the demographic characteristics and the chart diagnoses of the sample ($N = 454$) with data from the 1985 NNHS (Burns et al., 1988; National Center for Health Statistics, 1985). Compared with national averages, a larger proportion of the study sample was in the 75–84 year range, and fewer were older than 85 or younger than 65 years. Certain medical diagnoses such as cerebrovascular disease and malignant neoplasms appear more frequently in the study sample; however, for the most part, the frequencies of most medical conditions are quite similar.

TABLE 1. Demographic Characteristics and Chart Medical Diagnoses of Nursing Home Sample and Subjects in 1985 National Nursing Home Survey (NNHS)

Characteristic	Nursing Home Sample (N = 454)		1985 NNHS (N = 1.49 million)	
	n	(%)	n	(%)
Age (years)				
≤ 64	20	(4.4)	173,100	(11.6)
65 - 74	70	(15.4)	212,100	(14.2)
75 - 84	207	(45.6)	509,000	(34.1)
85 and older	157	(34.6)	597,300	(40.0)
Race				
White	429	(94.4)	1,374,600	(92.2)
Nonwhite	25	(5.6)	116,800	(7.8)
Sex				
Female	351	(77.3)	1,067,000	(71.5)
Male	103	(22.7)	423,800	(28.5)
<i>Chart medical diagnoses</i>				
Ischemic heart disease/congestive heart failure	150	(33.6)	504,400	(33.8)
Cerebrovascular disease	119	(26.6)	305,400	(20.5)
Arthritis	88	(19.7)	247,100	(16.6)
Fractures/injuries	82	(18.3)	277,100	(18.5)
Diabetes mellitus	48	(10.7)	175,700	(11.8)
Chronic obstructive pulmonary disease	48	(10.7)	106,000	(7.1)
Neoplasms	55	(12.3)	85,700	(5.7)
Gastrointestinal disease	57	(12.8)	190,000	(12.7)
Senile dementias	156	(34.9)	202,500	(29.9)
Other psychoses	34	(7.6)	152,200	(10.2)

Table 2 shows the prevalence of psychiatric disorders divided into four mutually exclusive diagnostic groups based on the presence and type of psychopathology:

1. Dementia complicated (DC): Patients with dementing disorders complicated by the co-occurrence of depression, delusions, or delirium (N equals 123, 27.1% of the entire sample; 40.2% of all demented patients).
2. Dementia only (DO): Patients with dementing disorders without delusions, depression, or delirium (N equals 183, 40.3%).
3. Other psychiatric disorders (OPD): Nondemented patients with affective disorders or schizophrenia (N equals 58, 12.8%).
4. No psychiatric disorder (NPD): Those without any disorder (N equals 90, 19.8%).

Overall, 364 new admissions (80.2%) had a psychiatric disorder according to the psychiatrists. The most common diagnosis was dementia (N equals 306, 67.4%). The most frequent etiology of dementia was primary degenerative dementia of the Alzheimer's type (N equals 172, 37.9% of the entire sample) followed by multiinfarct dementia (N equals 81, 17.8% of the entire sample). Other dementia syndromes included the dementia syndrome of depression, Parkinson's disease, and brain tumor. Of the nondemented patients (N equals 148, 32.6%), 58 (12.8% of the entire sample) had a psychiatric disorder such as an affective disorder (N equals 47, 10.4%) or schizophrenia (N equals 11, 2.4%).

TABLE 2. Prevalence of Dementia and Other Psychiatric Disorders in New Admissions to Nursing Homes (N = 454)

Diagnosis	n	%
<i>Dementias complicated by depression, delusions, or delirium</i>		
Primary degenerative dementia of the Alzheimer's type		
with delusions/hallucinations	43	9.5
with depression	7	1.5
with delirium	15	3.3
Multiinfarct dementia		
with delusions/hallucinations	14	3.1
with depression	8	1.7
with delirium	14	3.1
Dementia plus depression	14	3.1
Other dementias		
with delusions/hallucinations	4	0.9
with delirium	4	0.9
Subtotal	(123)	(27.1)
<i>Dementia only</i>		
Primary degenerative dementia of Alzheimer's type	122	26.9
Multiinfarct dementia	59	13.0
Other dementias	2	0.4
Subtotal	(183)	(40.3)
<i>Other psychiatric disorders</i>		
Affective disorders	47	10.4
Schizophrenia/other	11	2.4
Subtotal	(58)	(12.8)
<i>No psychiatric disorder</i>	<u>90</u>	<u>19.8</u>
TOTAL	454	100.0

Table 3 compares the demographic characteristics, cognition (MMSE) score, "nursing time requirement" (PGDRS score), the use of neuroleptic medications, use of restraints, and participation in activities of patients in the four diagnostic groups. There were significant differences in age ($p < .001$), cognition (MMSE score) ($p < .001$), and "nursing time requirement" (PGDRS score) ($p < .001$) in the four groups. Multiple comparisons testing showed that DC and DO patients were older than nondemented patients (OPD and NPD), but not different from one another. As expected, demented patients (DC and DO) scored lower on the MMSE than nondemented patients, but no difference existed between the dementia groups. Regarding nursing time, DC patients had higher PGDRS scores than patients in all other groups owing to their cognitive impairment, greater functional dependency, and more frequent and severe behavior disorders. DO patients also required significantly more nursing time than OMD and NPD patients for similar reasons. OPD and NPD patients did not differ from one another.

Next we examined the use of neuroleptic medications, restraints, and participation in nursing home activities to relate psychiatric diagnosis to these forms of treatment and found significant differences in each of these variables between patients in the four diagnostic groups. Demented patients were the most frequently medicated with neuroleptics and physically restrained, and were least likely to participate in nursing home activity programs.

TABLE 3. Demographic and Selected Clinical Characteristics of Nursing Home Patients by Diagnostic Group

Group	N	%	Age ^a (Mean Years)	Sex F/M (%)	MMSE ^b Mean	PGDRS ^c Mean	Neuroleptics (%) ^d	% of Patients Restrained more than 50% of Time ^e	% Who Participate in Activities ^f
Dementia, complicated (DC)	123	27.1	81.1*	76/24	11.4*†	30.0*†‡	44.4*†	47.9*†	38.8†
Dementia only (DO)	183	40.3	82.6 [§]	73/27	13.2 [§]	24.4 [§]	34.0	40.6	37.0
Other psychiatric disorder (OPD)	58	12.8	77.5	78/22	23.0	18.4	24.1 [¶]	26.8 [¶]	34.5
No psychiatric disorder (NPD)	90	19.8	79.4	87/13	27.1	15.2	6.7	12.9	55.2
Total	454	100.0							

Note. MMSE = Mini-Mental Status Examination. PGDRS = Psychogeriatric Dependency Rating Scale.

^aANOVA $F [3,450] = 6.5, p < 0.001$. ^bANOVA $F [3,450] = 60.0, p < 0.001$. ^cANOVA $F [3,434] = 26.6, p < 0.001$. ^dChi-square = 39.3, $df = 3, p < 0.001$. ^eChi-square = 31.8, $df = 3, p < 0.001$. ^fChi-square = 9.7, $df = 3, p < 0.05$.

Multiple comparisons indicating significant differences only between groups at $p < .05$: [†]DC vs DO. [‡]DC vs OPD. [§]DC vs NPD. ^{||}DO vs OPD. [¶]OPD vs NPD.

We also compared the reasons family members gave for admitting their relative to nursing homes by diagnostic group. For DC patients, "behavior problems that disrupted the household" was the most common reason (37%). In contrast, "behavior problems" was the reason for only 24% of DO patients, 16% of OPD patients, and 8% of NPD patients. The most common reason for DO patients and NPD patients was that "the primary caregiver was ill" (39% and 49%, respectively). For OPD patients, "need for specialized nursing care" was the most common reason (40%) (χ^2 equals 32.6, $df = 9$, $p < .001$).

When we examined whether the high prevalence of mental disorders in this population reflected "transinstitutionalization" from state mental hospitals to nursing homes, we found that only 36 patients (8.5% of the entire sample) had ever been admitted to a psychiatric hospital during their lifetimes. We also examined the use of mental health services in the six months preceding nursing home placement and found that only 32 patients (7.5%) had been seen by a mental health specialist before institutionalization.

DISCUSSION

This is the first study of new admissions to nursing homes in which research psychiatrists have systematically examined each patient using instruments of known reliability and validity, and made psychiatric diagnoses according to modern diagnostic criteria. We found that most new admissions had a mental disorder. Although it was previously unknown whether these disorders were the result or cause of institutionalization, our data indicate that many mental disorders are present on admission and are sometimes the cause for admission. We also found that when psychiatrists examined patients, the rates of mental disorders were higher than those reported in previous surveys relying on nonclinicians reviewing nursing home records and higher than those diagnosed by nursing home physicians (Table 1). We believe that these latter methods cannot replace a psychiatrist's examination when a differential diagnosis of psychiatric disorders is sought. Conducting these examinations enabled us to determine the prevalence of specific psychiatric disorders and also to predict the amount and kind of care patients with different diagnoses receive.

The absence of national census data on new admissions limits the generalizability of this study. The only large data set available with which to compare our sample is the 1985 NNHS. This survey reflected the characteristics of a cross-sectional sample of nursing home patients who differ from a new admission cohort in that they have survived varying lengths of time in the nursing home. We think, nevertheless, that the comparison is reasonable because the demographic characteristics and medical diagnoses of the two samples are similar, and because most new admissions we studied will remain as long-term residents (Keeler, Kane, & Solomon, 1981).

The method we used to make psychiatric diagnoses was based, clinically, on a single patient examination. Thus, what appeared to be a pervasive depressed mood might actually have been a transient depressive reaction, and, in the case of dementia, patients who lacked complete medical and laboratory evaluations may have had reversible dementing disorders. Using similar clinical approaches in nursing, however, Parmelee, Katz, and Lawton (1989) found a 12.4% rate of major depression, and Chandler and Chandler (1988) found a 37% rate of probable Alzheimer's disease. The similarity between these figures and our own increases our confidence in the diagnostic accuracy of our method. Furthermore, we demonstrated significant associations between psychiatric diagnosis and other independently ascertained

clinical measures such as PGDRS scores and neuroleptic and restraint use, which support the validity of the diagnoses.

This is particularly true for the diagnosis of patients with dementia syndromes complicated by depression, delusions, or delirium, who represented a distinct subgroup of demented patients whose additional psychiatric symptoms predicted an increased demand for nursing time over and above all other patients. Because these patients have a primary diagnosis of dementia, however, they would not be designated as having a "mental disorder" according to the OBRA regulations and would not be excluded from the nursing home. Our data suggest that, nevertheless, they need psychiatric care. Not only are these patients the most time-consuming for nurses, they also are among the patients most frequently restrained, most likely medicated with neuroleptics, and least likely to participate in nursing home activity programs. Because fewer than 5% can be expected to receive psychiatric consultation, their potentially treatable psychiatric symptoms may go unrecognized (Borson, Liptzin, Ninninger, & Rabins, 1987). Thus, failing to recognize dementia as a mental disorder may perpetuate the lack of recognition and treatment of these disorders.

Effective treatment exists. Depression can be treated with antidepressants, delusions can be treated with judicious use of neuroleptics, delirium can be reversed with identification of its underlying cause, and behavior disorders can be minimized by providing structured daily activity programs (Lipowski, 1989; Reifler, Teri, Raskind, Veith, & Barnes, 1989; Reisberg, Borenstein, Salop, Farris, Franssen et al., 1987; Rovner, Smith, Lucas-Blaustein, & Folstein, 1990). Untreated, the course and outcome of these syndromes probably vary, but clearly they require differential use of resources. For example, an untreated depression or an unrecognized delirium will progressively worsen, with the patient becoming increasingly dependent on staff for assistance; and the delusional patient, acting on misperceptions of reality, may become combative and require daily restraints. In all cases, the morbidity from these untreated disorders places unnecessary suffering on patients and unnecessary burdens on family members and staff, and detracts from the quality of life in nursing homes.

Nursing staff, untrained in psychiatric skills, often respond to behavior disorders with the methods available to them, such as restraints and neuroleptic medications. Ray, Federspiel, and Schaffner (1980) reported that 43% of nursing home patients receive neuroleptics and indicated that such drugs are misused. Although neuroleptics are indicated for the treatment of delusions and hallucinations, we found that fewer than 14% of patients had these symptoms during their first weeks in the nursing home, yet more than 31% received these medications. This figure probably underestimates the total neuroleptic use because it does not include "p.r.n." neuroleptic administration. Neuroleptics can cause delirium, extrapyramidal syndromes, falls, hip fractures, and anticholinergic toxicity, and, according to Beers et al. (1988), the particular neuroleptic drug classes prescribed in nursing homes do not reflect current concepts in geriatric psychopharmacology. Our data support previous observations of their widespread and perhaps uncritical use and underscore the importance of findings associating these medications with excess morbidity in elderly patients (Larson, Kukull, Buchner, & Reifler, 1987; Ray, Griffin, Schaffner, Baugh, & Melton, 1987).

We also found that mechanical restraints were frequently used, and that their use could be predicted by psychiatric diagnosis. The frequency of their use is consistent with a recent HCFA report that indicates that 41.3% of nursing home patients are restrained (U.S. Department of Health and Human Services, 1988). Although the rationalizations for their use include prevention of injury and falls, more commonly they are used to control behavior (U.S. Congress, Office of Technology Assessment, 1987). Studies examining their use more often

report their adverse effects such as an increased risk of falls, greater functional dependency, decubitus ulcers, contractures, infections, and accidental death rather than their benefits (Evans & Strumpf, 1989). Yet restraining patients remains an acceptable standard of care, and in Maryland, nursing homes are reimbursed \$4.73 per day for the additional nursing time required to restrain a patient. Thus, the unfortunate reality is that nursing homes have little incentive to find alternative, less restrictive, and less debilitating approaches to care.

The 1986 Institute of Medicine report on nursing homes recognized that many nursing home patients do not receive appropriate mental health care (Institute of Medicine, 1986). To improve their care, the Nursing Home Reform Act of OBRA now requires the psychiatric assessment of new and continuing patients of nursing homes to determine their need for psychiatric treatment. In its current form, however, OBRA suffers two major limitations. First, dementia is not considered a mental disorder even though it is classified as such by the DSM-III-R; is often associated with depression, delusions, and behavioral disorders; and, as we have shown, is frequently managed with restraints and neuroleptics. Second, policy makers have failed to recognize that no reasonable alternative to nursing home care exists. Our data show that only 7.5% of patients were seen by a mental health worker before admission, indicating that use of existing community psychiatric resources before nursing home placement is rare. Furthermore, state mental hospitals are actively attempting to transfer their elderly patients to community nursing homes; in Massachusetts, for example, a strict new admission policy severely limits admission to psychiatric hospitals and specifically excludes patients with the diagnosis of Alzheimer's disease. Inescapably, no matter what definitions are used, the available resources and societal commitment to providing psychiatric care for nursing home patients, especially those with dementia, remain uncertain.

We are faced with two choices: either discharge mentally ill nursing home patients to other, often unavailable psychiatric facilities, or care for them in nursing homes by providing acceptable standards of psychiatric care. In the latter case, nursing homes should not be financially penalized by being labeled "institutes for mental disorders" and thus made ineligible for federal reimbursement under Medicare and Medicaid regulations. We believe that most of these patients do require institutionalization, perhaps in nursing homes, and that psychiatric care can be provided in an effective and affordable way. Clinical trials are needed to demonstrate this point, and one is currently under way (Rovner, B. W. "A Randomized Trial of Dementia Care in Nursing Homes"; RO1 MH 45293-01). Such studies are needed to guide the future nursing home care of psychiatric patients.

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RESEARCH & REPORTS

PSYCHOTROPIC DRUG MONITORING—A CALIFORNIA EXAMPLE

Dianne E. Tobias

Abstract The process of implementation of the 1982 California Psychotropic Regulation in a nursing home is described.

The role of the consultant pharmacist in aiding facilities meet the intent of the regulation is presented. The role is fourfold: education, development of systems, implementation, and ongoing monitoring.

The 1987 Omnibus Budget Reconciliation Act (OBRA) and the Health Care Financing Administration's (HCFA) federal regulations regarding psychotropics may differ from the standing California regulation in scope and content; however, the role of the pharmacist as a consultant in the implementation phase is similar. The discussion includes broad and specific ideas concerning the steps consultants can take toward developing drug policies, identifying the specific manifestations of behavior, employing a quantitative monitoring system, and using a form for a monthly summary.

When a facility approaches the regulations and policies with enthusiasm and dedication, the pharmacists and physicians are presented with meaningful information that allows for useful recommendations in drug therapy.

The Omnibus Budget Reconciliation Act of 1987 (OBRA 87) included numerous nursing home reform provisions, among them the requirement that long-term care facility residents be free of psychoactive drugs administered for purposes of convenience and not required to treat specific medical conditions. The Health Care Financing Administration (HCFA) developed definitive interpretive guidelines that should clarify the scope and enforcement of the OBRA 87 provisions (see the feature article in this issue of TCP for more information). The consultant pharmacist will undoubtedly have a great opportunity to participate in helping facilities meet the intent of these regulations.

California has had a chemical restraint regulation in effect since 1982. Consultant pharmacists saw the 1982 regulations as opportunity for involvement. Though the OBRA 87 federal regulations differ significantly from the 1982 California regulations, the consultant's role will be similar in the implementation process.

There was some confusion in 1982 when the California regulations went into effect. The regulation (Table 1) was specific in that it mandated monitoring of a group of drugs, and yet vague about the specific drugs involved and methods of monitoring.

A colleague and I, as independent consultants, developed a program to implement the 1982 California regulations in the facilities we provided consulting services. The program had four components: (1) education of facility personnel and physicians about the new regulations, (2) development of systems for facilities to use to meet the intent of the regulations, (3) aid in implementing the system, and (4) participation in ongoing monitoring of those systems. The last continues to be a part of our monthly consulting function. Approximately 60 facilities are currently using a facsimile of the program described. We were not the only consultant pharmacists to develop chemical restraint programs in California; in fact, many consultants participated in developing and implementing systems for their facilities.

The California Requirements

California's regulation states that for drugs used to treat disordered thought processes, the

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- (d) When drugs are used to restrain or control behavior or to treat a disordered thought process, the following shall apply
- (1) The specific behavior or manifestation of disordered thought process to be treated with the drug is identified in the patient's health record
 - (2) The plan of care for each patient specifies data to be collected for use in evaluating the effectiveness of the drugs and the occurrence of adverse reactions
 - (3) The data collected shall be made available to the prescriber in a consolidated manner at least monthly
 - (4) PRN orders for such drugs shall be subject to the requirements of this section.

Table 1. State of California Regulation on Psychotropic Monitoring (Title 22 (72319 (j)) 2-10-82)

Dear Doctor

New Title 22 regulations require that certain classes of behaviorally altering medications be monitored more carefully in Skilled Nursing Facilities.

Specifically, the following is required:

1. The specific behavior requiring treatment be identified.
2. Therapeutic objectives be established for each drug used and be included in the patient care plan.
3. Adverse reactions be identified and monitored, and
4. Data collected be summarized for the prescriber at least monthly in the nurse's progress notes.

Your patient is on _____ To fulfill this requirement, will you please identify the behavior(s) this medication was prescribed for in your progress notes.

Thank You,

Administrator

Dianne Tobias, Pharm D
Consultant Pharmacist

Figure 1. Letter to physicians placed on the charts of patients receiving psychotropic agents

ANTIDEPRESSANT MEDICATION

1. Administer antidepressant medication per physician's order.
2. Monitor and record episodes of behavior per psychotropic policy.
3. Observe for side effects (listed below); document occurrence of side effects per psychotropic policy.
4. Summarize effectiveness and side effect data monthly for physician per psychotropic policy.

ANTICHOLINERGIC

CARDIOVASCULAR

CENTRAL NERVOUS SYSTEM

FOR LESS COMMON SIDE EFFECTS, CONSULT ANY DRUG REFERENCE

5. List non-drug approaches to reduce behavior, if appropriate:

COMMON SIDE EFFECTS:

(dry mouth, urinary retention, constipation, blurred vision)
(postural hypotension, various arrhythmias, EKG changes)
(sedation, confusion, hallucinations, agitation)

facility must identify why the drug is given, devise a method to determine whether the drug is effective, and determine whether it is producing side effects. The last section requires that as needed (p.r.n.) orders be subject to the regulation. The vagueness of the regulation allowed great latitude to develop systems tailored to different facilities. At the time, we were unsure which drug classes would be covered by the regulation. The determining factor was the indication, if the drug was being used for disordered thought processes, it was to be included. For example, diphenhydramine would be included if prescribed for agitation, but not if it were used for pruritus. Generally, the antipsychotics, antidepressants, anti-anxiety agents, and lithium were included under this regulation if used for disordered thought processes. Recently, we have seen such drugs as propranolol and carbamazepine used to treat behavior disorders; they must be monitored under this chemical-restraint regulation.

Education

The first step was to educate the facility personnel. We described the regulations to medical directors, directors of nursing, and local chapters of the state nursing home association. Figure 1 illustrates the mechanism used to educate the physicians in a 300-bed facility. This letter was placed on the charts of patients receiving psychotropic agents, and the drugs requiring monitoring were listed. The goal was twofold: to educate the physician about the regulations and to ask the physician to specify the reason the drug was ordered. As a result, about 25% of the orders were discontinued. Upon reflection, the prescriber could not find an adequate reason for the drug. I would encourage consultants in other states to formally study antipsychotic drug usage before and after implementing the new federal regulations and to measure the impact on reducing antipsychotic drug usage.

Developing the System

A general system of psychotropic drug monitoring was developed and presented to the facilities, with specific options. We created four stickers (Figure 2) that contained a summary of the facility's psychotropic drug policy and listed the side effects of the drug category. The four categories were antipsychotic, antidepressant, anti-anxiety, and lithium. The stickers were designed to be placed in the resident's plan of care as an approach to the problem (i.e., behavior or diagnosis). Item number five (Figure 2) encourages the nurse to expand the use of non-drug modalities as additional approaches to the problem.

Next, we helped the facilities write specific psychotropic drug policies that would meet

Figure 2. Antidepressant Sticker

PROB #	PATIENT PROBLEMS/NEEDS	MEASURABLE AND TIME ORIENTED OBJECTIVES	APPROACHES/ACTIONS				R E S C P	D I A G N O S T I C	R E S T R I C T I O N S
1	Depression as 1. Crying outbursts 2. ↓ Eating/wt 3. Withdrawal from activities	1. Decrease outbursts 2. Stabilize wt 3. ↓ Interaction	1. Desyrel 100 mg hs <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p style="text-align: center;">ANTIDEPRESSANT MEDICATION</p> <p>1. Administer antidepressant medication per physician's order.</p> <p>2. Monitor and record responses of patients per physician's orders.</p> <p>3. Report to supervisor if adverse effects or changes in response to side effects per physician's orders.</p> <p>4. Supplemental information and side effect data monthly for physician per physician's orders.</p> <p style="text-align: center;">COMMON SIDE EFFECTS:</p> <p>ANTICHOLINERGIC (dry mouth, urinary retention, constipation, blurred vision)</p> <p>CARDIOVASCULAR (postural hypotension, vertigo, arrhythmias, EKG changes)</p> <p>CENTRAL NERVOUS SYSTEM (sedation, confusion, hallucinations, agitation)</p> <p>FOR LESS COMMON SIDE EFFECTS, CONSULT ANTI DRUG REFERENCE</p> <p>1. Let the doctor adjust the dose when appropriate.</p> </div>						
Name			First	Initial	Attending Physician	Room No.	Patient No.		

Figure 3. Patient Care Plan

the intent of the regulation. We took prototype policies into facilities and encouraged them to customize their own psychotropic drug policy. We also provided a chart classifying common drugs into the four psychotropic categories corresponding to the stickers.

BEHAVIOR. Once an order for a psychotropic drug was received, the nurse identified it as a psychotropic and incorporated the sticker and diagnosis or behavior into the plan of care. Because the regulation did not specify covered diagnoses, behaviors were acceptable and nurses could specify them in lieu of the physician. The goal was to have the staff or physician identify the specific manifestations of the behavior in question that were more easily measured and evaluated than the behaviors. Examples of manifestations of the behavior of depression include withdrawal from activities, crying, or weight loss. The drug order was entered in the care plan and the sticker affixed under approach (Figure 3). I have listed a dietary and activities consult under nondrug modalities as important approaches to this patient's depression.

DATA COLLECTION. The second criterion of the regulation was monitoring. We soon learned from the surveyors that they wanted a quantitative method of assessing the effectiveness of the drug therapy. Qualitative measurements were not acceptable. We needed a system that would document that the patient had 20 episodes of crying in October, but only 5 in November. To accomplish this, a monitoring statement was added to the physician's order sheet and medication-administration record (MAR) for any psychotropic order. An example for an antidepressant was to "monitor for episodes of crying every shift using tally marks." These episodes could thus be documented on the MAR and totaled at least monthly. Side effects could be incorporated into a similar statement for the medication sheet or listed in the nurse's notes.

The last part of the California regulation, regarding p.r.n. orders, required that the monitoring data be summarized monthly for the prescriber. We developed a monitoring form (Figure 4) for summarizing data for two drugs for one year or one drug for two years. The tally marks were totaled from the MAR and transferred onto this form. Facilities assigned completion of this form in various ways; most incorporated it into the nursing weekly summary for the first week of the following month (e.g., May's data were summarized the first week of June). The form was placed in the physician progress note section of the chart, making the data available to the prescriber and complying with the regulation. As needed (p.r.n.) orders could also be monitored with

this form. Some facilities chose not to incorporate a form but developed the same information on a rubber stamp that was stamped on the physician progress notes. Consultant pharmacists could use this monitoring information to assess drug therapy and make useful recommendations. For instance, drug tapering might be considered if the behavior manifestations had decreased significantly. Conversely, dosage schedule changes might be recommended if monitoring data showed increased behavior episodes at specific times.

Implementation

Implementation of the psychotropic system involved discussions with facility management personnel, then adoption of the system, and, finally, in-service education. Two general in-service programs were developed: a pharmacologically oriented session describing differences in the indications, mechanisms, side effects, and monitoring of the four general classes of psychotropics; and a psychotropic monitoring program describing the facility's policy, including the use of stickers and forms. Both in-service programs could be repeated as personnel changed.

Monitoring

Our consulting system generally follows the quality assurance model, measuring a facility's performance in the broad category of the drug-delivery system. How close did the performance come to the standards, and what were the recommendations for improved performance? The assessment of psychotropic monitoring performance adapts well to this quality assurance model and was included in our monthly review.

Conclusion

Some of the problems encountered after six years include: nurses assigning nonspecific behaviors, failure to recognize new orders as psychotropics that need to be monitored, nonquantitative monitoring, and less-than-meaningful data. When a facility approaches the regulations and policies with enthusiasm and dedication, the pharmacists and physicians are presented with meaningful information that allows for useful recommendations in drug therapy.

Although state and federal psychotropic regulations may differ, the effective role of the consultant pharmacist in implementing the regulations is similar. By following the four-step process outlined in this article (education, development, implementation, and monitoring), consultant pharmacists can play a vital role in assuring compliance with new programs and regulations as they evolve.

Why Better Pharmacy Services Are Needed in Residential Care Facilities

An increasing number of elderly and chronically ill or functionally impaired Americans find themselves using residential care facilities to maintain a semi-independent lifestyle outside of nursing homes.

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Long-term care differs from acute care in the needs it meets and how they are addressed. The elderly live with great anxiety and even fear about whether they will be able to select and afford the long-term care facility that is best suited to their needs. With long-term care, individuals are primarily responsible for their own care, and that particularly applies to the community-based long term care facility.

By the year 2000, there will be 10 million more elderly than there were in 1980. The number of disabled elderly is likely to increase as the number of those 85 and over increases. The rate of dependency and the need for long-term care increases rapidly with advancing age. To a degree, this is reflected in hospital discharge data, which show that among those 65 to 74 years of age, only about four percent are discharged to long-term care, a percentage that rises to almost 25 percent among those 85 years old and over. Paramount among the continuing concerns about the current system (or non-system) are questions of cost, efficiency and effectiveness.

The Residential Care Sector

There are approximately seven million elderly Americans needing some form of long-term care assistance, of whom 22 percent are estimated to live in nursing homes and residential care settings described as board and care homes.¹ The latter sector represents care for nearly four percent of the dependent elderly,

OVERVIEW

- Residential care facilities are expected to grow as the elderly seek alternatives to institutionalized care.
- The spectrum of residential settings is broad and confusing, since terminology varies from state to state.
- Residents of these facilities are often improperly medicated and adequate assessment of their needs is often lacking.
- More intense pharmacy services are needed, especially in preventive care and drug monitoring.

Better pharmacy services will force patients to improve the manner in which they use the medications that are often the key to maintaining their health status and quality of life.

and this segment of long-term care is expected to grow rapidly as alternatives are sought to institutionalized care. In addition to dependent elderly, the mentally retarded/developmentally disabled and the chronically ill represent about four million more individuals who will require long term care, and that care will be delivered in the community setting. Residential care will, for this group as well, represent an important option of long-term care.

Good descriptive data and an understanding of people who are cared for in noninstitutional residential arrangements are lacking. Estimates on the number of people cared for in residential care facilities, such as

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The lack of monitoring of long-term care drugs is one of the three major reasons why adverse drug reactions frequently occur in the elderly.

Table 1 - Terminology Used in Residential Care Facilities

Assisted Living Homes	Homes for Adults
Board and Care Homes	Residential Homes
Chronic Custodial Care	Rest Homes
Congregate Care	Sheltered Housing
Domiciliary Care	

board and care homes, domiciliary care, personal care homes, etc., range from 350,000 to more than one million nationwide. 40 to 60 percent of these persons are elderly, the remainder are the developmentally disabled or mentally impaired. The spectrum of residential settings is broad and confusing, since terminology varies from state to state (Table 1). Licensure and certification requirements differ not only interstate, but intrastate, and added to this lack of standardized regulations are the number of unlicensed homes which exist outside state and local jurisdiction.

Service options in residential care: A residential home may supply no more than three meals a day, housekeeping and 24 hour supervision. Others may offer weekly visits by a nurse to monitor vital signs and ongoing health problems. Some offer assistance with routine daily activities, such as dressing and bathing, while others require total independence. Transportation, recreational activities, counseling and social services may be available, as well as case management services.² Others have been found to care for totally dependent bedbound elderly.³

Because of the level of dependency of the population that lives in residential care settings and the fact that this dependency is most often the result of chronic illnesses and conditions, many of these homes have become "quasi-health care facilities," in which medication supervision is a key service. Licensed residential homes range in size from three persons to 50 or even 100. In Maryland costs range from about \$900 to \$2000/month for care in sheltered housing or group home care. Only a fraction of this money is

covered by reimbursement. Some homes are converted single family homes, others may be renovated schools and still others have been built especially to serve this type of client. More recently multi-level care facilities have been built which provide a range of options from independent living units and assisted-care apartments to intermediate and skilled nursing care.

In addition to the traditional "mom and pop" provider of care in small homes, the long term care industry, the real estate industry and corporate hotel giants such as Marriott and Hyatt are entering the residential care marketplace.

The residential care sector faces major changes and increasing difficulties. Aging in place puts pressure on providers to accommodate the changing needs of their residents. The once mentally alert, albeit frail elderly, may now need assistance in toileting, medication administration and orientation.

The sheltered housing program in Maryland has attempted to deal with some of these concerns. There are two components to the Maryland program: group sheltered housing for elderly which licenses and certifies homes that care for 4-15 elderly residents in a one-family dwelling, and a program that licenses a certain number of rental units in a senior citizen congregate housing building for sheltered housing services.

In both settings, congregate meals, housekeeping and personal services are provided. The sheltered housing program is administered through the State Office on Aging. Maryland also has a domiciliary care program, which is regulated by Licensing and Certification, Department of Health and Mental Hygiene. This division is responsible for nursing home licensure as well, and domiciliary care facilities have more stringent requirements for medical and social interventions.

Licensure and certification for community-based facilities for mentally retarded/developmentally disabled fall under the Developmentally Disabled Administration, Department of Health and Mental Hygiene.

The regulatory imprint: A recent consensus conference sponsored by the University of Maryland addressed this issue.⁴ Regulations do not allow the system flexibility to meet the changing needs of the clients served, probably in an attempt to avoid

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Caregivers in RCFs have little, if any, special training or skills to prepare for work with the frail or mentally impaired elderly.

Table 2 - Psychotropic Drug Use in Assisted-Living Facilities

	No. of Residents	% of Total	No. Drugs/Resident
Sedative/hypnotics	138	31%	1.07
Antipsychotics	70	15.6%	1.02
Antidepressants	62	13.8%	1.03

overmedicalization of the residential care system. Conference participants saw the role of government as an advocacy role, where regulations need to be developed to monitor the system and to enforce standards that have been peer-driven.

The client/resident: Those choosing to live in the residential care sector are somewhat functionally or mentally impaired, lacking the ability to shop, travel and provide necessary personal care for themselves.

Many elderly are excluded from seeking residential care, either by choice or through lack of funds. Importantly, this sector of care is neither widely known by the general public nor understood and is often confused in the consumer's mind with nursing home care.

The caregivers/providers: Caregivers in residential facilities have little, if any, special training or skills to prepare for work with the frail elderly or mentally impaired (who may also be elderly). Despite the lack of training, they may be responsible for managing complex health and social problems. Supervision of staff may be provided by professionals who are trained and licensed, such as social workers, nursing home administrators or registered nurses. However, hands-on daily care including resident monitoring is given by the untrained staff person.

Some Concerns about the System

While regulations differ from state to state, medical supervision is usually not required to any significant degree; it takes the form of a health care system,

but is staffed by lay people.⁵⁻⁸ There is a paucity of information about clients/patients identified as suffering from psychiatric disorders. There is a particular lack of clarity regarding the outcome of those identified as suffering from both dementia and depression.⁹ While there has been a 250 percent expansion in the number of places in residential homes, there is still no requirement for an active therapeutic approach to residents in that sector.¹⁰⁻¹⁸ Adequate assessment of potential residents is crucial, yet there is no documentation that it does take place.

Age itself is a risk factor for inadequate treatment;¹⁹ that appraisal may be particularly applicable to residents especially as far as drug therapy is concerned. Good drug therapy may be difficult, since among significant and independent predictors of an unreliable drug history are depression, four or more active medical problems, and receipt of two or more drugs.²⁰ Many of those living in residential care probably meet these criteria. Antipsychotic drug use is high, even though the right to refuse these medications is now more than a decade old.²¹ Problems of use of psychotropic drugs in the medically ill have been amply demonstrated.²²⁻²⁴ While some of these drugs may often be used to address agitation, which is a significant problem for the elderly, their families and caregivers, it ought to be remembered that there are more than 100 drugs, distributed over many drug categories, that can cause psychiatric symptomatology in the elderly,²⁵ perhaps leading to overuse of psychotropics.

Drug Use in the Residential Care Facility (RCF)

For residents in North Carolina who receive at least one prescribed drug, an average of 5.8 per patient is concurrently prescribed.²⁶ For Maryland, drug use is similar.²⁷ Maryland residents receive an average of 5.6 drugs per day, both prescribed and non-prescription. Nursing home residents probably receive an average of six to seven drugs daily and community-living elderly probably take from three to four drugs daily.^{28,29} Based on these statistics, RCF residents more closely resemble nursing home residents than other community-living elderly. If the national trend continues, then both the number of drugs per patient and the average size of the individual prescription

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will continue to increase.

Very recently it was documented that 55 percent of 837 residents in rest homes are prescribed psychoactive medications.³⁴ Even higher use was documented some time ago,³⁵ yet often the personnel handling these medications have little or no training and few homes keep drug administration records.³⁶ Just based on a perusal of these kinds of numbers, one ought to expect (and thereby be able to avoid) a multitude of adverse effects, such as falls and fractures,³⁷ and perhaps hypothermia,³⁸ which may ensue from unsupervised psychoactive drug use. Importantly, patients with high anticholinergic levels (also a side effect common with psychoactive drug therapy) have greater impairment in self-care capacity than patients with low levels.³⁹

Congressional concern with the use of psychotropic drugs is reflected in the Omnibus Budget Reconciliation Act (OBRA) of 1987. The Health Care Financing Administration has also targeted psychotropic drug use in long-term care as an area of concern. Thus, it is interesting to study psychotropic drug use for RCF residents (Table 2).²⁷ Nationwide, about 32 percent of all elderly (in this instance, those 60 and over, representing 17 percent of the total population) receive psychotropic drugs.⁴⁰ As can be expected, psychotropic drug use varies considerably with the site of care.

Implications of RCF Drug Use

Drug use, then, is quite heavy among those living in residential care settings. The Food and Drug Administration, in a recent report, documented again that undesirable drug reactions are not necessarily related to age but are linked strongly to polymedicine, i.e. multiple drug use.⁴¹ The Royal College of Physicians adds that lack of supervision (monitoring) of long-term care drugs is one of the three major reasons for adverse drug reactions in the elderly.⁴² Even in a relatively well supervised home care environment, about 10 percent of patients, under the supervision of visiting nurses, either presented with a disease not being treated, with drug therapy for which there is no indication, or were receiving inappropriate drugs. More than 30 percent of all patients were exposed to potential drug-drug or drug-disease interactions.⁴³

Given the apparent lack of supervision and the lack

Table 3 - Comprehensive Pharmacy Services in the Alternative Care System

Provide compliance packaging
Maintain patient profiles
24 hour delivery service
Provide pharmacy system uniformity
Review therapeutic drug regimens
Review/update profiles to monitor disease states
Consult with patients and caregivers
Provide services to physicians
Educate providers
Assist with nutrition management
Provide preventative care services
Be a community resource to promote access to service

of training of the caregivers in the RCFs, one would expect a high rate of adverse drug effects. While it is generally agreed that 10 to 15 percent of all admissions of elderly to hospitals are due to adverse drug effects,⁴⁴ a 26 percent incidence of adverse drug reactions in residents of alternate care systems who were admitted to an acute geriatric facility was observed recently.⁴⁵

Continuity of Care and Drug Use

If the RCF is part of the continuum of long-term care, and patients are discharged from a higher level of care to a part of the RCF, then a number of medication concerns ought to be addressed in order to help make that change in the continuum of care successful. Before discharge, the patient's medication regimen should be reviewed with the following points in mind:⁴⁶

- If new drugs are to be added to the existing regimen, keep in mind the effects on drug action of primary (physiologic), secondary (pathophysiologic) and tertiary (environmental, behavioral) changes.⁴⁷
- If discharge is to a relatively unsupervised environment, consider whether patients will be able to handle a particular dosage form.
- Consider the patient's ability to meet cost of medication (both one-time cost and long-term cost).
- Consider whether a new environment is conducive to patient compliance with the drug regimen. For example, an elderly diabetic patient may have to create an environment built around an injection

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schedule, having refrigeration available, and the disposal of used syringes. There must also be an appropriate environment for urine testing and the storage of drugs and testing materials.

The patient's and caregiver's ability to meet specific challenges of a particularly therapeutic regimen should be re-assessed periodically.

Although in many instances, appropriately managed drug therapy is critical to continued living in residential care, certain regulations mandate that caregivers cannot administer medications, yet the patient may be incapable of self-administering drugs. In segments of the RCF where medications are taken by the patient, regulations vary from state to state. For example, in Washington State, RNs must administer medications. In Virginia, no training is required for persons to assist patients in administering medications. In Maryland, regulations with regard to medication administration vary from county to county.

Individuals, in an effort to help elderly remain at their highest level of independence, have developed all kinds of means to help administer medications. This may lead to the staff offering simple verbal reminders, to the technique of placing the medication in the patient's hand and guiding the hand to the mouth. Indeed, regulations are unrealistic for most sectors of care in the RCF, since sensory impairment, mental impairment, literacy level and multiple health problems of the patient make many individuals incapable of safely controlling their own drug use.

Directly contributing to drug mismanagement in the RCF are the large blocks of time needed to perform these functions, lack of the skills and knowledge needed to make an accurate assessment of drug therapy, the shortage of nursing personnel and the lack of reimbursement for these services.

Pharmacy Services in the Residential Care Facility

It is apparent that more intense pharmacy services are needed. Currently, pharmacy services are largely restricted to the provision of prescription and nonprescription drugs. Recommendations for change, issued by the American Public Health Association, emphasize the need for improved communication among physician, pharmacist, nurse and caregiver along with a mandatory requirement for periodic

drug regimen review as part of the communication process.⁴⁸

Judging from results of a survey in home health care, 85 percent of home health agencies use consultant pharmacy services,⁴⁹ but most felt unable to pay for them. Furthermore, Medicare, Medicaid and other third party payors do not reimburse home health agencies for these types of services, even though they are considered essential.

As the data indicate, the RCF resident population more closely resembles nursing home residents than the less disabled community-living elderly population. Indeed, it resembles very closely the nursing home population of the early 1970s, when the federal government mandated consulting pharmacy services for federally-financed skilled nursing patients. These services, found clinically cost-effective by the Comptroller General in a report to Congress, clearly are needed for the RCF population now, in view of multiple drug use and a high incidence of adverse drug reactions.

Moreover, pharmacists should be more involved in providing preventive care measures (preventing pressure sores, respiratory illness, etc) and even in opportunistic case findings. The pharmacist may well be the first to learn of declining routine daily activities, which could then be reported for follow-up. Indeed a wide range of services have been identified and are in place in some settings, to meet the needs of the RCF patient and his or her caregiver (Table 3).

In addition, research should be funded to allow pharmacists to develop a "risk avoidance" approach to adverse drug reactions, as outlined in the literature.^{50,51} Research should be funded to permit further development of user-friendly compliance packaging,⁴⁷ so that RCF residents need not be institutionalized by their inability to manage current packaging systems. Finally, pharmacists should be involved in education efforts directed towards RCF residents and caregivers in drug use and drug action, perhaps along a model recently launched in Maryland.⁵² ■

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Antipsychotic drugs in the nursing home: Some evaluative guidelines

Nancy L. Mace, MA
 David S. Sherman, RPh, FASCP
 Dorothy Coons

Introduction

Should psychotic drugs be used to control resident behavior in the nursing home? Are these powerful drugs effective for problem behaviors in nursing home residents who have dementia? The answers to these questions are often not clearcut.

Many studies have documented that antipsychotic drugs are used inappropriately and excessively in our nation's nursing homes.¹ Recent changes in the Health Care Financing Administration regulations specifically respond to this issue. The new regulations require that any resident receiving these drugs must have a specific reason for the drug therapy documented in the patient record. The interpretive guidelines for these regulations clearly define the circumstances in which antipsychotic drug therapy would be considered appropriate.

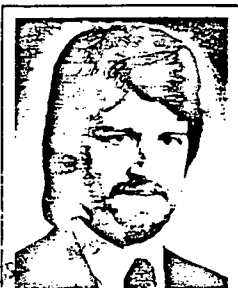
Antipsychotic drugs can cause a variety of adverse affects. These drugs can increase the risk of falls,² cause permanently disfiguring movement disorders, and cause urinary incontinence. A more subtle adverse consequence of

antipsychotic drug therapy in people with dementia, is further impairment of the person's cognitive abilities. This is often mistakenly interpreted as a progression of the individual's dementing disorder. It means the person is even less able to make sense of her environment or to function as well as possible.

Despite this potential for harm, families and providers have voiced concern that medications are needed to protect the confused person and others from unpredictable outbursts, to make necessary tasks such as bathing possible,

and to protect the resident from wandering into dangerous situations.

Clinicians expert in dementia care point out that some patients need small doses of medication to treat symptoms such as extreme agitation and hallucinations. Free of such symptoms, the patient can relax and enjoy life. Thus, the intent of this article is to provide guidelines that will enable families and nursing staff to determine when the use of antipsychotic medication is the appropriate choice. For more detailed pharmacological information, readers are referred to other sources.^{3,4}



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Psychoactive drugs can be divided into three main categories:

- Sedative/hypnotics (for anxiety and/or sleep disturbances).
- Antidepressants (for treatment of depression), and
- Antipsychotic drugs (for treatment of psychotic symptoms such as hallucinations and paranoia.)

Antipsychotic drugs (e.g. Haldol, Mellaril) were designed to treat schizophrenia and other major psychiatric disorders. However, if they are given in the correct dose and monitored appropriately, antipsychotic drug therapy may be useful in reducing specific behavioral symptoms in people with dementia. These symptoms include: frightening hallucinations or delusions, paranoia and severe agitated behavior that has not responded to non drug approaches. Unfortunately, these drugs are often used instead to sedate residents in an attempt to control behaviors such as restlessness, wandering, screaming, uncooperativeness and unsociability. Use of antipsychotic drugs for these purposes is at best inappropriate, and at worst,

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harmful to the resident.² The sedating side effects may subdue the patient, and sometimes reduce the frequency of behaviors. However, the cost of this

sedation may be a drowsy confused patient, and a rapid decline in the person's well being.

Management of antipsychotic drugs in the brain-damaged elderly is clinically challenging. This population is highly vulnerable to side effects and interactions with other medications. In prescribing these medications, the clinician walks a tightrope between small gains for the patient, and destructive side effects. In prescribing any medication, the clinician must have experience and training in working with the brain damaged elderly. Family and facility staff can assist by requesting that these medications be used only as a last resort.

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When these medications are used, they must be monitored very carefully. In order for the prescribing physician to make the best decision, he needs to have a complete picture. If the person is living in a nursing home, the physician should have information from the nursing staff, the pharmacist, and others.

The effect of the medication on the targeted symptoms, if any, should be documented, and the frequency and intensity of side effects should also be recorded. The decision to continue the use of an antipsychotic drug in the presence of side effects must be carefully considered.

Changes in the patient's environment — both the physical environment and the behavior of the people around him — can make a dramatic difference in behavior, and thus is the need for antipsychotic

medications. Modifications to the environment should be tried before medication should be considered.

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The following considerations will help to clarify the process of deciding whether or not to use these controversial medications.

- Does the behavior place the patient, staff or other residents at risk of injury?
- Is the behavior seriously upsetting other residents (e.g. rummaging in their rooms, screaming, spitting)? Repeating something, pacing, talking to oneself do not create serious nuisances. If the behavior does not constitute an emergency, then medications should not be used until efforts have been made to determine the cause of the behavior, and until non-drug interventions have been tried.
- Are the identified target symptoms likely to respond to treatment with an antipsychotic drug?
Antipsychotic drug therapy should be considered only for behaviors that are known to respond to this approach. A formal monitoring record should be developed to document response (or lack of it) to antipsychotic drug therapy.
- Ask whether illness, pain, problems seeing or hearing,

drug reaction, drug interactions, or discomfort might be causing the patient's behavior. Such excess disabilities can cause agitation and other behaviors.⁸ Medications should

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not be used until a physician has ruled out these factors as causes of the problem. If illness or other problems are found, each problem should be treated to the extent possible before medication for a behavior is used. (For an excellent review of medical causes of confusion and agitation, refer to the reading list.) Fear and fatigue also cause excess disability and should be treated with environmental support.

- Medications should not be used as a substitute for staff. Sadly, many facilities report that they do not have enough staff to provide an individualized care plan with adequate activity time, or that they do not have adequate time to supervise wanderers. When medication is being used as a substitute for staff or for a properly designed facility, this must be documented so that there is hard data with which to advocate for change.
- Although it is commonly done, the use of antipsychotic medications because the family member cannot get respite,

or because the nursing home does not have enough staff is not good care. Change in public policy is essential to protect the patient from this kind of inappropriate care.

- Whenever an antipsychotic drug is being considered to control a behavior, consider whether the risks to the patient or to others if the drug is not used outweigh the risks of using the drug, and can document the decision. Consider whether there are other less risky interventions. For example, if one were to use antipsychotic medication to stop a patient from cursing the aide

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pushed to
an extreme.*

who dresses him, the risks of medication to the patient are probably greater than those associated with frustration to the aide. Staff education and support may be the preferred intervention.

Wandering presents a more complicated dilemma. The risk of elopement can often be controlled with low cost devices sold in electronic stores. These devices signal patient movements or the opening of doors. Many facilities have found devices that are acceptable to fire inspectors. Sometimes the reason given for antipsychotic drug therapy is to prevent ambulation in a frail resident who is at risk of falling. However, that risk may increase when

medications are used.⁹ In addition, loss of ambulation can lead to problems such as incontinence. The risk of a fall in a frail resident must be considered on an individual basis in light of the complications caused by medication and the loss of ambulation.

Facilities have reported that they have used drugs or physical restraints because the facility fears a lawsuit if the resident falls. Ironically, as noted above, the evidence shows that a resident is at greater risk for falling if given antipsychotic drugs. Families, facilities, and state regulators must work together to address this issue, and dispel these common myths.

- If a behavior does not create an emergency situation, a log should be kept (for one week, if possible), or until the behavior has occurred several times. Hopefully, the log will determine the following:
 - What times of day does the behavior occur?

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- Who was interacting with the patient immediately before and during the behavior?
- Where did the behavior occur?
- What was going on?

From the log, the following can be attempted:

- If the behavior occurs, (usually with one person), separate that person and the patient. (It

There is usually a warning period before the person actually strikes out.

may not be possible to separate patients in a corridor, but to fail to have a different aide care for the patient is not justification for using medications.)

- If one person works more successfully with the person, that person should work with her. Other people should study and use her successful approach. If the behavior occurs in a certain situation, the person should be cared for in a less stressful (smaller, fewer people, less noise, less complex, less going on) setting.
- If the behavior occurs in certain situations (transfer from one setting to another, mealtime, bath-time), steps should be taken to reassure the patient. Each activity should be performed slowly to assure that the person feels secure. When evaluating episodes of agitation, it is useful to consider whether the caregiver might have acted rushed or stressed, instead of

providing a relaxed and low-key atmosphere during the activity.

- The person should be treated with dignity, and provided with privacy. It is helpful to explain to the person what is being done with each caregiving activity.
- Agitated behaviors often occur when the person does not understand what is happening. For instance, when the person thinks she

The person should be treated with dignity, and provided with privacy.

It is helpful to explain to the person what is being done with each caregiving activity.

is being mistreated or demeaned. "TLC" should be used, and consideration given to what the experience must be like for the person.

- Agitated behavior and some other behaviors result when the person has nothing to do. If a behavior occurs when the person is idle, enable the person to take part, at his own pace, in interesting and diverting activities, and in those parts of ADLs that he can do if he is given time and help. Activities and ADL's should be planned so that even a very impaired

person will be successful. Look for ways to provide pleasure. It is the best gift we can give these impaired people. A five minute one-to-one chat, a walk or song often saves twenty minutes of staff time responding to an angry outburst.

- When a person is upset, several different people should try — one at a time, to help the person respond or relax. The technique used by the person who is successful should be communicated to all staff.
- Combative behavior is agitated behavior pushed to an extreme. The antecedents of a combative incident should be reviewed and the precipitants avoided in the future. There is usually a warning period before the person actually strikes out. Staff should stop pressing the person

Each activity should be performed slowly to assure that the person feels secure.

or should remove the person from the situation at the first signs of irritability. Some facilities have been able to eliminate combative behavior

through a supportive environment, and the judicious use of low doses of antipsychotic medications for the few patients that do not respond to interventions.

- Document successes. Documenting has several benefits: it indicates that the facility tried less aggressive interventions, helps to create a list of ideas to try with the next patient, and provides evidence for staff that they do succeed.

The nursing facility worker may feel frustrated: staff are not trained to provide this kind

of care, it is difficult to hire good staff, and the facility cannot afford enough staff. They feel that families and inspectors make unrealistic demands. Most agree that different care would be better, but that such care is not possible. Certainly, there are broad national funding issues involved. This article is not intended to criticize hard working staff. It is intended to provide realistic guidelines for the safe and effective use of antipsychotic drug therapy to help manage behavior in people with dementia.

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Conclusion

In conclusion, antipsychotic medications may improve the quality of life in a few patients when used appropriately to treat specific symptoms, at doses which minimize side effects, and when they are carefully monitored. However, people with dementia will respond with improved psychosocial function when even small improvements are made in their human and physical environment. Every effort should be made to implement such changes before antipsychotic medication is tried. Unfortunately these drugs

have been overused to the detriment of the person with dementia. If the care-

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antipsychotic medication
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giver succeeds in creating a non drug therapeutic environment part of the time, he or she will have given the patient a better quality of life. □

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Item 14

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PHARMACY

New Regs Require Preparation



Re-evaluation of antipsychotic drug use is imperative

by David S. Sherman, R.Ph., FASCP

"To prescribe pills is easy, but to reach an understanding with people is very hard." When author Franz Kafka made this observation at the beginning of the 20th Century, he could easily have been describing the feelings of many care providers regarding psychoactive drug use in nursing homes today.

Multiple reports in the medical literature, as well as the lay press, have identified psychoactive drug misuse as a long-standing problem in our nation's nursing homes.

Recent changes in Health Care Financing Administration (HCFA) regulations point to the need for a renewed focus on quality of care issues. The new antipsychotic drug rule is very specific in its intent to discourage unnecessary use of antipsychotic drugs (e.g., haldol).

Facilities that do not already have a formal program to deal with this therapeutic area should work closely with their consultant pharmacist to develop one. Administrators should be aware that additional consultant pharmacist time will be required for this and this should be considered in budget planning.

Implementation of the antipsychotic drug regulation, originally scheduled to take effect Jan. 1, 1990, has been delayed until Oct. 1, 1990. The complexity of this new regulation, however, makes it imperative that nursing homes not suspend preparation despite the delay.

Development and implementation of a formal antipsychotic drug monitoring program is likely to take many months. The sooner facilities

start this process, the more likely it is they'll be prepared in October.

Program Development. Developing a program to reduce unnecessary use of antipsychotic drugs calls for change at both individual and organizational levels. Staff must seriously reconsider their attitudes and actions regarding use of these drugs.

Organizational change can be a complicated and challenging process. The collective practices, habits and beliefs of all individuals involved combine to produce an inertia that may require significant effort to alter.

Change at the individual level can be encouraged through education, but organizational change requires revision of facility policies. A new antipsychotic drug policy must re-

fect the goals of the facility. This requires a multidisciplinary effort to assure effective implementation. Ongoing education is necessary to help staff understand why the policy is important.

Administrators and directors of nursing can encourage a positive response from their staff only if they themselves are committed to the principles involved. If the new program is viewed by staff only as a knee-jerk response to a new regulation, chances of success are minimal.

Wise managers will use the introduction of this program as an opportunity to reinforce the mission of the facility. This will help staff remember the purpose of their work is to provide the best care possible.

(continued on page 80)

Table 1
Behaviors for which antipsychotic drugs
should not be used

Simple pacing	Insomnia
Wandering	Unsociability
Poor self-care	Indifference to surroundings
Restlessness	Fidgeting
Crying out, yelling or screaming	Nervousness
Impaired memory	Uncooperativeness
Anxiety	Any indication for which an order is prescribed "as needed" (PRN)
Depression	

NEW REGS

(continued from page 79)

Although the new regulations may provide an impetus for change, the thrust of the program should hinge on this philosophy. If a facility is committed to providing high quality care, systems must be designed to assure delivery of quality care. When this is done, compliance with new regulations will be a natural outgrowth.

Interpretive Guidelines. The new antipsychotic drug regulation will *not* prevent residents from receiving medication that is administered for appropriate reasons. The interpretive guidelines surveyors will use to implement the new regulation clearly delineate the "specific conditions" that must be documented in the clinical record if a resident receives an antipsychotic drug.

For example, although antipsychotic drugs may be used for behavioral symptoms in residents with "organic mental syndromes" (including dementia), the specific behavior(s) being treated must be documented quantitatively and qualitatively.

To justify use of these drugs, residents' described behaviors must present a danger to themselves or others, interfere with the staff's ability to provide care, or because of paranoia, hallucinations or delusions cause the resident "frightful distress." In addition, efforts must be documented which demonstrate periodic attempts to reduce the antipsychotic drug dose with the goal of discontinuation of the drug therapy unless this is "clinically contraindicated."

Clinically contraindicated means that in a resident receiving an antipsychotic drug for an appropriate reason (as defined by the interpretive guidelines), the drug has already been reduced to the lowest dose necessary to control symptoms.

The interpretive guidelines also contain a list of behaviors that antipsychotic drugs should *not* be used for if they are the *only* reason for the drug therapy (see table 1). If an antipsychotic drug is used in the absence of an appropriate reason or *for* a specific behavior listed in table 1 for even *one* resident, the surveyor is instructed to record a negative finding.

Monitoring Record. The monitoring record is the backbone of the pro-

gram. It should be designed for ease of use, but devised in a way that allows for collection of information in a form that can be quickly analyzed.

This record should not be viewed

It is important to manipulate the environment instead of the person. Staff must learn to stop thinking of the resident as a problem and look instead at their surroundings.

merely as a form of documentation to fulfill the requirements of a regulation. It should be a fundamental tool in the process of finding alternative ways of dealing with disruptive behavior. Information from this record will enable staff to determine how to approach potentially difficult residents without provoking them.

There is no magic formula that identifies how to handle each behavioral situation, but most care problems can be solved without resorting to chemical or physical restraints. This approach brings opportunities for creative care and with it a happier staff.

In devising alternative approaches, it is important to manipulate the environment instead of the person. Staff must learn to stop thinking of the resident as a problem and look instead at their surroundings. Encourage staff to look at causes underlying behavior. Reviewing information recorded in this behavioral log can help staff "tell

the forest from the trees," and discover reasons for behavioral outbursts that might otherwise have been overlooked.

For each episode of problem behavior, staff should identify the date, time and duration, and, answer a number of questions. For example, who was with the patient? What happened during the interaction? What seemed to help? What seemed to make it worse? Did the behavioral problem occur during an active time or an inactive time? What was the individual doing right before it happened? Other questions can also be helpful, and each log might be a little different, modified to the specific needs of each resident.

Team Effort. Development and implementation of a program to reduce unnecessary antipsychotic drug use requires a team effort. Staff must work together to serve each and every resident. The administrator, with multidisciplinary input, must develop an appropriate policy.

The director of nursing, medical director and consultant pharmacist should be actively involved in developing this policy. Nursing must be

comfortable with the policy and learn to use creative alternatives in place of antipsychotic drugs.

Nursing assistants should be drawn into the process of program development as well, since they are the primary providers of direct care. They will also be key participants in devising alternative approaches.

The consultant pharmacist should play a major role in this program with renewed emphasis on monitoring the benefits and adverse effects of antipsychotic drug therapy. Attending physicians should be notified of the facility policy and informed of the types of alternative approaches being used.

Social service staff can provide counseling, work with families and support staff and help identify the psychosocial needs of residents. Occupational therapists can help adapt the environment to accommodate the needs of demented residents. Other health personnel can also make important contributions.

All nursing home personnel must learn to be sensitive to the needs of confused residents. One wrong word or action by an uninformed staff

member can ruin weeks or months of work with particular residents.

In addition to dispelling myths, education can increase a person's sensitivity to another's emotions, well-being and fears. This can be accomplished during the orientation process for new employees.

Developing a program to reduce unnecessary antipsychotic drug use can be a challenging but rewarding process. Successful implementation of the program requires development of a well-considered policy, education specific to the needs of each discipline and the commitment of all nursing home staff and consultants.

An effective program will not only assure compliance with the new regulations, but will improve the quality of life for nursing home residents and provide greater satisfaction for all those involved with their care.

CLTC

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Psychoactive Drug Misuse in Long-Term Care: Some Contributing Factors

David S. Sherman

Surveys have identified inappropriate psychoactive drug prescribing patterns as a major problem in the care of nursing home residents. Residents without a documented history of mental illness often receive drugs intended to treat psychiatric problems. One of the greatest areas of misuse of these drugs is in the treatment of agitation in elderly demented residents. For example, although this purpose is likely the most common reason antipsychotic drugs are used in the nursing home setting, no well designed study has yet demonstrated that these agents are effective for this problem. Elderly individuals are particularly sensitive to the adverse effects of psychoactive drugs. Due to the gradual or insidious onset of some adverse effects, psychoactive drug toxicity may often be underestimated. The most serious example of a clinically underrecognized adverse effect of psychoactive drugs is tardive dyskinesia. Misinterpretation of certain nursing home residents' behaviors may lead to medication with tranquilizing drugs when other approaches may be safer and more effective. Excessive use of psychoactive drugs is not only physically harmful, but also encourages an apathetic attitude toward implementation of more humane ways of dealing with behaviorally disturbed nursing home residents.

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EXCESSIVE PSYCHOACTIVE DRUG use in nursing homes (NHs) occurs due to a combination of complex social, psychological, economic, and medical reasons. An exploration of the origins of this problem is useful in the process of devising approaches to improve these utilization patterns.

While drug therapy may be a cost-effective approach for many physical and some psychiatric illnesses, behavioral disturbances in NHs are often not amenable to drug treatment. Medication, often the first line of attack, rarely solves the problem, and sometimes masks it.¹ Psychoactive drug intervention in demented behaviorally disturbed NH residents has not been shown to do anything more than sedate the patient.² In many cases, sedation will comprise what little mental function that may be left, thus exacerbating an already challenging management problem.

Various surveys have reported that 46% to 75% of NH residents have behavioral, social, emotional, and mental disorders, yet the recip-

ients of psychoactive drugs often do not have psychiatric diagnoses.³ The 1976 Office of Long-Term Care Survey of Physicians' Drug Prescribing Patterns in Skilled Nursing Facilities revealed that although only 10% of their sample had a clearly documented mental illness, nearly 50% of all residents were prescribed antipsychotic or sedative/hypnotic drugs.⁴

More recent surveys reveal these numbers have not changed significantly since the 1976 report. A review of 5,902 residents in Tennessee NHs found that 43% of these residents received antipsychotic drugs. The authors concluded that their findings provided "epidemiologic evidence suggesting misuse of antipsychotic drugs in nursing homes."⁵ Further evidence of psychoactive drug misuse in NHs has been presented by experts in pharmacology during congressional hearings.^{6,7}

REASONS WHY PSYCHOACTIVE DRUG MISUSE OCCURS IN LONG-TERM CARE

Desire to Help NH Residents

It is natural for NH staff to feel moved to relieve a resident's apparent suffering. Unfortunately, drug therapy that seems therapeutically appropriate for this purpose often yields an over-medicated elderly person.

Physicians are likely aware of the minimal benefit of psychoactive drug therapy for most behaviorally disturbed residents. Although these drugs are sometimes used to treat individuals with a history of documented psychiatric illness, more frequently they are employed as a pragmatic, symptom-based approach for the treatment of agitation in elderly demented residents.

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No well-designed study has yet demonstrated antipsychotic drug efficacy for behavior problems of demented elderly NH residents.⁸

Belief in Psychoactive Drug Efficacy

No well-designed study has yet demonstrated antipsychotic drug efficacy for behavior problems of demented elderly NH residents.⁸ However, healthcare professionals often prescribe, dispense, and administer these drugs, truly believing it is in the best interest of the resident. They are trained that intervention with drug therapy is the most logical approach for a resident with a problem behavior pattern.

Many behavioral disturbances are situational, and therefore, episodic in nature. A drug is likely to be given credit for solving a behavior problem, when with time, it might just have likely resolved on its own. Staff are aware that a drug intervention is being employed and their expectation is that sedation is an effective and successful therapeutic approach.

Underestimation of Drug Toxicity

Some psychoactive drug side effects are gradual or insidious in onset. If a drug-induced problem is common in the population receiving the drug, association between the drug and the problem will be obscured. For example, a recent study identified sedative/hypnotics, particularly longer-acting benzodiazepines as the key cause of cognitive impairment in a sample of 300 elderly patients with suspected dementia.⁹ This type of problem is difficult to detect because patients frequently are unable to report side effects, and those who care for them may not know how to differentiate adverse effects from underlying dementia or other changes resulting from advancing age.

Psychoactive drugs have also been strongly associated with the risk of falling.¹⁰ This is a serious finding since falls are the leading cause of fatal and nonfatal injury in persons age 75 years and older.¹¹ One recent study found elderly recipients of psychoactive medications to be two to

three times more likely to experience a fractured hip.¹²

The most serious example of a clinically underrecognized adverse effect of psychoactive drugs is tardive dyskinesia. Contrary to popular beliefs, tardive dyskinesia is not a rare phenomenon. The only antipsychotic drug adverse effect more common in the elderly is oversedation.¹³ A recent study documented that despite its persistent nature, a diagnosis of tardive dyskinesia is often missed, especially when its symptoms involve the extremities rather than the "classic" orobuccal areas.¹⁴

The risks associated with psychoactive drug sedation of most demented patients far outweigh any perceived therapeutic benefit.

Behavioral Disturbance: Problem or Symptom?

An elderly NH resident may become agitated for a variety of reasons. Demented individuals frequently become agitated due to a misperception of environmental stimuli or due to unexpected actions of caregivers. An undiagnosed medical condition such as tumor, thyroid disease, acute myocardial infarction, or hypoxia could cause confusion and agitation.¹⁵ Reversible dementias can occur as the result of infections, sleep deprivation, and a host of other conditions.¹⁵ For a more complete review of this subject, the reader is referred to an excellent summary by Mahler, Cummings, and Bensen.¹⁶

The increased sensitivity of the elderly to a variety of drugs is well established. Elderly individuals are particularly susceptible to cognitive impairment as an adverse reaction to drug therapy.^{6,17} This frequently results in confused or agitated behavior, and can occur even when drug therapy is prescribed and maintained at therapeutic levels.^{18,19} Confusion or agitation in the elderly is often compounded with the addition of psychoactive drugs, which ironically have signifi-

Confusion or agitation in the elderly is often compounded with the addition of psychoactive drugs,

cant potential for causing behavioral disturbances themselves.²⁰

Patient Demand

Some NH residents place great demands on the physician and NH staff not to discontinue current medication and even to add new drugs. As with many members of our drug-oriented society, these individuals are in the habit of taking drugs. Whether the habit reflects physical or psychological dependence, the prospect to the elderly person of having the drugs withdrawn may be a frightening one. In the process of rapidly eroding support systems that aging often represents, medication may unconsciously be considered a symbol of love by the often attention-starved NH resident. From this perspective, it is easy to understand why the resident might cling so tenaciously to each morsel of medication.

Environmental Control

Sometimes residents are sedated purposely because they create a disturbance that interferes with the controlled environment the staff and/or administrator may want to create. This type of treatment action usually does not involve any malice on the part of the staff, rather it is based on their mistaken belief that a tranquilized resident will be easier to care for. In fact, this misperception has been actively promoted by drug manufacturers in their advertising. Advertisements for antipsychotic drugs have offered the staff a "less complaining," "less demanding," "less dependent," more "cooperative patient" who is "easier to manage."²¹ The message to the NH administrator is economic in nature and even less ambiguous: (1) "Relief of symptoms means a more amenable patient," and (2) "The less troublesome patient requires less nursing care."²² These "scientific" reasons for using a specific medication play very nicely into the strong desire of many NH staffs and administrators for just this kind of assistance.

The irony in this fallacy is that on a practical level, a sedated resident requires more care. These residents are less able to perform activities of daily living, are harder to feed, harder to get out of bed, more likely to be incontinent, and more likely to injure themselves. All of these aspects of care require more nursing time and

result in increased incontinence-related material costs.

Another management concern in the NH is the runaway resident, especially one who is confused or mentally disturbed. Possible accidents or injury and attendant personal liability and bad press are constant sources of apprehension and stress for the NH administrator.²³ Often psychoactive drugs are used to manage this problem instead of door alarms and other surveillance methods.

Consultant pharmacists are often approached by staff/administration requesting information on "what drug can we get the doctor to order to shut 'that one' up?" As the author of one study stated, "Indeed, it can be argued that in the absence of psychoses, the use of neuroleptics for elderly patients-residents serves institutional rather than individual needs."²⁴

Family Concerns

Family members may request that "annoying" roommates be tranquilized because they are disturbing Mom or Dad. Conversely, family members may request that Mom or Dad be tranquilized because they appear uncomfortable and they "can't bear to see them that way."

Most people, particularly older people, have a deep aversion to NHs. A family member may often feel that they have abandoned their loved ones by opting for NH care.²⁵ This guilt can sometimes result in requests for "comfort measures" (ie, tranquilizers) that might not be in the resident's best interest.

Nursing Staff Stress

The NH can be a stressful workplace, and some staff members are better able to tolerate this than others. The more stress an individual feels, the less disturbance they are able to tolerate in their environment. Caring for demented elderly residents can be very challenging. To many nursing staff members, it may be easier to get drugs prescribed that will keep residents quiet than actually deal with the behaviorally disturbed individual on a personal level.

Contrary to negative media portrayals, most NH staff members work hard to provide the best care possible. Given the opportunity, they are interested in learning new approaches that might help them provide a higher quality of care. Staff

trained to become attuned to the specific rhythms of each demented individual are more likely to consider options other than drug therapy. By identifying the cause of the resident's disturbed behavior, a nondrug solution often becomes readily apparent.

Inadequate Training

Several studies have reported that current resources of NHs appear to be inadequate to respond to the emotional and behavioral needs of their residents.¹ There is a lack of systematic approach to the care of persons with behavioral, social, and emotional problems, as well as the mentally ill.

One of the biggest obstacles of decreasing inappropriate psychoactive drug use in NHs is the dependence of physicians, nurses, and nursing assistants on the drug approach as the only one with which they are familiar. Since physicians are not trained in the skills of situational-behavioral problem solving, they may lack an organized approach with which to respond efficiently and effectively to the problem.²⁴ Although nurses and nursing assistants generally are able to acquire these skills experientially, they often feel unable or disinclined to implement them consistently due to the pressures inherent in their normal work day.

Influence of Drug Manufacturers

The busy physician tends to rely heavily on drug company literature, advertising, and "detail men" (sales representatives) for his information. This is unfortunate since drug manufacturers are in business to sell drugs, not to educate doctors. Information from pharmaceutical and manufacturers (via advertisements, direct mail, exhibits at conferences, and visits by sales representatives) is crisp, attractive and accessible, but understandably, it is oriented toward promoting a particular product. Consequently, the information drug companies publish and distribute is often calculated to emphasize the likely benefits

***... drug manufacturers are in
business to sell drugs, not to
educate doctors.***

of the drug and to minimize the potential dangers.

Over \$3 billion per year is spent on promotion by US pharmaceutical companies. About 13% of this is spent on journal advertising. Since nearly all physicians read medical journals, drug manufacturer advertisements and the images and information they contain are almost impossible to avoid.

Drug manufacturer advertising attempts to invoke powerful feelings in prescribers: compassion, guilt, fear, anger, control, and success to name a few. All of these feelings play a part in influencing the prescriber's future therapeutic decisions. The people who prepare these ads are very clever, and their intent is not to intellectually convince, but rather to plant a seed in the unconscious, ready for future harvesting.

One study of a group of randomly selected primary care physicians found drug manufacturer advertising encouraged inappropriate drug therapy. In this survey, drugs were chosen for which commercial messages on product efficacy differed markedly from objective, scientific sources of information. When the physicians were asked how effective these drugs were, their answers corresponded most closely to the commercial information.²⁵

Sales activities of pharmaceutical representatives account for over half of the \$3 billion per year spent by US pharmaceutical companies. Since the content of "detailers'" sales messages cannot be monitored as can the content of most other forms of advertising, this marketing approach represents an almost totally unregulated activity.

The proof of the effectiveness of this approach is the financial investment of pharmaceutical companies to continue this activity. If product sales in excess of detailing costs did not occur, other marketing avenues would take precedence.

EDUCATIONAL EFFORTS TO IMPROVE PRESCRIBING BEHAVIOR

All the factors mentioned earlier may contribute to inappropriate psychoactive drug use patterns, but the main reason this problem continues is due to the attitudes and beliefs of misinformed prescribers and NH staff. Logically, the best way to deal with misinformed individuals is through education. However, previous work has docu-

mented the failure of traditional methods of continuing medical education in influencing the quality of patient care.²⁴ Studies have also shown that provision of printed educational materials alone is not successful in influencing physician prescribing behavior.^{25,26}

New regulations from the Health Care Administration specifically address this problem of psychoactive drug misuse.²⁷ These regulations encourage the use of nondrug approaches and require that caregivers in NHs document the effectiveness of currently prescribed antipsychotic drugs. It is clear that a new approach to this problem is needed.

In view of the impact that marketing and promotional activities of drug manufacturers can have on prescribing behavior, it made sense to explore how an educator might use this approach to influence physicians in a noncommercially oriented fashion.²⁸ "Noncommercial detailing" is a face-to-face educational method that draws from and expands on marketing techniques that have been used by drug manufacturers for years. These techniques can be adapted to encourage appropriate and cost-conscious prescribing instead of promoting the vested interests of a particular pharmaceutical company. With this approach, clinical pharmacists can effectively expand their influence on physician prescribing behavior in a prospective manner.

Noncommercial detailing has been used to successfully influence prescribing behavior in office-based physician practices.^{27,29} In an ongoing project the author (DS Sherman) has trained clinical pharmacists in this approach in an effort to reduce pharmacy costs in a four-hospital Veterans Administration study. In a recently completed Harvard Medical School study the

author adapted this noncommercial detailing approach to influence prescribing of psychoactive drugs for NH residents. In addition to 1:1 sessions with physicians, a series of presentations describing specific nondrug behavioral techniques as alternatives to psychoactive drug therapy were provided for NH staff. Preliminary analysis reveals that unnecessary psychoactive drug use has been reduced significantly in 12 target NHs.

SUMMARY

Excessive psychoactive drug use is unhealthy for NH residents, an indirect expense and a public relations problem for NH administrators, and a source of frustration for consultant pharmacists concerned with encouraging appropriate drug use. Overmedicated NH residents experience a lower quality of life and are harder to care for. Misuse of psychoactive drug therapy is not only potentially dangerous for each individual patient, but it fosters an apathetic attitude towards implementation of more humanistic ways of dealing with the behavior problems of elderly NH residents.

This paper identifies factors contributing to the problem of psychoactive drug misuse in elderly NH residents. The identified factors are not intended to be a summary statement, but rather a stimulus for further discussion of this challenging problem in the health care community. Noncommercial detailing is an example of an innovative and effective educational approach for reducing inappropriate drug use. The consistent success of this approach in influencing physician prescribing behavior has made it clear that a wider application of these techniques would be useful to the health care community at large.

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Item 16

A Metaanalysis of Controlled Trials of Neuroleptic Treatment in Dementia

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Prior qualitative literature reviews about the use of neuroleptics in dementia suggest that they are "modestly effective" in treating agitation and that no single neuroleptic is better than another. To develop a more precise concept of the clinical efficacy of neuroleptics, a meta-analytic review of the existing literature was performed. From double-blind clinical trials that compared a neuroleptic with a placebo in agitated dementia patients, P values and effect-size estimates were obtained, and were assessed by metaanalytic techniques. Results indicated that neuroleptics were significantly more effective than placebo (one-tailed $P = .004$) and had a small effect size ($r = .18$). Clinically, neuroleptic treatment

changed the improvement rate in agitated dementia patients from .41 to .59 (binomial effect-size display). This indicates that 18 of 100 dementia patients benefited from neuroleptic treatment (beyond that of placebo) and is consistent with the modest efficacy described in previous qualitative reviews. In six studies comparing thioridazine with another neuroleptic, and in five studies comparing haloperidol with another neuroleptic, metaanalysis results did not show that these two medications differed significantly from the comparison medications, which is not inconsistent with the opinion that no single neuroleptic is better than another. J Am Geriatr Soc 38:553-563, 1990

Neuroleptics are frequently prescribed for treating behavioral symptoms associated with dementia and for treating agitation in general in older patients. The substantial literature on the use of neuroleptics in dementia has been reviewed on several occasions.¹⁻⁷ The most extensive of these was by Salzman,⁴ who reviewed the treatment of agitation in geriatric patients in general and identified 69 reports of neuroleptic use in older people. Approximately one half of the reports were uncontrolled, and 40% involved nondemented older patients. He concluded that "neuroleptics have consistent and reliable therapeutic effect in controlling agitation for elderly patients who are demented, psychotic, or both," that overall therapeutic efficacy of neuroleptics is "modest rather than striking," and that no particular neuroleptic is more advantageous than another.

Previously, Helms² had emphasized methodological features in his review of 21 studies. He considered only three to be of good quality by criteria such as random-

assignment, double-blind, parallel-group designs, and appropriate use of a statistical test. Methodological problems identified in the others included the failure to use an appropriate control group, the use of a comparison medication rather than a placebo, and the diagnostic heterogeneity of many subject samples. Together, the three studies of good methodological quality provided little evidence for the positive effects of neuroleptics in dementia patients.

Sunderland and Silver⁵ identified only 20 double-blind studies of neuroleptics in geriatric patients between 1954 and 1986. Of the 10 placebo-controlled studies identified, they considered five to show a positive effect for neuroleptics, three as showing no effect, and two as showing deterioration with active drug.

Devanand et al⁶ identified 15 major, double-blind trials of neuroleptics in dementia and concluded that there was "limited evidence to suggest that neuroleptics may be effective in relatively low doses in some demented patients with behavioral disturbance." They also commented that there was "weak evidence to support the use of neuroleptics in the treatment of symptoms like suspiciousness, hallucinations, sleeplessness, agitation, emotional lability, and aggressiveness."

Thus, most qualitative reviews concluded that, at best, neuroleptics are modestly effective in treating agitation in geriatric patients with or without dementia. But no quantitative estimate of the magnitude of this effect has been presented. We therefore undertook a meta-

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analytic review of this literature to assess quantitatively the efficacy of neuroleptic treatment in older dementia patients.

It was expected that by analyzing the group of placebo-controlled studies that included primary dementia patients and met minimal methodological standards, we would be able to quantify the magnitude of the effect of neuroleptics in treating behavioral disturbance in dementia patients. To assess the relative effects of one neuroleptic compared to another, we performed meta-analyses on controlled trials comparing the two most frequently studied neuroleptics, thioridazine and haloperidol, with other neuroleptics.

METHODS

A National Library of Medicine literature search was performed to identify published controlled clinical trials in which geriatric patients were treated with a neuroleptic medication. The time period searched was from 1954 to 1966, using *Index Medicus*, and from January 1966 to June 1989, using MEDLARS II. Recent reviews were scrutinized to identify other potentially relevant articles,¹⁻⁷ as were the references from each published clinical trial.

Studies were selected for inclusion in the initial meta-analysis if they described results of an individual clinical trial with a double-blind, placebo-controlled, parallel-group design, if the subjects were characterized as having a primary dementia, and if there was sufficient information to calculate an effect size. Adequate diagnostic descriptors of primary dementia included chronic or organic brain syndrome, organic or senile psychosis (ICD-9), senile brain disease, cerebral arteriosclerosis or atherosclerosis, senile or presenile dementia, atherosclerotic dementia (ICD-9), primary degenerative dementia (DSM-III), and multi-infarct dementia (DSM-III).

For the comparisons of thioridazine or haloperidol to other neuroleptics, studies had to fulfill the same criteria as above except for the placebo-control requirements.

Metaanalytic Methods Metaanalysis encompasses a variety of procedures that permit quantitative evaluation or integration of a group of studies designed to address a common theme.^{8,9} Unlike traditional qualitative literature reviews, metaanalysis focuses on methodology and allows quantification of the magnitude of the treatment effect. The dependent variables in a meta-analysis usually consist of effect-size estimates (eg, the magnitude of the difference between two treatments) derived from individual clinical trials.

A one-tailed significance level associated with the test statistic and an effect size was calculated for each study. All effect sizes were expressed as correlation coefficients, r . (In cases with dichotomous variables, r is defined by the ϕ coefficient, which is the square root of the χ^2 value [$df = 1$] divided by the square root of the number of subjects.) χ^2 test was used to assess the

degree of homogeneity of the significance levels or effect sizes among the group of studies to be analyzed. Homogeneous significance levels and effect sizes suggest that the studies represent samples from the same population and that it is likely that they are testing the same hypotheses.¹⁰

Next, the one-tailed P values of the studies were combined after converting them to their z normal deviates and weighting each study by the number of subjects. This was accomplished with a metaanalysis microcomputer program using the Stouffer method,^{9,11} where the test of significance value (in most cases the χ^2 value) and the sample size were entered whether or not the result was in the hypothesized direction.^{9,11} This determined how reliable the differences were between the neuroleptic and placebo groups. A "fail safe" number was calculated, one that represents the number of additional nonsignificant studies needed to bring the overall P value to a just significant level ($P = .05$).

The combined effect size of the studies was calculated using the Fisher z_r transformation of the effect size, r , and was expressed as both a mean correlation coefficient and as a binomial effect-size display (BESD).⁹ The BESD, defined as a change from $0.5 - r/2$ to $0.5 + r/2$, provides an estimate of the change in effect size between the two treatment groups.

RESULTS

A total of 33 studies were identified in which neuroleptic medications were compared to placebo or to other medications in geriatric samples that comprised some dementia patients.¹²⁻⁴⁴ In studies intended to compare several medication classes in parallel groups, only neuroleptic and placebo data were used for the metaanalyses.

Studies Comparing Neuroleptics with Placebo Of the 17 placebo-controlled studies identified,¹²⁻²⁸ 13 used parallel groups and four used cross-over designs. Eight of the 14 double-blind studies used random treatment assignment, and one used "preassignment" to treatment (Table 1). Two parallel group studies each compared two neuroleptics with placebo.^{25,26}

Only nine studies could be considered to contain exclusively, or a large predominance of, primary dementia patients (ie, > 78%). Four studies included mixed populations of approximately 21% to 60% dementia patients, and four did not adequately describe their subjects.

The medications and mean doses are listed in Table 1, and included chlorpromazine (five studies), thioridazine (four), haloperidol (three), loxepine (two), trifluoperazine, acetophenazine, thiothixine, penfluridol, and mifenperone (one study each). The duration of treatments ranged from three to 18 weeks. The number of subjects per study ranged from 18 to 71, except for one report—combining five studies—that included 358.

Only seven studies used a double-blind, placebo-controlled, parallel-group design to assess subjects who probably had primary degenerative dementia or vascular dementia. These studies are included in the meta-analysis and listed in Table 2. (An eighth clinical trial²⁷ would have met inclusion criteria except that it pooled data from five separate trials in three nursing homes and two state hospitals.)

The number of subjects who improved with treatment, based on the authors' clinical assessments, comprised the dependent variable in six of the seven studies used in the metaanalysis. (One study provided sufficient parametric statistical data with which to calculate an effect size.) Individual, 2×2 contingency tables were prepared for each of these studies (outcome vs treatment condition). No significant difference between neuroleptic and placebo was obtained in any single study when analyzed by χ^2 tests (two-tailed). However, the direction of effect was in favor of the neuroleptic in six of seven reports (Table 2). There was no significant heterogeneity among the reports of significance levels ($\chi^2 = 3.462$, $df = 6$, $P = .75$) or effect sizes ($\chi^2 = 3.671$, $df = 6$, $P = .72$).

Combining significance levels and weighting each study by the number of subjects per study resulted in a standard normal deviate, z , for the combination equal to 2.674 with an associated one-tailed P value equal to .004. The "fail safe" number of unreported studies averaging null results needed to make this P value equal to .05 was 13.9.

Combining effect sizes and weighting each study by the number of subjects per study resulted in a Fisher's z_k for the combination equal to .180, a mean effect size, r , equal to .18 and a BESD from .41 to .59. (When studies were weighted equally without regard to sample size, similar results were obtained: for the combination of P values, $z = 2.84$, $P = .002$; for the combination of effect sizes, $z_k = 0.20$, $r = .200$; and BESD from .40 to .60.)

Effect sizes were not significantly correlated with standardized medication dose ($r = .40$, $n = 7$, $P = .38$), treatment duration ($r = -.02$, $P = .97$), sample size ($r = -.34$, $P = .45$), mean age ($r = -.51$, $P = .24$), or publication year ($r = -.15$, $P = .74$).

Because of the small number of studies, linear orthogonal contrast weights were computed and used in a more sensitive focused test of the linear relationship between the effect sizes and the above-mentioned variables.¹¹ Still, there was no significant linear relation among effect size and medication dose, treatment duration, sample size, age, or publication year.

Studies Comparing Neuroleptics with Other Medications Twenty studies compared one neuroleptic with another medication.^{24-27,29-44} Seven compared a neuroleptic with a sedative/hypnotic.^{24,27,29,32-34,35} Five directly compared thioridazine with haloperi-

dol.^{31,33,37,39,42} but in three either the population was largely not demented^{31,33} or the statistics were unanalyzable.³⁷ One other study was not suitable for lack of appropriate populations, blinding, and statistics.³⁰ Therefore, nine studies remained in which diagnoses were compatible with a primary dementia in all subjects (Tables 3 and 4).

To examine if either thioridazine or haloperidol is more effective than other neuroleptics, two metaanalyses were undertaken: one combining six double-blind studies comparing thioridazine with other neuroleptics, and one combining five double-blind studies comparing haloperidol with other neuroleptics. (Two reports compared thioridazine with haloperidol and are included in each metaanalysis.^{39,42})

The results of the studies that compared thioridazine with other neuroleptics are shown in Table 3. The comparison medications were haloperidol, chlorpromazine, thiothixine, piperacetazine, and loxepine. Mean daily doses, doses expressed in chlorpromazine equivalents, treatment duration, and mean age are listed.

There was no significant heterogeneity among the studies' associated P values or effect sizes ($\chi^2 = 4.876$, $df = 5$, P [one-tailed] = .431; $\chi^2 = 4.44$, $df = 5$, $P = .488$, respectively). None of the individual reports revealed statistically significant differences for or against thioridazine. Combining significance levels resulted in a mean z normal deviate of either 1.195 (weighted by sample size) or 1.015 (unweighted) and associated nonsignificant P values of .116 or .155, respectively. Combining effect sizes and weighting each study by the number of subjects per study resulted in a Fisher's z_k for the combination equal to .073 (mean effect size, $r = .07$) and a BESD from .46 to .54.

Similarly, the combination of the five double-blind studies that compared haloperidol with other neuroleptics (Table 4) was not statistically significant (weighted: mean $z = 0.527$, $P = .284$; unweighted: mean $z = 0.445$, $P = .328$). The combination of effect sizes was $z_k = -.036$, mean $r = -.04$, BESD from .52 to .48.

DISCUSSION

These metaanalyses quantify the therapeutic effects of neuroleptics in agitated dementia. In particular, they confirm Salzman's conclusion that neuroleptic effects are modest but consistent and reliable, and that no particular neuroleptic is better than another.⁴ Although the relatively small effect size, $r = .18$, accounts for 3.2% of the variance and may seem clinically insignificant, its actual significance can be better understood intuitively within the context of the BESD—the expression of the effect size as a change in improvement rate.⁹ Specifically, the BESD indicates that neuroleptic treatment changes the improvement rate from .41 to .59 over placebo, or that 18 of 100 dementia patients with behavioral symptoms benefit from neuroleptic treatment.

TABLE 1. PLACEBO-CONTROLLED STUDIES OF NEUROLEPTICS IN DEMENTIA

Author	Year	Medications (mg/d)	Diagnoses	Design Features					
				L	R	DB	PC	PG	CO
Seager ¹²	1955	Chlorpromazine (190); placebo	Dementia (60%); depression (13%); schizophrenia (27%)	8		+	+		+
Judah et al ¹³	1959	Thioridazine (700); placebo	Schizophrenia (75%); dementia (25%)	9	+		+	+	
Abse et al ¹⁴	1960	Chlorpromazine (75); placebo	Chronic brain syndrome; senile psychosis	8	— ^a	+	+	+	
Hamilton and Bennett ¹⁵	1962	Trifluoperazine (8); placebo	Senile brain disease or cerebral AS with psychosis (78%)	8	+	+	+	+	
Hamilton and Bennett ¹⁴	1962	Acetophenazine (40); placebo	OBS with psychosis	3-8	+	+	+	+	
Sugarman et al ¹⁷	1964	Haloperidol (3-4.5); placebo	Senile brain disease; cerebral AS	6	+	+	+	+	
Barton and Hurst ¹⁸	1966	Chlorpromazine (138); placebo	Senile psychosis (68%); AS psychosis (30%)	3		+	+		+
Robinson ¹⁹	1969	Chlorpromazine (?); placebo	Chronic brain syndrome associated with senile brain disease	6-18	— ^c	+	+		+
									(modified)
Birkett and Boltuch ²⁰	1972	Chlorpromazine (50-200); control (no placebo)	Senile dementia and AS dementia (n = 27, 54%); psychosis (22%); other (24%)	6		— ^c	+		
Lehman et al ²¹	1972	Thioridazine (75-150); thioridazine (25-75) + fluoxymesterone (5-10); placebo	Paranoïds (41%); mixed functional (38%); organic (21%)	12	+		+	+	
Cahn and Diesfeldt ²²	1973	Penfluridol (?); placebo	Organic psychosyndrome	10		+	+	+	
Rada and Kellner ²³	1976	Thiothixine (6-15); placebo	OBS (DSM-II); nonpsychotic (57%); psychotic (43%)	4	+	+	+	+	
ter Haar ²⁴	1977	Haldol (2.5); chlormethiazole (960); placebo	Confusion of organic origin	9	— ^d	+	+		+
Petrie et al ²⁵	1982	Haloperidol (4.6); loxepine (22); placebo	Primary degenerative dementia (49%); MID (43%); other (8%)	8	+	+	+	+	
Barnes et al ²⁶	1982	Thioridazine (62.5); loxepine (10.5); placebo	Primary degenerative dementia (55%); MID (38%); other (7%)	8	+	+	+	+	
Stotsky ²⁷	1984	Thioridazine (10-200); placebo; (five studies combined)	"Senile, not psychotic"	4	+	+	+	+	
De Cuyper et al ²⁸	1985	Milnerperone (20); placebo	Aggressive behavior, not psychotic	6	+	+	+	+	

L = length (in weeks); R = randomized; DB = double blind; PC = placebo control; PG = parallel group; CO = cross-over; ADL = Activities of Daily Living; BPRS = Brief Psychiatric Rating Scale; CGI = Clinical Global Improvement; NOSIE = Nurses' Observation Scale for Inpatient Evaluation; HAM-A = Hamilton Anxiety Scale; SCAG = Sandoz Clinical Assessment-Geriatric; MACC = Motility Affect Cooperation Communication Scale; BOP = Beoordelingschaal Oudere Patiënten; VGRS = Verdun Geriatric Rating Scale; CPZ = chlorpromazine; OBS = organic brain syndrome; AS = athero- or arteriosclerosis; MID = multiinfarct dementia.

TABLE 1. (continued)

Sample Size	Mean Age (years)	Rating Scales	Proportion Improved ^a	Comments
46 (22/24)	72	Clinical	18/22; 6/24	Cross-over at four weeks; proportion improved are those at four weeks after initial assignment who could be analyzed as a parallel group.
33 (20/13)	63	None for outcome	13/20; 2/13	Improvement based on combined opinion of ward staff; seven dropouts.
32 (16/16)	75	Clinical, mental status, and neuropsychological rating scales	NS	Comparison of CPZ, opium, reserpine/pipradrol, placebo, and no treatment. Overall F test was NS, effect size for CPZ estimated from anxiety scale score, $r = -.03$.
27 (18/9)	71	MACC: behavioral adjustment scale; physicians' observation	4/18; 0/9	80% incontinent; all medically ill. Seven died within six months. Nurses' rating failed to show differences; significant side effects in 39% to 61% of medication-treated patients. Patients were deteriorated, apathetic, withdrawn.
19 (14/5)	71	Clinical	9/14; 1/5	All had chronic medical illness, three medication patients became worse, seven schizophrenics and one depressive included in results. Patients were hyperactive and agitated.
18 (9/9)	72	Checklist	8/9; 6/9	Four haloperidol patients had "marked" improvement compared to no placebo patients.
50	77	Clinical "rating scale"		Slight but significant improvement; $2.52 \pm .71$ SE, $n = 50$.
71 (50/21)	81	Clinical nursing psychometric		Chlorpromazine (CPZ), reserpine, pentylenetetrazol, and placebo were compared in a quasi-cross-over design; 21 inpatients received placebo for 18 weeks; 21 received CPZ for first six weeks; 50 received CPZ at some time during study. Author reports 34.7% deteriorated with CPZ compared to 5.3% on placebo, and two improved.
50 (30/20)	76	BPRS; NOSIE; CGI	14/30; 4/20	Controls did not receive placebo pills. BPRS mean improvement 1.97 vs 0.05 in favor of CPZ ($t = 1.20$, $p = .24$). No significant change on NOSIE. Global ratings are by occupational therapist. Six CPZ and three controls became worse.
45 (15/15/15)	72	BPRS; VGRS		Comparison of nicotinic acid, thioridazine (T), fluoxymesterone (F) and combinations. Eight treatment groups of 15. Only the T+F group showed improvement. No direct intergroup comparisons; 25 did not complete.
36 (12/12)	81	BOP	NS	Thirty-six nursing home patients assigned to receive penfluridol, placebo, or no intervention. Patients had restless, anxious, or aggressive behavior. Penfluridol dose, 10 mg twice per week. No significant differences.
42 (22/20)	76	BPRS; NOSIE; CGI	13/22; 11/20	Fifty-six of 63 completed study; 14 had protocol infringements. No significant change on BPRS; significant improvement on NOSIE psychosis factor ($P = .05$).
46	79	BOP; ADL		Chlormethiazole (C) is an anticonvulsant sedative. Subjects were given three-week trials and crossed over to each condition, C better than haloperidol and placebo at improving ADL ($P < .05$) and nightly unrest ($P < .01$).
61 (20/19/22)	73	BPRS; SCAG; NOSIE; CGI	CGI: 13/20; 11/19; 8/22	Thirty-seven of 64 completed trial. Two haloperidol, six loxepine, and five placebo patients became worse. BPRS total score was better with active medications.
53 (17/19/17)	83	BPRS; SCAG; NOSIE; CGI	CGI: 10/17; 13/19; 8/17	Thirty-four of 60 completed trial; 53 completed two weeks; nine became worse; nursing-home patients.
358 (183/175)	76	HAM-A; NOSIE; CGI		$P < .10$; three nursing homes and two state hospital studies combined. Hamilton Anxiety Scale results expressed as % improved on each of two factors. CGI results expressed as mean improvement; serious medical illness excluded; of the 197 nursing home patients, 103 improved more than 94 with placebo on multiple measures ($P < .10$).
20 (11/9)	76	Paranoid scale, target symptoms		Study medications added to existing neuroleptics.

^a As reported by authors or derived from contingency tables. "Improvement" means any improvement; ^b "preassigned"; ^c "blind raters"; ^d "matched group assignment"; ^e "control, no placebo"; ^f "balanced".

TABLE 2. DOUBLE-BLIND PLACEBO-CONTROLLED STUDIES OF NEUROLEPTICS IN PRIMARY DEMENTIA USED IN METAANALYSIS

Author	Year	Medications (dose, mg/d)	Standardized Dose*	Length (weeks)	Sample Size	Mean Age
Abse et al ¹⁴	1960	Chlorpromazine (75); placebo	75	8	32 (16/16)	75
Hamilton and Bennett ¹⁵	1962	Trifluoperazine (8); placebo	160	8	27 (18/9)	71
Hamilton and Bennett ¹⁶	1962	Acetophenazine (40); placebo	267	3-8	19 (14/5)	71
Sugarman et al ¹⁷	1964	Haloperidol (3.75); placebo	150	6	18 (9/9)	72
Rada and Kellner ²³	1976	Thiothixine (10.5); placebo	262	4	42 (22/20)	76
Petrie et al ²³	1982	Haloperidol (4.6); loxepine (22); placebo	184; 176	8	61 (20/19/22)	73
Barnes et al ²⁶	1982	Thioridazine (62.5); loxepine (10.5); placebo	66; 84	8	53 (17/19/17)	83

Therefore, although this is a small effect, especially when compared with the magnitude of the placebo response (which ranges from 0% to 67%), it is clearly clinically important and its significance should not be minimized. Withholding neuroleptic medication may keep 18% of agitated dementia patients from improving.

Conversely, considering both the high placebo response and the medication nonresponse rate observed, it is apparent that a substantial number of demented older people may receive neuroleptics unnecessarily—either because they would have responded to those factors associated with placebo treatment, or because they had not improved with neuroleptic but are continuing to receive it anyway.

Another way to interpret the small effect size of neuroleptic medication is to consider the number of patients required to perform a new study comparing neuroleptic with placebo so that there is adequate protection against a type II error (ie, against showing no difference between treatments when, in fact, there is a difference). Using a correlational test with $r = .18$, $\alpha = .05$, 239 subjects would need to be randomized to receive either neuroleptic or placebo to achieve an experimental power of .80 for a two-tailed test and 189 for a one-tailed test.⁴⁵

In no individual study included in this metaanalysis was neuroleptic treatment statistically significantly better than placebo by our χ^2 calculations (two-tailed test).

This was contrary to the claims of significant improvement by some of the authors. Reasons for this discrepancy include the fact that some authors chose to highlight particular factors or items of selected rating scales or did not report the value of the statistical test used.

The doses used in these studies were modest, ranging from 66 to 267 mg/d chlorpromazine equivalents, and dose was not correlated with effect size. It is possible that higher doses would have been more efficacious. Duration of treatment (range three to eight weeks) also was not correlated with effect size. Although it is possible that longer treatment would be more effective, a drug that takes more than eight weeks to act may not be clinically useful.

The nature of this analysis does not provide information on the symptoms that tend to improve with neuroleptic treatment. However, some indication of this can be gleaned from inspection of the placebo-controlled studies (Table 2). According to the authors' assessment of symptom improvement, agitation, uncooperativeness, and hallucinations tend to improve with medication and seem to do so reliably across the studies.

These metaanalyses highlight the difficulty of interpreting controlled studies comparing two active medications without a placebo condition. As can be seen from Tables 3 and 4, the effect size for neuroleptic treatment compared with placebo, $r = .18$, is within the range of effect sizes in studies comparing one neuroleptic with another. Therefore, without a placebo-control group it

Table 2. (continued)

Rating Scale Used	Proportion Improved†	χ^2 (df = 1)	P value (two-tailed)	r (effect size)	Symptoms That Tended to Improve
Anxiety rating scale	Not stated	NA		-.03‡	Anxiety and mood (both groups)
Physicians' observation	4/18; 0/9	2.348	.125	.29	None
Clinical observation	9/14; 1/5	2.898	.089	.39	Assaultiveness, combativeness, overactivity, insomnia, and night wandering
Psychiatric observation	8/9; 6/9	1.286	.257	.27	Agitation, overactivity, hostility, hallucinations, uncooperativeness (assessed from a checklist)
CGI	13/22; 11/20	0.072	.789	.04	NOSIE manifest psychosis factor: auditory, visual hallucinations; talking and giggling to self
CGI	13/20; 11/19; 8/22	3.574	.059	.24	BPRS items: hostility, uncooperativeness, hallucinations, excitement; BPRS activation and thought disturbance factors; NOSIE irritability and sociability factors
CGI	10/17; 13/19; 8/17	1.347	.246	.16	BPRS items: anxiety, excitement, uncooperativeness, emotional lability

Abbreviations as in Table 1.

Metaanalysis results: χ^2 for heterogeneity of P values (df = 6) = 3.462, P = .75; χ^2 for heterogeneity of effect sizes (df = 6) = 3.671, P = .72; combined z for significance levels = 2.674, P = .004; fail-safe number = 13.9; combined z_k for effect sizes = .180; mean effect size, $r = .18$, BESD, from .41 to .59.

* Expressed in chlorpromazine equivalents, mg/d.

† As reported by author or derived from contingency tables. "Improvement" was considered as any improvement. In the studies by Petrie et al and Barnes et al the two active drug groups were combined to calculate a χ^2 value with df = 1.

‡ Effect size estimated on the basis of means and standard deviations from anxiety scores according to Cohen's d statistic.⁴⁵

cannot be confidently ascertained whether, in any particular study, either kind of active treatment would have been more effective than placebo. Thus, as emphasized previously,^{14,26} future neuroleptic studies in agitated dementia should include a placebo-control group.

Studies chosen were more likely to consist of senile dementia or vascular dementia. Those that contained other psychiatric diagnoses tended not to be placebo-controlled and also to be poor in other methodological details. The issue of whether Alzheimer's patients show different behavioral symptomatology⁴⁶ or treatment response²⁶ from vascular dementia patients has been only recently addressed, but the rather small effect size found in this metaanalysis could have been influenced by dementia diagnosis (or by dementia misdiagnosis of non-organic disorders).

Limitations These interpretations are subject to certain constraints. Our interpretations of the diagnoses, experimental methods, and results differed, on occasion, from the interpretations of previous reviewers. This may be because the literature itself is difficult to review. Methods were not always adequately described,

results were not consistently placed in the appropriate sections, and statistics were not consistently reported. In most studies, diagnoses were not systematically rendered using reliable research criteria, exclusion and inclusion criteria were not systematically applied, symptomatic behaviors were specified only generally, and outcome criteria were not explicitly stated. There were, however, notable exceptions.

The minimal methodological criteria used to select the studies for this metaanalysis resulted in exclusion of about one half of the placebo-controlled studies. Generally, only clinical improvement data could be abstracted from the studies, such as clinical global improvement or a physician's blind rating. Therefore, effect-size estimates tended to be based on dichotomous outcomes (ie, improved vs not improved) rather than on continuous scales, and may have resulted in an underestimation of the overall effect or an unappreciation of gradations of response. Even among the better-designed studies, not enough data were presented to calculate effect sizes based on the parametric statistics reported (ie, appropriate means, standard deviations, or statistical test values were not provided).

TABLE 3. THIORIDAZINE VERSUS OTHER NEUROLEPTICS IN AGITATED DEMENTIA

Author	Year	Medications (dose, mg/d)	Standardized Dose*	Length (weeks)	Sample Size	Mean Age	Proportion Improved	χ^2 (<i>df</i> = 1)	<i>P</i> value (two-tailed)	<i>r</i> (effect size)
Altman et al ³⁸	1973	Thioridazine (67); chlorpromazine (82)	71; 82	6	51	72	Not reported			-.01
Smith et al ³⁹	1974	Haloperidol (2); thioridazine (107)	80; 113	6	46 (23/23)	77	19/23; 14/23	2.681	.102	.24
Katz and Itil ⁴⁰	1974	Thiothixine (NS); thioridazine (NS)		6	20 (10/10)	NS	Not reported		1.000	0
Goldstein and Birmom† ⁴¹	1976	Piperacetazine (30-45); thioridazine (30-90)	230; 63	2.1	50 (27/23)	78	18/27; 11/23	1.810	.179	.19
Cowley and Glent‡ ⁴²	1979	Haloperidol (2.1); thioridazine (153)	84; 161	12	38 (19/19)	65	11/19; 14/19	1.052	.305	-.17
Barnes et al ²⁸	1982	Thioridazine (62.5); loxepine (10.5); placebo	66; 84	8	365 (17/19)	83	10/17; 13/19; 8/17	0.358	.550	.10

All studies were random-assignment, double-blind, parallel-group design except for one cross-over analyzed after first treatment assignment. Abbreviations as in Table 1.

Metaanalysis results: χ^2 for heterogeneity of *P* values (*df* = 5) = 4.076, *P* = .431; χ^2 for heterogeneity of effect size (*df* = 5) = 4.440, *P* = .488; combined *z* for significance levels = 1.195, *P* = .12; combined *z*₈ for effect sizes = .073, mean effect size, *r* = .07; BESD, from .46 to .54.

* Expressed in chlorpromazine equivalents, mg/d, equivalence of piperacetazine estimated at 16.3 mg per 100 mg chlorpromazine.

† Cross-over study; data abstracted after first treatment assignment.

‡ Included organic schizophrenics.

§ Seventeen subjects randomly assigned to placebo were not included in the χ^2 analysis.

TABLE 4. HALOPERIDOL VERSUS OTHER NEUROLEPTICS IN AGITATED DEMENTIA

Author	Year	Medications (dose, mg/d)	Standardized Dose*	Length (weeks)	Sample Size	Mean Age	Proportion Improved*	χ^2 (df = 1)	P value (two-tailed)	r (effect size)
Smith et al ²⁹	1974	Haloperidol (2); thioridazine (107)	80; 113	6	46 (23/23)	77	CGI: 19/23; 14/23	2.681	.102	-.24
Cowley and Glen ⁴²	1979	Haloperidol (2.1); thioridazine (153)	84; 161	12	38 (19/19)	65	CGI: 11/19; 14/19	1.052	.305	.17
Gotestam et al ⁴³	1981	Haloperidol (0.5–1.0); clopenthixol (5–10)	30; NA	8	40 (19/21)	78	CGI (staff); 4/19; 6/21	0.301	.583	.09
Lovett et al ⁴⁴	1987	Trifluoperazine (1–6); haldol (0.5–3.0)	70; 70	6	44 (22/22)	81	CGI: 19/22; 20/22	0.226	.635	-.07
Petrie et al ²³	1982	Haloperidol (4.6); loxepine (22); placebo	184; 176	8	39† (20/19)	73	CGI: 13/20; 11/19; 8/22	0.208	.648	-.07

All studies were random-assignment, double-blind, parallel-group design. CGI, Clinical Global Improvement; NA, not applicable.

Metaanalysis results: χ^2 for heterogeneity of P values (df = 4) = 4.270, P = .37; χ^2 for heterogeneity of effect size (df = 4) = 4.019, P = .40; combined z for significance levels = .572, P = .28; combined z_{E} for effect sizes = -.036, mean effect size, $r = -.04$; BESD from .52 to .48.

* Based on Clinical Global Improvement scores.

† Twenty-two subjects randomly assigned to placebo are not included in the χ^2 analysis.

Moreover, clinical worsening, noncompleters, and the impact of treatment-emergent effects could not be accounted for in the analysis. Several studies reported clinical worsening or disabling side effects with neuroleptic treatment (see Table 1). These factors, if considered in the individual study analyses, could have substantially affected the overall effect size.

All studies included in the metaanalyses were of inpatients who probably had severe dementia, so results may not be generalizable to more mildly impaired outpatients. One random-assignment, double-blind outpatient study of a mixed diagnosis group (one half of which was not demented) was placebo-controlled, and showed very large improvement for both treatment groups.³⁵ In at least one placebo-controlled study, increased severity of symptoms was associated with better response.

CONCLUSIONS

The small effect size for neuroleptics revealed in the present metaanalysis suggests that more study be given to the treatment of symptomatic behaviors in dementia patients. Alzheimer's disease (AD) is associated with defects in multiple neurotransmitter systems, and multi-infarct dementia is associated with small lacunae in various areas of cerebral white matter. Noradrenergic system defects are well documented in AD⁴⁷ and have been associated with clinical depression in both AD⁴⁸ and stroke patients.⁴⁹ Serotonergic system defects are also well documented in AD,⁵⁰ and a platelet marker of serotonin dysfunction has been associated previously with agitation and delusions in AD.⁵¹

It is possible that medications with other mechanisms of action may be equally as efficacious as neuroleptics. These medications include, among others, lithium, beta-blockers, trazodone, and carbamazepine. Although many case reports and two cross-over studies have been published, no double-blind, placebo-controlled, parallel-group studies have been reported. Therefore, it is difficult to make even a preliminary estimate of the relative efficacy of these medications to neuroleptics.⁵²

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Item 17
Antipsychotic Medication Use in Nursing Homes:

Is Resident Payment Source Associated With Excessive Use?^a

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ABSTRACT

We explore the effects of resident payment source and selected resident characteristics on the quality of antipsychotic medication use among 216 residents of seven Wisconsin nursing homes. We measure quality of antipsychotic use as conformance with the Wisconsin Psychotropic Screening Protocol. Medicaid-paid residents are found to be significantly more likely to have deviations of excess antipsychotic use, even when controlling for effects of resident length of stay, age, sex, and diagnosis.

INTRODUCTION

There are continuing concerns regarding the inappropriate use of psychotropic medications among nursing home residents.¹ Medications of special interest are the major tranquilizers or antipsychotics, medications developed to relieve the symptoms of major psychotic disorders such as schizophrenia. Nursing home residents of special interest are those thought to be at increased risk for poor quality care, including those residents who rely upon Medicaid as their primary source of payment. This paper addresses an unexplored question, whether the quality of antipsychotic use is related to the resident's payment source.

In long-term care settings, antipsychotic medications often are prescribed for residents with non-psychotic problems, especially for those with organic brain syndrome and other forms of dementia.²⁻⁵ Studies show that antipsychotics frequently are: used for potentially excessive lengths of time,⁶ implicated in adverse drug reactions⁷ and anticholinergic toxicity, used in inappropriate combinations⁹ and given in inappropriate doses.⁴

Despite these concerns, there has been very little research systematically examining correlates of the quality of antipsychotic use. Published studies report that the quantity of antipsychotic use is related to resident age and presence of a diagnosed functional mental illness,^{3,4} but whether such factors are related to the quality of use is unknown. Further, no available studies have utilized an explicit, standardized protocol to assess quality of antipsychotic medication use, even though professional guidelines for screening such use are available in the literature^{10,11} and have been applied in other health care settings.¹²⁻¹⁵ We address these problems by using an explicit protocol based on recommendations of the APA-NIMH Task Force on Psychopharmacological Screening Criteria.^{10,11}

The goals of the present paper, then, are to describe the quality of antipsychotic medication use and to identify correlates of quality. Specifically, it examines whether Medicaid-paid residents have poorer quality use, controlling for a set of resident characteristics which may clarify any Medicaid effect (*viz.*, length of stay, age, sex, and diagnosis).

METHODS

Sample and Data Sources

Data were obtained in a study in seven skilled nursing facilities in southern Wisconsin.¹⁶ Facilities were selected on the bases of geographic proximity and association with a large pharmacy which maintained excellent computerized databases. They ranged in size from 55 to 256 average daily census (median = 118 residents). Four were located in a medium sized city and three were in nearby rural communities. Four facilities were for-profit and three were non-profit, church-affiliated. All were served by a single pharmacy that specializes in serving nursing homes, maintains computerized drug profile and billing systems, and uses a unit-dose drug distribution system. These systems made it possible to obtain accurate medication profiles and precise measures of doses actually administered.

From resident profiles, we obtained: resident age, sex, source of payment, length of stay in the facility, medical diagnoses, and all medication orders that were active on the audit date (including orders' start dates). Pharmacy billing records indicated the actual number of dosage units per medication order administered to the resident during the previous 30 days. Resident profile and pharmacy billing information matched for each resident was coded for "quality of medication use" using the instrument described below.

Of the 869 residents in the study facilities at the time of data collection, six (0.7%) refused to have their records reviewed. Inclusion criteria for the present analysis were that the resident: 1) was 65 years or older, 2) resided in the home on the original audit date, 3) was serviced by the pharmacy from which the data were gathered, and 4) had at least one order for an antipsychotic medication. Applying these criteria reduced the sample for the present study to 216 cases. Of these 216 residents, 75.5% were female and 63.9% were Medicaid recipients. Their mean age was 83 years (range = 65-102), and mean length of stay was 1,040 days (range = 9-2,294).

Measurement--Quality of Antipsychotic Use

We define quality of antipsychotic medication use as the extent to which antipsychotic orders conform to selected professional criteria. This was assessed using the Wisconsin Psychotropic Screening Protocol (WPSP), a written protocol based on criteria developed by the American Psychiatric Association-National Institute of Mental Health Task Force on Psychopharmacological Screening Criteria.¹⁰ The APA criteria were explicitly designed for screening and assessing the quality of drug prescribing and use in large populations within diverse settings. These criteria include specific guidelines for the treatment of psychotic and nonpsychotic disorders in elderly persons (≥ 65 years of age) with and without organic brain syndrome, making them particularly relevant to nursing home residents. The WPSP has high inter-rater reliability (for total number of antipsychotic deviations, Pearson $r = .92$). A copy of the WPSP is provided in Appendix A.

The protocol specifies nine types of deviations for screening antipsychotic medication orders. These are identified in Table 1. All nine are included in our description of the frequency of deviations. In analysis of correlates of deviations, we focus on deviations which indicate potentially excessive use of antipsychotics, either by themselves or in association with other psychotropic drugs. A resident was considered to have a deviation of excess if he or she had any deviation of long duration, therapeutic duplication, polymedicine, and/or high dosage (types 3-6 in Table 1).

Measurement—Correlates of Potential Deviations

As with previous studies,^{4,5} residents are classified into three diagnostic groups. The functional mental illness group (Functional MI) consists of residents with any mention of psychosis, psychotic symptoms, schizophrenia, depression, anxiety, substance abuse or other nonorganic mental disorders (with or without dementia). The organic brain syndrome group (OBS only) includes those residents with diagnoses of organic brain syndrome or a dementia-related disorder without any mention of psychotic symptoms or other mental illness. The no mental illness group (No Mental Illness) includes residents with no mention of mental illness or dementia. Reviews found that 35.6% of these residents with antipsychotic orders had a documented functional mental disorder, 49.5% had organic brain syndrome or dementia with no other mental illness, and 14.8% had no documented psychiatric diagnosis.

Remaining resident characteristics analyzed are: source of payment (0 = non-Medicaid, 1 = Medicaid), length of stay (in days), age of resident (in years), and sex of resident (0 = female, 1 = male).

Statistical Methods

Zero-order associations are examined by comparing percentages and means, using chi-square and t-tests of significance. Multivariate analyses are conducted using logistic regression techniques,¹⁷ with the normal distribution (Z-scores) to test for the significance of individual coefficients.

RESULTS

Table 1 presents the percentages of residents with each type of deviation. The most frequent types of deviations are use of an antipsychotic medication for more than six months for a non-psychotic disorder (33.3%) and use for less than three days or on a PRN-only basis (31.0%). Other frequent problems are the lack of a documented diagnosis or indication for use (21.3%) and receiving two or more other psychotropic medications (13.9%). Overall, 81.0% of the residents with antipsychotic orders had one or more deviations of any type and 52.3% had one or more deviations indicating potentially excessive use.

Bivariate Analysis

Table 2 presents the percentage of residents with different types of deviations of excess by resident payment source, length of stay, age, sex, and diagnosis. Only a few results are statistically significant. Two predictors, the resident's source of payment and age, show a consistent pattern in their relationship to the frequency of deviations. Residents funded by Medicaid are consistently more likely to have deviations of excess across all types of deviations. However, only the summary measure shows a statistically significant relationship (59.4% vs. 39.7%). Residents in the younger group (ages 65-84) are consistently more likely to have deviations of excess. These relationships are relatively small except in the case of therapeutic duplication: younger residents are significantly more likely than those 85 or older to have orders for multiple antipsychotics (18.4% vs. 6.7%).

Analysis of other resident characteristics, including length of stay, sex and diagnosis, yield no patterned or statistically significant results. It is likely that these characteristics are related to whether a resident has an antipsychotic order. Restricting the sample of residents to those having an antipsychotic order may account for the lack of relationship that we observe.

Multivariate Analysis

Table 3 shows the effect of resident payment source on deviations of excess when selected resident characteristics are considered simultaneously. Importantly, the effect of Medicaid status that appeared in the bivariate findings persists, even when effects of other resident characteristics are controlled. Of all resident characteristics analyzed, it is the only significant predictor of potentially excessive antipsychotic use. Overall, Medicaid-paid residents are far more likely than residents with other payment sources to have deviations of excess antipsychotic use.

DISCUSSION AND CONCLUSIONS

The major finding from these analyses is that Medicaid recipients generally have poor quality antipsychotic medication use even when the effects of other resident characteristics are controlled. This is a finding upon which the available literature casts little or no light. The most thorough published studies of antipsychotic use in long-term care^{4,6} analyzed only Medicaid residents and allowed no resident payment source comparisons.

Why are Medicaid residents more likely to have excessive antipsychotic use, as defined by deviations from published criteria? We consider four potential explanations: exposure, resources, resident and/or family monitoring, and status deference. The "exposure" hypothesis posits that Medicaid residents have greater exposure to or opportunity for excessive medication use because they have been in the nursing home for a longer period of time (due to the "spend down" phenomenon). This hypothesis can be discounted, however, as logistic regression results show that the effect of Medicaid status persists when controlled for length of stay.

The "resource" hypothesis is related to the fact that nursing homes receive less money for Medicaid residents than for private-pay residents. At the individual resident level, residents' Medicaid status may be known by nursing home administrators or care-providers (e.g., physicians, nurses, pharmacists). This awareness might result in less attention being given to these residents, less monitoring of their conditions and needs, and increased likelihood of chronic use of antipsychotic

Table 1. Percentage of Residents^a with Each Type of Deviation

Deviation Type	%
1. No documented diagnosis or indication for use	21.3 ^b
2. Prescribed for less than 3 days or PRN only	31.0
3. Used for more than 6 months for nonpsychotic disorder (long duration) ^c	33.3
4. Used 2 or more antipsychotic medications (therapeutic duplication) ^c	8.8
5. Used more than two other psychotropic medications (polymedicine) ^c	13.9
6. Used dosage higher than recommended for age and condition (high dosage) ^c	5.1
7. Used dosage lower than recommended for age and condition	0.5
8. Used anticholinergic or antispasmodic gastrointestinal medication	4.6
9. Presence of contraindicated diagnosis or documented allergy to drug	1.4
<hr/>	
% residents with any deviation	81.0
% residents with any deviation of excess	52.3
Mean number of deviations	1.21

^a N = 216 residents with antipsychotic prescriptions

^b Column total exceeds 100% as it is possible to have more than one deviation

^c Item included in "deviation of excess" measure

Table 2. Percentage of Residents with Deviations of Excess by Type of Deviation and Resident Characteristics^a

	n	Long Duration	Therapeutic Duplication	Poly-medicine	High Dosage	Any Deviation of Excess
<u>Source of payment</u>						
Medicaid	138	37.6	9.4	17.4	5.8	59.4*
Other	78	25.7	7.7	7.7	3.8	39.7
<u>Length of stay</u>						
0 - 2 years	91	19.8	14.3	17.6	3.3	47.3
3 - 4 years	51	37.3	7.8	7.8	7.8	52.9
5 years or more	74	47.3	2.7	13.5	5.4	58.1
<u>Age of resident</u>						
65 - 84	128	39.5	18.4*	15.8	7.9	63.2
85 & over	86	32.0	6.7	13.5	4.5	47.8
<u>Sex of resident</u>						
Female	163	33.1	8.6	14.1	6.1	52.8
Male	52	34.6	9.6	13.5	1.9	51.9
<u>Diagnosis</u>						
Functional MI	77	32.5	9.1	19.5	7.8	53.2
OBS Only	107	33.6	7.5	11.2	4.7	50.5
No Mental Illness	32	34.4	12.5	9.4	0.0	43.8

Note: * P < .05 (chi-square); Number of cases varies due to missing data.

Table 3. Logistic Regression Results for Regression of "Any Deviation of Excess" on Resident Characteristics^a

	Coefficient	Std. Error	Odds Ratio
Resident Payment Source (1 = Medicaid)	.766**	.321	2.15
Length of Stay (in days)	.0002	.0002	1.00
Resident Age (in years)	-.012	.018	0.99
Resident Sex (1 = male)	.214	.346	1.24
Diagnosis FMI (1 = present) ^b	.286	.460	1.33
Diagnosis OBS Only (1 = present) ^c	.513	.435	1.67
Constant	.014	1.694	
Likelihood Ratio (df = 6)	10.68		

** p < .01 (Z-score)

^a N=214 residents with antipsychotic prescriptions

^b FMI = functional mental illness, with or without dementia

^c OBS only = organic brain syndrome or other dementia-related disorder

medications. At the facility level, the resource hypothesis suggests that a large number of all Medicaid-paid residents may be clustered in Medicaid-dominant nursing homes. Thus, Medicaid effects observed at the individual level may reflect broader resource constraints experienced by such facilities. Distinguishing between these individual- and facility-level resource explanations requires analysis of a larger number of nursing homes than we consider here.

The "resident and/or family monitoring" hypothesis refocuses attention on private-pay residents. Why are those who pay their own bills (or whose families do so) less likely to have deviations of excess antipsychotic use than are those whose bills are paid by Medicaid? Unlike Medicaid-paid residents, private-pay residents and/or their families generally receive itemized bills for services provided, including a listing of specific medications used. This information might stimulate discussion and raise questions regarding the appropriateness of medication use. This greater monitoring potential may result in more conservative drug prescribing and use.

The "status deference" hypothesis proposes that private-pay residents' higher social status might prompt staff members to act in a deferential way toward these residents, pay greater attention to their special needs, and/or be more tolerant of disruptive behaviors. This explanation would be consistent with care patterns observed in other health care settings¹⁸ and may account for patterns of more conservative antipsychotic use.

Overall, our analysis has yielded interesting findings which reveal an effect of resident Medicaid payment status on the quality of antipsychotic use. These findings are of potential interest to researchers and policy makers, particularly in light of current policy initiatives (especially The Omnibus Budget Reconciliation Act of 1987) oriented toward improving the quality of antipsychotic medication use in nursing homes.

Consideration of this study's limitations points out directions for future research. First, this is an exploratory study, based on a relatively small sample of nursing homes, and one must be cautious in generalizing from the results. Second, analysis is limited to a restricted number of variables. To better understand these results, there is a clear need for more in-depth studies involving larger, representative samples of nursing homes and their residents.

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Appendix A--WISCONSIN PSYCHOTROPIC SCREENING PROTOCOL*

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PREFACE

The Wisconsin Psychotropic Screening Protocol (WSP) is a screening tool that can be used to identify potential psychotropic drug therapy problems in the institutionalized elderly. The tool allows the reviewer to identify cases in which the prescription deviates from published criteria or guidelines. The criteria DO NOT constitute definitive prescribing standards and should not be interpreted or applied as such. Nor do they include all possible criteria that might be examined. For example, they do not include criteria regarding critical adjunctive services or critical adverse developments.

The criteria are based primarily (though not exclusively) on two published sources: (1) American Psychiatric Association, Manual of Psychiatric Peer Review (3rd Ed). Washington, DC: American Psychiatric Association, 1985:74 and (2) USP Dispensing Information (USP DI): Drug Information for the Health Care Professional (10th Ed), Volumes 1A and 1B. Rockville, MD: United States Pharmacopeial Convention, Inc., 1990.

Coding Instructions: Circle "1" if a potential drug therapy problem is present; circle "0" if there is no problem.

A. CRITERIA FOR SCREENING ANTIPSYCHOTIC DRUG ORDERS [Do not use these criteria to evaluate drugs used for special purposes such as nausea/vomiting and other potentially appropriate nonpsychiatric conditions.]

Code	Criteria
1 0	A.1 No appropriate indication for use in the record
1 0	A.2 Drug prescribed for less than 3 days or PRN only
1 0	A.3 Continuous use for more than 6 months [Exception: psychotic disorders]
1 0	A.4 Use of two or more antipsychotic drugs at the same time
1 0	A.5 Used with ≥ 2 other psychotropic medications (count only once if patient has multiple psychotropics)
1 0	A.6 Other concomitancy (e.g., use of anticholinergic/ antispasmodic gastrointestinal medication)
1 0	A.7 Relative contraindications (e.g., history of allergy or hypersensitivity to this drug)
1 0	A.8 Dosage higher than recommended for age and diagnosis [Exception: failure to respond to lower dosage]
1 0	A.9 Dosage lower than recommended for age and diagnosis [Exception: responded to lower dosage]

General rule: The APA Manual suggests that persons 65+ without organic brain syndrome should receive 1/2 "usual adult dose" and that persons 65+ with organic brain syndrome should receive 1/4 "usual adult dose." This rule can be applied to the "usual adult dose" for non-extended release tablets found in the most recent USP-DI: Drug Information for the Health Care Professional.

ANTIPSYCHOTIC DEVIATION SCORE: ___ (Sum)

B. CRITERIA FOR SCREENING HYPNOTIC DRUG ORDERS [Do not use these criteria if drug is used as an anticonvulsant, as an antianxiety agent, or for other special purposes.]

<u>Code</u>	<u>Criteria</u>
1 0	B.1 No appropriate indication for use in record
1 0	B.2 Drug prescribed on a scheduled basis for ≥ 7 days
1 0	B.3 Continuous use of PRN hypnotic (≥ 15 nights/month)
1 0	B.4 Use of two or more hypnotics at same time
1 0	B.5 Used with ≥ 2 other psychotropic medications (count only once if patient has multiple psychotropics)
1 0	B.6 Other concomitancy (e.g., barbiturate or chloral hydrate with CNS depressant or coumarin anticoagulant)
1 0	B.7 Relative contraindication (e.g., history of allergy or hypersensitivity to this drug, use of barbiturate with porphyria or impaired hepatic function, use of chloral hydrate with marked hepatic or renal impairment)
1 0	B.8 Dosage higher than recommended for age (see USP-DI)
1 0	B.9 Dosage lower than recommended for age (see USP-DI)

HYPNOTIC DEVIATION SCORE: ____ (Sum)

C. CRITERIA FOR SCREENING ANTIANXIETY AGENT DRUG ORDERS [Do not use these criteria to screen drugs used as hypnotics or anticonvulsants, for relief of acute alcohol withdrawal symptoms, or for other special purposes.]

<u>Code</u>	<u>Criteria</u>
1 0	C.1 No appropriate indication for use in record
1 0	C.2 Prescribed on a scheduled basis for extended period (e.g., benzodiazepine for more than 3 months, meprobamate for more than 2 months)
1 0	C.3 Continuous use of PRN antianxiety agent (≥ 15 days/month)
1 0	C.4 Use of two or more antianxiety agents at the same time
1 0	C.5 Use with ≥ 2 other psychotropic medications (count only once if patient has multiple psychotropic orders)
1 0	C.6 Other concomitancy (e.g., use of antipsychotic drug for above indications, any other benzodiazepine)
1 0	C.7 Relative contradiction (e.g., history of allergy or hypersensitivity to this drug)
1 0	C.8 Dosage higher than recommended for age (see USP-DI)
1 0	C.9 Dosage lower than recommended for age (see USP-DI)

ANTIAXIETY DEVIATION SCORE: ____ (Sum)

D. CRITERIA FOR SCREENING TRICYCLIC AND SIMILAR ANTIDEPRESSANT DRUG ORDERS

<u>Code</u>	<u>Criteria</u>
1 0	D.1 No appropriate indication for use in record
1 0	D.2 Prescribed for less than 3 days or PRN only
1 0	D.3 Use of two or more tricyclic antidepressants
1 0	D.4 Use with ≥ 2 more psychotropic medications (count only once if patient has multiple psychotropic orders)
1 0	D.5 Other concomitancy (e.g., MAO inhibitor, guanethidine, clonidine, bethanadine, reserpine, anticholinergic, antiparkinsonian drug)
1 0	D.6 Relative contraindications (e.g., history of allergy or hypersensitivity to this drug, acute angle glaucoma)
1 0	D.7 Dosage higher than recommended for age (see general rule below)
1 0	D.8 Dosage lower than recommended for age

General rule: The APA Manual suggests 1/2 "usual adult dose" for adults over 65. Information regarding the usual adult dose can be found in most recent edition of USP DI: Drug Information for the Health Care Professional.

ANTIDEPRESSANT DEVIATION SCORE: ___ (Sum)

E. LIST OF SELECTED PSYCHOTROPIC DRUGS**E1. Antipsychotics**

<u>GENERIC NAME</u>	<u>COMMON BRAND NAME</u>
acetophenazine	Tindal
carphenazine	Proketazine
chlorpromazine	Chlor-PZ, Thorazine
chlorprothixene	Taractan
clozapine	Clozaril
fluphenazine	Permitil, Prolixin
haloperidol	Haldol
haloperidol decanoate	Haldol Decanoate
loxapine	Loxitane
mesoridazine	Serentil
molindone	Moban, Lidone
perphenazine	Trilafon
piperacetazine	Quide
prochlorperazine	Compazine
promazine	Sparine
thioridazine	Mellaril
thiothixene	Navane
trifluoperazine	Stelazine, Clinazine
triflupromazine	Vesprin

E2. Drugs Used as Hypnotics

<u>GENERIC NAME</u>	<u>COMMON BRAND NAME</u>
flurazepam	Dalmane
lorazepam	Ativan
temazepam	Restoril
triazolam	Halcion
amobarbital	Amytal
aprobarbital	Alurate
butobarbital	Butal, Butatran
pentobarbital	Nembutal
phenobarbital	Luminal
secobarbital	Seconal
talbutal	Lotusate
chloral hydrate	Noctec
diphenhydramine	Benadryl
doxylamine	Decapryn
ethchlorvynol	Placidyl
ethinamate	Valmid
glutethimide	Doriden
methprylon	Noludar
paraldehyde	Paral
promethazine	Phenergan

E3. Drugs Used as Antianxiety Agents

<u>GENERIC NAME</u>	<u>COMMON BRAND NAME</u>
* alprazolam	Xanax
bupirone	Buspar
* chlordiazepoxide	Libritabs, Librium, Reposans, Sereen
* chlorazepate	Tranxene
* diazepam	Valium, Valrelease
* halazepam	Paxipam
hydroxyzine HCl	Atarax, Anxanil, Atozine
hydroxyzine pamoate	Vistaril, Vamate, Hy-Pam
* lorazepam	Ativan, Alzapam, Loraz
meprobamate	Equanil, Miltown, Equagesic
* oxazepam	Serax
* prazepam	Centrax
* Limbitrol	SEE CHLORDIAZEPOXIDE
* = benzodiazepine	

E4. Antidepressants

<u>GENERIC NAME</u>	<u>COMMON BRAND NAME</u>
amitriptyline	Amitril, Domicol, Elavil, Endep
amoxapine	Asendin
bupropion	Wellbutrin
clomipramine	Anafranil
desipramine	Norpramin, Pertofrane
doxepin	Adapin, Curatin, Sinequan
fluoxetine	Prozac
imipramine	Imarate, Pramine, Tofranil
** maprotiline	Ludiomil
nortriptyline	Aventyl, Pamelor
protriptyline	Triptil, Vivactil
** trazadone	Desyrel
trimipramine	Surmontil
Etrafon, Limbitrol	Triavil

** = not a tricyclic antidepressant but considered similar

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