Upon completion of this program, the reader should be able to complete the following:
- Compare current dispensing practices with the newly approved short cycle dispensing in terms of logistics (e.g., dispensing, reporting) and clinical concerns (e.g., maintaining medications)
- Provide two examples of ethical concerns associated with new Drug Enforcement Administration proposed measures to reduce controlled substance diversion in long-term care settings.
- Compare and contrast community acquired pneumonia with nursing home–acquired pneumonia and hospital acquired pneumonia in terms of bacterial strains and treatment options.
- Identify the likely resistant pathogens of nursing home–acquired pneumonia and the complications that result from carrier status of elderly residents of long-term care facilities.
- Discuss likely pathogens and nonresistant antibiotic treatment options for nursing home–onset pneumonia compared with community acquired or hospital-acquired infections.
- Identify documented risks associated with psychotropic use in the elderly and the likelihood of occurrence associated with each psychotropic drug class.
- Provide vitamin D dosages for bone health and potential dosages for cancer prevention in elderly patients.

INTRODUCTION
Long-term care (LTC) pharmacy is a burgeoning practice setting in the 21st century. Within LTC pharmacy, practitioners at both independent and chain pharmacies as well as consultant pharmacist groups are assured of serving patients in need of care, along with having business and medication management opportunities. Geriatric and step-down care provided by LTC facilities, also known as nursing homes, differ in setting and nature from independent/assisted living and acute care facilities; patient care at nursing homes require supervised medication provision and, often, drug utilization reviews.

Traditionally, care is provided for residents around the clock by nursing staff, with regular physician and pharmacist visitations. Drug provision and review can be provided together through local independent or chain pharmacies, or clinical services may be provided separately from drug provision by an independent geriatric consultant pharmacist. According to the 2000 U.S. Census, more than 1.5 million elderly citizens resided in a long-term care facility, whether as a result of acute disease or debilitation (such as stroke) or as a result of longstanding and worsened disease (such as dementia) that precluded continued independent living but did not require hospitalization.
Care for nursing home residents accounts for extraordinary health care costs. In 2011, an independent market cost analysis estimated that nearly $180 billion is spent on nursing home care each year in the United States, with nearly one quarter of that cost coming directly from patients and their families. LTC facilities risk losing viability and impaired care of residents if costs cannot be controlled on business and individual levels. Appropriate drug review and medication management programs are keys to reducing costs, and pharmacists who work with LTC facilities by tracking medication use, drug interactions, and patient specific adverse drug reactions are crucial to the future of long-term care. The ongoing communication and connectivity with nursing staff at a LTC facility has played an important role for improving compliance, increasing state-of-the-art care, and reducing costs associated with drug misuse, over-use, or nonformulary use. The cooperative connectivity will continue to be crucial in coming years. The efficient teamwork of nurses, physicians, and pharmacists will reduce waste, prevent adverse drug reactions, lower administration costs, and offer the elderly improved quality and timeliness of care.

The varied nature of patient care needs and of the practice of pharmacy in the LTC setting introduces numerous complications that revolve around frequent policy changes, transient patients, and a confluence of disease states and treatment options without continuity of care. The balance of nursing, physician, and pharmacy staffing directly reflects optimal patient care and cost efficiency. As disease states, treatments, professional roles, and federal regulations become more complex, the pharmacist’s position in and importance to stellar long-term care have evolved drastically and require pharmacists to keep abreast of clinical and legal changes in the field.

LONG-TERM CARE POLICY UPDATES

Short-Cycle Dispensing Final Rule

In April 2011, the Centers for Medicare and Medicaid Services (CMS) released the final rule implementing Section 3310 of the Patient Protection and Affordable Care Act, requiring Part D sponsors to utilize specific, uniform dispensing techniques, such as weekly, daily, or automated dose dispensing when dispensing brand name, Part D covered drugs to enrollees residing in LTC facilities. The rule also requires Part D plans to collect data on the dispensing methodology and amount unused Part D drugs for each dispensing event. Commonly referred to as the Short Cycle Dispensing Rule, the intent is to reduce waste associated with traditional 30 day fills dispensed to beneficiaries. The final rule as it currently stands represents a compromise between the federal regulatory agencies and the LTC industry to include pharmacy organizations and professionals, with changes such as dispensations of 14-day or less, instead of the seven-day supplies and delay of enactment of dispensing and reporting requirements from January 2012 to January 2013. The later start date will allow LTC pharmacy providers time to restructure software, packaging, communication methods, and prescription processing, and provide extra time to conduct studies to identify the true cost effects of the new rule.

Effective Jan. 1, 2013, all solid oral doses of brand name drugs must be dispensed to Part D beneficiaries residing in LTC facilities in 14-day or less increments, with some exceptions which will be discussed as follows. The following summary highlights requirements of the final rule on short cycle dispensing that will affect LTC facilities:

Dispensing Considerations

• 14-Day Dispensing for Solid Oral Doses of Brand Name Drugs: as a result of the final rule, all pharmacies servicing LTC facilities (not only closed-door LTC pharmacies, but also retail and mail order pharmacies that dispense to LTC facilities), must dispense solid oral doses of brand name medications to patients in 14-day or less increments. This includes controlled substances, which are not exempt. CMS has specifically chosen to include controlled substances under the short cycle dispensing requirements. It believes that this will result in fewer unused controlled drugs in LTC facilities thereby decreasing the disposal burden and the risk of diversion. There are exceptions. CMS agreed
to limit short cycle dispensing to solid oral dosage forms only, excluding liquids. Two types of solid oral branded medications are excluded from the requirement to dispense solid oral doses of brand name drugs in 14-day supplies: antibiotics and medications that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information (such as inhalers) or those that are customarily dispensed in their original packaging to assist patients with compliance.

- **Dispensing Methodologies:** pharmacies will be required to use standardized communication codes on billing transactions to facilitate the reporting of information on the dispensing methodology utilized for each dispensing event. The CMS definition of dispensing methodology includes both the packaging system (such as punch cards, envelopes, or strip packaging) and the dispensing increment (14-day, 7-day, 2-2-3, daily, or automated dose dispensing). CMS clarified that a single facility may select multiple dispensing methodologies that meet the facility’s business needs in conjunction with its contracted LTC pharmacy. CMS will use these data to determine the extent to which the dispensing requirements reduce unused drugs and to help them determine whether the program should be extended to generic drugs in the future.

- **Dispensing Technique:** pharmacies are permitted to implement uniform dispensing techniques selected by each LTC facility, and may not be required to use a different packaging system or technology than that selected by the pharmacy in collaboration with the facility.

**Billing Issues**

- **Copayments:** copayments may be billed on the first dispensing event of the month, the last dispensing event of the month, or pro-rated with each dispensing event. Regardless of the number of incremental dispensing events, the total cost sharing cannot exceed the total cost share imposed for the drug if the 14-day requirements did not apply.

- **Dispensing Fees:** although CMS cannot be involved in negotiations between pharmacies and Part D plans to directly affect the contracted amount of dispensing fees, it has stated that it is reasonable to expect that dispensing fees be adjusted based on the newly proposed requirements. CMS also clarified the definition of dispensing fees, by including the salaries of pharmacists and other pharmacy personnel as reasonable costs for any pharmacy as well as the costs associated with the data collection of unused Part D drugs. Dispensing fees should take into consideration the number of dispensing events in a billing cycle, the acquisition and maintenance costs associated with the type of dispensing methodology utilized; and, with respect to Part D drugs dispensed in LTC facilities, the techniques to minimize the dispensing of drugs that go unused.

**Reporting Requirements**

- **Unused Drugs:** CMS is requiring that all unused drugs be reported by the plan sponsor, but as a result of concerns and comments submitted to CMS, has eliminated the proposed requirement that all unused drugs be physically returned to the pharmacy. This represents a substantial reduction in burden associated with the reporting requirements as compared to the proposed rule. CMS has indicated that the unused drugs may be calculated based on difference between the amounts dispensed and consumed. This may be determined by the date of discontinuation of the previous medication or the start date of a new prescription. CMS intends to use the reported information on unused drugs to show whether short cycle dispensing is successful in reducing waste on brand name drugs. An exception is that CMS will waive the reporting requirement for pharmacies that voluntarily adopt 7-day or less dispensing for both brand and generic drugs.

Even with the compromised changes, pharmacy representatives continue to express concerns about the necessity and effectiveness of short cycle dispensing. The potential for increased paperwork, greater staffing needs, more frequent medication transfers, differing requirements for non-Medicare patients and
for generic medications, and an undefined true cost to pharmacies and LTC facilities are some of the difficulties facing LTC health providers, and for smaller or non-urban pharmacies, these challenges will likely be even more pronounced.

Several potential negative impacts of the short cycle dispensing act have already been examined, and more impacts will likely be identified as the practice settings adapt to the new policy needs. Of great interest are workflow concerns regarding the need for increased numbers of pharmacists and support staff members to ensure effective transition to the new workload. Because patients will receive twice monthly supplies of medicines, the number of prescriptions to refill could double, requiring more communication and more processing time. As of yet, there have been no studies that have identified the true number of refills or new prescriptions or the likelihood of noncontinuous refills when a 14-day supply is not renewed.

Second, patients themselves will require more careful and accurate tracking to provide and maintain medications efficiently because the patients move frequently throughout the facility. Nursing staff must provide and document administration of the correct packaged medication to patients by assigned room and bed number in a timely manner, even when patients are away from their rooms. In the pharmacy, rapid and open communication is essential during the more frequent medication reordering to ensure medicines remain available and accurately labeled when fewer dosages are on hand in the facility.

Third, the data entry and electronic processing of prescriptions in the pharmacy will also likely double for the affected prescriptions. Computer entry adaptations will take time to implement and must be managed safely and efficiently to prevent incorrect input. Because only Medicare part D enrollees, not every resident, will require shorter medication cycles, and because only supplies of brand-name medications, not generics, will be restricted, two confusing layers of prescription checks will be added to the data entry workflow.

Fourth, biweekly billing, the initial influx of medication changes, and the more frequent use of only partially filled packaging can cause undue effects on pharmacies, including greater packaging waste and increased packaging costs, the need for more space as workflow adapts to separately fill 30-day and 14-day supplies for residents of a single LTC facility, and the risk of drug loss (through expiry or diversion) upon more frequent return of nearly empty medication packages.

Finally, the required technologic changes will complicate the pharmacy workload, because new or updated computer software will be required to correctly verify dispensing requirements at data entry. Costly software adaptations should provide automated checks on the drug quantity, patient Medicare enrollment status, bimonthly refill schedule and physician refill approval, and the numerous exempted medications. These technology changes, although necessary to ensure continuity of care and legal compliance with the short cycle dispensing act, will increase transaction volume and the risk of data entry error.

Although the intent of short cycle dispensing is to lower the costs of drug waste associated with 30-day medication fills, an observational study conducted in April 2011 by the Long-Term Care Pharmacy Association noted that only approximately 6 percent of medications—equivalent to less than 3 percent of the prescription cost of Medicare drug plans—for patients treated with 30 days supplies under Medicare part D prescription drug plans were returned to the pharmacy unused. In addition, according to the wording of the finalized short cycle dispensing law that is contradictory to federal regulations guiding LTC treatment, unused medications from the 14-day fills are not required to be returned to the pharmacy, possibly contributing to drug waste. The costs to implement and maintain short cycle dispensing for the long-term care facilities, the pharmacies, and the patients are as yet unknown.

Nurse as Agent and Controlled Substance Disposal

In mid–2010, as the short cycle dispensing debate was beginning, the Drug Enforcement Administration, the agency responsible for overseeing the lawful dispensing and use of controlled substances, released new inter-
pretation and enforcement of the Controlled Substances Act, outlining requirements for prescribing Schedule II medications to residents of LTC facilities. The new interpretation was in contrast to previous standard practices that allowed nursing staff to communicate with pharmacies on behalf of the physician (nurse as agent) for Schedule II medications. DEA requirements for Schedule II prescribing in LTC facilities have traditionally differed from those in outpatient settings, for which an original prescription with a physician signature is required before any dispensing, even partial dispensing, can occur.

Regulations in LTC that allow nurses to communicate on behalf of the physician enable efficient care, so patients can receive medication quantities sooner for urgent situations. Practice standards have traditionally allowed emergency approval for limited doses and faxed copies of Schedule II prescriptions written by a physician to be accepted and filled at pharmacies that supply LTC patients, in anticipation of receipt of the original prescription within a limited and defined time period. Such practices allowed pharmacists and nurses to provide pain management to patients in a timely manner, rather than by requiring direct communication with hard to reach physicians before dispensing. However, the 2010 reinterpretation of the controlled substance regulation has made both of these practices more legally restricted, hampering the ability of nurses and pharmacists to provide Schedule II substances to patients in LTC facilities without direct physician contact.

Under the October 2010 reinterpretation, nurses could act as agents for schedules III through V controlled substance prescriptions only, but new Schedule II prescriptions must be received by the pharmacy in the original form before any drug could be dispensed, thus still avoiding nurse participation and delaying patient receipt of medication. Emergency quantities of Schedule II pain management medications, for example, would no longer be legally provided in advance of the prescription receipt with only faxed notice by the nurse.

One complication of Schedule II controlled substance dispensing in LTC is the large quantities of unused Schedule II medications that remain in LTC facilities, increasing the risk of diversion and abuse. Unlike Schedule III through IV medications that can be returned to the pharmacy for destruction, Schedule II medications may not legally be credited back to the pharmacy from LTC settings, because the patient is not a registrant of the medication by DEA standards. The Secure and Responsible Drug Disposal Act of 2010 addresses the longstanding issue in which patients were prohibited from returning controlled substances to a DEA registrant because such a return would be outside the “closed chain of distribution” established by the CSA. This law provides DEA with the authority to promulgate regulations to facilitate such voluntary return programs, but does not mandate that entities establish a disposal program.

Throughout the early months of 2011, this regulation has been enacted primarily through community take back programs, which designated sites at which people could return unused medication for destruction. However, LTC facilities are not specifically included in or excluded from these programs, and Schedule II medications prescribed to LTC facility residents are not legally allowed to be returned through these programs or to the originating pharmacy according to wording of the existing controlled substance regulations that identify the patient as a nonregistrant of Schedule II medications. Current methods for disposal of controlled substances at LTC facilities vary by state and even by site, but they often involve a site visit by a consulting pharmacist and joint effort between the pharmacist and nursing supervisor to destroy the medications within the facility, rather than removal to a pharmacy for disposal. Clarity of the 2010 Controlled Substances Act and the Secure and Responsible Drug Disposal Act is in progress to ensure the legal and safe elimination of unused controlled substances from LTC facilities.

The DEA nurse as agent interpretation and the take back program may attempt to improve the rate and quality of care and may improve safety by limiting the quantity of medications on hand in the LTC facility, thus also lowering the potential diversion of Schedule II medications. However, careful consideration of the
ripple effects, including increased staffing needs, and pre-emptive education of health professionals, preferably as a team of physicians, nurses, and pharmacists together, are required to ensure seamless transition to new policies and avoid any delay of patient care.

**Overlapping Methods of Drug Review: Medicare Part D Medication Management Requirements and More**

Patients in LTC facilities nearly always have a high number of chronic disease states and medications that require careful management for safe and worthwhile disease control. Medicare Part D, enacted to provide treatment coverage for patients who are not covered by part B or other eligible programs, adds another confusing layer to drug therapy and pharmacist clinical services for patients at LTC facilities.

Pharmacists working at LTC facilities are required by federal law to provide monthly drug regimen (or drug utilization) reviews, which consist of basic chart reviews of all medications received by the patient, as a quality control check on treatment efficacy and safety. Pharmacy services required as part of the 2003 Medicare Modernization Act for Medicare enrollees in LTC facilities include medication therapy management, a legislative program for which pharmacists review drug therapy for patients with complicated, chronic disease states, such as diabetes or chronic obstructive pulmonary disease. Drug regimen reviews, also called medication regimen reviews, are broader than MTM and sometimes overlap in covered services and patient populations.

Drug regimen reviews are typically performed by pharmacists, are conducted every month, and are often paid for by the LTC facility. Common focuses of drug regimen reviews are drug allergies or cross-reactions, adverse drug reactions, interactions between multiple drugs or drugs and foods, and inappropriate prescribing or administration of medications. Pharmacists who circulate the LTC facilities for drug regimen reviews most often analyze treatment and communicate with other caregivers through chart notes with some goals of streamlining therapy, reducing waste, and providing counseling points to avoid side effects or improve administration methods.

MTM is only for select patients and is defined differently by each Medicare prescription drug plan. The MTM services are paid for by the drug plan, via CMS, rather than by the facility. Pharmacists must agree with each plan individually about what services are required and reimbursed. As of the original 2003 Act and reinterpretations during 2005, MTM has focused on disease state treatments and control in an effort to minimize health care costs by avoiding unnecessary treatment and by improving or preventing serious and costly chronic diseases in the elderly. Although a licensed nurse practitioner or similarly experienced health professional is legally allowed to provide MTM, consultant pharmacists are the most common providers of MTM, in part because the service overlaps with the drug regimen review service already provided by clinical and long-term care pharmacies. Moving forward, to ensure proper patient care and proven professional roles in LTC, pharmacists must continue their efforts to provide and be reimbursed for MTM provision even as new regulations change the eligibility and contractual details.

In 2011, MTM is again a legislative focus of the Medicare Decisions Accountability Act of 2011 (H.R. 452) to revise and ensure funding for Medicare beneficiaries and the Medication Therapy Management Empowerment Act of 2011 (S. 274) to amend Medicare part D coverage to increase the number of disease states covered for MTM services. In congressional committees, these acts in part propose continuation and enhancement of the original 2003 MTM requirements and reinforce the importance of pharmacy clinical services to Medicare enrollees with chronic diseases. The goals of MTM services, although varying between institutional and ambulatory settings, remain the optimization of drug use and the resultant improvement in treatment outcomes, with a particular focus on prospectively reducing the risk of adverse events and drug interactions. According to the current version of MTM revision in committees, the best practice for MTM includes annual direct interaction with the patient, a comprehensive written drug review and action plan, and follow up in person interventions as necessary. If passed,
the Empowerment Act of 2011 will expand MTM provision to cover even more concomitant conditions and part D treatments in any Medicare Part D enrollee whose medication costs exceed the threshold identified by CMS, $4,000 per year as set in 2007.

There is room for improvement in the existing and proposed MTM requirements, though. The best method of providing MTM involves not only patient interaction but also face-to-face meetings of nursing staff, physicians, and pharmacists. However, this interaction is often replaced with less frequent meetings or efficient but non-direct communication methods in place of in person care discussions. Also, MTM requires a greater time commitment than other review options provided to LTC patients and may require greater numbers of clinical pharmacists on site in the facility. Enhanced MTM that is expanded to a greater number of Medicare enrollees also may place a time burden on the nursing and pharmacy staff or may require a staff increase. Overall, though, MTM benefits patients, professionals, and facilities alike by producing higher quality care and reducing costs by identifying non formulary drug use, adverse drug reactions, drug interactions, and more.

### LONG-TERM CARE

**DISEASE STATE REVIEW**

**Hard to Treat Infections: Nursing Home–Acquired Pneumonia and Antibiotic Resistance**

Because LTC facilities are heterogeneous and disease states of residents are diverse, infection control is a complicated, facility specific problem. Guidelines released by the Society for Healthcare Epidemiology of America and the Association for Professionals in Infection Control and Epidemiology require interpretation for practical application because of the enormous challenges of antibiotic susceptibility, bacterial resistance, and complicated health care acquired infections for pharmacists who manage patient treatment in LTC facilities.

Although respiratory and urinary tract infections are both common in LTC settings, pneumonia is the infection most likely to cause the transfer of nursing home residents to a hospital. Frequent transfer of patients to acute care hospitals from LTC facilities and back again causes resistant pathogens to flourish resulting in infections difficult to treat. The resultant health care associated infection by resistant pathogens can often be misdiagnosed in both settings.

LTC residents are particularly high-risk patients, both for development of pneumonia and for likelihood of hospitalization. Patient groups at increased risk of pneumonia include elderly and male patients, those with poor ability to swallow (such as those with dementia, Parkinson’s, or stroke) or poor consciousness, and patients not able to receive medications orally. Additional factors that lead to greater risk of pneumonia in LTC residents are their extensive co-morbidities, frequent central or peripheral catheter use, polypharmacy, and numerous hospital stays. Treatments associated with pneumonia risk are also used commonly in residents of nursing homes and include antipsychotics, anticholinergic medications, and proton pump inhibitors. Health care related pneumonia is associated with increased mortality, longer hospital stays and higher rates of malnutrition than community acquired pneumonia.

Resistance is frequent; more than 25 percent of *Klebsiella* strains are resistant to levofloxacin and

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### Pharmacist Drug Review Services Comparison

<table>
<thead>
<tr>
<th>Drug Regimen Review</th>
<th>Medication Therapy Management</th>
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<tbody>
<tr>
<td><strong>Who is eligible?</strong></td>
<td>Every patient in long-term care</td>
</tr>
<tr>
<td><strong>What is covered?</strong></td>
<td>Regular, periodic review of drug use, adverse events, and interactions</td>
</tr>
<tr>
<td><strong>How is it funded?</strong></td>
<td>Services paid for by the long-term care facility</td>
</tr>
<tr>
<td><strong>When and how is it performed?</strong></td>
<td>Monthly on site chart reviews with written communication among health professional caregivers</td>
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ceftazidime, and a concerning, increasing resistance to imipenem has occurred over the last 10 years. Antibiotic resistance appears highest in LTC facilities that use greater numbers of antibiotics, and larger facilities with more beds. Resistance patterns also vary with geography. Colonization of bacteria without active infection is extremely common among residents of LTC facilities and is easily transferable in the close quarters of shared living spaces. Bacterial colonization of a nursing home patient during a hospital stay does not always cause a suprainfection or symptoms, but after the patient returns to the nursing home it increases the number of patients at the facility who become a reservoir of resistant pathogens for later disease. These future infections are more likely to exhibit multidrug resistant bacterial strains, such as methicillin resistant Staphylococcus aureus (MRSA) and vancomycin resistant enterococcus (VRE), even in seemingly healthy residents and even during first infections.

In 2008, more than one quarter of LTC residents were identified as carriers of MRSA, though rates varied drastically in patients at different facilities. The variance suggests that individual facility measures to monitor MRSA rates at intake (such as at patient entrance to the facility, whether from home or from an acute care hospital setting) are crucial to controlling the bacteria and preventing MRSA spread within the facility. Being a MRSA carrier increases the risk of complicating infections, particularly pneumonia, that are hard to treat and may be life threatening in an elderly patient.

In 2009, the Department of Health and Human Services examined methods to reduce the spread of MRSA in hospitals and issued guidelines to reduce hospital acquired infections overall, but particularly those associated with MRSA and Clostridium difficile from catheter or ventilator associated infections. These guidelines suggest supportive care strategies, such as controlling blood sugar, reducing ventilator and catheter use, and increasing sterility of all associated equipment (including gloves and stethoscopes) while treating patients at risk for resistant disease.

LTC pneumonia, also known as nursing home–acquired pneumonia or NHAP, is a prevalent cause of morbidity and mortality in elderly residents. In presentation NHAP may resemble community acquired disease more than nosocomial (hospital-acquired) disease. However, drug resistant bacteria strains, such as MRSA, occur more frequently than in community acquired pneumonia. Residents of LTC facilities experience nearly 2 million infections each year, which more closely resembles infection rates of acute care hospitals instead of community settings. Conversely, NHAP is associated with increased mortality rates when compared to community infections possibly because of their misidentification as community acquired disease, which may lead to improper initial treatment. NHAP infections are also associated with lower treatment costs when compared to hospital acquired infections.

NHAP pathogens have similarities to those

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<tr>
<th>Potential Pathogens</th>
<th>Combination Antibiotic Therapy</th>
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<tbody>
<tr>
<td><em>Streptococcus pneumoniae</em></td>
<td>Antipseudomonal cephalosporin (cefepine, ceftazidime)</td>
</tr>
<tr>
<td><em>Haemophilus influenzae</em></td>
<td>or Antipseudomonal carbapenem (imipenem or meropenem)</td>
</tr>
<tr>
<td>Methicillin sensitive <em>Staphylococcus aureus</em></td>
<td>or Beta lactam (piperacillin tazobactam)</td>
</tr>
<tr>
<td>Antibiotic-sensitive enteric gram-negative bacilli</td>
<td>plus Antipseudomonal fluoroquinolone (ciprofloxacin or levofloxacin)</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>or Aminoglycoside (amikacin, gentamicin, or tobramycin)</td>
</tr>
<tr>
<td><em>Klebsiella pneumonia</em></td>
<td>Methicillin resistant <em>Staphylococcus aureus</em> (MRSA)</td>
</tr>
<tr>
<td><em>Enterobacter species</em></td>
<td>plus Linezolid or vancomycin</td>
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<tr>
<td><em>Proteus species</em></td>
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<tr>
<td><em>Serratia marcescens</em></td>
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<tr>
<td>Multi Drug Resistant Pathogens</td>
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<tr>
<td><em>Pseudomonas aeruginosa</em></td>
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<tr>
<td><em>Klebsiella pneumonia</em></td>
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<tr>
<td><em>Acinetobacter</em></td>
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<tr>
<td>Methicillin resistant <em>Staphylococcus aureus</em> (MRSA)</td>
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acquired in the community setting, namely *Streptococcus pneumoniae* and *Haemophilus influenzae*. However, hospitalization as a result of pneumonia can quickly foster new pathogens and lead to a more severe infection by resistant bacteria, including *Pseudomonas aeruginosa*. The most common empiric treatment for nHAP is shown in Table 1. Prevention is especially important in all LTC facilities to prevent pneumonia and to slow the spread of disease. The pneumococcal vaccine should be given to any eligible residents.

How can patients at risk of health care-acquired infection be identified in order to reduce the risk of spreading resistant disease? First, any patient who has experienced health care services, such as home care, wound care, LTC living, or dialysis care within 30 days of diagnosis likely has health care-acquired pneumonia. Second, pneumonia is generally identified as non–hospital acquired disease if it is diagnosed within 48 hours of hospital admission. Third, microbial testing has identified increased rates of MRSA and pseudomonas in health care-acquired infection, so susceptibility testing can aid identification. Fourth, local prevalence and susceptibility results appear most important for empiric treatment.

Pharmacists working in conjunction with physicians and nursing staff can help minimize MRSA spread by appropriately treating nHAP. Stewardship programs being developed in the 21st century for LTC use of antibiotics provide a multitiered approach of appropriate antibiotic use and resistance monitoring, with goals of improving treatment outcomes; reducing adverse events associated with antibiotic use, through appropriate dosing; and halting resistance with appropriate drug choice. Antibiotic overuse and misuse, in particular, are two common practices that may be curbed by participatory stewardship programs. Up to 70 percent of patients in LTC settings receive antibiotic treatments each year, and prescribing practices of phone-in prescriptions without a check of symptoms or antibacterial efficacy are frequent.

The role of the pharmacist in the stewardship program is to review antimicrobial susceptibility, prescribing policies, and usage trends. Interventions range from passive observation or usage rates, trends, and susceptibility reports to more direct changes. Direct interventions can be made by influencing antibiotic choice via formulary use, algorithms, or prescription approval programs. These front end approaches are easier and more successful than hindsight assessments, although both methods require staff education. Even in hindsight, usage assessments by a consultant pharmacist can screen for adherence and set standards for future use. These efforts require health professional education and partnerships.

**Ongoing Pharmacologic Concerns About Dementia Treatments in LTC Settings**

At least 12 percent of adults age 65 years or older and 50 percent of those older than 85 have been diagnosed with Alzheimer’s dementia. LTC management requirements to care for these elderly are increasing greatly because of the patients’ poor cognition, physical decline, and behavioral changes associated with the dementia. Possibly three quarters of all LTC residents suffer from a form of dementia, and LTC stays are more extended in patients with Alzheimer’s dementia because of the gradually progressive nature of this non-terminal disease and the longer lifespan experienced in this generation. Dementia and LTC living individually and together require extra aid with activities of daily living, and both types of patients exhibit behavioral changes.

For more than a decade, patients with dementia admitted to LTC facilities have received psychotropic medications to control agitation and behavioral changes associated with dementia. In fact, as many as 50 percent of patients have received at least one psychotropic medication while at LTC facilities, and up to 17 percent of patients with dementia received an atypical antipsychotic medication for behavior and agitation within 100 days of admission to a nursing home in 2008. Psychotropics are used for short-term symptom control instead of extended maintenance or as a disease therapy. The dementia is not treated with antipsychotics.

At least four categories of psychotropic agents are traditionally used to control behavioral changes of dementia, namely antidepressants, antipsychotics, anxiolyt-
ics, and mood stabilizers. Drug interactions and adverse reactions are a risk in any patient population with drugs in these classes, and elderly patients experience a greater number of adverse events and more serious events than younger populations. No conventional (first generation) or atypical (second generation), antipsychotics are approved for the treatment or control of dementia, even for the behavioral aspects of the disease, and their use is associated with death and warrants a black box warning from the FDA. The risk of adverse events may be individualized to time and person; acute illness and co-morbid conditions have their effects, as does the length of antipsychotic drug use.

Adverse events from psychotropic medications are often extensions of pharmacologic action; because the drug activity is more pronounced in older populations, elderly patients usually require lower doses. Adverse events most often noted are sedation, extrapyramidal symptoms, anticholinergic effects, cardiac changes, and weight gain. The choice of agent should be based on the side effect profiles; doses should be tailored to individuals, and pharmacists should be willing to change the drugs to decrease adverse effects. Attention to possible delirium and changes in the diabetes or lipid profiles should be noted. Pharmacists should make sure monitoring for glucose, lipids, and mental status is in place and review the results. Pharmacists should also ensure if a psychotropic medication is to be discontinued or changed appropriate tapering methods are utilized if indicated.

Atypical antipsychotics replaced many of the older drugs of all classes because of their purportedly improved side effect profile; however, even these newer drugs have uncertain benefits on the psychosis, aggression, and agitation with dementia, and they have no definitive proof of efficacy in the elderly for Alzheimer’s dementia. For example, compared with no treatment, conventional antipsychotics have been four times more likely, and atypical antipsychotics have been three times more likely, to cause adverse events in an elderly LTC population. The behavioral problems associated with dementia may be better and more safely controlled with treatments aimed at the underlying cause and by therapeutic interaction strategies.

Patients exhibiting aggressive or anxious behavior, whether from dementia or not, are often treated with short-term prescriptions for psychotropic medications approved for the treatment of severe mental disorders, such as schizophrenia, to sedate, calm, or control them. With the advent of atypical antipsychotics, which seemed safer than conventional antipsychotics, even more elderly patients in LTC settings were treated for behavior changes, hallucinations, and agitation with off-label antipsychotic medications, often at dosages approved for severe mental disorders. However, in 2007, results of a meta analysis of 17 studies that included atypical antipsychotic use in elderly patients with dementia identified a nearly twofold increased risk of death associated with these medications. As a result of the health risks from psychotropic agents, LTC facilities have again begun adjusting recommendations for therapy. Behavioral aspects of dementia still require treatment, so practitioners must use their best judgment and carefully monitor use of psychotropics. Unfortunately, many facilities have merely focused on the legality of atypical antipsychotic use by requiring family signatures for informed consent rather than focusing on changing evaluation and treatment programs. The most common result of the black box warnings in atypical antipsychotics has been to reduce the dose of existing therapy in elderly LTC residents with dementia, not to remove the atypical agent as a result of danger. The drug alternatives to antipsychotic agents currently remain sedative psychotropic drugs, such as anxiolytics, which also have identified health risks in the elderly. Complicating the treatment options are the complex nature of the patients, their uneven health status, and the poor supervision of medication and diagnostic procedures with limited time spent on both, despite the distinct need for these geriatric services.

Nearly half of new admissions to LTC facilities in 2000 were admitted with a diagnosis of dementia; however, a more pressing concern may be the drastic change in mental status of the elderly, with or without ongoing dementia that occurs shortly after facility admission. The
status changes are often observed by family as a noticeable need for more help with activities of daily living, less interest in previously enjoyable activities, and poorer communication skills. These behaviors may be noted by staff and will likely result in prescription management for worsening dementia. In fact, behavior changes like these may be best treated with structured interactions provided by caregivers rather than with medications that are proven dangerous to the elderly population. In particular, partnered communication, verbal and pictorial cues, and structured conversations have all been identified as having positive influence on the ability of elderly to maintain mental status longer in an LTC facility. Caregivers who are trained to establish goals of these interactions and to document their use on a medication log each day are crucial to the well being of these elderly.

Health care in the 21st century faces a large influx of elderly into LTC as we live longer with complicated diseases states. Aged LTC patients, especially ones receiving psychotropics with known adverse event risks, require close drug monitoring and care by geriatric specialists in the medical and pharmaceutical fields. Appropriate care may require increased staff, more frequent drug utilization review, and additional hands-on patient time, but is essential for appropriate care of the elderly.

New Vitamin D Research and Guidelines for Bone Health and More
The rate of falls and the resultant fractures in people older than 65 years are high, greater than 33 percent, and are associated with prominent morbidity and even mortality; the rate of death associated with hip fracture nears 20 percent. The elderly in LTC facilities are also likely to have multiple chronic disease states, such as heart disease, that are difficult to manage. In 2010, a Canadian study identified a deficiency of vitamin D in nearly half of LTC residents. Low vitamin D levels are linked to bone disease, partly through inadequate calcium absorption, and recent studies have identified other potential health benefits as well.

Vitamin D is a fat soluble and potent, steroid like vitamin made in the body from cholesterol in varying amounts according to skin tone, region, and sun exposure. Its primary use is to affect bone health by keeping calcium and phosphorus levels stable. Vitamin D also plays a role in cell cycles; bone development; heart health; and muscle, pancreas, brain, and immune system functions. The active form is 1,25 dihydroxyvitamin D, or calcitriol. Calcitriol has a half life of 15 hours and is found at receptors throughout the body.

Vitamin D deficiency is not clearly defined but is estimated as blood levels less than 20 ng/mL of circulating 25 hydroxyvitamin D, and blood level increases are proportional to vitamin D intake amounts. Vitamin D deficiency is more likely in people with low sun exposure, with dark skin, with older age, and with obesity. Elderly nursing home residents, then, are at risk of deficiency because of their age and their limited diet and sun exposure. Symptoms of deficiency include musculoskeletal pain, periodontal disease possibly, vision changes, insomnia, and diarrhea. Common food sources of vitamin D are egg yolks, fortified dairy products, and fortified breakfast cereals. Vitamin D2 and D3 supplements are available in many forms, mostly containing 400 Iu. Cod liver oil, a good source of vitamin D, also contains vitamin A and may be toxic at high amounts.

According to the 1997 dietary reference intakes for vitamin D to prevent rickets and osteomalacia, people age 50 to 70 years old should receive 400 IU vitamin D and people older than 70 should receive 600 IU vitamin D. However, updated recommendations from 2010 data suggest that even these intake values are not enough for any age. The 2010 Institute of Medicine guidelines for vitamin D and calcium intake suggest a recommended daily allowance of 1,000 mg of calcium and 600 IU of vitamin D for men age 51 to 70 years old, and the same vitamin D intake but 1,200 mg of calcium in women of the same age range. All people older than 70 should receive 1,200 mg of calcium and 800 IU of vitamin D as a recommended daily allowance. A minimum of 800 IU daily is suggested for LTC residents in Canada, and supplements for up to 1,000 IU have been suggested because of the high risks of deficiency in elderly LTC residents. Varied data support the ability of vitamin D to prevent fractures,
particularly hip and nonvertebral breaks, which are more common causes of morbidity in LTC patients than in the general population.

Vitamin D appears especially effective in patients at higher risk of fracture from falls, such as elderly LTC residents with Alzheimer’s disease, Parkinson’s disease, and stroke. The importance of vitamin D to musculoskeletal health may also result from effects at receptors for the vitamin on muscle fibers that could support rapid response to falls by increasing the strength of those muscles. Doses of 800 IU have been identified with lower fractures in the hip and non-spinal areas, but 400 IU doses have not shown the same association. If effective, at least 700 to 800 IU per day is required for the prevention for hip and nonvertebral breaks. Department of Agriculture research data suggest that benefits start at 700 IU daily and increase proportionally with dose to prevent falls and fractures. The role of vitamin D in and the necessary dosages for bone health for elderly will become clearer as results of new trials, such as the vitamin D and omega-3 trial (VITAL) of 2010, emerge.

The 1997 vitamin D recommendations focused on preventable bone diseases rather than on other organ systems. Since 1997, though, studies have observed benefits of vitamin D in the prevention of chronic diseases, including cancer, autoimmune disorders, diabetes, heart disease, depression, and more.

Low vitamin D levels may be proportional to increased rates of colorectal cancer because vitamin D stops blood vessel growth and reduces inflammation. People taking high doses, greater than 1,000 IU per day, in addition to calcium had lower rates of colorectal cancer diagnoses, though 400 IU of vitamin D per day in addition to calcium did not appear to change the risk of breast cancer. Vitamin D has known anti-inflammatory activity likely to play a role in many chronic disorders. This activity, and perhaps an unknown direct blood vessel mechanism, may prevent acute and chronic heart deterioration. In the Framingham Heart Study, vitamin D blood levels lower than 15 ng/mL appeared to increased the risk of heart disease, heart attack, and hypertension, although no other studies have yet confirmed this positive evidence.

Vitamin D might affect the immune system as well, but no studies have definitely observed effects in multiple sclerosis, types 1 or 2 DM, depression, or influenza. The

Vitamin D and Omega 3 Trial (VITAL) initiated in 2010 will observe the use of 2,000 IU vitamin D3 and 1,000 mg EPA plus DHA and report on effects in the elderly, not only for bone disease but also for immune and heart functions. The 2010 recommendations tentatively support additional health benefits of vitamin D, especially reduced rates of heart disease and prevention or lower risk of some cancers.

Although the links between vitamin D use and these health benefits are not yet certain, the 21st century trend is clear—vitamin D supplementation in and out of LTC settings is being recommended by physicians and used by the public. Pharmacists have the opportunity to step in and guide safe use and appropriate dosages, particularly in LTC settings.

Vitamin D levels in the blood are not a standard request on a laboratory panel, but their importance might increase as vitamin D becomes more directly associated with health benefits. Normal values of 25 hydroxyvitamin D in the blood range from 35 to 40 ng/mL, a suggested goal for preventive use. Up to 50, 70, or 100 ng/mL may be considered as a goal for prevention of cancer or heart disease, pending additional studies. Healthy levels can be maintained with 800 to 1,000 IU/d supplements; intake of 100 IU increases blood levels by 1 ng/mL proportionally within two to three months of use.

Because vitamin D is fat soluble, it should be taken with a meal. Vitamin D effects in the body display a U curve, such that deficiency and excessive intake both damage the body. The upper intake level suggested by the Institute of Medicine in 2010 for all people older than 51 is 4,000 IU per day. Side effects, which are possible at 88 ng/mL, include nausea, vomiting, headache, constipation, sleepiness, and weakness. Extremely high vitamin D levels increase calcium levels and the risk of hypercalcemia and hypercalciuria, or high calcium in the blood and urine. Vitamin D absorption is impaired by some weight loss medications and levels may be reduced with concomitant corticosteroids or anti-seizure medications.
As more studies are conducted and the safety and usefulness of vitamin D is more clearly established, pharmacists can be an important resource to the public and to other health professionals about appropriate use of vitamin D for disease prevention.

**CASE STUDY 1**

Patient A.P., 72 years old, was admitted to your long-term care facility, with possible early stage Alzheimer’s disease but was untreated for dementia in outpatient care. He requires minimal to moderate assistance with daily living and can converse for short time periods with family and friends. Within 30 days of admission, A.P. has started receiving short-term treatment with alprazolam at least three times a week to control outbursts and reduce anxiety or agitation. He has been diagnosed with Alzheimer’s dementia. The patient’s chart also notes that family members are concerned about A.P.’s function, noting that his demeanor has drastically worsened after arriving at the nursing home; he is no longer able to focus on conversational visits and requires even greater assistance with walking, grasping objects, and recognizing friends. As the consulting pharmacist at the facility reviewing the chart for a monthly DUR, what concerns do you have about the patient’s treatment with psychotropics? What adverse effects would you look for in the chart’s nursing notes? Are the drastic changes in this patient associated with a disease state, with the treatment, or both? What treatment and/or therapeutic interventions would you recommend, and what benchmark improvements would you provide as goals? How would you counsel the patient’s family about his current state and potential decline?

**Response**

A.P. has received a diagnosis of Alzheimer’s dementia and should begin an appropriate treatment, such as low dose donepezil or a newer treatment like galantamine or rivastigmine, depending on dementia severity. Short-term benzodiazepines will not improve symptoms of dementia and are possibly causing undue side effects. After checking the chart notes, you identify irregular sleep patterns and dizziness as possibly related to the alprazolam administration. The cognitive and functional decline noted in A.P. could be a progression of the dementia that may stop or improve with medication, but these drastic declines may also be a response to his changed living environment. To supplement the initial dementia treatment, you suggest therapeutic interventions and stimulations. In addition, you recommend reducing the alprazolam dose by half to treat the occasional agitation with fewer side effects and include plans to taper the dose up gradually as needed for symptom control. You then note in the chart a plan to review the therapeutic and symptomatic treatments in one month with these goals: improving function, including the ability to identify meal choices and to converse calmly with visitors; reducing agitation with proper control of dementia symptoms and scheduled interactive scenarios; and eliminating the sleep and balance side effects. Next, you see A.P.’s daughter on your way out and counsel her that dementia is a progressive disease and that her father’s decline during the past month is reflective of the disease and the drastic change into an unfamiliar setting. You explain the need to ease anxiety and the lower dose of alprazolam, and you give her information about treating dementia with your recommended agent. Finally, you provide her a resource for the Alzheimer’s Foundation of America for additional information.

**CASE STUDY 2**

H.T., an 81 year old long-term care resident of seven years, repeatedly fluctuates between nursing home and acute care hospital for infection control and treatment. After being transferred to the hospital for treatment of her most recent pneumonia infection, she required a ventilator for breathing assistance and was treated with ampicillin plus cefixime. After her breathing improved, H.T. was discharged to her traditional LTC after five days, but the infection was not resolved after the antibiotic was completed in the nursing home. What is the next likely treatment course? What laboratory parameters or susceptibility evaluations may be needed? What risks did this patient have for resistance, for hospital acquired-infection, for health care-associated pneumonia, or for treatment complications? What are the likely pathogens, based on the most likely type of pneumonia? Is H.T. colonized with MRSA?

**Response**

Because H.T. experienced symptoms of pneumonia before being admitted to the hospital, the infection is probably nursing home acquired, instead of hospital acquired-pneumonia, so the pathogens more closely resemble community acquired disease. However, resistance is possible because the infection was not eradicated with two drug treatment, because of the use of a ventilator, and because of the patient’s frequent hospital admissions. Susceptibility testing can identify antibiotics that retain activity against the likely pathogens. Pseudomonas, MRSA, or other resistant bacterial strains are possible; thus, H.T. might require treatment with a three drug regimen and/or a microcline, vancomycin, or linezolid, depending on susceptibility testing results. H.T. is at high risk of MRSA colonization because of her frequent hospital stays and as indicated by her repeated and difficult to treat infections. As the consulting pharmacist overseeing treatment of the reinfection, you select a three or four drug treatment regimen on the basis of susceptibility results, and you recommend careful observation of sterile procedures. You also suggest treating H.T. in the nursing home without transfer to the hospital if possible to avoid additional opportunities for recurrent and resistant infection.

**CONCLUSION**

From both a clinical and a legal perspective, the field of long-term care pharmacy is rapidly expanding and changing. The population of patients requiring chronic, nonacute care will only increase, adding to the burden of care for pharmacists and enhance the need for new
pharmacists who specialize in geriatric care. While maintaining patient care for chronic disease states, pharmacists must become adept at treating ongoing acute problems in the elderly—particularly fracture risks, psychiatric complications from chronic dementia, and infections complicated by resistant pathogens.

It is also the ethical responsibility of the LTC pharmacist to ensure that the best care is provided according to the most current legal requirements for the practice setting. Current regulations on the needs of Medicare patients, the risks of diversion and waste, and the best disposal methods are not yet clear cut. Pharmacists must be a voice for geriatric patients in this setting as well as the clinical setting so that federal regulations put into place will clearly guide pharmacists toward efficient care and simultaneously protect elderly patients from harm. Appropriate patient care and observation of regulations both require ongoing teamwork among pharmacists, physicians, and nursing staff, and pharmacists are poised to enter this team in a leadership role to maintain clinical, ethical, and legal standards.

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CONTINUING EDUCATION QUIZ
Select the correct answer.

1. Vitamin D dosages of ___ IU/day are suggested by preliminary studies to prevent colon cancer?
   a. 400
   b. 600
   c. 800
   d. 1,000

2. New Institute of Medicine guidelines recommend ___ IU daily of vitamin D and ___ mg daily of calcium in people age ___ years or older?
   a. 400; 1,000; 70
   b. 400; 1,000; 51
   c. 800; 1,200; 70
   d. 800; 2,000; 70

3. Elderly long-term care patients are at risk of vitamin D deficiency because of ___?
   a. Their increased rate of falls
   b. Their limited sun exposure
   c. Their changing sleep patterns
   d. Two of the above

4. Vitamin D receptors are found in which of the following?
   a. Bone
   b. Pancreas
   c. Muscle
   d. All of the above

5. Vitamin D toxicity from too much supplementation can express itself as which of these?
   a. Diarrhea
   b. Kidney stones
   c. Insomnia
   d. Two of the above

Editor’s Note: For the list of references used in this article, please contact America’s Pharmacist Managing Editor Chris Linville at 703-838-2680, or at chris.linville@ncpanet.org.
6. Short cycle dispensing will apply to what and/or whom?
   a. Medicaid patients
   b. Brand name medications
   c. All insured patients
   d. Two of the above

7. The following short cycle dispensing requirements are true, except:
   a. Dispensing methodology includes both the packaging system and the dispensing increment
   b. Short cycle dispensing requirements apply only to solid oral dosage forms
   c. Controlled substances are exempt from 14-day or less requirements
   d. Reporting requirements are waived for pharmacies that voluntarily adopt 7-day or less dispensing for both brand and generic drugs

8. Medication therapy management required by Medicare varies according to which of the following?
   a. Part B plans
   b. Disease states
   c. Medications prescribed
   d. Two of the above

9. The Controlled Substance Act allows nurses to act as agents for physicians writing Schedule II prescriptions.
   a. True
   b. False

10. Schedule II medication disposal is legally limited in LTC facilities because of which of the following?
    a. The medications cannot be returned to the pharmacy.
    b. The risk of accumulation of Schedule II medications and diversion in the long-term care center
    c. Two of the above
    d. None of the above

11. The most likely pathogens to cause uncomplicated nursing home–acquired pneumonia include which of these?
    a. Klebsiella
    b. Pseudomonas
    c. Two of the above
    D. None of the above

12. Nursing home–acquired pneumonia complicated by recurrent hospitalization might require treatment that covers which bacteria?
    a. Pseudomonas
    b. MRSA
    c. Clostridium
    d. Two of the above

13. Which of the following are risk factors for developing pneumonia?
    a. Female
    b. Elderly
    c. Repeated community-acquired pneumonia
    d. All of the above

14. What are risk factors for being hospitalized after developing a lung infection?
    a. Anticholinergic use
    b. Long-term care resident
    c. Polypharmacy
    d. None of the above

15. What monitoring is needed for patients on psychotropic medication?
    a. Glucose
    b. Lipids
    c. Mental status
    d. All of the above

16. Treatment of complicated long-term care pneumonia, as identified by frequent hospitalization or frequent reinfection, might require what combination of antibiotics?
    a. Betalactam, cephalosporin, and fluoroquinolone empirically
    b. Cephalosporin only
    c. Linezolid only
    d. Cephalosporin and macrolide
17. What percentage of patients receive treatment with psychotropic medications within 100 days of long-term care admission?
a. 25  
b. 20  
c. 17  
d. 15

18. What types of psychotropic medications can be used to control behavior in people with dementia?
a. Barbiturates  
b. Selective serotonin reuptake inhibitors  
c. Benzodiazepines  
d. All of the above

19. Which medications are associated with an increased risk of death when used to control behavior in elderly patients?
a. Alprazolam  
b. Olanzapine  
c. Risperidone  
d. All of the above

20. What side effects might an elderly patient experience after being treated with benzodiazepines for agitation and anxiety related to dementia?
a. Weight loss  
b. Weight gain  
c. Insomnia  
d. Excessive salivation