



ANTIBIOTIC USE IN NURSING HOMES

Wisconsin Department of Health Services
Division of Quality Assurance
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Purpose

The purpose of this position paper is to:

- Provide information about antibiotic use to treat urinary tract infections and the types of deficient practices related to antibiotic use.
- Request nursing homes to join with the Division of Quality Assurance (DQA) and the Wisconsin Healthcare-Associated Infections in Long-Term Care Coalition (WI HAI in LTC Coalition) in the nationwide effort to reduce the use of unnecessary antibiotics through development of antibiotic stewardship programs.

WI HAI in LTC Coalition website: http://www.dhs.wisconsin.gov/rl_DSL/NHs/hai-intro.htm

Background

In September, 2013, the Centers for Disease Control and Prevention (CDC) released the report, Antibiotic Resistance Threats in the United States (<http://www.cdc.gov/drugresistance/threat-report-2013/>). The report notes that antimicrobial resistance is one of our nation's most serious health threats and outlines the potential catastrophic consequences of not taking immediate action to address this threat.

Antibiotics were first discovered in the 1940s and were considered to be wonder drugs because they were so effective in saving lives. Over the decades, bacteria have demonstrated the ability to become resistant to every antibiotic developed; the more we use antibiotics, the more quickly antibiotics develop resistance. While antibiotics continue to be the most important resource to fight life-threatening bacterial infections, their overuse has dramatically increased the development of drug-resistant pathogens and dramatically decreased the number of effective antibiotics available to treat infectious diseases at a time when the number of new antibiotics in the pipeline has steadily decreased. Research has shown that up to 50 percent of antibiotics prescribed are not needed.¹

According to the CDC, the single most important action needed to greatly reduce the development and spread of antibiotic-resistant infections is for physicians and other health care professionals to change the way antibiotics are used through adoption of the principles of responsible antibiotic use, known as antibiotic stewardship. Antibiotic stewardship is a commitment to use antibiotics only when necessary to treat and, in some cases, prevent disease; to choose the right antibiotics; and to administer them in the right way in every case.²

Antibiotic Use in Nursing Homes

Antibiotics are among the most commonly prescribed medications in nursing homes and place residents at risk for antibiotic-related complications to include adverse drug reactions, development of multi-drug resistant organisms (MDROs) and Clostridium difficile infection, which the CDC identifies as the number one urgent public health threat.

Urinary tract infections (UTIs) are considered the most common bacterial infection in nursing homes and the most common reason for initiation of antibiotics. Studies have consistently shown that about 30 to 50 percent of frail, elderly nursing home residents have asymptomatic bacteriuria, a state in which bacteria colonize the urine but do not cause symptomatic infection.³ Studies have consistently demonstrated that there is no benefit to treating asymptomatic bacteriuria. Unfortunately, many of these residents are treated inappropriately with antibiotics. The American Medical Directors Association Choosing Wisely Campaign® (<http://www.amda.com/tools/choosingwisely.cfm>) does not recommend obtaining a urine culture unless there are clear signs and symptoms that localize to the urinary tract.

Despite UTIs being recognized as the most commonly recognized infection in nursing homes, there is no universally accepted definition of UTI used for initiating treatment. Several consensus-based definitions have been developed over time to improve diagnosis and treatment of UTIs and have gained widespread acceptance among infection control experts. While there is variation among them, all of these definitions require the presence of urinary tract signs and symptoms. Urinary tract signs and symptoms include dysuria (painful urination), new onset frequency, urgency, incontinence, flank pain/tenderness, suprapubic pain, gross hematuria, or focal tenderness of the testis, epididymis, or prostate.⁴

Antibiotic Stewardship in Nursing Homes

Numerous organizations to include, but not limited to, the American Medical Directors Association (AMDA), the Association for Professionals in Infection Control and Epidemiology (APIC), the CDC, the Centers for Medicare and Medicaid Services (CMS), the Society for Healthcare Epidemiology of America (SHEA), and the WI HAI in LTC Coalition recommend nursing homes implement antibiotic stewardship programs to ensure judicious use of antibiotics. These organizations recommend that long-term care (LTC) facilities develop policies and procedures that establish minimum criteria for initiating antibiotics to ensure that residents are not started on antibiotics without a credible clinical picture; that antibiotics are treating infection, not colonization or contamination; and that the right drug is used for the right purpose and for the right duration. These organizations also recommend that LTC facilities develop procedures and a mechanism for monitoring antibiotic use, measure the extent to which antibiotic use has met accepted standards of practice, provide feedback to appropriate personnel, and develop facility-specific antibiograms to help clinicians select appropriate antibiotics.^{5 6 7 8 9 10 11 12 13}

There is a gap between calls for change and availability of tools to help nursing homes to improve antibiotic prescribing practices. Fortunately, there are a number of ongoing efforts both nationally and locally to reduce this gap. The Agency for Health Research and Quality has recently funded a project to assemble existing antibiotic stewardship tools for use in nursing homes, and this should be available for nursing homes in the near future. Locally, the WI HAI in LTC Coalition is developing a toolkit to help nursing homes improve use of antibiotics for treatment of UTI. This toolkit focuses on proper identification and testing of residents with suspected UTI, improving antibiotic choice, and use of ongoing monitoring to continuously improve the process. The toolkit will be presented at this year's FOCUS conference and should become widely available by early next year. Facilities interested in improving antibiotic use should strongly consider taking advantage of these resources.

Issue

In 2009, CMS released the *Updated Guidance to Surveyors for 42 CFR §483.65 (Federal tag F441) – Infection Control*. The F441 guidance included an Investigative Protocol that directs surveyors to review the appropriateness and effectiveness of antibiotics for residents receiving antibiotics.¹⁴ In 2012, CMS released the new Surveyor Quality Measure Reports that include a quality measure for UTIs. These reports are reviewed during the survey process to identify indicators of potential problems that may warrant further investigation and further contribute to the review of the appropriateness of antibiotics.¹⁵ Consequently, the Division of Quality Assurance (DQA) has seen a steady increase in the number of deficiencies issued for inappropriate antibiotic use cited at 42 CFR §483.25(l) (Federal tag F329) - Unnecessary Drugs or both F329 - Unnecessary Drugs and F441 - Infection Control.

Regulatory Requirements

F329 requires that each resident's drug regimen must be free from unnecessary drugs. As stated in F329, an unnecessary drug is any drug when used:

- i. In excessive dose (including duplicate therapy).
- ii. For excessive duration.
- iii. Without adequate monitoring.
- iv. Without adequate indications for its use.
- v. In the presence of adverse consequences, which indicates the dose should be discontinued.
- vi. Any combination of the reasons above.

Indications for use is defined by CMS as the identified, documented, clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals that is consistent with manufacturer's recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies, or evidence-based review articles that are published in medical and/or pharmacy journals.¹⁶

The most common reasons for these deficiencies were lack of an adequate indication for their use. Examples include, but are not limited to:

- Failure to document evidence of a resident's signs and symptoms that would support a diagnosis of infection.
- Failure to modify antibiotic therapy when culture results are negative.
- Failure to modify antibiotic therapy when culture results are positive for which the organism is resistant to the empirically prescribed antibiotic.
- Prophylactic use of antibiotics to prevent urinary tract infections.

F441 requires that the facility establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

The F441 guidance identifies antibiotic review as an essential component of a facility's infection prevention and control program and notes "it is the physician's (or other appropriate authorized practitioner's) responsibility to prescribe antibiotics and to establish the indication for use of specific medications. As part of the medication regimen review, the consultant pharmacist can assist with oversight by identifying antibiotics prescribed for resistant organisms or for situations with questionable indications, and reporting such findings to the director of nursing and attending physician. See the Guidance at §483.65, Tag F329 regarding use of a medication without adequate indication for use and at §483.65, Tag F428 regarding medication regimen review."

As indicated above, the F441 guidance directs surveyors to review the appropriateness and effectiveness of antibiotics for residents that are identified as receiving antibiotics. If concerns are identified, surveyors will interview the facility infection preventionist and other appropriate personnel, which may include the attending physician and medical director, regarding appropriate antibiotic use.

Deficiencies issued at F441 for inappropriate antibiotic use addressed systems issues. Examples include lack of policies and procedures that establish minimum criteria for initiating antibiotics, policies and procedures not consistent with current standards of practice, and failure to follow policies and procedures.

Since UTIs are the most common infection in nursing homes and drive antibiotic use, the infection prevention and control program needs to develop and implement policies and procedures that address appropriate management and surveillance of UTIs consistent with current standards of practice.

42 CFR §483.60(c) (Federal tag F428) – Medication Regimen Review requires that the drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist and that the pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

The CMS defines an irregularity as any event that is inconsistent with usual, proper, accepted, or right approaches to providing pharmaceutical services or that impedes or interferes with achieving the intended outcomes of those services.¹⁷

The pharmacist needs to play an active role in assisting the facility to practice antibiotic stewardship and ensure that each resident's medication regimen is free from inappropriate antibiotic use.

42 CFR §483.75(i) (Federal tag F501) – Medical Director requires that the facility designate a physician to serve as a medical director who is responsible for the implementation of resident care policies and the coordination of medical care in the facility.

The intent of this regulation is that the facility has a medical director who coordinates medical care in the facility and provides clinical guidance and oversight regarding the implementation of resident care policies that are consistent with current standards of practice. The medical director helps the facility identify, evaluate, and address/resolve medical and clinical issues that are related to the provision of services by physicians and other licensed health care practitioners that affect the provision of resident care, medical care, and/or quality of life.¹⁸

The medical director needs to play an active role in the oversight of the infection control program, which includes:

- Collaborating with facility leadership, staff, and other practitioners and consultants to provide clinical guidance and oversight of the development, implementation, and evaluation of resident care policies related to the identification, management, and surveillance of UTIs.
- Coordinating physician services and medical care to assure that each resident's physician attends to the resident's medical needs and complies with facility policies and procedures. The medical director is the most appropriate and authoritative facility representative to communicate infection control information and provide direct feedback to attending physicians on their antibiotic use practices.

42 CFR §483.75(o) (Federal tag F520) – Quality Assessment and Assurance requires the facility to have a quality assessment and assurance (QAA) committee that meets at least quarterly to identify issues and develop and implement appropriate plans of action to correct identified quality deficiencies.

The intent of this regulation is that the facility has an ongoing QAA committee that identifies quality deficiencies, develops and implements plans of action to correct these deficiencies, monitors the effect of implemented changes, and makes revisions to the action plans when necessary.¹⁹

Since UTIs are recognized as the most common infection in LTC and drive antibiotic use and CMS Quality Measures include a measure for UTI that is used for both public reporting²⁰ and during the survey process, each nursing home should track UTI management as part of their quality assurance/process improvement program.

¹ Antibiotic Resistance Threats in the United States, 2013. Available at <http://www.cdc.gov/drugresistance/threat-report-2013/>. Accessed August 6, 2014.

² Ibid

³ CDC Get Smart for Healthcare: Antibiotic Use in Nursing Homes, November 18-24, 2013. Available at <http://www.cdc.gov/getsmart/healthcare/factsheets/nursing-homes.html>. Accessed August 7, 2014.

⁴ Nace DA, Drinka PJ, Crnich CJ. Clinical Uncertainties in the Approach to Long Term Care Residents With Possible Urinary Tract Infection. *J American Medical Directors Association* 2014; 15: 133-139.

⁵ AMDA: Common Infections in the Long-Term Care Setting, 2011. Clinical Practice Guideline.

⁶ [APIC: Guide to Preventing Clostridium difficile Infections, 2013.](#)

⁷ Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., and the Healthcare Control Advisory Practices Committee. 2006 Guideline for Management of Multidrug-Resistant Organisms in Healthcare Settings. Pp. 34. Accessed August 13, 2014, from http://www.cdc.gov/hicpac/mdro/mdro_0.html.

⁸ [CMS Survey & Certification Letter 09-54. Issuance of Revisions to Interpretive Guidance at F Tag 441, as Part of Appendix PP, State Operations Manual \(SOM\), and Training Materials, August 14, 2009.](#) Accessed August 7, 2014.

⁹ Loeb, M., Bentley, DW., Bradley, S., et al. Development of Minimum Criteria for the Initiation of Antibiotics in Long-Term – Care Facilities: Results of a Consensus Conference. *Infection Control Hospital Epidemiology* 2001;22:120-124. Accessed August 13, 2014, from <http://www.jstor.org/stable/10.1086/501875>.

¹⁰ Smith, P.W., Bennett, G., Bradley, S., Drinka, Paul., et al. SHEA/APIC Guideline: Infection prevention and control in the long-term care facility. *Infection Control Hospital Epidemiology* 2008;29(9):785-814. Accessed August 13, 2014, from <http://www.jstor.org/stable/10.1086/592416>.

¹¹ Crnich, Dr. Christopher. "The Case for Antibiotic Stewardship in Nursing Homes," WI HAI in LTC Coalition Events page. September 20, 2013. Retrieved August 13, 2014, http://www.dhs.wisconsin.gov/rl_DSL/NHs/hais-events.htm.

¹² Boero, Dr. Joe. "Setting Up an Antibiotic Stewardship Program in a Nursing Home" WI HAI in LTC Coalition Events page. September 20, 2013. Retrieved August 13, 2014, http://www.dhs.wisconsin.gov/rl_DSL/NHs/hais-events.htm.

¹³ Podzorksi, Dr. Raymond. "Your Institution's Antibioqram – More Than Just A Table," WI HAI in LTC Coalition Events page. September 20, 2013. Retrieved August 13, 2014, http://www.dhs.wisconsin.gov/rl_DSL/NHs/hais-events.htm.

¹⁴ [CMS Survey & Certification Letter 09-54. Issuance of Revisions to Interpretive Guidance at F Tag 441, as Part of Appendix PP, State Operations Manual \(SOM\), and Training Materials, August 14, 2009.](#) Accessed August 7, 2014.

¹⁵ [CMS Survey & Certification Letter 12-45. Advance Copy of Interim Guidance - Revisions to State Operations Manual \(SOM\), Appendix P-Traditional Survey Protocol for Long-Term Care \(LTC\) Facilities and Chapter 9/Exhibits including Survey Forms 672, 802, 802S and 802P, September 27, 2012.](#) Accessed August 7, 2014.

¹⁶ [CMS State Operations Manual, Appendix PP, April 14, 2014.](#) Accessed August 7, 2014.

¹⁷ Ibid

¹⁸ Ibid

¹⁹ Ibid

²⁰ Medicare.gov – Nursing Home Compare. Accessed August 13, 2014, <http://www.medicare.gov/NursingHomeCompare/About/Quality-Measures-Info.html>.