



This document is scheduled to be published in the Federal Register on 09/05/2014 and available online at <http://federalregister.gov/a/2014-20422>, and on [FDsys.gov](http://FDsys.gov)

Billing Code 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Agency for Healthcare Research and Quality  
Agency Information Collection Activities:  
Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Guide to Nursing Home Antimicrobial Stewardship." In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the Federal Register on May 21st 2014 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by (insert date 30 days after date of publication).

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at [doris.lefkowitz@ahrq.hhs.gov](mailto:doris.lefkowitz@ahrq.hhs.gov).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at [doris.lefkowitz@ahrq.hhs.gov](mailto:doris.lefkowitz@ahrq.hhs.gov).

SUPPLEMENTARY INFORMATION:

Proposed Project

Guide to Nursing Home Antimicrobial Stewardship

This project seeks to contribute to AHRQ's mission by assisting nursing homes to optimize antimicrobial (e.g., antibiotics and antifungals) prescribing practices, also referred to as antimicrobial stewardship. Antimicrobial stewardship programs reduce the development of drug-resistant organisms, enhance patient outcomes, and reduce unnecessary costs.

Nursing homes serve as one of our most fertile breeding grounds for antibiotic-resistant strains of bacteria. This stems from high rates of infection in nursing home residents due to the effects of normal aging combined with multiple chronic diseases. The most common infections encountered in nursing home residents are pneumonia, urinary tract infections, and skin and soft tissue infections. In one study by Yoshikawa and Norman, researchers found that these three types of infections accounted for approximately 75 percent of all nursing home-associated infections (NHAIs). High rates of these infections lead to antimicrobials being among the most commonly prescribed pharmaceuticals in long-term care settings. In nursing homes, where polypharmacy is the rule rather than the exception, as many as 40 percent of all prescriptions are for antimicrobial agents, and depending on the study, 25 percent to 75 percent have been deemed inappropriately prescribed. Such inappropriate prescribing results in negative outcomes, including adverse drug events, hospital admissions, and higher health care costs. Most significantly, inappropriate antimicrobial prescribing gives rise to the development of multi-drug resistant organisms (MDROs), including Methicillin-resistant *Staphylococcus aureus*, Vancomycin-resistant *Enterococci*, and fluoroquinolone-resistant strains of a variety of bacteria, and leads to the development of *Clostridium difficile* infections.

In general, determining "appropriateness" of antimicrobial use in healthcare settings is challenging to standardize. This becomes even more complicated in the nursing home setting because most antimicrobial courses are started empirically (without results from labs) due to the limited diagnostics available to many nursing homes. In an effort to address the need for optimizing antibiotic use in the nursing homes, AHRQ is testing a Guide to Nursing Home Antimicrobial Stewardship (the Guide). The Guide is intended to help nursing home staff easily identify toolkits that have been shown to be effective in optimizing antimicrobial use. There are multiple toolkits that could be used by a nursing home, and nursing homes face a potentially time-consuming decision process to choose the most appropriate one. The Guide is intended to help nursing homes make this choice efficiently and effectively.

The research has the following goals:

- Develop a nursing home-specific antimicrobial stewardship guide, containing toolkits to assist nursing homes to optimize antimicrobial prescribing practices, monitor microbes and antimicrobial use, enhance communication between nursing home staff and attending clinicians, and enhance communication and engagement with residents and family members regarding optimizing antimicrobial practices.
- Evaluate the ability of nursing homes to use the Guide and improve antimicrobial use through better stewardship.
- Develop a plan to ensure wide dissemination of the findings and recommendations for antimicrobial stewardship uptake in nursing homes.

This study is being conducted by AHRQ through its contractor, American Institutes for Research, pursuant to AHRQ's statutory authority to

conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a) (1) and (2).

#### Method of Collection

To achieve the goals of this project the following data collections will be implemented:

1) Medical Record Review (MRR). The MRR will be used to obtain data about antimicrobial prescribing practices, infection prevalence, and residents' health and functional statuses. These data will be used in the evaluation of the Guide's impact. Members of the research team will review the nursing home's medical charts, the Nursing Home Minimum Data Set (MDS), and the nursing home's infection control log for an evaluation period of at least 12 months (6 months before and 6 months after the introduction of the Guide). The MDS is part of the federally mandated process for clinical assessment of all residents in Medicare and Medicaid certified nursing homes. This process provides a comprehensive assessment of each resident's functional capabilities and helps nursing home staff identify health problems. Care Area Assessments are part of this process, and provide the foundation upon which a resident's individual care plan is formulated. MDS assessments are completed for all residents in certified nursing homes, regardless of source of payment for the individual resident. AHRQ will support data abstraction at all nursing homes.

2) Cost Data Analysis. AHRQ will use the number and type of antimicrobial prescriptions and secondary estimates of the unit cost of these prescriptions, obtained from external sources, to compute the marginal impact of the Guide on the cost of antimicrobials for nursing homes.

3) Pre-intervention interviews with nursing home leaders. The purpose of these interviews is to gain an understanding of perceptions and current activities regarding antimicrobial stewardship and to assess the likelihood that the Guide will be used with a reasonable degree of fidelity to the implementation plan. This will involve both closed and open-ended interviews with nursing home leaders (administrator, director of nursing, assistant director of nursing, and/or medical director). The open ended interviews will examine (1) how the staff perceive antimicrobial stewardship; (2) the amount of experience the staff has in antimicrobial stewardship and its processes for handling the diagnosis and treatment of infections; and (3) which toolkit or toolkits are likely to be adopted and why. This information will help us identify interests by nursing homes and potential barriers to adopting a toolkit from the Guide. This information also will be used to develop dissemination guidance. The closed ended interview questions, will be comprised of the Absorptive Capacity for Change survey, which asks about (1) leadership culture; (2) clinician culture; (3) presence of certified medical directors; and (4) level of antimicrobial surveillance. For the Evaluation, two leadership staff at each nursing home will be interviewed for a total of 20 interviews prior to implementing the intervention.

4) Passive Technical Assistance (TA). The purpose of collecting these data is to obtain information on the types of TA needed as they emerge during the 6-month intervention period. This information will be used to improve the Guide. AHRQ projects 60 contacts from nursing home staff involved in implementing the Guide (10 sites, one per month at each site during the 6-month intervention period).

5) Proactive TA discussions. The purpose of collecting these data is to obtain information on the facilitators, challenges, and unintended consequences of implementing a particular tool or toolkit. These informal discussions will be held at each nursing home once a month during the 6-month intervention phase. Staff will be asked about what activities they are conducting, changes to implementation, any facilitators, any challenges, and how they have addressed any challenges. This information will be used to improve the Guide. For the Evaluation, two individuals from each nursing home are projected to attend each of the six conference calls for a total of 20 individuals and a total of 120 contacts.

6) Post-intervention interviews. The purpose of these interviews is to identify (1) facilitators and barriers to implementation; (2) perceived impacts of the Guide on the use of antimicrobials within the nursing home; (3) the nursing home's views on the business case for the Guide; and (4) ways to improve the tools. At a minimum two nursing home leaders and two champions (if different from leaders) will be interviewed. In addition, depending on the tool or toolkit selected, up to two prescribing clinicians, two nurses, or two residents or family members might be interviewed after the 6-month intervention period is completed. No more than six individuals per nursing home will be interviewed for a total of 60 interviewees. Interviews may take place together.

The information described above will be used to evaluate the Guide and, if found to be effective, develop a wide-spread dissemination plan for the Guide.

#### Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this information collection.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Passive TA Collection Protocol	20	3	20/60	20
General Review of the Guide	20	1	2	40
Pre-intervention interview protocol	20	1	1	20
Proactive TA discussion protocol	20	6	30/60	60
Post-intervention interview protocols	60	1	1	60
Total	140	na	na	200

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Passive TA Collection Protocol	20	20	\$30.34	\$607
General review of the Guide	20	40	\$30.34	\$1214
Pre-intervention interview protocol	20	20	\$30.34	\$607
Proactive TA discussion protocol	20	60	\$30.34	\$1,820
Post-intervention interview protocols	60	60	\$30.34	\$1,820
Total	140	200	na	\$6,068

\* National Compensation Survey: Occupational wages in the United States May 2013, "U.S. Department of Labor, Bureau of Labor Statistics." We used an average across the following types of staff: nursing home registered nurses (\$29.81) 29-1141, nursing home licensed practical/vocational nurses (\$21.14) 29-2061, and nursing home administrator (\$40.07) 11-9111. Our average was created by adding each of these three and dividing by three for the average. Sources:

<http://www.bls.gov/oes/current/oes291141.htm> and

<http://www.bls.gov/oes/current/oes292061.htm>;

<http://www.bls.gov/oes/current/oes119111.htm>

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following:

(a) whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 20, 2014

Richard Kronick, Ph.D.

AHRQ Director