## **SUPPORTING STATEMENT**

## Part A

# **Guide to Nursing Home Antimicrobial Stewardship**

Version: April 14, 2014

Agency of Healthcare Research and Quality (AHRQ)

## **Table of contents**

١	A. Justification	3 -
	1. Circumstances that make the collection of information necessary	
	2. Purpose and Use of Information	6 -
	3. Use of Improved Information Technology	7 -
	4. Efforts to Identify Duplication	
	5. Involvement of Small Entities	
	6. Consequences if Information Collected Less Frequently	7 -
	7. Special Circumstances	7 -
	8. Federal Register Notice and Outside Consultations	7 -
	8.b. Outside Consultations	8 -
	9. Payments/Gifts to Respondents	8 -
	10. Assurance of Confidentiality	8 -
	11. Questions of a Sensitive Nature	10 -
	12. Estimates of Annualized Burden Hours and Costs	10 -
	13. Estimates of Annualized Respondent Capital and Maintenance Costs	11 -
	14. Estimates of Annualized Cost to the Government	11 -
	15. Changes in Hour Burden	12 -
	16. Time Schedule, Publication and Analysis Plans	12 -
	17. Exemption for Display of Expiration Date	14-

### A. Justification

### 1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see http://www.ahrq.gov/hrqa99.pdf), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

- 1. research that develops and presents scientific evidence regarding all aspects of health care;
- 2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and
- 3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

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 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)<sup>1</sup>. 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<sup>2</sup>, and

Yoshikawa, T. T., & Norman, D. C. (1996). Approach to fever and infection in the nursing home. *Journal* <sup>1</sup> *.of the American Geriatrics Society*, 44, 74–82

depending on the study, 25 percent to 75 percent have been deemed inappropriately prescribed<sup>3</sup>. 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.
- 2) Evaluate the ability of nursing homes to use the Guide and improve antimicrobial use through better stewardship.
- 3) Develop a plan to ensure wide dissemination of the findings and recommendations for antimicrobial stewardship uptake in nursing homes.

To achieve the goals of this project the following information collections will be implemented in three phases as shown in table 1 below:

**Table 1. Information** Collected by Phase

Phase	Pre-intervention	6-month	Post-intervention

Nicolle, L. E., Strausbaugh, L. J., & Garibaldi, R. A. (1996). Infections and antibiotic resistance in nursing <sup>3</sup> .homes. *Clinical Microbiology Review*, 9, 1–17

		intervention period (9/1/14 - 2/28/15)	
When the information is	Approximately 1 month prior to the	Information collected	Approximately 1 month after the
collected	intervention	throughout the intervention period	intervention period
Information collected	<ul> <li>Pre-intervention interviews</li> <li>Medical record review of secondary data from 3/1/14 to 8/30/14</li> </ul>	<ul> <li>Technical         Assistance (TA)         Information and         Questions</li> <li>Proactive TA         discussions</li> <li>Cost data</li> </ul>	<ul> <li>Medical record review of secondary data from 9/1/14 to2/28/15</li> <li>Post- intervention interviews</li> </ul>

- 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. See Attachment A for the pre-intervention interview protocol.

- 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). See Attachment B for the Passive TA collection protocol.
- 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. See Attachment C for proactive TA discussion protocol.
- 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. See Attachment D for the post-implementation interview protocols.

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).

### 2. Purpose and Use of Information

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

### 3. Use of Improved Information Technology

The research team will abstract data from the nursing home infection logs, MDS assessments, and nursing home medical records using an electronic format, programmed in MS Access, and enter the data into an electronic database, which will be used for analysis.

### 4. Efforts to Identify Duplication

AHRQ has supported the development of four individual toolkits to facilitate antimicrobial stewardship in nursing homes and an environmental scan to identify other toolkits. Although there are some antimicrobial stewardship toolkits available to nursing homes, there is no comprehensive Guide to assist nursing home staff in deciding which tools or toolkits to adopt. No other project has developed and tested a comprehensive guide to nursing home antimicrobial stewardship.

### 5. Involvement of Small Entities

The sample for the evaluation will come from nursing homes across the United States certified by the Centers for Medicare & Medicaid Services . The average nursing home has about 108 beds. We will recruit some nursing homes that are part of larger chains and others that are independent. Thus, some nursing homes will be small businesses, but it is impossible to say how many will be small until they are recruited. There is no specific intention to study small businesses, other than to assure that there is some representation from small nursing homes in the study and the size of the nursing home will be taken into account in the analysis. Our methods will be tailored to the existing communication models used by each participating nursing home, so the needs of small businesses will be accommodated.

## 6. Consequences if Information Collected Less Frequently

This is a one-time data collection effort.

### 7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

## 8. Federal Register Notice and Outside Consultations

### 8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on May 21, 2014 for 60 days (see Attachment H). No comments were received.

#### 8.b. Outside Consultations

AHRQ's consultants for the design and conduct of this study include:

- Steven Garfinkel, PhD, MPH, of American Institutes for Research, project director
- Elizabeth Frentzel, MPH of American Institutes for Research, deputy project director
- Manshu Yang, PhD, of American Institutes for Research, statistician
- Chris Crnich, MD of the University of Wisconsin who is an expert in nursing home care and antimicrobial stewardship.
- Darcy McMaughan, PhD, of Texas A & M Health Science Center, evaluation lead
- Hongwei Zhao, PhD of Texas A & M Health Science Center, statistician
- David Mehr, MD of the University of Missouri, geriatrician with expertise in infections in nursing home care.
- David Nace, MD of the University of Pittsburgh, nursing home care and antimicrobial stewardship.
- Susan Purcell, RN, of TMF Health Quality Institute, nursing home care administration and nursing in long-term care.
- Kavita Trivedi, MD of Stanford University and Trivedi Consulting, nursing home clinical care and antimicrobial stewardship.

A Technical Expert Panel will meet four times to advise the project team on the study design and current nursing home communication models. The following organizations are represented on the panel:

- AARP
- American Association of LTC Nursing
- American Health Care Association
- American Medical Directors Association
- Centers for Disease Control and Prevention
- Gerontological Society of America
- Infectious Diseases Society of America
- LeadingAge
- Texas state nursing home ombudsman
- Society for Healthcare Epidemiology of America

## 9. Payments/Gifts to Respondents

No payments or gifts will be provided to respondents or nursing homes.

### 10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 944(c) of the Public Health Service Act. 42 U.S.C. 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied.

**Individual resident-level data** will be abstracted from four sources: the nursing home medical record, the MDS record, the infection log, and the individual record for the toolkit(s) from the Guide implemented by each nursing home. Although the data abstractors will be able to see identifiers, such as the resident's name, social security, and HIC numbers while they are abstracting data from some of these records, the resident's

nursing home medical record number is the only identifier that will be abstracted. The resident's medical record number will be collected so that we can link multiple episodes of infection for the same patient recorded in the infection log and so that we can merge data from the nursing home medical record, the MDS record, the infection log, and relevant toolkit information for each resident. None of these records will be removed from the nursing home. Only the abstracted data elements entered into the electronic form will removed and entered into the research database.

Until all information is collected, the linkage between the medical record number for each resident and the project-generated unique identifier will be kept on individual thumb drives in a secure location at TMF. It will not leave TMF and will only be referenced by the data collectors to determine whether an infection log entry is for someone who is already a study participant and to identify the correct medical record and MDS record for data abstraction. The medical record number will be destroyed and replaced by a project-generated unique identification number as soon as all data are collected and merged so that the data will no longer be identifiable.

We will seek a waiver of consent from the governing IRBs for record abstraction, because we will have no other reason to have any contact with the resident and the research could not practicably be carried out otherwise. In lieu of individual consent, we will propose to the IRB that we post an information sheet about the study in commons locations at each nursing home where residents and family members can readily see them (see Attachment F for the resident and family member information sheet). We will obtain data use agreements from each of the nursing homes and we will describe to them the purposes for which the infection and antimicrobial information will be collected and that identifiable information will not be used or disclosed for any other purpose.

Researchers will keep all study records locked in a secure location. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff at AHRQ's contractor, American Institutes for Research (AIR) and AIR's subcontractors, Texas A&M Health Sciences Center and TMF Health Quality Institute, will have access to the passwords and password-protected data. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and no resident or nursing home will be identified in any publications or presentations. The data will be collected by clinically trained staff (nurses and therapists) employed by TMF Health Quality Institute, AIR's subcontractor. These individuals are experienced data collectors and regularly work with nursing homes in their capacity as CMS Quality Improvement Organization (QIO) employees. Data collection will be on-site at the nursing homes using a password-protected database on a password protected laptop computer owned by TMF. All data collectors have been trained in the protection of research subjects.

For the **pre-intervention interviews, passive TA data collection, proactive TA discussions, and the post intervention interviews**, respondents will be told the purposes for which the information is collected and that, in accordance with the Privacy Act, any identifiable information about them will not be used or disclosed for any other purpose. Staff and clinicians who agree to be interviewed will receive a consent form (see

Attachment G for consent forms) explaining that participation is voluntary and that they will not be identified in our reports. The consent form will be sent prior to the interview and we will obtain verbal consent for telephone interviews. We will seek a waiver of documentation of consent for the telephone interviews from the governing IRBs as is common with interviews conducted by phone. For in-person interviews, we will provide a consent form and request documentation of consent.

Trained, experienced qualitative interviewers will conduct the interviews by phone. A staff member will take notes during the interviews. All interviews will be recorded for analysis. All recordings will be deleted within three years of the end date of the project. All notes will remove the name of the interviewee and the nursing home. All notes and recordings will be stored on password-protected computers. All interviewers have been trained in the protection of research subjects.

### 11. Questions of a Sensitive Nature

There are no questions of a sensitive nature in this data collection effort. Researchers will have no direct contact with residents and questions for nursing home staff and prescribing clinicians will only concern their job roles and activities, not their personal attitudes and behaviors, except with respect to their attitudes and behaviors about toolkits and the Guide.

### 12. Estimates of Annualized Burden Hours and Costs

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

<sup>\*</sup> 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:

## 13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no direct costs to respondents other than their time to participate in the study.

### 14. Estimates of Annualized Cost to the Government

Although data collection will require less than one year, the entire project will span 3 years. The annualized cost of this research is estimated to be \$657,881.

**Exhibit 3. Estimated Total and Annualized Cost** 

Cost Component	Total Cost	<b>Annualized Cost</b>
Project Development	\$768,284	\$256,095
Data Collection and Analysis	\$919,457	\$306,486
Publication of Results	\$0	\$0
Project Management	\$285,901	\$95,300
Total	\$1,973,642	\$657,881

Exhibit 4: Annual cost to AHRO for project oversight

Project Officer - GS 14 Step 7	7%	\$8,925.84
\$127,512		
Total		\$ 8,925.84

Annual salaries based on 2014 OPM Pay Schedule for Washington/DC area:

http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/ DCB.pdf

 $<sup>\</sup>frac{http://www.bls.gov/oes/current/oes291141.htm}{http://www.bls.gov/oes/current/oes292061.htm}; \\ \frac{http://www.bls.gov/oes/current/oes291141.htm}{http://www.bls.gov/oes/current/oes119111.htm}.$ 

### 15. Changes in Hour Burden

This is a new collection of information.

### 16. Time Schedule, Publication and Analysis Plans

### Time Schedule

Obtain pre-intervention information: begin as soon as approval is obtained from OMB and it will last approximately 1 month, approximately 8/1/14 through 8/30/14. Six months of pre-intervention medical record information will be collected. Intervention period: Approximately 9/1/14 through 2/28/15.

Post intervention data collection: Approximately 3/1/14 through 4/1/14. Analysis: 4/1/14 through 6/30/14Reporting: 7/1/14 through 9/30/14

### **Publications**

There is no funding for peer-reviewed journal publications.

### **Quantitative Analysis Plans**

**Data.** Analyses will be carried out at the nursing home, resident, and infection levels. Information on an estimated 1,836 infections that received antimicrobial treatment during the field test will be available for analysis.

**Dependent Variables.** The list of potential dependent variables contains both process and outcome quality measures. These are:

- Whether a prescription was prescribed appropriately (yes/no).
- Change in antimicrobial prescribing rates (at the nursing home level)

**Treatment Variable.** The treatment variable will be an indicator of which toolkit from the Guide the nursing home implemented. This variable can be used at the resident level (the resident resides in a nursing home that is classified as using Toolkit X).

**Sub-group analyses.** Through the use of interaction terms or subgroup analyses, the research will investigate differential impact of the Guide by several resident characteristics, including:

- residents residing in different type of nursing homes
- residents with infections at different body sites
- residents with different types of attending clinician (i.e., Medical Director or other)
- longer-stay or shorter-stay residents
- severely cognitively-impaired residents, or

residents with a terminal prognosis

Analysis Strategy. The basic analysis plan involves the development of descriptive statistics for the dependent variables for the entire sample and for sub-groups, as well as visual displays for all homes and for each home in each intervention type. This will be followed with mixed-effect logistic regression models using the dependent and independent variables noted above. The primary analysis will then use multilevel random intercept logistic regression models.<sup>4</sup>. The unit of analysis, each infection or resident, will be repeated measures (pre-intervention and post-intervention), nested within homes. If infection is the outcome, then the repeated measure is nested within residents, within homes (as a number of residents will have multiple infections).

The mixed-effects logistic regression method accounts for the lack of independence between the observations. A backwards elimination approach based on likelihood ratio testing will be used to create multivariate models for formal hypothesis testing. Significance testing for the coefficients will be set at alpha = 0.05 and the model parameter will be exponentiated so that they may be interpreted as odds-ratios. SAS version 9.1 will be used for performing the analysis. Due to the complexity with multilevel models for binary outcomes, we will use different procedures (PROC GLIMMIX and PROC NLMIXED) to perform our analysis and determine the robustness of our results.

### **Qualitative Analysis Plans**

**Information sources**. Information sources include pre-intervention interviews, passive technical assistance, proactive technical assistance, and post-implementation interviews.

**Analyses.** Through our analysis plan, we will seek to understand how to facilitate the adoption of antimicrobial stewardship programs, identify nursing home needs for the future, whether some tools are easier to adopt than others, how to address barriers for tool uptake in the future.

**Review and Analysis of Transcripts of Audio Recordings**. The transcript data will be analyzed using qualitative analytic techniques. Transcripts will be managed, coded, and analyzed using NVIVO 9.0 qualitative data analysis software. We will use the following process to analyze each form of information (pre-intervention interviews, post-intervention interviews, etc.):

- 1. Define initial key questions to develop a code list to capture key themes related to improving implementation and adoption on the future.
- 2. Code a small number of interviews to "test" the code list and revise it based on this test.
- 3. Apply codes to all transcripts collected using the final code list.
- 4. Develop "code summaries" or memoranda for each of the codes or groups of codes used in the analysis.
- 5. Examine relationships among codes and identify patterns and themes within and among codes to draw conclusions about the data. To ensure reliable and valid

Rabe-Hesketh, S., & Skrondal, A. (2008). Classical latent variable models for medical research. *Statistical* <sup>4</sup> *.Methods in Medical Research*, 17, 5–32

conclusions, we will attempt to disprove hypotheses and assumptions, including those derived from our guiding logic model and others that arise from the data itself.

6. Continue to examine the relationships across deliberative methods and identify themes both within and among methods.

All interviews will be audiotaped and attended by a note taker. We will use transcripts to identify variation in processes, facilitators, barriers to using the Guide. We will employ a variety of evidence-based qualitative analysis techniques to draw conclusions from the information, including data reduction, generation of themes, and validation of themes and findings to draw conclusions from the qualitative data.<sup>5,6</sup>

### 17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

### **List of Attachments:**

Attachment A – Pre-Intervention Interview Protocol

Attachment B – Passive TA Collection Protocol

Attachment C – Proactive TA Discussion Protocol

Attachment D – Post-Intervention Interview Protocols

Attachment E – Draft Guide to Nursing Home Antimicrobial Stewardship

Attachment F – Resident and Family Member Information Sheet

Attachment G – Consent Forms

Attachment H – Federal Register Notice

\_

<sup>&</sup>lt;sup>5</sup> Devers, K.J. (1999). How Will We Know "Good" Qualitative Research When We See It?, *Health Services Research*,.34 (5): Part II, S1153-1188.

<sup>&</sup>lt;sup>6</sup> Miles, M. B., & Huberman, A. M. (1994). *Qualitative data analysis: An expanded sourcebook* (2nd ed.). Thousand Oaks, CA: Sage.