ATTACHMENT F:

MEDICAL RECORD REVIEW DATA COLLECTION MANUAL AND FORMS

Data Collection Manual

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Monthly Antibiotic Abstracting Form Audit

Received Antibiotic or Hospitalized

Collaborative Studies of Long-Term Care

Standardized Antibiotic Use
In
Long-Term Care Settings

DATA COLLECTION MANUAL

1.29.2010

Data Collection and Processing Procedures

Data collection will be conducted in 12 nursing homes (NH) in North Carolina. Information related to antibiotic prescribing will be ascertained via chart audit every month for 9 months. All resident charts will be reviewed for each audit period. Descriptive information about the facility will be collected during the first audit.

I. Assignment of ID Numbers

A. Facility IDs: Each facility will be assigned an ID number beginning with "01" and will be assigned sequentially thereafter.

B. Staff IDs: Each unit nurse or health care supervisor (HCS) or other nursing staff responsible for contacting providers regarding resident health concerns will be assigned an identification number beginning with "101" in Facility "01" and assigned sequentially thereafter. In facility "02," the numbering will begin at "201." This pattern will be used for each facility.

C. Resident IDs: Each resident will be assigned an ID number as follows:
- For facility ID "01," the resident ID numbers will begin with "1001" and will be assigned sequentially thereafter.
- For facility ID "02," the resident ID numbers will begin with "2001" and will be assigned sequentially thereafter. This ID assignment method will be used for each facility.

D. Provider IDs: Each provider will be assigned an ID beginning with "01" and sequentially thereafter. The facility ID will not be considered in assigning provider IDs as providers may care for residents in more than one facility.

II. Facility Information

During the first audit, the research nurse will conduct an interview with the administrator to complete the ***Facility Information Form (FAC)***. When scheduling the interview, a copy of the form should be left with the administrator to review, so he/she will have the data necessary to complete all questions.

III. Resident Lists

Before beginning each audit, the research nurse will obtain a copy of the resident census from the facility. During the first audit, the name and birth month and day of each resident who resided in the facility the preceding month and was prescribed an antibiotic will be recorded on the ***Residents Who Received an Antibiotic List*** form. Resident IDs will be assigned as names are recorded. For audits 2-9, residents who received an antibiotic during the audit period and not previously listed will be added to the list and assigned an ID. THIS LIST WILL BE STORED IN A LOCKED FILING CABINET IN THE UNC PROJECT OFFICE BETWEEN AUDITS. IT WILL NOT BE STORED WITH DATA COLLECTION FORMS. Also, because this list has the names of residents, it will be destroyed at the end of the data collection period. The purpose of this list is to enable the research nurse to record information about residents receiving antibiotics across audit periods.

IV. Provider List

During the first audit, record the name and contact information for providers Provider List form. IDs will be assigned as names are recorded. During the subsequent chart audits (2-9), names of providers who prescribed an antibiotic during the audit period and were not previously listed will be added to the list. A copy of this list will be given to Julia Thorp, in-office research assistant, at the end of each audit to enable her to complete the ***Physician Information Form*** (see below).

V. Nurse List

During audit 2 and 9, all nursing staff will be recorded on the ***Nursing List*** form. A copy of this list will be given to Julia Thorp, in-office research assistant, at the end of audit 2 and 9 to forward to Abt.

VI. Chart Audit

Prior to the initial audit, the research nurse will familiarize herself with the structure of the charts at the facility being audited. She will confirm with facility nursing staff the location of nursing and provider notes, medication administration records (MAR) and any other necessary medical record data to complete the chart audit. For each data collection form, audit specific data fields at the top of each form should be completed before the audit begins. These fields may include IDs, dates, and auditor and audit numbers.

A. Resident Demographic Form

During the first chart audit, resident ID number, age, gender, and primary diagnoses will be recorded on the Resident Demographic Form for residents who have received an antibiotic. For audits 2-9, this form will be completed ONLY for residents not previously listed and who received an antibiotic during the audit period.

B. Monthly Antibiotic Abstracting Form

After recording resident demographic information on the Resident Demographic Form, the resident's id will be added to the ***Monthly Antibiotic Abstracting Form***. ONLY include residents who have received an antibiotic in the preceding month to the form.

If an antibiotic has been prescribed for a resident, the research nurse will record the prescription (Rx) start and stop date, the antibiotic code (see antibiotic coding sheet), whether the Rx was ordered during a hospital stay, the suspected infection, any adverse events including hospitalization that occurred <u>within 7 days</u> of the administration of the antibiotic, and the ID number of the prescribing provider. If there is any doubt about whether a prescribed medication is an antibiotic, record the name of the medication in the last column.

The type of infection (or suspected infection) will be determined by reviewing the provider notes dated <u>1 month</u> before or after the antibiotic was prescribed or the nurses notes dated <u>1 week</u> before or after the antibiotic was prescribed. The following codes will be used to record the type of infection:
- R: respiratory
- U: UTI
- S: skin/soft tissue
- F: fever, unexplained
- O: other
- U: Unknown

The adverse events of interest and the data sources to be used to determine if they occurred are:
- Diarrhea – provider or nursing notes
- Vomiting – provider or nursing notes
- Skin rash – provider or nursing notes
- Yeast infection (dermatitis or cystitis) – from lab results or provider/nursing notes
- C. difficile – positive culture from lab results
- Hospitalization – provider or nursing notes

Use the following codes for recording adverse events:
1=Yes; 0=No; 7=Unknown (not documented in the chart)

C. **Consensus Minimum Criteria Abstracting Form**
For each resident for whom an antibiotic has been prescribed, the research nurse will complete the *Consensus Minimum Criteria Abstracting Form*. She will also record whether the information was obtained from the QI Form developed for the project or from other chart sources, or both. For each infection type, respiratory, urinary tract, skin/soft tissue, unexplained fever, or other, "Yes," "No," or "Not noted" will be checked to indicate for which infection the antibiotic was prescribed. If "Yes" is selected, the specific items related to that infection should be completed. If the type is "Other Infection", the infection type and the verbatim description of the problem recorded in the chart should be recorded in the space provided including all relevant signs and symptoms. If there is no indication of the infection type, the verbatim description of the problem recorded in the chart should be recorded in the space provided including all relevant signs and symptoms.

D. **Physician Information Form**
The names of prescribing physicians during audits 2 and 9 will be recorded on the *Physician Information Form*. The specific contact information on will be completed by Julia Thorp, the in-office research assistant. These forms will be scanned and emailed to ▯▯▯▯▯▯▯▯▯ (name and email address) at Abt Associates as soon as they are received from the field and completed by Ms. Thorp. As an alternative, these may be put on a secure password protected FTP server folder at Sheps, and would be retrieved by a designated person at Abt Associates who would login to the folder.

VII. Data Collection Forms Processing

A. **Data editing**
All data collection forms will be reviewed for completeness by the research nurse before the end of each facility audit. If missing data are found, they will be retrieved prior to the completion of the audit. For specific data coding procedures the research nurse should refer to the Q X Q (question by question) manual.

B. **Data transfer**
After each audit, data forms will be transferred to Abt Associates for data entry and analysis. Interim storage at UNC will be in a locked filing cabinet and/or locked office. A copy of all data forms will be retained by UNC until the end of the study. Forms will be hand delivered to the Durham office of Abt Associates. No identifying information will be recorded on these forms.

C. **Resident, Staff, and Provider Lists**
All lists will be stored in a locked filing cabinet and/or locked office.

CONSENSUS MINIMUM CRITERIA
ABSTRACTING FORM

Consensus Minimum Criteria Abstracting Form

Resident ID: ___ ___ ___ ___   **Auditor ID:** ___ ___   **Audit #:** ___ **(1-9) Source:** 1☐ **QI Form**

(Check one or both) 2☐ **Chart**

Instructions: For each antibiotic prescribed during the audit period, indicate the infection type and whether the following signs or symptoms were noted in the chart. This information should be gathered from the QI form and the resident's medical chart.

I.   Antibiotic Name: _____

II.   Respiratory Infection?   1☐ Yes   0☐No ☐ If no, go to Section III.

A. With fever >37.9ºC [100ºF]	1☐ Yes 0☐No 7☐Not noted If **NO**, go to II.B. If Y or not noted, continue.
1. Fever >38.9ºC [102ºF]	1☐ Yes 0☐No 7☐Not noted
a) respiratory rate >25 breaths per minute	1☐ Yes 0☐No 7☐Not noted
b) productive cough	1☐ Yes 0☐No 7☐Not noted
2. (Fever >37.9ºC [100ºF] or a 1.5ºC [2.4ºF] increase above baseline temperature) AND ≤ 38.9ºC [102ºF]	1☐ Yes 0☐No 7☐Not noted
a) pulse >100	1☐ Yes 0☐No 7☐Not noted
b) delirium	1☐ Yes 0☐No 7☐Not noted
c) rigors (shaking chills)	1☐ Yes 0☐No 7☐Not noted
d) respiratory rate >25	1☐ Yes 0☐No 7☐Not noted
B. Without fever < 37.9ºC [100ºF]	1☐ Yes 0☐No 7☐Not noted If **NO**, go to III. If Y or not noted, continue.
1. With COPD	1☐ Yes 0☐No 7☐Not noted If **NO**, go to II.B.2. If Y or not noted, continue.
a) new or increased cough	1☐ Yes 0☐No 7☐Not noted
b) with purulent sputum production	1☐ Yes 0☐No 7☐Not noted
c) ≥ 65 years old	1☐ Yes 0☐No 7☐Not noted
OR	
2. Without COPD	1☐ Yes 0☐No 7☐Not noted
a) a new cough with purulent sputum production	1☐ Yes 0☐No 7☐Not noted
i. respiratory rate >25 breaths per minute	1☐ Yes 0☐No 7☐Not noted
ii. delirium	1☐ Yes 0☐No 7☐Not noted

III. **Urinary Tract Infection   1☐ Yes   0☐No ☐ If no, go to Section IV.**

A. With chronic indwelling catheter	1☐ Yes 0☐No 7☐Not noted If **NO**, go to III.B.2. If Y or not noted, continue.
1. Fever >37.9ºC [100ºF] or a 1.5ºC [2.4ºF] increase above baseline temperature AND ≤ 38.9ºC [102ºF]	1☐ Yes 0☐No 7☐Not noted
a) new or increased urgency	1☐ Yes 0☐No 7☐Not noted
b) new or increased frequency	1☐ Yes 0☐No 7☐Not noted
c) new or increased suprapubic pain	1☐ Yes 0☐No 7☐Not noted
d) new or increased gross hematuria	1☐ Yes 0☐No 7☐Not noted
e) new or increased costovertebral angle tenderness	1☐ Yes 0☐No 7☐Not noted
f) urinary incontinence	1☐ Yes 0☐No 7☐Not noted

OR	
B. Without an indwelling catheter	1☐ Yes 0☐No 7☐Not noted If **NO**, go to IV. If Y or not noted, continue.
1. Fever >37.9ºC [100ºF] or a 1.5ºC [2.4ºF] increase above baseline temperature AND ≤ 38.9ºC [102ºF]	1☐ Yes 0☐No 7☐Not noted
a) new costovertebral tenderness	1☐ Yes 0☐No 7☐Not noted
b) rigors (shaking chills) with or without cause	1☐ Yes 0☐No 7☐Not noted
c) new onset delirium	1☐ Yes 0☐No 7☐Not noted

IV.   Skin or Soft Tissue Infection   1☐ Yes   0☐No → If no, go to Section V.

A. New or increasing purulent drainage at a wound, skin, or soft-tissue site	1☐ Yes 0☐No 7☐Not noted
B. Fever >37.9ºC [100ºF] or a 1.5ºC [2.4ºF] increase above baseline temperature AND ≤ 38.9ºC [102ºF]	1☐ Yes 0☐No 7☐Not noted
C. Redness	1☐ Yes 0☐No 7☐Not noted
D. Tenderness	1☐ Yes 0☐No 7☐Not noted
E. Warmth	1☐ Yes 0☐No 7☐Not noted
F. Swelling that was new or increasing at the affected site	1☐ Yes 0☐No 7☐Not noted

V.   Unexplained Fever   1☐ Yes   0☐No → If no, go to Section VI.

A. Fever >37.9ºC [100ºF] or a 1.5ºC [2.4ºF] increase above baseline temperature AND ≤ 38.9ºC [102ºF]	1☐ Yes 0☐No 7☐Not noted If **NO**, go to VI. If Y or not noted, continue.
1. New onset of delirium	1☐ Yes 0☐No 7☐Not noted
2. Rigors (shaking chills)	1☐ Yes 0☐No 7☐Not noted

VI.   Other Infection 1☐ Yes   0☐No → If no, go to Section VII.

Describe below the infection type, signs, and/or symptoms related to this prescription. Record verbatim the reason the antibiotic was prescribed.

VII.   Infection type not noted 1☐ Yes   0☐No

Describe below any signs and/or symptoms related to this prescription. Record verbatim the reason the antibiotic was prescribed.

MONTHLY ANTIBIOTIC ABSTRACTING FORM AUDITS

Monthly Antibiotic Abstracting Form

Facility ID: ___ ___ **Auditor ID:** ___ ___ **Audit Date:** ___ ___/___ ___/___ ___ **Audit #:** ___ (1-9) **Page** ___ **of** ___ **for this audit**

Instructions: For each resident receiving an antibiotic during the audit period, complete the following information about each antibiotic prescribed. If a resident received more than one antibiotic, record each instance on a separate row. Write the name of the medication if you are unsure of its classification.

Resident ID	Hospice?	Antibiotic Start Date: MM/DD/YY	Antibiotic Stop Date: MM/DD/YY	Antibiotic Ordered in Hospital	Antibiotic Code	Infection: R: respiratory U: UTI S: skin/soft tissue F: fever, unexplained O: other U: Unknown	Adverse Event(s): 1: Yes; 2:No; 7:Unknown (not documented)						MD ID	Write the name of any Rx that is not on the coding list and that may be an antibiotic.
							Diarrhea Y/N	Vomiting Y/N	Skin rash Y/N	Yeast Y/N	C. difficile positive culture Y/N	Hospitalization Y/N		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		

Resident ID	Hospice?	Antibiotic Start Date: MM/DD/YY	Antibiotic Stop Date: MM/DD/YY	Antibiotic Ordered in Hospital	Antibiotic Code	Infection: R: respiratory U: UTI S: skin/soft tissue F: fever, unexplained O: other U: Unknown	Adverse Event(s): 1: Yes; 2:No; 7:Unknown (not documented)						MD ID	Write the name of any Rx that is not on the coding list and that may be an antibiotic.
							Diarrhea Y/N	Vomiting Y/N	Skin rash Y/N	Yeast Y/N	C. difficile positive culture Y/N	Hospitalization Y/N		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		
	1Y 0N			1Y 0N		1R 2U 3S 4F 5O 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U	1Y 0N 7U		

RESIDENTS WHO RECEIVED AN ANTIBIOTIC OR WERE HOSPITALIZED

Residents Who Received an Antibiotic or Were Hospitalized

Facility ID: ___ ___   **Auditor ID:** ___ ___   **Audit Date:** ___ ___/___ ___/___ ___   **Audit #:** ___ (1-9)

Instructions: For each audit, record the ID of each resident receiving an antibiotic or who was hospitalized during the audit period. This may include residents who have transferred or died. For residents who received an antibiotic, you will also complete the Resident Demographic Form, the Monthly Antibiotic Abstraction Form, and the Consensus Minimum Criteria Abstraction Form.

Resident ID	Was Hospitalized	Received an Antibiotic	Comments
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	

Residents Who Received an Antibiotic or Were Hospitalized

Resident ID	Was Hospitalized	Received an Antibiotic	Comments
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	
	1Y 0N	1Y 0N	