Prevention and Control of Vaccine-Preventable Diseases in Long-Term Care Facilities

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Table of Contents

Appendices

Preface

This document contains information that long-term care facilities (nursing facilities) can use to:

- Establish and maintain a sustainable immunization program for patients and staff.
- Establish a surveillance program to monitor acute respiratory illnesses.

Why formalize an immunization program?
The immunization program for residents of long-term care facilities, as outlined in this document, emphasizes vaccination against influenza and pneumococcal disease because these diseases pose the greatest risk to the elderly. Since an effective immunization program employs a comprehensive set of policies and procedures to assure that all recommended vaccines are delivered to all eligible residents and employees, information pertaining to diphtheria and tetanus boosters is included, where appropriate.

Why add surveillance?
The principal objective for promoting influenza and pneumococcal vaccination is to reduce the disease burden and mortality associated with influenza and pneumococcal disease. However, since a small number of residents may develop influenza or pneumococcal disease despite vaccination, a surveillance program is essential to enable staff to quickly recognize cases and contain outbreaks.

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Introduction

Persons 65 years and older constituted the most rapidly growing segment of the U.S. population during the past decade, and more attention is focusing on improving the quality of life--and health--among the elderly. People who reach the age of 65 can now expect to live into their eighties,(1) and preventive care--including vaccination--is one key to sustaining good health.

Approximately 43% of Americans who attained 65 years of age in 1990 will enter a nursing home; 55% of those who enter a nursing home will have a total lifetime use of one year, and 21% will have a total lifetime use of five years or more (2). Hence, long-term care facilities play an important role in the lives of many older adults in the U.S.

Pneumonia, Influenza, and the Elderly, Institutionalized Adult

Pneumonia and influenza (P&I) together remain one of the five principal causes of death for persons 65 years and older,(3) and the risks--including outbreaks and complications--are compounded in long-term care home settings. P&I associated mortality may be considerably reduced by the use of pneumococcal and influenza vaccines.

When infected with influenza, elderly persons and persons with underlying health problems are at increased risk for complications and are more likely than the general population to require hospitalization. An institutional influenza A outbreak can result in up to 60% of the population becoming ill, with 25% of those affected developing complications severe enough to result in hospitalization or death.(4) Influenza-associated mortality results not only from pneumonia, but also from subsequent events arising from cardiovascular, cerebrovascular and other chronic or immunocompromising diseases that can be exacerbated by influenza.(5)

Pneumococcal disease accounts for more deaths than any other vaccine-preventable bacterial disease.(6) Among the elderly, case fatality rates for pneumococcal bacteremia can be as high as 40%. During the antibiotic era, outbreaks of pneumococcal disease caused by a single drug-resistant pneumococcal serotype occurred in institutional settings including long-term care facilities.(7),(8) Early detection of outbreaks is essential to control outbreaks of pneumococcal disease in long-term care facilities.

Although both influenza and pneumococcal vaccines have been proven effective in preventing hospitalizations, and reducing case fatalities among older adults, their use in long-term care facilities remains lower than the Healthy People 2000 Risk Reduction goal of at least 80% vaccination levels among institutionalized chronically ill or older people(9). Long-term care facilities need to improve their vaccination services in order to achieve the proposed public health targets for 2010, of 90% use of both, influenza and pneumococcal vaccines among persons in long-term care facilities.

Vaccination in long-term care Facilities
The National Nursing Home Survey (NNHS), conducted in 1995 by the CDC, National Center for Health Statistics, indicated that a large number of nursing facilities did not maintain complete, easily-accessible information on the vaccination status of their residents. Nearly 21% of the nursing home residents did not have documentation regarding influenza vaccination, and 43% did not have documentation regarding pneumococcal vaccination. Thus, it was difficult to reliably estimate levels of influenza and pneumococcal vaccine use among nursing home residents in 1995.The 1995 NNHS also indicated that facilities with an organized immunization program had higher immunization rates than those without such a program (10).

To encourage the development of organized immunization programs in long-term care facilities, CDC has created this "how to" manual. It outlines general recommendations for establishing immunization programs that should integrate seamlessly into the facility's overall policies and procedures for quality care.

The authors hope that this manual serves as a practical, step-by-step guide that facilitates the process of creating or updating an immunization program. Included are several samples of standing orders, algorithms for decision making, consent forms, as well as forms for collecting information on immunization status and incidence of disease. Readers are encouraged to use the forms as models for updating data collection instruments for recording vaccination status of residents, and disease surveillance and control programs already in use in the facility.

This manual contains two sections of step-by-step recommendations for vaccination disease surveillance and control programs, as well as appendices that provide samples, background information, and ready reference for the administration of recommended adult vaccines.

Part I. **Developing and Maintaining an Immunization Program in Long-term care Facilities.**
Outlines and discusses steps for developing, implementing, and evaluating an immunization program within a long-term care facility and for billing Medicare. The overall objective of the proposed program is to integrate carefully developed policies and procedures for immunization into ongoing resident care and record-keeping practices.

The section concludes with a checklist for planning, conducting, and evaluating an annual influenza vaccination campaign.

Part II. **Developing and Maintaining a Surveillance Program for Influenza and Pneumococcal Disease and Controlling Outbreaks.**
Outlines and discusses steps for conducting surveillance for acute, febrile, respiratory illnesses and pneumonia. The proposed system may be used to

identify outbreaks of influenza or pneumococcal disease at an early stage, control the outbreaks (including use of antiviral agents), and evaluate the impact of a facility's immunization program.

Part III. **Clinical and Epidemiological Information for Influenza and Pneumococcal Disease and Indications for Td,** contains:

Clinical and epidemiological information for influenza, pneumococcal disease, tetanus and diphtheria.

Use of influenza and pneumococcal vaccines and tetanus-diphtheria toxoids (Td) in long-term care facilities.

Additional information on antivirals used to control influenza A outbreaks.

Part IV. **Immunizations Recommended for Staff of Long-term care Facilities**
Summary of the recommendations of the Advisory Committee on Immunization Practices (ACIP) for the immunization of health-care workers in long-term care facilities, including quick reference tabular summaries.

Appendices.

Include sample algorithms, charts, and forms that facilities may use as appropriate for information system in the facility as well as the program(s) they choose to adopt.

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Part I.

Developing and Implementing an Immunization Program in Long-term care Facilities

The purpose of this section is to provide guidelines that long-term facilities can use to create and implement an immunization program that fits within the facility's ongoing patient care and record keeping practices. It contains advice for putting together the leadership team for the immunization program, defining how the program will operate, preparing documentation for the program, and implementing and evaluating the program.

Five separate roles are defined in this section. These roles are not intended as separate staff positions. Facilities are urged to consider the staff composition of their own facility, and assign the roles as appropriate for their facility.

The guidelines in this section emphasize the importance of three aspects of successful programs:

- building consensus among facility staff members and external partners;
- developing efficient, effective information management strategies; and
- evaluating the immunization program at regular intervals.

Use Section E as a checklist for planning and conducting an annual influenza campaign.

A. Establish a Leadership Team for Planning and Implementation.

The working group for planning and conducting an immunization program should be led by the Medical Director and the Infection Control Committee. Other key members of the working group should include: Vaccination Coordinator, Education Coordinator, and Evaluation Coordinator. General descriptions of the roles and responsibilities of each of these team members are suggested below.

Experience has shown that the most successful new programs include early, meaningful involvement in the planning phase by members of every group who will participate in the program or be affected by the program. Therefore, every effort should be made to include all stakeholders in the planning phase. For example, all employees may be invited to review and comment on aspects of the policy document and implementation document, including what each staff member's role will be in the program implementation phase.

Members of the working group should include representatives of state and local health departments, and members of the Association for Practitioners in Infection Control and Epidemiology, Inc. (APIC) who could support the immunization, disease surveillance, and outbreak control strategies. The facility's Infection Control Nurse is most likely to be a member of APIC and therefore already a partner in the community's infection control practice network. Staff of Health Care Financing Administration (HCFA) Peer Review Organizations (PROs) and the facility's consultant pharmacist, can assist in Medicare

billing and reimbursement issues for influenza and pneumococcal immunization. To make the best use of their expertise and support, include these partners early in the planning process.

B. Define roles and responsibilities for team members.

Following are general guidelines for dividing roles and responsibilities among key staff members. Certainly, every facility is unique, and these guidelines should be adapted as appropriate. Long-term care facilities with few staff would necessarily have staff share extra responsibilities.

Begin by developing an organization chart indicating the roles and responsibilities of the staff within the long-term care facility who will be involved in the immunization program (See Appendix 1). Facilities may choose to expand this proposed organization chart by including the names and titles of the staff involved in immunization activities and their reporting channels and post it in a public space so that new members who are assigned to immunization activities can easily identify their role and the chain of command.

Note: In the following pages, responsibilities are listed under specific position titles. This enables generalized application for corporate entities as well as individual facilities. To get the most out of this section of the document, think about who would perform the function (role) and/or how the tasks (responsibilities) would be accomplished in your facility. For example, consider what the Medical Director of the facility should accomplish in order to establish vaccinations with a protocol (standing orders), at admission. Using the list provided, choose those that are appropriate to your facility, ignore those that are inapplicable and add others that are appropriate to your facility but not listed here.

Medical Director

The responsibilities of the medical director may include:

Communicating with the facility's administrative/ governing body, for approval to:

- begin the planning process, develop policy statements and implementation plan
- adopt standing orders for vaccine administration
- provide no-cost vaccines for staff
- initiate discussions with PROs, HCFA, consultant pharmacists
- monitor post-immunization events
- recommend a policy for immunization requirements as a condition of employment.

- Initiating the group process to develop the facility's immunization policy and implementation plan

Communicating with the residents' personal physicians and the medical consulting staff regarding the facility's immunization policies

- Determining whether written consent is needed for immunization by checking State requirements
- Overseeing the facility's immunization program
- Conducting an annual review of the program's accomplishments
- Contingency planning for use of antimicrobial agents against influenza and pneumococcal disease during outbreaks..

Project Coordinator

Under the direction of the Medical Director, the Project Coordinator should manage the startup and ongoing activities of the facility's immunization program.

The responsibilities of the Project Coordinator could include:

- Organizing the Infection Control Committee to developing a Facility Policy for vaccinations in the Admission Agreement.
- Assigning tasks in accordance with the program's documented policy and implementation plan
- Establishing time tables for staff to complete assigned tasks
- Providing guidance and resources needed to complete assigned tasks
- Revising existing job descriptions to include immunization program tasks
- Ensuring that staff are trained for their roles in the immunization program
- Purchasing vaccines and influenza antiviral medications
- Establishing contracts with laboratories for timely analysis of samples for the diagnosis of influenza and pneumococcal disease
- Coordinating immunization activities throughout the facility
- Assisting infection control staff in coordinating surveillance and outbreak control tasks for influenza and pneumococcal disease outbreaks

Vaccination Coordinator

Under the direction of the Project Coordinator, the Vaccination Coordinator is responsible for overseeing the implementation of the facility's policy in the Admission Agreement for

immunizing the residents. The Nursing Director is most often best suited for this role. The Vaccination Coordinator should supervise the clinical staff that administer immunizations. In addition, the Vaccination Coordinator's responsibilities could include:

- Organizing patient immunization schedules, including vaccines administered as part of an ongoing immunization program and vaccines administered during the influenza campaign
- Organizing staff immunization; those indicated as condition for employment and during the annual influenza campaign
- Assuring that clinical staff maintain accurate records of immunization and refusals in the medical charts
- Providing summaries of the immunization status of residents to the Evaluation Coordinator as established in the evaluation plan
- Maintaining accurate summaries for influenza, pneumococcal vaccines and Td use, in a central location within the facility.

Education Coordinator

Under the direction of the Project Coordinator, the Education Coordinator is responsible for developing all training and information materials, conducting training, and disseminating information materials to support both program startup and ongoing management. Specific tasks include:

- Developing lesson plans and study materials for staff training
- Conducting in-service training programs to teach staff members what their roles and responsibilities are in the facility's immunization program.
- Maintaining a resource list for information materials for residents, family, guardians and staff.
- Obtaining the most current recommendations for vaccinations from CDC and/or the state health departments.
- Make available, vaccine information statements and other information materials for residents, family members and guardians.
- Create admission packets which contain vaccine and adverse event information, copies of the facility policy on immunizations, and copies of the standing orders, informed consent forms, and other information as appropriate for prospective residents.

Evaluation Coordinator

Under the direction of the Project Coordinator, the Evaluation Coordinator is responsible for evaluating whether the facility's objectives for the immunization program are being met. Specific responsibilities could include:

- Providing a summary of baseline vaccination levels and respiratory illness cases
- Producing and distributing a monthly summary of the immunization status of residents at admission and discharge
- Producing and distributing a summary report on the percent of staff and residents receiving influenza immunization at the facility after each annual influenza vaccination campaign,
- Summarizing trends in the incidence of acute, febrile, respiratory illnesses in the facility on an annual basis as well as during the influenza season.

C. Define the Program and Document the Plan.

In general, the immunization program for residents should ensure that the following activities are carried out systematically, reliably, and correctly:

- Assessing the immunization status of newly admitted residents and residents transferred from other facilities
- Offering vaccinations to new and current residents on the basis of standing orders or protocol which allows for administration of vaccine by appropriate non-medical staff (Provide for physician override of vaccinating persons at admission)
- Conducting an annual influenza vaccination campaign

The Advisory Committee for Immunization Practices (ACIP) recommends standing orders for a sustainable immunization program in an organizational setting. (MMWR 2000; 49 RR-1: 15-26.) In nursing facilities where residents' personal physicians rather than the Medical Director of the facility have direct responsibility for care, and standing orders are not feasible, obtain physician's orders for the administration of vaccines and Td at the time of admission and/or while planning the annual influenza vaccination program in the facility. Copies of the orders should be available not only in the implementation manual, but also at all nurses' stations and at the registration desk for new admissions. Appendix 2 presents a sample standing order that may also be used as an advanced physician order for vaccines or antivirals. Program planners may modify this form to suit the unique needs of each facility.

The following documents are proposed for a long-term care facility's immunization program:

- A policy statement that guides implementation and evaluation activities

- An implementation manual that spells out the details of program implementation (including training, information, and the plan for evaluating the program)

Step 1. Develop the policy statement.

The policy statement summarizes the facility's position regarding the immunization program and forms the framework for the development of the detailed implementation and evaluation plans. In developing the policy statement, the Medical Director should lead the discussions with Board Members, facility staff and external partners.

The policy statement should contain:

- Rationale for incorporating immunizations as a standard of care for residents
- Objectives of the immunization program, including goals (time frames, coverage rates, etc.)
- Objectives of the annual facility-sponsored influenza vaccination campaign
- Summary of immunization requirements for residents at admission, including options for responding to those who refuse immunization,
- Statement emphasizing the need to obtain informed consent for immunizations from residents or their legal guardians, at arrival
- Statement authorizing the development and use of standing orders or advanced physician prescribed orders, for administering vaccines and monitoring residents after vaccine administration. This should be described in the Facility Policy in the Admission Statement outlining immunizations required for employment and/or statement recommending that employees consider vaccination for influenza or other vaccine-preventable diseases (see Part IV).
- Statement of the availability of vaccines without cost to both residents (through Medicare reimbursement) and employees (if feasible) .

After the policy statement is drafted and before the working group moves on to develop the implementation manual, the Medical Director should present the proposed policy statement to the Administration/Governing body and obtain their approval. Once approved, the policy statement should be placed in all public areas within the facility. It should also be included in the training program for the immunization program and in the orientation packet for new employees.

Step 2. Develop the implementation manual.

The implementation manual should serve as a resource for all immunization- related activities within the facility. As such, it should include:

- Description of the roles and responsibilities of staff members in the immunization program
- Tasks and time lines for conducting the annual influenza vaccination campaign
- Tasks and time lines for vaccinating current residents with pneumococcal vaccine and Td toxoids
- Description of the facility-wide system for collecting and maintaining immunization information, including examples of all immunization program forms with amplification of important concepts and detailed instructions for how to use the forms to record immunization status of residents (see Appendix 2 and Section 2.a. below). Electronic databases should be considered, for monitoring vaccinations and illnesses among residents.
- Training and information materials, including a list of Frequently Asked Questions (FAQs), with answers, that staff may use for their own information as well as for support in responding to questions from residents and family members.
- Instructions for evaluating the immunization program (see Part 2.E. below)

a. Create or revise data collection forms.

Accurate, accessible records speed the process of creating summary reports and evaluating the success of the immunization program. Since immunization practices should be incorporated as an essential element of standard care, long-term care facilities should review the system currently being used to record health events of residents and modify it to include immunization status of new arrivals, current residents, and residents who have been discharged from the facility.

Program planners should evaluate current paper or computer-based forms and revise them as necessary to be sure they can:

- If required by state law, obtain consent from persons eligible to receive the vaccine and/ or their relatives or guardians. Consider whether vaccination issues have legal restrictions that apply to invasive procedures or injection use. Refusal of vaccinations should be also be recorded on the consent forms.

Note: Policies regarding the need and requirements for informed consent vary from state to state: if you do not know the policies regarding informed consent for vaccinations in your state, contact your state or local health department before undertaking an immunization program.

- Record the immunization status of new arrivals and the administration of vaccines at admission. (Appendix 3 provides a checklist to assess immunization status at admissions, and record vaccinations administered at

admission. Appendix 3 also includes a permanent vaccination record form that can be included in the residents' medical charts.) The purpose of the admission documentation is to assess the effectiveness of a policy of screening and vaccination at admissions.

- Identify residents who refuse immunization and may be at higher risk for disease during outbreaks.
- Efficiently record and assess the immunization status of residents at selected times, for example, during and after the annual influenza vaccination campaign. (See Appendix 3: a sample immunization record that should be maintained for each resident in their medical charts.) The permanent immunization record which should be included in the resident's medical chart, provides a convenient, consistent method to record vaccination at any time, and serves as the basis for determining immunization coverage of residents.
- Summarize, on a monthly basis, the immunization status of persons discharged from the facility. A copy of the immunization record should also be provided to each patient upon discharge or transfer.
- Verify that a copy of the vaccination record was provided to each person discharged from the facility.
- Generate lists based on the vaccination records included in the medical charts to complete the annual state/ federal audit forms (HCFA Form 672).

In general, vaccination records for each resident should provide a history of vaccination events from admission to discharge. The history should include adverse events within the first week of influenza and pneumococcal vaccination. Program planners should consult state regulations and modify these forms--or include immunization information on existing forms--to suit the needs of the facility.

In addition to making sample forms available in the Implementation Manual, copies of forms that are not a part of a computerized system should be readily available throughout the facility. For example, copies of consent forms (if legally required) should be readily available at nursing stations and the admission desk, if they cannot be printed from the computer. If the facility employs the standing order approach to managing the administration of vaccines at entry, copies of consent forms should be attached to copies of orders. Once signed, the consent (or refusal form) should be placed in the medical records of each resident.

Separate consent and refusal forms will be needed for immunization of staff members. The consent / refusal forms should be presented to each staff member

when the vaccines are offered. Signed forms may be placed collectively in a vaccination file for all staff, or they may be filed individually in personnel folders maintained by each supervisor, depending upon the existing practices of the facility.

b. Assemble training and information materials.

The implementation manual should contain lesson plans and study materials to train employees for their new roles and responsibilities within the immunization program.

Vaccine information statements for influenza and pneumococcal vaccines and Td toxoids are available from CDC (www.cdc.gov/nip/publications), state and local health departments, and the National Coalition for Adult Immunization (http://www.nfid.org/ncai/). Vaccine information statements should be included in the student materials for staff training, posted throughout the facility, and also included in an orientation packet that is provided to friends, family members or legal guardians accompanying a patient for admission to the facility.

The additional duties related to immunization activities should be incorporated into the job descriptions of staff currently employed and in position descriptions for future recruitment. Facilities should cross-train staff in activities related to the immunization program, in order to prevent lapses in immunization among residents due to personnel changes.

c. Document a plan to evaluate the immunization program.

Evaluation should be considered an integral component of the facility's immunization program. The evaluation plan should describe the methods that will be used to assess whether or not the immunization program is achieving the goals set out in the policy statement. The evaluation plan should indicate sources of data which will be used to derive the following evaluation criteria:

- number and percentage of residents and employees who have received influenza vaccination, pneumococcal vaccination, and Td
- quantifiable data summarizing training of staff (e.g. 40 of 100)
- schedules for administration of vaccines
- on-time completion of assigned tasks in the immunization program
- number of Medicare claims filed for influenza and pneumococcal vaccinations
- any other measures that will assist leaders in making sure that the immunization program is operating effectively and efficiently.

More details on the evaluation plan are provided in Section D.

When determining who to assign to evaluation tasks, consider nurses who provide direct care, supervisors, and consultant pharmacists who audit medical records on a monthly basis, that is, any persons who handle the medical records and are familiar with the health status of the residents.

D. Implement the Immunization Program.

Step 1. Train staff members.

Using the training materials developed during the planning phase and included in the Implementation Manual, conduct training for staff that covers their responsibilities related to the immunization program. The training should include:

- An overview of the policy for the Immunization Program
- Vaccine recommendations, indications and contraindications and, permissible simultaneous administration of vaccines
- Detailed task lists and work flow for the ongoing immunization program
- Methods for obtaining consent, including how to address common questions from residents and family members
- Record keeping requirements and how to obtain and fill out required forms
- Adverse vaccine events, including locating and completing the Vaccine Adverse Events Reporting (VAERS) forms for reporting any serious event following the receipt of a vaccine (http://www.fda.gov/cber/vaers/vaers1.pdf).
- Infection control, including but not limited to surveillance, identification, reporting, and control of vaccine preventable diseases
- Task assignments and time frames for implementing the yearly influenza program, including purchasing, storing, and administering influenza vaccine; obtaining consent; and reporting adverse vaccine events

Step 2. Train personal physicians and Medical Directors

- Mail information packets regarding influenza and pneumococcal vaccinations. The information to physicians should include the most recent recommendations from the ACIP, anticipated post-vaccination adverse events, copies of vaccine information statements that each physician could send to their patients who are residents in the facility, and forms for the Vaccine Adverse Events Reporting System.
- Consider organizing a workshop with the collaboration of the American Medical Directors Association.

- Provide copies of the facility's immunization policy and disease surveillance forms. For standing orders see ACIP recommendations MMWR 2000; 49 (RR-1): 15-26.
- Facilities that do not have a 'standing order' policy should obtain advance orders for vaccinations from the residents' personal physicians at, or soon after admission. Consent and advanced physician order forms for influenza vaccination would be more effective if they are crafted as a one-time effort, e.g. "annual influenza vaccination as long as the person is a resident of the facility".

Step 3. Collect and record baseline vaccination rates for current residents.

Before beginning the facility-wide immunization program, audit residents' medical records and record the most recent administration dates for influenza vaccine and all dates for pneumococcal vaccine and the Td boosters. Consultant pharmacists could assist in this activity during their monthly audits of residents' medical records. To facilitate vaccination of current residents, the staff member or consultant pharmacist who audits records for baseline vaccination data could place reminders for needed immunizing agents in each resident's chart and produce a list of residents who:

- Did not receive influenza vaccine during the previous season
- If 65 years or older, and had never received pneumococcal vaccine
- If 65 years and older, received initial vaccination 5 years or earlier and when younger than 65 years of age
- Did not receive a Td booster within the past 10 years

Appendix 3 suggests a format for recording the immunization status of the residents in the long-term care facility at any time: baseline, during a facility-wide immunization campaign to kick off the immunization program, and for the annual influenza vaccination campaign.

Facilities that conduct disease surveillance (see Part II) should compile information on acute respiratory illnesses at the same time that medical records are audited for vaccine information.

The Evaluation Coordinator should prepare a summary report of the baseline immunization status of current residents. This report should be distributed to the staff through the Medical Director.

Long-term care facilities may choose to create a graph for each of the vaccines. The starting point for the graph should be the percent of residents with influenza, pneumococcal, and Td immunizations PRIOR to the facility-wide immunization program. The graph can be updated on a monthly basis as well as following the influenza campaign each year. A second graph showing the vaccination of staff might be useful in monitoring staff compliance with influenza vaccination.

A visual format for displaying vaccination status of current residents; incidence of acute, febrile, respiratory illnesses; and the cases of influenza and pneumococcal disease that have been diagnosed among persons with respiratory illness will be useful for communicating progress in the immunization program with Board members and other external partners.

Step 4. Vaccinate current residents.

After assessing the vaccination requirements of the current residents, as indicated by the baseline immunization coverage report, the Vaccination Coordinator should develop a schedule to systematically vaccinate current residents (and staff, if appropriate). If the pneumococcal vaccination status of the residents is unknown, they should be vaccinated.

Nurses assigned to each unit should be responsible for vaccinating all residents as indicated, and updating the immunization record in the resident's medical chart, as well as in the facility's record keeping system.

The nurses should also be responsible for the care of any post-vaccination incidents, while physicians should be accessible at least by telephone, during mass immunizations (both the startup of the immunization program and annual influenza vaccination campaigns) to manage post-vaccination reactions.

Note on administration of vaccines--influenza or pneumococcal vaccine and Td toxoids may be administered simultaneously in deltoid muscle of both arms. For residents who need all three immunizing agents, vaccinators may administer the influenza and Td intramuscularly in both deltoids, and the pneumococcal vaccine subcutaneously. Although life-threatening systemic reactions are rare among persons receiving the influenza and pneumococcal vaccinations, epinephrine should be available whenever mass immunizations are conducted in long-term care facilities, to respond to anaphylaxis, if this should occur.

Step 5. Vaccinate new arrivals (including transfers from hospitals).

Residents entering the facility, regardless of length of stay, should receive the influenza (October - March) and pneumococcal vaccines and the Td booster unless they can recall prior vaccination or provide a record of immunization. Use the facility's admission checklist for immunization (based on Appendix 3) to assess the immunization requirements of new arrivals. New admissions should also be assessed for primary series for Td, if patients cannot recall ever having received the recommended childhood vaccinations.

Note: Where the resident, family member/legal guardian, or personal physician is unsure of the patient's pneumococcal immunization status, the person should receive a dose of the pneumococcal polysaccharide vaccine. Recall of influenza

vaccine is usually reliable since this is an annual event. There are no data on the reliability of patient recall for Td.

Consent forms for influenza, pneumococcal and Td immunization (if required by the state) should be completed at admission, even if the immunizations are to be administered at a later time. Arriving residents and their family members or legal guardians should receive a packet containing the immunization policy of the facility and information regarding influenza and pneumococcal vaccines and Td boosters and have the opportunity to share their concerns and receive appropriate assurances and additional information as needed.

The same form used to assess immunization status at admission can be used to record vaccinations administered at admission. Remember, keeping a record of vaccinations administered at admission is one source of information for evaluating the success of the immunization program.

Step 6. Bill Medicare

Both influenza and pneumococcal vaccines are reimbursable by Medicare Part B. Claims for reimbursement of the vaccine as well as its administration may be submitted for individuals or for groups of residents. Detailed billing instructions for influenza and pneumococcal vaccines are included in Appendices 4 and 5 respectively. Appendices 6 and 7 are copies of roster billing forms for influenza and pneumococcal vaccines, respectively. Facilities should submit separate claims for influenza and pneumococcal vaccinations. Td is reimbursable by Medicare when administered as wound prophylaxis.

E. Evaluate the Immunization Program.

The facility's immunization program should be evaluated on an annual basis. The annual evaluation summary report may be used to complete HCFA Form 672, which is used by the state or federal surveyors for certification and licensing of long-term care facilities. In addition, the facility-wide influenza vaccination program should be evaluated separately at the end of the campaign in order to make sure that residents admitted to the facility after the facility-wide influenza vaccination campaign, had been assessed and vaccinated.

Step 1. Compile evaluation measures.

The plan for the immunization program, and the activities conducted during the program, should facilitate the efficient collection of these measures:

- The number of training sessions completed for staff
- Assigned and actual completion dates for major tasks
- The number of current residents up-to-date for influenza, pneumococcal immunizations and Td boosters (regardless of where they had been vaccinated)

- The *total number and percent* of residents who received influenza, pneumococcal immunizations and Td boosters in the facility
- The *total number and percent* of new arrivals who received influenza and pneumococcal vaccines and Td boosters within the period specified in the implementation plan. (Residents who had not received the immunizations within the specified period after arrival may be overlooked and remain unvaccinated. Adherence to established time lines for specific tasks is essential for the continued success of an immunization program in a long-term care facility.)
- The *total number and percent* of residents who received influenza and pneumococcal vaccines and, Td at the facility prior to discharge
- The number of Medicare reimbursement claims filed for influenza and pneumococcal immunizations and their outcomes (paid or rejected)
- Count the number of residents who are NOT vaccinated and record the reason(s) for not receiving the influenza and/or pneumococcal vaccination. (Use this as a program improvement tool).

F. Plan and Implement the Facility's Annual Influenza Immunization Campaign.

This section contains a quick-reference checklist of the activities that go into the annual influenza vaccination campaign. The time line reflects recommendations to conduct an influenza vaccination program within a facility between October to mid-November. However, arriving residents who have not been vaccinated should be vaccinated through the influenza season which may continue into April.

Facilities that elect to begin the facility's overall immunization program concurrently with an influenza vaccination campaign can extend this checklist, purchasing pneumococcal vaccine and Td toxoids, training staff on the comprehensive immunization program, and using forms for consent that include all vaccines. Use Appendix 8 as a sample check list for residents and staff who should be vaccinated during the campaign.

Step 1. Plan the campaign.

April/ May	Identify a Project Coordinator and staff to organize and conduct the influenza immunization program.
	Establish a deadline or end date (for example all immunizations must be administered by November 15th). Determine policy for influenza immunization for persons admitted after the facility's immunization campaign concludes, but before the end of the influenza season (which varies each year and can be as late as April).
	Establish policy for providing vaccine to facility staff and inform the staff regarding availability of the influenza vaccine at the facility.
	Identify a coordinator for ensuring that staff are vaccinated against influenza. This person should report to the annual immunization Project Coordinator.
	Establish an end date for the staff program goal and a coverage goal.
	Determine if consent forms will be needed for residents. If so, determine the most efficient method of obtaining consent forms for influenza and other vaccines in advance of the actual immunization day. (See Section C)
	Collect and develop education/information materials and plan training sessions for staff, residents, and family members and/or legal guardians. Assemble materials to be made available for patients and family members who cannot attend sessions. (See Responsibility for Education Coordinator)
	Order vaccines. The most common way to purchase vaccine in long-term care facilities is in 10-dose vials. Advantages of purchasing vaccine in 10-dose vials include the opportunity to select appropriate needle length (1¼-1½) and the lower cost of the vaccine per dose. Vaccine purchased in unit dose syringes have the advantage of saving time at administration.
June-July	If standing orders are not the policy, obtain advanced physician orders for the vaccine and for appropriate antiviral medication against influenza (rimantadine, amantadine, zanamivir, or oseltamivir) which may be needed in the event of an outbreak.

Estimate the number of residents and staff to be vaccinated, including new admissions during the influenza season. Determine the number of doses of influenza vaccine needed.

Calculate the total number of specimen collection supplies (swabs, and transport media) may be needed during the influenza season and make provisions for ready availability or in stock at the facility.

Develop contingency planning for purchase and administration of antivirals in case of influenza outbreak.

Coordinate with your contract pharmacy to purchase the vaccine and the antivirals.

Make arrangements with a qualified laboratory for specimen transport, direct antigen testing, and communication of results.

Determine how to maintain the "cold-chain" for the purchased vaccine. If refrigerator space at the facility is unavailable make arrangements to rent another refrigerator until the end of January.

Organize Medicare reimbursement claim forms.

August

Order general information materials on influenza and pneumococcal disease. Make sure you have a supply of the most recent vaccine information statements for influenza, pneumococcal vaccines and Td (http://www.cdc.gov/nip/publications/VIS/)

Obtain proof from the contract pharmacist that the required doses of antivirals (rimantadine, amantadine, zanamivir, or oseltamivir) are in stock.

Ensure that consent forms, if necessary, have been received and filed in the appropriate places. Follow-up on consent forms that are pending. Persons who refuse the immunization should have a form on file to document refusal.

Check on procedures for assessing immunization status of arrivals. Standing orders and orientation packets with consent forms and should be available at the registration desk for new arrivals.

Note on maintaining the proper temperature for vaccine storage, or"the cold chain": Place a thermometer in the refrigerator. Record the temperature daily. If the temperature is NOT between 35°F and 46°F, do not use the refrigerator for storing vaccines.

Step 2. Conduct the campaign.

October-November	Prepare a list of residents to be vaccinated and set daily schedules to vaccinate every resident and staff member. (Consent forms completed at the time of admission should already be available in each resident's medical record.) Record the immunizations into the resident's medical record and remove immunization reminders. The consultant pharmacist can verify the immunization record in the medical chart during routine monthly audits. Vaccinate all new admissions to the long-term care facility if they do not have a record of influenza (or other) vaccination. Remember to include the consent forms and vaccine information sheets in the admission packet and obtain consent at the time of admission or within the time period indicated in the facility's implementation manual. Submit claims to Medicare for reimbursement of vaccine and administration cost. Include a copy of the claim in the resident's medical record.
December-March	Continue to vaccinate new arrivals at admission.

Step 3. Evaluate the campaign.

- Using the list of residents to be vaccinated against influenza, total the number of persons vaccinated and calculate the percentage of those vaccinated among the total number of resident in the facility at the time of the vaccination campaign.
- Calculate the percentage of new arrivals who were vaccinated at entry.
- Calculate the percentage of staff who were vaccinated. It may also be useful to compare rates of immunization among staff members working in different areas of the long-term care facility. If rates vary substantially, examining characteristics of areas with high and low rates of immunization may provide information which will help improve the staff immunization program in the future.
- Compare immunization program objectives with actual results and determine the reasons for discrepancies.

- For non-vaccinated residents verify the reasons for refusal. If the resident consented to be vaccinated but was ill and was not vaccinated at the time of facility-wide influenza immunization, administer the vaccine.
- For residents refusing vaccination, make sure that the signed refusal form is filed in the resident's medical record.
- Determine improvements needed in the program next year.
- Present these recommendations to the Medical Director and the Project Coordinator and revise the influenza immunization plan for the next year based on lessons learned during the current influenza season.

Part II.

Developing and Maintaining a Surveillance Program for Influenza and Pneumococcal Disease and Controlling Outbreaks

Pneumonia is the second most common type of nosocomial infection in the United States and is associated with substantial morbidity, mortality, and attendant costs (11). Patients in long-term care facilities, due to age and underlying disease, are particularly susceptible. Influenza and pneumococcal diseases are vaccine-preventable. In addition to an organized vaccination program, it is imperative to:

prevent outbreaks by immunizing all residents of long-term care facilities against influenza and pneumococcal disease,

- identify outbreaks early and,
- follow appropriate infection control procedures.

Annual influenza vaccination can reduce the risk for hospitalization, pneumonia, and death in nursing facilities two- to six-fold during influenza outbreaks(12). Diligent year-round surveillance for influenza-associated pneumonia is essential for two additional reasons. First, recurrent institutional outbreaks of influenza A have been reported in long-term-care facilities despite high rates of vaccination(13)(14)(15), particularly in years in which there is a not a good match between the vaccine formulation and the circulating virus strains(12)(16). Second, institutional outbreaks can also occur during the summer (17)(18) although, these are infrequent.

Available data indicate that pneumococcal pneumonia accounts for more deaths in older adults than any other bacterial vaccine-preventable disease due to a high risk for bacteremia where case fatality rates can reach 40%(19). While penicillin has been the standard treatment for pneumococcal infections, empiric treatment of presumed pneumococcal infections has become difficult due to the rapid increase in multidrug resistance in this organism(20). Outbreaks of pneumococcal infections with multi-drug resistant types of the organism have occurred in long-term care facilities where few residents had received the pneumococcal vaccine(21). The pneumococcal vaccine is highly effective in preventing the most common cause of bacterial pneumonia acquired in long-term care facilities (22).

Monitoring pneumococcal infections is especially important among long-term care home residents who have one or more of these risk factors for pneumococcal disease: persons with chronic lung disease (chronic obstructive pulmonary disease and emphysema), chronic cardiovascular disease (chronic heart failure or cardiomyopathy), chronic liver disease and diabetes. Risk factors that are associated with nosocomial pneumonia of all causes also increase risk for pneumococcal infections. These include:

- conditions favoring aspiration or reflux such as being on a ventilator
- having a nasogastric tube in place

- any state of depressed consciousness and,
- prolonged antimicrobial therapy.

This section covers the detection and management of outbreaks due to influenza and pneumococcal disease in long-term care facilities. Included are surveillance for acute, febrile, respiratory illness (AFRI), pneumonia, early detection of influenza and pneumococcal infections, responding to influenza and pneumococcal disease outbreaks, and use of antivirals during influenza outbreaks.

Note: Several viruses, bacteria, and fungi can cause outbreaks of acute, febrile, respiratory illnesses (AFRI) and pneumonia among residents in long-term care facilities(23). Viruses that may cause nosocomial pneumonia include adenoviruses, influenza virus, parainfluenza viruses, respiratory syncytial virus (RSV), rhinoviruses, as well as measles and varicella-zoster virus(11). Precedent infections with parainfluenza viruses and RSV occur during late fall and winter and may predispose the affected person to secondary bacterial pneumonias(24). RSV is present in respiratory secretions of symptomatic persons and is transmitted through close contact that may include large droplets or contaminated hands or fomites(11). Influenza is transmitted by inhalation of virus-containing aerosols created by an infected person during coughing, sneezing, and speaking, as well as by person-to-person contact(11).

Most cases of bacterial nosocomial pneumonia occur by aspiration of bacteria that colonize the oropharynx or upper gastrointestinal tract. Because intubation and mechanical ventilation alter first-line patient defenses, these procedures greatly increase the risk for nosocomial bacterial pneumonia(11).

There are no commercially available vaccines to prevent diseases resulting from parainfluenza viruses and RSV infections nor most bacteria (except S. pneumoniae), and fungi that cause AFRI or pneumonia.

For additional information on control of pneumonia in long-term care facilities, please see the list of recommended reading at the end of this section.

A. Define the Disease Surveillance and Control Program and Document the Plan.

Long-term care facilities should identify a single staff member who, assisted by other staff, will be responsible for the ongoing surveillance program, as well as the implementation of control measures during an influenza or pneumococcal outbreak.

The team should also include the Medical Director, the infection control practitioner, a consultant pharmacist, a member from the laboratory serving the facility, and a representative from the administrative body of the facility . Facilities should also consider inviting an epidemiologist from the state or local health department to be a member of their team or to help in drafting their outbreak control plan.

The keys to successful outbreak management and control are:

- early recognition of the outbreak and reporting to local/ state health department
- laboratory diagnosis to determine etiology including rapid diagnosis of influenza
- prompt institution of control measures, including the use of antiviral medications during an influenza outbreak (see the special section on antivirals at the end of Part II).

The disease surveillance and infection control team should develop written descriptions for the following activities as a section of the facility's Immunization Implementation Manual, or under separate cover.

- Roles and responsibilities for staff who will participate in disease surveillance.
- A system for collecting and handling specimens obtained from all parts of the facility, and submitting them for laboratory diagnosis on a routine basis, in order to detect outbreaks and report to appropriate state/ local health departments
- Tasks and time lines for conducting routine disease surveillance, including chain of command for reporting surveillance results.
- Clear definitions to guide the identification of clusters and outbreaks. (Suggested definitions appear in Section B.2 below.)
- System for distributing medication and monitoring residents for adverse reactions to antibiotics or antiviral medication.
- Plan to offer vaccine and antiviral medication to staff who were not vaccinated if influenza is identified as the cause of the outbreak.
- Task re-assignments in the event of an outbreak. Section C.1. below contains a checklist of tasks that should take place in the event of an outbreak.

B. Implement Surveillance for Acute Febrile Respiratory Illnesses and Pneumonia

Long-term care facilities may already have a system to record illnesses in order to be in compliance with state and federal regulations(25), Joint Commission on Accreditation of Healthcare Organizations(26) regulations, and may already follow recommendations of the Association of Professionals in Infection Control and Epidemiology, Inc. (APIC), and The Society for Hospital Epidemiology of America (SHEA)(27). This section provides guidelines that can assist long-term care facilities in enhancing an existing system or in establishing a new system. However, long-term care facilities should also establish partnerships with their local health department in establishing, or enhancing an existing surveillance system for AFRI and pneumonia .

Contact the local or state health department to learn the public health requirements for reporting nosocomial (includes long-term care facility-acquired) infections.

Note: All outbreaks are to be reported to local or state health departments.

The flow chart (Appendix 9) illustrates the main steps in AFRI and pneumonia surveillance.

1. Derive normal (baseline) estimates of AFRI.

Potential outbreaks of influenza or pneumococcal disease are most quickly recognizable when the infection control practitioner can compare the number of cases per week to the number of cases that are "expected" for the facility in a "normal" week. Long-term care facilities that cannot maintain year-round disease surveillance should initiate the surveillance from October through April to identify influenza outbreaks. Use Appendices 10 and 11 as sample formats for surveillance of AFRI and pneumonia.

Note: More than one influenza outbreak may occur during the winter months, in any given facility.

If the surveillance operates year-round, the weekly summaries of AFRI and pneumonias may suffice to indicate an increase in cases during a non-influenza season. From October to April when influenza activity is higher, reviewing the number of AFRI cases identified in 24 to 36 hour intervals may be more effective in detecting clusters of potential influenza cases.

2. Gather and analyze surveillance data

Each week, members of the nursing staff should review the facility's surveillance log form (Appendix 10), and submit the forms to the infection control practitioner. The latter should review the logs and prepare a daily or weekly summary (Appendix 11) to identify clusters or unusual increases in acute respiratory illnesses.

The following definitions are provided to assist in the proper identification of disease incidence, clusters and outbreaks.

a. ***Acute, febrile, respiratory illness (AFRI):*** abrupt onset of fever of 100^0 F oral or 101^0 F rectal, or complaints of "feverishness", with or without myalgia, malaise, or headache and, at least one of the following respiratory symptoms:

sore throat, cough, rhinorrhea, or nasal congestion.

b. ***Pneumonia:*** fever and/or cough, with radiologically confirmed new or progressive pulmonary infiltrate(28). Changes in volume of sputum or its appearance or gram-positive diplocci may be indicative of pneumococcal infections.

c. ***Influenza cases*:** Influenza can only be confirmed through laboratory testing of nasopharyngeal or throat swab samples. Thus, patients with AFRI whose nasopharyngeal or throat swabs are positive for influenza virus via rapid direct antigen tests (less than 24 hour turnaround), should be considered cases of influenza. The *gold standard* for diagnosis is the isolation of influenza viruses from viral cultures. However, results of viral cultures may take up to10 days.

Since direct antigen tests may be falsely negative up to 30% of the time, nasopharyngeal or throat swab samples should be tested by both direct antigen test and viral cultures whenever possible, in order to confirm an influenza outbreak.

Note: Nasopharyngeal swabs are more likely to yield influenza viruses than throat swabs(29).

d. ***Pneumococcal infections:*** Since *Streptococcus pneumoniae* can colonize the respiratory tract, the following definitions are proposed to confirm pneumococcal infections in persons with AFRI and/or pneumonia.

Confirmed case: AFRI with or without pneumonia where *S. pneumoniae* is isolated from blood, cerebrospinal fluid or pleural fluid.

Probable case: AFRI with or without pneumonia, with purulent sputum. Sputum cultures yield *S. pneumoniae* and gram stains of sputum have moderate to large numbers of gram-positive diplococci.

Possible case: AFRI with or without pneumonia or observable changes in production of sputum where cultures yield *S. pneumoniae* but, gram stains of sputum do not indicate gram-positive diplococci, OR, gram stain of sputum smear may indicate moderate to large numbers of *S. pneumoniae* but cultures are negative for the organism.

e. ***A cluster*:** Three or more cases of AFRI occurring within 48 to 72 hours, in residents who are in close proximity to each other (e.g., in the same area within the facility)(30);

f. ***An outbreak***: When there is a sudden increase of AFRI cases over the background rate, outbreak control measures should be implemented. But, when are multiple cases considered an outbreak? There are no hard and fast rules for defining an outbreak. A practical definition is *a significant increase over the norm or baseline*. However, when more than 1 cluster is identified within 1 week the Medical Director may implement the facility's plan for outbreak control in the event of any ONE of these conditions:

- Influenza is diagnosed in at least one member of an identified cluster of persons with acute, febrile, respiratory illness; or,
- 10% of residents in the facility or an area of the facility develop AFRI during a 1-week period(14)(16).
- Cluster of 2 AFRI cases with a *confirmed* or *probable* diagnosis of pneumococcal infections occurring.within 2 weeks

When an AFRI cluster is identified, the infection control practitioner should communicate with the Medical Director immediately. When there are no clusters, summary data should be provided to the Medical Director in routine reports. Summary reports should include results of laboratory testing of AFRI cases where possible, and pneumonia cases.

3. Respond quickly when AFRI clusters are identified.

Follow these steps to reduce the potential for transmission while confirming whether or not disease is caused by influenza virus, *S. pneumoniae,* or another pathogen. See Appendix 9 (flowchart) for a visual summary of these steps.

a. Inform local and state health officials of the AFRI cluster.

b. Monitor cases on a daily basis; record cases among staff as well as residents.

c. Take preliminary precautions while waiting for definitive diagnosis of the causative agent:

- Confine symptomatic patients to their rooms or group them in the affected unit until more information is known.
- Place patients with symptoms on droplet precautions (as in C.1.a.ii)
- Monitor staff absenteeism for respiratory illness and offer the influenza and pneumococcal vaccine to residents and influenza vaccination to staff and residents, again.
- Consider alternate work-arrangements outside the facility, for symptomatic employees, until influenza and pneumococcal disease have been ruled out as possible etiologies.
- Discontinue “floating” of personnel where possible.
- If there are transfers during this time, notify the receiving facility of the potential for an outbreak of influenza or pneumococcal disease at your facility.

d. Confirm causative organism of AFRI or pneumonia

i. Influenza as a cause

- Collect nasopharyngeal and/or throat swabs for testing by **both** rapid antigen detection and viral culture, from patients in the AFRI cluster who have had symptoms for 4 days or less (31). **Request the laboratory to transmit rapid antigen results by telephone to the infection control practitioner as soon as they are available (usually less than 24 hours).**
- If influenza virus is detected from 1 or more specimens, institute influenza control measures as described below, Section II.C.1.

ii. Confirm *S. pneumoniae* as the cause of AFRI or pneumonia

- Since pneumococcal sepsis may present with fever alone, obtain at least 2 blood cultures from different sites from residents with fever exceeding 100.5°F (oral), prior to administration of antibiotics, when possible.
- Submit sputum from patients with AFRI or pneumonia, for Gram-stain and culture, prior to administration of antibiotics, when possible.
- For AFRI patients with systemic complications submit other specimens such as blood or spinal fluid for Gram-stain and culture when indicated.

C. Outbreak control

When a cluster of AFRI is detected, as defined in the facility's surveillance and outbreak control plan, involve the local or state health department. Use this checklist to promptly obtain the necessary supplies, train staff and plan for the administration of medication and vaccines. Reinforce compliance with good infection control practices and follow Standard Precautions (e.g., wear gloves prior to contact with any body fluid, wash hands after removing gloves, and clean the surfaces and objects that you may have touched).

1. Controlling an influenza outbreak

Institute outbreak control for influenza if one member of a cluster of AFRI tests positive for influenza with rapid antigen test or if the influenza viral culture is positive.

a. To reduce transmission of influenza A and B

Reduce contact with respiratory secretions as follows (11)(14):

i. Cohort patients in the affected unit;

ii. Place patients with symptoms on Droplet Precautions (gloves for contact with respiratory secretions or contaminated surfaces and wear a mask when within 3 feet of patient);

iii. Cancel or postpone group activities, when possible, to decrease the chance of person to person spread of influenza;

iv. Where possible, encourage staff with symptoms of AFRI to stay at home;

v. Where possible, reassign staff who have recently been caring for persons with respiratory symptoms to duties distant from residents (e.g., in administration);

vi. Encourage influenza vaccination for unvaccinated staff and residents, understanding that it takes up to two weeks to produce influenza-specific antibody following vaccination;

vii. Limit the number of staff 'floating' to different wards, as much as possible, to decrease the chance of influenza spreading to other floors or wards;

viii. Notify facility visitors that influenza has been diagnosed in the facility and request ill persons to postpone their visit;

ix. Limit new admissions;

x. Continue monitoring for new cases of AFRI;

xi. Notify the local or state health department of the outbreak within 24 hours.

b. Control influenza A outbreaks with antiviral drugs

i. Immediately upon confirmation of influenza A, prescribe amantadine or rimantadine for asymptomatic residents in the facility, to prevent further spread of influenza A viruses (32)(33). Influenza A antivirals should be administered for at least 2 weeks, or until approximately 1 week after the last AFRI(34)(35). Both rimantadine and amantadine are 70 - 90% effective in preventing influenza A when used for prophylaxis(32,35). Rimantadine has fewer side effects but is also more expensive than amantadine (35). Early administration of these medications during an influenza A outbreak has been effective in limiting outbreaks.

ii. Review the contingency plan for use of antivirals towards reducing transmission.

iii. Provide antivirals to symptomatic patients. For treatment of influenza A infections, either amantadine or rimantadine can be administered for three to five days. Treatment of influenza A infections with antiviral medications can reduce the number of days of illness and fever by as much as 50%, and reduce further transmission of influenza **if treatment is started within the first 2 days after illness onset.**

iv. Zanamivir and oseltamivir, are antiviral medications which are recently licensed for the treatment of laboratory-confirmed influenza. **Neither are approved for prophylaxis.** (See supplement to Part II, for more details on the use of all antivirals).

v. Zanamivir or oseltamivir can be used for the treatment of both, influenza A and B infections(36). Zanamivir can reduce the duration of influenza symptoms when started **within the first 2 days of illness onset** and is administered as 2 oral inhalations twice a day for 5 days.

vi. Zanamivir is licensed for use in persons 12 years and older. Oseltamivir is licensed for use in persons 18 years and older.

vii. Antivirals may be considered for prophylaxis of nursing home staff who have been vaccinated less than 2 weeks prior to outbreak, or who have not been vaccinated (32,38) .

viii. Separate symptomatic patients on antiviral treatment from others to the extent possible in the facility to decrease the possibility of transmitting antiviral-resistant influenza(37).

ix. Monitor adverse reactions to antivirals using the format of Appendix 12. Side effects can include disturbances of the central nervous system such as, confusion and dizziness as well as gastrointestinal disturbances.

x. Exercise precaution when administering rimantadine or amantadine to persons with:

- decreased renal function(37,38) (adjust the dose based on creatinine clearance)
- liver dysfunction
- seizure disorders(38).

Note: A more detailed description on dosing, drug-drug interactions, side effects and contraindications of the use of anti-influenza drugs is included as supplementary information on antivirals at the end of Part II of the Manual. Also consult the package inserts for these drugs and the ACIP recommendations for the use of antivirals (34,38).

a. "Close out" the outbreak control

i. On the basis of daily monitoring of AFRI, consider the outbreak to have been exhausted when there are no new cases recorded in the facility for 1 week.

ii. Prophylactic antiviral medications can be discontinued after a minimum of 2 weeks, or if no new AFRI cases have been detected for one week.

iii. Continue monitoring for AFRI on a weekly basis, since more than one influenza outbreak may occur in a single long-term care facility during the influenza season.

iv. Review the procedures used and discuss mechanisms that can be established to improve monitoring, detection, diagnosis and control of influenza in the event of a subsequent outbreak.

v. Incorporate modifications in control procedures immediately, in order to be prepared for the next outbreak of AFRI.

2. Controlling a pneumococcal disease outbreak.

Institute outbreak control measures for pneumococcal infections if 2 or more residents have symptoms of pneumonia, gram positive diplococci in the sputum or any other evidence of pneumococcal infection, such as isolation of *S. pneumoniae* from blood or cerebro-spinal fluid, during a 2 week*- period.

a. Reduce transmission of pneumococci from care givers to residents

Although difficult, isolation of the organism, should include typing and molecular characterization in order to distinguish between multiple or single source of infection.

The following control measures are recommended in addition to standard infection control practices for respiratory illnesses(11,28)

- Audit medical records to verify that all eligible patients have been vaccinated against pneumococcal disease. (Maintain a list of vaccinated residents.)
- Contact patients who initially refused vaccination and encourage them to accept immunization.
- Reinforce the policy of immunizing new admissions and transfers from hospitals to the facility.
- Group (cohort) symptomatic residents, in the area of the long-term care facility where the cluster had been detected.
- Reinforce compliance with good infection control practices among staff and follow standard precautions.
- Additional measures may be needed depending upon the extent of the outbreak; consult the the state or local health department epidemiologists.

a. "Closing out" pneumococcal outbreak activities

On the basis of the daily monitoring for AFRI and pneumonias, consider the outbreak to have been exhausted when there are no new cases recorded during the subsequent month.

Recommended Reading for Disease Surveillance

Control of pneumonia in long-term care facilities

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D. Supplementary Information on the Use of Antiviral Agents for the Control of Influenza in Long-Term Care Facilities

Antiviral drugs for influenza are an important adjunct to influenza vaccine for the control and prevention of influenza. Rimantadine hydrochloride and amantadine hydrochloride are 70%-90% effective as chemoprophylactic agents against influenza A but are not effective against influenza B. In 1999, the U.S Food and Drug Administration approved 2 members of a new class of antiviral agents that selectively inhibit the neuraminidase of both influenza A and B viruses. Zanamivir and oseltamivir have been approved for treatment but not for prophylaxis. Limited data are available on the use of zanamivir among elderly, institutionalized populations, and individuals whose chronic underlying conditions place them at high risk for severe illness.

Appropriate anti-influenza medications should be used in patients with **laboratory-confirmed influenza A or B**. There are currently four antiviral medications against influenza, and the choice of either of these drugs should depend upon the type of influenza virus identified in the patient, influenza vaccination status of the resident (or staff), environmental conditions (outbreak control or sporadic case), preexisting health conditions and prescribed medications, and the relative cost of the antivirals,(38)(39). Antiviral agents for influenza are an adjunct to vaccine and are not a substitute for vaccination.

Rimantadine and amantadine

Amantadine has been available since 1976 and, rimantadine since 1993. Both drugs have been extensively used for treatment and prophylaxis of influenza A. Rimantadine and amantadine interfere with the replication cycle of type A (but not type B) influenza viruses and are indicated for the prophylaxis and treatment of influenza A infections. When administered prophylactically to healthy adults, both drugs are 70%-90% effective in preventing illness caused by naturally occurring strains of type A influenza viruses (40)(41)(42)(43)

a. Indications for use

Amantadine or rimantadine should be considered for persons at high risk and care-givers who are vaccinated after influenza activity has begun, and persons who have immunosuppressive conditions, only during the period of peak influenza activity in the community. Because antiviral agents taken prophylactically may prevent illness but not asymptomatic infection, some persons who take these drugs can still develop immune responses that will protect them when they are exposed to antigenically related viruses at a later time. When administered as treatment within 48 hours of illness onset in healthy adults,

rimantadine and amantadine can reduce the severity and duration of signs and symptoms of influenza A illness (39)(40)(41)(42)(43).

b. Adverse reactions

Both drugs can cause central nervous system (CNS) and gastrointestinal side effects when administered to young, healthy adults at equivalent dosages of 200 mg/day. However, the incidence of CNS side effects (e.g., nervousness, anxiety, difficulty concentrating, confusion and lightheadedness) is higher among persons taking amantadine compared with those taking rimantadine (44). In a 6-week study of prophylaxis in healthy adults, approximately 6% of participants taking rimantadine at a dosage of 200mg/day experienced at least one CNS symptom, compared with approximately 13% of those taking the same dose of amantadine and 4% of those taking placebos. Gastrointestinal side effects (e.g., nausea and anorexia) occur in approximately 1%-3% among persons taking either drug, compared with 1% of persons receiving the placebo(44).

Side effects associated with both drugs are usually mild and cease soon after discontinuing the drug(40). Side effects can diminish or disappear after the first week, despite continued drug ingestion. Serious CNS side effects have been observed (e.g., marked behavioral changes, delirium, hallucinations, agitation, and seizures). These more severe side effects have been associated with high plasma drug concentrations and have been observed most often among persons who have renal insufficiency, seizure disorders, or certain psychiatric disorders and among elderly persons who have been taking amantadine as prophylaxis at a dosage of 200 mg/day. Because rimantadine has been marketed for a shorter period than amantadine, its safety in the chronically ill and older adults has been less frequently evaluated.

c. Drug interactions and contraindications

Concomitant administration of antihistamines or anticholinergic drugs (such as those used in Parkinsonism) can increase the incidence of adverse CNS reactions (40). Rimantadine and amantadine should be used with caution in persons with history of seizures and in pregnant women, and should be used only if the expected benefits outweigh perceived risks. Neither rimantadine nor amantadine are recommended for persons with known hypersensitivity to drugs of the adamantine class.

No clinically significant interactions between rimantadine and other drugs have been identified. Please consult the package inserts for more detailed information concerning potential drug interactions for either amantadine or rimantadine.

d. Use for prophylaxis and treatment

Rimantadine and amantadine are administered orally and are available in tablet or syrup form.

Prophylaxis: Chemprophylaxis is not a substitute for vaccination. When rimantadine or amantadine is administered as prophylaxis, factors related to cost, compliance, and potential side effects should be considered when determining the period of prophylaxis.

Prophylaxis for outbreak control: If confirmed outbreaks of influenza A occur in long term care facilities, chemoprophylaxis should be initiated among all asymptomatic residents to reduce the spread of the virus, regardless of whether they received influenza vaccine the previous fall. The drug should be continued for at least 2 weeks or until approximately 1 week after the end of the outbreak. For persons who receive vaccine during the outbreak, chemoprophylaxis can be administered for two weeks after vaccination. To reduce the spread of infection and the chances of prophylaxis failure due to transmission of drug-resistant virus, measures should be taken to reduce contact as much as possible between persons taking drug for treatment and others(45)(46). During outbreaks, chemoprophylaxis may also be considered for (a) unvaccinated persons who have frequent contact with residents (e.g. frequent visitors) and (b) unvaccinated long term care facility employees. Prophylaxis should be considered for all employees, regardless of their vaccination status, if the outbreak is caused by a variant strain of influenza A that might not be controlled by the vaccine.

Therapy: Rimantadine or amantadine may be used to reduce the severity and shorten the duration of influenza A illness. They are more effective when administered within 48 hours of illness onset(40). Because of the risk of emergence of amantadine- and rimantadine-resistant influenza A viruses, treatment should be discontinued as soon as clinically warranted, generally after 3-5 days of treatment or within 24-48 hours after the disappearance of signs and symptoms(45)(47)(48)(49)

Dosage: For treatment or prophylaxis, rimantadine and amantadine should be administered at a dose of 100 mg twice a day for persons aged 10-64 years, and $\leq$100 mg/day for persons aged $\geq$65 years with normal liver and renal

function(45)(50)(51). The dose of amantadine should be reduced for persons who have impaired renal or hepatic function. The dose of rimantadine should be reduced for persons who have impaired renal function or severe liver dysfunction (43)(50)(52)(53) and for persons with anuric renal failure. In persons with a history of seizures, these drugs must be used with caution. For elderly nursing home residents, dosage of rimantidine should be reduced to 100mg/day for both, prophylaxis or treatment.

Guidelines for dose reduction can be found in the package insert(53). Gomolin et. al.(46), recommend the following amantadine dosing schedule for residents in long-term care, based on serum creatinine:

Serum creatinine (mg/dl)	Amantadine dose
$\leq$ 1.0	100 mg once a day
1.1 - 1.9	100 mg once every other day
$\geq$ 2.0	100 mg twice a week
dialysis patients	100 mg once a week

e. Antiviral drug-resistant strains of influenza

Amantadine-resistant viruses are cross-resistant to rimantadine and vice versa(54). Drug-resistant viruses can appear in up to one third of patients when either amantadine or rimantadine is used for therapy(55). Antiviral-resistant influenza strains can replace sensitive strains within 2-3 days after starting therapy(56). Resistant viruses have been isolated from persons who live at home or in an institution where other residents are taking or, have recently taken amantadine or rimantadine as therapy(57). However, the frequency with which resistant viruses are transmitted and their impact on influenza control efforts are unknown. Rapid antigen tests and culture methods used for screening of epidemic strains of influenza A cannot detect amantadine and rimantadine-resistant viruses(56).

2. Zanamivir and Oseltamivir

Neither zanamivir nor oseltamivir is approved for influenza prophylaxis and there is limited experience with prophylactic use of these agents in institutional settings(58). Recently published studies of zanamivir and oseltamivir for prophylaxis of influenza in community settings demonstrated both drugs to be

similarly effective in preventing laboratory-confirmed clinical influenza with fever (efficacy: zanamivir, 84%; oseltamivir, 82%)(59)(60).

Zanamivir is available as a dry powder that is self-administered via oral inhalation using a plastic device (Diskhaler®) included in the package with the medication. Zanamivir is packaged in a disk with four blisters of medication, each containing a powder mixture of 5 mg of zanamivir and 20 mg lactose. Delivery of the medication requires loading of a medication disk into the Diskhaler. The recommended dosage of zanamivir for treatment of influenza in persons aged $\geq$12 years is two inhalations (one 5 mg blister per inhalation for a total dose of 10 mg) twice daily (approximately 12 hours apart) for five days(61) . Nursing home residents will need careful instruction and may need assistance with proper use of the device. Oseltamivir is administered orally. It is available as 75mg capsules.

a. Indications for use

Zanamivir is approved for treatment of uncomplicated acute illness caused by influenza virus in adults and adolescents aged greater than or equal to 12 years who have been symptomatic for no more than 2 days. No data are available to support zanamivir's efficacy if treatment is initiated more than 48 hours after onset of illness(61). Oseltamivir is approved for treatment of uncomplicated acute illness caused by influenza infection in adults aged greater than or equal to 18 years who have been symptomatic for no more than 2 days. No data are available to support oseltamivir's efficacy if treatment is initiated more than 48 hours after onet of illness(62). When administered within 2 days of illness onset among otherwise healthy adults, zanamivir and oseltamivir can reduce by approximately 1 day the duration of moderate or severe symptoms of uncomplicated influenza(63)(64)(65)(66)(67)(68). The evidence for the efficacy of both drugs is based primarily on data from patients with fever greater than or equal to 37.8 C (100 F) at the time therapy was started. Neither zanamivir nor oseltamivir has been demonstrated to be effective in preventing serious influenza-related complications, such as bacterial or viral pneumonia or exacerbation of chronic diseases. Data are limited and inconclusive concerning the effectiveness of zanamivir for treatment of influenza in persons at high risk for serious complications of influenza(60)(63)(64)(69). No published data are available concerning the effectiveness of oseltamivir for treatment of influenza in high-risk populations.

b. Persons with impaired renal function

Limited data are available regarding the safety and efficacy of zanamivir for patients with impaired renal function. Although pre-licensure studies of patients with renal failure who were administered a single intravenous dose of zanamivir indicated decreases in renal clearance and increases in half-life and systemic

exposure to zanamivir(61)(70), a small number of healthy volunteers tolerated high doses of intravenously administered zanamivir(71). On the basis of the cited studies, the manufacturer recommends no adjustment of the recommended oral inhalation dose for a 5-day course of treatment for patients with either mild-to-moderate or severe impairment in renal function(66). The dose of amantadine, rimantadine, and oseltamivir must be reduced for patients with renal failure.

c. Adverse reactions

In clinical studies of inhaled zanamivir for treatment of influenza, the frequency of reported adverse events was similar between persons receiving zanamivir and persons receiving the inhaled lactose vehicle alone. The most commonly reported adverse events were diarrhea, nausea, nasal signs and symptoms, bronchitis, sinusitis, cough and headach, dizziness, and ear, nose, and throat infections(59)(60)(61)(64). Each of these symptoms were reported by < 5% of persons in the clinical treatment studies combined(61). Patients with underlying chronic respiratory disease may experienced bronchospasm following administration of zanamivir(61).

Nausea and vomiting were reported more frequently among persons receiving Oseltamivir, although no one discontinued treatment because of these symptoms(62). Nausea and vomiting might be less severe if oseltamivir is taken with food(62)(72).

Limited data are available regarding the safety and efficacy of zanamivir among patients with impaired hepatic function. Zanamivir is not metabolized by the liver and is excreted renally.

Central nervous system side effects have been infrequently reported among patients taking zanamivir and oseltamivir(61)(62).

d. Drug interactions

Although limited clinical data are available regarding drug interactions with zanamivir, no clinically important drug interactions have been predicted on the basis of *in vitro* data(61). Zanamivir does not affect the cytochrome P450 isoenzymes in human liver microsomes(61)(73). No published data are available concerning the safery or efficacy of coadministering amantadine or rimantadine with oseltamivir.

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Part III. Clinical and Epidemiological Information for Influenza and Pneumococcal Disease and Indications for Td .

The following section is excerpted from the ACIP recommendations for the prevention of influenza (34) and pneumococcal disease (74), adult immunizations with Td (75) and use of diphtheria, pertussis, and tetanus vaccine(76). For more information, please consult the original documents.

A. Influenza

Clinical Characteristics

Influenza is an acute, febrile, respiratory infection. Common symptoms include sudden onset of fever, myalgia with headache, cough, rhinitis and sore throat. Fever in healthy adults usually lasts for 3 days and rarely beyond 5. Recovery is usually rapid but some patients may sustain lingering sequelae of depression and asthenia for several weeks. However, among elderly or persons with underlying medical problems, influenza can cause severe illness and lead to complications such as pneumonia. Among the elderly, complications due to influenza can be serious enough to require hospitalizations or result in death.

Outbreaks are most common from early autumn through late spring but may begin or extend into the warm season. Approximately 130,000 to 170,000 hospitalizations and an average of 20,000 deaths are associated with influenza illness each year in the U.S. Approximately 90% of the deaths are among persons 65 years and older.

The Organisms

Two types of influenza viruses cause substantial disease in man; influenza A and influenza B. Influenza A viruses are classified into subtypes on the basis of two surface antigens: hemagglutinin (H) and neuraminidase (N). Three subtypes of hemagglutinin (H1, H2, and H3) and two subtypes of neuraminidase (N1 and N2) are recognized among influenza A viruses that have caused widespread human disease. Immunity to these antigens--especially to the hemagglutinin--reduces the likelihood of infection and lessens the severity of disease if infection occurs(77).

Infection with a virus of one subtype confers little or no protection against viruses of other subtypes. Furthermore, over time, antigenic variation (antigenic drift) within a subtype may be so marked that infection or vaccination with one strain may not induce immunity to distantly related strains of the same subtype. For these reasons, major epidemics of respiratory disease caused by new strains of influenza A continue to occur. Since the influenza virus strains are constantly changing, the influenza vaccine strains must also be updated on a yearly basis. Influenza B viruses are more antigenically stable than influenza A viruses.

Impact of influenza outbreaks in long-term care facilities

Influenza is highly contagious and can spread rapidly through a long-term care facility. Influenza outbreaks can result in illness in up to 60 % of residents if the outbreak is not

recognized early and controlled in a timely manner. Up to 25% of residents with influenza illness may be hospitalized and one-third of hospitalized residents may die from influenza and influenza-related complications. Influenza A outbreaks generally lead to higher morbidity and mortality among long-term care populations than influenza B outbreaks. Vaccination of residents and staff against influenza in long-term care facilities has been shown to decrease the number of illnesses, hospitalizations, and deaths due to influenza.

Influenza vaccine

Each year's inactivated influenza vaccine contains three virus strains (two type A and one type B) representing the influenza viruses that are likely to circulate in the United States in the upcoming winter. The vaccine is made from highly purified, egg-grown viruses that have been made noninfectious (inactivated). Influenza vaccine rarely causes systemic or febrile reactions. Whole-virus, subvirion, and purified-surface-antigen preparations are available. Live, attenuated influenza virus vaccines which could be administered as intra-nasal sprays are being investigated.

Influenza vaccine effectiveness

The effectiveness of influenza vaccine in preventing or attenuating illness varies, depending primarily on the age and immunocompetence of the vaccine recipient and the degree of similarity between the virus strains included in the vaccine and those that circulate during the influenza season. When a good match exists between vaccine and circulating viruses, influenza vaccine has been shown to prevent illness in approximately 70%-90% of healthy persons aged less than 65 years.

Among elderly persons residing in long-term care facilities, influenza vaccine is most effective in preventing severe illness, secondary complications, and death. Studies of this population indicate that the vaccine is 50%-60% effective in preventing hospitalization and pneumonia and 80% effective in preventing death, even though efficacy in preventing influenza illness may often be in the range of 30%-40% among the frail elderly. Achieving a high rate of vaccination among residents in long-term care can reduce the likelihood of an outbreak in a facility. Vaccination of health-care workers in long-term care facilities has also been shown to reduce mortality among residents of the facilities.

Recommendations for the use of the influenza vaccine in institutional settings

Although the current influenza vaccine can contain one or more of the antigens administered in previous years, annual vaccination with the current vaccine is necessary because immunity declines during the year following vaccination.

Persons for whom annual influenza vaccination is recommended

Persons at increased risk for influenza-related complications

- Persons aged greater than or equal to 50 years
- **Residents of long-term care facilities that house persons of any age with chronic medical conditions**

- Adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including children with asthma
- Adults and children who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications)
- Women who will be in the second or third trimester of pregnancy during the influenza season

Persons who can transmit influenza to persons at high risk

Persons with some medical conditions (e.g., the elderly, transplant recipients, and persons with AIDS) can have a low antibody response to influenza vaccine. Efforts to protect these members against influenza can be improved by reducing the likelihood of influenza exposure from their care givers and contacts who may have asymptomatic influenza infections. Therefore, the following groups should be vaccinated:

- physicians, nurses, and other personnel in hospital and outpatient-care settings;
- employees of long-term care facilities who have contact with patients;
- providers of home care to persons at high risk (e.g., visiting nurses and volunteer workers); and,
- household members (including children) of persons in high-risk groups.

Other persons

Persons who provide essential community services should be considered for vaccination to minimize disruption of essential activities during influenza outbreaks. Students or other persons in institutional settings (e.g., those who reside in dormitories) should be encouraged to receive vaccine to minimize the disruption of routine activities during epidemics.

Persons who should not be vaccinated

Inactivated influenza vaccine should not be administered to persons known to have anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine without first consulting a physician (see side effects and adverse reactions). Use of an antiviral agent (amantadine or rimantadine) is an option for prevention of influenza A in such persons. However, persons who have a history of anaphylactic hypersensitivity to vaccine components but who are also at high risk for complications of influenza can benefit from vaccine after appropriate allergy evaluation and desensitization. Specific information about vaccine components can be found in package inserts for each manufacturer.

Adults with acute febrile illness usually should not be vaccinated until their fever has abated. However, minor illnesses without fever are not a contraindication to influenza vaccination.

Vaccine side effects and adverse reactions

Because influenza vaccine contains only noninfectious viruses, it cannot cause influenza. Respiratory disease after vaccination represents coincidental illness unrelated to influenza vaccination. The most frequent side effect of vaccination is soreness at the vaccination site that lasts up to 2 days. These local reactions generally are mild and rarely interfere with the ability to conduct usual daily activities.

Fever, malaise, myalgia, and other systemic symptoms can infrequently occur following vaccination and most often affect persons who have had no previous exposure to the influenza virus antigens in the vaccine (e.g., young children). These reactions begin 6-12 hours after vaccination and can persist for 1 or 2 days. Recent placebo-controlled trials suggest that among elderly persons and healthy young adults, split-virus influenza vaccine is not associated with higher rates of systemic symptoms (e.g., fever, malaise, myalgia, and headache) when compared with placebo injections.

Immediate--presumably allergic--reactions (e.g., hives, angioedema, allergic asthma, and systemic anaphylaxis) rarely occur after influenza vaccination. These reactions probably result from hypersensitivity to some vaccine component; most reactions likely are caused by residual egg protein. Although current influenza vaccines contain only a small quantity of egg protein, this protein can induce immediate hypersensitivity reactions among persons who have severe egg allergy. Persons who have developed hives, have had swelling of the lips or tongue, or have experienced acute respiratory distress or collapse after eating eggs should consult a physician for appropriate evaluation to help determine if vaccine should be administered. Persons who have documented immunoglobulin E (IgE)-mediated hypersensitivity to eggs -- including those who have had occupational asthma or other allergic responses to egg protein -- might also be at increased risk for allergic reactions to influenza vaccine, and consultation with a physician should be considered. Protocols have been published for safely administering influenza vaccine to persons with egg allergies (78),(79).

Hypersensitivity reactions to any vaccine component can occur. Although exposure to vaccines containing thimerosal can lead to induction of hypersensitivity, most patients do not develop reactions to thimerosal when administered as a component of vaccines--even when patch or intradermal tests for thimerosal indicate hypersensitivity. When reported, hypersensitivity to thimerosal usually has consisted of local, delayed-type hypersensitivity reactions.

Guillain-Barré Syndrome as a post-influenza vaccination event

Although the 1976 swine influenza vaccine was associated with an increased frequency of Guillain-Barré syndrome (GBS), evidence for a causal relationship of GBS with subsequent vaccines prepared from other virus strains is less clear. However, obtaining strong evidence for a possible small increase in risk is difficult for a rare condition such as GBS, which has an annual background incidence of only 10-20 cases per million adults. The potential benefits of

influenza vaccination clearly outweigh the possible risks for vaccine-associated GBS. More definitive data probably will require the use of other methodologies such as laboratory studies of the pathophysiology of GBS.

Investigations to date suggest no large increase in GBS associated with influenza vaccines (other than the swine influenza vaccine in 1976) and that if influenza vaccine does pose a risk, it is probably quite small -- slightly more than one additional case per million persons vaccinated. Cases of GBS following influenza infection have been reported, but no epidemiologic studies have documented such an association(80),(81). Good evidence exists that several infectious illnesses, most notably *Campylobacter jejuni* as well as upper respiratory tract infections in general, are associated with GBS(82),(83),(84),(85).

Whereas the incidence of GBS in the general population is very low, persons with a history of GBS have a substantially greater likelihood of subsequently developing GBS than persons without such a history. Thus, the likelihood of coincidentally developing GBS after influenza vaccination is expected to be greater among persons with a history of GBS than among persons with no history of this syndrome. Whether influenza vaccination might be causally associated with this risk for recurrence is not known. Avoiding subsequent influenza vaccination of persons known to have developed GBS *within 6 weeks* of a previous influenza vaccination seems prudent. However, for most persons with a history of GBS who are at high risk for severe complications from influenza, many experts believe the established benefits of influenza vaccination justify yearly vaccination.

Simultaneous administration of other vaccines

The target groups for influenza and pneumococcal vaccination overlap considerably. For persons at high risk who have not previously been vaccinated with pneumococcal vaccine, health-care providers should strongly consider administering pneumococcal and influenza vaccines concurrently. Both vaccines can be administered at the same time at different sites without increasing side effects. Remember, influenza vaccine is administered each year, whereas pneumococcal vaccine is not.

Antiviral medications for influenza

Use of rimantadine, amantadine, zanamivir, and oseltamivir were discussed in Part II.C.3. Please consult the CDC Recommendations for a detailed discussion of antivirals against influenza viruses (34, 38).

Sources of information on influenza control programs

Information regarding influenza surveillance is available through the CDC Voice Information System (influenza update), (888) 232-3228; through the CDC Fax Information Service, (888) 232-3299; or through the CDC Influenza Branch's World-Wide Web site at http://www.cdc.gov/ncidod/diseases/flu/weekly.htm. From October through May, the information is updated weekly. In addition, periodic updates about influenza are published in the weekly MMWR. State and local health departments should be consulted regarding availability of

influenza vaccine, access to vaccination programs, and information about state or local influenza activity.

B. *S. pneumoniae*: Disease and epidemiology

S. pneumoniae is a major cause of pneumonia and meningitis worldwide. Although any of a large number of microorganisms may cause pneumonia, typical primary lobar pneumonia is nearly always caused by the pneumococcus, which is also the most frequent cause of bronchopneumonia(86). Pneumococcal pneumonia of either variety is generally preceded by a simple acute infection of the upper respiratory tract such as the common cold and may also occur as a complication of influenza.

In 1996, , *S. pneumoniae* accounted for an estimated 106,00 to 175,000 cases of pneumococcal pneumonia in the United States, of which 31, 479 required hospitalization (87). Of these, 71,000 to 140,000 cases were estimated to be nonbacteremic pneumonias Pneumococcal infections have been estimated to result in 12,500 deaths annually, in the United States (87). Approximately half of these deaths potentially could be prevented through the use of vaccine.

Despite appropriate antimicrobial therapy and intensive medical care, the overall case-fatality rate for pneumococcal bacteremia is 15%-20% among adults. Among elderly patients, this rate is approximately 30%-40%(74)(88)(89)(90)(91)(92)(93). Case-fatality rates are highest for meningitis and bacteremia, and the highest mortality occurs among the elderly and patients who have underlying medical conditions.

The organism

S. pneumoniae is a gram positive diplococcus. There are at least 83 known serotypes of *S. pneumoniae*. As with other encapsulated organisms, the polysacharide capsule is an important virulence factor and capsular type-specific antibody is protective(74). *S. pneumoniae* is a frequent inhabitant of the upper respiratory tract and may be isolated from the nose and/ or throat of approximately 25% of persons at any given time. Nearly all persons carry pneumococci transiently or intermittently in the course of a year. The factors leading from carriage to invasive disease are not clearly understood. Transmission probably occurs mostly from asymptomatic carriers by respiratory droplets.

While penicillin has been the drug of choice for *S pneumoniae*, drug resistance has been increasing rapidly in this organism and treatment has become a serious problem in some areas of the U.S. Resistance to other antimicrobial agents has been reported from many areas and has accounted for therapeutic failures. Reports have included resistance to sulfonamides, tetracycline, erythromycin and newer macrolides (e.g. azithromycin, clarithromycin), quinolones, and chloramphenicol in addition to β-lactam antibiotics (94),(95). Pneumococci are also relative resistant to aminoglycosides.

Risk for pneumococcal disease

Persons 2 years of age and older who are at increased risk include:

- Persons with functional or anatomic asplenia (e.g., sickle cell disease or splenectomy) because asplenia leads to reduced clearance of encapsulated bacteria from the bloodstream;
- Persons who are generally immunocompetent but who have chronic cardiovascular diseases (e.g., congestive heart failure or cardiomyopathy), chronic pulmonary diseases (e.g., chronic obstructive pulmonary disease [COPD] or emphysema), or chronic liver diseases (e.g., cirrhosis);
- Persons with diabetes mellitus (when associated with cardiovascular or renal dysfunction, increases the risk for severe pneumococcal illness);
- Persons who have liver disease as a result of alcohol abuse(74)(96)(97);
- Long-term use of systemic corticosteroids;
- Immunosuppressive conditions (e.g., congenital immunodeficiency, human immunodeficiency virus [HIV] infection, leukemia, lymphoma, multiple myeloma, Hodgkins disease, or generalized malignancy);
- Organ or bone marrow transplantation;
- Therapy with alkylating agents, antimetabolites, or systemic
- corticosteroids(98);
- cigarette smokers
- Chronic renal failure or nephrotic syndrome(74).
- All persons 65 years and older

Note: S. pneumoniae is the most commonly identified bacterial pathogen that causes pneumonia in HIV-infected persons(99).

Antimicrobial resistance

Strains of drug-resistant *S. pneumoniae* have become increasingly common in the United States and in other parts of the world(87)(94), complicating empirical treatment with antibiotics.

Pneumococcal vaccines

The currently available pneumococcal vaccines include 23 purified capsular polysaccharide antigens of *S. pneumoniae*. These vaccines were licensed in the United States in 1983 and replaced an earlier 14-valent formulation that was licensed in 1977.

The 23 capsular types in the vaccine represent at least 85%-90% of the serotypes that cause invasive pneumococcal infections among children and adults in the United States(74). The six serotypes (6B, 9V, 14, 19A, 19F, and 23F) that most frequently cause invasive drug-resistant pneumococcal infection in the U.S. are represented in the 23-valent vaccine.

Recommendations for the use of the pneumococcal polysaccharide vaccine

All persons aged ≥ 65 years should receive the pneumococcal vaccine, including previously unvaccinated persons and persons who have not received vaccine within 5 years (and were <65 years of age at the time of vaccination). Persons older than 2 years of age and with chronic conditions that increase the risk of pneumococcal disease should be receive at least 1 dose of the pneumococcal vaccine.

Persons with uncertain vaccination status

All persons whose vaccination status is unknown should receive one dose of vaccine. To help avoid the administration of unnecessary doses, every patient should be given a record of the vaccination. However, providers should not withhold vaccination in the absence of an immunization record or complete medical record.

Simultaneous administration of pneumococcal vaccine with other vaccines

Pneumococcal vaccine may be administered at the same time as influenza vaccine (by separate injection in the other arm) without an increase in side effects or decreased antibody response to either vaccine(100)(101). Pneumococcal vaccine also may be administered concurrently with other vaccines and Td.

Because the indications for pneumococcal and influenza vaccines are similar, the time of administration of influenza vaccine, including mass vaccination at outpatient clinics, should be used as an opportunity to identify and vaccinate patients with pneumococcal vaccine. However, influenza vaccine is administered each year, whereas pneumococcal vaccine typically is administered only once for persons in most groups.

Revaccination

Routine revaccination of immunocompetent persons previously vaccinated with 23-valent polysaccharide vaccine is not recommended. However, a one-time revaccination is recommended for persons aged 65 years and older if they received the vaccine 5 years or more previously and were less than 65 years old at the time of primary vaccination.

Elderly persons with unknown vaccination status should be administered one dose of vaccine. See Appendix 13 for an algorithm for vaccinating persons aged 65 years and older.

C. Tetanus - Diphtheria Toxoid (Td)

Tetanus. Clinical information

Tetanus is an infectious but noncommunicable disease of humans and certain animal species, acquired through environmental exposure. *Clostridium tetani* is an anaerobic, spore forming bacterium, resident in the soil as well as in the intestinal tracts of a large proportion of animals and humans. The ubiquitous spores germinate to vegetative bacilli when introduced into the soft tissues of the host under conditions in which the partial pressure of molecular oxygen is low. The vegetative organisms produce a potent neurotoxin that acts on the central nervous system leading to the muscular contractions characteristic of the illness(102).

Tetanus. Epidemiology

Tetanus remains a severe disease that primarily affects unvaccinated or inadequately vaccinated persons. Adults aged greater than or equal to 60 years continue to be at highest risk for tetanus and for severe disease. The overall incidence of tetanus has decreased from 0.20 per 1,000,000 population from the late 1980s to 0.15 between 1995 and 1997. The decreased incidence was primarily among persons less than 20 years or 60 years and older.

From 1995 through 1997, a total of 124 cases of tetanus were reported from 33 states and the District of Columbia, accounting for an average annual incidence of 0.15 cases per 1,000,000 population. Sixty percent of patients were aged 20-59 years; 35% were aged greater than or equal to 60 years; and 5% were aged less than 20 years, including one case of neonatal tetanus. For adults 60 years or older, the increased risk for tetanus was nearly sevenfold that for persons aged 5-19 years and twofold that for persons aged 20-59 years. The case-fatality ratio varied from 2.3% for persons aged 20-39 years to 16% for persons aged 40-59 years and to 18% for persons aged greater than or equal to 60 years. Only 13% of patients reported having received a primary series of TT before disease onset. Previous vaccination status was directly related to severity of disease, with the case-fatality ratio ranging from 6% for patients who had received one to two doses to 15% for patients who were unvaccinated (103). Waning immunity is related to the antibody titer and the number of immunizations received. Waning of immunity to tetanus declines rapidly starting at the age of 40 years and, by the age of 70 years, only 27.8% of persons have protective levels of antibodies to tetanus toxoid (104).

Diphtheria. Clinical information

Diphtheria is an acute infectious and communicable disease involving primarily the tonsils, pharynx, larynx, or nose, and occasionally other mucous membranes or skin. A false membrane is formed in ore or more of these locations. This is the site of production of the diphtheria toxin, which is responsible for the general symptomatology and subsequent damage of many organs, including cardiac and central nervous system tissue.

Corynebacterium diphtheriae can be carried in the upper respiratory tract, particularly tonsillar tissue of otherwise healthy carriers, without causing disease. *C. diphtheriae* is transmitted through droplet infection or hand-to-mouth contact to susceptible individuals. Patients with cutaneous forms of the disease have been shown to frequently harbor *C. diphtheriae* in the respiratory tract and to have greater spread of infection to household contacts than patients with respiratory forms of the infection(105)(106). Transmission may occur as long as virulent bacilli are present in discharges and lesions; usually 2 weeks or less. Chronic carriers may shed organisms for 6 months or more. In outbreaks, high percentages of children are found to be transient carriers. Effective antibiotic therapy terminates shedding.

Diphtheria: Epidemiology(107)

Diphtheria occurs worldwide, but clinical cases are more prevalent in temperate zones where the disease most frequently occurs during winter and spring.

During the pre-toxoid era, the South-east had the highest incidence of diphtheria in the United States during the winter. More recently, highest incidence rates have been in states with

significant populations of Native Americans. In 1996, 10 isolates of *C. diphtheria* were obtained from persons in an American Indian community in South Dakota half of whom had pharyngitis or tonsillitis; none had classic diphtheria disease. No geographic concentration of cases is currently observed in the United States.

From 1980 through 1998, 43 cases of diphtheria were reported in the U.S.; no cases were reported in 1993 and 1995. Of the 39 reported cases with known age, in 1982-1997 38% of cases were among persons 40 years of age or older. Most cases occurred in unimmunized or inadequately immunized persons.

Td Indications (75)

All adults lacking a complete primary series of diphtheria and tetanus toxoids should complete the series with the combined preparation, Td. A primary series for adults is three doses of preparations containing tetanus and diphtheria toxoids, with the first two doses given at least 4 weeks apart and the third dose given 6-12 months after the second. Persons who have served in the military can be considered to have received a primary series of diphtheria and tetanus toxoids. All adults for whom 10 years or more have elapsed since completion of their primary series or since their last booster dose should receive a booster dose of Td. Thereafter, a booster dose of Td should be administered every 10 years. Doses need not be repeated if the primary schedule for the series or booster doses is delayed.

Use of Td in wound management (76)

For wound management the need for active immunization, with or without passive immunization, depends on the condition of the wound and the patient's vaccination history. Rarely has tetanus occurred among persons with documentation of having received a primary series of toxoid injections. Evidence indicates that complete primary vaccination with tetanus toxoid provides protection for 10 years or longer. Consequently, when wounds are minor and uncontaminated, Td boosters are appropriate only if 10 years or more had elapsed since the last booster.

a. For invasive wounds which are clean, minor, and uncontaminated

If vaccine history is uncertain, administer 0.5 mL Td as appropriate for medical history. If the primary series was completed and the last dose (primary or booster) of Td was more than 10 years ago, administer 0.5 mL of Td intramuscularly.

b. For wounds that are neither minor nor clean

A booster is appropriate if the patient has not received tetanus toxoid within the preceding 5 years. Persons who have not completed a full primary series of injections or whose vaccination status is unknown or uncertain may require tetanus toxoid and passive immunization at the time of wound debridement and cleaning.

If passive immunization is needed, human tetanus immune globulin (TIG) is the product of choice. The currently recommended prophylactic dose of TIG for wounds of average

severity is 250 units IM. When Td and TIG are given concurrently, separate syringes and separate sites should be used.

Toxoid side effects and adverse reactions (75)

Local reactions (usually erythema and induration, with or without tenderness) can occur after Td is administered. Fever and other systemic symptoms are less common. Arthus-type hypersensitivity reactions, characterized by severe local reactions starting 2-8 hours after an injection and often associated with fever and malaise, may occur, particularly among persons who have received multiple boosters of tetanus toxoid, adsorbed.

Rarely, severe systemic reactions, such as generalized urticaria, anaphylaxis, or neurologic complications, have been reported after administration of tetanus and diphtheria toxoids. Peripheral neuropathy has been rarely reported after administration of tetanus toxoid, although a causal relationship has not been established.

Contraindications for Td use(75)(76)

A history of neurologic reaction or a severe hypersensitivity reaction (e.g. generalized urticaria or anaphylaxis) after a previous dose is a contraindication to diphtheria and tetanus toxoids. Local side effects alone do not preclude continued use. If a prior systemic reaction suggests allergic hypersensitivity, appropriate skin testing to document immediate hypersensitivity may be useful before tetanus toxoid is discontinued. Although a minor illness, such as mild upper respiratory infection, should not be cause for postponing vaccination, a severe febrile illness is reason to *defer* routine vaccination.

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Part IV.

Immunizations Recommended for Staff of Long-term Care Facilities

This section contains the ACIP recommendations for vaccinations for health care workers (108) as they pertain to long-term care facilities. Please consult the recommendations for a detailed description of the agents and vaccines recommended for health care workers. The ACIP recommendations apply for immunization of health-care workers in hospitals and health departments, private physicians' offices, Long-term care homes, schools, and laboratories and first responders. Optimal use of immunizing agents safeguards the health of workers and protects patients from becoming infected through exposure to infected workers.

A. Hepatitis B Vaccine

Any health-care worker who performs tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps should be vaccinated. Hepatitis B vaccine should always be administered by the intramuscular route in the deltoid muscle with a needle 1-1.5 inches long. The recommended primary schedule is three doses--the first two 4 weeks apart and the third dose 5 months after the second dose.

Prevaccination serologic screening for previous infection is not indicated for persons being vaccinated because of occupational risk unless the hospital or health-care organization considers screening cost-effective. Post-vaccination testing for antibody to hepatitis B surface antigen (anti-HBs) is indicated for staff who have contact with blood or patient contact and are at ongoing riskf or injuries with sharp instruments or needlesticks. Knowledge of antibody response aids in determining appropriate postexposure prophylaxis. Post-vaccination screening should be conducted between 1 and 6 months after completion of the third dose of the vaccination series. Periodic serologic testing to monitor antibody concentrations after completion of the 3-dose series is not recommended. Booster doses of hepatitis B vaccine are not considered necessary.

Non-responders: If a person does not respond to the primary vaccine series, they should complete a second 3-dose vaccine series or be evaluated to determine if they are HbsAg-positive. Persons who do not respond to the second series, and who are HBsAg-negative should be considered susceptible to HBV infection and should be counseled regarding precautions to prevent HBV infection and the need to obtain HBIG prophylaxis for any known or probable parenteral exposure to HBsAg-positive blood.

Postexposure prophylaxis with hepatitis B immune globulin (HBIG) (passive immunization) and/or vaccine (active immunization) should be used when indicated (e.g., after percutaneous or mucous membrane exposure to blood known or suspected to be HbsAg-positive).

Needle stick or other per-cutaneous exposures of unvaccinated persons should lead to initiation of the hepatitis B vaccine series. Post-exposure prophylaxis should be considered for any per-cutaneous, ocular, or mucous membrane exposure to blood in the workplace and is determined by the HBsAg status of the source and the vaccination and vaccine-response status of the exposed person(109) (Table 1)

If the source of exposure is HBsAg-positive and the exposed person is unvaccinated, HBIG also should be administered as soon as possible after exposure (preferably within 24 hours) and the vaccine series started. The effectiveness of HBIG when administered >7 days after percutaneous or permucosal exposures is unknown. If the exposed person had an adequate antibody response ($\geq$10 mIU/mL) documented after vaccination, no testing or treatment is needed, although administration of a booster dose of vaccine can be considered.

B. Influenza vaccine

During community influenza outbreaks, admitting patients infected with influenza to hospitals has led to nosocomial transmission of the disease(110)(111) including transmission from staff to patients(112). Transmission of influenza among medical staff causes absenteeism and considerable disruption of health care(113),(114),(115),(116); CDC, un-published data). In addition, influenza outbreaks have caused morbidity and mortality in long-term care care facilities(117)(118)(119)(120)(121). In a recent study of long-term care facilities with uniformly high patient influenza vaccination levels, patients in facilities in which >60% of the staff had been vaccinated against influenza experienced less influenza-related mortality and illness, compared with patients in facilities with no influenza-vaccinated staff (122)(123).

To reduce staff illnesses and absenteeism during the influenza season and to reduce the spread of influenza to and from workers and patients, all health care workers who work in long-term care facilities should be vaccinated in the fall of each year. In addition, others who should receive influenza vaccination, include:

- Persons who attend patients at high risk for complications of influenza (whether the care is provided at home or in a health-care facility) ;
- Persons aged 50 years or older;
- Persons with certain chronic medical conditions (e.g., persons who have chronic disorders of the cardiovascular or pulmonary systems; persons who required medical follow-up or hospitalization within the preceding year because of chronic metabolic disease [including diabetes], renal dysfunction, hemoglobinopathies, or immunosuppression [including HIV infection]); and,
- Pregnant women who will be in the second or third trimester of pregnancy during influenza season.

Note: Long-term care facilities should improve influenza vaccination use among their employees. Here are a few suggestions towards this goal:

- *include an influenza vaccination reminder card with the paychecks*
- *use a reminder card to list and dispel common misconceptions about the vaccine.*
- *have the employee health nurse bring the influenza vaccination card to each employee unit on each shift.*

- *use strategies to make influenza vaccination part of Halloween or Thanksgiving festivities.*

C. Measles, Mumps, and Rubella vaccine

While older residents of long-term care facilities may have had these diseases and be immune, staff immunization requirements should comply with the ACIP recommendations for health-care workers i.e. demonstration of immune status either by means of a vaccination record or documentation of physician-diagnosed disease, or if they were born before 1957. For persons born during or after 1957 who work in health-care facilities, adequate vaccination consists of 2 doses of MMR separated by at least 28 days, with the first dose administered no earlier than the first birthday(124). If a staff member is unable to provide such a documentation, facilities should recommend a dose of MMR to staff who were born prior to 1957, and two doses of the trivalent measles-mumps-rubella (MMR) vaccine for those born during or after 1957 (120). MMR or its component vaccines should not be administered to women known to be pregnant.

D. Herpes zoster and varicella vaccine(125)

Varicella (i.e., chickenpox) is a highly contagious disease caused by the varicella zoster virus (VZV). Varicella vaccine is recommended for susceptible adults in the following high-risk groups: a) persons who live or work in environments where transmission of VZV is likely (e.g., teachers of young children, day care employees, and residents and staff members in institutional settings), b) persons who live and work in environments where transmission can occur (e.g., college students, inmates and staff members of correctional institutions, and military personnel), c) nonpregnant women of childbearing age, d) adolescents and adults living in households with children, and e) international travelers. ACIP now recommends the vaccine for use in susceptible persons following exposure to varicella. If exposure to varicella does not cause infection, postexposure vaccination should induce protection against subsequent exposure. If the exposure results in infection, no evidence indicates that administration of varicella vaccine during the presymptomatic or prodromal stage of illness increases the risk for vaccine-associated adverse events. Although postexposure use of varicella vaccine has potential applications in hospital settings, vaccination is routinely recommended for all susceptible health-care workers and is the preferred method for preventing varicella in health-care settings.

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Table 1 Recommended Postexposure Prophylaxis for Percutaneous or Permucosal Exposure to Hepatitis B Virus, United States

Immunization and Antibody Response Status of Exposed Person	Treatment When Source is: HBsAg* Positive	HBsAg* Negative	Source Not Tested or Status Unknown
Unvaccinated	HBIG† x1; initiate HB vaccine series§	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated			
Known responder¶	No treatment	No treatment	No treatment
Non-responder, no revaccination	HBIG x 1 and initiate revaccination	No treatment, consider revaccination	if known high-risk source, treat as if source were HbsAg positive
Non-responder after revaccination	HBIG x2 –2nd dose one month after the first	No treatment	If known high-risk source, treat as if source were HBsAg positive.
Antibody response unknown	Test exposed for anti-HBS**: 1. If adequate¶, no treatment. 2. If inadequate¶, HBIG x 1 and vaccine booster, evaluate antibody response at 6 months.‡	No treatment	Test exposed for anti-HBS 1. If adequate¶, no treatment 2. If inadequate¶, give booster and evaluate antibody response after 1-2 months, or revaccinate and evaluate antibody 1-2 months after last dose.

* HBSAG = Hepatitis B surface antigen.

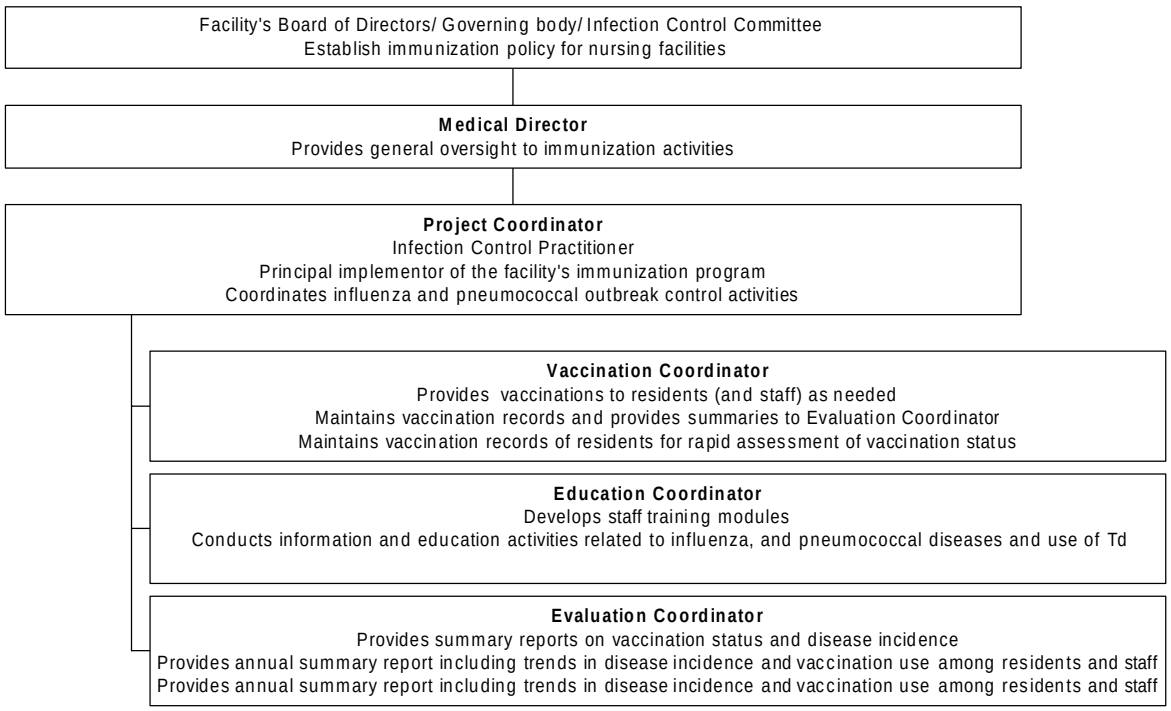
† HBIG = Hepatitis B immune globulin.; 0.06 mL/kg intramuscularly

§ HB = Hepatitis B vaccine.

¶ Responder is a person with levels of antibody to HbsAg (anti-HBs) $\geq$ 10 mIU/mL); antibody response less than 10 mlU/mL is considered an .inadequate response to immunization

‡ test at 5-6 months, rather than 1-2 months after booster dose to minimize detection of anti-HBs from HBIG.

Appendix 1. Sample Organization Chart with Roles and Responsibilities in a Long-term Care Facility's Immunization Program.



Appendix 2. Sample Standing Orders for Immunizations in a Long-term Care Facility

IMMUNIZATION POLICY: All residents will be immunized against vaccine-preventable diseases that may be encountered in this facility and as recommended by the Advisory Committee for Immunization Practices. These vaccines will be provided to all persons at admission, unless over-ridden by the patient's physician, medically contraindicated, or if refused by the patient or their legal guardian.

Indications for vaccines

All new residents will be assessed by the Long-term care staff, upon admission, for the following immunizations/ vaccination status: influenza and pneumococcal vaccines, and Td (tetanus and diphtheria toxoids).

- Patients will be counseled on the benefits and adverse events of each vaccine prior to administration of the vaccines.
- This rule will apply to new admissions at the time of registration, during the annual influenza vaccination campaign, and at any time that the facility conducts a vaccination campaign throughout the facility.
- Administer immunizing agents per manufacturer guidelines;
    - document the date, time, and injection site in resident's Immunization Record;
    - monitor for any adverse reactions for 72 hours after giving the vaccine.
    - document any adverse reactions in the resident's Immunization Record and notify attending physician.
    - include the Immunization Record with notes on adverse reactions in the resident's medical file.
- If patient or legal guardian refuses an immunizing agent included in these orders:
    - resident and/or guarantor should sign and date the appropriate refusal slip;
    - document the reason(s) the immunizing agent was refused, such as history and nature of adverse reaction, allergy, etc. on the permission slip.
    - for patients refusing influenza and/ or pneumococcal vaccine indicate the non-vaccination status in a clearly visible area to monitor for respiratory illness.
- When there is a physician's over-ride of vaccination orders or if patient/ legal guardian refuses any one of the three immunizing agents indicated in this order, complete the refusal check-list at the end of this order.

Appendix 3. Sample Resident Immunization Record

Keep this in the permanent section of the resident's medical chart

Part 1. Admission Check List

Assume that all persons being admitted to the facility need to receive the pneumococcal vaccine, Td, and influenza vaccine if admission is between October and January. If the patient being admitted to the facility has a vaccination record or verification from their personal physician that they have received the following immunizations, enter the information here.

If there is no vaccination record and/or admitting physician is uncertain, consider the patient as unvaccinated.

1. Pneumococcal Vaccine Year_____

   Does the person have a personal physician who can confirm? Yes ☐ No☐

   Where there is no documentation or if evidence of immunization is uncertain, offer the immunization with appropriate counseling. Document refusal at admission and offer again at a later time.

2. Tetanus-diphtheria (Td) toxoid during the past 10 years? Yes ☐ No☐

   Approximate date of Td:_____

   Td provider (hospital, doctor's office, etc): _____

3. During the months of October through March :

   Does the new arrival have evidence of an influenza vaccination for the current season?

   Yes ☐ No ☐

   If yes,

   Approximate date of influenza vaccination:_____

   Who provided the influenza vaccination? (doctor's office, hospital, community flu clinic, etc)

Reasons why Vaccinations were NOT administered at admission

Pneumococcal Vaccine	Influenza Vaccine	Td
☐ Previously vaccinated	☐ Previously vaccinated	☐ Booster within 10 years
☐ Not indicated for vaccination per algorithm in ACIP recommendations	☐ Physician Over-ride: __Medically contraindicated __Condition Terminal __Other	☐ Physician Over-ride: __Medically contraindicated __Condition Terminal __Other
☐ Physician Over-ride: __Medically contraindicated __Condition Terminal __Other	☐ Patient Refused	☐ Patient Refused
☐ Patient Refused		

Note: Immunosuppressive therapy is not a contraindication for the immunizing agents listed here.

Part II and Part III follow

Appendix 3. Sample Resident Immunization Record

Part II. Immunizations administered upon admission

NAME_____ Date of birth (mm/dd/yy)_____ SEX: F M (Circle one)

Room Number: _____ Resident's Identification Number _____

Immunizing agent	**Trade Name or Manufacturer**	**Date Received**	**Injection Site**	**Vaccine Lot Number**	**Adverse reactions (0-72 hrs.)**	**Administered by (Initial)**
Influenza vaccine						
Pneumococcal Vaccine						
Td						
Other (Specify)						

Part III. Immunizations administered while residing in the facility.

Immunizing agent	Trade Name or Manufacturer	Date Received	Injection Site	Vaccine Lot Number	Adverse reactions (0-72 hrs.)*	Administered by (Initial)
Td						
Pneumococcal						
Pneumococcal						
Influenza						
Influenza						
Influenza						
Other (Specify)						

* Codes to identify adverse reactions: s=swelling, e=erythema, m=myalgia, f=fever temp in F if greater than normal, a=anaphylaxis, 0=other (write out reaction)

Appendix 4. Instructions for Billing Medicare for Influenza Vaccine and its Administration Coverage

Medicare Part B began paying for influenza virus vaccines on May 1, 1993. Coverage of the vaccine and its administration is available only under Medicare Part B regardless of the setting in which it is furnished. Medicare beneficiaries who get the vaccine do not pay the usual coinsurance or deductible amounts. Medicare pays those amounts, along with an amount for the vaccine and the person who administers the shot. Typically, these vaccines are administered once a year in the fall or winter.

Medicare does not require, for coverage purposes, that the vaccine be ordered by a doctor of medicine or osteopathy. Therefore, the beneficiary may receive the vaccine upon request without a physician's order or supervision.

Diagnosis Coding

Influenza virus vaccine is billed using diagnosis code V04.8

HCPCS Coding

- Influenza virus vaccine is billed using HCPCS codes 90657, 90658 or 90659. This code is for the vaccine only and does not include administration.
- Administration of influenza virus vaccine is billed using HCPCS code G0008.

Intermediary Billing

- Providers other than independent rural health clinics (RHCs) and freestanding federally qualified health centers (FQHCs) bill for the influenza virus vaccine and its administration on Form HCFA-1450 using revenue code 636 for the vaccine and 771 for the administration of the vaccine in conjunction with the diagnosis and HCPCS codes.

Billing by Providers and Suppliers

- For the purpose of the influenza immunization benefit, any individual or entity meeting State licensure requirements may qualify to bill Medicare for furnishing and administering the influenza vaccine to Medicare beneficiaries enrolled under Part B.
- Provider facilities not participating in Medicare (e.g., Long-term care homes) are considered suppliers and bill their local carrier.

  The Part B carrier will provide the HCFA-855, the Provider/Supplier Enrollment application, to these facilities upon request.

Simplified Billing (Roster)

- To alleviate concerns expressed by some Public Health Clinics (PHCs) and other properly-licensed individuals and entities which bill Medicare sporadically, the Health Care Financing Administration (HCFA) initiated a simplified billing process in 1993 for these entities that bill the carrier.
- Effective for services furnished on or after October 1, 1994, the simplified billing process was expanded to other providers that bill carriers and intermediaries with the exception of independent RHCs and free-standing FQHCs.
- In response to our provider's request to simplify and quicken the provider enrollment process, Medicare has developed simplified instruction for our HCFA-855, Provider/Supplier Enrollment application. This enrollment process currently applies only to entities that will (1) bill the carrier; (2) use roster bills; and (3) bill only for flu and PPV shots. The Part B carrier will provide the HCFA-855.
- To qualify for roster billing, PHCs and other properly-licensed individuals and entities may use the simplified process if they: (1) conduct mass immunization programs; and (2) agree to accept assignment for influenza immunization claims when billing carriers.

  NOTE: The 5 immunizations per day requirement is waived for hospitals providing PPV shots to their inpatients.

  Effective July 1, 1998, FOR PART B CLAIMS ONLY, immunization of at least five beneficiaries on the same date is no longer required for any individual or entity to qualify for roster billing. However, the rosters should not be used for single patient bills and the date of service for each vaccination administered must be entered.
- Entities which submit claims on roster bills (and therefore must accept assignment) may not collect any "donation" or other cost-sharing of any kind from Medicare beneficiaries for PPV or influenza immunizations. However, the entity may bill Medicare for the amount which is not subsidized from its own budget. For example, an entity that incurs a cost of $7.50 per immunization and pays $2.50 of the cost from its budget may bill Medicare the $5.00 cost which is not paid out of its budget.
- For simplified billing carriers use Form HCFA-1500 and intermediaries use Form HCFA-1450 with preprinted standardized information relative to the provider/supplier.
- Mass immunizers attach a standard roster to a single pre-printed HCFA-1500 or HCFA-1450 which contains variable claims information necessary for processing each claim.
- A stamped "signature on file" is acceptable on a roster claim to qualify as an actual signature providing that the provider has a signed authorization on file to bill Medicare for services rendered.
- For more information mass immunizers can contact their local carrier or intermediary.

- Providers/suppliers that do not mass immunize should continue to bill for the influenza vaccine using the normal billing method, i.e., submission of a HCFA-1450, HCFA-1500 or electronic billing for each beneficiary.

Appendix 5. Instructions for Billing Medicare for Pneumococcal Vaccine (PPV) and its administration

Medicare Part B began paying for pneumococcal vaccines on July 1, 1981. Coverage of the vaccine and its administration is available only under Medicare Part B regardless of the setting in which it is furnished. Medicare beneficiaries who get the vaccine do not pay the usual coinsurance or deductible amounts. Medicare pays those amounts, along with an amount for the vaccine and the person who administers the shot. Typically, these vaccines are administered once in a lifetime to persons at high risk of pneumonia infection.

Persons who are considered at risk are: persons 65 years of age and older; immunocompetent adults who are at increased risk of pneumonia infection or its complications because of chronic illness (e.g., cardiovascular disease, pulmonary disease, diabetes mellitus, alcoholism, cirrhosis, or cerebrospinal fluid leaks),and individuals with compromised immune systems (e.g., splenic dysfunction or anatomic asplenia, Hodgkin's disease, lymphoma, multiple myeloma, chronic renal failure, HIV infection, nephrotic syndrome, sickle cell disease, or organ transplantation).

Typically, PPV is administered once in a lifetime. Claims are paid for beneficiaries who are at high risk of pneumonia infection and have not received PPV within the last five years or are revaccinated because they are unsure of their immunization status.

Diagnosis Coding

Pneumococcal vaccine is billed using diagnosis code V03.82.

HCPCS Coding

- Pneumococcal vaccine is billed using HCPCS code 90732. This code is for the vaccine only and does not include administration.
- Administration of pneumococcal vaccine is billed using HCPCS code G0009.

Intermediary Billing

- Providers other than independent rural health clinics (RHCs) and freestanding federally qualified health centers (FQHCs) bill for the pneumococcal vaccine and its administration on Form HCFA-1450 using revenue code 636 for the vaccine and 771 for the administration of the vaccine in conjunction with the diagnosis and HCPCS codes.

Billing by Providers and Suppliers

- For the purpose of the pneumococcal immunization benefit, any individual or entity meeting State licensure requirements may qualify to bill Medicare for furnishing and administering the pneumococcal vaccine to Medicare beneficiaries enrolled under Part B.
- Provider facilities not participating in Medicare (e.g., long-term care homes) are considered suppliers and bill their local carrier.

  The Part B carrier will provide the HCFA-855, the Provider/Supplier Enrollment application, to these facilities upon request.

- Providers, such as public health clinics, that have never submitted Medicare claims must obtain a provider number for Part B billing purposes by contacting their Part B carrier for a Provider/Supplier Enrollment application.

Simplified Billing (Roster)

- To alleviate concerns expressed by some Public Health Clinics (PHCs) and other properly-licensed individuals and entities which bill Medicare sporadically, the Health Care Financing Administration (HCFA) initiated a simplified billing process in 1993 for these entities that bill the carrier.
- Effective for services furnished on or after November 1, 1996 the simplified billing process was expanded to include the pneumococcal immunization. Providers that bill carriers and intermediaries with the exception of independent RHCs and free-standing FQHCs may roster bill for the pneumococcal immunization.
- In response to our provider's request to simplify and quicken the provider enrollment process, Medicare has developed simplified instruction for the HCFA-855, Provider/Supplier Enrollment application. This enrollment process currently applies only to entities that will (1) bill the carrier; (2) use roster bills; and (3) bill only for pneumococcal immunizations. The Part B carrier will provide the HCFA-855.
- To qualify for roster billing, PHCs and other properly-licensed individuals and entities may use the simplified process if they: (1) conduct mass immunization programs (at least 5 beneficiaries on the same day is required except as noted below); and (2) agree to accept assignment for pneumococcal immunization claims when billing carriers.

  NOTE: The 5 immunizations per day requirement is waived for hospitals providing PPV shots to their inpatients.

  Effective July 1, 1998, FOR PART B CLAIMS ONLY, immunization of at least five beneficiaries on the same date is no longer required for any individual or entity to qualify for roster billing. However, the rosters should not be used for single patient bills and the date of service for each vaccination administered must be entered.
- Entities which submit claims on roster bills (and therefore must accept assignment) may not collect any "donation" or other cost-sharing of any kind from Medicare beneficiaries for PPV or influenza immunizations. However, the entity may bill Medicare for the amount which is not subsidized from its own budget. For example, an entity that incurs a cost of $7.50 per immunization and pays $2.50 of the cost from its budget may bill Medicare the $5.00 cost which is not paid out of its budget.
- For simplified billing carriers use Form HCFA-1500 and intermediaries use Form HCFA-1450 with preprinted standardized information relative to the provider/supplier.
- Mass immunizers attach a standard roster to a single pre-printed HCFA-1500 or HCFA-1450 which contains variable claims information necessary for processing each claim.

- A stamped “signature on file” is acceptable on a roster claim to qualify as an actual signature providing that the provider has a signed authorization on file to bill Medicare for services rendered.
- For more information mass immunizers can contact their local carrier or intermediary.
- Providers/suppliers that do not mass immunize should continue to bill for PPV using the normal billing method, i.e., submission of a HCFA-1450, HCFA-1500 or electronic billing for each beneficiary.

Appendix 6. Medicare Roster Billing Form: Influenza Vaccine

Provider Payee Name: _____

Provider Number: _____ **Date of Service:** _____

	Insured's I.D. Number	Patient's Name (Last Name, First Name, Middle Initial)	Patient's Address (No., Street, City, State, Zip Code)	Patient's Signature	Amount Paid
EX	**123456789A**	**Doe, John L.**	**123 Main St Miami FL 33127**	**John L. Doe**	**0**
01					
02					
03					
04					
05					
06					
07					

Appendix 7. Medicare Roster Billing Form: Pneumococcal Vaccine

Provider Payee Name: _____

Provider Number: _____ **Date of Service:** _____

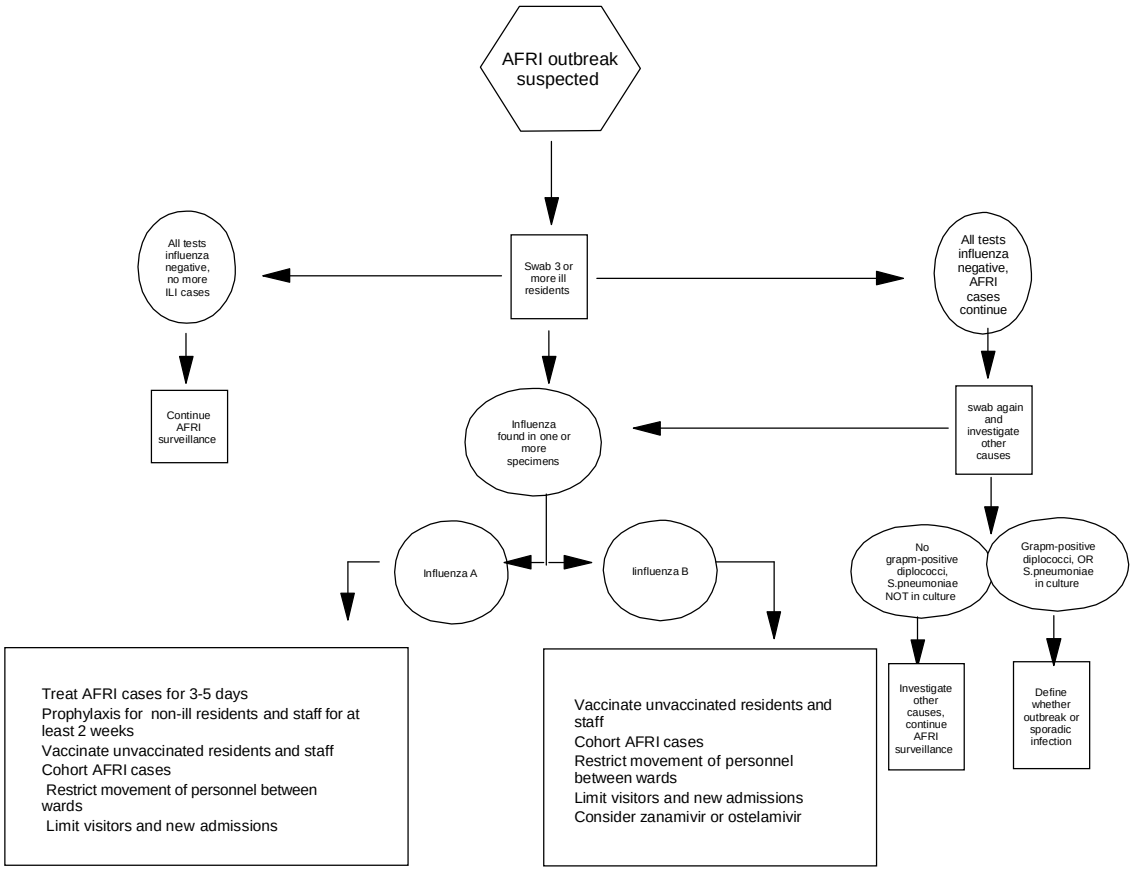
	Insured's I.D. Number	Patient's Name (Last Name, First Name, Middle Initial)	Patient's Address (No., Street, City, State, Zip Code)	Patient's Signature	Amount Paid
EX	**123456789A**	**Doe, John L.**	**123 Main St Miami FL 33127**	**John L. Doe**	**0**
01					
02					
03					
04					
05					
06					
07					

Appendix 8. Sample List of Residents Vaccinated during the Annual Influenza Immunization Campaign

From: _____ To: _____ **Page __ of __**

Unit No.	Room No.	Bed No.	Last Name, First Name	Date administered	Lot No.	Manu-facturer	Vaccinated by:

Appendix 9. Sample Flowchart for Surveillance of Acute, Febrile, Respiratory, Illness Outbreaks.



Appendix 10. Sample (Individual) Case Log of Residents with Acute Respiratory Illness and/or Pneumonia

From: Month, day, year **To: Month, day, year**

patient identification			patient location			vaccination status		illness description										influenza test results		Pneumococcal test results		anti-virals	antibiotic*	illness outcomes				
Name	age	sex (M/F)	building	unit	room#	Influenza	Pneumococcal vaccine (Y/N)	illness onset	highest temperature	cough	malaise	chest congestion	purulent sputum	rhinitis	sore throat	pneumonia (Y/N)	CXR confirmed (Y/N)	rapid antigen test (pos/neg/not done)	viral culture	Gram Stain	Sputum culture	date started/ date ended	date started/ date ended	influenza (Y/N)	Pneumonia. Sp (Y/N)	hospitalized (Y/N)	days hospitalized	died (Y/N)

Special instructions:

1. **For antibiotic use write the name of the antibiotic(s) administered with start and end dates and dosage in this space.**
2. **For Pneumonia S.p (Pneumonia with S. pneumoniae): Bacteremic pneumonia as BPSp**

Figure 6. Sample (Daily or Weekly)Summary Log of Acute Respiratory Illness and Pneumonia.

From: Month, day, year **To: Month, day, year**

Enter the number of persons with the indicated symptoms, test results, and illness outcomes, as indicated.

Location	*Vaccination status of ill persons*		*Summary of symptoms*									*Influenza Test Results*		*Pneumococcal Test results*		Anti-biotics	Anti-virals	*Illness Outcomes*				
Area within the facility (Building, wing, unit, etc)	No. vaccinated: influenza	No. vaccinated: PPV	temp > 99°F	Cough	malaise	chest congestion	purulent sputum*	rhinitis	sore throat	pneumonia	confirmed CXR	rapid antigen test results (pos/n/ pend/ not done)	viral culture results (Pos/N/ pend/ not done)	gram stain results (pos/N/ pend/not done)	sputum culture results (Pos/N/ pend/not done)	on antibiotics	on anti-virals	influenza positive	S. pneu positive	hospitalized	died in hospital	died in facility

Appendix 12. Sample Line list of Residents with Adverse Reactions to Anti-Influenza Medication.

Antiviral medication

adverse events line list

Facility name:_____

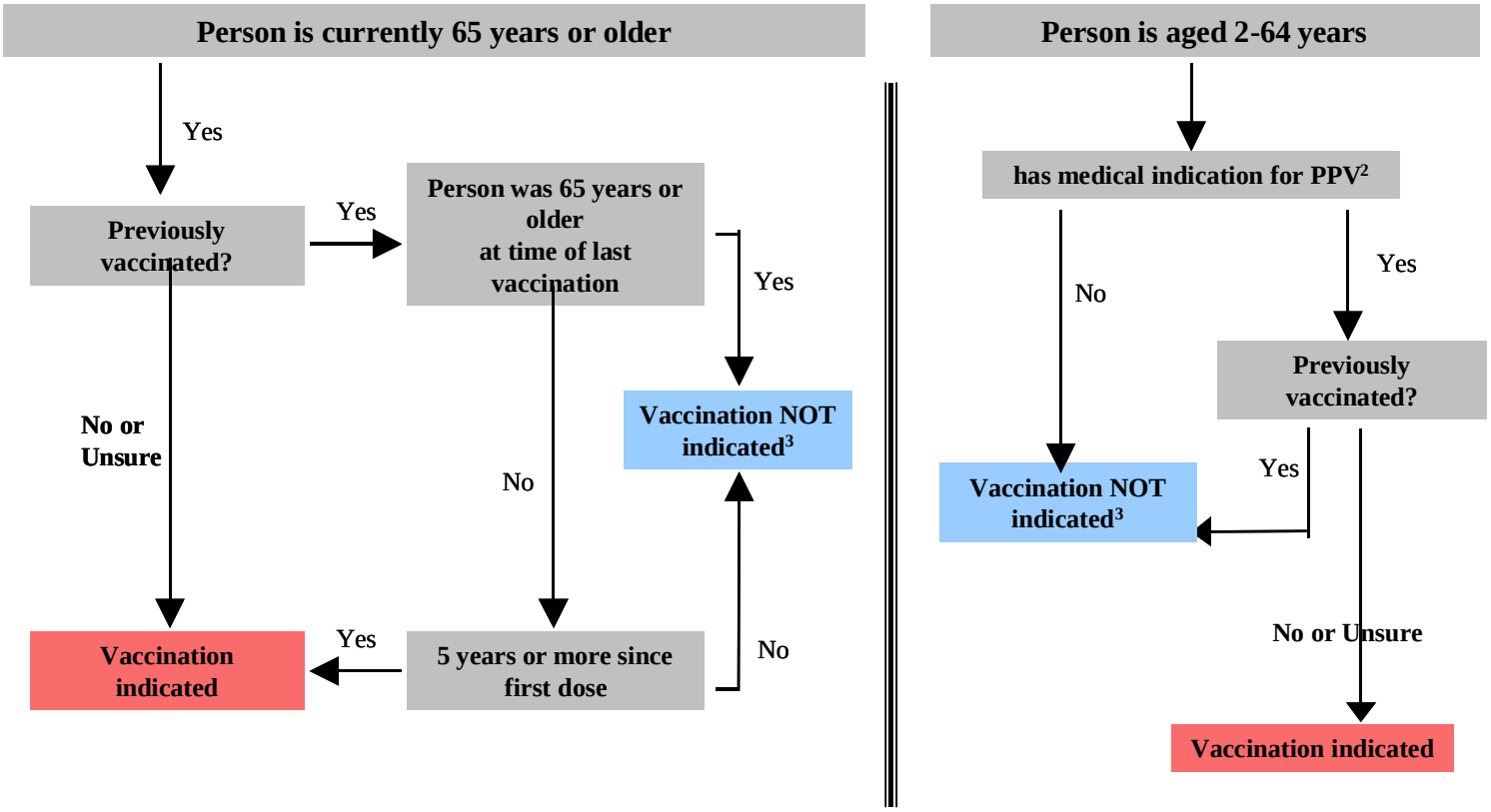
Infection Control Coordinator:_____

Phone Number:_____

Dates:_____

patient identification			patient location			respiratory illness		antiviral use/dosing					adverse reactions							actions taken		
Name	age	sex (M/F)	building	unit	room#	AFRI (Y/N)	date of illness onset	amantadine (A) or rimantadine (R)	date antiviral started	dose (mg)	frequency	creatinine level	nervous/anxious	confusion	nausea	anorexia	agitation	seizure	other symptom	antiviral discontinued (Y/N)	date antiviral discontinued	dose reduced (Y/N)

Appendix 13. Algorithm for Vaccinating Nursing Home Residents with Pneumococcal Polysaccharide Vaccine (PPV)[1]



[1] Adapted from CDC recommendations of the Advisory Committee on Immunization Practices. Prevention of Pneumococcal Disease. MMWR 1997; 46(RR-8). Pg.13

[2] Including those with chronic cardiovascular disease, chronic pu lmonary disease (excluding asthma), diabetes mellitis, alcoholism, chronic liver disease, CSF leaks, functional or anatomic asplenia, immunocompromised persons, and those living in special environments or social settings (e.g. Alaskan Natives and certain American Indian populations).

[3] In the case of immunocompromised individuals 10 years or older, consider *a single* revaccination if 5 years or more have elapsed since the *first* dose; aged 2-9, consider revaccination if 3 years or more have elapsed since *last* dose

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