

Slide 1

§483.65 Infection Control (F441)

Surveyor Training of Trainers:

Interpretive Guidance

Investigative Protocol

Instructor Notes:

Objectives:

Identify compliance with the regulation as it relates to infection prevention

Appropriately identify the severity of noncompliance

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Tags Collapsed

- **With regard to the revised guidance F441 Infection Control, there have been significant changes. Namely, F Tags 441, 442, 443, 444, and 445 have been collapsed into this single guidance at F441. However, the regulatory language has remained the same.**

Instructor Note:

The revisions to F441 were made to provide definition, education, explanation, and examples for the surveyors to reference

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Federal Regulatory Language

§483.65 Infection Control

The facility must establish and maintain an Infection Control Program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection.

Instructor Notes:

This is the regulatory language for Infection Control at F441. Please note that this regulatory language has not changed.

Understanding the regulation is key to facilitating the accurate documentation of the findings.

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§483.65(a) Infection Control Program

The facility must establish an Infection Control Program under which it –

- 1) Investigates, controls, and prevents infections in the facility;

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§483.65(a) Infection Control Program

- 2) Decides what procedures, such as isolation, should be applied to an individual resident; and

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§483.65(a) Infection Control Program

- 3) Maintains a record of incidents and corrective actions related to infections.

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§483.65(b) Preventing Spread of Infection

- 1) **When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.**

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§483.65(b) Preventing Spread of Infection

- 2) **The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.**

Instructor Notes:

Stress the importance of the second part of this statement, that the direct contact must be a means by which the disease will be transmitted. Ask surveyors for examples of diseases that are and are not transmitted in this manner.

Slide 9**§483.65(b) Preventing Spread of Infection**

3) The facility must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice.

Slide 10**§483.65(c) Linens**

Personnel must handle, store, process and transport linens so as to prevent the spread of infection.

Slide 11**Intent**

The intent of this regulation is to assure that the facility, develops, implements and maintains an Infection Prevention and Control Program in order to prevent, recognize, and control, to the extent possible, the onset and spread of infection within the facility.

Instructor Notes:

The facility is expected to take action to help the resident attain or maintain his or her highest practicable level of physical, mental, and psycho-social well-being, including managing the resident's infection status.

Slide 12**§483.65 Infection Control****Interpretive Guidelines Background**

Infections are a significant source of morbidity and mortality for nursing home residents and account for up to half of all nursing home resident transfers to hospitals.

Infections occur an average of 2 to 4 times per year for each nursing home resident.

Instructor Notes:

Infections result in an estimated 150,000 to 200,000 hospital admissions per year at an estimated cost of \$673 million to \$2 billion annually. When a nursing home resident is hospitalized with a primary diagnosis of infection, the death rate can reach as high as 40 percent.

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Endemic Infections in Nursing Home Residents

Most Frequently Occurring:

- Urinary tract
- Respiratory
- Skin and Soft Tissue

Other Commonly Occurring:

- Conjunctivitis
- Gastroenteritis
- Influenza

Instructor Notes:

There are many examples of respiratory infections, such as pneumonia and bronchitis. Ask surveyors for other examples.

Skin and soft tissue infections include pressure ulcers, a frequent type of infection in nursing home residents. There is a separate Tag that specifically addresses these infections. Discuss this issue.

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Critical Aspects of Infection Prevention and Control Programs

- Recognizing and managing infections at the time of a resident's admission to the facility and throughout their stay

- **Following recognized infection control practices while providing care**

Instructor Notes:

Bullet 1: Note that infection prevention and control is a continual process that must continue through the duration of a resident's stay at a nursing home. Older adults often have coexisting diseases (e.g. COPD, arthritis) and/or atypical or non-specific signs of infection (e.g. altered mental status, impaired fever response).

Bullet 2: Examples of recognized infection control practices include hand hygiene, handling and processing of linens, use of standard precautions, and appropriate use of transmission-based precautions and cohorting or separating residents.

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Considerations

It can be difficult to promote the individual resident's rights and well-being while trying to prevent and control the spread of infections.

Instructor Notes:

It is important to recognize the potential negative impact that a resident may experience as a result of the implementation of special precautions.

While this Interpretive Guidance will offer some general and specific information related to infection prevention and control, actual practices should reflect current CDC guidelines and must be updated as those guidelines are revised.

It is important that all infection prevention and control practices reflect current CDC guidelines.

Following current CDC guidelines will help ensure that infection control practices are implemented in a manner that is consistent and based upon the latest scientific evidence, therefore standardizing the care and treatment of the residents.

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Components of an Infection Prevention and Control Program

- **Program Development and Oversight**
- **Policies and Procedures**

- **Infection Preventionist**

Surveillance

- **Documentation**
- **Monitoring**
- **Data Analysis**
- **Communicable Disease Reporting**
- **Education**
- **Antibiotic Review**

Instructor Notes:

These are the components of an effective infection prevention and control program. We will discuss each of these aspects in more detail in the slides that follow.

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Program Development & Oversight: Core Focus

- **Establishing goals and priorities**
- **Monitoring implementation of the program**
- **Responding to errors, problems, or other identified issues**

Instructor Notes:

Program development and oversight emphasize the prevention and management of infections. Goals and priorities must be established in order for the program to be assessed in terms of effectiveness and utility.

The infection control and prevention program provides the foundation for clinicians and staff to help each resident attain and/or maintain his or her highest practicable level of well-being, including preventing or managing infections, to the extent possible.

Throughout this guidance, the infection prevention and control program has been based upon an interdisciplinary approach. This interdisciplinary team's infection control practices are monitored as part of the program oversight.

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Program Development and Oversight: Additional Activities

- **Identifying roles and responsibilities during routine implementation as well as unusual occurrences or threats of infection**
- **Defining and managing resident health initiatives**
- **Managing food safety**
- **Providing a nursing home liaison to work with local and state health agencies**

Instructor Notes:

These are just some examples of the many different activities that may be conducted as part of the infection prevention and control program development and oversight.

Bullet 1: Unusual occurrences may include an outbreak of a communicable disease, an episode of infection, or the threat of a bio-hazard attack.

Bullet 2: Resident health initiatives might include immunization programs or health screenings. F334 focuses on influenza and pneumococcal vaccination. Encourage surveyor discussion of various types of resident health initiatives and how they might relate to the infection prevention and control program.

Bullet 3: Food safety is addressed specifically in a separate Tag. However, it is mentioned here as it can be a source of infection (e.g. salmonella). Items to consider with regard to food safety include employee health and hygiene, pest control, investigating potential food-borne illnesses, and waste disposal.

Bullet 4: The nursing home liaison may work with the health agencies on a routine basis as well as during times of outbreaks, epidemics, natural emergencies, or other emergencies.

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Program Development and Oversight: Personnel

Personnel are identified as being responsible for overall program oversight.

May include the collaboration of the:

- **Administrator**
- **Medical Director (or a designee)**
- **Director of Nursing**
- **Other staff as appropriate**

Instructor Notes:

This team will:

- Define how and when the program is to be routinely monitored and situations that may trigger a focused review of the program
- Communicate the findings from collecting and analyzing data to the facility's staff and management
- Direct changes in practice based on identified trends, government infection control advisories, and other factors.

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Policies and Procedures

- **Written policies establish the program's expectations and parameters**
- **Procedures guide the implementation of the policies and performance of specific tasks**

These serve as the foundation to the program and should undergo periodic review and revision to conform to current standards of practice or to address specific facility concerns

Instructor Notes:

- Policies may: specify the use of standard precautions facility-wide and use of transmission-based precautions when indicated, define the frequency and nature of surveillance activities, require that staff use accepted hand hygiene after each direct resident contact for which hand hygiene is indicated, or prohibit direct resident contact by an employee who has an infected skin lesion or communicable disease

- Procedures may include, for example, how to identify and communicate information about residents with potentially transmissible infectious agents, how to obtain vital signs for a resident on contact precautions and what to do with the equipment after its use, and essential steps and considerations (including choosing agents) for performing hand hygiene.

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Infection Preventionist (IP)

Serves as the coordinator of the program and responsibilities may include:

- **Education and training;**
- **Collecting, analyzing, and providing infection data and trends to nursing staff and healthcare practitioners; and**
- **Consulting on infection risk assessment, prevention, and control strategies.**

Instructor Notes:

Infection Preventionist or the designee will most often have primary training in either nursing, medical technology, microbiology, or epidemiology and may possess additional training in infection control. However, there are no regulatory requirements regarding this position and therefore a facility may choose not designate a specific IP or may designate an individual with a background not mentioned here.

Responsibilities may also include: implementing evidence-based infection control practices, including those mandated by regulatory and licensing agencies, and guidelines from the Centers for Disease Control.

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Surveillance

- **Essential Elements**
- **Two Types**
 - **Process**
 - **Outcome**

Instructor Notes:

As a reminder, surveillance has been defined previously as the ongoing, systematic collection, analysis, interpretation, and dissemination of data to identify infections and infection risks, to try to reduce morbidity and mortality and to improve resident health status.

Essential elements of surveillance include:

- The use of standardized definitions and listings of the symptoms of infections;
- The use of surveillance tools such as infection surveys and data collection templates;
- Conducting walking rounds throughout the facility;
- The identification of segments of the resident populations at risk for infection;
- The identification of the processes or outcomes selected for surveillance;
- The statistical analysis of data that can uncover an outbreak; and
- The feedback of results to the primary caregivers so that they can assess the residents for signs of infection.

Slide 23**Process Surveillance**

Process surveillance reviews practices directly related to resident care in order to identify whether the practices are compliant with established prevention, control and policies based on recognized guidelines.

Instructor Notes:

Examples of this type of surveillance include monitoring of compliance with transmission based precautions, proper hand hygiene, and the use and disposal of gloves.

Process surveillance determines, for example, whether the facility:

- Minimizes exposure to a potential source of infection;
- Uses appropriate hand hygiene prior to, and after, all procedures;
- Ensures that appropriate sterile techniques are followed.; for example, that staff:

- Use sterile gloves, fluids and materials, when indicated; depending on the site and the procedure;
- Avoid contaminating sterile procedures; and
- Ensure that contaminated/non-sterile items are not placed in a sterile field.
- Uses Personal Protective Equipment (PPE) when indicated;
- Ensures that reusable equipment is appropriately cleaned, disinfected, or reprocessed; and
- Uses single-use medication vials and other single use items appropriately (proper disposal of after every single use)

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Outcome Surveillance

Outcome surveillance is designed to identifies and reports evidence of an infectious disease. The outcome surveillance process consists of collecting/documenting data on individual cases and comparing the collected data to standard written definitions (criteria) of infections.

Instructor Notes:

The IP or other designated staff reviews data (including residents with fever or purulent drainage, and cultures or other diagnostic test results consistent with potential infections) to detect clusters and trends.

Other sources of relevant data may include:

- antibiotic orders
- laboratory antibiograms (antibiotic susceptibility profiles)
- medication regimen review report and
- medical record documentation such as physician progress notes and transfer summaries accompanying newly admitted residents.

Regulatory language mandates that the facility must “maintain records of incidents and corrective actions related to infections.” Therefore, the facility’s program must choose to either track the prevalence of infections (existing/current cases both old and new) at a specific point, or focus on regularly identifying new cases during defined time periods. When conducting outcome surveillance, the

facility may choose to use one or more of the automated systems and authoritative resources that are available, and include definitions.

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Documentation

- **Various approaches to gathering, documenting and listing surveillance data**
 - **Infection control reports describe the types of infections and are used to identify trends and patterns**

It is up to the program to define how often and by what means surveillance data will be collected.

Instructor Notes:

Descriptive documentation provides the facility with summaries of the observations of staff practices and/or the investigation of the causes of an infection and/or identification of underlying cause(s) of infection trends.

The facility might create its own forms, purchases preprinted forms, or use automated systems.

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Monitoring

Monitoring of the implementation of the program, its effectiveness, the condition of any resident with an infection, and the resolution of the infection and/or an outbreak is considered an integral part of nursing home infection surveillance.

Instructor Notes:

The facility monitors practices (e.g., dressing changes and transmission-based precaution procedures) to ensure consistent implementation of established infection prevention and control policies and procedures based on current standards of practice. All residents shall be monitored for current infections and infection risks.

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Data Analysis

- **Comparing past and present surveillance data enables detection of unusual or unexpected outcomes, trends, effective practices, and performance issues.**
 - **Processes and/or practices can be changed to enhance infection prevention and minimize the potential for transmission of infections.**

Instructor Notes:

Determining the origin of infections helps the facility identify the number of residents who developed infections within the nursing home.

In order for data analysis to be useful, it is important that surveillance reports be shared with appropriate individuals including, but not limited to, the clinical professional staff.

In addition, it is important that the staff and practitioners receive reports that are relevant to their practices to help them recognize the impact of their care on infection rates and outcome.

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Communicable Disease Reporting

It is important for each facility to have processes that enable them to consistently comply with state and local health department requirements for reporting communicable diseases.

Instructor Notes:

State and local health departments have varying requirements for reporting communicable diseases. Engage the surveyors in a brief discussion of some examples of diseases that might require reporting.

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Education

- **Both initial and ongoing infection control education help staff understand and comply with infection control practices.**

- **In addition to general infection control principles, some infection control training is discipline and task-specific.**

Instructor Notes:

Updated education and training are appropriate when policies and procedures are revised or when there is a special circumstance, such as an outbreak, that requires modification or replacement of current practices.

Essential topics of an infection control training include, but are not limited to:

- routes of disease transmission
- hand hygiene
- sanitation procedures
- MDROs
- transmission-based precaution techniques and
- federally required OSHA education.

Examples of discipline and task specific training include:

- urinary catheter insertion
- Suctioning
- IV Care and
- blood glucose monitoring.

The facility should utilize follow-up competency evaluations to identify staff compliance.

Encourage the surveyors to provide additional examples of general and task/discipline specific training topics. Emphasize that this training may be conducted facility-wide, by department, or on an individualized basis. It may also include training that occurs off-site.

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Antibiotic Review

Because of increases in MDROs, review of the use of antibiotics (including comparing prescribed antibiotics with available susceptibility reports) is a vital aspect of the infection prevention and control program.

Instructor Notes:

It is the physician's (or other appropriate authorized practitioner's) responsibility to prescribe appropriate antibiotics and to establish the indication for use of specific medications.

The consultant pharmacist can assist with the oversight by identifying antibiotics prescribed for resistant organisms or for situations with questionable indications, and reporting such findings to the Director of Nursing and the attending physician.

See F329 regarding use of a medication without adequate indication for use and F428 regarding medication regimen review.

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Preventing the Spread of Infection

- **Individual and institutional factors contribute to the increased frequency and severity of infections in nursing homes**
- **Modes of transmission include:**
 - **Contact**
 - **Droplet**
 - **Airborne**

Instructor Notes:

In order to prevent the spread of infection, it is necessary to understand the factors and modes of transmissions.

While there are other modes of transmission, the three listed here (contact, droplet, and airborne) are further examined in this Guidance for their applicability to nursing homes.

Solicit examples of each mode of transmission from the surveyors.

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Individual Factors:

- **Medications**
- **Limited physiologic reserve**
- **Compromised host defenses**
- **Impaired responses**
- **Coexisting chronic diseases**
- **Complications from invasive procedures**
- **Increased frequency of therapeutic toxicity**

Instructor Notes:

These are examples of individual factors contributing to infections and the severity of the infection outcomes in facility residents. Many of these factors affect older adults in general.

- Medications affecting resistance to infection; e.g., corticosteroids and chemotherapy;
- Limited physiologic reserve (e.g., decreased function of the heart, lungs, and kidneys);
- Compromised host defenses (e.g., decreased or absent cough reflex predisposing to aspiration pneumonia, thinning skin associated with pressure ulcers, decreased tear production predisposing to conjunctivitis, vascular insufficiency, and impaired immune function);
- Coexisting chronic diseases (e.g., diabetes, arthritis, cancer, COPD, anemia);
- Complications from invasive diagnostic procedures such as skin or bloodstream infections;
- Impaired responses to infection (e.g., cell mediated responses); and
- Increased frequency of therapeutic toxicity (e.g., declining kidney and liver function).

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Institutional Factors:

- **Pathogen exposure in shared communal living space (e.g. handrails and equipment);**
- **Common air circulation;**

- **Direct/indirect contact with healthcare personnel/visitors/other residents;**
- **Direct/indirect contact with equipment used to provide care; and**
- **Transfer of residents to and from hospitals or other settings.**

Instructor Notes:

After reading the list the surveyors, ask for their input as to how or why these factors may facilitate transmission of infections among nursing home residents.

It is also important to note that residents can be exposed to potentially pathogenic organisms in several ways, including but not limited to the following:

- Improper hand hygiene
- Improper glove use (e.g., utilizing a single pair of gloves for multiple tasks or multiple residents)
- Improper food handling

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**Direct Transmission
(Person to Person)**

Direct transmission occurs when microorganisms are transferred from one infected/colonized person to another with a contaminated intermediate object or person.

Contaminated hands of healthcare personnel are often implicated in direct contact transmission.

Instructor Notes:

Some examples of agents that can be transmitted directly from person to person include MRSA, VRE, and Influenza.

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Indirect Transmission

Indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object or person. Examples include:

- Resident care devices
- Clothing, including Proper Protective Equipment (PPE)
- Toilets and bedpans

Instructor Notes:

Resident-care devices (e.g., electronic thermometers or glucose monitoring devices) may transmit pathogens if devices contaminated with blood or body fluids are shared without cleaning and disinfecting between uses for different residents.

Clothing, uniforms, laboratory coats, or isolation gowns used as PPE may become contaminated with potential pathogens after care of a resident colonized or infected with an infectious agent, (e.g., MRSA, VRE, and Clostridium difficile).

Indirect contact through toilets and bedpans. Examples of illnesses spread via a fecal-oral route include salmonella, shigella, and pathogenic strains of E. coli, norovirus, and symptomatic Clostridium difficile.

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Indirect Transmission (cont'd)

To reduce or prevent infections transmitted via indirect contact, resident equipment, medical devices, and the environment must be decontaminated.

- Single-use disposable devices may also be used.

Instructor Notes:

The choice of decontamination method depends on the risk of infection to the resident coming into contact with equipment or medical devices. This will be discussed further in the following slides.

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Indirect Transmission (cont'd)

3 Risk levels associated with instruments commonly used in Nursing Homes

1. Critical
2. Semi-Critical

3. Non-Critical

Instructor Notes:

1. Critical items (e.g. needles, intravenous catheters, indwelling urinary catheters) are defined as those items which normally enter sterile tissue, or the vascular system, or through which blood flows. The equipment must be sterile when used, based on one of several accepted sterilization procedures.
2. Semi-critical items (e.g., thermometers, podiatry equipment, electric razors) are defined as those objects that touch mucous membranes or skin that is not intact. Such items require meticulous cleaning followed by high-level disinfection treatment using an FDA approved chemo sterilizer agent, or they may be sterilized.
3. Noncritical items (e.g., stethoscopes, blood pressure cuffs, over-bed tables) are defined as those that come into contact with intact skin or do not contact the resident. They require low level disinfection by cleaning periodically and after visible soiling, with an EPA disinfectant detergent or germicide that is approved for health care settings.

Single-use disposable equipment is an alternative to sterilizing reusable medical instruments. Devices labeled by the manufacturer for single use are never to be reused, even if they are reprocessed.

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Prevention and Control of Transmission of Infection: Standard Precautions

- **based upon the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes may contain transmissible infectious agents**
- **intended to be applied to the care of all persons in all healthcare settings, regardless of the suspected or confirmed presence of an infectious agent**

Instructor Notes:

Implementation of Standard Precautions constitutes the primary strategy for preventing healthcare-associated transmission of infectious agents among residents and healthcare personnel. Appropriate infection control measures are used in each resident interaction.

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Standard Precautions (cont'd)

Examples of standard precautions include:

- **hand hygiene**
- **safe injection practices**
- **the proper use of personal protective equipment**
- **care of the environment, textiles and laundry**
- **resident placement**
- **appropriate waste disposal and management**

Instructor Notes:

Disposal of waste is also handled as though all body fluids are infectious. Potentially contaminated articles are stored and disposed of in appropriate containers (e.g. sharps containers, biohazard bags, etc.), and the environment is cleansed using germicidal agents to reduce the risk of transmission of infection.

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Personal Protective Equipment (PPE)

- **PPE includes items such as gloves, gowns, eye protection, and masks**
- **These items are used as barrier to any body fluids or other potentially infected materials**

Instructor Notes:

For example, in situations identified as appropriate, gloves and other equipment such as gowns and masks are to be used as necessary to control the spread of infections.

Standard Precautions are intended to protect health care personnel as well as residents by ensuring that healthcare personnel do not carry infectious agents to residents on their hands or via equipment used during resident care, or vice versa.

Any equipment or items in the resident environment likely to have been contaminated with infectious fluids or other potentially infectious matter must be handled in a manner so as to prevent transmission of infectious agents, (e.g. wear gloves for handling soiled equipment, and properly clean and disinfect or sterilize reusable equipment before use on another resident).

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Hand Hygiene

Primary means of preventing the transmission of infection

Requires proper hand washing facilities with available soap (regular or anti-microbial), warm water, and disposable towels and/or heat/air drying methods

ABHR may be utilized in situations where hand washing with soap and water is not specifically required

Instructor Notes:

Consistent use by staff of proper hygienic practices and techniques is critical to preventing the spread of infections.

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Hand Hygiene (cont.)

- 1. Wet hands with clean, running warm water**
- 2. Apply the amount of product recommended by the manufacturer to the hands**
- 3. Rub hands together vigorously for at least 15 seconds, covering all surfaces of the hands and fingers**
- 4. Rinse hands with water and dry thoroughly with a disposable towel or heat/air dryer**
- 5. Turn off the faucet on the sink with a disposable paper towel, if available**

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Other Staff-Related Preventive Measures

- Facility staff who have direct contact with residents or who handle food must be free of communicable diseases and open skin lesions, if direct contact will transmit the disease.**
- Personal hygiene must be maintained in a manner so as to minimize the potential for harboring and/or transmitting infectious organisms.**

Instructor Notes:

- Bullet 1: This is mandated by the regulatory language. Therefore, it is important that the facility maintain documentation of how they handle staff with communicable infections or open skin lesions.**

- **Bullet 2:** It is important that all staff involved in direct resident contact maintain fingernails that are clean, neat, and trimmed. It is important for dietary staff to wear hair restraints (e.g., hairnet, hat, and/or beard restraint) to prevent their hair from contacting exposed food. Since jewelry can harbor microorganisms, it is recommended that dietary staff keep jewelry to a minimum and remove hand jewelry when handling food. These recommendations apply even when the use of gloves is employed. This issue is further addressed in the F371 (Sanitary Conditions) Guidance.

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Transmission-Based Precautions (formerly Isolation Precautions)

- **Used for residents who are known to be, or suspected of being infected or colonized with infectious agents, including pathogens that require additional control measures to prevent transmission.**
- **It is appropriate to individualize decisions regarding resident placement based on a number of factors.**

Instructor Notes:

The facility may balance infection risks with:

- the need for more than one occupant in a room
- the presence of risk factors that increase the likelihood of transmission and
- the potential for adverse psychological impact on the infected or colonized resident

In order for transmission-based precautions to be an effective means of infection control and prevention, it is essential both to communicate Transmission-Based Precautions to all healthcare personnel, and for personnel to comply with requirements.

Pertinent signage, verbal reporting of findings, and observations for compliance all can enhance compliance and help minimize the transmission of infections within the facility.

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Transmission-Based Precautions (cont'd)

Transmission-Based Precautions shall be maintained for only as long as necessary to prevent the transmission of infection. It is appropriate to use the least restrictive approach possible that adequately protects the resident and others.

Instructor Notes:

- Maintaining isolation longer than necessary may adversely affect psychosocial well-being. The facility should document in the resident's medical record the rationale for the selected Transmission-based Precautions.
- The category of Transmission-based Precaution determines the type of personal protective equipment to be used. When transmission-based precautions are in place, the appropriate personal protective equipment should be readily available. Proper hand washing remains a key preventive measure, regardless of the type of Transmission-based Precaution employed.
- Standard approaches are defined by the CDC for Airborne, Contact, and Droplet Precautions.

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Airborne Precautions

- **Intended to prevent the transmission of organisms that remain infectious when suspended in the air.**
 - E.g. varicella zoster [shingles] and M. tuberculosis
- **Personnel caring for residents on Airborne Precautions wear a mask or respirator that is donned prior to room entry, depending on the disease-specific recommendations.**

Instructor Notes:

- Bullet 1: Management of some airborne infections such as active TB requires a single-resident airborne infection isolation room (AIIR) that is equipped with special air handling and ventilation capacity.
- Although not all residents with airborne infections will require an AIIR, residents with infections requiring an AIIR may need to be transported to an acute care setting unless the facility can place the resident in a private AIIR room with the door closed.

- It is important for the facility to have a plan in place to effectively manage a situation involving a resident with suspected or active TB while awaiting the resident's transfer.
- Bullet 2: Depending on the condition, staff can use N95 or higher level respirators or wear masks if respirators are not available.

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Contact Precautions

Contact transmission risk requires the use of contact precautions to prevent infections that are spread by person-to-person contact.

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Droplet Precautions

Respiratory droplets transmit infections directly from the respiratory tract of an infected individual to susceptible mucosal surfaces of the recipient.

Instructor Notes:

Respiratory droplets are generated when an infected person coughs, sneezes, or talks, or during procedures such as suctioning, endotracheal intubation, cough induction by chest physiotherapy, and cardiopulmonary resuscitation. Studies have shown that respiratory viruses can enter the body via the nasal mucosa, conjunctivae and less frequently the mouth. Examples of droplet-borne organisms that may cause infections include, but are not limited to influenza and mycoplasma.

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Airborne precautions require mask or respirator, gloves and private room or cohorting and room sharing with limited risk factors. Private AIIR room with active TB

Contact precautions require gown and gloves, and private room or cohorting and room sharing with limited risk factors.

Droplet precautions require mask/facila protection, gloves and private room or cohorting and room sharing with limited risk factors. 3-10 feet distance* for transmission

All Transmission-based Precautions require appropriate hand hygiene practices

Instructor Notes:

*The maximum distance for droplet transmission is currently unresolved, but the area of defined risk based on epidemiological findings is approximately 3-10 feet

It is important that facility staff clearly identify the type of precautions and the appropriate personal protective equipment to be used in the care of the resident. Personal protective equipment shall be readily available near the entrance to the resident's room. Signage can be posted on the resident's door instructing visitors to see the nurse before entering.

Slide 50**Implementation of Transmission-Based Precautions**

Since laboratory tests (especially those that depend on culture techniques) may require two or more days to complete, Transmission-Based Precautions may need to be implemented while test results are pending, based on the clinical presentation and the likely category of pathogens.

Instructor Notes:

It is not always possible to identify prospectively residents needing Transmission-Based Precautions. The diagnosis of many infections is based on clinical signs and symptoms, but often requires laboratory confirmation.

Use of appropriate Transmission-Based Precautions when a resident develops symptoms or signs of a transmissible infection or arrives at a nursing home with symptoms of an infection (pending laboratory confirmation) reduces transmission opportunities. However, once it is confirmed that the resident is no longer a risk for transmitting the infection, removing transmission-based precautions avoids unnecessary social isolation.

Slide 51**Safe Water Precautions**

Safe drinking water is also critical to controlling the spread of infections. The facility is responsible for maintaining a safe and sanitary water supply, by meeting nationally recognized standards set by the FDA for drinking water.

Instructor Notes:

The FDA nationally recognized standard for safe drinking water is <500 CFU/mL per heterotrophic plate count.

Slide 52**Handling Linens to Prevent and Control Infection Transmission**

If the facility handles all used linen as potentially contaminated (i.e. using Standard Precautions), no additional separating or special labeling of the linen is recommended

If Standard Precautions for contaminated linens are not used, then some identification with labels, color coding or other alternatives means of communication is needed.

Instructor Notes:

It is important that all potentially contaminated linen be handled with appropriate measures to prevent cross-transmission.

No special precautions (i.e. double bagging) or categorizing is recommended for linen originating in isolation rooms. Double bagging of linen is only recommended if the outside of the bag is visibly contaminated or is observed to be wet through to the outside of the bag. Alternatively, leak-resistant bags are recommended for linens contaminated with blood or body substances.

It is important that laundry areas have hand washing facilities and products, as well as appropriate PPE (i.e., gloves and gowns) available for workers to wear while sorting linens.

Slide 53**Handling Linens (cont'd)**

If linen is sent off to a professional laundry facility, the nursing home facility obtains an initial agreement between the laundry service and facility that stipulates the laundry will be hygienically clean and handled to prevent recontamination from dust and dirt during loading and transport.

Slide 54**Handling Linens (cont'd)**

An effective way to destroy microorganisms in laundry items is through hot water washing at temperatures above 160°F (71°C) for 25 minutes. Alternatively, low temperature washing at 71 to 77 degrees F (22-25 degrees C) plus a 125-part-per-million (ppm) chlorine bleach rinse has been found to be effective and comparable to high temperature wash cycles

Instructor Notes:

Laundry equipment shall be used and maintained according to the manufacturer's instructions to prevent microbial contamination of the system. If laundry chutes are used, they are properly designed, maintained, and used so as to minimize dispersion of aerosols from contaminated laundry (e.g. no loose items in the chute and bags are closed before tossing into the chute).

Damp linen is not left in machines overnight.

Slide 55**Handling Linens (cont'd)**

Standard mattresses and pillows can become contaminated with body substances during patient care

- **Clean and disinfect moisture-resistant mattress covers between patients with an EPA approved germicidal detergent. All fabric mattress covers are to be laundered between patients.**
- **Launder pillow covers and washable pillows in hot water cycle between residents or when they become contaminated with body substances.**

Instructor Notes:

A mattress cover is generally a fitted, protective material, the purpose of which is to prevent the mattress from becoming contaminated with body fluids and substances. A linen sheet placed on the mattress is not considered a mattress cover. Patches for tears and holes in mattress covers do not provide an impermeable surface over the mattress. Mattress covers are recommended to be replaced when torn or visibly stained.

Discarding mattresses if fluids have penetrated into the mattress fabric and washing pillows and pillow covers in a hot-water laundry cycle will also reduce the risk of indirect contact with infectious agents.

Slide 56**Recognizing and Containing Outbreaks**

An outbreak is typically one of the following:

- **One case of an infection that is highly communicable.**
- **Trends that are 10 percent higher than the historical rate of infection for the facility that may reflect an outbreak or seasonal variation and therefore warrant further investigation.**
- **Occurrence of three or more cases of the same infection over a specified length of time on the same unit or other defined areas.**

Slide 57

Recognizing and Containing Outbreaks (cont'd)

Once an outbreak has been identified, it is important that the facility take the appropriate steps to contain it.

- **State health departments offer guidance and regulations regarding responding to and reporting outbreaks.**
- **Plans for containing outbreaks usually include efforts to prevent further transmission of the infection**

Instructor Notes:

Bullet 2: This information is often received in advance of an outbreak and included in the infection prevention and control program.

Bullet 3: The facility should consider the needs of the residents and staff when developing plans for containing outbreaks.

Slide 58

Prevention of the Spread of Illness Related to Multidrug Resistant Organisms (MDROs)

- **Common MDROs include MRSA, VRE, and Clostridium Difficile**
- **Transmission-based precautions are employed for all MDROs**
- **Aggressive infection control measures and strict compliance can help minimize transmission of MDROs**

Instructor Notes:

Methicillin-resistant staphylococcus aureus (MRSA), vancomycin-resistant enterococcus (VRE), and clostridium difficile will be discussed in detail in the slides that follow.

Slide 59

MRSA

- **Staphylococcus is a common cause of infections**
- **Common sites of colonization include the rectum, perineum, skin and nares**
- **Colonization may precede or endure beyond an acute infection.**

- **MRSA is transmitted person-to-person (most common), on inanimate objects and through the air**

Instructor Notes:

MRSA infection is commonly treated with Vancomycin, which in turn can lead to increased Enterococcus antibiotic resistance.

These points illustrate why antibiotic review and monitoring of residents are important components of an effective infection prevention and control program.

Slide 60

VRE

- **Enterococcus is an organism that normally occurs in the colorectal tract.**
- **VRE is an infection with enterococcus organisms that have developed resistance to the antibiotic Vancomycin**
- **Preventing infection with MRSA and the limited use of antibiotics for individuals who are only colonized can also help prevent the development of VRE**

Instructor Notes:

VRE infections have been associated with prior antibiotic use.

This point illustrates why antibiotic review and monitoring of residents are important components of an effective infection prevention and control program.

Slide 61

Clostridium Difficile (C. difficile)

- **C. difficile is a bacterial species of the genus Clostridium, which are gram-positive, anaerobic, spore-forming rods (bacillus).**
- **When antibiotic use eradicates normal intestinal flora, the organism may become active and produce a toxin that causes symptoms such as diarrhea, abdominal pain, and fever.**

Instructor Notes:

Reference CDC guidelines.

Slide 62

Clostridium Difficile (cont'd)

More severe cases can lead to additional complications such as intestinal damage and severe fluid loss.

If a resident has diarrhea due to C. difficile, large numbers of C. difficile organisms will be released from the intestine into the environment and may be transferred to other individuals, causing additional infections.

Instructor Notes:

Treatment options include stopping antibiotics and starting specific ant Clostridial antibiotics, e.g. metronidazole or oral Vancomycin.

Reference current CDC guidelines

Slide 63

Clostridium Difficile (cont'd)

- **Contact Precautions are instituted for residents with symptomatic C. difficile infection**
 - **Another control measure is to give the resident his or her own toilet facilities that will not be shared by other residents**
- **C. difficile can survive in the environment (e.g., on floors, bed rails or around toilet seats) in its spore form for up to six months**

Instructor Notes:

Thorough hand washing with soap and water after caring for the resident can also reduce the risk of cross-transmission.

Rigorously cleaning the environment removes C. difficile spores, and can help prevent transmission of the organism. Equipment may need to be cleaned with a 1:10 dilution of sodium hypochlorite (bleach). This is one part water to nine parts sodium hypochlorite. Once mixed, the solution is effective for 24 hours.

Reference current CDC guidelines.

Slide 64

Preventing Infections Related to the Use of Specific Devices

- **Intravascular catheters**
 - **used widely to provide vascular access**
 - **increasingly seen in nursing homes**
 - **may increase the risk for local and systemic infections and additional complications such as septic thrombophlebitis**
- **Central venous catheters (CVCs) have also been associated with infectious complications.**

Instructor Notes:

Other catheters such as dialysis catheters and implanted ports may be accessed multiple times per day, such as for hemodynamic measurements, or to obtain samples for laboratory analysis, thus increasing the risk of contamination and subsequent clinical infection.

Slide 65

Preventing Infections Related to the Use of Specific Devices (cont'd)

- **Limit access to central venous catheters for only the primary purpose**
- **Consistently use appropriate infection control measures**
 - **surveillance**
 - **observation of insertion sites**

Instructor Notes:

Surveillance consistently includes all residents with vascular access, including those with venous access and implanted ports such as PICC lines, midlines, and peripheral access catheters.

Slide 66

Preventing Infections Related to the Use of Specific Devices (cont'd)

Consistently use appropriate infection control measures

- **routine dressing changes**
- **use of appropriate PPE and hand hygiene**
- **review of resident for clinical evidence of infection**

Slide 67

Investigative Protocol

Objectives determine if

- **The facility has an Infection Prevention and Control Program that prevents, investigates and controls infections in the facility**
- **The facility has a program that collects and analyzes data regarding infections acquired in the facility**
- **Staff practices are consistent with current infection control principles**
- **staff with communicable diseases are prohibited from direct contact with resident**

Instructor Notes:

The objectives of this investigative protocol are to focus the investigation. Surveyors use the protocol to determine whether the facility has a Infection and Prevention Control Program in place and if the facility's program collects and analyzes its data. The protocol helps the surveyor investigate the facility's overall Infection Prevention and Control Program.

Policy and procedures manuals, training documents and monitoring tools may be reviewed during this investigation to assist in determining the facility systems. However it is important to remember that the facility's written policy alone does not confirm compliance with Federal regulatory requirements.

Surveyors, use this protocol to investigate compliance at F441 for every initial and standard survey. In addition, use this protocol on revisit or abbreviated surveys (compliant investigations) as needed.

Slide 68

Procedures

- **Observations**
- **Interviews**
- **Record Reviews**
- **Review of Facility Practices**

Instructor Notes: It is helpful to review this protocol prior to beginning the survey.

- Review the facility's records of incidents of infection and corrective actions, as indicated, review the facility's infection control policies, procedures, documentation of staff training and, as necessary, interview facility staff with responsibility for oversight of the infection prevention and control program.
- Throughout the survey, the surveyors should determine if:
- The facility identifies where infections are acquired;
- Staff training includes critical areas of infection control;
- The program implements processes to identify and address infection control issues;
- Factors are used to help the facility appropriately determine when to implement and terminate transmission based precaution procedures;
- The facility has in place effective means to identify individuals (residents, staff, visitors, volunteers, practitioners with infections);
- The facility has policies and procedures monitoring how linens are stored, transported, and processed;
- The Infection and Prevention Control program identifies and addresses infection control issues; and
- The facility effectively identifies and prevents employees with a communicable disease from direct contact with residents.

Slide 69

Observe Staff

- **Observe various disciplines (nursing, dietary and housekeeping) to determine if they follow appropriate infection control practices and transmission based precaution procedures.**

Instructor Notes:

Ask surveyors, what are some examples of what you are looking for during the survey of how linens are handled, transported and stored.

- **Observe when linens are handled, processed, transported and stored**

- **Observe if staff exhibit overt signs of illness or communicable disease that have potential to transmit**
- **Observe if staff and visitors adhere to appropriate precautions**
- **Observe if staff use appropriate precautions if resident are on special precautions**
- **Observe if staff involved in the care and management of residents with special needs (e.g. urinary catheters, wound care, respiratory treatments)**

Slide 70

Observe Residents for:

- **Signs and symptoms of potential infections such as**
 Coughing and/or congestion
 Vomiting or loss of appetite
 Skin rash, reddened or draining eyes

Slide 71

Observe Cleaning and Disinfecting to determine:

- **If equipment in Transmission Based Precaution rooms are appropriately cleaned**
- **If high touch surfaces in the environment are visibly soiled**
- **If small non-disposable equipment are cleaned**

Instructor Notes:

Observe various disciplines (nursing, dietary and housekeeping) to determine if they follow appropriate infection control practices and transmission based precaution procedures.

Slide 72

Observe Staff practice to determine:

- **How single-use items are properly disposed of;**
- **How single resident use items are maintained**

- **How resident dressings and supplies are properly stored**
- **If multiple use items are properly cleaned/disinfected between each resident**

Slide 73

Observe Hand Hygiene and use of gloves during:

- **Resident care that requires use of gloves;**
- **Medication administration;**
- **Dressing changes and all resident care that requires use of gloves.**
- **Assisting Residents with Meals.**

Instructor Notes:

Note the availability of gloves and the equipment and products to perform hand hygiene.

Slide 74

Interview

During the resident review, interview the resident, family or responsible party, to the extent possible, to identify, as appropriate, whether they have received education and information about infection control practices, such as appropriate hand hygiene and any special precautions applicable to the resident.

Instructor Notes:

The interview questions may be asked while the observations are being conducted or separate from the observation. In either case, the surveyors should be sure to document responses accurately to include the name and title of the staff person interviewed. In addition to interviewing the staff involved in the residents care, interviews should also include other facility personnel.

During the course of the survey, also interview direct care staff who perform the tasks about the infection control procedures they follow to care for residents.

Slide 75

Record Review

Review facility documents and interview staff to establish if the facility has processes and practices to promote infection control and prevention the spread of infectious diseases.

Instructor Notes:

Record review is an important part of the investigative process. The necessary supporting data may be:

- Resident records
- Facility Record of Incidents as related to infection control
- Infection Control policies, surveillance documentation
- Employee records
- Documentation related to facility's review of antibiotics

As part of the investigative protocol, obtain the records and interviews to monitor the facility's practice in the procurement, storage, preparation, distribution and service of linen to residents. Conduct the documentation review and staff interviews to identify and analyze any concerns or facility practices that may put residents at risk of infectious diseases.

Ask surveyors to discuss additional information sources that would be helpful to review (e.g., training records, competency testing, equipment repair records, and infection control records regarding surveillance of infectious diseases and outbreaks).

If survey concerns are identified:

Interview facility staff who are responsible for implementing and overseeing the Infection Prevention and Control Program.

Slide 76

Determination of Compliance 483.65 Infection Control

Did the facility:

- **Demonstrate practices to prevent the spread of infections ?**
- **Demonstrate practices to control outbreaks?**

Instructor Notes:

Compliance with the Infection Control regulation occurs when a facility has met both aspects in the prevention of spread of infections and the implementing practices to control outbreaks. The next two slides relate to this discussion.

Slide 77**Criteria for Compliance with F441**

The facility is in compliance if staff:

- Demonstrates ongoing surveillance, recognition, investigation and control of infections to prevent the onset and the spread of infection;
- Demonstrates practices and processes consistent with infection prevention and prevention of cross-contamination;

Slide 78**Criteria for Compliance with F441 (cont'd)**

The facility is in compliance if staff:

- Demonstrates that it uses records of incidents to improve its infection control processes and outcomes by taking corrective action;
- Uses procedures to identify and prohibit employees with a communicable disease or infected skin lesions from direct contact with residents;

Instructor's Note:

Compliance at F441 is based in part on the facility's ability to be proactive and act appropriately to infection control issues.

Slide 79**Criteria for Compliance with F441**

The facility is in compliance if staff:

- **Demonstrates appropriate hand hygiene practices, after each direct resident contact; and**
- **Demonstrates handling, storage, processing and transporting of linens so as to prevent the spread of infection.**

Instructor's Note:

Discuss with the surveyors the criteria for determining Compliance and Noncompliance with this regulatory requirement.

Slide 80

Noncompliance with F441

May include, but is not limited to, one or more of the following, failure to:

- **Develop an Infection Control and Prevention Program in accordance with the standards summarized in this guidance**

Instructor Notes:

A clear understanding of the facility's noncompliance with requirements (i.e., deficient practices) is essential to determine how the deficient practice(s) relates to any actual harm or potential for harm to the resident. Noncompliance must be established before determining severity.

Slide 81

Noncompliance with F441 (cont'd)

Failure to:

- **Utilize infection precautions to minimize the transmission of infection;**
- **Identify and prohibit employees with a communicable disease from direct contact with a resident;**
- **Demonstrate proper hand hygiene;**
- **Properly dispose of soiled linens;**

Slide 82

Noncompliance with F441 (cont'd)

Failure to:

- **Demonstrate the use of surveillance; and**
- **Adjust facility processes as needed to address a known infection risk.**

Instructor Notes:

It is important that the facility monitor and track current infection control and prevention activities. The facility needs to act appropriately and institute processes to address infection risks to residents.

Observed facility practices (e.g., interviews), that reveal lack of knowledge among staff members about these processes, and inadequate facility documentation of compliant practices can confirm deficient practices in this area.

Slide 83

DEFICIENCY CATEGORIZATION

(Part IV, Appendix P) Severity Determination

Key Components

Harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services,

Degree of harm (actual or potential) related to noncompliance, and

Immediacy of correction required.

Instructor Notes:

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

Slide 84

Determining Actual or Potential Harm

Actual or potential harm/negative outcomes for F441 may include:

- **Onset of infections in the facility**
- **Spread of infection within the facility**

- **An infection outbreak in the facility**

Slide 85

Determining Degree of Harm

How the facility practices caused, resulted in, allowed, or contributed to harm (actual/potential)

- **If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and**
- **If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.**

Instructor Notes:

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for Tag F441. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q).

Slide 86

Level 4 Immediate Jeopardy

Has allowed/caused/resulted in, or is likely to cause serious injury, harm, impairment, or death to a resident; and

Slide 87

Level 4 Immediate Jeopardy (cont'd)

Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Instructor Notes:

Discuss examples of immediate jeopardy that you have seen in your experiences?

Slide 88

Level 4 Examples

The facility failed to clean the spring-loaded lancet devices before or after use and reused lancet devices on residents who required blood sugar monitoring. This practice of re-using lancet devices created an Immediate Jeopardy to resident health by potentially exposing residents to the spread of blood borne infections for multiple residents in the facility who required blood sugar testing.

Instructor Notes: level 4 examples cont.

- The facility failed to investigate, document surveillance of and try to contain an outbreak of gastrointestinal illness among residents; as a result, additional residents became ill with diarrheal illnesses and had to be hospitalized for dehydration.
- The facility failed to restrict a staff member with a documented open, draining and infected skin lesion that was colonized with MRSA from working without adequately covering the area, resulting in MSRA transmission and infection of several residents under that staff person's care.

Slide 89

Severity Level 3 Actual Harm that is *not* Immediate Jeopardy

The negative outcome may include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable level of well-being.

Instructor Note:

What is harm that is not immediate jeopardy?

Slide 90

Level 3 Example

The facility routinely sent urine cultures of asymptomatic residents with indwelling catheters, putting residents with positive cultures on antibiotics, resulting in two residents who get antibiotic-related colitis and significant weight loss.

Instructor Notes: Additional examples of level 3:

- The facility failed to institute internal surveillance for adherence to hand washing procedures or pertinent reminders to staff regarding appropriate respiratory precautions during an influenza outbreak, resulting in additional cases of influenza in residents on another, previously unaffected unit.

- The facility failed to ensure courses of antibiotic therapy for residents with urinary tract infections were effective resulting in two residents developing Urosepsis and requiring hospitalization for intravenous antibiotic therapy.

Slide 91

Level 2 No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

- **Noncompliance that results in a resident outcome of no more than minimal discomfort, and/or**
- **Has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being.**

Instructor Notes:

Next slide - Level 2 examples

Slide 92

Level 2 Example

The facility failed to ensure that their staff demonstrate proper hand hygiene between residents to prevent the spread of infections. The staff administered medications to a resident via a gastric tube and while wearing the same gloves proceeded to administer oral medications to another resident. The staff did not remove the used gloves and wash or sanitize their hands between residents.

Instructor Notes:

Other examples of level 2:

- The facility failed to implement a surveillance program including the investigation of infections or attempt to distinguish facility-acquired from community-acquired infections.
- The facility identified issues related to staff infection control practices, as part of its infection prevention and control program, but did not follow up to identify cause, institute measures to correct the problems.

Slide 93

Level 1 No Actual Harm with Potential for Minimal Harm

The failure of the facility to develop, implement and maintain an infection prevention and control program to prevent, recognize, and control the onset and spread of infections places this highly susceptible population at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

Slide 94

Questions?