Developing an Antibiotic Stewardship Infrastructure in Nursing Homes: from Theory to Practice

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Madison, WI
Disclosures

- R18HS023779-01
- 1R01HS026747-01

Consultant Activities:
1. Zurex Pharmaceuticals (Madison, WI): provide strategic advice on development and testing of the company’s novel anti-septic platform (<$5,000).

- Cooperative Studies Program #2001
- FOP 19-334 (VA-CDC Infection Control Practice Based Research Network)
Objectives

• Regulatory requirements for the structure and process of an antibiotic stewardship program.

• Assessing your facility’s compliance with existing regulatory requirements.

• Identification and involvement of individuals within the facility that should be involved in the antibiotic stewardship program.

• Identification of resources outside the facility that can assist with development of the antibiotic stewardship program.
Why Antibiotic Use in SNFs Matters

Up to **70%** of skilled nursing facility residents will receive **one or more** courses of systemic antibiotics in a year.

~**50%** of antibiotics started in skilled nursing facilities are **unnecessary**.

**A majority** of antibiotics prescribed in skilled nursing facilities are **broad-spectrum**.

**50% < 7d > 50%**

Half of antibiotic course for treatment of common infections are prescribed for **more than a week**.
**Why Antibiotic Use in SNFs Matters**

<table>
<thead>
<tr>
<th>HARMS AT INDIVIDUAL LEVEL</th>
<th>HARMS AT FACILITY LEVEL</th>
<th>HARMS AT POPULATION LEVEL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADE</strong></td>
<td><strong>CDI</strong></td>
<td><strong>ARO</strong></td>
</tr>
<tr>
<td>• 20% of all adverse drug events (ADEs) in nursing homes caused by antibiotics</td>
<td>• C. difficile infection (CDI) is a life-threatening intestinal disease caused by antibiotics</td>
<td>• ~50% of nursing residents are colonized with antibiotic-resistant organisms (AROs)</td>
</tr>
<tr>
<td>• Antibiotic-associated ADEs are one of the most common reasons for transfer to ER</td>
<td>• 12% of nursing home residents treated inappropriately for UTI develop CDI</td>
<td>• Antibiotic exposure is the single most important risk factor for ARO colonization</td>
</tr>
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<td><strong>HARMS AT POPULATION LEVEL</strong></td>
<td></td>
</tr>
<tr>
<td>Residents in nursing homes with higher antibiotic use have a 24% increased risk of antibiotic-related harm</td>
<td>• Half of the residents transferred to the hospital are colonized with <em>C. difficile</em> and/or antibiotic-resistant bacteria which may be spread to others</td>
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<tr>
<td></td>
<td>• Nursing homes have been repeatedly implicated in the regional spread of resistance</td>
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<tr>
<td></td>
<td>• Mathematical models suggest that antibiotic resistance cannot be controlled in hospitals without controlling resistance in nursing homes</td>
<td></td>
</tr>
</tbody>
</table>

Antibiotics account for 1/3 of all survey penalties for inappropriate medication use in Wisconsin nursing homes.
Our Government and Public Health Authorities Are Concerned

NATIONAL ACTION PLAN TO PREVENT HEALTH CARE-ASSOCIATED INFECTIONS: ROAD MAP TO ELIMINATION
APRIL 2013

CHAPTER 8: LONG-TERM CARE FACILITIES

NATIONAL ACTION PLAN FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA
MARCH 2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 431, 447, 482, 483, 485, 488, and 489
[CMS–3260–F]
RIN 0938-AR61

Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.
ACTION: Final rule.
Evolution of Nursing Homes & the Regulatory Environment

Marion Branch National Home for Disabled Volunteer Soldiers, Indiana

1965 – The Older Americans Act (Medicare & Medicaid)

2016 – CMS Updates “Requirements of Participation”

2009 – Infection Control Guidance Updated

Nursing Home Reform Act of 1987

OBRA 87
Regulatory Overview

• SNF’s are required to be “certified” in order to receive reimbursement from Medicare and Medicaid (majority are dually certified).

• Certification is renewed annually and involves an on-site inspection by team of surveyors.

• OBRA 87 led to the development of process standards that facilities must demonstrate during their inspection in order to remain certified

• 1991 introduced the MDS-derived outcome (QM/QI) measures

• Survey-identified deficiencies
  • Assigned to a specific category (F-tag)
  • Assigned a level of severity (“1” = no actual harm with potential for minimal harm → “4” = immediate jeopardy to resident health and/or safety
  • Assigned scope (isolated, pattern, widespread)
  • Matrix assigned rating (A → J)
  • All identified deficiencies require corrective action and may result in fines or denial of recertification (i.e., closure)
History of Infection Control Regulations

**1990-2009**

- 5 survey tags – *6 pages*
  - F441 – “Infection Control”
  - F442 – “Preventing Spread of Infection”
  - F443 – “Employees with Communicable Disease”
  - F444 – “Handwashing”
  - F445 – “Linens”

- No clear guidance on how to interpret the regulations
- Antimicrobial stewardship???
History of Infection Control Regulations

- **2005**
  - F329 – Unnecessary drugs
    - Often interpreted to apply only to antipsychotic medications
    - Actually applies to any high-risk medication

- **2009**
  - *Surveyor Guidance* updated - **34 pages**
  - Collapsed tags to F441 – “Infection Control” – Required infection control program
    - Person who oversees, but short of requiring “IP”
    - Oversight not a full FTE
    - Hand hygiene
    - Transmission based precautions
    - Antibiotic review – review data to ensure appropriate use ???
History of Infection Control Regulations

- **2016**
  - Sweeping change to regulations
    - Moved vaccination regs under IC regs
    - Focus expanded to include interrupting transmission in addition to preventing infections
    - Must follow national standards (NHSN or McGeer)
    - Facilities are required to base their IPCP program based on an annual facility assessment
    - Facilities must employ and designate an individual for responsibility the IPCP who has received specific training in IP&C
    - §483.80(a)(3): The facility IPCP must include an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

Interpretive guidance is 702 pages (IC-related sections 49 pages)


https://www.ahcancal.org/facility_operations/Documents/SC17-36.03.Appendix%20PP%20with%20Final%20IGs.pdf
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11/2019

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READY YOU'RE NOT
INCOMPLETE YOUR TRAINING IS
memegenerator.net
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
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<tr>
<td>Is key leadership supportive of this effort? Support by leadership (i.e., the board and/or administrator, director of nursing, or medical director) is critical to change.</td>
<td></td>
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</tr>
<tr>
<td>Is the medical director actively involved in quality improvement and/or infection control?</td>
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</tr>
<tr>
<td>Is the nursing home financially stable?</td>
<td></td>
<td></td>
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<tr>
<td>Is the nursing home’s ownership and/or management stable (i.e., no changes anticipated over the next six months)?</td>
<td></td>
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<td>Is the nursing home in good standing with the State Survey Agency (e.g., not identified as a Special Focus Facility, not under State receivership, has not had admissions frozen)?</td>
<td></td>
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</tr>
<tr>
<td>Are there at least two staff who can serve as program champions and commit to leading the activity? Program champions could include (but are not limited to) the director of nursing, assistant director of nursing, charge nurse(s), infection prevention consultant/practitioner, and the medical director or other prescribing clinician. It is critical that at least two, if not more, staff are willing to lead the effort and champion it.</td>
<td></td>
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<tr>
<td>Is there time to train staff? Implementation will require training for nursing staff and possibly prescribing clinicians, depending on the toolkit. Initial training for nurses and prescribing clinicians may take approximately 30 minutes to 2 hours. Are there sufficient resources (e.g., time, funds) to cover such training?</td>
<td></td>
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<tr>
<td>Are there sufficient funds to make copies of materials for nurses, prescribing clinicians, and, as appropriate, residents and family members?</td>
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<td>Are there resources for implementing mechanisms to sustain the effort (e.g., staff who can train new nurses as they are hired and include the topic in the annual education program)? The key to sustaining any new activity is ensuring everyone is knowledgeable about it.</td>
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</tbody>
</table>

Regs Modeled on CDC Core Elements

The Core Elements of Antibiotic Stewardship for Nursing Homes

- Leadership commitment: Demonstrate support and commitment to safe and appropriate antibiotic use in your facility.
- Accountability: Identify physician, nursing and pharmacy leads responsible for promoting and overseeing antibiotic stewardship activities in your facility.
- Drug expertise: Establish access to consultant pharmacists or other individuals with experience or training in antibiotic stewardship for your facility.
- Action: Implement at least one policy or practice to improve antibiotic use.
- Tracking: Monitor at least one process measure of antibiotic use and at least one outcome from antibiotic use in your facility.
- Reporting: Provide regular feedback on antibiotic use and resistance to prescribing clinicians, nursing staff and other relevant staff.
- Education: Provide resources to clinicians, nursing staff, residents and families about antibiotic resistance and opportunities for improving antibiotic use.

Checklist for Core Elements of Antibiotic Stewardship in Nursing Homes
Specific Regulatory Language

• ASP composition, governance and responsibilities

• Facilities will develop and implement an ASP protocol (policy) that includes the following:
  1. How program will be integrated into facility IPCP
  2. Frequency of program review
  3. Description of the procedures for establishing infection
  4. Description of expected antibiotic prescribing practices
  5. Description of antibiotic use and resistance outcome monitoring procedures and how these data will be communicated to facility staff and providers
  6. Method and frequency of staff/prescriber education
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ASP Team Membership

• ASP team should involve the facility leadership
  o Medical director
  o Director of Nursing
  o Administrator

• Facility pharmacist should be involved in ASP team
  • “Must perform a medication regimen review (MRR) at least monthly, including review of the medical record and identify any irregularities, including unnecessary drugs.”

• Facility infection preventionist should be part of ASP team
Who is doing the ASP work in NHs?

Crnich et al. IDWeek 2015
Taylor et al. IDWeek 2016
How can the Medical Director Help?

- Role modeling
- Active participant in QAPI meeting
  - Review antibiotic utilization data
  - Review antibiotic-related outcomes
- Review/development of policies and protocols
- Involved in staff and provider educational activities
- Involved in management of the “negative deviants”
How can the Medical Director Help?

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Drinka et al. JAMDA 2013; 14(6): 443
Furuno et al. Infect Control Hosp Epidemiol 2014
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- A MRSA outbreak in a 147-bed NH in WI led to an intensive review of facility microbiology and antibiotic prescribing data
- Review of urinary antibiogram identified
  - 31/100 (27%) all isolates were Enterococcus sp.
  - 87% of E. coli resistant to ciprofloxacin
- Facility embarked on several interventions:
  - Provided staff with antibiogram results
  - Guideline-concordant prescribing tracked by facility staff
  - Medical director sent out letters to outlier providers

Abx Starts per 1,000 Resident-Days

The Pew Charitable Trusts – A path to better antibiotic stewardship, 2016
How can the Pharmacist Help?

• Active participant in QAPI meeting
  • Review antibiotic utilization data
  • Review antibiotic-related outcomes

• Review/development of treatment protocols

• Play an active role in tracking and reporting of antibiotic utilization

• Play an active role in identification of potentially inappropriate antibiotic use & provision of recommendations for modification to providers

Specific Regulatory Language

• ASP composition, governance and responsibilities

• Facilities will develop and implement an ASP protocol (policy) that includes the following:
  1. How program will be integrated into facility IPCP
  2. Frequency of program review (at least annually)
  3. Description of the procedures for establishing infection
  4. Description of expected antibiotic prescribing practices
  5. Description of antibiotic use and resistance outcome monitoring procedures and how these data will be communicated to facility staff and providers
  6. Method and frequency of staff/prescriber education
Specific Regulatory Language

- ASP composition, governance and responsibilities
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  4. Description of expected antibiotic prescribing practices
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  6. Method and frequency of staff/prescriber education
Suspected UTI SBAR

Complete this form before contacting the resident’s physician.

Nursing Home Name    
Resident Name    
Physician/NP/PA    
Nurse    
Submitted by Phone    

Date/Time    
Date of Birth    
Fax    
In Person    
Other    

Situation
I am contacting you about a suspected UTI for the above resident.

Vital Signs: BP _______ / _______ HR _______ Resp. rate _______ Temp. _______

Background
Active diagnoses or other symptoms (especially, bladder, kidney/pulmonary conditions)

Specify

☐ No ☐ Yes The resident has an indwelling catheter
☐ No ☐ Yes Patient is on dialysis
☐ No ☐ Yes The resident is on insentient: ☐ Yes, new/worsening? ☐ No ☐ Yes
☐ No ☐ Yes Advance directives for limiting treatment related to antibiotics and/or hospitalizations
Specify

☐ No ☐ Yes Medication allergies
Specify

☐ No ☐ Yes The resident is on Warfarin (Coumadin®)

Assessment Input (check all boxes that apply)

Resident WITH indwelling catheter
The criteria are met to initiate antibiotics if one of the below are selected.

No Yes
☐ Fever of 100°F (38°C) or temperatures of 99.4°F (37°C)
☐ New back or flank pain
☐ Acute pain
☐ Rigors/shaking chills
☐ New dramatic change in mental status
☐ Hypotension (significant change from baseline BP or a systolic BP <90

☐ Single temperature of 100°F (38°C) and at least one new or worsening of the following:

New back pain or flank pain
Frequency
Gastrointestinal symptoms
Urinary incontinence

Resident WITHOUT indwelling catheter
Criteria are met if one of the three situations are met.

No Yes
☐ 1. Acute dysuria alone

☐ 2. Single temperature of 100°F (38°C) and at least one new or worsening of the following:

New back pain or flank pain
Frequency
Gastrointestinal symptoms
Urinary incontinence

☐ 3. No fever, but two or more of the following symptoms:

New back pain or flank pain
Frequency
Gastrointestinal symptoms
Urinary incontinence

Nurse: Please check box to indicate whether or not criteria are met
☐ Nursing home protocol criteria are met. Resident may require UA with C&S or an antibiotic.†
☐ Nursing home protocol criteria are NOT met. The resident does not need an immediate presentation for an antibiotic, but may need additional observation.‡

Request for Physician/NP/PA Orders

Orders were provided by clinician through ☐ Phone  ☐ Fax  ☐ In Person  ☐ Other_________

Order UA

Order urine cultures

Encourage _______ ounces of liquid intake _______ times daily until urine is light yellow in color

Review fluid intake

Assess vital signs for _______ days, including temp, every _______ hours for _______ hours.

Notify Physician/NP/PA if symptoms worsen or if unresolved in _______ hours.

Initiate the following antibiotic

Antibiotic: __________ Route: __________ Doxulant: __________

☐ No ☐ Yes Pharmacist to adjust to renal function

Other

Physician/NP/PA signature Date/Time

Telephone order received by Date/Time

Family/NPA notified (name) Date/Time

* For residents that regularly use a lower temperature, use a temperature of 99.4°F (37°C) above the baseline as a definition of a fever.
† This is according to our understanding of best practices and our facility protocols. Without evidence of a UTI, a UTI is not ordered.
‡ This is according to our understanding of best practices and our facility protocols. The information is insufficient to indicate an active UTI infection.

https://www.ahrq.gov/sites/default/files/wysiwyg/nhguide/4_TK1_T1-SBAR_UTI_Final.pdf
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Antibiotic Prescribing Practices & Treatment Protocols

• Practices
  • Documentation of treatment indication, drug, dose duration (high likelihood of survey focus)
  • Procedures for reviewing lab/imaging studies and communicating results to providers (high likelihood of survey focus)
  • Antibiotic time-out procedures (negative cultures & bug-drug mismatches will get you in trouble)

• Treatment Protocols
  • Preferred antibiotics for specific infections
  • Avoidance of specific agents (fluoroquinolones)
  • Minimizing long-course therapy
**What Am I Treating?**

**Uncomplicated UTI (Cystitis)**
- Urethral symptoms (dysuria, frequency) are predominant
- Signs of complication* are absent
- Can often wait for culture results before starting treatment
- **Females** can often be treated for less than 7 days depending on the agent used

**Complicated UTI or Upper Tract Infection (Pyelonephritis)**
- Signs of complication* are present
- **Don’t wait** for culture results if resident has high fever, rigors or hypotension/tachycardia
- Use agents that provide high blood and urine levels (IV agents, TMP/SMX, and fluoroquinolones)

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* * Signs of Complication

- Fever
- Flank pain
- Rigor/chills
- Urinary catheter
- Hypotension/Tachycardia
- Elevated WBC

7 Nace et al. JAMDA 2018
# Empiric Treatment of Cystitis

## Females

<table>
<thead>
<tr>
<th>Preference</th>
<th>Estimated Creatinine Clearance (eCrCl)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt;30</td>
</tr>
<tr>
<td>First</td>
<td>Nitrofurantoin 100mg BID (5 days)</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>TMP/SMX 160/800 BID (3 days)</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>TMP/SMX 80/400 BID (3 days)</td>
</tr>
<tr>
<td></td>
<td>Ciprofloxacin 250mg BID (3 days)</td>
</tr>
<tr>
<td>Second</td>
<td>Fosfomycin 3gm (Once)</td>
</tr>
<tr>
<td></td>
<td>Re-dose on day #3 if extending treatment &gt;3d</td>
</tr>
<tr>
<td></td>
<td>Fosfomycin 3gm (Once)</td>
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<tr>
<td></td>
<td>Re-dose on day #3 if extending treatment &gt;3d</td>
</tr>
<tr>
<td>Third</td>
<td>Ciprofloxacin 250mg BID (3 days)</td>
</tr>
<tr>
<td></td>
<td>Ciprofloxacin 250mg BID (3 days)</td>
</tr>
<tr>
<td></td>
<td>---</td>
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</tbody>
</table>

7 Nace et al. *J Am Geriatr Soc* 2018
8 University of Nebraska – Urinary Tract Infection and Asymptomatic Bacteriuria Guideline
Empiric Treatment of Cystitis

**Males**

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</tr>
<tr>
<td>Second</td>
<td>Fosfomycin 3gm (Dose on day #1, #3, #5)</td>
</tr>
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Antibiotic tracking and reporting requirements

• What needs to be tracked?
  • Utilization measure
  • Outcome measure (C. diff rates, MRSA rates, antibiogram)
  • Appropriateness measure

• What type of reporting?
  • QAA meeting
  • Providers
# Antibiotic Measures

<table>
<thead>
<tr>
<th>Utilization</th>
<th>Appropriateness</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Antibiotic start (event)</td>
<td>• Necessity</td>
</tr>
<tr>
<td>• Days of therapy (DOT/AUR)</td>
<td>• % of courses exceeding “X” days</td>
</tr>
<tr>
<td>• Length of therapy (LOT)</td>
<td>• Appropriateness of spectrum</td>
</tr>
<tr>
<td>• Defined daily dose (DDD)</td>
<td>• Appropriateness of dose</td>
</tr>
<tr>
<td>• Costs (per a-day/r-day)</td>
<td></td>
</tr>
</tbody>
</table>

Mylotte J. J Am Med Dir Assoc 2016; 17(7): e13-8
Antibiotic Starts

• Pros
  • Many facilities are already doing this (typically counts only)
  • Aligned with current 24-hour report & infection log processes
  • Relatively easy to marry with treatment indication
  • Not influenced by prophylactic therapy
  • Can be easily modified to exclude hospital-initiated antibiotics

• Cons
  • Current data systems dictate reliance on manual data abstraction methods
    • If automated, could be inflated by intermittent therapy (fosfomycin, vancomycin),
      treatment interruptions and treatment modifications
    • Suboptimal reliability of 24-hour report/infection logs
  • Does not address prophylactic antibiotics
  • Does not address dimensions of appropriateness (necessity, duration, spectrum)
Days of Therapy (DOT)

• Pros
  • Identical to the hospital AU measure
  • Does provide indirect information on length of therapy (not the case in hospitals)
  • More amenable to automation than antibiotic starts

• Cons
  • May be difficult to parse out hospital-initiate antibiotics
  • May be difficult to parse out prophylactic antibiotics
  • May be difficult to parse out relative contribution of different treatment indications
  • Only captures information on one dimension of appropriateness (duration)
Measures of Appropriateness

Loeb et al. *ICHE* 2001
Crnich et al. *IDWeek* 2012
Suggestions for developing tracking workflows

• Start having conversations with facility pharmacy
  • Most pharmacy services maintain a database that details drug, dispense date and days of therapy that was dispensed
  • They will not often have data on indication or appropriateness

• Offload primary data collection to frontline staff
  • Every facility uses a 24-hour board that can potentially be adapted to capture discrete resident information
  • Can get information on antibiotic starts, duration of therapy and indication
  • Will be difficult to incorporate appropriateness (duration being an exception)

• Integrate into infection surveillance activities
  • IP is required to maintain line-list of infections in the facility
  • It is minimal effort to capture data on antibiotic use
  • Can assess appropriateness
Other suggestions

- Use cross-sectional approaches to identify problem areas
- Design prospective tracking efforts with your improvement activities in mind
  - Focus on tracking UTI treatment if your efforts are only focused on UTI
  - Make sure you have some tool for assessing diagnosis shifting (everyone who used to have UTI now has respiratory tract infection)
- Trend your data using incidence densities (e.g., events per 1,000 resident-days) rather than count data
- Be careful when comparing your data to external data
Which of the following stewardship interventions are employed in your facility?

- **Education**
- **Abx TO**
- **FS Antibiogram**
- **Formulary**
- **Pre-auth.**

Abx = antibiotic; TO = timeout; FS = facility specific; Pre-auth. = preauthorization

Crnich et al. *IDWeek* 2015
Taylor et al. *IDWeek* 2016
Antibiotic-Related Outcomes

- 80% of cultures from a urine sample
- 85% of the antibiotic use in the 3 NHs was empiric (before cultures)
  - 54% involved a fluoroquinolone antibiotic
  - 65% of episodes associated with discordant (inappropriate) therapy
- Making antibiogram available reduced inappropriate use to 55%

Drinka et al. JAMDA 2013; 14(6): 443
Furuno et al. Infect Control Hosp Epidemiol 2014
Specific Regulatory Language

• ASP composition, governance and responsibilities

• Facilities will develop and implement an ASP protocol (policy) that includes the following:
  1. How program will be integrated into facility IPCP
  2. Frequency of program review
  3. Description of the procedures for establishing infection
  4. Description of expected antibiotic prescribing practices
  5. Description of antibiotic use and resistance outcome monitoring procedures and how these data will be communicated to facility staff and providers
  6. Method and frequency of staff/prescriber education
Focus on treatment of common infections (PUS)

Emphasize alternatives to problematic antibiotics in older adults (e.g., fluoroquinolones, macrolides, clindamycin, TMP/SMX)

Emphasize benefits of short-course therapy (most infections can be treated with ≤7 days of therapy)

Nursing education: https://www.coursesites.com/webapps/Bb-sites-course-creation-BBLEARN/courseHomepage.htmlx?course_id=_348931_1

How Can External ID & Pharmacy Stewards Help NHs?

• Facility assessment and improvement target identification
• Guidance on how facilities can best harness existing utilization data
• Guidance on which outcomes to track and how
  • Antibiogram?
• Development of antibiotic use protocols
  • Testing protocols
  • Treatment protocols for common infections (when/how to treat)
  • Testing/prescribing practices to avoid (test-of-cure UCx, suppressive Abx)
• Staff and provider education
• Detailing of outlier providers
Thank You

See Table 1 for good list of additional resources