Example 1.1 Children's Hospital & Research Center Oakland ASP Policy/Procedure (1 of 14)

Title: Antimicrobial Stewardship Program (ASP)	
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Owner/Responsible person: Infection Control Committee	**Title:** Antimicrobial Stewardship Program (ASP)

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SECTION I. PURPOSE

To establish an organization-wide program called the Antimicrobial Stewardship Program (ASP) which promotes the appropriate use of antimicrobial agents at Children's Hospital & Research Center Oakland (CHRCO). The goal of the ASP is to optimize clinical outcomes while minimizing the unintended consequences of inappropriate antimicrobial use including:

1. The development of antibiotic resistance and antibiotic-resistant infections
2. The selection of other pathogenic organisms such as *Clostridium difficile*
3. Medication toxicity
4. Excess healthcare costs

Antimicrobial stewardship is an essential component of patient safety and quality of care. As such, the development of ASPs has been endorsed by a number of professional organizations, including the American Academy of Pediatrics and the Pediatric Infectious Disease Society.[1]

In addition, the establishment of an institutional ASP is a "best practice"[2,3] process that complies with the following mandates:

1. California Senate Bill California Senate Bill No. 739 (approved in September 2006) and Senate Bill No. 158 (approved in September 2008) which require that "...general acute care hospitals develop a process for evaluating the judicious use of antibiotics..."
2. The Joint Commission's 2010 National Patient Safety Goal (07.03.01): implement evidence-based practices to prevent health care-associated infections due to multidrug-resistant organisms in acute care hospitals (including but not limited to methicillin-resistant *Staphylococcus aureus* (MRSA), *C. difficile*, vancomycin-resistant *Enterococcus* (VRE), and multidrug-resistant gram-negative (MDR-GN) bacteria), including the following Elements of Performance:
    a. Measure and monitor multidrug-resistant organism prevention processes and outcomes, including the following: (Scoring category A)
        i. Multidrug-resistant organism infection rates using evidence-based metrics
        ii. Compliance with evidence-based guidelines or best practices
        iii. Evaluation of the education program provided to staff and licensed independent practitioners
    b. Implement policies and practices aimed at reducing the risk of transmitting multidrug-resistant organisms. These policies and practices meet regulatory requirements and are aligned with evidence-based standards (for example, the Centers for Disease Control and Prevention (CDC) and/or professional organization guidelines). (Scoring category C)

SECTION II. RATIONALE

Antimicrobial resistance has been on the rise in both the community and hospital settings. Antibiotic-resistant infections (ARI) in the hospital have been associated with increased morbidity and mortality for patients.[4,5] Currently >70,000 deaths annually in the U.S. are due to health care-acquired, drug-resistant infections. In fact, more people now die of MRSA in U.S. hospitals than of HIV/AIDS and tuberculosis combined.[6]

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Despite the rise in ARI, the development of new antimicrobial agents has progressively declined over the past three decades. The lack of novel drugs with which to treat the growing threat of ARI has led to a global and national crisis. In fact, the World Health Organization has identified antibiotic resistance as one of the three greatest threats to human health, and antibiotic resistance is considered a major threat to both public health and national security by the Institute of Medicine, Interagency Task Force on Antimicrobial Resistance (which involves the CDC, Food and Drug Administration, National Institutes of Health, Agency for Healthcare Research and Quality, Centers for Medicare & Medicaid Services, Health Resources and Services Administration, Department of Agriculture, Department of Defense, Department of Veterans Affairs, and Environmental Protection Agency), and the Infectious Diseases Society of America.[7,8]

Because the inappropriate use of antimicrobial agents creates the selective pressure which drives the rates of resistance, there has been a growing recognition that antimicrobial effectiveness must be regarded as a limited resource that should be preserved through judicious use of our currently available drugs, i.e. antimicrobial stewardship.

SECTION III. ANTIMICROBIAL STEWARDSHIP PROGRAM CORE MEMBERS

The Director of the ASP must have expertise in pediatric infectious diseases and will be appointed by the hospital administration based on the recommendation of the Executive Committee of the Medical Staff (MEC) and the Director of the Division of Infectious Diseases. The Director of the ASP will also serve as the chair of the Antimicrobial Stewardship Committee (ASC), which is a subcommittee of the Infection Control Committee and a committee of the MEC.

The Antimicrobial Stewardship Committee (ASC) oversees the organization-wide effort to promote and evaluate the appropriate use of antimicrobial agents. The ASC is a multidisciplinary group that includes the following core members:

1. Director of the ASP (Pediatric infectious disease specialist)
2. At least (3) members of the Medical Staff with representation from the Pediatric Intensive Care Unit, Neonatology, Hospitalist Group, Emergency Medicine, Hematology/Oncology, Surgery, and/or Community Pediatrics
3. Chief resident
4. At least one (1) representative from Hospital Administration, Patient Safety, and/or Quality Assurance
5. Pharmacist with infectious disease training
6. Infection preventionist
7. Clinical microbiologist
8. Hospital epidemiologist
9. Information system specialist/data analyst

Responsibilities of the ASC include the following:

1. Develop and review policies and clinical guidelines related to appropriate use of antimicrobial agents (including drug choice, dose, route and duration).
2. Monitor compliance with policies and clinical guidelines.
3. Evaluate effectiveness of intervention efforts including monitoring of antimicrobial utilization and clinical outcomes.

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4. Review trends in antibiotic resistance patterns. Develop a system for routine monitoring of antimicrobial resistance rates to detect significant increases or outbreaks and to identify areas where additional interventions or resources are needed.
5. Review current literature with respect to appropriate antimicrobial utilization on an ongoing basis and incorporate strategies into practice as indicated
6. Assure that policies and interventions are consistent with regulatory requirements and state law.

The ASC will meet no less than 4 times a year, except by approval of the Medical Staff and Hospital Administration. The ASC shall maintain a record of its proceedings and shall submit reports of its activities and recommendations to the Medical Executive Committee. The ASC will also forward periodic reports to the Infection Control Committee, Pharmacy and Therapeutics Committee, Patient Safety Committee and Best Practices Committee for review, action and quality improvement.

SECTION IV. COMPONENTS OF THE ANTIMICROBIAL STEWARDSHIP PROGRAM

1. Hospital formulary:

The Pharmacy & Therapeutics (P&T) Committee maintains a comprehensive list of antimicrobial agents that are included in the hospital formulary. This list is reviewed and updated annually in collaboration with the ASP. When new antimicrobial agents are under consideration for the hospital formulary, the ASP will provide recommendations to the P&T Committee. Requests for nonformulary antimicrobial agents will require preauthorization by the ASP or Infectious Diseases (ID) prior to release by Pharmacy.

2. Formulary restriction and preauthorization

Formulary restriction with preauthorization is an additional means of limiting inappropriate use of antimicrobials, particularly broad-spectrum agents, last-line agents, or agents with concerning toxicities. The list of restricted agents will be reviewed and updated annually by the P&T Committee in collaboration with the ASP (see Appendix A for current list). Use of restricted antimicrobial agents will require preauthorization by the ASP or ID prior to release by Pharmacy.

Formulary restriction:

a. The ASP will review the antimicrobial formulary list and the list of restricted agents annually and will provide recommendations to the P&T Committee regarding changes.
b. The P&T Committee will review and approve the antimicrobial formulary and the list of restricted agents annually.

Preauthorization Procedure:

a. Physicians will prescribe antimicrobial agents via the computerized order entry system.
b. Computerized order entry system will alert the prescribing physician and pharmacy when a restricted or nonformulary antimicrobial agent is ordered.
c. Prescribing physician must contact the ASP or on-call attending ID physician to justify use of "restricted" or "nonformulary" agents and to discuss possible alternatives.

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d. The ASP or attending ID physician will contact Pharmacy and confirm the type of approval given:
Category 1: Approval for a defined course of therapy.
Category 2: Approval for 48 hours pending consultation. ASP or ID consultation will be required for agent to be continued beyond 48 hours.
Category 3: Approval denied. An alternative regimen has been recommended by the ASP or attending ID physician and agreed upon by the prescribing physician.
e. Pharmacy will not release any restricted or nonformulary antimicrobial unless the ASP or attending ID physician provides Category 1 or 2 approval. Pharmacy will document the following in the pharmacy profile notes: approval category, name of ASP or attending ID physician, date/time.

3. Prospective audit with intervention and feedback:

Prospective audit of antimicrobial use with intervention and feedback to the prescriber has been demonstrated to improve appropriate antimicrobial use. This process allows the opportunity for one-on-one education for prescribing physicians. This program will be available 5-7 days a week on inpatients at CHRCO. Opportunities to optimize antimicrobial therapy will be prospectively identified via several approaches:

a. Review of daily antimicrobial usage logs and culture reports to identify
- Inappropriate choice
  1. Use of nonformulary or restricted agents without prior approval
  2. Use of >2 antibiotic agents concurrently
  3. Inappropriately broad or narrow therapy
  4. Bug/drug mismatches
  5. Redundant coverage
- Inappropriate dosing
- Inappropriate route
- Inappropriate duration

b. Review of daily antibiotic usage logs to identify targeted antibiotics that remain in use for >2 days. See Appendix B for the list of targeted antimicrobial agents. This list will be reviewed and updated annually by the ASP.

Procedure:

a. After identification of patients for whom there may be opportunities for antimicrobial optimization, ASP personnel will review the patient's medical record to assess the rationale behind the current treatment regimen, including antibiotic selection, dosing, route, and duration. Families will not be interviewed and patients will not be examined during this process.
b. ASP personnel will formulate recommendations based on the best-available evidence from the medical literature, including published consensus treatment guidelines and/or expert opinion.
c. If the current treatment plan is justified, then no intervention will be made.
d. If there is an opportunity for optimization, then ASP personnel will contact the attending physician by telephone or in person to discuss the ASP's recommendations.

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e. If the ASP's recommendations are accepted or a mutually acceptable plan is agreed upon, then a brief note will be placed in the patient's chart outlining the recommendations and the rationale.
f. If the ASP's recommendations are not accepted and no agreement is reached, then documentation will NOT be placed in the medical record. The prescribing physician will be asked to consider an Infectious Disease Consultation.
g. When inappropriate antimicrobial use is continued despite the above discussions, the case will be referred to the peer review process. Appropriate use of antimicrobial agents is considered a measure of the quality of patient care, and inappropriate use will be noted in the prescribing physician's performance record.
h. If the patient's clinical situation is complex and/or requires interview of the family or examination of the patient in order to determine an appropriate recommendation, intervention by the ASP will be deemed inappropriate, and a recommendation will be made to obtain an Infectious Disease Consultation.

4. Antimicrobial stewardship consultation:

Physicians may directly request an antimicrobial stewardship consultation from the ASP when there is a focused question regarding antimicrobial selection, dose, route, and/or duration.

a. Upon request, the ASP personnel will review the patient's medical record to assess the clinical scenario. Families will not be interviewed and patients will not be examined during this process.
b. ASP personnel will formulate recommendations based on the best-available evidence from the medical literature, including published consensus treatment guidelines and/or expert opinion.
c. ASP personnel will contact the requesting physician by telephone or in person to discuss the ASP's recommendations.
d. If the ASP's recommendations are accepted or a mutually acceptable plan is agreed upon, then a brief note will be placed in the patient's medical record outlining the recommendations and the rationale.
e. If the ASP's recommendations are not accepted, then documentation will NOT be placed in the medical record. A recommendation will be made to consider an Infectious Disease Consultation.
f. If the patient's clinical situation is complex and/or requires interview of the family or examination of the patient in order to determine an appropriate recommendation, intervention by the ASP will be deemed inappropriate, and a recommendation will be made to obtain an Infectious Disease Consultation.

5. Clinical practice guidelines:

The development of hospital-specific clinical practice guidelines can standardize antibiotic usage and reinforce the principles of antimicrobial stewardship while optimizing patient care. This effort will be spearheaded by the ASP but will require close multidisciplinary collaboration and communication with the relevant disciplines to ensure that practices remains consistent with national guidelines, standards of care and/or expert opinion.

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a. Development of a clinical practice guideline for a specific diagnosis may be initiated by the ASP or may be requested by specific divisions or departments.
b. ASP personnel in collaboration with representatives from the relevant divisions or departments will review the medical literature related to the topic and may survey other pediatric institutions regarding their practices. If other institutions have a clinical practice guideline available, this too may be reviewed by the ASP.
c. ASP personnel in collaboration with representatives from the relevant divisions or departments will develop a draft clinical practice guideline that takes into consideration the best-available evidence from the medical literature (including published consensus treatment guidelines and/or expert opinion) as well as hospital-specific antibiotic resistance patterns and patient population.
d. The draft guideline will be reviewed and approved by the ASP and the appropriate divisions/departments as well as the Best Practices Committee.
e. Once completed, clinical practice guidelines will be incorporated into the computerized physician order entry system.
f. Approved clinical practice guidelines will be reviewed and updated every 2 years (or more frequently if there is a significant change in practice due to a change in the standard of care, in available antimicrobial agents, or in antibiotic resistance patterns).

6. Physician education:

In conjunction with the active strategies described above, ongoing education of the medical staff is an essential element of the ASP and can have a significant impact on antimicrobial prescribing behavior. Education can provide a foundation of knowledge to clinicians that will enhance and increase acceptance of antimicrobial stewardship strategies. ASP personnel will regularly participate in educational activities to highlight the importance of antimicrobial stewardship and to provide clinicians with practical strategies for optimizing antimicrobial use for their patients. Educational components may include:

- Regular participation in patient rounds throughout the hospital
- Production and dissemination of annual hospital antibiogram with inclusion of general cost information on antimicrobial agents
- Grand Rounds for community pediatricians
- Noon conferences for resident physicians and hospital-based medical staff
- Periodic emails to medical staff with antibiotic stewardship tips
- Participation in or presentations to divisional/departmental meetings, QA and/or M&M conferences when questions arise related to appropriate antimicrobial use

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SECTION V: PERFORMANCE MEASURES

Monitoring the impact of the ASP is an important component of quality improvement for the both the program and hospital. "Process" measures will be used to determine whether ASP interventions have had impact on the utilization of antimicrobials. "Outcome" measures will be used to determine if process changes have reduced or prevented the unintended consequences of antimicrobial use. The measurement strategies will be based on evidence-based guidelines and/or recommendations from professional organizations and regulatory agencies.

a. Process measures
   - Track utilization of targeted antimicrobials
   - Track utilization of antimicrobial agents for specific diagnoses

b. Outcome measures
   - Track trends in the antibiotic resistance patterns for target organisms (*Enterococcus* species, *S. aureus*, *Klebsiella* species, *Acinetobacter* species, *Pseudomonas aeruginosa*, & *E. coli*) hospital-wide and for high-risk units (5 South, 5 East, PICU, NICU)
   - Track incidence of health care-associated infections due to antibiotic-resistant target organisms hospital-wide and for high-risk units
   - Track incidence of health care-associated *C. difficile* infections hospital-wide and for high-risk units
   - Track relevant clinical outcome measures for specific diagnoses
   - Track incidence of adverse drug events related to antimicrobial agents
   - Track pharmacy drug acquisition costs for all antimicrobial agents and specific target agents

c. Other measures
   - Track number and types of interventions made by the ASP
   - Track compliance with ASP interventions
   - Track cost savings from ASP interventions

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SECTION VI: REFERENCES

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Approval Process:

Date	Committee/Legal	
	Infection Control Committee	
	Medical Executive Committee	

Distribution:

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Appendix A: Antimicrobial Formulary
(Restricted Agents and Approval Required in Italics)

Intravenous Antibiotics

Aminoglycoside
- *Amikacin (ASP/ID approval)*
- Gentamicin
- Tobramycin

Carbapenem
- *Ertapenem (ASP/ID approval)*
- *Meropenem (ASP/ID or Onc approval)*

Cephalosporin 1st generation
- Cefazolin

Cephalosporin 2nd generation
- Cefoxitin
- Cefuroxime

Cephalosporin 3rd generation
- Cefotaxime
- Ceftazidime
- Ceftriaxone

Cephalosporin 4th generation
- *Cefepime (ASP/ID or Onc approval)*

Fluoroquinolone
- *Ciprofloxacin (ASP/ID approval)*

Glycopeptide
- Vancomycin

Lincosamide
- Clindamycin

Macrolide
- Erythromycin

Monobactam
- *Aztreonam (ASP/ID approval)*

Nitroimidazole
- Metronidazole

Oxazolidinone
- *Linezolid (ASP/ID approval)*

Penicillin
- Ampicillin
- Ampicillin/Sulbactam
- Oxacillin
- Penicillin G
- Piperacillin
- *Piperacillin/Tazobactam (ASP/ID or Pulm approval)*
- *Ticarcillin/Clavulanate (ASP/ID or Pulm approval)*

Sulfonamide
- *TMP-SMX (ASP/ID approval for IV form)*

Tetracycline
- *Doxycycline (ASP/ID approval for IV form)*

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Oral Antibiotics

Cephalosporin 1st generation
- Cephalexin

Cephalosporin 2nd generation

Cephalosporin 3rd generation
- Cefixime

Fluoroquinolone
- *Ciprofloxacin (ASP/ID or Pulm approval)*

Lincosamide
- Clindamycin

Macrolide
- Azithromycin
- Clarithromycin
- Erythromycin

Nitrofu
- Nitrofurantoin

Nitroimidazole
- Metronidazole

Penicillin
- Amoxicillin
- Amoxicillin/Clavulanate
- Dicloxacillin
- Penicillin VK

Sulfonamide
- TMP-SMX

Tetracycline
- Doxycycline

IV Antiviral
- Acyclovir
- *Foscarnet (ASP/ID approval)*
- *Ganciclovir (ASP/ID approval)*

PO Antiviral
- Acyclovir
- Amantadine
- Oseltamivir
- Rimantadine
- *Valganciclovir (ASP/ID approval)*

HIV meds
- Combivir (AZT/3TC)
- Zidovudine (AZT)
- Lamivudine (3TC)
- Lopinavir/ritonavir
- Nelfinavir

IV Antifungal
- Amphotericin B
- Liposomal Amphotericin (Ambisome)
- Fluconazole
- *Micafungin (ASP/ID or Onc approval)*
- *Voriconazole (ASP/ID or Onc approval)*

PO Antifungal
- Clotrimazole
- Fluconazole
- Griseofulvin
- Nystatin
- *Voriconazole (ASP/ID or Onc approval)*

Antimalarial meds
- Chloroquine
- Primaquine
- Quinidine gluconate (IV)
- Quinine sulfate (PO)

TB meds
- *Ethambutol (ASP/ID approval)*
- Isoniazid
- *Pyrazinamide (ASP/ID approval)*
- *Rifampin (ASP/ID approval)*

Misc
- Albendazole
- Pentamidine (IV)

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Appendix B: Targeted Antimicrobial Agents

Ampicillin/sulbactam
Piperacillin
Piperacillin/tazobactam
Ticarcillin
Ticarcillin/clavulanate

Ceftriaxone
Cefotaxime
Ceftazidime
Cefepime

Meropenem

Vancomycin
Clindamycin

Gentamicin
Tobramycin

Ciprofloxacin

Acyclovir

Amphotericin B
Liposomal Amphotericin
Micafungin
Voriconazole

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Appendix C: Table of Legislative and Regulatory Mandates

SB 739: Hospital Infectious Disease Control Program	
Sec 2 [1288.8]a.4	**Judicious Use of ABX:** CDPH to require that general acute care hospitals develop a process for evaluating the judicious use of antibiotics, the results of which shall be monitored jointly by appropriate representatives and committees involved in quality improvement activities.

SB 158: Hospital Infection Control	
Sec 6.a.3	**Judicious Use of ABX:** SB 739 language repeated

TJC NPSG.07.03.01: Implement evidence-based practices to prevent health care-associated infections due to multidrug-resistant organisms in acute care hospitals. Note: This requirement applies to, but is not limited to epidemiologically important organisms such as MRSA, *C. difficile*, VRE, and MDR-GN bacteria.		
	Elements of Performance	
1.	Conduct periodic risk assessments (in time frames defined by the hospital) for multidrug-resistant organism acquisition and transmission.	A
2. M	Based on the results of the risk assessment, educate staff and licensed independent practitioners about health-care associated infections, multidrug-resistant organisms, and prevention strategies at hire and thereafter.	C
3. M	Educate patients, and their families as needed, who are infected or colonized with a multidrug-resistant organism about health care-associated infection strategies.	C
4.	Implement a surveillance program for multidrug-resistant organisms based on the risk assessment.	A
5.	Measure and monitor multidrug-resistant organism prevention processes and outcomes, including the following: - Multidrug-resistant organism infection rates using evidence-based metrics - Compliance with evidence-based guidelines or best practices - Evaluation of the education program provided to staff and licensed independent practitioners	A
6.	Provide multidrug-resistant organism process and outcome measure data to key stakeholders, including leaders, licensed independent practitioners, nursing staff, and other clinicians.	A
7.	Implement policies and practices aimed at reducing the risk of transmitting multidrug-resistant organisms. These policies and practices meet regulatory requirements and are aligned with evidence-based standards (for example, the Centers for Disease Control and Prevention (CDC) and/or professional organization guidelines).	C
8.	When indicated by the risk assessment, implement a laboratory-based alert system that identifies new patients with multi-drug-resistant organisms.	A
9.	When indicated by the risk assessment, implement an alert system that identifies readmitted or transferred patients who are known to be positive for multi-drug-resistant organisms.	A
	M=indicates measure of success if needed **A=y/n req. 100% compliance** **C=frequency based req. 90% compliance**	

TJC NPSG.07.05.01: Implement evidence-based practices for preventing surgical site infections.		
	Elements of Performance	
1. M	Educate staff and LIPs involved in surgical procedures about SSI and the importance of prevention. Education occurs upon hire annually thereafter, and when involvement in surgical	C

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	procedures is added to an individual's job responsibilities.	
2. M	Educate patients and their families, as needed, who are undergoing a surgical procedure about surgical site infection.	C
3. M	Implement policies and practices aimed at reducing the risk of SSI. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (for example, CDC and professional organization guidelines).	C
4.	As part of the effort to reduce SSI: • Conduct periodic risk assessments for surgical site infection in a time frame determined by the hospital • Select SSI measures using best practices or evidence based guidelines • Evaluate the effectiveness of prevention efforts • Note: surveillance may be targeted to certain procedures based on hospital's risk assessment	A
5.	Measure SSI rates for the first 30 days following procedures that do not involve inserting implantable devices and for the first year following procedures involving implantable devices. Measurement strategies follow evidence-based guidelines. Note: surveillance may be targeted to certain procedures based on the hospital's risk assessment.	A
6.	Provide process and outcome measure results to key stakeholders.	A
7. M	Administer antimicrobial agents for prophylaxis for a particular procedure or disease according to evidence-based best practices.	C
8.	When hair removal is necessary, use clippers or depilatories. Shaving is an inappropriate hair removal method.	A
	M=measure of success if needed **A=y/n req. 100% compliance** **C=frequency based req. 90% compliance**	

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