ANTIMICROBIAL STEWARDSHIP PROGRAM PROPOSAL SAMPLE

Background

Currently, the antimicrobial expenses at HOSPITAL, excluding antiretroviral medications, is approximately $XX million dollars per year, in the acute care setting. Another $XXX is being spent annually in the outpatient setting. However, there are significant costs associated with antimicrobial costs that are not reflected in the purchasing expenses for antimicrobial use.

Inappropriate selection leads to therapeutic failures which prolong length of stay and necessitate use of additional drugs, lab tests and other resources. Parenteral antimicrobial use of antibiotics contributes to IV related complications, again impacting quality of care and increasing consumption of resources unnecessarily. Developing antimicrobial resistance also reduces the effectiveness of antimicrobial use and increases resource consumption. Clearly, a program to make wiser use of antibiotics and limit antibiotic resistance has the potential to make a large favorable impact on patient outcome at HOSPITAL.

The costs of antimicrobial resistance may have the most significant impact on costs. Globally and regionally, the use of antimicrobial agents is the key driving force for the emergence of antimicrobial resistance. Antibiotic resistance is of increasing prevalence amongst gram-positive and gram-negative bacteria as well as fungal pathogens in both the community and hospital settings.

In recent years HOSPITAL has experienced a significant increase in the prevalence of antibiotic resistant pathogens. In 1995 each case of VAP was associated with an excess cost of $XXX Numerous well-performed studies have documented that antimicrobial resistance results in increased morbidity, mortality, and cost. The Institute of Medicine estimates that the annual cost of treating antibiotic resistant infections in the United States may be as high as $30 billion dollars. Examples of the impact of antibiotic resistance include the following: Abramson, et al observed that a case of MRSA (methicillin-resistant *Staphylococcus aureus*) bacteremia cost approximately $17,000 more than a case of bacteremia due to MSSA. Rubin et al, found that attributable mortality for bacteremia due to MRSA compared to that due to MSSA was 21% vs 8%. Linden found, that in a population of liver transplant patients, the attributable mortality for VRE (vancomycin-resistant enterococci) bacteremia vs VSE bacteremia was 46% vs 25%. Kollef observed that patients treated for ventilator-associated pneumonia (VAP) with inadequate antimicrobial therapy (due to antibiotic resistance) had a mortality rate of 60.8% compared to 33% for those treated with antibiotics to which the pathogen was sensitive. The most recent data (2000) from the CDC National Nosocomial Surveillance System indicate that approximately 47% and 54% of nosocomially-acquired *S. aureus* strains are methicillin resistant in non-ICU patients and ICU patients respectively. In addition, the prevalence of MRSA is rising steeply. Similar trends are evident for vancomycin-resistant enterococci.

Studies have shown joint, infectious-pharmacy programs for managing antimicrobial programs produce significant benefits in terms of both quality of care and cost effectiveness. A program at the Departments of Infectious Diseases and Pharmacy at the Oklahoma City Veterans Administration Medical Center (VAMC) produced not only reduction in product costs, but also reductions in length of stay and mortality. Analysis of clinical outcomes and antimicrobial costs revealed a 2.4 reduction in length of stay and a reduction in infection related mortality from 8.28 percent to 6.61 percent. Additionally, the institution experienced an 11.8 percent reduction in antimicrobial acquisition costs, after adjustments for change in census.

A similar program at Summa Health System in Akron, Ohio produced similar results. During an eight month period, the physician and pharmacist team intervened in 953 cases. The most common actions taken by the team included:

1. Changing the antibiotics for better coverage.
2. Modifying the iv dose, frequency and/ or duration of treatment.
3. Conversion of parenteral antibiotics to oral antimicrobial drugs.

As a result, the program produced a reduction in antimicrobial costs of $7.66 (10.4%) per discharge.

Other programs have reported a 0.5 day reduction in length of stay with the implementation of IV to PO conversion programs. While HOSPITAL has implemented an IV to PO conversion program, the implementation of Antimicrobial Stewardship programs enhances the impact of the programs. The formal stewardship program helps to resolve those more difficult conversions that have high impact on utilization.

Proposed Program:

We proprose establishment of an antimicrobial management program (formally Antimicrobial Stewardship Program) at HOSPITAL. The program elements will include:

1. We propose hiring a staff of infectious disease trained professionals to focus specifically on antimicrobial use in the institution. The program personnel will spend their time monitoring specifically monitoring, evaluating and intervening on management of antimicrobial therapy. Program personnel will include:
   a. one infectious diseases faculty member. The faculty member will commit 75% of his/ her budgeted time to the program. HOSPITAL will assume responsibility for XX percent of the infectious diseases faculty member's salary and benefits. This will limit the ID service's ability to distract the individual's focus on the program. The cost to HOSPITAL is estimated at $XXX.
   b. one infectious disease-trained pharmacist. The pharmacist will commit 100% of his/ her time to the program. The cost to HOSPITAL is estimated at $XXX.
   c. Program personnel will be supplemented by PharmD students, ID fellows, residents, medical students, etc. The program will be a popular clerkship rotation for students, residents and fellows.

2. Program personnel will develop and maintain an antimicrobial use, sensitivity and outcomes database. The program personnel will use the database to guide a dynamic antimicrobial formulary process that will assure appropriateness of availability antimicrobial agents relative to documented sensitivity patterns and antimicrobial treatment outcomes.
3. Program personnel will accrue evidence documenting antimicrobial regimens that permit the optimal patient outcomes and cost effectiveness. Program personnel will publish information and conduct training for health care personnel to assure rapid disssemination of the evidence accrued and help to establish standards of practice.
4. Program personnel will develop and maintain an approval process for criteria managed antimicrobial and non-formulary drugs with the objective of optimizing antimicrobial effectiveness.
5. All Antimicrobial medication orders will be reviewed by the pharmacist. The pharmacist will review all antimicrobial orders and culture and sensitivity reports on a daily basis. The pharmacist will round with the ID faculty member on high risk cases. Program personnel will be given authority to approve initiation, continuation or discontinuation of non-formulary or criteria managed antimicrobial drugs.
6. The ID physician will interact with the prescriber on the more difficult cases.
7. The Antimicrobial Management Team will maintain utilization data on antimicrobial data and antimicrobial sensitivity, and make recommendations to the P&T committee on changes to the antimicrobial formulary in response to changes in sensitivity patterns.

Goals of the program will be to:

1. Decrease selective pressure for the emergence of antibiotic resistance microbes.
2. Optimize utilization of antimicrobial agents in order to realize improvement in patient outcomes and economic benefit. This program should be coordinated with existing infection control efforts in order to significantly decrease the prevalence of antibiotic resistant pathogens at HOSPITAL.
3. Increase effectiveness and timeliness of antimicrobial formulary management by:
4. Eliminating redundant/unnecessary antimicrobials by:
    a. Responding to emergence of resistance to antimicrobial drugs by recommending alternations to the formulary of available antimicrobial drugs,
    b. Instituting therapeutic interchanges where appropriate and advantageous, and
    c. Instituting antibiotic restrictions/usage guidelines where appropriate and advantageous (e.g. drotrecogin approval process, vancomycin stop orders)
5. Expansion and Optimization of IV to po conversion plan
6. Initiate focused program in 1 high use area. This program would be individualized for the specific unit or patient population and could include protocols for prophylaxis, guidelines for empiric therapy, or innovative utilization programs (cycling, selective decontamination, etc). Outcome determinants in the specific unit could include measures of infectious morbidity, antibiotic use, rates of resistance, length of stay. Examples of units and programs that could benefit greatly from an antibiotic stewardship program include the following:
    a. Bone marrow transplant unit

b. Solid organ transplant service
c. ICU (adult)
d. ICU (other – NICU, PICU, Hemodialysis, etc)
e. Surgical Prophylaxis

7. Initiate CDC 12-step antimicrobial utilization campaign throughout HOSPITAL (inpatient and outpatient)
8. Apply for extramural support for 1 project
9. Coordinate antibiotic stewardship program with ongoing infection control efforts directed at antimicrobial resistant pathogens (MRSA, VRE, ESBL-producing *Enterobacteraciae,* etc) regarding focused surveillance, isolation, tracking.

In each of these program areas baseline measures will be taken and assessment of outcome will be performed. In some areas baseline data is lacking and part of the program will be to optimize data gathering and analysis.

Benefits/ Measures of Outcome: The Pharmacy and Therapeutics committee Antimicrobial Subcommittee will serve as an Advisory steering committee for program personnel. Program personnel will be assigned to the Subcommittee as staff and will be accountable for documenting outcomes of the program by monitoring at least the following indicators.

- Reduction in antibiotic use (defined daily dose/pt census, antibiotic budget). Experiences at other institutions have shown a reduction in antimicrobial drug use. Patients receive fewer antimicrobial drugs due to reductions in the need to re- treat therapeutic failures. Duration of IV drug therapy will decrease because the program will emphasize identification of opportunities to treat patients with non-parenteral dosage forms. Note: a 10% reduction in antimicrobial use equates to $XXX from the acute care environment per year. We expect an additional 5.5 percent increase in savings per year, based on projected price increases in drug product that will be avoided.
- Reduction in prevalance of antimicrobial resistance prevalence (MRSA, VRE, ESBL, multi-resistant gram negative bacilli). However, it must be recognized that antibiotic resistance is a complex multidimensional problem that is dependent on factors in the community, other facilities, and the environment. It is anticipated that appropriate antibiotic usage will have some beneficial impact on this problem, but other factors, outside the control of the antibiotic stewardship program, may counteract these effects.
- Reduction in hospital length of stay. Reductions in antimicrobial resistance will result in diminished need to retreat patients with therapeutic failures from antimicrobial failures and the concommitant increased duration of hospital stays. Our target level will be an average reduction of 0.5 day in length of stay. Seventeen percent of our acute care drug expenditures are for antimicrobial drugs. Assuming a 17 percent of our case load receives antimicrobial drugs, and a 10 percent efficiency level, $XXX incremental income will accrue to the hospital in the first year of the program. Our objective will be to increase our efficiency level to 25 percent in five percent increments per year. At that level, HOSPITAL will achieve incremental

income of $XXX per year. Over a four year period, the proposed program will yield a net present value of $XXX at discount rate of two percent.

- Reduced incidence of *Clostridium difficile* associated colitis: This will contribute to reductions in both length of stay.
- Antibiotic toxicity, side effects, drug interactions:
- Publication in peer-reviewed literature:
- Improved antimicrobial effectiveness:

Future Plans

- Outcomes research programs and extramurally-funded programs
- Investigator initiated and industry initiated antibiotic treatment protocol
- Development of regional consultation program in antibiotic utilization
- Collaboration with XXX regarding antibiotic audits and utilization programs