Evaluation and Research on Antimicrobial Stewardship's Effect on *Clostridium difficile* (ERASE *C. difficile*) Project

Toolkit for Reduction of Clostridium difficile Through Antimicrobial Stewardship

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Toolkit on Antimicrobial Stewardship To Reduce *C. difficile* Infection

Overview

Clostridium difficile infection (*C. difficile*) is a serious public health problem that has recently increased in both incidence and severity. Centers for Disease Control and Prevention (CDC) surveillance data show that U.S. hospital discharges with *C. difficile* doubled between 2000 and 2003[1] and rates are highest in the northeastern United States.[2] Persons over age 65 years have been most affected, but recent changes in epidemiology suggest that lower risk populations, including healthy postpartum women and community dwellers with no recent healthcare contact or antimicrobial exposures, may also be affected.[3]

Further, there are indications of recent increases in the severity of *C. difficile*, including increased complications and *C. difficile*-related mortality. In addition to advanced age, the major risk factors for *C. difficile* are exposure to antimicrobials and hospitalization. Studies have found major costs associated with *C. difficile*, such as longer inpatient lengths of stay, and a significant increase in costs both for inpatient care and at 180 days after the initial hospitalization when the *C. difficile* occurred.[4]

Taking steps to reduce *C. difficile* is a major health and public health imperative. Twenty-seven States and the District of Columbia now require reporting of healthcare-associated infections to the National Healthcare Safety Network (NHSN).[5] Moreover, CDC's NHSN created a reporting module for *C. difficile* as part of its Patient Safety Component to encourage infection surveillance or laboratory-identified event reporting across hospitals nationwide.[6]

What is antimicrobial stewardship and how can it help us in reducing *C. difficile*?

Significant progress has been made in working to control *C. difficile* through targeted strategies such as infection prevention measures and environmental cleaning using a hypochlorite-based solution.[7] However, particularly as new resistant *C. difficile* strains emerge, the problem persists and additional strategies are needed. ***Antimicrobial stewardship*** targeted to *C. difficile* reduction shows promise as a complementary strategy for addressing the problem of *C. difficile*, because inappropriate antibiotic use may contribute to increased rates of *C. difficile*.

An **antimicrobial stewardship program (ASP) is a systematic approach to developing coordinated interventions to reduce overuse and inappropriate selection of antibiotics, and to achieve optimal outcomes for patients in cost-efficient ways.** Through both monitoring and, when necessary, altering current antimicrobial prescribing practices, antimicrobial stewardship has been shown to improve patient care, reduce antimicrobial use, reduce antimicrobial resistance, and reduce pharmacy, and overall hospital operating costs.[8]

How can this toolkit help us?

The aim of this toolkit is to assist hospital staff and leadership in developing an effective ASP with the potential to reduce *C. difficile*. It responds to the challenge facilities face as they translate guidelines into practice, in this case the implementation of an ASP. The toolkit:

- Is designed as a **companion to the Antimicrobial Stewardship Program toolkit** developed by the Greater New York Hospital Association (GNYHA) and the United Hospital Fund (UHF) for the New York State Department of Health, which supports the basic development and implementation of antimicrobial stewardship. The New York toolkit follows the **Roadmap to Stewardship** shown in **Figure 1**. This new toolkit assumes that your hospital already has components that make up the foundation for an ASP from which to launch the ASP targeted to *C. difficile* reduction.
- Is designed to help hospitals consider the **organizational changes and resources needed** to create and sustain an effective ASP for reducing *C. difficile*. The toolkit covers the full planning and implementation process from deciding to make changes to monitoring sustainability. While all the steps outlined here are important, some sections may be more relevant than others, depending on whether your hospital has an ASP framework on which to build and how you tailor your strategies and implementation to your needs, structures, and culture.

How do we use the toolkit?

This toolkit is organized by four major questions and multiple supporting questions that will guide you through the full process of developing, implementing, and sustaining an ASP for *C. difficile*. The four questions are:

1. Is our organization ready for an ASP to assist with *C. difficile* reduction efforts?
2. How do we determine which interventions for reducing *C. difficile* to implement?
3. How do we monitor the intervention and measure outcome?
4. How do we sustain the ASP for reducing *C. difficile* over time?

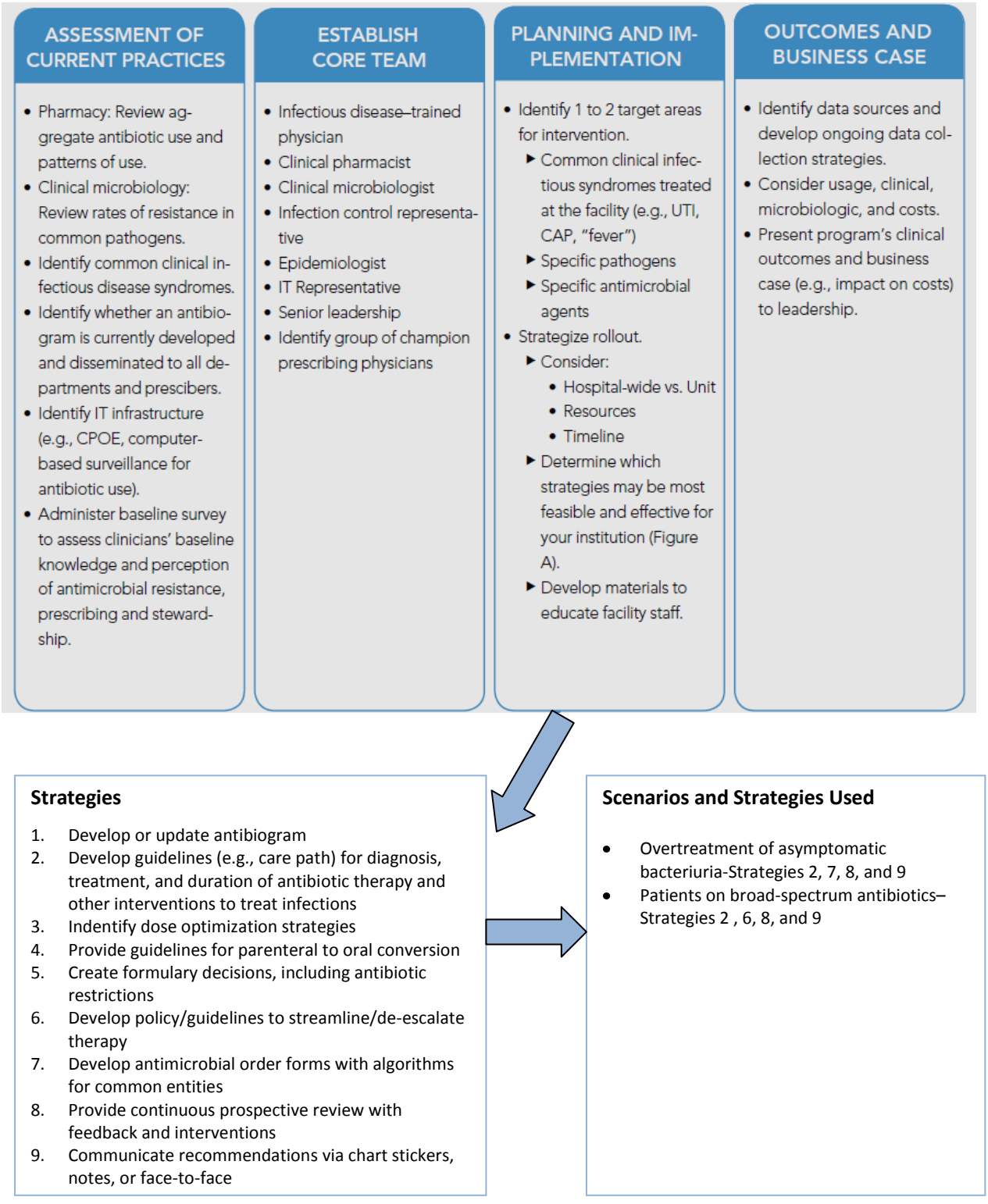
Each question has detailed discussion of the issues to be considered and references to tools and resources that will support the stewardship initiative. **Tools and other resources** are highlighted by a symbol: **Ø**.

How was the toolkit developed?

This toolkit was developed under a contract from the Agency for Healthcare Research and Quality (AHRQ) through its Accelerating Change and Transformation in Organizations and Networks (ACTION) initiative. Boston University School of Public Health (BUSPH) collaborated with Montefiore Medical Center (MMC) and GNYHA together with UHF to implement and evaluate ASP interventions to reduce *C. difficile*. The team worked with a collaborative of 10 New York hospitals that included 6 intervention sites and 4 nonintervention sites.

Despite the inability to demonstrate an association with reduced *C. difficile* rates in the time available, this project had many measured and unmeasured benefits. Among them, the project provided for growth and development of ASP infrastructures at each intervention site, measurable decreases in prescribing of target antibiotics at intervention facilities, and potential reduction of *C. difficile* with future ASP activities or with longer timeframes. The toolkit incorporates lessons learned from the experiences of the intervention hospitals, including facilitators of and barriers to building successful stewardship to reduce the use of antibiotics associated with high rates of *C. difficile*.

Figure 1. GNYHA/UHF Roadmap to Antimicrobial Stewardship



Source: Antimicrobial stewardship toolkit. New York, NY: Greater New York Hospital Association/United Hospital Fund; 2011. Available at: www.gnyha.org/antimicrobial/toolkit.

Questions To Consider in Developing an Antimicrobial Stewardship Program To Reduce C. difficile Infection

1. Is our organization ready for an ASP to reduce *C. difficile*?

An ASP for reducing *C. difficile* offers a potentially promising path for facilities invested in and committed to the effort. Developing and implementing a successful ASP will involve structural, process, and cultural changes in your organization. To effect the changes needed in clinical practice, organizations require multiple adjustments in roles, responsibilities, workflow, decisionmaking, and communication.

Failure to assess your organization's readiness for the change at multiple levels can lead to unanticipated implementation challenges. Bringing about organizational change of any type is difficult. You will not want to move ahead until you are confident of your organization's readiness. Even then, it will be important to balance the need to proceed thoughtfully with the need to move quickly enough to show progress and maintain momentum.

Consider the following questions as you evaluate your organization's readiness and identify action steps to prepare.

1.1. Do we have the appropriate ASP foundation on which to build?

This toolkit assumes that your hospital already has an ASP or the foundation for an ASP from which to launch the ASP targeted to promote appropriate antibiotic use and potential *C. difficile* reduction. Implementing and maintaining an effective ASP requires a dedicated multidisciplinary team and ongoing communication and collaboration as well as ongoing monitoring of systems. Further, ongoing monitoring may necessitate adjustments and corrections as you move forward.

Before going further, you should review your facility's current ASP or, if necessary, take steps to develop a basic ASP from which to target *C. difficile* reduction. To develop an ASP, you can use the GNYHA ASP toolkit. Also remember that antimicrobial stewardship is intended to complement other antibiotic prescribing practices and efforts to promote *C. difficile* prevention practices in your organization. You may also want to review the other prevention measures you have in place.

Is there an active ASP in place? Who are its members and how does it operate?

While team membership will vary among organizations, the traditional core ASP team should include an infectious disease physician and a PharmD with infectious disease training or experience. The clinical microbiologist, infection preventionist, hospital epidemiologist, information technology (IT) representative, and senior administrator will act as liaisons to support and supplement the core ASP team members. Ideally, the team should be supported by an in-house lab and IT resources.

A newer policy statement from the Society for Healthcare Epidemiology of America (SHEA) suggests expanding the team and allowing members without formal infectious disease training to be part of the ASP team. They can facilitate implementation of ASPs and related

activities at more health care facilities, including those that may have fewer resources. **Resource 1A** is the Policy Statement on Antimicrobial Stewardship by SHEA, the Infectious Diseases Society of America (IDSA), and the Pediatric Infectious Diseases Society.

Resources 1B, 1C, and 1D provide background information on ASPs that can serve as reference points for reviewing your current program's team members and activities. 1B is the GNYHA/UHF Antimicrobial Stewardship Toolkit. 1C is the IDSA and SHEA Guidelines for Developing an Institutional Program To Enhance Antimicrobial Stewardship. 1D contains examples of State and local stewardship programs.

Tool 1E can help you assess your current ASP staff resources and practices to determine whether you will need to strengthen the program to most effectively target *C. difficile*.

What other *C. DIFFICILE* prevention practices are in place?

A range of infection prevention and control practices have been effective in preventing *C. difficile*. **Tool 1F** highlights some of the common practices (and provides a reference for *C. difficile* clinical practice guidelines). You will need to consider how ASP can complement those efforts, or you may decide to strengthen some practices in conjunction with new antimicrobial targeting strategies.

Resources and Tools

- **1A RESOURCE:** SHEA/IDSA/PIDS Policy Statement. Policy Statement on Antimicrobial Stewardship by the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA), and the Pediatric Infectious Diseases Society (PIDS)
- **1B RESOURCE:** GNYHA/UHF Antimicrobial Stewardship Toolkit
- **1C RESOURCE:** Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program To Enhance Antimicrobial Stewardship
- **1D RESOURCE:** Examples of State and Local Stewardship Programs
- **1E TOOL:** Assessment of Current ASP Elements
- **1F TOOL:** Common Evidence-Based Infection Prevention Measures

1.2. What do we need to do before we begin to use our ASP to target C. difficile?

Even if you have a strong stewardship foundation in place, you will need to assess your facility's stage of readiness for targeting an ASP to *C. difficile* reduction. Developing an ASP to work toward reducing *C. difficile* will require a coordinated systems approach with readiness to change on many levels. Staff support and timing are important elements of assessing your facility's readiness.

You will need to begin the process of further developing your facility's ASP by addressing six questions about timing, readiness, and support from various components of your organization. You will need to cycle back to the last five questions throughout your change process. Reviewing these questions will reinforce communication with colleagues and stakeholders and strengthen answers about the clinical case, business case, and resources needed as you gather data and experience.

Do multiple disciplines understand why a structured ASP is needed? Is there an urgency to change?

Changing clinical practices and the organizational structures and processes to support new practices is difficult. There must be a strong motivation to change in order to successfully introduce new practices. You will need to identify a current and compelling reason that makes *now* the opportune time to undertake this initiative. Has some recent event brought attention to the problem of *C. difficile* rates and precipitated the desire to change?

Participating Facility Reflections

- A poor patient outcome, unrelated to *C. difficile*, prompted the facility to examine what was discovered to be a hospitalwide shift in susceptibilities. This discovery resulted in the development of new guidelines that, once instituted, resulted in a decrease in *C. difficile*.

There are many potential reasons to implement an ASP to bring about a reduction in *C. difficile*. Relevant statistics, potential negative patient outcomes, and financial considerations all offer support for establishing an ASP. But local reasons or cases may prompt a more tangible and immediate increase in awareness, with a concurrent desire to move to implement an ASP to reduce *C. difficile*. For example:

- Your facility experienced a significant increase or spike in *C. difficile* rates.
- New mandated reporting requirements bring additional external scrutiny to *C. difficile* rates.
- Your facility is responding to changes in insurance reimbursement policies.
- Your facility had a notable adverse event that was *C. difficile* related.
- Your facility has been the target of a legal action related to *C. difficile.*
- Your staff has personal experience of a family member affected by *C. difficile*.

While the motivation to change may be helped along by external factors, such as Federal mandates, it is most likely to be strong and persistent if all levels of the organization understand the concerns behind the planned change.

Do senior leaders and other key stakeholders support and provide guidance to planning and implementing an ASP?

While individuals who initiate the effort to reduce *C. difficile* through antimicrobial stewardship may have a clear understanding of the needed changes and the reasons for them, others may not. The level of knowledge and motivation in this area may vary greatly across the organization. Others in your hospital may have different reasons or may not understand the need to change, so it is important to define the issues and state the reasons that now is the time to institute this change. Laying the groundwork in this manner will help support a *C. difficile* reduction initiative through ASP.

It is crucial to ensure that your organization's leadership team and key stakeholders share the urgency to support development of an ASP to reduce *C. difficile* and are willing and able to provide support for this change effort. Lessons learned from other antimicrobial stewardship initiatives provide evidence that support is needed from both the top-level

administration and those at the bedside. **Tool 1G** provides a checklist that can help you assess the level of leadership support you have for an ASP to reduce *C. difficile.*

If senior leaders do not already support the effort to reduce *C. difficile* through strengthening ASP, you will need to build the case for change by framing the issues and your plans most effectively to gain their attention:

- For some leaders, such as your chief financial officer, it may be a business case: How much does *C. difficile* cost the hospital each year in terms, for example, of longer lengths of stay, additional staff time, increased readmissions, and actual medication costs?
- For senior clinical leaders, such as the clinical chiefs and nurse executive, it may be a clinical case around increased morbidity and mortality associated with *C. difficile*.
- For your chief executive officer, you need to consider how support for this effort fits with institutional values, current initiatives, and other commitments.

In making your case, you will need to assess the leaders' level of support and their understanding of the need for ongoing practical support in further developing your ASP. Support will involve allocation of needed resources and ongoing senior leadership oversight to ensure focus and accountability for results.

Do key stakeholders in multiple disciplines understand why a structured ASP is needed?

Your senior leadership must understand the need for both structure and staff designated to conducting and enhancing ASP activities. Beyond your senior leaders, you will need to identify key individuals of importance to this initiative by conducting a stakeholder analysis. **Tool 1H** can help you structure the stakeholder analysis to identify which departments and individuals are needed, what their views are about expanding the ASP, where barriers might exist, and what actions will be needed to obtain the necessary buy-in of departments and individuals.

In addition to the stakeholder analysis, you may want to survey the prescribers in your organization about their views on an ASP. Understanding current attitudes will help you determine where education is needed and where resistance may be encountered. Lack of knowledge or negative attitudes may undermine change efforts if left unaddressed.

Tool 1I is a survey instrument that was used in the *ERASE C. difficile* Project to assess physician and pharmacist perceptions about antimicrobial resistance. The survey includes the scope of the problem, antibiotic prescribing practices, and thoughts about ASP prior to the intervention.

While prescribers are the key target group in ASPs, *C. difficile* reduction is a multidisciplinary responsibility. Engaging other clinical staff in supporting ASP and coordinating it with other *C. difficile* control practices will be critical. Therefore, you may want to also assess their knowledge of *C. difficile* control best practices and their receptivity to ASP. **Tool 1I** or another established survey tool may help you in that assessment.

Participating Facility Reflections

Facilities talked about:

- The importance of empowering all staff to feel comfortable in speaking up if, for example, infection control procedures were not being carried out.
- The difficulty committing to additional activities without getting additional staff, reassigning responsibilities, or creatively deciding how to engage and bring on board those who have not previously been involved in the ASP effort.
- The potential for nursing involvement through education and involvement in compliance with infection control procedures.
- The enormous and absolutely interdisciplinary effort that starting an ASP was at their facility.
- The crucial relationship between Infectious Disease and Pharmacy.
- The resistance among nurses to change to piperacillin/tazobactam extended infusion because the additional nursing time required to set up pumps and the extra time the pump was in use with each patient made this intervention unmanageable.

Is there a clinical and business case for creating an ASP for reducing *C. difficile*? Do leadership and prescribers understand and support it?

You may decide that the most efficient and effective way to justify your wish to further develop your facility's ASP is by developing and presenting a business case to your senior leadership. In some organizations a business case may be required. In brief, this document will succinctly describe the project and its aims, the risks associated with your plan, the expected outcomes, and the benefits and cost estimates. **Resource 1J,** Antimicrobial Stewardship: Implementation Tools & Resources: Other Resources, includes a link to two sample program proposals in the Business Case section that you may find helpful.

While the goal of an ASP is to improve patient outcomes, potentially substantial financial benefits may be realized in cost savings. A well-conceived and presented business case that demonstrates to your facility administrators that the resources invested in implementing an ASP will be offset by benefits to the organization may help justify ongoing support. These benefits should be noted both in your original plan for establishing an ASP for *C. difficile* reduction and in the ASP's results after implementation.

Part of justifying certain ASP costs may require identification of areas where cost savings can be realized. **Tool 1K** provides a worksheet for developing a business case. Factors that you should consider in developing a business case include:

- *Calculating anticipated savings.* You may decide to generate anticipated savings data by calculating costs based on current standard of care practices and comparing these costs with estimated costs of proposed ASP activities. In many cases if an ASP already exists, there will probably not be many additional costs for new staff or equipment. Rather, existing staff time and resources will be redirected to highlight the topic of *C. difficile* in daily ASP activities.
- *Calculating actual savings.* You may decide to calculate actual costs for treating patients (on individual, unit, or hospitalwide basis) before introduction of ASP activities and after to show actual savings. You can perform this calculation using pilot data for a briefer timeframe or smaller scale to demonstrate savings. These pilot data can then be used to estimate savings if the ASP is implemented on a larger scale.

- *Translating ASP activities into cost savings.* These calculations will be based on the particular interventions at your facility, such as a shift from an expensive IV antimicrobial agent to an oral equivalent (which is likely less expensive) or a more narrow oral agent, discontinuation of the antibiotic completely, or shortening of the treatment course. Each of these scenarios has potential savings from the drug cost and administration costs, as well as potential savings from earlier discharge of the patient. In addition to the savings realized through the specific ASP activities at your facility, other costs should be accounted for (e.g., certain agents require more frequent laboratory monitoring, adding to the cost of using that particular agent). Finally, your facility may find that through smart antibiotic prescribing practices, your facility as a whole is spending less on antibiotic agents, realizing hospitalwide savings.
- *Showing that improved patient outcomes bring about cost savings.* Your facility may choose to estimate cost savings realized through improved patient outcomes associated with ASP activities. Such outcomes may include reduced rates of *C. difficile* (because of strict adherence to all infection control and environmental cleaning, along with the specific stewardship activities); shorter lengths of stay; reduction in toxicity through dose optimization of targeted agents; and reduction in rates of antibiotic resistance. It might be important not to overstate the potential from the hospital-perspective of savings associated with these types of outcomes, as they may: (1) be hard to achieve, (2) take time to see, and (3) in some instances yield mixed financial outcomes for the facility (e.g., when looking purely at the business case, shortened length of stay may or may not actually save the hospital money).

What kinds of resources are needed to develop an effective ASP?

While you may not know at the outset *all* the kinds of support that will be needed, it is clear that the changes are going to require new or reallocated resources, most likely both human and material.

A critical question, of course, will be *who will be responsible for growing the ASP?* Beginning with the current ASP team, factoring in the results of the stakeholder analysis conducted with **Tool 1H,** and including your plans for new ASP strategies, *are additional staff members needed? Do the resources exist to augment current staffing?*

Less immediately obvious, but equally important, *what other resources might be needed?* These may include, for example, training, education, actual supplies/equipment/technical equipment and support. **Tool 1L** provides a worksheet for assessing these other resource needs.

Participating Facility Reflections

Both intervention and nonintervention sites shared their creative solutions and the downsides of those to cope with not having staff dedicated to the work of ASP, such as:

- Use pharmacy residents who rotate through in short time periods.
- Use infection disease fellows who assume a large portion of the workload associated with select interventions.
- Use ASP team (infectious disease physician and PharmD) to supervise residents and fellows.

What barriers might we face and how might we deal with them?

No new practice or innovation is seamlessly implemented without any difficulties. For example, in the current fiscally tight climate, your facility may be considering a number of programmatic options, all of which are competing for the same limited resources. You will need to think through the barriers you are likely to encounter so that you can anticipate and address them to prevent them from delaying or stopping the ASP. To stimulate your thinking, **Tool 1M** describes potential barriers to implementing an ASP, drawn from the hospitals participating in the *ERASE C. difficile* Project, and offers strategies needed to address them if an ASP is to be implemented.

Participating Sites' Reflections

- Attempting to institute oversight of the prescribing practices of private physicians is likely to be politically complex.
- Physicians may resist taking direction from pharmacists, even those trained in Infectious Diseases.
- It will be important to create educational opportunities to help staff across disciplines understand their role and the interconnectedness of the various jobs in making ASP

Resources and Tools

- **1G TOOL:** Assessing Leadership Support
- **1H TOOL:** Stakeholder Analysis
- **1I TOOL:** Survey of Staff Attitudes Toward ASP and Current Practices
- **1J RESOURCE:** Antimicrobial Stewardship: Implementation Tools & Resources: Other Resources
- **1K TOOL:** Developing Business Case
- **1L TOOL:** Assessing Resource Needs
- **1M TOOL:** Potential Barriers to Implementing an ASP

2. How do we determine which interventions for reducing *C. difficile* to implement?

This toolkit describes an individualized approach and tailoring of selected stewardship interventions based on the results of limited case-control studies and identified issues at each facility. As you begin to identify antibiotics to target, you will also need to look at prescribing practices that will be targeted for change. You will need to plan the strategies you will use with prescribers to appropriately limit the targeted antibiotics in use. The strategy will depend on a combination of known evidence-based promising practices and what will work in your organization. To address these issues, you should consider the four questions discussed in the following sections.

2.1. What is the institutional risk assessment approach? How can it help us?

A targeted risk assessment offers a promising path for identifying antimicrobial stewardship interventions to reduce *C. difficile*, for reasons that include the following:

- Most ASPs have limited resources, time, and staff to have activities that affect all antimicrobial prescribing within their health care facility.
- Some traditional components of a stewardship program may have little impact on *C. difficile* rates.

- While there may be less variability in practices for infection control and environmental cleaning so that bundled approaches have controlled outbreaks and prevented healthcare-associated infections, the same is unlikely to be true of antimicrobial prescribing. Prescribing can vary widely among facilities due to factors such as patient populations, antibiotic formularies, prescriber preference, and local microbiology.
- Antibiotic type and use vary considerably at health care facilities throughout an area (formularies are large).

The institutional risk assessment approach offers a more sophisticated approach than a uniform bundle of interventions at each facility. The tools below provide a roadmap for performing an assessment and information for tallying antimicrobial use in your facility.

The major components of conducting an institutional risk assessment at your facility follow:

- **Conduct a limited case-control study** to identify antimicrobial risk factors for *C. difficile*. Specifically, which of the large and diverse array of antibiotics is associated with *C. difficile* at your facility and potentially among facilities in multicampus institutions? Review the magnitude of the odds ratio (OR; strength of association) and overall use (to address attributable risk, or probability of contracting a disease; e.g., one antibiotic or class may have a lower OR but be used in large volume).
- **Identify and select targeted antibiotics** for stewardship intervention based on the results of your case-control study.
- **Study patterns of use,** including, but not limited to, the target populations and infections for which the antibiotics are being prescribed; who is prescribing them; and duration of use. Identify which strategies and how many different strategies should be implemented for each specific target. Your aim is to identify an approach that will address the majority of use of that antibiotic at your facility (i.e., aiming for 80%+ of use).
- **Include the following elements in the stewardship strategies** and potential interventions, based on antibiotic target:

    - Restrictions and preauthorization of implicated antimicrobials.
    - Audits and feedback to providers of implicated antimicrobials.
    - Flow and algorithms for empiric and streamlined regimens for specific diagnoses/pathogens.
    - Antibiotic order form; automatic stop orders.
    - Novel approaches to use of stewardship staff or technology for stewardship (e.g., software, text paging, Pyxis pharmacy machines for tracking and promoting proper antibiotic prescribing).
    - Educational efforts for clinicians and patients upon diagnosis.

Resource 2A, Institutional Risk Assessment Approach to Selecting Stewardship Interventions, provides a roadmap for this process. **Resource 2B,** A Comparison of Antibiotic Data Sources, can be used by facilities when considering sources of antibiotic

data, including strengths and weaknesses. **Resource 2C** describes methods for evaluating antibiotic use.

For example, suppose an antibiotic associated with *C. difficile* at your facility (i.e., with a high OR or high attributable risk [high volume of use, but an OR that may not be as high]) is found to be used primarily for surgical prophylaxis. Strategies to address surgical prophylaxis choices or automatic stop orders may be appropriate to address this antibiotic. However, if the antibiotic is used for a specific syndrome or specific diagnoses, then flows and algorithms for empiric regimens for specific diagnoses, restrictions, or audit and feedback may be useful at your facility.

- The case-control results and use patterns described above would guide your interventions; the literature, resources, and current activities at your facility would also be taken into account when the strategy is designed.
- The approaches your facility develops must address how best to anticipate possible barriers and how to implement the strategy.
- Compliance with the intervention and success (including changes in antibiotic use and rates of *C. difficile*) would be monitored to decide whether the strategy should be modified or additional interventions added.
- A list of triggers for implementing an additional tier of interventions should be developed.

Resources and Tools
Ø 2A RESOURCE: Institutional Risk Assessment Approach to Selecting Stewardship Interventions **Ø 2B RESOURCE:** A Comparison of Antibiotic Data Sources **Ø 2C RESOURCE:** Possible Methods for Evaluating Antibiotic Use

2.2. How do we conduct a time-limited internal case-control study for C. difficile? What are some of the challenges?

To identify antibiotics most associated with *C. difficile* cases that may be targets of stewardship interventions, an internal, time-limited, focused retrospective case-control study can be performed. The limited case-control study was chosen for a variety of reasons. *C. difficile* is a rare event, so each facility would need to look at a large volume of patients and antibiotic use to perform a cohort study. In addition, many facilities may not have the resources or expertise to perform complex formal studies. Thus, a "limited" case control focusing primarily on antibiotic exposures seemed more feasible, even for facilities with limited resources.

There is no single perfect way to perform the case-control study. The best methods may vary by the specific characteristics of your facility, such as number of *C. difficile* cases, resources, personnel, availability of medical records and antibiotic use data, time, and interest. However, in selecting your method, there are common factors to consider, including the following:

- **What is the timeframe? How many cases of *C. difficile* should we use?** You can use *C. difficile* cases identified by the system already in place at your facility. From our experience, looking at cases during a 3- to 6-month period, at least 30 cases will probably be needed to show a statistically significant relationship between exposure to antibiotics and *C. difficile*. If feasible, looking at more cases or a longer time period may make it easier for you to find targets.
- **How should we choose the controls?** A discussion of the advantages and disadvantages of choosing controls for case-control studies in general are beyond the scope of this toolkit. (See annotated bibliography for further resources.) From our experience, the most parsimonious method is to compare controls (patients who did not have *C. difficile* admitted to your facility during the same period as each case) to cases at a 2:1 ratio. However, since patients who develop *C. difficile* may be different from the hospital population in general, some additional criteria for choosing the controls can be considered, including matching for age, gender, diagnosis, and length of stay or other severity of illness markers.

    - Matching for age (within +/- 5 years), admission date (admitted at same time to same facility as the *C. difficile* case within +/- 5 days), and no documented *C. difficile* within 3 months before or after hospital stay seemed to yield similar data as matching for the above additional factors.
    - In addition, it may be practical for stewardship staff to identify controls by choosing the controls by hand from preprinted lists obtainable from hospital administrative sources. **Resource 2D,** Does Choice of Control Group Affect the Association of Antibiotics With *C. difficile*-Associated Diarrhea?, is a slide presentation that addresses these issues.

- **How should we choose and obtain the needed data**? The goal of this focused case-control study is to identify the antibiotics or antibiotic classes most associated with *C. difficile* (not **all** factors associated with *C. difficile*) as a way to identify which antibiotics to target with your interventions. Thus, from our experience, focusing on a few exposures (mostly antibiotic and a few demographics) is optimal. Some observations and suggestions about the data collection follow:

    - The antibiotic and other related data to be aggregated in this suggested case-control study are likely already collected on all patients routinely as part of either patient care or hospital safety measures.
    - The antibiotic data to collect may include: generic antibiotic name, dose, route, interval, and start and stop dates (which gives enough elements to be able to calculate the standard antibiotic metrics).
    - The same antibiotic and related fields are needed for the controls, including all documented antibiotic exposures in the 30 days prior to admission and throughout their inpatient stay. Although not always feasible, it would be ideal to collect data on "all" antibiotic exposures. However, some may have occurred during outpatient visits or at other facilities, and you may not be able to document them completely even if you conduct a detailed retrospective chart review. Thus, including all

antibiotics dispensed and documented within your facilities may be more realistic (and obtainable in many facilities in electronic form).

- Collected data that allow description of cases and controls and ensure that these are similar populations at risk of *C. difficile* should also include: admission service, admission diagnosis, and top two discharge diagnoses (age and gender are likely to already be collected).
- Retrospective antibiotic use data may be extracted from electronic patient medical and pharmacy records at your facility, but review of paper medical records may be needed.
- Antibiotic use data can be summarized in electronic files (e.g., Microsoft Excel) to avoid using additional paper worksheets.

Resource 2E, Sample Tracking and Summary Forms for Case-Control Study, can be used to organize your case-control comparisons and summarize results and potential antibiotic targets.

Participating Facility Reflections

- The nice thing about doing the case-control study is that everyone is interested in their own data; it lets people make decisions about what they want to do at their own hospital. It's a trial run of sorts.
- Interestingly, it was more difficult and time consuming to get the data than to actually conduct the case-control study, even if done by hand.

- **How do we analyze the data? What are resources for calculating odds ratios and p values?**

  - Data on cases and controls can be entered or transferred into an Excel® spreadsheet and analyzed with a Chi square, Fisher's exact, or other appropriate bivariate analysis. You can use SPSS, SAS, STATA, or another statistical software program if your facility has the specific software and capability. Although more detailed analysis including regression can be used for more complex case-control studies, for most facilities it will not be feasible or necessary.

    This is a limited case-control technique and only select antibiotic exposures will be examined. Smaller facilities or those with limited computer support can make the comparison using the Epi Info statistical calculator, a free download that is widely accessible and simple to use (available at www.cdc.gov/epiinfo/). You can also perform the patient tally and calculations by hand using this formula:

    Odds ratio (OR) = [a/b]/[c/d] or OR= [a x d]/[b x c]).

	Exposure to Antibiotic X	**No exposure to Antibiotic X**
C. difficile	a	b
No *C. difficile*	c	d

Resources and Tools
Ø 2D RESOURCE: Does Choice of Control Group Affect the Association of Antibiotics With *Clostridium difficile*-Associated Diarrhea? **Ø 2E RESOURCE:** Sample Tracking and Summary Forms for Case-Control Study (can be used to organize your case-control comparisons and summarize results and potential antibiotic targets)

2.3. What methods can we use to review the use of potential target antibiotics for intervention activities?

As shown in the Institutional Risk Assessment Roadmap in **Resource 2A**, multiple approaches can be taken to reviewing the use of potential target antibiotics. You will need to choose the approach that best fits your organization. For example, you can conduct a formal medication review for several weeks or longer of prescribing patterns of the targeted antibiotic. For many facilities, this timeframe is unrealistic; a review of only a few days of prescribing patterns (potentially on random days) may suffice to begin to strategize interventions.

Details to review will include but are not limited to:

- Number of patients given prescriptions/length of therapy.
- Most common prescribers.
- Most common wards or patients receiving target.
- Reason for target drug prescribing (e.g., empiric therapy, directed therapy, prophylactic regimen).
- Most common syndromes and diagnoses treated by the target drug.
- Appropriateness and potential for prescribing changes (choice, length, other options, including not treating if not indicated).

Participating Facility Reflections
➢ Narrowing the focus from several to just one antibiotic target can allow an increase in the number of interventions used and a higher number of interventions accepted. ➢ Case-control study helped confirm overuse of a particular class of antibiotics (quinolones) and the results gave the impetus to get the usage under control. ➢ Therapeutic mismatches provide opportunities for changing to an agent that will adequately cover the infection. ➢ One tool is simply looking at the antibiogram, which almost all institutions already have on hand. One can then ask if the targeted antibiotic is really adding anything to empiric therapy and what are the alternatives. ➢ It is important to discuss alternative antibiotic regimens or at least examples of how alternatives could be used in lieu of the target. ➢ An example from our UTI guidelines was the discovery that both quinolone and sulfamethoxazole/trimethoprim sensitivities for *E. coli* were very poor on the antibiogram. Because of that observation, a urine pathogen-specific antibiogram (able to do rapidly with electronics) was run, demonstrating that sensitivities to nitrofurantoin and cephalosporins were still good and use of those was encouraged in the guidelines. The guidelines also call for a periodic review because sensitivities could again change as selective pressure is placed on these bugs over a period of time.

Resources and Tools

Ø 2A RESOURCE: Institutional Risk Assessment Approach to Selecting Stewardship Interventions

2.4. What factors do we need to consider in choosing interventions?

The target antibiotic from the case-control study and the medication review will start to guide your intervention decisions. **Resource 2F** lists the major intervention types and their respective advantages and disadvantages, and **Resource 2G** reviews types of antimicrobial stewardship interventions, comparing process measures, antibiotic metrics, and other factors to track. These comparisons may help you determine what might be appropriate for your hospital. Other factors will also need to be considered, including:

- Stewardship staffing and skill set;
- Ability to affect a large enough burden of prescribing, IT, and other external resources;
- Acceptability of activities to prescribers, stewardship team, pharmacy, administration, and other key players at your facility;
- Previous and current stewardship activities (what has and has not worked in the past; what will complement current activities); and
- Literature and best practices.

Examples of intervention strategies from other hospitals as listed in **Resource 2H** may help you identify the interventions most likely to fit your organization.

Participating Facility Reflections

- Without staff dedicated to ASP, creatively using available resources is crucial; using CPOE [computerized physician order entry] to enhance current ASP activities by making them more automated, e.g., issuing alerts.
- It's important to strike the balance between targeting too many antibiotics and having efforts spread too thin, and targeting too few and not having enough opportunities to intervene.
- The challenges of implementing an ASP in an academic setting are enormous.
- Training is another challenge; taking away the antibiotic approvals from the fellows and assigning to dedicated ASP staff is dramatic as that was long considered a cornerstone in the training process.
- Preemptive measures such as requiring prior approval were probably one of the single most effective means of control at my facility.

Resources and Tools

Ø 2F RESOURCE: A Comparison of Potential Antimicrobial Stewardship Interventions
Ø 2G RESOURCE: A Review of Antimicrobial Stewardship Interventions With Suggested Process/Monitoring, Antibiotic Use, and Additional Measures of Impact
Ø 2H RESOURCE: Specific Intervention Examples From ERASE *C. difficile* Project

2.5. How do we implement the intervention?

Once you determine what the interventions will be in terms of the factors described above, you need to develop strategies tailored to your organization for implementing the interventions. With leadership support, the *C. difficile* ASP team will need to guide, coordinate, and support the implementation efforts during the initial phases and as the ASP practices are rolled out across the hospital to intended populations and prescribers.

Because the interventions may involve changes in the way people work, you may have difficulty incorporating them into practice. Our experience has been that many of these efforts can take longer to implement and have the full effect than initially anticipated. Consider the following questions to determine the changes that will be needed:

- **Whose help is needed to implement and sustain the interventions?**
    - Staff within your facility. A formal review of your intended stewardship activities (especially if these include formulary changes, restrictions, or new policies) may be needed with facility staff, including the antibiotic subcommittee and pharmacy and therapeutics committee, infectious diseases department (including practicing private infectious disease doctors), and pharmacy staff.
    - Senior leadership. Buy-in and ongoing support are needed from your senior leaders.
    - Other departments. Interdepartmental cooperation and other supportive liaisons may be needed. Based on your intervention, you may need support and resources from other departments, such as pharmacy, other practicing infectious disease physicians, IT, microbiology, and infection preventionists.

Participating Facility Reflections

- Complimentary partnership of infectious disease doctors with specialty trained infectious disease PharmDs is effective in working with prescribers; PharmDs have expertise in dosing and infectious disease doctors can talk with prescribers as a peer.
- All restriction changes have to be approved by the pharmacy and therapeutics committee; changes to CPOE screens have to be approved by a committee that oversees our clinical information systems; and information technology needs to be involved in the design, implementation, and auditing of the changes.

- **Do we need to pilot test the new practices?**
    - Piloting may give your stewardship team a chance to work out the logistics of the activity, identify unexpected barriers, and develop best practices for monitoring and tracking outcomes.
    - Piloting will allow you to obtain some early data to determine feasibility to continue activities or gain additional support from administration and other stakeholders in your facility.
    - Piloting may help you identify other areas for stewardship activities or opportunities to implement an intervention.

Participating Facility Reflections

- Piperacillin/tazobactam audit and feedback with an educational component was piloted with infectious disease fellows for 4 months, followed by increased activity with a restructuring via the addition of clinical pharmacists.

- **How do we engage staff in an ASP to reduce *C. difficile*? How should we work with staff at the unit level? How can we help staff learn new practices?**

    - Survey prescribers on their perceptions about issues related to *C. difficile*, prescribing practices, willingness to comply with stewardship activities, and concerns. This may help you understand some of the barriers you may face in implementation. **Tool 1I**, Survey of Staff Attitudes Toward ASP and Current Practices, is one of many similar surveys that will help you understand at baseline your prescriber perceptions. This tool can be administered over time to measure changes in perceptions.
    - Plan educational and communication activities to complement your stewardship interventions. This may include efforts to disseminate baseline data on *C. difficile* and prescribing concerns, along with new policies and prescribing aids (e.g., one-on-one education, lectures, clinical information systems, and hospital intranet pages).
    - Identify "physician and prescribing champions" who will help educate and disseminate information and act as model prescribers from whom others can learn and emulate best practices. These may include hospitalists, chief residents, infectious disease physicians, supervising physician assistants, and other staff. In some facilities, attending physicians and physician assistants are often comfortable prescribing only a few different antibiotics and use them for many indications. Enlisting these different types of prescribing champions may help others in their prescribing.

Participating Facility Reflections

- Through in-house educational efforts, staff's misconceptions that patients were coming into their hospital with *C. difficile* when, in fact, the patients were acquiring it in-house were corrected.

3. How do we monitor the intervention and measure outcomes?

At all points in this process you will need to monitor appropriate processes and outcomes of the stewardship efforts. The frequency that data are collected, compiled, and analyzed will vary by facility. Perhaps your facility has internal committees or boards who require regular submission of data; perhaps your State has a reporting requirement (e.g., *C. difficile* is reportable in New York State).

It will be important to know the requirements at your facility so that you can make the proper preparations in terms of reporting mechanisms. In deciding how to monitor your intervention and outcomes, you should consider six questions. Some of the tools and resources from earlier sections will help you in this process.

3.1. How do we measure rates of C. difficile over time?

Many facilities are already tracking patient cases and rates of *C. difficile*. If your facility (or State/local health department) does not have a formal system, it will be easier to use or adapt from CDC's NHSN system rather than creating your own definitions and surveillance.

Participating Facility Reflections

Activities suggested by facilities to enhance, monitor, and sustain implementation, including *C. difficile* rates and prescribing:

- Doing spot checks on prescribing.
- Reviewing at regular intervals select tracking sheets/databases on prescribing.
- Updating and initiating discussion of barriers to the antibiotic subcommittee/pharmacy and therapeutics committee.
- Holding meetings with groups of prescribers from areas affected by ASP and inquiring about the acceptability of prescribing changes.
- Doing spot checks of microbiology and NHSN for volume of *C. difficile* cases.
- Reviewing newer/ongoing cases of *C. difficile* and assessing antibiotic prescribing (including whether there was a missed opportunity to decrease exposure).

The following are questions to consider:

- **Whom might we need help from?** You will need assistance from your microbiology laboratory and infection preventionists.
- **What is key information we need to be aware of?** You must be aware of the methods of *C. difficile* testing and data collection in your facility. Optimally, your testing methodology and data collection should remain constant throughout the period of your intervention. While it is possible to change to a different type of testing, including more sensitive PCR methods, that will make meaningful comparison before and after your intervention activities more difficult. Also, it is important to know if there are any other changes that may influence *C. difficile* rates, such as any changes in environmental cleaning or infection control policies and procedures.
- **How should we track *C. difficile* cases?** Calculating *C. difficile* cases per 10,000 patient days will allow comparison both within your facility over time and against national benchmarks. Tracking can be done monthly (or at longer intervals if not feasible) and compared quarterly.
- **Is it important to know whether *C. difficile* cases are acquired in our facility or in the community**? NHSN has definitions to assess whether cases are likely acquired in the community or in facilities (see Web page definitions). Because many ASPs and targeted interventions are likely to have effects mainly in the inpatient setting, you may want to compare *C. difficile* rates for facility-onset cases (as defined by NHSN) before and after your intervention, rather than looking at all *C. difficile* cases.
- **Are we mandated to report *C. difficile*?** Currently, public health laws in New York State (Public Health Law 2819) require hospitals to report several healthcare-associated infections, including *C. difficile*. New York State uses the NHSN MDRO/*C. difficile* module that includes use of NHSN platform, definitions, and formatting for submitting required data, as shown in **Resource 3A**.
- As of May 2012, five States in addition to New York (CA, IL, OR, TN, UT) mandate public reporting of facilitywide laboratory-identified (LabID) *C. difficile* events. As a result of the Centers for Medicare & Medicaid (CMS) Inpatient Prospective Payment System rule, starting in 2013, all hospitals will be required to report facilitywide LabID *C. difficile* events using NHSN. There has also been discussion that in the near future CMS is looking at the wider issue of requiring facilities to have a more formal stewardship

activities/program (see Resource 1A, Policy Statement on Antimicrobial Stewardship by the Society for Healthcare Epidemiology of America, the Infectious Diseases Society of America, and the Pediatric Infectious Diseases Society).

- **Are there Web resources to help with *C. difficile* surveillance?** The following resources may be useful to your facility.

Resources and Tools
Ø 3A RESOURCE: Hospital-Acquired Infection (HAI) Rates in New York State Hospitals **Ø 3B RESOURCE:** About NHSN **Ø 3C RESOURCE:** NHSN Manuals and Protocols **Ø 3D RESOURCE:** NHSN Patient Safety Component, MDRO/CDI Module (customizable reporting forms, including Laboratory-Identified MDRO or CDI Event) **Ø 3E RESOURCE:** Instructions for Completion of the Laboratory-Identified MDRO or CDI Event Form

3.2. How do we obtain, measure and analyze antibiotic data?

One of the biggest challenges in antimicrobial stewardship in general and specifically in measuring the potential effect of an intervention is obtaining needed data on antibiotic volume for more than one patient at a time. Once the data are obtained, challenges arise in cleaning, aggregating, summarizing, and comparing the data in a meaningful way. It is beyond the scope of this toolkit to address every potential issue, but the following questions may be helpful in guiding your process:

- **What are possible antibiotic data sources?** The strengths and weaknesses of the four main types of antibiotic data (purchasing, orders, antibiotics dispensed, and antibiotic receipt) are summarized in **Resource 2B,** A Comparison of Antibiotic Data Sources. If your facility is just starting ASP efforts or has little IT support, purchasing can be both a feasible way to start to identify problem drugs and a quick way to show the effects of early intervention measures.
- **What are some common antibiotic data cleaning and aggregation challenges**? Getting the right data from even the most sophisticated hospital or pharmacy clinical information system is often an iterative process. Even with good IT support, data may be given to you that are not ready for immediate analysis. We recommend some validation to ensure that the data make sense. Reviews of purchasing data or focused chart reviews are two means to reality check the larger volume of use data. Check the data to verify that all drugs are included. Many facilities use generic drugs; with drug shortages, products may vary throughout the year; and some drugs will need to be removed as they are no longer used for their antimicrobial properties. In multifacility medical centers, it is important to standardize drugs and dosing to aggregate and compare over campuses.
- **What are some antibiotic metrics we can consider using? Resource 2C,** Possible Methods for Evaluating Antibiotic Use, describes methods for summarizing and comparing antibiotic use. It includes definitions, strength, considerations regarding use, and references to learn more about each measure. **Resource 2G,** A Review of Antimicrobial Stewardship Interventions With Suggested Process/Monitoring, Antibiotic Use, and Additional Measures of Impact, links some of the common

intervention activities and suggested potential antibiotic metrics to access and compare prior to, during, and after the interventions.

- You will likely need IT support to obtain aggregate data. Often if antibiotic receipt data are obtained, the database can be large and difficult to manage. It also may require cleaning and combining data substantially before any metrics or comparisons can be used.
- Often using more than one metric will give you a more complete picture of the baseline and postintervention use.
- Depending on the extent and nature of the intervention activities, it may take time for you to see changes in antibiotic use, depending on the metric chosen for that particular intervention. For example, restrictions likely see effects sooner, while audit and feedback activities or new algorithms may take longer to take hold and change prescribing. Some interventions may be in specific units or populations, so a hospitalwide metric may not be refined enough to show differences.

Participating Facility Reflections

- Piperacillin/tazobactam turned out to be a very challenging target; the strategies initially identified—de-escalation and duration—did not make a very big dent.
- Implementing an intervention in one unit may make it difficult to see results if antibiotic data and *C. difficile* rates are calculated on a hospitalwide basis.

Resources and Tools

Ø 2B RESOURCE: A Comparison of Antibiotic Data Sources
Ø 2C RESOURCE: Possible Methods for Evaluating Antibiotic Use
Ø 2G RESOURCE: A Review of Antimicrobial Stewardship Interventions With Suggested Process/Monitoring, Antibiotic Use, and Additional Measures of Impact
Ø 3F RESOURCE: World Health Organization Defined Daily Dose Definition and General Considerations (links on left side of page go to DDD lists)

3.3. How can we monitor the intervention and why should we?

It is important to monitor the interventions for multiple reasons. You will need to:

- Be able to verify that the interventions are occurring.
- Look for early and tangible signs of success (antibiotic metrics may be slow to show effects).
- Identify barriers to success and ways to improve the intervention.
- Assess whether additional interventions are needed.
- Determine whether the interventions are sustainable.
- Learn whether the intervention could be an effective way to affect other outcomes, such as *C. difficile* and antibiotic resistance.

This last point is important because many stewardship interventions have been successful in reducing targeted antibiotic use and cost but have fallen short in reducing more concrete outcomes such as *C. difficile* rates and antibiotic resistance. If these outcomes are not achieved, monitoring the intervention is important to distinguish why the intervention did

not demonstrate an impact. Was it because the activities were not completed; the intervention could not affect prescribing practices, antibiotic use, or outcomes; the activities were not implemented long enough to see impact; transmission was a bigger problem than anticipated; or the mechanism of resistance presented problems? **Resource 2G,** A Review of Antimicrobial Stewardship Interventions, summarizes some suggested monitoring or process measures for specific antibiotic stewardship intervention activities.

Participating Facility Reflections

- The lowest rates of intervention "acceptance" are in July-September, which coincides with the new group of pharmacy residents who are tentative in their recommendations and whose recommendations are less likely to be accepted. This is known because of ongoing monitoring.
- Similar comments were made about infectious disease fellows having the knowledge, experience, confidence, and backing enforcing restrictions early in the academic year.

Resources and Tools

Ø 2G RESOURCE: A Review of Antimicrobial Stewardship Interventions With Suggested Process/Monitoring, Antibiotic Use, and Additional Measures of Impact

3.4. What other processes do we need to monitor and measure?

It is also important to ensure that your interventions do not have unintended consequences for your patients. Thus, looking at rates of reinstitution of broad antibiotic therapy, missed or delayed antibiotic doses, or readmission (especially for infection) should be part of your ongoing surveillance, along with examination of mortality data. In addition, your interventions may have other positive outcomes (e.g., reduced length of stay for patients receiving the intervention) that you will need to monitor and keep track of.

Further, your institution's infection control, isolation precautions, and environmental cleaning policies and practices should be monitored throughout your intervention as changes in these can also affect *C. difficile* rates. **Resources 3G and 3H** offer examples of tools for monitoring prevention practices.

Finally, it is important to assess how the intervention affects your stewardship team and other prescribers. Qualitative data collection (ideally pre- and postintervention) such as prescriber surveys (see **Tool 1L**), informal discussions, or focus groups may enrich your understanding of the ASP and activities at your facility.

Resources and Tools

Ø 1L TOOL: Survey of Staff Attitudes Toward ASP and Current Practices
Ø 3G/3H RESOURCE: Environmental Cleaning and Infection Prevention Checklists

3.5. How do we analyze financial data?

It will be important to conduct a financial impact analysis at your facility to estimate the costs associated with running an ASP, including staffing, software, and equipment; estimate the cost savings from reduced antimicrobial use; and understand the potential reimbursement impact of reducing infections. In addition, you may want to estimate

indirect savings, including savings on isolation equipment or estimated savings from meeting external quality measures, such as those from CMS.

You may choose to examine antibiotic purchasing data if those data are available, or you may need to use industry sources to estimate costs associated with antibiotic purchasing. Data from the hospital should be available as they are routinely compiled for internal hospital purposes or required external use (e.g., billing). In the current climate of competing demands, leadership is frequently interested in the ways patient safety initiatives translate into financial savings.

3.6. How do we assess the overall impact of our interventions? How do we decide which interventions have been the most successful (and which interventions were not) and why?

Assessing the overall impact of an intervention can be complex. Following are some important points gleaned from the participating facilities and interpretation of the analysis and evaluation components by our ERASE *C. difficile* leadership team.

Simplistically showing a decrease in the targeted antibiotic consumption might suggest success. One issue that we encountered is that depending on the specific antibiotic, dosing, and type of intervention, the commonly used antibiotic metrics of defined daily dose, days of therapy, and number of courses may not reflect the changes in prescribing exactly the same way.

In addition, a large enough proportion of the prescribing needs to be affected to be measurable in the aggregate antibiotic use measures or to potentially improve other outcomes (e.g., *C. difficile* infections). For example, in several of the participating facilities, piperacillin/tazobactam was a target. But this is a broad antibiotic an array of prescribers often use for empiric regimens or for various infections. Thus, an intervention that targets only a fraction of that prescribing may be successful in decreasing that specific indication for prescribing but may not be able to be measured when overall prescribing is summarized.

Since *C. difficile* has multifactorial causes, affecting only one drug or the prescribing of only a proportion of the prescribing of that specific drug may not affect the rates of *C. difficile.* This is likely also true of antibiotic resistance patterns. In addition, it may take longer to influence *C. difficile* and other microbiologic targets. Thus, for interventions of short duration, it will be difficult to show changes and you may not be guaranteed to see changes in these measures even in the long run.

Further, **some interventions may shift antibiotic prescribing but not reduce use.** If the shift is to a more narrow antibiotic, an oral antibiotic regimen, or no antibiotics, the patient may have positive outcomes but experience unintended consequences. For example, if an antibiotic is restricted and prescribers move to an alternative nonrestricted antibiotic, an unintended increase can occur in use of the second antibiotic. Patients may then experience secondary unintended consequences (e.g., have more side effects, be more difficult to dose). The drug also may have other effects on the local microbiologic flora, be a mismatch

to the patient's culture results, and result in readmission or increased length of stay. Thus, a shift in prescribing can be good and bad, **so reviewing the patterns of antibiotic prescribing** in general and not just of single agents is important.

Other potential surrogates or outcomes for review are length of stay and cost. A decrease in the length of treatment may allow more prompt discharge of patients, which should be balanced with a review of readmissions for infections. An assessment of cost to implement the intervention and potential cost savings from fewer or different patterns of antibiotic use can be useful, especially when advocating for more formal resources from hospital administration.

Several other factors are important to consider when assessing the impact of an intervention. It is important to explore the **ability to implement the intervention** in terms of cost, staffing, IT support, and timeframe. You also need to **assess the acceptability to the stewardship team** (does not impede other needed stewardship activities) **and to prescribers**. Not all activities will be welcomed, but some may be less popular than others. This can make it difficult to cast the ASP team in an educational role with prescribers, making it more difficult to implement other needed changes.

All these factors can **also affect the ability to sustain activities**. Thus, **activities have to be considered in the setting of longer range goals for the ASP.**

Ultimately, **your facility will probably weight a combination of these factors** when you choose to implement new or supplement existing antibiotic stewardship activities. Interventions need to be tailored and must complement other factors in your facility's environment.

Participating Facility Reflections

- A dramatic drop in cost has been realized; a 7-day course of antibiotics is not the norm anymore.
- Quinolone use was reduced by 20 percent through a variety of interventions.
- A notable dip in piperacillin/tazobactam use after systemwide restriction led to a shift from one broad spectrum agent to another.

Resources and Tools

Ø **2H RESOURCE:** Specific Intervention Examples From ERASE *C. difficile* Project

4. How do we sustain the ASP for reducing *C. difficile* over time?

Early in the process of developing your ASP aimed at reducing *C. difficile*, you will need to think ahead about sustaining the program once it is in place. Often, sustaining changes in clinical practice introduced through a new initiative is more difficult than implementing them initially. To maintain your ASP for *C. difficile* reduction so that it thrives and continues to be useful, consider at least four questions; you may have others.

In considering these questions, reflect on the challenges you currently face and consider strategies for working on them in the future. **Tool 4A** provides a worksheet for doing that.

The four questions are discussed below. The tools and processes introduced in earlier sections, such as the business plan **Tool 1K,** also can be used in developing your sustainability plan.

Will our current ASP staffing work on an ongoing basis?

How well is your stewardship team working across departments and disciplines? What is the current distribution of responsibilities? Are there changes that you would need to make?

What is the plan for ongoing measurement and feedback?

A plan is only as good as the systems in place that ensure sustainability. It is crucial to plan at the onset for ongoing monitoring, maintenance, and evaluation of the ASP for reducing *C. difficile*. **Section 3** talked in detail about monitoring the ASP for *C. difficile* intervention and outcomes as you are planning and initially implementing the program. Measurement and feedback will be equally important as you transition to sustaining the program.

What ongoing organizational support will we need to keep the new ASP practices in place?

Maintaining your ASP requires organizational support on multiple levels. Ongoing organizational support for ASP to reduce *C. difficile* will be strongest if you can demonstrate that it is aligned with the medical center's strategic priorities and that it addresses pressing problems.

How do we keep the ASP efforts relevant and a continued focus?

As discussed in greater detail in **Section 1.2,** given the environment of tightening resources in most medical centers, you will likely need to keep your preliminary business case updated and current to ensure continued or expanded investment in your ASP.

Resources and Tools Used by Participating Facilities
Ø 4A TOOL: How Do We Sustain ASP for Reducing *C. difficile* Over Time? **Ø 4B TOOL:** UTI Guidelines Form **Ø 4C TOOL:** Piperacillin/Tazobactam De-Escalation Form **Ø 4D TOOL:** Medication Use Evaluation Template

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Summary of Tools and Resources		
Section	**Question Addressed**	**Resources and Tools**
1. Is our organization ready for an ASP to reduce *C. difficile*?	1.1. Do we have the appropriate ASP foundation on which to build?	**Ø 1A RESOURCE:** SHEA/IDSA/PIDS Policy Statement. Policy Statement on Antimicrobial Stewardship by the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA), and the Pediatric Infectious Diseases Society (PIDS) **Ø 1B RESOURCE:** GNYHA/UHF Antimicrobial Stewardship Toolkit **Ø 1C RESOURCE:** Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program To Enhance Antimicrobial Stewardship **Ø 1D RESOURCE:** Examples of State and Local Stewardship Programs **Ø 1E TOOL:** Assessment of Current ASP Elements **Ø 1F TOOL:** Common Evidence-Based Infection Prevention Measures
	1.2. What do we need to do before we begin to use our ASP to target *C. difficile*?	**Ø 1G TOOL:** Assessing Leadership Support **Ø 1H TOOL:** Stakeholder Analysis **Ø 1I TOOL:** Survey of Staff Attitudes Toward ASP and Current Practices **Ø 1J RESOURCE:** Antimicrobial Stewardship: Implementation Tools & Resources: Other Resources **Ø 1K TOOL:** Developing Business Case **Ø 1L TOOL:** Assessing Resource Needs **Ø 1M TOOL:** Potential Barriers to Implementing an ASP
2. How do we determine which interventions for reducing *C. difficile* to implement?	2.1. What is the institutional risk assessment approach and how can it help us?	**Ø 2A RESOURCE:** Institutional Risk Assessment Approach to Selecting Stewardship Interventions **Ø 2B RESOURCE:** A Comparison of Antibiotic Data Sources **Ø 2C RESOURCE:** Possible Methods for Evaluating Antibiotic Use
	2.2. How do we conduct a time-limited internal case-control study for *C. difficile*? What are some of the challenges?	**Ø 2D RESOURCE:** Does Choice of Control Group Affect the Association of Antibiotics With *Clostridium difficile*-Associated Diarrhea? **Ø 2E RESOURCE:** Sample Tracking and Summary Forms for Case-Control Study (can be used to organize your case-control comparisons and summarize results and potential antibiotic targets)
	2.3. What methods can we use to review the use of potential target antibiotics for intervention activities?	**Ø 2A RESOURCE:** Institutional Risk Assessment Approach to Selecting Stewardship Interventions
	2.4. What factors do we need to consider in choosing interventions?	**Ø 2F RESOURCE:** A Comparison of Potential Antimicrobial Stewardship Interventions **Ø 2G RESOURCE:** A Review of Antimicrobial Stewardship Interventions With Suggested Process/Monitoring, Antibiotic Use, and Additional Measures of Impact **Ø 2H RESOURCE:** Specific Intervention Examples From ERASE *C. difficile* Project

Summary of Tools and Resources		
Section	**Question Addressed**	**Resources and Tools**
3. How do we monitor the intervention and measure outcomes?	3.1. How do we measure rates of *C. difficile* over time?	**Ø3A RESOURCE:** Hospital-Acquired Infection (HAI) Rates in New York State Hospitals **Ø 3B RESOURCE:** About NHSN **Ø 3C RESOURCE:** NHSN Manuals and Protocols **Ø 3D RESOURCE:** NHSN Patient Safety Component, MDRO/CDI Module (customizable reporting forms, including Laboratory-Identified MDRO or CDI Event) **Ø 3E RESOURCE:** Instructions for Completion of the Laboratory-Identified MDRO or CDI Event Form
	3.2. How do we obtain, measure, and analyze antibiotic data?	**Ø 2C RESOURCE:** Possible Methods for Evaluating Antibiotic Use **Ø 2G RESOURCE:** A Review of Antimicrobial Stewardship Interventions With Suggested Process/Monitoring, Antibiotic Use, and Additional Measures of Impact **Ø 3F RESOURCE:** World Health Organization Defined Daily Dose Definition and General Considerations (links on left side of page go to DDD lists)
	3.3. How can we monitor the intervention and why should we?	**Ø 2G RESOURCE:** A Review of Antimicrobial Stewardship Interventions With Suggested Process/Monitoring, Antibiotic Use, and Additional Measures of Impact
	3.4. What are other processes we need to monitor and measure?	**Ø 1I TOOL:** Survey of Staff Attitudes Toward ASP and Current Practices **Ø 3G/3H RESOURCE:** Environmental Cleaning and Infection Prevention Checklists
	3.6. How do we assess the overall impact of our interventions? How do we decide which interventions have been the most successful (and which interventions were not) and why?	**Ø 2H RESOURCE:** Specific Intervention Examples From ERASE *C. difficile* Project
4. How do we sustain the ASP for reducing *C. difficile* over time?		**Ø 4A TOOL:** How Do We Sustain ASP for Reducing *C. difficile* Over Time?
Resources Developed and Used by Participating Facilities		**Ø 4B TOOL:** UTI Guidelines Form **Ø 4C TOOL:** Piperacillin/Tazobactam De-Escalation Form **Ø 4D TOOL:** Medication Use Evaluation Template

Ø 1E TOOL: Assessment of Current Antimicrobial Stewardship Program Elements

Purpose: To help assess which ASP elements are currently in place in terms of staff and strategies.

Source: Adapted from Greater New York Health Assocation/United Hospital Fund ASP Chapter 2, "The Antimicrobial Stewardship Core Team," and Chapter 3-B, "Core Strategies."

Instructions: Complete checklist, review responses to ascertain the level of leadership support, and target areas that need strengthening to move forward.

STAFF RESOURCE	Check If Available:
Infectious disease–trained physician	☐
Clinical pharmacist	☐
Clinical microbiologist	☐
Infection control representative	☐
Hospital epidemiologist	☐
Information technology	☐
STRATEGIES IN PLACE	
Prospective audit with intervention and feedback	☐
Education	☐
Guidelines and clinical pathways	☐
Antimicrobial cycling	☐
Antimicrobial order forms	☐
Formulary restriction and preauthorization	☐
Combination therapy	☐
Streamlining or de-escalation of therapy	☐
Dose optimization	☐
Parenteral to oral conversion	☐
Health care information technology	☐

Ø 1F Tool: Common Evidence-Based Infection Prevention Measures

Purpose: To understand and assess infection control measures in use at your facility and give suggestions for additional measures to be taken.

Source: Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults: 2010 Update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). Available at: www.jstor.org/stable/10.1086/651706.

Instructions: Complete checklist and review procedures currently in place for infection prevention. Consider additional measures that may be needed and identify areas that need strengthening.

Infection Control and Prevention for *C. difficile* Infection: What Health Care Workers, Patients, and Visitors Can Do

Precaution	In Use: Y/N	Corrective Measures To Be Taken
Use of immediate contact precautions for suspected cases of *C. difficile*	☐ Yes ☐ No	
Hand hygiene protocol in place (soap and water preferred) before and after contact with *C. difficile* patients	☐ Yes ☐ No	
Personal protective equipment readily available/used (gloves, gowns)	☐ Yes ☐ No	
Policy for use of private rooms for *C. difficile* patients	☐ Yes ☐ No	
Policy for cohorting patients if private room not available	☐ Yes ☐ No	
Policy for dedicated commode for each patient	☐ Yes ☐ No	

Ø 1G TOOL: Assessing Leadership Support

Purpose: To assess senior administrative leadership support for improving *C. difficile* prevention and allocating needed resources for improvement activities.

Source: Developed by ERASE *C. difficile* project team**.**

Instructions: Complete checklist, review responses to ascertain the level of leadership support, and consider which areas and strategies need strengthening.

Leadership Support Assessment	Yes	No	Partial	Comment
C. difficile prevention beyond current practices is a high priority within the facility				
There are visible role models/champions for antimicrobial stewardship for reducing *C. difficile*				
The facility has implemented antimicrobial stewardship policies				
There is a dedicated budget allocated for infection control activities				
The budget includes funding for education and training on infection control, including antimicrobial targeting				
The budget includes funding for information technology to support infection control, including antimicrobial targeting				

Ø 1H TOOL: Stakeholder Analysis

Purpose: To help identify how specific departments and disciplines will be involved in planning and implementing ASP strategies and to identify actions needed to obtain buy-in and participation.

Source: Adapted from Project Agency. Blank project management templates. Available at: http://www.businessballs.com/project%20management%20templates.pdf.

Instructions: Interview key institutional stakeholders, and identify actions to involve them in the planning and eventual implementation of an ASP. Modify stakeholder list to meet the needs of your institution.

Stakeholder/ Discipline	What will be this stakeholder's role in planning and implementing ASP?	What are the anticipated activities this stakeholder can be involved in to plan and implement ASP?	What are some of this stakeholder's general perceptions about planning and implementing ASP?	What actions can be taken to strengthen the buy-in from this key stakeholder to plan for the implementation of ASP?
Infectious disease physician				
Clinical pharmacist				
Microbiologist				
Infection prevention representative				
Information technology representative				
Senior leadership representative				
Prescribing provider				
Other (e.g., hospital epidemiologist)				

Ø 1I TOOL: Survey of Staff Attitudes Toward ASP and Current Practices

Purpose: To assess prescribers' perceptions about antimicrobial resistance, including the scope of the problem, antibiotic prescribing practices, and thoughts about antimicrobial stewardship programs. This information should inform implementation strategies and identify education needs.

Source: Developed by Greater New York Health Association/United Health Fund ERASE *C. difficile* Project team. Based on the AHRQ Hospital Survey on Patient Safety Culture. Available at http://www.ahrq.gov/qual/patientsafetyculture/hospsurvindex.htm.

Instructions: Have prescribers complete the survey. Consider handing it out and collecting it at a faculty meeting or Grand Rounds where they are already gathered. Tally results for use by the ASP team and clinical educators. Also consider presenting survey results to prescribers to provide feedback about the collective attitudes and perceptions in your facility.

Note: The survey is separate from these instructions so that it may be easily duplicated for use.

ERASE- *C. diff.* Antimicrobial Stewardship Survey

(This survey is designed to be administered pre- and postintervention and to both intervention and control institutions.)

Please indicate your level of agreement with the following statements about your institution.

Antimicrobial Resistance: Scope of the Problem and Key Contributors

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
1. Antibiotic resistance is a problem in this institution.	☐	☐	☐	☐	☐
2. Patient rooms are cleaned according to hospital cleaning protocol once a *C. difficile* patient has been discharged.	☐	☐	☐	☐	☐
3. Adherence to hand hygiene protocols is excellent at this institution.	☐	☐	☐	☐	☐
4. Adherence to isolation and contact precautions is excellent at this institution.	☐	☐	☐	☐	☐
5. This institution does **NOT** do enough to control the development of *C. difficile*.	☐	☐	☐	☐	☐
6. This institution provides adequate staff education regarding *C. difficile.*	☐	☐	☐	☐	☐
7. A patient is likely to develop a *C. difficile* infection during a stay at this institution.	☐	☐	☐	☐	☐

Antibiotic Prescribing Practices

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
1. Microbiology lab results are efficiently communicated to the treating physician.	☐	☐	☐	☐	☐
2. I regularly refer to the susceptibility/sensitivity patterns at this institution (e.g., an antibiogram) when prescribing antibiotics.	☐	☐	☐	☐	☐
3. If medically appropriate, intravenous antibiotics should be stepped down to an oral alternative after 3 days.	☐	☐	☐	☐	☐
4. Restrictions on antibiotics impair my ability to provide good patient care.	☐	☐	☐	☐	☐
5. Antibiotics are overused at this institution.	☐	☐	☐	☐	☐
6. A majority of patients admitted to this institution will be prescribed at least one antibiotic during their hospital stay.	☐	☐	☐	☐	☐
7. Many of my patients receive 5 or more days of antibiotics during their stay at this institution.	☐	☐	☐	☐	☐
8. Few of my patients are discharged from this institution on antibiotics.	☐	☐	☐	☐	☐
9. When discharged to a nursing home or long-term care facility, most of my patients are on IV antibiotics.	☐	☐	☐	☐	☐

Antimicrobial Stewardship Programs (a formal program that monitors and manages the appropriate use of antibiotics)

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
1. Antimicrobial stewardship programs can improve patient care.	☐	☐	☐	☐	☐
2. Antimicrobial stewardship programs reduce the problem of antimicrobial resistance.	☐	☐	☐	☐	☐
3. Antimicrobial stewardship programs can affect this institution's *C. difficile* rates.	☐	☐	☐	☐	☐
4. This institution has an effective antimicrobial stewardship program.	☐	☐	☐	☐	☐
5. This institution does **NOT** provide adequate training on antimicrobial prescribing and use.	☐	☐	☐	☐	☐
6. Additional staff education on antimicrobial prescribing is needed.	☐	☐	☐	☐	☐
7. Prescribing physicians are the only disciplines who need to understand antimicrobial stewardship.	☐	☐	☐	☐	☐

Background Information

1. What is your primary work area or unit in this health care facility? (Please check ONE answer)

☐ Many different units/No specific unit
☐ Medicine (nonsurgical)
☐ Surgery
☐ Obstetrics
☐ Pediatrics
☐ Emergency department
☐ Intensive care unit (any type)
☐ Psychiatry/mental health
☐ Rehabilitation
☐ Pharmacy
☐ Laboratory
☐ Radiology
☐ Anesthesiology
☐ Other (please specify: _____)

2. How long have you worked in this health care facility?

☐ Less than 1 year
☐ 1 to 5 years
☐ 6 to 10 years
☐ 11 to 15 years
☐ 16 to 20 years
☐ 21 years or more

3. What is your staff position in this health care facility?

☐ Attending/staff physician
☐ Resident physician/Intern
☐ Fellow
☐ Pharmacist
☐ Physician assistant
☐ Nurse practitioner
☐ Infection control practitioner
☐ Other (please specify:_____)

4. How long have you worked in your current specialty or profession?

☐ Less than 1 year
☐ 1 to 5 years
☐ 6 to 10 years
☐ 11 to 15 years
☐ 16 to 20 years
☐ 21 years or more

Ø 1K TOOL: Developing the Business Case

Purpose: To make the case for ASP implementation for reducing *C. difficile*. Early in the project, the arguments will be prospective, looking at expected benefits. After your ASP for reducing *C. difficile* is implemented, you can use the same form to document realized benefits.

Source: Adapted from Project Agency. Blank project management templates. Available at: http://www.businessballs.com/project%20management%20templates.pdf

Instructions: Complete the form to be used in presentations and discussions with senior leaders and stakeholders.

Project Background
General Aims
Initial Risks
Expected Outcomes, Both Clinical and Financial
Benefits of Project
Initial Estimates of Cost and Time $: Time:
Outcome of the Business Case
Decision From (xxx)
Date

Ø 1L TOOL: Assessing Resource Needs

Purpose: To identify resources needed to initially implement and later sustain an ASP for reducing *C. difficile*. The ASP team may revise or amend assessment as implementation proceeds and other resources are needed.

Source: Developed by AHRQ Pressure Ulcer Prevention Toolkit project team.

Instructions: Complete checklist to assess resources available and resources needed.

Resource Needs Assessment	Needed: Yes/No	Notes on What Is Needed
Funds		
Other resources:		
Education department		
Printing/copying		
Graphics/design		
Facilities and supplies		
Physical therapy/occupational therapy consultation on work practices		
Interdisciplinary implementation team		
Nonclinical time for team meetings and activities		
Information Technology support		
Specific products/tools (e.g., mattress surfaces)		

Ø 1M RESOURCE: Potential *barriers* to implementing an ASP

Purpose: In the current fiscally tight climate, your facility may be considering a number of programmatic options, all of which may be competing for the same limited resources. The following information was collected on visits to several project nonintervention sites and describes potential barriers to implementing an ASP, as well as what is **needed** to implement an ASP.

Source: ERASE *C. difficile* Project team.

Instructions: Review document to identify if a barrier exists and if resolution is available.

Potential Barriers to Implementing an ASP		
Category	**Barrier**	**What You May Need To Implement an ASP**
Organizational Issues	• Insufficient understanding of the scope of the problems/lack of sufficient training and education • Potential for savings realized from ASP to return to hospital's general operating fund rather than enhancing ASP services and overall programming	• Expanded education and training for staff at all levels and in all services • Administrative approval to direct savings realized from ASP to staff dedicated to enhancing ASP (rather than these additional funds going back to hospital general fund)
Resources and Staffing	• Insufficient staffing (information technology [IT], pharmacy, infectious diseases [ID]); lack of dedicated staff and capabilities • Potential to compromise clinical care without dedicated staffing • Lack of ID/administrative champion onsite	• Ability (via administrative support) to convert demonstrated savings into additional dedicated staff (assigned PharmD) • Outreach and training to make interdisciplinary cooperation seamless • Dedicated IT/pharmacy/ID staff • Ability to maintain clinical services without additional staff dedicated to ASP activities in IT, ID, and pharmacy
Data Systems	• Insufficient baseline and ongoing data collection or review • Need for system to alert ID pharmacists of target patients • Medical record system either not fully electronic or not fully integrated	• Ability to formally track outcomes • System in place to alert ID pharmacists of target patients • Improved data collection and review system • Improved medical records system (conversion to electronic or fully integrated system) • Enhanced reporting capabilities of pharmacy

Potential Barriers to Implementing an ASP		
Category	**Barrier**	**What You May Need To Implement an ASP**
Prescriber Culture	• Issue of private ID physicians doing hospital consults • Issue of house staff taking clinical directives from pharmacy; current prescribing culture • Issue of private ID physicians assisting with surveillance • Issue of hospitalists not taking responsibility for decisionmaking on rounding	• Training in proper use of antibiogram • Training to encourage collaboration of infection prevention and pharmacy services • Training of hospitalists
Institutional Demographics	• Smaller facilities that lack onsite full-time ID physicians and full-time dedicated staff • Larger facilities whose staffing to bed size ratios only allow limited review of antibiotic prescribing • Facilities with different economic constraints and many other competing priorities	• Ways to tailor activities and interventions to your needs, size, resources, patient and prescriber populations, and staffing • Among smaller facilities, an option for stewardship activities a few times per week (audit and feedback with contracted ID staff)

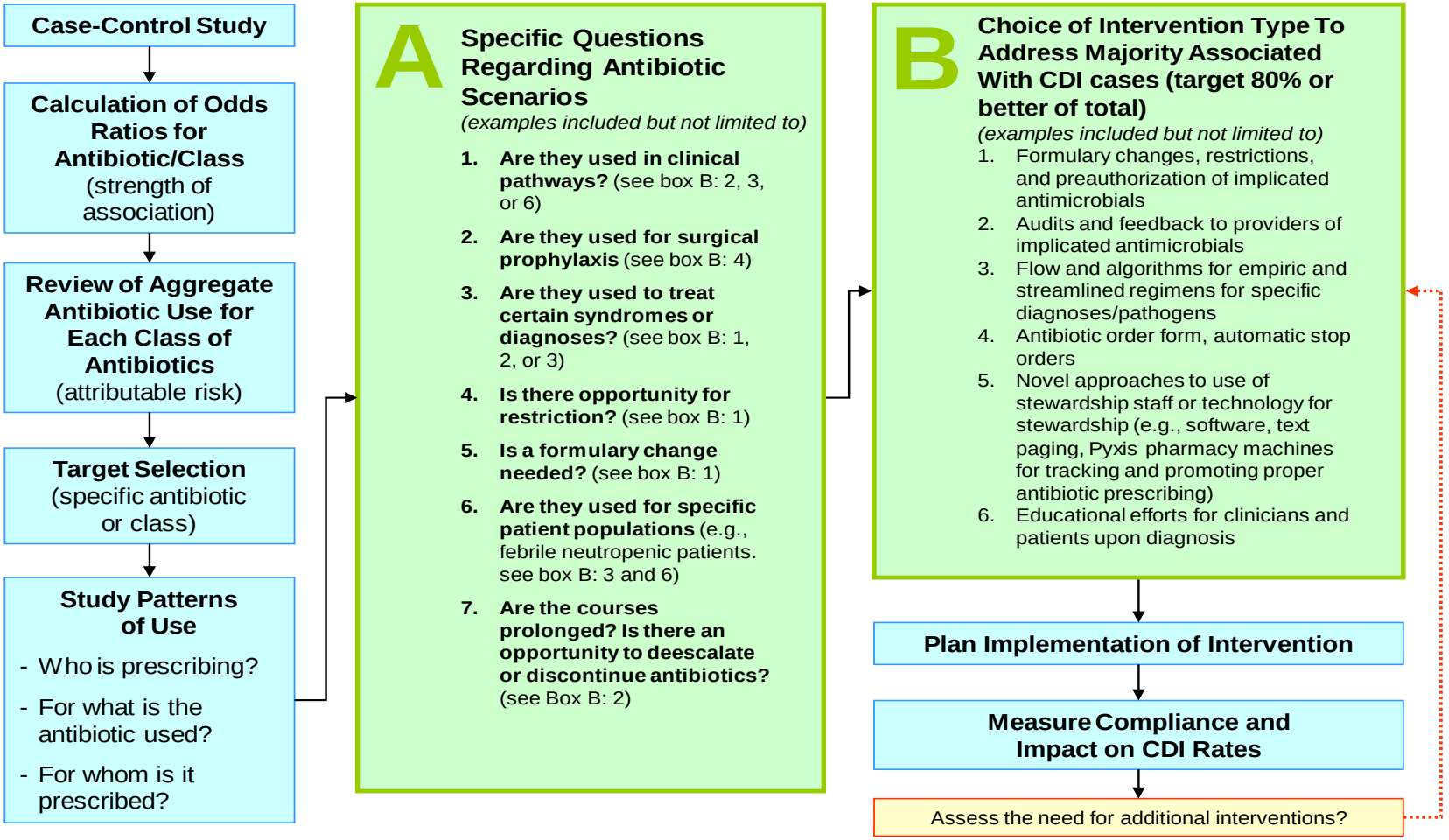
Ø 2A RESOURCE: Institutional Risk Assessment Approach to Selecting Stewardship Interventions

Purpose: A roadmap to illustrate the steps involved in developing an institutional risk assessment approach to antimicrobial stewardship.

Source: Adapted from ERASE *C. difficile* Project tools.

Instructions: Follow steps to identify antibiotic targets and plan and implement interventions.

Institutional Risk Assessment
Approach to Selecting Stewardship Interventions



Ø 2B RESOURCE: A Comparison of Antibiotic Data Sources

Purpose: A tool to review sources of antibiotic data.

Source: Developed by B. Ostrowsky and P. Chung, Montefiore Medical Center, for ERASE *C. difficile* Project toolkit.

Instructions: Use this chart when considering sources of antibiotic data, including strengths and weaknesses.

Source	Advantages	Disadvantages
Purchasing	• Easiest data to obtain for baseline (most pharmacies track, even if not full computerized physician order entry [CPOE]) • Can be converted into defined daily doses to get estimates of use • Comparison possible before and after interventions • Simple to convey results to stakeholder	• Likely aggregated facility-level data only (not patient level) • May be influenced by contract pricing • Can vary at different times of year (since ordering can be sporadic and availability of generic and other drugs can vary over time)
Orders	• Can be aggregated by patient	• Represents only prescriber intent (orders change) and not necessarily what patients receive • Unless done by chart review, requires some pharmacy electronic tracking system
Medication dispensed	• Can be aggregated by patient	• Represents what pharmacy dispenses and not necessarily what patients actually receive (medication may be wasted) • Unless done by chart review, requires some pharmacy electronic tracking system
Medications received	• Best data; represents actual medication receipt • Can be aggregated by patient	• Unless done by chart review, requires CPOE or other advanced pharmacy electronic tracking system • Needs information technology to help obtain, organize, and aggregate data in meaningful way • Labor intensive to clean and aggregate (often large files)

Ø 2C RESOURCE: Possible Methods for Evaluating Antibiotic Use

Purpose: A tool to review types of antibiotic use metrics.

Source: Developed by R. Ruiz, Greater New York Healthcare Association, for ERASE *C. difficile* Project toolkit.

Instructions: Use when considering ways to measure antibiotic use. Includes descriptions, strengths, consideration, types of stewardship interventions for which metrics have monitoring potential, and resources/references.

Metric	Description	Strengths	Considerations	Monitoring Potential	References
Defined daily dose (DDD)*	Average maintenance dose per day for a drug used for its main indication in adults. Gives an estimate of antibiotic consumption.	DDD allows comparison of antibiotic consumption between groups/facilities Standardized DDD is independent of price and dose DDDs exist for common combination therapies Calculated DDDs account for dose and frequency given	DDD does not reflect the recommended or prescribed dose Most times the DDD is a compromise of doses used in different countries Standardized DDD is rarely the prescribed dose due to averaging of common doses used DDD can only be used for adults Calculation over time may be affected by changes in the standardized DDDs	Antibiotic restriction Audit and feedback Computer triggers Clinical prompts (e.g., indication)	a, b
Days of therapy (DOT)	Number of days when at least one dose of a medication was administered irrespective of dose or route of administration	Allows comparison of the length of treatment Can be used for children Not dependent on standardized dose (like DDDs) for uncomplicated calculation over time	Does not take into account dose or frequency	Audit and feedback Clinical prompts (e.g., indication)	b

Metric	Description	Strengths	Considerations	Monitoring Potential	References
Number of courses	Number of prescribed courses of unique antibiotics per person. Courses cannot have more than a 48-hour window between any two consecutive administrations.	Allows comparison of antibiotic prescription patterns	Does not take into account dose or frequency Does not take into account route of administration	Antibiotic restriction Computer triggers Clinical prompts (e.g., indication)	
≥Three antibiotics	Number of patients on three or more antibiotics	Can be used to identify patients with more severe acuity and possibly at higher risk for complications (e.g., *C. difficile*)	Does not take into account dose or frequency Does not take into account specific combinations of antibiotics May be prone to a small number of patients	Audit and feedback	

References

a. World Health Organization Collaborating Centre for Drug Statistics Methodology. International language for drug utilization research. Oslo: Norwegian Institute of Public Health; 2012. Available at: www.whocc.no.

b. Polk RE, Fox C, Mahoney A, et al. Measurement of adult antibacterial drug use in 130 U.S. hospitals: comparison of defined daily dose and days of therapy. Clin Infect Dis 2007 Mar 1;44(5):664-70. Epub 2007 Jan 22.

Ø 2D RESOURCE: Does Choice of Control Group Affect the Association of Antibiotics With *Clostridium difficile*-Associated Diarrhea?

Purpose: A poster showing the process of describing if choice of control group affects the association of antibiotics with *Clostridium difficile*-associated diarrhea.

Source: Developed by P. Chung, Y. Gao, and B. Ostrowsky, Montefiore Medical Center, for 2011 Society for Healthcare Epidemiology of America annual meeting. Abstract available at: http://shea.confex.com/shea/2011/webprogram/Paper4443.html.

Instructions: Use as a reference.

Ø 2E RESOURCE: Sample Tracking and Summary Forms for Case-Control Study

Purpose: A tool to track and organize comparisons of antibiotic exposures in a case-control study to identify potential antibiotic targets associated with *C. difficile.*

Source: Adapted from ERASE *C. difficile* Project.

Instructions: Electronic form formatted in Excel. Use this form to enter data. Select each field, enter the data, and use "Save as" to save your facility's data.

Internal case control summary form and case control form

Adopted from the ERASE C.diff Project

For Internal Hospital Use Only

Hospital Name
Hospital Name

Matching Criteria								
	C. diff Cases				Controls			
	# of Cases	Mean	Min	Max	# of Cases	Mean	Min	Max
Age								
Admission Date		N/A				N/A		

	Antibiotics Evaluated										
		C. diff Cases			Controls			Significance			
	Antibiotics (Class/Combinations)	# of Cases	% of Total Patients	% of Total Patients on	# of Cases	% of Total Patients	% of Total Patients on	p-value	Odds Ratio [OR]	OR Lower CI	OR Upper CI
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
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22											
23											
24											
25											

Adapted from the ERASE *C.diff. Project*

Hospital Name
Hospital Name

Matching Criteria

	C. diff Cases				Controls			
	# of Cases	Mean	Min	Max	# of Cases	Mean	Min	Max
Age								
Admission Date		N/A				N/A		

Antibiotic Targets Selected

		C. diff Cases			Controls			Chosen Criteria				
	Antibiotic Targets[1]	# of Cases	% of Total Patients	% of Total Patients on Antibiotics	# of Cases	% of Total Patients	% of Total Patients on Antibiotics	p-value	Odds Ratio (OR)	OR Lower CI	OR Upper CI	Other
1												
2												
3												
4												
5												

[1] List antibiotic targets for your intervention and provide the criteria used to select them (p-value or OR)

Comments[2]

[2] Please provide any input on barriers encountered, methodology, or potential plans for interventions

OPTIONAL FIELDS (Recommended, but not required)

	Total # of Patients	% of total Patients	# of Patients	% of total Patients
Number of Patients on Antibiotics				
Number of Patients on ≥3 Antibiotics				

Ø 2F RESOURCE: Comparison of Potential Antimicrobial Stewardship Interventions, With an Emphasis on Reducing *C. difficile*[1]

Purpose: A tool to review types of antimicrobial stewardship interventions, comparing strengths and weaknesses and providing examples.

Source: Developed by B. Ostrowsky and S. Brown, Montefiore Medical Center, for ERASE *C. difficile* Project toolkit.

Instructions: Use when choosing and implementing targeted interventions.

Intervention Type[1,2]	Advantages	Disadvantages	Examples
Formulary changes, restrictions, and preauthorization	• Effective in decreasing targeted antibiotics • Can influence choice of antibiotics before patients receive therapy • Has education built into process of discussing therapy choice	• Less evidence as a means of reducing long-term antimicrobial use or outcomes, such as resistance • May shift prescribing to alternative agents (e.g., "squeezing the balloon") and resulting resistance/*C. difficile* • Effectiveness dependent on skills of staff making recommendations and reviewing requests • Mainly affects initial regimen choice and not length of treatment • May be less acceptable to prescribers (viewed as policing antibiotics) • May involve delays in therapy (to obtain approval)	• Restricting empiric use of antibiotics associated with most *C. difficile* cases (may be whole hospital, for specific patient populations/prescribers) • Choosing specific drugs for the formulary (e.g., limit multiple/redundant quinolones, carbapenems) • Mandating Infectious Diseases consultation for specific drugs
Audit and feedback to providers, including strategies for de-escalating and streamlining antibiotics	• Has been shown to improve antimicrobial use and outcomes • Can be adapted to many hospital environments (including small facilities or facilities with limited resources) • Can be done a few times per week • Facilitates a team approach to patient care • Allows intervention in cases of inadequate therapy • Allows flexibility of therapy based on patient response and clinical status	• Labor intensive; effectiveness dependent on skill of staff making the recommendation • Need systems in place to identify patients on whom intervention can be done (helpful to have information technology [IT] or computer software support) and how best to convey suggestions to prescribers (e.g., verbal, written in medical record) • Mainly affects length of treatment (depending on when performed, may have variable impact, especially if patients have been on antibiotics for long periods of time) • May be less acceptable to prescribers (viewed as interfering with prescribing)	• Obtaining lists of patients on extended spectrum β-lactams and third/fourth generation cephalosporins at 72 hours and approaching clinicians after chart review for de-escalating antibiotics • Targeting cefepime-containing empiric therapy in ICU patients with daily rounds with ICU teams (identifying opportunities to shorten course or streamline therapy)

Intervention Type[1,2]	Advantages	Disadvantages	Examples
Flow and algorithms for empiric and streamlined regimens for specific diagnoses or pathogens	• Improves prescribing, including adapting national guidelines to local microbiology and population • Can be multidisciplinary in development • Can affect initial antibiotic choice and further tailoring of antibiotic	• Requires an outlay of effort over time to develop and educate in their use • Needs to be appropriately disseminated and accepted • Needs to be an agreement on therapy by all involved parties	• Protocols for workup and/or empiric regimens for sepsis, community-acquired pneumonia, and urinary tract infections
Novel approaches to use of technology and stewardship staff	• Allows interventions to be tailored to unique populations and local microbiology • Broadens pool of resources for stewardship activities • Allows use of local systems to obtain data and supplement activities	• Shorter track record and less ability to predict impact • Outlay of effort by stewardship team and others (e.g., IT) • Technology costs	• Training clinical pharmacists, pharmacy residents, and infectious disease fellows to prescreen candidates for de-escalation or streamlining initiatives • Involving nursing and nursing leadership ("non" prescribers) in stewardship activities • Using pharmacy tools, including automated pharmacy technology (e.g., Pyxis Medstation™) to offer and track antibiotic prescribing in the emergency department
Educational component for clinicians and patients	• Necessary for prescriber buy-in and prescribing in general • Supplements above activities	• Have been less successful on their own; should be coupled with other interventions	• Case-based learning, including how to use algorithms and when and how to de-escalate antibiotics • Lectures on antibiotic use

1. Traditional methods such as intravenous to oral switch programs and dose optimization may be used by a well-rounded antimicrobial stewardship team, but on their own will likely not be effective interventions directed at decreasing *C. difficile* infection.
2. Categories adapted from Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program To Enhance Antimicrobial Stewardship.

Ø 2G RESOURCE: A Review of Antimicrobial Stewardship Interventions With Suggested Process/Monitoring, Antibiotic Use, and Additional Measures of Impact

Purpose: A tool to review types of antimicrobial stewardship interventions, comparing process measures, antibiotic metrics, and other factors to track.

Source: Developed by B. Ostrowsky and P. Chung, Montefiore Medical Center, for ERASE *C. difficile* Project toolkit.

Instructions: Use when considering ways to monitor processes and outcomes related to targeted interventions.

Intervention Type [1,2]	Process/Monitoring	Possible Antibiotic Use Measures To Access Impact	Additional Measures, Including Benefits/Unintended Consequence
Formulary changes, restrictions, and preauthorization	• Number of calls/requests for restricted drug (changes over time) • Percentage of requests approved (over time by staff) • Number of formal Infectious Diseases consultations	• Total number of courses or patients on restricted antibiotics, alternative antibiotics to the restricted drug • Defined daily doses	• Time to receipt of antibiotics (delays) • Number of doses dropped/missed • Antibiotic costs
Audit and feedback to providers	• Number of patients who met criteria for auditing, reviewed, advice given, intervention made, and advice accepted • Number of formal Infectious Diseases consultations	• Days of therapy for antibiotics and total patients on redundant antibiotic combinations • Defined daily doses	• Length of stay • Clinical failure—reinstitution of broad antibiotic regimens • Readmissions • Antibiotic costs
Flow and algorithms for empiric and streamlined regimens for specific diagnoses or pathogens	• Web hits for educational pages with algorithms • Educational assessment of understanding of guidelines • By limited chart/patient review—percentage of patients receiving/tailoring antibiotics per protocols	• Total number of patients with syndrome or diagnosis on appropriate antibiotics (may have external validated measure such as Centers for Medicare & Medicaid Systems [CMS] core measures, e.g., pneumonia) • Total number of courses or patients on antibiotics and duration of antibiotics involved in protocol	• Length of stay • Readmissions

Intervention Type [1,2]	Process/Monitoring	Possible Antibiotic Use Measures To Access Impact	Additional Measures, Including Benefits/Unintended Consequence
Antibiotic order forms and automatic stop orders	• Number of patients per month where antibiotic form used • By limited review—percentage of patients where antibiotic order form was used, e.g., to continue or stop antibiotics	• Total number of patients with syndrome or diagnosis on appropriate antibiotics or for appropriate length (may have external validated measure such as CMS core measures for surgical prophylaxis) • Total number of courses or patients on antibiotics and duration of antibiotics involved in the automatic orders (may be by service, prescriber, patient population, or forms/order)	
Novel approaches to use of technology and stewardship staff	• Will depend on nature of intervention • Number of calls, requests, or interventions by specific staff (percentage acceptance rates) • Number of patients per month/timeframe where technology used	• Will depend on nature of intervention • Comparison of specific antibiotic courses before and after intervention	• Will depend on nature of intervention
Educational component for clinicians and patients	• Number of educational programs • Number of attendees • Survey of attitudes or understanding about prescribing topic	• Will depend on nature of education • Total number of courses or patients on antibiotics and duration of antibiotics involved	• Improved visibility of program • Collaborative care or camaraderie with other services • Possible exchange of ideas about processes and choice of therapy

1. Traditional methods such as intravenous to oral switch programs and dose optimization may be used by a well-rounded antimicrobial stewardship team, but on their own will likely not be effective interventions directed at decreasing *C. difficile* infection.
2. Categories adapted from Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship.

Ø 2H RESOURCE: Specific Intervention Examples From ERASE *C. difficile* Project

Purpose: Overview of implemented antimicrobial stewardship by ERASE *C. difficile* participants. Describes examples of antimicrobial stewardship interventions implemented by six participating facilities in ERASE *C. difficile* Project, including details of activities, timeframes, locations, and stewardship staffing or activities.

Source: Adapted from ERASE *C. difficile* Project by H. Jalon, United Hospital Fund, and B. Ostrowsky, Montefiore Medical Center.

Instructions: Use as a reference.

Facility Description	Interventions	Start Date	Location	Notes/Comments
481-bed teaching hospital	Specific programming of antibiotic stewardship computer software to identify patients with longer antibiotic lengths (> 14 days)	Approximately 1 year	Hospitalwide	• Overall issue with staffing (no infectious disease fellows). • For IV to oral, computer prompt done at 3-day mark for fluoroquinolones. • Antibiotic policy change catalyzed by patient experience; very new official policy, but education started September 2011. • Had intended to target piperacillin/tazobactam, including de-escalation; more opportunities with ciprofloxacin. • Ciprofloxacin policy verbalized in September-November 2011 and officially implemented in December 2011.
	Clinical computer prompts IV to oral switch (asks for indication)	July 2011	Hospitalwide	
	Antibiotic change policy away from ciprofloxacin for urinary tract infections	September-November 2011 December 2011-January 2012	ER(ED), then hospitalwide	
863-bed teaching hospital	Piperacillin/tazobactam restriction	August 2010	Hospitalwide	• Overall limited resources (pharmacist part time); activities sporadic some months. • Piperacillin/tazobactam restriction (mainly by infectious disease fellows) saved money; push toward cefepime/ceftriaxone; main outcome number of courses. • Background—auditing, de-escalation, days of therapy/defined daily dose.
	Audit and feedback	Ongoing (predates ERASE *C. difficile* Project)	Hospitalwide	

Facility Description	Interventions	Start Date	Location	Notes/Comments
709-bed teaching hospital, with two sites (each similar size): Activities at Site 1	Piperacillin/tazobactam restriction (many years old)	Ongoing (predates ERASE *C. difficile* Project)	Hospitalwide	• ASP and infection control activities ongoing prior to ERASE C*. difficile* Project; resulted in significant decrease in *C. difficile* rates. • Overall staffing problems (PharmD for both hospital sites, used pharmacy residents). • Audit/feedback (pharmacy residents with PharmD—both campuses): educational component in ICU to reduce cefepime use, infectious disease guidance, days of therapy/defined daily dose (infectious disease attending with ICU, primarily at one site). Reemphasized beginning July 2011.
	Audit and feedback (de-escalation; emphasis on cefepime)	Ongoing July-September 2011	Hospitalwide	
		Ongoing October 2011-present		
709-bed teaching hospital, with two sites (each similar size): Activities at Site 2	Piperacillin/tazobactam restriction (many years old)	Ongoing (predates ERASE *C. difficile* Project)	Hospitalwide	
	Audit and feedback (de-escalation; emphasis on cefepime)	Ongoing July-September 2011	Hospitalwide	
		Ongoing October 2011-present		
	Algorithms/education targeting efepime use specifically in ICU	January 2011	MICU (7EM Medical)	
1,038-bed teaching hospital, with two sites: Activities at Site 1, approximately 700 beds	Azithromycin restriction	April-May 2011	Hospitalwide	• More interventions overall done at one of the two sites. • Azithromycin first restricted, then unrestricted to move patients away from moxifloxacin; formal medication utilization review for fluoroquinolones (ciprofloxacin and moxifloxacin). • Followup medication utilization review showed increase in azithromycin and decrease in moxifloxacin (by 25%) at both campuses. • Piperacillin/tazobactam audit mainly on medicine services (teaching and nonteaching services). • Education in conjunction with interventions (series of educational programs to different clinical services showing *C. difficile* rates, data, and teaching about de-escalation). • More sensible antibiotic choices, especially for sepsis.
	Piperacillin/tazobactam audit and feedback Educational component	Pilot (with infectious disease fellow): February-April 2011 Increased activity (restructuring with clinical pharmacists): May-October 2011	Medicine (Teaching and PA) Klau and NW	
	Sepsis antibiotic protocols	May 2011	ER(ED); reflected in hospitalwide prescribing	
1,038-bed teaching hospital, with two sites: Activities at Site 2, approximately 300-400 beds	Azithromycin restriction	April-May 2011	Hospitalwide	
	Piperacillin/tazobactam audit and feedback Educational component	Pilot (with infectious disease fellow): February-April 2011 Increased activity (restructuring with clinical pharmacists): May-October 2011	Medicine (Teaching and PA)	

Ø 3G/3H RESOURCES: Environmental Cleaning and Infection Prevention Checklists

Purpose: Examples of tools that participating facilities used to train and track compliance with environmental cleaning infection prevention practices.

Source: Adapted from GNYHA/UHF *C. difficile* Collaborative.

Instructions: Could be used as template for development of similar tool to be used at health care facilities.

EXAMPLE Environmental Checklist
Observation Form

For Daily and Terminal Cleaning - Room Observations:
Observe *two* daily cleanings per week and *one* terminal cleaning per month.
Report your results in the cells highlighted in yellow.

Check the type of cleaning:

Routine:	
Terminal:	

Date:	
Patient Name:	
Medical Record Number:	
Unit:	
Room Number:	

Instruction	Component	Yes	No	Not Applicable
At start, perform hand hygiene				Applicable to ALL
Put on PPE				
Needed supplies/equipment				
High touch surfaces: Damp dust/Clean:	Door knobs			
	Light switches			
	Windowsills			
	Spot clean walls with disinfectant cloth			
	Medical equipment (e.g., IV controls)			
	Bed rails and Call Button			
	Phone			
	Over bed table & drawer			
	Furniture			
	Overhead light (if the bed is empty)			
	TV & stand			
Bathroom: Disinfect w/ hypochlorite-based disinfectant	Bathroom door knob			
	Tub/shower			
	Bathroom handrails			
	Sink including faucet			
	Call button			
	Toilet (lever/flush, horizontal surface/seat)			
Clean floor:	Dust mop tile/wet mop tile			
For terminal cleaning, damp dust:	Bed frame			
	Mattress covers			
	Pillows			
	Blood pressure cuffs, as per hosp policy			
	Remove unused linen and other such items			
EXIT ROOM AFTER CLEANING IS COMPLETE:				
Remove trash, mops, soiled curtains, discard wipes/cloths, etc.				
Dispose of gloves, gown, wash hands				
RE-STOCK ROOM with SUPPLIES and EQUIPMENT as needed:				
After Daily Cleaning (Replace as needed)	Hand sanitizer/handsoap			
	Paper towels			
	Replace trash liner			
After TERMINAL CLEANING, gowns/gloves not needed: It's a clean room	Remake bed with clean linen			
	Replace as needed: Pillows, mattresses, pillowcovers, mattress covers			
	Replace curtains as needed			
Other:				
Change mop heads after each room				Applicable to ALL
Remove PPE before walking in hallway				
Perform hand hygiene				

EXAMPLE Infection Prevention Checklist for *Clostridium difficile* Observation Form

Instructions: <<Modify instructions as needed to comply with data collection protocol or internal policies>>

Observe 20 patients with suspected or confirmed *Clostridium difficile* (*C. difficile*) for the reporting month. Try to observe approximately 5 patients per week, making sure that you are not observing the same patient more than once. If you had fewer patients with *C.difficile*, observe all of them.

Date:
Patient Name:
Medical Record Number:
Unit:
Room Number:

Component	Not Applicable	Yes	No
Patient placed on CONTACT PRECAUTIONS per hospital's policy?[1]			
SIGN PLACED at infected patient's room per hospital's policy?			
PPE readily available?			
Dedicated Rectal thermometer?[2]			
HAND HYGIENE observed per hospital's policy?[3]			
PATIENT PLACEMENT:			
Patient placed in PRIVATE ROOM?			

For Patients in Shared Room:	Yes	No
Patient COHORTED with other patients suspected or known to have *C. difficile*?		

For patients sharing room with patients without *C. difficile*:	Yes	No
Is bathroom shared between patients?		

Notes: <<Modify notes as needed to comply with data collection protocol or internal policies>>

1. Contact precautions should be maintained by all disciplines. A physician order is NOT needed to place patients with symptoms of *C. difficile* on contact precautions.
2. Under the column labeled *Not Applicable*, enter the number of patients for whom rectal thermometers were not used.
3. Review all the hand hygiene observations (e.g., if there are 2 observations for 1 patient, count the 2 observations). Report the count of Yes's and No's.

Other Notes:

* Cleaning and disinfecting equipment and environment is NOT included on this form. This will be captured on the environmental checklist form. (see separate form for environmental checklist).
* To capture transport precautions in a meaningful way, standardized education for transporters will be developed through this collaborative. Educational sessions will be held with transporters, and a pre- and post-test will be developed to assess transporters' knowledge before and after education.

Ø 4A TOOL: How Do We Sustain ASP for Reducing *C difficile* Over Time?

Purpose: To help assess systems currently in place and ability to maintain and sustain ASP over time.

Source: ERASE *C. difficile* Project team.

Instructions: Complete checklist, review responses to ascertain the level of leadership support, and consider which areas need strengthening to move forward.

1. Will our current ASP staffing work on an ongoing basis? How well is your stewardship team working across departments and disciplines? What is the current distribution of responsibilities? Do you need to make changes?		**Action/remedy/plan if needed**:
Who are the staff dedicated to [and $ supported] for ASP?	**List Staff:** **Is this sustainable?** ☐ yes ☐ no	If Yes, describe: If No, what is the plan to make this sustainable?
What is the rotation/schedule for residents and fellows?	Describe: Is this sustainable? ☐ yes ☐ no	If Yes, describe: If No, what is the plan?
Is our ASP hospital wide?	☐ yes ☐ no If No, describe the scope of the program:	If No, describe where implemented:
How do we maintain inter-disciplinary communication?	Describe processes [committees, meetings, etc.]:	
What are ASP members' responsibilities?	Describe:	
Is the distribution of responsibilities fair?	☐ yes ☐ no	If No, describe changes needed:
Do we need to make changes?	☐ yes ☐ no	If Yes, describe changes needed:

2. What is the plan for ongoing measurement and feedback? A plan is only as good as the systems in place that ensure sustainability. It is crucial to plan at the onset for ongoing monitoring, maintenance, and evaluation of the ASP for reducing *C. difficile*		**Action/remedy/plan if needed:**
Do we have a plan for monitoring the ASP?	☐ yes ☐ no If Yes, describe:	If No, what should the plan be?
Do we have a plan for maintenance of the ASP?	☐ yes ☐ no If Yes, describe:	If No, what should the plan be?
Do we have a plan for evaluation of the ASP?	☐ yes ☐ no If Yes, describe:	If No, what should the plan be?
Are our data in a workable format?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to obtain?
What are our current IT systems, staffing, and capabilities?	Describe:	
Do we have appropriate IT software?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to obtain?
3. What ongoing organizational support will be needed to keep the new ASP practices in place? Maintaining your ASP requires organizational support on multiple levels. Ongoing organizational support for ASP for reducing *C. difficile* will be strongest if you can demonstrate that it is aligned with the medical center's strategic priorities and that it addresses pressing problems.		**Action/remedy/plan if needed:**
Is there organizational support for ASP?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to obtain?
Do we have the resources to maintain adequate and dedicated ASP staffing?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to obtain?
Do we have the appropriate IT support to produce the most useful data?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to obtain?
Do we have educational opportunities and forums to keep staff current on our ASP practices?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to provide?
Do we have systems in place to maintain best practices for ASP?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to maintain?
Do we have clinical leadership support for ASP?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to obtain?

Do we have medical center leadership for ASP?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to obtain?
Does ASP fit in the hospital's overall-strategic planning?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to include ASP in strategic planning?
4. How do we develop an effective business case? Given the environment of tightening resources in most medical centers, you will likely need to make a strong business case for continued or expanded investment in your ASP to include *C. difficile*.		**Action/remedy/plan if needed:**
Are there financial barriers to implementing ASP?	☐ yes ☐ no	If Yes, describe:
Do we have a good estimate of cost savings realized through full implementation of ASP?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to obtain estimates?
Have we calculated anticipated savings?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to obtain?
Have we calculated actual savings?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to calculate?
Do we have a description of how ASP activities translate into cost savings?	☐ yes ☐ no If Yes, describe:	If No what is the plan to create a description?
Do we have a description of how improved patient outcomes bring about cost savings?	☐ yes ☐ no If Yes, describe:	If No, what is the plan to create a description?

Please note: The following three tools are examples developed by facilities participating in the ERASE *C. difficile* Project to implement interventions.

Ø 4B TOOL: UTI Guidelines Form

Purpose: Urinary tract infection (UTI) treatment guidelines. Gives background, local microbiology data, and suggested empiric regimens.

Source: F. Palmieri, Bronx-Lebanon Hospital.

Instructions: Review and adapt as appropriate.

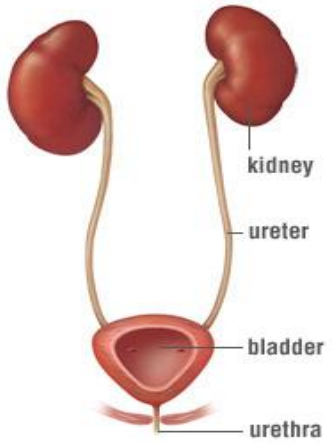
Empiric Therapy Regimen

Acute Uncomplicated Cystitis			
Antibiotic Recommendations	**Caution**	**Duration**	**Possible Side Effects (selected)**
Nitrofurantoin (Macrobid) 100 mg twice daily	**Do not use if CrCl < 60. Do not use for elderly patient > 65 years old. Do not use during pregnancy at term** (38 to 42 weeks gestation). Caution in cholestatic jaundice and hepatic dysfunction.	5 days	GI intolerance; Lupus-like reactions; rash Rare: peripheral neuropathy; trigeminal neuralgia pulmonary reactions; hepatitis; hemolytic anemia in G6PD deficiency
Cefuroxime 250 mg oral q12h	Avoid in penicillin allergy. If CrCl < 10mL/min, administer once daily.	7 days	Anaphylaxis (PCN allergic); diarrhea; other super infections; eosinophilia; positive Coombs test; interstitial nephritis; hemolytic anemia
Cefpodoxime 100 mg oral q12h	Avoid in penicillin allergy. If CrCl < 30mL/min, administer once daily.	7 days	As above
Ciprofloxacin 250 mg oral q12h - **3rd line therapy due to resistance.** If selected, urine culture with followup is recommended.	If CrCl < 30mL/min, administer once daily.	5 days	*C. difficile* colitis; QTc prolongation; nephritis; tendon rupture; neuropathy
Acute Uncomplicated Pyelonephritis			
Antibiotic Recommendations	**Caution**	**Duration**	**Possible Side Effects (selected)**
Initial Therapy			
Ceftriaxone 1 g IV/IM 1st dose	Avoid in serious, type-I PCN allergy	Initial dose	As above for cefuroxime plus pseudocholelithiasis
Gentamicin IV 3 mg/kg x1 dose	No adjustment for ***initial dose*** needed for renal failure	Initial dose	Renal function
Followup Therapy – Tailor Therapy to Culture and Sensitivity Report; Otherwise:			
Ciprofloxacin 500 mg oral q12h	As above	7 to 14 days	As above
Cefuroxime 250 mg oral q12h	As above	7 to 14 days	As above
Cefpodoxime 200 mg oral q12h	As above	7 to 14 days	As above

BRONXcare™
BRONX-LEBANON HOSPITAL CENTER

URINARY TRACT INFECTION

Treatment Guidelines



Bronx Lebanon Hospital Center
1650 Grand Concourse
Bronx, New York

Bronx-Lebanon Hospital Center
Antibiotic Stewardship Committee

BACKGROUND

- *Escherichia coli* constituted 91 percent of community-acquired urinary isolates in the past year in BLHC.
- Bacterial resistance to sulfamethoxazole/trimethoprim (SMZ/TMP) and fluoroquinolones has increased.
- Urine culture and susceptibility (C & S) tests are strongly recommended for any therapy changes.
- Modify therapy according to BLHC UTI guidelines.
- **Do not use SMZ/TMP as empiric therapy or ciprofloxacin as initial therapy due to high resistance to *E. coli*.**

% Sensitive Urinary Isolates, Community Acquired (2010)	
E. COLI	**ANTIBIOTICS**
45	Ampicillin/sulbactam
75	Amoxicillin/clavulanate
92	Ceftriaxone
78	Cefazolin
74	Ciprofloxacin
87	Cefuroxime
94	Nitrofurantoin
95	Piperacillin/tazobactam
63	Sulfamethoxazole/trimethoprim
88	Gentamicin
39	Ampicillin

GUIDELINE RECOMMENDATIONS

STEP 1: Urinalysis

- Urinalysis (UA)
- Urine micro
- Urine culture
  - Before antibiotics are started
  - For ED patients
  - Inpatients with UTIs
  - All patients with suspected pyelonephritis

STEP 2: Empiric Antibiotics

- **See table on back.**

STEP 3: Pathogen-Directed Therapy

- With culture and susceptibility results, change antibiotic to pathogen-specific agent.
- Follow up on all discharged patients to provide appropriate therapy based on culture and sensitivity results.
- SMZ/TMP can be used at this point as dictated by the C & S results.
- Reserve fluoroquinolones for pyelonephritis and major systemic infections due to resistance development.

STEP 4: Duration

- As important as the therapy itself.
- Excessive use can lead to:
  - Adverse reactions.
  - Increased antimicrobial resistance.
- See table on back for specific duration recommendations.

STEP 5: Epidemiologic Surveillance

- With time and selective pressure, resistance patterns will change.
- At least once a year, susceptibility patterns will be reassessed and the need to change treatment recommendations evaluated.

ASYMPTOMATIC BACTERIURIA

- Asymptomatic bacteriuria is defined as isolation of a specific quantitative count of bacteria in an appropriately collected urine specimen from an individual without sign or symptoms of a urinary tract infection.
- Avoiding treatment of asymptomatic bacteriuria is important for reducing the development of antibiotic resistance.
- Treatment of asymptomatic bacteriuria is not appropriate for: women (premenopausal, nonpregnant), diabetics, elderly people, nursing home residents, or patients with spinal cord injury or indwelling urethral catheters.
- Treatment of asymptomatic bacteriuria is appropriate for pregnant women and for patients undergoing urologic procedures in which mucosal bleeding is expected.

REFERENCES

1. Gupta K, Hooton TM, Naber KG, et al. International clinical practice guidelines for the treatment of acute uncomplicated cystitis and pyelonephritis in women. A 2010 update by the Infectious Diseases Society of America and the European Society for Microbiology and Infectious Diseases.Clin Infect Dis 2011:52(5):e103-20. Review.
2. Nicolle LE, Bradley S, Colgan R, et al Infectious Diseases Society of America guidelines for the diagnosis and treatment of asymptomatic bacteriuria in adults. Clin Infect Dis 2005;40:643-54.

Ø 4C TOOL: Pipercillan/Tazobactam De-Escalation Form

Purpose: Forms for tracking piperacillin/tazobactam audit/feedback. The tracking forms give a way to track number of patients with criteria for review and then a way to document stewardship interventions.

Source: Y Guo & B. Ostrowsky, Montefiore Medical Center.

Instructions: This 2-page form may be tailored for possible use at your facility; review and adapt as appropriate.

ANTIMICROBIAL STEWARDSHIP TEAM (AST) SUGGESTIONS

1. Run/obtain daily list of piperacillin/tazobactam utilization report.
2. Select patient who has been on piperacillin/tazobactam for >72 hours without ID consult.
3. Review Carecast/chart for indication, duration, culture susceptibility, etc., to determine the appropriateness of piperacillin/tazobactam usage.

Date: _____

Total number of patients who have been on piperacillin/tazobactam: _____

Total number of patients who have been on piperacillin/tazobactam for >72 hours: _____

Total number of patients who have been on piperacillin/tazobactam >72 hours with ID consult _____

Total number of patients who have been on piperacillin/tazobactam >72 hours without ID consult _____

From patients who have been on piperacillin/tazobactam >72 hours without ID consult, number of patients reviewed:

Date: _____ Patient name: _____ MR# _____ Unit/room _____

Presumptive diagnosis:

- ❑ Culture documented pseudomonas/gram negative resistant infection
  - o Site of documented culture _____
- ❑ Healthcare-associated pneumonia (continued empiric coverage)
- ❑ Healthcare-associated intra-abdominal infection (continued empiric coverage)
- ❑ Healthcare-associated urinary tract infection (continued empiric coverage)
- ❑ Necrotizing soft tissue infection (not cellulitis) (continued empiric coverage)
- ❑ Other healthcare-associated sepsis/infection. List syndrome _____
- ❑ Other. List syndrome _____

Piperacillin/tazobactam (dose/frequency/duration)

_____

Based on information available, we suggest the following modifications to your patient's antimicrobial therapy.

1. _____
2. _____
3. _____

These changes are recommended based on:

- ❑ Culture/sensitivity data
- ❑ Drug toxicities/side effects
- ❑ Opportunity to change to oral therapy
- ❑ More narrow spectrum antibiotic regimen
- ❑ Specific diagnosis
- ❑ Others: _____

Comments:

Notes left in the chart:
❑ Yes ❑ No

Did the team accept your recommendation?
❑ Yes ❑ No

If a thorough analysis of this case is desired, please request an ID consultation.

_____
Pharmacist

Ø 4D TOOL: Medication Use Evaluation Template

Purpose: A template for reviewing use patterns, including graphic comparison over time.

Source: S. Brown & B. Ostrowsky, Montefiore Medical Center.

Instructions: This template may be tailored for possible use at your facility; review and adapt as appropriate.

MEDICATION USE EVALUATION

Unit/Area: XXX Medical Center (XXX Campus)

Submitted by: Antibiotic Stewardship Program

Title: Oral Azithromycin Utilization Evaluation

Date: XXX

==========

INDICATORS: (1) Usage and mean duration of oral azithromycin before and after unrestriction; and (2) whether there is a decrease in quinolone use before and after unrestricting azithromycin.

PLAN

Disciplines Involved: Antibiotic Stewardship Program

Monitoring Period: XXX – XXX

Sample Size: XXX patients at Campus and XXX patients at Campus according to SYBASE query listing.

Methodology: Retrospective reviews of antibiotic usage were conducted in patients who received oral azithromycin from XXX to XXX. The total numbers of patients on oral azithromycin, ciprofloxacin, moxifloxacin, and various other antibiotic combinations (i.e., azithromycin plus ceftriaxone, piperacillin/tazobactam, ciprofloxacin, or moxifloxacin) were calculated. Analyses were conducted to determine the usage and mean duration of oral azithromycin before and after unrestriction.

DO

Reports were generated using the SYBASE query listing all patients who received oral azithromycin, ciprofloxacin, moxifloxacin, piperacillin/tazobactam, and ceftriaxone between XX and XX.

CHECK

- A total of XXX (nonexclusive) patients were included in this review (Table 1).

Table 1

	Month	Month	Month
Campus			
Mean duration of azithromycin (range), days of therapy	X (Y-Z)	X (Y-Z)	X (Y-Z)
Antibiotics	**Number of Patients**		
Azithromycin PO	XX	XX	XX
Moxifloxacin PO	XX	XX	XX
Ciprofloxacin PO	XX	XX	XX
Campus			
Mean duration of azithromycin (range), day	X (1-X)	X (1-X)	X (1-X)
Antibiotics	**Number of Patients**		
Azithromycin PO	XX	XX	XX
Moxifloxacin PO	XX	XX	XX
Ciprofloxacin PO	XX	XX	XX

Table 2. Azithromycin PO and Ceftriaxone

	Month	Month	Month
Campus			
Number of patients	XX	XX	XX
Duration of azithromycin (range), day	X (1-X)	X (1-X)	X (1-X)
Campus			
Number of patients	XX	XX	XX
Duration of azithromycin (range), day	X (1-X)	X (1-X)	X (1-X)

Table 3. Number of Patients on Azithromycin PO and Moxifloxacin

	Month	Month	Month
Moses	XX	XX	XX
Weiler	XX	XX	XX

Table 4. Number of Patients on Azithromycin PO and Ciprofloxacin

	Month	Month	Month
Moses	XX	XX	XX
Weiler	XX	XX	XX

Table 5. Number of Patients on Azithromycin PO and Piperacillin/ tazobactam

	Month	Month	Month
Moses	XX	XX	XX
Weiler	XX	XX	XX

Figure 1. Comparison of Oral Azithromycin and Quinolone Usage at Campus, Before Unrestriction

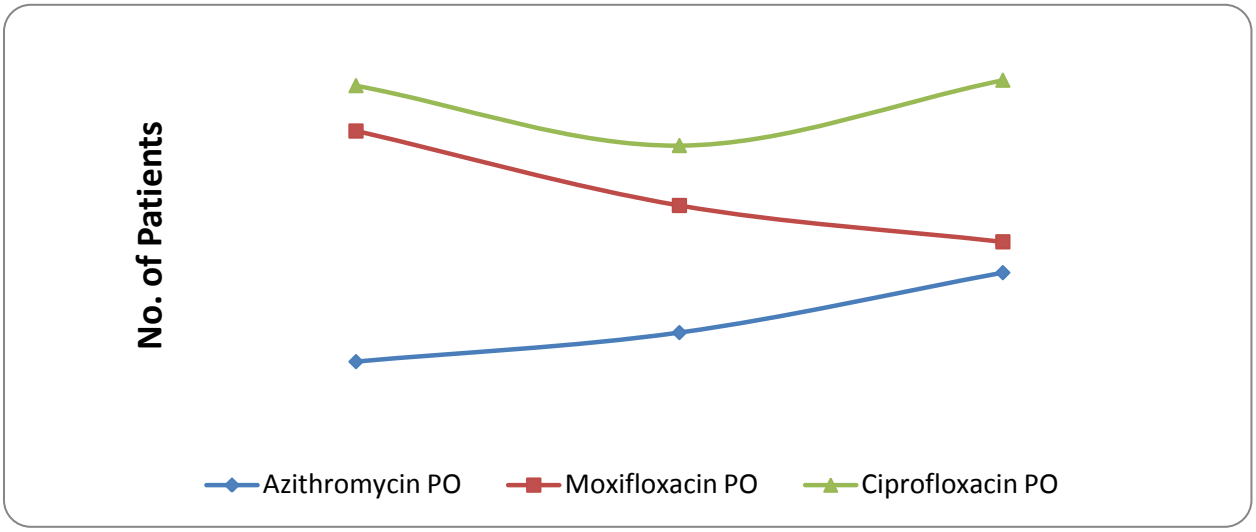
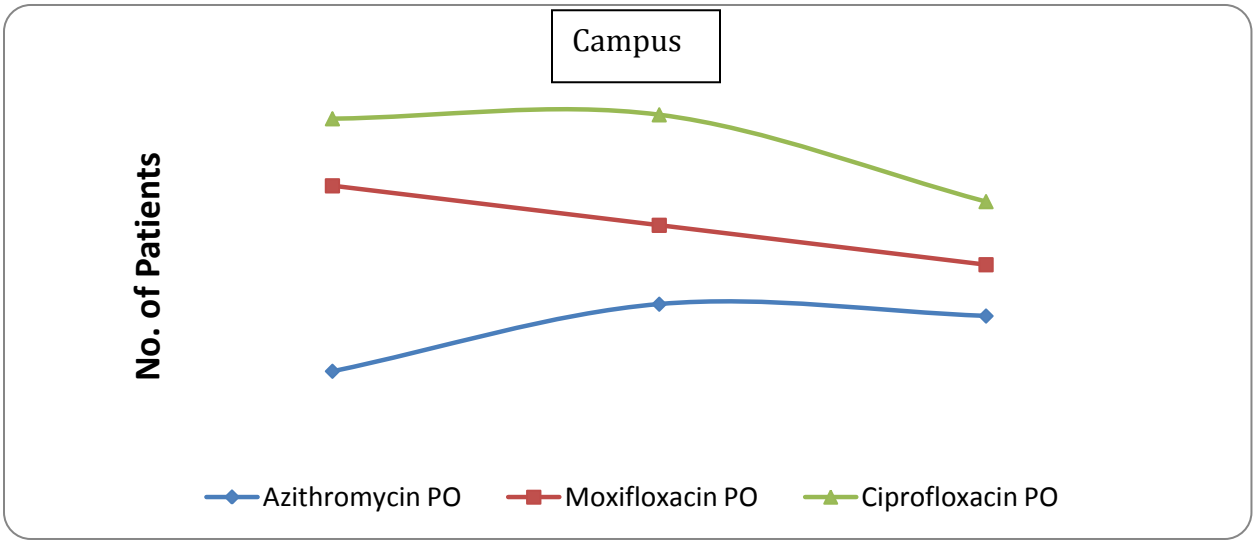


Figure 2. Comparison of Oral Azithromycin and Quinolone Usage at Campus, After Unrestriction



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- There was a trend of XX oral azithromycin usage comparing XX to XX after unrestriction.
- There was a trend of decreasing oral moxifloxacin usage comparing XX to XX; however, it might be an artifact of seasonal change. Comparing XX to XX, the total number of patients on oral moxifloxacin did not change significantly.
- The antibiotic stewardship program will continue to monitor oral azithromycin usage via pharmacist/house staff education on duration of therapy and prevent double atypical coverage for asthma, chronic obstructive pulmonary disease, or community-acquired pneumonia.