Optimizing Antimicrobial Prescribing Practices While Watching the Hospital Bottom-Line: Development and Application of Business Models to Support Antimicrobial Stewardship Programs (ASPs)

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Introduction. The movement towards formalized ASPs has gained a significant momentum in the last five years. Despite over 25 years of literature on antimicrobial stewardship, including guidelines and white papers from professional societies, the recent upsurge of activity in development of institutional ASPs is remarkable. There are many factors which could be listed as contributing to this new movement (see Table 1) and likely not a single one of these has sole responsibility for carrying the momentum for this changing landscape. The reason for this is that, in general, it is the cost-savings offered by effective ASPs which reduce the hospital's drug budget. Regardless of the cause one fact remains: society, payers, hospitals, and patients benefit from the reduction of nosocomial infections. Consumers and payers of healthcare no longer consider HAIs as "business-as-usual" scenarios. But any new program will come under the purview of hospital administrators when increased resource allocation is requested. Given that ASPs require a significant investment and commitment by the institution, the core team of an infectious diseases physician champion and clinical pharmacist with specialized training, along with supporting clinicians, the launching of a successful ASP plan needs a robust business model and written formal proposal for funding.

Table 1. Potential Factors Contributing To The Rise In ASPs

Reality	Hospital administrators understand that hospital-acquired infections (HAIs) owe in part to selective pressure exerted by inappropriate antibiotic use and such infections increase resources in light of lowered reimbursement
Training and certification	The growth of antimicrobial stewardship training and certification programs foster popularity of ASPs and support the unmet needs for trained clinicians
Technology	The evolution of technology and computer decision support systems (CDSS) point the way despite the relatively high costs of their products
Benchmarks	The federal government, through the CDC, levies penalties to hospitals for certain infections which exceed a benchmark referred to as the standardized infection ratio (SIR)
Literature and reports	Numerous governmental reports estimate the costs of antibiotic resistant infections to the national GDP which trickles down to the individual hospital. This is in contrast to many years of data showing mortality and length of stay increase for infections due to resistant pathogens when compared to infections due to antibiotic-susceptible pathogens of the same species
Improved surveillance	Literature, reports, and society white papers would not be possible without the data-mining capabilities which focus on antibiotic resistance surveillance. Insurers, state governments, and Medicare have been analyzed to supply data for these reports.

Elements of ASP funding.

A business case analysis requires an objective estimation of the costs associated with a new ASP or any change therein. These are strongly dependent on the goals and objectives of the ASP, which need to be developed first. The scope of these will dictate the activity and documentation plans for the first phase of the ASP. Obviously, the more intense and broader program requires more resources. These will primarily come in the form of full-time employees (FTEs). If the hospital's information technology department is to be utilized, for example, then some allocation for FTE should be calculated. The same applies for pharmacy, infection prevention, microbiology, and other departments. On the other side, expected benefits of the ASP should be listed and converted into US dollars. These may include decreased drug budget, fewer healthcare-associated infections (i.e., *Clostridium difficile* infections), fewer healthcare-associated infections due to multidrug-resistant pathogens, and improved outcomes such as decreased length of stay. In other words, all elements which compose program costs and revenue generation should be listed to create a net value.

The role of the infectious diseases specialist.

The infectious diseases specialist has a well-established role in antimicrobial stewardship. ID specialists are uniquely qualified to direct ASP efforts, both at a programmatic and concurrent review level that will ensure the success of these programs. On a frequent basis, they can meet with pharmacists to review patient records, laboratory data, and antibiotic regimens which are identified before the meeting. Sometimes an ID physician may contact the prescriber. The most educational role is serving as an

example of prudent antibiotic use. Although clinical practice guidelines have been developed by the Infectious Diseases Society of America, implementation of these guidelines must be adapted to the institution's physician structure. ID physicians may be more successful when communicating with other physician peers when acting as the director of the ASP. There is no conflict of interest when recommendations are consistent with institutional guidelines and the medical staff has been educated on prudent antibiotic use.

Regardless of whether the ASP's ID physician is in private practice or not, an FTE value can be assigned as a program cost. Fair market value (FMV) should be calculated to compensate the physician for time spent out of the office or generating revenue from consultation. For example, an ASP ID physician devoting 8 hours each week within a standard 40-hour work week constitutes 20% (or 0.2) of that physician's time "lost" in generating revenue from non-ASP activities. Depending on the hourly rate requested in the ASP plan and budget the hospital "C" suite should execute a financial agreement with the physician.

The role of the clinical infectious diseases pharmacist.

For most programs, at least in the first one to two years, focus will be on developing and executing an activity plan. While this will be based upon several qualities of the ASP pharmacist (expertise, time allotment, business plan, urgent needs), activities will result in some measurable output. Traditionally the simplest translation has been the drug budget. Therefore, activities should be identified, perhaps 4 or 5 of these, which will generate decreased inappropriate antibiotic prescribing. While the potential number of such activities are numerable and beyond the scope of this paper it relies on the ASP team to identify the most urgent needs which translate into lower drug utilization and costs. However, safety and adverse events could also be lower and these should always be taken into account. There is adequate literature to assign costs to such adverse events as nephrotoxicity, neuropathy, and even nausea and vomiting.

The Department of Pharmacy will need to add resources to replace the time required for ASP pharmacist activities. Many programs do not reach a maximal potential when the pharmacist in charge of ASP activities works less than 1.0 FTE. This is a reality. But it is also dependent on the ASP goals and objectives and the ability of the ASP to "discover" a sufficient number of concurrent activities which will constitute 1.0 FTE of time. Certainly, projects identified in a sequential order may not need 1.0 FTE, and may require "bursts of activity" and additional "project days". Regardless, these can still be converted to FTE aliquots. The calculation of time needed to develop and execute projects will be determined partly by the ability to analyze the institution's data. An important question to ask – "is the data there?" – may dictate much of the time requirements. Impediments to data mining and data synthesis is a major contributor to FTE calculations. Interestingly, computerized decision-support systems (CDSS) has in many ways rescued FTE but with technology cost outlays of their own.

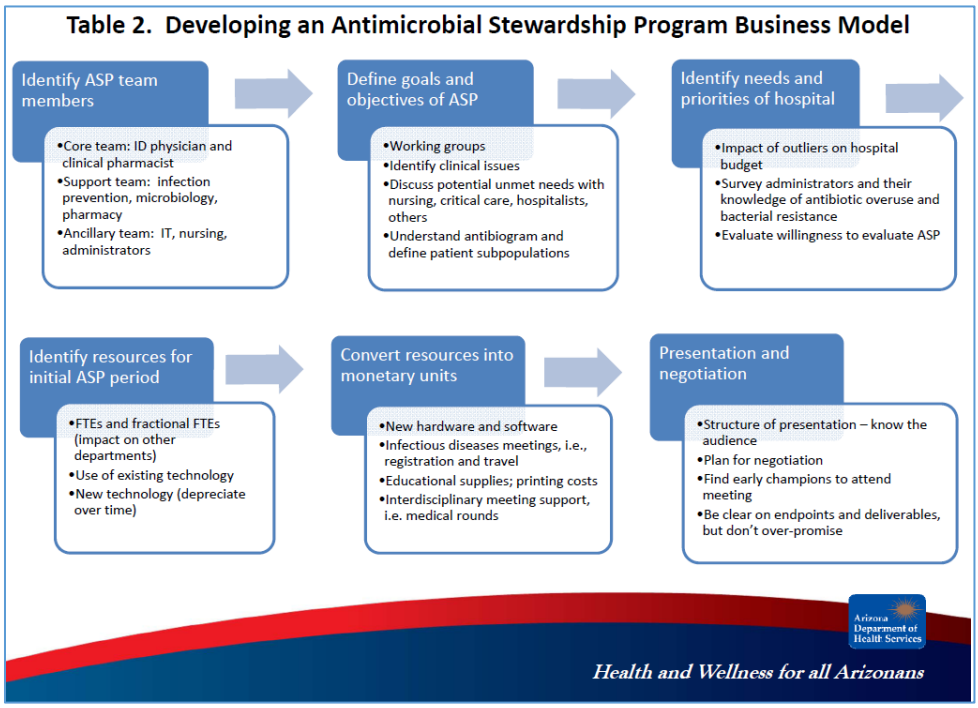
ASPs can generate revenue.

Fortunately, there is no longer a debate regarding the financial and clinical benefits of an ASP. There is a plethora of literature which continues to be generated in an ever-rising stream of data providing the benefits of projects undertaken by ASPs. It would be folly to argue the point. The challenge is to identify the amount of resources (cost) needed to generate a defined return on investment (revenue).

Generating the cost side of the ASP business model.

Remember that hospital administrators, pharmacy directors, and quality assurance staff will need to evaluate an ASP business plan/model prior to committing resources. The business model should be developed as a commitment to the institution, healthcare practitioners, and its patients. Therefore, the smart business plan needs to be developed in a way in which both ASP participants and the hospital are winners. The business plan consists of both perspectives – the ASP team and hospital administration.

Table 2. Developing an Antimicrobial Stewardship Program Business Model



The latter includes the Chief Medical and Nursing Officers, Pharmacy and Therapeutics and Medical Executive Committees, and preferably medical, nursing, pathology, and epidemiology department heads. The clinicians and administrators within these groups must endorse the goals and objectives, activities, and business plan of the ASP. They will constitute important stakeholders for the ASP.

The steps to developing the ASP business model is dependent on 6 activities shown in Table 2.

1. The ASP is initiated by identifying its team members, and logically, the more team members the greater the chance that the budget will be greater. Some team members may be easily capable of incorporating ASP activities into their daily responsibilities. However, some may not without sacrifice. This may come in the form of additional FTEs.
2. Once the team members and individual HCP time allotments have been identified, the goals and objectives are defined. Too often, these are defined by the core team – the ID physician and pharmacist. However, subsequent ASP activities should be thought of in the context of working groups. The ASP budget should incorporate working groups, who more effectively identify clinical issues and unmet needs, and the compilation of which issues requires multiple meetings with numerous potential stakeholders or "enablers." Working groups, however, may require a larger budget.
3. In step 3 in Table 2, the business model must take the perspective of hospital and medical administration. Their clinical needs and issues help identify deliverables, but the paths taken may be expensive. The audience which will evaluate the ASP model must see that their needs are addressed also. Two potential needs are listed in the Table. But the most important aspect of the business model is identifying the willingness to evaluate the ASP model and business plan.

Therefore, the plan for an ASP must be scalable to the needs of the institution. For example, a hospital with a high proportion of ICU beds needs to see several projects involving ICU antibiotic prescribing practices. Priming your audience is important and the core team should meet frequently with hospital administration prior to the larger meeting.

4. The fourth step is to identify resources. These will generally be in the form of FTEs. But ASP team members will always need to devote some time even is the fractional FTE does not result in a dollar assignment. For example, infection prevention may allot 0.1 FTE to working with the ASP team but can meld this into their daily activities. The 0.1 FTE in this case results in no monetary consideration (but this may need to change later). Therefore, it is helpful to identify work group activities based on need. Contrary to this example, an optimal contribution of 1.0 FTE from the pharmacy department will usually require hiring additional staff. If the hospital is academic with an ID fellowship program then another resource could be available and accounted for. Also, data analysts may be needed. Hospitals which cannot contribute such resources rely on sequential projects which can take several months and delay materialization of revenue sources from an intervention. Finally, technology is very important in an era of computerized physician order entry (CPOE) which requires significant financial outlays. Using these systems, such as EPIC and CERNER, for ASP activities can be frustrating as these CDSSs are not built with the primary purpose of antimicrobial stewardship. Additional CDSSs exist (TheraDoc, Sentri 7, and many others) but are also expensive and need to be integrated into EPIC, CERNER, or other main frames. Using existing technology may come with a cost, but perhaps less than contracting for an entire system specifically for the ASP or infection prevention.
5. All projects anticipated in the first 6 to 12 months, the working groups involved, and human resources need conversion to dollar units. The ASP cost will need to be balanced against potential revenue. Will the ASP program be self-supporting? Frequently, budgets have not included many aspects of the ASP. Some are listed in the Table. A program which emphasizes education must account for costs involved in luring prescribers to a meeting. The costs of printing, mailing, and analyzing surveys for purposes of understanding baseline knowledge concerning antimicrobial agents costs something. Also listed is attendance to infectious disease meetings, such as ICAAC and ID Week.
6. The presentation of the ASP model, including goals and objectives, activities, scope, and costs will need careful consideration. Outcomes measurements are essential to the presentation. Will readmissions be tracked? What are the metrics – antibiotic costs per patient-day? Also, remember that administrators gravitate to statements such as “I will cut your costs AND increase your revenue.” Better hospital performance improves patient satisfaction, increases reputation. While societal costs are important, they should not replace the argument for an ASP and benefits to the institution. There are additional suggestions. The core team should rehearse several times with ASP champions who have already established trust and credibility with hospital administrators. The Pharmacy Director, an essential member of the ASP planning process, must be fully supportive. The ID physician ASP director is assumed to be supportive, but the ID division as whole must be willing to work within the ASP to serve as role models. Importantly, a “best negotiating platform (BNP)” must be developed. Hospital administrators have competing financial interests and will need to know why they should provide capital in the ASP. Lack of a negotiating alternative is a failure of many programs. It is common that a fixed cost proposal is met with a simple “no” from administrators who pay fair market value for services.

Generating the revenue side of the ASP business model.

Where will the revenue come from? A search of PubMed (accessed 1/5/2015) revealed no articles using the linked term "antimicrobial stewardship AND business model(s)". But revenue or cost-savings is another important part of the ASP business model. Estimates must be realistic, commensurate with the activities and time commitments proposed, and conservative. Cost-savings from reduced antibiotic expenditures are obviously basic calculations. However, cost savings estimated for prevention of adverse drug events and toxicities, decreased length of stay, decreased resistance, and decreased infections due to MDR pathogens and *Clostridium difficile* infections pose more difficult challenges. Extrapolation of the deliverables to real revenue for these interventions are difficult and therefore examples from the literature would be useful. Cost-savings should be adjusted to hospital census or number of beds. Intermediately challenging revenue calculations would derive from guideline concordance, but how does this result in lower overall costs to the hospital? Dozens of additional examples can be located in the literature and business models should be supported by these. The CDC has posted a table of references to use to justify potential cost savings (http://www.cdc.gov/getsmart/healthcare/evidence/asp-int-costs.html) as well as multiple endpoints (http://www.cdc.gov/getsmart/healthcare/evidence/asp-mep.html). An excellent starting point with regards to justifying the ASP would be the Arizona Slide sets for ASPs (http://www.azdhs.gov/phs/oids/hai/advisory-committee/antimicrobial-stewardship.htm). Specific business models are located on the Society for Healthcare Epidemiology of America (SHEA) website (http://www.shea-online.org/PriorityTopics/AntimicrobialStewardship.aspx). An Excel spreadsheet is complete with several tabs which take the user in a logical stepwise process through cost expenditures and program revenue (http://www.shea-online.org/PriorityTopics/AntimicrobialStewardship/ImplementationToolsResources.aspx).

Final Note and Summary.

Remember the average tenure of a hospital CEO is 3 years. Maintaining the ASP contract will require interim reports and annual re-justifications to new CEOs and other stakeholders. Demonstrate positive trends and baseline data to measure the value of your ASP. Track percent of recommendations accepted, antibiotic therapy durations greater than 7 days, antimicrobial resistance, hospital-acquired infections, and other deliverables established in the first set of goals and objectives. New ASP infrastructures and projects are expected to maintain the ASP. Finally, compare your institution with others regionally but adjust for obvious confounders such as case-mix index (CMI) and services such as transplant, oncology, and specialty units. The successful ASP is based on trust and credibility. Face-to-face interactions with prescribers and other HCPs is no different from other business-like relationships. Consider a "business card" as a good start to advertising you and the services the ASP team provides. Good luck.

Healthcare-Associated Infections (HAI) Antimicrobial Stewardship Subcommittee
http://www.azdhs.gov/phs/oids/hai/advisory-committee/antimicrobial-stewardship.htm

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