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IDSA
Infectious Diseases Society of America

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Dear PACCARB Members:

IDSA greatly appreciates this opportunity to provide feedback to the Presidential Advisory Council for Combating Antibiotic Resistant Bacteria (PACCARB) on the critical issues of antibiotic stewardship, infection control and data collection. We appreciate that the PACCARB is seeking information on these topics in both human health and agricultural settings, both domestically and globally. We hope our responses to the Council's questions below will be useful in your deliberations and that the Council will not hesitate to contact IDSA with any questions.

1. **Describe how organizations are influencing curricula regarding primary prevention (antibiotic stewardship, infection prevention, and control). Please include information about certification examinations, requirements, and continuing education, if relevant.**

IDSA is committed to providing state of the art education on antibiotic stewardship to our members through a variety of mechanisms to ensure that new and current ID physicians have the training and knowledge necessary to lead antimicrobial stewardship programs at their institutions and to drive the culture change needed to ensure successful adoption of stewardship practices by both providers and patients. Stewardship remains a primary focus of IDWeek, our annual scientific meeting, at which ID physicians and others can earn continuing medical education credits, in partnership with the HIV Medicine Association (HIVMA), Pediatric Infectious Diseases Society of America (PIDS) and the Society for Healthcare Epidemiology of America (SHEA). There are currently 10 stewardship focused sessions planned for IDWeek 2016:

1. Approaching Antimicrobial Stewardship in Outpatient Settings
2. Electronic Antibiotic Stewardship Tools
3. The ID Physician New to Antimicrobial Stewardship and/or Infection Prevention
4. Getting Everyone's Attention: Using Social Media to Advance Infection Prevention and Stewardship
5. Stewardship at the Bedside: Engaging Front-Line Providers

6. Pediatric Antimicrobial Stewardship
7. Leveraging Human Factors Engineering to Advance Infection Prevention and Antimicrobial Stewardship
8. Guidelines and Core Measures: Impact on Stewardship
9. Antimicrobial Stewardship in Skilled Nursing Facilities
10. Diagnostics in Stewardship

IDWeek 2016 will also feature two pre-meeting workshops focused on stewardship:

1. Vincent T. Andriole Board Review Course: Antibiotic Resistance (one lecture)
2. Best Practices for Antimicrobial Stewardship Programs

IDSA also provides maintenance of certification module on infection control, which includes questions on antimicrobial resistance and stewardship.

IDSA convenes a committee of the directors of ID training programs at institutions across the country, and in 2015, mandated that this committee develop a national curriculum for all ID Fellowship programs to teach antimicrobial stewardship and to train ID fellows for leadership roles in stewardship programs. Also, the committee is in the process of collecting best practices regarding the current teaching of stewardship in fellowship programs for dissemination.

IDSA is assessing the need for any additional education resources needed for ID physicians regarding antimicrobial stewardship and will continue updating our tools as needed.

2. Describe how healthcare organizations can best: (a) Educate and provide feedback to providers in clinics/facilities about infectious diseases diagnostic testing, optimal antibiotic prescribing, and infection prevention; where relevant, please include information about what incentives and disincentives these organizations have in place with the goal of improving antibiotic prescribing (*e.g.*, using clinical decision support) and prevent spread of resistant infections; and, (b) encourage and/or incentivize providers to report antibiotic use and resistance data for all patient populations.

<u>ID Physician Led Antimicrobial Stewardship Programs</u>
Antimicrobial stewardship programs (ASP) led by ID physicians are the ideal tool for educating health care providers about ID diagnostic testing and optimal antibiotic prescribing. In April, 2016, IDSA and the Society for Healthcare Epidemiology of America (SHEA) released new antibiotic stewardship guidelines to provide for implementation of ASP. The guidelines note that passive educational materials (lectures, brochures, etc.) alone are not sufficient to maintain progress in improving antibiotic prescribing, but should instead complement more robust interventions, such as preauthorization of broad spectrum antibiotics and prospective review after two or three days of treatment. Ultimately, antibiotic stewardship must be integrated into each health care facility's culture as a quality measure. A variety of educational efforts geared toward administrators and providers can contribute toward that goal.

ASP should be operated by multidisciplinary teams, led by an ID physician and supported by ID-trained pharmacists, clinical microbiologists, infection preventionists, and nurses. ID physicians

possess a comprehensive knowledge of antimicrobial prescribing, diagnostics, local resistance trends, and the proper care and management of patients with complex infections. They also have experience leading multidisciplinary teams of health practitioners to provide education to colleagues, as they have done successfully with certain infection prevention interventions. Having an ID specialist lead an ASP can be done effectively through performance-based contractual agreements, whereby the ID specialist is paid as a physician executive for time dedicated to antimicrobial stewardship as measured by specific metrics such as the number of training sessions conducted, the reduction in antibiotic drug expense on the pharmacy budget, meaningful outcomes such as reduction of resistance, etc. It is important to recognize that ASPs require the investment of time and resources in order to produce measureable results.

ASP teams establish and update diagnostic bundles for common clinical syndromes and protocols for their institutions' antibiotic prescribing and review (based upon professional society guidelines and appropriately taking into account local resistance patterns and other relevant data). ASP teams can also conduct a variety of large group, small group and individual educational activities.

Specific topics on which ID physicians leading ASPs can provide education and one-on-one support to fellow clinicians include interpretation of diagnostic test results and corresponding modification of therapy, antimicrobial dosing, and duration of therapy. For example, clinicians typically order a broad spectrum antibiotic while awaiting diagnostic test results. If the patient exhibits clinical improvement, the physician may be reluctant to alter therapy, even though diagnostic test results indicate that a narrower spectrum antibiotic or no antibiotic is appropriate. An ID physician leading an ASP is well positioned to educate providers on the risks to individual patients and broader public health associated with such behavior, as well as more appropriate interpretation and utilization of diagnostic test results. The CDC suggests an antibiotic time out to review the dose, duration, and indication when test results and other clinical information become available 48-72 hours after initiation of empiric therapy. However, in the absence of a formal ASP, such interventions are unlikely to occur. An ASP team that provides guidance and accountability can greatly increase clinician adherence to CDC antibiotic recommendations.

As another example, ASP education and interventions are effective in reducing the duration of antimicrobial therapy for patients. Many patients continue to receive traditional, longer courses of antibiotic therapy despite evidence from systematic reviews and randomized control trials showing that for certain infections, shorter courses of antibiotic therapy are just as effective as longer ones, with fewer adverse events such as *C. difficile* infection. A shorter course of therapy also lessens antibiotic exposure, reducing the selective pressure that favors drug resistance.

Critical for the physician-led ASP to be effective is financial support for the entire program, including salary support for the leadership physician so that they consider this effort to be part of their core responsibilities, and devote sufficient time to the program to assure success.

<u>Research on Stewardship and Dissemination of Best Practices</u>

As healthcare facilities continue to implement and refine their ASP, the federal government must support robust research to test a variety of stewardship interventions across a range of health care settings, including acute care hospitals, long term care facilities, and outpatient clinics. This

information will increase knowledge and understanding to enable identification of the most impactful strategies for optimizing antibiotic use.

The Antibacterial Resistance Leadership Group (ARLG), a strategic research effort funded by the National Institute for Allergy and Infectious Diseases (NIAID), supports design and implementation of studies on several resistance topics, including stewardship, infection control, and diagnostics. Specific examples include rapid diagnostics for gram negative bacteria in blood, bacterial pneumonia in patients on ventilators, and carbapenem-resistant organisms; oral step down for *S. aureus* bacteremia and for complicated urinary tract infections; diagnostic tests and strategies to direct antibiotic use in lower respiratory infections; master protocols for diagnostics; short course therapy of pediatric community-acquired pneumonia; and ASP effectiveness in community hospital settings. With additional funding, the ARLG would be able to support additional research to better inform stewardship activities and approaches.

Disincentives: Diagnostics Education, Facility Turnaround Time, and Reimbursement

Despite strong federal acknowledgement that rapid diagnostics are critical for guiding appropriate antimicrobial drug use, clinicians continue to face barriers to diagnostic use, including insufficient education about diagnostics and their impact on patient outcomes, facility workflow processes that delay testing turnaround time, and inadequate testing reimbursement.

Many physicians and other health care providers may be hesitant to use new diagnostic tests, in part because they are often uncertain of how best to integrate them in their practice. Physicians often look to education, such as clinical guidelines developed by their professional societies, such as IDSA, and government bodies, such as the Agency for Healthcare Research and Quality (AHRQ), to suggest the best methods to diagnose and treat an infection. Little guidance currently exists on the use of diagnostic tests for a particular type of infection, or what bundles of tests should be used if a patient has a particular set of symptoms. The ability to construct useful guidelines is hampered by the lack of clearly designed outcomes studies demonstrating patient benefit when tests are used as part of clinical decision making. Federal funding to support such research would be extremely beneficial.

The potential of rapid diagnostics can only be realized by improving coordination between physicians, the laboratory running the tests, public health officials, and antimicrobial stewards to quickly relay diagnostic information to inform patient care and public health protocols. A test that can provide results in under an hour cannot fully impact patient care if the treating physician and other appropriate individuals do not receive the test results until several hours later. New electronic health records (EHR) systems have the potential to significantly improve this coordination, but unfortunately, many EHR systems do not integrate diagnostic tests and their results effectively. IDSA has recommended that the federal government explore ways to promote the integration of diagnostic information into EHR systems, allowing for more rapid transmission of diagnostic test results to clinicians and, for reportable diseases, to state, local, and federal health departments.

Inadequate Medicare reimbursement is also a crucial barrier to the clinical integration of new diagnostic technologies. If these tests are more expensive than older counterparts, they often do not receive reimbursement levels via gap-filling or cross-walking that covers the cost of the test

until a new procedural code has been assigned. As a result, hospitals and physicians are frequently unable to offer new tests to patients until a new procedural code is assigned to allow for appropriate billing. Such delays impede patient access to newer tests that may offer faster, more precise results that can reduce unnecessary treatments, speed access to appropriate treatment, improve patient outcomes and reduce healthcare costs. Even when new codes are assigned, they still often do not adequately reimburse the full cost of testing, further limiting patient access to innovative tests.

IDSA greatly appreciates that the Protecting Access to Medicare Act (PAMA) of 2014 directed the Centers for Medicare and Medicaid Services (CMS) to make improvements to diagnostic reimbursement, including forming an expert advisory panel to guide CMS activities in this area and collecting data from laboratories on payment rates for existing tests to help inform new reimbursement rates. Unfortunately, the expert panel does not include sufficient representation from the infectious diseases field. However, IDSA has continued to engage with CMS on this important issue to provide ID input. Last year, CMS published a proposed rule requiring laboratories that receive 50% of their Medicare revenues and over $50,000 annually for services billed under the Clinical Lab Fee Schedule (CLFS) or Physician Fee Schedule (PFS) to report reimbursement rates and volumes on which the new weighted median reimbursement level for a test will be calculated. This threshold excludes nearly all hospital based laboratories, which may have higher costs than commercial laboratories due to differences in volume of tests. Exclusion of hospital based laboratories may result in inappropriately low new reimbursement rates for tests, making it difficult for physicians to access these tests and even creating disincentives for companies to develop new tests. IDSA recognizes that reporting requirements may be overly burdensome for hospital laboratories. To help ensure that CMS collects data for the purposes of determining reimbursement rates that reflects the broad scope of the market, and the value of local, rapid laboratory services that are critical in ID patient care, IDSA has recommended that CMS seek data from private insurers on the rates paid to hospital laboratories and physician offices for diagnostic tests. If that is not possible, IDSA recommend CMS consider a mechanism that allows hospital laboratories and physician offices to submit their information voluntarily.

Incentivizing Providers to Report Antibiotic Use and Resistance Data

IDSA strongly supports ongoing federal efforts to help more healthcare facilities report data through the National Healthcare Safety Network (NHSN) Antibiotic Use and Resistance (AUR) module. IDSA continues to advocate for additional funding for NHSN, which can be used to provide technical assistance to facilities to support increased reporting. IDSA also supports the addition of NHSN AUR data transmission to the health information technology certification criteria. This policy should help ensure that health IT vendors provide, and facilities adopt, health IT systems with the necessary capabilities for collecting and reporting antibiotic use and resistance data. IDSA has also expressed support to CMS for inclusion of the NHSN AUR quality measure in the Medicare Inpatient Hospital Payment System. Such regulatory levers are useful in accelerating the rate at which facilities begin reporting.

3. **Please provide examples of successful behavior change models that can be applied to preventive strategies, such as infection control and antibiotic stewardship.**

ID physician leadership of ASP is critical to successful efforts to alter prescriber behavior. It is difficult for a non-physician to approach a clinician about his or her prescribing habits. The ASP ID physician, aided by pharmacists and other ASP team members, is in a more favorable position and more likely to effect change in a colleague's poor prescribing practices. This role is critical, given that non-ID physicians prescribe the majority of antibiotics, and changing their behavior is the lynchpin of any successful effort to reduce inappropriate antibiotic use. The ASP infectious diseases physician has the unique advantages of already being viewed as a content expert who can lead prescribing practices by example and more globally through interactions during other ASP activities that teach sensible prescribing. Below are some examples of successful ID physician-led ASP:

- The ID physician-led ASP at Miami Valley Hospital in Dayton, OH, reduced broad-spectrum antibiotic use in the intensive care unit (ICU) by 18% in its first year. The physician leader conducts most of the physician education and communication with other providers on complex cases and issues. He also runs the ASP meetings attended by all of the ID doctors at the facility.
- Under the NorthShore University HealthSystem ASP, an ID physician reviews all antimicrobial new prescriptions and utilizes an antibiotic assist tool to agree with the regimen started by the primary care physician or suggest a therapeutic change or a formal ID consult. Pharmacy personnel also review diagnostic results on day 2 or 3 to determine if any change in therapy is appropriate. Pharmacists can directly recommend such changes, and ID physicians mediate disagreements between ASP pharmacists and treating physicians that arise. This ASP initially found that 25% of antibiotic treatment in this facility was unnecessary. Importantly, more than 70% of the ASP ID physician and pharmacist recommendations were accepted, significantly reducing unnecessary antibiotic use. This same group has also found that 5% of the patients not needing antibiotic therapy go on to develop *Clostridium difficile* infection when they are given the unnecessary therapy – pointing to the patient safety aspect of a successful ASP.
- The ID physician-led ASP at Montefiore Medical Center in Bronx, NY showed a 10-15% reduction across antimicrobials and estimated direct pharmacy savings of more than $900,000 in its first two years. This has translated into greater appropriateness of antibiotic use across several syndromes. For example, community acquired pneumonia antibiotic use appropriateness, which is tracked by CMS, improved by over 30%. The ASP also reduced *C. difficile* infection rates by up to 40% of some campuses. The antibiogram improved as well, with quinolone susceptibility in gram negative rods increasing by more than 10%. An ID physician oversees all aspects of this ASP, including education, development of prescribing tools, integration of diagnostics, prior authorization, and case review. Education activities are tailored to different prescriber types and include distribution of local microbiology data and a prescribing app.

4. **Please provide information on the best ways to collect data on antibiotic use [and resistance] in animal agriculture through public-private collaborations. Your response can include information on the types of data to be collected, including the method of collection, and the metrics for reporting the data. If helpful, please cite sample models as examples to depict your answer.**

There is substantial scientific evidence supporting the claim that non-judicious use of antibiotics in both humans and food animals contributes to antibiotic resistance in pathogens that infect humans. Better information on the use of antibiotics in food animals will enable public health officials and scientists to better understand and interpret trends and variations in antibiotic resistance. This will improve the understanding of the relationship between animal uses of these drugs and antibiotic resistance that impacts human and animal health, to identify agricultural sectors with barriers to judicious antibiotic use, and to evaluate interventions to prevent and control resistance.

The current lack of adequate US antibiotic consumption data impedes our understanding of geographic and temporal trends in antibiotic resistance. To effectively combat the antibiotic resistance crisis, governmental and non- governmental public health, animal health and infectious diseases experts need timely access to reliable data on the scope of antibiotic consumption in animals, and in a unit of measure that can be assessed across time, species, and geography. Sales data alone will not increase our knowledge about how and why antibiotics are used in animals. Such data should be coordinated with other sources of on-farm and antibiotic resistance data in order to yield meaningful information.

We appreciate the recent addition of species-level reporting by the FDA, but believe more needs to be done to obtain the full picture of the impacts of antibiotic use in food animals:

- FDA should publish monthly sales data. Since 2008, the FDA has collected data from animal pharmaceutical manufacturers about the amounts sold every month. Accordingly, FDA should include a table that reports aggregate unit (i.e. container, strength, dose) sales by month for each drug class. This information may help scientists identify connections between antibiotic use and the occurrence of specific diseases, which could help advance novel treatment or prevention approaches.
- FDA should publish state or regional level data. FDA should report state-by-state data (and, where informative, smaller geographic areas) on antibiotic sales rather than a national aggregate. Such data would be useful to benchmark antibiotic use based on the density of food-animal production in a particular state or region. The Centers for Disease Control and Prevention (CDC) has successfully used outpatient antibiotic subscribing for humans by region.
- The US Department of Agriculture (USDA) and FDA should improve the National Animal Health Monitoring System (NAHMS) reporting of on-farm antibiotic use. NAHMS collects qualitative information on antibiotic use in livestock production but reporting is voluntary and not comprehensive. Better information about on-farm antimicrobial usage (e.g., prophylactic vs. therapeutic use), including what factors influence livestock producers' decisions about using antibiotics and a method to quantify use will help to target outreach and education activities related to antibiotic use and resistance.
- FDA, USDA and CDC should develop a public communication plan to explain the implications of collected data for human and animal health. It is important that farmers, ranchers, and the public understand exactly what data on antibiotic sales and use mean in terms of threats to human and animal health. FDA, USDA and CDC should create a public dissemination and education plan so that confusion is minimized.

The Netherlands is one example of a country with a national program under which the Veterinary Medicines Authority collects robust data on antibiotic use in agriculture and issues regular reports. Under this approach, livestock farmers must register all antibiotics they use, to show how much each animal receives. While the US may face unique obstacles in collecting antibiotic use data in agricultural settings, we hope this example can be instructive.

5. **Please provide information on the different resources that exist to promote the understanding of how antibiotics are being used in humans and animals in different parts of the world. Your response can include information on the types of support to connect with such resources, as appropriate (examples include public-private partnerships, strategic resourcing, or other means)**

There is significant variance in how different countries monitor antibiotic use. The European Surveillance of Antimicrobial Consumption (ESAC) system collects and makes public robust antibiotic use data from 34 countries in the European Union (EU). Unfortunately, many other nations, particularly those with fewer resources and insufficient infrastructure, are not collecting and reporting data in a regular and meaningful way.

In 2014, IDSA joined with the World Alliance Against Antibiotic Resistance (WAAAR) to call for a set of actions to address resistance, including integrated surveillance of antibiotic use. Ideally, such surveillance should include standardized monitoring of antibiotic use at institution, regional, and country levels to allow comparative benchmarking. Such data should be updated preferably in real-time and at least every 12 months. This will require adequate laboratory capacity using standardized methods.

In 2012, medical societies in India held their first major joint meeting on the issue of tackling antibiotic resistance. Leaders of this meeting published the Chennai Declaration in 2013 to guide the formulation of a national policy on resistance, including collecting data on antibiotic use. In 2014, a 5 year road map was published, which includes the introduction of online modules to track antibiotic use as a key strategy, with a goal of 5,000 doctors participating in the module by the end of year 1; 50,000 doctors participating by year 3; and all doctors participating within 5 years.

The Global Health Security Agenda (GHSA) was launched in 2014 to forge an interconnected multinational network to improve global capabilities to prevent, detect and respond to infectious diseases in humans and animals. The first of the agenda's nine objectives focuses on antimicrobial resistance. Participating countries are developing action plans for combating antibiotic resistance, which include improved surveillance and efforts to promote appropriate antibiotic use. The GHSA is an important initiative to build robust data collection activities across countries. The countries leading GHSA's antibiotic resistance activities are Canada, Germany, Netherlands, Sweden, and the United Kingdom; and Australia, India, Indonesia, Italy, Japan, Norway, Portugal, Switzerland, Thailand, and the United States is also participating.

Once again, IDSA thanks you for this opportunity to provide input on these important topics and we look forward to future opportunities to work with the Advisory Council. Should you have any questions, please contact Amanda Jezek, IDSA's Vice President for Public Policy and Government Relations, at 703-740-4790, or ajezek@idsociety.org.

Sincerely,

Johan S. Bakken, MD, PhD, FIDSA

IDSA President