Accelerating Improvements in Antimicrobial Stewardship
Request for Proposals

Pfizer Medical Education Group and The Joint Commission
December 6, 2012

I. Purpose

Pfizer Medical Education Group (PMEG) and The Joint Commission are collaborating to offer a new grant opportunity focused on antimicrobial stewardship. The goal of this request for proposals (RFPs) is to accelerate the development and adoption of evidence-based approaches that have the capacity to prevent or contain antimicrobial resistance (AMR), and that support and promote appropriate use of antimicrobial agents. This collaboration will drive efforts to improve patient outcomes and slow AMR.

This grant mechanism will support the development, testing and implementation of sustainable antimicrobial stewardship strategies and programs that can be shown to contain and prevent antimicrobial resistance in:

- acute care hospitals (academic medical centers and community based hospitals);
- long term care facilities;
- ambulatory care facilities and other out-patient settings.

For the purpose of this RFP antimicrobial stewardship is defined as a systematic, evidence-based approach to the use of antimicrobial agents in order to achieve optimal outcomes. This entails using the right agent, at the correct dose, administered by the correct route and for the appropriate duration in order to cure or prevent infection while minimizing adverse events and the emergence of resistance. Antimicrobial stewardship programs (ASPs) have the potential to reduce antimicrobial resistance, health care costs, and drug-related adverse events while improving clinical outcomes.[1] The program should be well balanced and focus on all four key objectives of the ASP described above.

The collaborators recognize the healthcare quality and patient safety issues associated with the overuse of selected procedures, treatments and medications, including (but not limited to), the use of antibiotics for viral illnesses.

This RFP has two stages. **Stage 1** is the submission of a letter of intent. If your letter of intent is selected you will be invited to submit a full proposal. **Stage 2** is the submission of the full grant proposal.

This RFP is being issued by both organizations. The Joint Commission will lead the application evaluation process and oversee a proposal review committee that will make the funding decision. All grant funding will be provided by Pfizer.

II. Background

Disease Burden Overview:

The World Health Organization (WHO) defines AMR as resistance of a microorganism to an antimicrobial agent to which it was previously sensitive.[2] The WHO has warned that "…the use of any antimicrobial for any infection, in any dose, and over any time period forces microbes to either adapt or die…"[3] Microbes that adapt and survive will carry genes for resistance, which can be transmitted from person to person and spread beyond continental boundaries.

AMR, as noted by the Transatlantic Taskforce on Antimicrobial Resistance, can slowly work to reverse the progress that has been made over the last century with the advent of antimicrobial agents.[4] It has been noted that the selection of resistant pathogens has been associated with antimicrobial use, particularly misuse.[5] The inappropriate use of antimicrobials, therefore, is a key focus for intervention.[5] A large national study funded by the Agency for Healthcare Research and Quality (AHRQ) found that more than half of healthcare associated pneumonia (HCAP) patients receive antibiotic therapy that is not concordant with the American Thoracic Society guidelines for management of adults with HCAP.[6] (S, 2012)

The Infectious Diseases Society of American (IDSA) and the Society for Healthcare Epidemiology of America (SHEA) published guidelines for antimicrobial stewardship in 2007, aimed at providing information on how to establish antimicrobial stewardship programs in hospitals.[5] The guidelines present two proactive core strategies, along with nine supplemental strategies that are not mutually exclusive (see table below).

Strategies for Establishing Antimicrobial Stewardship Programs

Core Strategies	Supplemental Strategies
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

At the center of an effective ASP is a proactive strategy that incorporates prospective audit with direct intervention and feedback and/or requirements for preauthorization of the use of antimicrobials. On the basis of available resources, local antimicrobial use and resistance issues, these core strategies may be supplemented with the additional strategies listed in the table above.

In their antimicrobial stewardship guidelines, the IDSA and SHEA note that an effective ASP, combined with a comprehensive infection prevention and control program, has been shown to

limit antimicrobial-resistant bacteria emergence and transmission.[5] The literature contains reports that have consistently shown that these programs decrease antimicrobial use (22%-36%) and provide facilities with annual savings of $200,00-$900,000.[5] More recently IDSA and SHEA, along with the Pediatric Infectious Disease Society (PIDS), recommended antimicrobial stewardship programs (ASPs) be made mandatory throughout the US health care delivery system.[7]

Stewardship Related Guidelines and Recommendations

IDSA/SHEA Antimicrobial Stewardship Guidelines[5]

- Guidelines for developing institutional programs to enhance antimicrobial stewardship

IDSA Antimicrobial Resistance Guidelines

- Guidelines for the prevention of antimicrobial resistance in hospitals[8]

IDSA/SHEA *C. difficile* Guidelines[9]

- Clinical practice guidelines for *Clostridium difficile* infections in adults

IDSA/SHEA MRSA Guidelines[10]

- Strategies to prevent transmission of methicillin-resistant *Staphlococcus aureus* in acute care hospitals

American Society of Health System Pharmacists (ASHP) Position Statement[11]

- Statement on the pharmacist's role in antimicrobial stewardship and infection prevention and control

Transatlantic Taskforce on Antimicrobial Resistance[4]

- Recommendations for future collaboration between the U.S. and EU. 2011
- Recommends the development of a common structure and process indicators for hospital antimicrobial stewardship programs

Quality Measures Related to Antimicrobial Resistance

Organization	Measures
National Quality Measures Clearinghouse[12]	14
Physician Consortium for Performance Improvement[13]	6
2011 Physician Quality Reporting System[14]	9

Pending Legislation

Strategies To Address Antimicrobial Resistance (STAAR) Act[15]

- Would require the Secretary of Health and Human Services to establish an Office of Antimicrobial Resistance within the Office of the Assistant Secretary for Health and a Public Health Antimicrobial Advisory Board

Antimicrobial Stewardship Programs (ASPs)

A 2009 survey of 3,500 practitioners in various hospital settings by the IDSA and SHEA found only 48% of US hospitals had an ASP in place. When broken down by facility type it was found that teaching hospitals/academic centers were much more likely than non teaching hospitals

(78% vs. 17%) to have an ASP in place.[16] Many earlier surveys showed a similar or more striking lack of ASPs.[17,18] It is important to note that more than 80% of the registered US hospitals are nonteaching hospitals[15] resulting in a startling number of non teaching hospitals without ASPs.

While not every hospital has an ASP, many have some components in place. A survey of 88 US hospitals found two-thirds had an antimicrobial formulary, 28% required prior approval of an infectious diseases clinician before dispensing certain antimicrobials, and 21% required approval by a clinical pharmacist.[19]

Lack of staffing is commonly noted as a reason for the absence of an ASP[17,20] yet reports demonstrating significant cost savings justify the additional staff needed.[20-35] Additional studies in various settings to further delineate the optimal strategies, or groups of strategies, that could maximize clinical outcomes and the containment of antimicrobial resistance, would greatly advance the field in this critical area impacting healthcare.

Several barriers exist to successful implementation and acceptance of ASPs.

- Personnel shortages[17] and finding appropriate personnel willing to devote the extra time and effort toward developing and enforcing ASPs, as well as the need to provide additional compensation for added responsibility[1]
- Administrators hesitant to fund such programs without a guarantee of future pharmacy savings[1] and higher priority clinical initiatives frequently take precedence[17]
- ASP team members afraid to antagonize colleagues and damage the potential for future consultations[1, 18]
- Physician resistance due to a perceived loss of autonomy in clinical decision making[1]

Current National Efforts to Promote Antimicrobial Stewardship:
Many efforts have been made to combat antimicrobial resistance and promote antimicrobial stewardship. Below are some examples of efforts made by various organizations both public and private. Many more exist.

- CDC's Get Smart for Healthcare, a site that not only provides evidence to support stewardship but provides examples of programs that worked as well as helpful tools http://www.cdc.gov/getsmart/healthcare/
- Joint Commission Resources The Cost of Antibiotic Resistance Toolkit http://www.jcrinc.com/Antibiotic-Resistance-Toolkit/
- MAD-ID's Antimicrobial Stewardship Programs provide basic skills to develop an ASP http://mad-id.org/antimicrobial-stewardship-programs/
- IDSA's Efforts to Promote Antimicrobial Stewardship in Human Medicine http://www.idsociety.org/Stewardship_Policy/
- University Hospital of South Manchester NHS Antimicrobial Self Assessment Toolkit http://www.researchdirectorate.org.uk/uhsm/asat/asat.asp
- Antimicrobial Stewardship Initiative Tool Kit http://www.abxstewardship.com/asi-toolkit

Further research on optimal strategies to maximize clinical outcomes and contain antimicrobial resistance would greatly advance the field.

III. RFP Requirements

Total Awards	Up to $2 million will be disbursed across 3-5 projects. Individual projects can be funded for up to a maximum of 24 months duration.
Clinical Area	Antimicrobial Stewardship
Target Settings	Long term care, academic medical centers, community hospitals, and out-patient /ambulatory care settings
Geographic Scope	United States only
Specific Area of Interest for this RFP	Antimicrobial stewardship programs within the one or more of the targeted settings specified above. The intent is to accelerate the development and adoption of evidence-based approaches that prevent or contain antimicrobial resistance, and that support and promote appropriate use of antimicrobial agents.
Applicant Eligibility Criteria	Not-for-profit entities including medical, nursing, allied health, and/or physician practices, healthcare systems, pharmacy, professional schools, healthcare institutions, professional associations and others with a mission related to health care improvement may apply. Collaborations across providers, institutions, organizations, and associations are encouraged. Inter-professional collaborations that promote teamwork among institutions and community and state-based organizations and associations are also encouraged.
Selection Criteria	Applicant organizations will be evaluated based upon: • Potential impact and expected outcomes of the project • Knowledge of and experience with the area • Capability of carrying out the work • Innovative approaches and applications • Collaboration if appropriate • Dissemination strategies
Key Dates/Deadlines	**December 6, 2012** – RFP released **December 17, 2012** – All questions due **December 21, 2012** – Responses to questions posted on PMEG Website if any specific to this RFP are received **January 17, 2013** – Letter of Intent due **Mid February 2013** – Applicants notified via email; Invited to submit full proposal **TBD** – Full proposals due date to be communicated on acceptance of an LOI **May 13-31, 2013** – Notification of decisions **June 2013** – Funded projects start

IV. How to Apply

Letter of Intent
The letter of Intent is a brief concept document that describes the proposed project at a high level. The Proposal Review Committee will select letters of intent that are best aligned with the purpose of the RFP. All applicants will be notified with either an acceptance or a declination. Successful applicants will be asked to submit a full grant proposal for funding consideration.

Submission Requirements

1. The letter of intent should be no more than three (3) pages, single spaced using Calibri 12 point font and 1-inch margins. It should contain the following information about the proposed project:
    a. Project title;
    b. Organization(s) involved;
    c. Principal Investigator;
    d. PI Curriculum Vitae (CV does not count against the 3 page limit).
    e. High level project description including
        i. Primary goal(s)
        ii. Description of how the proposal builds upon existing work, projects, or programs
        iii. Anticipated challenges and solutions
        iv. Expected outcome and how the impact of the project will be evaluated
    f. Deliverables and dissemination strategies
    g. Preliminary one (1)-page budget (budget does not count against the 3 page limit; there is no template)
2. A letter of intent longer than three pages will be **RETURNED UNREVIEWED**.
3. Submit the letter of intent, CV and budget online via the Pfizer Medical Education Group website
    a. On or after January 2, 2013, please go to the website at www.pfizer.com/independentsupport and click on the button "Go to the Grant System".
    b. You will be prompted to take the *Eligibility Quiz* to determine the type of support you are seeking. Please ensure you identify yourself as a first-time user.
    c. Submit your letter of intent in the *LOI*- Antimicrobial Stewardship clinical area.
4. Complete all required sections of the online application and upload the completed letter of intent template.

Full Proposals
A limited number of applicants will be invited to submit for consideration a full proposal of no more than 10 pages, accompanied by a line item budget. The full proposal format will be shared with the invitation to submit.

V. Questions

If you have questions regarding this RFP, please direct them in writing to the Education Director for this clinical area, Susan Connelly at (susan.connelly@pfizer.com), with the subject line "RFP Antimicrobial Stewardship". Responses to common questions may be posted on the *"Request for Proposals"* section of the Medical Education Group website at www.pfizer.com/independentsupport.

You may also contact The Joint Commission via the Medical Education Group through e-mail (mededgrants@pfizer.com).

VI. Terms and Conditions

1. Complete TERMS AND CONDITIONS for Certified and/or Independent Professional Healthcare Educational Activities are available upon submission of a grant application on the Medical Education Group website www.pfizer.com/independentsupport.
2. This RFP does not commit Pfizer to award a grant, or to pay any costs incurred in the preparation of a response to this request.
3. Pfizer reserves the right to accept or reject any or all applications received as a result of this request, or to cancel in part or in its entirety this RFP, if it is in the best interest of Pfizer to do so.
4. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media.
5. For compliance reasons and in fairness to all applicants, all communications about the RFP must come exclusively from the Medical Education Group. Failure to comply will automatically disqualify applicants.
6. All output (e.g., products, research, data, software, tools, processes, papers and other documents) from funded projects will reside in the public domain.

VII. Transparency

Consistent with our commitment to openness and transparency, Pfizer publicly reports its medical educational grants and support for medical and patient organizations in the United States. A list of all letters of intent selected to move forward may be publicly disclosed, and whatever emanates from this RFP is in the public domain. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports etc) may be posted on the website. Grantees will be required to submit periodic quarterly reports and/or updates.
Issued RFPs are posted on the Pfizer Medical Education Group website (www.pfizer.com/independentsupport) and are e-mailed to all registered organizations and users in our grants system.

VIII. About the Administrators

The mission of the Pfizer Medical Education Group is to accelerate the adoption of evidence-based innovations that align the mutual interests of the healthcare professional, patients, and Pfizer, through support of independent professional education activities.

The mission of The Joint Commission is to continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.

IX. References

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Common Questions and Answers

Program Scope

- Would Pfizer support a grant proposal in this area for something other than a CME program? In addition, would you be interested in supporting a program to develop antimicrobial stewardship programs in hospitals that do not presently have a program?

    - The review committee will consider all programs incorporating independent education of healthcare professionals and is not limited to the review of programs offering CME. As a matter of fact, education is not required to be the central component of the program. Further, patient education is a key component of improving patient care and is considered within the scope of this RFP. It is within the scope of this RFP to support a program to develop an ASP in a hospital that does not presently have a program.

- The scope of the RFP seems broad. What types of programs would apply

    - The intent of this RFP is to accelerate the development and adoption and/or enhancement of antimicrobial stewardship programs that have the capacity to prevent or contain antimicrobial resistance (AMR), and that support and promote appropriate use of antimicrobial agents

- Would other types of clinical research studies not involving a process intervention would be considered.

    - The scope of Pfizer Medical Education Group funding does not include research evaluating the efficacy of any therapeutic interventions. Researchers seeking funding for studies of this nature can submit requests to our Investigator Initiated Research (IIR) group. There may be a perceived overlap and we are happy to provide feedback on specific scenarios.

Budget

- What will the grant cover? Will it cover the salary, computer expenses, or travel?
    - Institutional overhead and indirect costs can be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as

additional initiative expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment.

- Will the grant cover Laboratory instrumentation or Laboratory test assays (not routinely tested in hospitals)?
  - Pfizer does not provide funding for capital equipment. Pfizer also cannot provide grant support for the direct acquisition of therapeutic or diagnostic agents through this grant process.
- How many grants will be funded?
  - The RFP notes that 3-5 grants will be funded. The total budget for this RFP is $2,000,000. The number of grants funded will depend on the total amount requested from the highest quality submissions. There is no minimum dollar limit set for this RFP.

Timeline

- How much time will be given to develop a full proposal once an LOI has been accepted to move forward?
  - It is estimated applicants will be given 4 weeks to develop a full proposal.

Although not received for this RFP, common questions submitted in response to past RFPs are included below.

Educational Partners

We received one question, in multiple formats, related to educational partners.

- In reference to the Applicant Eligibility Criteria , can you clarify if is it acceptable for corporations (for-profit organizations) to be involved as partners as long as a not-for-profit organization directly submits the grant?

  - Pfizer's policy regarding the elimination of all direct funding for CME/CE programs by commercial providers remains in effect. MECCs are not eligible to register and should continue to partner with other organizations on collaborative projects.

Ongoing Programs

- Could we include ongoing interventions that have been implemented? Or does it have to be a future intervention?

- Pfizer cannot retroactively fund programs that have already been implemented. We encourage the use of pre-existing material in future programming if it appropriately addresses the identified need. Programs that build on previous or ongoing interventions will also be considered.

Format and Layout

- Is the LOI Guidance a suggestion or should the format be followed?
  - Failure to follow the LOI Guidance makes it very difficult for the external review panel to review a request. It is highly suggested the format be followed.
- The instructions state a 3-page limit (excluding the 1-pg budget) to the LOI. Does this include references?
  - If extensive, references can be included on a separate page.
- Can an appendix be included within the LOI?
  - No. Aside from references and the 1-page budget, the LOI should not exceed 3 pages. ***A submission exceeding this limit WILL BE REJECTED and RETURNED UNREVIEWED.***