

Pfizer Medical Education Group Request for Proposals (RFP) Bacterial Infections

I. Background

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 intent of this document is to encourage organizations with a focus in healthcare professional (HCP) education and/or quality improvement to submit letters of intent (LOIs) in response to a Request for Proposal (RFP) that is related to education in a specific disease state, therapeutic area, or broader area of educational need. The new RFP model is a two stage process: Stage 1 is the submission of the LOI. If, after review, your LOI is accepted, then you are invited to submit your full program proposal. Stage 2 is the submission of the Full Grant Proposal.

When an RFP is issued, it is posted on the Pfizer Medical Education Group website (www.Pfizermededgrants.com) as well as those of other relevant organizations and is sent via e-mail to internal lists of all registered organizations and users in our grants system.

II. Requirements

Date RFP Issued:	6/28/2012
Clinical Area:	Bacterial Infections
Specific Area of Interest for this RFP:	<p>It is our intent to support quality improvement based programming focused on improving the care of patients who acquire or are in danger of acquiring serious bacterial infections caused by MRSA and/or Gram-negative pathogens such as hospital, healthcare associated, and community-acquired pneumonia, complicated skin and complicated intra-abdominal infections.</p> <p>Our goal is to support hospital or healthcare system-, team-, and practice- based projects involving Quality Improvement or Patient Safety that have some component of continuing professional development, training, or medical education.</p> <p>Eligible projects include Resident-based projects if addressing quality parameters.</p> <p>Hospital EMR technology staff or Registry staff may also be interested in partnering with their CME/CE departments on projects related to this grant opportunity.</p> <p>Team-based and multi-professional projects are encouraged (physicians, nurses, pharmacists etc.)</p> <p>Education does not necessarily have to be certified for CME/CE credit.</p>

Disease Burden Overview:	<p>Healthcare-associated Infection (HAI) Annually, close to 35 million patients are treated in hospitals for infectious diseases, staying on average 4.8 days.¹ Regardless of the reason for admission, it is estimated that 1 out of every 20 hospitalized patients will contract a healthcare-associated infection.²</p> <p>Pneumonia In 2009 1.1 million patients were discharged from hospitals after being treated for pneumonia.³ Their average length of stay was 5.2 days.³ Pneumonia is responsible for 3.4% of hospital inpatient deaths.¹ Overall, pneumonia was responsible for 50,774 deaths in 2009.⁴</p> <p>Typically, 2.3% of nursing home residents are suffering from pneumonia.⁵</p> <p>Complicated Skin Infections¹ On an annual basis, 589 thousand patients are discharged from hospitals after being treated for complicated skin infections such as cellulitis and abscess. Their average length of stay is 4.4 days.</p> <p>Complicated Intra-abdominal Infections¹ On an annual basis, 318 thousand patients are discharged from hospitals after being treated for complicated intra-abdominal infections such as appendicitis. Their average length of stay is 3.1 days.</p>
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<p>Recommendations and Target Metrics:</p>	<p>Example Guidelines and Recommendations Related to Serious Infections</p> <p> IDSA/ATS CAP Guidelines⁶ <ul style="list-style-type: none"> Guidelines for the management of community-acquired pneumonia in adults </p> <p> IDSA/ATS HAP/VAP/HCAP Guidelines⁷ <ul style="list-style-type: none"> Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia </p> <p> SIS/IDSA Intra-abdominal Infections Guidelines⁸ <ul style="list-style-type: none"> Guidelines for the diagnosis and management of complicated intra-abdominal infections in adults and children </p> <p> SIS Complicated SSTI Guidelines⁹ <ul style="list-style-type: none"> Guidelines for the treatment of complicated skin and soft tissue infections </p> <p> IDSA Surgical Site Infections¹⁰ <ul style="list-style-type: none"> Guidelines for the prevention of surgical site infections in acute care hospitals </p> <p> IDSA MRSA Guidelines¹¹ <ul style="list-style-type: none"> Guidelines for the treatment of MRSA infections in adults and children </p> <p> CDC <i>Enterobacteriaceae</i> Guidance¹² <ul style="list-style-type: none"> Guidance for the control of infections with carbapenem-resistant or carbapenemase-producing <i>Enterobacteriaceae</i> in acute care facilities </p> <p> There are many guidelines and recommendations related to HAIs. A summary of these can be found at http://www.cdc.gov/HAI/prevent/prevent_pubs.html </p> <p> Target Metrics The US Department of Health and Human Services (HHS) Steering Committee for the Prevention of Healthcare-Associated Infections set a 5-year goal related to nine targets in the HHS Action Plan to Prevent HAIs for reducing the incidence of specific HAIs and increasing adherence to specific sets of recommended prevention practices.¹³ </p> <p> Additional quality metrics can be found at the HHS's National Quality Measures Clearing house. http://www.qualitymeasures.ahrq.gov/ </p>
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<p>Gaps Between Actual and Target and Possible Reasons for Gaps:</p>	<p>Gaps in Guideline Compliance</p> <p>A survey of 855 faculty and house-staff indicated that guideline-concordant antibiotic regimens were chosen 78% of the time for CAP, but only 9% of the time for HCAP.¹⁴ There can be a disconnect between intent and action. It has been noted that physicians report that they are aware, agree, and practice according to published pneumonia guidelines; however, they may not choose guideline-concordant therapy when tested.¹⁴</p> <p>Antimicrobial courses on medical/surgical wards may not follow the CDC's recommended 12 steps for prevention of antimicrobial resistance.¹⁵</p> <p>Compliance with national guidelines varies among institutions, for example in Buffalo NY compliance with guidelines for the treatment of nursing-home acquired pneumonia was poor.¹⁶</p> <p>Results of Interventions</p> <p>Since setting its goals in the Action Plan to Prevent HAIs, HHS has reviewed the progress on an annual basis.¹³ The end goal is December 31, 2013. HHS has noted timely progress has been made towards achieving most targets. For example the target for HA-MRSA invasive infections is a 50% reduction from a baseline of 26.24 infections per 100,000 persons in 2007-2008. The 2010 assessment shows an 18.2% reduction (21.46 infections per 100,000 persons). HHS notes continued efforts are still needed and must be enhanced and accelerated in order to achieve the targets.</p> <p>Interventions have changed behavior. It has been noted that internal medicine teams are more likely to initiate antibiotics within 72 hrs of presentation, choose the appropriate empirical therapy, and effectively change an antibiotic upon receipt of cultures if they receive intervention from an antibiotic utilization team.¹⁷</p>
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<p>Barriers:</p>	<p>Disparities</p> <p>Race</p> <ul style="list-style-type: none"> • Blacks may be 5 years younger than whites when hospitalized for bacterial pneumonia¹⁸ • Blacks and Hispanics may receive their first antibiotic dose within the recommended 4 hour window less frequently than whites¹⁹ • Blacks, Hispanics, and Asians may be less likely than whites to receive all NHQA processes for pneumonia²⁰ <p>Age</p> <p>Older patients may be less likely than patients younger than 50 years to receive all NHQA processes for pneumonia²⁰</p> <p>Barriers</p> <p>Health Plans/Systems</p> <p>Antibiotic utilization may vary substantially among commercial health plans and may not be related to differences in the age and sex distribution of plan members²¹</p> <p>HCPs</p> <ul style="list-style-type: none"> • Lack of HCP awareness of antibiotic treatment guidelines²² • Lack of HCP awareness of the concept of Healthcare Associated Pneumonia (HCAP)²³ • Failure to collect appropriate specimens for identification of relevant pathogens²⁴
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<p>Current National Efforts to Reduce Gaps:</p>	<p>There are many tools related to serious infections. Many relate to topics such as HAI and antimicrobial resistance. Below are some examples of efforts made by various organizations both public and private. Many more exist.</p> <ul style="list-style-type: none"> • HHS’s HAI site includes a number of resources http://www.hhs.gov/ash/initiatives/hai/index.html <ul style="list-style-type: none"> ○ National Action Plan to Prevent Healthcare-associated Infections provides a roadmap for preventing HAIs in acute care hospitals, ambulatory surgical centers, end-stage renal disease facilities, and increasing influenza coverage of healthcare personnel http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html • CDC’s HAI site includes resources related HAI <ul style="list-style-type: none"> ○ HAI Prevention toolkits http://www.cdc.gov/HAI/prevent/prevention_tools.html ○ State-based HAI Prevention http://www.cdc.gov/HAI/state-based/ • Joint Commission Resources The Cost of Antibiotic Resistance Toolkit http://www.jcrinc.com/Cost-of-Antibiotic-Toolkit/ • University Hospital of South Manchester NHS Antimicrobial Self Assessment Toolkit http://www.researchdirectoriate.org.uk/uhs/asm/asm.asp
<p>Target Audience:</p>	<p>Local health systems</p>
<p>Geographic Scope:</p>	<p><input checked="" type="checkbox"/> United States Only <input type="checkbox"/> International(specify country/countries) _____</p>
<p>Applicant Eligibility Criteria:</p>	<p>Medical, dental, nursing, allied health, and/or pharmacy professional schools, healthcare institutions, professional associations and other not-for-profit entities with a mission related to healthcare improvement may apply. Collaborations between schools within institutions, as well as between different institutions/organizations/associations, are encouraged. Inter-professional collaborations that promote teamwork among institutions/organizations/associations are also encouraged.</p>
<p>Expected Approximate Monetary Range of Grant Applications:</p>	<p>Individual grant requests ranging from \$20,000 to \$50,000 are expected. All requests up to \$50,000 will be considered. The total available budget related to this RFP is \$500,000.</p> <p>The amount of the grant Pfizer will be prepared to fund for any full proposal will depend upon the external review panel’s evaluation of the proposal and costs involved and will be clearly stated in the grant approval notification.</p>

<p>Key Dates:</p>	<p>RFP release date: 6/28/2012</p> <p>Questions regarding the RFP are due: 7/12/2012</p> <p>Responses to common questions will be posted on the PFE MEG RFP Web site: 7/20/2012</p> <p>Letter of Intent due date: 7/31/2012 <i>(Please note you must be registered in the system to submit an LOI. Please attempt to complete this process at least one week prior to submission in order to avoid delays as all registrations must be approved before access to the system is granted).</i></p> <p>Anticipated LOI Notification Date: 9/7/2012</p> <p>Please note, full proposals can only be submitted following acceptance of an LOI</p> <p>Full Proposal Deadline: To be communicated on acceptance of an LOI</p> <p>Anticipated Full Proposal Notification Date: 12/12/2012</p> <p>Anticipated award delivered following execution of fully signed LOA</p> <p>Period of Performance: 1/2013 to 7/2015</p>
<p>How to Submit:</p>	<p>Submit LOIs online via the Pfizer Medical Education Group website www.pfizermededgrants.com Submit LOIs in the clinical area: LOI-RFP Infectious Disease.</p> <p>Requirements for submission: If not already registered, register in the system to submit an LOI. Please attempt to complete this process at least one week prior to submission in order to avoid delays as all registrations must be approved before access to the system is granted.</p> <p>Complete all applicable sections of the online application and upload the completed LOI guidance template <i>(See Appendix)</i>.</p> <p>Note that only certain sections/questions of the application are applicable to the Letter of Intent submission.</p>
<p>Questions:</p>	<p>If you have questions, please submit them in writing so that, if appropriate, Questions and Answers can be posted on the website. Send questions to MedEdGrants@Pfizer.com with the subject line "RFP Serious Infections 6-28-12" Responses to common questions will be posted on the PFE MEG RFP Web site.</p> <p>Other communications may also be directed to the Education Director for this clinical area, Susan Connelly, via email susan.connelly@pfizer.com.</p>

Mechanism by Which Applicants will be Notified:	All applicants will be notified via email by the dates noted above. Providers may be asked for additional clarification or to make a summary presentation during the review period.
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References:

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III. 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.Pfizermededgrants.com.
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.
4. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means ensures transparency, such as on the Pfizer website, in presentations, and/or in other public media.
5. For compliance reasons and in fairness to all providers, all communications about the RFP must come exclusively to the Medical Education Group. Failure to comply will automatically disqualify providers.
6. Pfizer reserves the right to share the title of your proposed project, and the name, address, telephone number and e-mail address of the requestor for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations).

IV. Transparency

Consistent with our commitment to openness and transparency, Pfizer reports its medical educational grants and support for medical and patient organizations in the United States. In the case of this RFP, a list of all LOIs selected to move forward will be publicly disclosed. In addition, all approved full proposals, as well as all resulting material (e.g., status updates, outcomes reports etc) will be posted on the website.

Appendix : Letter of Intent Submission Guidance

LOIs should be single spaced using Calibri 12-point font and 1-inch margins. *Note that the main section of the LOI has a 3-page limit.*

LOIs will include the following sections

Main Section (not to exceed 3 pages):

A. Project Title

B. Description of project goal(s)

C. Assessment of Need for the Intervention

- Please include quantitative baseline data summary, initial metrics (e.g., quality measures), or project starting point (prevalence data is NOT sufficient here; please cite data on gap analyses or relevant patient-level data that describes the problem). Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed.

D. Intervention Design and Methods

- Describe the way the intervention planned (quality improvement and/or educational) addresses the established need and produces the desired results. Please provide a rationale showing the desired results are feasible using the intervention being proposed

E. Design of Outcomes Evaluation

- Describe how you will determine if the practice gap identified in the needs assessment was addressed for the target group in terms of the metrics used for the needs assessment.
- Identify the sources of data that you anticipate using to make the determination.
- Describe how you expect to collect and analyze the data.
- Identify the method used to control for other factors outside this intervention (e.g., use of a control group)

F. Preexisting Work

- Explain what measures you have taken to assure that this project idea is original and does not duplicate other programs or materials already developed. Describe how this initiative builds upon existing work, pilot projects, or ongoing programs, etc

G. Plan for public sharing of methods and outcomes

H. Project timeline

I. Requested amount

Organizational Detail (not to exceed 1 page)

A. Name of the person(s) responsible for this project, physician champion or medical advisor, and description of the members of the team that will be responsible for implementing this project.

- B. List any partner organizations (or departments) that will be involved in this initiative.
- C. Describe the attributes of the institutions/organizations/associations that will support and facilitate the execution of the project.

Submission: LOIs should be submitted online via the Pfizer Medical Education Group website www.pfizermededgrants.com

**Pfizer Medical Education Group
Request for Proposals (RFP)
Bacterial Infections**

Common Questions and Answers

Target Audience

The target audience states “local health systems.” Many questions have been submitted related to this notation. Below are the most common questions and our response.

- ❖ Can non-hospital settings such as long-term care, ambulatory care, and home health organizations be the focus of the RFP rather than hospitals?
 - The target audience listed as local health systems is intended to represent the larger focus of care for patients suffering from the serious infections caused by MRSA and/or Gram-negative pathogens such as hospital, healthcare associated, and community-acquired pneumonia, complicated skin and complicated intra-abdominal infections. Given this, programs in non-hospital settings such as long-term care may be appropriate but those in ambulatory care or home health organizations may be beyond the scope of this RFP.

- ❖ Is the intent is really for major health care systems and not rural nursing homes?
 - In line with the stated target audience of local health systems there was no intent to focus on urban vs. rural settings. A rural nursing home could be considered within the scope of the RFP as long as the focus of the program related to the care of patients suffering from serious infections as noted in the RFP. The intent is to focus on areas where these infections are most often treated. A grant request demonstrating a strong need for an intervention in a rural nursing home would be considered. Requests including clear forms of measurement of specific metrics related to the goal will be given priority.

Geographic Scope

One question related to the geographic scope.

- ❖ Would a multi-health system program be acceptable or not?
 - The geographic scope of this RFP is only limited to the United States. Programs involving the partnership of multiple health systems will be considered. The impact on patient care will be a deciding factor in all requests.

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.

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.

Organizational Detail

The guidance indicates LOIs should include the name of the person(s) responsible for this project, physician champion or medical advisor, and description of the members of the team that will be responsible for implementing this project.

- ❖ For the "*physician champion or medical advisor*," are you asking for the person on our staff that meets this description OR for the lead faculty member for the project that meets this description?
 - The intent behind this request is to inform the review committee that an appropriate medical lead will be guiding the development of the programming. It has been noted, specifically in health systems that a key champion is integral to programming success. Ideally the medical lead should be affiliated with the target health system.
- ❖ When you ask "*description of the members of the team*," do you mean the internal staff members that will be working on the project OR the faculty team that will be assembled to execute the project?
 - The description of the members of the team that will be responsible for implementing this project does not require specific names. It can be expected that some members of the implementing team may eventually serve as faculty in an educational activity that is part of the project. The request is to describe only the team responsible for implementing the project.
- ❖ In the past Pfizer has indicated they do not request perspective faculty members in grant requests. Is that still the case?
 - Regarding Proposed Speakers: Pfizer shall not provide funding of CME when Pfizer has knowledge at the time of the decision to fund CME that a proposed CME faculty member has conducted a promotional speaking engagement on similar topic(s) on behalf of Pfizer in the past 12 months

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. Pfizer does 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.

Timelines

- ❖ Is the 7/2015 end date for the funding timeline or educational timeline (e.g., can program evaluation/final reporting extend beyond that date)?
 - The final reporting can extend beyond 7/2015

Format and Layout

- ❖ The instructions state a 3-page limit to the main section of 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 the main section of the LOI should not exceed 3 pages and the organizational detail should not exceed 1 page. *A submission exceeding this limit WILL BE REJECTED and RETURNED UNREVIEWED.*