



# IDSA

Infectious Diseases Society of America

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**IDSA Headquarters**  
1300 Wilson Boulevard  
Suite 300  
Arlington, VA 22209  
**TEL:** (703) 299-0200  
**FAX:** (703) 299-0204  
**EMAIL ADDRESS:**  
info@idsociety.org  
**WEBSITE:**  
www.idsociety.org

September 11, 2014

[By e-mail submission [jyselby@pcori.org](mailto:jyselby@pcori.org)]

Joseph V. Selby, MD, MPH  
Executive Director  
Patient-Centered Outcomes Research Institute  
5185 MacArthur Boulevard, NW  
Suite 632  
Washington, DC 20016

RE: Infectious Diseases Research Opportunities at the Patient-Centered Outcomes Research Institute

Dear Dr. Selby:

The Infectious Diseases Society of America (IDSA) represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases (ID). Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, antibiotic-resistant bacterial infections such as those caused by methicillin-resistant *Staphylococcus aureus* (MRSA) vancomycin-resistant enterococci (VRE), and Gram-negative bacterial infections such as *Acinetobacter baumannii*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*, and, finally, emerging infections such as the 2009 H1N1 influenza virus and bacteria containing the New Delhi metallo-beta-lactamase (NDM) enzyme that renders them resistant to a broad range of antibacterial drugs.

For patients suffering from chronic illnesses, such as diabetes or cancer, complications from infection can add significant patient burden and lead to poor outcomes. Since its formation in 2010, the Patient-Centered Outcomes Research Institute (PCORI) has become a leader in supporting comparative effectiveness research. In 2012, IDSA [highlighted](#) how PCORI supported research could help address major challenges facing patients who have or may contract an infectious disease. Many areas within infectious diseases research easily meet the five key criteria PCORI uses to review research proposals: patient centeredness, patient burden, potential for improving clinical care, timeliness of the research objective, and level of engagement with relevant stakeholders.

Unfortunately, comparative effectiveness research focusing on acute infections has remained noticeably underrepresented in the portfolio of research supported by PCORI. Multi-drug resistant microbes, healthcare-associated infections, and emerging infectious diseases all remain major challenges to patient care, and require strong, patient-engaged research to assess the effectiveness of new advances in clinical care, such as rapid diagnostics or alternative prevention and treatment

approaches. IDSA is eager to work with PCORI leaders to increase the appreciation for how infectious diseases research aligns with PCORI's research priorities and review criteria. Below we highlight several examples of ID issues for which we believe comparative clinical effectiveness research could significantly improve patient decision-making, healthcare and health outcomes.

### **Assessment of Prevention, Diagnosis, and Treatment Options**

- Research to observe the impact of outpatient parenteral antimicrobial treatment in reducing extended hospitalizations as well as healthcare-associated infections and this alternative method of treatment's impact on improving patient care and outcomes.
- New technologies, such as rapid diagnostics, can provide patients with more timely and accurate information regarding their disease and treatment options, benefit patients, and shorten hospital stays. Comparative effectiveness research can measure these new diagnostics for their potential to provide early diagnosis and guide accurate treatment as well as their impact on patient outcomes.
- Assessing the impact of activities to improve adult immunization rates (such as improved insurance coverage, educational approaches and physician actions) in preventing primary infectious diseases, such as influenza, as well as secondary infections like post-influenza pneumonia to reduce burden of disease. Such research could inform patient decision-making regarding vaccines—an area ripe for improvement as evidenced by extremely low adult immunization rates, overall vaccine hesitancy, and alarming resurgences of vaccine-preventable illnesses.
- Determining whether optimizing the route, length and dose of antimicrobial treatment for complicated infections, such as endocarditis, bone or joint infections, and multi-drug resistant infections can reduce the patient burden from side effects while improving outcomes.
- Evaluating whether reconstituting the intestinal microbiota helps reduce infection and improve outcomes in at risk patient groups such as those with cancer, poly-microbial infections or hematopoietic stem cell transplantation.
- Research that assesses best practices in engaging and educating high risk populations, including partners of HIV-infected individuals on use of pre-exposure prophylaxis.

### **Improving Healthcare Systems**

- Examining the deployment of technology and coordinated care to effectively treat patients through outpatient parenteral antimicrobial therapy, both clinic-based or in patients' homes while under the care of ID-specialists, and its impact on avoiding unnecessary patient readmissions and improving patient outcome.
- Comparative research evaluating whether the inclusion of diagnostic information into electronic health records (EHR) along with the existence of a formal antibiotic stewardship program and coordinated multidisciplinary care results in improved healthcare decision-making, reduction in unnecessary or inappropriate antibiotic use, shorter hospitalization, and a decrease in complications, such as *C. difficile* colitis.
- Studies that assess patient acceptance of diagnostic test results and their use in the healthcare decision-making process, for example, the decision to treat or not to treat with antibiotics.

- Research measuring the impact of rapid diagnosis of infection and administration of antimicrobial drug treatment on outcomes of transplant patients with serious infections.
- Determining how integration of new simple, rapid, accurate diagnostic technologies into at-home diagnostic tests for infections can impact patients, including reducing unnecessary hospital or physician visits, improving patient experiences and improving health outcomes.
- Evaluating the impact of improved best practices that standardize approaches to monitoring adverse effects of antimicrobial therapy.
- Research assessing the impact of enhancing existing immunization registries to include adverse event evaluation systems on the ability to rapidly track vaccine side-effects in patients.

### **Communication and Dissemination of Research**

- Research developing and implementing simple, rapid approaches that promote the dissemination of clinical research studies that yield negative results, such as a candidate therapy regimen that does not improve patient care. Such studies are currently very difficult to publish. This leads to unnecessary duplication of ineffective research, which can put patients at risk, delays new research, and wastes limited resources.
- Projects developing and implementing processes to input simplified diagnostic information in electronic health records can improve patients' understanding of their diagnoses, a key foundation to allow patients to take a more active role in their healthcare decision-making.

### **Addressing Disparities**

- Research evaluating how the development and clinical integration of new low cost, point of care diagnostics can yield more rapid, more accurate diagnoses and improve patient decision-making and patient outcomes in resource-constrained settings, including rural areas, inner city settings, and other low income communities.
- Comparative studies determining how targeted changes in diagnosis impact care and outcomes for certain patient populations. For example, infections in children and the elderly can present different symptoms and result in more severe disease than infections in healthy adults.
- Studies assessing how to increase patient access to ID expertise in rural areas where few or no ID specialists are present and evaluating the impact of these approaches on patient decision-making and patient outcomes.

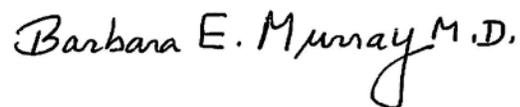
### **Accelerating Patient-Centered Outcomes Research and Methodological Research**

- Linking databases could have a major impact on patient-centered outcomes research. With better database linking, research could provide better estimates of vaccination rates in the US, earlier detection of immunization “deserts” or potential epidemics for public health targeting, and better evaluation of the risk of antimicrobial resistant infections in a given area. Research that improves database linkage can also facilitate large, pragmatic trials of comparative antibiotic effectiveness and antimicrobial stewardship.

IDSA has been active in promoting awareness of PCORI funding to our members. As a result of our efforts, several members submitted letters of intent (LOI) to the recent program announcement, ‘Improving Healthcare Systems.’ The projects detailed in these LOIs are focused on the implementation of effective outpatient parenteral antimicrobial therapy (OPAT) within integrated health systems to deliver patient-centered care, an example cited above which has significant potential for improving patient outcomes.

IDSA urges PCORI reviewers to consider applications that address acute infection during the PCORI merit review process. IDSA also asks that ID experts have the opportunity to serve on PCORI advisory panels to ensure that the challenges of infection can be appropriately evaluated. IDSA looks forward to working with PCORI in the future on tackling the many challenges patients face, including those from infection. If you should have any questions, please contact Greg Frank, PhD, IDSA’s Program Officer for Science and Research Policy at [gfrank@idsociety.org](mailto:gfrank@idsociety.org) or 703-299-1216.

Sincerely,

A handwritten signature in black ink that reads "Barbara E. Murray M.D." The signature is written in a cursive style with a large, looped 'B' and 'M'.

Barbara Murray, MD, FIDSA  
IDSA President