

Funding Mechanisms for Stewardship Research Opportunities

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Obtaining grant funding

- **now some agencies have direct language around funding AS research**
- review agency web sites
- be responsive to agency priorities (at least) or FOA/RFA (even better)
- review successful applications
- talk to the project officer
- collaborate with experienced investigators
- be persistent

Antibiotic Resistance Leadership Group (ARLG)

- main NIH mechanism for antimicrobial stewardship
- variable funding limits
- 2-page proposal (more if accepted)
- Fellowships
 - up to 2-years, fully funded, designed for ID fellows interested in pursuing research training in patient-oriented AR
 - Salary, Mentoring, Formal training in epidemiology
- Early Stage Investigator Seed Grants
 - Each year, up to \$50,000 in direct costs will be provided to up to 5 ESIs for research in areas related to AR
 - to generate preliminary data leading to additional funding
 - early in their research career (5 years or less)

<http://www.ahrq.gov>

ARLG

- ARLG aims to advance research by building transformational trials that will change clinical practice and reduce the impact of antimicrobial resistance through the following strategies:

ARLG

- Early clinical evaluation of new antibacterials
- **Comparative effectiveness** or efficacy trials
- Strategy trials to optimize currently licensed antibacterials (**dose, duration, need for drug**) to reduce the risk of resistance
- **Clinical algorithm** testing strategies
- Treatment-based prevention measures
- **Diagnostics testing** in the context of treatment trials, epidemiologic elements, or behavioral modification
- Effective infection control programs which include surveillance for resistant organisms, outbreak investigation, and **antibiotic stewardship** to prevent the development and spread of resistant organisms
- **Novel facilities level activities** to prevent the development of resistance

arlg.org

ARLG: Research Priorities

1. Infections caused by Gram-negative bacteria
2. Infections caused by Gram-positive bacteria
- 3. Infection Control/Stewardship**
4. Diagnostics

ARLG: Research Priorities

- seeks proposals for clinical studies (e.g., randomized controlled trials, case-control studies or cohort studies) to prevent, diagnose, treat, or eradicate antibiotic-resistant bacterial pathogens
- **Ideal studies:**
 - have the potential to transform medical practice, and
 - would be unlikely to occur without ARLG support

Agency for Healthcare Research and Quality (AHRQ)

- specifically mentions stewardship in priorities
- LOTS about ambulatory care
- Comparative effectiveness, “real world” studies
- Dissemination and implementation
- R01, R03, K
- R18 (dissemination and implementation)
- R01 max \$500K, including indirects

AHRQ

- **Mission:** produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and make sure that evidence is understood and used

AHRQ: CARB R01

- FOA solicits applications for grant funding to conduct Large Research Projects (R01) focused on Combating Antibiotic-Resistant Bacteria (CARB) in the following ways: by **promoting appropriate antibiotic use**, reducing the transmission of resistant bacteria, and preventing healthcare-associated infections (HAIs) in the first place.
- The CARB NAP is available at:
https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf.

AHRQ: CARB R01

Research Objectives

- AHRQ intends to expand the number of grant-supported projects that address AR issues
- Additional research in **long-term care and ambulatory settings** is especially needed

AHRQ: CARB R01

Promoting appropriate antibiotic use

- Improving the appropriateness of antibiotic selection and use in all healthcare settings, including but not limited to **identifying and modifying factors influencing prescriber decisions** about the use and choice of antibiotics
- The role of the **patient's perceptions and preferences and patient engagement** in influencing antibiotic use
- Developing **improved methods for conducting antibiotic stewardship**, particularly in ambulatory and long-term care settings, including multidisciplinary approaches to antibiotic stewardship
- Developing **EHR-based approaches to AS** in and across various settings
- The **role of rapid diagnostics in improving antibiotic use**, including how to integrate into clinicians' decision making

Research Networks

- May work with funded and unfunded proposals- collaborative groups of facilities interested in participating in multi-center studies

Process- Submit proposal for central approval

- Examples:
- SHEA Research Network
- American College of Clinical Pharmacy Practice Research Network
- Critical Care Pharmacotherapy Trials Network
- MAD-ID Research Network

Professional Societies

- SHEA
- SIDP
- IDSA Education and Research Foundation Awards
- American College of Clinical Pharmacy (ACCP)
 - Fronteirs Fund Research Awards
- MAD-ID Antimicrobial Stewardship Research Grant

Foundations

- Cardinal Health Foundation E3 Grant Program
 - Awards up to \$35,000 per project
- Bill and Melinda Gates Grand Challenges Program
 - Grandchallenges.org
- Roberts Wood Johnson Foundation
 - www.rwjf.org

Pharmaceutical Industry and Partners

- Investigator-Initiated Research Mechanisms
- Merck
 - Engagezone.msd.com
- Pfizer
 - Independent Grants for Learning and Change
- Unique Partnerships
 - CDC Foundation
 - Pfizer/The Joint Commission 2012

Stewardship Research Funding

□ NIAID

- Support diagnostics and vaccine development activities
- DEVELOPMENT of such diagnostics
 - small business grants (SBIR/STTR)
 - yearly “partnerships” solicitation for product development
<https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-16-034.html>
- VTEUs
<https://www.niaid.nih.gov/about/organization/dmid/researchers/clinical/vteu/Pages/default.aspx>

Stewardship Research Funding

□ AHRQ

- <http://www.ahrq.gov/funding/fund-ops/index.html>
- **Priority #2. Make Health Care Safer**
- **AHRQ encourages an interdisciplinary patient safety approach. In addition to health services research, perspectives from organizational theory, human factors, industrial engineering, facilities design, education, and other disciplines can be incorporated in research plans**
 - **the surveillance, measurement, detection, and reporting of patient safety events**
 - **diagnostic error; the safe use of medications**
 - **the challenges inherent in transitions of care and handoffs between health care providers**
- **hospital, long-term care, ambulatory care, home health care, pharmacy, and transitions of care between settings**

Stewardship Research Funding

- ❑ **State HAI AR Programs**
 - **Through CDC's Epidemiology and Laboratory Capacity Cooperative Agreement**
 - **All States (and several Large Metro areas)**
 - **Support for surveillance, detection, response, and prevention including stewardship coordination**
 - **NOT appropriate for research (by design)**
 - **However, process improvement, targeting action, surveillance improvement**

The Patient-Centered Outcomes Research Institute (PCORI)

- independent nonprofit, nongovernmental organization was authorized by Congress in 2010
- CER (\$2M)
- large pragmatic clinical trials (\$10M)
- priority topics influenced by patients
- needs patient/stakeholder engagement
- Lots of RFAs

PCORI: national priorities

- Assessment of Prevention, Diagnosis, and Treatment Options (CER)
- Improving Healthcare Systems
- Communication and Dissemination Research
- Addressing Disparities
- Accelerating Patient-Centered Outcomes Research and Methodological Research

What is patient centered research?

VIEWPOINT

Stakeholder-Driven Comparative Effectiveness Research An Update From PCORI

- PCORI directs applicants to engage patients and other stakeholders or their organizations throughout study planning, conduct, analysis, and dissemination

PCORI Review Criteria

- impact of the condition on the health of individuals and populations
- potential for the study to improve health care and outcomes
- technical merit
- **patient-centeredness**
- **patient and stakeholder engagement**

Assessment of Merit Review

- 1 patient, 1 other stakeholder, and 2-3 scientists
- quantitative analyses of scores:
 - participation of stakeholders leads to a different overall ranking of proposals than ranking by scientist scores alone (scores change after discussion)

CDC Safety and Healthcare Evaluation and Research Development (SHEPheRD)

- This funding opportunity will allow CDC to continue its ability to address questions related to healthcare epidemiology and healthcare-associated infection (HAI) prevention research, including antimicrobial resistance, and also extend this work into diverse healthcare settings.