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.org
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

http://www.ahrq.gov
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

http://www.ahrq.gov
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

http://www.ahrq.gov
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

http://www.ahrrq.gov
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
  - VTEUs
    https://www.niaid.nih.gov/about/organization/dmid/researchers/clinical/vteu/Pages/default.aspx
Stewardship Research Funding

- AHRQ
  - 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?

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

Selby et al, JAMA December 1, 2015, Volume 314, Number 21
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

Frank et al, JAMA October 15, 2014 Volume 312, Number 15
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)

Selby et al, JAMA December 1, 2015, Volume 314, Number 21
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.