Why Patients Need New Antibiotics

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Agenda for This Talk

– Overview of IDSA
– What Antibiotic Resistance Means for Patients
– The Antibiotic Pipeline Crisis
– IDSA’s Strategy to Combat Resistance and Stimulate Antibiotic R&D
IDSA’s Motivation/Perspective

Our patients need new antibiotics to survive

• IDSA represents 10,000+ physicians, scientists, public health practitioners – most provide clinical care

• Unlike other disease areas (cancer, HIV/AIDS, etc.), there are no easily identifiable patient advocacy groups to push for change and to put a human face on the antibiotic resistance problem

• IDSA decided it must step in to advocate on our patients’ behalf

• We have not taken any pharmaceutical funding to support these advocacy efforts

Antibiotic Resistance Threats Grow

• Conservative estimates indicate that over 2 million Americans are sickened every year by antibiotic resistant infections and at least 23,000 die.
  – The actual numbers are likely far higher.

• One example of an “urgent threat” according to CDC: Carbapanem-Resistant Enterbacteriaceae
  – The actual numbers are likely far higher.
  – 9,000 drug resistant infections per year, 600 deaths
  – resistant to all or nearly all current antibiotics
  – at least one type of CRE in in 44 states.

• Up to half of all bloodstream infections caused by CRE result in death.
Lives Devastated/Lost Due to Antibiotic Resistant Infections

Premature Death

Rebecca Lohsen (17 yr)--Dead
Mariana Bridi da Costa (22 yr)--Dead
Carlos Don (12 yr)--Dead
Ricky Lannetti (21 yr)--Dead

Life-altering Disability

Tom Dukes: colostomy, lost 8” colon
Addie Rereich, 11yo Double lung transplant Stroke, nearly blind $6 million hospital bill

www.AntibioticsNow.org

One Patient’s Story: María Julia

Dear Dr. Benjamin:
My name is Mario Manzanares. I'm neonatologist and work at the Pereira Rossell Hospital in Montevideo, Uruguay. I wrote you in January 2010, asking you for help in the treatment of a very ill preterm that was born with a gestational age of 25 weeks and weight of 650 grams.

Her name was María Julia. When she left our NICU her brother said that she looked like E.T. Then I sent you a photograph.
A Good Ending

It’s a pleasure for me to send you now another photograph of her. She is now 3 1/2 years old and lives in Rivera, Uruguay. She is a completely normal girl. I really enjoy sharing this with you.

Once more time, thank you very much.
Yours sincerely
Dr. M. Manzanoares

Two forthcoming papers illustrate the direct relationship between resistance and mortality:

- Increased mortality with Gram-negative rod bloodstream infections that are resistant to Ampicillin in premature and term infants

- Shows that, among hospitalized infants, greater mortality for MRSA bloodstream infections compared to MSSA BSI.
Antibiotic Resistance: Realities for Patients and Physicians

- The only antibiotic remaining to treat many Gram negative bacterial infections is Colistin.
- Colistin is toxic; it causes kidney failure; its efficacy is questionable.
  - Colistin had not been used in 30 years, but has been pulled off the shelves because there is nothing else.
- Gram negative bacteria are now developing resistance to Colistin.
- Economic burden on U.S. health care system: $21-34 billion cost annually; 8 million add’l hospital stays

Current alternatives for these patients: “Do you want to die, or to be on dialysis for the rest of your life or until you can get a kidney transplant?”

Antibiotic Effectiveness is Also Declining

Antibiotics caused US deaths to decline by ~220 per 100,000 in 15 years

- Sulfa
- Penicillin

All other medical technologies reduced deaths by ~20 per 100,000 over the next 45 years

New Antibacterial Drug Approvals Are in Decline


Status of the 10 x ‘20 Initiative

• Global commitment to develop 10 new systemic antibacterial drugs by 2020  (CID; April 2010)
Variety of Incentives Needed to Spur Antibiotic R&D

• **Economic**
  – *Generating Antibiotic Incentives Now (GAIN)* Act—Enacted 2012
  – Improving reimbursement such as through the *DISARM* Act
  – **Stronger funding** for federal agencies to support antibiotic R&D, including the National Institute for Allergy and Infectious Diseases (*NIAID*) and the Biomedical Research and Development Authority (*BARDA*)
  – **Tax Credits**

Regulatory solution: Antibiotic Development to Advance Patient Treatment (ADAPT) Act

• Establishes a limited population antibacterial drug (LPAD) approval pathway to address serious or life-threatening infections where an unmet medical need exists
• ADAPT/LPAD drugs would be approved based upon smaller, faster, and less expensive clinical trials; drugs must still be demonstrated to be safe and effective for indicated population based upon current FDA evidentiary standards
• ADAPT/LPAD drugs’ labeling must make clear to the healthcare community that these drugs are approved for a limited population and must be used appropriately
• ADAPT/LPAD drugs’ use would be monitored by CDC’s National Healthcare Safety Network (NHSN)
Increased Federal Funding for AR is Desperately Needed

To strengthen the U.S. federal response to resistance, IDSA recommends robust funding for the following agencies and initiatives:

- CDC Detect and Protect Against Antibiotic Resistance initiative
- CDC National Healthcare Safety Network (NHSN)
- CDC Advanced Molecular Detection (AMD)
- National Institute of Allergy and Infectious Diseases (NIAID)

Stewardship Protects the Effectiveness of Antibiotics and Improves Patient Care

- **Antibiotic stewardship** programs in every healthcare facility as a condition of Medicare/Medicaid participation
- Increased research on the optimal ways to use current antibiotics to improve patient care and protect the drugs’ utility
- Improved *surveillance* to rapidly identify and respond to emerging threats
- Enhanced antibiotic use and resistance *data collection* to help us better understand the scope of the problem and evaluate interventions
- Better *infection control* practices
The Global Response is Gaining Momentum; It’s Time for the U.S. to Help Lead the Way

  - Highlights major gaps in resistance data in both developed and developing countries
- May 2014: The 67th World Health Assembly (WHA) approves a resolution urging Member States to:
  - Strengthen drug management systems;
  - Support research to extend the lifespan of existing drugs; and
  - Encourage the development of new diagnostics and treatment options.

Thank You.

Prior generations gave us the gift of antibiotics. Today, we have a moral obligation to ensure this global treasure is available for our children and future generations.