NARMS Update and Request for Science Board Subcommittee Review

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Origins of NARMS

• Established in 1996 under the recommendation of an FDA Veterinary Medical Advisory Committee reviewing concerns over the approval of fluoroquinolones in food animals.
• Originally intended to function as a post-approval safety monitoring system for FDA-regulated products
• Partnership of FDA-CVM, CDC, and USDA
• Primary Objectives:
  – **Monitor trends** in antimicrobial resistance among foodborne bacteria from humans, retail meats and animals
  – **Disseminate timely information** on antimicrobial resistance to promote interventions that reduce resistance among foodborne bacteria
  – **Conduct research** to better understand the emergence, persistence, and spread of antimicrobial resistance
  – **Assist the FDA** in making decisions related to the approval of safe and effective antimicrobial drugs for animals
Data Integration

**Animal Population**
Slaughterhouse

**Retail Meats**
(2002)
Grocery Store
• Chicken
• Ground turkey
• Pork chop
• Ground beef

**Imported Foods**
Distributors
• Spices
• Seafood
• Produce
• Feed
• Etc.

Human Population (1996)
Medical Office

- Physician Visit
- Local Lab
- State Lab
- ORA Denver lab
- CDC

**Data Integration**

- Campylobacter
- Salmonella
- Enterococcus
- E. coli

*Other organisms surveyed*
2007 Science Board Subcommittee Review

• The Science Board Advisory Committee to the FDA established a subcommittee to:
  – Evaluate the NARMS program
  – Address four questions relevant to continued success of the program:
    • Are there inherent biases in the sampling strategies employed in NARMS? If so, how can they be improved to ensure that the data and interpretation are scientifically sound given current resources?
    • Are there epidemiological and/or microbiological research studies that would better serve the goals of NARMS and the regulatory work of FDA?
    • Are current plans for data harmonization and reporting appropriate? If not, what are the top priorities for advancing harmonized reporting?
    • Are the current NARMS international activities adequate to address the worldwide spread of antimicrobial-resistant food-borne bacteria?
Subcommittee Recommendations

The science board provided a number of recommendations—all of which have been addressed or are still in progress.

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<tr>
<th>Recommendations</th>
<th>Status</th>
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<tr>
<td>Redesign the food animal sampling strategy to become nationally representative</td>
<td>Nationally representative cecal sampling program developed in 2013</td>
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<td>Adjust the retail meat sampling strategy to allow broader interpretation and inference of data</td>
<td>The retail meat program expanded in 2013 and again in 2017 to now include 20 sites</td>
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<td>Expand hypothesis-driven research including research on the flow of resistance genes and resultant human health impact</td>
<td>In 2014, WGS analysis was implemented in all arms of NARMS. Historical retail isolates are being sequenced. Since 2007, NARMS has published over 100 peer-reviewed articles.</td>
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<td>Create a real-time integrated database</td>
<td>An integrated database was created and finalized in 2016</td>
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<td>Move toward a database that can be readily shared with researchers and other users</td>
<td>Deployed NARMSNow: Integrated Data in 2015 which allows others to access isolate level NARMS data. Interactive visualizations have been utilized since 2008 to give stakeholders greater autonomy in viewing and interpreting the data.</td>
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## Subcommittee Recommendations, cont.

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<td>Improve speed of reports</td>
<td>Lag in reporting time has been reduced (now 1-2 years) and will continue to improve with increased reliance on new testing and reporting technologies</td>
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<td>Continue and expand NARMS international activities</td>
<td>NARMS representation on several international committees, trainings, and forums</td>
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<td>Develop a 10 year plan</td>
<td>NARMS developed a 2012-2016 strategic plan. A 2017-2021 plan is in development</td>
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New developments

Global challenge of antibiotic resistance has received increased visibility
New developments

- Slow the Emergence of Resistant Bacteria and Prevent the Spread of Resistant Infections
- Strengthen National One-Health Surveillance Efforts to Combat Resistance
- Advance Development and Use of Rapid and Innovative Diagnostic Tests for Identification and Characterization of Resistant Bacteria
- Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines
- Improve International Collaboration and Capacities for Antibiotic-resistance Prevention, Surveillance, Control, and Antibiotic Research and Development
New developments

Changing lab technologies

- Organism ID
- Serotype
- Antibiotic Susceptibility Testing
- Speciate

Whole Genome Sequencing

- Confirm all organisms
- ID Serotype and Species
- ID resistance genes and mutations; also plasmid types

www.fda.gov
2016 Science Board Request

• The Science Board establish a new subcommittee to answer the following questions:
NARMS is focused on specific commodities and sampling intervals. Could changes to sampling strategies improve our understanding of resistance dynamics within a One Health paradigm?

Examples of How Antibiotic Resistance Spreads

- Animals get antibiotics and develop resistant bacteria in their guts.
- Drug-resistant bacteria can remain on meat from animals. When not handled or cooked properly, the bacteria can spread to humans.
- Fertilizer or water containing animal feces and drug-resistant bacteria is used on food crops.
- Drug-resistant bacteria in the animal feces can remain on crops and be eaten. These bacteria can remain in the human gut.
- Simply using antibiotics creates resistance. These drugs should only be used to treat infections.

CDC, Antibiotic Resistance Threats Report, 2013
FDA publishes annual antimicrobial sales and resistance data. Is our analysis and presentation of these data adequate? What is the best way to report relationships between antimicrobial sales data and antimicrobial resistance in our national surveillance?

**2014 SUMMARY REPORT**

**Antimicrobials Sold or Distributed for Use in Food-Producing Animals**

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**NARMS Integrated Report: 2014**

The National Antimicrobial Resistance Monitoring System: Enteric Bacteria

**Introduction**

This report summarizes the major findings of the National Antimicrobial Resistance Monitoring System (NARMS) for calendar year 2014, including the most important resistance findings for Salmonella and Campylobacter, Enterococci of the (E. coli) and Enterococci.

Salmonella and Campylobacter are the leading bacterial causes of foodborne illness in the United States. The latest data (2014) from the CDC ranked Salmonella first in incidence at 10.5 cases per 100,000 hospitalizations resulting over 2,100 hospitalizations and 30 deaths. Campylobacter ranked second in incidence at 13.5 cases per 100,000 resulting in 1,080 hospitalizations and 11 deaths.

E. coli and Enterococci from fecal and retail meat samples also are tested for antimicrobial susceptibility. While these are not major food-borne disease-causing organisms, these are used as indicator organisms for testing of resistance to antimicrobials that are active against gram-negative and gram-positive bacteria, respectively.

This report presents consolidated information from the four data sources that form the NARMS system: 1. Human clinical isolates; 2. (and 3.1) Food-producing animal isolates from both fecal (intestinal) isolates from slaughter animals and isolates from processing plants collected as part of Pathogen Reduction/Hazard Analysis Critical Control Point (PR/HACCP) testing; and 4. Raw unprocessed retail meats.

Isolates from human laboratory-confirmed infections are tested for susceptibility to antimicrobials, and compared with bacteria derived from various stages in the food production chain. This includes fecal (intestinal) samples that are collected at slaughter from eight animal production classes - young chickens, young turkeys, dairy cows, beef cows, steers, hogs, market swine and swine, along with (PR/HACCP) isolates from the processing line recovered from chicken carcasses thighs, turkey carcass swabs, ground beef and trimmings, and ground or comminuted chicken and turkey products. Salmonella and Campylobacter isolates are collected monthly from four retail meat products (chicken, ground turkey, ground beef and pork chops) purchased at retail outlets in 14 states.
NARMS now does whole genome sequencing as a routine part of surveillance. What is the best way to report whole genome sequence data, and trends in the resistome?
2016 Science Board Request

• We would like to share the results at the next NARMS public meeting (September 2017)

• The subcommittee response will help us finalize our 2017-2021 NARMS Strategic Plan