

# National Antimicrobial Resistance Monitoring System (NARMS) Program Review



# Charge to Subcommittee

The Science Board Advisory Committee to the Food and Drug Administration (FDA) established a subcommittee to evaluate the National Antimicrobial Resistance Monitoring Systems (NARMS) Program and to address four questions relevant to the continued success of the program.



# The Four Questions included:

1. 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?
2. Are there epidemiological and/or microbiological research studies that would better serve the goals of NARMS and the regulatory work of FDA?
3. Are current plans for data harmonization and reporting appropriate? If not, what are the top priorities for advancing harmonized reporting?
4. Are the current NARMS international activities adequate to address the worldwide spread of antimicrobial-resistant food-borne bacteria?

# Panel Approach:

The NARMS Subcommittee met on April 10-11, 2007 in Rockville, MD and heard presentations from: the three federal partners of NARMS; and, external presenters as part of a public hearing. In addition, the Subcommittee reviewed multiple reports, studies and analyses distributed to the group prior and during its meeting.

# Introduction to NARMS

NARMS is a national collaborative network involving the FDA, CDC, and USDA. The system was developed to monitor changes in susceptibility/resistance of select zoonotic bacterial pathogens and commensal organisms recovered from animals, some retail meats, and humans to antimicrobial agents of public health and animal health significance. NARMS was started in 1996 in response to a public health concern based on the recognition of the growing problem of antimicrobial resistance.

# The Goals of NARMS

1. Provide descriptive data and trends on antimicrobial susceptibility/resistance patterns in zoonotic, food-borne bacterial pathogens, and select commensal organisms;
2. Respond to unusual or high levels of bacterial drug resistance in humans, animals, and retail meats in order to contain or mitigate resistance disseminations;
3. Design follow-up epidemiology or research studies to better understand the phenomenon of resistance; and
4. Assist the FDA in decision-making for approving safe and effective drugs for humans and animals, as well as promote prudent and judicious use of antimicrobials.

# General Considerations and Common Themes:

- Need for an improved sampling strategy
- Timeliness of reporting and issuing reports
- Harmonization of data and results
- Creation of a contemporary surveillance platform
- High priority for future support and attention
- Consider other potential partners and funding sources
- Unappreciated benefits for meeting needs of veterinary medicine and animal health
- Need to keep the focus on the public health impact
- Limitations due to lack of drug use data

*Question 1: Are there inherent biases in the sampling strategies employed in NARMS? If so, how can they be improved to ensure that the data and our interpretations are scientifically sound given current resources?*

Findings:

- Human samples need stratification and targeted strategy
- Importance of sampling from healthy populations
- Retail meat sample is small and needs to be adjusted to more a specific, hypothesis-driven focus
- Animal component sampling needs to be a nationally representative sample
- NARMS on-farm data should focus on answering specific hypothesis-driven research questions
- Clinical diagnostic laboratory sampling should best be limited to mainly an early warning system

*Question 2:* Are there epidemiological and/or microbiological research studies that would better serve the goals of NARMS and the regulatory work of FDA?

Findings:

- Suggest a further expansion of the program's research portfolio to include: lab methods; platform development; and more pilot projects that would enhance goals
- Expand hypothesis-driven research with a special emphasis on assessing human risks
- Encourage more collaborations and partnerships
- Key research focus is to gain understanding of the flow of resistance genes and/or bacteria across the “farm-to-fork” continuum

*Question 3: Are our current plans for data harmonization and reporting appropriate? If not, what alternative approaches would you consider, and what should be the top priorities for harmonization and reporting?*

Findings:

- Critical need to create a real-time, integrated database for all components of NARMS
- Need for a web-based, real-time system flexible enough to allow separate, collective and confidential report generation
- Suggest that data and information be more accessible and shared with researchers and other end users
- Support the need for drug-use data to be added
- Strong need for faster reporting and data/report publications to improve utility of information; consider pre-marketing approvals; and better link animal and human health communities

*Question 4: Are the current NARMS international activities adequate to maintain a significant collaboration with worldwide efforts to mitigate the spread of antimicrobial-resistant food-borne bacteria?*

Findings:

- Strongly endorse continuation and expansion as a global activity
- Need to improve coordination of NARMS' components for international purposes and serve as a global model
- Need to adopt new technologies and ensure quality data and reporting
- Suggest that there is a single position and spokesperson to represent NARMS in global settings
- Important to continue and expand global training

# Final Findings and Suggestions:

- Commitment and dedication of NARMS team is laudable
- Outstanding progress and acceptance over last decade
- Evaluation of program to: improve what is and create what isn't
- Suggest visioning, strategic and business planning processes be adopted
- Suggest that the program should evolve and become more predictive, responsive, and expansive
- Endorse development of a 10-year plan with wide public involvement in order to consider a new opportunity horizon