Introduction

Antimicrobial stewardship, as defined by the AVMA, encompasses the actions veterinarians take individually and as a profession to preserve the effectiveness and availability of antimicrobial drugs through conscientious oversight and responsible medical decision-making while safeguarding animal, public, and environmental health.\(^1\) One of the core principles outlined in the AVMA’s policy is the evaluation of antimicrobial drug use practices, including the analysis and sharing of antimicrobial drug use data while preserving veterinarian-client confidentiality. The FDA Center for Veterinary Medicine recognizes that tracking antimicrobial use (AMU) in animals is a key component to advancing antimicrobial stewardship efforts in the US. In addition, data collected from FDA-funded projects demonstrate that AMU data are valuable for monitoring trends; informing national, regional, or local policies and interventions; and understanding the drivers of resistance in veterinary and agricultural settings. While there are ongoing, university-led, or private industry-funded data collection efforts in certain sectors, such as poultry and companion animals, the US currently lacks a coordinated, national-scale database repository or monitoring system to collect and track these data across multiple food-producing and companion animal sectors.

To gain a better understanding of how antimicrobial drugs are used in livestock production and gauge the impact of ongoing antimicrobial stewardship efforts, the FDA funded 2 cooperative agreements for AMU data collection in food-producing animals beginning in 2016. These efforts were intended to (1) provide baseline information on antimicrobial drug use practices in the 4 major food-producing animal species (cattle, swine, turkeys, and chickens). Initiated in 2016, the projects aimed to establish baseline AMU information and pilot methodologies. This article describes the methodologies used by grantees for data collected from 2016 to 2021, emphasizing the diverse data sources and metrics utilized. Instead of summarizing the trends, it provides a list of publications generated from the grants. Factors contributing to successful data collection included early interaction and trust building between the producers/data holders and researchers. Shared challenges include limitations stemming from convenience sampling, variable industry participation, and lack of data covering all segments of a particular commodity (eg, data on breeding or young animals were lacking). Future collaborative efforts are needed to enhance data standardization, contextualization, representativeness, and reporting of national-scale AMU data going forward. Addressing these challenges and data gaps is essential for effective monitoring of AMU in veterinary settings and animal agriculture, in alignment with national strategies to combat antimicrobial resistance.

Keywords: antimicrobial stewardship, antimicrobial drug use, antimicrobial monitoring, metrics, animal agriculture

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continued to develop robust methodologies to collect AMU data and generate baseline information on AMU practices in the US through 2021. While the cooperative agreement project period ended in 2021, several of the projects continued work under a no-cost extension through 2023 due to effects of extenuating circumstances (eg, a highly pathogenic avian influenza outbreak in poultry and the COVID-19 pandemic). It is also notable that certain data collection efforts in the poultry sector are ongoing, with continued support from industry groups (eg, the US Poultry and Egg Association [USPOULTRY]). While the scope of this present article is not focused on AMU results or trends, a list of the comprehensive body of work generated by the cooperative agreements to date is publicly available in the peer-reviewed literature (Supplementary Table S1).

The aim of this article is to summarize the types and availability of food animal AMU data sources and data components gathered through 2 pilot projects funded by the FDA, identify data gaps and challenges, and signal how these efforts may intersect with future AMU data collection efforts within the US. This paper does not attempt to summarize the key findings or trends about the AMU data reported by the papers but rather focuses on the data collection methodologies.

**Antimicrobial Use Data Sources in US Animal Agriculture**

Antimicrobial use data encompass the amount and type of antimicrobials prescribed, authorized, administered, delivered, and/or purchased for administration in a defined animal species or population. Antimicrobial use data are ideally extracted as close as possible to the point of administration in the animal or population of animals and are accompanied by qualifying information that provides important context regarding the use of those drugs (eg, indications for use, disease prevalence or incidence, and other factors). Collection and analysis of antimicrobial drug use at different levels of aggregation, such as by farm or veterinary practice level or by animal production class or sector, are essential to the implementation of antimicrobial stewardship programs, but these data must be interpreted with appropriate context, including qualitative and quantitative information about how the data are collected.

Examples of raw AMU data sources include individual- or population-level animal health records available in electronic or, in some cases, paper form. Examples of animal health records containing information on AMU include farm delivery notes, treatment logbooks, veterinary prescription data, Veterinary Feed Directive orders (for medically important antimicrobials administered in feed), or accounting records (ie, invoices). Veterinarians, pharmacies, feed mills, and end users/consumers, such as animal producers or animal industry organizations, are examples of individuals or entities that may have access to raw AMU data. In most cases, the raw data will contain sensitive identifying information about businesses or farms or other metadata. A condition of the FDA cooperative agreement funding was to collect data in a manner that protected disclosure of farm- or production unit-identifying information or other confidential business information.

Another data source of AMU data reported in the US includes survey data. The USDA APHIS National Animal Health Monitoring System (NAHMS) conducts national-level periodic studies on the health and health management of US domestic livestock, equine, aquaculture, and poultry populations. The NAHMS has collected information on AMU, stewardship, and resistance during many of the NAHMS studies, including most recently for US swine operations and feedlot cattle. These reports summarize the percentage of operations that use an antimicrobial for a specific indication or disease or of animals that received the antimicrobial rather than quantifying the actual amounts (eg, milligrams of antimicrobial used). Limitations of survey-based studies for collection of AMU data include relative subjectivity of survey data, recall bias, and limited focus on specific production classes rather than throughout the lifetime of the animal.

Another distinct type of data related to consumption of antimicrobials that are sometimes misinterpreted as AMU data are antimicrobial sales data. The FDA annually reports estimates in volume of antimicrobial sales and distribution for antimicrobials approved for use in food-producing animals. Sales data are expressed as total kilograms of active antimicrobial drug ingredient and reported by antimicrobial drug class and importance in human medicine (ie, the FDA Guidance for Industry No. 152 contains Appendix A, which provides a ranking of antimicrobial drugs according to their importance in human medicine). Sales data are an indicator of overall market trends related to antimicrobial drugs; however, in contrast to AMU data, sales data do not capture how these drug products are being used in the context of animal operations, including in what way these drugs are being used to prevent, control, and/or treat specific animal diseases. In addition, while population correction factors, such as a target animal biomass denominator, can be applied to sales data retrospectively, sales data are inherently limited to estimated volumes of product distributed in the marketplace, which lacks temporal information about when they are used and the specific populations of animals in which they are used. Conversely, AMU data may provide granular information, including the context for use and other information about animal demographics and animal health. For these reasons, data on AMU are considered a more robust indicator to inform progress on antimicrobial stewardship.

**The Structure of Animal Sectors Impacts Availability of Antimicrobial Use Data**

The availability of different types of AMU data sources from the cooperative agreement projects is
presented in Figure 1. Within the 4 major food-producing animal species groups, data were available for certain animal subsectors, including feedlot cattle, dairy cattle, layer chickens, broiler chickens, turkeys, and growing finisher pigs. However, data were not available for other animal subsectors; for example, the studies did not include information about breeding animals, calves, or nursery swine. Detailed descriptions about the scope of data collection by each sector are provided in the following sections.

There were a wide array of animal health record formats and challenges associated with accessing AMU data across diverse animal production settings. Across all studied animal sectors, the pilot projects faced shared barriers in collecting informative data in any kind of standardized or automated manner. Animal health records about AMU practices were collected in different formats ranging from sophisticated electronic health record software systems to paper treatment logbooks, drug product purchasing

Figure 1—Antimicrobial use data sources available to the FDA-funded cooperative agreements for food-producing animals varied. There were some differences in data source availability by subsector; however, for the purposes of this figure, the cattle icon represents both dairy and feedlot subsectors combined and the chick icon represents broiler, layer, and turkey subsectors. Drug product purchase records, such as invoices, were available for broiler chickens and turkeys but not in layers. Lot-level administration records for feedlot cattle were available for medicated feed ration data or injectable antibiotics, but lot-level administration records were not data sources for the dairy studies. In the feedlot studies, feedlot manager survey response data were collected via an in-person survey instrument and used to supplement the other data sources. In the swine study, supplementary information was requested via an online survey from veterinarians with oversight of antimicrobial use in participating systems, for example, to supplement qualitative information on indications for use, perceived distribution of use across age groups, and the common dosing protocols of administration for those antimicrobials administered by water or injection.
or accounting information, delivery notes, pharmacy records, discharge records, individual animal or lot level data, or farm invoice information. The task of combining these various data collection methods and extracting usable and relevant AMU data involved significant manual data entry and labor-intensive validation steps, resulting in varying levels of granularity (ie, the scale or level of detail present in a set of data) depending on the data source.

The pilot studies also demonstrated the effects of vertical integration in animal agriculture on data source availability and collection methodologies. In highly vertically integrated systems (eg, poultry), where multiple stages of animal production are consolidated under a single entity, data collection is more streamlined, involving fewer points of contact, such as company representatives or veterinarians, and more standardized data capture systems. This can result in a more uniform and comprehensive dataset, especially when data granularity is sufficient. In contrast, less vertically integrated industries (eg, feedlot or dairy cattle), which are often managed by separate companies or producers operating at different scales and stages of animal production, present unique challenges for data collection. This is notable in sectors that are distributed across variably sized farm operations (eg, cow-calf operations, beef growers/backgrounders, dairy calf– or heifer-raising operations, etc). Recognizing these variations is critical for tailoring effective data collection strategies to the specific dynamics of each sector.

Antimicrobial Use Data Collection from Beef Feedlots and Dairy Farms

The FDA-funded cooperative agreement cattle pilot study was conducted as 2 separate and distinct projects—beef feedlot and dairy—to account for variations between the 2 sectors. Sampling approaches for AMU data in both the beef feedlot and dairy studies involved a convenience sample of farms, where farms were included in the study on the basis of voluntary participation and recruitment by the investigators directly. In some cases, additional supporting information was gathered through surveys completed by farm managers and veterinarians.

Beef cattle feedlots were recruited through established relationships with state beef producer organizations and consulting veterinarians and by direct contact of feedlot management staff who were known to the investigators. Twenty-two feedlots participated, all situated in 1 of the top 5 states with the highest reported feeder cattle production (Colorado, Iowa, Kansas, Nebraska, and Texas). During 2016 to 2017, the participating feedlots represented approximately 2.5% and 2.6% of the USDA-reported annual steer and heifer slaughter animals, respectively. Similarly, for 2018 to 2019, the participating feedlots accounted for approximately 2.2% of the USDA-reported annual steer and heifer slaughter.

Dairy cattle farms for the study were recruited through consulting veterinarians with whom the investigators had previously established relationships. Thirty-two dairy farms initially participated, ranging in size from 180 to 6,000 adult cows. An intentional effort was made to include dairy farms representing multiple regions of the US, with a focus on the West, Midwest, and Northeast. Data were reported for 2016 to 2019 from 29 of the dairy farms; 3 of the initial 32 farms were excluded due to changes in management or ownership and/or insufficient retrospective data.

In the feedlot cattle studies, the records of antimicrobial administration varied considerably, ranging from comprehensive electronic data capture programs to drug product purchase invoices from veterinarians and distributors. The data were reported by individual animal drug administration records or lot-level administration records. The dairy studies incorporated multiple sources of on-farm data, primarily relying on farm treatment records in both electronic and hard copy, which were converted into a standardized format by the study investigators. Additional sources included farm treatment protocols, drug product purchase records, and survey responses. A limitation of both the beef feedlot and dairy studies was the inability to capture AMU information during the entire life cycle of animals, accounting for factors such as cattle movement between operations under different management or ownership and information in specific cattle populations such as young stock and breeding stock.

Antimicrobial Use Data Information Collected from Poultry Farms

The FDA-funded cooperative agreement poultry pilot studies were approached as distinct projects to accommodate differences among broiler, layer, and turkey sectors. This effort was first piloted in 2014 with funding from USPOULTRY. In 2016, funding from both the FDA-funded cooperative agreement and continued funding from USPOULTRY allowed the effort to continue to advance toward becoming more sustainable and nationally representative of commercial poultry production. Companies listed by WATT Poultry, which catalogs the largest poultry and egg production companies in the US, were invited to participate. This outreach was facilitated by USPOULTRY as well as professional organizations and trade groups, including the American Association of Avian Pathologists, National Turkey Federation, National Chicken Council, United Egg Producers, Association of Veterinarians in Egg Production, Association of Veterinarians in Broiler Production, and Association of Veterinarians in Turkey Production. Consistent with the other animal sectors and terms of the cooperative agreement, participation in all poultry studies was voluntary, with companies assured data confidentiality and public release of only industry-wide aggregated data.

Data collection for the 3 poultry sectors occurred on a calendar-year basis. The USDA poultry production statistics were used to characterize the
representativeness of the data for US flock populations. Participating companies' data were estimated to account for approximately 40% to 45% of national egg production (for layers in 2016 to 2021), approximately 82% to 89% of broiler chicken production (for broilers in 2013 to 2021), and approximately 67% to 70% of turkey production (for turkeys in 2013 to 2021).

The granularity of data sources varied among participating companies, encompassing prescription records, annual summary data quantifying total amounts used, feed mill data (total feed production), and drug purchase records (invoices). Notably, companies provided data at different levels of granularity, ranging from detailed flock levels to annual totals for farms. Over the course of the project reporting period, there was a trend for increasing levels of granularity in later years of data collection, including details on disease indications, bird age at time of therapy, and antimicrobial treatment duration. Contextual information was also accounted for during analysis and interpretation of the data, such as the impacts of the COVID-19 pandemic on antimicrobial availability and industry-wide effects on management, such as extended time birds spent on farm before slaughter. An acknowledged limitation of the studies was the lack of information regarding animal health outcomes following antimicrobial administration.

**Antimicrobial Use Data Collection on Swine Farms**

The swine pilot study was combined with the FDA-funded cooperative agreement for poultry. This part of the project collected data from a convenience sample of US swine production systems that were willing to voluntarily share AMU data. Study investigators initially consulted with a group of experts convened by the National Pork Board, including specialist swine veterinarians representing both integrated systems and clinics servicing independent farms and swine producers. The initial discussions by that group were to raise and address priority issues pertaining to establishment of a voluntary system for reporting AMU, including feasibility of data collection, data confidentiality, and metrics. Seventeen swine production companies were approached by the study investigators through direct personal contacts, mostly veterinarians associated with the companies. Not all of these 17 companies, 11 systems expressed initial willingness to participate, while 10 systems proceeded to formalize nondisclosure agreements to safeguard proprietary data and 1 system subsequently withdrew from participation, leaving a total of 9 swine systems that contributed AMU data. These 9 systems were widely distributed among major swine-producing states and collectively raised approximately 20% of national swine production for the years reported (2016 to 2017). The study was limited to growing pigs (weaning to market) and represented large, integrated swine operations.

To minimize administrative burden and resources to production company staff, companies were asked to provide data in easily accessible formats. Consequently, data granularity varied widely across systems, encompassing aggregate annual use, use by phase of growth (eg, growing, finishing), use attributed to individual lots (groups) of animals including animal weight marketed by lot, and data by lot derived from administration records (limited to 1 system). Except for 1 farm system, the data represented amounts delivered to farms and served as maximal estimates of amounts administered to animals.

**Antimicrobial Use Data Components and Metrics**

Antimicrobial use data metrics (ie, measures of quantitative assessment used for tracking data on AMU) are typically calculated from different data elements, which can be broken down into numerator and denominator components. The available numerator and denominator data elements collected in the FDA-funded cooperative agreements are summarized in Supplementary Tables S2 and S3. Antimicrobial use numerator information refers to measures of the quantity of antimicrobial drugs administered to animals, while denominator information includes information about the animal populations potentially receiving the drug(s), often based on weight or age at treatment, veterinary visits, animal age, or animal production class.

There is no standardized "one size fits all" metric of AMU across animal species or populations, and decisions regarding appropriate AMU metric choice are influenced by several factors, including the purpose or objectives for data collection and data availability. Antimicrobial use data metrics can vary depending on the data sources available and purpose to data collection but are generally characterized as mass-based, count-based, or dose-based metrics. Metric choice can also depend on the scale of data collection (regional vs national vs global) and whether the purpose is to inform individual farm stewardship programs in relation to a representative population (ie, benchmarking) or for national trend analysis, such as to inform policy. Figure 2 summarizes various AMU metrics that were reported in the cooperative agreements, including the number of regimens, total grams per unit animal, total milligrams per kilogram (mg/kg) animal liveweight, grams per animal year, regimens per animal year, and percent (%) of operations that treat. Additional information and metadata, such as temporal aspects of data collection or treatment outcome information, in some cases is available to aid in the interpretation of AMU data.

Apley et al explored the influence of AMU metric choice across feedlots using data from this cooperative agreement and reported that conclusions drawn about AMU and stewardship are substantially affected by choice of metric used to report the data. This study illustrates that distinct AMU metrics can produce notable changes in the results and conclusions drawn, emphasizing the critical need for transparency in the methods used to calculate AMU metrics to ensure that comparisons among different populations are both meaningful and accurate.
**Discussion**

The cooperative agreement projects spanning beef, dairy, poultry, and swine sectors of animal agriculture demonstrated significant progress in developing methodologies to collect AMU data throughout the 5-year FDA-funded cooperative agreement projects. This progress is evident in the trend for increased data granularity collected during the second phase of the projects, incorporating additional tracking of detailed data elements such as treatment outcomes, indications for use, and durations of AMU and increasing industry participation. These projects benefited from incorporating a champion approach, with the study investigators being well-respected individuals involved in their respective animal industries, encouraging voluntary participation by producers and educating them about the value of monitoring their AMU practices. In addition, the projects demonstrated that AMU metric choice is nuanced, emphasizing the need for appropriate interpretation of AMU data and underscoring the challenges associated with standardization efforts.

The projects shared challenges related to AMU data analysis due to variations in available data sources and granularity. Certain data elements, such as animal health and treatment outcomes, were often not available to collect. The COVID-19 pandemic also impacted antimicrobial drug availability and drug use patterns in some cases, such as a penicillin shortage in turkeys.\(^\text{10}\) There were industry-wide supply chain impacts such as compromised production inputs (ie, feed), restricted live animal transport, and packing plant shutdowns resulting in delayed slaughter and other changes to typical management of animal production.\(^\text{11}\) In addition to the potential impacts of the pandemic on AMU patterns, the COVID-19 pandemic also contributed to delays in data collection in certain years of the cooperative agreement (2020 to 2021) and, with regard to the poultry project, a highly pathogenic avian influenza outbreak in the US (2022 to 2023) contributed to delays in data analysis and reporting. These examples demonstrate that external challenges such as disease outbreaks or natural disasters may temporarily affect the ability of participants to contribute data and such events should be considered in context when evaluating AMU trends.

All sectors faced unique limitations in collecting AMU data that were fully representative of all animal production phases; for example, limited information was available about breeding animals, young animals, or animals housed on smaller operations. Another shared limitation across some of the projects was the introduction of potential sampling bias due to reliance on convenience samples of participating farms. The poultry industry exhibited the highest degree of industry participation and data representation during the period of the cooperative agreement, and this success may be attributable to multiple factors. The poultry studies began data collection prior to the start of the FDA cooperative agreement funding, leveraging funds from USPOULTRY. This early interaction and investment into the project likely facilitated early buy-in, trust, and development of an effective working relationship between stakeholders, including between the principal investigator and the major professional and trade organizations. The AMU data sets may also have been more complete for poultry compared to other sectors, attributable in part to the greater degree of vertical integration as compared to the cattle and swine industries, where the structure of animal production in those sectors are less integrated (eg, cow-calf farms, small dairy operations). Regarding data collection or reporting frequency, the prevailing approach used in the cooperative agreements was to report on an annual basis, with some companies providing fiscal-year data. Aligning data collection and reporting timing to span across time frames during which antimicrobial stewardship policy measures go into effect could offer valuable insights into the impact of those measures. However, the complexity of uncontrolled temporal associations across multiple factors validates the need for data to be interpreted with great caution around any frames of reference.

**Future Directions**

The FDA-funded cooperative agreement projects summarized in this article establish valuable foundational methodologies and baseline information for...
AMU data collection in US animal agriculture during a period when national-scale monitoring of AMU in the US is still in early stages of development. The data collection efforts in poultry are ongoing with funding from USPOULTRY, including a mechanism for public reporting through a dashboard to view AMU data. However, coordinated data collection and reporting across other animal production and veterinary sectors will require additional infrastructure development before being considered a successful national program. As demonstrated through these cooperative agreements, the success of future monitoring efforts based on voluntary participation hinges on stakeholder buy-in through early interaction and trust in the data collection methodology. In addition, incentive to participation, subject matter expertise regarding both data collection methodologies and the use of antimicrobials in animal production settings, and other programmatic support are required to encourage industry participation in AMU monitoring programs across other sectors. Additionally, continued advancements in methodologies to extract data from diverse record sources is needed for a comprehensive understanding of AMU trends, but data standardization remains a complex issue. While increased data granularity is beneficial, it can be complicated and is often invalid for making comparisons, especially across sectors, as each has its own unique management practices and animal disease pressures. Challenges associated with data standardization further complicate interpretation of trends, and the value of different metrics may vary on the basis of the context and end consumer of such data. Furthermore, it is crucial to underscore the importance of contextualizing AMU data during interpretation and reporting; for example, interpreting those data in the context of animal disease pressures, which may vary widely across sectors and regional geography.

Collecting data to monitor AMU in humans and animals is a key element of the US National Action Plan to Combat Antimicrobial Resistant Bacteria and remains a critical part of the FDA’s strategy to support antimicrobial stewardship in veterinary settings. The FDA recognizes the need for additional scientifically sound data on AMU in veterinary settings and animal agriculture for the purposes of monitoring trends, informing national antimicrobial stewardship interventions and policy, and understanding drivers of antimicrobial resistance. As such, the FDA continues to consider strategies to develop a sustainable mechanism to collect and report this information at a national level.

As part of these efforts, the FDA, with help from the Reagan-Udall Foundation for the FDA, has explored the feasibility of a potential public-private partnership framework to collect, analyze, and report AMU data for food-producing animals. The framework described in the Reagan-Udall Foundation’s report describes key findings from a series of targeted conversations and working group meetings with stakeholders from animal agriculture, professional and trade associations, and other interested stakeholders and outlines a potential collaborative approach based on voluntary participation from data holders. As such, a critical element for success of such a framework is to protect the confidentiality of producers, production companies, and veterinarians who agree to contribute such data. Further, the success of future efforts will require broad participation from both public and private sectors as well as continued collaboration among US federal agencies, animal industries, and other stakeholders. The accomplishments and challenges of the FDA-funded cooperative agreement projects underscore the need for continued momentum in this field for national AMU monitoring efforts.

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Disclosures
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References

**Supplementary Materials**

Supplementary materials are posted online at the journal website: avmajournals.avma.org.