Validation, use and interpretation of health data: an epidemiologist's perspective

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Abstract

The Canadian National Animal Health Project was launched in 2006 in an attempt to stimulate the consistent recording of important health events on Canadian dairy farms, and to move these event data into the national milk recording database. In 2005, the year prior to the launch, just over 14% of herds nationally were contributing health event data to the national database. The contributing herds increased to almost 50% in 2007 and reached a peak of just over 70% in 2011. The primary use of these event data is at the farm level, where dairy producers and their veterinarians and other advisors use these data to monitor health and productivity, to motivate changes in management and to measure the outcomes of these changes. Moving these data into a central system for surveillance, benchmarking and genetic evaluation is a secondary use and still does not get much attention from many producers. As a consequence, there are issues with variability in disease definition and in the consistency of recording across various disease conditions. The most frequently recorded health event across the country is mastitis. Based on data from 6,438 herds of 10,021 enrolled in milk recording in 2008, we estimated that the incidence of clinical mastitis in Canadian dairy herds was 19 cases/100 cow-years. A very intensive farm level study involving 91 herds from across Canada as part of the Canadian

Mastitis Research Network National Cohort of Dairy Herds program reported a clinical mastitis incidence of 26 cases/100 cow-years. A comparison of these data would suggest that we still have an under-reporting of health events, even in those herds who are actively recording and forwarding health event data. Nonetheless, these data have been used to generate genetic parameters for health traits in Canadian Holstein cattle, and continue to increase in quantity and quality.

Keywords: health data, validation, incidence, monitoring.

Introduction

Dairy herd improvement (DHI) organizations have a longstanding history of recording production data, event data and some regularly assessed health data on dairy farms for fuelling the record of performance and genetic evaluation processes. While there are challenges to collecting and validating these data, they have the advantage that they occur regularly on every farm for every animal. For instance, every cow must calve to produce milk, hence she will have a calving date. Every lactating cow should produce milk on DHI test day, the milk will have an

associated weight, composition (fat, protein, lactose) and can readily be assessed for subclinical mastitis by measuring the somatic cell count (SCC). Issues around the accuracy of animal inventories, measurement instruments and animal identification are the primary focus of data validation.

Sporadic health events (diseases that occur irregularly, if at all, to some animals at certain stages of lactation/life) have been recorded by dairy farmers on dairy farms since the earliest days of organized herd health (Harrington, 1979) and likely well before that. These data have value at the farm for managing animal health, for sorting and segregating individuals and groups, for making therapeutic and preventive treatment decisions and for deciding which animals to keep and to breed. These data also have potential value beyond the farm, aggregated at the local, regional, national or international level for the purposes of benchmarking, surveillance, documenting health status for international trade and genetic evaluation (Koeck, 2012). The Canadian National Animal Health Project was launched in 2006 in an attempt to stimulate the consistent recording of important health events on Canadian dairy farms, and to move these event data into the national milk recording database. In 2005, the year prior to the launch, just over 14% of herds nationally were contributing health event data to the national database. The contributing herds increased to almost 50% in 2007 and reached a peak of just over 70% in 2011. Recording of 8 diseases that are believed to have an effect on herd profitability are recorded voluntarily by dairy farmers. These diseases are mastitis, displaced abomasum, ketosis, milk fever, retained placenta, metritis, cystic ovaries and lameness. These data have been used to generate genetic parameters for health traits in Canadian Holstein cattle (Neuenschwander *et al.*, 2012; Koeck *et al.*, 2012), and continue to be the source of research investigators nationally and regionally.

For disease data to be useful for benchmarking (a collection of summary statistics for all herds within an appropriate group based on farm type or geographic location that a member of that group can compare themselves to) and surveillance (the routine of collection and reporting of disease data for the purpose of identifying unusual patterns, either the emergence of a disease that has not been present previously or an increase in the frequency or severity of endemic disease), they must be readily aggregated and transformable into summary statistics. Disease data are most commonly presented as prevalence proportions (proportion of diseased individuals at a point in time) or incidence rates (number of new cases per animal unit time at risk) (Dohoo *et al.*, 2009). Generating these summary values depends upon being able to accurately count the number of individuals affected (the numerator), the number of individuals at risk (the denominator), and the duration of time that each individual or group are at risk and are being observed. Recommendations for these in the context of the diseases of major significance in dairy cattle have been published (Kelton *et al.*, 1998). Given the quality of inventory data in most milk recording databases, the denominator and time components are relatively easy to generate. The most difficult element to estimate accurately at either the animal or aggregate level is the numerator.

There are many challenges to aggregating these disease numerator data beyond the farm, including variability in disease definition at the farm, inconsistency in case definition and regular accurate data validation.

Since diseases of dairy cattle vary from the simple to the complex, the identification and recording of these disease events also varies. A number of approaches to disease recording have evolved and these may vary dramatically among farms in the same geographical region. These disease classification systems can be based on aetiology, severity, epidemiology, duration and target body system. In some cases diseases are subdivided by etiologic agent (mastitis), while in other instances diseases are combined based on a belief that they have a shared causal pathway (ketosis and displace abomasum). Ultimately, it is important to understand and refine the level of classification relative to the intended use of the disease data, especially if these data are being aggregated across farms.

The Numerator: disease definition

Consider the decision to record cases of ketosis on a dairy farm. This is based on agreement among the herd owner/manager, farm staff and perhaps the herd veterinarian, that the disease is of importance and knowing which cows had the disease is useful in guiding treatment or prevention. If the disease is not considered of importance, then the disease will not be routinely recorded. The absence of ketosis events in a farm data file does not mean the disease is absent, only that the disease was not considered important enough to identify and recored.

The challenge in agreeing upon a consistent disease definition is not small. For example, will ketosis be recorded simply as a binary event (yes/no) or on the basis of clinical progression (no ketosis, sub-clinical ketosis, clinical ketosis)? Does there need to be a distinction between primary ketosis and ketosis secondary to disease conditions such as displaced abomasum? Will the recording of ketosis be based on a definitive diagnosis of the disease condition by the herd veterinarian or the treatment of a putative ketosis case by the herd owner/manager or farm staff? Will the diagnosis be based on cow-side tests (milk or urine tests) or laboratory tests (blood or milk)? Which cow-side test(s) will be used (breath, powder, tablet, reagent strip) and what do we know about the sensitivity and specificity of the test(s)? Which ketone body (acetone, acetoacetate or beta-hydroxybutyrate) will be measured and which body fluid will be used (urine, milk or blood)? Should there be a distinction between a mild case (off-feed) and a severe case (nervous ketosis)? Will the diagnosis be based on human observation or on in-line sensors that are becoming more common in milking systems (Rutten, 2013). The answers to these questions will determine the disease definition for ketosis on one farm, but may be dramatically different on a neighbouring farm. Aggregating these disparate ketosis cases into a common database can be problematic and will add to the variability and perhaps inaccuracy of the summary data produced for benchmarking, surveillance and genetic evaluation.

Disease coding and standardization of nomenclature is an important area of discussion both in human and veterinary medicine (Case, 1994). Less attention has been directed towards the standardization of disease definitions and recording protocols. The International Dairy Federation (IDF) has established a set of international guidelines for bovine mastitis (Osteras *et al.*, 1996), the American Association of Bovine Practitioners has made recommendations for reproductive performance (Fetrow *et al.*, 1994) and standard definitions for eight clinically and economically significant diseases of dairy cattle are currently under discussion in Canada (Kelton *et al.*, 1997). While some classification guidelines are being developed, there is still a general lack of utilized standard disease definitions and recording guidelines.

The Numerator: case definition

One of the greatest challenges in aggregating disease data and calculating incidence is deciding what constitutes a disease event, and do we count all disease events for a cow or just the first one in a lactation (a common practice when calculating a lactational incidence rate or risk). If we consider the ketosis example once more, is the recording of a case being triggered by a diagnosis and treatment, or simply by the preventative treatment of a cow considered at risk for developing ketosis? Should all treatments be recorded and counted as unique and individual events, or should only the first in a string of treatments for a unique case be recorded? How does one distinguish when a second diagnosis of ketosis, in the same animal, during the same lactation is a new case as opposed to a relapse or continuation of an existing case? The challenge becomes greater when we consider mastitis, which can be differentiated both by udder quarter and by etiologic agent or pathogen. Do we count only the first case of mastitis, regardless of quarter or pathogen, in a lactation? Do we enumerate each uniquely infected quarter and further distinguish by pathogen? These issues may seem trivial, yet they are critically important to consider when we summarize data from multiple sources. It is important to realize that there is no one correct answer to each of these questions, but it is important that our methods are recorded and that when we compare among regions or groups, that we use the same protocols.

The Denominator: Time at risk

In order to generate appropriate summary statistics that account for the number of animals at risk of either having or developing disease, we need to have accurate inventory numbers and we need to consider the dynamics of the population or herd. When we calculate disease prevalence, the denominator is simply the total number of animals that could be diseased that are present at that point in time. To calculate an incidence rate however, the denominator becomes considerably more difficult as we are seldom dealing with a closed population. Even in herds of static size that do not buy and sell cattle for commercial purposes, the average herd turnover of 35% means that one third of the cows will leave in a 12 month period, and will be replaced by new individuals. The matter becomes more complex when we consider that the period of risk varies by disease. Let us consider the ketosis example once more. When summarizing the data do we consider all cows equally at risk of developing ketosis, or is there a parity consideration? Should all lactating cows be considered at risk of developing disease, or are cows only at risk for clinical ketosis during the first 4 weeks post-partum? All of these questions must be asked and answered before a uniform and consistent estimate of cow time at risk can be developed for a herd. In addition, if the data are to be pooled or compared across farms, then there must be consistency of definition across all herds contributing to the system.

Disease event validation

The final challenge in using aggregated health data from many herds is validating the accuracy and consistency of recording. Moving the health data into a central system for surveillance, benchmarking and genetic evaluation is a secondary use for these records and as such does not get much attention from many producers. As a consequence, there are issues with variability in disease definition and in the consistency of recording across various disease conditions (Wenz, 2012). The most frequently recorded health event across Canada is mastitis. Based on data from

6,438 herds of 10,021 enrolled in milk recording in 2008, we estimated that the incidence of clinical mastitis in Canadian dairy herds was 19 cases/100 cow-years. A very intensive farm level study involving 91 herds from across Canada as part of the Canadian Mastitis Research Network National Cohort of Dairy Herds program reported a clinical mastitis incidence of 26 cases/100 cow-years. A comparison of these data would suggest that we still have an under- reporting of health events, even in those herds which are actively recording and forwarding health event data.

Under reporting is a common issue and can have many component causes, including; the starting and stopping of recording of a particular disease event at unpredictable and undocumented times; failure to transcribe all events to a repository (farm computer for instance) from which the records move up the data chain (Figure 1); the many individuals or technologies responsible for identifying and generating the disease event data; and seasonal variation in the intensity and consistency of animal observation needed to identify disease events.

Data validation varies in complexity depending on the types of data being captured. For instance, in traditional milk recording data it is relatively easy to identify a missing milk weight or SCC value if the cow has a record at the preceding test and the following test. Having identified that the data element is missing, one can move ahead and determine how to deal with the missing value. With health data, one does not know if the lack of a disease event is because the event did not happen (the cow did not experience the disease), if it was missed (failure to identify or correctly attribute the disease event), if it was not recorded by the observer, if it was not transcribed correctly into the farm record (paper or computer), or if it was not transferred to the central database. In this case the absence of a single case of ketosis on a 50 cow dairy might be indicative of a healthy herd (a good thing) or the failure to recognize and record a potentially important health event (not so good). The time and effort involved in validating health records is substantial, and in most cases well beyond the resources of most organizations. Even in well established systems with a strong history of support, deficiencies have been indentified (Espetvedt, 2013).
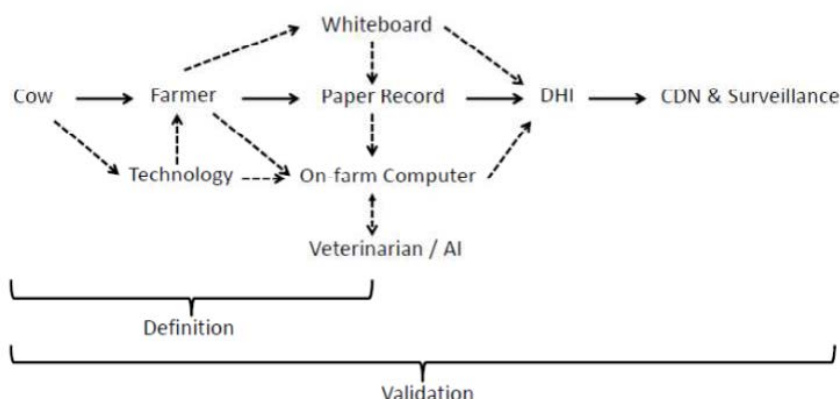

Figure 1. Disease data flow incorporating issues of definition and validation.

Conclusions

There are many good reasons to aggregate health data from many dairy farms into a single database, including benchmarking, surveillance and genetic evaluation. In the ideal world, we would choose to establish standardized disease definitions, use standardized case definitions, count animal time at risk in a consistent manner and then generate well defined summary statistics from accurate and consistent data. Our attempts in this area have been only partially successful at best. Recognizing that the aggregating of disease events represents a secondary use of these data (the primary use is at the farm level), we must decide how important the inevitable variability will be, the impact it will have on our benchmarks or genetic evaluations, and hence whether the degree of error in the system is acceptable.

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