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Managing laboratory errors throughout the total testing process

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Introduction

It has been estimated that over 70 percent of all critical medical decisions associated with admission, discharge or drug therapy in human patients are made upon review of laboratory test results.[1] Veterinarians would likely agree that diagnostic data is equally critical in their management of animal and public health. Veterinary practitioners in the field, and diagnosticians in the laboratory, share a commitment to provide services that will result in reliable and accurate diagnoses, treatment monitoring and disease surveillance. These shared goals will be met when:

1. Practitioners effectively assess the clinical evidence presented to them, formulate an informed diagnostic strategy, collect appropriate samples, ensure the quality of testing performed within their practice, and, when outside testing is required, collect, transport, and submit appropriate specimens to a reliable laboratory; and

2. Laboratory diagnosticians consistently ensure that sample traceability, data integrity and test validity is maintained in order to provide a reliable laboratory test result or case interpretation to the practitioner.

Clearly, practitioners and diagnosticians need accurate laboratory data to inform their critical decision making, to maintain their credibility, and to reliably serve their clients. While relying on data integrity and validity, they must also understand the challenges or circumstances that affect the quality of these data, both internally (within-practice) and externally (cooperation with external partners).

The shared (but not always coordinated) experience between the practitioner and diagnostician has been referred to as the 'Total Testing Process', (TTP) in laboratory medicine parlance. In 1981, George Lundberg described a 'brain-to-brain' loop concept that captured the following activities: the clinician forms a clinical question based on the presented health scenario, tests are selected, samples are collected, samples are transported to the laboratory, analyses are performed, results and interpretations are received, and decision making and follow-up is performed.[2] Considering that mistakes could occur during any of these activities, it must be recognized that result invalidation could be an unexpected, and potentially unrealized, outcome anywhere throughout this process. Therefore, strategies are needed to assure that the steps and hand-offs along the way have not resulted in compromises to the quality of the test result or interpretation. Lundberg's simple description of a complex cycle has led to a system of activity and error categorization known as the Total Testing Process, (TTP) which is used to account for errors in order to analyze them and, ultimately, reduce their recurrence.

The total testing process

The TTP is typically divided into the following three phases: preanalytical, analytical and postanalytical. Alternative categories include pre-examination, examination or post-examination (ISO terminology), and additional sub-phase descriptions (eg: pre-pre-analytical) also occur in the literature. Basically, these categories reflect the potential for critical errors to occur before the sample is analyzed in the lab, at the time of the technical procedure or analysis, or after the results are available or provided to the practitioner. Table 1 provides a list of typical error events that might occur in the categories for veterinary diagnostic medicine.

Preanalytical, analytical and postanalytical error rates

Multiple studies in human medicine have shown that most diagnostic errors occur before, or after, the analytical phase of activity (3-5). In 1997, Plebani et al reported a review of 40,490 stat clinical chemistry results in which it was determined that the overall error rate was 0.45%. Of those errors, 68% were preanalytical, 13% were analytical and 19% were post analytical.[3] Ten years later, the same author repeated the previous study design and reported a reduction in error rates. However, as he reported previously, the pre-and postanalytical steps still had the highest error prevelences.[4] Bonini, et al. performed a literature review of eight years of articles. They write that "even when different study designs, patient numbers, and discovery techniques were used, the distribution of errors across the different phases of the entire testing process was very similar." "In particular, all available studies demonstrated

Table 1: The Total Testing Process: Categories and sources of potential error events.

Preanalytical error	Analytical error	Postanalytical error
Inappropriate test request Ordering	Sample preparation; Contamination, dilution	Inappropriate reference intervals used
Patient preparation	Sample analysis Procedure	Results/readout/raw data incorrectly communicated or recorded
Sample identification	Validation	Final review
Sample collection procedures	Quality control	Data Integration/report/chart
Sample transportation	Sample loss	Transcription
Sample preparation for analysis	Equipment	Security
Sample storage	Computer, lab information system (LIMS)	Computer, LIMS
Sample receipt and unpacking	Documentation	Documentation
Sample quantity	Reagent/supply	Calculation
Sample characteristic (hemolysis, lipemia, pH)	Preliminary result review	Transmission
Breakage, loss	Power	
	Calculation, decimals, units	

that a large percentage of laboratory errors occurred in the pre- and postanalytical phases, with fewer mistakes occurring during the analytical step".[5] Preanalytical errors account for nearly 60-70 percent of all mistakes occurring in human laboratory diagnostic testing due to the intensive processes associated with sample collection, handling, and preparation for testing. Additionally, as extensive technical control processes and quality assurance management systems have been implemented within human clinical laboratories in order to meet accreditation standards and requirements, the number of analytical errors has decreased.[6]

Recently, a comprehensive review of errors occurring in a commercial veterinary clinical laboratory provided error distributions similar to that seen in previous human diagnostic error reports.[7] In that study, the amount and types of error were recorded during an 8-year interval between 2003 and 2010. Hooijberg, et al reported a range of annual error rates of 1.3% in 2007 to 0.7% in 2010. Of those errors, preanalytical errors ranged from 52 to 77%, analytical errors from 4 to 14%, postanalytical from 9 to 12% and 'other' from 6 to 19% of total errors. These data reflect error rates associated with test procedures that included hematology, clinical chemistry, endocrinology, serology, coprology, urinalysis, cytology and microbiology. Comprehensive error data related to other diagnostic tests used in veterinary medicine are not currently available in the literature. While error rates from individual laboratories may not be readily available to practitioners, it is possible (and recommended) to request information from a laboratory service provider that describes their quality management system in order to assess the laboratory approach to error management. Similarly, veterinary practice leaders can control their own internal TTP by implementing their own quality assurance practices.[8]

Quality and error management in veterinary diagnostic labs

Quality Assurance is a planned program of activities and procedures that are implemented in order to ensure that test results are valid, and conform to established technical requirements. While quality can be defined in several ways, an appealing definition is the one offered by Juran who stated that 'Quality is fitness for use'.[9] Laboratory data should be fit to use for the diagnosis of disease, for the monitoring of treatment and for the surveillance of disease. Most quality assurance models require a defined and rigorous approach to monitoring and responding to laboratory errors. In human medicine, countries have developed laboratory regulations with systems of standards, certification, accreditation and monitoring (for example: Clinical Laboratory Improvement Amendments, CLIA program) in order to assess the quality of their results.[10] Likewise, in veterinary medicine, laboratories that perform specific tests for the identification of some infectious agents are required to become certified by international,

federal or local government agencies (World Organization for Animal Health (OIE), Federal Drug Administration (FDA), United States Department of Agriculture (USDA)) because of expectations of international trading partners related to the export of animals and animal products as well as issues related to disease identification and surveillance.[11] However, in general, veterinary laboratories performing most clinical tests are not bound by government regulations. For that reason, it is noteworthy that many veterinary laboratories are voluntarily implementing quality assurance programs in order to meet their own performance goals for the service they provide. Some state, provincial and university laboratories will become accredited by the American Association of Veterinary Laboratory Diagnosticians (AAVLD) which provides an excellent opportunity to meet clearly articulated and extensive quality requirements in order to become certified as an AAVLD accredited laboratory.[12] Commercial laboratories may also voluntarily meet specific work standards such as Good Laboratory Practices (GLP) provided by the FDA,[13] and laboratories may also design and integrate their own internal program of quality assurance in order to incorporate best practices into their service programs.[14] An example of the procedures followed at the AAVLD accredited University of Minnesota Veterinary Diagnostic Laboratory (VDL) when nonconforming work (error) occurs is provided in Figure One. Additional error categorization and frequency data from the VDL will be provided during the seminar remarks.

Opportunities for Improvement: Could we do more?

Veterinary practice leaders and laboratory directors expect and promote quality within their internal organizations by implementing approved processes and requiring best practices.[1] In this way they strive to achieve reliable and accurate data to support effective diagnoses, treatment and disease surveillance. In AAVLD accredited laboratories, it is expected that effective procedures are operational in order to identify, mitigate, and hopefully, prevent, errors that may occur. However, because the reliability of laboratory processes is also affected by preanalytical and postanalytical events that may have their origin outside of the laboratory, it would make sense for practitioners and diagnosticians to coordinate strategies for reducing the opportunity for these types of error. The following examples may illustrate opportunities for collaboration throughout the TTP.

1. Because diagnosticians frequently provide the expertise that is required for the development, optimization, evaluation and approval of diagnostic test protocols, it makes sense that diagnostic laboratories should ensure that sample submission, transport, and handling requirements are readily available, sufficiently descriptive and clearly communicated. However, practitioners will have valuable insight related to the practical challenges they face in submitting or transporting samples to the lab, that could inform, and influence the procedure steps recommended by the diagnostic laboratories.
2. The laboratory professionals that receive, route and analyze samples must be able to recognize samples that do not fit submission or suitability criteria, and follow approved and typically, risk-based, procedures related to sample rejection. However, practitioners may have insight related to the true root cause of inappropriate sample submission (examples: unclear submission forms, limited access to sample collection protocols, out-dated form use) that could help create an opportunity for improving both systems.

It is not surprising that in the early days of integrating quality management systems, laboratories were focused internally as they created and implemented the processes necessary to meet or exceed accreditation criteria. Now that these systems are operational, it may be time to encourage additional collaborative effort with external partners within the total testing process. Potential outcomes of cooperatively addressing the TTP might include: (1) improved communication when errors occur, (2) improved recognition of potential trends in pre- or postanalytical error events, or (3) the creation of resources that could be used to promote best practices related to processes such as sample traceability, handling, submission and transport.

Summary

Categorizing, counting, evaluating, and trending errors throughout the total testing process provides a mechanism for improving procedures anywhere along the path of George Lundberg's 'brain-to –brain' loop. Valid and correctly interpreted laboratory test results are the cornerstone of diagnostic and predictive medicine. Veterinary practitioners in their clinics, and diagnosticians in their laboratories, are already doing much to sustain and promote quality and reduce errors in their settings. That said, it is likely that more could be done to collectively reduce errors, especially where errors are known to occur most frequently, during the preanalytical and postanalytical phases of the TTP. Strategies and further discussion related to improving communication, providing effective resources, and sharing/ trending error data associated with processes that overlap between practice and laboratory would be a welcome, enhancement to the practitioner/ diagnostician collaboration.

Footnote 1: This current discussion of error has focused on the TTP that describes the processes operational when samples are collected at one site (practice) and submitted and analyzed at an independent site (diagnostic laboratory). It is important to remember that within each site, there are additional opportunities for site-specific error events. For example, in the diagnostic lab, samples are received and unpacked within a Sample Receiving Unit and transferred to the appropriate section for test specific analytical testing. An error that occurs prior to the sample appearing in the analytical section (misidentified sample or incorrect procedure code entered) would be categorized as an internal (non- client origin) preanalytical error, and addressed as an internal nonconforming work event (Figure 1). Similarly, preanalytical, analytical and postanalytical errors will occur within practices that are performing their own internal testing, and these errors should be addressed internally by the practice quality program.

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Figure 1: Error management procedures at the University of Minnesota Veterinary Diagnostic Laboratory