Topics in Compan An Med 31 (2016) 2–10

Review Article

Quality Assurance and Quality Control in Point-of-Care Testing

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Keywords:
laboratory
management
diagnostic
in-clinic
error
POCT

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With advancements in the standard of care in veterinary medicine and instrument technology, performing in-house laboratory work on a variety of point-of-care instruments, ranging from glucometers to benchtop chemistry analyzers, has become increasingly commonplace. However, the ability of an instrument to perform a test does not guarantee that those results are accurate. Ensuring that your in-clinic laboratory is providing reliable data requires a comprehensive plan that encompasses both common sense practices aimed at preventing errors at each stage of the testing process, as well as standard operating procedures to validate and monitor analyzer performance. These 2 arms of the plan are known as quality assurance and quality control. Although these concepts are typically out of the comfort zone for veterinarians, just as the thought of business management may deter some veterinarians from practice ownership, it is not beyond the capabilities of veterinarians to learn, understand, and incorporate them into their practice. The objectives of this article are to convey the importance of quality assurance and quality control, walk you through the American Society for Veterinary Clinical Pathology guidelines on this topic, and provide direction to additional resources for further education on this topic, all with the focus on point-of-care testing in the in-clinic laboratory.

Introduction

Although arguably every veterinary practice uses some sort of point-of-care testing (POCT) that would benefit from the content of this article, the title may deter many veterinary practitioners from reading further because of their unfamiliarity with the terms “quality assurance” (QA) and “quality control” (QC). Defining and distinguishing these terms is challenging for most veterinarians and veterinary technicians, perhaps largely as a consequence of minimal instruction in veterinary school curricula.[1,2] In a recently published Veterinary Information Network (VIN) survey, over half of respondents used some form of the word “accurate” in their definitions of QA and QC, indicating that even though it is challenging to put into words what these terms mean or entail, they evoke a positive connotation.[1] QA is defined as the laboratory procedures that monitor and improve all aspects of laboratory performance and seek to minimize preanalytical, analytical, and postanalytical laboratory error.[2,3] QC is defined as the laboratory procedures, including daily statistical and nonstatistical procedures, that monitor the analytical performance of instruments detecting mostly analytical error.[2,3]

Given that QA and QC involve laboratory procedures, the reader may wonder how they apply to a typical practicing veterinarian. The answer lies in the second part of the title: point-of-care testing, which is a more familiar, yet often too narrowly applied term. Hand-held analyzers, such as glucometers and blood gas analyzers, are examples of what are widely recognized as point-of-care instruments because of their hand-held nature allowing close proximity to the patient.[2] However, POCT encompasses a broad range of analytical tools and methodologies including small hand-held analyzers, noninstrumental systems such as urine dipsticks, and desktop or benchtop instruments including hematology and chemistry analyzers.[2] In this broader sense, POCT refers to any laboratory testing performed outside the traditional “reference” clinical pathology laboratory.[2] Therefore, if diagnostics ranging anywhere from a SNAP test (trademarked and owned by IDEXX Laboratories, Inc.) to a complete blood cell count (CBC) are being performed at your place of work, as is the case for most veterinary professionals, this topic is of practical relevance for you.[1]

All nonresearch laboratory testing performed on human specimens in the United States are regulated by the Centers for Medicare and Medicaid Services[4] through the Clinical Laboratory Improvement Amendments of 1988. This amendment to the Public Health Services Act established quality standards for laboratory testing including mandates to maintain a QA and QC program, requirements for proficiency testing programs, and inspections to ensure compliance with requirements. The overriding goal of these regulations is to ensure the validity and reliability of laboratory testing.[4] In contrast, there is no equivalent regulatory oversight of diagnostic laboratory testing in veterinary medicine.[2,5] Without government regulations, the veterinary profession has been charged with the task of self-monitoring and ensuring that laboratories, both reference and in-clinic, are producing quality results. In the 1950s, driven by the rapidly changing livestock and poultry industry coinciding with diagnostic technological advances, an organization of veterinary laboratory diagnosticians was formed.[6] This group held annual meetings entitled the Conference of Veterinary Laboratory Diagnosticians, and in 1968 named their group as the American Association of Veterinary Laboratory Diagnosticians (AAVLD).[6] The original objectives included the exchange and dissemination of information relating to the diagnosis of animal diseases and establishment of guidelines for the improvement of diagnostic laboratories.[6] In addition to advancing the discipline of veterinary diagnostic laboratory science, the AAVLD also provides a formal accreditation process for veterinary medical diagnostic laboratories. Additional organizations exist including the Veterinary Laboratory Association (VLA) and the College of American Pathologists (CAP), which seek to improve the quality of diagnostic medicine through QA programs,

http://dx.doi.org/10.1053/j.tcam.2016.05.003
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such as proficiency testing (to be defined later in this article). Although the focus of these organizations is on larger referral diagnostic laboratories, not in-clinic laboratories, it is important for veterinary professionals to be aware of these organizations that are working toward improving the standard of diagnostics in veterinary medicine.

The American Society for Veterinary Clinical Pathology (ASVCP) created the Quality Assurance and Laboratory Standards Committee (QALS) in 1996, in response to concerns by ASVCP members about QA and QC in veterinary diagnostic laboratories.[3] The mission of the committee is "to encourage and promote the establishment of standards for the performance of laboratory procedures" on veterinary samples, and has done this through the development of QA guidelines available for free to the veterinary community.[7] The initial ASVCP QALS guidelines were targeted at laboratory professionals in reference clinical pathology laboratories.[2,3] However, QALS went on to form a subcommittee in 2009 with the specific purpose of devising QA guidelines for POCT, expanding its educational purpose to include guidance for laboratory testing in private practice, academic veterinary medical centers, and beyond.[2] These guidelines, aimed at veterinarians and veterinary technicians, provide a minimum standard for the management of POCT instruments, are available in their entirety for free online, and are published in the *Veterinary Clinical Pathology* journal.[2,7] The goal of this review is to highlight the ASVCP guidelines for POCT and provide recommendations for how these guidelines can be integrated into daily practice, both general and specialty.

Making the Case for QA and QC for POCT

Clinicians rely on the results of diagnostic testing to reach a diagnosis, monitor patient progress, and modify treatment plans for their patients. The accuracy and precision of these results are paramount to the success of these core tasks and should not be assumed or taken for granted. Test results are only as good as the analyzers or test systems that produce them, as well as the knowledge base of the individuals operating them. This involves more than simply researching and purchasing an analyzer with solid manufacturer claims, but also requires regular maintenance and testing to monitor its performance. This is analogous to the purchase of a new car that despite being made by a trustworthy manufacturer, still requires regular oil changes and inspections to ensure its optimal performance and longevity.

More and more private practices are offering in-house diagnostic testing in lieu of or in addition to sending specimens to reference clinical pathology laboratories, to provide faster turnaround times for clients, testing capabilities for emergency/after-hours cases, and to increase practice revenue. Approximately 92% of respondents in the previously mentioned VIN survey had an in-clinic laboratory, with 90% and 99% performing hematology profiles and clinical chemistry testing, respectively.[1] A study evaluating the quality of in-clinic and reference laboratory biochemical testing found that reference laboratories were able to achieve desirable quality requirements for more biochemical analytes than in-clinic laboratories.[8] Although reference laboratories are operating more sophisticated instrumentation, they are also adhering to QA and QC procedures, which are lacking or insufficient for many in-clinic laboratories.

Optimal patient care is the ultimate goal, and high-quality reliable data are essential for accomplishing this. Embracing the value of QA and QC for POCT behooves clinicians striving to practice excellent medicine. Given that POCT is often used for the diagnosis and management of critically ill patients in an emergency setting, it is even more imperative that rapid results be accurate. Sometimes simple QA procedures can help to prevent treatment errors. For example, one of the authors reviewed a case in which an animal was unnecessarily given blood products because a hemoglobin (Hgb):hematocrit (Hct) mismatch was not noted, and the erroneously low Hct was acted upon.

Laboratory Error

Before discussing the actual procedures and recommended guidelines, it is important to understand the types of errors they are intended to prevent. As previously stated, laboratory error is divided into preanalytical, analytical, and postanalytical error. The preanalytic phase of testing includes the steps preceding analytic examination of the specimen including the clinician's request, preparation and identification of the patient, sample collection, and as well as transportation to and within the laboratory.[9] These include both technical variables such as choice of anticoagulant and temperature of a stored/shipped sample, but also biologic factors inherent with the sampled animal such as fed or fasted state, stress/excitement, age, etc.[9]

An example of a preanalytical error is underfilling an EDTA tube for a CBC, commonly referred to as a "short sample." EDTA is hyperosmolar in relation to plasma, and when excess is present in a tube, this causes an osmotic draw of water from the red blood cells (RBCs) resulting in decreased RBC size, and thus an artifactual decrease in the Hct and mean corpuscular volume (MCV). The smaller RBCs also lead to an artifactually increased mean corpuscular Hgb concentration (MCHC). In this scenario, the most reliable indicators of red cell mass are the Hgb and RBC counts. If liquid EDTA tubes are used, the excess EDTA solution can also dilute the sample resulting in a decreased Hct by this means, as well. To prevent this preanalytical error, if only a small sample volume can be drawn from a patient, use of a microtainer is recommended. Microtainers are specifically made with a smaller volume of EDTA for small sample volumes. Dry EDTA tubes would prevent the dilutional artifact, but not the osmotic artifact.

The biologic factors are more relevant during the stage of data interpretation. The analytic phase involves the specimen testing and includes the quality of instruments, equipment, reagents, laboratory technique, and QC program.[10] Postanalytical errors include errors in result transcription (written and electronic) and interpretation because of the effects of report formatting.[10] Many QA practices are "common sense" and are routinely used in well-run hospitals and laboratories, which function to try and avoid these errors.[2] However, some of the less obvious steps to QA and QC can still be effectual, and it is our hope to draw attention to these and outline practical steps to help clinicians improve the performance of their laboratory testing.

Major QA Recommendations

The major recommendations outlined in the ASVCP guidelines for POCT QA are as follows: (1) take a formalized approach to POCT within the facility, (2) use written policies, standard operating procedures (SOPs), forms, and logs, (3) conduct operator training including periodic assessment of skills, (4) assess instrument analytical performance and use both statistical QC and external QA programs, (5) use properly established or validated reference intervals (RIs), and (6) ensure accurate patient result reporting.[2]

Some of these recommendations are more intuitive to understand than others, and are often referred to as nonstatistical QA, because they do not involve the analysis of numerical data. An example is the repeat testing of a second specimen when an unexpected abnormal result is obtained from a healthy patient.[2]