Principles of Repeat Patient Testing-Quality Control for Veterinary Hematology

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Learning Objectives:

1) Define and explain Repeat Patient Testing – Quality Control (RPT-QC)
2) Describe the principles underlying the use of RPT-QC for veterinary hematology
3) Describe the process and calculation of RPT-QC control limits
4) Describe the advantages and disadvantages of RPT-QC for veterinary hematology

Introduction

Repeat patient testing-quality control (RPT-QC) is an alternative quality control method that uses excess patient samples to produce quality control data. Fresh samples are tested initially and then tested again at defined intervals after storage under controlled conditions (refrigeration). It uses patient samples with results that are within reference interval or very close to the reference interval in order to avoid extremes in standard deviation/coefficient of variation that may occur with very high or very low results. We elected to use canine samples in our laboratory since this is the species with the most submissions in our laboratory network (6 Sysmex analyzers in 5 veterinay commercial laboratories).

Basis for RPT-QC

The DIFFERENCE between the first and second measurements is used as the QC data point. Control limits are calculated from 20-40 data points. The SD of the duplicate measurements (SDdup) is used to calculate the control limits, providing a sound statistical basis for use as QC.

Process and Calculations for determining RPT-QC limits

A total of 60 data points were collected for time intervals of Day1-2, Day1-3 and Day1-4, allowing for appropriate time intervals for RPT-QC based on days of operation (some laboratories closed on Saturday, as well as Sunday). Measurands for which data was collected were Red Blood Cell Count (RBC), Hemoglobin (HBG), Hematocrit (HCT) and White Blood Cell Count (WBC). Calculations were done according to Westgard[1].

The first 20 data points collected for each measurand were used for initial calculations. A scatterplot (Excel spreadsheet) was used to visually evaluate the data for outliers. If there was any question as to whether a particular point represented an outlier, calculations were done with and without the data point(s) in question and assessed to determine if the points in question resulted in significantly different control limits. The control limits were subjected to validation with a further set of 20 data points. If no more than 2 data points were outside the calculated limits and a scattergram of the dataset is shown to adequately fill the range between the calculated limits, then the control limits were considered to be validated. If more than 2 data points were outside of the control limits and/or the data distribution did not adequately fill the calculated control limits or was skewed to high or low results compared to the range, then all 40 data points were combined and evaluation for outliers and calculations were repeated.

An Excel spreadsheet with directions was provided to technicians for data collection and the calculations were performed by the author since she knows the process from previous research and publications and is familiar with the visual evaluation and decision-making process required. This experience is quickly gained and is not difficult for laboratorians accustomed to evaluation of traditional quality control data.

Calculations included the average of the duplicate measurements, difference of the duplicate measurements, differences of the duplicates squared, SD of the duplicates(SDdup), and CV of the duplicates ([SDdup/Mean of Averages of duplicates] x 100).

Specifications for control rules were to use a simple rule (1-2.5s or 1-3s, with Ped > 0.90 for 1-2.5s or > 0.85 for 1-3s), and Pfr < 0.05. The SDdup was used to calculate the upper and lower control limits for the 1-2.5s and 1-3s rules. These were then evaluated by a second set of 20 data points and the distribution within a scatter plot and the position of the control limits. If there were more than 2 data points outside of the calculated control limits or the data points were not distributed across the control range to suggest adequate sensitivity in detection of abnormality, the entire group of 40 data points was then visually assessed for outliers and used for calculation of control limits. These were subjected to an additional validation using the third set of 20 data points (60 data points in total). No control limits calculated using the 40 data points were found to be unsatisfactory.

QC Validation

QC validation can be undertaken to determine if ASVCP recommended total error quality goals can be achieved and to determine the lowest controllable total error given the laboratory's specifications for QC. For QC in our network of laboratories, preferred QC specifications included use of a simple control rule (1-2.5s or 1-3s) with a single level of control, and probability of error detection > 0.85 for the 1-3s rule or > 0.90 for the 1-2.5s rule with Pfr < 0.05. We found that RPT-QC was able to achieve the ASVCP recommended total error quality goals or better for RBC, HBG and WBC. It was not able to achieve the ASVCP total error quality goal for HCT, but the controllable total error was considered useful for QC purposes.

Disadvantages of RPT-QC

Disadvantages of RPT-QC include the inability to assess bias compared to an assigned target mean, such as that available from assayed traditional quality control materials, use of a single level of control, and occasional absence of a fresh hematology specimen for RPT-QC in some laboratories.

The emphasis of internal statistical QC is imprecision; with RPT-QC there is no instrument/method specific target mean as there is with assayed quality controls. To address this disadvantage, an internal laboratory comparative testing program for a network of analyzers, participation in a peer-group EQA program or point-of-care/reference laboratory comparative testing program is needed to assess bias. We elected to introduce and internal laboratory comparative testing program with 6 events per year, assessing hematology specimens with a range of results.

Use of a single RPT-QC specimen does not demonstrate stable performance across a range of clinically significant results; this is also a limitation of using a single commercially available QC material, as is traditional in the United Kingdom. This was considered unlikely to be of high importance because of the

significant nonstatistical technical and pathologist quality assessment that occurs with veterinary hematology.

Rarely there was not a fresh hematology specimen for use for RPT-QC in some laboratories. This was addressed by using Day1-3 limits instead of Day1-2 limits, a factor that was taken into account in the development of the automated RPT-QC Recording and Documentation Spreadsheet.

Advantages of RPT-QC

Advantages of RPT-QC include commutability with patient samples; patient sample use provides a veterinary matrix and a level of results of interest for the species being evaluated (within reference interval or close to it). There is no need to purchase a commercial quality control material.

Furthermore, we found that RPT-QC could achieve the ASVCP recommended quality goals for total error or better for RBC, HBG and WBC; RPT-QC was not able to achieve the ASVCP recommended quality goal for HCT, but the data was still considered to be useful for control purposes.

Other advantages include the fact that advanced statistics or special statistics packages are not required; all data collection and calculations can be easily done with an Excel spreadsheet. Visual evaluations of easily generated scatter plots are sufficient for determination of outliers and assessment of control limits. All control limits were customized for the individual analyzers since results were produced by each analyzer in each laboratory.

Summary

RPT-QC can provide a cost-effective, sensitive and efficient alternative to traditional commercial quality control materials. It has a sound statistical basis for use in QC. It requires some 'mental adjustment' to recognize that the DIFFERENCE between duplicate measurements is used as the control data point, not the result generated by specimen analysis.

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Prototype for a Point of Care Testing and Reference Laboratory Comparative Testing Program

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Learning Objectives:

1) Describe 10 challenges identified for a point of care testing and reference laboratory comparative testing program

2) Describe how a comparative testing program differs from a traditional external quality assessment program

3) Describe the elements of the result evaluation for comparative testing results 4) Discuss why an educational approach is important in helping clinics participating in the comparative testing program

Introduction

Some external quality assessment programs or comparative testing programs with a reference laboratory are available for point of care testing analyzers. Participation is voluntary and the cost, program design, frequency and format vary amongst providers. This presentation will describe a prototype point of care testing and reference laboratory comparative testing program developed within the VPG network of veterinary laboratories.

Challenges associated with comparative testing programs for point of care testing

Initial planning discussions amongst selected members of the VPG internal Quality Education, Planning and Implementation Group, composed of technicians and pathologists from 5 laboratories within the VPG network, identified 10 challenges associated with development of a comparative testing program for point of care testing analyzers. These challenges applied to hematology, biochemistry and limited endocrine testing (total T4), but examples for this presentation will be limited to hematology. The challenges included: (1) How to encourage participation, (2) Program design, (3) Frequency and delivery of the materials, (4) Specimen types included, (5) Range of results to be covered, (6) Quality goals to be used in the evaluation, (7) Result collection, (8) Result submission, (9) Analysis and(10) Reporting.

Frequency and delivery

A decision to provide comparative testing events 6 x per year (approximately every 8 weeks) was based on other comparative testing programs occurring within the reference laboratory network since this allows sufficient time for problem-solving should suboptimal performance be identified. Delivery was by overnight courier with specimens run on the same day by the point of care laboratory and the reference laboratory (fresh specimen on the day it was shipped). An email was sent the week prior to scheduled shipping to alert the clinic of the upcoming comparative testing event, the day to expect the delivery and importance of running the sample on the day it was received.

Specimen types and range of results to be covered

Clinics could sign up for canine, feline or equine specimens with a range of results to be covered in 'bins' of very low, low, within reference interval, high and very high results based on hematocrit levels of 10-15%, 20-25%, 30-45%, 50-60% and > 70%. This resulted in proportionate alterations in other measurands and was achieved by addition or subtraction of plasma from pooled fresh EDTA whole blood specimens. We used canine EDTA blood specimens for the prototype development and offered free analysis for participation in the development phase. Measurands evaluated were red blood cell count (RBC), hemoglobin (HGB), hematocrit (HCT), white blood cell count (WBC), platelet count (PLT), red cell distribution width-CV (RDW-CV) and mean platelet volume (MPV) since these were available from most inclinic analyzers.

Differences from traditional external quality assurance (EQA) programs

Initial discussions with clinicians with inclinic point of care testing laboratories indicated that clinics had a variety of analyzers and that sufficient numbers of clinics with the same analyzers to provide peer group comparison was not possible. Furthermore, inclinic technicians/nurses and veterinarians were not familiar with the vocabulary or interpretation of EQA and unable to understand results without an explanation. Five repeats by the inclinic analyzer were requested; this is a compromise based on cost and time involved, but allowed an estimate of standard deviation and coefficient of variation that could be used to calculate sigma metrics using ASVCP or internal expert opinion quality goals and the observed CV and bias for the inclinic instrument. Comments were provided by a designated POCT specialist technician and by the QEPI group pathologist in the laboratory which was the 'home reference laboratory' for the participating clinic. The comments were designed to have an educational emphasis with further problem-solving help available if performance problems were identified.

Addressing Challenges

Participation in comparative testing programs is often part of clinical hospital certification standards (RCVS, AAHA, other) and participation is often marketed as part of a package that includes POCT equipment and reference laboratory volume-related discounts and/or continuing education presentations. Each laboratory was asked to verify that they conducted routine maintenance and software updates, as recommended by the manufacturer of their instrument.

Program Design

A spreadsheet was developed for each participating inclinic laboratory, with tabs for instructions and each of the 6 comparative testing events with blank templates for data entry for each of the 5 repeats conducted. The clinic provided the reference intervals used for their instrument. Reference laboratory results, SD and CV were provided by the reference laboratory. SD and CV had been previously determined for the 'bins' of interest as part of an internal laboratory comparative testing program within the laboratory network. Calculations were they done to determine the mean result, SD, and CV of the inclinic analyzer, and to determine if the inclinic result was within the range for ASVCP or internal expert opinion quality goals compared to the reference laboratory result. A sigma metric for the inclinic laboratory performance was calculated [Sigma = (quality goal% -Bias%)/CV%]. A performance key ranking results as Excellent, Good, Fair or Poor provided a rapid visual assessment of performance based on the inclinic result using ASVCP or internal expert opinion goals and the sigma metric. Coefficients of variation > 2.5% and Biases > 5% were highlighted in red for easy recognition of possible problematic bias levels. A technician specialist in POCT provided a comment highlighting any problematic

measurands, explaining possible reasons and whether these were likely of clinical significance. A plan for ongoing evaluation and monitoring was provided. The technician was responsible for following the performance in subsequent events and identifying ongoing patterns of excellent, good, fair or poor performance and updating the plan(s) associated with these. The QEPI group pathologist from the 'home reference laboratory' for the participating clinic also commented on the results, their clinical significance and double-checked and altered, if necessary, the plan proposed by the POCT specialist technician.

What we found

Some inclinic analyzers had excellent or good performance for a majority of measurands with few sigma metrics < 4.0. Some inclinic analyzers had significant bias but reference intervals virtually the same as the laboratory, indicating possible need for reference interval validation for the practice population. It was commented on if present!

Some inclinic analyzers had consistently poor performance for one or more measurands with low sigma metrics (< 4), leading to discussions regarding maintenance, software updates, and technical support from the manufacturer of the instrument.

Feedback from participating clinics

The participating clinics appreciated the educational approach. Some are now recognizing the importance of knowledge of SD and CV in laboratory result interpretation. Some are now recognizing the importance of knowledge of bias in laboratory result interpretation and what to expect in the relationship between the inclinic results and those of the reference laboratory.

Future Improvements or Additions

Discussions have included a desire to include blood smear evaluations in the future. This may include photographs or inclusion of smears with various morphologic abnormalities. Biochemistry and endocrine comparative testing are conducted similarly to hematology. Serum samples may be spiked with standard solutions or diluted with saline if clinical samples with significant abnormal results are not identified. It may be interesting to include some interferents (hemolysis and/or lipemia) to illustrate their effects and the importance of observing the serum or plasma condition.

Acknowledgements

A special 'thank you' is extended to members of the VPG Quality Education, Planning and Implementation group for their contributions. Susan Daly and Matthew Garland are acknowledged for their technical expertise and contributions to the prototype program development and recruiting the practices participating in the development phase.

Further Reading

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Laboratory Errors

ACVP/ASVCP Annual Meeting 2022

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Introduction

Medical errors, although not included in death rankings or on death certificates, are a leading cause of morbidity and mortality in human medicine, estimated to account for 98,000 to 250,000 deaths per year in the United States, making them potentially the third leading cause of death.[1,2] Medical errors are not frequently discussed or documented in veterinary medicine, but similar trends presumably occur, with one veterinary study documenting 5.3 errors for every 1000 patient visits to a triad of emergency and referral hospitals.[3] Error rates in laboratory testing are often lower than overall health care, with studies documenting 0.01 to 0.6% of laboratory submissions are associated with errors.[4] In the veterinary study noted above, laboratory errors were rare, accounting for approximately 5% of total errors. However, since 60-70% of all medical decisions involve the laboratory and medical errors can have serious consequences, it is important to minimize errors at every reasonable opportunity.

A medical error has been defined as any act of commission or omission, in planning or execution, that contributes to or could contribute to patient harm. These errors can occur at the individual or system level and many errors are the result of multiple converging factors. Laboratory errors have been further defined as any error that occurs throughout the total testing process (TTP), including pre-analytical, analytical and post-analytical phases. Some variations to these phases and their nomenclature exist but multiple studies indicate that more laboratory errors occur in the pre-analytical and post-analytical phases (46-68% and 19-47%, respectively), compared to the analytical phase.[5] Strict laboratory operating procedures, availability of internal and external quality controls and operations limited to trained personnel are likely the main contributors to the low error rate in the analytical phase.

Pre-Analytical Errors	Analytical Errors	Post-Analytical Errors
Inappropriate test request	Failure in QC	Inaccurate data entry
Order entry error	Failure to follow SOP	Delay/failure in reporting
Misidentification of sample	Equipment malfunction	Improper reference intervals
Inappropriate container	Sample interference	Illegible result/formatting
Sample contamination		Improper interpretation
Sample hemolyzed, clotted, lipemic		
Insufficient sample volume		
Transport/storage error		
Sorting/labeling error		

Reducing Errors

Acknowledge and Work Together

Acknowledging the existence of errors and being willing to address them is a necessary starting point. Even though some error is inevitable, processes can be developed to reduce their frequency and minimize their impact. The processes detailed below must be a collaborative effort and the emphasis must be on process improvement: not blame of individuals, laboratories or clinics.

Identify

The first step in reducing errors is to identify the errors that are most common or significant to the laboratory in question. The International Federation of Clinical Chemistry and Laboratory Medicine has developed a standardized set of key quality indicators (QIs) that can be used to model data collection.[6] However, not all QIs will be applicable to all laboratories and many laboratories will benefit from focusing on a few key indicators, those they suspect or know are problematic in their workspace.

All errors should be recorded, whether they affect patient care or not. Most medical errors do not cause significant patient harm but identifying them can help uncover contributing factors and prevent the less common errors that do cause significant harm.[3,7] Error details can be collected in whatever format suits the laboratory in question: via a laboratory information system, an online form or manual notations. No matter the method of collection, the system used to identify errors should not be used to place blame, initiate disciplinary action or affect performance reviews. The goal is to identify contributing factors, develop interventions and limit similar errors in the future, not blame individual personnel.

Pre-Analytical Phase

Much of this phase is outside the laboratory's control but error identification in this phase is still important for potential reduction opportunities. If a certain type of error is identified repeatedly, it is a potential focus for client communication, continuing education or other collaboration.

Analytical Phase

Although the analytical phase has the lowest incidence of laboratory errors, it is an area directly under the laboratory's control and worthy of close attention. A good quality control program, utilizing both internal and external control materials, is paramount to limiting analytical errors. However, while good QA/QC can reduce analytical errors, it cannot prevent them entirely. Random analyzer errors and sample interferences will still occur and need to be identified as often as reasonably possible.[8]

Flags/Error Codes: most analyzers present flags or error codes with suspect data. The number of codes/flags can be overwhelming and some are more significant than others. Critical and uncommon flags/codes should be identified and linked to verification procedures. Depending on the analyzer in question and test ordered, examples might include Delta Hgb errors, WBC count discrepancies and results outside of analytical range.

Critical values or improbable scattergrams: Certain analytes, such as potassium and calcium, have cut-off values that are incompatible with life or highly unlikely to be encountered in a clinical situation, even if they do not trigger an error code. Such values can be identified and set to trigger verification procedures. Hematology analytes are often less definitive in this regard but suspect errors can still be identified via critical cut-offs, discrepant results and improbable scattergrams. Many of these hematology discrepancies will also be identifiable via analyzer flags.

Delta checks: If a patient has had previous bloodwork, comparison of that bloodwork to the current sample can potentially identify errors. This practice is more common in human hospitals where patients can have extended stays with serial bloodwork. The practice has the potential to be cumbersome and, even under optimal situations, most delta checks will identify true pathology, not laboratory error. However, certain analytes have been shown to be more predictive than others (eg MCV) and other analytes may be useful in particular health situations (eg. creatinine in acute kidney injury).[9,10]

Post-Analytical Phase

A laboratory result is not complete until it is delivered and incorporated into patient care. Unclear reporting, communication failures and delayed results are post-analytical errors with varying significance amongst laboratories. Post-analytical transcription errors, on the other hand, often have a significant impact. Luckily, small cues can often be employed to minimize transcription errors (eg. color coding, shading of forms). Minimizing manual entry also plays a significant role in this regard, discussed further below.

Role of Technology

Virtually all phases of error identification and reduction can benefit from automation and computerization. Well-trained staff are irreplaceable, but all humans make mistakes, especially if they are tired or overworked. Electronic submission forms can reduce identification and test ordering errors while bar codes and scanners can reduce transcription errors and improve sample tracking. All the analytical checks mentioned above can be monitored by well-trained laboratory staff. But a computer system that can hold flagged data for review or automatically rerun suspect samples is even more reliable. Manual data entry is error prone and should be limited as much as possible. If manual entry is necessary, automated checks of addition or unexpected values are often beneficial.

Role of People

Tired and overworked staff are prone to making mistakes, not just in laboratory work or medicine. If there are staffing shortages or an overwhelming number of samples, it is important to note that errors and patient safety problems may not be immediately obvious but will become evident in the long term.

Dealing with Errors

Even if all the information is not yet known, immediate communication regarding the error or possibility of an error is recommended. If a medical error is known to have affected a patient, the AVMA Professional Liability Insurance Trust recommends an honest, upfront apology and acknowledgement of mistakes to the client. Similar acknowledgement and apologies should be presented to veterinarians when laboratory errors affect reported results. The error should then be reviewed to determine its cause, or causes, and how it or similar errors can be prevented in the future.

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Recruitment, Retention, and a Dose of Reality: How to Confront the Laboratory Workforce Shortage

Miles Tompkins, MLT(ASCP)CM

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Conflict of interest statement:

My employer, Diagnostic Laboratory of Oklahoma (DLO) is a Joint Venture partially owned and operated by Quest Diagnostics. Quest Diagnostics offers a monetary bonus for recruitment. Only if an individual lists me by name in their application process do I receive an award.

I am neither requesting to be listed as a recruiter, nor am I promoting employment with any specific company, including DLO/Quest Diagnostics.

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- My Role:

Recruitment
- Attend Job Fairs
- Visit College and Technical School Campuses
- Contact external applicants for placement with DLO
- Work with internal employees for transfer or career progression with DLO

Retention
- Oversee the Step Progression Program
- Manage the DLO Scholarship Loan Program
- Provide support to Med Techs and ESLT
- Encourage participation in Med Tech engagement activities

Education
- Serve as MLT/MLS Clinical Coordinator for all DLO sites
- Organize and lead Technical New Employee Orientation Program
- Provide opportunities for further education to DLO employees

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Objectives:

- Describe past barriers to laboratory staffing in comparison to those challenges today
- Identify pathways to recruit laboratory employees
- Develop methods to increase retention in the face of growing internal demands and external threats
- Generate awareness and excitement for the field of Laboratory Science.
- Collaborate with other laboratorians to improve workforce shortage conditions.

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Which of these phrases have you heard or said in the past year?

- "Well, once the pandemic is over..."
- "We just have to figure out the new normal."
- "Nobody wants to work anymore."
- "We don't get any good applicants anymore."
- "All anyone cares about is money."
- "What ever happened to loyalty?"

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Zoom meeting, audio only | Zoom meeting with video

"Well, once the pandemic is over..."

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The Reality:

THE PANDEMIC IS NOT THE PROBLEM	There is always a pandemic/outbreak:
• Amplified cracks in the system that have long existed. • Burnout • Older workforce • Staffing/Workforce Shortage • Attitudes towards work/life balance	• HIV/AIDS • H1N1 Flu • Ebola • Zika • Covid-19 • Monkey Pox

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Friend: How's your day going?

Me:

"We just have to figure out the new normal."

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The Reality:

The "new normal" isn't new or normal

The old normal:

- Discrepancies in access to:
  - Education
  - Technology
  - Transportation
- Failures in Diversity and Inclusion
- Stagnation in corporate actions and procedures
  - "It has worked this way before."
  - "It's not us… it's them"

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You threw it. You fetch.

"Nobody wants to work anymore."

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The Reality:

The Great Resignation

Low-wage workers switching to better jobs

Produced a large number of early retirees

Not about burnout

Increase of jobs in most markets, especially in applied sciences

329,000 jobs reported in 2021

Additional 20,000 jobs per year

Projected annual increase of 7%

New graduates being more selective

Still live at home

Care more about short term goals

Impatient with hiring process

Willing to hold out for what they want

Every previous generation has said this about the next.

"We defy anyone who goes about with his eyes open to deny that there is, as never before, an attitude on the part of young folk which is best described as grossly thoughtless, rude, and utterly selfish."

- -The Conduct of Young People, Hull Daily Mail, 1925

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"We don't get any good applicants anymore."

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The Reality:

A passive approach is no longer a successful approach	• Attend college job fairs • Go speak at schools • Host groups to tour your facility • Reach out to online communities • Look outside the "perfect degree"
Reevaluate what the ideal candidate is	• Continuous Improvement • Passionate about the ***field*** • Self aware

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"All anyone cares about is money."

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The Reality:

Why Employees Quit

- Toxic culture
- Job insecurity and reorganization
- High levels of innovation or change
- Failure to recognize performance.
- Poor response to external events
  - BLM
  - Covid-19
- Stalled career progression
- Lack of flexibility

Only 56% of those who quit in 2021 are earning more pay

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Me: I am going to get so much done after work today ...

Also me:

"What ever happened to loyalty?"

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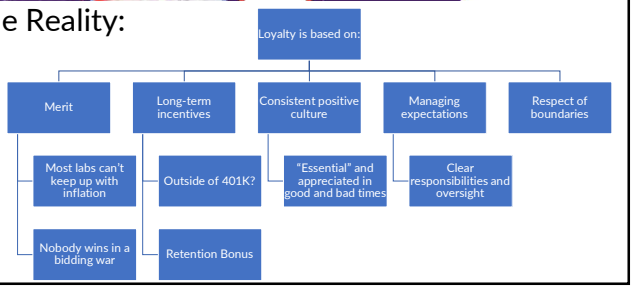
The Reality:



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Discussion topic:

What do you think is the biggest challenge to obtaining lab professionals?

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Identify your bottlenecks:	Create solutions:
• Number of college programs • Poor resume or applications • Competition with other fields	• Build your own program • Host a resume building workshop • Have a pathway for other fields to join your lab

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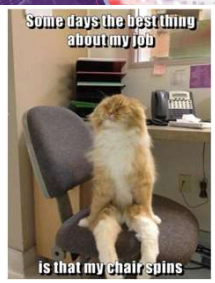

Discussion topic:

What do you think is the biggest challenge to keeping lab professionals?

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What is burnout?

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Burnout is a Mental Health Issue

- Active boredom
- Rapid stagnation
- "Pre-existing" exhaustion
- Crowded isolation
- Unrewarding stress

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Reprioritize Proactive Compassion:

Promote empathy for your employees	Involve them in the process	Engage personally	Take meaningful action
	Invite employees to hiring events	Stay Interviews*	Mix it up!
	Ask them to help with interview questions	Surveys	
		Retention events • On-site • During shift	

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ACVP · ASVCP 2022 ANNUAL MEETING
BOSTON, MA
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Discussion Topic:

Share your ideas or positive experience in recruitment and retention.

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The End