Medical Laboratory Science (MLS) 470: Medical Laboratory Science Capstone Course

"Real-World Learning Experience: A Redesign of an Online Capstone Health Professions Course"

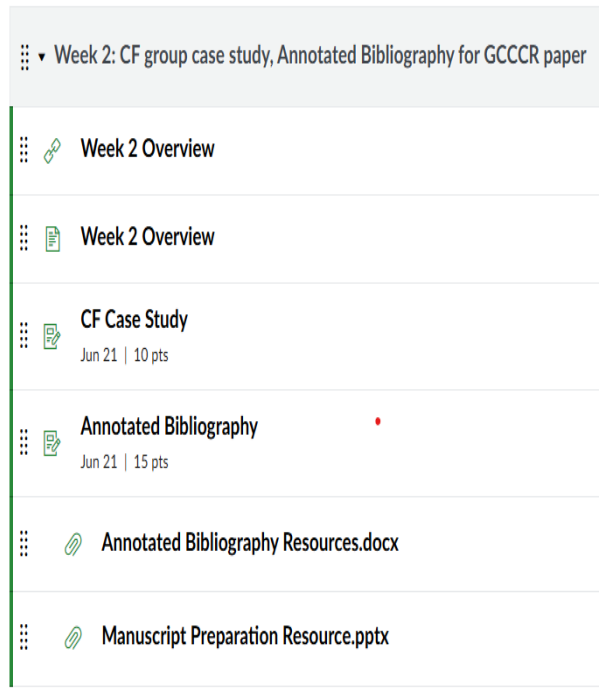
Overview

This capstone course integrates all prior classroom theory into preparation for taking the board of certification exam (BOC). The course quality redesign aimed to improve student learning outcomes, accessibility, and engagement, while ensuring alignment with online standards with the help of a professional instructional designer. The main impetus for the quality design program was to improve board of certification pass rates and develop a new activity to meet new accreditation requirements to address research principles. Students will be asked to analyze study data and statistically evaluate two generic methods leading to a selection justification. Requiring real world problem-solving writing assignments and assessments allows students to practice and develop MLS professional behaviors and critical thinking skills.



1 *Module Overview*

Create weekly outlines of assignments, readings, and learner activities that connect back to the weekly modules.



2 *New Assignment: Method Validation Objectives*

Method Evaluation and Comparison of Methods Learning Objectives

Cognitive Objectives:

1. Define the following terms:

Imprecision	Inaccuracy	Systematic error
Constant error	Proportional error	Random error
Total error	Recovery	Lipemia
Interferents	Non-parametric Statistics	Regression analysis
Interference	Parametric Statistics	Matrix
Bias	Hemolysis	Icteria

2. Explain the purpose of performing method evaluation in the clinical laboratory.
3. State the five parameters of a test method that should be validated when considering a new methodology for your lab.
4. Discuss the role of regulatory agencies in the performance of method validation
5. Match a characteristic of a method with whether it is a performance, application or method characteristic.
6. List all the studies that should be performed during a validation procedure and briefly describe the purpose of each type of study.
7. For the Linear Regression by Least Squares procedure, explain the purpose of the test, how the y-intercept is determined, how the slope of the line is determined, and how the results are interpreted.
8. State the formula for the linear regression line
9. Describe a Difference plot and explain how it can be used in the validation of a method.
10. Describe the procedure for performing method comparison on different methodologies for the same analyte.
11. State the factors that can result in random and systematic of errors.
12. Explain how random error is calculated and what values are considered acceptable in a validation procedure.
13. Explain the difference between random error and systematic error.
14. Explain the difference between constant systematic error and proportional systematic error.
15. Explain how imprecision studies are performed and how it is determined if the results are acceptable or not.
16. Explain the difference between in-run imprecision, between-run imprecision, and between day imprecision and total imprecision.
17. Explain the purpose of Medical Decision Levels and how they are used in Method Validation studies.
18. State the three types of studies that assess accuracy.
19. State the purpose of an interference and recovery experiment.
20. Explain how interference and recovery studies are performed during a method validation process.
21. Explain how the data from interference and recovery studies are analyzed and what values indicate an acceptable result.
22. Explain what Total Allowable Error is and how is it used in method validation.
23. State which statistical value assesses bias.
24. Explain how Comparison of Method studies are performed and how the data is interpreted, including acceptable results.
25. Define the correlation coefficient (*r*) and when given the result determine acceptability.

Learn real world method validation procedures by analyzing data produced from method validation experiments.

Method Evaluation - Replication and Comparison of Methods Experiments

From CLIA Charts: Allowable Error for Glucose = Target value ± 6 mg/dL or 10%, whichever is greater.

Medical Decision Levels for Glucose

		Ref. Range	Level 1	Level 2	Level 3
Glucose	mg/dL	60-95	45	120	180

Replication Study for Imprecision

Precision

You investigated the precision of the new method for glucose around a medical decision level of 126 mg/dL. This is the point at which a diagnostic decision is made on a fasting serum for a patient suspected of having diabetes. **The allowable error (E_A) for this medical decision point is 12.6 mg/dL.**

A glucose standard of 126 mg/dL was analyzed 20 times with the following results.

125	126	126	127	128
130	125	126	127	132
125	122	125	126	126
124	126	125	126	130

Units = mg/dL

1. Calculate the mean for replicate experiment.
2. Calculate the standard deviation for the replicate experiment.
3. Calculate the coefficient of variation for the replicate.
4. Calculate the random error for the method.
5. Is the precision of the new method acceptable?

Accuracy

You investigated the accuracy of your method by performing a linearity experiment. Using five standards, each was analyzed 4 times. The average of the 4 replicates was plotted against the known concentration of the standard. The following data was obtained.

Standard	*Rep 1*	*Rep 2*	*Rep 3*	*Rep 4*
50 mg/dL	46 mg/dL	50 mg/dL	52 mg/dL	50 mg/dL
100 mg/dL	102 mg/dL	99 mg/dL	101 mg/dL	99 mg/dL
200 mg/dL	200 mg/dL	200 mg/dL	200 mg/dL	199 mg/dL
400 mg/dL	399 mg/dL	400 mg/dL	399 mg/dL	403 mg/dL
600 mg/dL	598 mg/dL	600 mg/dL	603 mg/dL	602 mg/dL

3 *Method Validation Project: Writing Assignment*

Compare methods statistically, then write a report of the results of your method comparison study.

Method Validation Writing Assignment
Project: Evaluation of Laboratory Methods

Heading/Procedure Title/Page Format: Author, date, procedure being replaced, title, page numbers

For all methods explored (glucose oxidase and hexokinase) please write up the following for each method compared.
Principle:

- Type of method used, specific substance measured and reaction sequence
- How response is measured and how measured response is related to final test result

Clinical Significance:

- Medical usefulness and clinical rationale of measured substance
- Causes of increased/decreased test results
- Specimen: Patient preparation, sample collection criteria, specimen type and amount
- Specimen stability and specific handling and storage requirements
- Criteria for unacceptable specimens and action to follow when unacceptable specimen is received

Method Comparison

You must write an evaluation for the method validation you performed.
Describe in detail the following:

Purpose of the method evaluation
Medical usefulness statement
Null hypothesis statement for this evaluation
Needs assessment evaluation of specimen and personnel requirements
Needs assessment evaluation of instrument and reagent requirements, including safety
Needs assessment evaluation of quality control and calibration requirements
Method's analytical performance evaluation

Reflection

As I reflect on the redesign of this online course, one of my primary goals moving forward is to strengthen the alignment among course learning objectives, instructional activities, and assessments. An important next step will be finalizing the module-level learning objectives so that they can serve as a consistent framework for future online offerings. I plan to incorporate brief, anonymous, unofficial student surveys throughout the course rather than relying solely on end-of-semester feedback. These formative surveys can provide timely insight into students' experiences with course organization, learning activities, workload, and newly implemented assignments. I also plan to specifically evaluate and refine the newly implemented assignment. Rather than viewing its initial implementation as a finished product, I will examine how well the assignment supports the intended learning objectives, whether expectations are clear to students, and whether the structure provides meaningful opportunities to apply course concepts. Finally, I would like to rethink the assessment approach for the final GCCR assignment by incorporating principles of *Ungrading*. Rather than emphasizing a single summative grade, the redesigned assignment would include multiple opportunities for formative instructor feedback throughout the development process, along with structured peer feedback. Students would have opportunities to reflect on that feedback and revise their work before final submission.

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