The Glucometer: A Study in Uncertainty

1 LEARNING OBJECTIVES

At the conclusion of this activity you should be able to:

- Calculate the mean, standard deviation, and standard error (or standard deviation of the mean) for a sample.
- Explain the difference between the standard deviation and the standard deviation of the mean (SDOM) of a sample.
- Experimentally determine the accuracy and precision of the home glucose meter or glucometer.

2 BACKGROUND

2.1 PRE-LAB READING

The pre-lab quiz for this experiment is mostly based on readings from John R. Taylor's "An Introduction to Error Analysis". **Please read Chapters 4.1 through 4.5.**

Key concepts for this lab: *e.g.* average, standard deviation, and standard deviation of the mean (SDOM) are introduced and explained in the reading.

2.2 USEFUL LABORATORY STATISTICS

2.2.1 AVERAGE

The average[1] of N measurements is given by:

$$\bar{x} = \frac{x_1 + x_2 + x_3 + \ldots + x_N}{N} = \frac{\sum x_i}{N} \tag{2.1}$$

and describes our best estimate of the quantity being measured.

2.2.2 Standard Deviation

The standard deviation is used to describe the spread observed in a sample of N measurements. Mathematically, the standard deviation σ_x is given by:

$$\sigma_x = \sqrt{\frac{1}{N-1}\sum\left(x_i - \bar{x}\right)^2}. \tag{2.2}$$

The standard deviation not only describes the spread of an entire sample but it can also be used to estimate the uncertainty associated with an *individual* measurement. That is:

$$\delta_{x_i} = \sigma_x. \tag{2.3}$$

2.2.3 Standard Error or Standard Deviation of the Mean

In most cases, as more measurements are made, we expect that the precision of the best estimate for the value of interest should improve. This trend is typically not observed in the standard deviation alone. Instead a quantity called the *standard error* or *standard deviation of the mean* is used.

The standard error[2] describes the uncertainty associated with our best estimate for a given quantity x. Our best estimate is often the average, $\bar{x}$. The standard error of the mean, $\sigma_{\bar{x}}$, is given by:

$$\sigma_{\bar{x}} = \frac{\sigma_x}{\sqrt{N}} \tag{2.4}$$

where σ_x is the standard deviation of the sample and N is the total number of measurements.

The important feature of the standard error of the mean is that as more data are taken (*i.e.* N increases), the standard error of the mean, $\sigma_{\bar{x}}$, decreases. Large samples lead to a higher degree of confidence in the final measurement. Note that Equation 2.4 only applies if the variable being measured is truly random. For example, measuring the length of nail with a ruler an infinite number of times will not yield a measurement with zero uncertainty.

When stating a result, that is the result of an average, it is often appropriate to quote the standard error of the mean as the uncertainty. That is, the final result will be presented as:

$$\bar{x} \pm \sigma_{\bar{x}}. \tag{2.5}$$

The standard error of the mean can be calculated in a spreadsheet by using something like:
`=STDEV(`*`sample`*`)/SQRT(COUNT(`*`sample`*`))`.

2.3 Accuracy and Precision

Accuracy and *precision*[4] are two words that are often used to mean similar things in common conversation. However, in the physics lab, they have separate and distinct meanings.

Accuracy is generally used to describe how close a given measurement is to an accepted or true value. In many “real world” experiments the “true” value is not known making it difficult to quantify how accurate a given measurement may be. Accurate measurements have small *systematic* uncertainties. Thus, the goal of most scientific experiments is to identify, quantify, and control systematic uncertainties.

Precision is generally used to describe the repeatability of a measurement. Precise measurements have small *random* uncertainties. Precision also may be referred to as the *resolution* of a measurement or an instrument.

The ideal scenario is a measurement that is both accurate and precise. It is however possible for a measurement to be both precise and inaccurate or, conversely imprecise and accurate.

2.4 HISTOGRAMS[3]

See the accompanying Jupyter Notebook for information on how to visualize data using histograms.

2.5 GLUCOMETERS

Home glucose meters – glucometers – are used by many people with diabetes to monitor their blood sugar. A small amount of blood is drawn and sampled with a test strip. The glucometer measures the electrical signal that is produced by a chemical reaction on the test strip to determine the blood sugar concentration in the sample.

Like many medical devices, the United States Food and Drug Administration (FDA) regulates the accuracy and precision standards that glucometers must meet.

In 2014, the FDA published a draft version of the standards that they were planning to require for self-monitoring blood glucose test systems (SMBG)[5]

> "Blood glucose test results are used by people with diabetes to make critical decisions about their treatment; therefore, it is important that the results are accurate so that nutritional and drug dosing errors are better avoided. In order to demonstrate that your SMBG device is sufficiently accurate to be used safely by diabetic patients for this purpose, you should demonstrate that **95% of all SMBG results in this study are within** $\pm 15\%$ **of the reference measurement** across the entire claimed measuring range of the device and that 99% of all SMBG results are within $\pm 20\%$ of the reference measurement across the entire claimed measuring range of the device."

3 PROCEDURE

Suppose that you work for a company that produces glucometers. Your job is to determine the accuracy and precision of an instrument.

To test the instrument, you have been provided with a solution that claims to have a glucose concentration of 400 mg/dl with negligible uncertainty.

Using **all** of the test strips in a bottle, repeatedly measure the glucose concentration of the solution. Test strips work by sucking a small amount of the solution into a small capillary. Be sure that you allow the strip to sufficiently "drink" from the provided sample.

Record your measurements in a CSV file. Post your data to the discussion board on Blackboard. The idea is that you will do the analysis on your data as well as the rest of the data that is collected by the class.

As part of your analysis, do the following:

- Calculate the mean concentration, standard deviation, and standard deviation of the mean for 5, 10, 25, 50, 100, 200, 300, and 400 measurements.
- Using the calculated values above, generate a plot of the mean concentration (with standard deviation error bars) vs. the number of measurements.
- Using the calculated values above, generate a plot of the mean concentration (with standard deviation of the mean error bars) vs. the number of measurements.

3.1 DISCUSSION

You may find references [6] and [7] useful as you discuss and interpret the implications of your measured results.

Does your measurement agree with the published value of 400 mg/dl for the glucose solution?

Does your instrument meet the FDA standard[5] for home glucose meters of 15% accurate 95% of the time? Compare to both the published concentration and your own measured concentration.

4 Lab Notebook

Your submission will be evaluated using the following rubric:

Lab Notebook Practices

- Lab Notebook Mechanics (4 points)
  - Relevant information *e.g.*: your name, your lab partner's name, date, *etc.* is present.
  - The notebook is organized and easy to read. Markdown cells are used for narrative text. Code cells are clearly organized and commented.
  - The ZIP file of the notebook is healthy and runs correctly.
- Experiment Purpose (2 points)
  - In your own words, state the purpose of this experiment.
  - The work you record in your notebook should specifically address the stated purpose.
- Calculations & Error Propagation (6 points)
  - Present the equations used to analyze your collected data.
  - Present the equations used to account for and propagate error.
- Data Collection & Analysis (6 points)
  - The notebook tells a scientific story; it is an accurate record of the work that you did.
  - Record the informal observations you made during the experiment.
  - The notebook should show evidence of trial and error. Keep a good record of your work – recording mistakes is useful.
  - *Briefly* describe the methods you used to collect your data.
  - Measured quantities – that do not appear directly in your plot(s) – are clearly recorded.
  - Record rough data and plots that you used to verify that the analysis was on the right track.

Results and Interpretation

- Results (5 points)
  - Clearly state the final result(s) of your experiment. Remember to quote your result with units and appropriate significant digits.
  - Final result plots are well formatted and meet the standards described in the Figure Formatting reference.
- Physical Interpretation (4 points)
  - Throughout the notebook, interpret the data, rough plots, and final results in terms of the underlying physics.

- Significance (5 points)
  - Compare measured results to each other and/or to a known/expected value.
  - Choose the best available tools for your comparison (*e.g.* plots, pictures, discrepancy, significance, etc).
- Confidence (8 points)
  - Communicate to your audience how seriously your result should be taken. How confident you are in your result?
  - Discuss factors that may be affecting the *accuracy* and *precision* of your result.
  - Suggest improvements to your experiment to address your confidence, accuracy, and precision.

Acknowledgments

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References

[1] Taylor, J. R. (1997) *An Introduction to Error Analysis*. Sausalito, CA: University Science Books. Chapter 4.2 (pp. 97-101).

[2] Ibid. Chapter 4.4 (pp. 102-106).

[3] Ibid. Chapter 5.1 (pp. 122-126).

[4] Ibid. Chapter 4.1 (pp.94-97).

[5] U. S. Food and Drug Administration. (2016). *Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use*. Washington, DC. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM380327.pdf.

[6] William L Clarke *et al*: Evaluating Clinical Accuracy of Systems for Self-Monitoring of Blood Glucose, *Diabetes Care* 10:622-628 (1987). http://care.diabetesjournals.org/content/diacare/10/5/622.full.pdf.

[7] Joan L. Parkes *et al*: A New Consensus Error Grid to Evaluate the Clinical Significance of Inaccuracies in the Measurement of Blood Glucose, *Diabetes Care* 23:1143-1148 (2000). http://care.diabetesjournals.org/content/diacare/23/8/1143.full.pdf.