Introduction to Statistical Process Controls (SPC)

A Primer for the Non-Statistically Minded

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Section 1
Introduction to the Tools

Spurred on by the need to please customers and follow government regulations, real quality organizations are always looking for ways to improve the quality of their products or services. One important phrase used by the manufacturing industry is ***total quality management***, or TQM. ***Total quality management*** focuses on developing ways to continually monitor, assess, and improve processes, from the beginning of the process to the end. TQM was popularized in the United States by a famous and beloved statistician, Dr. W. Edwards Deming, who developed a nationally known, and often-used list called "14 Points for Management." Demings philosophy was that if you build quality into the process in the first place, you'll lower costs, increase productivity, and ultimately be more competitive.

Statistics play an important role in process quality…product quality. Statistics are useful in determining and setting specifications, and in monitoring all aspects of a process to ensure that those specifications are consistently met. Statistics are useful to help decide when a process needs to be stopped, as well as in identifying problems before they occur. In an over all sense, statistical data provide feedback (often continuously) to management about process quality…and ultimately about product quality as part of the total quality management philosophy. The role of statistics in monitoring and improving quality through all of the processes is called ***statistical process control*** (SPC). The subject of ***statistical process control*** can fill up an entire book by itself; however, this course is designed to give you a basic sense of how statistics factor into quality by understanding and applying some of the concepts taught in this course

There are many statistical tools referenced in this primer…graphs, forms, and tools used in Six Sigma and SPC

- Line Grafts
- Pareto Charts
- Bar Charts
- Pie Charts
- Control Charts
- Histograms
- Scatter Diagrams
- Flow Charts
- Ishikawa Diagram
- Countermeasures Matrix
- Action Plan
- FMEA/FMEcA
- QFD House of Quality
- Tree Diagrams

90% of common problems can be diagnosed with line grafts, pareto charts, and Ishikawa diagrams. Microsoft Excel can be used to create all of these charts, graphs, forms, and tools.

Excel Workbooks—Entering your data.

Using an Excel **workbook**, you can create the labels and data points for any chart—line, bar, pie, pareto, histogram, scatter, or control.
This gives you a worksheet that looks like this:

	A	B	C	D
1		Plant 1	Plant 2	Plant 3
2	Jan	15	77	44
3	Feb	23	56	33
4	Mar	56	33	55
5	Apr	33	33	22
6	May	77	23	66
7	Jun	33	15	11
8	Jul	14	14	77

Getting the Big Picture: Charts and Graphs

Someone once said that "a picture is worth a thousand words." In statistics, a picture may be worth a thousand data points – as long as that picture is done correctly, of course. Data displays, such as charts and graphs, appear often in every day life. These displays show everything from election results (broken down by every conceivable characteristic), to how the stock market has fared over the past few weeks…months…years.

The main use of statistics is to boil down information into summary form, and data displays are a natural way to do that. But do data displays give you the whole picture of what's happening with the data? That depends on the quality of the data display and its intended purpose. Pictures can be misleading (sometimes intentionally, and sometimes by accident). The following sections of this primer are designed to give you a better understanding of the use of different types of charts and graphs, and attempts to demonstrate which type of graph or chart would be used in displaying different types of data.

Getting Graphic with Statistics

The main purpose of data display is to make a certain point…make the point clearly and effectively…and make the point correctly. A chart or graph, for example, is used to give impact to a specific characteristic of the data, highlight changes over time, compare and contrast opinions or demographic data, or show links between pieces of information. **Data displays "break down" a statistical story that the author wants to relay about a data set, so that the reader can quickly see the issue at a glance and come to some conclusion.** For this reason, data displays are powerful: Used properly, they can be informative and effective; used improperly, they can be misleading and destructive.

The most common types of data displays for categorical data are as follows:

- Pie Charts
- Bar Graphs
- Line Charts
- Histograms
- Tables
- Control Charts

For numerical data, tables are commonly used to display the data. As a matter of fact, Pie Charts, Bar Graphs, Line Charts, and Histograms first begin with the organization of data in a table.

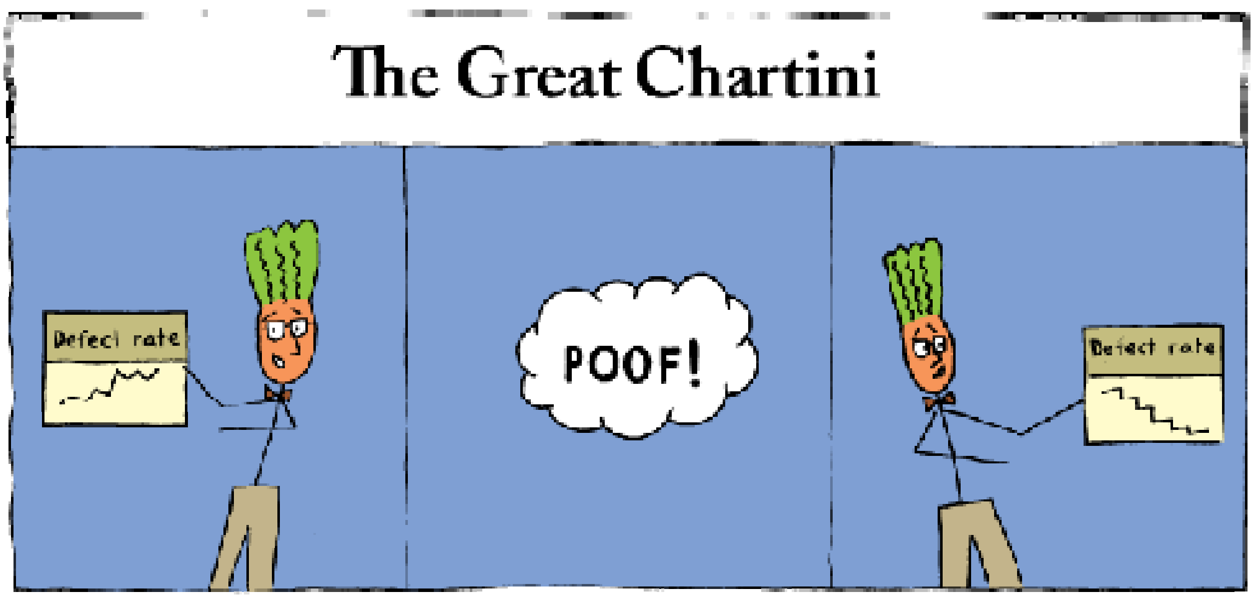
In the Sections that follow, I will present examples of each type of data display, some thoughts on interpretation, and tips for critically evaluating each type.

Section 2

Vital Statistics About Statistics

(The Jargon)

In every industry, there is a basic set of tools to learn…and statistics is no different. When I think about the statistical process as a series of stages that one goes through to get from a question to an answer, I also think about the group of tools, and the set of terms (or statistical jargon) to go along with it. Don't worry…no one is asking you to become a statistics expert and plunge into the heavy-duty stuff…and no one is asking you to become a "statistics nerd" and use this jargon all the time. And you don't have to carry a calculator and pocket protector in your front left shirt pocket like statisticians do, either.



Nevertheless, for the purpose of this course on "statistical techniques," it would probably be helpful if you understand some of the "basic jargon" – so here you go.

Population

For virtually any question that you may want to investigate about the world, you have to center your attention on a particular group of individuals (a particular group of people…cities…animals…exam scores…problems…errors…etc.). For example:

- What do Americans think about the President's foreign policy?
- What percentage of planted crops were destroyed by deer last year?
- What percentage of deviations represent documentation errors?
- What percentage of nonconformances are the result of human error?
- What is the percentage of donors who are rejected for positive serologies?

In each of these examples, a question is posed. And in each case, you can identify a specific "population" being studied. The group that you wish to study in order to answer your research question is called a ***"population."***

Sample

When you ***sample*** some soup, what do you do? You stir the pot, reach in with a spoon, take out a bit of soup, and taste it. Then you draw a conclusion about the whole pot of soup, without actually having tasted all of it. If your sample is taken in a fair way (for example, you didn't just grab all the good stuff), then you will get a good idea how the soup tastes without having to eat it all. That's what is done in statistics. Researchers want to find out something about a ***"population,"*** but they don't have the time, money, or inclination to study every single individual in the population. So what do they do? They select a small number of individuals that are "representative" of the population, and study those individuals. They then use that information to draw conclusions about the whole population. That is called a ***sample***.

Notice, I said ***select a sample***. That sounds like a simple process, but in fact, it isn't. The way a sample is selected from the population can mean the difference between results that are correct and fair (representative of the population), and results that are garbage.

Example: Suppose you want to get a sample of teenagers' opinions on whether they are spending too much time on the Internet. If you send out a survey over e-mail, your results won't represent the opinions of ***all teenagers***, which is your intended population. They will represent only those teenagers who have Internet access. This sort of statistical mismatch happens all the time.

Random

A ***random sample*** is a good thing; it gives every member of the population an equal chance of being selected, and it uses some mechanism of chance to choose them. What this really means is that people don't select themselves to participate, and no unit in the population is favored over another unit in the selection process.

A good example of random sampling involves the manufacturing sector and the concept of quality control. When a manufacturer makes a large number of widgets, (i.e. in the thousands or millions), it is not possible to inspect every single unit. Therefore a ***random sampling*** of an ***acceptable quality level*** (AQL) - which is determined to be a statistically relevant sample (large enough population) to be representative of the whole population (usually based on a recognized standard, e.g., MIL-STD-109E, or ANSI Z1.4 – *Sampling Procedures and Tables for Sampling by Attributes*, and ANSI Z1.9 – *Sampling Procedures and Tables for Sampling by Variables by Percent Nonconforming*).

An example of *non-random sampling* (in other words – bad) would be polls for which you phone in your opinion. That is not a random sample, because it doesn't represent everyone in the population. It only represents those who were listening…or reading…at the time, and who already feel strong enough to call in and give their opinion.

Bias

Bias is a word you hear all the time, and you probably know that it means something bad. But what really constitutes ***bias***? ***Bias*** is a systematic favoritism that is present in the data collection process, resulting in lopsided, misleading results…and most often collected and presented in a manner designed to sway opinion.

There are at least two (2) ways that ***bias*** frequently occurs:

- **In the way the sample is selected:** For example, if you want to get an estimate of how much Christmas shopping people in your community plan to do this year, you take your clipboard and head out to the mall on the day after Thanksgiving to ask people about their shopping plans….you have ***bias*** in your sampling process. Your sample tends to favor those die-hard shoppers at that particular mall who were braving the massive crowds that day.

- **In the way data are collected:** Poll questions are a major source of ***bias***. Because researchers are often looking for a particular result, the questions they ask can often reflect that expected result. For example, the issue of raising taxes to help support local schools is something every voter faces at one time or another. A poll question asking, "Don't you think it would be a great investment in our future to support the local schools?" does have a bit of ***bias***. On the other hand, so does the question, "Aren't you tired of paying money out of your pocket to educate other people's children besides your own? The phrasing of questions can have a huge impact on the results.

Data

Data are the actual measurements that you collect through your study (Remember that "data" is plural – the singular is ***datum*** – so sentences that use the word data always sound a little frumpy, but they are grammatically correct). Most ***data*** fall into one of two groups: ***numerical data*** and ***categorical data***.

- ***Numerical data*** are data that have meaning as a measurement, such as a person's height, weight, IQ, or blood pressure; or the number of deviations documented, or anything else that can be counted. Statisticians also refer to numerical data as ***quantitative data***.

- ***Categorical data*** represent characteristics, such as a person's gender, opinion, race…or the type of deviation (i.e., documentation error, human error). Categorical data can also have numerical values. Statisticians call this ***qualitative data***.

Not all data are created equal. Finding out how the data were collected can go a long way toward determining how you weight the results and what conclusions you are able to draw from them.

Data Set

A data set is the collection of all the data taken from your sample. For example, if you are trending your deviations for FY 2007, the total number of deviations, and all the categories of deviations constitute your data set.

Statistic

A statistic is a number that summarizes the data collected from a sample. You can use many different statistics to summarize data. For example, data can be summarized as a percentage (60% of all American families own more than two cars), an average (the average price of a gallon of gas in Tennessee is $2.899), a median (the median annual salary of Quality Managers in the tissue industry is $100,000., or a percentile (the number of documentation errors in your organization is within the 90th percentile this year, based on data collected from over 1,000 tissue banks).

Mean (average)

The ***mean***, also referred to by statisticians as the ***average***, is the most common statistic used to measure the center, or middle, of a numerical data set. The ***mean*** is the sum of all the numbers divided by the total number of numbers.

The ***mean*** may not be a fair representation of the data, because the average is easily influenced by ***outliers*** (very large or very small values within the data set that are not typical…or representative of the whole).

Median

The ***median*** is another way to measure the center of a numerical data set (besides the good old standby…the ***average***). A *statistical median* is much like the median on the interstate highway. On the highway, the median is the middle of the road, with an equal number of lanes on either side of the median. In a numerical data set, the median is the point at which there are an equal number of data points whose values lie above and below the median value. Thus, the median is truly the middle of the data set.

The next time you hear an average reported, look to see whether the median is also reported. If not, ask for it! The average and the median are two different representations of the middle of a data set, and can often give two very different stories about the data.

Standard Deviation

The ***standard deviation*** is a method statisticians use to measure the amount of ***variability*** (or spread) among the numbers in a data set. As the term implies, a ***standard deviation*** is a standard (or typical) amount of deviation (or distance) from the average (or mean). So, the standard deviation, in very rough terms, is the average distance from the mean (average).

The ***standard deviation*** is also used to describe where most of the data should fall, in a relative sense, compared to the average. For example, in many cases, about **95% of the data will lie within two (2) standard deviations of the mean**. This result is called the ***empirical rule***.

The ***standard deviation*** is the most useful measure of dispersion. The formula for calculating standard deviation is:

$$\sigma = \sqrt{\frac{\sum X^2 - \frac{(\sum X)^2}{N}}{N}}$$

The symbol for standard deviation is a σ (sigma) or s. Following are the other symbols of standard deviation:

σ	=	standard deviation (of an entire population)
s	=	standard deviation (of a sample from the population)
$\sum$	=	capital of σ
X_n	=	value of each reading
X	=	average value of the series
N	=	number of readings

Let's break this down into simpler steps:

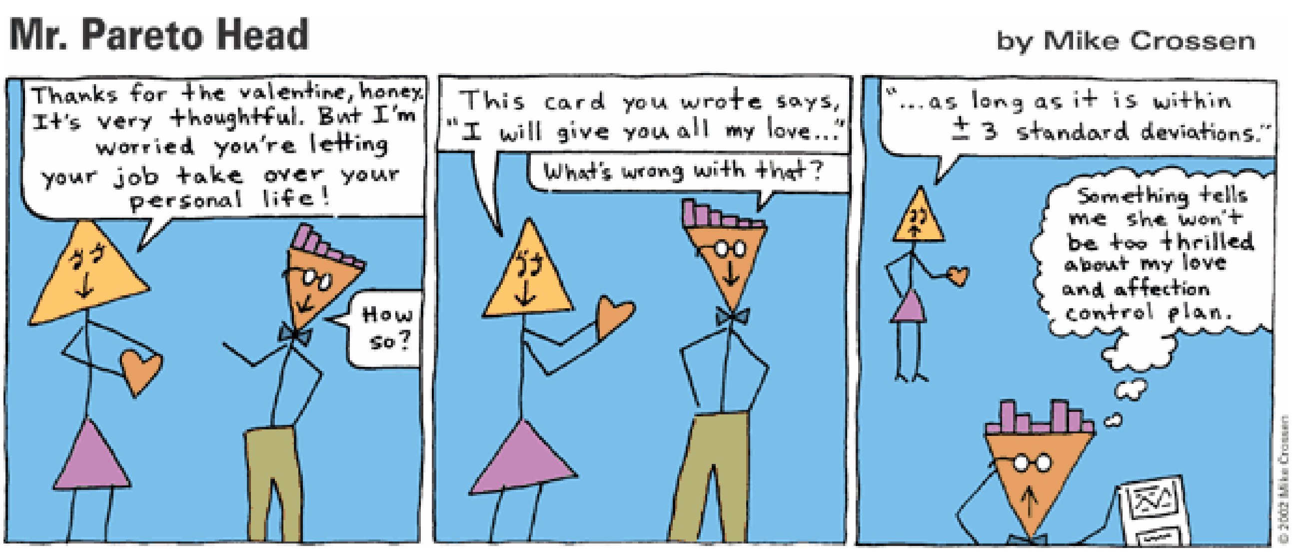
1. Find the average of the data set (to find the average, add up all the numbers and divide by the number of numbers in the data set = *n*)
2. Take each number and subtract the average from it.
3. Square each of the differences.
4. Add up all of the results from Step 3.
5. Divide the sum of squares (found in Step 4) by the number of numbers in the data set, minus one (n -1).
6. Take the square root of the number you get.

The ***standard deviation*** is an important statistic, but it is often absent when statistical results are reported. Without it, you're getting only part of the story about the data. Statisticians like to tell the story about the man who had one foot in a bucket of ice water and the other foot in a bucket of boiling water. He said that, on average, he felt just great! But think about the variability in the two temperatures for each of his feet.

Let's get closer to home: The average salary of ABC Tissue Bank may not fully represent what really is going on in your organization, if the salaries are extremely spread out (i.e., 3 executives make $200,000 each (total of $600,000), and 5 worker bees make $30,000 (total of $150,000)…the average salary could be reported as $93,750, without taking the ***standard deviation*** into account.

Exercise: Using the formula for calculating *standard deviation*, find the *standard deviation* for salaries of ABC Tissue Bank.

Don't be satisfied with finding out only the average – be sure to ask for the standard deviation, as well. Without a standard deviation, you have no way of knowing how spread out the values may be (if you're talking starting salaries, for example, this could be very important!) That's why organizations place people into "salary levels."



Percentile

If you've ever taken a standardized test, you know that when your score was reported, it was presented to you with a measure of where you stood, compared to the other people (population) who took the test. This comparison measure was most likely reported to you in terms of a ***percentile***. The percentile reported for a given score is the percentage of values in the data set that fall below that certain score. For example, if your score was reported to be at the 90th ***percentile***, that means that 90% of the other people who took the test with you scored lower than you did (and 10% scored higher than you did).

Percentiles are used in a variety of ways for comparison purposes and to determine relative standing (that is, how an individual data value compares to the rest of the group). ***Percentiles*** are also used by companies to get a handle on where they stand compared to other companies in terms of sales…profits…customer satisfaction…etc.

Standard Score

The ***standard score*** is a slick way to put results in perspective without having to provide a lot of details – something the media loves to do. The ***standard score*** represents the number of ***standard deviations*** above or below the mean (without caring what that standard deviation or mean actually are).

Example: Bob takes his statewide 12th grade test, and scores 265. What does that mean? It may not mean much to you because you can't put that 265 into perspective. But….if you know that Bob's standard score is +2, that puts it into perspective. It tells you that Bob's score is 2 ***standard deviations*** above the mean (Bravo, Bob!). But Bill's standard score is -2 (not so good), because it means that Bill's score is 2 ***standard deviations*** below the mean (-2).

The formula for calculating standard score is: $\text{Standard Score} = \dfrac{(\text{original score} - \bar{x})}{s}$

To Recap: A standard score is the standardized version of the original score; it represents the number of standard deviations above or below the mean. To convert an original score to a standard score:

1. **Find the mean and the standard deviation of the population that you're working with.**

   For example, you can convert Bob's exam score of 265 to a standard score. If you know the mean is 250, and the standard deviation is 5, Step 1 is done.

2. **Take the original score, and subtract the mean.**

   Find the actual distance from the mean by taking 265 – 250 = +15 (which means his score is 15 points above the mean)..

3. **Divide your result by the standard deviation.**

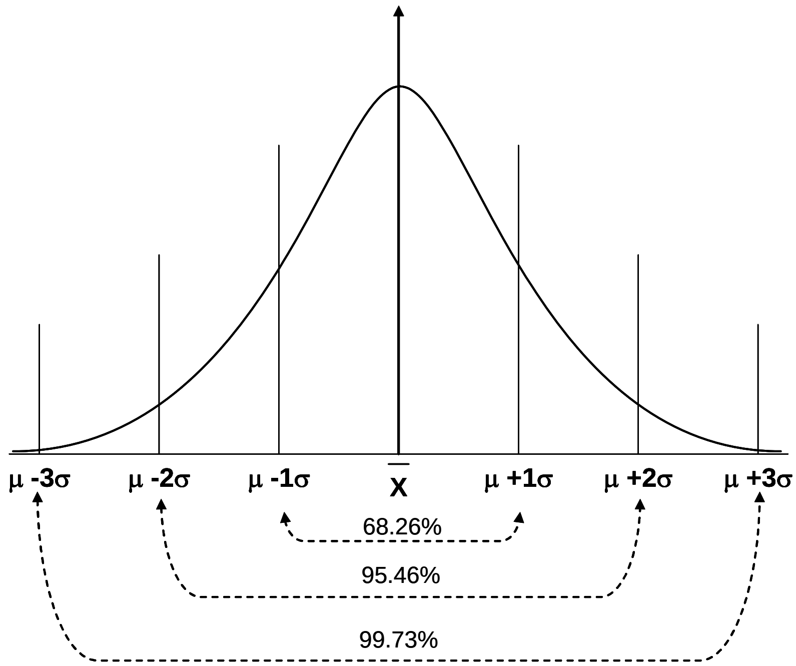
   In Bob's case, the distance is +15. Converting this distance in terms of number of standard deviations means taking + 15 / 5 = +3, which is Bob's standard score.

Normal Distribution (or bell-shaped curve)

When numerical data are organized, they're often ordered from smallest to largest, broken into reasonably sized groups, then put into graphs and charts (called histograms) to examine the shape, or distribution, of the data. The most common type of data distribution is called the ***bell-shaped curve***, in which most of the data are centered around the average in a big lump, and as you move farther out on either side of the mean, you find fewer and fewer data points. This is often referred to as ***normal distribution***. Hard core statisticians call this ***binomial distribution***.

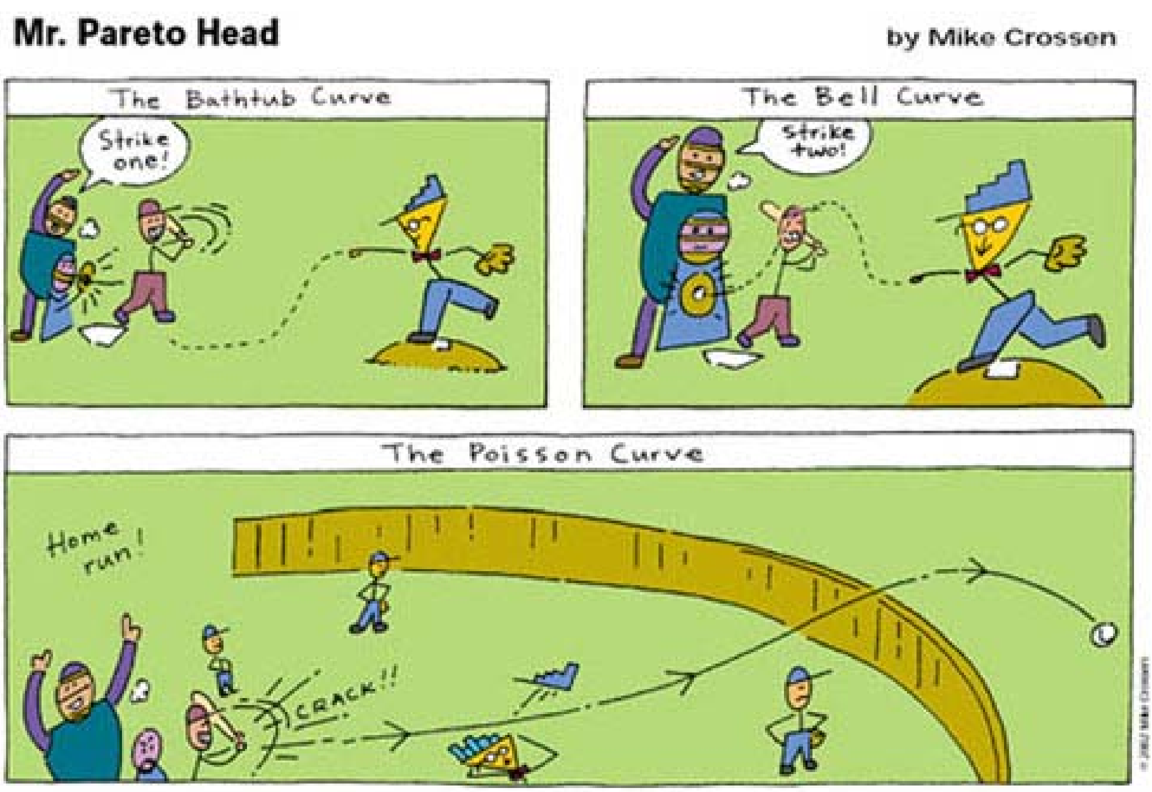
Normal Distribution follows the 68-95-99.7% Rule *(Empirical Rule)*

All normal density curves satisfy the following property which is often referred to as the *Empirical Rule*.



- **68.26%** of the observations fall within **1 standard deviation** of the **mean**.
- **95.46%** of the observations fall within **2 standard deviations** of the **mean**.
- **99.73%** of the observations fall within **3 standard deviations** of the **mean**.

Thus, for a normal distribution, almost all values lie within **3 standard deviations** of the mean.



Variation

The concept of variation holds that no two items are perfectly identical. This variation is a fact of nature. The difference may be small, but it still exists. Statisticians recognize two types of variation…***usual*** and ***unusual***.

Usual variation is the amount of deviation that can be naturally expected. This type of variation is said to be ***unassignable*** – having ***no assignable cause***, and is therefore, expected. It is, thus, inherent in the process.

Unusual variation is deviation that is greater than normally expected. This type of variation is said to be ***assignable*** – having ***an assignable cause***. A process that is operating "in control" or "in a state of control" is operating within usual variation…operating without assignable causes.

Two important characteristics of variation:

1. Central tendency, the most representative value (the average, or mean)
2. Spread of dispersion, how much variation is there (the range…or standard deviation)

(these characteristics will be illustrated in the exercises of the section on Histograms)

Frequency Distribution

A frequency distribution is a tabulation…or tally…of the number of times an event occurred within a sample. This simple type of record provides a great deal of information about a process…or a product. This transforms the data from a random list of numbers into a picture of the process.

Experiments

An experiment is a study that imposes a certain amount of control on the study's subjects and their environment. The purpose of most experiments is to pinpoint a cause-and-effect relationship between two variables (Example: alcohol consumption and impaired vision).

Here are some of the questions that experiments try to answer:

- Does taking zinc help reduce the duration of a cold? Some studies show that it does/
- Does the shape and position of your pillow affect how well you sleep at night? The Emory Spine Center in Atlanta says, "Yes."
- Does shoe heal height affect foot comfort? A study done at UCLA says up to one inch heels are better than flat shoes.

Treatment Group vs. Control Group

Most experiments try to determine whether some type of treatment (or some important factor) has some sort of effect on an outcome. For example, does zinc help to reduce the length of a cold? Subjects who are chosen to participate in the experiment are typically divided into two groups…a treatment group…and a control group. The ***treatment group*** consists of those who receive the treatment that supposedly has an effect on the outcome (in this case, zinc). The ***control group*** consists of those who do not receive the treatment, or those who receive a standard, well-known treatment whose results will be compared with this new treatment (such as vitamin C, in the case of the zinc study).

Placebo

A ***placebo*** is a fake treatment, such as a sugar pill. It is often given to the members of the control group, so that they will not know whether they are taking the treatment (for example, zinc) or receiving no treatment at all. Placebos are given to the control group in order to control for a phenomena called the ***placebo effect***, in which patients who receive any sort of perceived treatment by taking a pill (even though it is a sugar pill) report some sort of result, be it positive ("Yes, I feel better already", or negative ("Wow, I am starting to feel a bit dizzy!"), due to a psychological effect. Without a ***placebo***, the researchers could not be certain that the results were due to the actual effect of the treatment, because some (or all) of the observed effect could have been due to the ***placebo effect***.

Blind and double-blind

A ***blind experiment*** is one in which the subjects who are participating in the study are not aware of whether they are in the ***treatment group***, or in the ***control group***. In the zinc study example, a placebo would be used that would look like the zinc pill, and patients would not be told which type of pill they were taking. A ***blind experiment*** attempts to eliminate any ***bias*** in what the study subjects might report.

A ***double-blinded experiment*** controls for potential bias on the part of both the patients and the researchers. Neither the patients nor the researchers collecting the data know which subjects received the treatment and which ones didn't. A ***double-blind*** study is best, because even though the researchers may claim to be ***unbiased***, they often have a special interest in the results – otherwise they wouldn't be conducting the study.

Estimation

One of the biggest uses of statistics is to ***"guestimate"*** something (the statistical term is ***estimation***), as in the following examples:

- What is the average household income in America?
- What percentage of households tuned in to the World Series this year?
- What is the average life expectancy of a baby born in America today?
- How effective is this new drug?
- How clean is the air today, compared to 10 years ago?

All questions like this require some sort of numerical estimate to answer the question.

Margin of error

All surveys are based on information collected from a sample of the population, not the entire population. A certain amount of error is bound to occur – not in the sense of calculation error (although that can happen also)…but in the sense of ***sampling error***, or error that's bound to happen simply because the researcher isn't collecting data from the entire population. The ***margin of error*** is supposed to measure the maximum amount by which the sample results are expected to differ from those of the entire population. Because the results of most survey questions are reported in terms of percentages, the ***margin of error*** most often appears as a ***percentage***, as well.

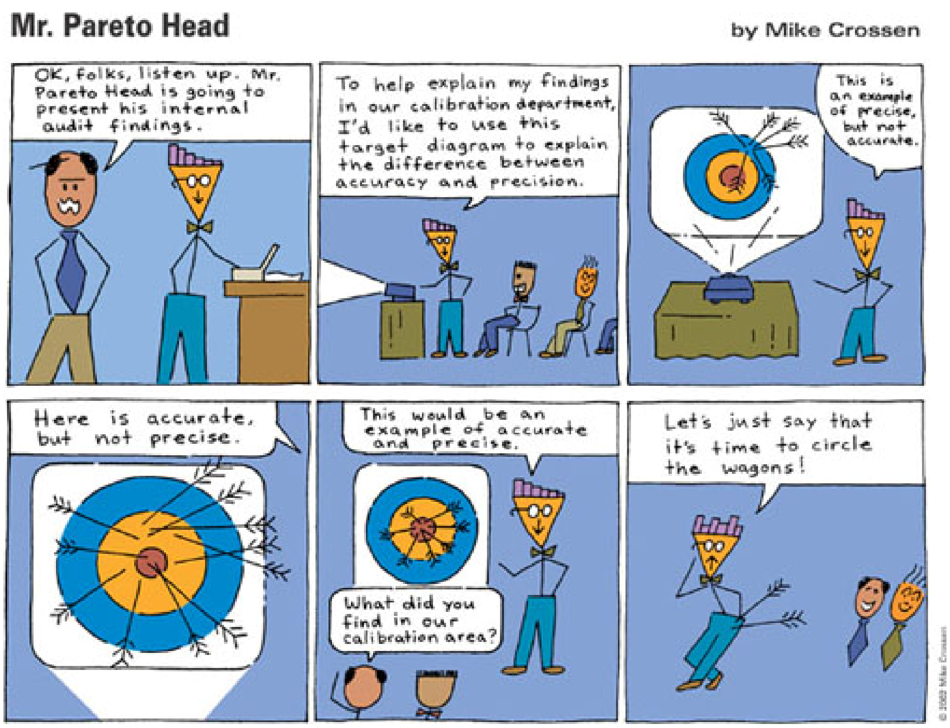
So…how do you interpret a ***margin of error***? Suppose you know that 51% of those sampled say they plan to vote for Mr. Pareto Head in the upcoming election. Now, projecting these results to the whole voting population, you would have to add and subtract the ***margin of error*** and give a range of possible results in order to have sufficient confidence that you're bridging the gap between your sample and the population. So, in this case (supposing a margin of error of plus or minus 3 percentage points) you would be fairly confident that between 48% and 54% of the population will vote for Mr. Pareto Head in the election, based on the sample results.

The ***margin of error*** measures accuracy; it ***does not measure the amount of bias*** that may be present. Results that look numerically scientific and precise don't mean anything if they were collected in a bias manner.

Confidence interval

When you combine your ***estimate*** with the ***margin of error***, you come up with a ***confidence interval***. For example, suppose the average time it takes a recovery team of 3 technicians to perform a full osteoarticular recovery of a donor is 2 hours, with a margin of error of plus or minus 20 minutes. You ***estimate*** that the average time to perform the recovery would be anywhere from 1 hour 40 minutes to 2 hours 20 minutes. This ***estimate*** is a ***confidence interval***. It takes into account the fact that sample results will vary and gives an indication of how much ***variation*** to expect.

Some ***confidence intervals*** are wider than others (and wide is not good, because it equals less accuracy). Several factors influence the width of a confidence interval, such as sample size, the amount of variability in the population being studied, and how confident you want to be in your results (Most researchers are happy with a 95% level of confidence in their results).



Probability vs. Odds

A ***probability*** is a measurement of the likelihood of an event happening. In other words, a ***probability*** is the chance that something will happen. For example, if the chance of rain tomorrow is 30%, it is less likely to rain than not rain tomorrow, but the chance of rain is still 3 out of 10 (given those odds, will you bring your umbrella with you tomorrow?). A chance of rain of 30% also means that over many, many days with the same conditions as those predicted for tomorrow, it has rained 30% of the time.

Probabilities are calculated in many ways:

- Math is used to grind out the numbers (for example, figuring your chances of winning the lottery or determining the hierarchy of hands in poker).
- Data are collected, and the probabilities are estimated based on the history of the data (for example, to predict the weather).
- Complex math and computer models are used to try to predict future behavior and occurrence of natural phenomena (for example, hurricanes and earthquakes).

The ***laws of probability*** often go against your intuition and your own beliefs about what you think can happen (that's why casinos stay in business).

Odds and ***probability*** are slightly different. The best way to describe this difference is by looking at an example: Suppose the ***probability*** that a certain race horse is going to win a race is 1 out of 10. That means his ***probability*** of winning is 1 in 10…or 1 ÷ 10…or 0.10…or 10%. A ***probability*** reflects the chances of winning. Now what are this horse's ***odds*** of winning? They are 9 to 1. That's because odds are actually a ratio of the chances of losing to the chances of winning. The horse has a 9 in10 chance of losing, and a 1 in 10 chance of winning. Take 9/10 over $\frac{1}{10}$ and the 10s cancel, leaving you with 9/1…which in ***odds*** lingo is stated as "9 to 1."

Correlation and Causation

Of all of the misunderstood statistical issues, the most problematic is the misuse of the concepts of ***correlation*** and ***causation***.

Correlation means that two numerical variables have some sort of linear relationship. For example, the number of times crickets chirp per minute is related to temperature; when it's cold outside, they chirp less frequently, and when it's warm outside, they chirp more frequently. Does the outside temperature ***cause*** crickets to chirp faster or slower? Some people speculate that changes in the outside temperature ***cause*** crickets to chirp at different frequencies. However, I don't know of any data based on experiments (as opposed to observational studies) that would confirm or deny a ***cause-and-effect*** relationship here.

Here is another example of correlation: When more police officers patrol an area, crime tends to be lower, and when fewer police officers are present, crime tends to be higher.

However, seeming unrelated events have also been found to be ***correlated***. One such example is the consumption of ice cream (pints per person) and the number of murders in certain areas. Now, maybe having more police officers does deter crime, but does having people eat less ice cream deter crime? What's the difference? The difference is that with ***correlation***, a link…or relationship…is found to exist between two variables…*x* and *y*. With ***causation***, one makes the leap and says, "a change in *x* will cause a change in *y* to happen." Too many times in research (and especially in the media), that leap is made when it shouldn't be. The only time that can be done is when a well-designed experiment is conducted that eliminates any other factors that could have been related to the outcomes.

Section 3

Getting a Piece of the Pie Chart

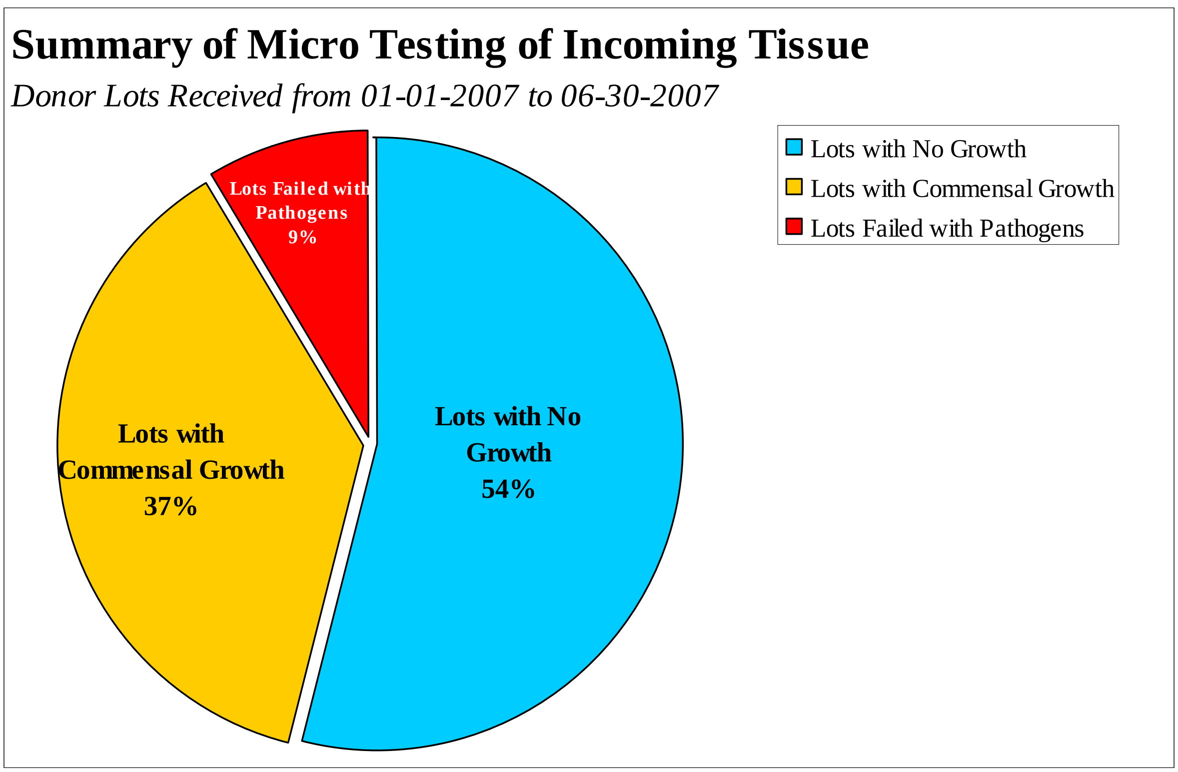
The "pie chart" is one of the most commonly used data displays because it is easy to read and can quickly make a point. A pie chart takes categorical data and breaks them down by group. Because a pie chart takes the shape of a circle…or a pie…the "slices" that represent each group can easily be compared and contrasted to one another. Because each individual in the group falls into one and only one category, the sum of all the slices of the pie should be 100%...or close to it (subject to a bit of round-off error).

Example of data that might be displayed in a pie chart:

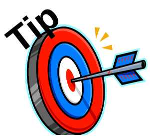
Microbial Profile of Tissue

Donor Tissues Received from 01-01-2007 to 06-30-2007

	Total No. Incoming Lots	**% of Total**
Lots with No Growth	940	53.99%
Lots with Commensal Growth	649	37.28%
Lots Failed with Pathogens	152	8.73%
Total No. Donor Lots	1741	



Pie Charts often show the breakdown of the portion, or percentage of the total that falls in each group or category. But they often do not show you the total number in each group, in terms of original units (number of dollars, number of people, or in the case of our chart, the number of different types of Commensal organism, or pathogenic organisms). This approach results in a loss of information, may not necessarily present the whole story behind the data, and leaves you wondering what the total amount is that's being divided up. You can always go from amounts to percents, but you can't go from percentages back to the original amounts without knowing a total..



Ideally, a pie chart shouldn't have too many slices, because a large number of slices distracts the reader from the big issues that the pie chart is trying to relay. However, if lumping all those remaining categories into a category called "other" results in a category that's one of the largest ones in the whole pie chart, readers are left wondering what's included in that slice of the pie.

Evaluating a Pie Chart

To "taste test" a pie chart for statistical correctness

- Check to be sure the percentages add up to 100%...or very close to it (any round-off error should be very small).
- Beware of slices of the pie called "other" that are larger than many of the other slices.
- Look for a reported total number of units, so that you can determine how big the pie was before being divided up into the slices that you're looking at.

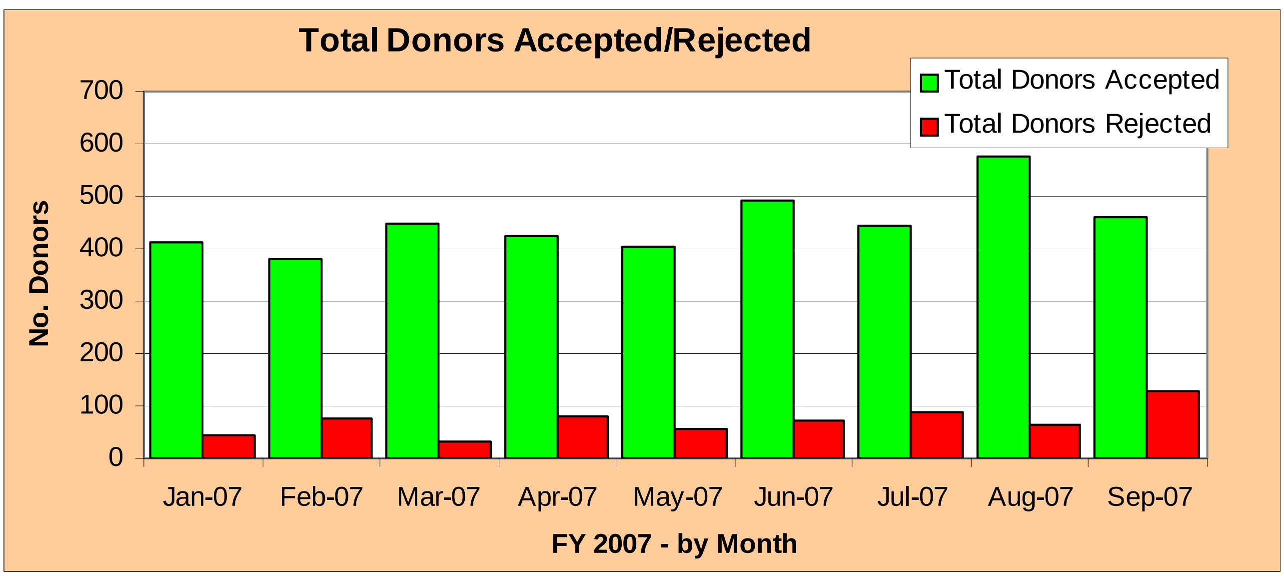
Section 4
Raising the Bar on Bar Graphs

A “bar graph” or a “bar chart” is perhaps the most common data display used by the media. Like a “pie chart,” a bar graph breaks categorical data down by group, showing how many are in each group. However, a bar graph represents those groups by using bars of different lengths, rather than as pie slices of varying sizes. And whereas a pie chart most often reports the amount in each group as percentages, a bar graph uses either the number of individuals in each group, or the percentage of the total in each group. In a bar graph, the length of each bar indicates the number or percent in each group.

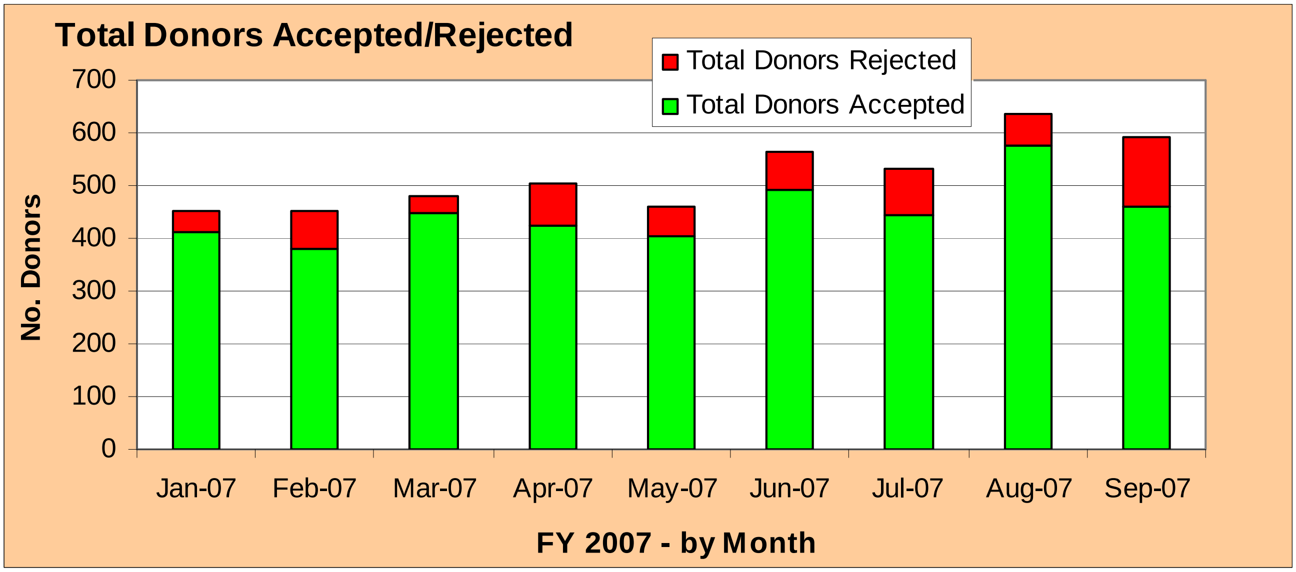
Example of a “bar chart”:

Donor Reject Rates

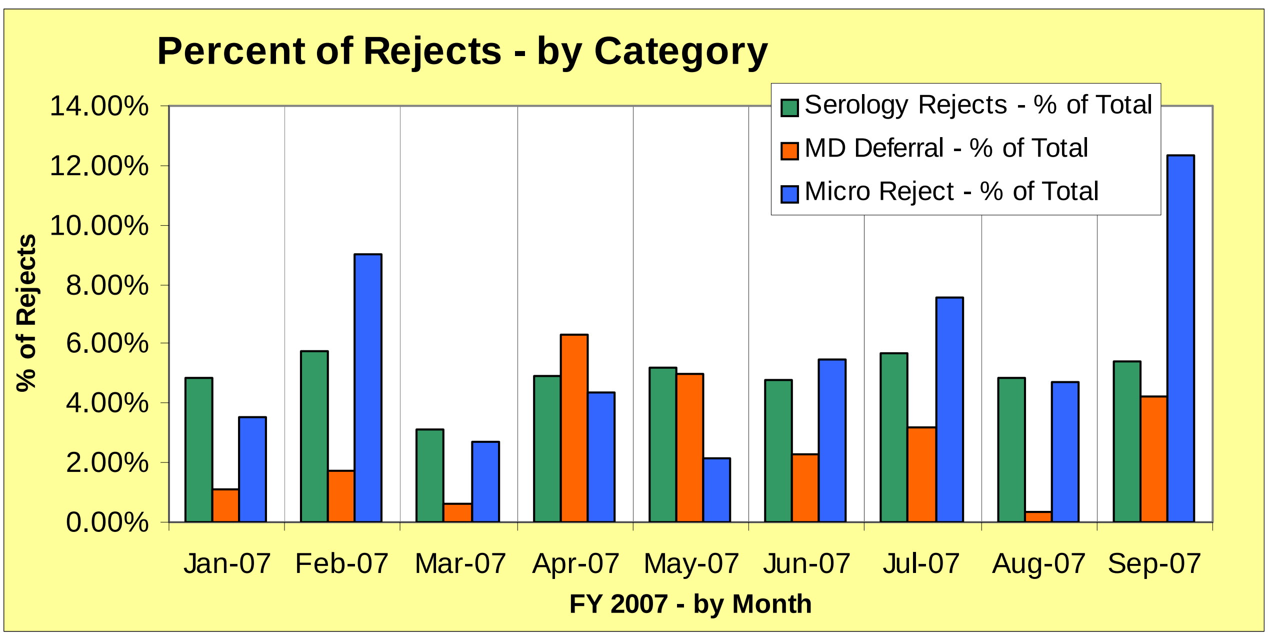
	Jan-07	Feb-07	Mar-07	Apr-07	May-07	Jun-07	Jul-07	Aug-07	Sep-07	Totals
Total Donors Recovered:	**454**	**454**	**480**	**505**	**462**	**565**	**531**	**638**	**591**	
Serology Rejects	22	26	15	25	24	27	30	31	32	232
Medical Director Deferrals	5	8	3	32	23	13	17	2	25	128
Micro Rejects	16	41	13	22	10	31	40	30	73	276
Total Donors Accepted	**411**	**379**	**449**	**426**	**405**	**494**	**444**	**575**	**461**	**4044**
Total Donors Rejected	**43**	**75**	**31**	**79**	**57**	**71**	**87**	**63**	**130**	**636**
Serology Rejects - % of Total	4.85%	5.73%	3.13%	4.95%	5.19%	4.78%	5.65%	4.86%	5.41%	4.95%
MD Deferral - % of Total	1.10%	1.76%	0.63%	6.34%	4.98%	2.30%	3.20%	0.31%	4.23%	2.76%
Micro Reject - % of Total	3.52%	9.03%	2.71%	4.36%	2.16%	5.49%	7.53%	4.70%	12.35%	5.76%
Total % of Rejects	**9.47%**	**16.52%**	**6.46%**	**15.64%**	**12.34%**	**12.57%**	**16.38%**	**9.87%**	**22.00%**	**13.47%**



Example of a "stacked bar chart"



Notice in this bar chart, the grid lines are aligned vertically. When you have multiple bars in a time period, it is good to separate the periods with grid lines to keep the data from being confusion.

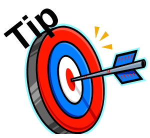


Don't assume that the information being presented in a data display represents everything you need to know; be prepared to dig deeper if you need to fill in any missing information (for which charts and graphs in the media are notorious!). It usually doesn't take too long to find what you are looking for (or to at least discount the information you're being presented, if what you find shows bias or inaccuracy).

Also, bar graphs allow a great deal of poetic license to whoever designs them. That's because the person designing the bar graph determines what scale he or she wants to use, and that means the information can be presented in a misleading way. Bu using a smaller scale you can stretch the truth, make differences look more dramatic, or exaggerate values.

By using a larger scale you can downplay differences, making results look less dramatic than they actually are, or even make small differences appear to be non-existent.

Notice that in the pie chart, the scale can't be changed to over-emphasize (or downplay) the results. No matter how you slice up a pie chart, you are always slicing up a circle, and the proportion of the total pie belonging to any given slice won't change, even if you make the pie bigger or smaller.



Evaluating a bar graph

To raise the statistical bar on bar graphs, check out these items:

- Bars that divide up values of a numerical variable (such as income) should be equal in width for fair comparison**.**
- Be aware of the scale of the bar graph (the units in which heights of the bars are represented) and determine whether it is an appropriate representation of the information.
- Don't assume the information being presented in the bar graph represents everything you need to know; be prepared to dig deeper if you feel you need to.

Section 5

Putting Statistics on the Table

A ***table*** is a data display that presents summary information from a data set in a **row-and-column format**. Some tables are clear and easy to read; others leave much to be desired. Although a ***pie chart*** or a ***bar chart*** is usually intended to make one or two points at most, a ***table*** can make several points at once (which can be good or bad, depending on the effect this has on the reader).

Almost all display charts begin with information organized in a ***table***. Statistical information is compiled by researchers not only for their own reports, but also so that others can use the information. ***Tables*** are often used in these situations.

Beware of conclusions that are drawn from a data display that compares the number of units, as opposed to the percentage of units. Percentages represent a relative comparison of quantities (often over a period of time; this is usually an accurate way of comparing quantities, especially when the total number of items or events also changes over time. By looking at the percent change, you take into account the fact that the total number has also changed.

See example in table below:

Donor Reject Rates

	Jan-07	Feb-07	Mar-07	Apr-07	May-07	Jun-07	Jul-07	Aug-07	Sep-07	Totals
Total Donors Recovered:	**454**	**454**	**480**	**505**	**462**	**565**	**531**	**638**	**591**	**4680**
Serology Rejects	22	26	15	25	24	27	30	31	32	232
Medical Director Deferrals	5	8	3	32	23	13	17	2	25	128
Micro Rejects	16	41	13	22	10	31	40	30	73	276
Total Donors Accepted	**411**	**379**	**449**	**426**	**405**	**494**	**444**	**575**	**461**	**4044**
Total Donors Rejected	**43**	**75**	**31**	**79**	**57**	**71**	**87**	**63**	**130**	**636**

The table above shows the total ***numbers*** receive, the numbers rejected for positive serologies, medical director deferrals, and micro failures, as well as the total ***numbers*** accepted and rejected. But what we don't know…is that good, or bad? Is the rate of rejection consistent or fluctuating? Is there something that we should be concerned about here? This table does not give us enough information.

Now compare the information in the table below:

Donor Reject Rates

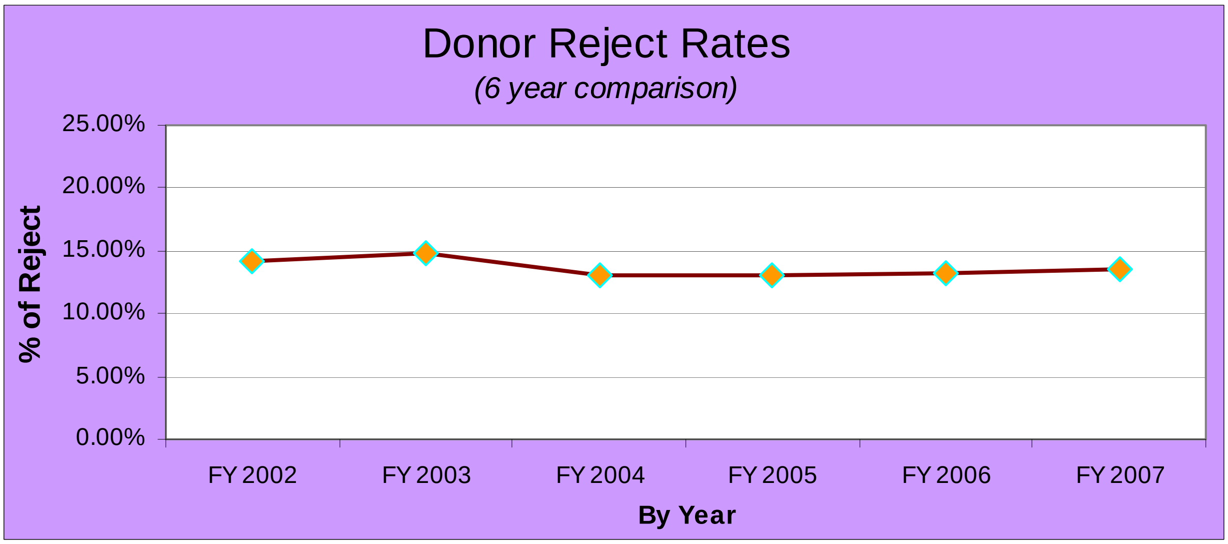
	Jan-07	Feb-07	Mar-07	Apr-07	May-07	Jun-07	Jul-07	Aug-07	Sep-07	Totals
Total Donors Recovered:	**454**	**454**	**480**	**505**	**462**	**565**	**531**	**638**	**591**	
Serology Rejects	22	26	15	25	24	27	30	31	32	232
Medical Director Deferrals	5	8	3	32	23	13	17	2	25	128
Micro Rejects	16	41	13	22	10	31	40	30	73	276
Total Donors Accepted	**411**	**379**	**449**	**426**	**405**	**494**	**444**	**575**	**461**	**4044**
Total Donors Rejected	**43**	**75**	**31**	**79**	**57**	**71**	**87**	**63**	**130**	**636**
Serology Rejects - % of Total	4.85%	5.73%	3.13%	4.95%	5.19%	4.78%	5.65%	4.86%	5.41%	4.95%
MD Deferral - % of Total	1.10%	1.76%	0.63%	6.34%	4.98%	2.30%	3.20%	0.31%	4.23%	2.76%
Micro Reject - % of Total	3.52%	9.03%	2.71%	4.36%	2.16%	5.49%	7.53%	4.70%	12.35%	5.76%
Total % of Rejects	**9.47%**	**16.52%**	**6.46%**	**15.64%**	**12.34%**	**12.57%**	**16.38%**	**9.87%**	**22.00%**	**13.47%**

What additional information is gained from adding ***percentages*** to the ***numbers***?

Putting percents into perspective

Don't be fooled into thinking that just because certain percentages are small, they aren't meaningful and/or comparable. All of the percentages in the table above look relatively low, but do they represent a change (an increase or decrease) over time? A percentage is a relative measure, and to be relevant, should be looked at over a considerable period of time, also taking the total numbers into perspective.

	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Donor Reject Rates	14.22%	14.84%	13.07%	13.03%	13.15%	13.47%



When looking at a table, be sure you understand the units that are being expressed, and watch for changes in units throughout the table.

Evaluating a table

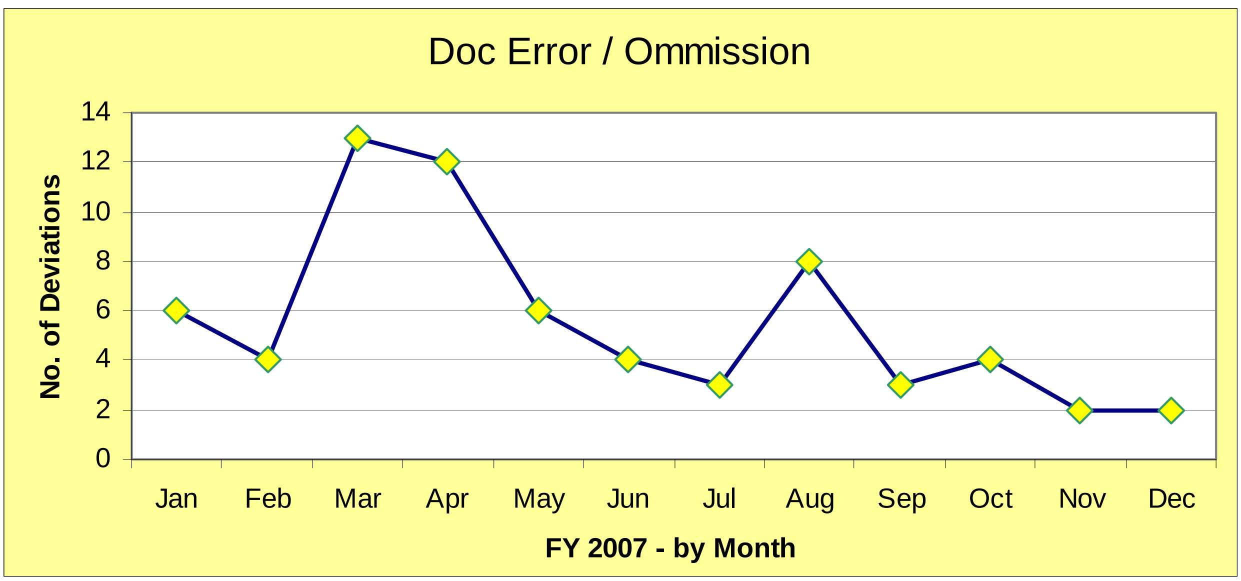
To find out whether a table is sturdy enough, statistically:

- Know the difference between percentages and total numbers, and how these two statistics are used to interpret the results. Percentages are often the most sensible statistic to use for comparing different results.
- With numerical data, be sure that the groups in the table don't overlap and that the groups are divided evenly for an equitable comparison.
- Look closely at the units and how they are presented in the table.
- Look at the way the information is presented. Often tables are designed to downplay certain points while highlighting only the points that the researcher or reporter wants you to notice.

Section 5
Keeping Pace with Time Charts (Line Graph)

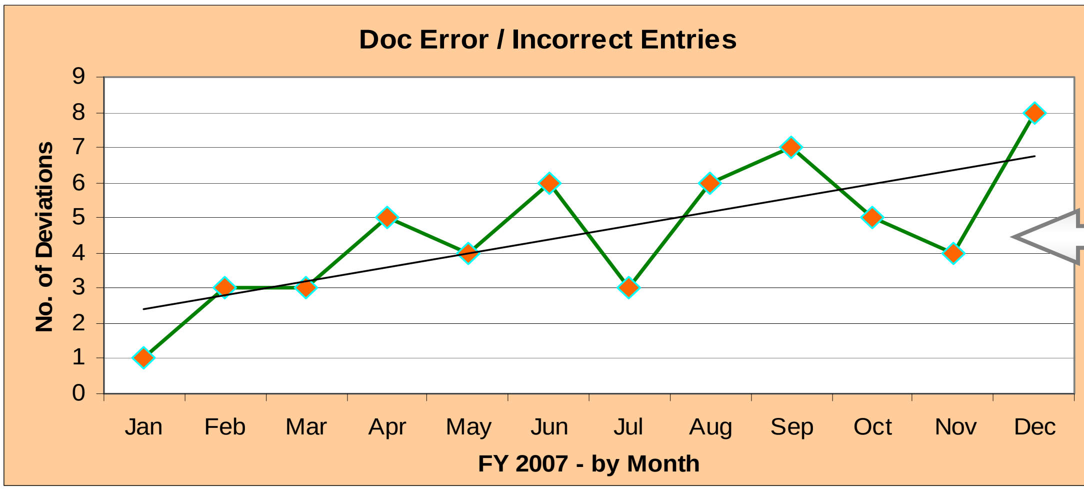
A "time chart" is a data display whose main point is to **examine trends over time**. Another name for a time chart is a "line graph." Typically a time chart will have some unit of time on the horizontal axis (such as year, day, month, etc.) and some measured quantity on the vertical axis (such as average household income, birth rate, total sales, percentage of errors, etc.). At each time period, the amount is represented by a dot, and the dots are connected to form the time chart.

	Quarter 1			Quarter 2			Quarter 3			Quarter 4			
Deviation Waivers	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Totals
Doc Error / Omission	6	4	13	12	6	4	3	8	3	4	2	2	67
Doc Error / Incorrect	1	3	3	5	4	6	3	6	7	5	4	8	55
Missed Media Change	1	1	1	4	3	2	1	6	2	0	2	4	27
Equipment Calib. Dev.	0	0	1	7	1	1	1	0	2	1	0	1	15
Processing Error	1	1	0	0	9	0	1	1	0	0	0	0	13
QC Inspection Error	0	1	4	1	0	0	3	1	2	1	0	0	13
Recovery Error	0	2	2	6	1	0	1	0	0	0	0	0	12
Hemodilution Calc Error	2	2	0	1	0	2	0	1	1	1	1	1	12
Labeling Error	0	0	0	0	4	0	0	2	1	1	1	1	10
Packaging Error	0	0	0	0	0	0	0	1	0	5	0	4	10



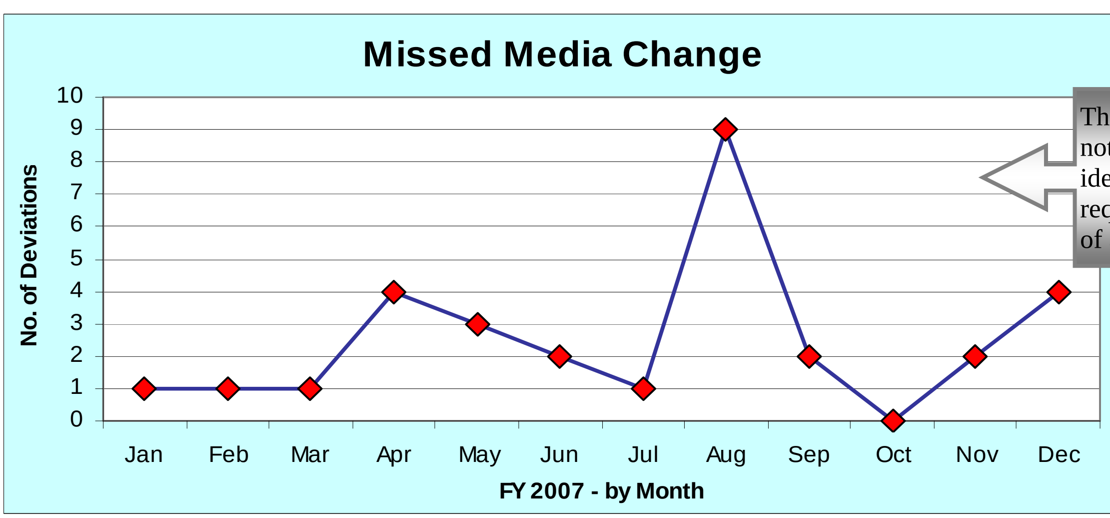
The "line chart" above identifies a trend in "Documentation Errors – Omissions"

	Quarter 1			Quarter 2			Quarter 3			Quarter 4			
Deviation Waivers	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Totals
Doc Error / Omission	6	4	13	12	6	4	3	8	3	4	2	2	67
Doc Error / Incorrect	1	3	3	5	4	6	3	6	7	5	4	8	55
Missed Media Change	1	1	1	4	3	2	1	6	2	0	2	4	27
Equipment Calib. Dev.	0	0	1	7	1	1	1	0	2	1	0	1	15
Processing Error	1	1	0	0	9	0	1	1	0	0	0	0	13
QC Inspection Error	0	1	4	1	0	0	3	1	2	1	0	0	13
Recovery Error	0	2	2	6	1	0	1	0	0	0	0	0	12
Hemodilution Calc Error	2	2	0	1	0	2	0	1	1	1	1	1	12
Labeling Error	0	0	0	0	4	0	0	2	1	1	1	1	10
Packaging Error	0	0	0	0	0	0	0	1	0	5	0	4	10



This line chart identifies a **trend** in “Doc. Errors – Incorrect Entries”

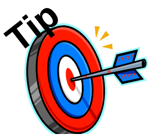
	Quarter 1			Quarter 2			Quarter 3			Quarter 4			
Deviation Waivers	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Totals
Doc Error / Omission	6	4	13	12	6	4	3	8	3	4	2	2	67
Doc Error / Incorrect	1	3	3	5	4	6	3	6	7	5	4	8	55
Missed Media Change	1	1	1	4	3	2	1	9	2	0	2	4	30
Equipment Calib. Dev.	0	0	1	7	1	1	1	0	2	1	0	1	15
Processing Error	1	1	0	0	9	0	1	1	0	0	0	0	13
QC Inspection Error	0	1	4	1	0	0	3	1	2	1	0	0	13
Recovery Error	0	2	2	6	1	0	1	0	0	0	0	0	12
Hemodilution Calc Error	2	2	0	1	0	2	0	1	1	1	1	1	12
Labeling Error	0	0	0	0	4	0	0	2	1	1	1	1	10
Packaging Error	0	0	0	0	0	0	0	1	0	5	0	4	10



This line chart does not necessarily identify a trend, but requires evaluation of an outlier.

Statistics tell you facts – in other words, they tell you what's occurring…but they don't explain why events are occurring as they are. Many folks try to take a simple data display and use it not only to show what's happening, but also to try to explain why things are happening as they are. Without sufficient data, they may be arriving at false conclusions. Always question whether conclusions are justified.

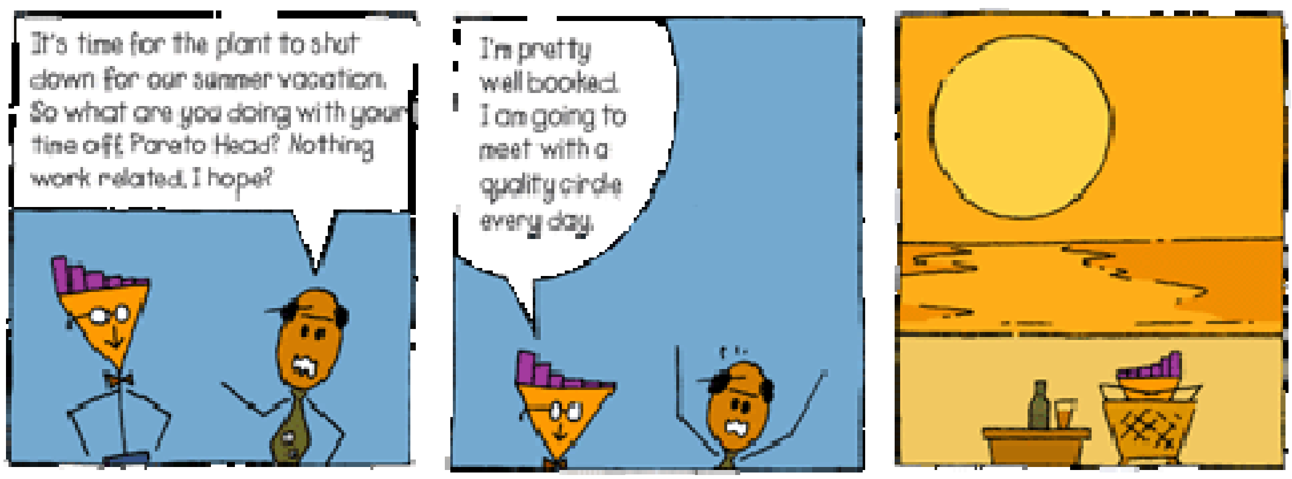
Also, remember…as with a bar graph…differences that are represented using a line chart (time chart) can be played up or down by changing the scale on the vertical axis, so be sure to take the scale into account when interpreting the results of a time chart.



Evaluating a time chart

To see whether a line chart is on pace, statistically:

- Examine the scale on the vertical (quantity) axis, as well as the horizontal (timeline) axis; results can be made to look more or less dramatic than they actually are simply by changing the scale.
- Take into account the units used in the chart, and be sure they are appropriate for comparison over time.
- Beware of people trying to explain why a trend is occurring without using additional statistics to back up their claims. A time chart generally shows what is happening…not why.



Section 6

Looking for the Bell Curve in a Histogram

Numerical data in their raw, unorganized form are hard to absorb. For example, look at the table below which shows the first half of 2007 population of organisms found on the skin samples from each donor recovered. After looking closely at the table, answer the questions found right after the table.

Organism ID	Pathogen or Commensal	No. Occurrences	%
Acinetobacter sp.	Pathogen	5	0.23%
Aeromonas sp.	Pathogen	2	0.09%
Anaerobic GNR	Pathogen	1	0.05%
Bacillus sp., not anthracis	Commensal	96	4.45%
Bacteroides sp.	Pathogen	1	0.05%
Beta Hemolytic Strep not Group A	Commensal	2	0.09%
Chryseobacterium sp.	Pathogen	1	0.05%
Citrobacter sp.	Pathogen	1	0.05%
Clostridium sp.	Pathogen	47	2.18%
Coag. Neg. Staph.	Commensal	522	24.21%
Corynebacterium sp.	Commensal	41	1.90%
Diptheroids	Commensal	13	0.60%
Enterobacter sp.	Pathogen	13	0.60%
Enterococcus sp.	Pathogen	40	1.86%
Escherichia sp.	Pathogen	16	0.74%
Flavimonas sp.	Pathogen	1	0.05%
Fungus	Pathogen	3	0.14%
Gram negative rod	Pathogen	1	0.05%
Group B Beta Hemolytic Strep	Commensal	5	0.23%
Group D Streptococcus	Commensal	4	0.19%
Klebsiella sp.	Pathogen	9	0.42%
Micrococcus sp.	Commensal	2	0.09%
Morganella sp.	Pathogen	1	0.05%
No growth	N/A	940	43.60%
Pantoea sp.	Pathogen	2	0.09%
Peptostreptococcus sp.	Commensal	9	0.42%
Proprionibacterium acnes	Commensal	317	14.70%
Proteus sp.	Pathogen	2	0.09%
Pseudomonas sp.	Pathogen	8	0.37%
Serratia sp.	Pathogen	2	0.09%
Staphylococcus aureus	Pathogen	14	0.65%
Streptococcus pneumoniae	Pathogen	1	0.05%
Streptococcus sp	Commensal	3	0.14%
Streptococcus viridans group	Commensal	15	0.70%
Veillonella sp.	Commensal	1	0.05%
Xanthomonas sp.	Pathogen	3	0.14%
Yeast, not Candida albicans	Pathogen	11	0.51%
Yokenella sp.	Pathogen	1	0.05%
	Total No. of Occurrences:	2156	

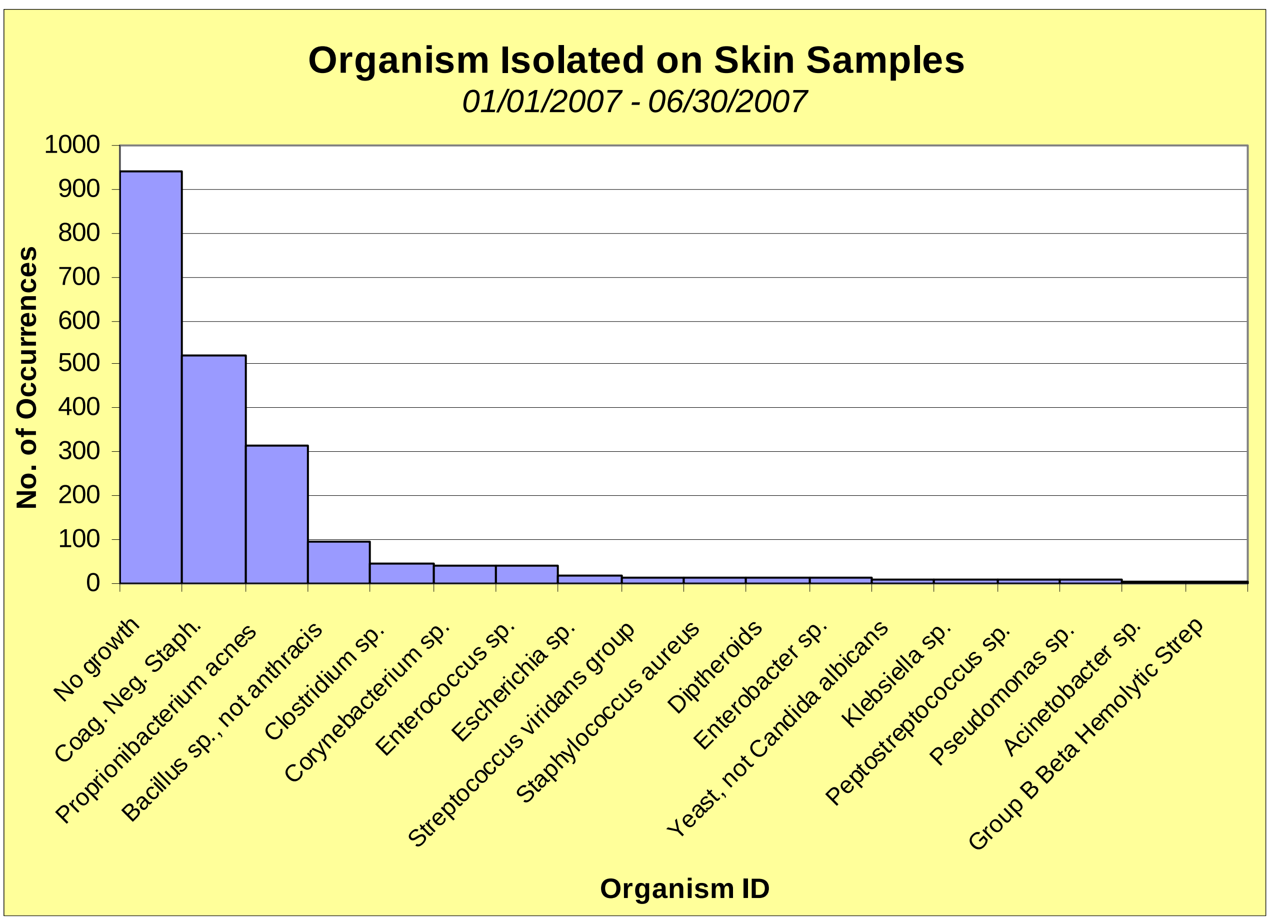
- **Which organisms were most often isolated on the samples?**
- **On the average, how many organisms are typically found on a sample of skin from a donor**
- **How much variability exists between the different types of organisms.**

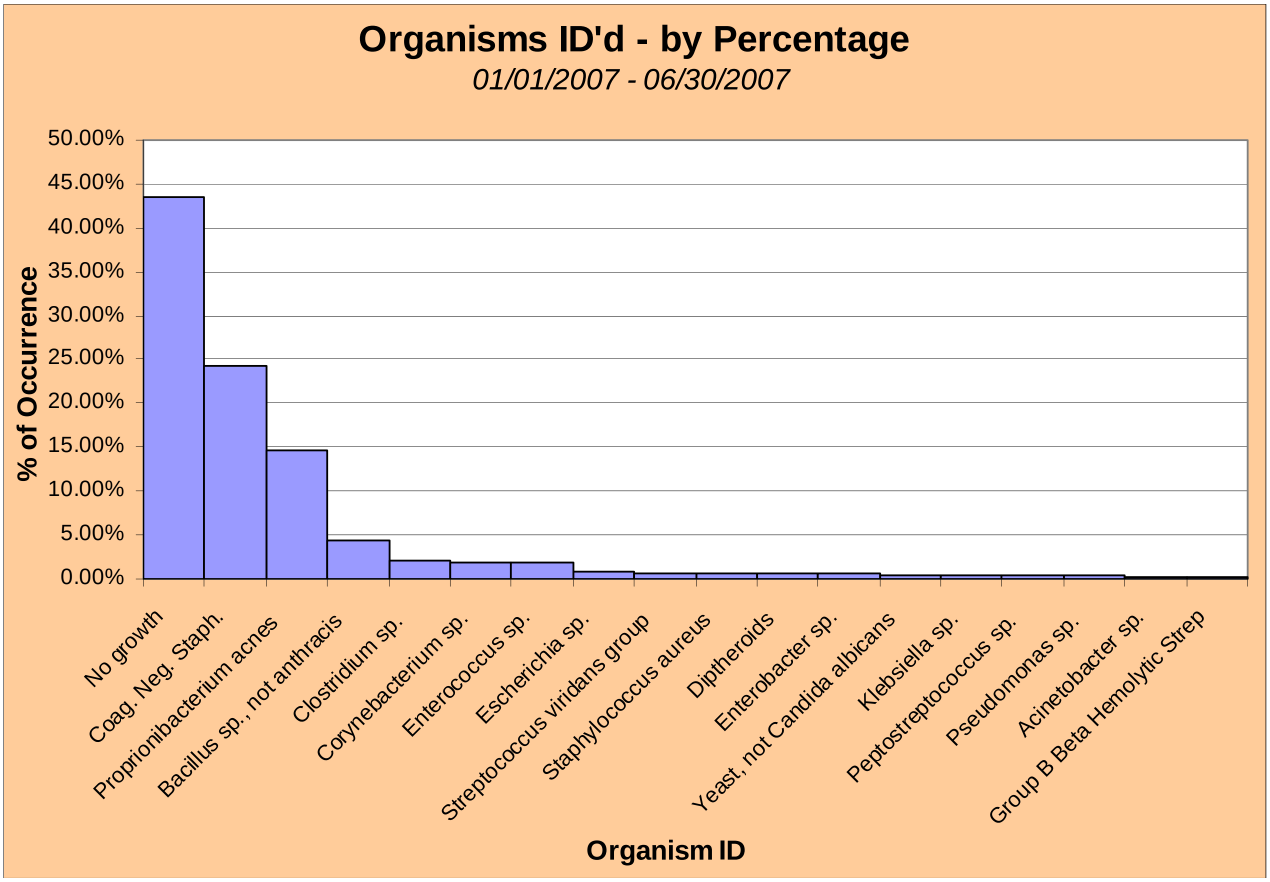
Without some way of organizing these data, these questions are difficult to answer. Although many people like to use tables to organize numerical data, statisticians favor the histogram as their data display of choice for these kinds of data. What is a ***histogram***?

A ***histogram*** is basically a bar graph that applies to numerical data. Because the data are numerical, the categories are ordered from smallest to largest (as opposed to categorical data – such as organism name, or type, which has no inherent order to it). And because you want to be sure each number falls into exactly one group, the bars on a histogram touch each other, but don't overlap. Each bar is marked on the x-axis (or horizontal axis) by the value representing its mid-point.

The height of each bar of a ***histogram*** represents either the number of individuals in each group (also know as the ***frequency*** of each group), or the percentages of units in each group (also known as the ***relative frequency*** of each group).

Below is a histogram of the organisms isolated on the skin samples from each donor in the Organism ID table above (only isolates of 5 or more occurrences were included in the histogram).





By examining the above ***histograms***, you can now answer most of the questions asked following the table on the previous page. The ***histograms*** provide a more organized summary of the data set than does a table.

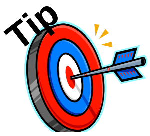
Another feature that a ***histogram*** can show you is the so-called ***shape*** of the data (in other words, how the data are distributed amoung the groups). Are the data distributed evenly, in a uniform way? Are the data ***symmetric***, meaning that the left-hand side of the ***histogram*** is a mirror image of the right-hand side of the ***histogram***? Does the ***histogram*** have a ***U-shape***, with lots of data on extreme ends and not much in the middle? Does the ***histogram*** of the data have a ***bell-shape***, meaning that it looks like a mound in the middle with tails trailing off in either direction as you move away from the center? Or is the histogram skewed, meaning that it looks like a lopsided mound with one long tail either going to the right (indicating the data are ***skewed right***) or going off to the left (indicating the data are ***skewed left***)?

Exercise: Go to Appendix A of this Primer, and do the exercises on Frequency Distribution.

Interpreting a Histogram

You can use a histogram to tell you three main features of numerical data:

- How the data are distributed (symmetric, skewed right, skewed left, bell-shaped, and so on)
- The amount of variability in the data
- Where the center of the data is (approximately)



Evaluating a histogram

To picture the statistical quality of a histogram:

- Examine the scale used for the vertical (frequency or relative frequency) axis and beware of results that appear exaggerated or played down through the use of inappropriate scales.
- Check out the units on the vertical axis to see whether the histogram reports frequencies (numbers) or relative frequencies (percentages), and then take this into account when evaluating the information.
- Look at the scale used for the groupings of the numberical variable (on the horizontal axis). If the range for each group is very small, the data may look overly volatile. If the ranges are very large, the data may appear to be smoother than they really are.

Section 7

Using Control Charts to Monitor Quality

(Quality = Accuracy + Consistency)

To most successful organizations, quality control is an important function. They want the customer to be satisfied with their products or services. They want customers to be so pleased that they will tell their friends, neighbors, coworkers, and even people they come in contact with how wonderful their products are. How do companies ensure that customers are going to be satisfied with their products or services? One criterion for customer satisfaction is product quality…and statistics plays a vital role in the assessment of product quality and in quality improvement.

Full-Filling Expectations

Customers expect products to fulfill their expectations…and one expectation is that a package contains the amount of product that was promised. Another expectation is a certain level of consistency each time the product is purchased. How full do you expect a bag of potato chips to be? Doesn't it seem strange that an 8-ounce bag of potato chips can look so large, yet actually contain so few potato chips? (Manufacturers say they insert air into the package before sealing it in order to protect the product from damage). If the package labeling indicates that the weight of the package is 8 ounces, and the package contains 8 ounces, you really can't complain. But will you feel slighted if the bag turns out to be under-filled?

Suppose the package says it contains 8 ounces, but it actually contains only 7.8 ounces; will you be upset? You probably wouldn't even notice that amount of difference. But what if the bag contains only 6 ounces of chips? How about 4 ounces? At some point, you're going to notice…and what will your reaction be? You may…

- Just let it slide (unless the problem happens over and over again)
- Return the product to the store and demand a refund
- Write a letter to the company and complain
- Decide not to buy the product again
- Organize a boycott of the product
- Try to get a job with the company to be "part of the solution instead of part of the problem"

Now, some of these options may seem to be a bit over the top, especially if you only got cheated out of a couple of handfuls of potato chips. But suppose the product was a new car that turned out to be a lemon…or your child almost choked on a part that came loose in his/her crib…the graft that was transplanted in you was contaminated with *Clostridium sp.*? Quality can be a critical and serious issue. The tissues that are recovered…processed…distributed…and transplanted in our industry are regulated by the Food and Drug Administration. We all know that problems can arise in the recovery process that can contribute to the disease state of the tissues. Problems can arise in the manufacturing processes that can affect tissue safety, stability, or the efficacy of the graft?

Here are a few of the factors that can affect the quality of human tissue products:

- ✘ The employees perform inconsistently (due to differences in skill levels, training, and working conditions, or due to the effect of shift changes, poor morale, human error, etc.)
- ✘ Managers and/or supervisors are inconsistent or unclear about expectations and/or their responses to problems that arise
- ✘ The production equipment performs inconsistently (due to insufficient calibration, insufficient maintenance, parts wearing out, machines breaking down or malfunctioning, or simply because of differences between individual machines, or machine settings)
- ✘ The machines and equipment aren't designed to be precise or sensitive enough
- ✘ The supplies and/or reagents used in the manufacturing processes are inconsistent
- ✘ The environment (temperature, humidity, air purity, etc.) isn't consistently controlled
- ✘ The monitoring process is insufficient or ineffective

Spurred on by the need to please customers and follow government regulations, real quality organizations are always looking for ways to improve the quality of their products or services. One important phrase used by the manufacturing industry is ***total quality management***, or TQM. ***Total quality management*** focuses on developing ways to continually monitor, assess, and improve processes, from the beginning of the process to the end. TQM was popularized in the United States by a famous and beloved statistician, Dr. W. Edwards Deming, who developed a nationally known, and often-used list called "14 Points for Management." Demings philosophy was that if you build quality into the process in the first place, you'll lower costs, increase productivity, and ultimately be more competitive.

Statistics play an important role in process quality…product quality. Statistics are useful in determining and setting specifications, and in monitoring all aspects of a process to ensure that those specifications are consistently met. Statistics are useful to help decide when a process needs to be stopped, as well as in identifying problems before they occur. In an over-all sense, statistical data provide feedback (often continuously) to management about process quality…and ultimately about product quality as part of the total quality management philosophy. The role of statistics in monitoring and improving quality through all of the processes is called statistical process control (SPC). The subject of statistical process control can fill up an entire book by itself; however, this course is designed to give you a basic sense of how statistics factor into quality by understanding and applying some of the concepts taught in this course.

Example: Squeezing Quality out of a Toothpaste Tube

Do you think that toothpaste manufacturers know how hard you struggle to squeeze that last bit of toothpaste out of the tube. The "tube-filling industry" (which includes its own Tube Council) rises to the occasion and takes the whole tube-filling concept very seriously. I'll bet you didn't know that you can even find "Tube-Filling Frequently Asked Questions" on a web site set up by one of these companies…and one of the frequently asked questions addresses the issue of how quality is ensured in tube filling.

The goals of the tube-filling equipment, according to the industry, are accuracy and consistency. The dosing mechanism is the key to achieving these goals (Dosing mechanism is the industry's lingo for the machine that actually fills the tubes). Here are some important features of toothpaste-tube-dosing equipment:

- A mechanism for properly cutting off the flow, to eliminate drip or stringing
- A system to eliminate air in the filling process
- A mechanism that stops the machine from trying to fill tubes that, for some reason, are missing
- A system that's designed for rapid cleaning and changeover

If this level of complexity and attention to detail is required for quality in the toothpaste-tube-filling industry, what level of care must be involved in the recovery, handling, storage, processing, packaging, labeling, and delivery of human tissues for transplant?

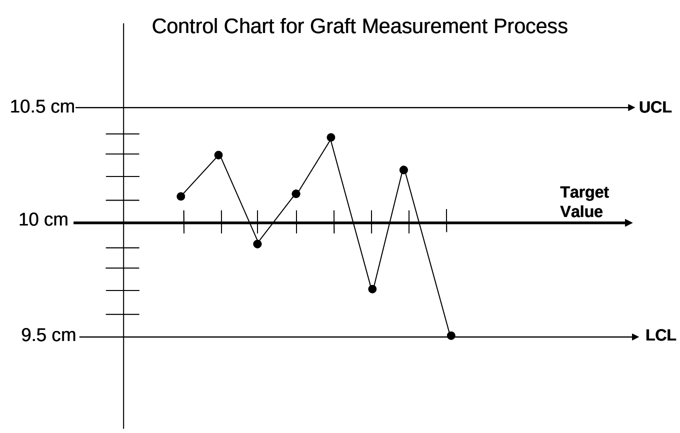
It turns out that tube-fill quality is affected by several factors, including those listed in the preceding bullet list. Problems that toothpaste manufacturers want to avoid include under-filling (mainly due to air pockets) and overfilling (resulting in tubes that "give way" or burst, not to mention that it also eats into the profits). The dimensions of the inside of the tube play a role in tube-fill quality. For example, undersized tubes (even though they are filled with the proper amount of toothpaste) will bulge when sealed, and oversized tubes will give the appearance that they are under filled.

Understanding that quality = accuracy + consistency

Statistics are involved in providing necessary data to evaluate tube-filling equipment on each of the criteria. The role of statistics in quality control is most clearly emphasized by the organization's criterion for quality, as measured by ***consistency*** and ***accuracy.*** These two words – ***consistency*** and ***accuracy*** – scream statistics louder than any other words…how about in your industry?

Accuracy and ***consistency*** are monitored statistically by using control charts. A control chart is a specialized time chart that displays the values of the data in the order in which they were collected over time (refer back to ***Section 5 – Keeping Pace with Time Charts***). Control charts use a line to denote where the manufacturer's specified value – or ***target value*** – is (this deals with the ***accuracy*** issue) and boundaries to indicate how far above or below the target the values are expected to be (this deals with the ***consistency*** part). The values being charted represent weights, volumes, or counts from individual products, or, as is more often the case, they represent average measurement…average weights…average volumes…average counts…average times, etc., from sample populations (in the case of the toothpaste tube filling industry, samples of products). The upper and lower boundaries of a control chart are called the ***upper control limit*** (UCL) and the ***lower control limit*** (LCL).

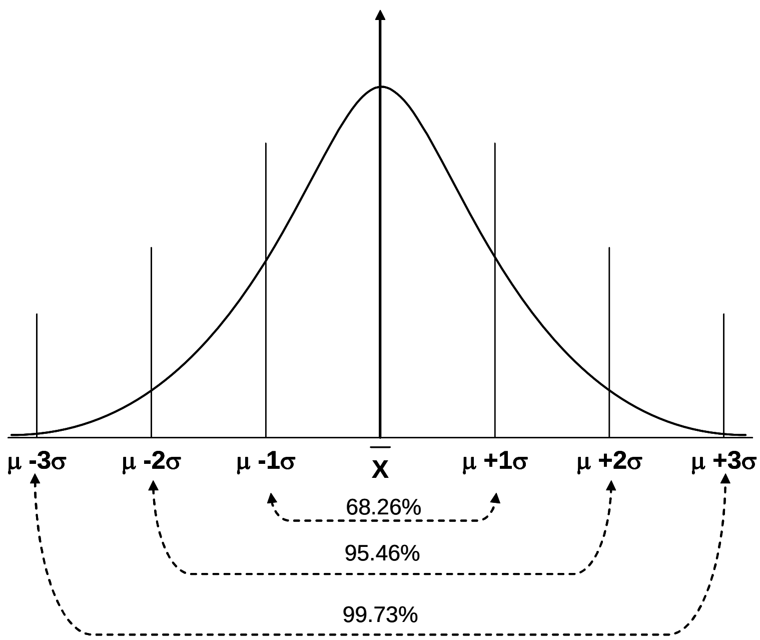
Example: Suppose a tissue processor is making bone grafts that are to be 10 cm. long, with the UCL = 10.5 cm and the LCL = 9.5 cm. Supposed Quality Control is going to measure a sampling of 8 grafts, and the results are displayed in the control chart below. Is the process (at least for the time being) in control?



To use statistics to monitor quality, you must first figure out a way to define and measure accuracy and consistency. Then you have to set the target value, determine the upper and lower control limits, and collect data from the process. The data then need to be recorded on the control chart, and the process needs to be monitored to determine whether the process is in control. The last step can be tricky. On the one hand, you don't want to stop the process with false alarms (which you could be doing if you stopped it the first time a value went outside of the control limits). On the other hand, you don't want to let the process get out of control if it's beginning to produce inferior products (or service).

Defining accuracy

What does it mean to be accurate? Even the most sophisticated process is not perfect; some variation in any process is normal due to random fluctuation. This means that you don't do everything right all the time. So, when you define accuracy in a process, you need to build in some allowance for variation (upper and lower control limits). How many standard deviations are needed to cover about 95% of the values around the target? In other words "quality" would be defined as your target $\pm 3\sigma$.



Defining consistency

Once again, we must keep in mind that in any process, some variation must be expected due to random fluctuation. ***Accuracy*** defines the tightness of the target itself, ***consistency*** is determined by how often the expected variation is observed. If I were shooting a gun at the target range, ***accuracy*** would be hitting the target…***consistency*** would be maintaining a tight pattern.

Charts used to measure accuracy and consistency are called ***control charts***. The Father of the control chart is Dr. Walter A. Shewart of Bell Laboratories, who developed the concept in 1924, and has become known as the "bread and butter" of quality control. Control charts deal with variation in a process.

Important to remember::

1. As we have already learned, there are two (2) types of variation: ***normal variation*** (expected variation with unassignable causes) and ***unusual variation*** (unexpected and with assignable causes).

2. It is also important to remember that there are two types of data: ***variable data***, which are measured and described numerically (quantitative – have an assigned quantity); and ***attribute data***, which classify data (qualitative – have a descriptive quality).

   - $\overline{X}$/R charts are used for variable data. $\overline{X}$/R charts deal with the average and range of a set of samples.
   - p-charts and c-charts deal with the number of defects per item. p-charts deal with the percent-defective with a sample; and c-charts deal with the number of defects per item.

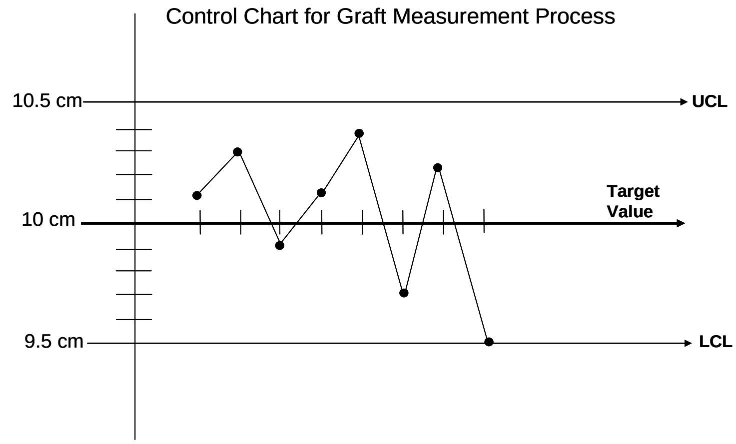
Note the use of the terms ***defective*** and ***defect***. A ***defect*** is any characteristic (attribute) which is not in conformance. A ***defective*** part is one that possesses more than the allowable number of defects.

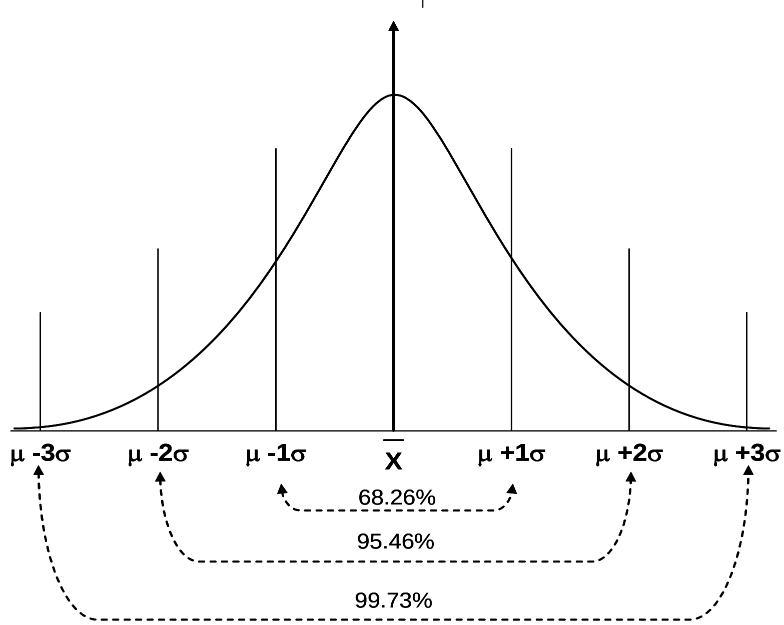
Interpretation of Control Charts

$\overline{X}$/R Chart (XbarR – Average and Range Chart) – tracks small samples of continuous data

The ***normal/inherent/unassignable variation*** will fall within the control limits. Variation which falls outside these limits indicates variation other than normal – for which there is an assignable cause. When assignable cause is identified, we have a means for controlling. A process is "in control" when it is not affected by assignable causes.

Look again at the control chart on the right. There is ***variation***…but it is ***normal***, expected variation – no assignable cause. All measurable parameters are within the expected 3 standard deviations. There are not enough data points to create a histogram, but if the process continued as is for at least 25+ data points, the histogram would show a clear ***bell curve.*** This process would be "in control."





Exercise: Demonstrate the creation of an XbarR Chart from the sample data, illustrating how data must be arranged for this type of chart.

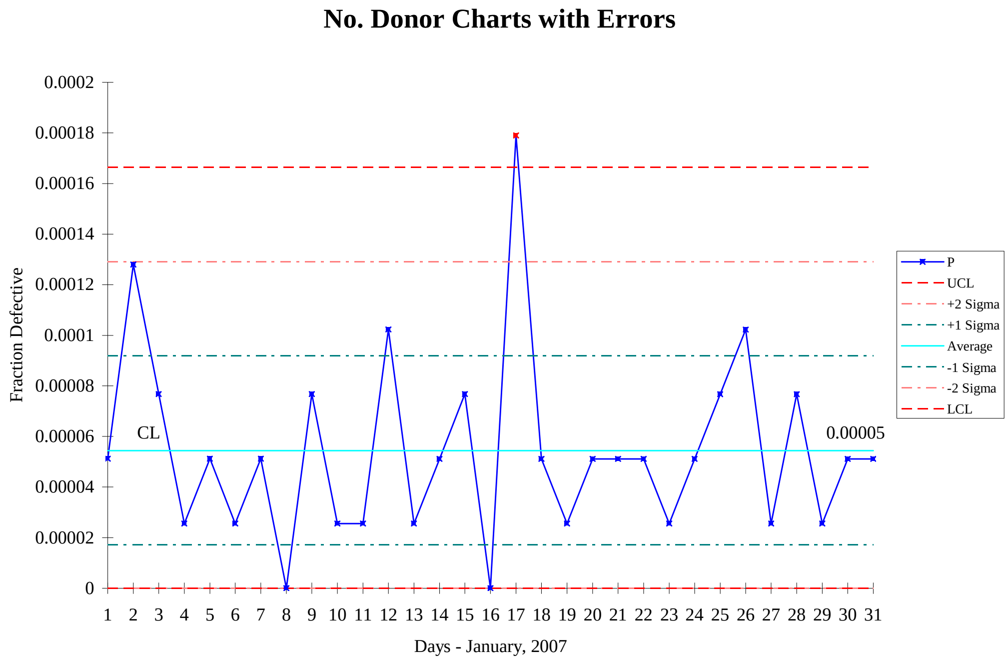
p and np Charts (measuring attribute data)

p and np charts will help you evaluate process stability when counting the number or fraction defective. The example that we are going to use, is "number of donor charts incomplete." (Other examples might be number of defective parts, number of bad meals in a restaurant, number defective teller interactions in a bank, number of defective invoices, etc. – you get the idea).

The **np-chart** is useful when it's easy to count the number of defective items and the sample size is always the same.

The **p-chart** is used when the sample size varies: the total number of donor charts, total number of meals, total number of invoices, etc.

Example: We are going to investigate why the month of January, 2007 had so many errors in the donor chart. We want to see if this process is stable. Because the daily number of donors (sample) varies, we are going to create a p-chart.



A fully capable process delivers zero defects. Although this may be difficult to achieve, it should still be our goal. Once we resolve the out-of-control point, we could, we would begin performing root cause analysis to begin to eliminate the common causes of errors in the donor charts.

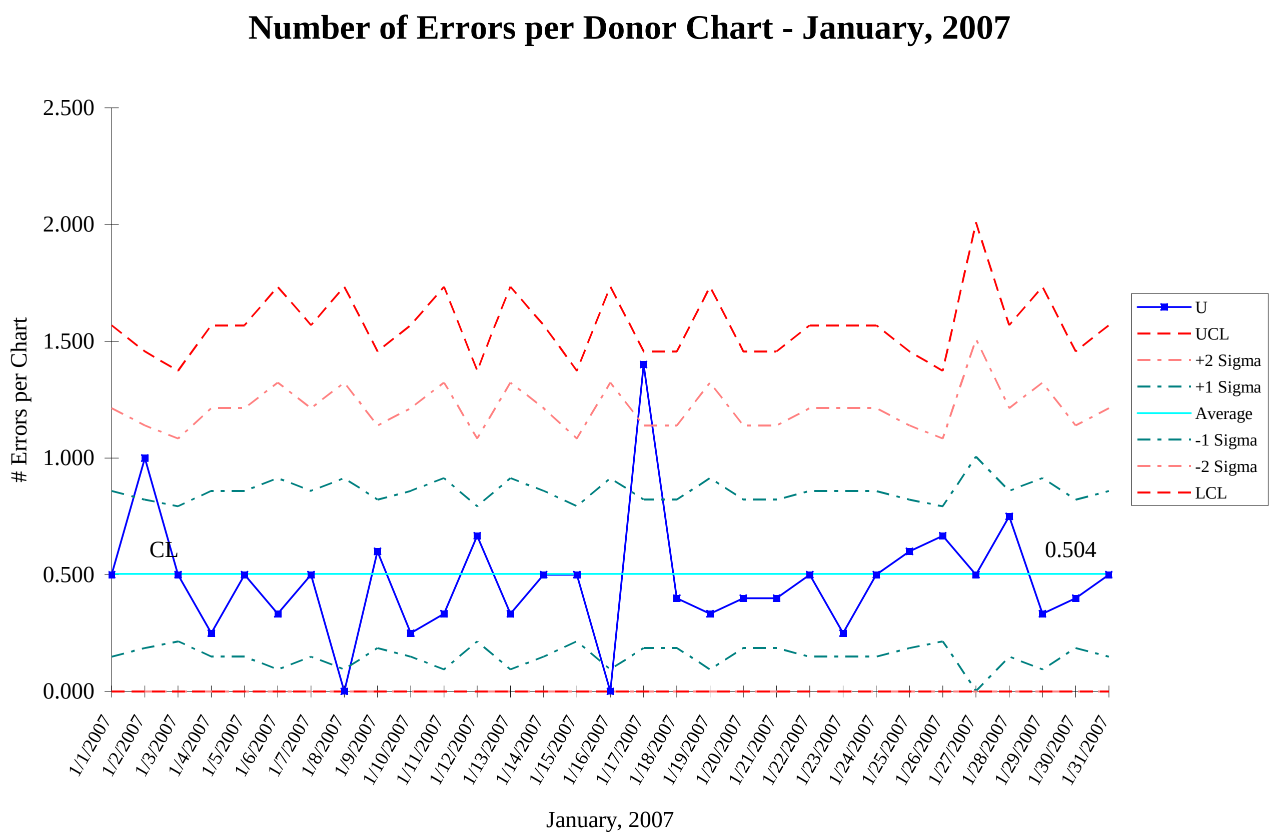
Root cause questions:

- What are the most common types of errors?
- Why do they occur?
- Why do they occur when they occur?
- Why….
- Why…
- Why…

c-charts and u-charts (measures attribute data)

The c-chart and u-chart will help you evaluate process stability when there can be more than one defect per unit. Examples might include: the number of defects on a circuit board, the number of defects in a donor chart (e.g., omissions, incorrect entries, incorrect Hemodilution calculation, etc.). This chart is especially useful when you want to know how many defects there are, not just how many defective items there are. It's one thing to know how many defective donor charts there are; it is another thing to know how many defects are found in these defective donor charts.

The c-chart is useful when it's easy to count the number of defects and the sample size is always the same. The u-chart is used when the sample size varies: the number of donor charts each day varies. The u-chart below shows the number of errors in each donor chart in the month of January, 2007.



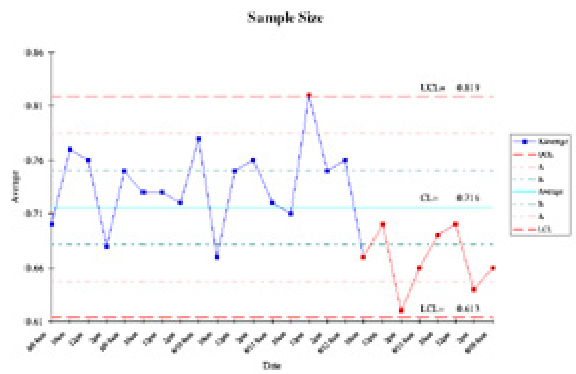
Given this information we would want to begin our investigation with January 17th and January 2nd. We would then want to understand why we were experiencing this level defects, and how we could eliminate the causes resulting in a continual tightening of the range between the upper and lower control limits.

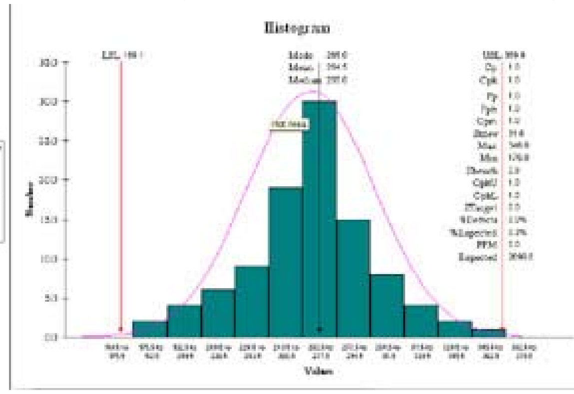
A fully capable process would deliver ***zero defects***.

QI Macros

https://www.qimacros.com/excel-spc-software.html

If you are looking for a simple, easy-to-use way to accelerate your success with Six Sigma, consider the QI Macros. The QI Macros are a series of Excel add-ins that include both Excel templates and Excel macros. They automate all of the charts, graphs, and diagrams you need. With the macros, simply select the data you want to graph and click on the pull-down menu; the QI Macros will do all the math and draw the graph for you. Watch Now! Actual graphs look like the following:





Here's what you get for $139:

You get all these Charts	**Plus 60+ "Fill in the Blank" Templates**	**Plus Statistical Tools**
New Control Chart Wizard: Selects the correct chart based on your data. **Control Charts** with Stability Analysis • c chart • np chart • p chart • u chart • Cusum • Levey Jennings • Moving Average • EWMA • XmR chart • XbarR chart • XmedianR chart	• Action Plan • Affinity Diagram • APQP tools for AIAG ISO/TS 16949: Control Plan, PFMEA, DFMEA • Arrow Diagram • Balanced Scorecard (Tree) • Block Diagram • Checksheet • Control Plans for ISO/TS 16949 APQP • Control Charts for SPC requirements (e.g., ISO/TS 16949) 1. Attribute: c, np, p, u, g charts 2. Variable: Cusum, EWMA, Moving Average, XmR (individuals), XbarR, XbarS and XMedianR charts with histogram and normal probability plot (also includes short run templates). 3. Histogram • Cost of Quality	• Anova: Single and two factor • Chi-square • Correlation • Covariance • Exponential smooting • f-Test two factor • Moving average • NonParametric • Normality Test • Rank and percentile • Regression Analysis • Sample Size Calculator • t-test one factor • t-test two factor • z-test two

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- XbarS chart
- Control Chart Wizard

Histograms with Capability Analysis - Cp, Cpk

Dot Plots

Multivariate Analysis

- Scatter Plot Matrix
- Hotelling T2
- Scatter Plot Diagram

Other Charts

Run Chart
Pareto Chart
Line Graph
Bar Chart
Pie Chart
Box & Whisker Plot
Multivari Chart

Includes QI Macros Help File for each chart and tool.

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- Countermeasures
- Cp, Cpk Template
- Design of Experiments (Plackett-Burnham 2-3-4 Factor and Taguchi 4-8-16)
- Failure Prevention Analysis Template
- Fault Tree
- Ishikawa Fishbone Diagram
- Flowchart
- Force Field Analysis
- FMEA , DFMEA and PFMEA for APQP
- Gage R&R (for ISO/TS 16949 MSA) with range method, anova method, bias, linearity, and attribute Gage R&R
- Gantt Chart
- MSA - Measurement Systems Analysis using Gage R&R
- Non-Parametric Testing
- PFMEA
- PPAP Templates for AIAG ISO/TS 16949
- PDPC Chart
- Pre Control Chart
- Pugh Concept Selection Matrix
- QFD House of Quality
- Relationship/Systems Diagram
- ROC Curve
- ROI Analysis
- Targets and Means
- Time Tracking
- Transition Planning
- Tree Diagram
- Value-Added Analysis
- Value Stream Map
- Voice of the Customer

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Plus Data Analysis Tools

- Box Cox Transformation
- Stack and Restack tables
- Get Sample from table
- Paste Link
- Paste Link Transpose
- Cross Tabulate 1 to 4 columns
- Count Words in selection

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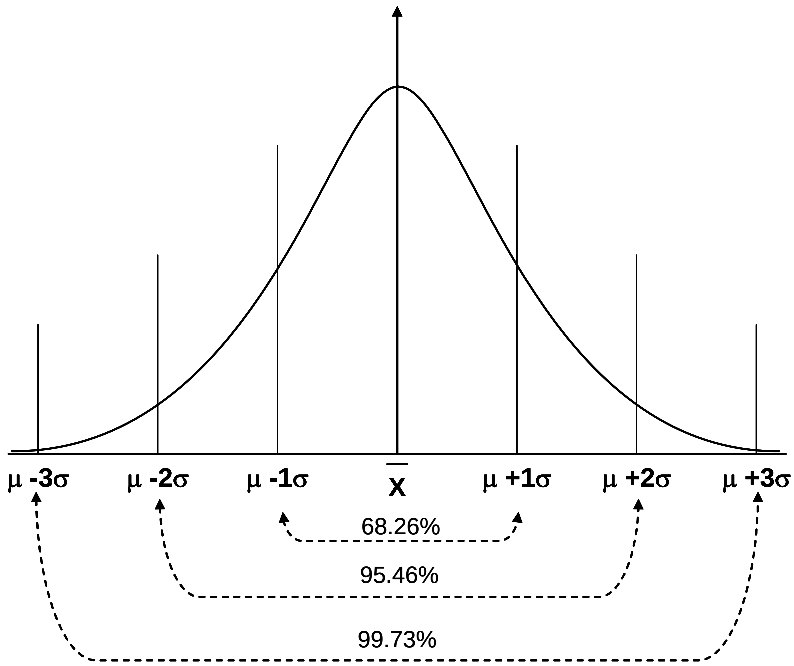
Appendix A

Exercises on Variation and Frequency Distribution

Review:

Normal Distribution follows the 68-95-99.7% Rule *(Empirical Rule)*

All normal density curves satisfy the following property which is often referred to as the *Empirical Rule*.



- **68.26%** of the observations fall within **1 standard deviation** of the **mean**.
- **95.46%** of the observations fall within **2 standard deviations** of the **mean**.
- **99.73%** of the observations fall within **3 standard deviations** of the **mean**.

Thus, for a normal distribution, almost all values lie within **3 standard deviations** of the mean.

RAW DATA – HEIGHTS OF 100 MALE STUDENTS
(in inches)

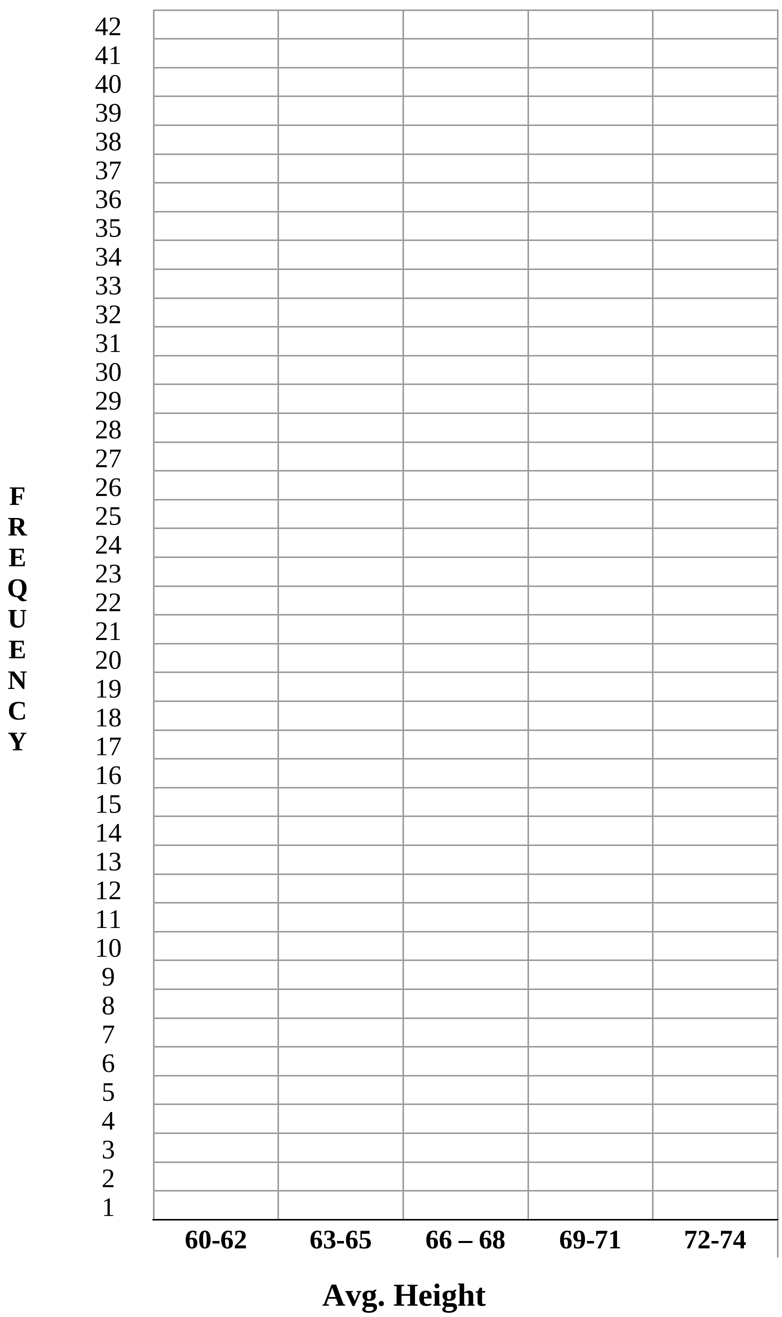
60	63	66	68
63	70	68	69
67	66	71	65
70	74	66	70
66	63	60	66
73	67	66	64
67	66	65	71
63	71	71	62
69	70	68	66
72	69	70	73
67	68	64	68
64	60	72	67
71	70	68	71
66	67	66	64
70	72	69	67
65	71	67	70
68	67	70	68
69	73	65	65
67	64	66	71
68	70	68	67
64	68	63	69
69	67	67	67
70	65	69	63
68	68	61	68

Frequency Distribution – Heights of 100 Male Students

Height in inches	Frequency
60 – 62	
63 – 65	
66 – 68	
69 – 71	
72 - 74	

CONSTRUCTING A HISTOGRAM

1. Determine the range of the data. Subtract the smallest data value from the largest data value. This result is the range.
2. Set up a **Frequency Tally Sheet** to record the number of times a data value occurs. The scale of the Tally Sheet should reflect the range of values.
3. Select a scale for the horizontal line of the histogram.
4. Select a scale for the vertical line of the histogram. It should be large enough to include the most frequently occurring value.
5. Plot the frequency of data values on the histogram.
6. If the range of the data is large, then the data can be grouped into classes. A good number of classes is 7 or 8. Those classes can then be used for the horizontal scale of the histogram.



Frequency Distribution – Dice Rolling Tally Sheet

2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	

HISTOGRAM - Dice Rolling

	18											
	17											
	16											
	15											
	14											
F	**13**											
R	**12**											
E	**11**											
Q	**10**											
U	**9**											
E	**8**											
N	**7**											
C	**6**											
Y	**5**											
	4											
	3											
	2											
	1											
		2	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

ROLL NUMBER