PIP Digest

Canadian Cancer Research Alliance
Alliance canadienne pour la recherche sur le cancer

Patient Involvement in Cancer Research Program
Programme de Participation des Patients à la recherche sur le cancer

RESEARCH STUDIES: Statistics 101

This PIP Digest uses a simple set of data to illustrate fundamental statistical concepts needed to interpret the results of cancer research studies.

Key concepts

- Measures of central tendency
- Statistical significance
- Correlation
- Clinical significance

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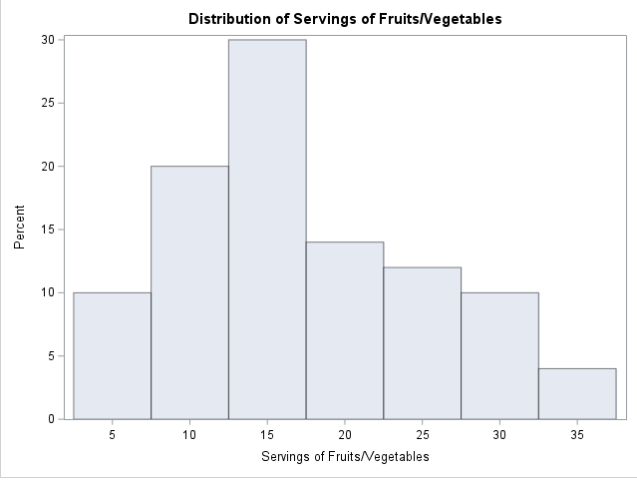
To help illustrate key statistical concepts, we use this hypothetical case study: A researcher investigates the effects of an education intervention to promote fruit and vegetable consumption among colorectal cancer survivors. She asks 100 survivors how many servings of fruits and vegetables they eat each week. Here is a graph (called a histogram) of her results:



Concept 1: Measures of Central Tendency

Researchers calculate what are called "**measures of central tendency"** to interpret this kind of data. Different types of measures offer different insights.

- The Mode is the most commonly occurring number on the graph—in the sample graph, the Mode is 15 servings per week
- The Median is the entry that is smaller than half the numbers, and larger than the other half — 20 in this graph.
- The Mean is the total number of servings divided by the number of respondents. In our sample case, the hundred respondents eat a total of 1,775 servings among them, which makes the Mean 17.75.

In some surveys, responses tend to be very similar, while in others they vary greatly. Statisticians divide the results into four equal parts to measure how variable the results are. This measurement is known as the Interquartile Range or IQR.

In addition to the IQR, researchers often also want to compute the **standard deviation** (SD) to see, for instance, the extent to which the weekly servings of fruits and vegetables vary (deviate) from the Mean. A higher SD indicates greater variety in how much people eat. These concepts are shown on the box and whisker plot shown on the following page.

Concept 2: Statistical Significance

In scientific papers and presentations, authors refer to **statistical significance**. Statistical significance assesses the likelihood of findings being due to chance. It uses probability (the *p*-value) to determine this likelihood.

Sometimes, researchers have access to data for an entire population (using census data, for example). Most studies, though, use smaller samples of a population of interest. I**nferential statistics** allow researchers to make inferences or deductions about the whole population, based on sample data from a smaller group. Inferential statistics indicate whether the relationships between variables in the sample group, could reasonably be considered to reflect the whole population.

Imagine the researchers randomly assigned 50 of the 100 survivors in our case study to participate in an educational intervention around eating fruits and vegetables. The educational intervention is known as the **independent variable** (the researcher controls whether participants receive or do not receive the intervention), while the **dependent variable** (weekly servings of fruits and vegetables) is what may be affected by the educational intervention.

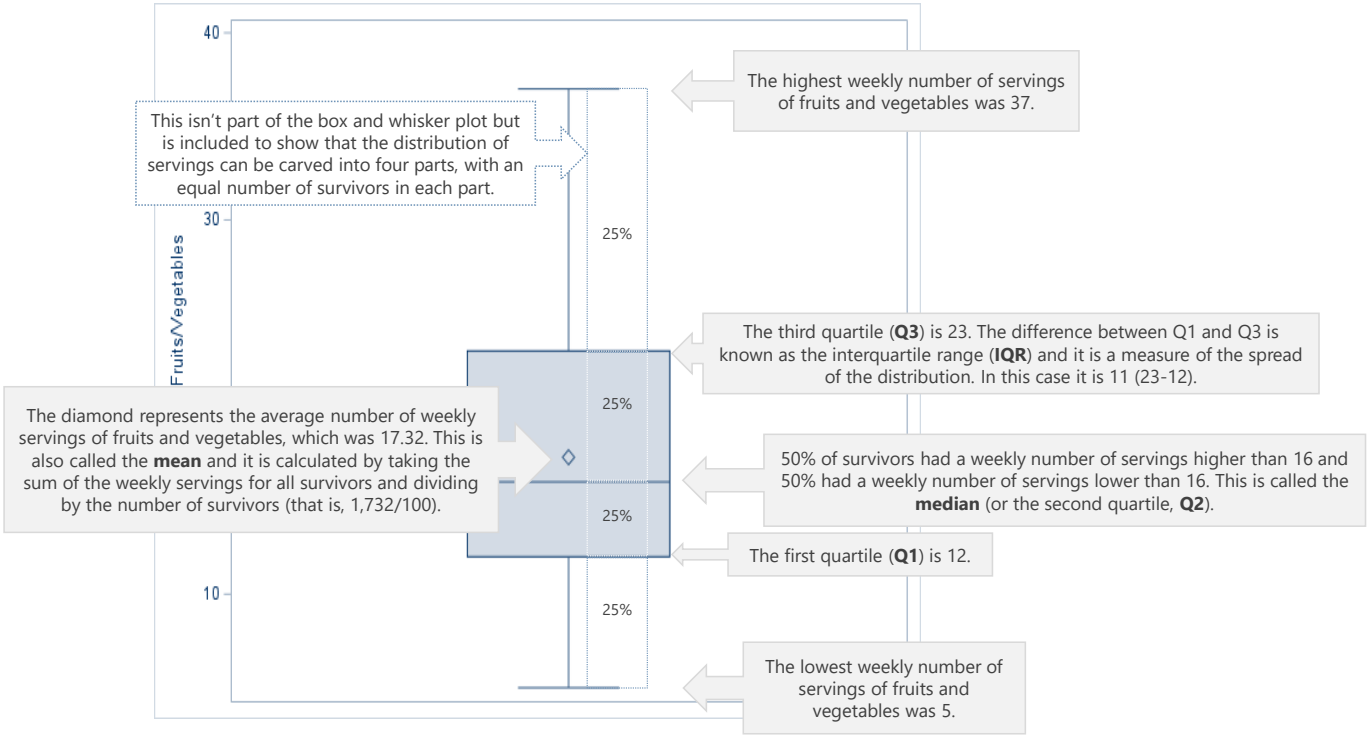
The researcher's **hypothesis** (H_1) is that survivors who participate in the educational intervention will increase their weekly consumption of fruits and vegetables compared to the others. The **null hypothesis** (H_0) is that there will be no difference in the fruit and vegetable consumption — the educational intervention will have no effect. The researcher finds the following results:

	Change in weekly fruit and vegetable consumption (Mean and SD)	95% Confidence Interval (Lower)	95% Confidence Interval (Upper)
Received educational intervention (n=50)	4.54 $\pm$ 1.20	4.20	4.88
No intervention (n=50)	-0.50 $\pm$ 0.51	-0.64	-0.36
p-value	<.01		

This table shows **confidence intervals** or CIs for short, which are used to indicate how certain the results are.[1] In this case, researchers expect that, were their study repeated with other groups of colorectal cancer survivors, mean changes in fruit and vegetable consumption would fall within the lower and upper CI estimates 95% of the time.

Researchers use a statistic called the t-test, which compares the means of two samples to see if they are statistically different from one another. The t-value was 27.40, which had a p-value of < .01, so the researcher can say that this result is statistically significant (usually a $p < .05$ is taken as a statistically significant result). This means that such a result could have occurred by chance only 1 time out of 100. She can be confident in rejecting H_0, the null hypothesis.

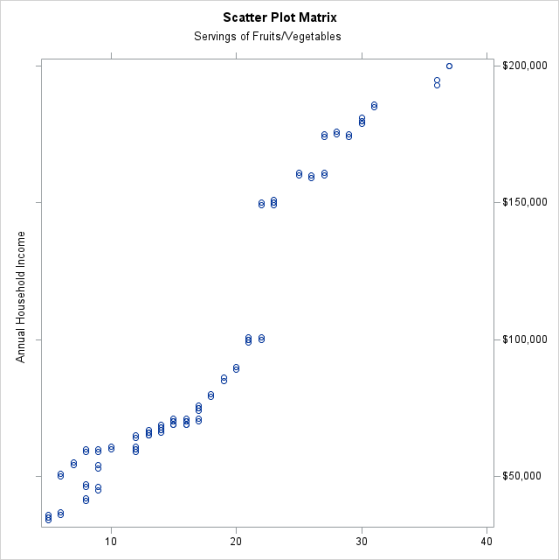
Researchers select a p-value in advance of conducting the study to represent how much of a difference they would expect between the intervention and control group results to be confident that the results represent a true, or statistically significant, difference. If the researcher repeats the study with another sample of patients (or even better, another researcher does this) and gets the same results, the researcher can be more confident in stating that the intervention has benefit.



[1]The confidence intervals are computed by adding (upper CI) or subtracting (lower CI) from the mean the calculation of (1.96 x (SD/√n)).

Concept 3: Correlation

The researcher also compared fruit and vegetables consumption to annual household income and found a positive correlation — which means those people with higher the incomes eat more fruits and vegetables. The graph below, a scatter plot, shows how annual household income (y-axis) correlates with fruit and vegetable consumption (x-axis).



Given this association, the researcher must ensure that differences between people receiving the educational intervention and those in the control group did not result from household income disparities between the two groups. Even though she randomly assigned participants, she must compare and report on other variables to ensure her results reflect the intervention and not a **confounder** — a variable like household income that could distort the results.

The results below show no income difference between the two groups. That means the researcher can be confident that her results related to the intervention.[2]

	Household Income (Mean and SD)	95% Confidence Interval (Lower, Upper)
Received educational intervention (n=50)	$95,000 ($50,559)	$80,631, $109,368
No intervention (n=50)	$95,040 ($50,679)	$80,637, $109,443

Concept 4: Clinical Significance

While the researcher's results are statistically significant, are they **clinically significant**? Statistical significance certainly informs a determination of clinical significance, but the two are not synonymous. An intervention may have been shown to be statistically significant but is so expensive or complex that it is not feasible to implement. Likewise, an

[2]Note that there are statistical methods that can be used to control for confounders, and those would likely be used in a study of this kind.

intervention may lack high statistical significance and still have some clinical relevance. While confidence intervals play a role in determining clinical significance, there are other approaches that are used to assess clinical significance.[3]

Conclusions about the merits of any intervention become better informed if the study could be replicated (preferably by another researcher) and, in this case, if the results of the intervention were found to have a long-lasting effect in terms of improving fruit and vegetable consumption.

Check out these short videos for more information:

- Dr Nic's Maths and Stats. *Understanding the p-value - Statistics Help*. (YouTube) October 31, 2011 [4:42 minutes] https://www.youtube.com/watch?v=eyknGvncKLw
  (Dr. Nic's entire series on Math and Stats at https://www.youtube.com/channel/UCG32MfGLit1pcqCRXyy9cAg may be useful for better understanding a broad range of statistical concepts.)
- BMC. *Statistical vs clinical significance: Are medical trials being misinterpreted?* (YouTube) June 28, 2017 [2:08 minutes] https://www.youtube.com/watch?v=vB-9QVbKNTY

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[3]For more, see Fethney J. (2010). Statistical and clinical significance, and how to use confidence intervals to interpret both. *Australian Critical Care*, 23(2):93-7. Available at: https://www.researchgate.net/profile/Judith_Fethney2/publication/42610049_Statistical_and_clinical_significance_and_how_to_use_confidence_intervals_to_help_interpret_both/links/5a00ef034585159634c128fb/Statistical-and-clinical-significance-and-how-to-use-confidence-intervals-to-help-interpret-both.pdf