

Quick Start Manual

PASS Power Analysis and Sample Size System

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Dr. Jerry L. Hintze
Kaysville, Utah**

PASS Quick Start Manual

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About This Manual

Congratulations on your purchase of the **PASS** package! **PASS** offers:

- Easy parameter entry.
- A comprehensive list of power analysis routines that are accurate and verified, yet are quick and easy to learn and use.
- Straightforward procedures for creating paper printouts and file copies of both the numerical and graphical reports.

Our goal is that with the help of this quick start manual, you will be up and running on **PASS** in less than one hour. **We recommend you read the first eight chapters first.** After that, you will only need to refer to the chapters corresponding to the procedures you want to use. The discussion of each procedure includes one or more tutorials or examples that will take you step-by-step through the tasks necessary to run the procedure.

I believe you will find that these user's guides provide a quick, easy, efficient, and effective way for new **PASS** users to get up and running.

I look forward to any suggestions you have to improve the usefulness of this manual and/or the **PASS** system. Meanwhile, good computing!

Jerry Hintze, President

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Dr. Jerry L. Hintze & NCSS, Kaysville, Utah

Preface

PASS (Power Analysis and Sample Size) is an advanced, easy-to-use statistical analysis software package. The system was designed and written by Dr. Jerry L. Hintze and other members of the development team over the last twenty years. Dr. Hintze drew upon his experience both in teaching statistics at the university level and in various types of statistical consulting.

The present version, written for 32-bit and 64-bit versions of Microsoft Windows (7, Vista, XP) computer systems, is the result of several iterations. Experience over the years with several different types of users has helped the program evolve into its present form.

NCSS maintains a website at www.ncss.com where we make the latest edition of **PASS** available for free downloading. The software is password protected, so only users with valid serial numbers may use this downloaded edition. We hope that you will download the latest edition routinely and thus avoid any bugs that have been corrected since you purchased your copy.

We believe **PASS** to be an accurate, exciting, easy-to-use program. If you find any portion which you feel needs to be changed, please let us know. Also, we openly welcome suggestions for additions and enhancements.

Verification

All calculations used in this program have been extensively tested and verified. First, they have been verified against the original journal article or textbook that contained the formulas. Second, they have been verified against second and third sources when these exist.

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Chapter 1

Installation

Before You Install

Minimum System Requirements

In order to run **PASS**, your computer must meet the following minimum standards.

| | |
|------------------------------|---|
| Processor: | 450 MHz or faster processor 32-bit (x86) or 64-bit (x64) processor |
| RAM: | 256 MB (512 MB recommended) |
| Operating Systems: | Windows XP with Service Pack 2 or higher Windows Vista Windows 7 or later Windows Server 2003 Windows Server 2008 Windows Server 2008 R2 or later |
| Privileges: | Administrative rights required during installation only |
| Third Party Software: | Microsoft .NET 3.5 SP1 (included with PASS CD, comes pre-installed with Windows 7 and Windows Server 2008 R2) or higher Microsoft Windows Installer 3.1 or higher Adobe Reader 7 or higher (required for the Help System only) |
| Hard Disk Space: | 120 MB for PASS (plus space for Microsoft .NET 3.5 SP1 if not already installed) |
| Printer: | Any Windows-compatible inkjet or laser printer |

Installing PASS

The installation procedure creates the necessary folders and copies the **PASS** program from the installation file. The files in the installation file are compressed, so the installation program decompresses these files as it copies them to your hard disk. During the installation wizard dialog, you will be able to choose the **PASS** installation location.

This section gives instructions for installing **PASS** on your computer system. You must use the **PASS** setup program to install **PASS**. The files are compressed, so you cannot simply copy the files to your hard drive.

1-2 Quick Start – Installation

Follow these basic steps to install **PASS** onto your computer system:

1. If you are installing from a CD, insert the CD in the disc drive on your computer. The installation program should start automatically. If it does not, use your file browser to explore the CD, locate the executable **PASS** setup file (ends with .exe), and run the file to start the installation. If you are installing from a download, simply run the downloaded installation file.
2. Once the setup starts, follow the instructions on the screen. **PASS** will be installed to the drive and folder you designate during the installation process.

If Something Goes Wrong During Installation

The installation procedure is automatic. If something goes wrong during installation, restart the installation procedure from the beginning. It may help to restart your computer before retrying the installation. If trouble persists, contact our technical support staff.

Starting PASS

PASS may be started using your keyboard or your mouse using the same techniques that you use to start any other Windows application. You can start **PASS** from your Start menu using standard mouse or keyboard operations. The installation procedure will also place a shortcut to **PASS** on your desktop for your convenience.

The first time you run **PASS**, enter your serial number in the pop-up window that appears when the program begins. After entering a serial number, the **PASS** Home window will appear.

Entering Your Serial Number

The first time you run **PASS**, enter your serial number in the pop-up window that appears. If you do not enter a serial number, you will be able to navigate among **PASS** windows, but none of the procedures will run and you will not be able to obtain output. If you would like to evaluate **PASS** procedures and reports, you must first obtain an evaluation serial number from NCSS. For more information about starting your trial or purchasing a license, visit <http://www.ncss.com>.

While in trial mode, **PASS** is fully-functional and gives you access to all procedures, reports, and graphics. You can enter a serial number anytime by going to the **Help** menu and choosing **Registration (Serial Number)**. Once you enter a purchased license serial number, the trial version will become the professional version. You do not need to reinstall **PASS**.

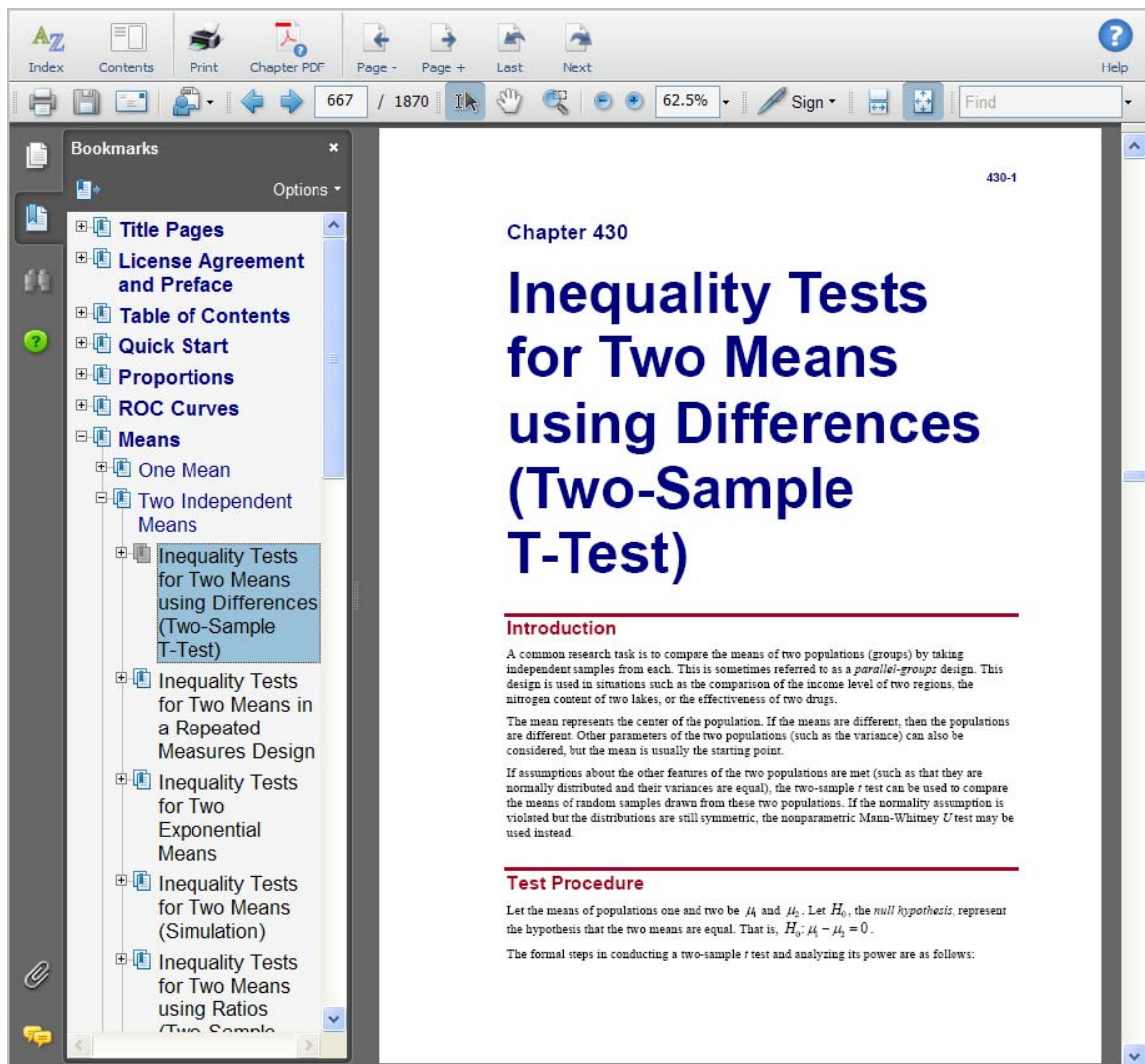
Updating PASS

NCSS periodically releases updates that fix bugs or provide enhancements to your current version of **PASS**. These updates are provided with all purchased licenses, free of additional charge. You can view the problems that each update fixes and download updates from our website, <http://www.ncss.com>. To determine whether you have the most recent update, click on **About** from the **Help** menu to find the current version and release date of your installed software. Compare this information to that of the updates available at our website.

Obtaining Help

The PASS Help System

To help you learn and use **PASS** efficiently, the material in this manual is included in the **PASS** Help System. The Help System is started from the Help menu or by clicking on the help icon on the right side of the toolbar. Adobe Acrobat or Adobe Reader version 7 or later is required to view the help system. You can download Adobe Reader for free by going to <http://www.adobe.com>. An Adobe Reader setup file is included in the *Utilities* folder on your **PASS** installation CD.



1-4 Quick Start – Installation

Navigating the Help System

There are a few key features of our help system that will let you use the help system more efficiently. We will now explain each of these features.

Index Window

The Index Window can be launched at any time by clicking on the Index button on the **PASS** Help System display window. The index allows you to quickly locate keywords and/or statistical topics. You can narrow the list of index entries displayed by selecting a specific topic category in the uppermost dropdown box.

Select a general topic category:

All

Type the first few letters of the word you are looking for:

Absolute deviation --- STANDARD DEVIATION ESTIMATOR

A B C D E F G H I K L M N O P Q R S T U V W Z

Double-click the index entry you want, or select the index entry and click "Display":

Absolute deviation --- STANDARD DEVIATION ESTIMATOR
Accrual time --- LOGRANK TESTS (LACHIN AND FOULKES)
Agreement between two raters --- PROPORTIONS - MANY - KAPPA TEST FOR AGREEMENT
Alias --- DESIGN OF EXPERIMENTS - TWO-LEVEL DESIGNS
All-contrasts power --- MULTIPLE CONTRASTS (SIMULATION)
All-pair power --- MULTIPLE COMPARISONS - PAIR-WISE (SIMULATION)
All-pair power --- MULTIPLE COMPARISONS - TREATMENTS VS CONTROL (SIMULATION)
Alpha - adjusting --- MEANS (QUICK START)
Alpha - simulation --- MULTIPLE COMPARISONS - PAIR-WISE (SIMULATION)
Alpha - simulation --- MULTIPLE COMPARISONS - TREATMENTS VS CONTROL (SIMULATION)
Alpha - simulation --- MULTIPLE CONTRASTS (SIMULATION)
Alpha spending function --- LOGRANK TESTS - GROUP-SEQUENTIAL
Alpha spending function --- MEANS - TWO - GROUP-SEQUENTIAL - INEQUALITY
Alpha spending function --- PROPORTIONS - TWO - GROUP-SEQUENTIAL - INEQUALITY
Alternative hypothesis --- INTRODUCTION TO POWER ANALYSIS (QUICK START)
Alternative hypothesis --- MEANS (QUICK START)
Analysis of variance --- ANALYSIS OF VARIANCE - FIXED EFFECTS
Analysis of variance --- ANALYSIS OF VARIANCE - ONE-WAY
Analysis of variance --- ANALYSIS OF VARIANCE - RANDOMIZED BLOCK
Analysis of variance --- ANALYSIS OF VARIANCE - REPEATED MEASURES
Analysis of variance --- MULTIPLE COMPARISONS

Show: ☐ Chapter Names Only ☐ Chapter Names After Index
☒ Chapter Names Before and After Index ☐ Chapter Names Before Index

Display Close

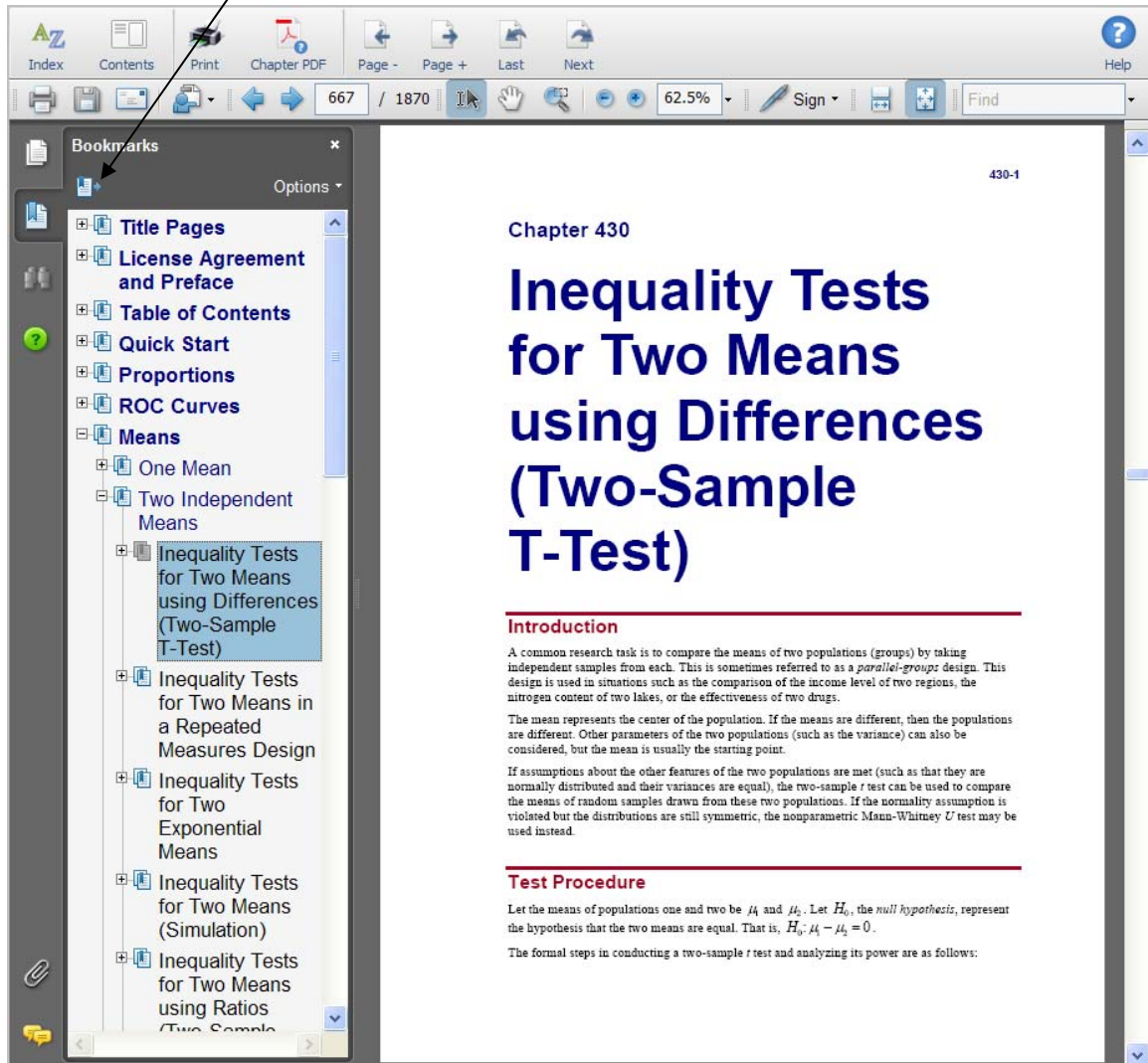
Index entries are displayed in the format

Index Entry --- CHAPTER or CHAPTER --- Index Entry.

You can control which entries are displayed by clicking on the radio buttons at the bottom of the window.

Contents Window

Clicking on the Contents button opens the Contents (Bookmarks) Window of the viewer. From this window you can expand the table of contents to view nested headings. You can click on the “Expand Current Bookmark” icon to instantly find the bookmark location for the currently-displayed page in the help document.



1-6 Quick Start – Installation

Search Window

To initiate a search of the help system for any word or phrase, type your search word(s) in the “Find” box in the viewer or click on the “Find” tab icon and enter a search term.

The screenshot displays a software interface with a search window on the left and a PDF document on the right. The search window, titled "Search", contains a text input field with the word "equivalence" entered. Below the input field are four checkboxes: "Whole words only" (checked), "Case-Sensitive", "Include Bookmarks", and "Include Comments". A "Search" button is located at the bottom of the search window. Below the search window are two links: "Use Advanced Search Options" and "Find a word in the current PDF". The PDF document on the right is titled "210-2 Non-Inferiority & Superiority Tests for Two Proportions". It contains text discussing the margin of equivalence and the statistical hypothesis to be tested. A table is provided for the 2-by-2 contingency table. The table has columns for Group, Success, Failure, and Total, and rows for Treatment, Control, and Totals. The text below the table discusses the binomial proportions p_1 and p_2 and the power of a test.

Index Contents Print Chapter PDF Page - Page + Last Next

338 / 1870 62.5% equivalence

Search

What word or phrase would you like to search for?

equivalence

☒ Whole words only

☐ Case-Sensitive

☐ Include Bookmarks

☐ Include Comments

Search

[Use Advanced Search Options](#)

[Find a word in the current PDF](#)

210-2 Non-Inferiority & Superiority Tests for Two Proportions

adopted if 69% respond? 68%? 65%? 60%? There is a percentage below 70% at which the difference between the two treatments is no longer considered ignorable. After thoughtful discussion with several clinicians, it was decided that if a response of at least 63% were achieved, the new treatment would be adopted. The difference between these two percentages is called the *margin of equivalence*. The margin of equivalence in this example is 7%.

The developers must design an experiment to test the hypothesis that the response rate of the new treatment is at least 0.63. The statistical hypothesis to be tested is

$$H_0: p_1 - p_2 \leq -0.07 \text{ versus } H_1: p_1 - p_2 > -0.07$$

Notice that when the null hypothesis is rejected, the conclusion is that the response rate is at least 0.63. Note that even though the response rate of the current treatment is 0.70, the hypothesis test is about a response rate of 0.63. Also notice that a rejection of the null hypothesis results in the conclusion of interest.

Technical Details

The details of sample size calculation for the two-sample design for binary outcomes are presented in the chapter "Two Proportions Non-Null Case," and they will not be duplicated here. Instead, this chapter only discusses those changes necessary for non-inferiority and superiority tests.

Approximate sample size formulas for non-inferiority tests of two proportions are presented in Chow et al. (2003), page 90. Only large sample (normal approximation) results are given there. The results available in this module use exact calculations based on the enumeration of all possible values in the binomial distribution.

Suppose you have two populations from which dichotomous (binary) responses will be recorded. Assume without loss of generality that the higher proportions are better. The probability (or risk) of cure in population 1 (the treatment group) is p_1 and in population 2 (the reference group) is p_2 . Random samples of n_1 and n_2 individuals are obtained from these two populations. The data from these samples can be displayed in a 2-by-2 contingency table as follows

| Group | Success | Failure | Total |
|-----------|----------|----------|-------|
| Treatment | x_{11} | x_{12} | n_1 |
| Control | x_{21} | x_{22} | n_2 |
| Totals | m_1 | m_2 | N |

The binomial proportions, p_1 and p_2 , are estimated from these data using the formulae

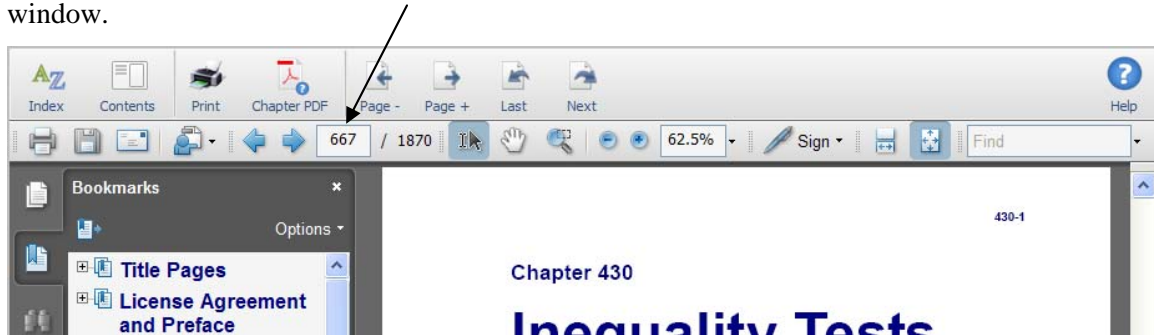
$$\hat{p}_1 = \frac{a}{m} = \frac{x_{11}}{n_1} \text{ and } \hat{p}_2 = \frac{b}{n} = \frac{x_{21}}{n_2}$$

Let $p_{1,0}$ represent the group 1 proportion tested by the null hypothesis, H_0 . The power of a test is computed at a specific value of the proportion which we will call $p_{1,1}$. Let δ represent the smallest difference (margin of equivalence) between the two proportions that still results in the conclusion that the new treatment is not inferior to the current treatment. For a non-inferiority test, $\delta < 0$. The set of statistical hypotheses that are tested is

$$H_0: p_{1,0} - p_2 \leq \delta \text{ versus } H_1: p_{1,0} - p_2 > \delta$$

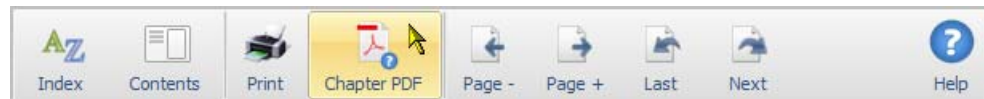
Printing the Documentation

To print pages from the documentation, click on the **Print** button on the **PASS** Help System toolbar. This will launch the print dialogue screen. You can choose to print a single page or a range of pages from the help file. When entering page numbers, remember to use the actual PDF file page numbers (e.g., 667-670) and not the page numbers found in the document pages (e.g., 430-1 to 430-4 is not a valid page range). The actual page numbers can be seen in the viewer window.

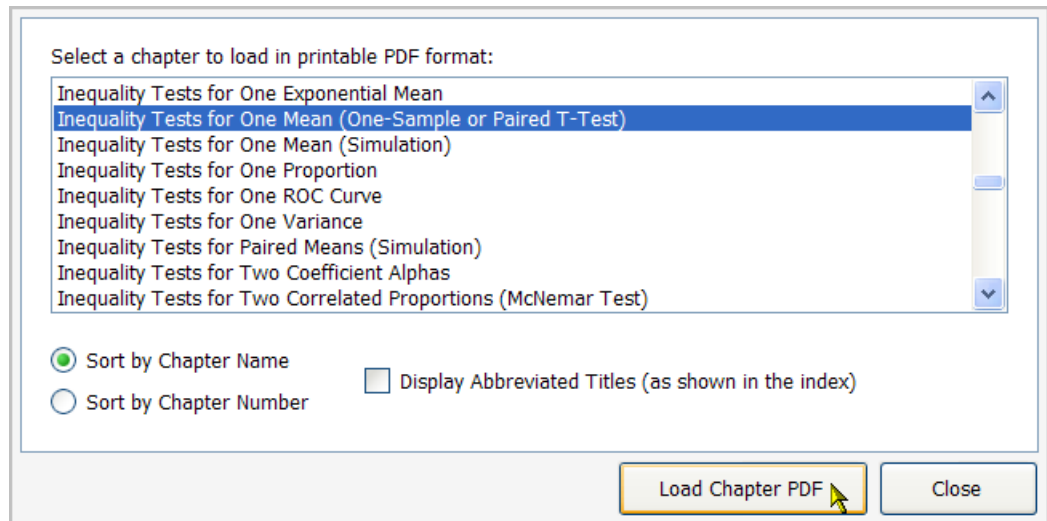


One of the benefits of the **PASS** Help System is the ease with which you can print any chapter or topic from the electronic help manual. To print a single chapter or topic using your default PDF viewer, take the following steps:

1. Click on the **Chapter PDF** icon in the **PASS** Help System toolbar.



2. Choose the chapter you would like to print from the list and click **Load Chapter PDF**. This will launch the individual chapter PDF in a separate window using your default PDF viewer (e.g., Adobe Reader).



3. Use the **Print** function of your PDF viewer to print the entire chapter or individual pages from the chapter.

1-8 Quick Start – Installation

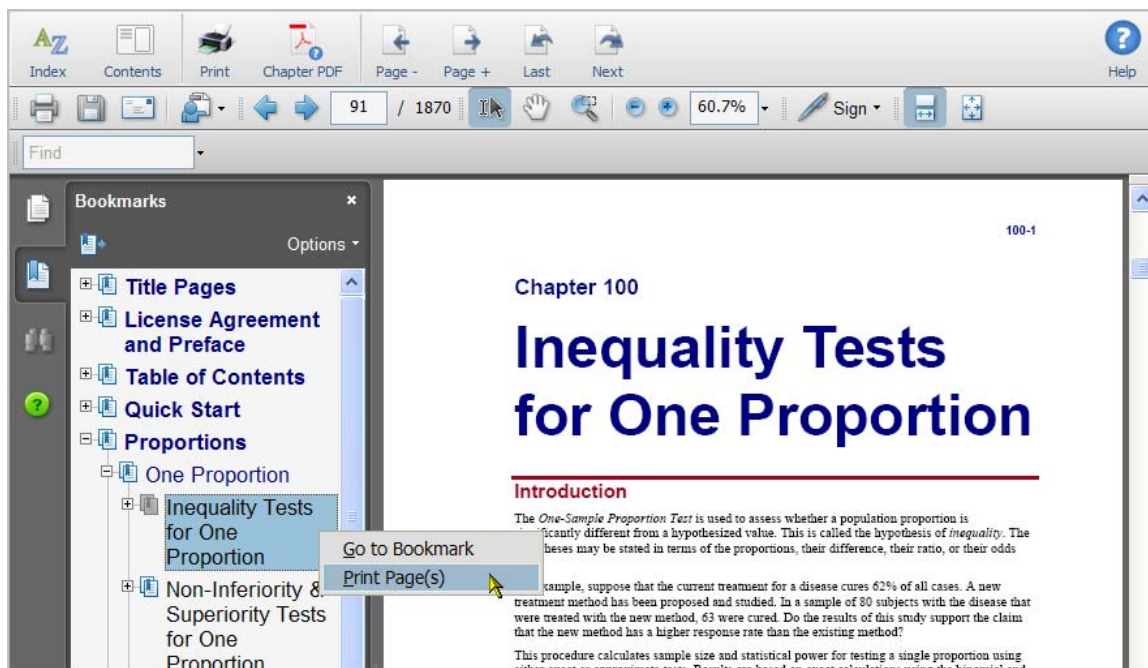
If you have Adobe Reader 8 or later, you can print entire chapters using an alternative method as follows (**This will not work with Adobe Reader 7**):

1. Open the Contents (Bookmarks) Window by clicking on the **Contents button** at the top of the **PASS Help System** display window.



2. Expand the bookmarks to display the chapter or topic name you wish to print (e.g., the Two-Sample T-Test Chapter). Then, **highlight** the chapter name, **right-click** on the highlighted selection (or select Options in the panel above), and select **Print Page(s)**. This will automatically print only the pages from the selected chapter.

CAUTION: When you click Print Page(s), the command is sent to the printer automatically without any intermediate Print Setup window being displayed. Make sure that you have selected only the topic you want before clicking Print Page(s).



If you do not want to print the entire chapter, continue to expand the bookmark tree to the topic you wish to print before completing step 2. The Print Page(s) command prints all pages containing bookmarks that are nested within the highlighted bookmark.

Technical Support

If you have a question about **PASS**, you should first look to the printed documentation and the included Help system. If you cannot find the answer there, look for help on the web at www.ncss.com/support.html. If you are unable to find the answer to your question by these means, contact NCSS technical support for assistance by calling (801) 546-0445 between 8 a.m. and 5 p.m. (MST). You can contact us by email at support@ncss.com or by fax at (801) 546-3907. Our technical support staff will help you with your question.

If you encounter problems or errors while using **PASS**, please view our list of recent corrections before calling by going to our website to find out if your problem or error has been corrected by an update. If updating your software does not correct the problem, contact us by phone or email.

To help us answer your questions more accurately, we may need to know about your computer system. Please have pertinent information about your computer and operating system available. You can obtain system information from the **Help** menu by choosing **About** and then clicking on the **System Info** button.

Chapter 2

Running PASS

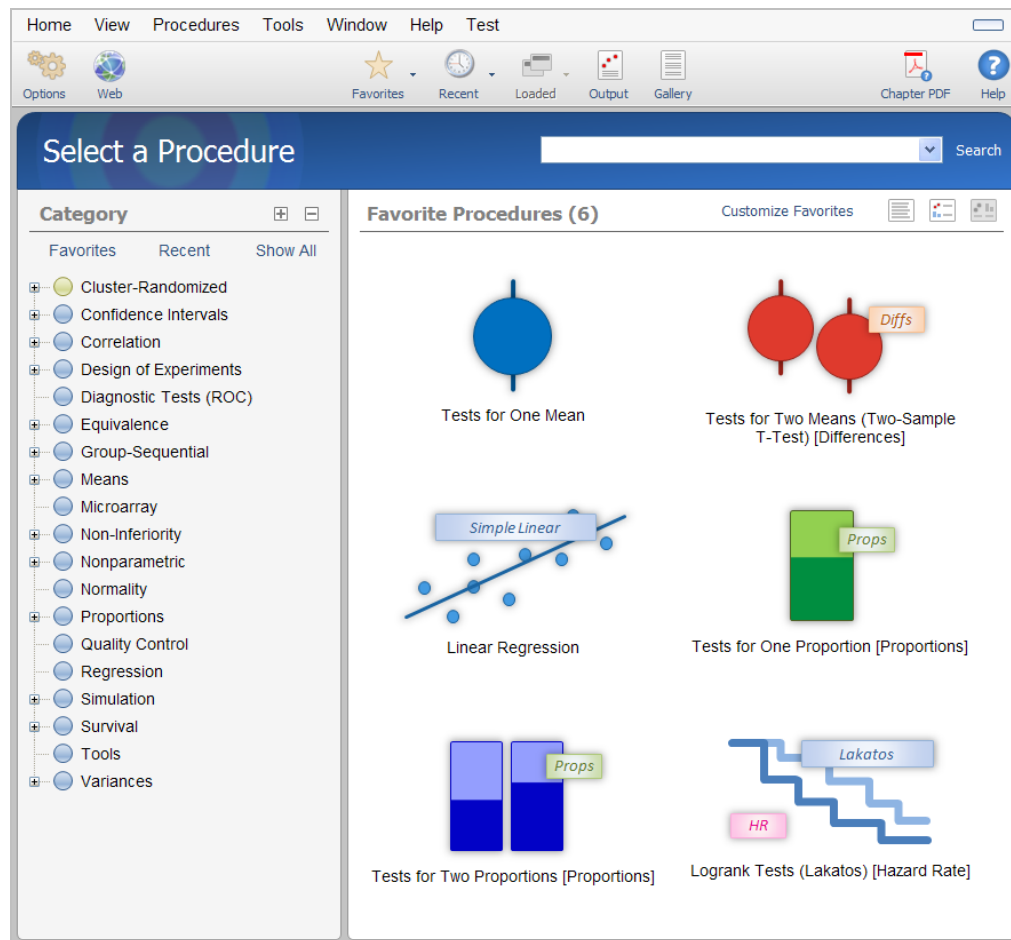
About This Chapter

This chapter will show you how to start up and run a power analysis of the two-sample t test. It will give you a brief introduction to the windows used in **PASS**: the *PASS Home* window, the *Procedure* window, and the *Output* window.

Starting PASS

To start **PASS**, select the shortcut from the Windows Start menu or double-click the shortcut icon on your desktop. If you are licensed for **PASS**, the following PASS Home window will appear.

PASS Home



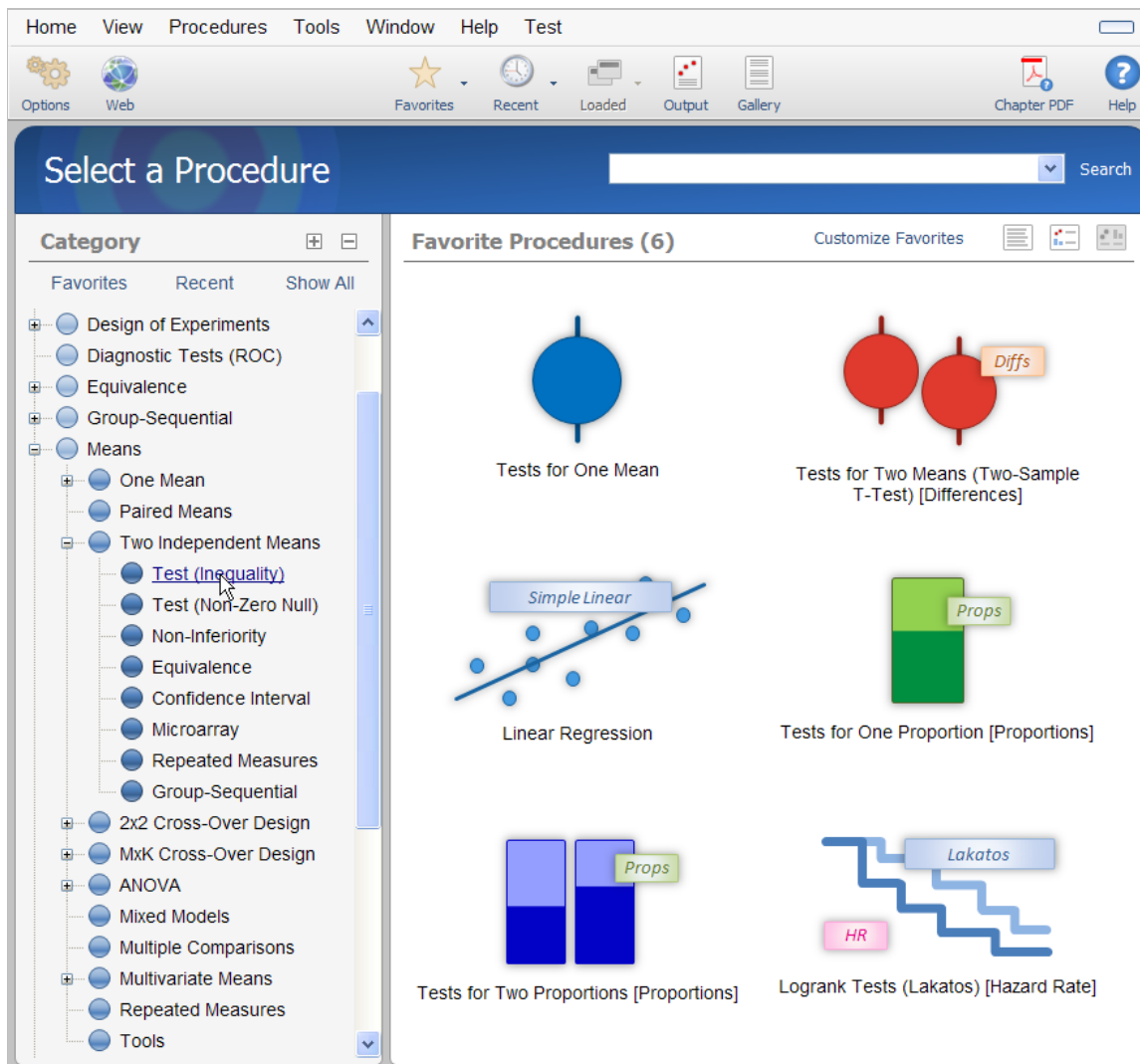
2-2 Quick Start – Running PASS

This window gives you access to all of the **PASS** procedures. Clicking on the plus sign or double-clicking on a phrase will expand the list so that you can see the procedures in that group. To load a specific procedure window, double-click on it or highlight it and click the Load button.

Loading a Procedure

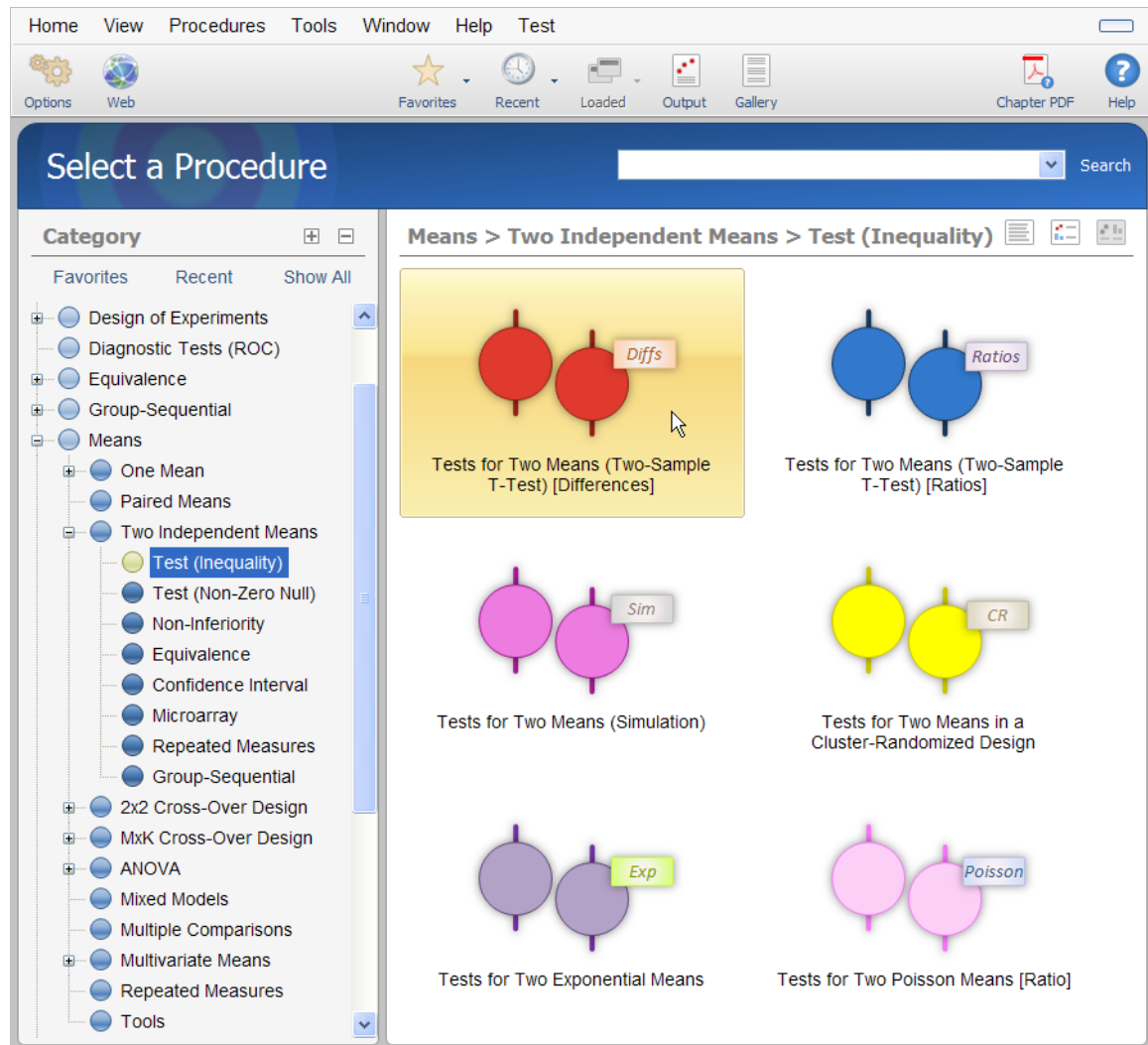
The *Two-Sample T-test* is a procedure to test the inequality of two means from independent samples. Take the following steps to load this procedure. Expand the Means clicking the + next to the word **Means**. Then expand **Two Independent Means**, and then click on **Test (Inequality)**.

PASS Home



The top left button is **Tests for Two Means (Two-Sample T-Test) [Differences]**. Click this button.

PASS Home



The **Tests for Two Means (Two-Sample T-Test) [Differences]** procedure window will appear. Procedure windows let you specify parameters, load and save templates, and run the analyses.

Entering Parameters and Running the Procedure

We will run a power analysis using the default values except that the value of **Mean2** will be **2** and the value of **S1** will be **3**.

Tests for Two Means (Two-Sample T-Test) [Differences]

1. Click the **Reset** button to set all options to their default values.

2. Click in the box next to **Mean2**.

3. Enter **2**.

4. Click in the box next to **S1**.

5. Enter **3**.

6. Click the **Run** button to run the procedure

File View Run Procedures Tools Window Help

Reset Open Save As Home Favorites Recent Loaded Output Gallery Chapter PDF Help

Run

Data

Solve For

Find (Solve For): Power and Beta

Error Rates

Power (1-Beta): 0.90

Alpha (Significance Level): .05

Sample Size

N1 (Sample Size Group 1): 5 to 45 by 10

N2 (Sample Size Group 2): Use R

R (Sample Allocation Ratio): 1.0

Effect Size

Means

Mean1 (Mean of Group 1): 0

Mean2 (Mean of Group 2): 1

Standard Deviations

S1 (Standard Deviation Group 1): 1

S2 (Standard Deviation Group 2): S1

☐ Known Standard Deviations

Test

Alternative Hypothesis: Ha: Mean1 ≠ Mean2

Nonparam. Adj. (M-W Test): Ignore

Find (Solve For)

Select the parameter to be solved for in terms of the other parameters.

Note

This parameter will be displayed on the vertical axis of the plot(s).

Procedure: 110
Name: M2D
Option: 1

Guide Me: Start

Viewing the Output

The Output window displays the output of the power analysis. It allows you to view, edit, save, and print your output. You may want to scroll down to view the graph at the end of the report.

When you are finished, you can quit **PASS** by selecting **Exit PASS** from the Home menu.

PASS Output

The screenshot shows the PASS software interface. The top menu bar includes File, View, Edit, Window, and Help. Below the menu is a toolbar with icons for Save As, Print, Copy, Find, Add Output to Gallery, Auto Add, Home, Favorites, Recent, Loaded, Gallery, Chapter PDF, and Help. The left pane is titled 'Navigation Pane' and contains a tree view with the following items: Two-Sample T-Test Power Analysis, Numeric Results, References, Report Definitions, Summary Statements (selected), and Chart Section. The main window displays the output for 'Two-Sample T-Test Power Analysis'. The output includes the date and time (9/16/2010 10:08:31 AM), the title 'Two-Sample T-Test Power Analysis', the null hypothesis (Mean1=Mean2), the alternative hypothesis (Mean1≠Mean2), and a note that standard deviations were assumed to be unknown and equal. A table of numeric results follows, showing Power, N1, N2, Allocation, Ratio, Alpha, Beta, Mean1, Mean2, S1, and S2. Below the table are sections for References, Report Definitions, and Summary Statements. The bottom status bar shows 'Page: 1 of 2', 'Page: 1', 'View: 1', 'Fit: 1', and a zoom level of 57%.

9/16/2010 10:08:31 AM 1

Two-Sample T-Test Power Analysis

Null Hypothesis: Mean1=Mean2. Alternative Hypothesis: Mean1≠Mean2
The standard deviations were assumed to be unknown and equal.

| Power | N1 | N2 | Allocation | Ratio | Alpha | Beta | Mean1 | Mean2 | S1 | S2 |
|---------|----|----|------------|---------|---------|------|-------|-------|-----|-----|
| 0.15367 | 5 | 5 | 1.000 | 0.05000 | 0.84613 | 0.0 | 2.0 | 3.0 | 3.0 | 3.0 |
| 0.42206 | 15 | 15 | 1.000 | 0.05000 | 0.57794 | 0.0 | 2.0 | 3.0 | 3.0 | 3.0 |
| 0.63673 | 25 | 25 | 1.000 | 0.05000 | 0.36327 | 0.0 | 2.0 | 3.0 | 3.0 | 3.0 |
| 0.78504 | 35 | 35 | 1.000 | 0.05000 | 0.21486 | 0.0 | 2.0 | 3.0 | 3.0 | 3.0 |
| 0.87852 | 45 | 45 | 1.000 | 0.05000 | 0.12148 | 0.0 | 2.0 | 3.0 | 3.0 | 3.0 |

References
Meehin, D., Campbell, M., Fayers, P., and Pinol, A. 1997. Sample Size Tables for Clinical Studies, 2nd Edition. Blackwell Science, Malden, MA.
Zar, Jerrold H. 1984. Biostatistical Analysis (Second Edition). Prentice-Hall, Englewood Cliffs, New Jersey.

Report Definitions
Power is the probability of rejecting a false null hypothesis. Power should be close to one.
N1 and N2 are the number of items sampled from each population. To conserve resources, they should be small.
Alpha is the probability of rejecting a true null hypothesis. It should be small.
Beta is the probability of accepting a false null hypothesis. It should be small.
Mean1 is the mean of populations 1 and 2 under the null hypothesis of equality.
Mean2 is the mean of population 2 under the alternative hypothesis. The mean of population 1 is unchanged.
S1 and S2 are the population standard deviations. They represent the variability in the populations.

Summary Statements
Group sample sizes of 5 and 5 achieve 15% power to detect a difference of -2.0 between the null hypothesis is that both group means are 0.0 and the alternative hypothesis is that the mean of group 2 is 2.0 with estimated group standard deviations of 3.0 and 3.0 and with a significance level (alpha) of 0.05000 using a two-sided two-sample t-test.

Page: 1 of 2 Page: 1 View: 1 Fit: 1 57%

2-6 Quick Start – Running PASS

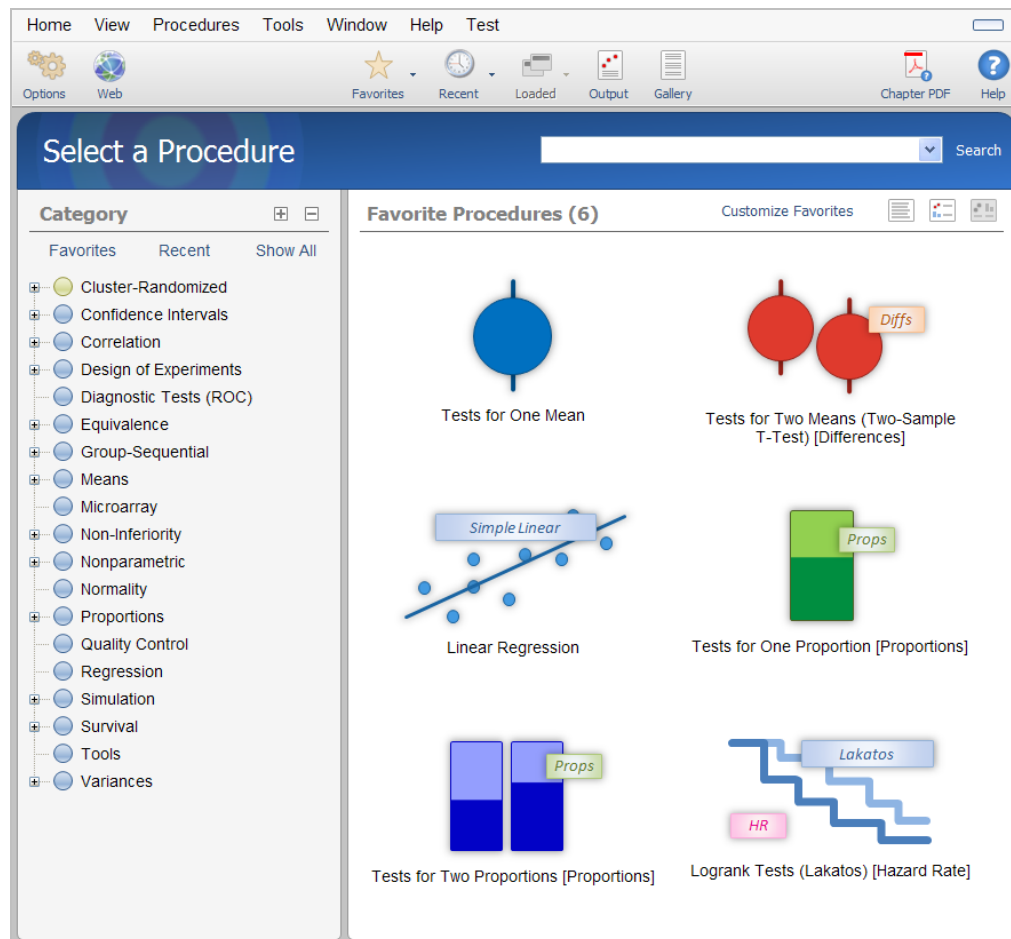
Chapter 3

The PASS Home Window

Introduction

The **PASS** Home window lets you quickly and easily find the appropriate procedure to be loaded.

PASS Home



Procedure categories and subcategories are given on the left. Clicking on any category or subcategory gives a list of all procedures in that category or subcategory. The list of procedures can be shown as large buttons, medium tile buttons, or small list buttons. Favorite procedures and

3-2 Quick Start – The PASS Home Window

recently run procedures can be shown by clicking on the respective buttons. Procedures may also be found by entering keywords and clicking on Search.

Using the PASS Home Window

The **PASS** Home window was designed to be easy to use. The window has a set of menus, a toolbar, and a large display area. On the left side of the display area is an outline list of the major categories of procedures in **PASS**. The right side displays the procedures corresponding to the chosen category or the results of the search.

Menus

Most of the selections available in the menus are also available through the toolbar buttons and other buttons.

Home Menu

This menu is used to view or change system options or to exit **PASS**.

Options

A System Options window is opened. This window gives general options about the appearance of the reports, calculation constants, default spreadsheet numbers, whether power or beta is the primary input, and other minor options.

Exit PASS

This option closes the PASS Home window and exits **PASS**.

View Menu

This menu is used to change the appearance of the procedure buttons or to expand and collapse the tree of procedure categories.

Procedures Menu

The procedure menu allows you to quickly find and load **PASS** power analysis procedures.

Tools Menu

The tools menu contains links to various **PASS** utilities.

Window Menu

This menu allows you to open other windows in the **PASS** system such as the the Output window, the Output Spreadsheet, or recent, favorite, or currently loaded procedures.

Help Menu

This menu allows you to view the **PASS** Help System, modify your serial number, get information about the program and load various portions of the printable PDF documentation.

Toolbar

The toolbar gives you one-click access to several of the menu items. Notes about each button are displayed when the mouse is held over the button for a few seconds.



Options. This button opens the System Options window.

Web. This button sends the user to the support web site.

Favorites. This drop-down button shows a list of procedures that have been added to the favorites list.

Recent. This drop-down button shows a list of procedures that have been recently run.

Loaded. This drop-down button shows a list of procedures that are currently loaded.

Output. This takes the user to the primary output window.

Gallery. This takes the user to window with output that has been sent from the primary output window.

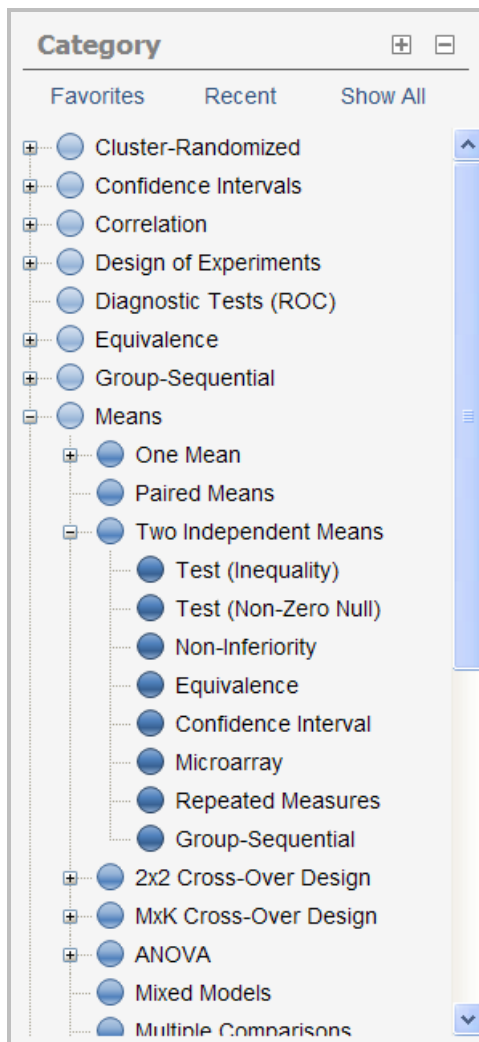
Chapter PDF. This opens the PASS Home Window chapter (this chapter) as an individual PDF.

Help. This opens the PASS Help System and goes to the current topic.

Category Tree

The Category Tree expands and contracts as you either click on a plus or minus sign at the left. This gives you quick, intuitive access to all of the procedures in **PASS**. Procedures are not selected here directly, but instead a category is chosen. When you click on a category or subcategory, all the procedures corresponding to that category or subcategory are displayed to the right.

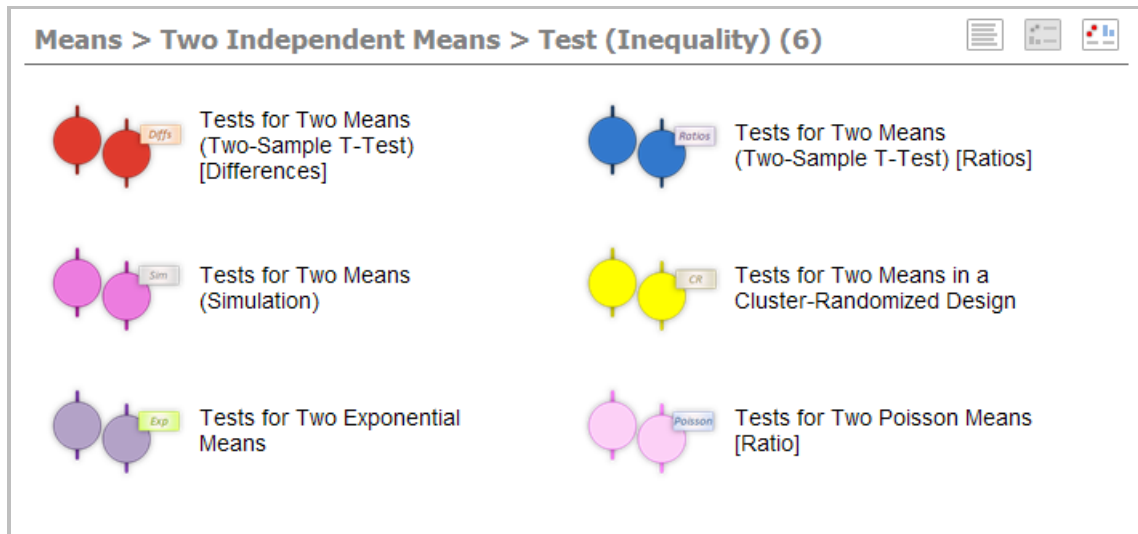
The plus and minus buttons at the top right can be used to expand and contract the entire tree, respectively.



The Favorites, Recent, and Show All buttons can be used to display the corresponding procedures in the box on the right.

Procedure List

The procedure list shows all the procedures corresponding to the selected category or all the procedures with keywords matching those of the search. The procedure list below is the result of clicking on the Test (Inequality) node of the Two Independent Means branch of the Means root of the Category Tree.



The number in parentheses shows the number of procedures in the group. The three buttons on the top right are used to change the view of the list of procedures. The left button gives a list, the middle button gives tiles (above), and the right button gives large buttons.

The procedure is loaded by a single-click on the procedure button. The user can right-click the procedure button to load the procedure, add or remove the procedure to/from the favorites list, or to view the PDF documentation for the procedure.

Search for a Procedure

The search bar is used to find a procedure. The program contains a list of key words for each procedure. As you type a key word in the search bar, a list of words will be generated below the bar. The down arrow or the mouse can be used to select these words, or the word(s) can be typed.



When the desired search words are in the box, the Search button is pressed to generate a list of procedures corresponding to the words. These procedures can be viewed or opened as described in the Procedure List section above.

3-6 Quick Start – The PASS Home Window

Chapter 4

The Procedure Window

Introduction

All **PASS** procedures are controlled by a *procedure* window that contains all of the settings, options, and parameters that determine the input and output of the program. These options are separated into groups called *panels* or *tabs*. A particular panel is viewed by pressing the corresponding tab that appears at the left side of the window. For example, in the window below, the Data panel is active. Other common panels include Reports and Plot Setup.

Tests for Two Means (Two-Sample T-Test) [Differences]

The screenshot displays the PASS Procedure Window for the 'Tests for Two Means (Two-Sample T-Test) [Differences]' procedure. The window is organized into several panels and sections:

- Top Menu Bar:** File, View, Run, Procedures, Tools, Window, Help.
- Top Toolbar:** Reset, Open, Save As, Home, Favorites, Recent, Loaded, Output, Gallery, Chapter PDF, Help.
- Left Panel:** Contains tabs for Data (selected), Iterations, Reports, and Plot Setup. A 'Run' button is also present.
- Main Content Area:**
 - Data Panel:**
 - Solve For:** Find (Solve For): Power and Beta.
 - Error Rates:** Power (1-Beta): 0.90; Alpha (Significance Level): .05.
 - Sample Size:** N1 (Sample Size Group 1): 5 to 45 by 10; N2 (Sample Size Group 2): Use R; R (Sample Allocation Ratio): 1.0.
 - Effect Size:**
 - Means:** Mean1 (Mean of Group 1): 0; Mean2 (Mean of Group 2): 1.
 - Standard Deviations:** S1 (Standard Deviation Group 1): 1; S2 (Standard Deviation Group 2): S1. A checkbox for 'Known Standard Deviations' is present.
 - Test:** Alternative Hypothesis: Ha: Mean1 ≠ Mean2; Nonparam. Adj. (M-W Test): Ignore.
 - Find (Solve For) Panel:** Select the parameter to be solved for in terms of the other parameters. A note states: 'This parameter will be displayed on the vertical axis of the plot(s).' A 'Guide Me' button is at the bottom.
- Bottom Left:** Procedure: 110; Name: M2D; Option: 1. A button 'Add This Procedure to Favorites List' is also visible.

4-2 Quick Start – The Procedure Window

The values of all options available for a procedure are referred to as a *template*. A template may be stored for future use in a *template file*. By creating and saving template files (often referred to as *templates*), you can tailor each procedure to your own specific needs. Each time you use a procedure, you simply load your template and run the analysis you have preset. You do not have to set all the options every time. The specific operations needed to do this are shown later.

At most six procedure windows can be opened at a time. You can widen the window to increase the size of the immediate help window by dragging the corners of the window.

Default Template

Whenever you close a procedure, the current settings are automatically saved in a default template file. This template file is automatically loaded when the procedure is next opened.

Procedure Window Anatomy

This section explains the various objects found on the procedure window.

Menus. The menus allow you to open/save templates, go to other windows, get help, etc.

Run. Clicking this button runs the program and generates output.

Options. These fields set values that control the analysis.

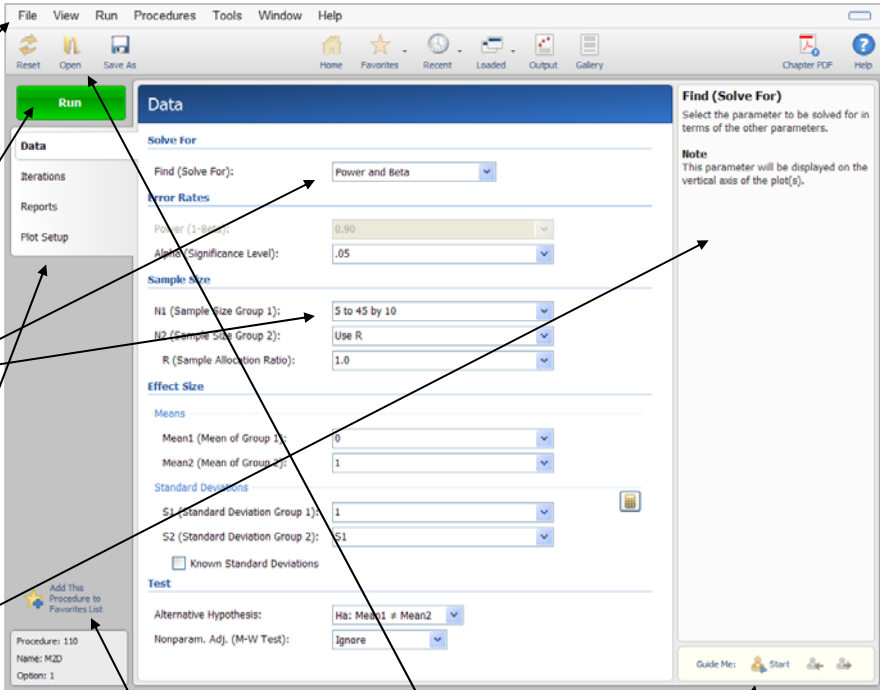
Tabs. These let you view different groups of options analysis.

Immediate Help. This box displays a brief help message about the field over which the mouse is currently positioned.

Add Procedure to Favorites. This button adds this procedure to the favorites list for easy access later.

Reset, Open, Save As. These buttons are used to set or save a group of options for the whole procedure at once. A group of saved options is called a template.

Guide Me. These buttons instruct the program to step you through the main options that must be set for an analysis.



Menus

The menus provide a convenient way to transfer from module to module within the **PASS** system. Each set of menus will be briefly described here.

File Menu

The File Menu is used for initializing, loading, and saving a file of a template. Each set of options for a procedure, called a *template*, may be saved for future use. In this way, you do not have to set the options every time you use a procedure. Instead, you set the options the first time, save them as a template, and re-use the template whenever you re-use the procedure.

New Template (Reset)

This menu item resets all options to their default values. It performs the same function as the Reset button.

Open Template

This option is used to open an existing template file that has been saved by the user.

Open Example Template

This option is used to open an example template file that corresponds to one of the examples at the end of each chapter.

Save Template As

This option is used to name and save a template file of the current options to the location of your choice.

Options

A System Options window is opened. This window gives general options about the appearance of the reports, calculation constants, default spreadsheet numbers, whether power or beta is the primary input, and other minor options.

Close Procedure

This option closes this procedure window.

Exit PASS

This option terminates the **PASS** system. Before using this option, you should save all templates and output documents that you want to keep.

View Menu

This menu controls two viewing aspects of the procedure window.

Show/Hide Toolbar

This option controls whether the toolbar is shown.

Show/Hide Procedure Info

This option controls whether a box is shown in the bottom left corner giving the procedure number, procedure short name, and the option number when each option is moused over.

Run Menu

This menu controls the execution of the program.

Run Procedure

The Run Procedure option runs the analysis, displaying the output in the Output document.. After you have set all options to their appropriate values, select this option to perform the analysis.

Note that the procedure may also be run by pressing the green run button.

Procedures and Tools Menus

These menus allow you to transfer to various **PASS** procedures and utilities.

Window Menu

This menu lets you display any of the other windows in the **PASS** system that are currently open such as the Output window, the Output Spreadsheet window, the PASS Home window, or favorite, recent, or currently open procedure windows.

PASS Home

Select this option to display the PASS Home window.

Output

Select this option to display the output window.

Output Gallery

Select this option to display the output gallery window.

Output Spreadsheet

Select this option to display the output spreadsheet.

Favorite Procedures

Select this option to display a list of the procedure that have been added to the favorites list.

Recent Procedures

Select this option to display a list of the recently run procedures.

Currently Loaded Procedures

The last menu options contain the procedures that are currently open.

Help Menu

This menu gives you access to the **PASS** Help System and PDF documentation, including references and the Quick Start Manual. This menu also gives the citation information for PASS and access to the website and other support information.

Toolbar

The toolbar is a series of buttons that appear just below the menus at the top of the procedure window. Each of these buttons provides quick access to a menu item.



Reset. This button sets all parameters to their default values.

Open. This button opens an open file window so you can load a saved template.

Save As. This button is used to name and save a template file of the current options to the location of your choice.

Home. This button brings the PASS Home Window to the front.

Favorites. This drop-down button shows a list of procedures that have been added to the favorites list.

Recent. This drop-down button shows a list of procedures that have been recently run.

Loaded. This drop-down button shows a list of procedures that are currently loaded.

Output. This takes the user to the primary output window.

Gallery. This takes the user to window with output that has been sent from the primary output window.

Chapter PDF. This opens the chapter for the current procedure as an individual PDF.

Help. This opens the PASS Help System and goes to the current topic.

Procedure Window Tabs

The procedure window contains several sets of options on panels (or tabs). Each panel is displayed by clicking on the appropriate tab. We will now describe the purpose and operation of each tab.

Data Tab

The Data tab displays most of the options specific to the procedure. This is where you set the values of power, sample size, alpha, etc. These options are described in detail in the chapters corresponding to each procedure. Once you have set the options, click the **Run** button to generate the output.

Run

Data

Iterations

Reports

Plot Setup

Data

Solve For

Find (Solve For): Power and Beta

Error Rates

Power (1-Beta): 0.90

Alpha (Significance Level): .05

Sample Size

N1 (Sample Size Group 1): 5 to 45 by 10

N2 (Sample Size Group 2): Use R

R (Sample Allocation Ratio): 1.0

Effect Size

Means

Mean1 (Mean of Group 1): 0

Mean2 (Mean of Group 2): 2

Standard Deviations

S1 (Standard Deviation Group 1): 3

S2 (Standard Deviation Group 2): S1

☐ Known Standard Deviations

Test

Alternative Hypothesis: Ha: Mean1 ≠ Mean2

Nonparam. Adj. (M-W Test): Ignore

Known Standard Deviation

If the standard deviation is known, the normal distribution is used.

If the std. deviation is not known, the t distribution is used.

Since calculations involving the normal distribution are quicker than those involving the t distribution, you might want to use KNOWN for preliminary work and then assume NOT KNOWN for the final results.

Add This Procedure to Favorites List

Procedure: 110

Name: M2D

Option: 5

Guide Me: Start

Entering Multiple Values

In most cases, boxes that are extra wide allow you to enter multiple values. When this is done, a separate analysis is done for each combination of all multiple values. For example, if you enter four sample sizes and three alpha values, the resulting report will contain $3 \times 4 = 12$ rows, one for each combination.

You can enter multiple options using list or the *to-by* syntax. The *to-by* syntax is most easily described by an example.

The *to-by* phrase *20 to 100 by 20* is translated to the values: *20 40 60 80 100*.

Find (Solve For)

Specify the parameter that is to be solved for in terms of the other parameters. For example, you might want to solve for power or sample size.

In most cases, the algorithm for the calculating the power is programmed within *PASS*. When other parameters (such as sample size or difference) are selected, a binary search is conducted using the power algorithm. These searches can be time consuming, so the best place to start is with **Find (Solve For)** set to *Power and Beta*.

Iterations Tab

The Iterations tab presents the parameters that control the searching process.

The screenshot shows the 'Iterations' tab in a software window. On the left is a sidebar with a 'Run' button at the top, followed by a menu with 'Data', 'Iterations' (selected), 'Reports', and 'Plot Setup'. Below this menu is a button 'Add This Procedure to Favorites List' and a box showing 'Procedure: 110', 'Name: M2D', and 'Option: 8'. The main area of the 'Iterations' tab has a title bar 'Iterations' and a section 'Maximum Iterations' with a label 'Maximum Iterations Before Search Termination:' and a dropdown menu set to '500'. On the right side of the window, there is a help panel with sections: 'Alpha' (defining it as the probability of a FALSE POSITIVE), 'Range' (stating it is bounded by 0 and 1), 'Recommended' (suggesting 0.05 for two-sided tests), and 'Notes' (providing input examples like '.05 .10 .15' or '.05 to .15 by .01'). At the bottom right of the help panel is a 'Guide Me:' section with icons for 'Start', a question mark, and a person.

Maximum Iterations

Maximum Iterations Before Search Termination

This option specifies the maximum number of iterations before a search for the parameter of interest is halted. When the maximum number of iterations is reached without convergence, the criterion is left blank. We recommend that at least 500 iterations be specified.

Reports Tab

The Reports tab displays the options that control the output reports.

The screenshot shows the 'Reports' tab in a software interface. On the left is a sidebar with buttons for 'Run' (green), 'Data', 'Iterations', 'Reports' (selected), and 'Plot Setup'. Below these is a section 'Add This Procedure to Favorites List' and a box showing 'Procedure: 110', 'Name: M2D', and 'Option: 11'. The main area is titled 'Reports' and contains sections for 'Select Output', 'Numeric Reports', 'Plots', 'Decimal Places', and 'Page Title'. The 'Numeric Reports' section has four checked options: 'Show Numeric Report', 'Show References', 'Show Definitions', and 'Show Summary Statements' (set to 1). The 'Plots' section has one checked option: 'Show Plots'. The 'Decimal Places' section has five dropdown menus: 'Numeric Report Probabilities' (5), 'Plot Probabilities' (2), 'Mean and Standard Deviation' (1), 'Allocation Ratio' (3), and 'Effect Size' (3). The 'Page Title' section has a text input field. On the right is a 'Show Report' section with a description: 'Indicate whether to display the designated numeric reports.' At the bottom right is a 'Guide Me' section with icons for 'Start' and other help options.

Select Output – Numeric Reports

Show Numeric Report

Determines whether the numeric report is displayed in the output.

Show References

Check this box to cause the literature reference(s) to be displayed on the report.

Show Definitions

Check this box to show the definitions at the end of the numeric report. Although these definitions are helpful at first, they tend to clutter the output and this option lets you skip them.

Show Summary Statements

The program will output a text statement summarizing the results for each scenario. This option specifies the number of scenarios (rows) from the Numerical Report that will have a summary statement displayed.

Select Output – Plots

Show Plots

Check this box to display plots in the output.

Decimal Places

Decimals

These options set the number of decimal places in corresponding values of the numeric and graphic output.

Page Title

Page Title

This option allows you to enter an option title phrase that will appear in the heading of each page of the output.

Plot Setup Tab

The Plot Setup tab displays the options that control the output plots.

The screenshot shows the 'Plot Setup' tab in a software interface. On the left is a sidebar with buttons for 'Run' (green), 'Data', 'Iterations', 'Reports', and 'Plot Setup' (selected). Below these is a button 'Add This Procedure to Favorites List' and a box showing 'Procedure: 110', 'Name: M2D', and 'Option: 24'. The main area is titled 'Plot Setup' and contains three sections: 'Axis and Legend Parameters', 'Appearance', and 'Abbreviations for Titles, Labels, and Legend'. The 'Axis and Legend Parameters' section has 'Vertical Axis Parameter' set to 'Solve For' Parameter, 'Horizontal Axis Parameter' set to 'Automatic', 'Legend Parameter' set to 'Automatic', and a checked box for 'Show Power (not Beta) on Plots'. The 'Appearance' section has a 'Format' icon showing a scatter plot and an unchecked box for 'Edit During Run'. The 'Abbreviations for Titles, Labels, and Legend' section has dropdown menus for N1, N2, Alpha, Beta, Power, Mean1, Mean2, S1, and S2. On the right is a 'Legend Parameter' section with a text box explaining that it selects the parameter displayed on the legend, with 'Automatic' selecting the parameter with the most values.

Run

Data

Iterations

Reports

Plot Setup

Add This Procedure to Favorites List

Procedure: 110
Name: M2D
Option: 24

Plot Setup

Axis and Legend Parameters

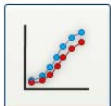
Vertical Axis Parameter: 'Solve For' Parameter

Horizontal Axis Parameter: Automatic

Legend Parameter: Automatic

☒ Show Power (not Beta) on Plots

Appearance

Format:  ☐ Edit During Run

Abbreviations for Titles, Labels, and Legend

N1 (SS Grp 1): N1

N2 (SS Grp 2): N2

Alpha: Alpha

Beta: Beta

Power: Power

Mean1: M1




Mean2: M2

S1 (Std Dev 1): S1

S2 (Std Dev 2): S2

Legend Parameter

Select the parameter displayed on the LEGEND of the plot. This cannot be the parameter that was solved for. Choosing "Automatic" selects the parameter with the most values from those available.

Guide Me:  Start  

Axis and Legend Parameters

Vertical and Horizontal Axis Parameters

This option selects which of the parameters from the Data tab is displayed on the horizontal axis. The vertical axis always contains the **Solve For** parameter, so you cannot select the parameter that was listed in the Find option. Also, you would normally only select a parameter that has multiple entries.

When this option is set to *Automatic*, the parameter with the most values is selected.

Legend Parameter

A separate line is drawn for each value of this parameter. The lines are labeled in the legend. When this option is set to *Automatic*, the parameter with the second most values is selected.

Show Power (not Beta) on Plots

When checked, power is displayed on the plots. When unchecked, power quantities are displayed on the plots as beta using the relationship: **Beta = 1 – Power**.

Appearance

Format

Click this button to edit the format of the plots with random data. The Scatter Plot chapter is devoted to the options available in this window.

Edit During Run

This option controls whether the plot may be reformatted interactively after it has been generated. When checked, this option allows charts to be formatted interactively using a plot-editing window.

Abbreviations for Titles, Labels, and Legend

Parameter Abbreviations

These options specify the abbreviations that are used for the parameters in the titles of the plots and the axis labels. It is usually necessary to keep these abbreviations as short as possible since the titles may become very large if the abbreviations are large.

Chapter 5

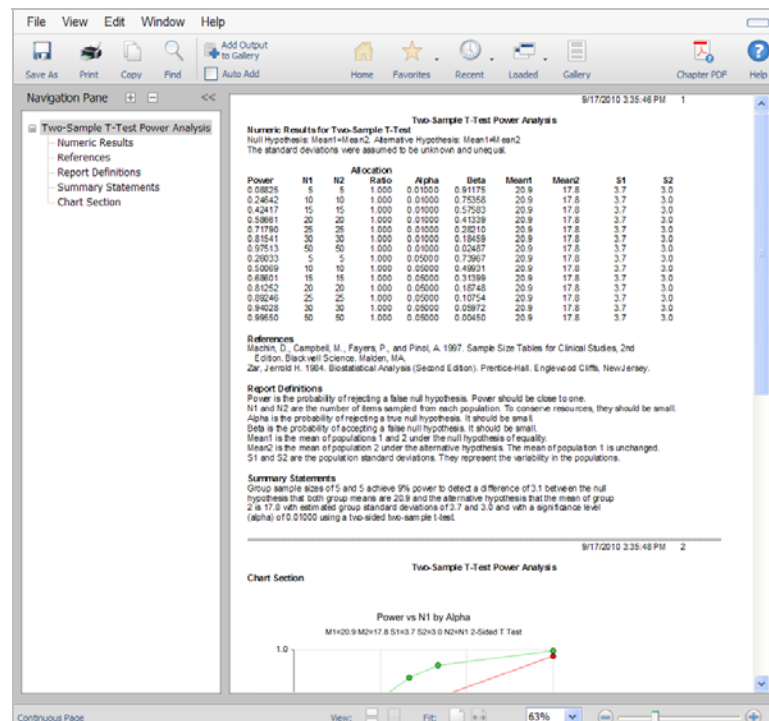
The Output Window

Introduction

PASS sends all statistics and graphics output to its built-in output viewer from where they can be viewed, edited, printed, or saved. Reports and graphs are saved in rich text format (RTF). Since RTF is a standard document transfer format, these files may be loaded directly into your word processor for further processing. This chapter covers the basics of the built-in output viewer in **PASS**.

Viewing the Output

The output of the Example 1 template of the Two-Sample T-Test procedure is shown below. The output window is in full-screen mode. The screen will look similar to this. Note that the actual size of your screen depends on the resolution of your monitor, so it may vary.



Output and Gallery

The **PASS** output system maintains two documents: *Output* and *Output Gallery*. Although both of these documents allow you to view your data, the *Output* document serves as a viewer while the *Output Gallery* document serves as a recorder.

You can load additional documents as well. For example, you might want to view the output from a previous analysis to compare the results with the current analysis. To do this, you open a third document that has been saved from a previous analysis.

All **PASS** documents are stored in the RTF format. This is a common format that is used by most word processors, including Microsoft Word. When you save a **PASS** report, you will be able to load that report directly into your own word processor. All text, formatting, and graphics will appear in your word processor ready for further editing. You can then save the document in your word processor's native format. In this way, you can easily transfer the output of a **PASS** procedure to almost any format you desire.

Output Document

The Output document displays the output report from the current analysis. Whenever you run a **PASS** procedure, the resulting reports and graphs are displayed in the Output document. Each new run clears the existing Output document, so if you want to save a report, you must do so before running the next report.

The Output document provides four main functions: display, print, add to gallery document, and save as an RTF file.

Output Gallery Document

The Output Gallery document provides a place to store a permanent record of your analysis. Since the Output document is erased by each new analysis, you need a place to store your permanent work. The Output Gallery document serves this purpose. When you have a report or graph that you want to keep, copy it from the Output document to the Output Gallery document.

The Output Gallery document provides four main word processing functions: load, display and edit, print, and save. When you load a file into the Output Gallery document, you can add new output to it. In this way, you can record your work on a project in a single file, even though your work on that project is spread out over several days.

Menus

The menus provide a convenient way to perform several functions or transfer from module to module within the **PASS** system. Each set of menus will be briefly described here.

File Menu

The File Menu is used for opening, saving, and printing **PASS** word processor files. All options apply to the currently active document (the document whose title bar is selected). We will now discuss each of the options on this menu.

New (Clear This Window)

This option clears the output document.

Open

This option opens a saved document. This option is only available on the Gallery document window and on additional document windows. You cannot open a saved report into the Output document window.

Recent

This option opens a saved document from the list of recently saved documents. This option is only available on the Gallery document window and on additional document windows. You cannot open a saved report into the Output document window.

Open a New Report Window

This option opens an empty document. You might use this when you want to start a new project.

Open a Report File in a New Window

This option opens a saved document in a new window.

Add Output to Gallery

Selecting this option copies the contents of the Output document to the Gallery document. The Output document remains unchanged. This allows you to save the current output document for further use.

Auto-Add Output to Gallery

When Auto-Add is on, the contents of the Output document are automatically copied to the Gallery document. The Output document remains unchanged. If you want to keep a copy of all the output that has been placed in the Gallery document, you will still need to save it manually.

This function allows you to automatically save all output for further use.

Save

This option lets you save the contents of the currently active document. This option is only available on the Gallery document window and on additional document windows.

Save As

This option lets you save the contents of the currently active document to a designated file using the RTF format. Note that only the active document is saved. Also note that all file names should have the “RTF” extension so that other systems can recognize their format.

Export

This option lets you save the contents of the currently active document to a designated file using the RTF, doc, docx, pdf or other formats.

5-4 Quick Start – The Output Window

Print

This option lets you print the entire document or a range of pages. When you select this option, a Print Dialog box will appear that lets you control which pages are printed.

Print Preview

This option displays the output report as it will appear on the printed page. Use it to preview your report before printing it out.

Report System Options

This option displays the system options window. The Reports tab is used to set up the pages of the output for procedure runs. These options take effect when a procedure is run. Examples of options are titles, page numbers, font, page breaks, page size, and page orientation.

Hide This Window

This option minimizes the document that is currently being viewed. Note that this option does not clear the document, it simply minimizes it.

Exit PASS

This option exits the **PASS** system. All documents, spreadsheets, and procedure windows are closed.

View Menu

This menu lets you designate the views of the output page.

Show/Hide Toolbar

This option controls whether the toolbar at the top is displayed.

Show/Hide Navigation Pane

This option controls whether the navigation pane at the left is displayed.

Show/Hide Bottom Bar

This option controls whether the bar at the bottom is displayed.

Show/Hide Horizontal Ruler

This option controls whether the ruler and tabs bar is displayed. The ruler displays the physical dimensions of the document and lets you set the margins and tabs of your document. Only the currently selected part of your document is affected by a change in the tabs and margins.

Expand Navigation Headings

This option expands all headings in the navigation pane to show sub-headings (if the navigation pane is showing).

Collapse Navigation Headings

This option collapses all headings in the navigation pane to show only headings (if the navigation pane is showing).

Page Layout

Click here to show the output divided into the pages as specified in the System Options when the procedure was run.

Continuous Page

Click here to show the output as a single, continuous page.

Maintain Page Size

If this option is selected, the size of the document remains unchanged when the Output window is resized.

Fit to Width

If this option is selected, the size of the document grows or shrinks to fit the width of the window when the Output window is resized.

Fit to Width and Height

If this option is selected, the size of the document grows or shrinks to fit the width and height of the window when the Output window is resized.

Zoom

Use this option to specify a specific viewing size.

Previous Page

Click to move backward one page.

Next Page

Click to advance forward one page.

Edit Menu

This menu contains options that let you edit a document.

Undo

This item reverses the last edit action. It is particularly useful for replacing something that was accidentally deleted.

Redo

This item un-reverses the last edit action.

5-6 Quick Start – The Output Window

Cut

This item copies the currently selected text to the Windows clipboard and erases it from the document. You can paste the information from the clipboard to a different location in the current document, into another document, into a datasheet in the spreadsheet, or into another application. The selected text is erased.

Copy

This item copies the currently selected text from the document to the Windows clipboard. You can paste this information from the clipboard to a different location in the current document, into another document, into a datasheet in the spreadsheet, or into another application. The selected text is not modified.

Paste

This item copies the contents of the clipboard to the current document at the insertion point. This command is especially useful for moving selected information from the Output document to the Log document.

Font

This option is used to specify the font of the currently selected text region.

Delete

This option deletes the currently selected region.

Select All

This item selects the entire document. Although you can select a portion of the document using the mouse or a shift-arrow key, this is much faster if you want to select the entire document.

Insert Page Break

This option inserts a page break at the current cursor location.

Find

This item opens the Search dialog box. You can specify text that you want to search for. This is especially useful when you are looking for a certain topic or data value in a large report.

Replace

This item opens the Search and Replace dialog box. This allows you to make repetitive changes. For example, you might want to change the name of one of the variables to a more useful name.

Window Menu

This menu lets you display any of the other windows in the **PASS** system that are currently open such as the Output Gallery window, the Output Spreadsheet window, the PASS Home window, or favorite, recent, or currently open procedure windows.

PASS Home

Select this option to display the PASS Home window.

Output Gallery

Select this option to display the output gallery window.

Output Spreadsheet

Select this option to display the output spreadsheet.

Favorite Procedures

Select this option to display a list of the procedure that have been added to the favorites list.

Recent Procedures

Select this option to display a list of the recently run procedures.

Currently Loaded Procedures

The last menu options contain the procedures that are currently open.

Help Menu

This menu gives you access to the **PASS** Help System and PDF documentation, including references and the Quick Start Manual. This menu also gives the citation information for PASS and access to the website and other support information.

Toolbar

A toolbar is a series of small buttons that appear just below the menus at the top of the procedure window. The output window has two toolbars. Each button on the toolbar provides quick access to a menu item.



Save As. This button lets you save the contents of the currently active document to a designated file using the RTF format.

Print. This button lets you print the entire document or a range of pages. When you select this option, a Print Dialog box will appear that lets you control which pages are printed.

Copy. This button copies the currently selected text from the document to the Windows clipboard. You can paste this information from the clipboard to a different location in the current document, into another document, into a datasheet in the spreadsheet, or into another application. The selected text is not modified.

Find. This button opens the Search dialog box. You can specify text that you want to search for. This is especially useful when you are looking for a certain topic or data value in a large report.

Add Output to Gallery. Selecting this option copies the contents of the Output document to the Gallery document. The Output document remains unchanged. This allows you to save the current output document for further use.

Auto-Add Output to Gallery. When Auto-Add is on, the contents of the Output document are automatically copied to the Gallery document. The Output document remains unchanged. If you want to keep a copy of all the output that has been placed in the Gallery document, you will still need to save it manually.

Home. This button brings the PASS Home Window to the front.

Favorites. This drop-down button shows a list of procedures that have been added to the favorites list.

Recent. This drop-down button shows a list of procedures that have been recently run.

Loaded. This drop-down button shows a list of procedures that are currently loaded.

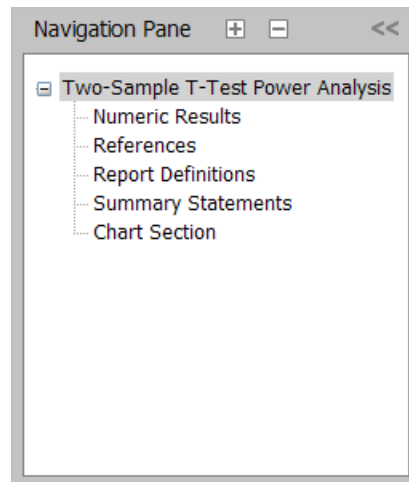
Gallery. This takes the user to window with output that has been sent from the primary output window.

Chapter PDF. This opens the chapter for the output window (this chapter) as an individual PDF.

Help. This opens the PASS Help System and goes to the current topic.

Navigation Pane

The navigation pane is a tree outline that gives the user quick access to major sections of the output.



The plus and minus buttons at the top can be used to expand and contract the entire tree, respectively. The arrow button at the top right can be pressed to hide the entire Navigation Pane.

Pressing any node of the navigation tree will jump the output to the top of that section. Clicking anywhere in the output will highlight the corresponding section title in the navigation pane.

You can right-click the nodes to go to a location or cut, copy, or delete a section of the output.

Bottom Bar (View Buttons)

The bottom bar of the output window gives quick access to many of the options available in the View menu.



Previous Page. Click to move backward one page.

Next Page. Click to advance forward one page.

Page Layout. Click here to show the output divided into the pages as specified in the System Options when the procedure was run.

Continuous Page. Click here to show the output as a single, continuous page.

Maintain Page Size. If this option is selected, the size of the document remains unchanged when the Output window is resized.

Fit to Width. If this option is selected, the size of the document grows or shrinks to fit the width of the window when the Output window is resized.

Fit to Width and Height. If this option is selected, the size of the document grows or shrinks to fit the width and height of the window when the Output window is resized.

Zoom Box. Use this option to specify a specific viewing size.

Zoom Slider. Sliding along this bar changes the zoom percentage.

Chapter 6

Introduction to Power Analysis

Overview

A statistical test's *power* is the probability that it will result in statistical significance. Since statistical significance is the desired outcome of a study, planning to achieve high power is of prime importance to the researcher. Because of its complexity, however, an analysis of power is often omitted.

PASS calculates statistical power and determines sample sizes. It does so for a broad range of statistical techniques, including the study of means, variances, proportions, survival curves, correlations, bioequivalence, analysis of variance, log rank tests, multiple regression, and contingency tables.

PASS was developed to meet several goals, including ease of learning, ease of use, accuracy, completeness, interpretability, and appropriateness. It lets you study the influence of sample size, effect size, variability, significance level, and power on your statistical analysis.

Brief Introduction to Power Analysis

Statistical power analysis must be discussed in the context of *statistical hypothesis testing*. Hence, this discussion starts with a brief introduction to statistical hypothesis testing, paying particular attention to topics that relate to power analysis and sample size determination. Although the theory behind hypothesis testing is general, its concepts can be reviewed by discussing simple case: testing whether a proportion is greater than a known standard.

Following the usual terminology of statistical hypothesis testing, define two complementary hypotheses

$$H_0: P \leq P_0 \text{ vs. } H_1: P > P_0$$

where P is the response proportion in the population of interest and P_0 is the known standard value.

H_0 is called the *null hypothesis* because it specifies that the difference between the two proportions is zero (null).

H_1 is called the *alternative hypothesis*. This is the hypothesis of interest to us. Our motivation for conducting the study is to provide evidence that the alternative (or research) hypothesis is true. We do this by showing that the null hypothesis is unlikely—thus establishing that the alternative hypothesis (the only possibility left) is likely.

6-2 Quick Start – Introduction to Power Analysis

Outcomes from a statistical test may be categorized as follows:

1. Reject H_0 when H_0 is true. That is, conclude that H_0 is unlikely when it is true. This constitutes a decision error known as the *Type-I error*. The probability of this error is alpha (α) and is often referred to as the *significance level* of the hypothesis test.
2. Do not reject H_0 when H_0 is false. That is, conclude that H_0 is likely when it is false. This constitutes a decision error known as the *Type-II error*. The probability of this error is beta (β). *Power* is $1 - \beta$. It is the probability of rejecting H_0 when it is false.
3. Reject H_0 when H_0 is false. This is a correct decision.
4. Do not reject H_0 when H_0 is true. This is also a correct decision.

The basic steps in conducting a study that is analyzed with a hypothesis test are:

1. Specify the statistical hypotheses, H_0 and H_1 .
2. Run the experiment on a given number of subjects.
3. Calculate the value of a test statistic, such as the sample proportion.
4. Determine whether the sample values favor H_0 or H_1 .

Binomial Probability Table

In the current example, suppose that a random sample of ten individuals is selected, i.e. $N = 10$. The number of individuals, R , with the characteristic of interest is counted. Hence, R is the test statistic. A table of binomial probabilities gives the probability that R takes on each of its eleven possible values for various values for P .

| P | | | | | | | | | |
|-----|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| R | 0.1 | 0.2 | 0.3 | 0.4 | 0.5 | 0.6 | 0.7 | 0.8 | 0.9 |
| 0 | 0.349 | 0.107 | 0.028 | 0.006 | 0.001 | 0.000 | 0.000 | 0.000 | 0.000 |
| 1 | 0.387 | 0.376 | 0.121 | 0.040 | 0.010 | 0.002 | 0.000 | 0.000 | 0.000 |
| 2 | 0.194 | 0.302 | 0.233 | 0.121 | 0.044 | 0.011 | 0.001 | 0.000 | 0.000 |
| 3 | 0.057 | 0.201 | 0.267 | 0.215 | 0.117 | 0.042 | 0.009 | 0.001 | 0.000 |
| 4 | 0.011 | 0.088 | 0.200 | 0.251 | 0.205 | 0.111 | 0.037 | 0.006 | 0.000 |
| 5 | 0.001 | 0.026 | 0.103 | 0.201 | 0.246 | 0.201 | 0.103 | 0.026 | 0.001 |
| 6 | 0.000 | 0.006 | 0.037 | 0.111 | 0.205 | 0.251 | 0.200 | 0.088 | 0.011 |
| 7 | 0.000 | 0.001 | 0.009 | 0.042 | 0.117 | 0.215 | 0.267 | 0.201 | 0.057 |
| 8 | 0.000 | 0.000 | 0.001 | 0.011 | 0.044 | 0.121 | 0.233 | 0.302 | 0.194 |
| 9 | 0.000 | 0.000 | 0.000 | 0.002 | 0.010 | 0.040 | 0.121 | 0.376 | 0.387 |
| 10 | 0.000 | 0.000 | 0.000 | 0.000 | 0.001 | 0.006 | 0.028 | 0.107 | 0.349 |

Let us discuss in detail the interpretation of the values in this table for the simple case in which a coin is flipped ten times and the number of heads is recorded. The column parameter P is the probability of obtaining a head on any one toss of the coin. When dealing with coin tossing, one would usually set $P = 0.5$, but this does not have to be the case. The row parameter R is the number of heads obtained in ten tosses of a coin.

The body of the table gives the probability of obtaining a particular value of R . One way to interpret this probability value is as follows: conduct a simulation in which this experiment is repeated a million times for each value of P . Using the results of this simulation, calculate the proportion of experiments that result in each value of R . This proportion is recorded in this table. For example, when the probability of obtaining a head on a single toss of a coin is 0.5, ten flips of a coin would result in five heads 24.6% of the time. That is, as the procedure is repeated (flipping a coin ten times) over and over, 24.6% of the outcomes would be five heads.

Calculating the Significance Level, Alpha

We will now explain how the above table is used to set the significance level (the probability of a type-I error) to a pre-specified value. Recall that a type-I error occurs when an experiment results in the rejection of the null hypothesis when, in fact, the null hypothesis is true. By studying the table, the impact of using different *rejection regions* can be determined. A rejection region is a simple rule that states which values of the test statistic will result in the null hypothesis being rejected.

For example, suppose we want to test $P_0 = 0.5$. That is, the null hypothesis is that $P = 0.5$ and the alternative hypothesis is that $P > 0.5$. Suppose the rejection region is R equal to 8, 9, or 10. That is, H_0 is rejected if $R = 8, 9, \text{ or } 10$. From the above table, the probability of obtaining 8, 9, or 10 heads in 10 tosses when $P = 0.5$ is calculated as follows:

$$\begin{aligned}\Pr(R = 8, 9, 10 | P = 0.5) &= \Pr(R = 8 | P = 0.5) + \Pr(R = 9 | P = 0.5) + \Pr(R = 10 | P = 0.5) \\ &= 0.044 + 0.010 + 0.001 \\ &= 0.055\end{aligned}$$

That is, 5.5% of these coin tossing experiments using this decision rule result in a type-I error. By setting the rejection criterion to $R = 8, 9, \text{ or } 10$, alpha has been set to 0.055.

It is extremely important to understand what alpha means, so we will go over its interpretation again. If the probability of obtaining a head on a single toss of a coin is 0.5, then 5.5% of the experiments that use the rejection criterion of $R = 8, 9, \text{ or } 10$ will result in the false conclusion that $P > 0.5$.

The key features of this definition that are often overlooked by researchers are:

1. **The value of alpha is based on a particular value of P .** Note that we used the assumption “if the probability of obtaining a head is 0.5” in our calculation of alpha. Hence, if the actual value of P is 0.4, our calculations based on the assumption that P is 0.5 are wrong. Mathematicians call this a conditional probability since it is based on the condition that P is 0.5. Alpha is 0.055 if P is 0.5.

Often, researchers think that setting alpha to 0.05 means that the probability of rejecting the null hypothesis is 0.05. Can you see what is wrong with this statement? They have forgotten to mention the key fact that this statement is based on the assumption that P is 0.5!
2. **Alpha is a statement about a proportion in multiple experiments.** Alpha tells us what percentage of a large number of experiments will result in 8, 9, or 10 heads. Alpha is a statement about what to expect from future experiments. It is not a statement about P . Occasionally, researchers conclude that the alpha level is the probability that $P = 0.5$. This is not what is meant. Alpha is not a statement about P . It is a statement about future experiments, given a particular value of P .

Interpreting P Values

The term *alpha value* is often used interchangeably with the term *p value*. Although these two terms are closely related, there is an important distinction between them. A *p* value is the largest value of alpha that would result in the rejection of the null hypothesis for a particular set of data. Hence, while the value of alpha is set during the planning of an experiment, the *p* value is calculated from the data after experiment has been run.

Calculating Power and Beta

We will now explain how to calculate the power. Recall that power is the probability of rejecting a false null hypothesis. A false H_0 means that P is some value other than P_0 . In order to compute power, we must know the actual value of P .

Returning to our coin tossing example, suppose the actual value of P is 0.7. What is the power and beta value of this testing procedure? The decision rule is to reject the null hypothesis when R is 8, 9, or 10. From the above probability table, the probability of obtaining 8, 9, or 10 heads in 10 tosses of a coin when probability of a head is actually 0.7 is

$$\begin{aligned}\Pr(R = 8, 9, 10 | P = 0.7) &= \Pr(R = 8 | P = 0.7) + \Pr(R = 9 | P = 0.7) + \Pr(R = 10 | P = 0.7) \\ &= 0.233 + 0.121 + 0.028 \\ &= 0.382\end{aligned}$$

This is the power. The value of a type-II error is $1.000 - 0.382$, which is 0.618. That is, if P is 0.7, then 38.2% of these coin tossing experiments will reject H_0 , while 61.8% of them will result in a type-II error.

It is extremely important to understand what beta means, so we will go over its interpretation again. If the probability of obtaining a head on the toss of a coin is 0.7, then 61.8% of the experiments that use the rejection criterion of $R = 8, 9$, or 10 will result in the false conclusion that $P = 0.5$.

The key features of this definition that are often overlooked by researchers are:

1. **The value of beta is based on a particular value of P .** Note that we used the assumption “if the probability of obtaining a head is 0.7” in our calculation of beta. Hence, if the actual value of P is 0.6, our calculation based on the assumption that P was 0.7 is wrong.
2. **Beta is a statement about the proportion of experiments.** Beta tells us what percentage of a large number of experiments will result in 8, 9, or 10 heads. Beta is a statement about what we can expect from future experiments. It is not a statement about P .
3. **Beta depends on the value of alpha.** Since the rejection region (8, 9, or 10 heads) depends on the value of alpha, beta depends on alpha.
4. **You cannot make both errors at the same time.** A type-II error can only occur when a type-I error did not occur, and vice versa.

Specifying Alternative Values of the Parameters

We have noted a great deal of confusion about specifying the values of the parameters under the alternative hypothesis. The alternative hypothesis is usually that the value of one parameter is different from another. The hypothesis does not usually specify how different. It simply gives the direction of the difference. The power is calculated at specified alternative values. These values should be considered as values at which the power is calculated, not as the true value.

Effect Size

The *effect size* is the size of the change in the parameter of interest that can be detected by an experiment. For example, in the coin tossing example, the parameter of interest is P , the probability of a head. In calculating the sample size, we would need to state what the baseline probability is (probably 0.5) and how large of a deviation from P that we want to detect with our experiment. We would expect that it would take a much larger sample size to detect a deviation of 0.01 than it would to detect a deviation of 0.40.

Selecting an appropriate effect size is difficult because it is subjective. The question that must be answered is: what size change in the parameter would be of interest? Note that, in power analysis, the effect size is not the actual difference. Instead, *the effect size is the change in the parameter that is of interest* or is to be detected. This is a fundamental concept that is often forgotten after the experiment is run.

After an experiment is run that leads to non-significance, researchers often ask, “What was the experiment’s power?” and “How large of a sample size would have been needed to detect significance?” To compute the power or sample size, they set the effect size equal to the amount that was seen in their experiment. This is incorrect. *When performing a power analysis after an experiment has completed, the effect size is still the change in the parameter that would be of interest to other scientists.* It is not the change that was actually observed!

Often, the effect size is stated as a percentage change rather than an absolute change. If this is the case, you must convert the percentage change to an absolute change. For example, suppose that you are designing an experiment to determine if tossing a particular coin has exactly a 50% chance of yielding a head. That is, P_0 is 0.50. Suppose your gambling friends are interested in whether a certain coin has a 10% greater chance. That is, they are concerned with the case where P is 0.55 or greater. The effect size is $|0.50 - 0.55|$ or 0.05.

Types of Power Analyses

There are several types of power analyses. Often, power analysis is performed during the design phase of a study to determine the sample size. This type of study would determine the value of N for set values of alpha and beta. Another type of power analysis is a post hoc analysis, which is done after the study is concluded. A post hoc analysis studies such questions as:

1. What sample size would have been needed to detect a specific effect size?
2. What is the smallest effect size that could be detected with this sample size?
3. What was the power of the test procedure?

These and similar questions may be answered using power analysis. By considering these kinds of questions after a study is concluded, you can gain important insights into how to make your research more efficient and effective.

Nuisance Parameters

Statistical hypotheses usually make statements about one or more parameters from a set of one or more probability distributions. Often, the hypotheses leave other parameters of the probability distribution unspecified. These unspecified parameters are called ‘nuisance’ parameters.

For example, a common clinical hypothesis is that the response proportions of two drugs are equal. The null hypothesis is that the difference between these two drugs is zero. The alternative is that the difference is non-zero. Note that the actual values of the two proportions are not stated in the hypothesis—just their difference. The actual values of the proportions will be needed to compute the power. That is, different powers will result for the case when $P1 = 0.05$ and $P2 = 0.25$ and for the case $P1 = 0.50$ and $P2 = 0.70$. In this example, the proportion difference ($D = P1 - P2$) is the parameter of interest. The baseline proportion, $P1$, is a nuisance parameter.

Another example of a nuisance parameter occurs when using the t-test to test whether the mean is equal to a particular value. When computing the power or sample size for this test, the hypothesis specifies the value of the mean. However, the value of the standard deviation is also required. In this case, the standard deviation is a nuisance parameter.

When performing a power analysis, you should state all your assumptions, including the values of any nuisance parameters that were used. When you do not have any idea as to reasonable values for nuisance parameters, you should use a range of possible values so that you can analyze how sensitive the results are to the values of the nuisance parameters. Also, do not be tempted to use the nuisance parameter’s value from a previous (or pilot) study. Instead, a reasonable strategy is to compute a confidence interval and use the confidence limit that results in the largest sample size.

Choice of Test Statistics

Many hypothesis tests can be tested with a variety of test statistics. For example, statisticians often have to decide between the t-test and the Wilcoxon test when testing means. Similarly, when testing whether two proportions are equal, they have to decide whether to use a z-test or an exact test. If they choose a z-test, they have to decide whether to apply a continuity correction.

In most cases, each test statistic will have a different power. Thus, it should be obvious that *you must compute the power of the test statistic that will be used in the analysis*. A sample size based on the t-test will not be accurate for a nonparametric test.

The next question is usually “Which test statistic should I use?” You might say “The one that requires the smallest sample size.” However, other issues besides power must be considered. For example, consideration must be given to whether the assumptions of the test statistic will be met by the data. If your data is binary, it is probably unreasonable to assume that they are continuous.

These are simple principles, but they are often overlooked.

Types of Hypotheses

Hypothesis tests work this way. If the null hypothesis is rejected, the alternative hypothesis is concluded to be true. However, if null hypothesis is not rejected, no conclusion is reached--the null hypothesis *is not* concluded to be true. The only way that a conclusion is reached is if the null hypothesis is rejected.

Because of this, it is very important that the null and alternative hypotheses be constructed so that the conclusion of interest is associated with the alternative hypothesis. That way, if the null hypothesis is rejected, the study reaches the desired conclusion.

There are several types of hypotheses. These include inequality, equivalence, non-inferiority, and superiority hypotheses. In the statistical literature, these terms are used with completely different meanings, so it is important to define what is meant by each. We have tried to adopt names that are associated with the alternative hypothesis, since this is the hypothesis of interest.

It is important to note that even though two sets of hypotheses may be similar, they often will have different power and sample size requirements. For example, an equivalence test (see below) appears to be the simple reverse of a two-sided test of inequality, yet the equivalence test requires a much larger sample size to achieve the same power as the inequality test. Hence, you cannot select the sample size for an inequality test and then later decide to run an equivalence test.

Each of the sections to follow will give a brief definition along with an example based on the difference between two proportions.

Inequality Hypothesis

The term ‘inequality’ represents the classical one-sided and two-sided hypotheses in which the alternative hypothesis is simply that the two values are unequal. These hypotheses are called tests of superiority by Julious (2004), emphasizing the one-sided versions.

Two-Sided

When the null hypothesis is rejected, the conclusion is simply that the two parameters are unequal. No statement is made about how different. For example, 0.501 and 0.500 are unequal, as are 0.500 and 0.800. Obviously, even though the former are different, the difference is not large enough to be of practical importance in most situations.

$$H_0: p_1 - p_2 = 0 \text{ vs. } H_1: p_1 - p_2 \neq 0 \text{ or } H_1: p_1 - p_2 < 0 \text{ or } p_1 - p_2 > 0$$

One-Sided

These tests offer a little more information than the two sided tests since the direction of the difference is given. Again, no indication is made about how much higher (or lower) the superior value is to the inferior.

$$H_0: p_1 - p_2 \leq 0 \text{ vs. } H_1: p_1 - p_2 > 0 \text{ or } H_0: p_1 - p_2 \geq 0 \text{ vs. } H_1: p_1 - p_2 < 0$$

Non-Inferiority Hypothesis

These tests are a special case of the one-sided inequality tests. The term ‘non-inferiority’ is used to indicate that one treatment is not worse than another treatment. That is, one proportion is not less than another proportion by more than a trivial amount called the ‘margin of equivalence’.

For example, suppose that a new drug is being developed that is less expensive and has fewer side effects than the standard drug. Producers must show that its effectiveness is no worse than the drug it is to replace.

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When testing two proportions in which a higher proportion is better, the non-inferiority of treatment 1 as compared to treatment 2 is expressed as

$$H_0: p_1 - p_2 \leq -\delta \text{ vs. } H_1: p_1 - p_2 > -\delta \text{ or } H_0: p_1 \leq p_2 - \delta \text{ vs. } H_1: p_1 > p_2 - \delta,$$

where $\delta > 0$ is called the margin of equivalence. Note that when H_0 is rejected, the conclusion is that the first proportion is not less than the second proportion by more than δ .

Perhaps an example will help introduce this type of test. Suppose that the current treatment for a disease works 70% of the time. Unfortunately, this treatment is expensive and occasionally exhibits serious side-effects. A promising new treatment has been developed to the point where it can be tested. One of the first questions that must be answered is whether the new treatment is as good as the current treatment. In other words, do at least 70% of subjects respond to the new treatment?

Because of the many benefits of the new treatment, clinicians are willing to adopt the new treatment even if it is slightly less effective than the current treatment. They must determine, however, how much less effective the new treatment can be and still be adopted. Should it be adopted if 69% respond? 68%? 65%? 60%? There is a percentage below 70% at which the difference between the two treatments is no longer considered ignorable. After thoughtful discussion with several clinicians, it is decided that if a response of at least 63% is achieved, the new treatment will be adopted. The difference between these two percentages is called the *margin of equivalence*. The margin of equivalence in this example is 7% (which is ten percent of the original 70%).

The developers must design an experiment to test the hypothesis that the response rate of the new treatment is at least 0.63. The statistical hypothesis to be tested is

$$H_0: p_1 - p_2 \leq -0.07 \text{ versus } H_1: p_1 - p_2 > -0.07.$$

Notice that when the null hypothesis is rejected, the conclusion is that the response rate is at least 0.63. Note that even though the response rate of the current treatment is 0.70, the hypothesis test is about a response rate of 0.63. Also, notice that a rejection of the null hypothesis results in the conclusion of interest.

Non-zero Null Hypothesis

These tests are a special case of the one-sided inequality tests. The term ‘non-zero null’ is used to indicate that one treatment is better than another by more than a trivial amount. For example, suppose that a new drug is being developed that is thought to have superior performance to the existing drug. Producers must show that its effectiveness is better than the drug it is to replace.

When testing two proportions in which a higher proportion is better, the superiority of treatment 1 over treatment 2 is expressed as

$$H_0: p_1 - p_2 \leq \delta \text{ vs. } H_1: p_1 - p_2 > \delta \text{ or } H_0: p_1 \leq p_2 + \delta \text{ vs. } H_1: p_1 > p_2 + \delta,$$

where $\delta > 0$ is called the difference margin. Note that when H_0 is rejected, the conclusion is that the first proportion is higher than the second proportion by more than δ .

Equivalence Hypothesis

The term ‘equivalence’ is used here to represent tests designed to show that response rates of two treatments do not differ by more than a trivial amount called the ‘margin of equivalence’. These tests are the reverse of the two-sided inequality test.

The typical set of hypotheses are

$$H_0: p_1 - p_2 \leq \delta_L \text{ or } p_1 - p_2 \geq \delta_U \text{ vs. } H_1: \delta_L \leq p_1 - p_2 \leq \delta_U ,$$

where $\delta_L < 0$ and $\delta_U > 0$ are called the *equivalence limits*.

Suppose 70% of subjects with a certain disease respond to a certain drug. The company that produces the drug has decided to open a new facility in another city. They must show that the drug produced in the new facility is equivalent (all most the same) as that produced in existing facilities. After thoughtful discussion with several clinicians and regulatory agencies, it is decided that if the response rate of the drug produced at the new facility is between 65% and 75%, the new facility will go into production. In this case, the *margin of equivalence* is 5%.

The statistical hypothesis to be tested is

$$H_0: |p_1 - p_2| \geq 0.05 \text{ vs. } H_1: |p_1 - p_2| < 0.05 .$$

Chapter 7

Proportions

Introduction

This chapter introduces power analysis and sample size calculation for proportions. When the response is binary, the results for each group may be summarized as proportions. Usually, hypothesis tests are conducted to compare two proportions.

There are many issues that must be considered when designing experiments that use proportions. For example, will the proportions be analyzed directly, or will they be converted into differences, ratios, or odds ratios? Which test statistic will be used? Will the design use independent groups or will subjects be measured twice? Will the study have an active control?

The various answers to these and other questions result in a large number of situations. This chapter will introduce you to the issues that are common to all the tests of proportions.

Designs

There are several experimental designs for comparing two proportions. You can use a one-sample design to compare a sample proportion to a specific value. You can compare proportions from two independent samples using independent, stratified, cluster-randomized, or group-sequential designs. You can compare two correlated proportions. And finally, you can compare several categories in a contingency table.

Comparing Proportions

Two proportions may be compared by considering their difference, ratio, or odds ratio. Each of these cases may lead to different test statistics with different powers and sample size requirements.

Assume that p_1 is the response proportion of the experimental group and p_2 is the response proportion of the control (standard or reference) group. Mathematically, these alternative parameterizations are

| <u>Parameter</u> | <u>Computation</u> |
|------------------|--|
| Difference | $\delta = p_1 - p_2$ |
| Ratio | $\phi = p_1 / p_2$ |
| Odds Ratio | $\psi = \frac{p_1 / (1 - p_1)}{p_2 / (1 - p_2)}$ |

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Once you know p_1 and p_2 , you can calculate any of these values, and you can easily change from one parameterization to another. Thus, the choice of which parameter you use may seem arbitrary. However, since different parameterizations lead to different test statistics, the choice can lead to a different power and sample size. These parameterizations will be discussed next.

Difference

The difference $\delta = p_1 - p_2$ is perhaps the most common method of comparing two proportions. This parameter is easy to interpret and communicate. It gives the absolute impact of the treatment. However, there are subtle difficulties that can arise with its use.

One difficulty occurs when the event of interest is rare. If a difference of 0.001 is reported for an event with a baseline probability of 0.40, we would dismiss this as being trivial. That is, there is usually little interest in a treatment that decreases the probability from 0.400 to 0.399. However, if the baseline probability of a disease is 0.002, a 0.001 decrease in the disease probability would represent a 50% reduction. Thus, the interpretation of the difference depends on the baseline probability of the event.

When planning studies, the value of p_2 is usually known and the power is calculated at various values of δ . The value of p_1 is then calculated using $p_1 = p_2 + \delta$. Because of the requirement that $0 < p_1 < 1$, the values of δ are restricted to the interval $-p_2 < \delta < 1 - p_2$, not $-1 < \delta < 1$ as you might expect. Likewise, the values of p_2 are restricted to $0 < p_2 < 1 - \delta$ if $\delta > 0$ and $-\delta < p_2 < 1$ if $\delta < 0$.

Because typical values of δ are usually between -0.2 and 0.2, the allowable values of p_2 are restricted to be between 0.2 and 0.8. When the values of p_2 are outside this range, it may be more convenient to use the odds ratio.

Ratio

The (risk) ratio, $\phi = p_1 / p_2$, gives the relative change in the probability of the outcome under each of the hypothesized values. This parameter is direct and easy to interpret. To compare the ratio with the difference, examine the case where $p_1 = 0.1437$ and $p_2 = 0.0793$. One should consider which number is more enlightening, $\delta = -0.0644$, or $\phi = 55.18\%$. In many cases, the relative change (the ratio) is easier to interpret than the absolute change (the difference).

When planning studies, the value of p_2 is usually known and the power is calculated at various values of ϕ . The value of p_1 is then calculated using $p_1 = p_2 \times \phi$. Because of the requirement that $0 < p_1 < 1$, the values of ϕ are restricted to the interval $0 < \phi < 1 / p_2$, not $0 < \phi < \infty$ as you might expect. Likewise, the values of p_2 are restricted to $0 < p_2 < 1 / \phi$ if $\phi > 1$ and $0 < p_2 < 1$ if $\phi < 1$.

Because typical values of ϕ are usually between 0.5 and 1.5, the values of p_2 are restricted to be between 0 and 0.667. When the values of p_2 are outside this range, it may be more convenient to use the odds ratio.

Odds Ratio

Chances are usually communicated as long-term proportions or probabilities. In betting, chances are often given as odds. For example, the odds of a horse winning a race might be set at 10-to-1 or 3-to-2. Odds can easily be translated into probabilities, and vice versa. An odds of 3-to-2 means that the event is expected to occur three out of five times. That is, an odds of 3-to-2 (1.5) translates to a probability of winning of 0.60.

The odds of an event are calculated by dividing the event risk by the non-event risk. Thus the odds are

$$Odds_1 = \frac{p_1}{1 - p_1} \text{ and } Odds_2 = \frac{p_2}{1 - p_2}$$

For example, if p is 0.6, the odds are $0.6/0.4 = 1.5$. Rather than represent the odds as a decimal amount, it is re-scaled into whole numbers. Thus, instead of presenting the odds as 1.5-to-1, they present as 3-to-2.

Two odds could be compared by considering their difference, but it is more convenient in many situations to form their ratio. Thus, another way to compare proportions is to compute the ratio of their odds. The odds ratio is

$$\begin{aligned} \psi &= \frac{Odds_1}{Odds_2} \\ &= \frac{\frac{p_1}{1 - p_1}}{\frac{p_2}{1 - p_2}} \end{aligned}$$

Unlike the difference and the ratio, the odds ratio is not restricted by the value of p_2 . The range of possible values of the odds ratio is $-\infty < \psi < \infty$. Because of the freedom in specifying the parameters, the odds ratio is a popular parameterization, even though it is not as easy to interpret as the difference and the ratio.

Specifying the Proportions – Important!

It is important to understand the interpretation of p_1 and p_2 within **PASS**. Suppose p_1 represents the proportion in the treatment group and p_2 represents the proportion in the control group. In most hypothesis tests, these values are equal under the null hypothesis and different under the alternative hypothesis. Thus, under the null hypothesis, all that is needed is the value of p_1 or p_2 , but not both. Under the alternative hypothesis, both values are necessary. So, when the input screen asks for p_2 and the difference, these values should be interpreted as follows. The value of p_2 is actually the value of both p_1 and p_2 under H_0 . Under H_1 , the value of p_1 is calculated from p_2 and δ using the formula $p_1 = p_2 + \delta$.

Also, it is important to understand what we mean by ‘under H_1 ’ in the above discussion. Notice that H_1 does not specify the exact value of p_1 . Instead, it specifies a range of values. For

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example, H_1 might be $p_1 > p_2$ or $p_1 - p_2 > \delta$. However, even though H_1 gives a range of values for p_1 , the power is computed at a specific value of p_1 .

Selecting an appropriate value for p_1 must be done very carefully. We recommend the following approach. Select a value of p_1 that represents the change from p_2 that you want the experiment to detect. When you calculate a sample size, it is interpreted as the sample size necessary to detect a difference of at least $p_1 - p_2$ when the significance level is α and the power is $1 - \beta$.

The important point is that p_1 is not the value you anticipate obtaining from an experiment. Instead, it is that value of p_1 at which you want to compute the power. This is a very important distinction! This is why, when investigating the power after an experiment is run, we recommend that you do not simply plug in the values of p_1 and p_2 from that experiment. Rather, you use values that represent the size of the difference that you want to detect.

Chapter 8

Means

Introduction

This chapter introduces power analysis and sample size calculation for tests that compare means. In many situations, the results for each treatment group are summarized as means. There are many issues that must be considered when designing experiments for comparing means. For example, are the means independent or correlated? Which test statistic to use? Will a parametric or nonparametric test be used? Are the data normally distributed? Are there more than two treatment groups? The answers to these and other questions result in a large number of situations.

Specifying the Means

Assume that μ_1 is the mean of an experimental group and μ_2 is the mean of a control (standard or reference) group. Suppose δ represents their difference. That is, $\delta = \mu_1 - \mu_2$. In most hypothesis tests, the null hypothesis (H_0) is $\delta = 0$ and the alternative hypothesis (H_1) is $\delta \neq 0$. Since H_0 assumes that $\delta = 0$, all that is really needed to compute the power is the value of δ under H_1 . So, when the input screen asks for μ_1 and μ_2 , these values should be interpreted as follows. The value of μ_1 is actually the value of both μ_1 and μ_2 under H_0 . Under H_1 , the values of μ_1 and μ_2 provide the value of δ at which the power is calculated.

The above discussion is summarized in the following chart:

| Input Parameter | Under H_0 | Under H_1 |
|-----------------|----------------|-------------|
| Mean1 | μ_1, μ_2 | μ_1 |
| Mean2 | ignored | μ_2 |

Also, it is important to understand what we mean by ‘under H_1 ’ in the above discussion. H_1 defines a range of values for δ at which the power can be computed. To compute the power, the specific values of δ must be determined. Thus, there is not a single power value. Instead, there are an infinite number of power values possible, depending on the value of δ .

Selecting an appropriate value for μ_1 must be done very carefully. We recommend the following approach. Select a value of μ_1 that represents the change from μ_2 that you want the experiment to detect. When you calculate a sample size, it is interpreted as the sample size necessary to detect a difference of at least δ when the significance level is α and the power is $1 - \beta$.

It is important to realize that δ is not the value you anticipate obtaining from the experiment. Instead, it is that value of δ at which you want to compute the power. This is a very important

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distinction! This is why, when investigating the power after an experiment is run, we recommend that you do not simply plug in the values of μ_1 and μ_2 from that experiment. Rather, you use values that represent the size of the difference that you want to detect.

Specifying the Standard Deviation

Usually, statistical hypotheses about the means make no direct statement about the standard deviation. However, the standard deviation is a parameter in the normal distribution, so its value must be specified. For this reason, it is called a *nuisance parameter*.

Even though it is not of primary interest, an estimate of the standard deviation is necessary to perform a power analysis. Finding such an estimate is difficult not only because it is required before the data are available, but also because the physical interpretation of the standard deviation is vague. How do you estimate a quantity without data and without a clear understanding of what it is? This section will try to help.

Understanding the Standard Deviation

The standard deviation has two general interpretations. First, it is similar to the average absolute difference between each observation and the mean. Second, it is the average absolute difference between every pair of observations.

The standard deviation of a population of values is calculated using the formula

$$\sigma_X = \sqrt{\frac{\sum_{i=1}^N (X_i - \mu_X)^2}{N}}$$

where N is the number of items in the population, X is the variable being measured, and μ_X is the mean of X . This formula indicates that the standard deviation is the square root of an average of the squared differences between each value and the mean. The differences are squared to remove the sign so that negative values will not cancel out positive values. After summing up these squared differences and dividing by N , the square root is taken to put the result back in the original scale. Bottom line—the standard deviation can be thought of as the average absolute difference between the data values and their mean.

Estimating the Standard Deviation

Our task is to find a rough estimate of the standard deviation to use in a power analysis. Several possible methods could be used. These include using the results of a previous study or a pilot study, using the range, using the coefficient of variation, etc. **PASS** includes a Standard Deviation Estimator procedure that will help you obtain a standard deviation estimate based on these methods. It is loaded from the Tools menu. Remember that as the standard deviation increases, the power decreases. Hence, an increase in the standard deviation will cause an increase in the sample size. To be conservative in sample size calculation, you should use a large value for the standard deviation.

Simulations

Most of the formulas used in **PASS** were derived by analytic methods. That is, based on a series of assumptions, a formula for the power and sample size is derived mathematically. This formula is then programmed and made available in **PASS**. Unfortunately, the formula is only as realistic as the assumptions upon which it is based. If the assumptions are inaccurate in a certain situation, the power calculations may also be inaccurate. An alternative to using analytic methods is to use *simulation* (or *Monte Carlo*) techniques. Because of the speed of modern computers, simulations can now be run in minutes that would have taken days or weeks only a few years ago.

In power analysis, *simulation* refers to the process of generating several thousand random samples that follow a particular distribution, calculating the test statistic from each sample, and tabulating the distribution of these test statistics so that the significance level and power of the procedure may be estimated.

The steps to a simulation study are

1. Specify how the study is carried out. This includes specifying the randomization procedure, the test statistic that is used, and the significance level that will be used.
2. Generate random samples from the distributions specified by the null hypothesis. Calculate each test statistic from the simulated data and determine if the null hypothesis is accepted or rejected. Tabulate the number of rejections and use this to calculate the test's significance level.
3. Generate random samples from the distributions specified by the alternative hypothesis. Calculate the test statistics from the simulated data and determine if the null hypothesis is accepted or rejected. Tabulate the number of rejections and use this to calculate the test's power.
4. Repeat steps 2 and 3 several thousand times, tabulating the number of times the simulated data leads to a rejection of the null hypothesis. The significance level is the proportion of simulated samples in step 2 that lead to rejection. The power is the proportion of simulated samples in step 3 that lead to rejection.

How Large Should the Simulation Be?

As the number of simulations is increased, the precision and running time of the simulation will be increased also. This section provides a method for estimating of the number simulations needed to achieve a given precision.

Each simulation iteration (or simulation) generates a binary outcome: either the null hypothesis is rejected or not. Thus, the significance level and power estimates each follow the binomial distribution. This knowledge makes it a simple matter to compute confidence intervals for the significance level and power values.

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The following table gives one-half the width of a 95% confidence interval for the power when the estimated value is either 0.50 or 0.95.

| Simulation Size M | Half-Width when Power = 0.50 | Half-Width when Power = 0.95 |
|-------------------------|------------------------------------|------------------------------------|
| 100 | 0.100 | 0.044 |
| 500 | 0.045 | 0.019 |
| 1000 | 0.032 | 0.014 |
| 2000 | 0.022 | 0.010 |
| 5000 | 0.014 | 0.006 |
| 10000 | 0.010 | 0.004 |
| 50000 | 0.004 | 0.002 |
| 100000 | 0.003 | 0.001 |

Notice that a simulation size of 1000 gives a precision of plus or minus 0.014 when the true power is 0.95. Also, as the simulation size is increased beyond 5000, there is only a small amount of additional accuracy achieved. Since most sample-size studies require an accuracy of within one or two percentage points, simulation sizes from 2000 to 10000 should be ample.

You are Running Two Simulations

It is important to realize that when you run a simulation in **PASS**, you are actually running two separate simulations: one to estimate the significance level and the other to estimate the power. The significance-level simulation is defined by the input parameters labeled “[H0]”. The power simulation is defined by the input parameters labeled “[H1]”. Even though you have complete flexibility as to what distributions you use in each of these simulations, it usually makes sense to use the same distributions for both simulations—only changing the values of the means.

Unequal Standard Deviations

One of the subtle problems that can make the results of a simulation study misleading is to specify unequal standard deviations unknowingly when you are investigating another feature, such as the amount of skewness. It is well known that if the standard deviations differ (a situation called heteroskedasticity), the accuracy of the significance level and power is doubtful. When investigating the power of the t or F tests in non-normal situations, care must be taken to insure that the standard deviations of the groups remain about the same. Otherwise, the effects of skewness and heteroskedasticity cannot be separated.

Finding the Hypothesized Means

It is important to set the mean difference of each simulation carefully. In the case of analytic formulas, the mean difference is specified easily and directly. Usually, the mean difference is set to zero under the null hypothesis and to a non-zero value under the alternative hypothesis. You must make certain that you follow this pattern when setting up a simulation.

For most distributions, the means are set explicitly (the exception is the multinomial distribution, where this is impossible). Hence, for both the null and alternative simulations, it is relatively simple to calculate the mean difference. You must do this! We will now present two examples showing how this is done.

For the first example, consider the case of a simulation being run to compare two independent group means using the two-sample t-test. Suppose the **PASS** setup is as follows. Note that $N(40\ 2)$ stands for a normal distribution with a mean of 40 and a standard deviation of 2.

| <u>Distribution</u> | <u>PASS Input</u> | <u>Mean Value of Simulated Data</u> |
|---------------------------|-------------------|---|
| Group 1 Distribution H0 | $N(40\ 2)$ | 40.0 |
| Group 2 Distribution H0 | $N(40\ 2)$ | 40.0 |
| Group 1 Distribution H1 | $N(42\ 2)$ | 42.0 |
| Group 2 Distribution H1 | $N(40\ 2)$ | 40.0 |

The mean difference under H_0 is $40 - 40 = 0$, which is as it should be. The mean difference under H_1 is $42 - 40 = 2$. Hence, the power is being estimated for a mean difference of 2.

Next we will consider a more complicated example. Suppose the **PASS** setup is as follows. Note that $N(40\ 2)[70];K(0)[30]$ specifies a mixture distribution made up of 70% from a normal distribution with a mean of 40 and a standard deviation of 2 and 30% from a constant distribution with a value of 30.

| <u>Distribution</u> | <u>PASS Input</u> | <u>Mean Value of Simulated Data</u> |
|---------------------------|-------------------------|---|
| Group 1 Distribution H0 | $N(40\ 2)[70];K(0)[30]$ | $40(0.7) + 30(0.3) = 37.0$ |
| Group 2 Distribution H0 | $N(40\ 2)[70];K(0)[30]$ | $40(0.7) + 30(0.3) = 37.0$ |
| Group 1 Distribution H1 | $N(42\ 2)[70];K(0)[30]$ | $42(0.7) + 30(0.3) = 38.4$ |
| Group 2 Distribution H1 | $N(40\ 2)[70];K(0)[30]$ | $40(0.7) + 30(0.3) = 37.0$ |

The mean difference under H_0 is $37.0 - 37.0 = 0$, which is as it should be for the null hypothesis. The mean difference under H_1 is $38.4 - 37.0 = 1.4$. Hence, the power is being estimated by simulation for a mean difference of 1.4.

You must always be aware of what the mean differences are under both the null and alternative hypotheses.

Adjusting the Significance Level

When faced with the task of designing an experiment that will have a specific significance level for a situation that does not meet the usual assumptions, there are several possibilities.

1. A statistician could be hired to find an appropriate testing procedure.
2. A nonparametric test could be run that (hopefully) corrects for the implausible assumptions.
3. The regular parametric test could be run, relying on the test's 'robustness' to correct for the implausible assumptions.
4. A simulation study could be conducted to determine an appropriate adjustment to the significance level so that the actual significance level is at the required value.

We will now present an example of how to do the simulation adjustment alluded to in item 4, above.

The two-sample t-test is known to be robust to the violation of some assumptions, but it is susceptible to inaccuracies when the data contain outliers. A mixture of two normal distributions

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will be used to generate data with outliers. The mixture will draw 95% of the data from a normal distribution with a mean of 0 and a standard deviation of 1. The other 5% of the data will come from a normal distribution with a mean of zero and a standard deviation of 10. A simulation study using 10,000 iterations and a sample size of 100 per group produced the following results when the nominal significance level was set to 0.05.

| Nominal <u>Alpha</u> | Actual <u>Alpha</u> | Lower 95% Confidence <u>Limit</u> | Upper 95% Confidence <u>Limit</u> | <u>Power</u> |
|---------------------------------|--------------------------------|--|--|---------------------|
| 0.050 | 0.045 | 0.041 | 0.049 | 0.816 |
| 0.055 | 0.051 | 0.047 | 0.055 | 0.843 |
| 0.060 | 0.057 | 0.053 | 0.062 | 0.835 |

The actual alpha level of the t-test is 0.045, which is below the target value of 0.50. When the nominal alpha level is increased to 0.055, the actual alpha is 0.051—close to the desired level of 0.05. Hence, an adjustment could be applied as follows. Analyze the data with the two-sample t-test even though they contain outliers. However, instead of using an alpha of 0.050, use an alpha of 0.055. When this is done, the simulation shows that the actual alpha will be at the desired 0.05 level.

There is one limitation to this method: the resulting test procedure is not necessarily efficient. That is, it may be possible to derive a testing procedure that is more efficient (requires a smaller sample size to achieve the same power). For example, in this example, a test based on the trimmed mean may be more efficient in the presence of outliers. However, if you do not have the time or ability to derive an alternative test, this adjustment allows you to obtain reasonable testing procedure that achieves a desired significance level and power.

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