Communicating Data Visually:
Data Presentation Formats at
U.S. Food and Drug Administration
Drug Advisory Committee Meetings

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A thesis submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Arts in the School of Journalism and Mass Communication.

Chapel Hill
2011

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Abstract

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Communicating Data Visually: Data Presentation Formats at
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Drug Advisory Committee Meetings
(Under the direction of Anne Johnston)

This thesis investigated the use of tables and graphs to present quantitative data at U.S. FDA drug advisory committee meetings. A total of 7, 422 slides presented at such meetings in 2010 comprised the sample. All slides were coded for slide type; slides displaying graphs were also coded for graph type. Analyses were conducted to determine differences in data presentation format between the FDA and drug sponsors, slides shown to different types of advisory committees, and slides shown at meetings held for different purposes.

The study found that tables and graphs are used in almost equal measure at drug advisory committee meetings. However, the FDA is more likely than drug sponsors to display data in tables versus graphs. The study also found that the most prevalent graph formats are bar graphs, forest plots, line graphs, and Kaplan-Meier curves. Only one slide, shown by a drug sponsor, displayed a pictograph.

Acknowledgements

Gratitude and recognition belong to my thesis committee: Dr. Anne Johnston, Dr. Lois Boynton, and Dr. Wayne Jack Wallis; to my coder, Andrea Simpson; and to my classmates, family, and friends. Thank you.

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2D	Two dimensional
3D	Three dimensional
AIDAC	Anitinfectives Drugs Advisory Committee
CRDAC	Cardiorenal Drugs Advisory Committee
DSaRM	Drug Safety and Risk Management Advisory Committee
EMDAC	Endocrinologic and Metabolic Drugs Advisory Committee
FDA	Food and Drug Administration
GDAC	Gastrointestinal Drugs Advisory Committee
NASA	National Aeronautics and Space Administration
NDA	New Drug Application
ODAC	Oncologic Drugs Advisory Committee
Perip. C. Nerv.	Peripheral and Central Nervous System Drugs Advisory Committee
Psychopharm	Psychopharmacologic Drugs Advisory Committee
Pul. Allergy	Pulmonary Allergy Drugs Advisory Committee
Repro. Health	Reproductive Health Drugs Advisory Committee

Introduction

Corporate communication is the exchange of information between a business and its publics (Huang & Kleiner ,2005). Companies must communicate effectively in order to remain competitive in the marketplace (Huang & Kleiner,2005). As case studies have shown, failure to communicate effectively may lead to stock devaluation and unwanted attention from outside stakeholders (Reese, 2001).

Effective communication does not simply mean exposing an audience to information, but also making sure that information is received, comprehended, agreed with, retained, and retrieved (McGuire, 1976). In order to allow audiences to travel through these steps, companies must focus not just on *what* they communicate but also *how* they communicate. If a communication format does not allow an audience to travel through the steps of information processing, it is not effective.

Research into the communication of quantitative data has focused on whether such data are communicated more effectively via tables or graphs, and, if graphs, what type. Such research has demonstrated that decisions regarding data—the "agreed with" step of effective communication—vary depending on the format in which it is presented (Tait et. al, 2010).

The purpose of this research is to determine how quantitative data are presented at FDA advisory committee meetings. An advisory committee is a panel of independent experts who advise the FDA regarding drug safety and effectiveness (U.S. FDA, 2010d). Committee advice is delivered following oral and slideshow presentations by pharmaceutical companies and the FDA, and that advice affects the availability of prescription and over-the-

counter drugs in the United States. If a company cannot convey information effectively at an advisory committee meeting, it risks failure to obtain new drug approval, placement of additional label restrictions on approved drugs, and drops in stock valuation. And, while a pharmaceutical company's primary audience at advisory meetings is the committee itself, other important publics such as the FDA, the news media, and investors also hear the company's messaging at these meetings.

There are three theories prevalent in the literature regarding data presentation formats. Those theories—cognitive fit, perception, and dual-coding—provide a foundation for the following investigation into data presentation formats at FDA advisory committee meetings.

Literature Review

Presenters, such as those speaking to advisory committees, need a scientific basis for their choice of data presentation format (Cleveland & McGill, 1984). Unfortunately, the number of variables involved in graphical data display and different approaches to studying each—without concurrence as to what the theoretical foundations for data presentation research should be—make it difficult to establish what that scientific foundation should be (Ancker et al., 2006; Arunachalam et al., 2002; Cleveland & McGill, 1984; Feldman-Stewart, et al., 2007; Price et al., 2006; Smerecnik et al., 2010; Speier, 2006; Tait et al., 2010; Vessey, 1991).

Some researchers have investigated which *type* of data presentation format is most effective (Cleveland & McGill, 1984; Elting et al., 1999; Feldman-Stewart et al., 2007; Hawley et al., 2008; Schapira et al., 2006; Smerecnik et al., 2010; Speier, 2006; Tait et al., 2010; Vessey, 1991), while others have focused on which elements of design *within* formats are most effective (Arunachalam et al., 2002; Feldman-Stewart et al., 2007; Mackiewicz, 2007; Price et al., 2007; Stewart et al., 2009). Difficulty applying the results of these studies arises, in part, because the outcomes measured in display research vary: accuracy (Elting et al., 1999; Feldman-Stewart, et al., 2007; Price et al., 2006; Speier, 2006), knowledge (Hawley et al., 2008; Tait et al., 2010), comprehension (Price et al., 2006; Stewart et al., 2009), response times (Feldman-Stewart et al., 2007; Price et al., 2006), perception (Hawley et al., 2008; Mackiewicz, 2007; Schapira et al., 2006; Tait et al., 2010) format preference (Price et al., 2006; Schapira et al., 2006), and more have all been used as outcome measures.

Further complicating things is that even when outcome measures are similar, findings vary (Ancker et al., 2006; Feldman-Stewart et al., 2007; Smerecnik et al., 2010; Vessey, 1991). Write Feldman-Stewart et al. (2007), "when comparing performance using graphs to that using tables, there is evidence that graphs lead to better performance, equal performance, and poorer performance than tables" (p. 35). Some researchers theorize that the differences in findings result from difference in the tasks research participants are asked to perform with the data (Ancker et al., 2006; Arunchalam et al., 2002; Feldman-Stewart et al., 2007; Vessey, 1991), while others do not comment on it at all.

Despite this murkiness, several themes have emerged from the literature, including cognitive fit theory (Baker et. al, 2009; Feldman-Stewart et al., 2007; Hawley et al., 2008; Speier, 2006; Tait et al., 2010; Vessey, 1991), perception (Baker et. al, 2009; Cleveland & McGill, 1984; Price et al., 2006; Speier, 2006; Tait et al., 2010; Vessey, 1991), and dual-coding theory (Mackiewicz, 2007; Tait et al., 2010; Vessey, 1991). The approach taken here is to review each of these themes in turn, since inclusive research is limited.

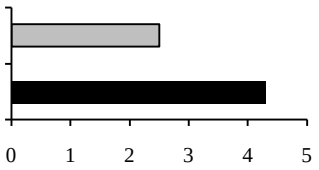
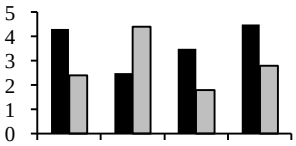
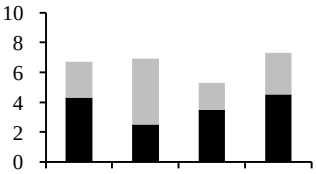
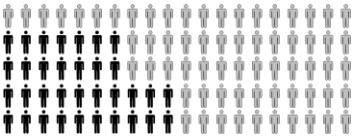
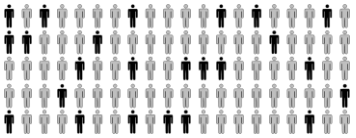
First, a review of cognitive fit theory will reveal the importance of taking into consideration how data will be used when selecting a display format. Next, a discussion of perception theory will explain how viewers obtain data when they look at a table or graph, and, finally, an exploration of dual-coding theory will show how researchers think graphs should be designed when used as part of an oral presentation. Together, these three theories provide a framework within which to consider the most-effective format for data presentation at FDA advisory committee meetings.

First, a note regarding terminology: most of the research reviewed here utilized different versions of each data presentation format. Bar graphs studied by Hawley et al.

(2008), for example, vary slightly from bar graphs studied by Schapira et al. (2006). Some researchers used bar graphs with axes and some did not, some researchers used bar graphs with multiple bars and some did not, etc. Some researchers used similar display formats as others, but referred to the formats by different names. For example, Ancker et al. (2006) studied the "icon array," a type of display more commonly referred to as a pictograph (p. 610). Here, for clarity, the same terms will be used to refer to similar formats regardless of the terminology the original researcher used. Table 1 offers general definitions and representative examples of commonly studied formats. Keep in mind that the actual formats studied by each researcher may vary for the examples shown in the table.

Table 1

Definitions and Examples of Common Presentation Formats

Presentation Format	Representative Definition	Representative Example
Bar graph	"A graph consisting of vertical or horizontal bars whose lengths are proportional to amounts or quantities"[1]	 
Stacked bar graph	Similar to a bar graph, except each bar is divided into sections to represent the different variables.	
Pictograph with consecutive shading	"An icon array [most commonly referred to in the literature as a pictograph] portrays a risk at the discrete level of measurement as a group of individual icons, such as dots or stick figures" (Ancker et al., 2006, p. 610).	
Pictograph with random shading		
Pie chart	A chart that consists of a circle divided into two or more sections by radii of the circle. The size of the sections indicates the size of the variables they represent.	
Sparkline	"Small, high-resolution graphics usually embedded in a full context of words, numbers, images;" they are "word-sized graphics" (Tufte, 2001, p. 171).	Refer to Tufte, 2001

[1] http://dictionary.reference.com/browse/BAR+GRAPH

Cognitive Fit Theory

The discrepancies in the literature regarding whether tables or graphs—and which type of graph—are the best format for data presentation may be explained through cognitive fit theory (Feldman-Stewart et al., 2007; Vessey, 1991). Cognitive fit theory posits that presentation format should be determined by the task at hand; that is, that the format and the task the viewer is asked to perform with the data should "fit" (Vessey, 1991).

The most-effective choice of format is the one that matches the nature of the task (Ancker et al., 2006; Arunachalam et al., 2002; Smerecnik et al., 2010; Speier, 2006; Vessey, 1991). If, for example, tables convey specific numerical values more effectively than graphs do—and the viewer needs to garner specific numerical values from a display—then a table is a better cognitive fit for that task than a graph is. Confusion has arisen as to which display formats are most effective because different researchers have investigated formats in the context of varied tasks (Feldman-Stewart et al., 2007; Vessey, 1991). This practice has led Vessey (1991) to conclude that a "taxonomy" of tasks should be established to prevent apparent conflicts among research findings in this field.

Task type. Typical characterizations of task types in the literature include *spatial* versus *symbolic* tasks (Speier, 2006; Vessey, 1991), *gist* versus *verbatim* knowledge (Hawley et al., 2008; Tait et al., 2010) and *situation model* versus *text base level* knowledge (Smerecnik et al., 2010). Although they use different terminology, the nature of each pair of characterizations is similar. Tasks are characterized "based on the type of information that facilitates their solution" (Vessey, 1991, p.219). Spatial, gist, or situation model tasks require the audience to evaluate relationships between variables (Vessey, 1991). Symbolic,

verbatim, or text base level tasks require the audience to extract specific data values from a display (Vessey, 1991).

Tufte (1997) provides a clear example of a spatial task and cognitive fit theory. In an analysis of the decision to launch the space shuttle Challenger in 1986, which blew up 78 seconds into launch, he determined that there was a "scandalous discrepancy between the intellectual tasks at hand and the images created to serve those tasks" (p. 45). Specifically, engineers tried to communicate to NASA that low temperatures on the day of the launch might lead to failure of the shuttle's O rings. However, none of the visual aids created by the engineers displayed temperature and likelihood of failure together—a poor cognitive fit for the goal of establishing a causal relationship between the two variables.

Like tasks, data presentation formats *themselves* can be categorized as either spatial or symbolic. Intuitively, graphs are spatial representations and tables are symbolic representations (Smerecnik et al., 2010; Vessey, 1991). Thus, the prevailing theory is that graphs are the best format for spatial tasks and tables are the best format for symbolic tasks (Smerecnik et al., 2010).

Empirical testing. Hawley et al. (2008) and Tait et al. (2010) empirically tested the fit between data presentation format and task. Both studies were conducted in the context of health risk communication. Participants viewed benefit/risk data for two drugs—one of which was medically superior—and asked to make a choice between them (Hawley et al., 2008; Tait et al., 2010).

The primary outcome measures for both studies were verbatim knowledge ("actual numerical knowledge") and gist knowledge ("overall impression") (Tait et al., 2010, p. 489). Hawley et al. (2008) investigated the impact of (1) pie charts, (2) bar graphs, (3) pictographs,

(4) sparklines, (5) modified pie charts, and (6) tables on knowledge, while Tait et al. (2010) investigated (1) pictographs, (2) tables, and (3) text. Participants were tested for gist and verbatim knowledge after viewing the data and asked to make a choice between treatments for themselves (Hawley et al., 2008) or for their child (Tait et al., 2010) in a fictional medical scenario. Secondary measures of perception were also evaluated (Hawley et al., 2008; Tait et al., 2010).

Feldman-Stewart et al. (2007) similarly studied the impact of data presentation formats on hypothetical cancer treatment decisions. They did not test cognitive fit theory explicitly, but they did evaluate display formats in the context of gist knowledge (Feldman-Stewart et al., 2007). Primary outcomes were (1) accuracy in choosing the treatment option with the best chance of survival, (2) accuracy in choosing the treatment option with the smaller chance of side effects, and (3) response times among participants randomized to view the various display format.

Feldman-Stewart and colleagues had previously conducted research into gist *and* verbatim information, studying the impact of pie charts, vertical bars, horizontal bars, numbers, and pictographs with oval icons (with either consecutive or random shading) (Feldman-Stewart et al., 2007). They concluded from that research that different formats were in fact better for conveying gist versus verbatim information, and thus, "performance is task dependent" (p. 35). Specifically, vertical bar graphs, followed by pictographs with consecutively shaded icons, were best for conveying gist information. Text, followed again by pictographs with consecutively shaded icons, was best for conveying verbatim knowledge. The findings from this earlier research led to the conclusion that "the best way to present risk information for treatment decisions" either (a) incorporates vertical bars and

numbers, or (b) uses pictographs with consecutively shaded icons (p. 35). Subsequent research by the same authors was intended to investigate option A.

The follow-up study evaluated the same presentation formats as the earlier research; however, three "add-on conditions" evaluated the incorporation of numbers with each format (Feldman-Stewart et al., 2007, p. 50). The conditions, applied to each of the six formats, were: (1) the addition of the numeric value as text, (2) the addition of a scale, or (3) the addition of both the numeric value and a scale. Graph colors were also evaluated in this study, either black and white or blue or yellow, with either a white or blue background.

The Hawley et al. (2008) and Tait et al. (2010) studies were controlled for numeracy (the capacity for quantitative thought and expression,[2] also, quantitative literacy). The results for high and low numeracy individuals as well as results in the aggregate were reported. The findings for participants with high numeracy are likely the most relevant here.

The findings differed slightly among the three studies (Feldman-Stewart et al., 2007; Hawley et al., 2008, Tait et al., 2010). Hawley et al. (2008) found the highest verbatim knowledge, regardless of numeracy, with those randomized to view the table. They found the highest levels of gist knowledge, regardless of numeracy, with those randomized to view the pie chart. Tait et al. (2010) found the highest levels of both types of knowledge, regardless of numeracy, with those randomized to view the pictograph. Feldman-Stewart et al. (2007), who only studied gist knowledge, found that vertical bars with scales led to the fastest and most-accurate responses. Additionally, neither foreground nor background color were found to impact knowledge (Feldman-Stewart et. al 2007).

All three groups of researchers, despite seeing different *findings,* reached similar *conclusions*. The findings are summarized in Table 2. The pictograph was the most-

[2] http://www.merriam-webster.com/dictionary/numeracy

effective format tested by Tait et al. (2010), but not by the other researchers. However, the pictograph was the *second* most-effective format for conveying both types of information in the Hawley et al. (2008) and the Feldman-Stewart et al. (2007) studies. Consequently, all three groups of researchers assert that the pictograph may be the optimal format for presentation of medical benefit/risk information. Medical treatment decisions often require both gist and verbatim knowledge, and the pictograph effectively communicates both.

Table 2

Findings Regarding Best Format for Presentation of Gist or Verbatim Information

	Feldman-Stewart et al. (2007)	**Hawley et al. (2008)**	**Tait et al. (2010)**
Gist information	Vertical bars with scales	Pie charts	Pictographs
Verbatim information	Not studied	Tables	Pictographs
Both gist and verbatim information	Pictographs with consecutive shading	Pictographs	N/A

Task complexity. An additional concept associated with cognitive fit theory is task complexity (Speier, 2006). The idea here is that not only task type, but also the complexity of that task informs fit. Tasks are either simple or complex. Simple tasks require only the acquisition of information (Vessey, 1991). Complex, decision-making tasks also require the acquisition of information and an evaluation of that information (Speier, 2006; Vessey, 1991). Complex information must be processed by the audience in some way (Speier, 2006).

Speier (2006) investigated how data presentation format influences both simple and complex tasks. Her research used cognitive fit theory as a foundation, and thus considered task type—spatial or symbolic—as well as task complexity. This design led to the

investigation of four categories of tasks: spatial-simple, spatial-complex, symbolic-simple, or symbolic-complex.

Spatial tasks require *perceptual* cognitive processes (Speier, 2006; Vessey, 1991). That is, they are solved through "immediate or intuitive recognition"[3]. Symbolic tasks require *analytical* cognitive processes—they are solved through study and analysis. However, Speier hypothesized that there is a "crossover point" at which tasks become so complex that decision makers turn to intuitive perceptual processes to solve analytic symbolic-complex tasks (p. 1120). Thus, at a given level of complexity, spatial graphs become more helpful than symbolic tables in solving symbolic tasks. This means that cognitive fit is moderated by task complexity.

Speier (2006) measured the timing and accuracy of decisions in experimental tests of her hypotheses. Participants evaluated warehouse location and workload scheduling data presented in either tables or bar graphs. The results were generally consistent with cognitive fit theory—for *all* spatial tasks, graphs led to superior accuracy and decision time versus tables. For symbolic-simple tasks, such as comparisons between machine capacity and scheduling, tables were expectantly superior versus graphs for accuracy but not for decision time—a result inconsistent with cognitive fit theory. However, for symbolic-complex tasks, such as comparisons of cost across six periods to the lowest possible cost, tables and graphs led to equivalent accuracy and timing. Speier concludes that this finding results from increased reliance on perceptual processes as complexity increases, as hypothesized. The ultimate conclusion is that cognitive fit theory should be extended to state that "as task complexity increases, decision-makers appear to rely more heavily on their perceptual

[3] http://dictionary.reference.com/browse/perception

processes such that the use of spatial information presentation formats allows for equivalent decision accuracy (at the task level) with symbolic formats" (p. 1126).

In summary, cognitive fit theory purports that, in order to display data effectively, one must take into account how the data will be used. Although it is difficult to draw conclusions from the varied research that has been conducted, graphs seem to be a better fit than tables for tasks that require gist knowledge. However, if specific data values need to be conveyed, tables may be a better cognitive fit than graphs. Because some tasks require both gist and verbatim knowledge and because fit may be moderated by task complexity, however, it may be best to use a display format that conveys both types of knowledge effectively.

Perception

Baker et al. (2009) believe that research into *which* type of graph is most effective should extend beyond cognitive fit theory. They agree that most graphs are spatial representations and thus have a good cognitive fit with spatial tasks. They turn to graphical perception theory for exploration of the perceptual cognitive processes that spatial tasks call for.

Cognitive fit theory focuses on how information gleaned from a display is processed by an audience after it is received—what the viewer does with the information. Perception theory, on the other hand, focuses on how that information is conveyed in the first place—how the viewer obtains the information (Baker et al., 2009, McGuire, 1976). Baker et al. theorize that a data display format is effective if the individual parts of the display—say the bars or the pie pieces that represent variables—help the viewer acquire information.

Perception theory. Perception, with regard to information presentation formats, has been approached from a variety of ways. Cleveland and McGill (1984), statisticians whose

work on graphical communication is cited extensively, worked with a goal of establishing a "science of graphical perception" (p. 537). They focused on both theory and experimental tests of theory to do so. Baker et al. (2009) also studied graphical perception from a theoretical perspective. Other researchers, however, have tested how graphs are perceived without explicitly linking their research to perception theory (Hawley et al., 2008; Mackiewicz, 2007; Schapira et al., 2006; Tait et al., 2010). Those studies investigate the perception of conclusions, such as how scientific the presentation format is, derived after viewing graphical or tabular displays of data.

Cleveland and McGill (1984) define ten "elementary perceptual tasks" that are fundamental to "extracting quantitative information from graphs" (p. 532). Consider how a viewer derives the value of a variable displayed on a bar graph. He or she perceives where the bar that represents the variable ends in relation to the graph's axis. Cleveland and McGill call this activity the "perception of position along a common scale," one of their ten perceptual tasks. The other nine tasks are position along non-aligned scales (as with two bars with different size axes), length, direction, angle, area, volume, curvature, shading, and color saturation. A viewer of a graph perceives the length of a bar, the shading of icons, or the angle of pie pieces, and is able to determine the value of the data based on these perceptions. Similarly, Bertin (as cited in Baker et al., 2009, p. 540) identified four "visual perceptual approaches" that allow for perception and comparison of variables on a graph. The four approaches are association, dissociation, perception of order and perception of quantity.

Both groups of researchers (Baker et al. 2009; Cleveland & McGill, 1984) recognize that different types of graphs naturally elicit performance of different perceptual tasks; for example, pie charts elicit perception of angle and bar graphs elicit perception of position

along a scale (Baker et al., 2009; Cleveland & McGill, 1984). Note that some types of graphs lead to the performance of more than one of these tasks, such as a pie chart, which naturally leads to perception of angle, curvature, and volume.

Cleveland and McGill (1984) theorize that some of the perceptual tasks lead to a more-accurate understanding of the underlying quantitative data than others. Thus, some formats—the ones that elicit those tasks—are superior to others. For example, the value of a variable represented by position along a common scale (e.g., with a bar graph) is theoretically more easily discernible than the value of a variable represented by angle (for example, with a pie chart). Cleveland and McGill suggest that the perceptual tasks, from most to least accurate, are: position (common scales), position (non-aligned scales), length, direction, angle, area, volume, curvature, and shading. Baker et al. (2009) hypothesize that the more a graph encourages the four visual perception approaches, the more effective it is as a format for the presentation of information.

Cleveland and McGill (1984) conducted two experiments to test their theory; Baker et al. (2009) did not conduct empirical research, but suggested experimental designs that may be useful in doing so. The Cleveland/McGill experiments evaluated bar graphs, stacked bar graphs, pie charts, and statistical maps with shading. Judgments of data values that were based on the perception of position were more accurate than judgments based on perception of length in the first experiment and more accurate than perception of angle in the second experiment. The researchers, however, ultimately argue for the use of three alternative information presentation formats that were not evaluated in their study—the dot chart, dot chart with grouping, and framed-rectangle chart. The rationale behind their recommendation is that these formats elicit perceptual tasks that are higher in the ordering of effectiveness

than other formats. Tasks, and thus formats, that lead to a more-accurate understanding of the data should be used whenever possible. However, Cleveland and McGill do note that "the ordering of the perceptual tasks does not provide a complete prescription for how to make a graph. Rather, it provides a set of guidelines that must be used with judgment in designing a graph" (p. 552).

Perception as an outcome measure. Several health risk communication researchers use perception as an outcome measure in evaluations of data display formats (Hawley et al., 2008; Mackiewicz, 2007; Price et al., 2007; Schapira et al., 2006; Tait et al., 2010). These studies evaluate not the method of how quantitative values are perceived by the viewer, but how viewers perceive some thing, after viewing the graphs, other than the values themselves. Examples include conclusions about the data or graph format. Price et al. (2007) explain this interest in conclusions in terms of the goal of health risk communication. That goal is to communicate the level of risk and benefits of a treatment, and thus, interest is in how such things are perceived (Price et al., 2007). For example, in the Hawley et al. and Tait et al. research, the perception of the effectiveness of the graphs and trustworthiness of the data was measured.

Additional perception measures have included helpfulness (Tait et al., 2010) and truthfulness (Schapira et al., 2006) of display formats and how scientific the format is perceived to be (Tait et al., 2010). As with other outcome measures, findings have varied. For example, both the table (Hawley et al, 2008) and the pictograph (Tait et al., 2010) have been rated as the most effective, trustworthy, and scientific format.

PowerPoint/Projection Research and Dual-Coding Theory

Neither cognitive fit nor perception theory address, as a variable, the circumstances under which information is viewed. However, whether graphs and tables are viewed on paper without oral narration or via projection while a presenter is speaking likely has an impact on what type of display is most effective. A third theory, dual-coding theory, informs the selection of data display format under these circumstances.

Communication can be broadly categorized as verbal or nonverbal (Doumont, 2002; Paivio, 1991). Dual-coding theory holds that verbal and nonverbal information is processed along separate channels in the brain (Mackiewicz, 2007; Tait, 2010). The difference between the two types of communication is not whether information is received through the eyes (visual communication) or the ears (auditory communication) but whether or not language is necessary to process the message (Doumont, 2002). Verbal information cannot be understood without language, while nonverbal information can. Either type of information, however, can be communicated via visual or auditory channels.

While verbal and nonverbal information are processed via separate channels, they *are* processed simultaneously. If complementary information is presented via each channel, it can aid recall (Doumont, 2002; Paivio, 1991; Tait, 2010). That is why a visual aid used by a presenter can aid recall of information delivered orally. Complementary verbal (the speech) and nonverbal (the visual aid) information is being presented simultaneously. However, if the information being presented simultaneously is of the same type—either verbal or nonverbal—it can harm recall. Such communications would compete for the same cognitive resources (Doumont, 2002). This competition leads some researchers to argue that if

information presentation formats meant to serve as visual aids are too verbal, they can distract from the overall communication and be less effective.

There is far less empirical research into how dual-coding theory informs the use of tables and graphs in oral presentations than is needed. The available research in this area, which is a start, demonstrates only that two-dimensional graphs are more effective, from an accuracy and comprehension perspective, than three-dimensional graphs (Mackiewicz, 2007; Stewart et al. 2009). Also, Doumont (2002) has used the theory to argue against busy, cluttered slides.

Summary

Cognitive fit theory, perception theory, and dual-coding theory are valuable tools to determine how data should be displayed. How the data will be used, how the viewer will glean information from the display, and whether the display will be used as an aid to an oral presentation should all be taken into account in deciding which format is most effective. The complex number of variables involved in display format research and different approaches to studying them, however, make it difficult to draw practical conclusions from the existing literature. Research that might be informative is made less so because it can only be narrowly applied to circumstances with the same variables.

The difficulties inherent in display format research led Feldman-Stewart et al. (2007) to conclude that "there is virtually no information about what format is best for patients making medical treatment decisions" (p. 35). Likewise, due to a lack of specific research into how data should be presented (1) when used as a visual aid, (2) during an oral presentation, (3) for a medical risk/benefit analysis, there is virtually no information about what format is best for FDA/sponsors to use in presentations to external FDA advisors. This

thesis, the focus of which is to describe how data is currently presented at advisory committee meetings, does not fill the research void. However, it provides a foundation for further research into the field. An understanding of how speakers currently present data to advisory committees is a necessary first step in determining how they *should* present data. In order to explore any of these questions further, an overview of the mechanics of an advisory committee meeting is first in order.

FDA Advisory Committee Meetings: Background and Overview

FDA Advisory Committee Overview

The FDA holds advisory committee meetings to obtain advice from independent experts about the safety and effectiveness of food, drugs, veterinary products and other items regulated by the agency (U.S. Dept. of Health and Human Services, 2008b; U.S. FDA, 2009b). There are 32 different advisory committees, 16 of which provide guidance on drug safety and effectiveness (U.S. FDA, 2009a). Each drug advisory committee focuses on a specific area of medicine such as oncology, endocrinology, or cardiovascular health.

Advisory committees comprise medical or scientific experts who are able to interpret complex data and understand their significance to public health (U.S. FDA 2010b). Many committees also include a patient, consumer, and non-voting pharmaceutical industry representative (U.S. FDA, 2010c). Members serve four-year terms. Their role is to provide advice to the Commissioner of Food and Drugs—the head of the FDA. As such, they are considered Special Government Employees, are paid for their time, and must disclose financial and other conflicts of interest.

Each drug advisory committee meets approximately four times per year. The Food and Drug Cosmetics Act requires meetings under some circumstances and gives the FDA discretion as to when to convene a meeting under others (U.S. Dept. of Health and Human Services, 2008b). The agency outlines three factors it takes into consideration in its decision to call a meeting:

(1) “Is the matter at issue of such significant public interest that it would be highly beneficial to obtain the advice of an advisory committee as part of the agency’s regulatory decision-making process (U.S. Dept. of Health and Human Services, 2008b, p.4)?”

(2) “Is the matter at issue so controversial that it would be highly beneficial to obtain the advice of an advisory committee as part of the agency’s regulatory decision-making process (U.S. Dept. of Health and Human Services, 2008b, p.4)?”

(3) “Is there a special type of expertise that an advisory committee could provide that is needed for the agency to fully consider a matter (U.S. Dept. of Health and Human Services, 2008b, p.4)?”

In the past, the agency has called for meetings to consider new drug applications, to consider proposed new indications for existing drugs, and to discuss controversy regarding a drug’s risk/benefit profile (U.S. Dept. of Health and Human Services, 2008a; U.S. Dept. of Health and Human Services, 2008b,).

Committee members consider issues at meetings by listening to presentations from the drug sponsor, the FDA, and other interested parties. Advisory committee meetings are intended to be open forums where the public may hear presentations and discussion and participate if desired. The FDA is required to notify the public of a meeting at least 15 days in advance and to allow at least one hour during the meeting for public comments (U.S. Dept. of Health and Human Services, 2004). The FDA encourages public participation and holds meetings in facilities, such as hotel ballrooms or conference centers, that accommodate sizable audiences. A typical room setup is depicted in Figure 1. According to FDA guidance (U.S. Dept. of Health and Human Services, 2008b), advisory committee meetings “facilitate public discussion of important topics and provide a means for the public to provide comments to the agency” (p.3).

Figure 1. FDA Advisory Committee Meeting Room Setup

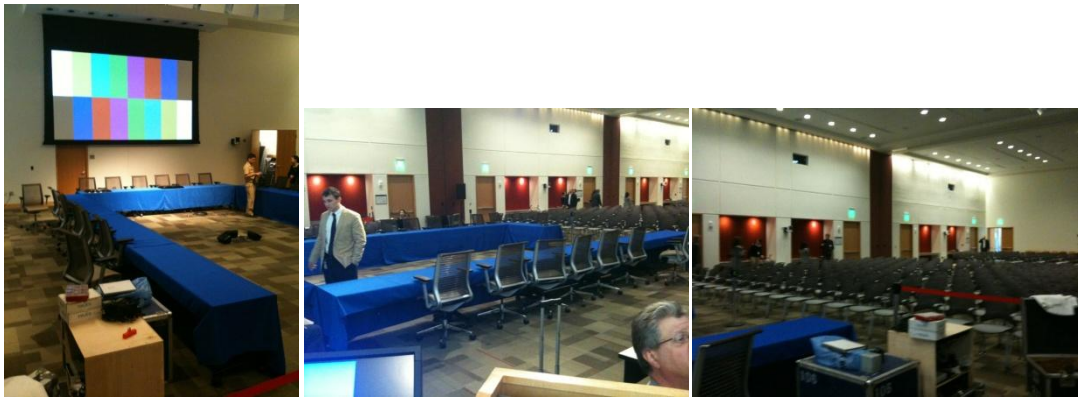


Figure 1. The Great Room of the FDA's White Oak Conference Center, set up for an EMDAC meeting on December 7, 2010, is indicative of a typical advisory committee meeting room setup and size. Committee members sit at the U-shaped table. In keeping with the public nature of committee discussions, the open end of the table faces the audience. Photos ©2010, Celina Mount. Used with permission.

Pre-Meeting Materials

Both the drug sponsors and FDA are required to provide background information on an issue before a committee to its members 14 to 21 days in advance of the meeting at which it will be discussed (U.S. Dept. of Health and Human Services, 2008a). According to the agency, the amount and type of background information—called a briefing document—varies based on the purpose of the meeting. As such, when the FDA notifies a drug sponsor that a meeting will take place—approximately 55 days prior to the meeting—it may also "advise the sponsor about the information it may wish to include in its briefing materials" (U.S. Dept. of Health and Human Services, 2008a, p.8). Importantly, sponsors may only include information derived from drug studies and must exclude any information that is misleading, promotional, defamatory, irrelevant, or intemperate. For many drug advisory committee meetings, the briefing documents are data driven, lengthy—upwards of 200 pages—and detailed.

Conduct of a Meeting

While meeting agendas vary between types of committees, a typical meeting consists of a formal call to order by the committee chairperson, the reading of a conflict of interest statement by the committee's executive secretary, the sponsor's presentation to the committee followed by clarifying questions from the committee, the FDA's presentation to the committee followed by clarifying questions from the committee, the open public hearing, questions from the committee to any speaker, and, finally, public discussion and voting by the committee (U.S. FDA, CDER, 2010). Meetings usually last either four or eight hours, during which the committee must hear presentations, conduct discussions, and make recommendations to the agency.

The discussion and voting portions of a meeting are arguably the most important, since the intent of an advisory committee meeting is to obtain feedback and opinions from the panel members. Since it is the FDA that calls for the meeting and requests the advice, it is also the FDA that determines the topics of discussion. It does so by posing a series of questions to the committee, some of which require only discussion and some of which require a vote from the committee. Voting questions are included in the committee members' advance briefing material. The intent is to provide the committee with the opportunity to thoroughly review the questions prior to the meeting and ensure thoughtful guidance is provided to the FDA at the meeting (U.S. Dept. of Health and Human Services, 2008a). The FDA encourages all committee members to take part in the discussion portion of the meeting, since such activities "help inform the agency's own deliberations on scientific and regulatory matters' (U.S. Dept. of Health and Human Services, 2008c, p.4).

In 2008, the agency adopted new voting procedures to ensure the integrity and consistency of the voting process (U.S. Dept. of Health and Human Services, 2008c). The guidance elucidates both the question format and the voting process itself. Voting questions should "have minimal qualifiers, not be leading, and should avoid the use of double or triple negatives," and the committee chairperson should clarify any confusion panelists may have about a question before a vote is called (p.5) When it is time to vote, members cast their votes simultaneously—versus sequentially—to help prevent influence from the votes that have been cast on ones that have not yet been cast. Votes were often cast sequentially prior to the release of the 2008 guidance.

All information presented at an advisory committee meeting—whether by the agency, the sponsor, the public, or the committee discussion itself—becomes a permanent part of public record. Some information, such as the briefing documents, must be made available to the public at least two days prior to a meeting (U.S. Dept. of Health and Human Services, 2008a). Other information, such as meeting slides and transcripts, are made available to the public following the meeting.

The advice a committee gives the FDA is non-binding; however, the agency usually follows committee advice—by some accounts, as often as 74% of the time (Herper, 2010). Therefore, the substance and conduct of advisory committee meetings are important parts of drug safety evaluation in the United States. On behalf of U.S. taxpayers, the agency spends $8 million annually to conduct advisory committee meetings (Nguyen, et al., 2006).

Previous Advisory Committee Research

A 2006 study into the decision-making process at advisory committee meetings speaks to the impact of communication at these meetings (Nguyen, Cook, & Bero, 2006).

The research entailed a comparative case study of Non-Prescription Drugs Advisory Committee meetings where a prescription to over-the-counter drug switch was considered. The researchers examined the meeting transcripts, the FDA and sponsor slides, and the questions posed by the FDA to the committee to determine the "extent to which committee discussion adhered to" the questions asked of the panel by the FDA (p. 1232).

Nguyen et al. (2006) found that committee questions about the wording and specific meaning of individual words in the FDA questions led committees to wonder how the questions should be interpreted. These interpretations led the committees to change the FDA questions or to create new questions before voting. Only two-thirds of all questions were answered as worded by the FDA.

No research has been specifically conducted in regard to the graphical display of quantitative information at FDA advisory committee meetings. The data presentation that is available is limited here in that it is not specific to graphical displays that are *projected* or used as visual aids while a presenter is speaking. Research most valuable as to how to present slides at advisory committee meetings would regard (1) effective graphical displays (2) of quantitative information (3) that is viewed via projection (4) while a presenter is speaking (5) for the audience to use in a risk/benefit analysis.

Summary

As the previous section demonstrates, FDA advisory committee meetings provide an opportunity for the FDA to obtain independent advice about drug safety and effectiveness. Effective communication on the part of the FDA and drug sponsors is crucial at these meetings. Committees deliver advice at the very meetings where they hear material presented for the first time. Quantitative, clinical trial trail data, in particular, must be presented

clearly. It is the data from clinical trials and real-world experience that drive decisions about drug safety and effectiveness. The tables versus graphs literature—which focuses on cognitive fit, perception, and dual-coding theory—provides a framework within which to consider how data should be displayed at FDA drug advisory committee meetings. More research into communication practices at advisory committee meetings is needed because of a void of research into how data are displayed at these meetings. The first step to learning how data should be displayed must be determining how data currently are displayed. Specifically, the research questions that follow are posited.

Research Questions

RQ1: What types of data presentation formats are prevalent in sponsor and FDA slides shown at U.S. FDA drug advisory committee meetings?

RQ2: Are there differences in data presentation formats based on:

RQ2a) the presenter of the slides (FDA or drug sponsor)?

RQ2b) the type of committee?

RQ2c) the purpose of the meeting? (i.e. new drug applications, drug withdrawals/safety issues, and request for general advice?)

Method

A content analysis was conducted to answer the research questions. The study considered all core slides presented at FDA drug advisory committee meetings in 2010 by either sponsors or the FDA. Slides were coded for two variables: *slide type* and *graph type.*

Sample

There are sixteen different drug advisory committees. They are the:

- Anesthetic and Life Support Drugs Advisory Committee,
- Anti-Infective Drugs Advisory Committee,
- Antiviral Drugs Advisory Committee,
- Arthritis Advisory Committee,
- Cardiovascular and Renal Drugs Advisory Committee,
- Dermatologic and Ophthalmic Drugs Advisory Committee,
- Drug Safety and Risk Management Advisory Committee,
- Endocrinologic and Metabolic Drugs Advisory Committee,
- Gastrointestinal Drugs Advisory Committee,
- Nonprescription Drugs Advisory Committee,
- Oncologic Drugs Advisory Committee,
- Peripheral and Central Nervous System Drugs Advisory Committee,
- Pharmaceutical Science and Clinical Pharmacology Advisory Committee,
- Psychopharmacologic Drugs Advisory Committee,
- Pulmonary-Allergy Drugs Advisory Committee, and the
- Reproductive Health Drugs Advisory Committee.

The sample included all slides that were shown to these committees in 2010 by either drug sponsors or the FDA, with the following exceptions: slides that were not yet posted to the FDA website as of January 3, 2011, slides shown during the question-and-answer portion of the meeting (i.e., backup slides), and slides that were shown to the Pharmaceutical Science and Clinical Pharmacology Advisory Committee. Slides shown to that committee were excluded because it has a different function than the other committees do (U.S. FDA, 2010a).

There were no slides posted as of January 3, 2011 for the following committees: Antiviral Drugs, Arthritis, Dermatologic and Ophthalmic Drugs, and Nonprescription Drugs. Meetings held jointly by two committees were categorized as joint meetings. As such, 12 types of committees held a total of 38 meetings in 2010 for which presentations were available for analysis. This yielded a final sample of 86 presentations (38 by the FDA and 48 by sponsors[4]) and 7,422 slides. Presentations on average lasted for 70 minutes and included 86 slides; additional detail is provided in Table 3. The unit of analysis for this research is the individual slide.

Table 3

Length of Presentations

	Overall	**FDA**	**Sponsors**
Length of presentations (mean)	70 minutes	74 minutes	67 minutes
Length of presentations (range)	10–175 minutes	10–175 minutes	10–105 minutes
Slides per presentation (mean)	86	92	82
Slides per presentation (range)	10–330[a]	20–330[a]	10–144

[a]The next-longest presentation consisted of 162 slides.

[4] There were more sponsor presentations than FDA presentations in the sample. At some advisory committee meetings, such as those held to evaluate a class of drugs, the FDA gave one presentation while several sponsors presented. Other variables, such as whether or not the FDA had posted all 2010 presentations at the time the sample was taken, also account for the difference in number of FDA and sponsor presentations. Details of the sample, including how many presentations were made at each meeting, are available in Appendix A.

Availability of Materials

Materials presented at advisory committees are readily available for analysis because, by law, the FDA must make them available to the public. Meeting announcements, slides, questions posed to committees, meeting agendas, transcripts, and more are posted to the FDA website, http://www.fda.gov/. Each committee has a page on the site where its materials are posted. The slides used in the sample were downloaded from the committee pages on January 3, 2011.

Figure 2. EMDAC Page From fda.gov

Figure 2. Each drug advisory committee has a page on the FDA website, similar to the EMDAC page shown here, where meeting materials were accessed.

Initial Coding

The researcher assigned a unique code to each presentation in the sample and coded each for (a) presenter (either sponsor or FDA), (b) committee, (c) meeting purpose, (d) number of slides in the presentation, and (e) length of presentation. Three coding categories were established for meeting purpose: *new drug application*, *withdrawal/safety issue*, and

general advice. The category for each presentation was determined through a review of the FDA's formal meeting announcement.

Content Categories

Coding was conducted for two variables: slide type and graph type. Seven categories were established for slide type: *text, diagram,/picture, table, graph, table+graph, build*, and *other*. Sixteen categories were established for graph type: *bar graph (2D, horizontal), bar graph (2D, vertical), bar graph (3D, horizontal), bar graph (3D, vertical), stacked bar graph (2D, vertical), stacked bar graph (3D, vertical), line graph, Kaplan-Meier curve, pie chart (2D), pie chart (3D), pictograph, forest plot, XY scatter plot, multiple graphs (same type) , multiple graph (mixed types)*, and *other*. Categories were established based on a qualitative review of slides shown in 2009 at FDA advisory committee meetings, the researcher's experience,[5] and the graph types investigated in the literature reviewed above.

Slide type was determined according to the content of the body of the slide, exclusive of slide title, background, and background graphics. The definitions of the seven categories for slide type are:

- Text
    - Text slides contain only text, contain text as the primary focus with diagram(s) or picture(s) serving as secondary visuals, or contain text and diagrams/pictures in approximately a 50/50 ratio.
- Diagram
    - Diagram slides contain diagrams or pictures as the primary focal point of the slide. Although they may contain a lot of text, a schematic is clearly being used to convey an idea(s).

[5] The researcher developed advisory committee presentations for sponsors from 2005-2008.

- Table
    - Table slides contain tables—"a systematic arrangement of data usually in rows and columns"[6]—either with or without accompanying text. Slides that show text and/or bullets in tabular format were excluded from this category; those slides will be coded as diagram/picture slides (an example is shown in Figure 2). If the information displayed in the table could not have been displayed in graphical format, the slide is not a table slide Only slides that show *data* in table format meet the definition of a table slide.
- Graph
    - Graph slides contain graphs—diagrams "that represent the variation of a variable in comparison with that of one or more other variables"[7]—either with or without accompanying text.
- Table+graph
    - Table+graph slides contain both a table(s) and a graph(s).
- Build
    - Build slides are nearly identical slides shown in a sequence. Slides are often shown in such a series to emphasize or call attention to specific data. It would be inappropriate to code each slide in the series as a separate slide, as the series is usually perceived as one slide by the audience. Every slide in this type of sequence will be coded as a "build" slide except the final slide, which will be categorized appropriately. Note that this will require the coder(s) to go backwards and re-code slides as he or she moves to the next slide and realizes the build nature of the sequence.
- Other
    - Slides that do not fall into any of the categories above.

Examples of all of the categories for slide type are included in Appendix B.

[6] http://www.merriam-webster.com/dictionary/table
[7] http://www.merriam-webster.com/dictionary/graph

Figure 3. Example of Text and/or Bullets in Table Form

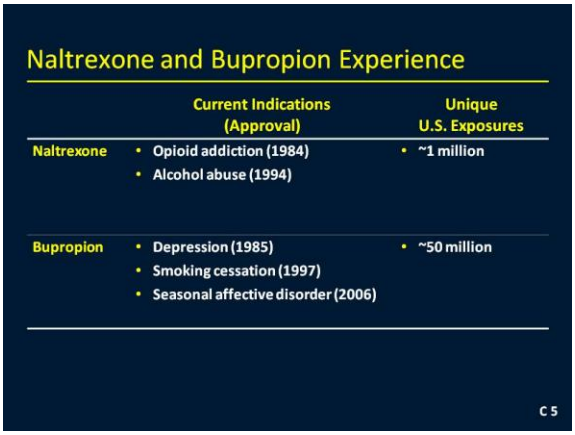


Figure 3. Slides similar to the one shown here were coded as diagram/picture slides. This slide does not meet the operational definition of table. While it does include numbers, it does not display quantitative data (Orexigen Therapeutics, 2010).

Figure 4. Example of a Build Sequence

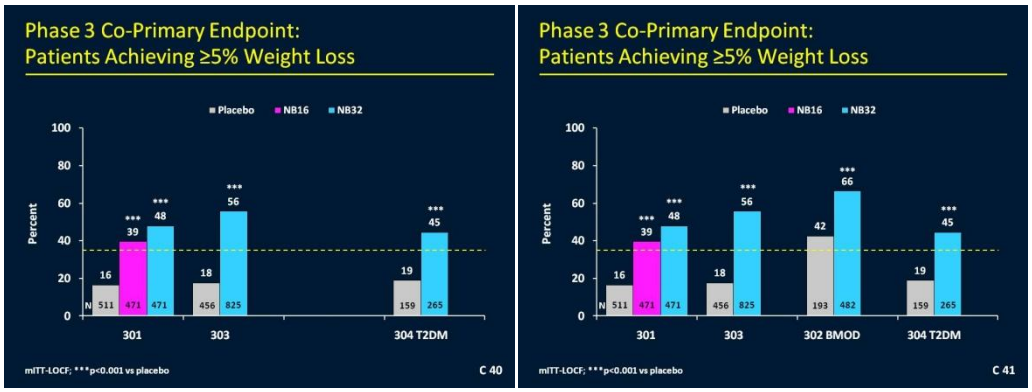


Figure 4. These slides, identical with the exception of the third pair of bars, were shown sequentially (as indicated by the slide numbers and positions in the file). When viewed full-size on-screen, the build nature of these slides is readily apparent. In this example, slide C40 would be coded as a build slide and slide C41 would be coded as a graph slide (Orexigen Therapeutics, 2010).

As slides were coded for type, slides that fell into the graph or table+graph category were also coded for graph type. The definitions of the 16 categories for graph type are:

- Bar graph (2D, horizontal),
    - A graph that uses the comparative length of rectangles, ovals, or some other shape to indicate the size of variables. The shapes are displayed next to each other in a column along the Y axis and may or may not be adjacent. The shapes are displayed horizontally and in two dimensions. Bars may or may include error bars;
- Bar graph (2D, vertical),
    - A graph that uses the comparative length of rectangles, ovals, or some other shape to indicate the size of variables. The shapes are displayed next to each other in a row along the X axis and may or may not be adjacent. The shapes are displayed vertically and in two dimensions. Bars may or may include error bars;
- Bar graph (3D, horizontal),
    - A graph that uses the comparative length of rectangles, ovals, or some other shape to indicate the size of variables. The shapes are displayed next to each other in a column along the Y axis and may or may not be adjacent. The shapes are displayed horizontally and in three dimensions;
- Bar graph (3D, vertical),
    - A graph that uses the comparative length of rectangles, ovals, or some other shape to indicate the size of variables. The shapes are displayed next to each other in a row along the X axis and may or may not be adjacent. The shapes are displayed vertically and in three dimensions;
- Stacked bar graph (2D, vertical),
    - A graph that uses the comparative length of rectangles, ovals, or some other shape to indicate the size of variables. The shapes are placed on top of each other in a continuous stack. The stack is displayed vertically and in two dimensions;

- Stacked bar graph (3D, vertical),
    - A graph that uses the comparative length of rectangles, ovals, or some other shape to indicate the size of variables. The shapes are placed on top of each other in a continuous stack. The stack is displayed vertically and in three dimensions;
- Line graph,
    - A graph that plots data points along one axis. The data points are connected by a line. Data points may or may not include error bars;
- Kaplan-Meier curve,
    - A statistical graph that plots the estimated amount of time it takes for a particular event to occur (time to event).[8] These graphs are recognizable by the stair-like progression of the plot lines;
- Pie chart (2D),
    - A chart that consists of a circle divided into two or more sections by radii of the circle. The size of the sections indicates the size of the variables they represent. The sections may or may not be pulled out from the "pie" as a whole. The sections of the pie are represented in two dimensions;
- Pie chart (3D),
    - A chart that consists of a circle divided into two or more sections by radii of the circle. The size of the sections indicates the size of the variables they represent. The sections may or may not be pulled out from the "pie" as a whole. The sections of the pie are represented in three dimensions;
- Pictograph,
    - A graph that displays geometric or human-shaped icons in relation to other icons to indicate the size of the variable(s) they represent;
- Forest plot,
    - A graph that plots data points and their confidence intervals along one axis. The data points are usually plotted along a horizontal axis and stacked in a column, however, they may also be plotted along a vertical axis and appear in a row;

[8] http://faculty.chass.ncsu.edu/garson/PA765/kaplanmeier.htm

- XY scatter plot,
    - A graph that displays data points plotted along both an X and Y axis. The graph may or may not include a line of regression;
- Multiple graph, same type (specify),
    - A slide that shows two or more graphs of the same type;
- Multiple-graph, mixed types (specify),
    - A slide that shows two or more graphs of different types;
- Other,
    - Graph slides that do not fall into any of the categories above. These slides will be recoded if additional graph categories emerge during the first round of coding.

Examples of each graph type are included in Appendix B.

Coding

Approximately half of the sample (43 presentations, 3, 975 slides) was coded by the researcher, the rest of the sample (43 presentations, 3,477 slides) was coded by a volunteer coder. In order to assign presentations to either the researcher or the coder, the presentations were listed in alphabetical order by committee name. Every other FDA presentation on the list was assigned to either the researcher or the coder, as was every other sponsor presentation. The group that included presentation F14 was assigned to the coder because the researcher helped create that presentation as a consultant to the sponsor.

Coder Training

Prior to coding, the coder received (a) instructions, (b) a quick-reference list of slide types/graph types, and (c) definitions and example(s) of each category. Copies of these training materials can be found in Appendix B.

Initial training consisted of a review of the coding instructions and category definitions. The coder then practiced coding two presentations that had been shown at advisory committee meeting in 2009. This coding was done orally, and miscodes were discussed as they occurred. Fourteen of 244 practice slides were miscoded. Almost all of the miscodes, 13, involved table or diagram slides. Therefore, a third presentation was spot-coded for those two slide types. A second training session was held at a later date to further assure the coder's ability to distinguish between table and diagram slides.

Intercoder Reliability Sample and Testing

In order to conduct tests for intercoder reliability, a random sample of the slides assigned to the coder (stratified by type of committee) was also coded by the researcher. A random number (20) was obtained from random.org. The presentations assigned to the volunteer coder were listed in alphabetical order by committee name and then by presentation code. Every 20th FDA presentation and every 20th sponsor presentation to each committee was selected for the intercoder reliability sample. There were 19 presentations and 1,476 slides in the intercoder reliability sample. This is 22.09% of the total sample of presentations and 19.89% of the total sample of slides.

Initial tests for intercoder reliability, calculated using Hayes' 2007 macro for Krippendorff's alpha, revealed an α of 0.8172 for slide type and 0.8410 for graph type. Despite this acceptable level of reliability, two additional training sessions were held to further ensure the coder could categorize slides/graphs appropriately. At these training sessions, all disagreements that occurred in the intercoder reliability sample were reviewed and discussed.

Coding Procedures

The coder received a memory stick with copies of all of the presentations to be coded. The presentations were in PDF format, which is how the FDA provides the files. Each file that had been downloaded from the FDA website was renamed with a unique code assigned by the researcher, for example, F16.pdf or S24.pdf. The coder also received a spreadsheet that listed (1) the unique file code for each presentation, (2) committee, (3) whether the presentation was an FDA or sponsor presentation, and (4) number of core slides in the presentation.

Slides were coded via online coding instrument. One coding instrument was completed for each presentation in the sample. Presentations were viewed in full-screen mode on a computer screen during coding.

The first six questions in the code sheet required the coder/researcher to enter information from the provided spreadsheet. Those questions are shown in Figure 5 below.

Figure 5. Initial code sheet questions

The primary code sheet question was "Is slide 1 a. . .," with the choices being the seven slide type categories. Only one response per question was allowed, and that

response was required in order to proceed to the next question. If the coder/researcher chose text, diagram, table, build, or other, the coding instrument proceeded to the next question, which inquired about slide 2, etc. If the coder/researcher identified any slide as a graph or table+graph, the next question inquired as to what to of graph it was, with the choices being the sixteen graph types. If the slide contained multiple graphs, same type or multiple graphs, mixed types, the coder/researcher was required to specify the graph type(s) in a text box. The coder/researcher then proceeded to the slide type question for the next slide in the presentation.

Figure 6. Primary code sheet questions

Results

A final sample of 7, 422 slides (86 presentations) was coded for slide type and, when applicable, graph type. The results are reported overall, by FDA/sponsor, by committee, and by meeting purpose.

Research Question 1: Prevalence of Data Presentation Formats

Text slides dominated the sample at 57.65% of the overall slides, as indicated in Table 4. In fact, the non-data slides, which, in addition to text slides, included diagram/picture slides, build, and other slides—comprised 69.93% of the slides shown at advisory committee meetings in 2010.

Table 4

Slides by Type (Overall)

	Total N=7,422 n (%)
Text	4,279 (57.65)
Diagram/picture	761 (10.25)
Table	1,008 (13.58)
Graph	1,099 (14.81)
Table+Graph	125 (1.68)
Build	136 (1.83)
Other	14 (0.19)

The 30.07% of the sample that represents data slides—that is table, graph, or table+graph slides—are the slides of interest here, because those are the slides that speak to the research questions of how data are presented. The data slides are detailed in Table 4. Of

the data slides, table slides and graph slides were seen almost equally across the sample, at 45.16% and 49.23%, respectively. Slides that used tables and graphs in combination were rare, less than 2% of the slides overall (as shown in Table 3) and only 5.6% of the data slides (as shown in Table 5).

Table 5

Data Slides by Type (Overall)

	Total N=7,422 n (%)
Non-data slides	5,190 (69.93)
Data slides	2,232 (30.07)
Table	1,008 (45.16)
Graph	1,099 (49.23)
Table+Graph	125 (5.6)

There were 1, 224 slides in the sample that featured graphs—that is, graph slides or table+graph slides. Those slides were subcategorized into one of sixteen categories, for example, line graph or Kaplan-Meier curve, according to graph type.

With only 1,224 slides displaying graphs, the graph types were quite spread out across the sixteen categories (detailed in Table 6). Some categories held as few as 0% to 2% of the graphs. For this reason, some categories with smaller slide counts were collapsed into others before further analysis. Specifically, the first six categories—which represented some form of bar graph—were collapsed into the new category *all bar graphs*, the two types of pie charts were collapsed into *all pie charts*, and XY scatter plots were folded into the *other* category. The multiple graph, same type category was eliminated, and those slides were redistributed into the appropriate graph type category. For example, 27 of the 179 slides initially coded into the multiple graph, same type category displayed more than one line

graph. This was evident because coders were required to specify, by way of a text box, the type of graph displayed on multiple graph slides. Those 27 slides were recoded as line graphs; other graphs in the multiple graph, same type category were similarly recoded, and the category was eliminated.

Table 6

Original Distribution of Graphs by Type (Overall)

	Total N=1,224 n (%)
Bar graph (2D, horizontal)	21 (1.72)
Bar graph (2D, vertical)	288 (23.53)
Bar graph (3D, horizontal)	1 (0.08)
Bar graph (3D, vertical)	14 (1.14)
Stacked bar graph (2D, vertical)	23 (1.88)
Stacked bar graph (3D, vertical)	1 (0.08)
Line graph	200 (16.34)
Kaplan-Meier curve	143 (11.68)
Pie chart (2D)	20 (1.63)
Pie chart (3D)	7 (0.57)
Pictograph	0 (0)
Forest plot	189 (15.44)
XY scatter plot	12 (0.98)
Multiple graph, same type (specify)	179 (14.62)
Multiple graph, mixed types (specify)	31 (2.53)
Other	95 (7.76)

After revisions, there were eight graph categories, shown in Table 7, instead of sixteen. The most prevalent formats seen were all bar graphs, (33.17%), forest plots (18.63%), line graphs (18.55%), and Kaplan-Meier curves (14.05%). Together, these four

graph types account for 84.40% of all graph usage. Only one slide in the entire sample, shown by a sponsor at a psychopharmacologic drugs meeting, used a pictograph.

Table 7

Graphs by Type (Overall)

	Total N=1,224 n (%)
All bar graphs[a]	406 (33.17)
Line graph	227 (18.55)
Kaplan-Meier curve	172 (14.05)
All pie charts[b]	39 (3.19)
Pictograph	1 (0.08)
Forest plot	228 (18.63)
Multiple graphs, mixed types	31 (2.53)
Other[c]	120 (9.8)

[a]All bar graphs includes: bar graphs (2D, horizontal), bar graphs (2D, vertical), bar graphs (3D, horizontal), bar graphs (3D, vertical), stacked bar graphs (2D, vertical) and stacked bar graphs (3D, vertical).
[b]All pie charts includes: pie charts (2D), and pie charts (3D).
[c]Other includes: XY scatter plots and other.

Figure 7. Pictograph

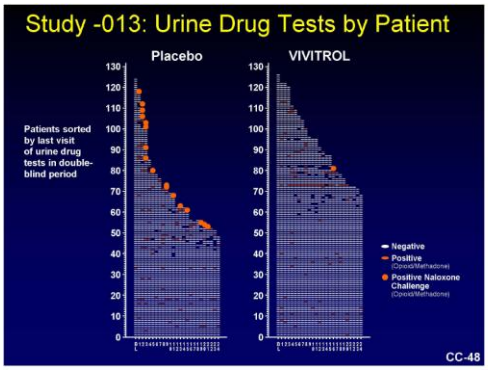


Figure 7. This slide, shown by drug sponsor Alkermes, Inc at a Psychopharmacologic Drugs Advisory Committee meeting in September 2010, was the only pictograph shown to a drug advisory committee by a sponsor in 2010 (Alkermes, Inc., 2010). The FDA showed no pictographs.

Research Question 2a: Results by Presenter (FDA/Sponsor)

Of the 7,422 slides in the sample, 3,508 were shown by the FDA and 3,914 were shown by drug sponsors. The breakdown of these slides by type is shown in Table 8. The FDA was much more likely than sponsors to show data in tables versus graphs—50.96% of the FDA's data slides were tables, as opposed to 40.97% of sponsors'.

Table 8

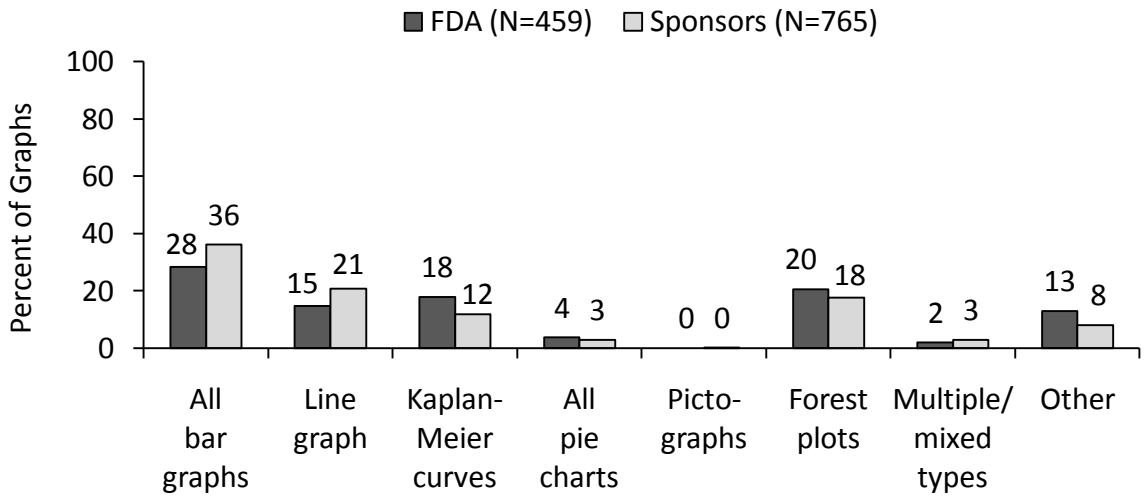
Data Slides by Type (by FDA/Sponsor)

	FDA N=3,508 n (%)	**Sponsor N=3,914 n (%)**
Non-data slides	2,572 (73.32)	2,618 (66.89)
Data slides	936 (26.68)	1,296 (33.11)
Table	477 (50.96)	531 (40.97)
Graph	427 (45.62)	672 (51.85)
Table+Graph	32 (3.42)	93 (7.18)

Graph type usage was very similar between the FDA and sponsors. Both groups were more likely to use bar graphs than any other format and least likely to use pie charts or pictographs. Seven of the eight graph types were utilized by both the FDA and sponsors, and the proportion of graph use by type was similar between the two groups.

Figure 8

Graphs by Type (by FDA/Sponsor)



[a]All bar graphs includes: bar graphs (2D, horizontal), bar graphs (2D, vertical), bar graphs (3D, horizontal), bar graphs (3D, vertical), stacked bar graphs (2D, vertical) and stacked bar graphs (3D, vertical).
[b]All pie charts includes: pie charts (2D), and pie charts (3D).
[c]Other includes: XY scatter plots and other.

Research Question 2b: Results by Committee

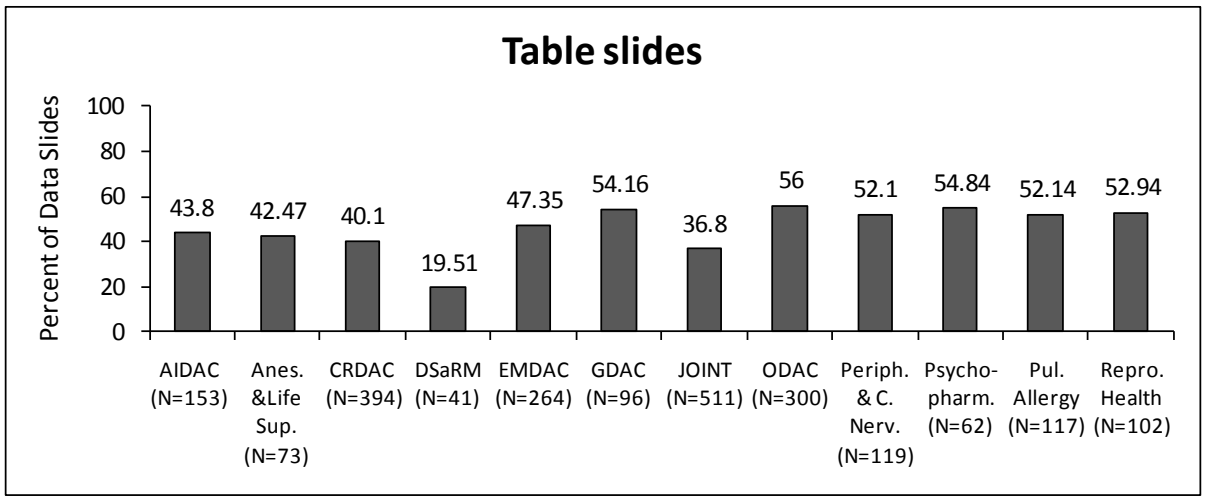
As Figure 9 shows, a broad range of data slide usage was found across committees. The largest difference occurred during Drug Safety and Risk Management Committee meetings, where the difference in percent of data shown via graph versus table was 59%. The smallest difference occurred with the Reproductive Health Drugs Advisory Committee, which saw a 6% difference in data slide types. Six committees saw more table slides than graph slides, five saw more graph slides than table slides, and one saw an equal split of the two types of slides.

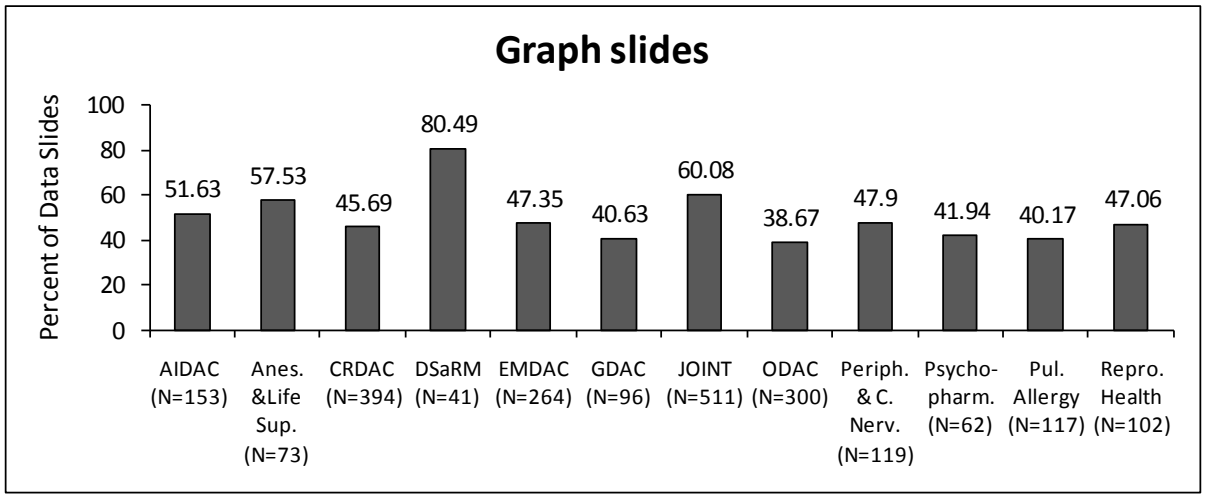
The only committee for which a substantial portion of data was presented via table+graph slides was the Cardiorenal Drugs Advisory Committee. Fourteen percent of the data slides shown to that committee utilized both tables and graphs in combination. The next highest percentage was eight, with all other committees seeing 0% to 5% of data slides in the table+graph combination.

A broad range of graph types, too, was seen across committees. Graph use is displayed in Figure 10. The bar graph was the most-common graph used at nine out of twelve committees, though its use ranged from 22% (at cardiorenal meetings) to 60% (at peripheral and central nervous system meetings) of the graphs overall. That format's lower usage at cardiorenal meetings drove that committee to see a more even distribution of graphs than other committees did. The reproductive health committee saw the least variation, with only three types of graphs used: bar graphs, line graphs, and forest plots. Only one committee saw any pictographs, and only half of the committees saw all seven of the other graph types.

Figure 9

Data Slides by Type (by Committee)





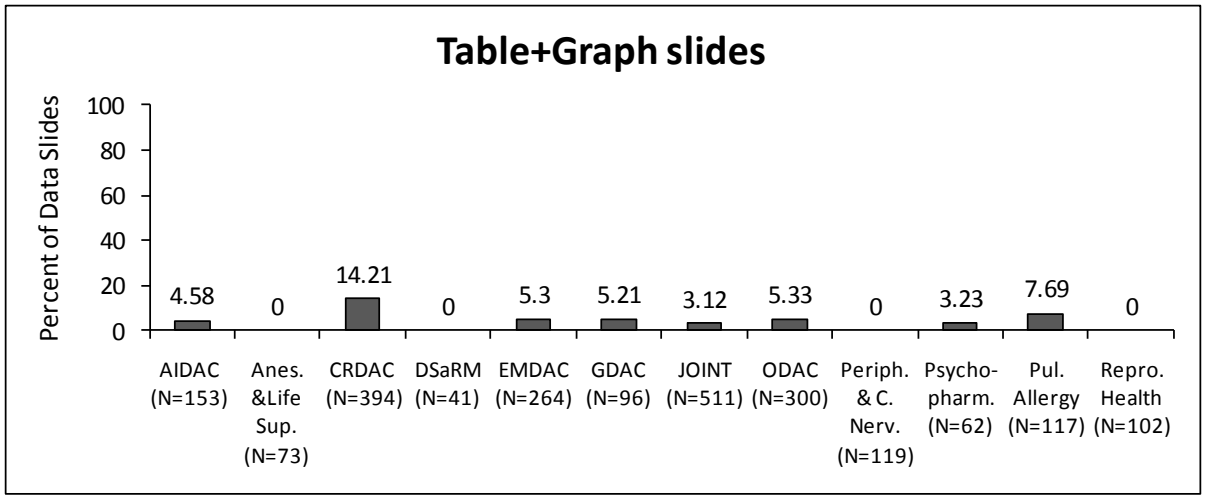
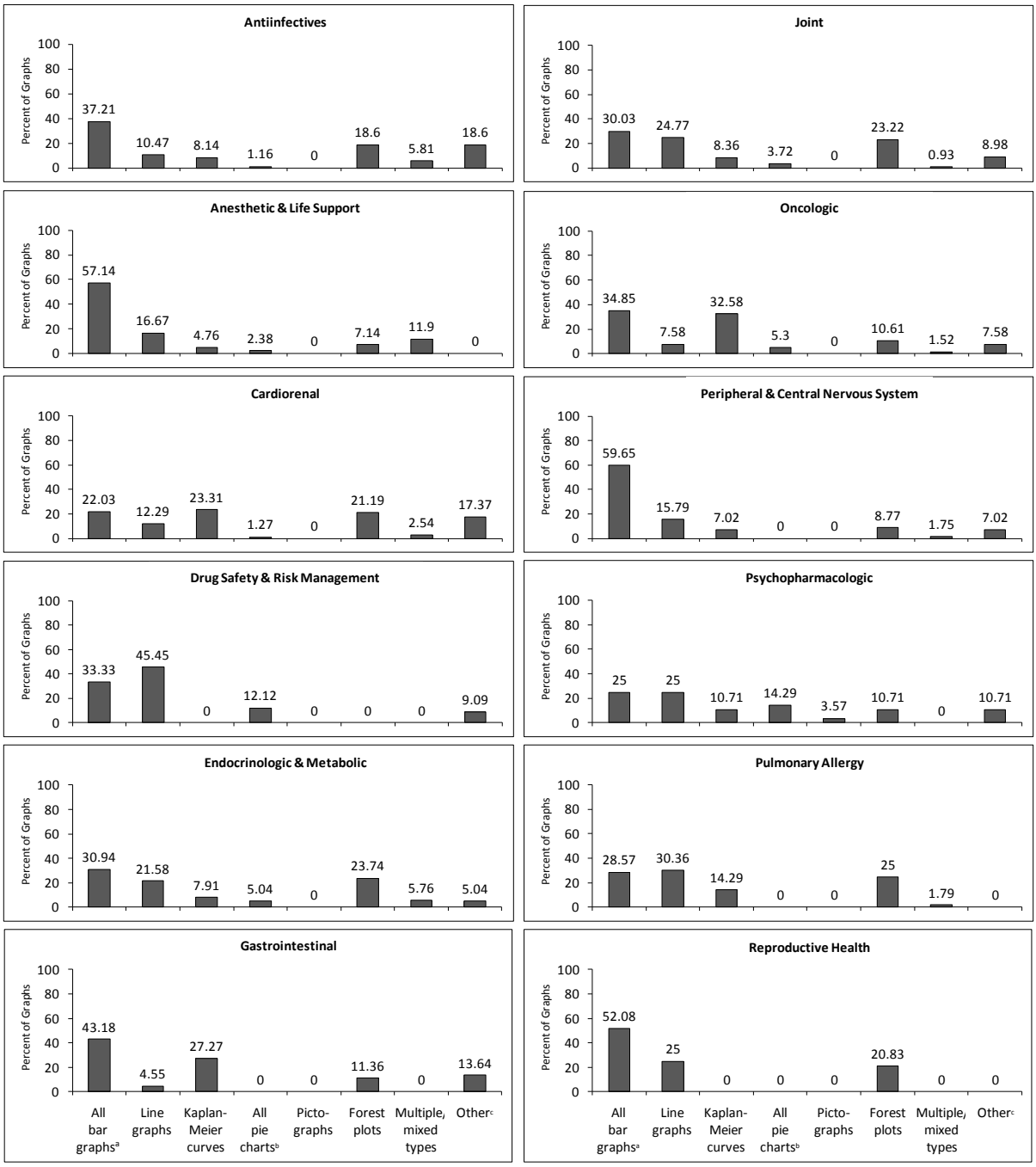


Figure 10

Graphs by Type (by Committee)



[a]All bar graphs includes: bar graphs (2D, horizontal), bar graphs (2D, vertical), bar graphs (3D, horizontal), bar graphs (3D, vertical), stacked bar graphs (2D, vertical) and stacked bar graphs (3D, vertical).
[b]All pie charts includes: pie charts (2D), and pie charts (3D).
[c]Other includes: XY scatter plots and other.

Research Question 2c: Results by Meeting Purpose

As there was across committees, there was a large difference in data slide type use across meeting purposes, shown in Table 9. Slides that displayed tables and graphs in combination were, again, used rarely and in approximately equal measure across groups. Tables and graphs were presented in nearly equal measure at meetings held to consider New Drug Applications (at 47.59% and 46.49% of the data slides, respectively). However, there was a 19% difference between table slide use (37.8%) and graph slide use (56.84%) at withdrawal/safety issue meetings, and 17% difference (39.55% and 56.82%) at general advice meetings.

Table 9

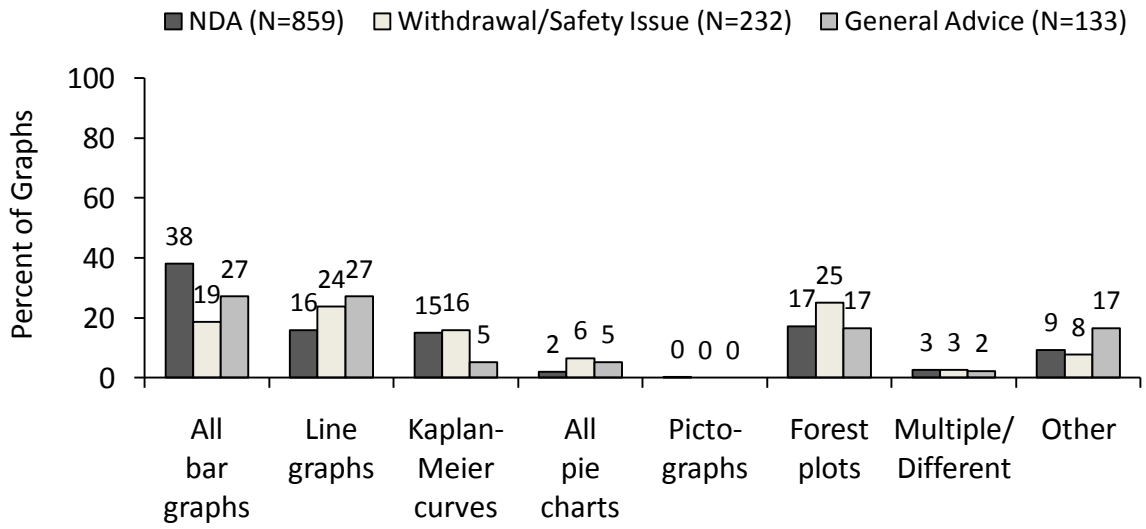
Data Slides by Type (by Meeting Purpose)

	NDA N=4,832 n (%)	**Withdrawal/ Safety Issue N=1,230 n (%)**	**General Advice N=1,360 n (%)**
Non-Data slides	3,193 (66.08)	857 (69.67)	1,140 (83.82)
Data slides	1,639 (33.92)	373 (30.33)	220 (16.18)
Table	780 (47.59)	141 (37.8)	87 (39.55)
Graph	762 (46.49)	212 (56.84)	125 (56.82)
Table+Graph	97 (5.92)	20 (5.36)	8 (3.64)

In terms of graph types across meeting purposes, NDA meetings saw more bar graphs (38.07%) than any other type of graph, followed by forest plots, line graphs, and Kaplan-Meier curves, each at about 15% of the overall graphs. These same four graph types were the most common at withdrawal/safety issue meetings, at which each of the four graph types represented about 20% of the total. So, withdrawal/safety issue meetings see the same types of graphs as NDA meetings and in a similar makeup, just with slightly fewer bar graphs. Three of the same formats—bar graphs, line graphs, and forest plots—were also prevalent at general advice meetings. Kaplan-Meier curve usage, however, was drastically reduced at these meetings compared to those held for other purposes, at only 5.26% of the overall graphs. Instead, "other" graphs are the fourth-most-common graph type at general meetings, at a full 16.54 % of overall graphs.

Figure 11

Graphs by Type (by Meeting Purpose)



[a]All bar graphs includes: bar graphs (2D, horizontal), bar graphs (2D, vertical), bar graphs (3D, horizontal), bar graphs (3D, vertical), stacked bar graphs (2D, vertical) and stacked bar graphs (3D, vertical).
[b]All pie charts includes: pie charts (2D), and pie charts (3D).
[c]Other includes: XY scatter plots and other.

Discussion and Conclusions

This research sought to understand how data are presented at FDA drug advisory committee meetings. Two primary data displays were investigated—tables versus graphs. The prevalence of different graph types was also investigated. As the results showed, there were both similarities and differences across groups in how data were displayed.

Tables versus Graphs

Overall, about half of the data presented at FDA drug advisory committee meetings are presented in tables and about half are presented in graphs. The prevalence of both tables and graphs seems to indicate that presenters at advisory committee meetings want to convey verbatim information and gist information in equal measure. The table+graph combination, studied in the interest of both (a) having mutually slide categories and (b) interest in whether presenters combine the best format for verbatim information (tables) with the best format for gist information (graphs), was used rarely.

Tables and graphs were found almost equally across the sample. However, the FDA is much more likely to display data in tables versus graphs than sponsors are— 51% of the agency's data slides were tables, as opposed to 41% of sponsors'. While reasons as to this difference are speculative, they may indicate a preference on the part of the FDA for communicating verbatim information versus conclusions (gist information) about the data. Or, the reasons may result from the fact that sponsors are in a position to hire outside slide developers for advisory committee meeting preparation, while the FDA is not. Such vendors specialize in the use of software programs typically employed to make slides, such as

Microsoft PowerPoint, and may have more expertise in graph construction than the FDA does.

About half of the committees saw more data in tables than in graphs in 2010. There was a broad range among committees in the proportion of slides that utilized each format. Graphs dominate at drug safety and risk management committee meetings (80.49% graphs) and at joint meetings (60.08% graphs). Meanwhile, the six committees that saw more tables than graphs saw them in a narrower proportion, with a range of 6%-17% more table slides than graph slides. These observations indicate that there are differences in how data are presented at each committee.

Not surprisingly, data slides overall were much less common at meetings held to obtain general advice from committees than at meetings held to discuss new drug applications or drug safety issues. Data slides only account for 16.18% of all slides shown at general advice meetings, as opposed to 33.92% and 30.33% at NDA and withdrawal/safety issue meetings. This makes sense, because decisions at NDA and withdrawal/safety issue meetings are data-driven, while decisions at general advice meetings may not necessarily be. If the FDA is seeking advice from a committee about appropriate study designs (as was the case with the joint pulmonary allergy/DSaRM meeting on March 10, 2010), for example, there may be little clinical data to share. The focus of those presentations would not on the results of drug trials or on data collected from real-world drug use, but on elements of study design and potential endpoints, issues that would not call for the presentation of data.

There is a substantial difference in the way data are presented based on meeting purpose. Table slides and graph slides were used in approximately a 50/50 ratio at meetings held to discuss new drug applications. This is in striking contrast to meetings held for any

other purpose, where about approximately 20% more data slides were graphs versus tables. This disproportion seems to indicate more of an interest in presenting verbatim information at NDA meetings than at meetings held for any other purpose.

Graph Type

Graph use overall was dominated by the four most-prevalent types of graphs: all bar graphs, forest plots, line graphs, and Kaplan-Meier curves. Each of these graph types typically serves a mutually exclusive purpose; for example, bar graphs are used to display parts of a whole (Cleveland & McGill, 1984) and line graphs are used to display data in a time series (Reynolds, 2010). Pie charts and bar graphs, in contrast, do not serve mutually exclusive purposes. Both are often used to show parts of a whole (Cleveland & McGill, 1984). The exclusivity of the graph types that were prevalent in the sample would seem to indicate that each of the common graph types is commonly accepted/preferred over others for its particular function by presenters in this environment.

The collapse of the original sixteen graph categories into eight was necessary to see any real similarities or differences in graph types across groups (particularly committees). What was lost due to the collapse was the opportunity to explore more-refined graph options, such as 2D versus 3D bar graphs. Nevertheless, the sample was not large enough for this exploration.

The findings regarding graphs do beg the question of why pictographs are not used more commonly in the advisory committee setting. Tait et al. (2010) make a strong case for the format, finding pictographs to be better than text or tables at conveying both gist and verbatim information, even in high numeracy individuals. Participants in the Tait et al. study also rated pictographs as more effective, helpful, scientific, and trustworthy than text or

tabular formats. One cause for the format's absence might be the fact that pictographs are not a built-in graph option in standard slide development software programs. However, that is also the case with Kaplan-Meier curves, which made up 14.05% of the graphs in the sample. Further exploration of this question is warranted. Are Kaplan Meier curves easily produced in statistical software, and thus find their way onto slides more easily than pictographs do? Are other factors, such as a perception within the pharmaceutical community that pictographs are unscientific, causing the format to be overlooked? Or, is simple lack of awareness of the utility of the pictograph driving its absence from advisory committee presentations?

The distribution of graph types by presenter—FDA versus sponsor—was strikingly similar. The largest difference was only 8%, seen with bar graphs, with sponsors being more likely to use that format than the FDA was. So, while differences in graph type usage between the FDA and sponsors were evident, they were not pronounced. This similarity in graph choice seems to indicate that the factors that drive decisions regarding graph type are similar for both sets of presenters. The data themselves, and not other, external factors, are the most likely candidate.

There were similarities and differences in graph type use between committees. The four most common graphs overall were all seen by 11 of the 12 committees. Some committees (GDAC, Perip. & Cent. Nerv. Sys., Pul. Allergy, and Reproductive Health) saw no pie charts, while that format constituted a full 12.12% of graphs shown to the DSaRM committee. Because graph type did not vary much across presenters (FDA/sponsors) or across meeting purposes, it is possible that the difference here are driven by the small n's. A larger sample would have been useful in evaluating difference across committees further.

As with FDA/sponsors, findings for graph type were similar across meeting purposes. When data are presented graphically there is little variation in graph format regardless of meeting purpose.

Limitations

This research describes how data *are* presented at FDA drug advisory committee meetings. It does not speak to *why* data are presented the way they are or suggest how they *should* be presented. Neither does this research speak to whether choice of format affects the decisions made by advisory committee members.

Slides are only one part of overall communications at advisory committee meetings. This research considered only data presentation formats, and considered them in the absence of other things that may affect their effectiveness. The oral presentation that accompanies the slides and the lengthy briefing documents that committee members receive in advance of a meeting likely impact committee members' understanding of the data. The research presented here did not evaluate data presentation formats in the context of these other elements of communication.

Finally, as previously stated, the sample size here did not allow for additional distinctions in graph use across groups, such as the use of 3D graphs versus 2D graphs. These and explorations of other factors that impact graph effectiveness, such as extraneous information, color, and labels, were not conducted.

Conclusions

The utility of this research lies in its ability to provide a baseline understanding of how quantitative data are communicated at drug advisory committee meetings. To the researcher's knowledge, communication practices at these meetings have never been

investigated via an academic rubric. The research led to three key findings; one of which was general and two of which were in regard to how the FDA communicates compared to drug sponsors. We now know that (1) tables and graphs are used in nearly equal measure at advisory committee meetings, (2) that the FDA is more likely than drug sponsors to display data in tables versus graphs, and (3) that graph types are used in strikingly similar proportions by the FDA and sponsors.

What are the implications of these findings? The literature, though inconclusive, suggests that tables are the most effective format for the presentation of verbatim information and graphs are the most effective format for the presentation of gist information (Smerecnik et al., 2010). Since both formats are used in equal measure at advisory committee meetings, it is safe to conclude that presenters in this arena give weight to both types of information. They want committee members to have access both to specific data values—verbatim information, and to data that offer comparisons—most likely of the sponsor's drug to a placebo or the standard of care.

That the FDA is more likely to use tables than graphs may mean that the agency's focus is on providing verbatim data to committee members. Sponsors, on the other hand, may be more interested in communicating conclusions about the data than the verbatim values. This dichotomy makes sense and may even be beneficial to the drug approval process; after all, sponsors are more familiar with their data than other advisory committee participants and may be in the best position to draw conclusions. The FDA, on the other hand, does not want to impart their conclusions to a committee as much as garner *the committee's* opinion about the data. Committee members, thus, become privy to verbatim

information via the FDA and gist information via sponsors. Both types of information are necessary to weigh medical benefit/risk information—the very act the committee engages in.

The research presented here informs how groups communicate at advisory committee meetings. However, without further research, it is impossible to know if they communicate in the most-effective manner. Remember, information is communicated effectively if the audience receives, comprehends, agrees with, retains, and retrieves it (McGuire, 1976). When it comes to the communication of quantitative information, effectiveness may hinge upon the format used to display the data. The oral nature of advisory committee presentations, however, must be taken into account when determining the effectiveness of data display formats.

Dual-coding theory suggests that tables, with their inherent verbal nature, may not be the best format for communicating verbatim information *during an oral presentation*. Remember, dual-coding theory holds that verbal information—information that requires language to be comprehended—should not be delivered over auditory and visual channels at the same time (Doumont, 2002; Paivio, 1991; Tait, 2010). Are committee members too focused on the verbal speech to make sense of the verbal information presented in a table? Are they too focused on the table to make sense of the speech? In other words, are advisory committee presenters lowering the effectiveness of their communications when they use tables by delivering competing information simultaneously? If dual-coding theory holds true, they are. The data would be delivered more effectively if displayed in a format that was more non-verbal in nature, like a graph.

Only through additional research will questions of effectiveness be answered. Research designs that take cognitive fit and dual-coding theory, at a minimum, into account

are a necessary first step. An experiment that would best approximate the conditions at a committee meeting would use participants randomized to view medical benefit/risk information in a table or graph while they listen to an oral presentation. A more-refined investigation of graphic visuals is also in order. Color (Mackiewicz, 2007), 2D versus 3D formatting (Mackiewicz, 2007; Stewart et al., 2009), gridlines (Tufte, 2001), and labels (Tufte, 2001) are all known to affect the effectiveness of graphs. Are decisions regarding these and other formatting choices being made wisely by advisory committee presenters? A determination cannot be made until formatting choices are investigated in an environment that approximates the advisory committee setting.

Until the research outlined above is conducted, the FDA and sponsors can turn to theories such as cognitive fit and dual-coding to inform their decisions regarding data presentation. If the presentation format should fit the task, as cognitive fit theory suggests, then data that inform spatial tasks should be presented via graphs. Data that need to be communicated verbatim should be presented via tables. Presenters will thus provide information to committee members via a format that will fit with the task the committee will undertake. However, all slides, whether they forward spatial or verbatim thinking, should be kept as non-verbal as possible. The reason for this is that advisory committee slides are accompanied by an oral presentation—which is inherently verbal in nature. Dual-coding theory holds that verbal information presented simultaneously via visual and auditory channels cannot be processed by the audience. Speakers, in essence, cancel out their communications when both their slides and accompanying speech are verbal. Slides can be kept non-verbal by following commonly purported advice to reduce clutter, use consistent scales, and eliminate unnecessary visual elements. Tables are verbal in nature and may

present a challenge—appropriate pausing by speakers to allow committee members to process tabular data may be one solution. Another solution may be to explore use of the pictograph in lieu of tables to present verbatim data. Although, since committee members are unaccustomed to seeing pictographs in advisory committee presentations, the FDA and sponsors would be wise to first test the format in other arenas or to seek feedback on the format from outside medical consultants.

Lives and livelihoods are on the line at FDA drug advisory committee meetings. The former, for patients who depend upon the availability of safe, effective medications; the later, for drug company employees and investors who depend on the financial success of drug development. While advisory committees do not have the final say regarding drug approval, their advice plays an influential role. Those who have the privilege of addressing advisory committees, whether they represent the FDA or drug developers, have an obligation to represent the data well.

The understanding of how quantitative data are communicated at drug advisory committee meetings gleaned from this research provides a basis for future research. Furthermore, it may bring attention to the understudied question of how data are evaluated by committees chartered to advise the government about drug safety and effectiveness in the United States.

Appendix A

Details of the Sample

- Anesthetic and Life Support Drugs Advisory Committee
  - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/ucm193298.htm
  - 6 meetings listed for 2010 (2 were cancelled)
  - 3 meetings were joint with DSaRM
  - Final sample size of:
    - 1 meeting
    - 1 FDA presentation
    - 1 sponsor presentation

- Anti-Infective Drugs Advisory Committee
  - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/ucm208081.htm
  - 2 meetings listed for 2010
  - Note: at the Sept 7 meeting, the committee considered one drug for two indications. Both the FDA and the Sponsor presented on each indication separately.
  - Final sample size of:
    - 2 meetings
    - 3 FDA presentations
    - 3 sponsor presentations

- Antiviral Drugs Advisory Committee
  - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AntiviralDrugsAdvisoryCommittee/ucm206847.htm
  - 1 meeting listed for 2010
  - Note: no slides were posted as of 3 Jan 2011
  - Final sample size of:
    - 0 meetings
    - 0 FDA presentations
    - 0 sponsor presentations

- Arthritis Advisory Committee
    - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisDrugsAdvisoryCommittee/ucm203434.htm
    - 3 meetings listed for 2010
    - 2 meetings were joint with DSaRM
    - Note: no slides were posted for the 16 Nov meeting as of 3 Jan 2011
    - Final sample size of:
        - 0 meetings
        - 0 FDA presentations
        - 0 sponsor presentations

- Cardiovascular and Renal Drugs Advisory Committee
    - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm192863.htm
    - 7 meetings listed for 2010
    - Note: at the 8 Dec meeting, there was no FDA presentation. There was no sponsor, but there was a presentation from "industry" that was included in the sample.
    - Final sample size of:
        - 7 meetings
        - 6 FDA presentations
        - 7 sponsor presentations

- Dermatologic and Ophthalmic Drugs Advisory Committee
    - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DermatologicandOphthalmicDrugsAdvisoryCommittee/ucm211780.htm
    - 1 meeting listed for 2010 (but it was cancelled)
    - Final sample size of:
        - 0 meetings
        - 0 FDA presentations
        - 0 sponsor presentations

- Drug Safety and Risk Management Advisory Committee
    - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/ucm199874.htm
    - 10 meetings listed for 2010 (one of which was cancelled, 8 of which were joint)
    - Note: at the 14 Sept meeting, there was no sponsor presentation per se. CHPA gave a presentation in a role similar to that of a sponsor and that presentation was included in the sample.
    - Final sample size of:
        - 1 meetings
        - 1 FDA presentations
        - 1 sponsor presentations

- Endocrinologic and Metabolic Drugs Advisory Committee
    - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm191113.htm
    - 7 meetings listed for 2010 (one of which was cancelled, 1 of which was joint)
    - Note: no slides were posted for the 12-13 Jan or 27 May meetings as of 3 Jan 2011.
    - Final sample size of:
        - 3 meetings
        - 3 FDA presentations
        - 3 sponsor presentations

- Gastrointestinal Drugs Advisory Committee
    - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/GastrointestinalDrugsAdvisoryCommittee/ucm195280.htm
    - 3 meetings listed for 2010
    - Note: a "sponsor presentation" is listed on the agenda for the 4 Nov meeting and that presentation is included in the sample. It is not clear from the agenda, the meeting announcement, or the slides who the sponsor is. Based on the topic of the meeting and the affiliations of the speakers, it seems that this is an "industry' presentation.
    - Note: multiple companies are listed as sponsors for the 5 Nov meeting. The FDA presentation at this meeting was very short, 10 minutes and 26 slides, but is included in the sample.

    - Final sample size of:
        - 3 meetings
        - 3 FDA presentations
        - 3 sponsor presentations

- Nonprescription Drugs Advisory Committee
    - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/default.htm
    - Note: no meeting information at all is posted for 2010
    - Final sample size of:
        - 0 meetings
        - 0 FDA presentations
        - 0 sponsor presentations

- Oncologic Drugs Advisory Committee
    - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/ucm195226.htm
    - 6 meetings listed for 2010 (one of which was postponed, one of which was a meeting of the ODAC pediatric subcommittee)
    - Note: The 22 March meeting considered two separate issues. There were two FDA presentations and two sponsor presentations.
    - Note: The 30 Nov meeting included one FDA presentation and 4 separate presentations from 4 different sponsors.
    - Note: The 1 Dec meeting considered two separate issues. There were two FDA presentations and two sponsor presentations.
    - Final sample size of:
        - 5 meetings
        - 7 FDA presentations
        - 10 sponsor presentations

- Peripheral and Central Nervous System Drugs Advisory Committee
    - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/ucm204899.htm
    - 4 meetings listed for 2010 (one of which was joint with DSaRM)
    - Note: no FDA presentation was given at the 6 May or 11 Aug meetings.

    - Final sample size of:
        - 3 meetings
        - 1 FDA presentation
        - 3 sponsor presentations

- Psychopharmacologic Drugs Advisory Committee
    - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/ucm221387.htm
    - 1 meeting listed for 2010
    - Final sample size of:
        - 1 meeting
        - 1 FDA presentation
        - 1 sponsor presentation

- Pulmonary-Allergy Drugs Advisory Committee
    - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/ucm199877.htm
    - 3 meetings listed for 2010 (one of which was joint with DSaRM)
    - Final sample size of:
        - 2 meetings
        - 2 FDA presentations
        - 2 sponsor presentations

- Reproductive Health Drugs Advisory Committee
    - Materials accessed 3 Jan 2011 from: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/ucm210869.htm
    - 2 meetings listed for 2010
    - Final sample size of
        - 2 meetings
        - 2 FDA presentations
        - 2 sponsor presentations

- Joint meetings
    - Materials accessed 3 Jan 2011. All joint meetings were between DSaRM and some other committee. Materials were accessed from the 'other' committee's page, e.g., materials from joint meetings of DSaRM and CRDAC were accessed from the CRDAC page.

- Joint DSaRM and Anesthetic and Life Support Drugs Advisory Committee
  - 3 joint meetings
  - 3 FDA presentations
  - 5 sponsor presentations
- Joint DSaRM and Arthritis Drugs Advisory Committee
  - 2 joint meetings
  - 2 FDA presentations
  - 2 sponsor presentations
- Joint DSaRM and Peripheral and Central Nervous System Drugs Advisory Committee
  - 1 joint meetings
  - 1 FDA presentation
  - 1 sponsor presentations
- Joint DSaRM and Endocrinologic and Metabolic Drugs Advisory Committee
  - Note: there were two sponsors listed for this meeting, but in one set of sponsor slides, there were only two slides. Furthermore, those slides did not appear to constitute a presentations, rather, they looked like slides that would appear anywhere in a presentation. Therefore, that presentation was excluded from the sample.
  - 1 joint meetings
  - 1 FDA presentation
  - 1 sponsor presentations
- Joint DSaRM and Pulmonary-Allergy Drugs Advisory Committee
  - 1 joint meetings
  - 1 FDA presentation
  - 3 sponsor presentations
- Total sample size for all joint meetings of
  - 8 meetings
  - 8 FDA presentations
  - 12 sponsor presentations

Appendix B

Copies of Training Materials

Instructions

Thank you for volunteering to code slides for my thesis. You will be categorizing slides that were shown to FDA advisory committees in 2010 by either the FDA or a pharmaceutical sponsor.

The slides are part of presentations that have been sent to you on a memory stick. Other resources you will need include these instructions and an Excel spreadsheet that has been emailed to you.

You will code slides into one of seven categories listed on the next page. You will subcategorize slides that fall into either the 'graph' or 'table+graph' categories into one of 16 subcategories, also listed on the next page. Definitions of each category and subcategory are included in these instructions. In many cases, examples have also been provided. Take your time and remember to ask yourself: "what is the intent of this slide?" as you code.

You will code the slides via online surveys. The surveys are accessible at: https://uncodum.qualtrics.com/SE/?SID=SV_3elF4D2xGQYZuJu. The surveys require a password, which is 'thesis'. Answer one survey for each presentation assigned to you.

The Excel spreadsheet that was emailed to you lists all of the presentations that you will code. It also includes additional information that you will enter into each survey. This information includes: the survey code (filename), the committee that the slides were presented to, whether the presentation was given by the FDA or sponsor, and the number of slides in the presentation.

If you have any questions, you can reach me at lmsmith2@yahoo.com or at (919) 607-5844.

Instructions, cont.

Code slides into one of the following seven categories:

- Text
- Diagram
- Table
- Graph
- Table+graph
- Build slide
- Other

Subcategorize graph slides and table+graph slides as:

- Bar graph (2D, horizontal)
- Bar graph (2D, vertical)
- Bar graph (3D, horizontal)
- Bar graph (3D, vertical)
- Stacked bar graph (2D, vertical)
- Stacked bar graph (3D, vertical)
- Line graph
- Kaplan-Meier curve
- Pie chart (2D)
- Pie chart (3D)
- Pictograph
- Forest plot
- XY scatterplot
- Multiple graph, same type (**specify**)
- Multiple-graph, mixed types (**specify**)
- Other

If 'multiple-graph, same type' or 'multiple-graph, mixed types' is selected, you will be asked to specify the type(s) of graphs. Refer to the graphs using the same terminology listed here. For example, if a slide contains a line graph and a 2D vertical bar graph, enter: "Line graph, bar graph (2D, vertical)," not, "Line graph, 2D vertical bar graph". Separate graph types with a comma. If the graphs are the same type, you need only list the graph once. For example, if a slide has multiple line graphs, you need only enter "Line graph," not "Line graph, line graph."

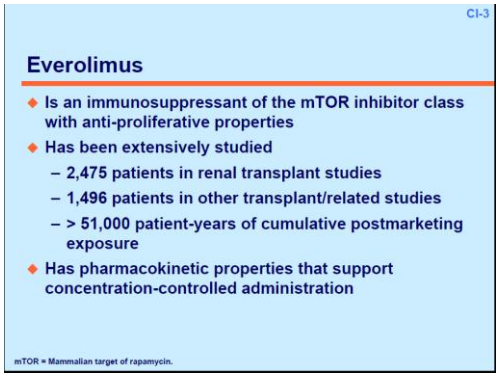
Categorizes slides based on the content of the body of the slide, exclusive of slide title, background, and background graphic.

Text

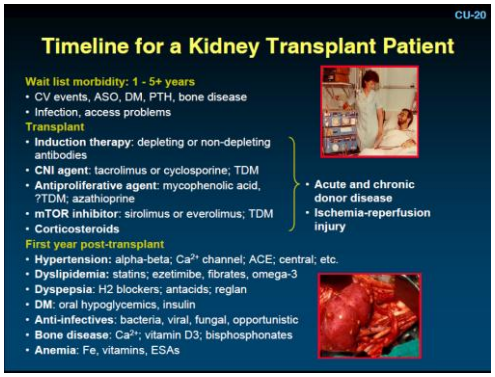
Text slides contain: (a) only text, (b) text as the primary focus with diagram(s) or picture(s) serving as secondary visuals, or (c) text and diagrams/pictures in approximately a 50-50 ratio.

Example(s)

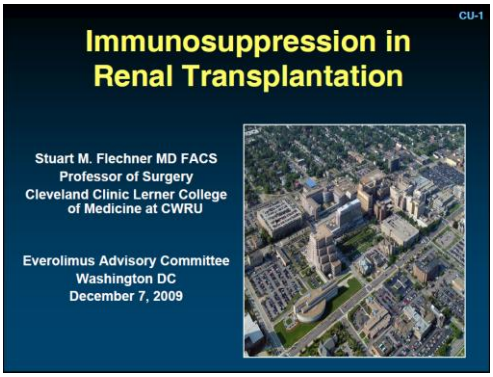
(a)



(b)



(c)

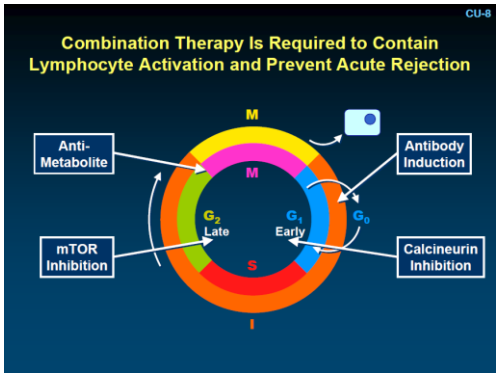


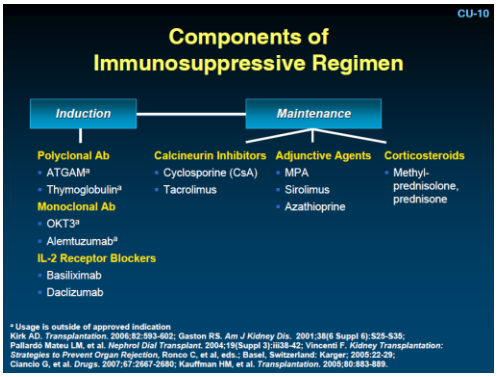
Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm195971.htm

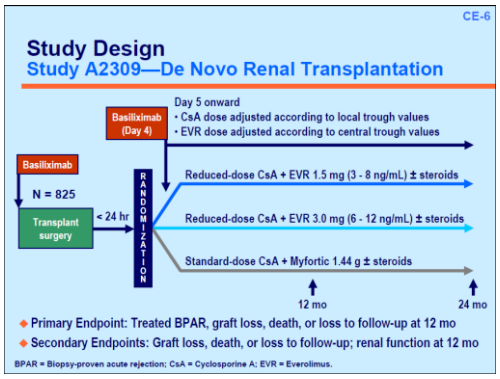
Diagram

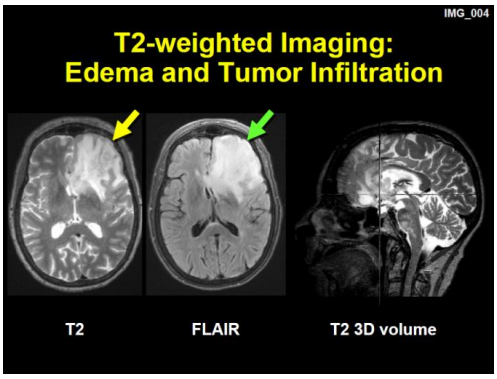
Diagram slides contain diagrams or pictures as the primary focal point of the slide. Although they may contain a lot of text, a schematic is clearly being used to convey an idea(s).

Example(s)







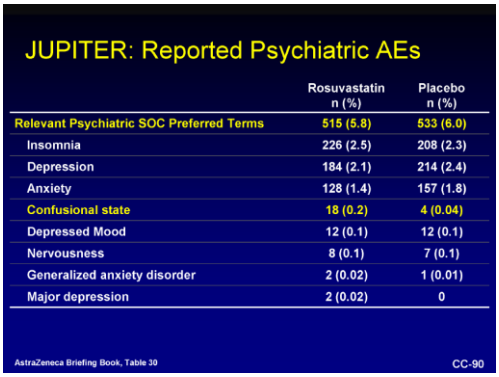


Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm195971.htm;
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/ucm148865.htm

Table

Table slides contain tables—"a systematic arrangement of **data** usually in rows and columns"—either with or without accompanying text. Slides that show text and/or bullets in table form will be excluded from this category; those slides will be coded as diagram/picture slides. If the information displayed in the table could not have been displayed in graphical format, the slide is not a table slide. Only slides that show *data* in table format meet the definition of a table slide .

Example(s)



JUPITER: Reported Psychiatric AEs

	Rosuvastatin n (%)	Placebo n (%)
Relevant Psychiatric SOC Preferred Terms	515 (5.8)	533 (6.0)
Insomnia	226 (2.5)	208 (2.3)
Depression	184 (2.1)	214 (2.4)
Anxiety	128 (1.4)	157 (1.8)
Confusional state	18 (0.2)	4 (0.04)
Depressed Mood	12 (0.1)	12 (0.1)
Nervousness	8 (0.1)	7 (0.1)
Generalized anxiety disorder	2 (0.02)	1 (0.01)
Major depression	2 (0.02)	0

AstraZeneca Briefing Book, Table 30

CC-90

Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm194913.htm

Graph

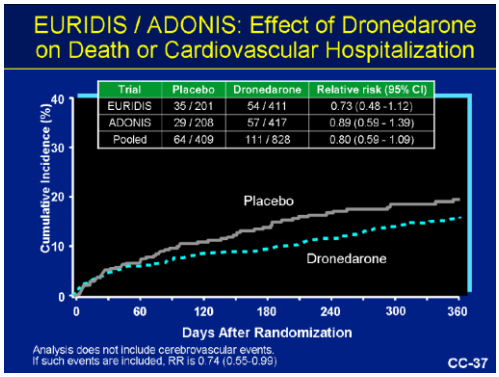
Graph slides contain graphs—diagrams "that represent the variation of a variable in comparison with that of one or more other variables"—either with or without accompanying text.

See "subcategories" for example(s)

Table+graph

Table+graph slides contain both a table(s) and a graph(s).

Example(s)



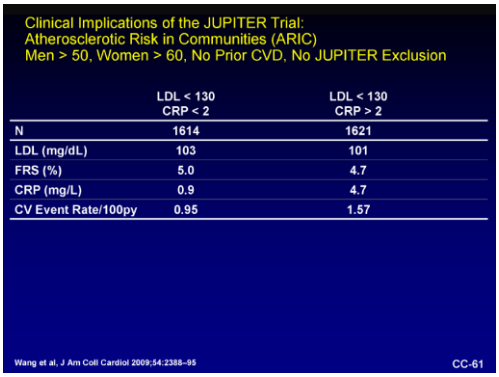
Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm194913.htm

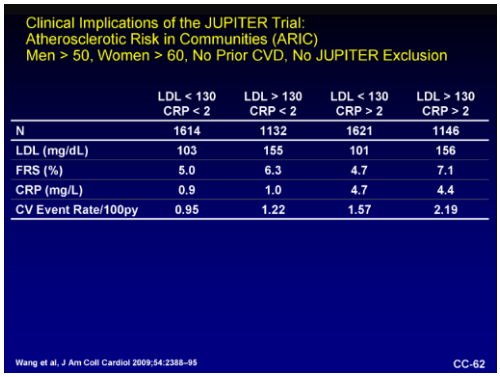
Build slides

Build slides are nearly identical slides shown in a sequence. Slides are often shown in such a series to emphasize or call attention to specific data. It would be inappropriate to code each slide in the series as a separate slide as the series is usually perceived as one slide by the audience. Every slide in this type of sequence will be coded as a "build" slide except the final slide , which will be categorized appropriately.

You will not recognize a build sequence until you move forward through the slides in a series. In the example shown below, you will have coded slide CC-41 as a table slides before realizing it is part of a build. This means you will have to go backwards and re-code the earlier slides in a build sequence as you realize the build nature of the series.

Example(s)





Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm194913.htm

Other

Slides that do not fall into any of the categories above. Blank slides are included in this category. Other than blank slides, there should be very few slides in this category.

Things to consider

Slides should be coded according to the definitions provided here. If a slide is difficult to categorize, use your best judgment. Think, "what is the intent of this slide?" or "what is the intent of this tabular format?".

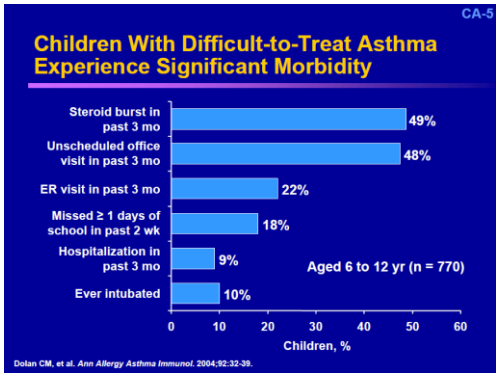
A note about screen grabs: screen grab slides may be coded as "diagram/picture slides" or may be coded as text, table, graph slides (as appropriate). If it is clear that the intent of the screen grab was to show a picture of something (as in the case of a form or a journal article), code the slide as a picture/diagram slide. If the intent was just to display the text/table/graph without emphasis on the fact that it is a picture, code the slide as appropriate. Again, ask yourself, "what is the intent of this screen grab?".

Subcategories for Graph and Table+Graph Slides

Bar graph (2D, horizontal)

A graph that uses the comparative length of rectangles, ovals, or some other shape to indicate the size of variables. The shapes are displayed next to each other in a column along the Y axis and may or may not be adjacent. The shapes are displayed horizontally and in two dimensions. Bars may or may include error bars.

Example(s)

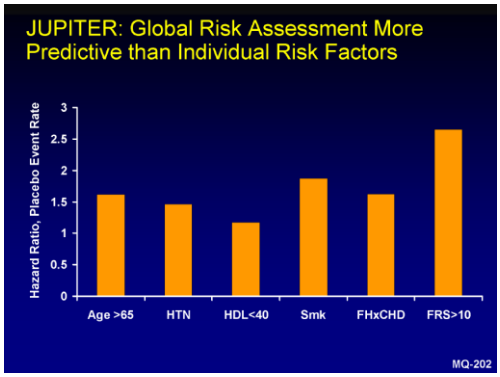


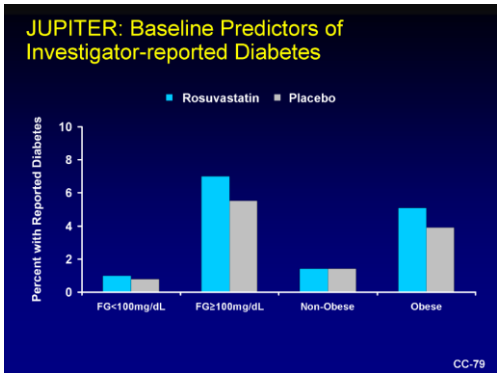
Samples slides downloaded from:
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/ucm194063.htm

Bar graph (2D, vertical)

A graph that uses the comparative length of rectangles, ovals, or some other shape to indicate the size of variables. The shapes are displayed next to each other in a row along the X axis and may or may not be adjacent. The shapes are displayed vertically and in two dimensions. Bars may or may not include error bars.

Example(s)



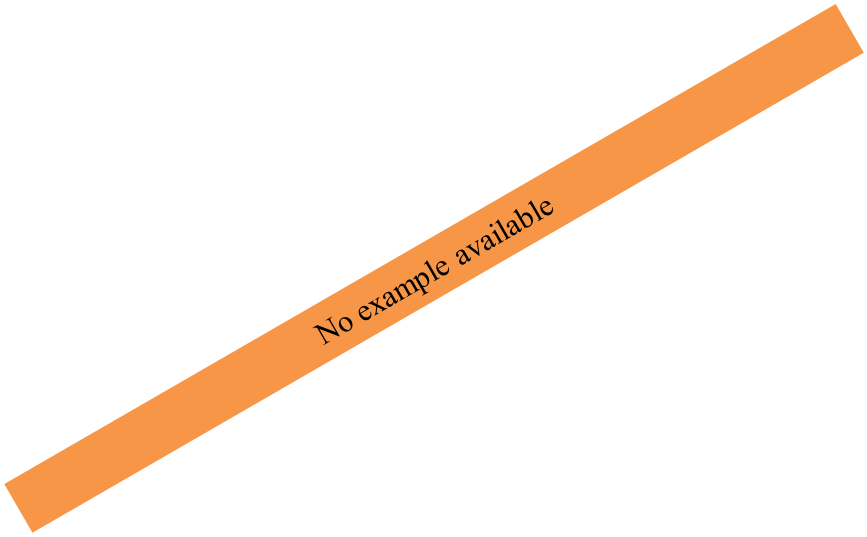


Samples slides downloaded from:
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm194913.htm

Bar graph (3D, horizontal)

A graph that uses the comparative length of rectangles, ovals, or some other shape to indicate the size of variables. The shapes are displayed next to each other in a column along the Y axis and may or may not be adjacent. The shapes are displayed horizontally and in three dimensions.

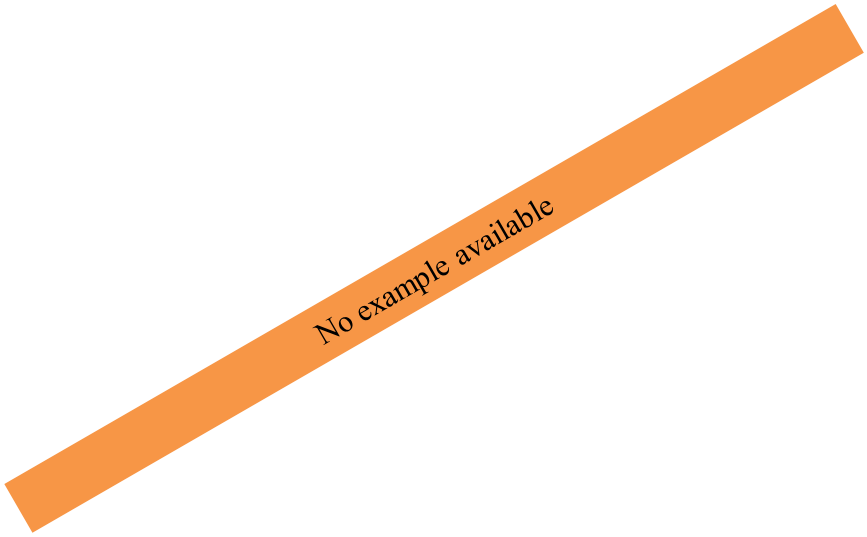
Example(s)



Bar graph (3D, vertical)

A graph that uses the comparative length of rectangles, ovals, or some other shape to indicate the size of variables. The shapes are displayed next to each other in a row along the X axis and may or may not be adjacent. The shapes are displayed vertically and in three dimensions.

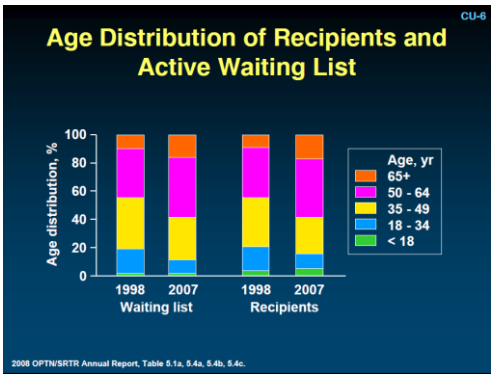
Example(s)

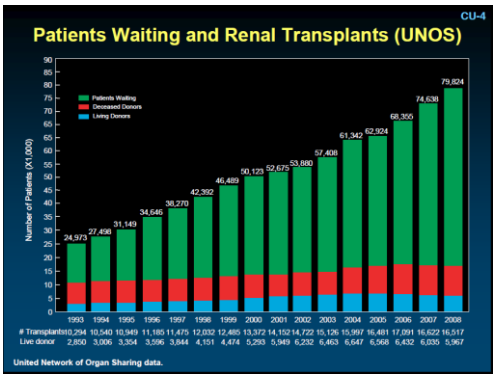


Stacked bar graph (2D, vertical)

A graph that uses the comparative length of rectangles, ovals, or some other shape to indicate the size of variables. The shapes are placed on top of each other in a continuous stack. The stack is displayed vertically and in two dimensions.

Example(s)



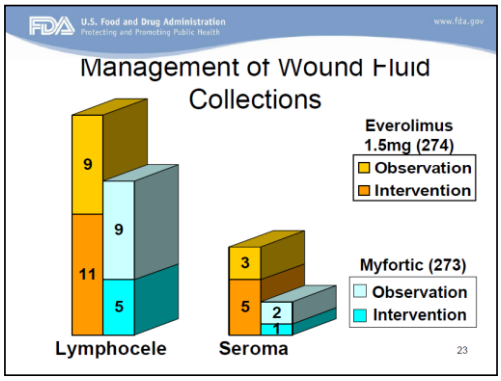


Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm195971.htm

Stacked bar graph (3D, vertical)

A graph that uses the comparative length of rectangles, ovals, or some other shape to indicate the size of variables. The shapes are placed on top of each other in a continuous stack. The stack is displayed vertically and in three dimensions.

Example(s)

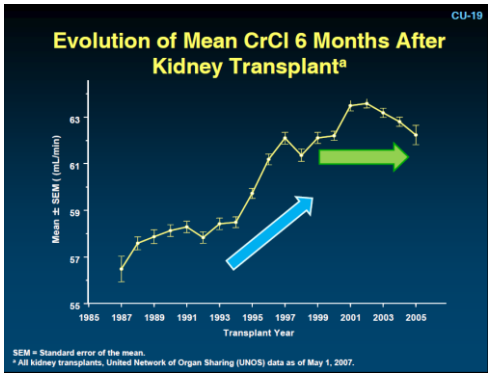


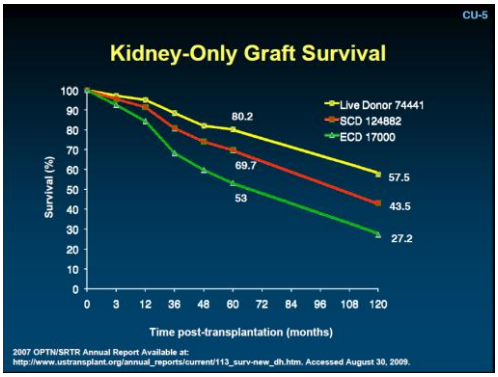
Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm195971.htm

Line graph

A graph that plots data points along one axis. The data points are connected by a line. Data points may or may not include error bars.

Example(s)



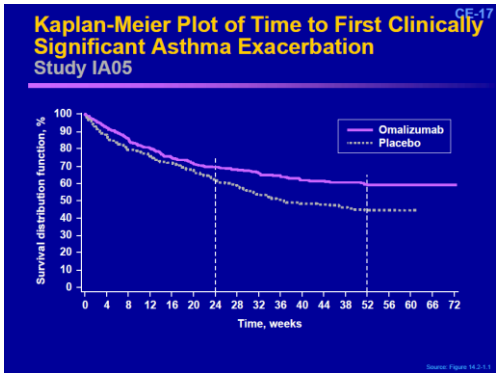


Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm195971.htm

Kaplan-Meier curve

A statistical graph that plots the estimated amount of time it takes for a particular event to occur (time to event). These graphs are recognizable by the stair-like progression of the plot lines.

Example(s)

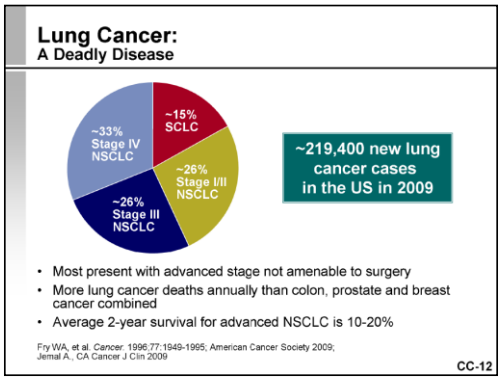


Samples slides downloaded from:
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/ucm194063.htm

Pie chart (2D)

A chart that consists of a circle divided into two or more sections by radii of the circle. The size of the sections indicates the size of the variables they represent. The sections may or may not be pulled out from the "pie" as a whole. The sections of the pie are represented in two dimensions.

Example(s)

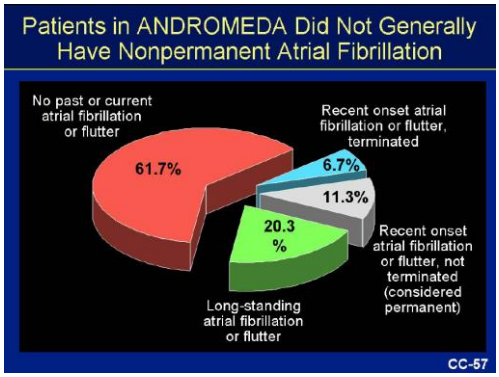


Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/ucm195675.htm

Pie chart (3D)

A chart that consists of a circle divided into two or more sections by radii of the circle. The size of the sections indicates the size of the variables they represent. The sections may or may not be pulled out from the "pie" as a whole. The sections of the pie are represented in three dimensions.

Example(s)

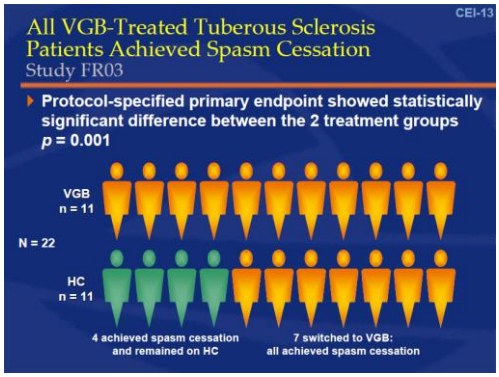


Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm194913.htm

Pictograph

A graph that displays geometric or human-shaped icons in relation to other icons to indicate the size of the variable(s) they represent.

Example(s)

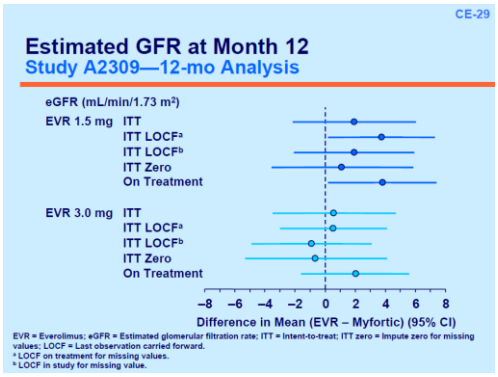


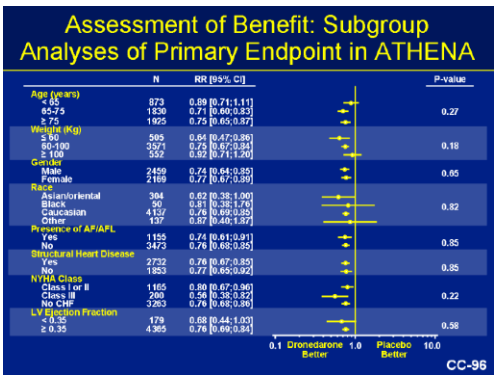
Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/ucm154399.htm

Forest plot

A graph that plots data points and their confidence intervals along one axis. The data points are usually plotted along a horizontal axis and stacked in a column, however, they may also be plotted along a vertical axis and appear in a row.

Example(s)



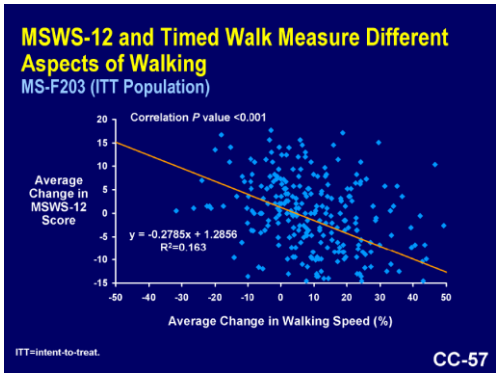


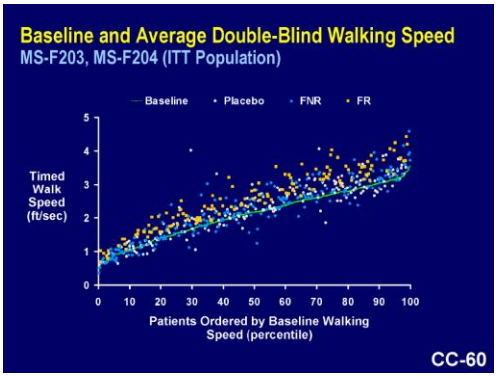
Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm195971.htm;
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm136947.htm

XY scatterplot

A graph that displays data points plotted along both an X and Y axis. The graph may or may not include a line of regression.

Example(s)



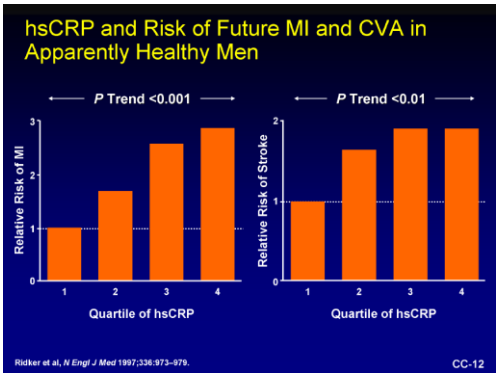


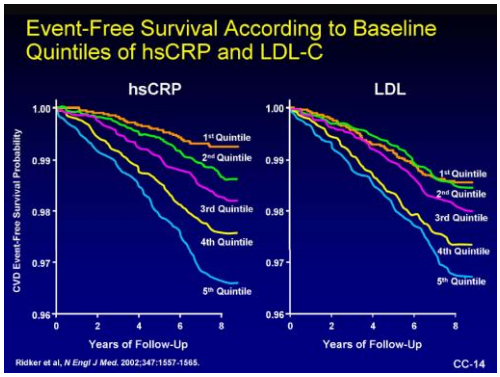
Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/ucm191027.htm

Multiple graph, same type

A slide that shows two or more graphs of the same type.

Example(s)



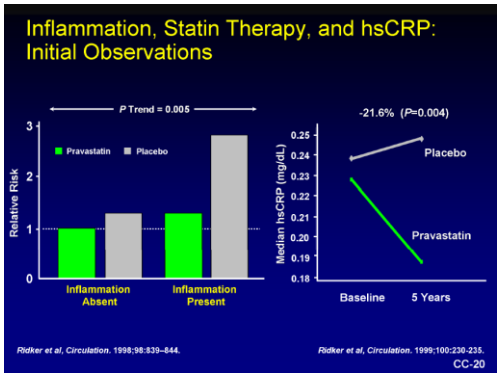


Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm194913.htm

Multiple graph, mixed types

A slide that shows two or more graphs of different types.

Example(s)



Samples slides downloaded from: :
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm194913.htm

Other

Graph slides that do not fall into any of the categories above.

Note that mixed-type graphs, such those with both bars (similar to a bar graph) and lines (similar to a line graph) should be coded as ‘other’.

References

Alkermes, Inc. (2010). *Alkermes, Inc. core presentations, vivitrol (naltrexone for extended-release injectable suspension), for the September 16, 2010 meeting of the psychopharmacologic drugs advisory committee* [PowerPoint slides]. Retrieved from http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/ucm232757.htm

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