ADVANCING REGULATORY SCIENCE

Translating complex clinical trial and post-market safety data into visual stories

The Safety Graphics Working Group produces guidelines for creating graphs that clearly communicate data without extensive captions or cluttering annotations

"Seeing is believing: Good graphic design principles for medical research"

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Statistical graphs should exploit the brain's pattern recognition ability

- Adverse events data during medical product development is complex.
- Good designs can help decision makers (e.g., regulators) interpret data accurately

Graphics Principles from the Safety Graphics Working Group

1. Content: Every graph should stand on its own.
2. Communication: Tailor each graph to its primary communication purpose.
3. Information: Maximize the data-to-ink ratio.
4. Annotation: Provide legible text and information.
5. Axes: Design axes to aid interpretation of a graph.
6. Styles: Make symbols and plot lines distinct and readable.
7. Colors: Make use of color appropriate for the medium.
8. Techniques: Use established techniques to clarify the message.
9. Types of plots: Use the simplest plot that is appropriate for the information to be displayed.

Example 1: Tailor graphs to their primary communication purpose

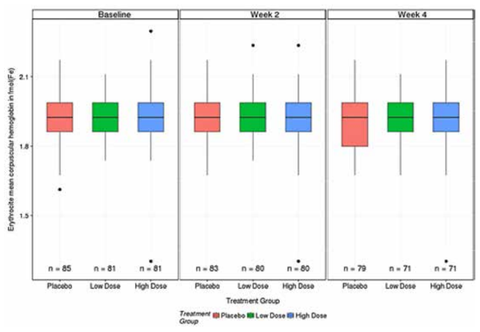
Erythrocyte Mean Corpuscular Hemoglobin (fmol Fe) in Males vs Females Over Time in Three Treatment Groups

The human eye might not immediately capture from a standard graph the distribution differences over time and by treatment group.

Violin plots can address this problem.

Box Plot

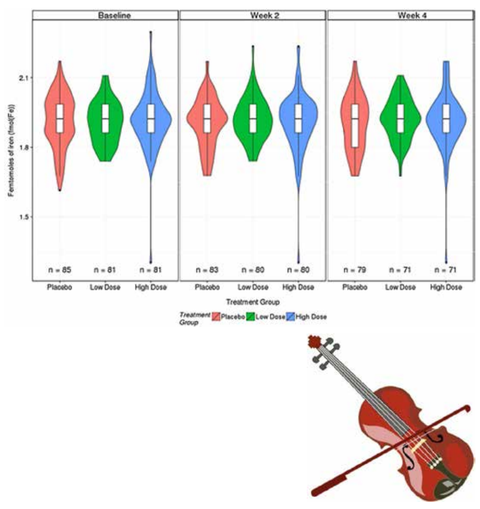
Standard Option



- Boxplot size = interquartile range (IQR). Horizontal bar in box = median.
- Box whiskers = minimum and maximum if maximum is within 1.5 IQR from box.
- Single dots (outliers) = values beyond 1.5.

Violin Plot

SGWG Option



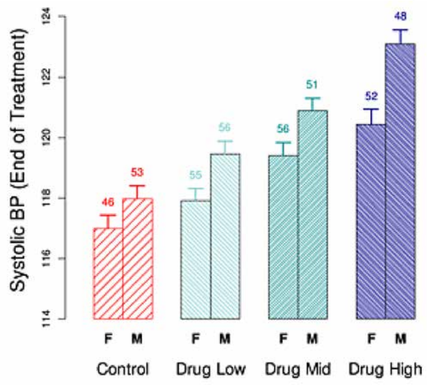
- Violin plot of data is smoother and adds details of the distribution of the variable than boxplots.
- The reader's mental map easily interprets the visual changes in the violin shapes and associates it with the corresponding differences in the distribution.
- Broadening and narrowing of violin plots represent the levels of hemoglobin iron among the samples tested.

Example 2: Bring closer together the items readers must compare to understand the meaning of the data

Comparing Effect of Multiple Doses of Experimental Treatment "X" on Systolic Pressure Males (M) and Females (F); 95% confidence interval (CI)

Bar Plot

Standard Option

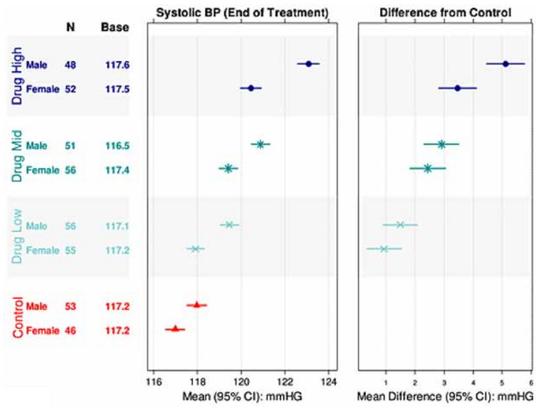


- Error bars and sample size number create optical illusion of "additional" data.
- Error bar does not indicate meaning of tail on top; lower bound of CI is masked by bar.
- Comparing differences in the variable requires moving eye from left to right -- complicated by additional effect of gender.

Dot Plot

SGWG Option

- Dotplot uses single plotting character to depict uncluttered view of parameter estimates; lines correspond to 95% CI.
- Adjacent panels enable easy comparison of mean systolic blood pressure and CI between treatment arms and the control.



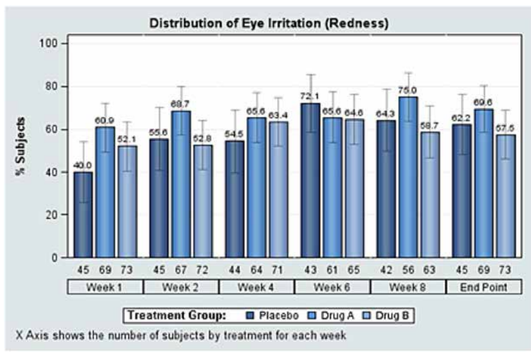
- Right panel clearly shows difference between doses and control for each gender.

Example 3: Handle x-axis data properly and avoid misinterpretation by separating endpoint data from time-elapsed data

Percentage of subjects with eye redness over time among three treatment groups

Bar Chart

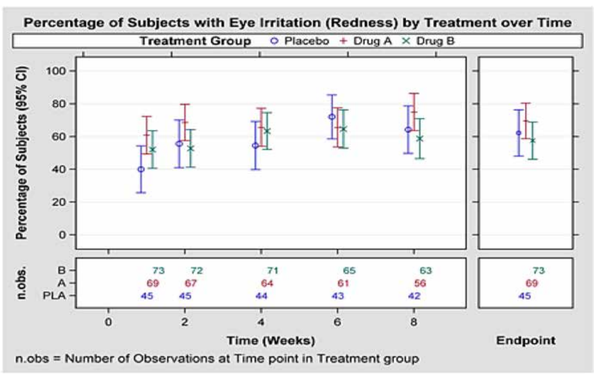
Standard Option



- Color in bars obscures measure of variability: height is important, not color.
- Variable (% subjects with eye redness) was not measured at equal time intervals, but X-axis makes it appear it was.
- Dark to light coloring of bars can be mistaken as quantitative changes in values, rather than different groups (placebo, Drug A, Drug B).
- Endpoint not clearly distinguished from data at specific weeks.

Dot Plot

SGWG Option



- Trends are easier to see using only point estimates of % of subjects with eye redness; CI is visible.
- Weeks 1 and 2 are visually closer than weeks 2, 4, and 6: Time shown as quantitative rather than categorical value.
- Endpoint is clearly delineated from time in weeks by appearing in a separate box.

Effective statistical graphics quickly communicate key findings to decision makers who rely on statistical analyses in medical research reports, regulatory applications, and publications.