



Use of Graphics in Clinical Trials

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- Repeated DMC and final reports
- Reviewers need help
- Make patterns and signals apparent
- Handling multiple dimensions
- Tables often require categorization of continuous variables



Guidelines for High Information Graphics

Graphics in Clinical Trials

RCT Reporting

Guidelines

General Examples

Safety Displays

Mixing Tables and Graphics

References

- Exclude unneeded dimensions and chartjunk
- Graphics don't need to be "dumbed down"
- Keep continuous variables continuous
- Use graphical perception research
 - Emphasize position along a common scale
- Don't choose a graphic requiring an arbitrary choice
 - E.g., rotation of pie chart
- Avoid bar charts
- Choose *descriptive* descriptive statistics
- *Show* differences
- Use real estate to show useful information, not Table 1



Showing the Difference

Graphics in Clinical Trials

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Reporting

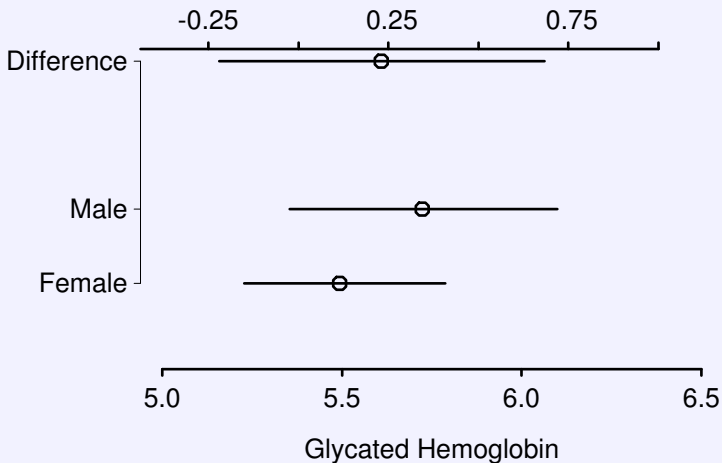
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Showing Differences, *continued*

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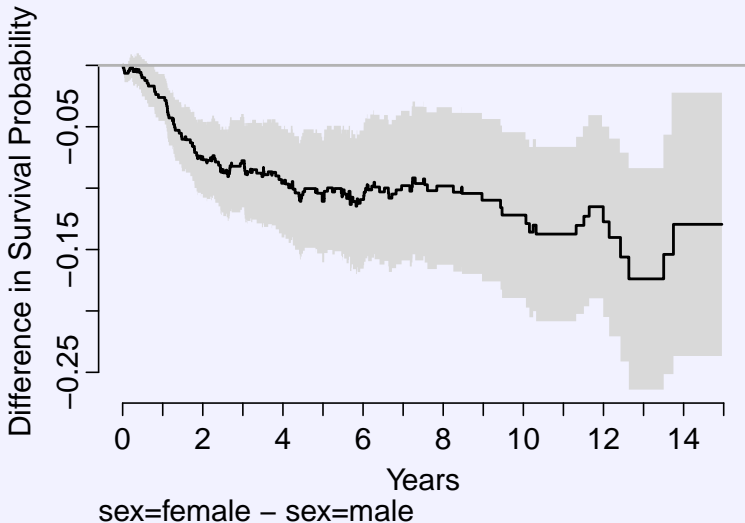
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Depicting Uncertainty

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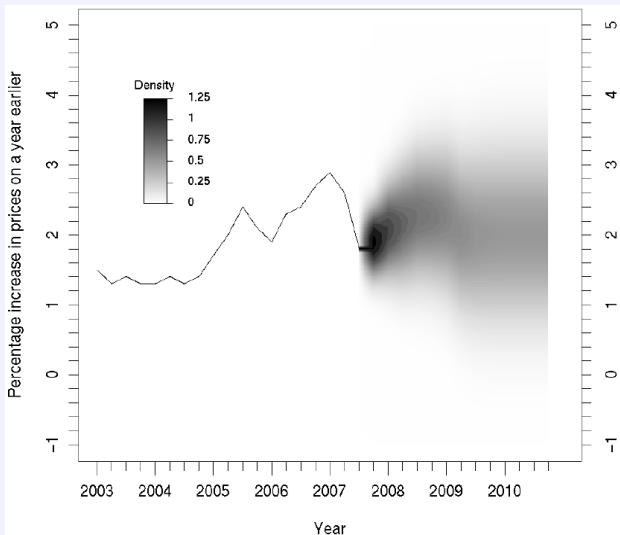
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Jackson [2008]



Empirical CDFs

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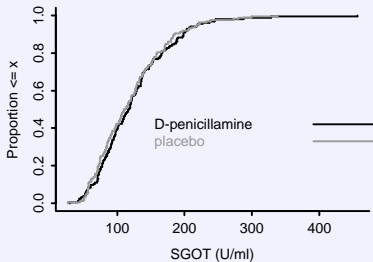
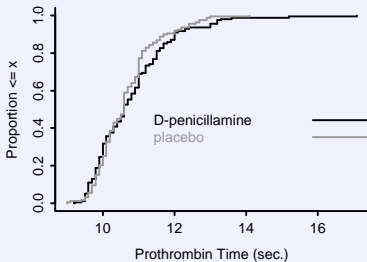
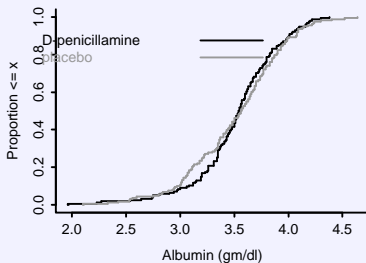
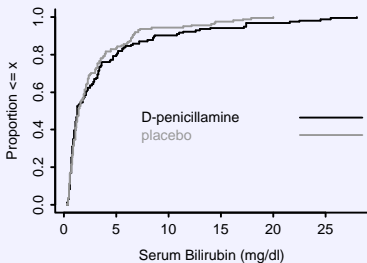
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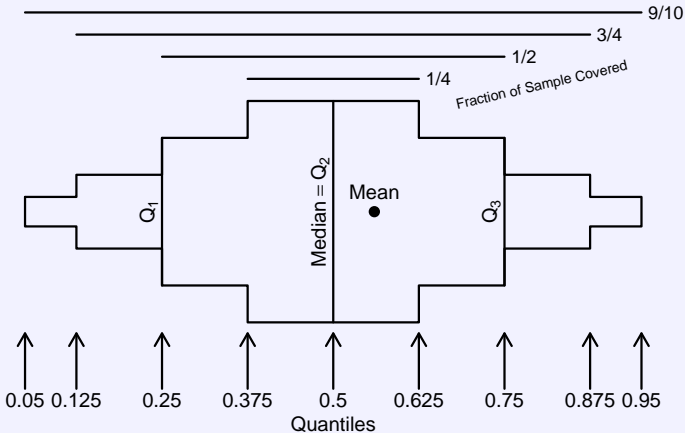
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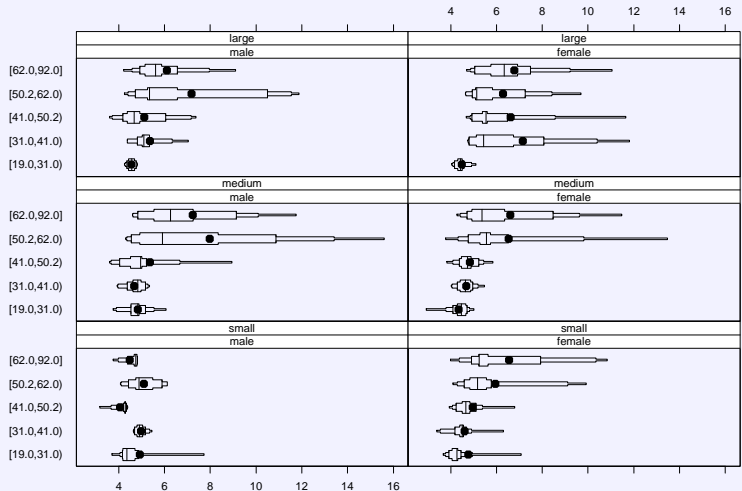


Extended Box Plots





Multi-Panel Extended Box Plots



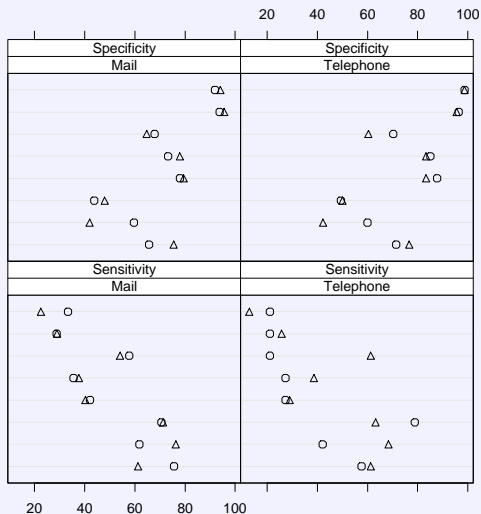


Multi-Panel Dot Plots

Male ○
Female △

Use of medication
Attack of asthma
Waking with an attack of cough
Waking with shortness of breath
Waking with tightness in the chest
Wheezing without a cold
Wheezing and breathless
Wheezing at any time

Use of medication
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Dispense with Lab Parameter Change Tables

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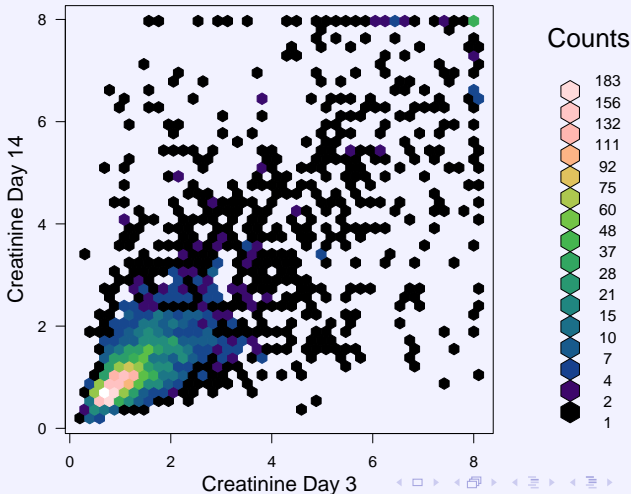
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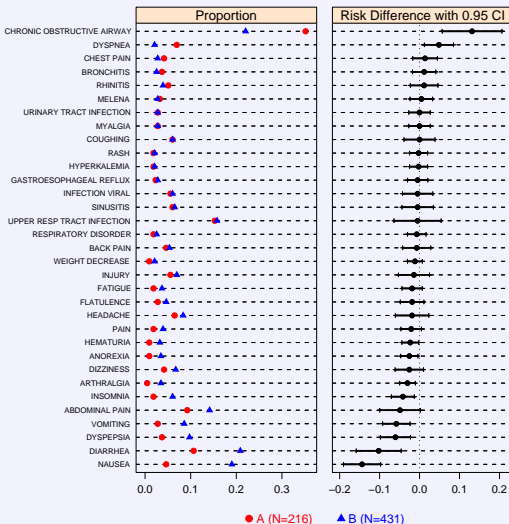
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Most Frequent On-Therapy Adverse Events Sorted by Risk Difference





SAEs by Body System and Preferred Term

Graphics in
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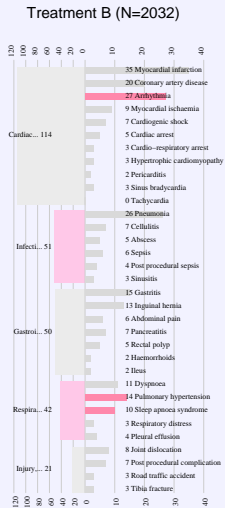
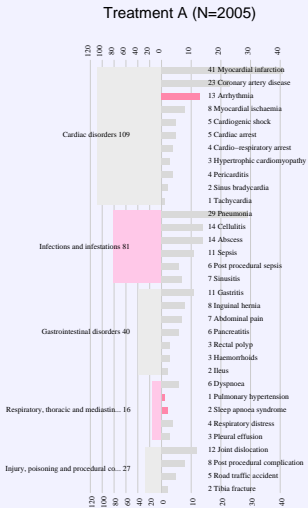
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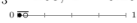



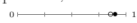
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Mixing Tables and Graphics

		D-penicillamine		placebo		Test Statistic		
		<i>N</i> = 154		<i>N</i> = 158				
Serum Bilirubin	mg/dl	0.725	1.300	3.600	0.800	1.400	3.200	$F_{1,310} = 0.04, P = 0.842^1$
Albumin	gm/dl	3.34	3.54	3.78	3.21	3.56	3.83	$F_{1,310} = 0, P = 0.951^1$
Histologic Stage Ludwig Criteria							$\chi_3^2 = 4.63, P = 0.201^2$	
1		3%	$\frac{4}{154}$		8%	$\frac{12}{158}$		
2		21%	$\frac{32}{154}$		22%	$\frac{35}{158}$		
3		42%	$\frac{64}{154}$		35%	$\frac{56}{158}$		
4		35%	$\frac{54}{154}$		35%	$\frac{55}{158}$		
Prothrombin Time	sec.	10.0	10.6	11.4	10.0	10.6	11.0	$F_{1,310} = 0.29, P = 0.589^1$
sex							$\chi_1^2 = 0.96, P = 0.326^2$	
female		90%	$\frac{139}{154}$		87%	$\frac{137}{158}$		
Age		41.4	48.1	55.8	43.0	51.9	58.9	$F_{1,310} = 5.52, P = 0.019^1$
spiders		29%	$\frac{45}{154}$		28%	$\frac{45}{158}$		$\chi_1^2 = 0.02, P = 0.885^2$

a b c represent the lower quartile *a*, the median *b*, and the upper quartile *c* for continuous variables.

Tests used: ¹Wilcoxon test; ²Pearson test



Mixing Tables and Graphics, *continued*

$$\chi_3^2 = 4.63, P = 0.201^2$$



$$F_{1,310} = 0.29, P = 0.589^1$$

$$\chi_1^2 = 0.96, P = 0.326^2$$





References

- O. Amit, R. M. Heiberger, and P. W. Lane. Graphical approaches to the analysis of safety data from clinical trials. *Pharm Stat*, 7:20–35, 2008. URL <http://www3.interscience.wiley.com/journal/114129388/abstract>.
- C. H. Jackson. Displaying uncertainty with shading. *Am Statistician*, 62(4):340–347, 2008.