Use of Graphics in Clinical Trials

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JOINT STATISTICAL MEETINGS 3 August 2010

Clinical Trial Reporting

Graphics in Clinical Trials

RCT Reporting

Guidelines

General Examples

Safety Displays

Mixing Tables and Graphics

References

- 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

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- 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

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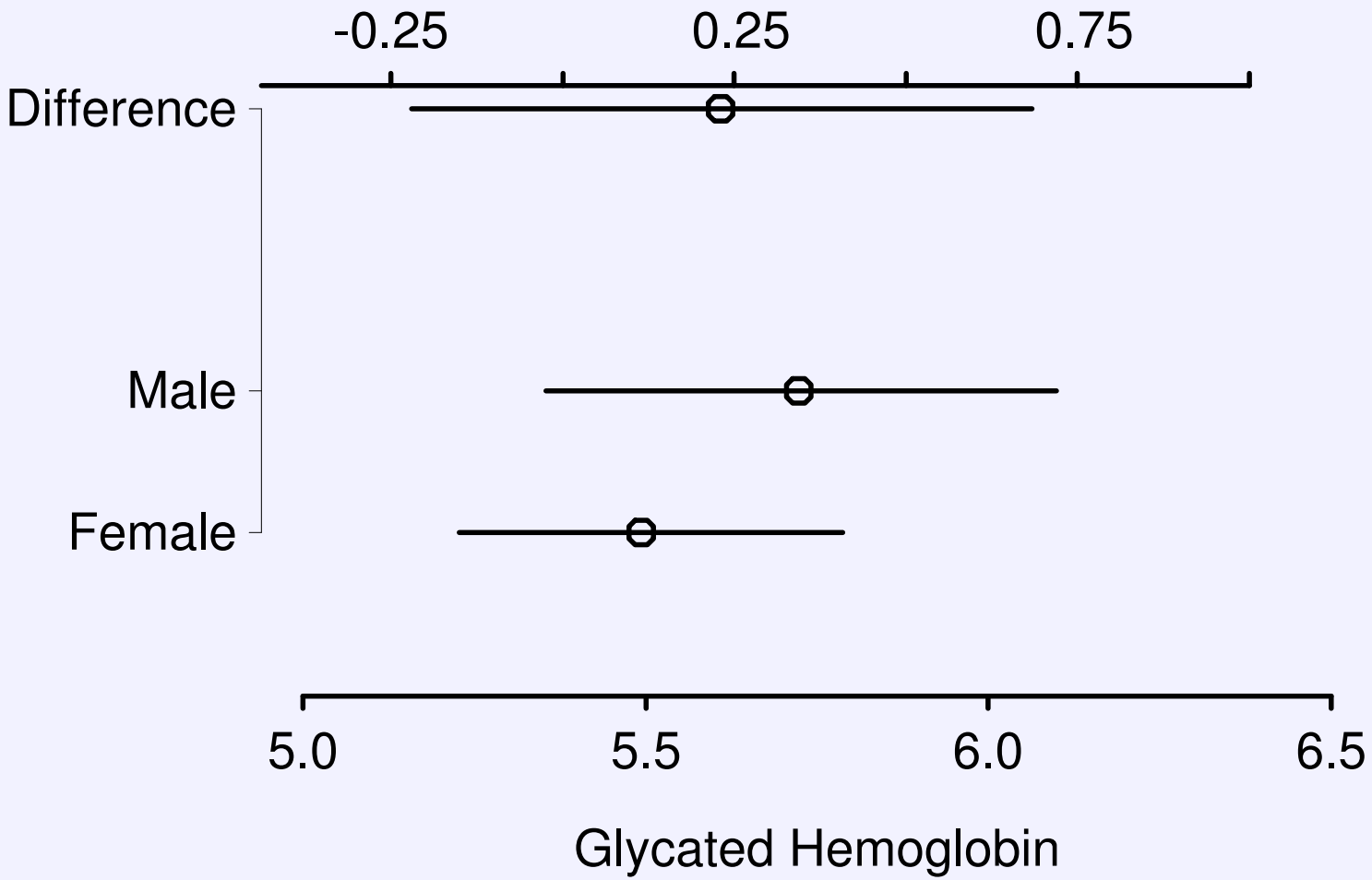

Showing Differences, *continued*

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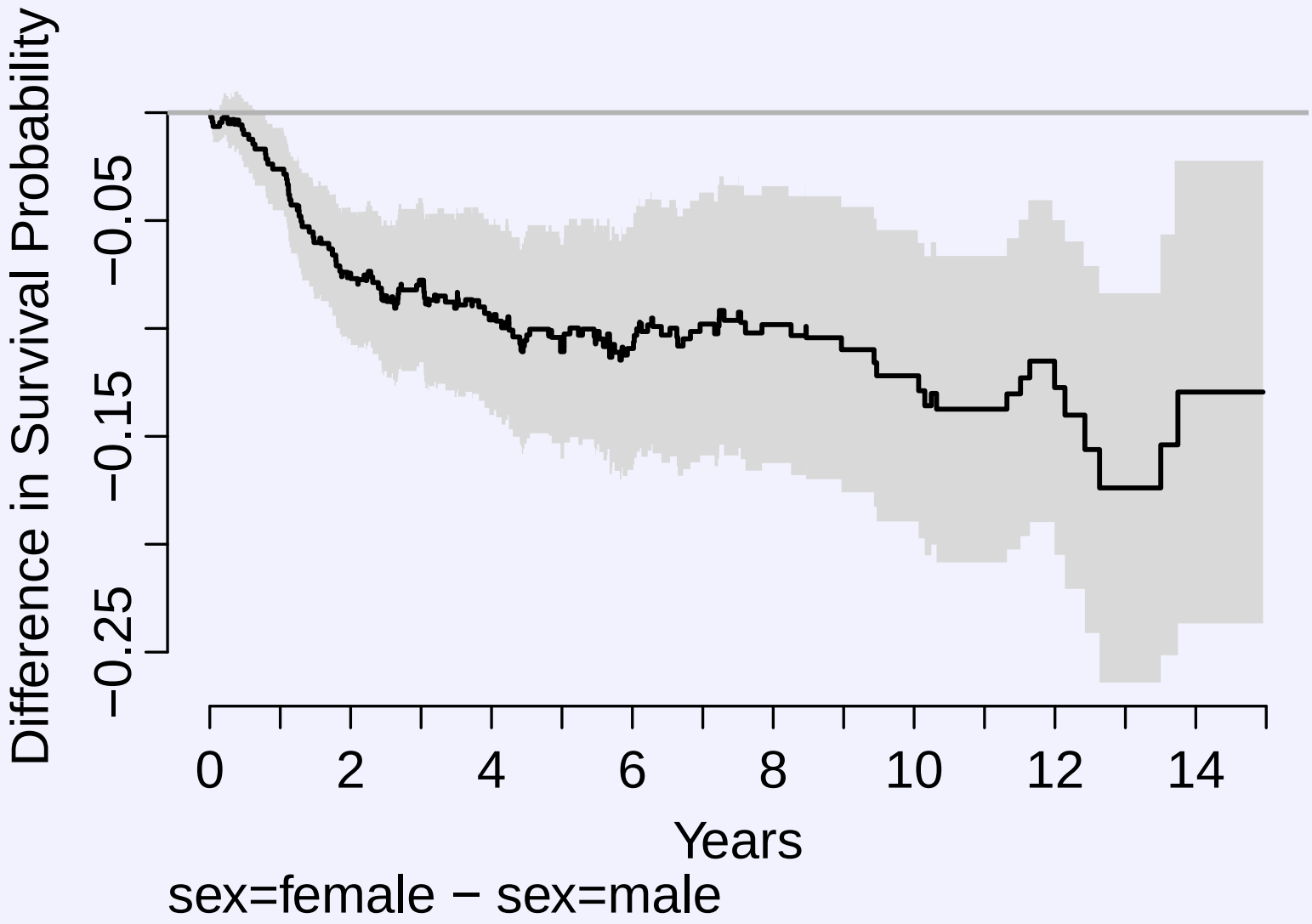

Depicting Uncertainty

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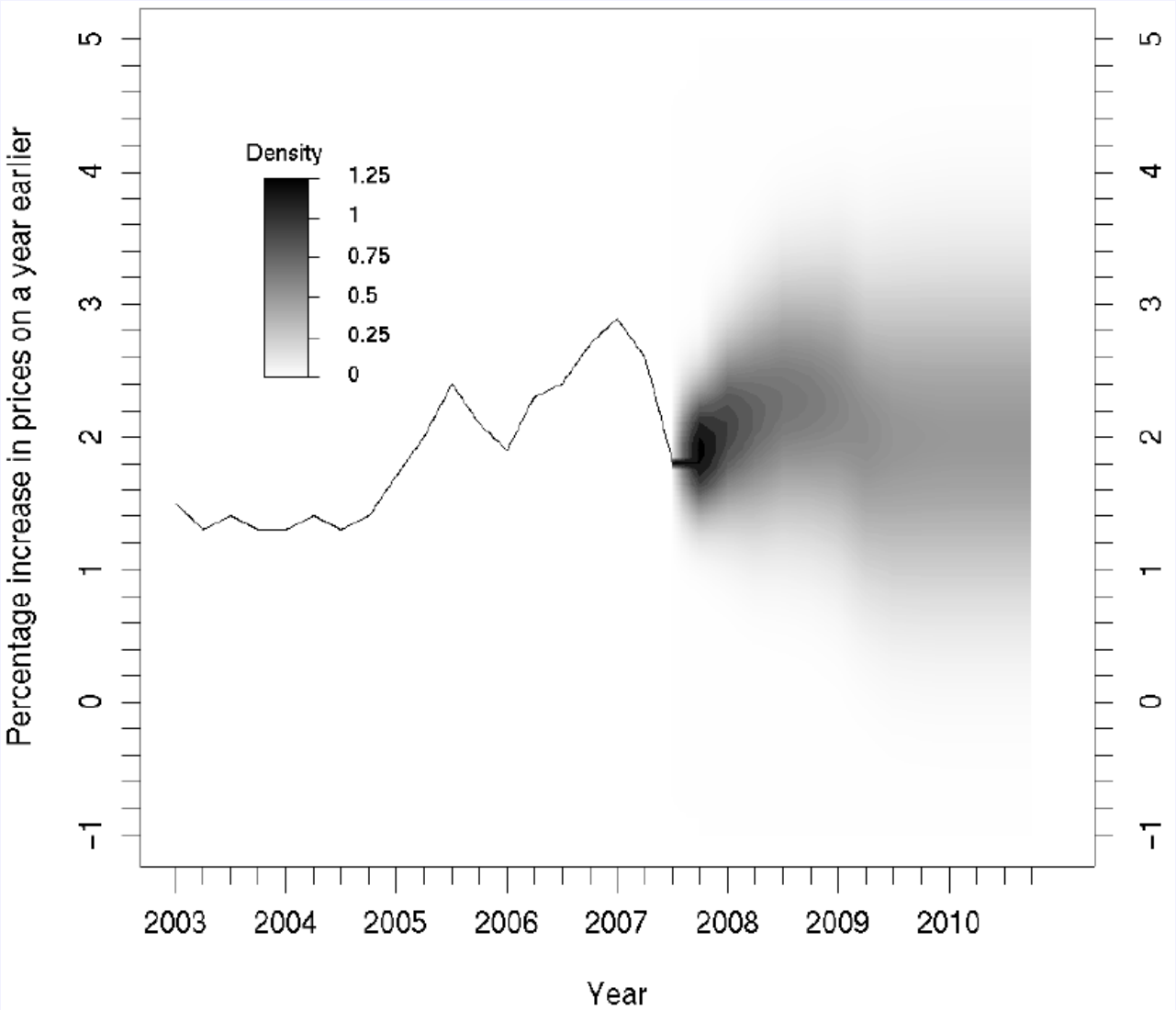

Jackson [2008]

Empirical CDFs

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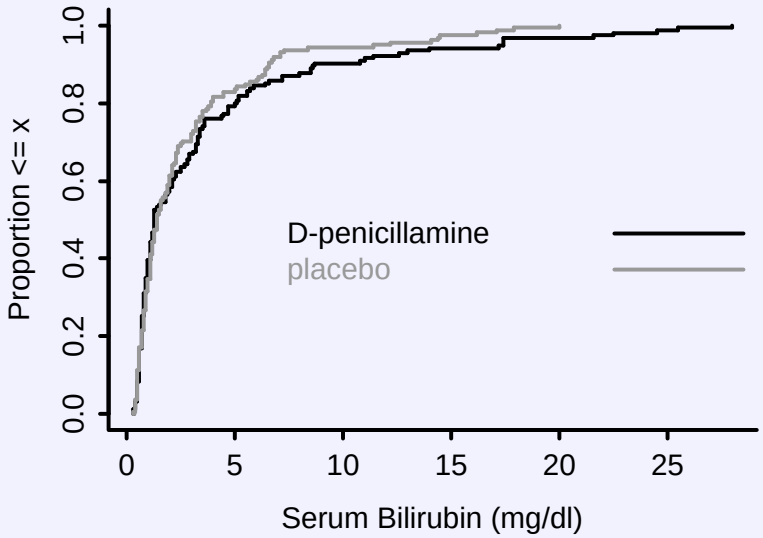

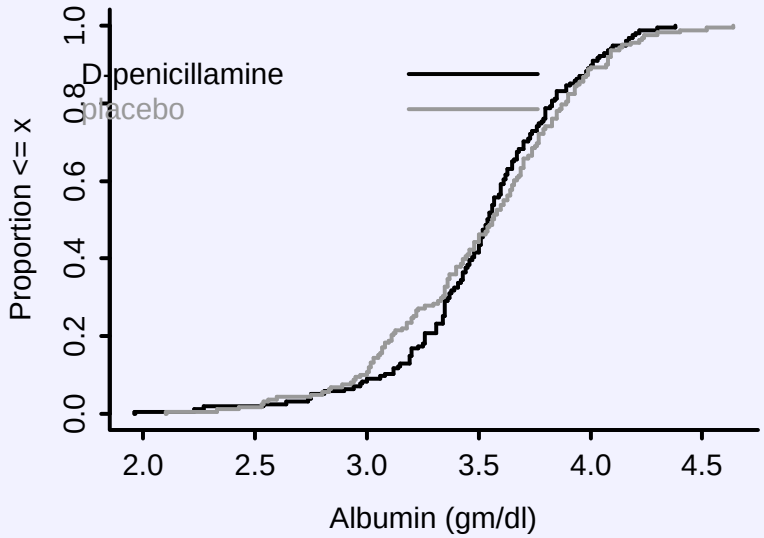

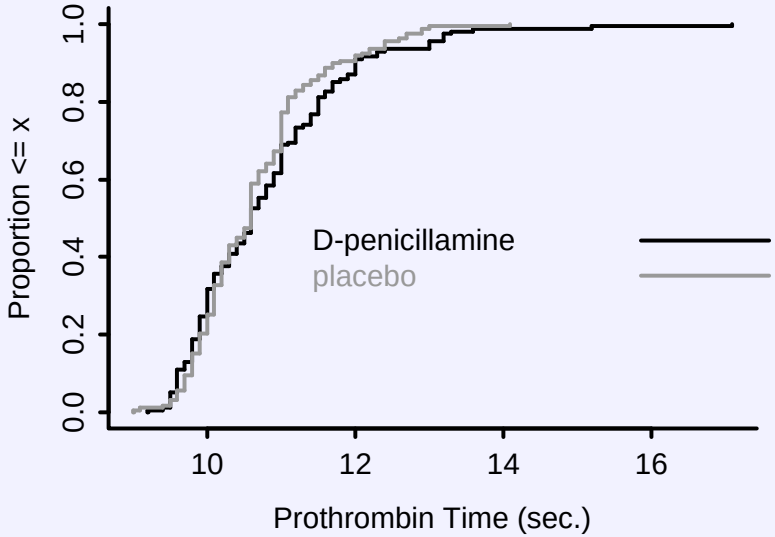

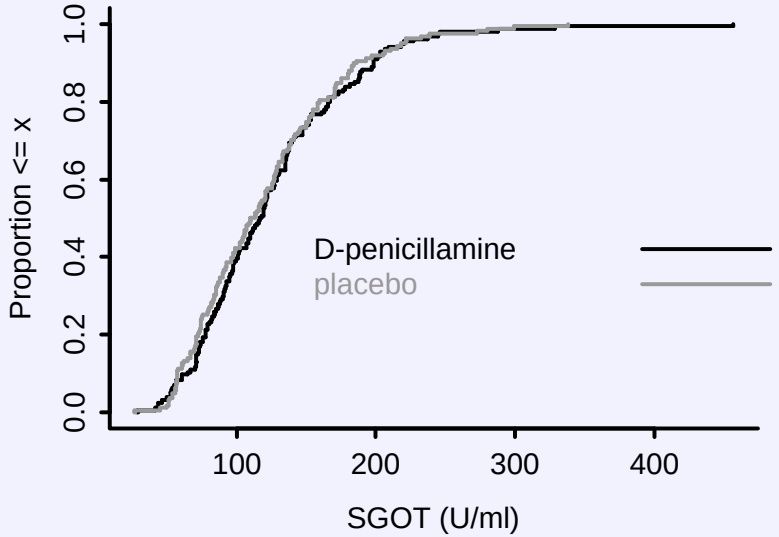

Extended Box Plots

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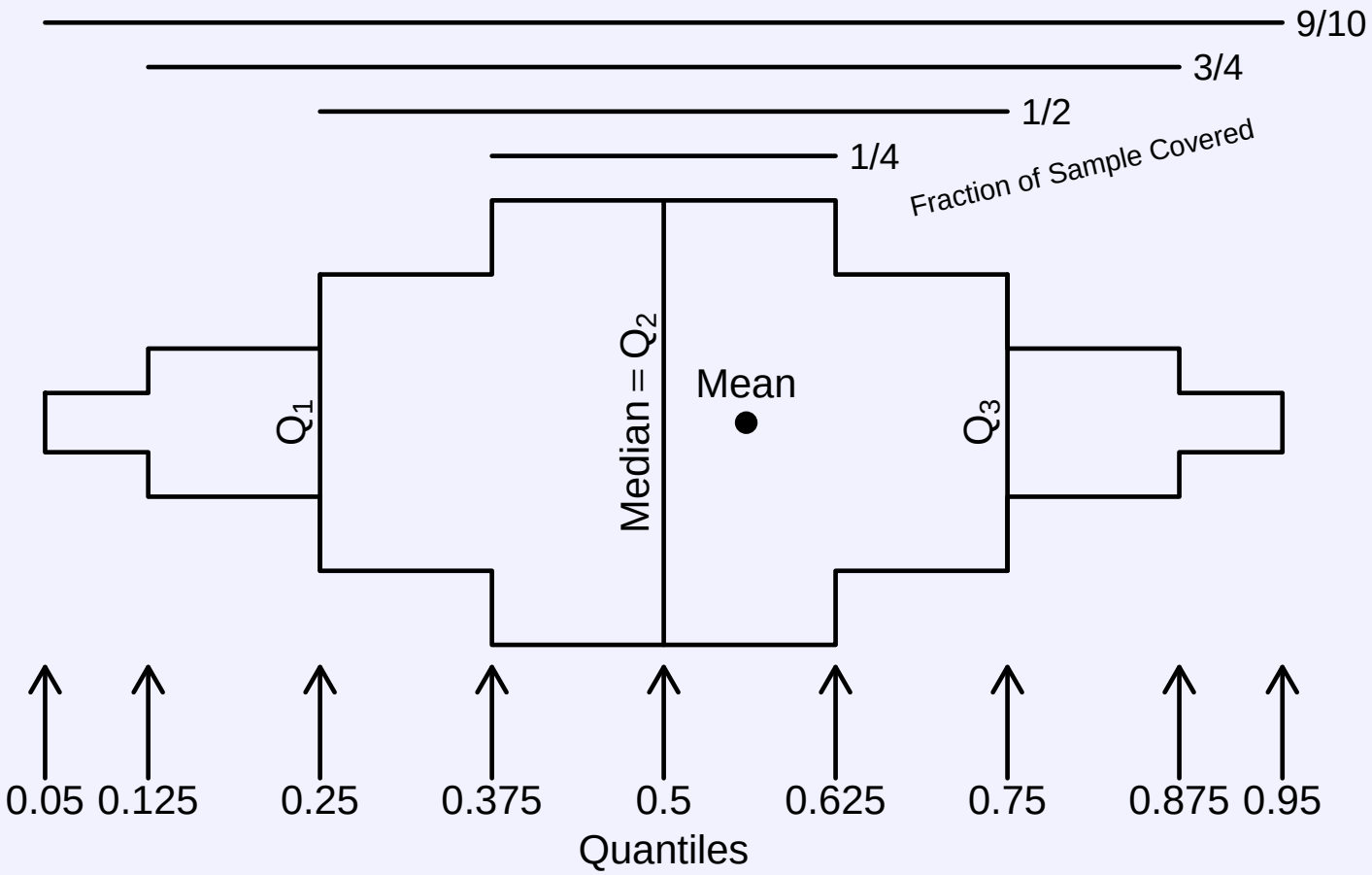

Multi-Panel Extended Box Plots

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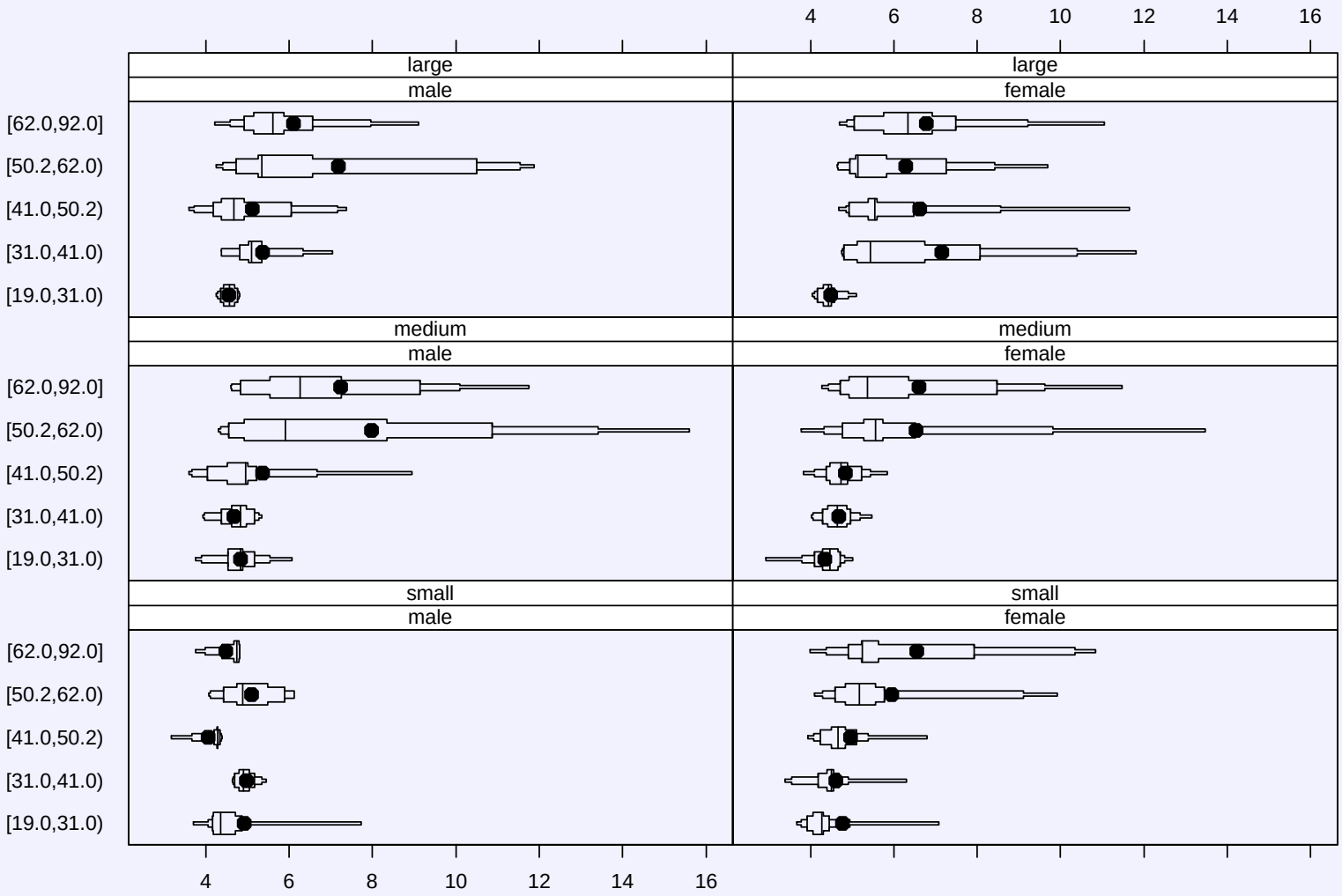

Multi-Panel Dot Plots

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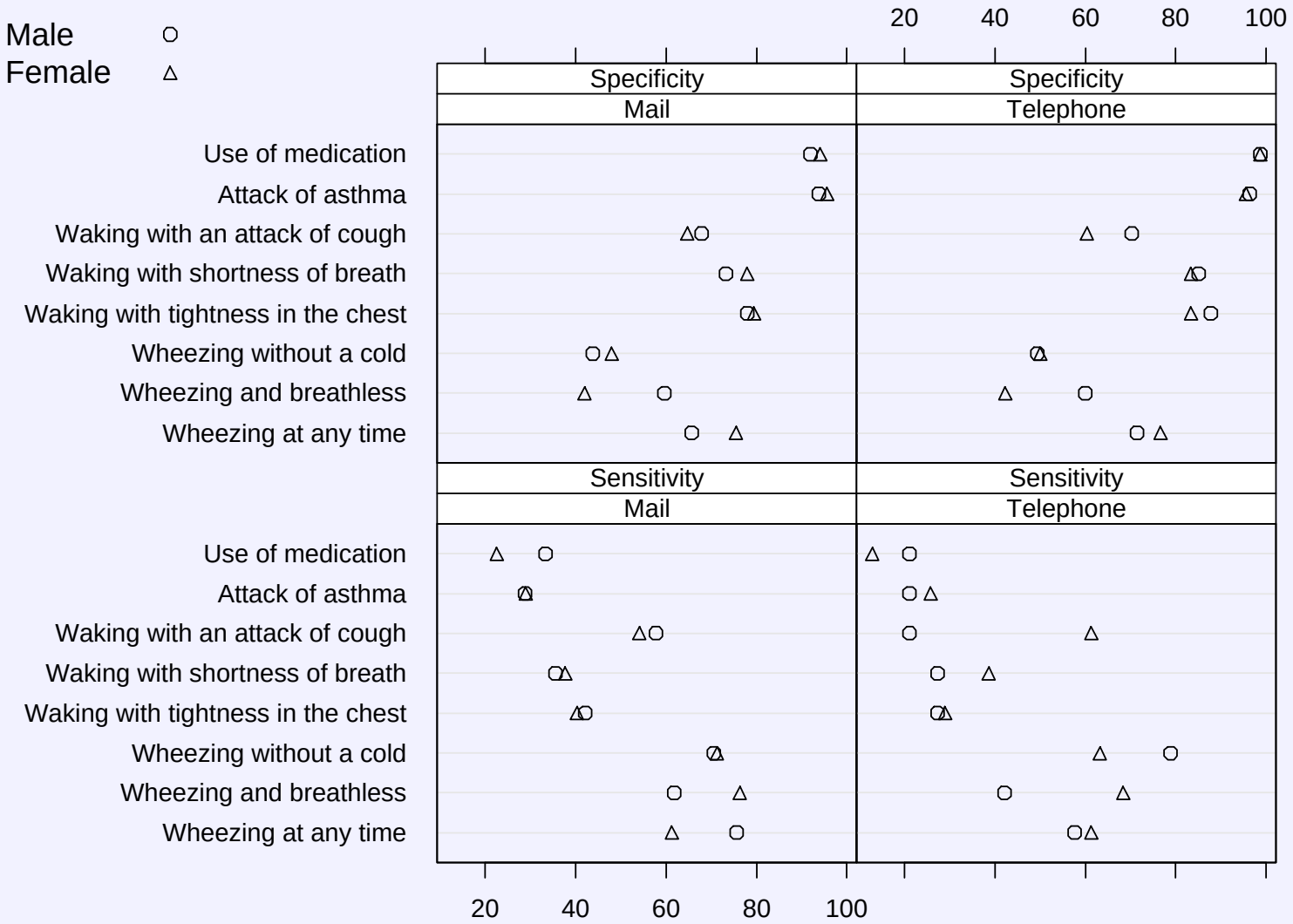

Dispense with Lab Parameter Change Tables

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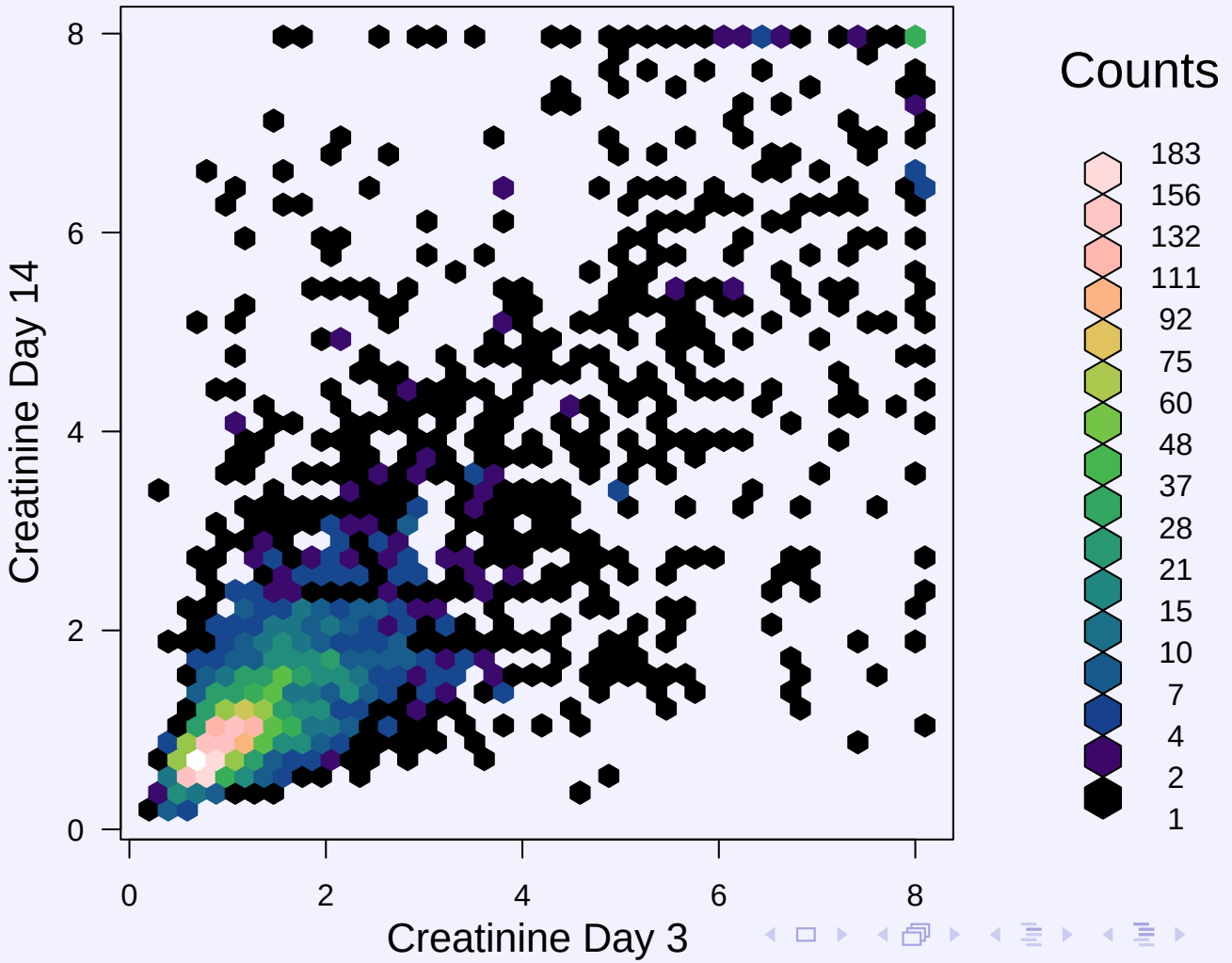

AEs

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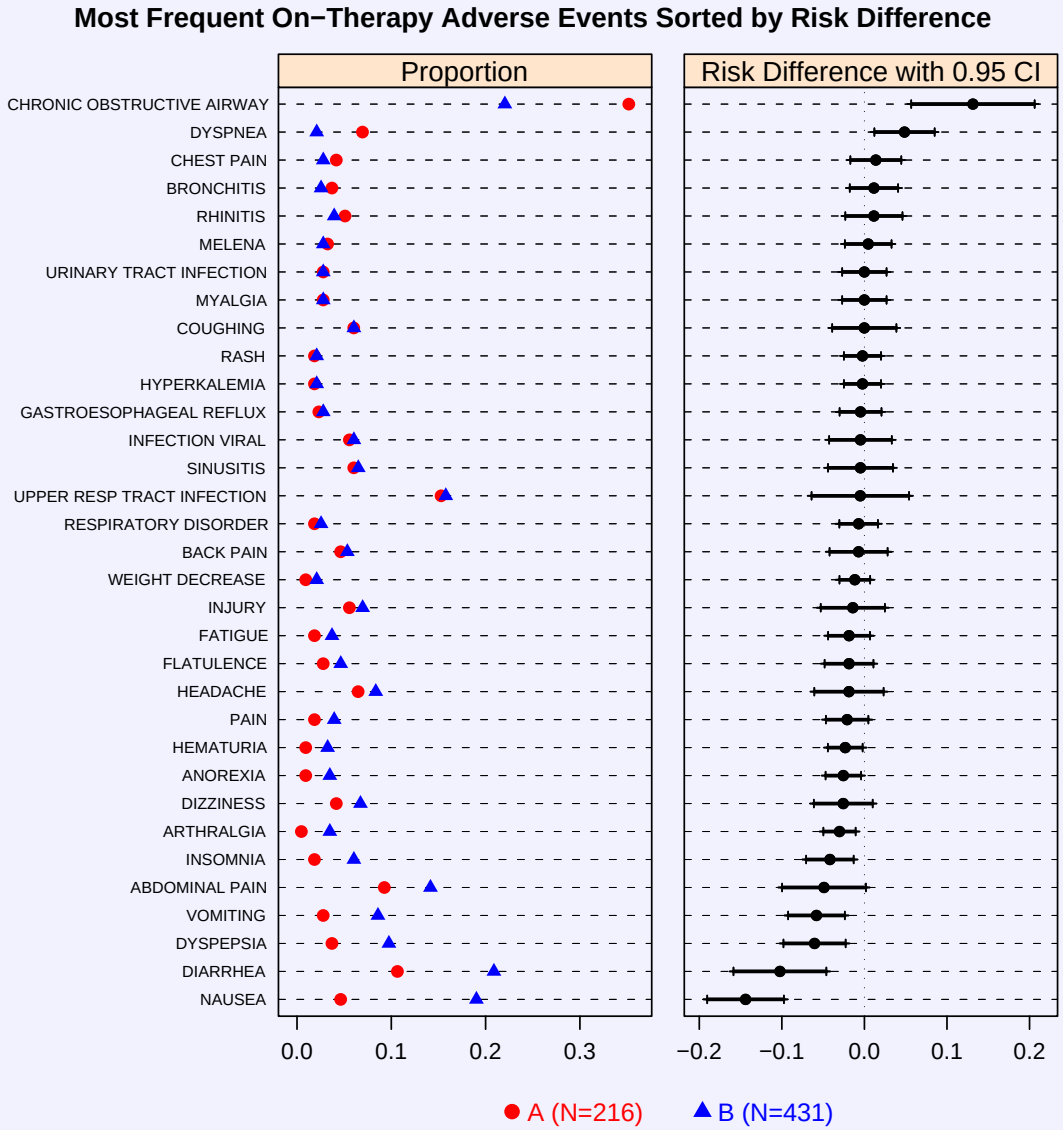

Modification of Amit et al. [2008]

SAEs by Body System and Preferred Term

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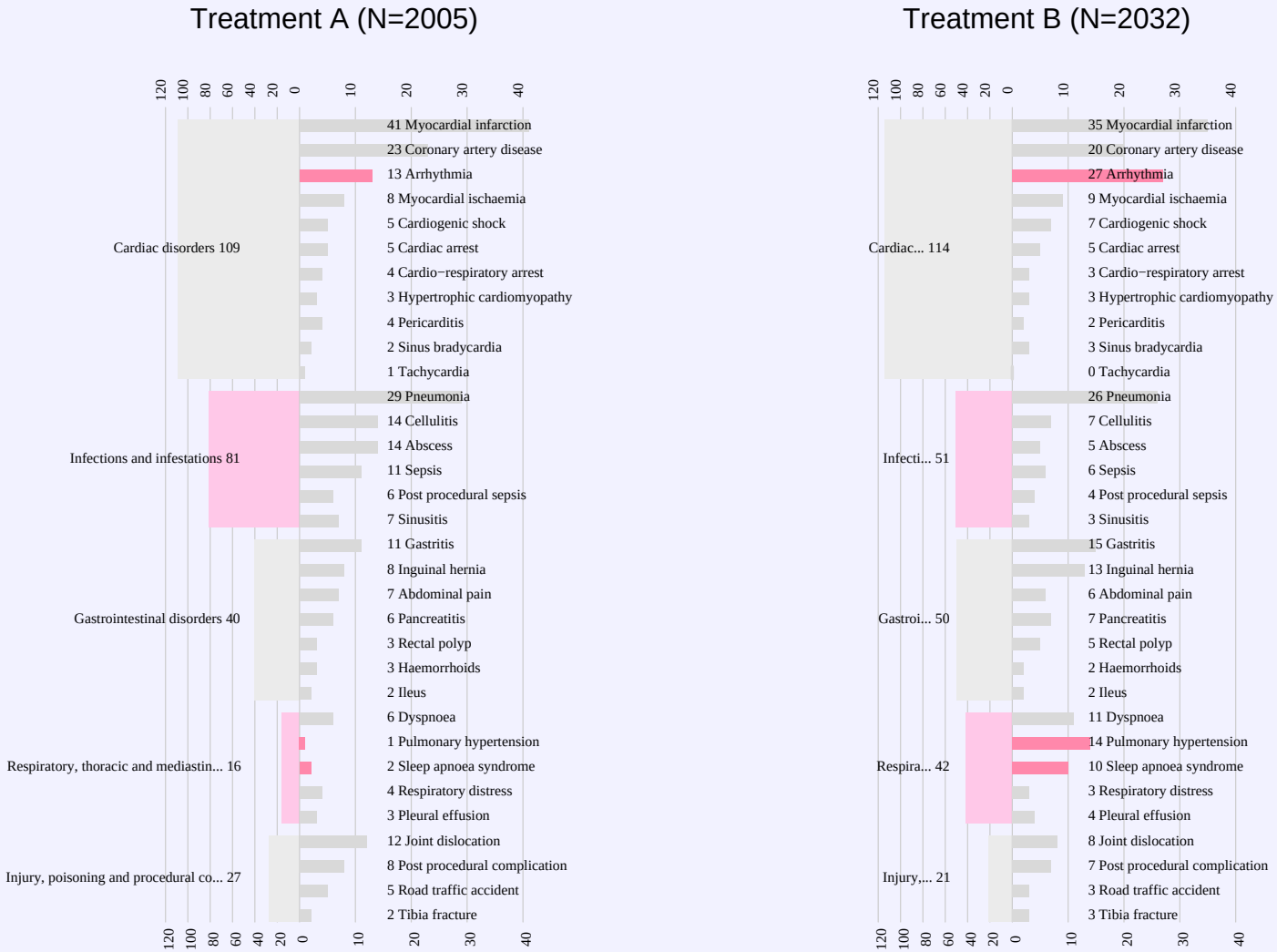

By Svetlana Eden, Vanderbilt; part of R `rreport` package

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		D-penicillamine $N = 154$	placebo $N = 158$	Test Statistic
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				$\chi^2_3 = 4.63,\ P = 0.201^2$
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				$\chi^2_1 = 0.96,\ P = 0.326^2$
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% $\frac{45}{158}$	$\chi^2_1 = 0.02,\ P = 0.885^2$

$a\ b\ c$ represent the lower quartile a, the median b, and the upper quartile c for continuous variables.
Tests used: [1]Wilcoxon test; [2]Pearson test

Mixing Tables and Graphics, *continued*

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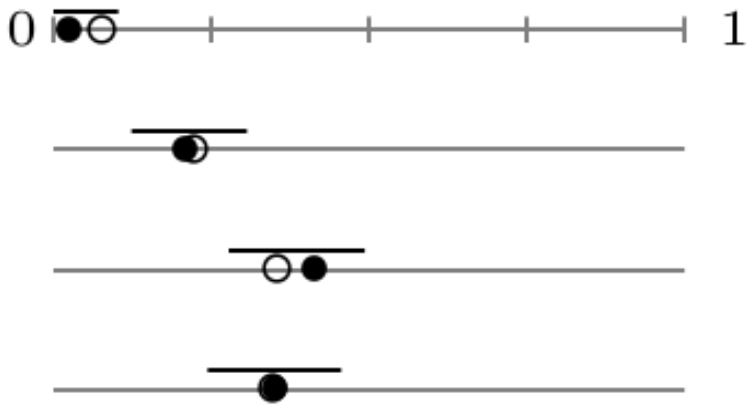
$$\chi^2_3 = 4.63, \ P = 0.201^2$$



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

$$\chi^2_1 = 0.96, \ P = 0.326^2$$

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.