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Statistical Competencies for Clinical & Translational Science: Evolution in Action

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Introduction

- CTS is a relatively new discipline
  - Competencies in flux
- Competencies serve to define the discipline
  - Program evaluation
  - Learner evaluation
    - Self-assessment
    - Validated instruments
  - Provide guidance regarding training
    - Statistics is too big to teach everything

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Overview

- Refining the competencies
- Assessing the competencies
- Assessing CTS learners
- Consensus on the competencies

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Refining the Competencies

Enders (2011) “Evaluating mastery of biostatistics for medical researchers: need for a new assessment tool.” Clinical and Translational Science, Dec 2011; 4(6): 448–454.

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Who Are CTS Learners?

- CTS learners are typically not statisticians
  - Similar to Public Health students
  - Graduate level
- Variety of learner goals
  - Read the literature
  - Co-I; co-author
  - PI; first or last author
- Variety of learning modalities
  - Traditional graduate level coursework
  - CME or other on-demand access

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CTS Statistics Competencies (2009)

Describe the basic principles and practical importance of random variation, systematic error, sampling error, measurement error, hypothesis testing, type I and type II errors, and confidence limits

Compute sample size, power, and precision for comparisons of two independent samples with respect to continuous and binary outcomes

Explain the uses, importance, and limitations of early stopping rules in clinical trials
Scrutinize the assumptions behind different statistical methods and their corresponding limitations
Generate simple descriptive and inferential statistics that fit the study design chosen and answer research question
Describe the uses of meta-analytic methods

Workgroup CECC. Core Competencies in Clinical and Translational Science for Master's Candidates. http://www.ctsaweb.org/index.cfm?fuseaction=committee.viewCommittee&com_ID=5

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Statistics-Related Competencies

Sources of Error

- Describe the concepts and implications of reliability and validity of study measurements
- Evaluate the reliability and validity of measures

  - Assess sources of bias and variation in published studies.
  - Assess threats to study validity (bias) including problems with sampling, recruitment, randomization, and comparability of study groups

Scientific Communication

- Communicate clinical and translational research findings to difference groups of individuals, including colleagues, students, the lay public, and the media
- Write summaries of scientific information for use in the development of clinical health care policy

Study Design

- Propose study designs for addressing a clinical or translational research question

Workgroup CECC. Core Competencies in Clinical and Translational Science for Master's Candidates. http://www.ctsaweb.org/index.cfm?fuseaction=committee.viewCommittee&com_ID=5

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Other Sources of Competencies

- Calhoun et al. Development of a Core Competency Model for the Master of Public Health Degree.
  American Journal of Public Health. 2008; 98(9):10.
- Moher et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials.
  BMJ. 2010; 340:c869, 1–28.
- Des Jarlais et al. Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND statement.
  Am J Public Health. 2004; 94(3):361–366.
- Vandenbroucke et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration.
  PLoS medicine. 2007; 4(10):e297.

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Why Public Health?

- Public Health graduate students are nonstatisticians in a medical field
- They will use statistics to read and publish in the medical research literature
- Competencies were compared, condensed, and extended in Enders (2011)

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Competency Comparison

Clinical and Translational Science	Public Health	Guidelines
Assess sources of bias and variation in published studies Assess threats to study validity (bias) including problems with sampling, recruitment, randomization, and comparability of study groups		CONSORT TREND STROBE
Propose study designs for addressing a clinical or translational research question		STROBE
Describe the basic principles and practical importance of random variation, systematic error, sampling error, measurement error, hypothesis testing, type I and type II errors, and confidence limits	Describe the basic concepts of probability, random variation, and commonly used statistical probability distributions	
Compute sample size, power, and precision for comparisons of two independent samples with respect to continuous and binary outcomes		CONSORT TREND STROBE

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Competency Comparison

Clinical and Translational Science	Public Health	Guidelines
Explain the uses, importance, and limitations of early stopping rules in clinical trials		CONSORT TREND
Describe the concepts and implications of reliability and validity of study measurements Evaluate the reliability and validity of measures	Calculate basic epidemiologic measures Draw appropriate inferences from epidemiologic data	TREND
Scrutinize the assumptions behind different statistical methods and their corresponding limitations	Describe preferred methodologic alternatives to commonly used statistical methods when assumptions are not met	

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Competency Comparison

Clinical and Translational Science	Public Health	Guidelines
	Distinguish among the different measurement scales and the implications for selection of statistical methods to be used on the basis of these distinctions	
Generate simple descriptive and inferential statistics that fit the study design chosen and answer research question	Apply descriptive techniques commonly used to summarize public health data Apply common statistical methods for inference Apply descriptive and inferential methodologies according to the type of study design for answering a particular research question	CONSORT TREND STROBE
Describe the uses of meta-analytic methods		

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Competency Comparison

Clinical and Translational Research	Public Health	Guidelines
Communicate clinical and translational research findings to difference groups of individuals, including colleagues, students, the lay public, and the media Write summaries of scientific information for use in the development of clinical health care policy	Interpret results of statistical analyses found in public health studies Develop written and oral presentations on the basis of statistical analyses for both public health professionals and educated lay audiences	CONSORT TREND STROBE

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Competencies Added from Guidelines

Competency	Guidelines
Describe size of the effect with a measure of precision	CONSORT TREND STROBE
Describe the study sample, including sampling methods, the amount and type of missing data, and the implications for generalizability	TREND STROBE
Interpret results in light of multiple comparisons	CONSORT TREND STROBE
Identify inferential methods appropriate for clustered, matched, paired, or longitudinal studies	TREND STROBE
Describe adjusted inferential methods appropriate for the study design, including examination of interaction	CONSORT TREND STROBE
Describe statistical methods appropriate to address loss to followup	STROBE

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Assessing the Competencies

Oster R, et al (In Press) “Assessing statistical competencies in clinical and translational science education: one size does not fit all.” Clinical and Translational Science, In Press

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BERD Education Working Group

- Goal: assess need for training in each competency
- Methods: 18 BERD members surveyed for training needed (high/some/none) by trainee type
- Trainees categorized by background (no research experience/reader/research experience) and intended role (reader/co-I/PI)
- Asked for missing competencies

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Competencies Added by Reviewers

Competency
Describe statistical methods appropriate to address loss to follow-up
Understand the reasons for performing research that is reproducible from data collection through publication of results
Understand appropriate methods for data presentation, especially effective statistical graphs and tables
Characterization of diagnostic testing, including sensitivity, specificity, and ROC curves
Describe appropriate data quality and data management procedures

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Division of the Competencies

- Based on predicted **high need for training for future PIs**
  - Fundamental >=70% high need for training
  - Intermediate 60%-69% high need for training
  - Specialized <60% high need for training

  - Cutoffs assigned post hoc

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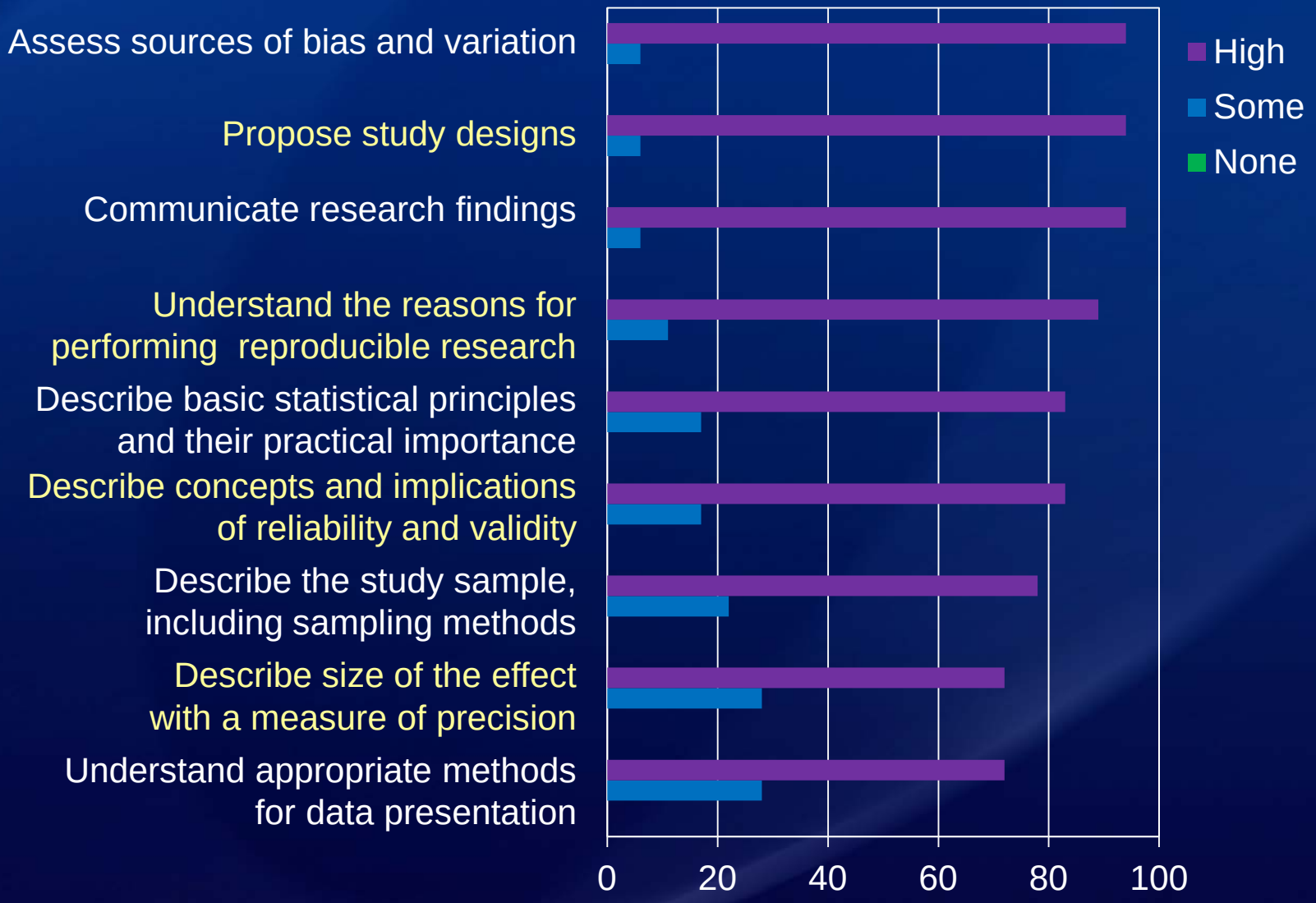
Fundamental Competencies
Goal: **PI**



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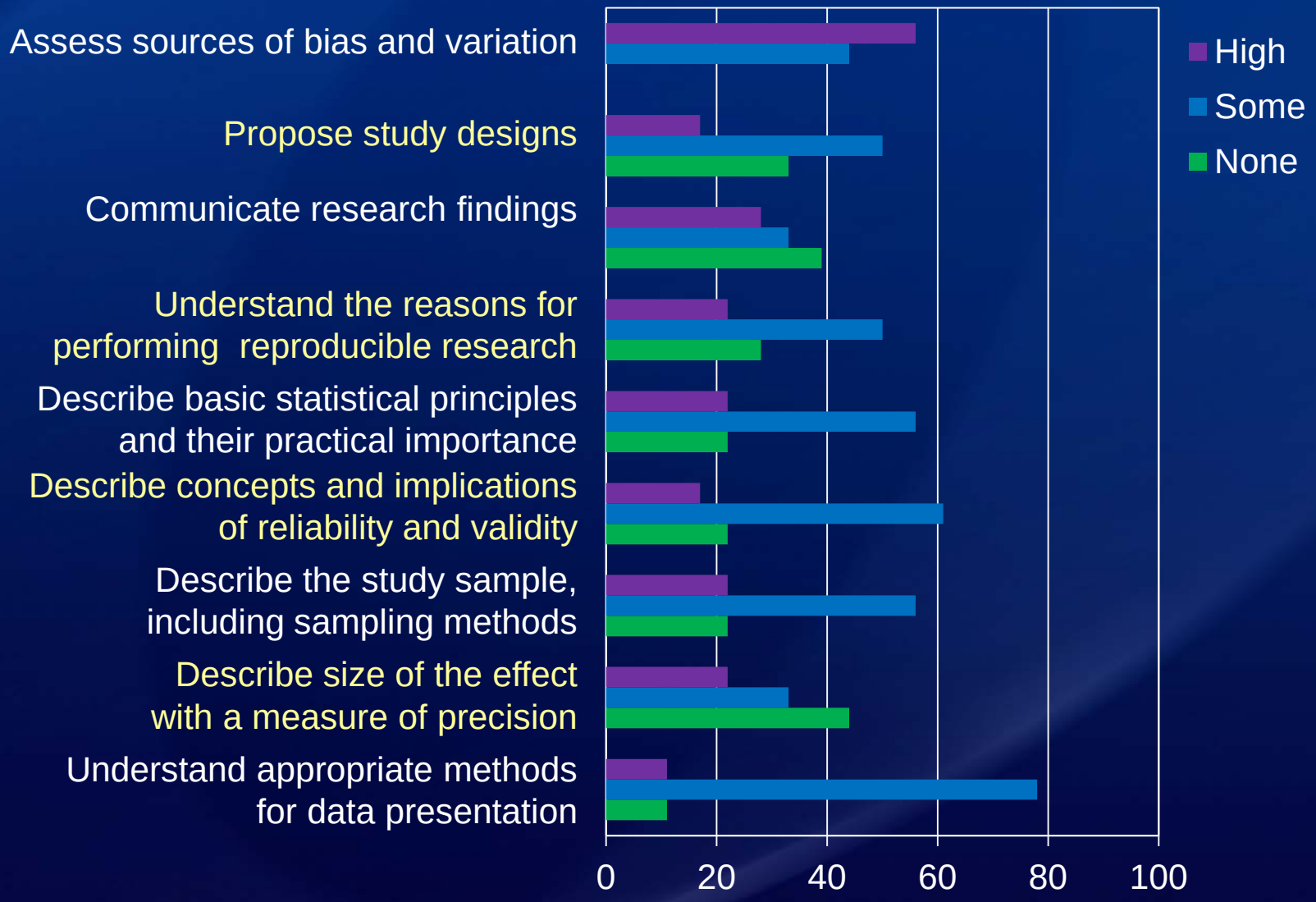
Fundamental Competencies
Goal: **Informed Reader**



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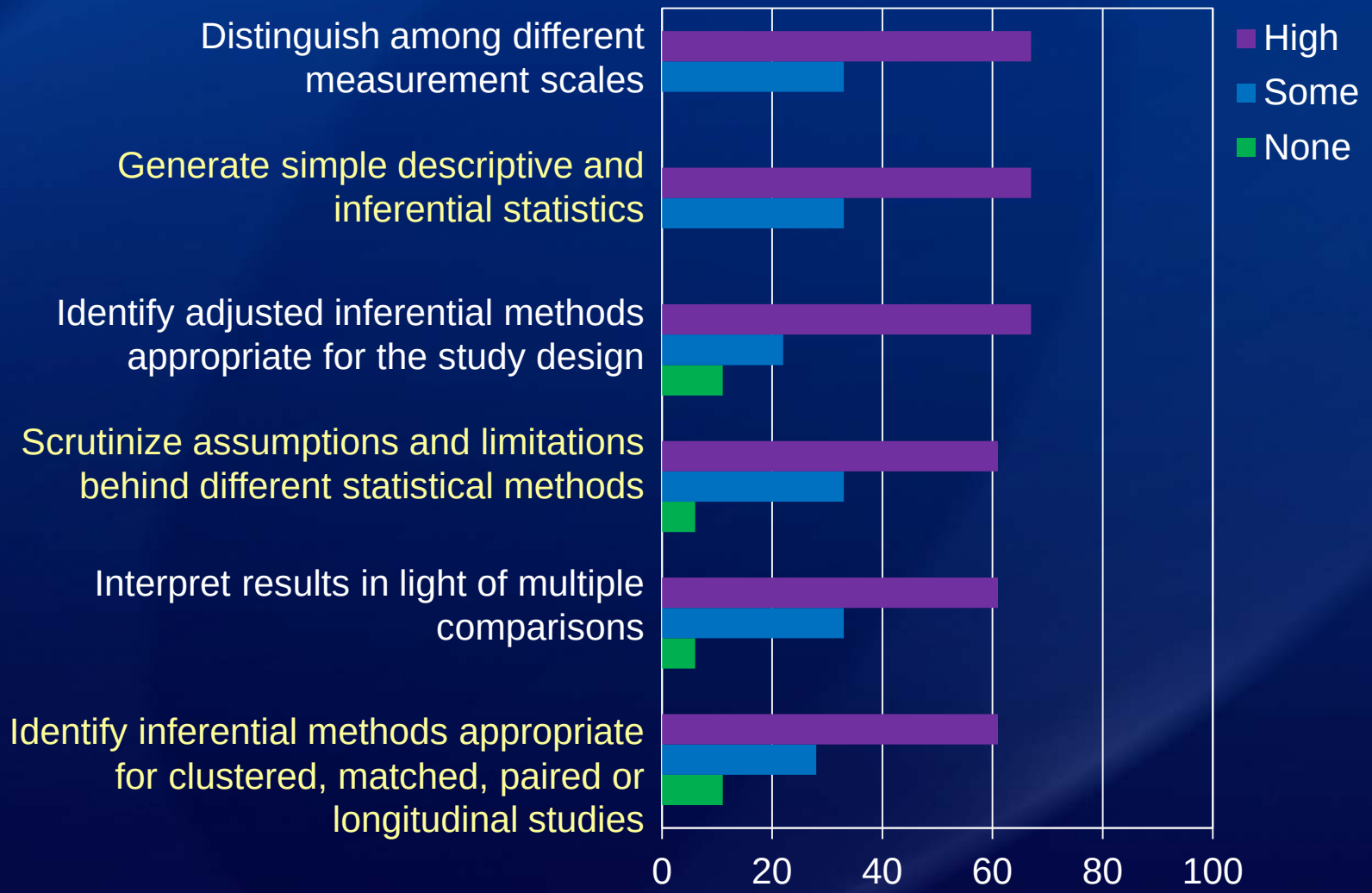
Intermediate Competencies
Goal: **PI**



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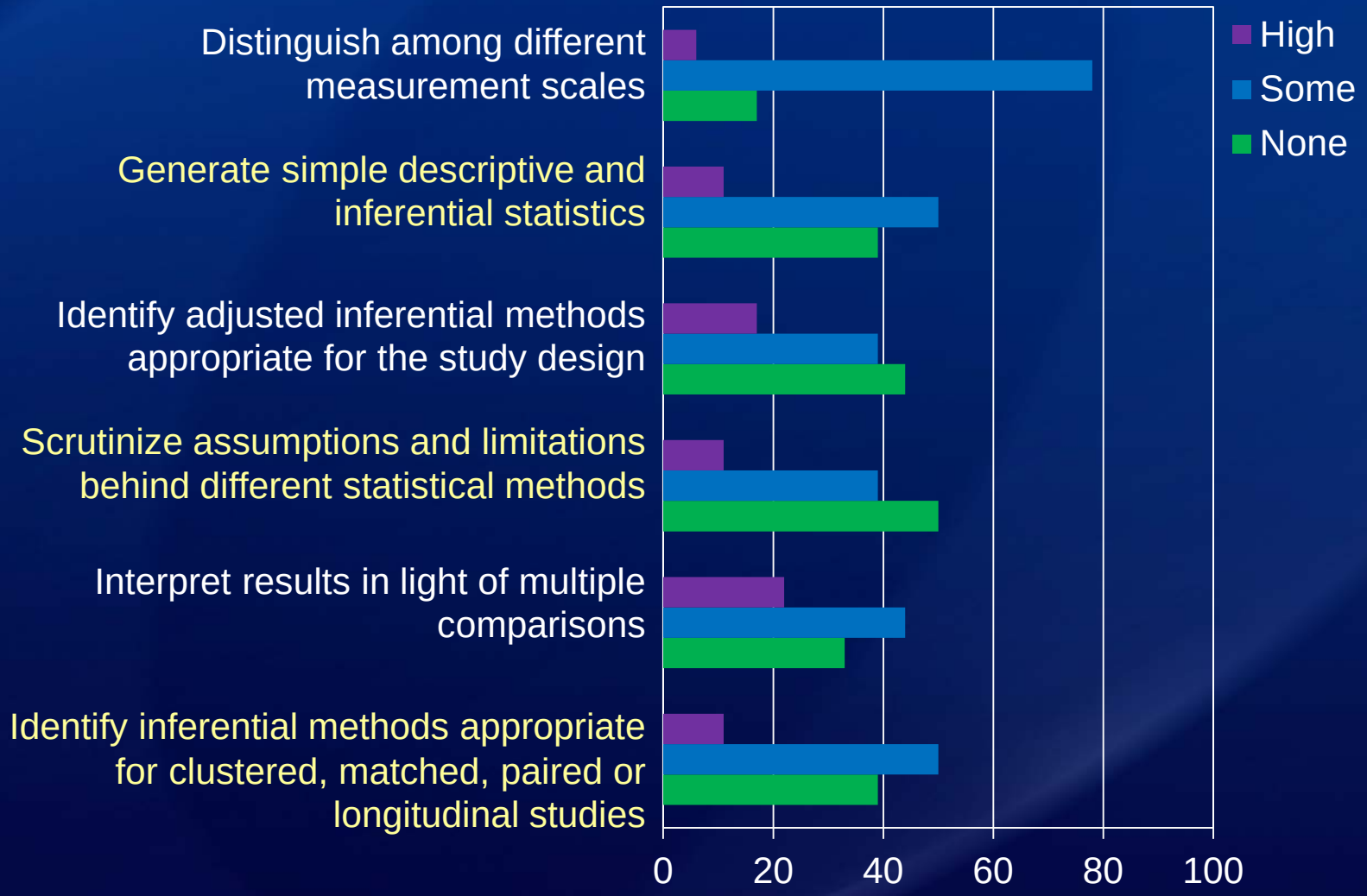
Intermediate Competencies
Goal: **Informed Reader**



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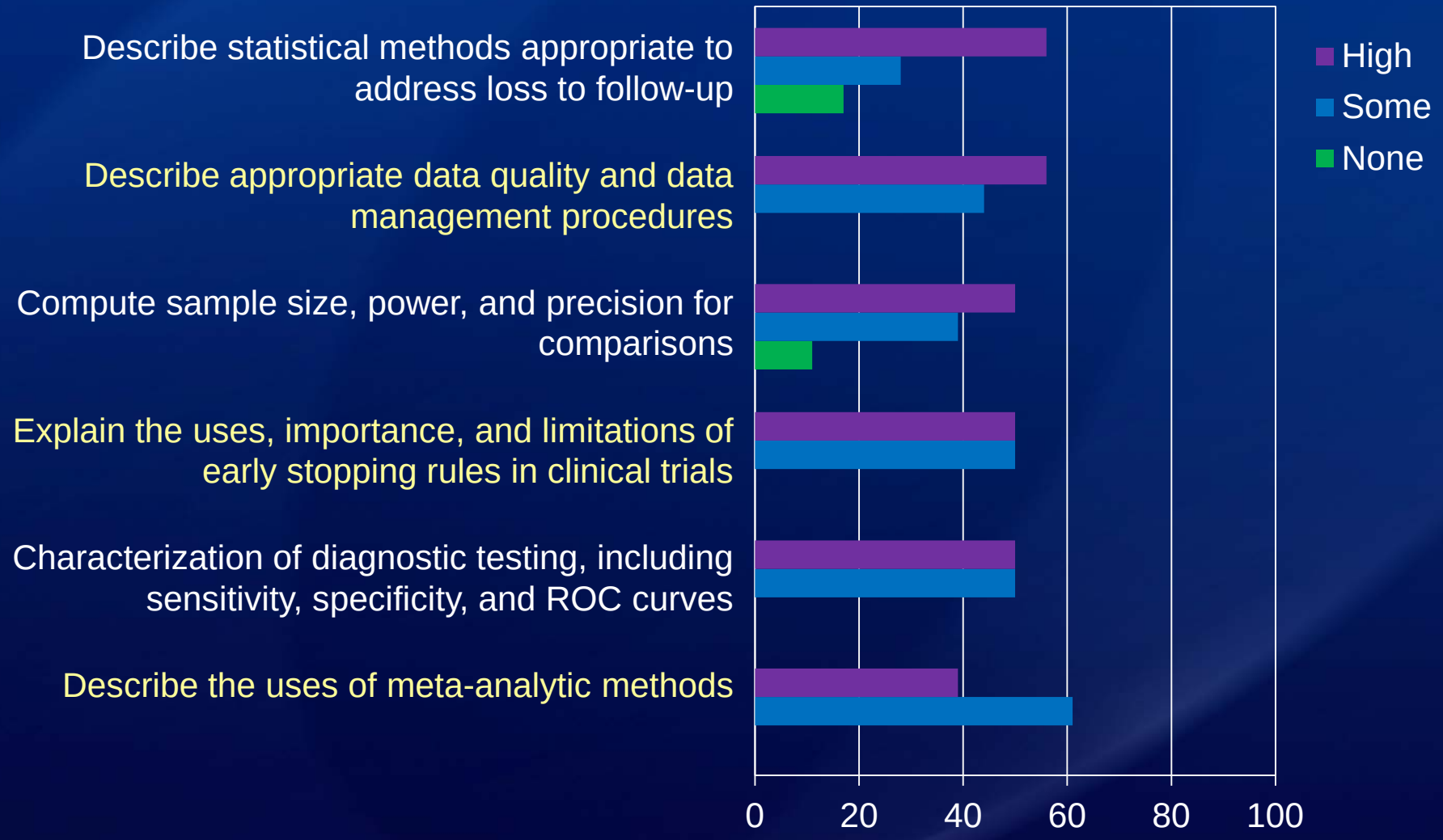
Specialized Competencies
Goal: **PI**



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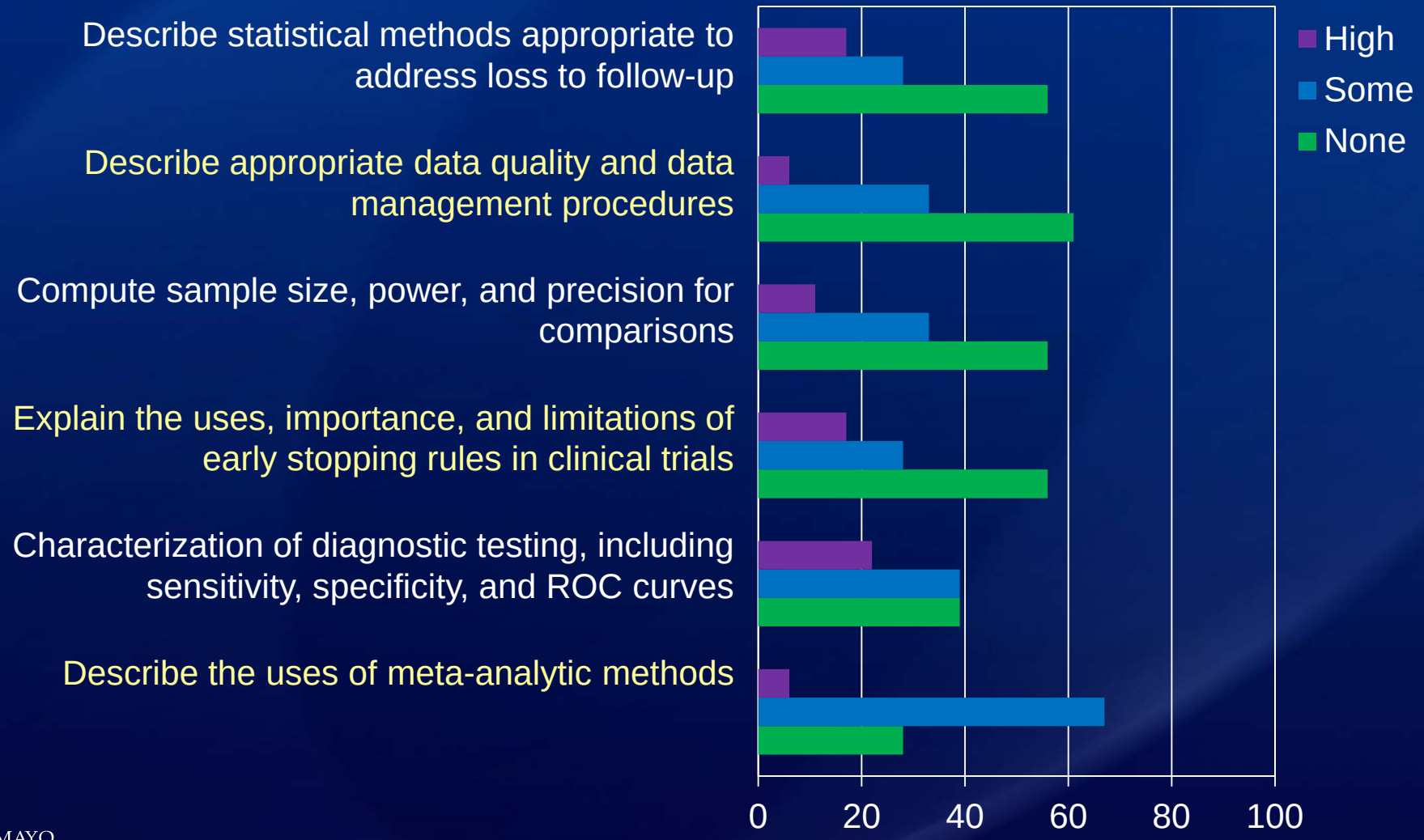
Specialized Competencies
Goal: **Informed Reader**



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Suggested Modifications

- Comments on the competencies suggested wording changes
  - Critical verb often proposed to change level of competency
- Example **[proposed modification]**
  - **Propose [Assess]** study designs for addressing a clinical or translational research question
- Modifications have not yet been assessed

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Summary of Competency Assessment

- Strengths
  - First assessment of competencies
  - Added competencies
  - Considered learner's background and role

- Limitations
  - N of 18
  - Cutoffs for competency types determined post hoc
  - Survey did not use terms "specialized" and "fundamental"

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Assessing CTS Learners

Enders F. (2013) “Do Clinical and Translational Science Graduate Students Understand Linear Regression? Development and Early Validation of the REGRESS Quiz.” Clinical and Translational Science, 2013 Dec;6(6):444-51.

Kidwell K, Enders F (In Press) “Initial External Validation of REGRESS in Public Health Graduate Students.” Clinical and Translational Science, In Press.

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Related Work: Assessment Tools for CTS

- In order to evaluate learner competency, validated measures will be needed
- Such instruments need to be:
  - Linked to CTS statistical competencies
  - Normed for CTS learners
  - Relatively quick to complete

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Assessment Instruments: Existing tools

- Windish (2007)
  - Well validated
  - For physicians reading the literature
- delMas (2007) CAOS test
  - Well validated
  - For undergraduates after 1st stat course
- For others, see Enders (2011)

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Assessment Instruments: New Tools

- Biostatistics Mastery Assessment of Proficiency (Biostatistics MAP)
  - Aligned with first course in biostatistics
  - Univariate and bivariate methods
- Global Regression Expectations in StatisticS (REGRESS)
  - Aligned with training on linear regression
  - Simple & multiple regression models

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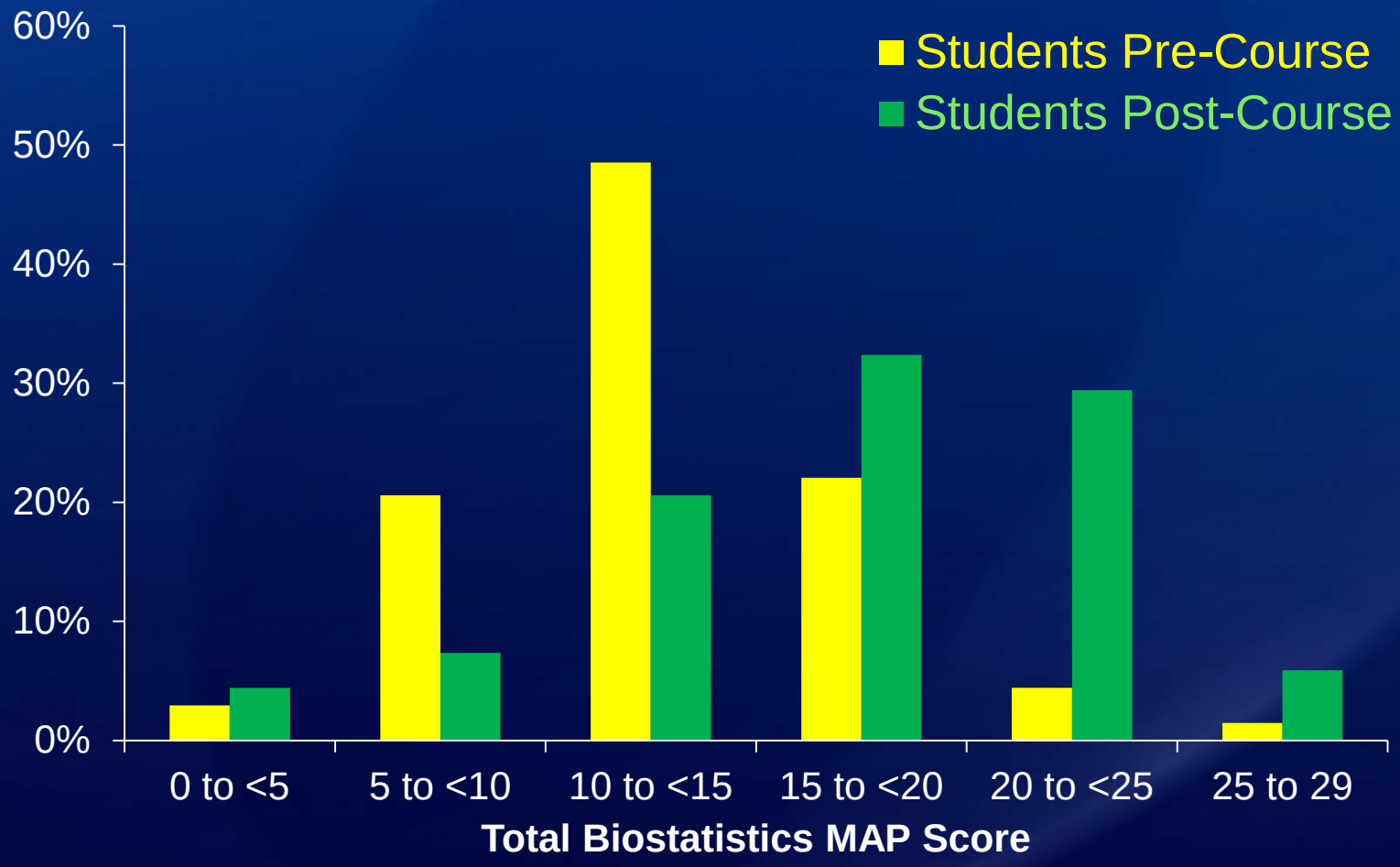
Biostatistics MAP



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Biostatistics MAP

	Student Pre-course N=68	Student Post-course N=68	Post-course-Pre-course N=68	p-value
Total Score (of 30)	**12 (1-25)**	**18 (0-29)**	**4 (-10 to 15)**	**<0.001**
Domains	Median (range)	Median (range)	Median (range)	
Definitions (of 3)	1 (0-3)	2 (0-3)	0 (-3 to 2)	0.043
Study Design (of 3)	1 (0-3)	2 (0-3)	0 (-1 to 3)	<0.001
Choice of Method (of 7)	3 (0-7)	5 (0-7)	1 (-5 to 7)	<0.001
Application (of 6)	3 (0-6)	4 (0-6)	1 (-2 to 6)	<0.001
Interpretation (of 8)	3 (0-7)	5 (0-8)	2 (-4 to 5)	<0.001
Assumptions (of 3)	1 (0-3)	1 (0-3)	0 (-2 to 2)	0.019
Topics				
General (of 8)	4 (0-8)	5 (0-8)	1 (-6 to 5)	<0.001
Categorical Outcome (of 8)	4 (0-8)	5 (0-8)	1 (-3 to 5)	<0.001
Continuous Outcome (of 8)	3 (0-7)	5 (0-8)	1.5 (-3 to 6)	<0.001
Time to Event Outcome (of 2)	0 (0-2)	0 (0-2)	0 (-1 to 2)	0.123
Diagnostic Testing & Agreement (of 4)	2 (0-4)	3 (0-4)	1 (-3 to 3)	0.010

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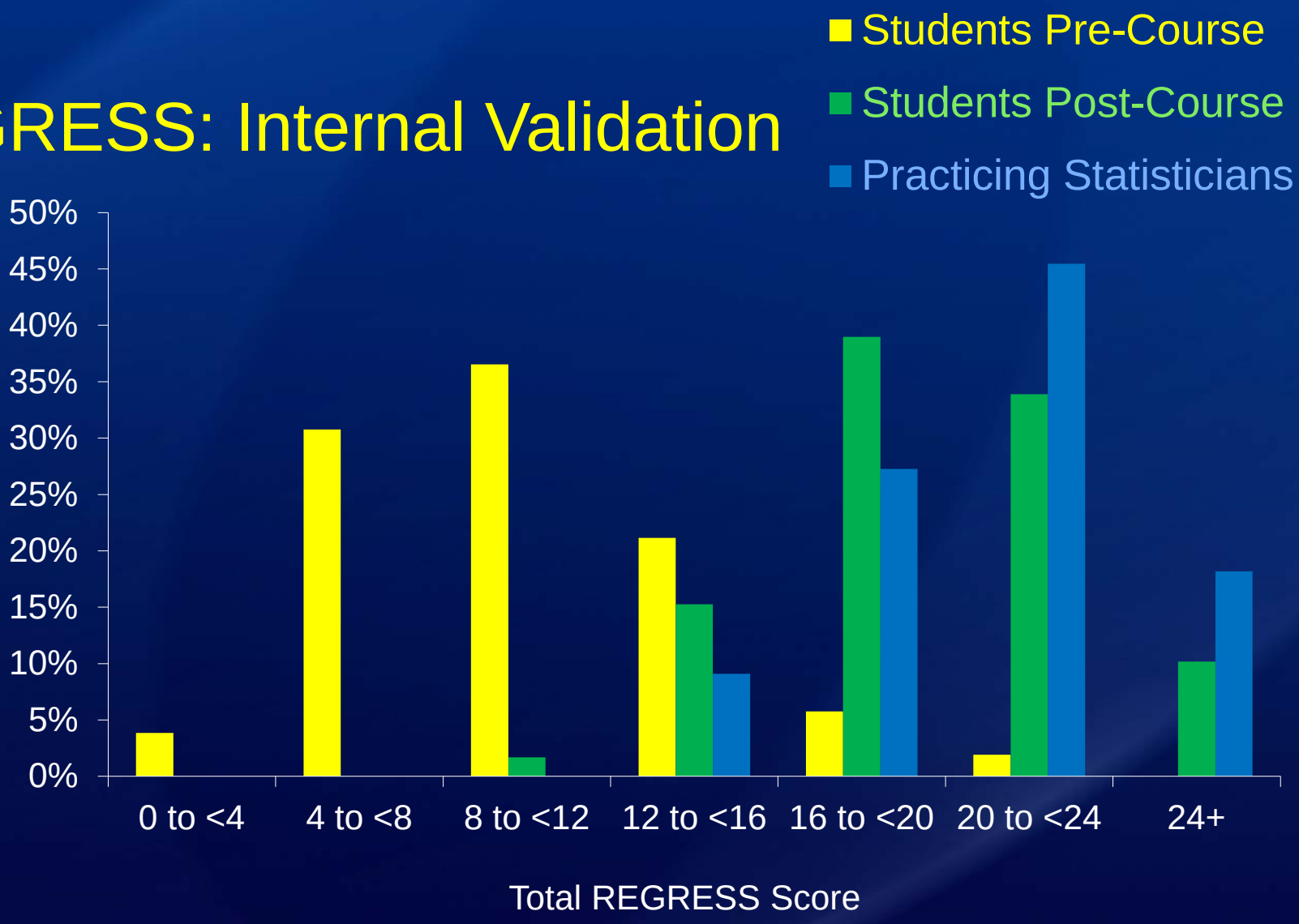
REGRESS: Internal Validation



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REGRESS

	Mayo pre-course N=52	Mayo post-course N=59	p-value	Practicing Statisticians N=22	p-value vs. pre	p-value vs. post
Summary Scores	Mean (SD)	Mean (SD)		Mean (SD)		
REGRESS Score (of 27)	**9.3 (4.3)**	**19.0 (3.5)**	**<0.001**	**20.1 (3.5)**	**<0.001**	**0.21**
SLR Score (of 11)	6.3 (2.5)	8.3 (1.6)	<0.001	9.8 (1.2)	<0.001	<0.001
Domains	Median (range)	Median (range)		Median (range)		
Interpreting & Using SLR Equation (of 8)	4 (0-8)	6 (3-8)	<0.001	7 (5-8)	<0.001	0.001
Interpreting & Using MLR Equation (of 4)	1 (0-4)	3 (0-4)	<0.001	3 (2-4)	<0.001	0.37
Modeling & Statistical Significance (of 4)	2 (0-4)	3 (2-4)	<0.001	3 (2-4)	<0.001	0.86
Assessing Assumptions (of 4)	1 (0-4)	2 (1-4)	<0.001	2 (0-4)	<0.001	0.84
Confounding & Colinearity (of 4)	0 (0-3)	3 (0-4)	<0.001	3 (0-4)	<0.001	0.53
Interaction (of 3)	0 (0-3)	2 (0-3)	<0.001	2 (0-3)	<0.001	0.82

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REGRESS: Initial External Validation

REGRESS Scores (out of 27)	N	Mean (SD)	P-value
Pre-Course			
University of Michigan Students	52	11.3 (2.8)	
Mayo Students	52	9.3 (4.3)	0.018
Post-Course			
University of Michigan Students	52	15.2 (3.1)	
Mayo Students	59	19.0 (3.5)	<0.0001
Statisticians	22	20.1 (3.5)	<0.0001

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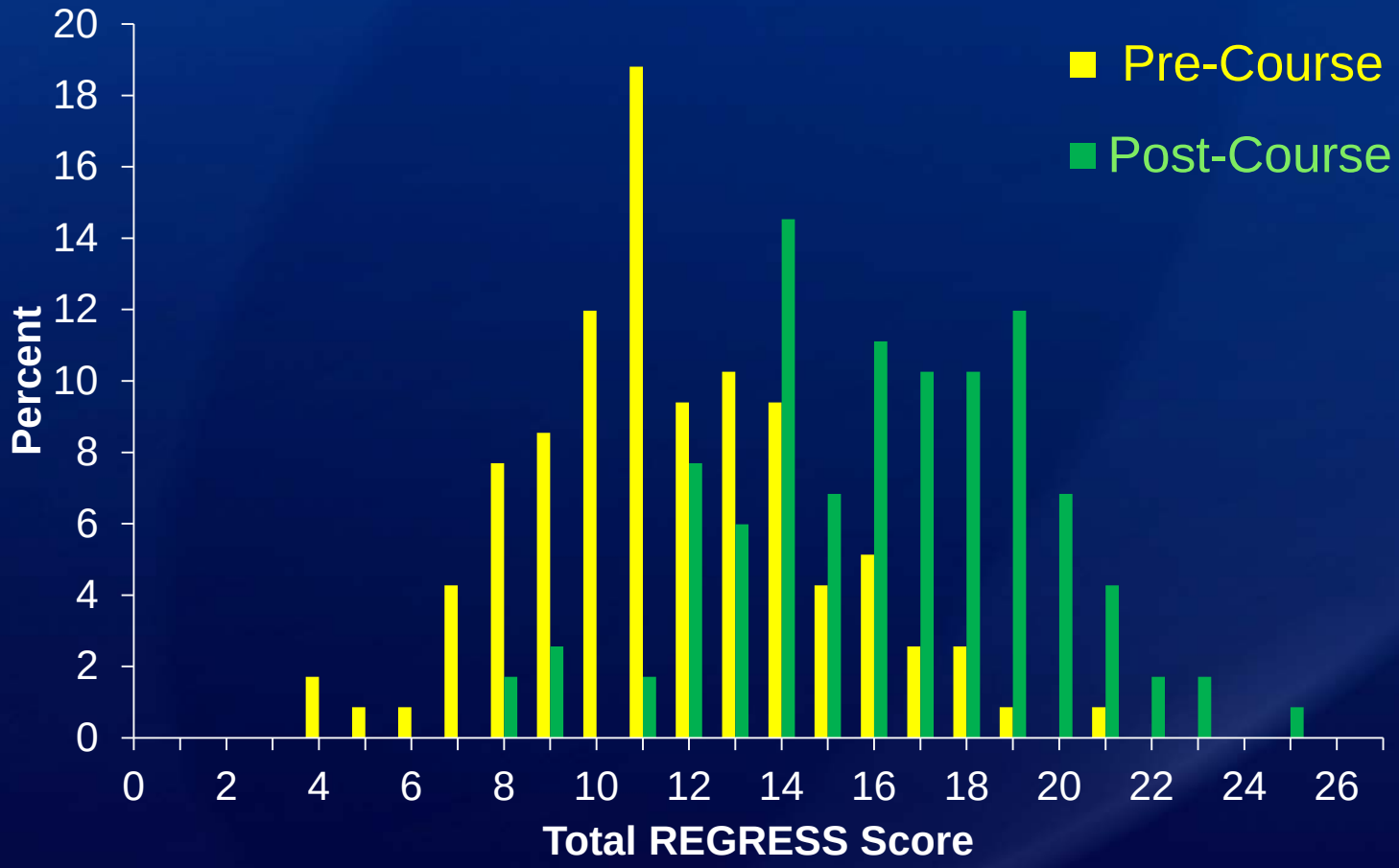
REGRESS: Initial External Validation



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REGRESS: Initial External Validation

	Pre-course	Post-Course	Pre vs. Post
Summary	Mean (SD)	Mean (SD)	P-value
REGRESS (out of 27)	**11.29 (2.84)**	**15.17 (3.05)**	**<0.0001**
SLR Score (out of 11)	7.37 (1.46)	7.92 (1.61)	0.0145
Domain	Median (range)	Median (range)	
Interpreting and Using SLR Equation (of 8)	5.0 (2-7)	5.5 (2-8)	0.0054
Interpreting and using MLR Equation (of 4)	1.5 (0-4)	2.0 (0-4)	<0.0001
Modeling and Statistical Significance (of 4)	2.0 (0-4)	3.0 (1-4)	<0.0001
Assessing Assumptions (of 4)	1.0 (0-3)	2.0 (0-4)	0.0052
Confounding and Colinearity (of 4)	1.0 (0-3)	2.0 (0-4)	<0.0001
Interaction (of 3)	1.0 (0-2)	1.0 (0-3)	0.0007

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Assessment Instruments: Current Status

- Biostatistics Mastery Assessment of Proficiency (Biostatistics MAP)
  - Internal validation done
- Global Regression Expectations in StatisticS (REGRESS)
  - Internal validation done (Enders, 2013)
  - 1st external validation done (Kidwell, 2014)
  - Currently creating next version
  - Planning a larger external validation for 2014-2015

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Consensus on the Competencies

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CTS Statistics Competencies (2011)

Four Competencies Added by CTSA Consortium

Describe the role that biostatistics serves in biomedical and public health research.

Defend the significance of data and safety monitoring plans.

Collaborate with biostatisticians in the design, conduct, and analyses of clinical and translational research.

Evaluate computer output containing the results of statistical procedures and graphics.

Workgroup CECC. Core Competencies in Clinical and Translational Science for Master's Candidates. https://www.ctsacentral.org/documents/CTSA%20Core%20Competencies_%20final%202011.pdf

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Next Steps

- Update CTS competencies for statistics
  - Modify further?
  - Get buy-in from CTSA PIs
- Assess which competencies are taught to whom
  - For which competencies would Consortium-wide training materials be helpful?
- Update instruments/items to better reflect CTS competencies

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Survey of ACTStat Attendees

- Consensus among statisticians
  - Preferred wording
  - Additions
  - Exclusions
- Competency level
  - Fundamental − Specialized

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ACTS Survey

- Competencies
  - Which wording do you prefer?
  - Should this competency be excluded?
  - Specialized = 1
    - Only advanced learners in some areas need to achieve these competencies
  - Fundamental = 9
    - Every CTS learner needs to achieve these competencies
- What's missing?
  - Propose additional statistical competencies for CTS learners

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Questions & Discussion