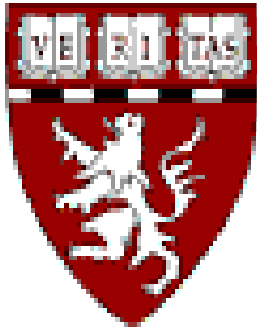


The Context of Clinical Research in AHCs: Challenges and Opportunities



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The Plan

- Questions to Answer
- Methods
- Results
- Conclusions

Questions to Answer

- What is the current state of clinical research in AHCs?
- What are the current challenges to the clinical research missions of AHCs?
- What strategic choices are being made at the institutional and department levels to adapt to the challenges in the clinical research environment?

Status of Clinical Research in Academic Health Centers Views From the Research Leadership

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CLINICAL RESEARCH, DEFINED AS research that involves using humans as subjects, is composed of a wide spectrum of research types such as clinical trials, translational research, epidemiological research, health services research, and outcomes research and is critical to translating the results of basic science into feasible health care products and services.¹ The challenges facing the clinical research enterprise in the United States have become major concerns of the academic medical community. One reason is that these challenges could eventually reduce the flow of future medical knowledge by inhibiting the amount or reducing the quality of the research conducted.²⁻⁴ Realizing this potential, the Institute of Medicine recommended the establishment of a US\$1 billion fund to incorporate, rapidly and appropriately, the results of scientific research into clinical practice—one of the causes of low-quality health care.⁵

Much of the “crisis” in clinical research has been attributed to numerous changes in the health care environment.⁶⁻⁷ First, insurers are less willing to pay the higher costs of patient care at academic health centers (AHCs).

For editorial comment, see p 845.

Context: The changing state of the health care system in the United States may be adversely affecting clinical research conducted in academic health centers (AHCs). Few formal data have been gathered about the nature and extent of the problems facing clinical research or the effects of various undertakes by AHCs.

Objective: To assess the perceived quality and health of the clinical research enterprise and to determine challenges and adaptations to current environmental pressures.

Design, Setting, and Participants: Mailed survey conducted between December 1999 and March 2000 of a subsample of department chairs and senior research administrators (SRAs) in all US medical schools. Of the 712 potential respondents, 478 completed a questionnaire, yielding an overall response rate of 67.1% (64.8% for SRAs and 67.8% for department chairs).

Main Outcome Measures: Ratings of overall health/robustness of clinical research, quality of research in 5 domains, extent of challenges to performing research, and extent of urgency in responding to research challenges. Binary ratings for research-related tasks and best efforts.

Results: Slightly more than half (52%) of all respondents rated the health of the clinical research enterprise as good or a medium compared with 63% for nonclinical research ($P < .001$). Respondents were most likely to rate nonclinical research as high in quality (79%) compared with 70% for phase 2 clinical trials, 67% for translational research, 65% for phase 1 and 2 trials, and 57% for health services research (for all comparisons with nonclinical research, $P < .001$). Pressure on clinical faculty whose patients are perceived as a moderate-to-large problem for clinical research by the largest percentage of respondents (57%), followed by insufficient clinical research (52%), recruiting trained researchers (50%), lack of a strong support for clinical research (52%), competition from contract research organizations (48%), problems introduced by the institutional review board process (48%), and finding research participants (57%). In total, 81% of respondents considered the challenges facing clinical research in AHCs to be urgent or a strongly urgent.

Conclusions: Academic health centers perceive clinical research activities in AHCs to be less healthy, of poorer quality, and facing greater challenges than nonclinical research activities. Many AHCs do not have policies or mechanisms to address challenges facing the clinical research mission. Even among those with such policies, more than half do not believe these policies have had large positive effects. Our findings support the view that the clinical research workforce and infrastructure may need to be expanded and strengthened to keep pace with advances in basic research.

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Methods

- Institutions--U.S. 4 year medical schools
- Department Chairs
 - Medicine, Pediatrics, Psychiatry, Neurology, Anesthesiology
- Senior Research Administrators (SRA)
 - The senior institutional official, other than the dean, who has primary responsibility for the research activities of the medical school.
 - Associate/Assistant/Vice Dean of/for Research
 - Associate/Assistant/Vice Dean of/for Research Affairs
 - Associate/Assistant/Vice Dean of/for Academic Affairs

Survey Methods

- 2 survey instruments
- Cognitive interviews
- Administered by CSR at UMASS Boston
- Mixed Mode: Mail and heavy telephone follow-up
- Results:
 - 65% Overall response rate (n=472 out 712)
 - 66% Chairs response rate (n=390)
 - 65% SRAs response rate (n=82)
- Results published in Aug. 15, 2001 JAMA

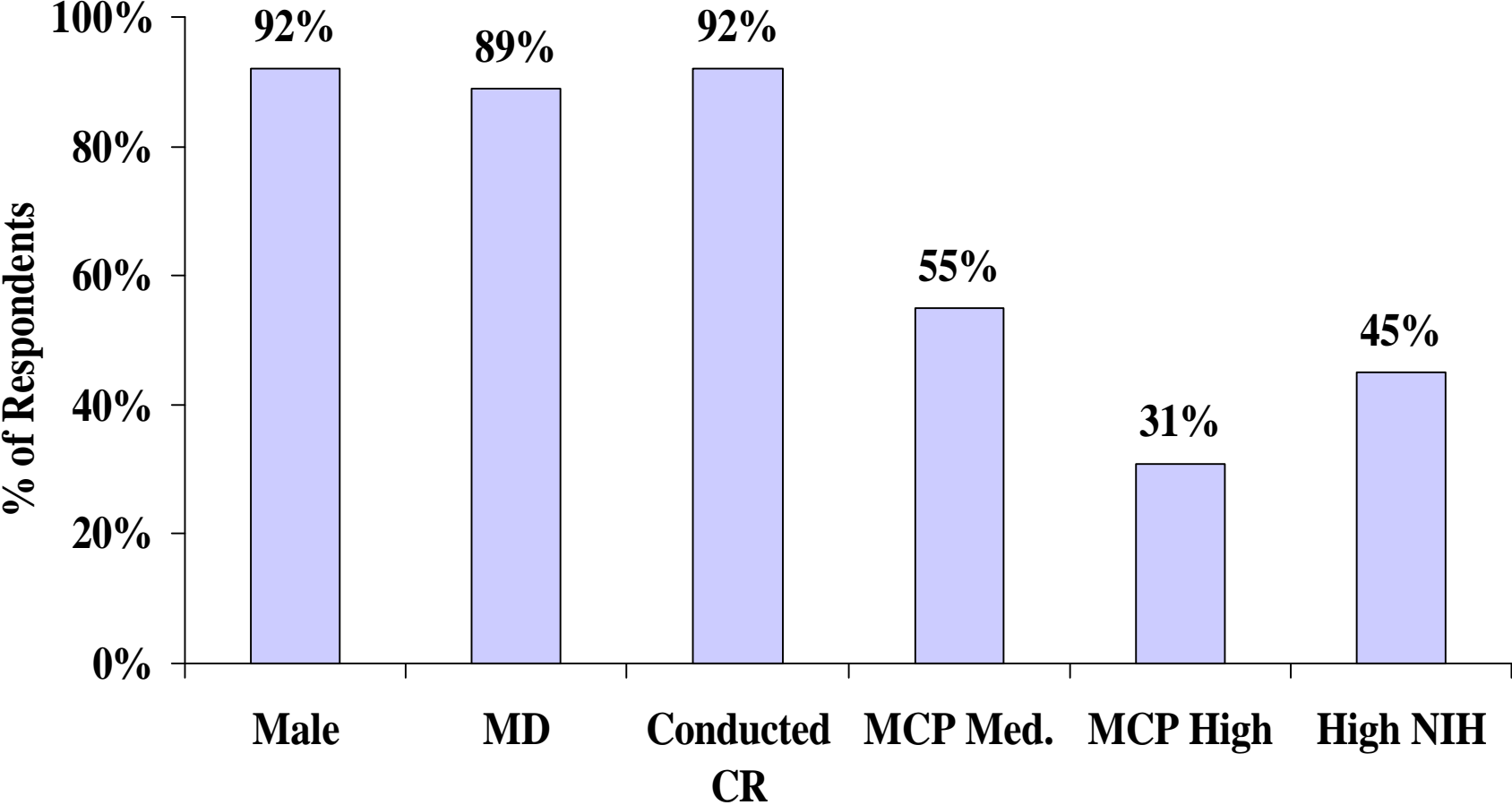
Analyses

- SAS
- Bivariate
 - Chi-square
- Multivariate
 - Regression adjusted percentages controlling for:
 - Respondent type (SRA v. Chair)
 - Research intensity (NIH Top 50 v. NIH not top 50)
 - MCP (High >40% v. Medium 21%-40% v. Low <20%)

Results

- Characteristics of Respondents
- Health and Robustness of Clinical Research
- Quality
- Challenges
- Adaptations

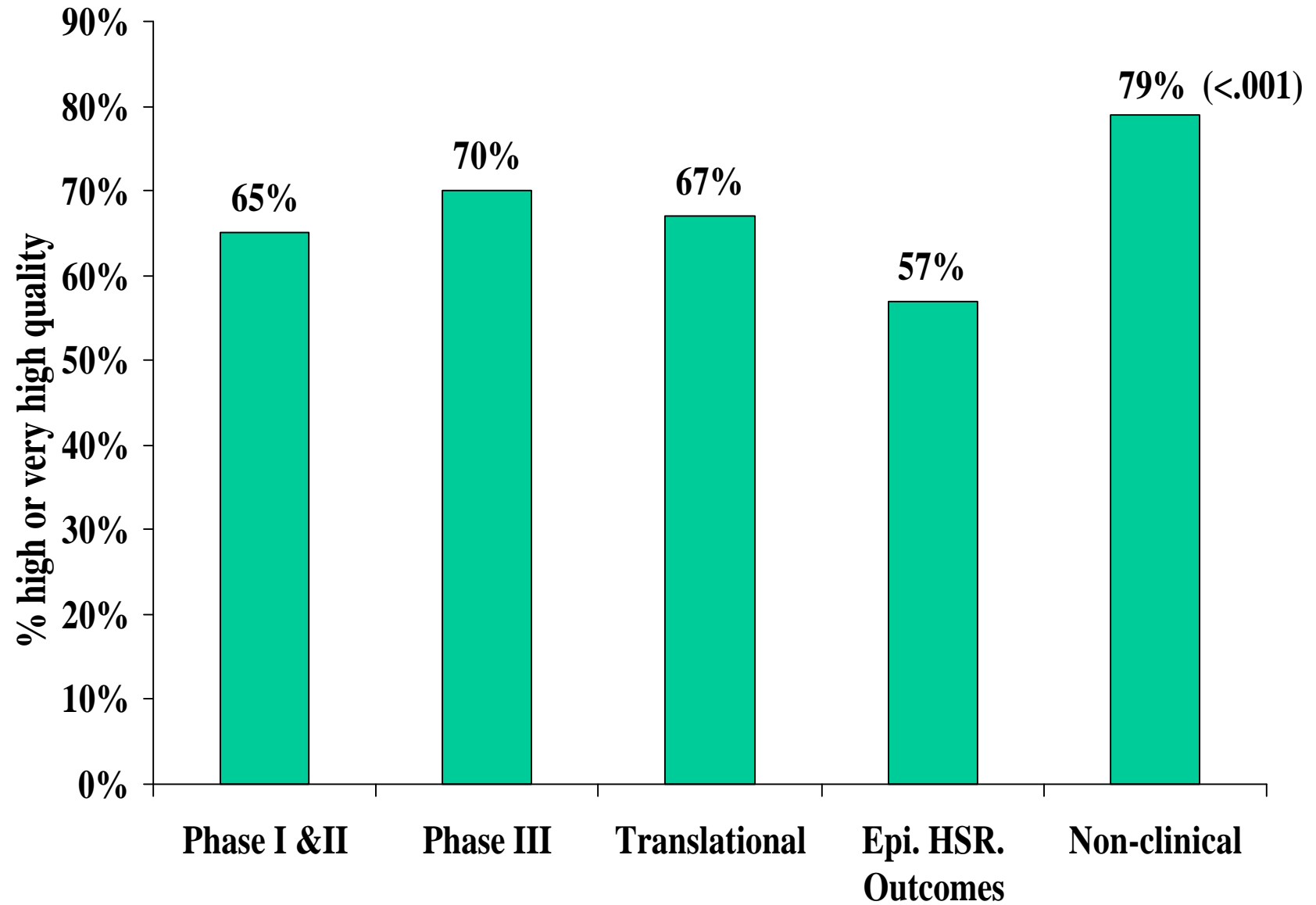
Characteristics of Respondents



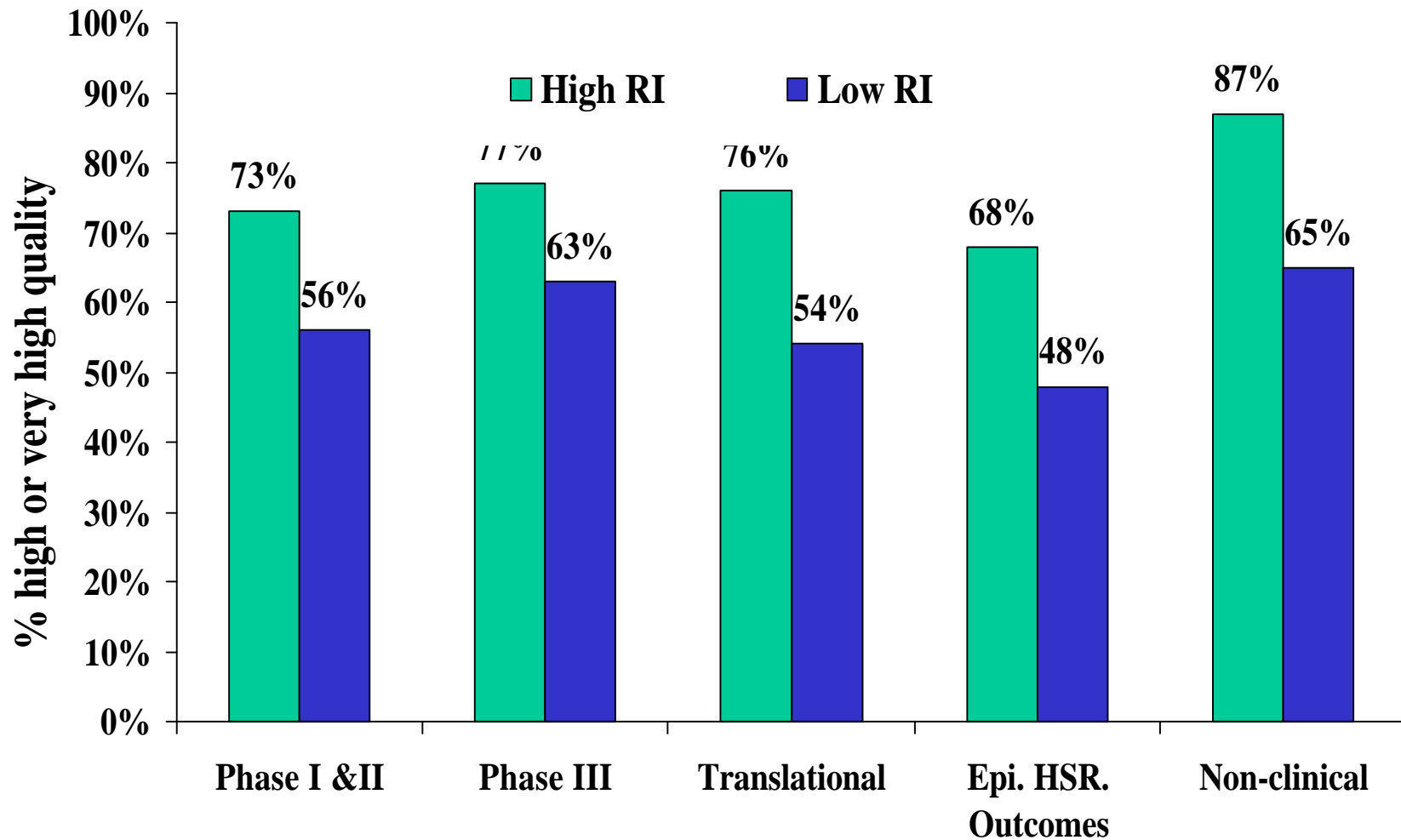
Current Health and Robustness

	Percentage Rating the Current Health and Robustness of Clinical Research as Good/Excellent (n=461)	Percentage Rating the Current Health and Robustness of Non-clinical Research as Good/Excellent (n=459)
All	52	63 (<.001)
Respondent Type:		
SRAs	50	85
Dept. Chairs	53	55 (<.001)
Research Intensity:		
Low	35	43
High	72 (<.001)	80 (<.001)
Managed Care Penetration:		
Low	37	55
Medium	53 (.04)	63
High	58 (.01)	66

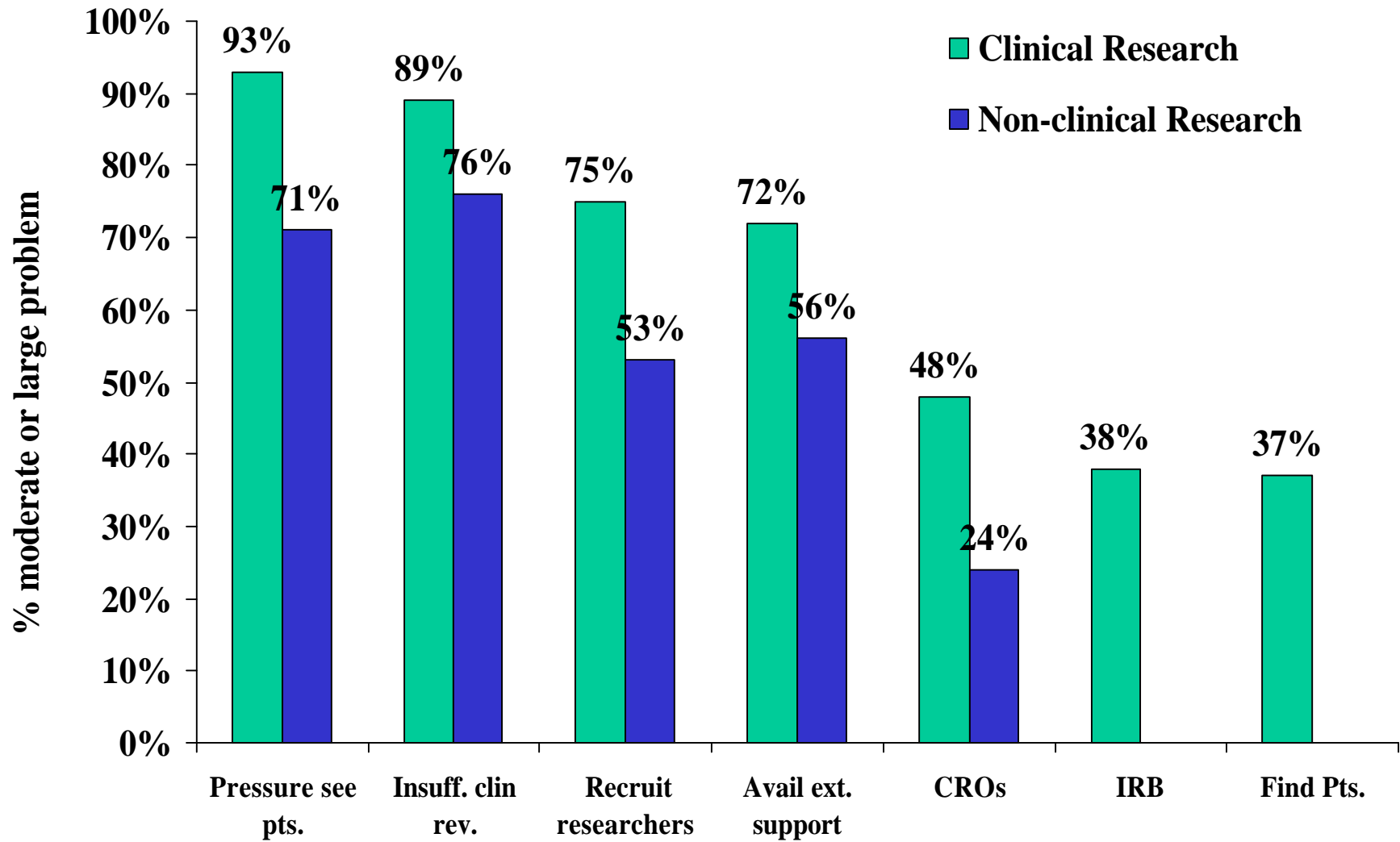
Overall Quality of the Research



Quality of the Research by Research Intensity



Challenges



Challenges to Clinical Research

	Pressure to See Patients <i>(n=449)</i>	Insufficient Clinical Revenues <i>(n=447)</i>	Recruiting Trained Researchers <i>(n=445)</i>	Availability of External Support <i>(n=442)</i>	Finding Research Subjects <i>(n=439)</i>
Research Intensity:					
Low	93%	88%	81%	80%	34%
High	93%	90%	66%*	59%*	41%
Managed Care					
Low	90%	80%	78%	86%	32%
Medium	90%	87%	76%	70%*	37%
High	97%*	93%*	61%	66%*	38%

*p<.05

Urgency

Please rate your overall sense of urgency as you respond to the challenges facing the conduct of clinical research in your department:

	%
Extremely Urgent—we are in a crisis with respect to clinical research	12%
Urgent—delays in facing challenges will be costly to clinical research	69%
Not very urgent—normal management will address our clinical research issues	17%
Not at all urgent—there are no important challenges to clinical research	1%

Adaptations and Impact

Does your department or institution have formal procedures or mechanisms in place to assist investigators with:		If Yes, what has been the effect on the amount of clinical research performed?
	% Yes	%Moderate or Large Positive Effect
Identifying funding sources?	69	30
Identifying potential collaborators?	48	40
Scientific review prior to submission?	45	47
Writing grants?	45	43
Recruiting research subjects?	34	53
Grant revision following a rejection?	34	48

Conclusions

- Substantial concern over health and robustness of clinical research
- Similar concern about quality of clinical research
- Biggest challenges relate to pressures to see patients, lack of clinical revenue and an insufficient supply of clinical research
- Most frequent adaptations have smallest positive impact