

Opportunities for Recruitment & Retention in Clinical Research: The Clinical Research Coordinator Perspective

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Health of Women (HoW) Public Workshop

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Purpose

- To summarize the barriers to and opportunities for identified by CRCs related recruiting and retaining participants in clinical trials



Clinical Research Coordinator

- “Hands on” research experience
- Responsible for the day to day activities
- Success of the research study
- Duties include
 - Identifying and screening potential participants
 - Participant recruitment
 - Administering informed consent
 - Adverse event reporting
 - Completion of the case report form
 - Obtaining participant follow-up



Methods - Online Questionnaire

- August 17, 2009 - email invitation outlining the project
- August 28, 2009 - follow-up email reminder
- Included link to the questionnaire (28 questions)
- Sent to 8,963 ACRP members
- Survey was open for a two week period, from August 17 – August 31, 2009



Results - Respondents

- 1,024 recipients completed the survey

Role

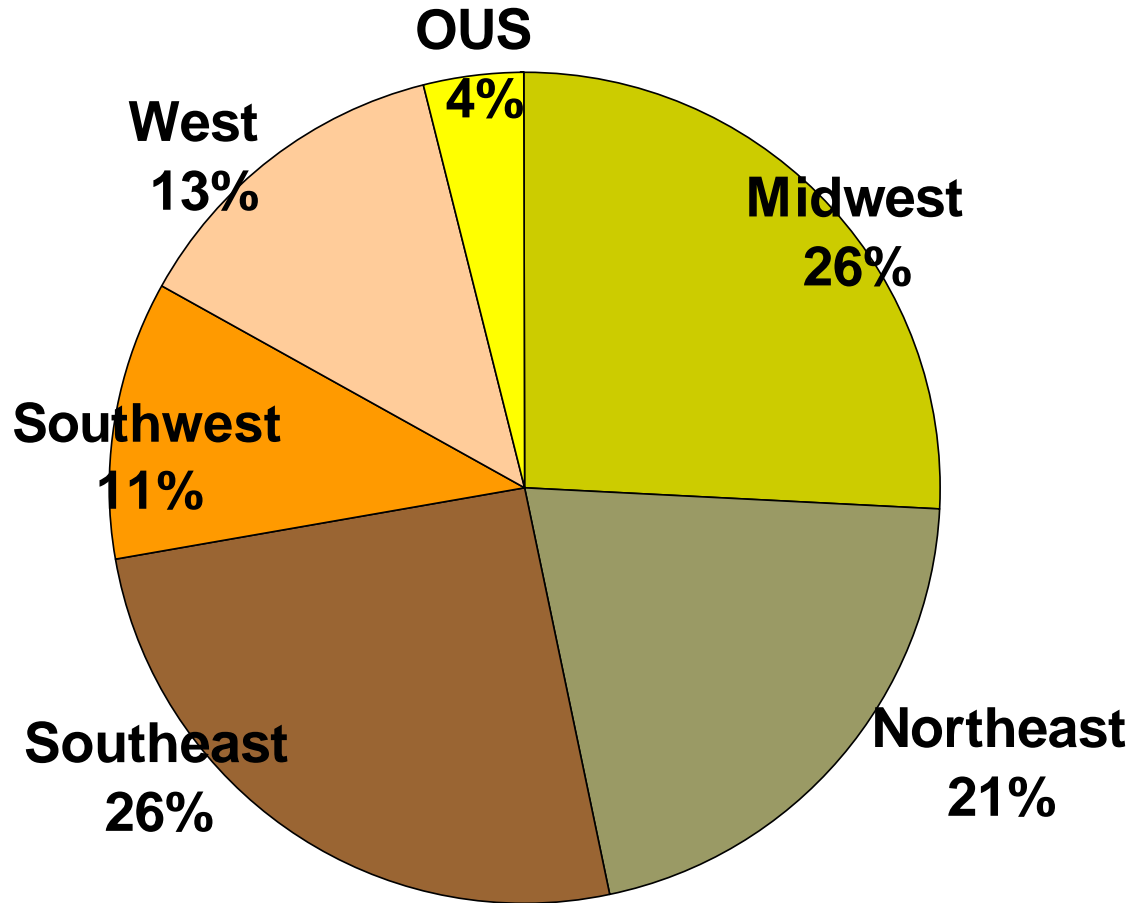
- 75% - Coordinator
- 9% - Project Management

Work Environment

- 57% - Clinical Study Site
- 19% - Academia
- 9% - Healthcare Associations/Organizations

Results - Respondents

Location





Results - Respondents

Experience

- 29% - 13 or more years
- 32% - 8 - 12 years
- 26% - 4 - 7 years
- 13% - 3 years or less

Types of Studies

- 89% - Drug Studies
- 36% - Medical Device Studies
- 23% - Biologic Studies

Results - Respondents

Clinical Area

- 13% - Cardiology
- 11% - Oncology or Hematology
- 7% - Neurology
- 4% - Gastroenterology
- 4% - Endocrinology
- 4% - Psychiatry
- 4% - Pulmonology
- 4% - Pediatrics



Results – Respondents

Study Phase

- 35% - Phase 1
- 86% - Phase 2
- 95% - Phase 3
- 78% - Phase 4
- 43% - Disease, procedure or treatment registries



Recruitment

Barriers to Recruitment of Subjects

Barrier to Recruitment	Number (%)
Finding eligible patients	780 (77%)
Refusal - time commitment	54 (54%)
Refusal – concern about risk	475 (47%)
Refusal – distance/transportation	344 (34%)
Refusal – want standard care	343 (34%)
Competing protocols	294 (29%)
Refusal – protocol concern/consent	158 (16%)
Refusal – low payment	147 (15%)

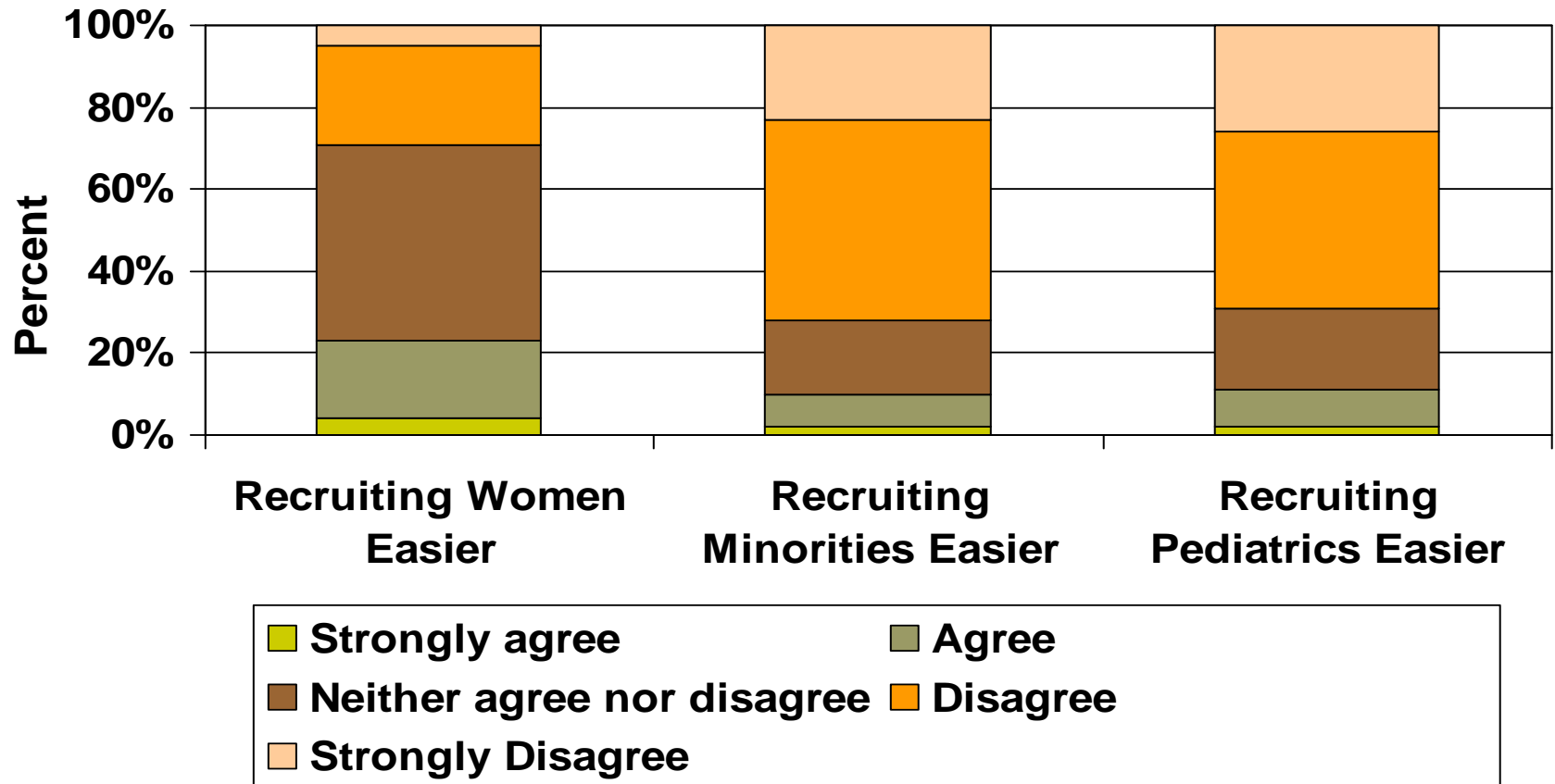
Factors That Ease Recruitment

Ease Recruitment	Number (%)
Physician mention	772 (76%)
Benefit to self	770 (76%)
Monetary incentive	540 (53%)
Answering questions	460 (45%)
Benefit to others	425 (42%)
Detailed consent	219 (21%)

Demographics that Impact Recruitment

Barrier to Recruitment	Number (%)
Comorbidities	596 (59%)
Distance/transportation	553 (55%)
Older age	386 (38%)
Hx of non-compliance	359 (36%)
Language barriers	313 (31%)
Lack of social support	206 (20%)
Race/ethnicity	199 (20%)
Younger age	194 (19%)
Insurance coverage	169 (17%)

Recruitment of 3 Subgroups





Retention

Barriers to Retention of Subjects

Barrier to Retention	Number (%)
Too much time	614 (60%)
Don't see benefit	434 (43%)
Lose interest	385 (38%)
Move out of area	303 (30%)
Health difficulties	262 (26%)
Lack of social support	151 (15%)

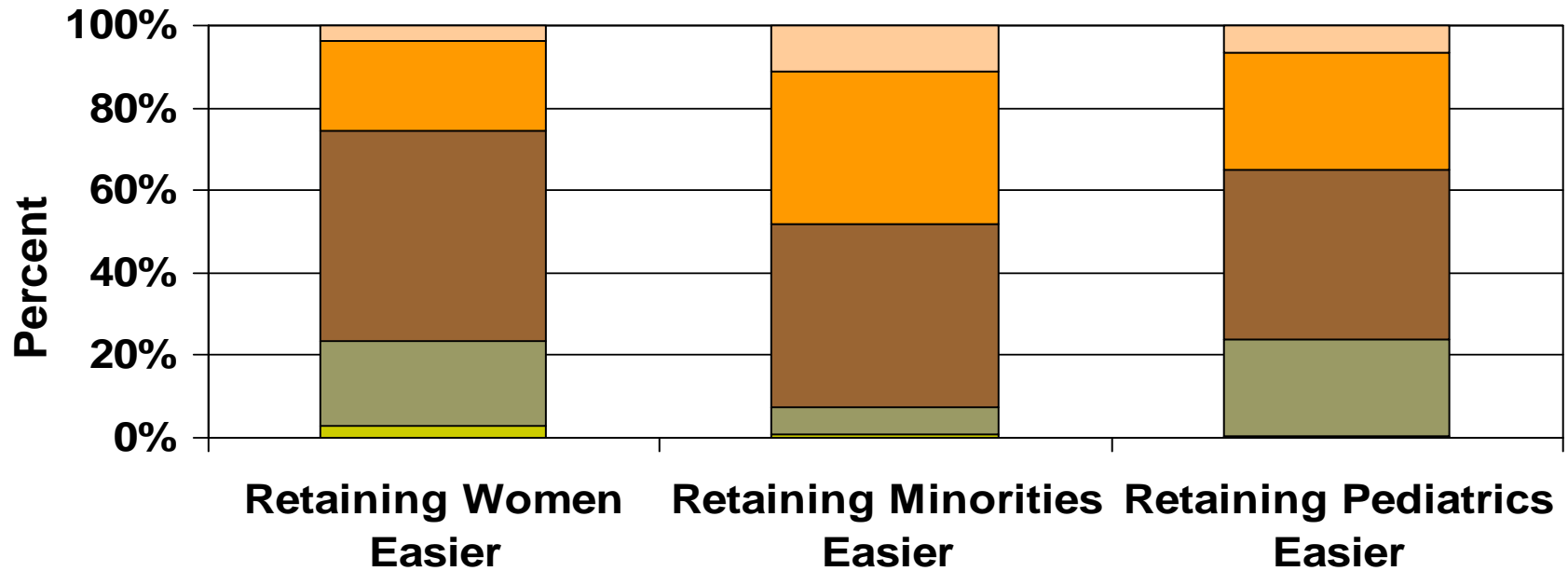
Methods to Ease Retention of Subjects

Strategy to Ease Retention	Number (%)
Flexible schedule	899 (88%)
Monetary incentive	663 (65%)
Both phone and in-person	525 (51%)
Reminder	495 (49%)
Exclusive phone follow-up	489 (48%)
Answering questions	264 (36%)
Birthday card, newsletter, etc	242 (24%)

Demographics that Impact Retention

Demographic	Number (%)
Distance/transportation	598 (59%)
Comorbidities	486 (48%)
Hx of non-compliance	390 (38%)
Older age	361 (35%)
Lack of social support	256 (25%)
Younger age	182 (18%)
Language barriers	148 (15%)
Race/ethnicity	123 (12%)

Retention of 3 Subgroups



- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly Disagree

Additional Analyses

- Years of experience
 - Most frequent recruitment & retention barrier same
 - Higher frequency report for those with more experience
- Region of the country
 - Monetary incentive - highest in SE
 - Social support & language barrier - highest in SW
 - “Time” barrier to retention – highest in NE



Additional Analyses

- Clinical area
 - Evaluated 4 largest clinical areas
 - Refusal due to risk - lowest in Oncology/Hematology and Neurology
 - Monetary incentive on recruitment and retention – lowest in Oncology
 - Retention impacted due to loss of interest - highest in Oncology/Hematology and Neurology
 - Older age impact on recruitment and retention – highest in Cardiology



Focus Group



Focus Group - How Conducted

- Guided Discussion
 - Experience with types of studies coordinated (pre/post-market, research area, etc)
 - Experience with recruitment
 - Experience with retention
 - Perception of patient compliance



Findings – Participants

- September 22, 2009
- 7 participants
- Cardiovascular, Dermatologic, multiple areas
- Drug and Device experience represented
- 5-30+ years experience



Findings - Recruitment

- Finding potentially eligible subjects
- Role of principal investigator
- Role of site location / logistics
- Financial and other incentives
- Motivation vs. coercion
- Challenge to recruit patients who are compliant / follow protocol



Findings - Retention

- Rapport with Clinical Research Coordinator
- Financial and other incentives
- Visit and other contact schedule

- Retention difficult for extended timeframe



Findings – Patient Compliance

- Indicators at recruitment
- Suggested strategies to improve compliance
 - Only recruit compliant patients
 - Collect multiple contacts
 - Highlight additional medical attention with study involvement



Analysis of Focus Group Findings

- Similarities to survey
- Use of incentives
- Potential pitfalls to data analysis
- Potential pitfalls to generalizability



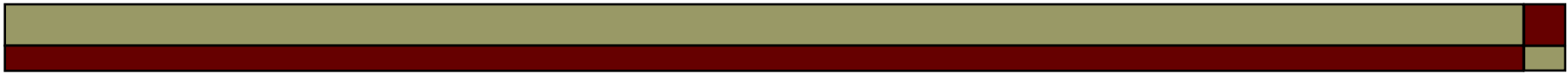
Relevance

- Importance recruitment and retention
- Critical role of CRC
- Identified perceived barriers and opportunities
- Identified potential places for improvement



Future Directions

- FDA needs to continue to gather knowledge from CRC
 - What works/What does not
 - Identify study phase specific strategies
 - Identify strategies unique to product types (device, drug, biologic)
 - Identify demographic specific strategies

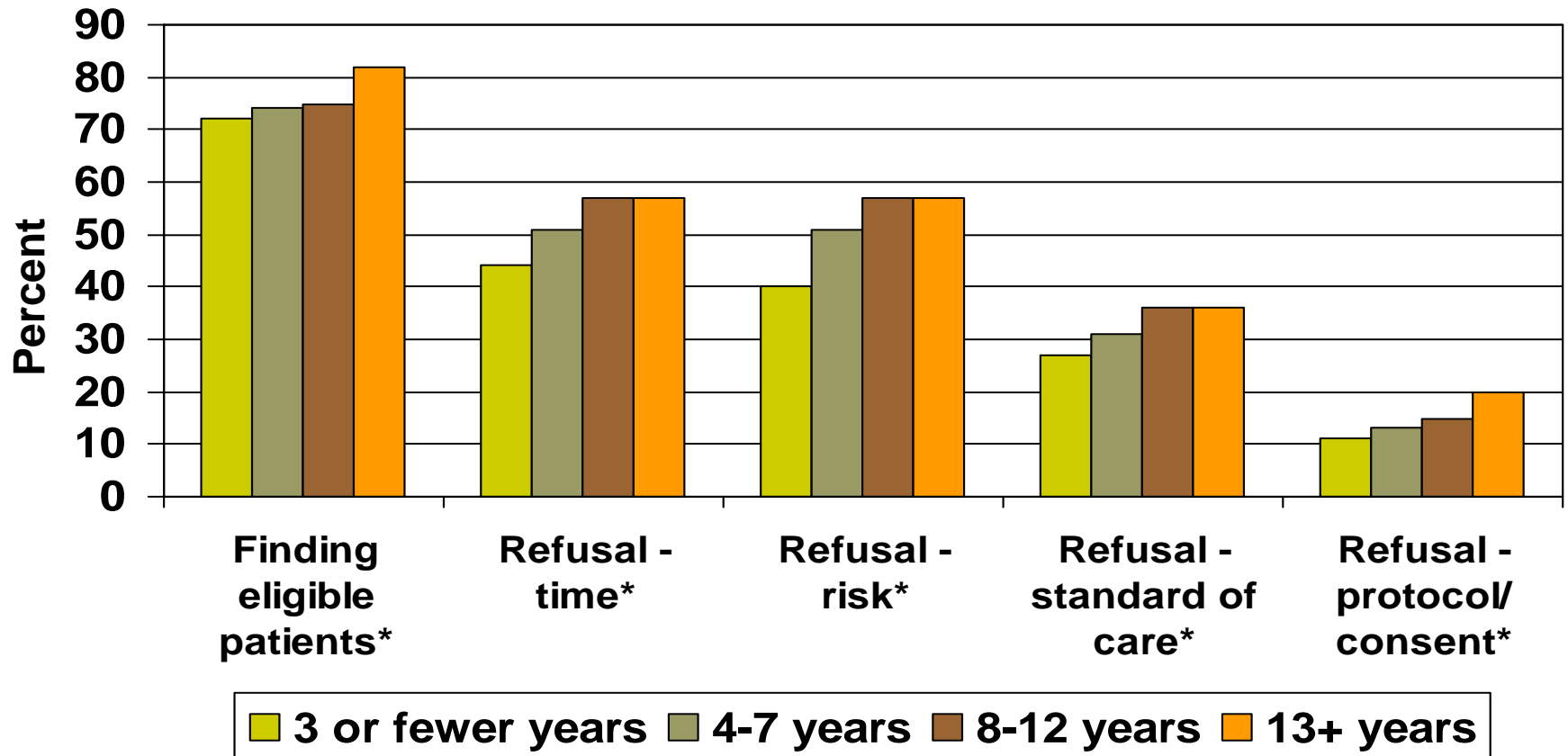




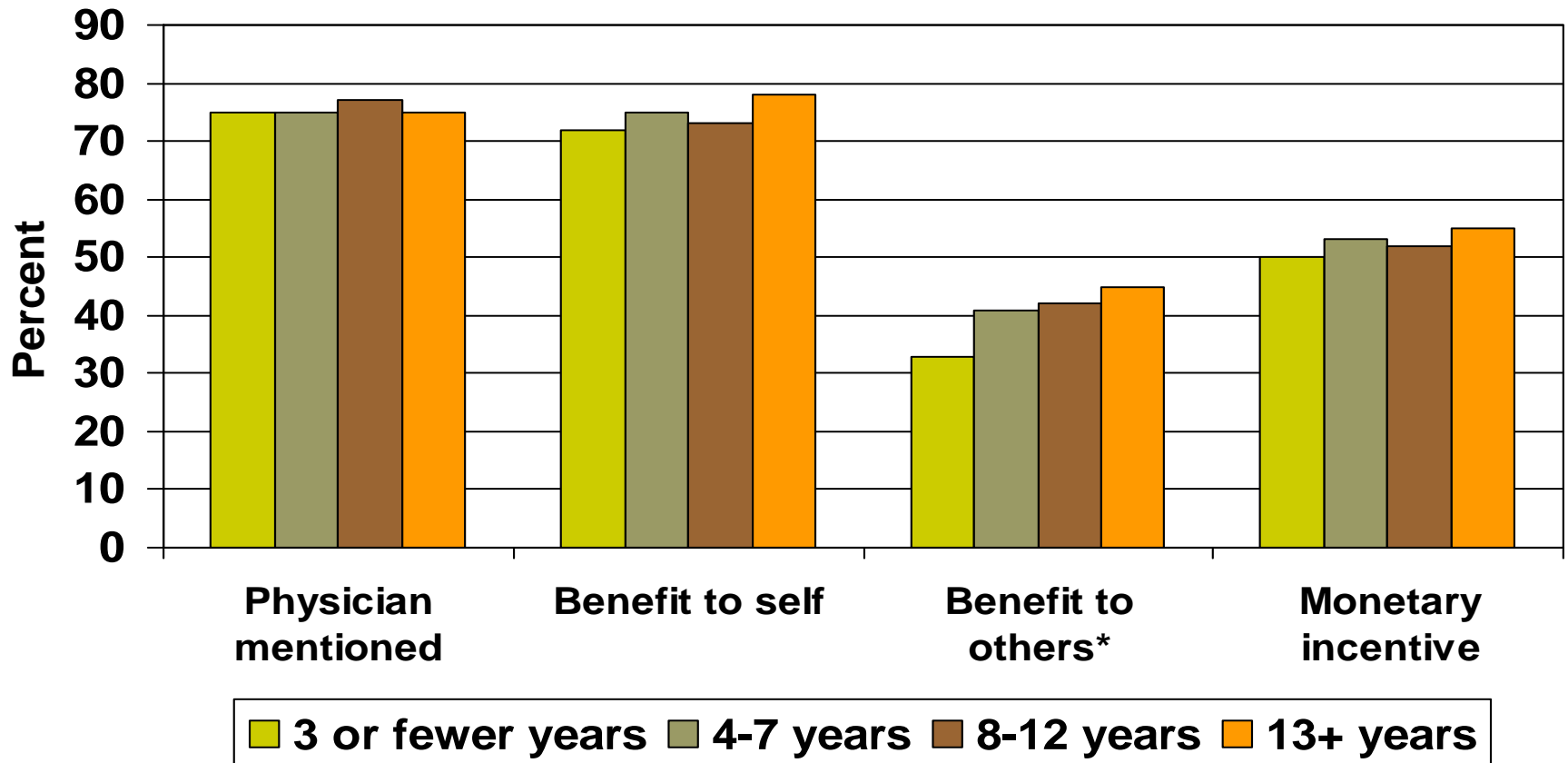


Recruitment and Retention Strategies by Years of Experience

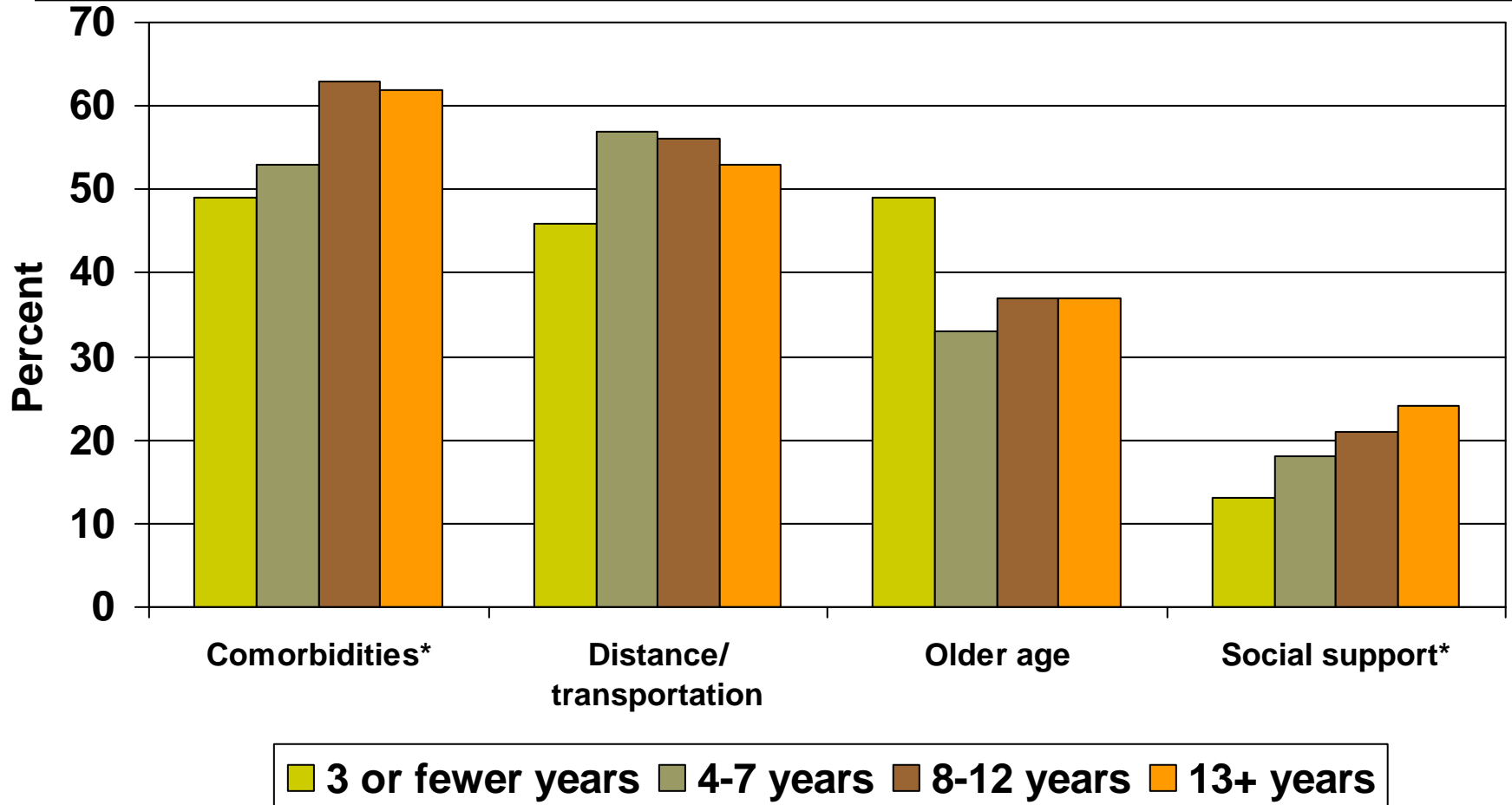
Percent of CRC Reporting Selected Recruitment Barriers by Years of Experience



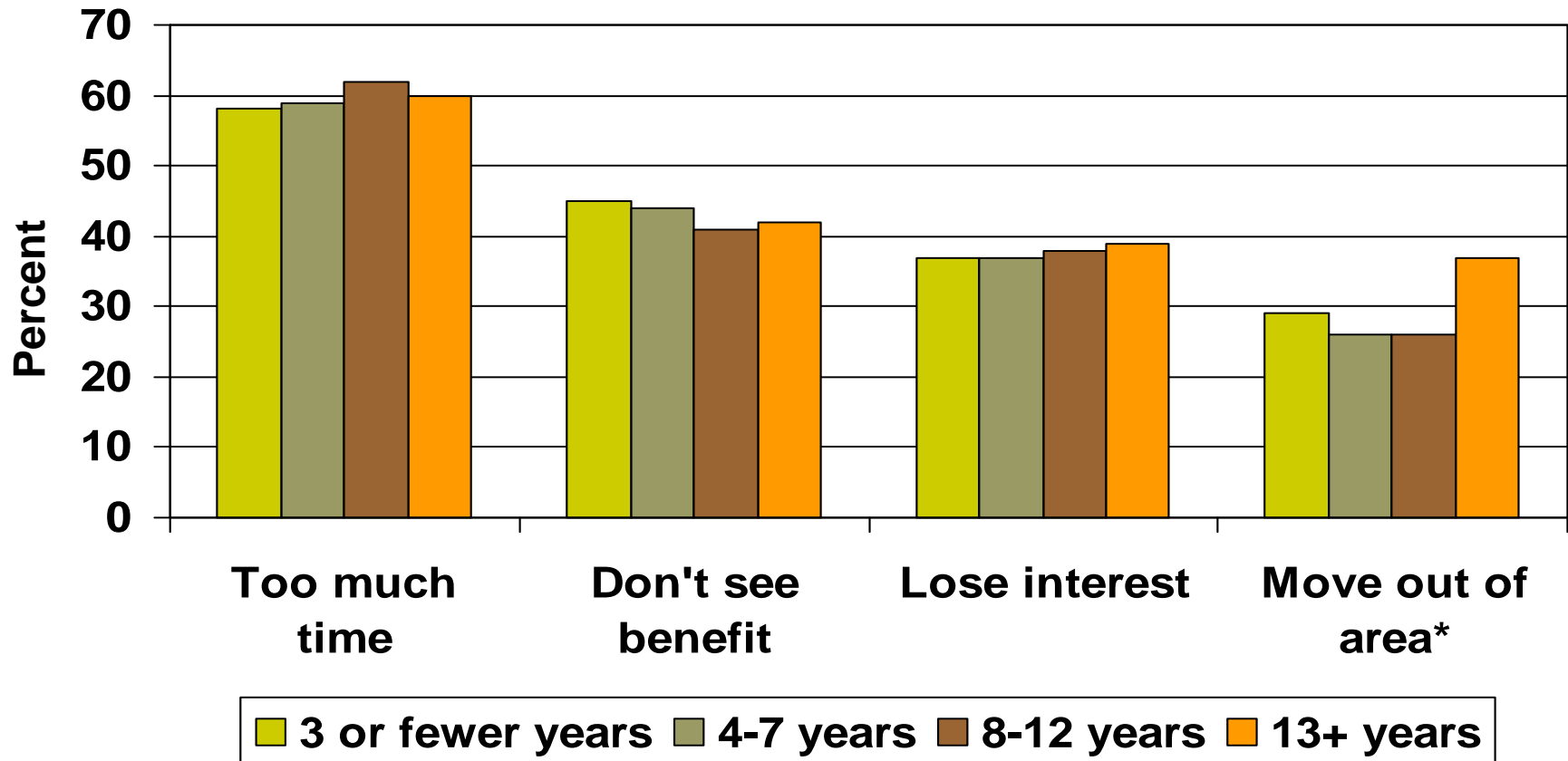
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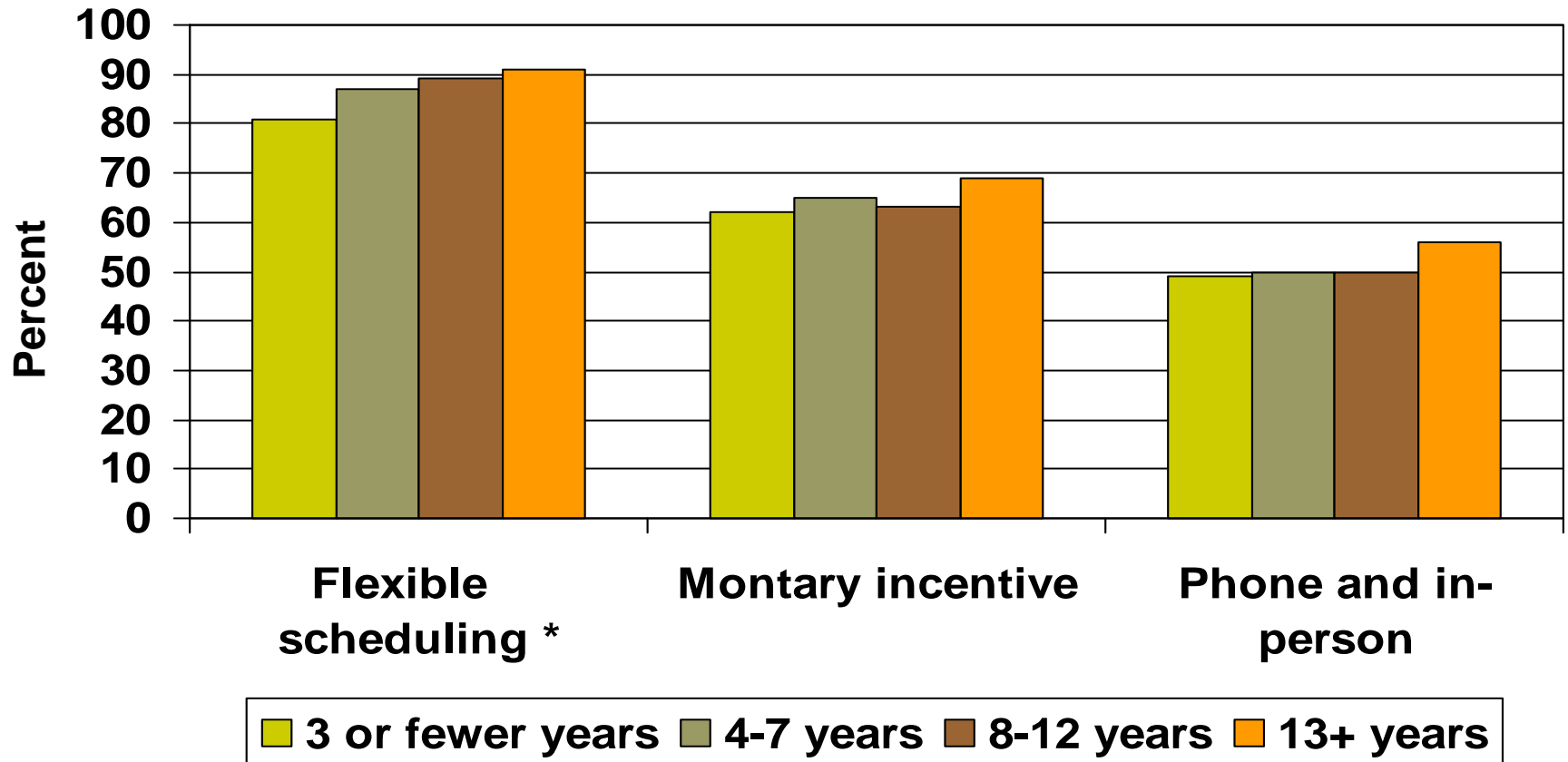
Percent of CRC Reporting Effects of Selected Demographics for Recruitment by Experience



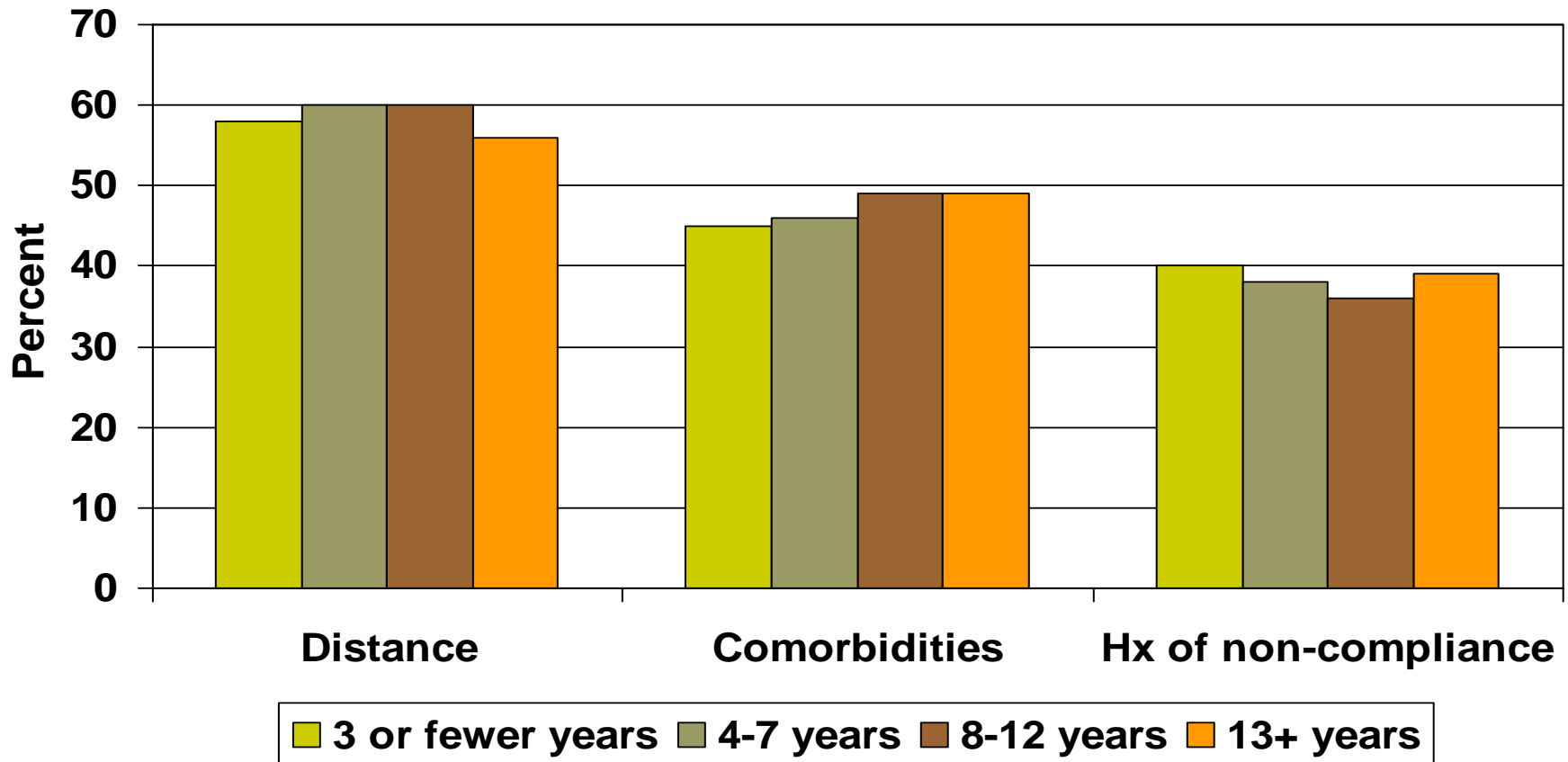
Percent of CRC Reporting Selected Retention Barriers by Years of Experience



Percent of CRC Reporting Selected Retention Strategies by Years of Experience



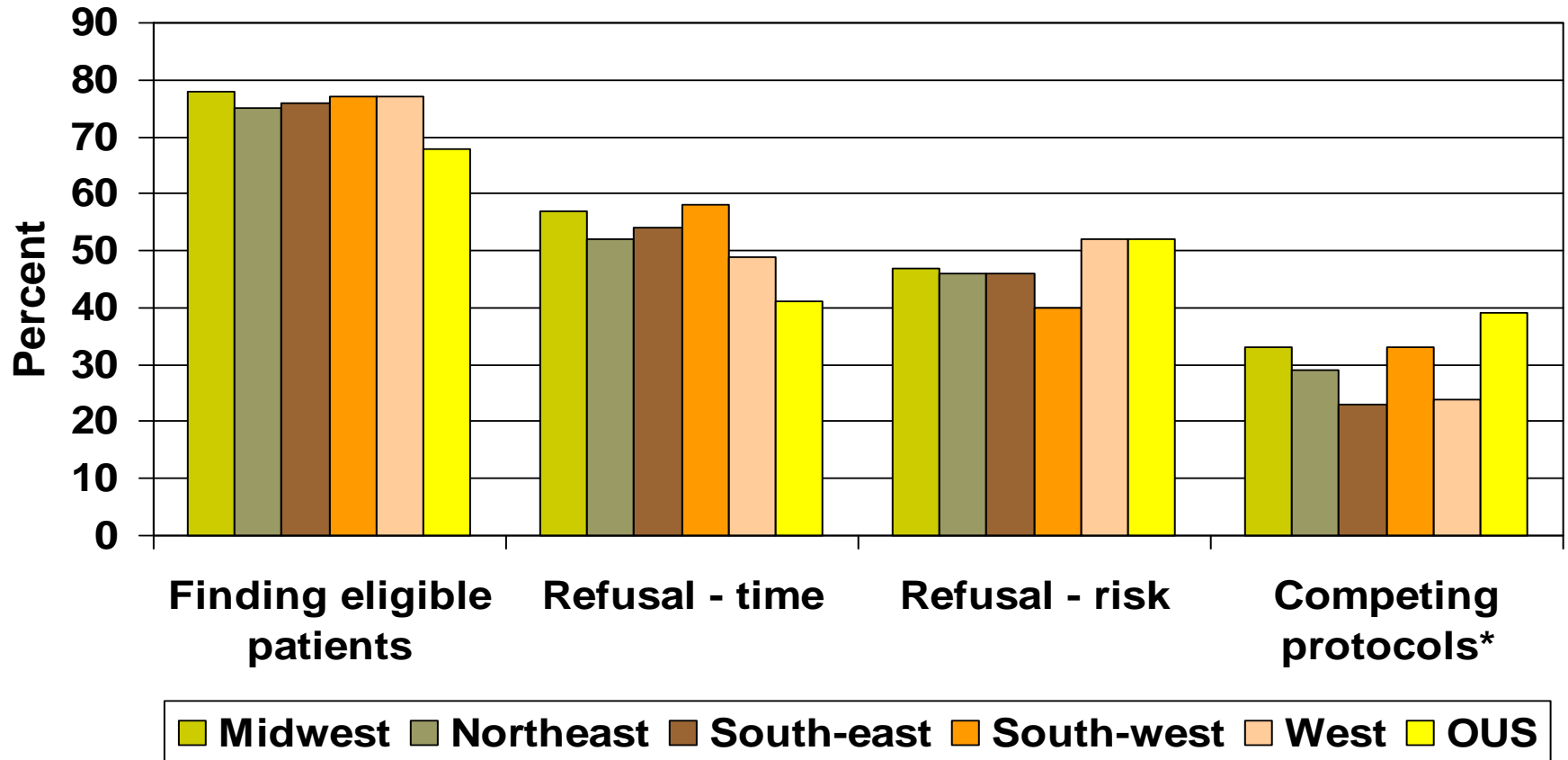
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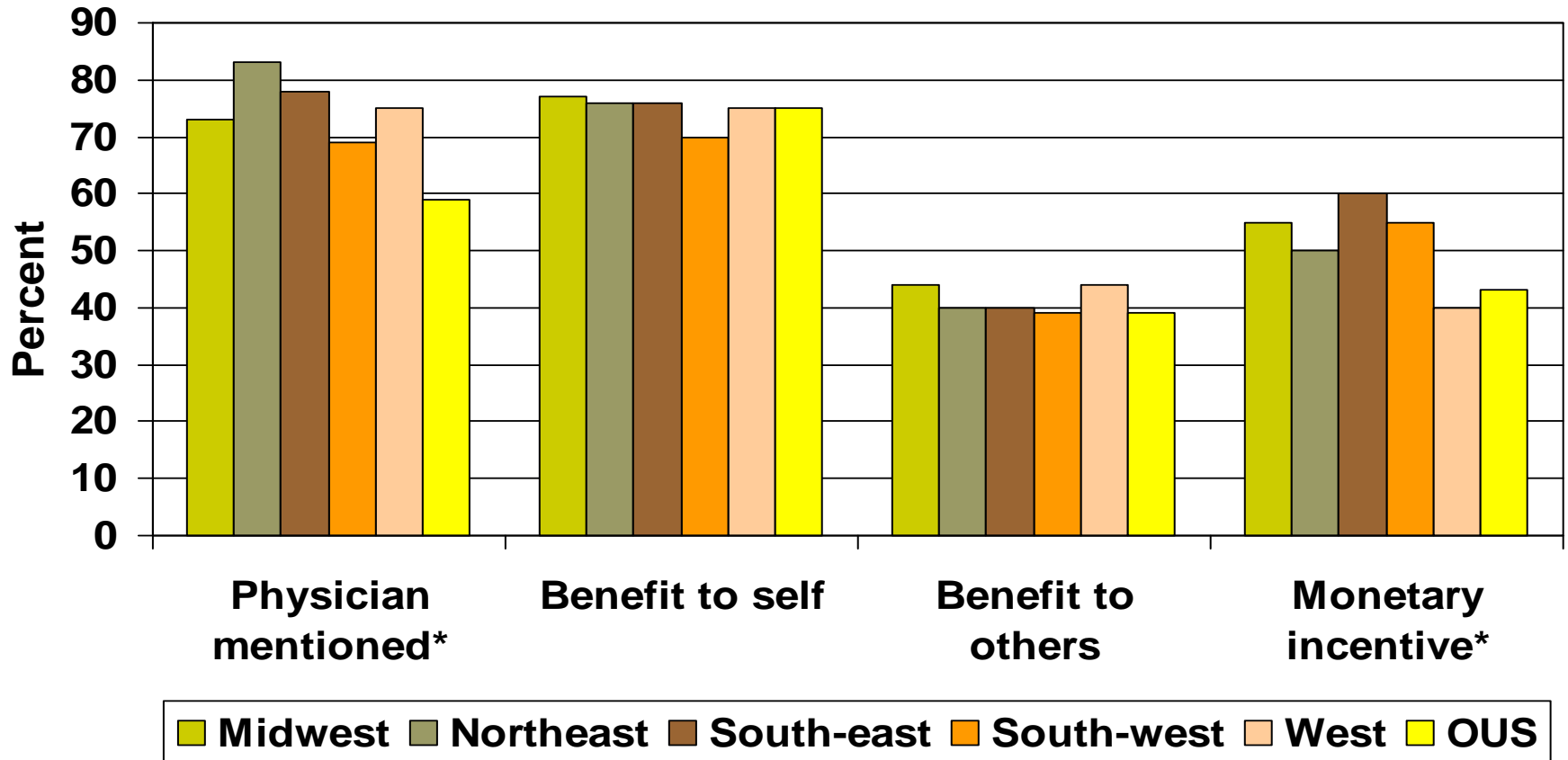


Recruitment and Retention Strategies by Region

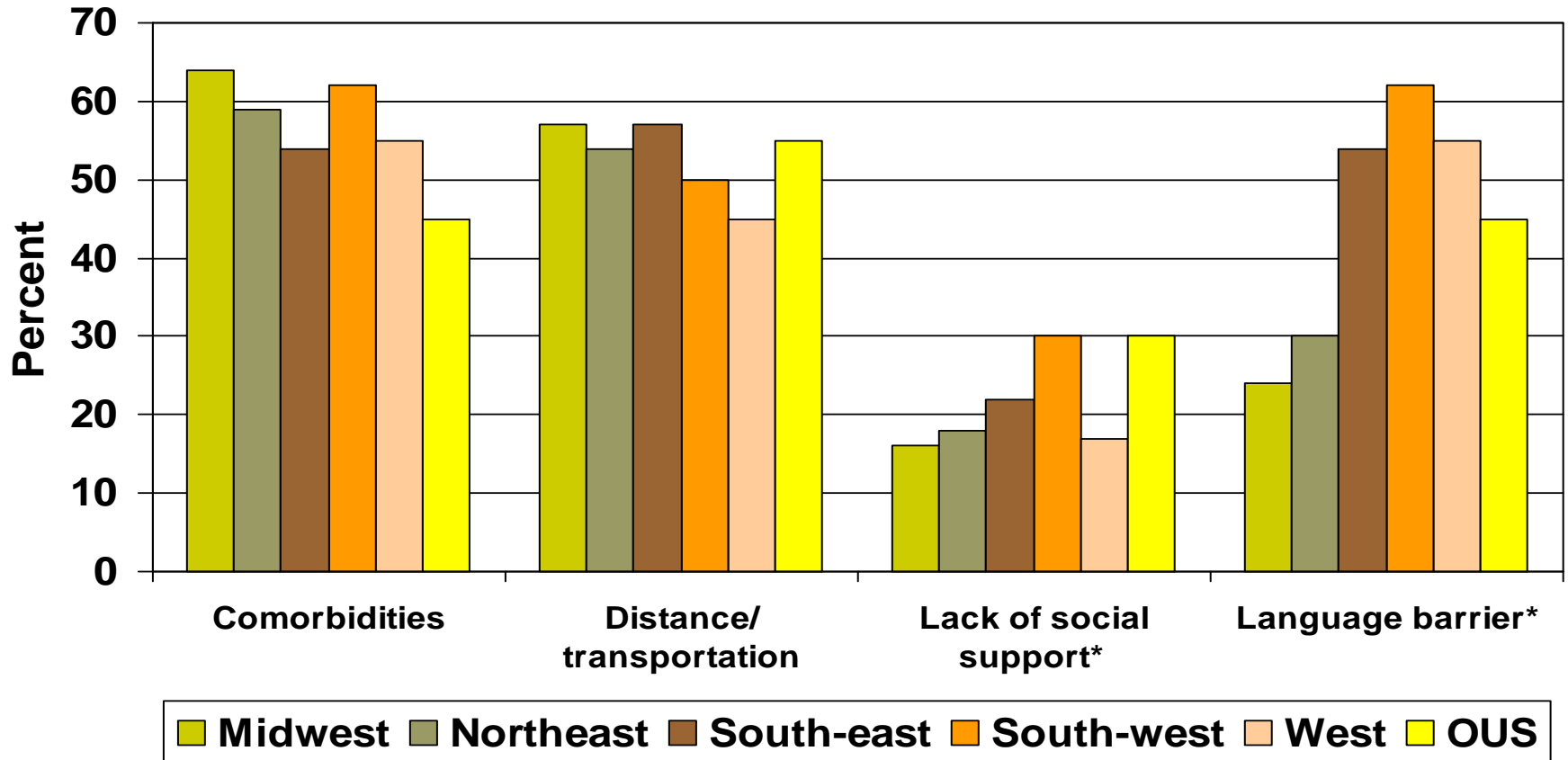
Percent of CRC Reporting Selected Recruitment Barriers by Location



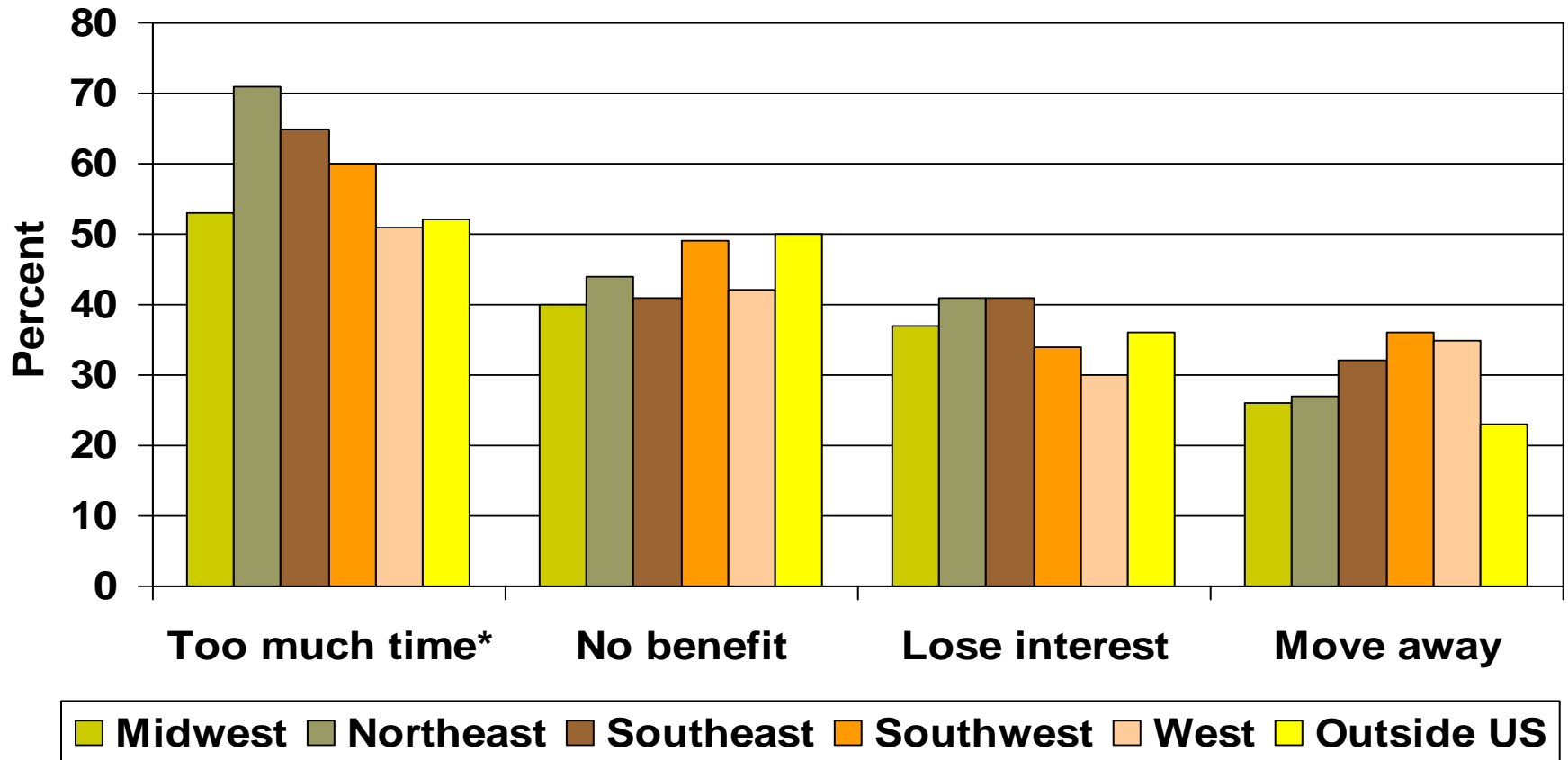
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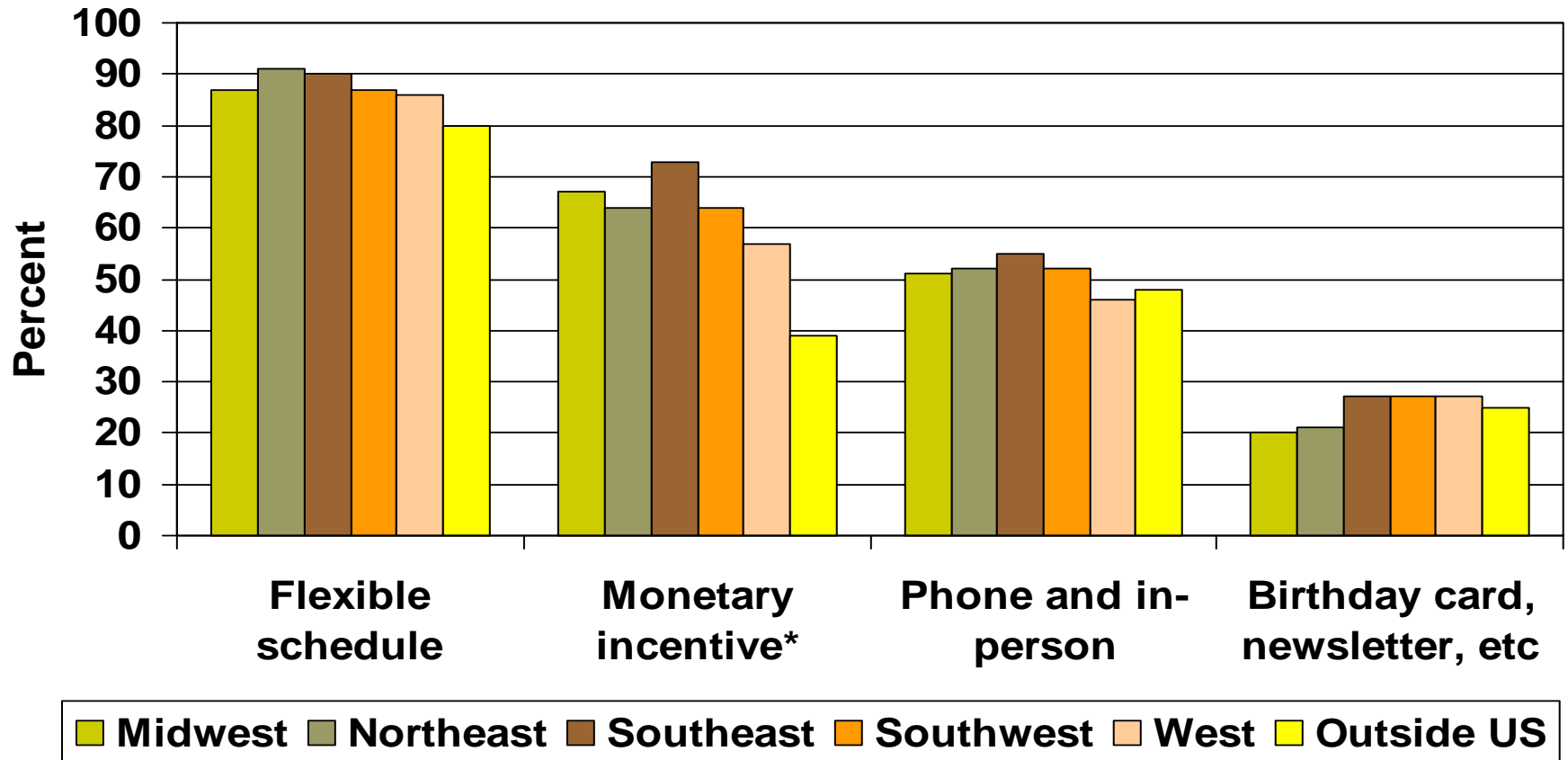
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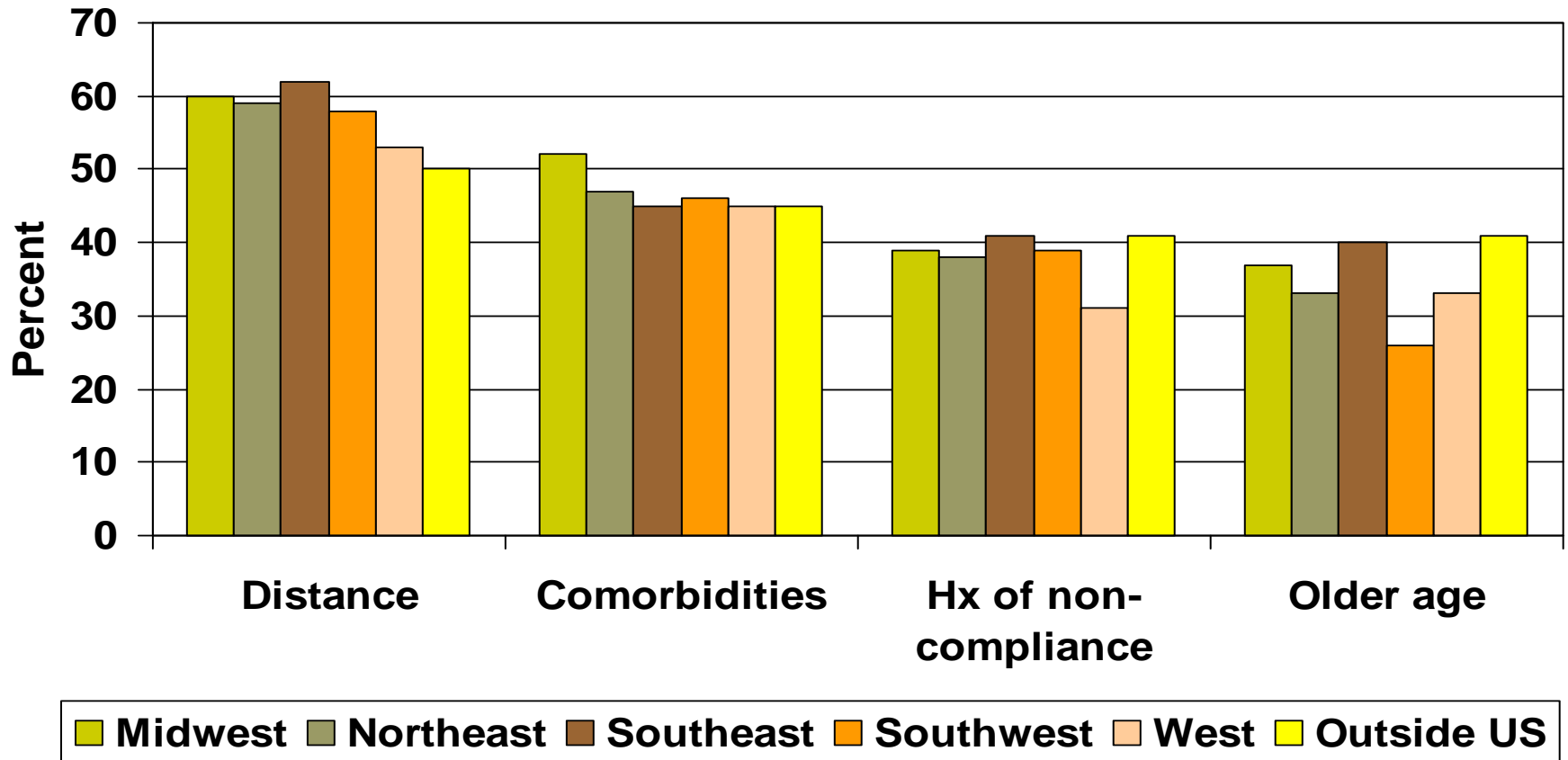
Percent of CRC Reporting Selected Retention Barriers by Location



Percent of CRC Reporting Selected Retention Strategies by Location



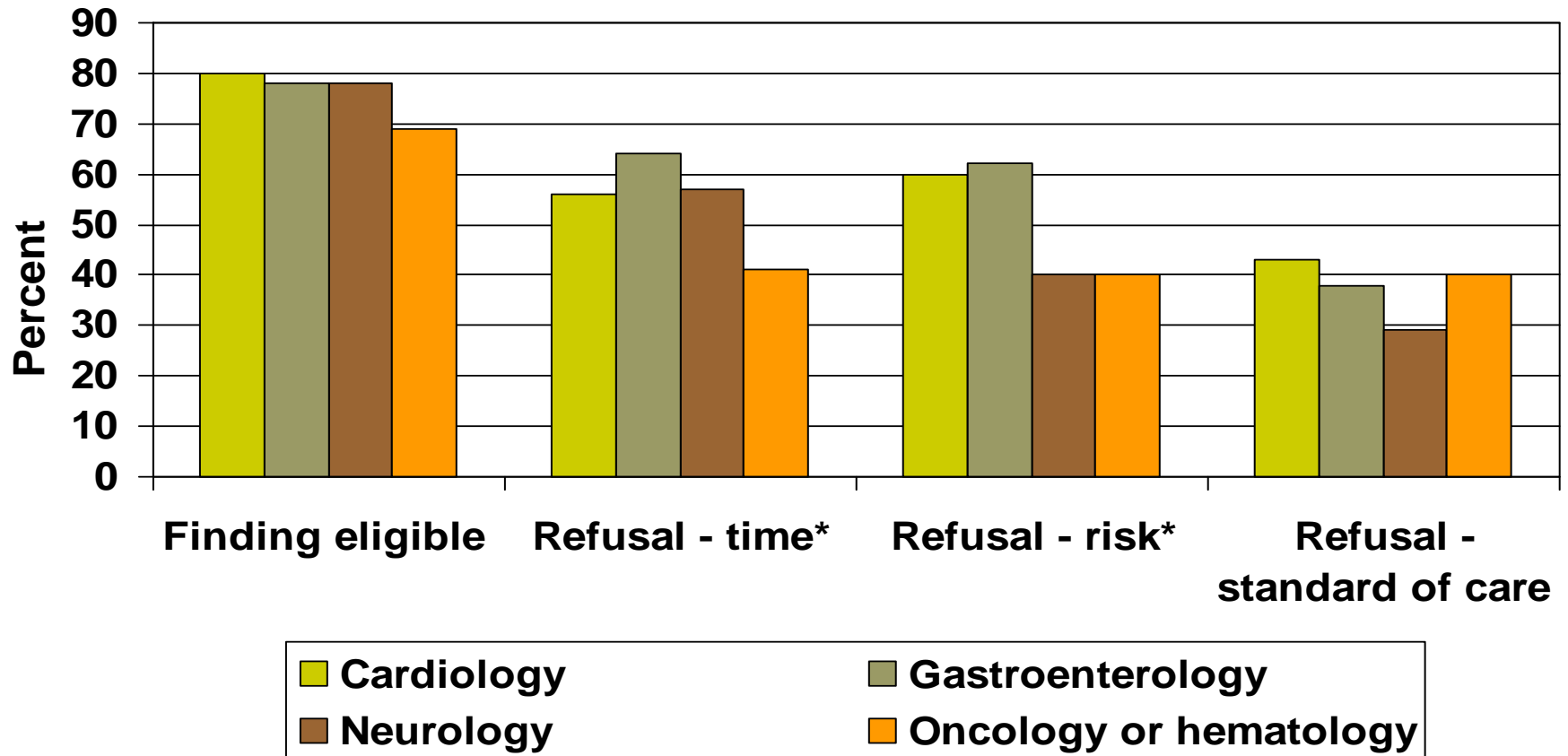
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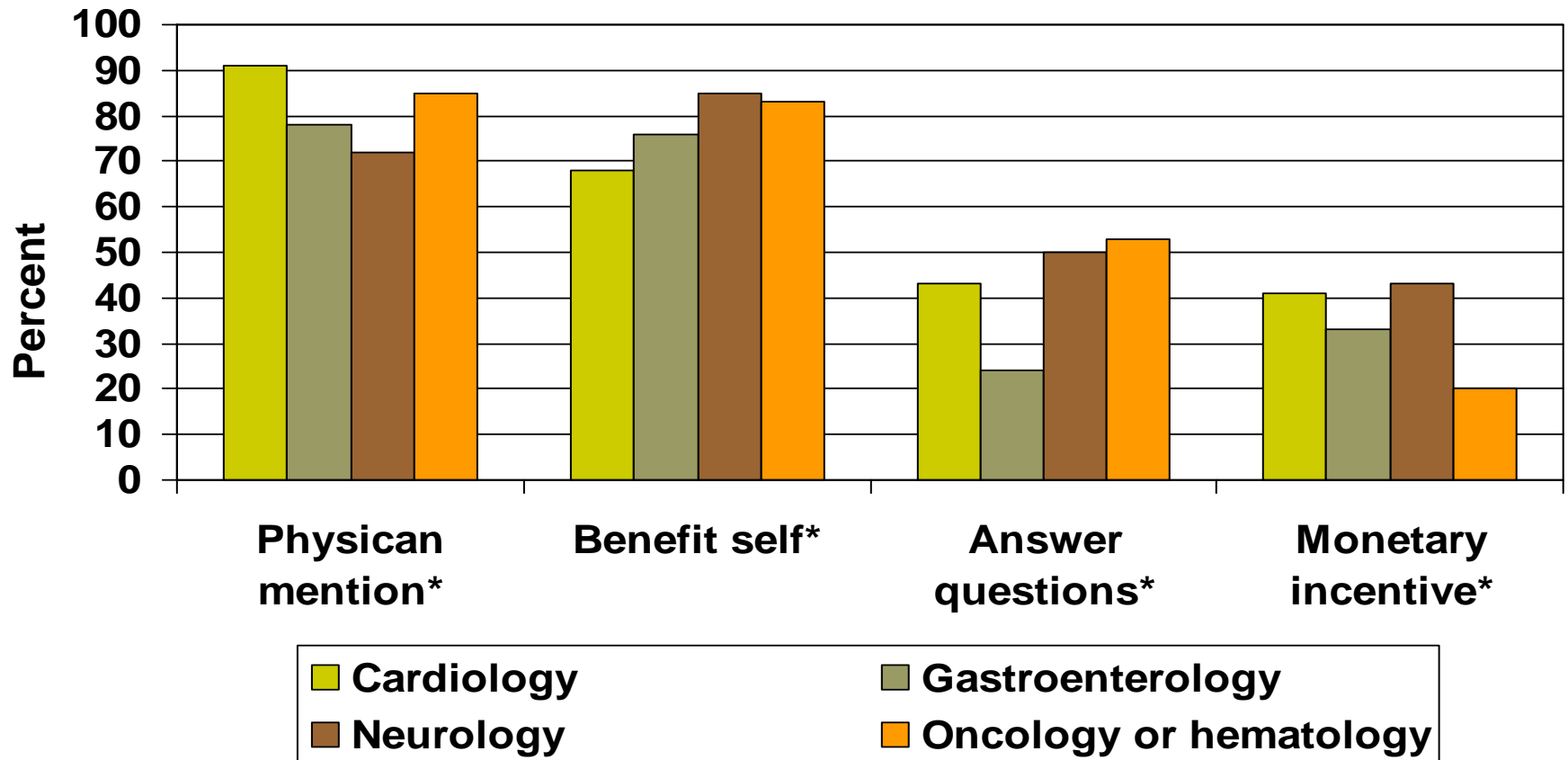


Recruitment and Retention Strategies by Clinical Area

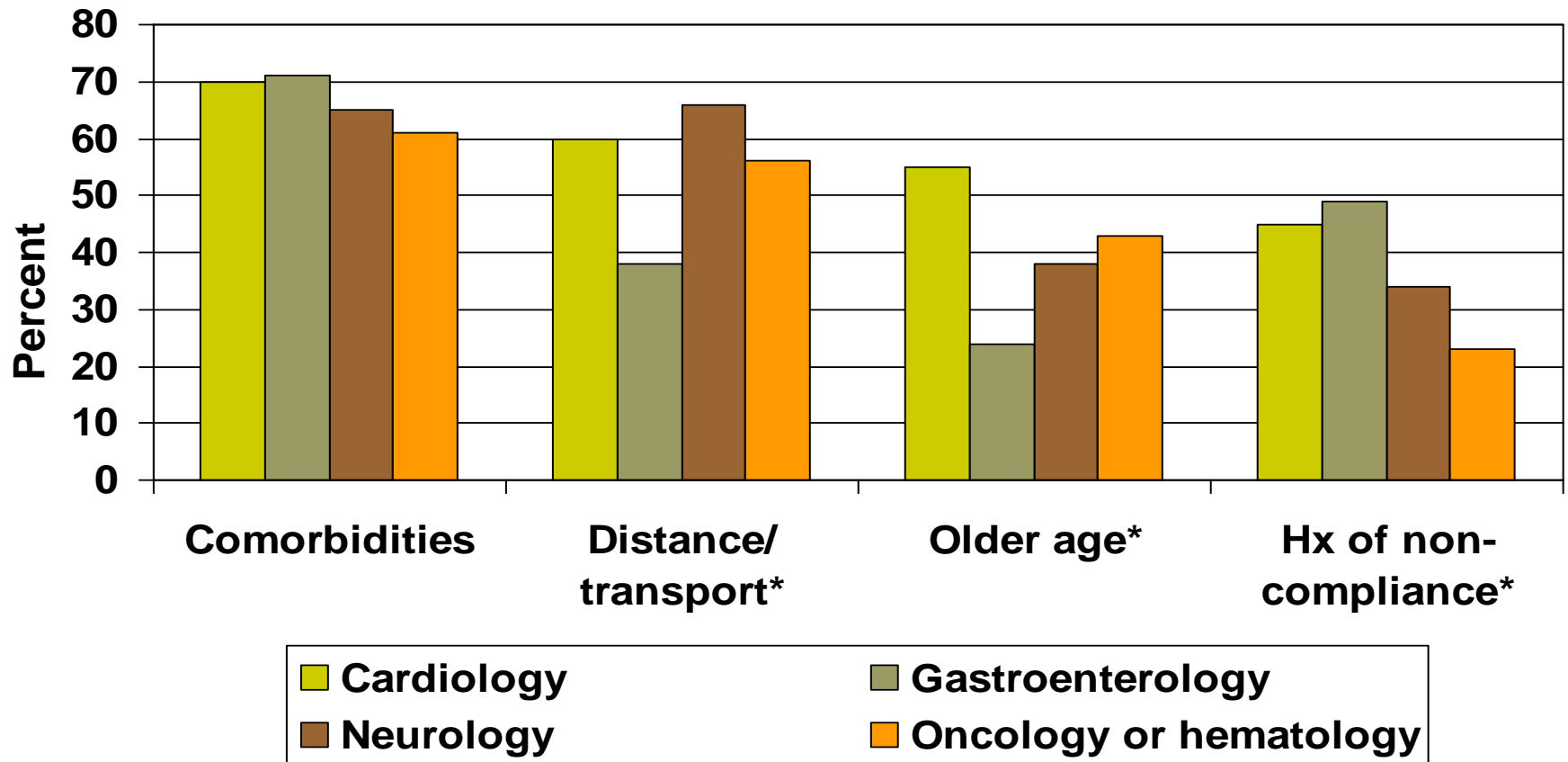
Percent of CRC Reporting Selected Recruitment Barriers by Research Area



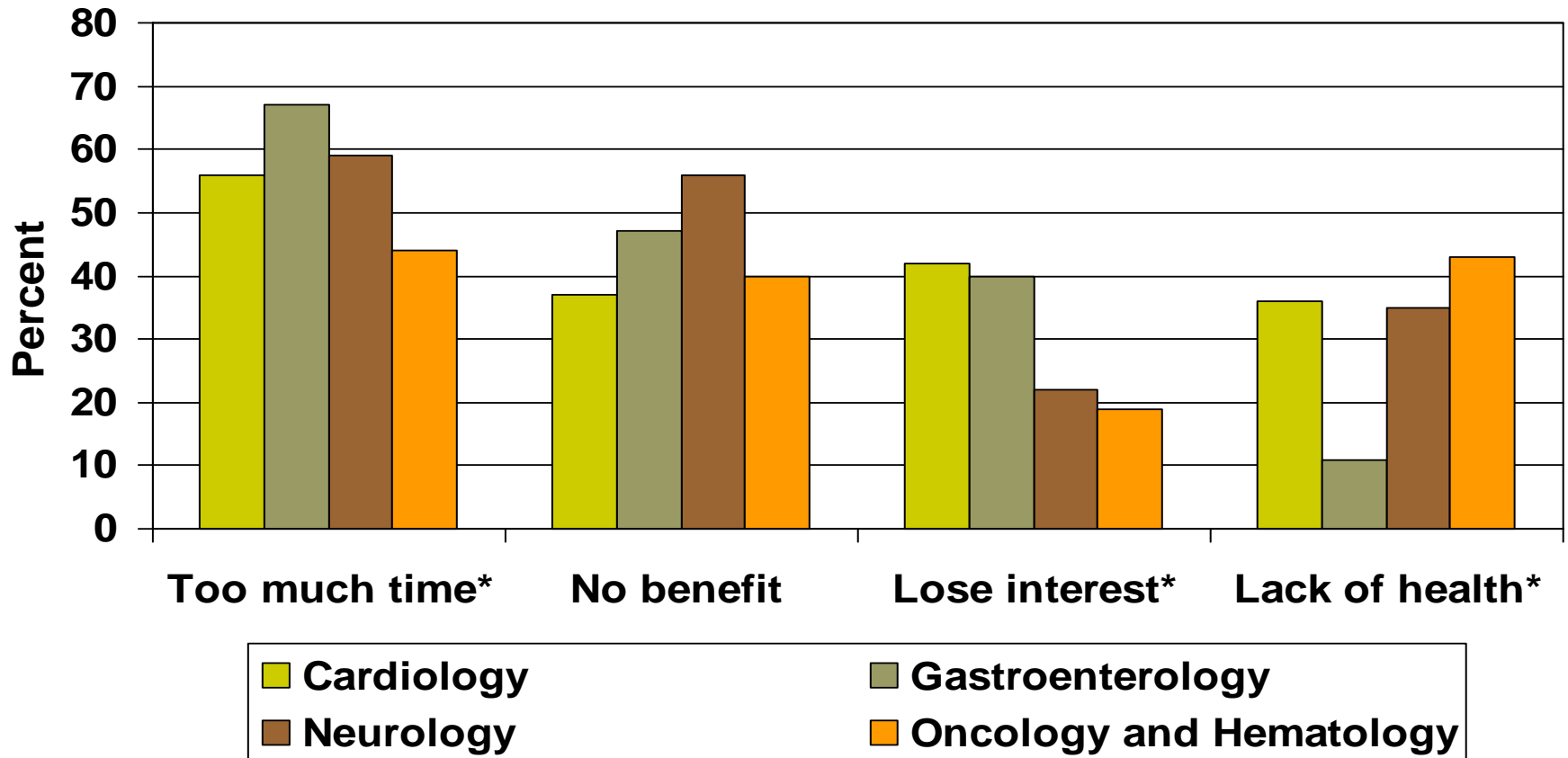
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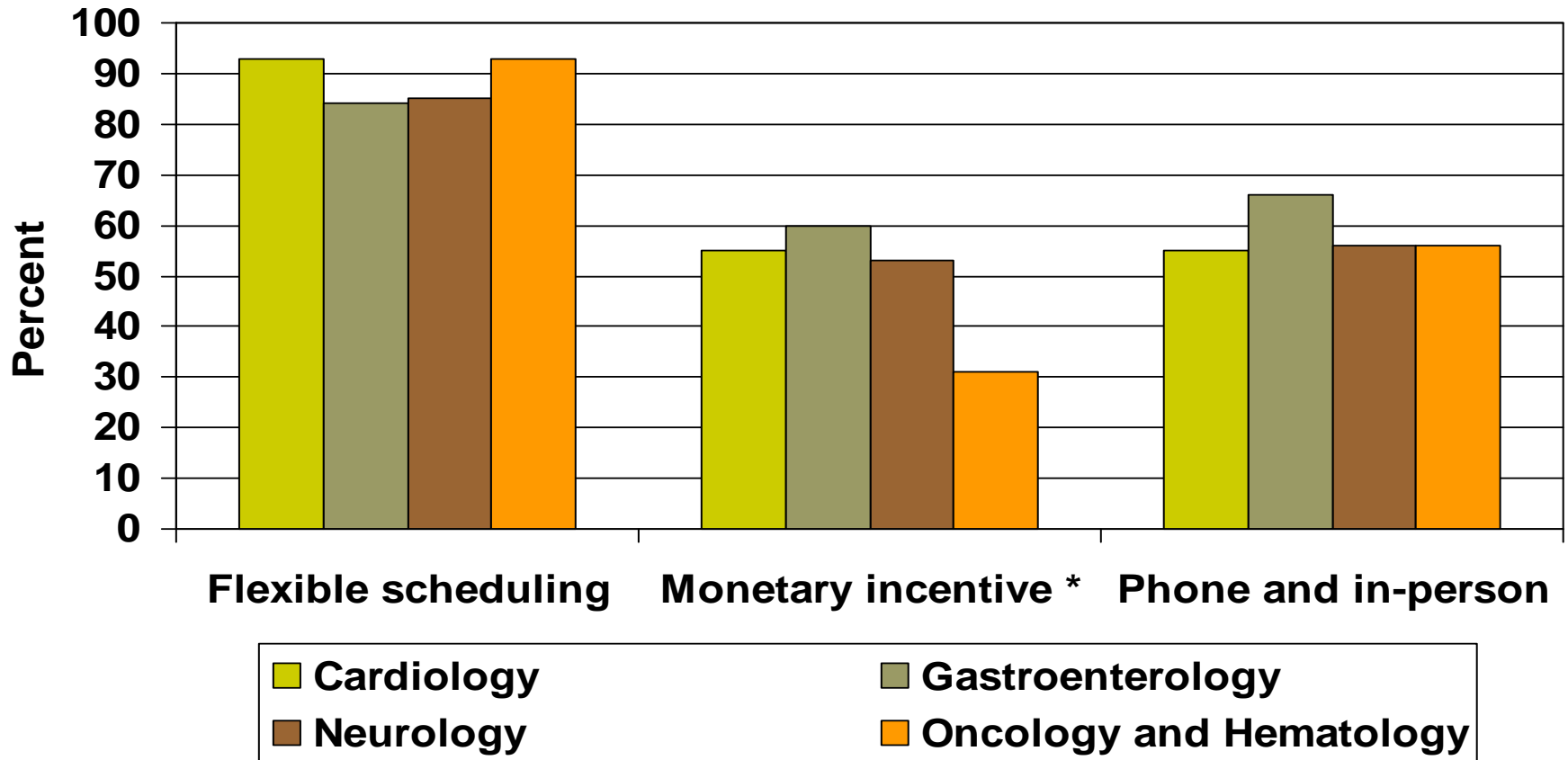
Percent of CRC Reporting Effects of Selected Demographics for Recruitment by Research Area



Percent of CRC Reporting Selected Retention Barriers by Research Area



Percent of CRC Reporting Selected Retention Strategies by Research Area



Percent of CRC Reporting Effects of Selected Demographics for Retention by Research Area

