

Evidence Report on Recruitment of Underrepresented Populations to Cancer Clinical Trials

Jean G. Ford, MD

Mollie W. Howerton, PhD, MPH

Neil R. Powe, MD, MPH, MBA

Eric B. Bass, MD, MPH

Objectives

- Describe results of a systematic review of evidence on recruitment of under-represented populations into cancer clinical trials
- Present recommendations based on report findings

Background

- 1993 NIH Revitalization Act called for inclusion of women & minorities in all human subjects research
- NCI budget nearly doubled from 1993 to 2002
 - Trial accrual increased
 - Not clear if all populations benefited
- Some populations remain under-represented in NCI-funded clinical trials

Background (II)

- Numerous recruitment barriers
- Increased attention to recruitment promoters
- Questions about effectiveness of strategies to increase trial participation

Key Questions

- What are **barriers & promoters** for participation of under-represented populations in cancer trials?
- What effects do healthcare **providers** have on recruitment of under-represented populations?
- What **recruitment strategies** are **efficacious**?
- What **measures** of recruitment **success** have been used?
- What **methods** have been used to study recruitment strategies?

Steps Toward Participation



Examples of Factors Influencing Each Step

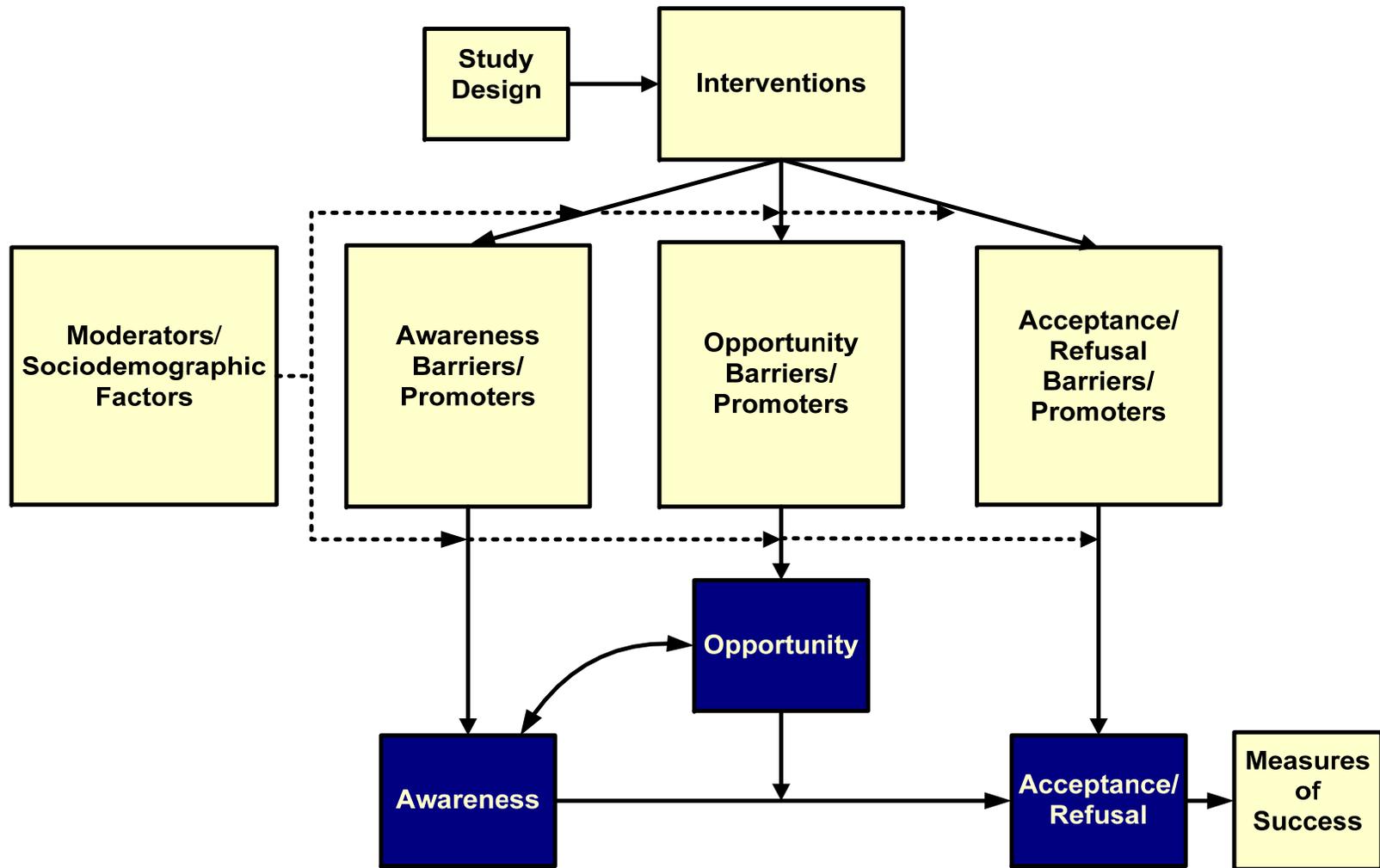
- Race/ethnicity
- Socioeconomic

- Perceived harms
- Perceived benefits
- Health status
- Past exposure
- Trust
- Altruism
- Religiosity

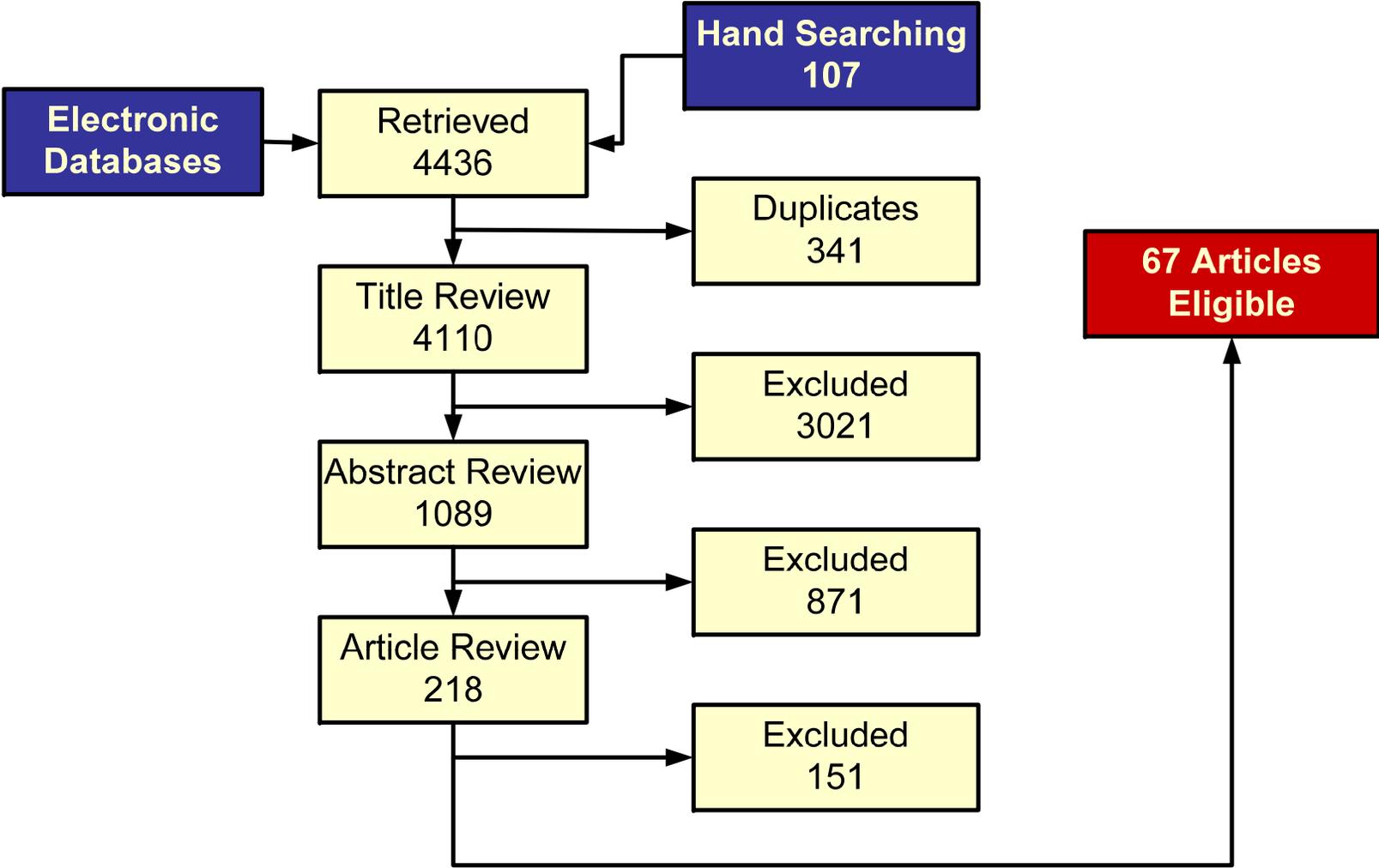
- Continued interest
- Actual benefits
- Time

Powe & Gary, 2004

Conceptual Framework



Summary of Search



Barriers to & Promoters of Enrollment

Key Findings from 45 studies

Study Characteristics

- Dates published
 - < 1996: 10
 - 1996 – 2000: 14
 - 2001 – 2004: 21
- Study Design:
 - Observational/Experimental: 9
 - Descriptive (registry reviews, surveys): 15
 - Qualitative (focus groups, semi-structured interviews): 21
- Setting:
 - Hospital inpatient or outpatient: 29
 - Community: 25
 - Other: 7

Study Characteristics (II)

- Target group
 - Patients / Participants: 38
 - Physicians: 11
 - Researchers: 3
- Type of trial
 - Therapeutic: 34
 - Prevention: 16
- Actual accrual vs. behavioral intention
 - Accrual: 21
 - Intention: 16

Study Characteristics (III)

- **Type of population:**
 - African-American: 27
 - Older adults: 14
 - Latino/Hispanic: 6
 - Asian/Pacific Islander: 2
 - Native American / Alaskan Native: 4
 - Adolescent: 3
 - Rural: 2
- **US-based: 40**

Levels of Barriers & Promoters

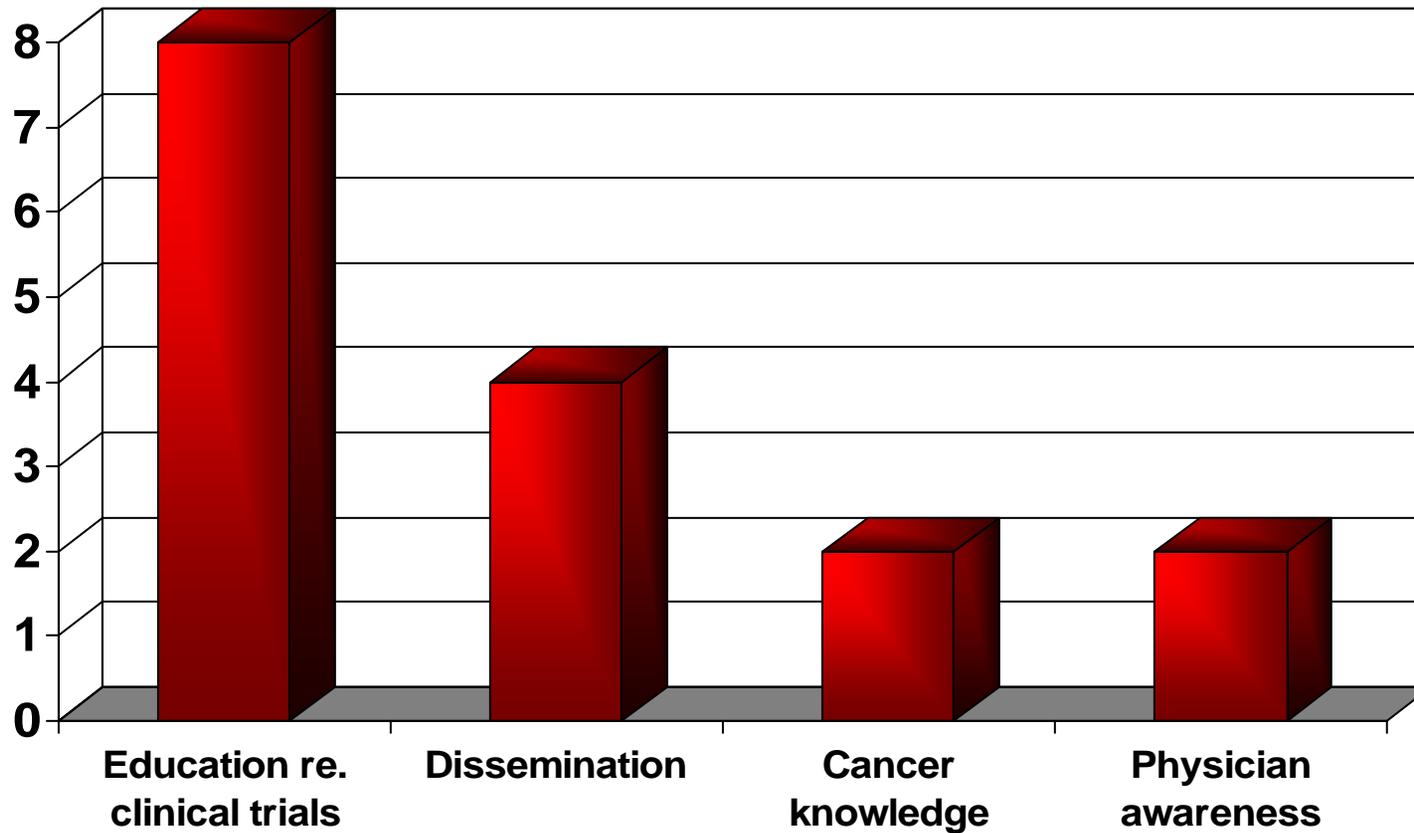
Level	# of Barriers	# of Promoters
Patient	70	39
Provider	31	12
Healthcare system	7	2

Most Frequently Reported Barriers

- Mistrust of research & medical system (n = 17)
- Perceived harms (n = 11)
- Lack of education about clinical trials (n = 10)
- Availability of transportation (n = 9)
- Time commitment required (n = 8)
- Mistrust of researchers (n = 6)

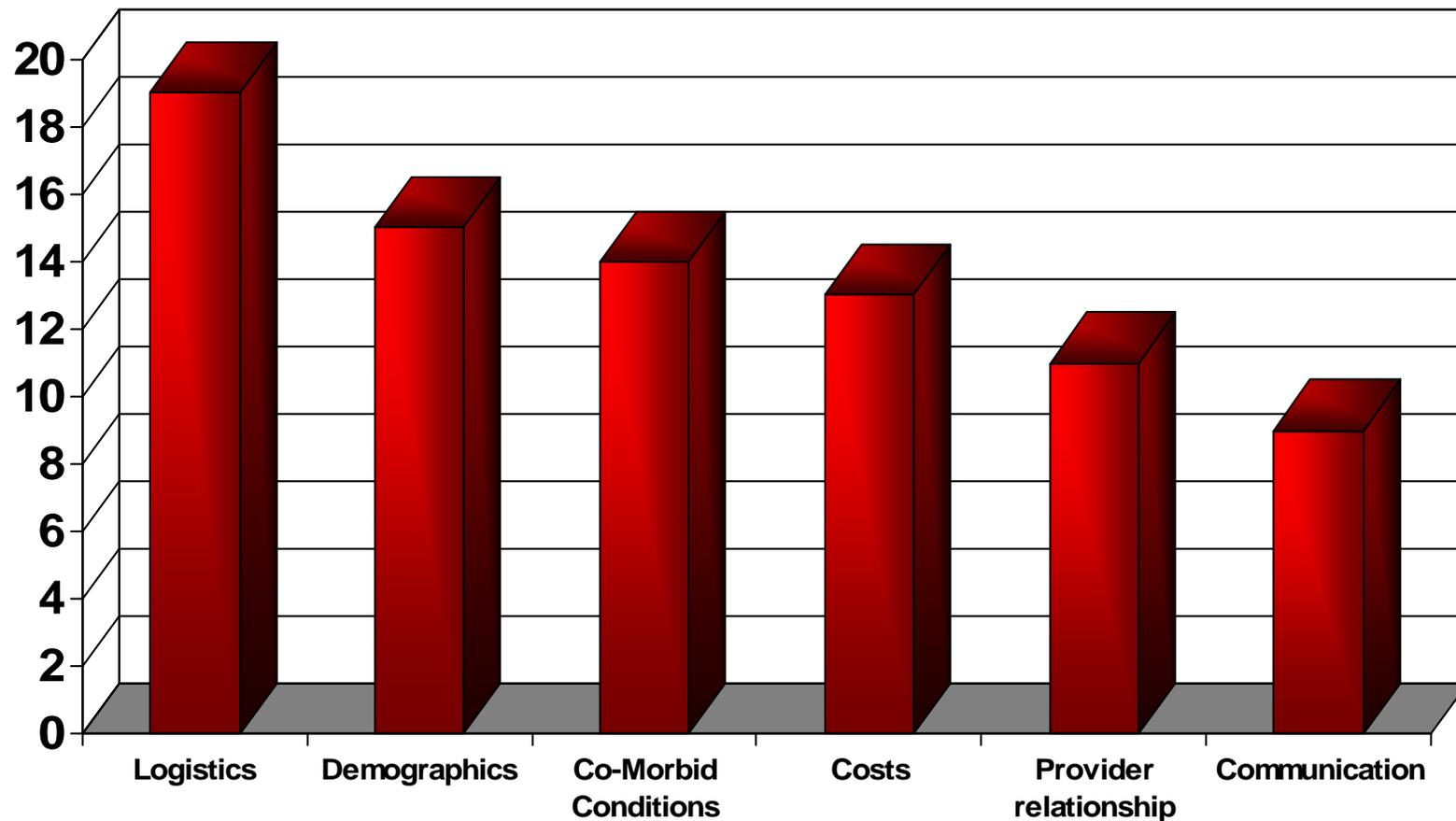
Barriers to Awareness

(N = 15 studies)



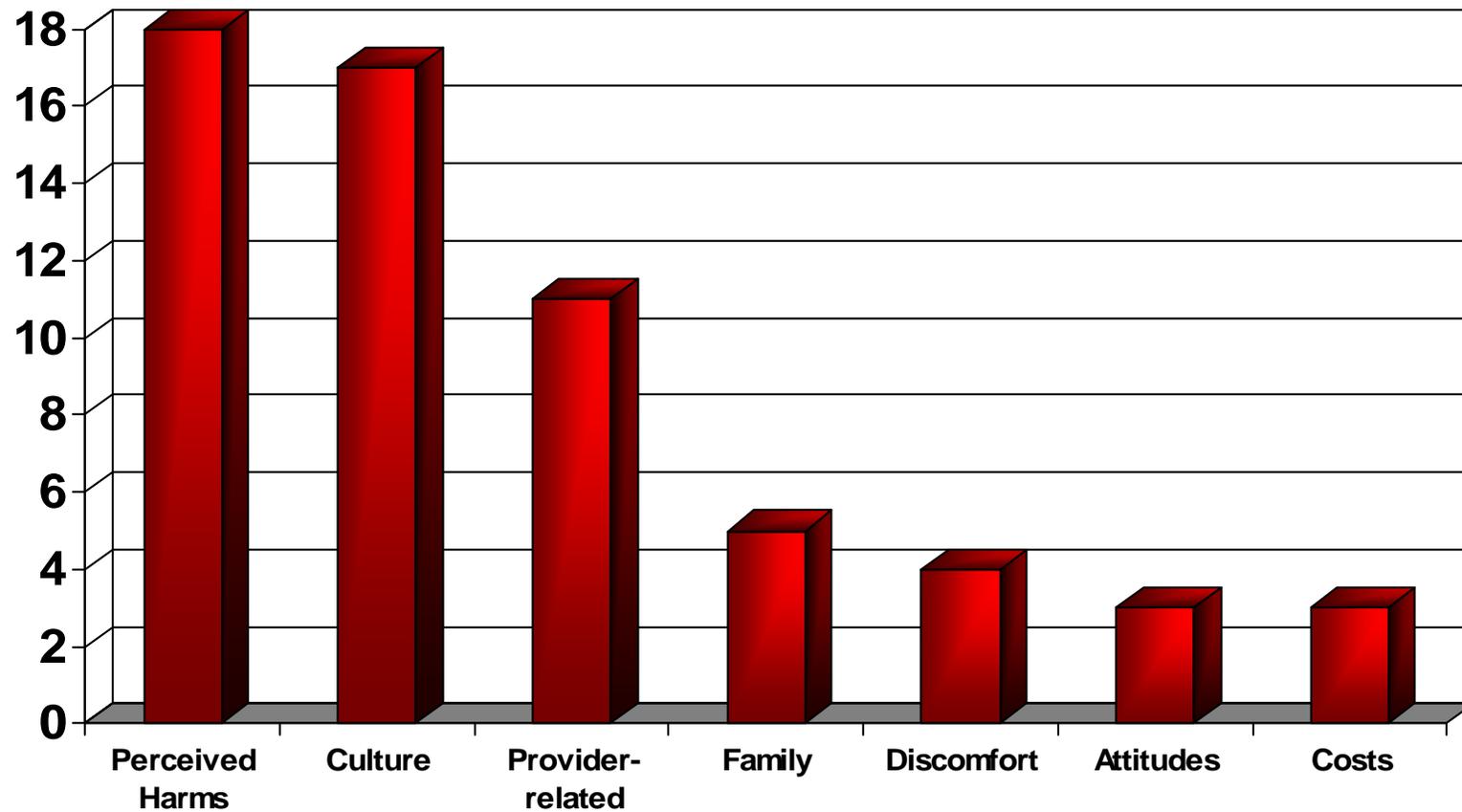
Barriers to Opportunity

(N = 35 studies)



Barriers to Acceptance

(N = 23 studies)



Most Frequently Reported Promoters

- Perceived benefits of trial participation (n = 7)
- Patient incentives (n = 6)
- Altruism (n = 6)
- Culturally relevant education about trials (n = 4)
- Provider incentives (n = 3)

Other Key Findings on Barriers & Promoters

- Available evidence mostly about accrual to **therapeutic** trials
- Barriers to **opportunity** frequently reported for both prevention & treatment trials
- Limited data on Latinos/Hispanics, Asian/Pacific Islanders, American Indians/Alaska Natives, older adults, & adolescents
- Barriers differed across populations

Relation of Barriers & Promoters to Conceptual Framework

- **Awareness:**
 - 8 barriers, 6 promoters
- **Opportunity to participate:**
 - 81 barriers, 29 promoters
- **Acceptance/refusal of participation:**
 - 25 barriers, 25 promoters

Healthcare Provider Effects

Key Findings from 10 studies

Healthcare Professional Barriers

- Insufficient resources / cost to patient (n=4)
- Healthcare professional attitudes (n=4)
- Patient age (n=3)
- Communication/method of presentation (n=2)
- Time (n=2)
- Disease stage (n=2)
- Co-morbidity (n=2)
- Treatment risk (n=2)
- Mistrust of researchers (n=2)
- Potential for non-compliance (n=2)

Study Design Barriers

- Eligibility (n=7)
 - Age exclusion (n=2)
 - Co-morbidity exclusion (n=2)
 - Disease stage or location (n=1)
 - Medication exclusion (n=1)
- Length of study/visit structure (n=2)
- Protocols too complex (n=2)

Healthcare System Barriers

- Lack of minority investigators/personnel (n=1)
- Lack of dissemination of study opportunities to providers (n=1)
- Lack of cultural competence among providers and/or staff (n=1)
- Lack of access to institutions conducting cancer trial (n=1)

Efficacy of Recruitment Strategies

Key findings from 5 studies

Recruitment Strategies/Interventions

Author, Year	Target Population	Recruitment Intervention
Ford, 2004	African Americans	4 increasingly intensive strategies <ul style="list-style-type: none"> ■ Enhanced mailings ■ Minority interviewers ■ Letter & phone reminders ■ Church-based project sessions
Linnan, 2002	Workers in a manufacturing company	<ul style="list-style-type: none"> ■ Active recruitment arm <ul style="list-style-type: none"> –Employees signed up to participate ■ Passive at worksites <ul style="list-style-type: none"> –Company provided list of employee names & home phone #s
Brewster, 2002	Latina/Hispanic women	Clinic registry vs. media campaign

Recruitment Strategies/Interventions

Author, Year	Target Population	Recruitment Intervention
Paskett, 2002	Rural physicians in North Carolina & South Carolina	<ul style="list-style-type: none">■ Tumor-reporting system■ Nurse facilitator■ Quarterly newspapers■ Health educator
Moinpour, 2000	African Americans (Sites A-D); Latino/Hispanic (Site E)	<ul style="list-style-type: none">■ Minority recruiter

Results

Author	Descriptor of Point Estimate	Point Estimate (p value)
Ford, 2004	Difference in enrollment (Arm C vs. Arm D)	1.0% (p<0.01)
Linnan, 2002	Difference in enrollment	36.6% (p<0.0001)
Brewster, 2002	Odds ratio of women presenting in clinic	3.00 (2.38, 3.78)
	Odds ratio of women screened by telephone	2.97 (2.52, 3.51)

Results (II)

Author	Descriptor	Point Estimate
Paskett, 2002	Enrollment change of breast cancer patients, 1991-1996 (NC)	-9%
	Enrollment change of colorectal cancer patients, 1991-1996 (NC)	1%
	Enrollment change of breast cancer patients, 1991-1996 (SC)	44%
	Enrollment change of colorectal cancer patients, 1991-1996 (SC)	-5%

Results (III)

Author	Descriptor	Point Estimate
Moinpour, 2000	Change in Site A enrollment, 1995-1996	-0.3%
	Change in Site B enrollment, 1995-1996	-0.5%
	Change in Site C enrollment, 1995-1996	-1.8%
	Change in Site D enrollment, 1995-1996	-0.6%
	Change in Site E enrollment, 1995-1996	0.5%

Limitations of Studies of Efficacy of Recruitment Interventions

- Very few evaluations reported
- Limited generalizability
- Varying quality of study methods

Measures of Recruitment Success

Key findings from 23 studies

Recruitment Goals

- “Recruitment” = actual participation in all studies
- 2 studies reported *a priori* recruitment goal:
 - Maurer et al, 2001
 - At least 22% of rural study population eligible for trial
 - Met recruitment goal
 - Moinpour et al, 2000 (Prostate Cancer Prevention Trial)
 - At least 8% of study population to be African American, based on % of U.S. men > age 54 who are African American
 - Recruitment yielded 4% instead of 8%

Recruitment Success

- 10 articles discussed recruitment success, but did not report *a priori* recruitment goal
- 1 article suggested an *a priori* recruitment goal (M. Ford, 2004)
 - Tested “a priori” recruitment hypotheses
 - Reported need to look at absolute differences in recruitment vs. statistically significant differences

Challenges in Defining “a priori” Recruitment Goals

- Increased study costs
- Competing priorities
 - Disease-specific requirements
 - Participant retention concerns
 - Institutional Review Board requirements
 - Timeline requirements

Methods to study recruitment

Key findings from 13 studies

Study Designs

- Descriptive studies (n=5)
- Randomized controlled trials (RCT) (n=4)
- Concurrent controlled trial (CCT) (n=1)
- Quasi-experimental (n=1)
- Case series (n=1)
- Qualitative (n=1)

Overall Summary

- More barriers to opportunity than to awareness or acceptance
 - More evidence on barriers than on promoters
 - Mistrust a common theme
- Provider barriers at level of professionals, study design & healthcare system
- Sparse evidence on efficacy of recruitment strategies
- Recruitment goals rarely reported *a priori*
- Variety of methods used to study recruitment

Limitations of Evidence Report

- Heterogeneity
 - study design
 - data quality
- Relation between barriers & promoters unclear
- Overlap between underrepresented populations
- More evidence from therapeutic trials than prevention trials
- Excluded studies other than clinical trials
- Recruitment experience not always reported

Recommendations

- **Report**
 - *a priori* recruitment goals & results
- **Consider**
 - conceptual framework in design & evaluation of recruitment strategies
- **Train investigators**

Recommendations (cont'd)

■ Evaluate

- **R**ole of underrepresented healthcare professionals & community health workers
- **C**ost-effectiveness of interventions
- **T**ailored & targeted recruitment interventions

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The EPC Team

Principal Investigators:

Jean G. Ford, MD

Mollie W. Howerton, PhD, MPH

Co-Investigators:

Tiffany L. Gary, PhD, Gabriel Y. Lai, MHS.

Shari Bolen, MD, MPH, Jon Tilburt, MD

M. Chris Gibbons, MD, MPH, Charles Baffi, PhD, MPH

Renee F. Wilson, MS, Carolyn J. Feuerstein

Peter Tanpitukpongse, Neil R. Powe, MD, MPH, MBA

Eric B. Bass, MD, MPH