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Improving the Consent Process: Which Components Are Broken?

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Institute of Medicine
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Protecting Human Subjects

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The Consent Process:

- Developing Appropriate, IRB-Approved Consent Forms
- **Discussing Consent Forms with Patients**
- Gaining Signatures as Documented Consent

*"Ideally, the process of obtaining consent for participation in a treatment trial is **extensive** and **comprehensive**. The process should address the **patient's expectations and concerns** and may require more than one visit. The degree of effort involved is hardly reflected by the signature obtained in the document procured during this process…"*

*Baer A, Good M, Shapira L. "A new look at informed consent for cancer clinical trials" **J Oncol Pract 2011** 7(4)267-270.*

Protecting Human Subjects: **The Consent Matrix**

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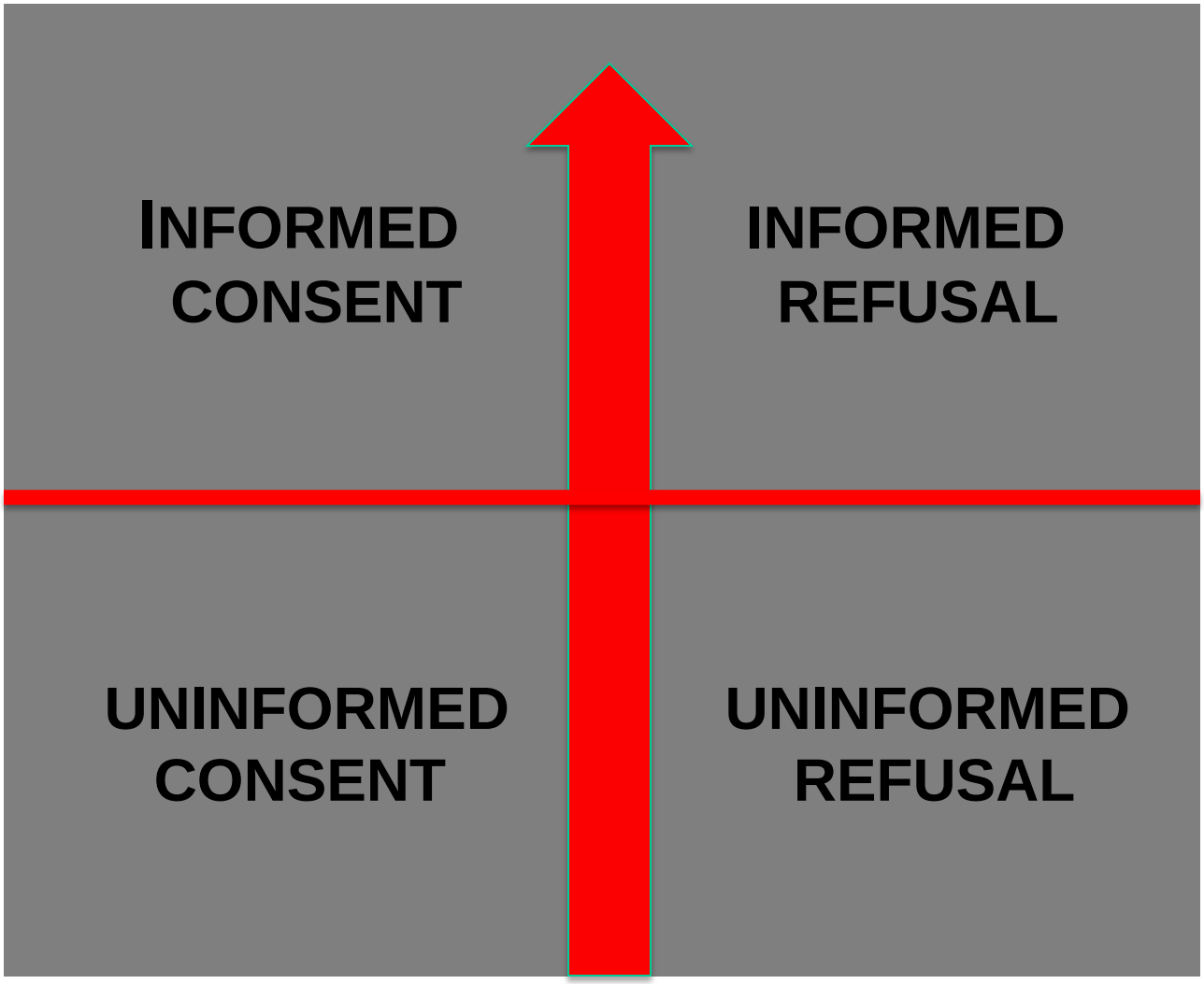

Informed Consent Discussions: The Convergence Model

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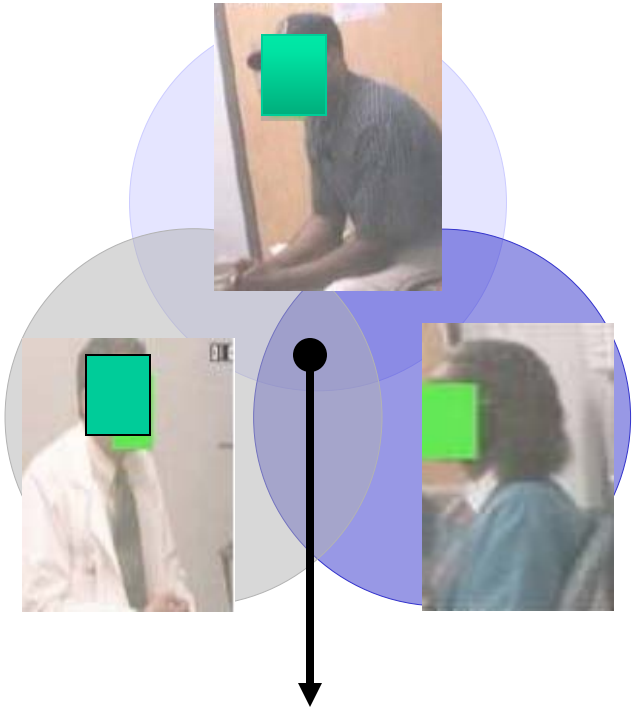
FAMILY/COMPANION



PHYSICIAN **PATIENT**

Shared Accuracy and Agreement About Clinical Trials and the Meaning of "Consent"

The Convergence Model of Communication

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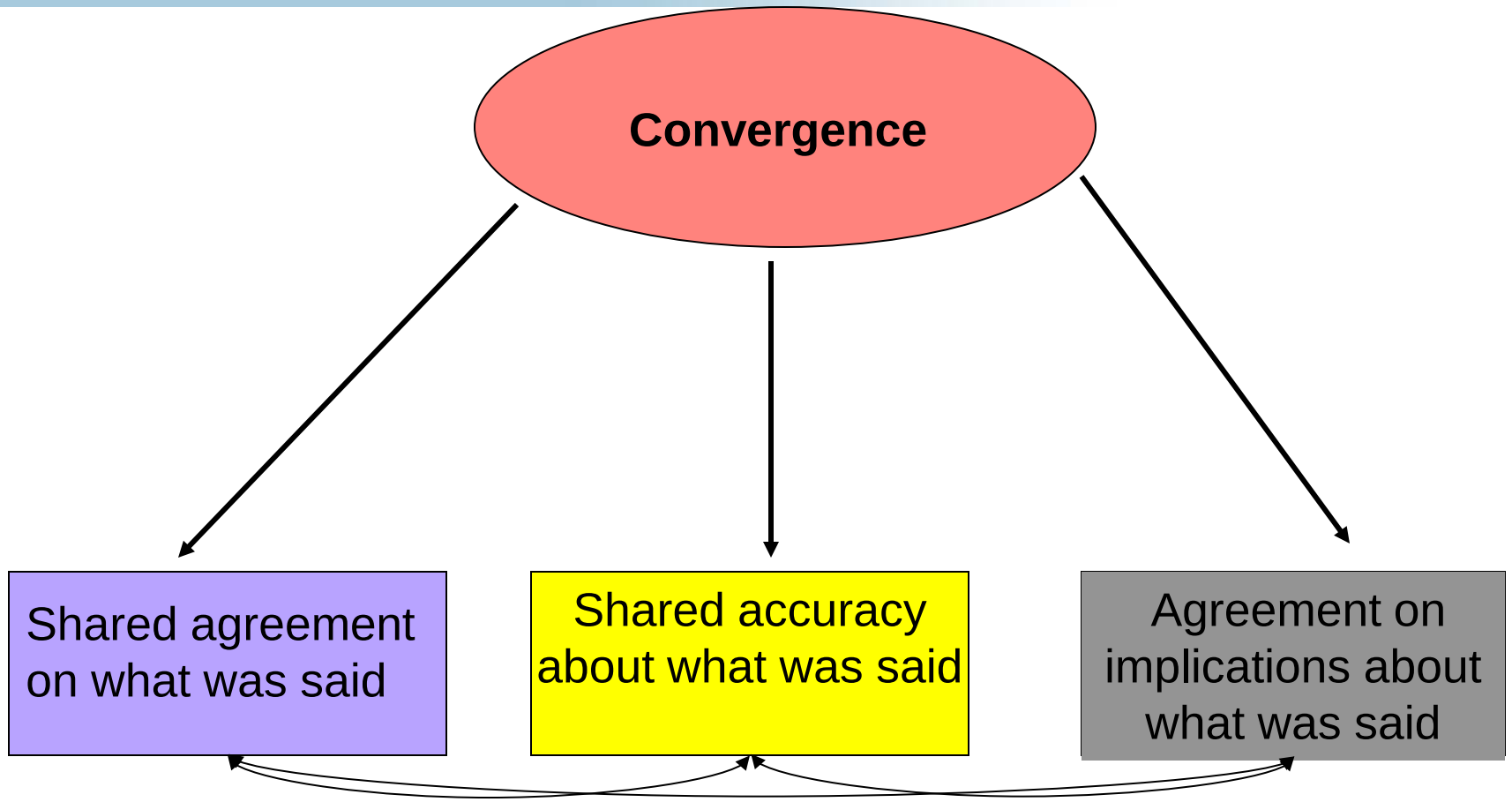

Albrecht et al., J Human Commun, 2009
Adapted from Rogers E, Kincaid L *Commun networks,* 1982
Eggly et al.,Psychooncology, 2013

Inside the "black box" of the Consent Discussion:

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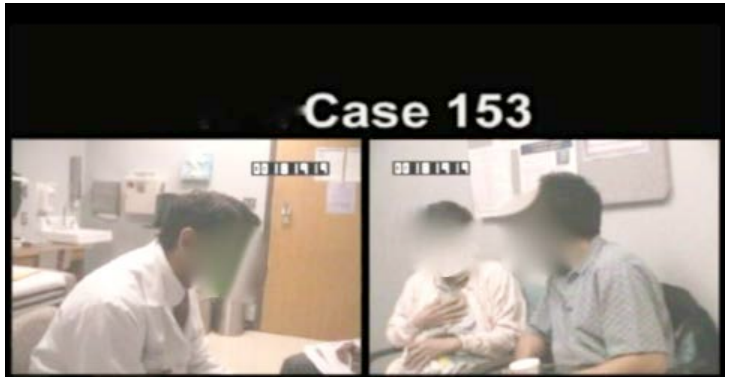
Analyses of Physician-Patient Trial Consent Discussions Across Three Decades



Observable Factors:

1. Is consent form present?
2. Who is present?
3. How much of the consent information is discussed?
4. Is trial accrual recommended?
5. Is the trial offered?
6. Is it a monologue or a dialogue?
7. Is racial bias evident in the discussion?

Is Consent Form Present?

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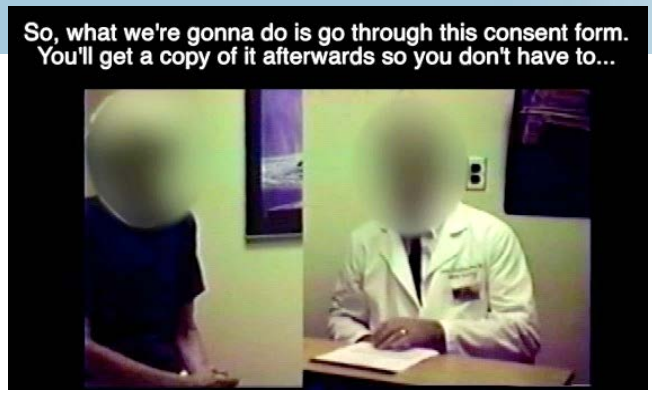
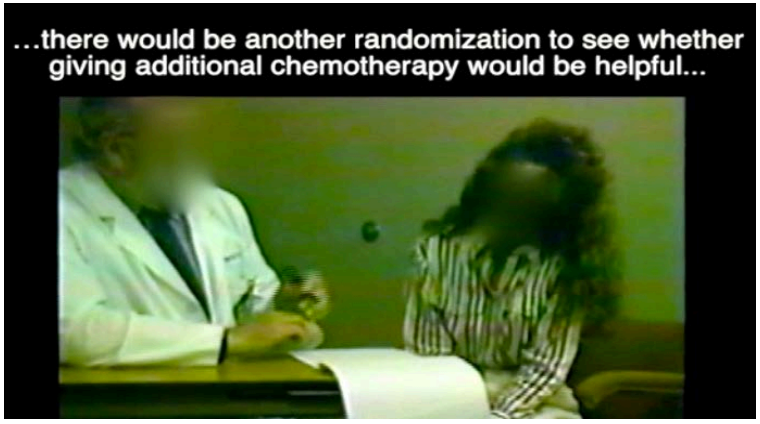
1995:



1996:



2007:

Who is Present?
(and who makes the decision?)

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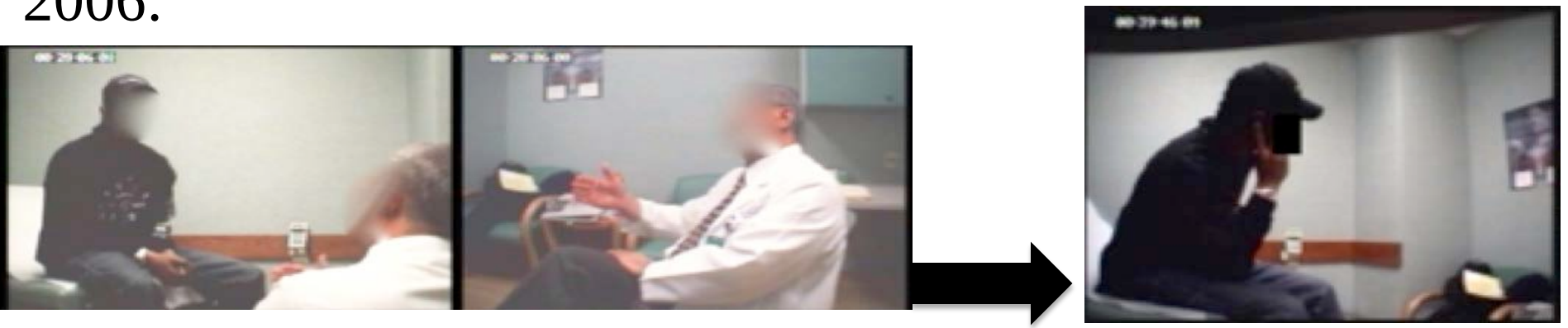
2006:



- 82% of White Patients Bring ≥ 1 Companion(s) to Visit
- 50% of African American Patients Bring ≥ 1 Companion(s) to Visit
- African American Patients Ask Significantly Fewer, Direct Questions
- Have Fewer Questions Asked on Their Behalf

Eggly et al., Patient Educ Couns, 2011

How Much Consent Information Discussed?

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Coder Rated Checklist Results				
Checklist Item	NonAccrued (n=13)		Accrued (n=31)	
(*Albrecht et al., J Clin Oncol, 1999*)	Yes (%)	No (%)	Yes (%)	No (%)
Study defined as research?	8	92	45	55
Confidentiality reviewed?	15	85	35	68
Told participation is voluntary?	52	38	65	35
Can withdraw at any time?	38	62	48	52
Contact persons identified?	15	85	39	64
Need for signature explained?	31	69	35	65
Clinical concept defined?	38	62	39	61
Study purpose explained?	92	8	93	7
Treatments, tests, reviewed?	100	0	93	7
Study procedures reviewed?	92	8	81	19
Publication of results reviewed?	0	100	19	83
Study time frame clarified?	69	31	71	29
Randomization explained?	40	60	53	47
Random procedures described?	50	50	89	11
Alternatives to study reviewed?	85	15	81	19

How Much Consent Information Discussed?

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Mean Number of Content Messages Observed for Each Information Category		
Checklist/Example Items	**Mean**	**S.D.**
Checklist items from Informed Consent Document (Score Range: 0-19)	7.43	2.28
Adverse Effects, Side Effects, Toxicities (Score Range: 0-38+)	4.77	4.22
Reassurance/Support About Consent Decision: "Won't hurt my feelings if you refuse;" "We'll continue to treat you if you don't participate, won't prejudice your care;" "If you aren't doing well on the study we will stop and reevaluate your care" (Score range : 0-6)	0.97	0.95
Reassurance/Support for Adverse Effects, Side Effects, Toxicities (Score Range: total # messages across all adverse events mentioned)	2.94	4.24
Benefits Regarding Consent and Trial Participation: eg, no cost, new treatment, good study, will help others (Score Range: 0-9+)	1.54	1.22

Albrecht et al., J Clin Oncol, 2008

Is Trial Recommended During Consent Discussion?

(and other types of undue influence?)

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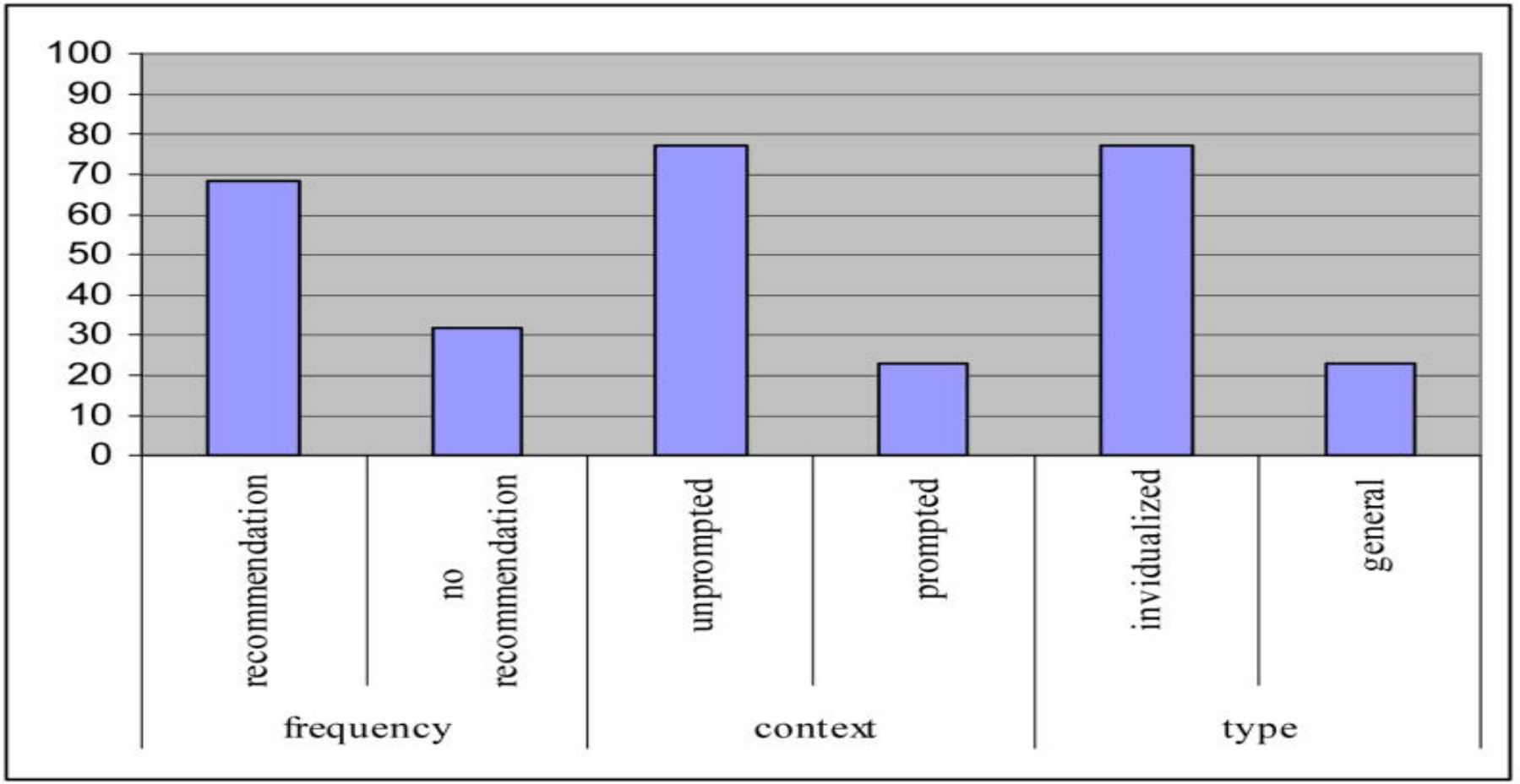

Eggly et al., Patient Educ Couns, 2008

Is Trial Offered During Consent Discussion?

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- Offer Rate:
  - 35/235 video recorded visits
  - 15% of patients offered a trial
    - Of those offered a trial, 77% consented/enrolled
    - No differences by race/ethnicity
- What Is An “Offer”?
  - Patients’ misconceptions about offers:
    - 39% of patients who only discussed a trial said they were offered a trial
    - 14% of patients who were offered a trial said they were not offered a trial (some also consented)

Monologue or Dialogue?

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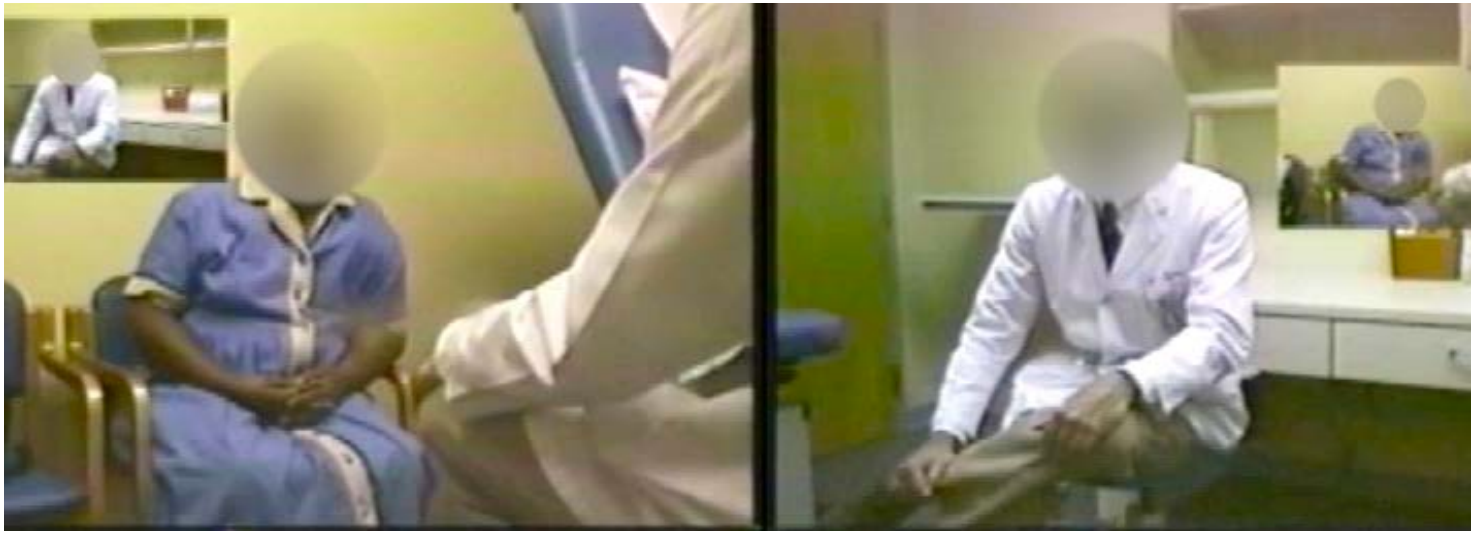
- Definition of a conversation:
  - ***"Equal rights to speak"***



(Wilson J, Res Lang Soc Interac, 1987)

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MD: Um, are you familiar with what a clinical trial is?
PT: I heard about it-
MD: Do you know what I'm talking about?

MD: What-what is your idea of it?
PT: My idea that you go into trials, you try this drug and…
and they take data from what's goin' on with you..

MD: Yeah.
PT: ..ya know, and-I don't know. The only thing about…
I don't know if you can get out if you want to or if you...

...have to stay in.
MD: Yeah, ok. I-well, um, you know, your actually
very close…First of all, you can get out, ok.

Is Racial Bias Evident in Discussion?

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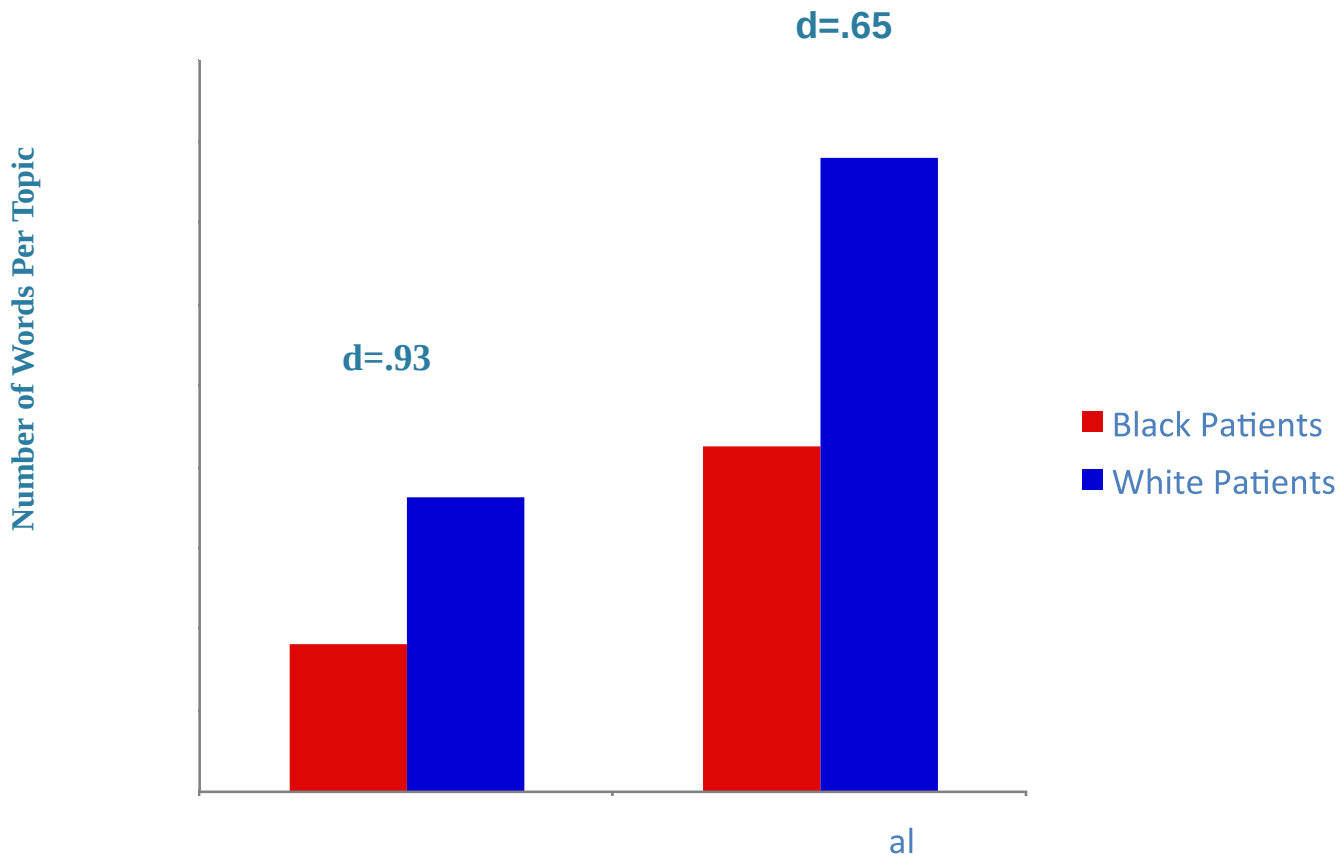
Blacks Receive Less Information About Trials Than Whites



Eggly, et al., Health Expectations, 2013

Determinants of Convergence: Relational and Informational Messages

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Time 1
Observed
Physician/Patient/Family
Communication

Time 2
Patients' Self-Reported
Decision Outcomes

Relational Communication
PT Interaction Control
FM Interaction Control
MD-PT Relational Affiliation
MD-FM Relational Affiliation

Message Content
Legal-Informational Messages
Benefits of Clinical Trial Messages
Legal-Informational/Support Messages
Side Effects Messages
Side Effects Support Messages

r =.40

r =.40 to .51

r = -..49 to -.58

r =.47

r=.38 to .53

Decision

Decision Related Affect/Cognition
Decision Confidence
Therapeutic Alliance
Positive Relationship Synchrony
Decision Agreement Synchrony

Factors Influencing Decision
Costs Manageable
MD Listened/Was Supportive
Side Effects Manageable
Family Opinion

Summary
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- Informed consent and informed refusal begin with the physician-patient-companion interaction
- The quality of the interaction is related to the extent to which all parties achieve convergence:
  = Mutual understanding
  = Shared accuracy/agreement about research participation
- The level of convergence is related to relational and information messages exchanged
- Consent is a process of giving balance to the “rights to speak” in order for the “rights to be informed”

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