

EFIC RESEARCH
CONCERNS,
NEW METHODS AND
THINKING ABOUT THE FUTURE
(ESPECIALLY THE INTERNET)

Session B5

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LOOKING BACK (SHAH & SUGARMAN, ANNALS OF EMERGENCY MEDICINE 2003)

- What to do about people who express a desire to opt out?
- Concerns about minority populations
 - Do they carry an unfair burden?
 - Already high levels of distrust in many of these populations

LOOKING BACK

D.F. RAGIN, ET AL., *DEFINING THE "COMMUNITY" IN COMMUNITY CONSULTATION FOR EMERGENCY RESEARCH: FINDINGS FROM THE COMMUNITY VOICES STUDY*. 66 SOCIAL SCIENCE AND MEDICINE 6 (2008)

- **Considerable difficulty in defining community (and the guidelines still don't help much)**
 - Demographic Cohorts: defining community as other people, or people with similar demographic characteristics such as age; Experience Cohorts: defining community as people with similar experiences, interests, activities or religious beliefs; Geographic Cohorts: defining community as location; Intimates: defining community as family or close friends; and, Profession/Workplace Cohorts: defining community by occupation or workplace
- **Spokespeople for community rarely the same as active decision makers**

THE BIGGEST PROBLEM? VERY FEW PARTICIPANTS ACTUALLY KNOW ABOUT THE STUDY PRIOR TO ENTRY

- FDA Guidance does not require evaluation of effectiveness of community consultation and public disclosure, but it is encouraged (IRBs are required to assess the *adequacy*—but that is not the same thing)
- Data indicates effectiveness is very limited—especially where the target group cannot be *actually* identified prior to the study taking place

METHODS OF PUBLIC DISCLOSURE AND COMMUNITY CONSULTATION

- **targeted mailings to households in the communities, with information about how to obtain further details;**
- **advertisements and articles in the English language, and if appropriate, foreign language, newspapers**
- **clearly marked links and information on the sponsor's and participating hospitals' Internet web sites;**
- **summary materials that are accessible to non-English speaking or homeless populations who reside in the community from which research subjects are likely to be drawn;**
- **meetings of community, local government, civic, or patient advocacy groups;**
- **letters to local and regional community leaders and first responders (e.g., police, paramedics);**
- **announcements to local/regional hospital staff(s);**
- **public service announcements and interviews or discussions on “talk” radio or television programs;**
- **press conferences and briefings; and**
- **meetings or activities provided by hospitals' and institutions' existing community outreach programs.**

COMMON METHODS OF PUBLIC DISCLOSURE AND COMMUNITY CONSULTATION

- Little research on which methods are preferred by participants in studies
- Tendency to go back to “tried and true” methods
- Need greater flexibility –for example pay attention to methods used by political campaigns
 - E.g. random dialing surveys



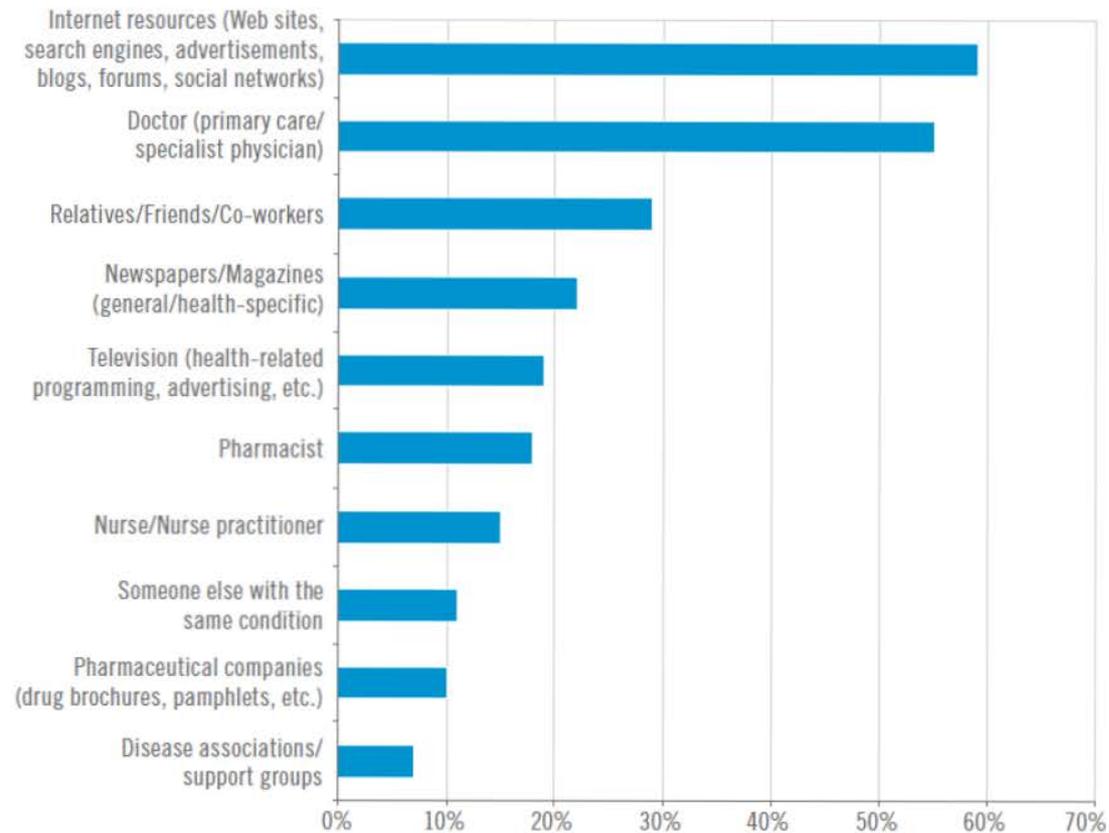
IS GREATER USE OF THE
INTERNET AND SOCIAL
MEDIA WARRANTED?

SOURCES USED TO FIND OR ACCESS HEALTH- AND WELLNESS-RELATED INFORMATION IN THE PAST 12 MONTHS

Which of the following resources have you used to find or access health- and wellness-related information in the past 12 months? Please select all that apply.

Base: All respondents (n=1,084)

Source: iCrossing



HEALTH INFORMATION AND THE INTERNET —PEW RESEARCH

(SOURCE

[HTTP://PEWRESEARCH.ORG/PUBS/2206/SMARTPHONES-CELL-PHONES-BLACKBERRY-ANDROID-IPHONE](http://PEWRESEARCH.ORG/PUBS/2206/SMARTPHONES-CELL-PHONES-BLACKBERRY-ANDROID-IPHONE), MARCH 1, 2012)

- Nearly Half of American Adults Are Smartphone Owners
- Eight-in-ten internet users look online for health information, making it the third most popular online pursuit following email and using a search engine.
- Since one-quarter of adults do not go online, the percentage of health information seekers is 59% among the total U.S. adult population.
- Depending on the target community, that number could be much larger (or smaller)

HEALTH INFORMATION AND THE INTERNET—PEW RESEARCH

- **The most likely groups to look online for health information include:**
 - Adults who, in the past 12 months, have provided unpaid care to a parent, child, friend, or other loved one
 - Women
 - Whites
 - Adults between the ages of 18 and 49
 - Adults with at least some college education
 - Adults living in higher-income households

HEALTH INFORMATION AND THE INTERNET —PEW RESEARCH

- **By contrast, fewer than half of adults in the following groups in the U.S. look online for health information:**
 - African Americans
 - Latinos
 - Adults living with a disability
 - Adults ages 65 and older
 - Adults with a high school education or less
 - Adults living in low-income households (\$30,000 or less annual income)

POTENTIAL BENEFITS OF INCREASED INTERNET USE

- **Low Cost**
- **Targeted Audience**
- **Greater Response**
 - Some clinical trial recruitment has shown dramatic response rates
 - Can be at convenience of participant
- **Easy Provision of large amounts of information**

POTENTIAL NEGATIVES OF INCREASED INTERNET USE

- May exclude minorities
- Privacy
 - Targeting adds additional concerns
- Social Networking can be more than “two-way”—does multi-way mean confusion?
- May be harder to track community reaction
- Computer interaction is not the same as “face to face.”
- FDA still unsure about a great deal of social networking

PUBLIC DISCLOSURE

- Increased internet use seems like a “no-brainer”
- But care must be taken that it does not exclude important parts of the concerned community

COMMUNITY CONSULTATION



- FDA Guidance says that this involves two-way communication
 - Discussion(s) with wide group of representatives
- Many IRBs believe that this necessitates face to face interaction
- But FDA guidance allows flexibility (and specifically mentions interactive websites)

FINAL THOUGHTS

- No “one size fits all” solution
- Sites participating in EFIC research should take steps to evaluate and publish the effectiveness of the methods used