Information Behavior of Clinical Research Participants

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Background and Significance

* We need clinical research volunteers

* Often cited that <5% of eligible cancer patients enroll in CTs (Murthy, Krumholz, & Gross, 2004)
Background and Significance

* Over the last decade the deaths of several healthy volunteers in clinical research studies have been well publicized
* Impacts the public’s view of clinical research in general
* We need to understand the experience from the participants’ perspective: Holistically

Purpose

* To help understand the clinical research experience from the participants’ perspective through the lens of information behavior
* To help inform researchers of participants’ needs
* In turn, to help participants receive the (information) they need

Research Questions

1) How do clinical study participants find a study to join or determine which study to join?
2) What information do they need, or seek, to decide to enroll?
3) What was the extent of information seeking before they made their decision to participate?
4) How confident are they about their decision to enroll?
Methods

* Study was approved by the Health Sciences and Behavioral Sciences Institutional Review Boards (IRB-HSBS) at the University of Michigan (U-M).
* Recruitment: Flyers and website posting
* Qualitative: 10 semi-structured interviews

Methods

* Brenda Dervin’s Sense-Making methodology, Micro-moment timeline interviews
* Open coding, content and narrative analyses, based on Dervin’s work, were used to find themes emerging in the data
* Schamber (2000) discusses the strengths of combining time line interview techniques with inductive content analysis

Findings and Discussion

1) How do clinical study participants find a study to join or determine which study to join?

* None approached by a clinician
* 60% found the study electronically
* 40% found the study by noticing a posted, paper flyer

Explain well by Bates (2007) work on browsing and Saracevic (1996) work on the relationship between cognitive relevance and interest
Findings and Discussion

2) What information do they need, or seek, to decide to enroll? 3) What was the extent of information seeking before they made their decision to participate?

* Short answer is “lots”
* Questions best answered by personal interaction (not paper) with coordinator or research assistant (FTF, Phone, E-mail)
* Prompt response cannot be emphasized enough
* “play within a play”

Findings and Discussion

Based on qualitative comments from P3:

1) where would the study be held?
2) what would be the duration?
3) what would I have to do as a participant
4) what are the criteria?
5) I am eligible?
6) what do I need to do?

Findings and Discussion

Themes regarding motivation for participation
Interest (relevance)
Compensation
Altruism
Convenience
(level of physical/emotional invasiveness and/or time commitment/level of involvement)
Implications
System / Study design issue: automated e-mails

Engaging Health Sciences Librarians and informationists

Use of Clinical Research Nurses

Theoretical Framework
Hildegard. E. Peplau
*Interpersonal Relations in Nursing*, 1952
Describes nursing: “therapeutic, interpersonal process”
Common themes of trust, goals, needs, uncertainty, anxiety
(see summary: [http://nursingworld.org/nursing_theory/interpersonal_theory.html](http://nursingworld.org/nursing_theory/interpersonal_theory.html))
Implications
Nurses best situated to be Clinical Study Coordinators
Unique skills Trust
Focused on participants motivation/goals/understanding: natural Patient Advocates
Attending to spoken and unspoken participant needs, concerns, uncertainty/anxiety
Links between caring and information provision
Advanced Practice Role (CRN)

Conclusions

"...health research ultimately depends on the participation of human volunteers as research subjects...Under these circumstances, searching for evidence of what happens to these volunteers...is ethically mandatory...The onus is on the research community to collect and use that evidence to good effect."

Be grateful to your research participants!

Key References


Key References

- Dervin, B. (1992). From the mind’s eye of the user: The sense-making qualitative-quantitative methodology. In J. Glazier & R. Powell (Eds.), Qualitative research in information management, (pp. 61-84), Englewood, CO: Libraries Unlimited.
Acknowledgments

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Questions?

* Please contact: eisen@umich.edu
Nurses as Research Participants: Ethical Considerations

Margo Moore BSN, RN, CCRP
Stephanie Sealschott BSN, RNC-NIC

Objective
Background:
- Major Healthcare system changes
- Nurses are frontline caregivers in patient care
- Research on care delivery practices
- Protections for nurses as vulnerable human subjects

The Belmont Report
Basic Ethical Principles

Respect For Persons
The principle of respect for persons divides into two separate moral requirements:
- Individuals should be treated as autonomous agents
- Persons with diminished autonomy are entitled to protection.
Recruitment Strategies

Needed: Registered Nurses Working in the NICU at Cincinnati Children's

Join us for an Information session about the study, ask questions, and receive a $5 meal ticket for your time.

Information Sessions:
- 3/13 Wednesday 18:30 - 20:00 NICU Classroom
- 3/14 Thursday 6:30 - 8:00 NICU Classroom
- 3/18 Monday 6:30 - 8:00 NICU Classroom
- 03/19 Tuesday 18:30 - 20:00 NICU Classroom
- 03/21 Thursday 18:30 - 20:00 NICU Classroom
- 03/22 Friday 6:30 - 8:30 NICU Classroom
- 3/11 Monday 6:30 - 8:00 Outside Breakroom
- 3/15 Friday 6:30 - 8:00 Outside Breakroom
- 3/19 Tuesday 6:30 - 8:00 Outside Breakroom
- 3/20 Wednesday 6:30 - 8:00 Outside Breakroom
- 3/21 Thursday 6:30 - 8:00 Outside Breakroom

NNCQ
Neonatal Nursing Care Quality Study

Information Sessions:
- NICU Ward Tuesday 6:30 - 8:00 NICU Ward
- NICU Ward Wednesday 6:30 - 8:00 NICU Ward
- NICU Ward Thursday 6:30 - 8:00 NICU Ward
- NICU Ward Friday 6:30 - 8:00 NICU Ward
- NICU Ward Monday 6:30 - 8:00 NICU Ward
- NICU Ward Wednesday 6:30 - 8:00 NICU Ward
- NICU Ward Thursday 6:30 - 8:00 NICU Ward
- NICU Ward Friday 6:30 - 8:00 NICU Ward

Internet Consent
Protocol Title: [Redacted]
Conduct research with neonates using context-based assessments.

[Redacted]

[Redacted]
Beneficence

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.

- do not harm
- maximize possible benefits and minimize possible harms

Certificate of Confidentiality

Social Justice

- The burdens and benefits of research should be justly distributed.
Enrollment

• All registered nurses in CCHMC NICU
• Primary position includes direct patient care
• Permanent NICU employees
• Completed orientation
Data Collection
6 week quarterly cycles over 1 year
Each Nurse receives:
• Questionnaire(s) for each baby cared for on each shift worked
• Assessment of shift workload form

How to keep the data safe during collection?
• Each nurse has their own special 4 digit number they created, no names
• Questionnaires are given directly to nurses and collected prior to their shift ending

Data Collection Hurdles
Data Entry and Storage

- Over 120 pieces of paper to be entered daily into the protected database
- All forms are in a locked cabinet and office in a separate building from NICU
- Further de-identification

Summary

- End of Cycle 3
- Best Research Practices
- Careful planning = high quality research data and outcomes.

Questions?