National Cancer Institute

Affective Science Perspectives on Cancer Control:

A Focus on Informed Consent

Laura Buccini, DrPH, MPH
Nonniekaye Shelburne, C.R.N.P., M.S., A.O.C.N
William Klein, PhD
Rebecca Ferrer, PhD

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Outline

- Enrollment Cancer Clinical Trials
- Cancer Clinical Trials
  - Consent
  - Decision Making
- Pediatric Cancer Clinical Trials
  - Consent/Assent
  - Decision Making
- Challenges
- Potential Emotional and Cognitive Outcomes
- Managing Challenges
- Looking Forward

Enrollment
Cancer Clinical Trials

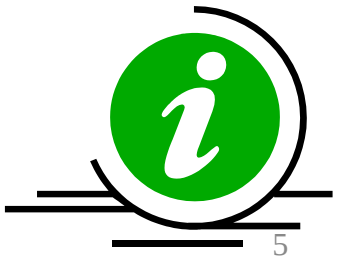
- **Adolescents**
  - *10% of 15-to-19 year old adolescent cancer* patients are entered into trials, compared to 60% of those under the age of 15[1,2]
- **Adults**
  - average rate of accrual is between 1 -5%, with cancer patients aged 20 to 29 having the lowest rate of participation of all age groups[1]
- **Elderly**
  - *61% of new* cancer cases occurred among the elderly in 2003, but only 25% of participants in national cancer clinical trials were over 65 years of age[3]
  - in Phase II and III clinical trials, the elderly carried 60% of the disease burden but represented only 32% of enrolled patients[3]

Enrollment
Cancer Clinical Trials

- **Racial/Ethnic Groups**
  - nationally, enrollment in cancer clinical trials is disproportionately low among African Americans/blacks and Hispanics/Latinos[4,5]
- **Rural**
  - among 24,332 patients enrolled in NCI sponsored cancer clinical trials over a one-year period, investigators found marked regional and state variations in patient accrual, suburban geographic areas had the highest overall accrual[6]
- **Women**
  - an investigation of nonsurgical NCI cancer trial demonstrated that women were less likely than men to be enrolled in colorectal and lung cancer trials[4]

Informed Consent

- Goal: Provide individuals with sufficient information so they can make informed decisions about whether to begin or continue participation in research (clinical care)
- Informed consent (IC) is a dynamic *process*
- IC document is simply a starting point



Informed Consent

- Acknowledges the rights of patients to participate voluntarily in a research study
- Requires adequate disclosure of information to patients/participants regarding a proposed intervention
- Dominant guiding ethical principle
  - adults: respect for persons (autonomy)
  - pediatrics: best interests of child (beneficence)

Decision Making

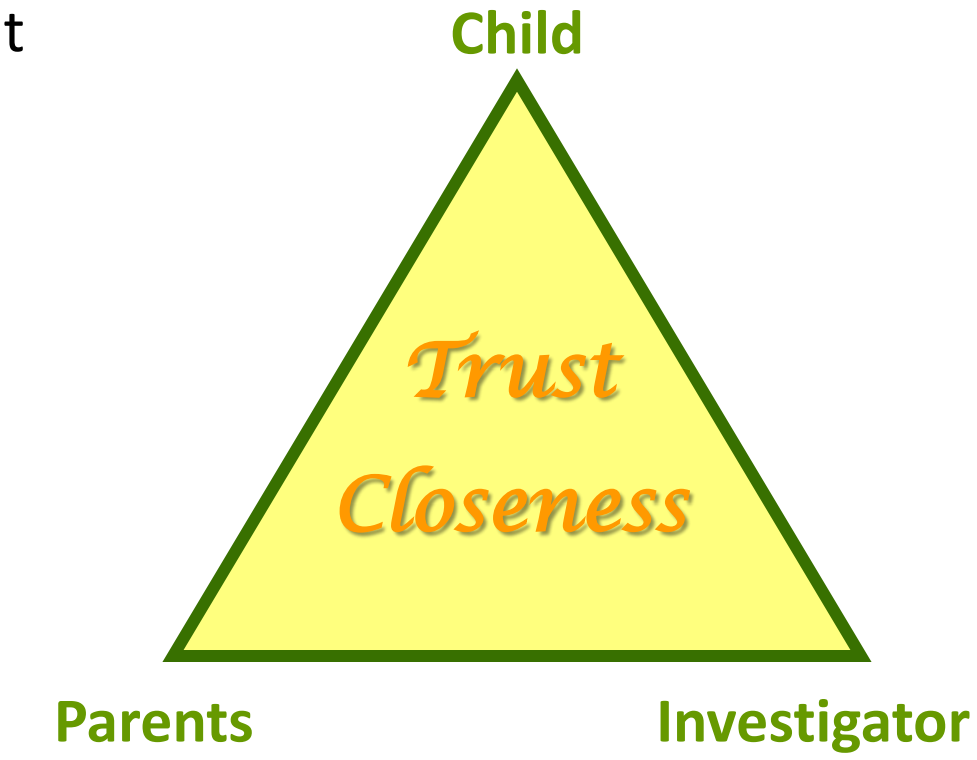
- Provide **information** relevant to making a meaningful decision whether or not to participate (or continue participating)
- Takes place in the **absence of coercion** or duress
- Is **competent** to make decision (surrogate decision maker)
- Has decision-making **capacity** needed to make a meaningful choice about whether or not to participate in the study

Balance Act

Informed Consent/Assent in Pediatrics

Triadic Model

- Parental permission and patient assent (depending on age)
- Trusting and "close" relationship between research staff, the parents and the child are of crucial importance and have been shown to be the major factors for parents agreeing to a clinical study



Pediatric Decision Making

Infants/Young Child

No significant decision-making capacity

Not able to provide consent

Primary School

Unable to fully understand implications

Assent sought

Adolescents

Assess ability to weigh potential risks/benefits

Some may participate in decision making

Own body → Personhood → Moral agent → Control

Challenges: Informed Consent/Decision Making

The Patient

- Language/linguistic differences and literacy
- Public attitude/opinion
- Logistics and psychosocial barriers

The Physician/Investigator

- Communication
- Lack of minority investigators/ cultural competence
- Persuasion or coercion

The Consent Document

- Long and complex
- Readability and comprehension
- Dependant on IC documents to communicate study information

Specific to Pediatrics

- Determining child's decision making capacity
- Relational dynamics (parent/child)
- Child's refusal to participate (dissent) against parents wishes

Potential Outcomes Emotional Overload

Informed Consent & Decision Making

- Fear/anxiety
- Shock
- Sadness / depression
- Anger
- Denial
- Guilt

Clinical Trial

- Confused
- Unable to process
- Unable to understand
- Unknowns
- Need for decision making support
- Study withdrawal

Anticipated Emotion

Incidental Emotion

Potential Outcomes Cognitive Overload

Informed Consent & Decision Making

- Treatment choices →
- Family concerns →
- Financial worries →
- Employment concerns →

Clinical Trial

- ← Risks/Benefits
- ← Standard vs. trial
- ← Confidentiality
- ← Randomized
- ← Study withdrawal

Anticipated Emotion

Incidental Emotion

Managing Challenges

Information Flow

- Multimedia interventions
- Corrected feedback
- Multiple learning trials
- Organized /simple consent forms
- Decision aids

Resources

- Payment/ reimbursement
- Social work
- Psychological services
- Access to care
- Potential enhanced quality of care

Research Initiatives Looking Forward

- How can emotion theory and research inform our understanding of the informed consent process and patient decision making in cancer research?
  - How/to what extent might incidental and anticipated emotions impact patients' understanding and influence informed decision making?
  - How might emotional interactions between physicians, patients, patient-parents and family/companions influences patients' decision making process?
  - What emotional states inhibit decision making capacity– interventions?

References

1. National Cancer Institute. *Facts and Figures About Clinical Trials.* from http://www.cancer.gov/clinicaltrials/facts-andfigures#patients.
2. Newburger PE, Elfenbein DS, Boxer LA. Adolescents with cancer: access to clinical trials and age-appropriate care. *Current Opinion in Pediatrics. 2002.* 14(1):1-4.
3. Lewis JH, Kilgore ML, Goldman DP, et al. Participation of patients 65 years of age or older in cancer clinical trials. *Journal of Clinical Oncology. 2003. 21(7):1383-*1389.
4. Du W, Gadgeel SM, Simon MS. Predictors of Enrollment in Lung Cancer Clinical Trials. Cancer. *Cancer. 2006.106(2):420-5.*
5. Stewart JH, Bertoni AG, Staten JL, Levine EA, Gross CP. Participation in surgical oncology clinical trials: gender-, race/ethnicity-, and age-based disparities. *Ann Surg. Oncol. 2007.14(12):3328-34.*
6. Sateren WB, Trimble EL, Abrams J, et al. How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *Journal of Clinical Oncology. 2002. 20(8):2109-17.*

NATIONAL® CANCER INSTITUTE