Affective Science Perspectives on Cancer Control:
A Focus on Informed Consent

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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

Risk

Benefit

Risk

Benefit
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**

<table>
<thead>
<tr>
<th>The Patient</th>
<th>The Physician/Investigator</th>
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| • Language/linguistic differences and literacy  
• Public attitude/opinion  
• Logistics and psychosocial barriers | • Communication  
• Lack of minority investigators/cultural competence  
• Persuasion or coercion |

<table>
<thead>
<tr>
<th>The Consent Document</th>
<th>Specific to Pediatrics</th>
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| • Long and complex  
• Readability and comprehension  
• Dependant on IC documents to communicate study information | • 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 influence patients’ decision making process?
  – What emotional states inhibit decision making capacity—interventions?


