Innovative Person-Centered Clinical Cancer Research: A Workshop

Session 1: Integrating Person-Centeredness into Clinical Cancer Research

The Patient / Family Caregiver Dyad & Engagement in Clinical Research

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September 29, 2025

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Disclosures

Acknowledgement of funding from the National Cancer Institute of the National Institute of Health for the two studies I will be discussing:

- Stakeholder Perspectives on Family Caregiver Involvement in Oncology Clinical Trial Decision-Making 3R37CA240707-04S1

- Building Family Caregiver Skills Using a Simulation-Based Intervention for Care of Patients with Cancer R37CA240707

Family Caregivers

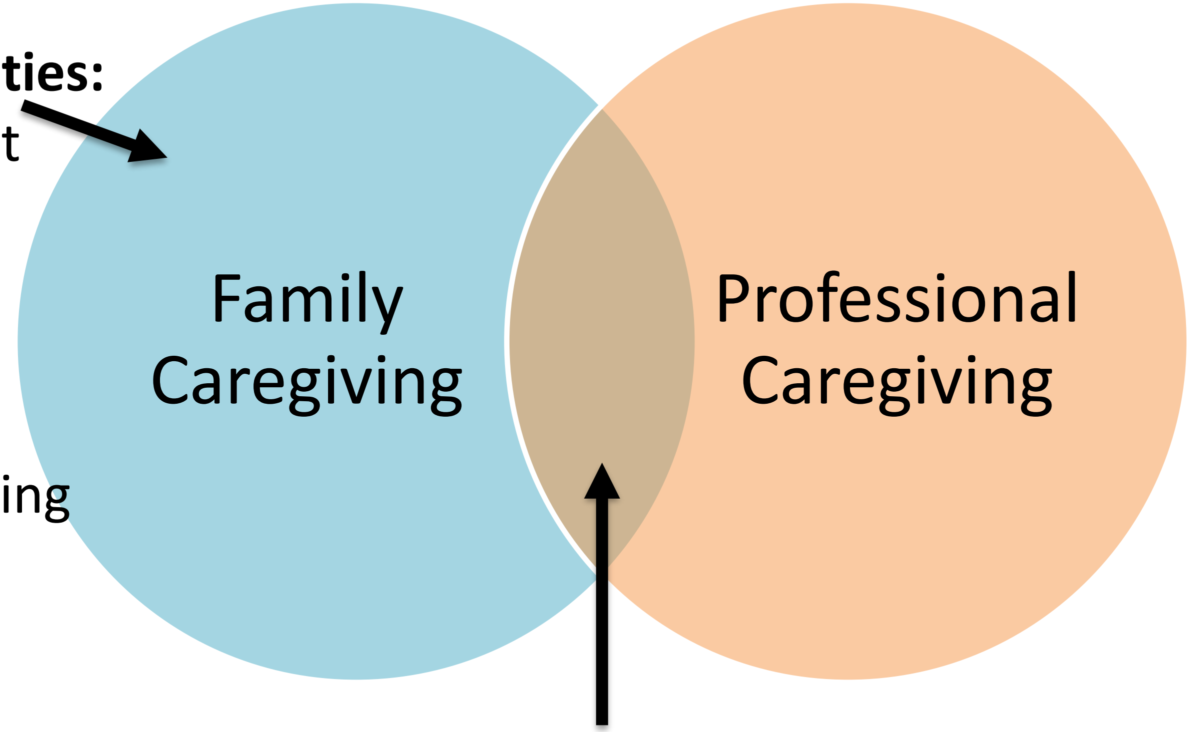
- Family Caregiver = adult family member or other individual who has a significant relationship with, and who provides a broad range of assistance & uncompensated care to an individual with cancer

- Family Caregivers are essential members of the healthcare team, yet are rarely recognized & acknowledged

- Well-documented descriptions of physical, emotional, economic, and social impact of caregiving, yet there is little application of these data in the real world.

Blum & Sherman, 2010; Carter, 2002; Family Caregiver Alliance, 2006; Klemm & Wheeler, 2005; Schulz & Sherwood, 2008; Kent et al., 2019; Longacre et al., 2021; Chia et al., 2021

Pushing the Boundaries of Caregiving



Routine Responsibilities:

- Emotional support
- Physical care
- Communication
- Decision-making
- Transportation
- Symptom monitoring

New Advanced Responsibilities:

- Perform medical /nursing technical skills
- Follow complex regimens for medications & chemo
- Manage venous access lines
- Oversee technology in home
- Recognize subtle changes in patient status

Caregiver Burden

- The extent to which CGs perceive that their health, schedule, family & social life, and financial status have suffered due to being a CG. (Given, 2012)
- Often goes unrecognized by healthcare team
- Potential for influencing patient and CG engagement in clinical research
  - Enrollment
  - Meeting trial requirements (#visits, reporting symptoms, etc.)
  - Drop out rates

Family Caregiver Engagement in Clinical Trials Decision-Making

(3R37CA240707-04S1)

- Qualitative study that examined:
  - How Cgs conceptualized their role in clinical trials decision-making
  - Motivating factors for endorsement participation
  - Current staff practices and attitudes towards Cgs
- Methods: focus groups and individual interviews

Blackstone, E. C., Mazanec, S. R., Daly, B. J., Dorth, J. A. Montero, A. J., Aulisio, M. P., Brandt, P., Foley, H., & Loue, S. (2025). Stakeholder perspectives on the role of caregivers in cancer clinical trial decision-making: results of a qualitative study. *Supportive Care in Cancer, 33*, 464.
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Study Results

Caregiver Themes

- Promoting patient autonomy
    - CGs viewed role as supportive in decision-making
- Influential factors on endorsement of participation
    - Hope for therapeutic benefit
    - Availability of alternative treatments
    - Contributing to cancer research for future patients
- Caregiver burden
    - Financial due to missed work & transportation
    - Anxiety
        - Fear of loss of loved one
        - Uncertainty about side effects during trial

Family Caregiver Engagement in Clinical Research (R37CA240707)

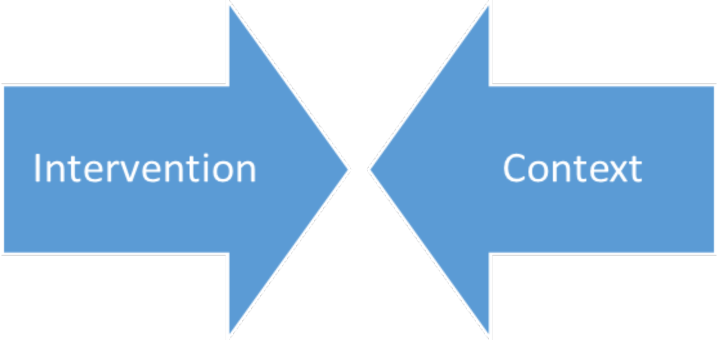
- RCT testing a CG intervention during radiation therapy
- Enrolled 242 patient / family CG dyads
  - Refusal rates: Patient = 28%; Caregiver = 37%
  - Challenge of consenting dyads
  - Primary refusal reasons:
    - Patient = "Not interested" & "Caregiver does not need intervention"
    - Caregiver = "Overwhelmed/busy"

Mazanec, S. R., Blackstone, E., & Daly, B. J. (2021). Building family caregiver skills using a simulation-based intervention for care of patients with cancer: protocol for a randomized controlled trial. *BMC Nursing,* 20:93. https://doi.org/10.1186/s12912-021-00612-4

Barriers to Accrual in Caregiver Study

- Timing of Enrollment
  - Start of treatment is a vulnerable time
  - Coping with many types of complex information
  - Interfacing with many clinicians
- Participation not viewed as a priority
  - Some patients are struggling with basic life needs (food, transportation, housing, support, etc.)
- Mistrust of research
  - Concern with data security
- Logistics of trial – fit into daily schedule, work

Lessons Learned



- **Flexibility of complex clinical intervention**
  - Caregivers often have needs beyond scope of study
  - Must build in flexibility for delivery of intervention, tailor intervention to CG
  - Need for comprehensive fidelity measures to monitor delivery, receipt, & enactment of the intervention
- **Screening for health literacy**
  - 37% have limited to marginal health literacy scores
  - Training of all staff to use universal health literacy strategies

Opportunities to Enhance Person-Centeredness in Clinical Research

- Recognize & respect
    - Diverse CGs and caregiving situations
- Engage CG as member of HC team early in discussion of patient treatment trial
    - Intentional inclusion of CGs in consent process
    - Clear information about study & CG involvement
- Support the CG in their complex role
    - Systematically screen for CG distress and assess CG for needs, burden, & satisfaction with role
    - Healthcare team’s responsibility to offer education, training, & support throughout care trajectory with a key focus on transitions