UNIVERSITY OF KENTUCKY
College of Medicine

Optimization of Smoking Cessation Strategies in Community Cancer Programs for Newly Diagnosed Lung and Head and Neck Cancer Patients

Joe Valentino, MD, FACS
Professor
Division of Head & Neck Cancer Surgery

Jamie L. Studts, PhD
Associate Professor
Department of Behavioral Science

UKHealthCare
Markey Cancer Center

Collaborators

- Christina R. Studts, PhD, MSPH
  - Department of Health Behavior, Public Health
- Brent Shelton, PhD
  - Department of Biostatistics, Public Health
- Kris Damron, CCRP & Tim Mullett, MD, FACS
  - Kentucky Clinical Trials Network

Kentucky Clinical Trials Network

UK UNIVERSITY OF KENTUCKY College of Medicine

The benefits of tobacco cessation after cancer diagnosis are well-documented and important.

- Improved quality of life
- Increased treatment efficacy
- Improved wound healing
- Reduced risk of second primary
- Reduced risk of recurrence
- Improved survival
- Impact on family (cessation role model)

UK
UNIVERSITY OF KENTUCKY
College of Medicine

Very few studies have examined cessation interventions following cancer diagnosis.

- Wewers et al.
- Schnoll et al.
- Gritz et al.
- Park et al.
- Ostroff et al.

TABLE 2
Quit Smoking Percentages at 1 and 3 Months by Treatment Condition

	CBT		*GHE*		*Overall*		
Patient Quit Smoking Status	*N*	%	*N*	%	*N*	%	*p*
No. of patients	52		57		109		
1-month follow-up							
Deceased	3	5.8	2	3.5	5	4.6	1.0
Lost/refused to be interviewed	15	28.8	13	22.8	28	25.7	
Quit smoking							
Yes	22	44.9	26	47.3	48	46.2	0.8457
No	27	55.1	29	52.7	56	53.8	
3-month follow-up							
Deceased	8	15.4	6	10.5	14	12.8	0.2831
Lost/refused to be interviewed	6	11.5	12	21.1	18	16.5	
Quit smoking							
Yes	19	43.2	20	39.2	39	41.1	0.8346
No	25	56.8	31	60.8	56	58.9	

Note. CBT = cognitive-behavioral therapy; GHE = general health education.

None have demonstrated results that demonstrate substantial impact.

UK UNIVERSITY OF KENTUCKY College of Medicine

These studies have a range of methodological and practical limitations.

1) Some have been too small to identify effect
2) Some have lacked pharmacotherapeutic arms or behavioral support arms (or combined arms)
3) Some have lacked appropriate controls
4) Most have been conducted at tertiary care cancer centers

UK UNIVERSITY OF KENTUCKY College of Medicine

Aims

- To identify an efficacious, implementable cessation strategy for lung and head and neck cancer patients undergoing cancer therapy in Kentucky cancer centers.
- To assess the feasibility of routinely implementing an array of smoking cessation strategies for this population.
- To deliver high quality smoking cessation to all subjects.

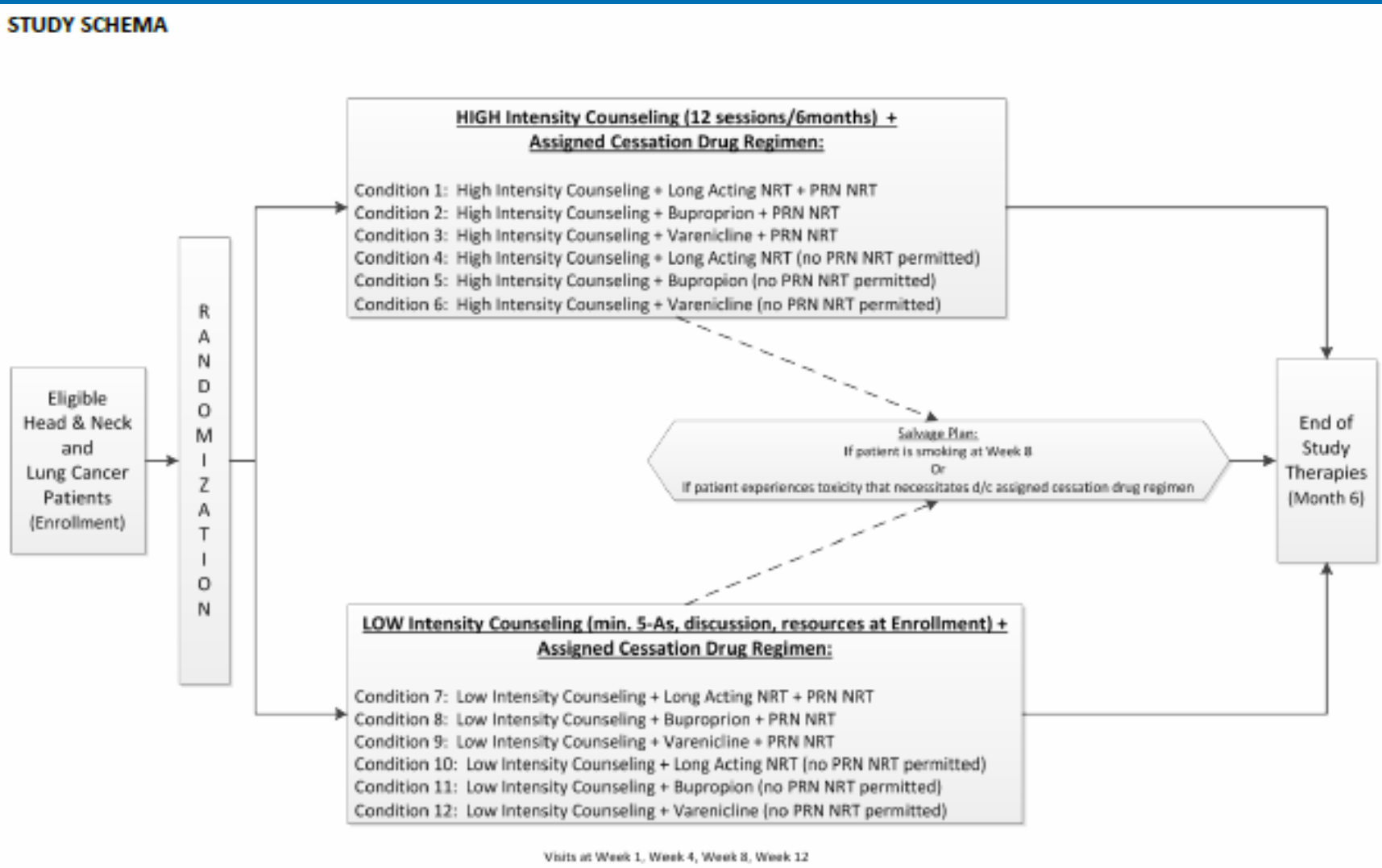
UK
UNIVERSITY OF KENTUCKY
College of Medicine

Methods

- Employ a Multiphase Optimization Strategy (MOST) approach to study design
- Conduct study in partnership with the Kentucky Clinical Trials Network (KCTN)
- Evaluate tobacco cessation outcomes using both patient-reported outcomes and biochemical verification (CO)

UK UNIVERSITY OF KENTUCKY College of Medicine

Study Protocol → MOST



Kentucky
Clinical Trials Network

- Kentucky Lung Cancer Research Program (KLCRP):
  - Established 2000 by Kentucky General Assembly to stimulate research in lung cancer. (KRS 164.476)
- KCTN: Provide innovative clinical trials, support and education for our research centers and scrupulous quality assurance.
- Alliance of physicians conducting trials in the prevention, early detection, and treatment of lung cancer.
- Multidisciplinary: medical oncologists, CT surgeons, pulmonologists, radiation medicine, cancer control, behavioral science, pharmacy.

Kentucky
Clinical Trials Network

- Sites located in every federal congressional district
- Research at Home: Patients remain in their community
- Physicians:
  - Opportunity to conduct clinical trials, expand research enterprise, pick & choose studies that support research goals and serve patient populations, from balanced study pipeline.
  - Expand IITs to multi-site
- Conduct investigator-initiated and industry sponsored trials. Phases I – IV
- Study Portfolio
  - Therapeutic Intervention, Screening Intervention,
  - Non-Interventional - epidemiologic, observational, behavioral, biospecimen

Kentucky
Clinical Trials Network

- Coordinating Center, housed at Markey Cancer Center, liaison between sponsors and network investigators, facilitating operations:
    - Site Membership
    - Study & Site Selection
    - Network Committee & Data Safety Monitoring Committees
    - Research Education & Training
    - Monitoring & Quality Assurance Auditing
    - Data Management
    - Project Development & Management
    - Centralized Recruitment Support
    - Contract & Budget Negotiation
    - Regulatory; support, Central IRB

- Study Chair Support :

  - Assist to meet GCP & CFR responsibilities of Sponsor-Investigator (21 CFR 312.3)

    - ✓ Select Qualified Investigators (21 CFR 312.50)
    - ✓ Inform Investigators (Safety, Amendments, Ongoing Progress)
    - ✓ Select Qualified Monitors & Ongoing Review of Investigation
    - ✓ Maintain Adequate Records (Safety, FD, TMF)
    - ✓ Assure IRB Reviews

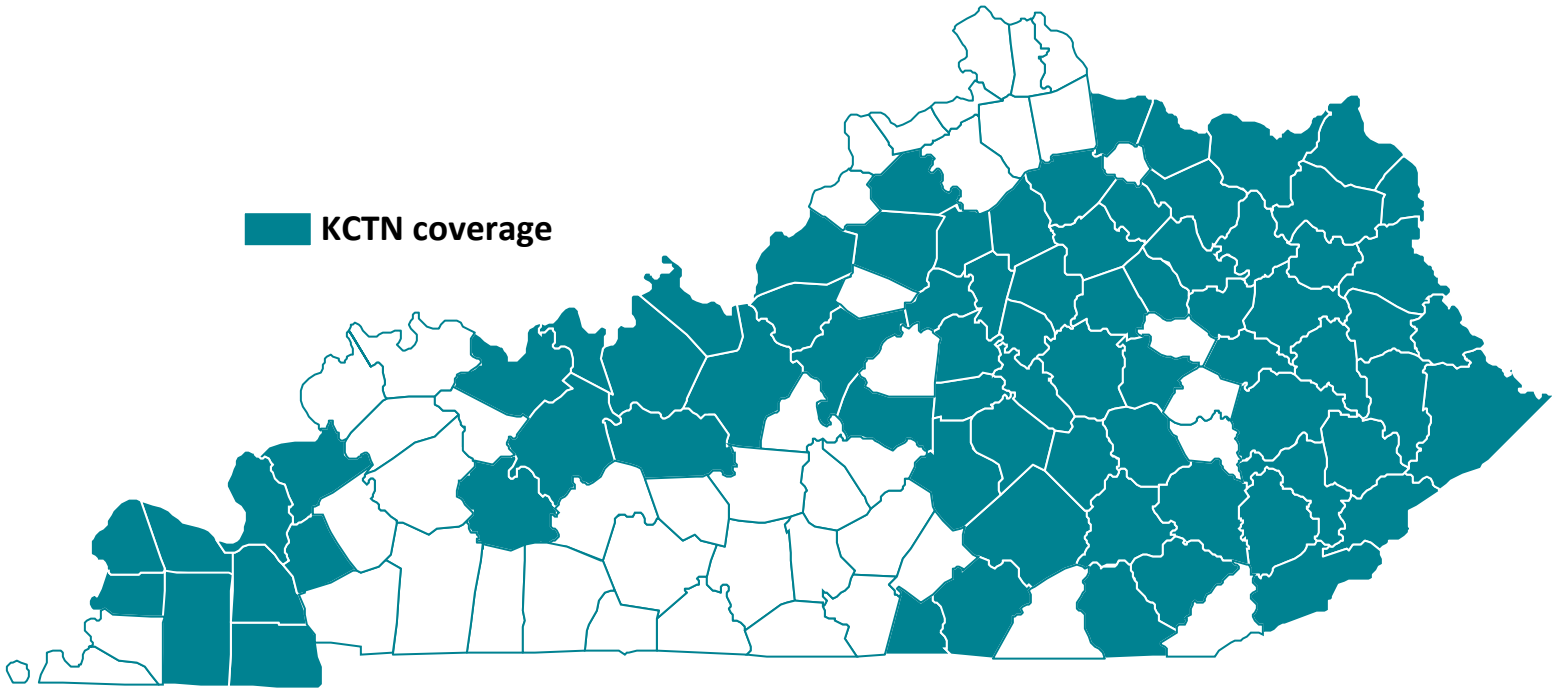
  - Project Planning Teams: develop trials with insight to community-based sites, while maintaining integrity and scientific value of projects.

- Member Commitments:

  - ✓ Compliance with applicable Code of Federal Regulations (CFR)
  - ✓ Compliance with Good Clinical Practices (GCP) - assures that the rights & safety of study subjects are protected and integrity of study data.
  - ✓ Belmont Report:
    - Respect for Persons, individual treated as autonomous agent and those with diminished autonomy (vulnerable) are entitled to protection.
    - Beneficence – DO NO HARM - minimize harm, maximize benefits and well being. Obligations of beneficence apply to individuals and society as a whole.
    - Justice – fair distribution of benefit and risks
  - ✓ Institutional Assurance (FWA) & IRB Registration:

Kentucky
Clinical Trials Network

- 1,817 Subjects, in 75/120 counties (63% of state).
  - Strong engagement to IITs
  - 1,574 subjects to IITs



Cessation Outcomes

- Clinician Reported Procedures & Outcomes
- Patient-Reported Outcomes
  - Tobacco use/cessation
  - Psychosocial moderators
    - anxiety, depression, social support
  - Quality of Life/Symptoms (FACIT)
  - Others
- Biochemical Verification
  - carbon monoxide

Study Strengths

- Innovation
  - MOST approach to trial design
  - Generalizability of sample

- Significance
  - Focus on high risk group where impact is quick
  - Generalizability of sample and setting
  - Preparation for strong RCT

UK
UNIVERSITY OF KENTUCKY
College of Medicine

Kentucky
Clinical Trials Network

MOST Cessation Participating Sites:

1. UK, Markey Cancer Center:	Valentino & Studts
2. UL, Brown Cancer Center:	Perez & Kloecker
3. Lexington VAMC:	Valentino
4. Norton Cancer Institute - Louisville:	Davis
5. Owensboro Health:	Faught
6. Baptist Health Paducah:	Gould & Lopez
7. Harding Memorial Hospital – Elizabethtown:	Lye
8. Hazard ARH – Hazard:	Elsoueidi
9. KY Cancer Clinic – Hazard:	Ghazal
10. St. Claire Regional Medical Center – Morehead:	Lim
11. King's Daughters Medical Center – Ashland:	Goebel
12. St. Mary's Medical Center, HIMG – Huntington, WV:	Bir