

BMSF Grant:
**C3: Lung Cancer Prevention and
Early Detection**

Lung Cancer Prevention and Early Detection
Network Meeting

October 17, 2014

Drs. Tim Mullett and Jennifer Redmond Knight

Framework of Overall Lung Cancer Survivorship Program

- Administrative Core
 - Led by Jamie Studts, PI
- Component 1: Provider education
 - Led by U of L
- Component 2: Survivorship Care
 - Led by UK
- Component 3: Prevention and Early Detection
 - Led by UK

Purpose of C3: Prevention and Early Detection

- Facilitate lung cancer care by helping lung cancer screening programs implement best practices in lung cancer screening
 - 10 sites
 - High quality screening to high risk individuals
 - Shared decision making
 - Incorporating care coordination pathways and patient navigation
 - Incorporating tobacco treatment, reduce exposure to second-hand smoke, radon prevention

Timeline

- January 21, 2014
 - Catherine Grimes from Bristol Myers Squibb Foundation and David Richwine, Bristol Myers Squibb and Kentucky Cancer Consortium (KCC) member met with small group of Kentucky Cancer Consortium members identified by BMSF to discuss lung cancer survivorship grant opportunity
- February 21, 2014
 - KCC convened small group to develop overall plan and idea for BMSF lung cancer grant application. Determined 3 components and leadership for grant
- March 2014
 - Component leaders worked on proposed sections and plans
- April 2014
 - Component leaders continued work on proposed sections, plans, budgets and began participating in weekly planning conference calls. Requested letters of support from potential participating sites throughout Kentucky

Timeline Continued

- May 2014
 - Continued work on grant, finalized plans, budgets, letters of support
- May 28, 2014
 - Grant was submitted to BMSF
- June 6, 2014
 - Answered questions and provided re-organized budgets to BMSF
- June 24, 2014
 - Catherine Grimes, BMSF, presented the Kentucky Lung Cancer Survivorship grant to the BMSF board who approved funding the overall project with \$7 million over 3 years

Timeline Continued

- June 30, 2014
 - Submitted revised application based on BMSF requests, changes to budgets, etc.
- July 14, 2014
 - Submitted additional revisions into a truly final document for BMSF
- August 11, 2014
 - Welcome call from BMSF to component leaders. Discussion of press announcements and plans
- August 12, 2014
 - Provided email notification to Medical Advisory Board and component 3 participants
- August 14, 2014
 - Catherine Grimes with BMSF announced grant award and CDC Comprehensive Cancer Control Program Director's Meeting

Timeline Continued

- August 27, 2014
 - C3 leaders met to plan for next steps, hiring, deliverables
- September 1, 2014
 - Planned start date for BMSF grant
- September 19, 2014
 - Signatures completed; Announced BMSF grant start to KCC Lung Cancer Prevention and Early Detection Committee
- October 3, 2014
 - C3 leaders plan for first overall C3 team meeting
- October 17, 2014
 - C3 team meets for the first time

Roles and Responsibilities for C3

- Timothy Mullett
 - Co-PI for C3, Clinical and research leadership and expertise, leads development of study protocol, site visit teams, screening database, assures quality development, implementation and analysis of the project. Facilitates the Medical Advisory Board (MAB).
- Jennifer Redmond Knight
 - Co-PI for C3, Strategic planning, organization and communication leadership, facilitation and management of project. Facilitates the Community Advisory Board, which is the KCC Lung Cancer Prevention and Early Detection Network.

Roles and Responsibilities: C3

- Kris Damron
 - Kentucky Clinical Trials Network liaison. Provides assistance in strategic planning, development and administration. Oversees program operations and staff, site recruitment, assessment, auditing and contract management. Leads development of management, data, monitoring and communication plans to assure quality management
- Joseph “Trey” Alexander
 - Project Coordinator. Primary liaison between participating sites and project team, day-to-day coordination including: communication, logistics, organization, budget, materials, reports and meetings

Roles and Responsibilities: C3

- Jamie Studts
 - PI of the overall BMSF project, PI of the Survivorship Component (C2), Co-I of C3. Overall vision and connection to all components, oversight for the referral pathways to high-quality care, tobacco treatment and shared decision making expertise
- Michael Brooks
 - Co-I for C3, provides medical and clinical consultation, particularly supporting sites who do not have capacity to review low dose CT screens in house. Serves on MAB

Roles and Responsibilities: C3

- Dana Lee
 - University of Louisville, Co-I for C3, Thoracic Oncology Navigator. Provide technical assistance to sites for screening program elements, checklists and best practices. Participate as member of site visit team.
- Amy Copeland
 - Lung Cancer Alliance, Director of Medical Outreach. Provide technical assistance and expertise in National Framework for Lung Cancer Screening Excellence and Continuum of Care. Will provide support in development, testing and implementation of lung cancer screening in participating sites.
- John Hamm
 - Norton Cancer Institute, Co-I. Liaison with Norton Cancer Institute. Provides support in the development and implementation of best practices for lung cancer screening in diverse healthcare settings

Roles and Responsibilities: C3

- Lara Sutherland
 - Clinical Project Data Manager (Screening Registry). Database design, validation, quality control. Develop and manage Clinical Project Data Management and Quality Management Plans. Provides technical and training of project team and sites on database, data entry and good data handling practices. Works closely with informatics, statisticians and is jointly funded by this and KCTN.
- Informatics
 - TBD. Eric Durbin will name lead person to provide database platform support and support for merging data sets to link to the Kentucky Cancer Registry. Will work closely with Clinical Project Data Manager.
- Research Assistant
 - TBD. Support for research, including regulatory start-up and maintenance of participating sites, including IRB submissions, organizing and maintaining the project files. Research and support liaison with sites. Assists clinical project data manager and project coordinator with coordination of research efforts.

Roles and Responsibilities: C3

- Medical Advisory Board
 - Clinical and subject matter experts. Will review, advise and provide technical support for prevention and early detection efforts. Convene 2 times/year. Responds to specific medical/screening/prevention issues within sites
 - R. Douglas Adams (Owensboro)
 - Eric Bensadoun (UK, Lung Cancer Screening Program)
 - Michael Brooks (UK, Radiologist)
 - Roberto Cardarelli (UK, Kentucky Ambulatory Network, PCP)
 - Ellen Hahn (UK, Kentucky Center for Smoke-free Policy and Clean Indoor Air Partnership)
 - Goetz Kloecker (U of L), Co-PI of Component 1 (Provider education), Surgery, Oncology, Hematology

Roles and Responsibilities: C3

- Community Advisory Board
 - Kentucky Cancer Consortium (KCC) Lung Cancer Prevention and Early Detection Network
 - Provides feedback and insight on development and implementation plans
 - Supports education, outreach and dissemination of C3 deliverables
 - Builds partnerships and encourages community participation in C3 efforts

Roles and Responsibilities C3:

- Consultants
 - Nationally renowned experts in lung cancer prevention and early detection who will provide subject matter expertise, review and feedback for the project
 - Lung Cancer Alliance Medical and Professional Board Representative (TBD). Will be recruited by Amy Copeland.
 - Northwest Arkansas Lung Cancer Screening Program at the Center for Chest Care. First community-based multi-disciplinary chest care clinic in the U.S. and meets the Lung Cancer Alliance “Screening Centers of Excellence” criteria

Project Activities and Deliverables:

Prevention & Early Detection (C3/P&ED):

Year 1: C3/P&ED Development Phase

Project Activities and Deliverables: Prevention & Early Detection (C3/P&ED):

Year 1: C3/P&ED Development Phase

- 1) Conduct bi-weekly team meetings via videoconferencing.
- 2) Conduct quarterly face-to-face meetings.
- 3) Develop process and site visit templates for working with prevention and early detection participating sites.
- 4) Develop guidelines and definitions around stratification of sites.
 - a. Tier 1 – Initiating
 - b. Tier 2 – Developing
 - c. Tier 3 – Established
- 5) Develop checklist and site visit materials based on National Framework for Excellence in Lung Cancer Screening and Continuum of Care to evaluate identified lung cancer screening programs.
- 6) Develop Lung Cancer Screening Excellence in a Continuum of Care Manual as a resource for centers identified in Tier 1 (initiating) and Tier 2 (developing) and Tier 3 (established) phases of implementation.
 - a. Includes information on follow-up care for negative screens by address anxiety and stigma issues that adversely impact program retention following false positive results.
 - b. Providing referrals to high-quality lung cancer treatment and survivorship programs.

Year 1: C3/P&ED Development Phase

- 7) Develop Tobacco Treatment Best Practice Training/manual targeting those at risk for lung cancer, those diagnosed with lung cancer and caregivers of those diagnosed with lung cancer.
 - a. Developing and testing tailored tobacco treatment programs for patients receiving various lung cancer screening results (positive, negative, and indeterminate) as well as caregivers or family members of program participants.
- 8) Develop secondhand smoke educational information to be used at participating sites/communities.
- 9) Develop radon prevention educational information to be used at participating sites/communities.
- 10) Develop resources that support increasing awareness and decreasing stigma related to lung cancer prevention and early detection in order to create a more nurturing and supportive environment for care.
- 11) Develop database and screening program registry to be utilized by all participating sites.
- 12) Explore synchronization of Kentucky data and screening program registry with the International Early Lung Cancer Action Program data registry or other identified national registry as appropriate.
- 13) Develop process for negotiating ways for each site to spend their stipends.

Year 1: C3/P&ED Development Phase

- 14) Develop in-depth Continuing Education modules for lung cancer screening program implementation with CE Central.
- 15) Develop outcome measures and evaluation methods for each continuing education module.
- 16) Present and discuss development plans to KCC Lung Cancer Prevention and Early Detection Network, who serves as the Community Advisory Board for this component.
- 17) Present and discuss development plans to Kentucky Cancer Program Regional Cancer Control Specialists.
- 18) Present and discuss development plans with Medical Advisory Board through a video conference.
- 19) Finalize external advisory panel of national experts for consultation during the project.
- 20) Develop a Project Communication Plan for overall prevention and early detection effort. Maps out and defines the communication structure, escalation paths, methods, timelines for the Management of the Project with the entire Project Team. Coordinate with other components.
 - a. Develop a listserv for lung cancer screening program patient navigators in order to connect and share best practices among sites located throughout the state.

Year 1: C3/P&ED Development Phase

- 21) Develop a Marketing/External Communication Plan for overall prevention and early detection effort. Coordinate with other components.
 - a. As part of communication plan, develop Public Service Ad campaign on risk, screening and where to be screened responsibly in Kentucky targeting key urban and high-risk rural communities.
 - b. Complete Lung Cancer Alliance website enhancements to include manual, listing of Kentucky Centers of Excellence and updates on coverage and reimbursement
- 22) Submit 1 national conference presentation.
- 23) Attend a national conference and host the in-person Medical Advisory Board meeting.
- 24) Conduct 1 national expert consultant visit (development).
- 25) Submit 1 scholarly manuscript.
- 26) Complete component evaluation report – internal.

Project Activities and Deliverables:

**Prevention & Early Detection (C3/P&ED):
Year 2: C3/P&ED Development Phase**

Year 2: C3/P&ED Implementation Phase

- 1) Conduct bi-weekly team meetings via videoconferencing.
- 2) Conduct quarterly face-to-face meetings.
- 3) Achieve 10 implementation sites for the Lung Cancer Prevention and Early Detection Program and assign them to “tiers.”
 - a. Ensure that 100% of screening centers identified as Tier 3 are included as LCA Screening Centers of Excellence.
- 4) Enroll 50 participating providers to provide lung cancer screening.
 - a. Establish screening “champions” based on practice patterns.
 - b. Track “lessons learned” from screening providers.
- 5) Conduct site visits with each participating site and develop tailored site assessment reports.
- 6) Provide technical assistance and negotiation of stipend for each site to spend based on site assessment reports.
- 7) Develop and implement media plan that focuses on the enrollment of these sites and communities as well as the project overall (includes press releases, media events, etc.).
 - a. Roll out public service ads on risk and screening in partnership with providers in key markets.
 - b. Provide technical support to Kentucky Cancer Program Regional Cancer Control Specialists in promoting this effort to their District Cancer Councils.

Year 2: C3/P&ED Implementation Phase

8) Promote utilization of continuing education credits and modules among implementation sites.

9) Enroll 50 participating providers to provide tobacco treatment, secondhand smoke and radon prevention education.

10) Evaluate outcomes of continuing education modules.

11) Maximize site-level participation in the screening database.

12) Achieve 4 sites who incorporate lung cancer screening questions in their Electronic Medical Records.

13) Maintain KCC Lung Cancer Prevention and Early Detection Network as Community Advisory Board and conduct one in-person meeting solely focused on implementation discussion.

14) Present and discuss implementation efforts with Medical Advisory Board through a video conference.

Year 2: C3/P&ED Implementation Phase

- 15) Conduct 1 national expert consultant visit (implementation).
- 16) Submit 1 national conference presentations.
- 17) Attend a national conference and host the in-person Medical Advisory Board meeting.
- 18) Submit 1 scholarly manuscripts.
- 19) Complete 1 component evaluation report – internal.

Project Activities and Deliverables:

**Prevention & Early Detection (C3/P&ED):
Year 3: C3/P&ED Development Phase**

Year 3: C3/P&ED Implementation Phase (cont.) and Evaluation Phase

- 1) Conduct bi-weekly team meetings via videoconferencing.
- 2) Conduct quarterly face-to-face meetings.
- 3) Ensure that each site that began as a Tier 1 or 2 site moves to the next Tier, or even to Tier 3, and those who began at Tier 3 will maintain that status for the Lung Cancer Prevention and Early Detection Program.
 - a. Ensure that 100% of screening centers identified as Tier 3 are included as LCA Screening Centers of Excellence.
- 4) Develop and implement media plan that focuses on the outcomes achieved by these sites and communities as well as the project overall (includes press releases, media events, etc.).
 - a. Roll out public service ads on risk and screening in partnership with providers in key markets.
 - b. Provide technical support to Kentucky Cancer Program Regional Cancer Control Specialists in sharing outcomes related to this effort to their District Cancer Councils.
- 5) Promote utilization of continuing education credits and modules.
- 6) Enroll 80 participating providers to provide tobacco treatment, secondhand smoke and radon prevention education.
- 7) Evaluate outcomes of continuing education modules.

Year 3: C3/P&ED Implementation Phase (cont.) and Evaluation Phase

- 8) Achieve 90% site participation in screening database.
- 9) Achieve 6 sites who incorporate lung cancer screening questions in their Electronic Medical Records.
- 10) Achieve completion of pilot data synchronization into national registry identified during year 2 exploration process.
- 11) Maintain KCC Lung Cancer Prevention and Early Detection Network as External Advisory Board.
- 12) Conduct 2 national expert consultant visits (program evaluation – training evaluation).
- 13) Conduct 4 State/Regional Training Programs based on lessons learned from the sites to encourage other sites and communities to consider these best practices.
- 14) Work with KCC to revise state cancer plan to be a model for lung cancer that includes screening and its entire continuum of care.

Year 3: C3/P&ED Implementation Phase (cont.) and Evaluation Phase

- 15) Conduct 1 national expert consultant visit (implementation and evaluation).
- 16) Submit 1 national conference presentation.
- 17) Attend a national conference and host the in-person Medical Advisory Board meeting.
- 18) Submit 1 published manuscripts on outcomes of a state-wide screening initiative.
- 19) Complete 1 final component evaluation report – internal.

Subgroups

- Potential subgroups for C3 team:
 - Project Management, Clinical, Education, Marketing, Site Assessment/Implementation Team, Data Management?

Draft Internal Communication Plan

- C3 Leadership (Tim, Jennifer, Kris, Trey)
 - Weekly teleconference/email check in
- Co-Investigators (Jamie, Mike, Dana, Amy, John)
 - Frequency? Method?
- Subgroups (Screening Registry/Clinical, Sites, others??)
 - Frequency? Method?
- Medical Advisory Board (Doug, Eric, Mike, Roberto, Ellen, Goetz)
 - 2 times/year
- Lung Cancer Prevention and Early Detection Network
 - 2 times/year
- Consultants
 - 1 time/year
- Sites
 - Frequency/method?