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IRB Approval: September 9, 2020

NCT04763824

Protocol and Statistical Analysis Plan

Study Title: KANSURVIVE: TESTING A MODEL FOR IMPROVING CANCER SURVIVORSHIP CARE IN RURAL PRACTICE

Principal Investigator: JENNIFER KLEMP, PHD, MPH AND ALLEN GREINER, MD, MPH

Co-Investigator(s): EDWARD ELLERBECK, MD, MPH, CHRISTIE BEFORT, PHD, EVE-LYNN NELSON, PHD, ANNE O'DEA, MD

University of Kansas Medical Center
RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS

Version date: 7APRIL2021

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Purpose, Background and Rationale

A. Specific Aim and Hypotheses

While evidence-based practice (EBP) guidelines exist (1) for cancer survivorship care, implementation in rural practices has fallen short. Approximately 72.5% of Kansas cancer survivors who have completed their cancer treatment receive a majority of their health care from Primary Care Providers (2), yet these providers describe a lack of basic awareness of risk-based surveillance, effects of cancer treatment and their management, as well as inadequate resources, and growing administrative demands
as reasons for not working to improve survivorship care (3). These factors may also prevent shared care management of cancer survivors between primary care and rural oncology care providers. There is a pressing need to understand primary care practice capacity to implement guideline informed management and follow-up for cancer survivors in the acute and extended phases of care. (4) To address this need, we adapted an in-clinic 4 session cancer survivorship educational curriculum, which resulted in change in knowledge but not in practice (5). We then piloted an updated in-person curriculum plus basic practice facilitation training model in seven primary care practices across Kansas to establish feasibility and acceptability within our network. Our program adaptation (KanSurvive) was also based on needs identified during focus groups (3) with rural practice providers and staff and included help with formal identification of survivors within the practice, ability to access and incorporate evidence-based practice (EBP) guidelines in care management, and for a more comprehensive understanding of the risks of cancer treatment. However, participants in KanSurvive reported interest in receiving more case-based examples, access to survivorship specialists, and ongoing quality improvement (QI) support to implement EBP guidelines in hectic rural practices. (3) The Project Extension for Community Healthcare Outcomes (ECHO), (6), provides a telementoring approach that addresses many of the limitations that we encountered with our preliminary work. Through an interactive "community of practice" and case-based learning, ECHO includes identification and support of practice-champions; sharing "how-to"/workflow lessons across rural practices; reinforcement of KanSurvive QI and electronic health record (EHR) processes; ongoing facilitation using checklists; and ongoing support from survivorship experts and rural provider peers. Thus, we propose to blend our in-person curriculum ad practice facilitation with ECHO telementoring to increase the "dose" of implementation support, lead to a sustainable "community of practice" and promote better adoption of EBPs. In this project, we will recruit 20 rural primary care practices to participate in a delayed intervention-controlled trial. We will start by conducting more formal and structured work flow evaluations to better identify specific gaps in processes of care while assessing what on-going training is needed for adoption of high-quality cancer survivorship care in rural practice. These will be incorporated into the ECHO sessions (Aim 1). We will then test the effectiveness of the novel KanSurvive-ECHO intervention (Aim2) and finally identify barriers and facilitators to implementation of KanSurvive-ECHO (Aim 3). Specific Aim 1. Formally assess gaps in processes of care and additional training needed to result in actual adoption of high-quality care for acute and chronic survivors of breast, colorectal, lung, and prostate cancer in 20 rural primary care practices. Utilize this formative information to further refine the KanSurvive-ECHO.
Specific Aim 2. Evaluate the effectiveness of KanSurvive-ECHO for enhancing evidence-based survivorship care for rural breast, colorectal, lung, and prostate cancer survivors. Hypothesis: Compared to delayed intervention control, rural primary care practices randomized to KanSurvive-ECHO will demonstrate greater concordance with evidence-based survivorship care guidelines as measured by a composition score determined by change in EHR documentation consistent with guideline concordant care.

Specific Aim 3: Utilizing the Integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework (6) describe key facilitators and barriers to implementation of KanSurvive-ECHO including innovation, recipients, context, and facilitation. This novel project will provide a model for development of a community of practice using practice facilitation and Project ECHO to improve the management and follow-up of cancer survivors in the acute and extended phases of cancer survivorship.

B. Background and Significance

Access to Acute and Extended Survivorship Care in Rural Cancer Survivors: In Kansas (82,279 miles^2 and the 15th "largest" state by area), 26% of the population lives in designated rural counties, and the rural population is spread out over 99% of the land area. Multiple factors such as limited availability of cancer treatments and providers, distance and transportation, financial issues and insurance status, and cultural and language barriers in rural Kansas impact the quality of cancer care and produce rural/urban cancer disparities. Many cancer patients living in rural areas go undiagnosed or are diagnosed with late stage disease, often due to difficulties accessing specialty oncology care services.(1, 2) Accessing cancer care is a more involved process for rural patients, who may have to drive significant distances or wait for oncology care teams to travel to their community hospital on an infrequent basis (monthly or bi-monthly).(3) Outreach to rural communities over the last twenty years has kept patients closer to home, with an increase in the rate of chemotherapy administration among rural patients from 10% to 24% (Ward MM, Ullrich F, Matthews K, et al). However, intermittent availability of visiting oncologists, limited teleoncology adoption due to reimbursement gaps, and lack of access to the full interprofessional oncology care team may not meet the needs of all cancer patients, may lead to treatment delays, and puts more of the day-to-day patient care on locally available primary care teams.(3, 4) On the upside, there has been a significant increase in the overall number of cancer survivors living with and through their disease, but many have more than one primary cancer (Figure 1),(5, 6) and approximately 72.5% of cancer survivors in Kansas who have completed their cancer treatment receive a majority of their health care from Primary Care Providers (5), thus increasing the importance of rural primary care providers engaging in the acute (during treatment) and extended phases (post-treatment) of survivorship care. (7, 8)

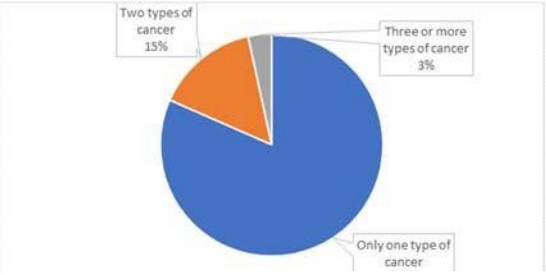


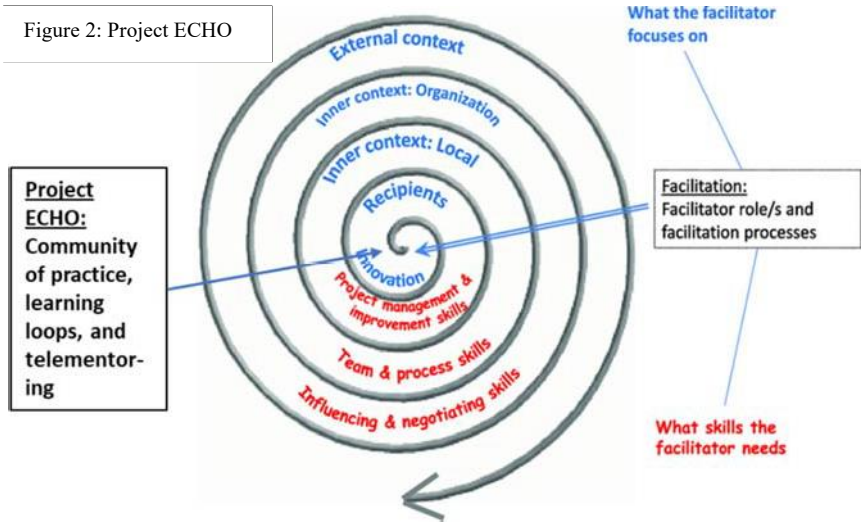
Figure 1: Cancers in Kansas Survivors

A1. Gaps in Knowledge, Attitudes, and Practice: Primary care providers may not feel adequately prepared or informed to handle survivorship needs, (7, 9, 10) particularly in rural settings with limited access to oncology colleagues. Preliminary data suggests that cancer survivors in these settings are not receiving appropriate guideline-based services, are less likely to participate in clinical trials, and have overall worse survival outcomes. For instance, in a large CMS population of women within 10-years of a breast cancer diagnosis, screening mammography rates dip to almost 60%. (11) Rural primary care practices have limited capacity and few incentives to implement guideline concordant cancer survivorship care. It is also unclear whether practices are aware of survivorship care deficiencies and if they have received survivorship care plans (treatment summary plus follow-up recommendations) from oncology providers. Even in the most innovative practices, survivorship care is unlikely to be incorporated into routine follow-up care unless it is recognized as a distinct clinical category and is supported by a functional information systems infrastructure. (12)

A2. Importance of an implementation and dissemination framework to guide all study activities. Applying research advances to address the needs of cancer survivors in real world settings is complex. Because primary care practices have few incentives to prioritize cancer survivorship care, improving outcomes for these patients may be difficult to achieve. There are few investigations of the impact of implementation strategies on the uptake of evidence-based practices (EBPs) by primary care providers managing cancer survivors. Our project seeks to fully understand these difficulties across rural settings and includes both formative and intervention effectiveness testing activities. We propose a two-phase approach to developing and testing implementation strategies to support uptake of EBPs for cancer survivorship. During all phases of the project, data collection and analysis will be guided by an implementation and dissemination framework. This will allow us to systematically address "which practices and why" the KanSurvive intervention has influence. During recent decades as practice facilitation and other quality improvement strategies have been deployed to improve outcomes in primary care, scholars have found the need to more closely analyze how practices think, act and organize improvement efforts. (13) Clearly, practices and health care systems are complex systems that may have many reasons for adopting or not adopting research advances or evidence-based guidelines. Facilitators and barriers to adoption are important but a more holistic framework may be crucial to evaluation in such settings. The Integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework will guide both the formative and intervention

effectiveness components of our project (14). Within the i-PARIHS framework there are four core components of successful implementation. We adapted Harvey & Kitson's framework to include Project ECHO (Figure 2). Key elements include: innovation, recipients (individual and collective), context (inner and outer), and facilitation.

Figure 2: Project ECHO



According to the i-PARIHS developers (14), the more positively the components of an intervention affect each domain, the more likely primary care practices are to routinize a new and improved way of delivering care, such as EBP. To be effective, practice-improvement projects must make rational changes to workflows and explain to users their benefits and purposes. The facilitation process must convince recipients that alterations will deliver innovation while tending to the internal and external context of the practices. Facilitation strives to minimize not only internal and external barriers to adoption of new systems of care but also the effects of these systems on users' roles and responsibilities. Qualitative assessments have indicated that complex interventions become routine practice when they are perceived to improve patient-provider interactions and care-team interactions. (15) Our formative activities will help us better understand the four components of i-PARIHS as they pertain to cancer survivorship care improvement and these key interactions. They will also help us further refine our intervention to maximize its positive influence on the four i-PARIHS components. Throughout the study, we will use an i-PARIHS guided process evaluation to determine how well our intervention is succeeding or failing. This process evaluation will help us understand which intervention components are working well, as well as the implementation facilitators and barriers that practices experience as they attempt to alter survivorship care. We posit that with a successful intervention, implementation occurs when practice facilitation leads to the acceptance and deployment of an innovation that fulfils recipients' needs and is tailored to the specific context of the practice. The process evaluation will use observational and interview data to examine these four components, adapting the intervention as necessary. Process evaluation questions will be developed based on prior i-PARIHS structured interventions. (16, 17)

Practice facilitation. Through more intensive practice facilitation onsite and through ECHO activities, we aim to improve care delivery by creating an ongoing, trusting relationship between all practice staff and an expert facilitator who will help clinic staff redesign workflows and improve quality.(18) This promotes a clinical culture of learning, consensus building, goal setting, quality improvement, and achievement, as demonstrated by the Institute for Healthcare Improvement's Learning Collaborative Breakthrough Series,(19) (20). One study using similar methods, the EPIC cluster randomized trial, used a practice facilitation intervention to produce a 100% increase in diabetic patient foot examinations, compared to a 33% increase in a control arm, which used self-directed provider education for quality improvement.(21) Rural clinics in this study will use brief plan-do-study-act cycles, to improve clinic and provider adherence to cancer survivorship care guidelines. The steps involved include: 1) practice-level discussion until reaching consensus on a specific, measurable, quality-improvement goals for using electronic health records (EHRs) to improve survivorship care clinical performance; 2) identifying barriers to implementation in achieving the goal; 3) selecting one or more changes to improve the status quo in survivorship care; 4) instituting these changes; and 5) measuring change in provider and clinic performance via assessments of EHR change for cancer survivors in the practice. In successive cycles, practice staff will brainstorm ways to overcome emerging barriers to achieving plan-do-study-act goals. We will support this process using visiting practice facilitators assigned to rural primary care practices. Facilitators will be trained and certified using the University of Buffalo Practice Facilitator online training program (22) and will be selected and assigned based on previous experience working with rural teams. Practice facilitators will in turn train practice staff to use a consistent approach for quality improvement work and workflow redesign. Facilitators will communicate at least weekly with a clinic-designated nurse or practice manager in each rural study practice (the Practice Champion), and at least monthly with a clinic physician designated as the Practice Lead. The role of the Practice Champion and Lead will be to legitimize the intervention in their clinics, assist with training/orientation of other clinicians and clinic staff, and ensure response to facilitators and EHR data being fed back to practices. The Facilitator will aim to maximize inter-professional impact by coaching Practice Champions and Leads to use a team-building, collaborative approach adapted to the organizational context of each practice. Facilitators will

not provide clinical care directly but will coach the Practice Champion and other practice staff (the "Practice Improvement Team") to solve problems and build improvement into routine clinical operations.

Prior studies have shown that practice improvement teams are able to effectively recruit others to take part in IT-related quality-improvement projects. (23)

A4. Building an ongoing "community of practice." Practice facilitation does not utilize approaches that leverage practice-to-practice interaction, resulting in inefficiencies and missed shared learning opportunities. Practices work in isolation with facilitators to make change. Opportunities for co-learning, sharing best practices between peers and benchmarking may be missed when practices work to make improvements in isolation. A "community of practice" is a group of practices working in some joint fashion to improve the care they deliver. They work as a group to help each other and proceed through improvement cycles together. The Project Extension for Community Healthcare Outcomes (ECHO) telehealth approach was developed as a virtual method for developing a community of practice for rural practice groups. The model expands primary care provider (PCP) capacity to manage complex diseases by sharing knowledge, disseminating best practices, and building a community of practice. Project ECHO originated when Arora, et al. (24) completed a randomized trial showing rural primary care physicians were able to launch hepatitis C treatment programs and achieve the same outcomes as academic center-based hepatologists. This work demonstrated ECHO's ability to support practice change and best practice adoption in rural primary care. In 2016, Zhou et al., (25) completed a systematic review of 39 studies, which addressed 17 different medical conditions and found that these studies support the ECHO model's effectiveness in improving the knowledge (n = 4) and self-efficacy of participating PCPs (n = 8), as well as changes in provider behavior (n = 1), improved patient outcomes (n = 7), and cost-effectiveness (n = 2). Project ECHO's mission is to democratize knowledge and decrease health disparities across underserved populations. (26) A facilitator assists throughout ECHO sessions by advancing engaged discussion between the hub team and spokes and between spoke sites. The ECHO model has been extended to include additional health care expertise on the specialist team at the hub site in order to support primary care practice needs, including expertise/supports across quality improvement, health information technology, and patient-centered care/health literacy support. Serhal et al. (27) describe the educational theory supporting ECHO, summarizing "the ECHO model uses both situational and social cognitive learning theories and enables participating primary care practices to identify learning gaps (cognitive dissonance) and reflect critically on their learning process.(24, 27-29) Project ECHO allows for problem-centered learning to occur in the clinical context where new knowledge will be applied; promotes interprofessional collaboration among participants; models best-practice care; supports learners to feel that they are benefiting and improving self-efficacy; and allows participants to receive positive feedback and reinforcement from clinical opinion leaders." The Project ECHO model (University of New Mexico figure below) has rapidly expanded in recent years, with over 140 international ECHO projects covering a range of chronic diseases (hepatitis C, HIV/AIDS prevention, behavioral health and addiction medicine, chronic pain management among others).

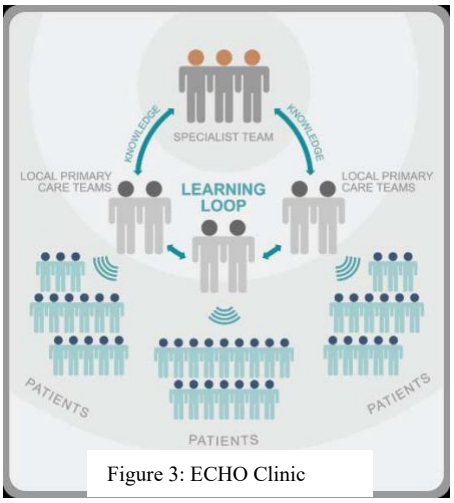


Figure 3: ECHO Clinic

Through regularly scheduled virtual clinics (Figure 3), Project ECHO creates a supportive community network where rural primary care teams can connect with specialists and with other providers practicing in similar settings via multipoint video technology to discuss best practices in care and complex cases managed within their practice. This multifaceted knowledge and capacity-building intervention includes three components: a didactic lecture delivered by a member of the hub team (based on curriculum developed from guidelines, best practices, and/or a needs assessment); recommendations for case management (telementoring) offered by the community in response to anonymized clinical cases presented by spoke sites; and in some cases, review and reinforcement of practice quality improvement approaches in implementing best practices. Low-cost, user-friendly ECHO technology (secure Zoom videoconferencing) leverages scarce healthcare resources. The ECHO model is not "telemedicine" where the specialist assumes the care of the patient, but instead a guided practice model where the primary care practice team retains responsibility for managing the patient following national guidelines and best practices.

There is growing interest in cancer-related ECHO topics, including cancer survivorship. (30) ECHO programs have been deployed to improve cancer screening in underserved areas (30, 31) and to advance cervical cancer prevention and treatment. (32) Cancer survivorship care in primary care meets ECHO criteria as there is an extensive gap between existing cancer survivorship guidelines and community practice, particularly in rural areas. There are large numbers of survivors seen in primary care and primary care professional guidelines encourage management in the primary care setting. There are improved health outcomes for patients with

survivorship best practices and evolving treatment strategies that require periodic practice updates. Finally, cancer survivorship has high societal impact in terms of symptom burden, quality of life, (33) and health care expenditures.

We identified Project ECHO as an implementation strategy to build a community of practice around survivorship care improvement and enhance our onsite KanSurvive practice facilitation strategies. We believe this approach and its comingling of primary and specialty care providers will also strengthen relationships and communication between primary and oncology care teams as they both engage in ECHO activities.

1. Innovation

This project builds from pilot work highlighting the common themes and opportunities for managing rural cancer survivors from diagnosis through the lifespan using a collaborative model between primary care and cancer care teams. This project will include: (a) an examination of current patterns of care in managing patients from the time of diagnosis of the cancer through their life span, (b) the delivery of a unique intervention combining education, practice facilitation, and tele-mentoring with ECHO, aimed at increasing evidence-based practice, and (c) and evaluation to identify key elements of practice change that could be used on a larger scale for widespread dissemination. This multi-system intervention is innovative as it has been informed by rural primary care providers, cancer care teams, survivors and advocates, and subject matter experts to address established barriers in rural cancer care delivery. Use of low-cost telehealth technology and engaging interactive ECHO content will provide innovative means to develop a community of practice that supports initial and long-term learning and mentoring. Though there are unique challenges to addressing the survivorship care needs of rural cancer survivors, the combination of practice facilitation and ECHO support adoption of quality improvement processes and problem-solving skills to advance ongoing implementation of cancer survivorship guidelines and updates across the breast, colorectal, lung, and prostate survivor guidelines.

D. Preliminary Studies and Investigators

Preliminary Studies and Previous Experience: The study team is comprised of investigators who have collaborated on pilot and large-scale projects and form a multi-disciplinary team with complementary skills including: medical oncology, primary care, preventive medicine and public health, tele-health, biostatistics, behavioral health, and implementation science, with a strong focus in rural communities.

The Co-PIs bridge the strengths of primary care, cancer control and rural health (Dr. Greiner) along with cancer survivorship, genetics, practice facilitation, and certification in Project ECHO (Extension for Community Healthcare Outcomes) (Drs. Klemp and Nelson). Dr. Greiner is a family medicine physician-scientist who has engaged PCPs in rural Kansas in preventive health research for the past 15 years; and has been the lead or co-investigator on 4 NIH R01 trials and a NIH Community Networks Program Center (U54) targeting enrollment of rural minorities into clinical trials. (34-37) He is the Director of Kansas Patients and Providers Engaged in Prevention Research (KPPEPR) network, a rural practice-based research network. Dr. Klemp is a clinical-researcher in clinical health psychology and cancer genetics; she has worked with rural oncology practices for more than 15 years delivering tele-health cancer genetic consultation and practice and practice transformation; and is the Director of Cancer Survivorship, at KUCC. She has led or been an integral team science member of a CDC Survivorship Award, two NCI RO1's, and other peer-reviewed work focused on risk and late effects in cancer survivors. Drs. Klemp and Greiner are currently collaborating on the delivery of a cancer survivorship training and practice facilitation pilot program in seven primary care practices across Kansas (CDC15-1501). Drs. Greiner (Co-PI), Befort (Co-PI), and Ellerbeck (Co-I) have just launched a P30 Rural Supplement, "Developing Cancer Control Research Capacity in Kansas Rural Primary Care Networks", which will inform this proposal with regards to EHR and data sharing capabilities among primary care practices across Kansas. Drs. Greiner (Co-I), Befort (PI), and Ellerbeck (Co-I), also collaborate on a large pragmatic PCORI trial testing practice change to facilitate weight loss in 21 KPPEPR practices (OB-1402-09413). Dr. Befort is a health psychologist who has led efforts to expand our rural primary care clinical research toward pragmatic effectiveness-implementation trials wherein local clinic personnel are trained to implement interventions in their local practice as well as serve as research personnel who consent patients and collect data.(38) Dr. Ellerbeck is a primary care physician-scientist with 25 years of experience conducting healthcare delivery research in rural primary care practices including two NIH R01 trials. Dr. O'Dea is a medical oncologist who established a successful rural oncology practice at Hays Med, Hays, KS, and recently returned to KUCC, still providing 2nd opinion consultation across the state via telemedicine. She is a busy oncologist and serves as a national thought leader in treating women with breast cancer and is the Medical

Director of Breast Cancer Survivorship. She has collaborated with Drs. Klemp and Befort for the past 10-year focused on major survivorship issues including genetic and weight control. (39-41) Dr. Nelson has researched and delivered telehealth services in Kansas for almost 20 years. She is a national telemedicine fellow, directs telehealth research at the University of Kansas Medical Center, and is PI for the federally funded tri-state Heartland Telehealth Resource Center. She and her team pioneered ECHO in Kansas and have developed eleven Project ECHO initiatives across Kansas based on unmet needs of high-risk populations (ADHD, Airways, Asthma, Autism, Back to School, Epilepsy, Opioid Use Disorder, Pain Management, Pediatric Psychopharmacology, Problem Behaviors, Pulmonary Fibrosis), spanning over 200 participating sites across all regions in Kansas (Figure 4). (42-47) Consultant, Dr. Reddy, is hematologist/oncologist with over 20 years' experience in rural oncology as a partner with Cancer Center of Kansas with 21 locations across the state of Kansas. He has done both oncology and bone marrow transplant fellowships' and has expertise in cancer survivorship. He has collaborated with Dr. Klemp since 2006 on implementing cancer genetics and survivorship programs via telemedicine across Kansas along with research in symptom management of breast cancer survivors. (48)

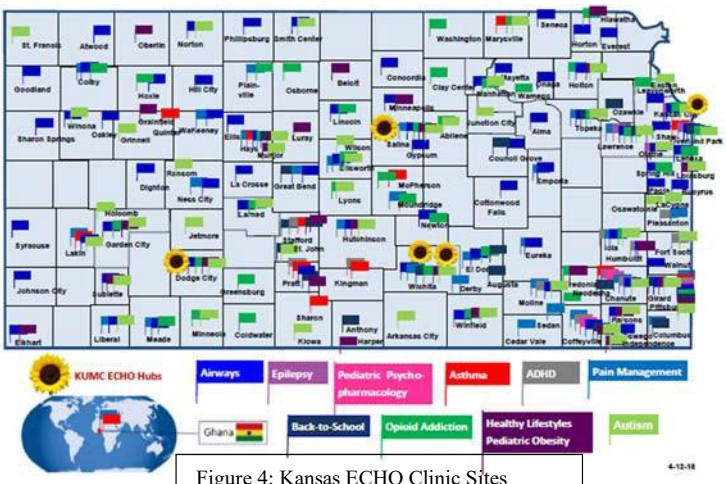


Figure 4: Kansas ECHO Clinic Sites

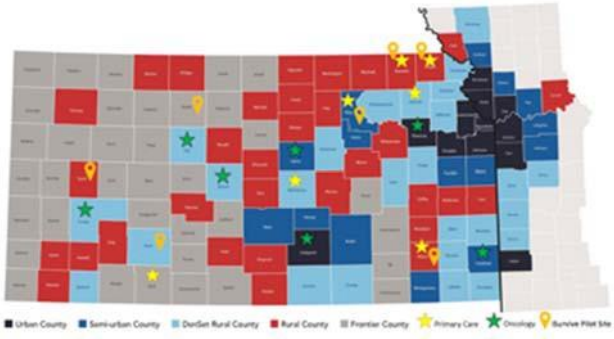
Preliminary Assessment and Practice Facilitation/Educational Pilot (KanSurvive): Our team has conducted pilot work to establish the need, feasibility, and acceptability across the state-wide practice based primary care and oncology research networks to inform the current proposal (CDC15-1501).

Understanding current practice and management of cancer survivors by primary care and oncology care teams. The Midwest Cancer Alliance (MCA), the outreach arm of The University of Kansas Cancer Center (KUCC), and Kansas Patients and Providers Engaged in Prevention Research (KPPEPR), completed semi- structured interviews and focus groups in rural primary care and oncology practices across Kansas in 2016-17. Qualitative methods were used to obtain in-depth information regarding providers' beliefs, current practices and barriers related to cancer survivorship care so that future interventions could be tailored to this population of providers in rural Kansas. Focus groups were audio-taped and transcripts were produced. Qualitative analysis was conducted by independent reviewers using an iterative process to reach consensus on primary themes and definitions. Thematic categories were identified and recorded. Transcripts were then reread by each team member to assure thematic fit for all focus group content. Triangulation and consensus were used throughout the analysis phase to maximize trustworthiness of findings. Primary care and oncology teams face similar cross-cutting barriers in caring for cancer survivors including: educational gaps; communication of history, treatment and recommendations; EHR integration; and lack of resources, highlighted in table 1. Based on the complex needs of cancer survivors and the complexity of health care delivery, an organized approach is needed to align survivorship care delivery across settings. (49)

Table 1: Cross-Cutting Themes

Cross-cutting Themes	Summary Statements from Primary Care interviews	Participant Quotes from Primary Care interviews
Organizational Structure	• Broader healthcare issue • Lack of EHR integration and systems within practice: **cannot identify survivors.** • Difficulty finding and consolidating information from various sources: ***scanned documents are essentially worthless. If it is not on the problem list, it is not on the providers radar.*** • Practices participating in ACOs appeared more equipped to support care coordination.	• *"It's one thing to collect the data, it's another thing to input the data and then it's another thing to put the data in the right place where you can come back and retrieve it in a systematic format. So you have three areas then that have the potential for breakdown or challenges."* • *"Have a more organized approach to what we do would be very helpful, yes. But that requires the whole system to change, not just one part of it."* • *"So a single EMR that everybody uses that was the same format…that would change medicine."*
Provider and Patient Engagement & Communication	• Broader healthcare issue • PCP's want 1-2 pages with specific recommendations. PCP's still see oncologists as the experts who should be providing recommendations. • PCPs mentioned the different approaches to transitioning to palliative care. Oncology wants to continue treatment. PCP's are concerned about the negative effects of the treatment on the patient and their family. • No consensus on how much responsibility patients should have. Some wanted the patient to have more responsibility, but others felt like patients were not reliable. • Rural: personal relationships, better communication with patients and specialists than in urban communities.	• *"There's nothing more confusing to the patient than we tell them three years and the oncologist says seven, the internet says don't take it at all… so if we had a way to know what the oncologist was thinking."* • *"We'll pick oncologists that have an excellent coordinator. I won't go to an oncologist or send someone to someone that doesn't have a good coordinator to help me. We use doctors who either call us directly themselves or they have someone that contacts us. When they need help, they don't leave us in the dark."* • ***"And then you get like 432 pages of notes that you have to try to sift through and figure out where everything is."*** • *"We do know them (specialists) very personally. We will go out to dinner with them when they are here… when I have a diagnosis of cancer, I will text them right away and say can you see them and they'll say yup… We do have those good relationships."*
Access to Survivorship Care and Resources	Lack of survivorship resources in rural communities, particularly with mental health support.	• *"I don't know of any community that has good mental health, not in Kansas. We have probably the poorest mental health there is."* • *"A lot of patients can't go see a specialist because they can't afford to go or they don't have the transportation means. We have very limited resources out here."*
Knowledge Gaps	PCP teams shifted the conversation to acute cancer treatment issues (transportation, fundraisers for treatment), rather than long-term survivorship issues.	• *"I always just assume that I'm letting the oncologist figure that stuff out, but I am not real well-educated on all those things I should be doing 5, 20, 15 years later. For sure, I think there's a gap in knowledge base for more physicians."*

Figure 5: Map of Focus Group Locations:



KanSurvive

1.1.a. Test the feasibility and acceptability of a survivorship care educational and practice facilitation intervention. The KanSurvive Pilot Intervention was undertaken to establish

feasibility and acceptability within our network. Klemp, Greiner, and team adapted materials (50) for a pilot project to use practice facilitation to deliver in-person content on EBP survivorship care guidelines for acute and extended cancer survivorship care in rural primary care (CDC15-1501). The team worked with rural primary care providers and oncologists to develop a series of patient case summaries for colon, breast, and prostate cancer, as well as for an adult survivor of childhood cancer. Patient cases were then merged with appropriate content for delivery during practice facilitation sessions. The curriculum was informed by findings from the focus groups conducted in 2016-2017 (49) and reviewed by Kansas cancer survivors and advisors (Patient and Investigator Voices Organizing Together or PIVOT) (Figure 2). Seven rural primary care practices (Figure 5) completed 4 hours (1 hour per session) of on-site practice facilitation + cancer survivorship training. Practice facilitation was delivered by an oncology nurse/navigator with >25 years of experience and community health Physician Assistant (PA). Sessions included skills for identifying survivors within the practice, where to find EBP guidelines, and reviewing common causes and management of acute and extended survivorship issues. Facilitation activities also provided access to additional local, regional, and national web resources (http://kscancerpartnership.org), though a collaboration with the Kansas Cancer Partnership and the Kansas Department of Health and Environment (CDC15-1501). Follow-up data collection has recently been completed and we identified that participating rural primary care practices reported high satisfaction with the approach and knowledge gains, but challenges in translating knowledge into practice. They reported benefiting from the onsite practice facilitation but the majority felt they would like additional facilitation and other support over a longer period of time due to the complexity of the practice change needed to implement cancer survivorship guidelines across breast, colorectal, lung, and prostate cancer. Participants liked “real life” examples from the facilitators. They were interested in talking with other rural practices about how they worked through challenges in putting EBP guidelines into practice in very busy, often low-resource settings. Participants asked for consultation and ways to increase communication with survivorship experts in order to support specific patients in their practices. Finally, practices had needs for quality improvement strategies with limited trained staff and strategies to extract and utilize their own cancer survivor data. Since most practices reported rarely seeing “survivorship care plans” (or post treatment plans from oncologists), they were interested in easy tools and resources for moving their care processes in line with survivorship guidelines. Throughout the pilot intervention and focus groups, the need for role delineation and improved communication between primary care and cancer care teams was evident.

Approach: Research Design will include observational research plus pilot testing of the KanSurvive-ECHO intervention

Conceptual Framework: Informed by the Integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) implementation framework, the KanSurvive intervention will target EBP improvement in rural primary care. Our recent pilot work using an updated 4-session case-based curriculum relied on utilization of practice facilitators providing on-site training to rural primary care teams. This project will expand to move beyond traditional training models, to a hands-on practice re-organization. Additional formative data collection with site visits and practice observation will inform final refinement of the KanSurvive ECHO Intervention. The delayed intervention control and KanSurvive-ECHO practices will be compared on outcomes specified by the RE-AIM evaluation framework (e.g., Reach, Effectiveness, Adoption, Implementation fidelity and acceptability, and Maintenance after 6 months).

Study Design: Using a Hybrid Type II study design, (51) the proposed study includes a three-aim plan for further assessing the rural practice environment and refining the KanSurvive-ECHO intervention (Aim 1), testing the effectiveness of KanSurvive-ECHO (Aim 2), and describing key facilitators and barriers to adoption of KanSurvive-ECHO intervention components in rural primary care (Aim 3). We will recruit 20 rural (defined using RUCA-UR codes) primary care practices from the KPEPPER network for a delayed intervention control trial.

Target population: The project will recruit rural-dwelling cancer survivors and KPPEPR primary care practices that care for these patients. The 2016 estimates for The University of Kansas Cancer Center (KUCC) catchment area, were for 22,000 people with a cancer diagnosis, and more than 8,500 cancer deaths. (52) The catchment area, includes 123 counties in Kansas and western Missouri (78%) are either classified as rural or frontier counties, with a total population of 4.4 million. Utilizing the 2010 Rural Urban Commuting Areas (RUCA) the data demonstrates that the KUCC catchment area includes a high percentage of individuals residing in rural communities with RUCA categories 4-10. The rural counties (RUCC 4-9) in our project area have a range of percent individuals in poverty from 7.5 to 22.3% and has a slightly higher percentage of those without health insurance at 11.74%.(53, 54) The poverty threshold in 2017 for a household with one adult under 65 years of age was $12,752 and for two adults with two children was $24,782.(53)

Recruitment of sites

Rural Primary Care Clinics: We have experience recruiting rural primary care clinics across all of rural Kansas. The Kansas Patients and Providers Engaged in Prevention Research (KPPEPR) network is a practice-based research network that has served as host to four previous NIH R01-funded trials. The Board of the network has unanimously agreed to support this project, (see letter of support). They have advised us that they believe we will have no difficulty recruiting the twenty practices needed for this study. We will identify clinics that care for an average of 200 patients that are survivors of breast, colon, lung or prostate cancer. This volume will allow participating practices to observe meaningful changes in patient survivorship care implementation and outcomes. From our pilot work, primary care providers described sending almost all (~95%) of their newly diagnosed cancer patients to the same, local oncology providers/practices. Currently, no EHR-based mechanisms are in place in any of the pilot practices we have worked with to systematically identify cancer survivors or to guide survivorship care through best practice alerts, orders sets, health maintenance modules or other tools. However, an improved understanding of the capacity of the participating primary care clinics will be informed by a recently awarded rural supplement to the KUCC cancer center P30 (Greiner & Befort, co-leads). Data from all participating clinics will be extracted from EHRs by an "honest broker" who will utilize a consistent algorithm across all EMR systems to record evidence of guideline concordant survivorship care. We anticipate receiving a HIPAA waiver to allow such data abstraction without consenting individual patients.

Planning and engagement

Phase 1 In order to address the cross-cutting implementation barriers in caring for cancer survivors identified in the pilot, (55) we propose to formally describe care gaps, infrastructure needs and processes of care for acute and chronic cancer survivorship in rural primary care focusing on breast, colorectal, lung, and prostate cancer survivors and utilize this formative information to further refine the KanSurvive intervention, including the practice facilitation and Project ECHO approaches.

The Integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework will guide (Harvey & Kitson, (14) the discovery of capacity for implementing the EBP for cancer survivors and further refining the KanSurvive practice facilitation strategies. i-PARIHS posits that core components of successful implementation are innovation, recipients (individual and collective), context (inner and outer), and facilitation. Successful implementation takes place when facilitation (i.e., KanSurvive) promotes the acceptance and use of an innovation (i.e.,EBPs) based on recipients' needs (i.e., primary care and cancer care teams see improving survivorship care as important) and on the nature of the implementation context (i.e., unique external and internal features of rural primary care). We will also use concepts from this framework to identify facilitators/barriers to implementation of KanSurvive ECHO (Aim 3). Definitions and associated evaluation questions will be drawn from the i-PARIHS developers (14, 16) as well as informed by the PARIHS implementation guide (Table 2). (17)

Table 2	**I-PARIHS DOMAINS TO INFORM PRE-TRIAL (Aim 1) and POST-TRIAL (Aim 3) EVALUATION**		
i-PARIHS Domain	**i-PARIHS Subdomains**	**Informant(s)**	**Measurement**
Innovation	Underlying knowledge sources Clarity Degree of fit with existing practice and values (compatibility or contestability) Usability Relative advantage Trialability Observable results	Rural primary care and oncology practices: leadership and team members Rural ACO leaders and transformation specialists Subject Matter Experts	A mixed methods approach will be used across domains including: Semi-structured Interviews informed by Harvey & Kitson (56) as well as related implementation domains from the CFIR interview guide and consistent with Stettler et al.(17) Practice environment checklist Organizational Change
Recipients	Motivation Values and beliefs Goals Skills and knowledge Time, resources, support Local opinion leaders Collaboration and teamwork Existing networks Power and authority Presence of boundaries		

Context	Local level: Formal and informal leadership support Culture Past experience of innovation and change Mechanisms for embedding change Evaluation and feedback processes Learning environment Organizational level: Organizational priorities		Manager(57)
	Senior leadership and management support Culture Structure and systems History of innovation and change Absorptive capacity Learning networks External health system level: Policy drivers and priorities Incentives and mandates Regulatory frameworks Environmental (in)stability Inter-organizational networks and relationships		
Facilitation			
On-Site ECHO Telehealth	Purpose, external and/or internal role Expectations and activities Skills and attributes of facilitators	Facilitators Rural primary care and oncology practices ECHO expert panels	Practice Environment Checklist Facilitator logs Acceptability, Feasibility, & Fidelity ratings

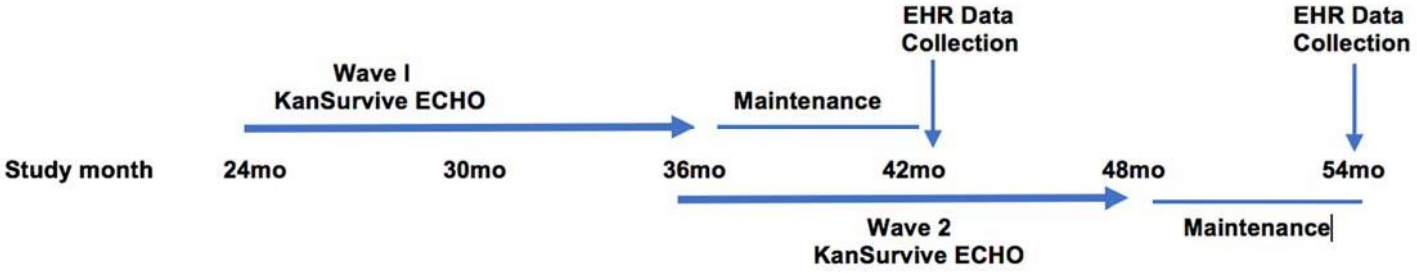
With enrolled study sites will complete an assessment of baseline organizational characteristics informed by the i-PARIHS framework. Semi-structured interviews will be completed with clinical and administrative key informants to further assist in identifying potential barriers and facilitators to implementing cancer survivorship guidelines and the KanSurvive intervention, focused on organizational processes and workflow. Based on the revised questions from the pilot, practice teams will complete interviews to inform the I-PARIHS domains (innovation, recipients, and context). This information will in turn inform KanSurvive content and implementation strategy modification. Organizational readiness to change will be assessed using the interview guides and the Organizational Change Manager survey, a validated readiness tool. (57)

Data collection:

1.) Key informant interviews. We will conduct key informant interviews with the following: a) Rural primary care practice providers, managers, nursing and staff members; b) Rural Oncology practice providers, managers, nursing and staff members; c) Rural Accountable Care organization leaders and practice transformation specialists (also involved in P30 Rural Supplement); d) Subject matter experts including the ECHO expert panelists; and e) Rural cancer survivors. We will use a semi-structured interview guide organized by i-PARIHS constructs. This includes gaining input on workflow mapping, processes of care and any ongoing quality improvement efforts. Drs. Klemp and Greiner will recruit key informants and conduct interviews alongside the project manager. 2.) Baseline study site assessment. Using direct observation and on-site data collection the project manager will gather data on practice-level variables that impact the implementation of EBP, including number of FTE staff, turnover rates, clinic volume, policies and systems, and technology use (EHR and telehealth). We will develop and use a practice environment checklist to inventory current policies, workflows, and staff roles and responsibilities in relation to cancer survivorship. Fieldnotes and schematics will be recorded and kept for team analysis. Practice personnel will also complete the Organizational Change Manager (Gustafson et al., 2003), a validated 60-item readiness measure with 15 domains that complement many i-PARIHS subdomains.

Data analysis:
1.) Key informant interview analysis. Key informant interviews will be audio-taped and transcribed. Qualitative analysis will be conducted by independent reviewers using an iterative process to reach consensus on primary themes and definitions. Thematic categories will be identified and recorded. Transcripts will then be reread by each team member to assure thematic fit for all key informant content. Triangulation and consensus will be used throughout the analysis phase to maximize trustworthiness of findings. 2.) The baseline study site assessment information will be tabulated and summarized per practice, including general descriptive information on staff, patient volumes, policies and technology use. Workflows and schematics will be mapped. Site summary data will be merged with organizational readiness measures to characterize practices in relation to peers.
Intervention refinement: The research team will work to review Phase 1 data with participating practice leads and champions, Rural ACO leaders and transformation specialists, regional content experts, and the KPPEPR Board to come up with a set of 4-8 major recommendations for intervention. They will then review previously developed pilot KanSurvive materials and suggest refinements based on these major recommendations. The research team and staff will utilize these suggestions to refine and finalize the KanSurvive intervention for Phase 2 (See Figure 6, Suggested study schema).

4.6 Phase 2: Implementation of the cluster-randomized controlled trial, with delayed start control arm Figure 6: Suggested Study Schema



Practice Facilitation. Due to the complexity of translating evidence-based guidelines into practice, significant gaps continue to exist between research evidence and practice.(58, 59) Knowledge is rarely sufficient to support the adoption of EBP behavior,(60, 61) with didactic education or passive dissemination strategies largely ineffective. Practice facilitation has emerged as an effective practice change approach and will be a key implementation strategy in the proposed study. Taken literally, facilitation means "to make easier". (56, 62)Practice facilitation is broadly defined as "a supportive service provided to a primary care practice by a trained individual or team of individuals. (63)These individuals use a range of organizational development, project management, quality improvement (QI), and practice improvement approaches and methods to build the internal capacity of a practice to help it engage in improvement activities over time and support it in reaching incremental and transformative improvement goals. This support may be provided onsite, virtually (through phone conferences and Webinars), or through a combination of onsite and virtual visits" (AHRQ, https://pcmh.ahrq.gov/page/practice-facilitation). Practice facilitators, also known as practice coaches or quality improvement coaches, are specially trained individuals who help practices engage in implementing guidelines and developing capacity for continuous quality improvement. (18)
Baskerville, Liddy, & Hogg (64) completed a systematic review and meta-analysis showing primary care practices are 2.76 (95% CI, 2.18–3.43) times more likely to adopt evidence-based guidelines through practice facilitation. Consistent with the strategies used in KanSurvive practice facilitation, all the systematic review studies included audit with feedback, practice consensus building, and goal setting as key components, as well as basing the change approach on the system level and the organization change on common quality improvement tools, such as plan-do-study-act. Many also incorporated collaborative meetings, most using resource intensive onsite meetings and a handful utilizing virtual meetings. We considered options including increasing onsite facilitation, but this proved cost prohibitive in terms of travel and time as facilitators traveled 2- 8 hours one-way in order to meet with practices. There was repetition with some training needs across practices which lends itself to group training. In addition, facilitators noted common process challenges across many sites and sought additional ways to share these "lessons

learned" across sites. The combined KansSurvive-ECHO and enhanced facilitation approach provides greater exposure to implementation strategies from the Expert Recommendations for Implementing Change (ERIC) project,(65) both in terms of number of strategies and duration of the strategies.
The Project ECHO telementoring approach was identified as an implementation strategy to enhance the onsite practice facilitation strategies. We anticipate that the blend of in-person and telehealth strategies will address barriers around cost and scalability. The increased dose of facilitation provided through ECHO will provide repetition of key principles and will develop a community of practice. ECHO benefits are associated with social learning theory, with participants learning from the expert panel and from one another. ECHO sessions will include brief practice updates as well as de-identified cases related to both guideline content and "how to" processes for clinic adoption and sustained use. De-identified quality improvement information will also be shared.

In this study we will use a delayed intervention control arm design to evaluate the effectiveness of a combined practice facilitation (KanSurvive) plus Project ECHO improvement model for improving survivorship care in rural primary care practice. Our group has used validated implementation frameworks, such as Damschroder's (2009) Consolidated Framework for Implementation Research (CFIR) and Proctor's (2011) taxonomy of implementation outcomes to (1) create a set of questions to assess organizational readiness and suitability for ECHO and (2) provide those who commit to Project ECHO with a checklist to support successful implementation. Using adaptations of I-PARIHS and CFIR constructs, we created ECHO-specific organizational readiness questions, as well as a process guide for implementation. Each consideration was mapped onto Proctor's (2011) implementation outcomes, and questions relating to the constructs were developed and reviewed for clarity. The Preimplementation list included 20 questions; most questions fall within Proctor's (2001) implementation outcome domains of "Appropriateness" and "Acceptability." The Process Checklist is a 26-item checklist to help launch an ECHO project; items map onto the constructs of Planning, Engaging, Executing, Reflecting, and Evaluating. Given that fidelity to the ECHO model is associated with robust outcomes, effective implementation is critical. These tools will enable practices to work through key considerations as they implement KanSurvive plus Project ECHO.
Evaluation: RE-AIM (66)
1. Reach measured as %Expressed Interest /%Enrolled. As a marker of reach, participation rates will be calculated as the total number of rural primary care practices who express interest in the program divided by the total number of rural primary care sites eligible. Percent enrolled will be calculated as the total number of rural primary care practices who complete enrollment procedures divided by the total number of rural primary care practices who expressed interest. *Structured Interviews with Non-participants*. Structured interviews will focus on identifying the barriers associated with lack of participation in KanSurvive-ECHO, as well as facilitators/solutions to these barriers.
2. Effectiveness will be measured as *% change in electronic health record evidence of guideline concordant care from pre- to 6-months post- KanSurvive-ECHO in intervention versus delayed intervention control practices.* Using baseline EHR assessments in charts of cancer survivors identified from hospital registries we will compare the pre- and post- percentages of these survivors with best practice alerts, orders sets, health maintenance modules or other tools that notate specific survivorship care services that they should be receiving to meet guidelines (Table 3) (67-74)
3. Adoption will be measured by calculating the representativeness of the participating rural primary care practices. Specifically, participating rural primary are practices will be measured on their size and their patient panels and will be compared as a group to the overall data that is available for all rural primary care practices in the state of Kansas on these key variables to assess for the representativeness of participating practices.
4. Implementation Consistency: In addition to project feasibility and acceptability, we will assess facilitators and barriers to KanSurvive adoption using the i-PARIHS framework (Aim 3). Fidelity: We will refine KanSurvive fidelity assessment consistent with Schoenwald et al.(55): (1) identifying relevant components for monitoring across practice facilitation and ECHO components (e.g., specificity, necessity, degree of precision), (2) determining who would provide the ratings, (3) obtaining the ratings, and (4) creating a summary score for the ratings. We will monitor fidelity to the KanSurvive components, with checklists associated with practice facilitation from multiple perspectives (e.g., participating practice teams, facilitators, ECHO subject matter experts). *Attendance and Participation.* Percent attendance will be

calculated for each rural primary care practice as the percent of practice facilitation and ECHO sessions attended divided by the total number of sessions offered. For both groups' participation the amount of between session work completed (as a percent).

5. Maintenance: Our experienced team will conduct structured interviews with participating rural primary care practices to assess their ability to sustain key components of the KanSurvive ECHO program over time and maintain effects at 6-months, including policies and procedures to support the cancer survivorship guidelines. Identification of cancer survivors with breast, lung, colon and prostate cancer. In order to identify survivors under the care of a particular PCP, we will engage the local/affiliated hospital's tumor registry. A list of all primary care providers participating in the intervention will be compiled using several key fields: "following doctor" (primary care provider) and the type of cancer (breast, colon, lung, and prostate cancer). This PCP list will be given to local hospitals, which will run a report to identify all cancer survivors with breast, lung, colon and prostate cancer affiliated with the "following doctor". Additional variables from the tumor registry will include demographics, stage, treatment, treating oncologist. Each primary care provider participating in the intervention will receive their list of affiliated patients. (75)

Data extraction will be completed by an "honest broker" who will utilize a consistent algorithm across all EMR systems to record evidence of guideline concordant survivorship care through a HIPAA waiver to allow such data abstraction without consenting individual patients. Medical record extraction is considered the "gold standard" and will be the primary objective data source for this trial. Practice-level data gathered from participating practices will be recorded directly into a secure KUMC REDCap database which requires username and password verification. Only designated research staff will have access to research information. The data collection survey tool built in REDCap will be pilot tested internally and modified as needed to ensure clarity for the data collector.

Table 3: Measure change in EHR documentation Concordant with Evidence-based Cancer Screening by Diagnosis

Cancer Diagnosis	Breast	Lung	Colon	Prostate	EHR Documentation Baseline (Yes/No)	EHR Documentation Post (Yes/No)
Recommended screening based on diagnosis*	**Mammogram (annual)**	**CT (annual)**	**Colonoscopy (frequency specified by risk)**	**PSA (annual or more frequent based on risk and time since diagnosis**		
Distress/Depression Screen (PHQ9) (annual)	X	X	X	X		
Lifestyle Recommendations Diet/exercise/smoking cessation (annual)	X	X	X	X		
Review of Family History of Cancer (one time)	X	X	X	X		
Evidence of Changes to "Problem List" (one time, cancer diagnosis or history of)	X	X	X	X		
Evidence of Changes to "Health Maintenance/Preventive Services" or "Order/Smart set" or "Smart Phrases" or "Annual Wellness Visits" Since Cancer Diagnosis (one time)	X	X	X	X		
Treated with Anthracycline Y or N**						
ECHO Cardiogram (frequency specified by risk) **						
Bone Mineral Density (treated with anti-hormone or androgen deprivation therapy) (frequency specified by risk) **						

*if not deemed medically necessary, is their clarification in EHR (e.g., due to type of cancer surgery - total colectomy or bilateral mastectomy)

** exploratory variables: applicable to subset of patients based on treatment exposure

Limitations and strengths to EHR data are inherent to this type of project. There will be cancer survivors missed by the method of using local hospital registries, however, >95% of referrals from our focus group primary care providers are to the same oncologist/practices (49), thus keeping missing cancer survivors to a minimum. Use of a trained honest broker for data extraction will reduce the confounder of a lack of familiarity with EHR and where to find documentation within the EHR also will eliminate potential bias within the practice and patient population.

Study Timeline

Phase/Activity	Year 1	Year 2	Year 3	Year 4	Year 5

4.9 Dissemination and Future Plans: Using the i-PARIHS and RE-AIM frameworks for evaluation, relevant findings will be submitted for abstract (poster or presentation) at regional and

Patient & advisory board engagement	x	x	x	x	x	x	x	x	x	x
Phase 1	x	x	x							
Site recruitment	x	x								
Workflow analysis		x	x							
Assess practice & EHR capabilities + P30 rural supp		x	x							
Explore facilitators & barriers of successful process		x	x						x	x
Finalize intervention & assessment tools			x	x						
Phase 2				x	x	x	x	x	x	x
Intervention				x	x	x	x			
Wave 1				x	x	x				
Wave 2						x	x	x		
Data extraction								x	x	
Evaluation								x	x	
Data analysis, Dissemination									x	x
Identify opportunities-sustain community of practice									x	x

Location where study will be performed: The study will be performed at KUMC sites. Research staff are located in 2330 Shawnee Mission, Parkway, Westwood, Kansas 66205. Additionally, the rest of the research staff is being supported by the Masonic Cancer Alliance (MCA) located in 4350 Shawnee Mission Pkwy, Fairway, KS 66205. Other study activities will be completed online through Project ECHO.

Collaboration (with another institution, if applicable): The MCA will provide research support to complete various phases of the protocol.

Personnel who will conduct the study, including: The sponsor and principal investigators for the study are Jennifer Klemp, PhD, MPH and Allan Greiner, MD, MPH.

Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan:
Since this study does not involve any therapeutic intervention we do not anticipate the need for any safety monitoring.

Informed consent process and timing of obtaining of consent: Participating clinics will provide verbal consent to confirm they will participate in the project.

Alternatives to Participation: any of the recruited clinics will the option to participate or not as the study is completely voluntary.

Costs to Subjects: Participating clinics will not incur any cost while in the project. Participating clinics will get a total of $1,500 as compensation for their time and participation.

Publication Plan: Results will be published as deemed appropriate by the investigators Drs. Klemp and Greiner.
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ANALYSES

Quantitative Data:

- Differences in cancer survivorship performance indicators before and after intervention were assessed using Chi-square or Fisher Exact tests.
- Clinical characteristics are summarized with frequencies and percentages.
- Demographic and patient characteristics are summarized descriptively with respect to frequencies and percentages for categorical variables, and mean, standard deviation, median, minimum and maximum for continuous variables.
- Differences in surveillance rates by tumor types before and after intervention were assessed using Fisher Exact tests.
- Statistical tests were considered significant if $p<0.05$.

Qualitative Data:

- Interview notes, transcripts of practice facilitation meetings, and field records were compiled and analyzed using the i-PARIHS framework to evaluate barriers and facilitators to implementation.
- A thematic network analysis was employed by first noting initial impressions.
- Transcripts were independently reviewed line-by-line and preliminary codes were applied to relevant passages.
- A coding framework was developed with clear code descriptions, organizing data into themes and sub-themes.
- This framework was systematically applied to all transcripts using Dedoose software to ensure consistent and meaningful codes across the dataset.