

Intervention IP-073: A System-Based Intervention to Reduce Black-White Disparities in the Treatment of Early Stage Lung Cancer

Summary

This system-based intervention is a five-year pragmatic trial performed at five cancer centers where Black and White patients were randomized into intervention or control groups to reduce lung cancer treatment disparities. The intervention uses real-time digital warnings, accountability through race-specific quality improvement, and enhanced communication through navigators trained on race-related barriers to treatment. Findings show Black-White treatment gap reduced and there was improved care for patients of both races.

Overview

Purpose of Intervention:

To reduce lung cancer treatment disparities using real-time transparency, race-specific accountability, and enhanced communication

Intervention Type:

Research-Tested — *Interventions with strong methodological rigor that have demonstrated short-term or long-term positive effects on one or more targeted health outcomes to improve minority health and/or health disparities through quantitative measures; Studies have a control or comparison group and are published in a peer-review journal; No pilot, demonstration or feasibility studies.*

Intervention Details

Intervention was Primarily Driven, Led, or Managed by:

Both Community and Academic/Clinical Researchers

Citations:

- Cykert S, Eng E, Walker P, Manning MA, Robertson LB, Arya R, Jones NS, Heron DE. A system-based intervention to reduce Black-White disparities in the treatment of early stage lung cancer: A pragmatic trial at five cancer centers. *Cancer medicine*. 2019 Mar;8(3):1095-1102. Epub 2019 Feb 4.

Adaptation of Another Research-based Intervention:

Yes

Name of Original Intervention:

A tracking and feedback registry to reduce racial disparities in breast cancer care.

URL to original Intervention:

N/A

Citations:

- Bickell NA, Shastri K, Fei K, Oluwole S, Godfrey H, Hiotis K, Srinivasan A, Guth AA. A tracking and feedback registry to reduce racial disparities in breast cancer care. Journal of the National Cancer Institute. 2008 Dec 3;100(23):1717-23. Epub 2008 Nov 25.

Intervention Primary Outcomes were comparable to the original:

Yes

Contact Information

Primary Contact Affiliation:

UNC School of Medicine

Intervention URL:

<https://onlinelibrary.wiley.com/doi/10.1002/cam4.2005>

Results

Intentions

1. **Improve minority health or the health of other populations with health disparities (e.g. rural populations, populations with low SES)**

Intervention Primary Outcome:

Increased curative treatment completion (defined as lung resection surgery) or full course of stereotactic radiation for Black patients experiencing stage I or stage II, non-small cell lung cancer

Intervention Secondary Outcome:

Surgical rates alone for Black patients

Key Findings:

At baseline, crude treatment rates were 69% for Black patients for all curative treatment and 59% for lung resection surgery alone. In the intervention group, the overall completed treatment rate for Black patients improved to 96.5% while the rate of lung resection surgery improved to 75%. As the primary goal of the

study was to prove that care of Black patients could be improved to the care standard of White lung cancer patients and that treatment completion could be optimized for all, logistic regression models were performed to compare treatment improvements for Black patients as well as White patients. Control treatment rates were higher for White patients. However, black patients improved dramatically compared to the White referent group. The data reported supports the effectiveness of the intervention among Black patients alone.

Statistical Method Used:

Patient characteristics were summarized using descriptive statistics and compared across study groups and within study groups between races using Chi-square and F-tests for categorical and continuous variables, respectively. Separate analyses were performed for the primary outcome and the secondary outcome. Since we were interested in estimating treatment differences between Blacks and Whites within each study group, a logistic regression model was performed for each outcome.

Was statistical method used to analyze data from original Intervention comparable to the original:

Yes

2. Reduce health disparities (study must show that health disparities are being measured between a population with health disparities and a reference group)

Intervention Primary Outcome:

Overall treatment for Black and White patients and Black-White treatment differences in a retrospective control group, a concurrent control group, and the intervention group

Intervention Secondary Outcome:

Surgical rates for Black and White patients in both control groups and the intervention group

Key Findings:

Overall treatment rate for surgery/radiation, regardless of race, was 76% for retrospective group, 96% for intervention group, and 83% for concurrent group. For the retrospective baseline, crude treatment rates were 78% for White vs. 69% for Black patients ($p < 0.001$); difference by race was confirmed by a model adjusted for age, treatment site, cancer stage, gender, comorbid illness, and income – odds ratio (OR) 0.66 for Blacks (95% CI 0.51 – 0.85, $p = 0.001$). Within the intervention group, the crude rate was 96.5% for Black vs. 95% for White patients ($p = 0.56$). OR for the adjusted analysis was 2.1 (95% CI 0.41 – 10.4, $p = 0.39$) for Black vs. White patients. Between group analyses confirmed treatment parity for the intervention. The White retrospective group was the gold standard comparator at 78% while the Black intervention group had a treatment rate of 96%. In the between group regression model the OR for Black treatment compared to the referent group was 11.9 (2.9-49, $p=.001$)

Statistical Method Used:

Since we were interested in estimating differences between Blacks and Whites within each study group, a logistic regression model was performed for each outcome examining Black compared to White outcomes within each group, controlling for age, income, gender, co-morbidities, clinical stage and site. For the between group analysis, all data from each group of interest were placed into a single model and study group by race combinations were employed to estimate differences by race and group.

Was statistical method used to analyze data from original Intervention comparable to the original:

Yes

Evaluations and Assessments

Were Any of the Following Assessments Conducted (Economic Evaluation, Needs Assessment, Process Evaluation)?:

No

Demographic and Implementation Description

Diseases, Disorders, or Conditions:

Lung Cancer

Race/Ethnicity:

African American or Black, White

Populations with Health Disparities:

People with Lower Socioeconomic Status (SES), Racial and Ethnic Minority Populations

Age:

Adults

Socio-demographics / Population Characteristics

Community Type:

Unspecified

Other Populations with Health Disparities:

Unspecified

Geographic Location:

North Carolina, Pennsylvania, South Carolina

Socio-Economic Status:

Low SES, Middle SES, High SES

Minority Health and Health Disparities Research Framework

		Levels of Influence			
		Individual	Interpersonal	Community	Societal
Determinant Types	Biological				
	Behavioral	✓			
	Physical / Built Environment				
	Sociocultural Environment	✓	✓		
	Health Care System	✓	✓	✓	✓

Community Involvement

The community's role in different areas of the Intervention (Choices are "No Role", "Participation", and "Leadership"):

Design:

Participation

Dissemination:

Participation

Evaluation:

Participation

Implementation:

Participation

Outreach:

Participation

Planning :

Participation

Recruitment:

Participation

Sustainability:

Participation

Characteristics and Implementation

Intervention Focus Area:

Patient-Clinician Communication, Quality Improvement or Organizational Change, Transparency through using digital electronic health record data to create real time warnings for missed appointments (office visits, tests, or procedures) and missed milestones in care even when appointments kept (clinical inertia)

Disease Continuum:

Tertiary Prevention, Treatment

Delivery Setting:

Clinic / Health Care Facility, Navigation involved communication away from health facilities at times

Mode of Delivery:

In-person, m-Health (mobile)

Who delivered the Intervention?:

Health Educator, Healthcare Professional (Physician, Nurse, Technician)

Conceptual Framework

Intervention Theory:

Theories of Organization Change (e.g. Dimensions of Organizational Change, Stage Theory, Interorganization Relations Theory, Community Coalition Action Theory), The People's Institute for Survival and Beyond (PISAB) Undoing Racism™ framework was used as a conceptual model for medical care. The model uses transparency in measuring system effects and accountability to implement system change as key concepts.

Intervention Framework:

None

Implementation

Intervention Study Design:

Quasi-Experimental (does not require random assignment, but requires a comparison/control group with pre and post intervention outcome assessments)

Targeted Intervention Sample Size:

360

Actual Intervention Sample Size:

3798

Start Year:

2013

End Year:

2017

Intervention Exposures

Duration of Intervention/How Long it Lasted:

10-12 months

Frequency of Intervention Delivery:

The 3798 sample was intervention (360) plus control (3438). Real-time registry system was continuous to generate alerts for missed appointments and milestones; Race-specific QI sessions for care completion/quarterly; Navigation communication/monthly.

Number of Sessions/Meetings/Visits/Interactions:

More than 10 Sessions

Average Length of Each Session/Meeting/Visit/Interaction:

Less than 1 Hour

Format of Delivery:

Group (e.g. Community leaders), Individual

Highest Reading Level of Intervention Materials Provided to Participants:

Grade 4-5

Adaptations and Modifications

Were modifications made?

Intervention Elements	Modified
Content	Yes
Context	Yes
Implementation	Yes
Funding	No
Organization	Yes
Participants	Yes
Providers	Yes
Sociopolitical	No
Stages of Occurrence	Yes

Modification Details

	Explanation
Content	
Adding Elements, Tailoring, None	In the Bickell study (published 2008), the breast cancer patient registry was filled out manually - research personnel had to review medical records and call various specialty offers to fill out the dates and types of treatments for each patient then had to verbally communicate, mostly by phone, to the practice to suggest that a treatment was omitted or incomplete. Given that our study occurred after Congress passed the HITECH act and essentially all cancer centers had adopted electronic health records (EHRs), we could actually upload data from the various EHRs and program algorithms to generate automated warnings for appointments missed and milestones that were not reached. These warnings could then be downloaded by the navigators on a daily basis then the clinical team was informed about inertia or the patient was contacted for missed appointments to ascertain barriers and ensure that these barriers were addressed, and the next appointment could be kept.
Context	
Population	Early stage ("curable") non-small cell lung cancer patients were the target population rather than breast cancer patients.
Implementation	
Delivery, Duration, Study Design	The real time registry was not the lone intervention. We added navigation and quarterly, QI audit and feedback on treatment completion according to race. These components met our community partners' requirements for enhanced communication and accountability, respectively. Also, our navigators pro-actively contacted patients at least once a month over the course of one year.
Organization	
Availability of Staffing / Technology / Space	See explanation of modifications to content. In addition, all participating clinical settings had password protected access to our real time registry system.
Participants	
Ethnicity	We did not enroll Latin-X patients because we did not have a documented lung treatment disparity in that group.
Providers	
None	Clinical specialties of participants were different given the change in cancer type.
Stages of Occurrence	
Implementation, Planning/Pre-implementation/Pilot, Sustainability	We knew from the beginning that given the relatively large population of lung cancer patients at participating systems, that a system reliant on manual entry would not be broadly usable or sustainable. Therefore, our

	Explanation
	<p>plan from the beginning was to use automation. Implementation was modified based on clinic workflows and community advice on how to communicate to patients who were initially equivocal about the study. Because the major functions of the registry and the data obtained for the accountability - audit and feedback - part of the study were largely automated, we knew that re: long term diffusion and implementation of the work that the intervention would be sustainable.</p>

Impact, Lessons, Components

Produced an impact or change beyond the primary or secondary outcome:

Yes

Not only did completion of lung cancer care improve for Black patients and care become more equitable relative to White patients, but completion of cancer care for White patients also markedly improved by using a system-based approach to real time transparency, accountability, and enhanced communication.

Essential Aspects for Success:

The real time warning system must account for patient factors (missed appointments) and clinical inertia (missed milestones in care). The navigation approach must be patient-centered rather than specialty-centered and training must include local and system barriers specific to disadvantaged groups.

Lessons Learned

Key Lessons Learned and/or Things That Could be Changed or Done Differently:

To remedy institutional-level bias: Work with affected communities through a system-level lens to help determine appropriate measures and interventions, measure serial outcomes according to race (or other disadvantages) and apply interventions in real time using automation of available EHR data.

Insights Gained During Implementation

Insight Category	Insight Description
Cost of Implementing or Sustaining	Programming needed to build the real time, warning system for 5 cancer centers for stages I and II, non-small cell lung cancer including salary and benefits (9 months, one full-time programmer) was approximately \$110,000 then \$11,000 were yearly maintenance. Navigator training cost about \$500 each.
Logistics	Navigators met patients face to face at initial visits then second face to face visits were used to build rapport. Monthly check-ins were pro-active to maintain this rapport. Quarterly feedback meetings for clinicians were better attended if we used scheduled standing meetings instead of new ones.
Administrative Resources	Racial equity efforts could be led by either an established navigation program or cancer quality improvement program. Disparities/Equity expertise should be included in the administrative structure of these programs.
Equipment / Technologies	Because of multiple EHRs at study institutions, we programmed an umbrella system for the real time warning system at the UNC Sheps Center that was password protected and accessed at the individual sites. However, this programming can be done within an EHR. One participant has done this in Epic.
Training / Technical Assistance	Navigators were trained using the Racial Equity Institute's Phase I Training then the concepts were applied by doing role plays with input from community advisors. Note that navigators were both Black and White and given the training, there was no difference in success rates.
Staffing	Navigators were able to support 30 to 70 patients in active treatment using a proactive approach. Maintenance and periodic quality checking of the real time warning system required a 0.1 FTE of a programmer.
Recruitment	The initial, patient recruitment scripts were edited and tailored by community partners. In early recruitment, we experienced some "soft" refusals. When this issue was presented to our community partners, their advice about removing time pressure from the decision with thoughtful follow-up worked.

Intervention Components

Intervention Has Multiple Components:

Yes

Assessed Each Unique Contribution:

No

Products, Materials, and Funding

Expertise, Partnerships, and Funding Sources

	Used for Implementation	Needed for Sustainability
Expertise		
Technology	Yes	Yes
Clinical Care	Yes	Yes
Patient Navigation	Yes	Yes
Community mobilization, community organization/coalition building	Yes	Yes
Research/Data science	Yes	Yes
To elucidate on technology need electronic health record (EHR) programming expertise to build the real time warning system within the EHR	Yes	Yes
Partnerships		
Community groups (e.g. faith-based organizations, barbershops, beauty-salons, laundromats, food markets, community centers, cultural associations, tribal groups)	Yes	Yes
Health care facilities (local clinics)	Yes	Yes
Funding Sources		
Public funding (e.g., federal, state or local government)	Yes	No
Private funding (e.g., foundations, corporations, institutions, facilities)	No	Yes
The funding needed to build informatics support is significant upfront but maintenance is <20,000 dollars per year. Therefore, institutional funds or outside sources needed initially; fees/reimbursement likely to cover system maintenance.	No	Yes

Product/Material/Tools

	Tailored For Language	Language(s) if other than English	Material
Outreach/Recruitment Tools			
Informed Consent Form	No		Attachment available for request at the bottom of the page.
Participant Educational Tools			
Brochures/Factsheets/Pamphlets	No		Attachment available for request at the bottom of the page.
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Brochures/Factsheets/Pamphlets	No		Attachment available for request at the bottom of the page.
Brochures/Factsheets/Pamphlets	No		Attachment available for request at the bottom of the page.
Measurement Tools			
Non-Standardized Instruments/Surveys/Questionnaires	No		Attachment available for request at the bottom of the page.
Non-Standardized Instruments/Surveys/Questionnaires	No		Attachment available for request at the bottom of the page.

Implementation Materials and Products

	Material
Implementation/Delivery Materials	
These are case examples used for role play training of navigators.	Attachment available for request at the bottom of the page.
Intervention implementation guidelines	Attachment available for request at the bottom of the page.
Intervention implementation guidelines	Attachment available for request at the bottom of the page.
Implementation/Output Materials	
No Implementation/Output Materials provided.	

Articles Related to Submitted Intervention

	Article
Reports/Monographs	
No Reports/Monographs provided.	
Additional Articles	
Evaluation	https://ascopubs.org/doi/abs/10.1200/jco.21.01745
Qualitative findings	https://doi.org/10.1177/15248399221136534

Materials Available for Request

- Patient_Consent_Form_FINAL3.docx
- Lung cancer decision aid pneumonectomy bad health.docx
- Lung cancer decision aid pneumonectomy good health_10-3-11clean.docx
- Lung cancer decision aid stage 1_10-3-11clean.docx
- Lung cancer decision aid stage 2_10-3-11clean.docx
- Patient questionnaire_December 2011.doc
- Pt satisfaction Q for 6mos and 12 mos.docx
- Nav Role P Lay.docx
- Communication Flow Straw Man 5-29-12.docx
- Navigation Engagement Protocol.docx