Building Networks of Practice Based Research Networks From South Africa to the USA and back

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Session Outline

- Introduction to Clinical Directors Network (CDN) Practice-based Research Network (PBRN), USA Federally Qualified Health Centers (FQHCs) and their South African Community Health Center (CHC) origins
- 2. Overview of CDN's Webcast Library and online CME-accredited Research Training Modules
- 3. Example of a Practice-based Research and Learning Collaborative: Cluster Randomized Clinical Trial (cRCT) for patients living with HIV and elevated Cardiovascular Disease (CVD) Risk ("GREAT-2 Study")
- 4. Discussion of Interest and Feasibility in Creating an Initial Observational Study of HIV and CVD risk





Part 1 - Background: Federally Qualified Health Centers (FQHCs) Practice-based Research Networks (PBRNs) Clinical Directors Network (CDN)

Drs. Sidney and Emily Kark & John Cassel: Social Medicine Pioneers and South African Emigrés

WIDELY RECOGNIZED AS ONE

of the 20th century's most original, inspirational, and influential leaders in social medicine, Sidney Kark was born in 1911 in Johannesburg, South Africa, to which his family had emigrated from Lithuania in the 1880s.1 After graduating from high school. Kark entered the medical school at Witwatersrand University in 1929 but was forced to abandon his studies in the early 1930s because of the economic depression. He later returned to medical school and graduated in 1936. While in medical school, Kark was active in a variety of progressive student organizations, including the National Union of South African Students and its affiliated Labor Party.

Several liberal faculty members active in the interracial South Africa Institute of Race Relations influenced Kark, as did a history professor, W.M. MacMillan, whose analysis of South African history highlighted reasons for the poverty and deprivation of the native African populations, and Eustace Cluver, a lecturer in public health.

In 1938, when Cluver was appointed secretary of health of South Africa, he chose Kark as the clinical medical officer for a year-long survey of the health and nutritional state of South African children. After this assign-



Drs. Sidney and Emily Kark, Pholela, Natal, circa 1940. Courtesy of Dr. Jeremy D. Kark.

ment, he appointed Kark head of a pioneering health unit at Pholela in rural Natal Province. The Health Ministry intended this to be a model for health centers across the country. Sidney Kark and his new wife, Emily, who was also a physician, went to Pholela in 1940. During the 6 years they spent there, they began to develop the concepts, methods, and programs of applied social medicine for which they would later become famous. In 1946, Kark moved to the city of Durban to direct the newly created Institute of Family

and Community Health (IFCH), whose mission was to train personnel for the large network of health centers on the Pholela model, as projected in the recently released Gluckman Report of the National Health Services Commission.2 Students were trained at Pholela and at 6 new urban health centers, whose populations lived in municipal housing projects, urban slums, and shack settlements. In 1951, a medical school admitting only "Black, Indian, and colored students" was created in Durban.

In 1952, reactionary changes in the national government prevented the growth of the planned health centers and threatened the existence of the IFCH. With the help of the dean of the Durban Medical School and a grant

- In 1942, Drs. Sidney and Emily Kark founded a health center in Pholela, an impoverished Zulu tribal reserve in the eastern province of Natal, South Africa
- The Karks understood that poverty played a key role in the health problems that persisted in the region
- They expanded their work to include improvements in housing, sanitation and better access to food and water
- They developed the concept of Community-Oriented Primary Care (COPC)
- Their novel approach was recognized and was the foundation for the first two Community Health Centers (CHCs) in the USA



Brown TM, Fee E. Sidney Kark and John Cassel: social medicine pioneers and South African emigrés. Am J Public Health. 2002;92(11):1744-1745. doi:10.2105/ajph.92.11.1744



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H. Jack Geiger, MD, MSci Hyg (Epidemiology), ScD (hon) (1925-2020)



H. Jack Geiger, M.D., M.Sci. Hyg. (Epidemiology), Sc.D. (hon.) Community Health Centers and Primary Care Teaching: A Look at the Future

H. Jack Geiger, M.D., M.Sci. Hyg. (Epidemiology), Sc.D. (hon.) is the Arthur C. Logan Professor Emeritus of Community Medicine at Sophie Davis; a founding member and Past President of Physicians for Human Rights, which shared in the Nobel Prize for Peace in 1998; a founding member and Past President of Physicians for Social Responsibility, the U.S. affiliate of International Physicians for the Prevention of Nuclear War, which received the Nobel Prize for Peace in 1985; and a founding member and Past President of the Committee for Health in Southern Africa. He received his M.D. degree from Western Reserve University School of Medicine in 1958 and trained in internal medicine on the Harvard Service of Boston City Hospital from 1958-64. During this period he also earned a degree in epidemiology from the Harvard School of Public Health, and was a Research Fellow, Research Training Program in Social Science and Medicine, Harvard University. Most of his professional career has been devoted to the problems of health, poverty and human rights. He initiated the community health center model in the U.S., combining community-oriented primary care, public health interventions, and civil rights and community empowerment and development initiatives, and was a leader in the development of the national health center network of more than 900 urban, rural and migrant centers currently serving some twelve million low-income patients. Dr. Geiger's work in human rights spans more than six decades. He was a founding member of the Congress of Racial Equality (CORE) in 1943 and was Civil Liberties Chairman of the American Veterans Committee from 1947-51, leading campaigns to end racial discrimination in hospital care and admission to medical schools.



After studying with the Karks in South Africa, Dr. Geiger founded the Community Health Center (CHC) model in the USA, combining:

- Community-oriented primary care
- Public health interventions

•

Civil rights, community empowerment, and development initiatives

Dr. Geiger created the first 2 Community Health Centers (CHCs) in the USA in 1965 in Mound Bayou, MI (Delta CHC) & Dorchester, MA (Columbia Point CHC) initially funded by the US Office of Economic Opportunity (OEO)

Dr. Geiger was a leader in the development of the national USA Health Center Network now funded by the US Department of Health and Human Services – Health Resources and Services Administration (DHHS-HRSA)





The Primary Health Care Safety-

Net:

Federally Qualified Health Centers (FQHCs)



Source: <u>www.hrsa.gov</u> \rightarrow <u>http://datawarehouse.hrsa.gov/tools/mapgallery.aspx</u>

National FQHC Network:

- Community-board Directed (>51% Community Directors)
- Comprehensive Primary Care and Preventive Services
- Behavioral Health
- Oral Health/Dental
- Vision/Optometry
- Pharmacy
- Social Services/Social Determinants of Health

FQHCs: Patients and Encounters, 2021

FACILITIES, PATIENTS & VISITS	National
Total # Grantees	1,373
Total # Delivery Sites	15,300
Total # Medical Users	25,759,024
Total # Medical Encounters	83,368,500
Total # Dental Users	5,701,053
Total # Dental Encounters	13,766,648
Total # Medical/Dental Users	30,193,278

(Source: HRSA BPHC UDS, 2021 – Special Tabulation)





What is a Practice-based Research Network (PBRN)?

- Group of ambulatory care practices
- Network structure transcends a single research project
- Link practicing clinicians with experienced clinical investigators
- Enhance research skills of network clinician members
- Mission.
 - Service primary care of patients
 - Goal improve quality of primary care
 - Investigation questions related to community-based practice





Clinical Networks and Clinician Retention: The Case of CDN

Alice Sardell, PhD

ABSTRACT: Since the mid-1980s, clinicians working in community and migrant health centers formed clinical networks to provide administrative and clinical training, regular interaction with peers, and opportunities for participation in policy formulation. The subject of this article is the most developed of the regional clinical networks, the Clinical Directors Network of Region II (CDN). CDN was created in 1985 to meet the needs of clinicians working at health centers in New York, New Jersey, Puerto Rico and the Virgin Islands. Its activities since that time suggest the potential of clinical networks to help to create professionally satisfying work experiences for health center clinicians and thus to increase clinician retention. The creation of CDN is described and its training and research activities are discussed within the context of the universe of health center clinical networks and practice-based research networks.



Sardell, Alice. "Clinical Networks and Clinician Retention: The Case of CDN." Journal of Community Health 21(6):437-51, 1996. PMID: 8912120. https://pubmed.ncbi.nlm.nih.gov/8912120/





The Network of Safety-net Practice Based Research Networks (N²-PBRN)

(Established in 2012 by CDN)



To build the **infrastructure for a network** (N²) of primary care practice-based research networks (PBRNS) in primary care practices in medically underserved communities using evidence-based practices for **clinical research management (CRM)** and **knowledge transfer (KT)** in order to **accelerate** selection, design, initiation, completion, dissemination and implementation of research that:

- Improves patient outcomes
- Has widespread utility within the national (and international) clinical and public health domains
- Does not compromise patient safety



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www.pbrn.ahrq.gov/pbrn-profiles/P30-Centers

http://pbrn.ahrq.gov/sites/default/files/docs/page/N2.pdf





CDN Ce

Part 2: CDN Online CME Courses Webcast Library & Research Training Modules



CDN's Webcast Library: On-Demand 24x7 CME Courses

Link to eTraining: www.CDNetwork.org/PBRN



Funded by: CDN Center of Excellence (P30) for Practice-based Research and Learning, N²-PBRN Learning Collaborative AHRQ, Grant No. 1P30HS021667





Certificate Program in Practice-Based Research Methods

Program Summary

- A practice-based research network (PBRN) is a group of ambulatory practices devoted principally to the primary care of patients and
 affiliated in their mission to investigate questions related to community-based practice and to improve the quality of primary care. PBRNs
 draw on the experience and insight of practicing clinicians to identify and frame research questions whose answers can improve the
 practice of primary care. By linking these questions with rigorous methods, PBRNs produce research and quality improvement findings
 that are relevant to clinicians and readily translated into everyday practice.
- The Certificate Program in Practice-Based Research Methods seeks to develop a new generation of independent investigators within the PBRN community. The program will provide training in concepts, skills, and methods for conducting practice-based research and building PBRNs.

Link to eTraining: www.CDNetwork.org/PBRN

PBRM Webinar Sessions

Session 1: Introduction and Theory of Practice-Based Research Networks (PBRNs)	Session 8: Research Designs, Sampling Methods and Nested Analyses
Session 2: Program orientation for Fellows & Primary Mentors	Session 9: Obtaining Funding for PBRN Research
Session 3: PBRN development and maintenance: Use of practice facilitators	Session 10: Comparing and contrasting U.S. and Canadian healthcare systems and
Session 4: Recruitment and engagement of clinicians, practices, patients, & healthcare	research infrastructures
systems	Session 11: Translational research in PBRNs – Linking research to policy
Session 5: Participatory Research in PBRNs Patient Centered Outcomes Research	Session 12: Qualitative methods and multimethod research methods in PBRN research
Session 6: Research Using Electronic Health Records & Big Data	Session 13: Writing PBRN research for publication – Methods of research
Session 7: Quality improvement Research; Alliances and methods for practice	dissemination
improvement	Session 14: Methods for implementation of complex interventions in PBRNs



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Enhancing Community Health Center Patient Centered Outcomes Program Summary Research (PCOR) Engagement (EnCoRE)

- EnCoRE is a year-long training curriculum designed to educate and engage Health Center teams including patients, clinical and administrative staff in Patient Centered Outcomes Research (PCOR).
- The objective of EnCoRE is to build infrastructure to strengthen the patient-centered comparative effectiveness research (CER) capacity of Health Centers as they develop or expand their own research infrastructure. EnCoRE is an innovative online training, that is targeted to and accessible at no cost to all Health Centers and other primary care practices. Content will prepare Health Center patients, staff, and researchers in the conduct of community-led PCOR.

EnCoRE Webinar Sessions

	Session 1: Introduction to Patient Centered Outcomes Research (PCOR): Developing a Study and Study Questions Session 2: Patient Engagement in Selecting and Designing Interventions for Testing Session 3: Enhancing Community Health Center PCORI Engagement (EnCoRE) Session 4: Measurement, Measurement Error, And Session 5: Sample Size, Power Calculations, & Sampling Methods Session 6: Study Design and Clinical Statistics Session 7: Basic Concepts in Biostatistics	Session 8: Bioinformatics Session 9: Research Ethics, IRB, and Good Clinical Research Session 10: Grant Planning and Writing Session 11: Budgeting, Work-plans, and Timelines Session 12: Planning Dissemination & Implementation
l	Session 7: Basic Concepts in Biostatistics	

Link to eTraining: www.CDNetwork.org/encore

Funded by:

Enhancing Community Health Center PCOR Engagement (EnCoRE) (NCHR 1000-30-10-10 EA-0001)

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Health Choice Network (HCN) Capacity Building Project

Program Summary

- Provide education, training, career development, and mentoring to enhance research excellence in our Clinical and Translational (C/T) research workforce
- Advance C/T research through partnerships and innovative methods of engaging diverse stakeholders
- Integrate disciplines and translational phases to accelerate discovery that benefits the health of diverse populations and individuals across the lifespan
- Ensure research processes expedite the conduct of research and add to our understanding of the principles of advancing translational science
- Manage a dynamic program of informatics and computational functionality, training, consultation, and development for researchers to effectively use technology to advance their research
 Webinar Sessions

Session 1: Research Done Differently: The Ins and Outs of Patient-	Session 5: Measurement, Measurement Error and Descriptive
Centered Outcomes Research.	Statistics
Session 2: Intersection of Quality Improvement (QI) and Research.	Session 6: Sample Size, Power Calculations & Sampling Methods
Session 3: Introduction to Patient Centered Outcomes Research	Session 8: Grant Planning and Writing
(PCOR): Developing a Study and Study Questions.	Session 9: Enhancing Community Health Center PCOR
Session 4: Research Ethics, IRB, and Good Clinical Research.	Engagement (EnCoRE).
Session 5: Navigating Community Data: HRSA's Universal Data	Session 10: Patient Engagement in Selecting and Designing
System (UDS) and Current Population Health Tools.	Interventions for Testing.
Session 6: Taking the Pain out of P-Values.	Session 11: Incorporating Patient Voice into Meaningful Research
Session 7: Partnering with Community to Improve Health.	Lessons learned from a Eugene Washington Engagement Award

Link to eTraining: www.CDNetwork.org/HCN

Funded by:

CLINICAL-DIRECTORS-NETWORK www.CDNetwork.org Health Choice Network (HCN) in partnership with AllianceChicago, Miami Clinical and Translational Science Institute, NCATS/Miami CTSI Grant # 1UL1TR002736-01 (CTSI) CDN Center of Excellence (P30) for Practice-based Research and Learning, N²-PBRN Learning Collaborative (AHRQ, Grant No. 1P30HS021667)

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Development and Implementation of Innovative Interventions that Effectively Address Health Disparities Research

Patient-Centered Outcomes Research (PCOR) Research Training Seminars (2021-2022)

Program Summary

Join Clinical Directors Network and Henry J. Austin Health Center (HJAHC) for a webinar series designed to educate and engage HJAHC teams, including clinical and
administrative staff, in patient- centered outcomes research (PCOR). The training activities will be case-based, team-based and practice-based, and will address priority
conditions based on:

1) Community prevalence

- 2) Community perceptions of needs
- 3) FQHC leadership, clinician and team commitment to studying:
- a) unmet needs; and b) testing and evaluating novel interventions.
- This course will teach you how:
 - * To conduct PCOR in primary care practices
 - * Enhance your understanding of PCOR
 - * Develop new research projects and seek funding for these initiatives

Webinar Sessions

Session 1: Introduction to Research/Patient-Centered Outcomes	Session 5: Measurement, Measurement Error and Descriptive
Research (PCOR)	Statistics
Presenter:	Session 6: Sample Size, Power Calculations & Sampling Methods
Session 2: Developing a Patient-Centered Outcomes Research	Session 7: Study Design & Clinical Statistics
(PCOR) Study	Session 8: Biostatistics/Univariate Data Analysis
and Study Questions	Session 9: Bioinformatics
Session 3: Patient Engagement in Selecting and Designing	Session 10: Research Ethics, IRB, FDAA Regulations and Good
Interventions for Testing	Clinical Practices
Session 4: Community Engagement for Selecting and Designing	Session 11: Grant Writing, Fundraising, & Project Planning
Interventions for Testing	Session 12: Preparing Budgets, Work Plans, and Timelines

Link to eTraining: www.CDNetwork.org/hja

Funded by:



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Part 3: Case Study

Reducing Cardiovascular Disease (CVD) Risk in HIV+ Patients (GREAT2 Study)



ABCS for HIV



Implementation Research: Translating the ABCS into HIV Care (GREAT 2)

Principal Investigators (Multiple PIs):

Kevin Fiscella, MD MPH (University of Rochester)

Amneris Luque, MD (Parkland Health & Hospital System/UTx Southwestern) Jonathan N. Tobin, PhD (Clinical Directors Network & The Rockefeller University)

<u>Funded by:</u> NHLBI Grant # 1 U01 HL 142107-01 CDN Center of Excellence (P30) for Practice-based Research

and Learning, N²-PBRN Learning Collaborative (AHRQ Grant No. 1P30HS021667)









Background



Cardiovascular Disease (CVD) among HIV+ Patients

- Use of highly effective, often single pill HIV antiretroviral therapy has dramatically reduced deaths from AIDS related causes
- This produces an aging population among people living with HIV (PLH) who increasingly experience cardiovascular (CVD) morbidity and mortality
- Age and sex-adjusted deaths from CVD are appreciably higher among PLH than among the general population









ABCS-HIV Study Rationale and Objectives



The overall **goal is to reduce ASCVD risk** by supporting patients using proven **ABCS** interventions that are deemed clinically appropriate by their clinicians and desired by the patients. We have used **evidence-based**, **multilevel implementation strategies** to improve discussion and uptake of the ABCS among Persons Living with HIV (PLH)



"A" - for taking "<u>a</u>spirin"
"B" - for "<u>blood pressure control</u>"
"C" - for "<u>cholesterol control</u>"
"S" - for "<u>smoking cessation</u>"

Specific Aims

- 1) To assess the impact of the implementation of an evidence-based, **multilevel strategy** to reduce CVD risk among PLH (n=600)
- 2) To assess the process of implementation of these strategies using **RE AIM** QuEST (Reach, Effectiveness, Adoption, Implementation and Maintenance)











Project Partners & Team Members

University of Rochester Medical Center

Kevin Fiscella, MD, MPH Principal Investigator

Mechelle Sanders, PhD Co - Investigator

Emma Strujo, MPH Senior Health Project Coordinator

> Marie Thomas Health Project Coordinator

Brent Johnson, PhD Statistician

Alain Leblanc, MS Data Analyst

Erica Dobson, PharmD, BCPS-AQ ID Pharmacologist

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University of Texas Southwestern (Parkland Hospital)

> Amneris Luque, MD Principal Investigator

Claudia Sanchez Lucas, MPH Research Study Coordinator

Alegandro Deets Research Study Coordinator

University of Colorado Jennifer Carroll, MD, MPH Co - Investigator

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Clinical Directors Network (CDN)

Jonathan N. Tobin, PhD Principal Investigator

Andrea Cassells, MPH Project Director

Tameir Holder, MPH Project Manager

Chamanara Khalida MD, MPH Research Associate

> Elia Flores, BME Research Assistant

Karen Morton, MA, CASAC Research Associate

New York University Stephen Williams, MD, MS Co - Investigator







Study Design



Stepped Wedge Cluster Randomized Clinical Trial (SW-cRCT)

Table 1. SWT timeline

	Year	1	Year	2	Year	3	Ye	ar 4
Baseline data collection								
#1Wedge								
#2Wedge								
#3Wedge								
Final data collection								
Data analysis								









Intervention



Clinicians

- <u>Two</u> Audit Feedback Reports
- One Study Overview
- <u>Two</u> Learner-Centered Academic Detailing (AD) Sessions
- Four online interactive educational continuing medical education (CME) Modules
 - AD sessions and online modules will carry CME credit

Patients

- One Coaching Session (one on one) that will promote/include:
 - Calculating the patient's ASCVD risk score using the ASCVD Risk Estimator
 Plus
 - Goal setting and empowerment
 - Behavioral change techniques
 - Involvement in values affirmation
- Texting through a mobile application which will promote ABCS goal setting and self-management
- Phone Check-Ins with HIV+ peer educators









Outcomes - Primary Endpoint



Primary Endpoint

Change in CVD risk (from baseline to 12 months) using the validated American College of Cardiology (ACC) ASCVD Risk Estimator Plus

Variables in Calculator

- Medical Records Data (via EHR)
 - Age
 - Sex
 - Diabetes (history of)
 - Systolic Blood Pressure
 - Diastolic Blood Pressure
 - Lipids (HDL, LDL, Total Cholesterol)
 - Medication Use (antihypertensives, statins)
- Pre- and post- Patient Surveys
 - Race
 - Smoking Status
 - Medication Use (Aspirin Intake)

ASCVD Risk Estimator Plus





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Outcomes – Secondary Endpoint



Secondary Endpoints

- Pre and Post Changes in:
 - Systolic Blood Pressure control
 - LDL Cholesterol
 - Smoking Cessation

Exploratory Outcomes

- Changes In
 - BMI
 - HbA1c
 - Risky drinking (Behavioral Risk Factor Surveillance System [BRFSS])
 - Physical activity (Rapid Assessment of Physical Activity)
 - Diet (Starting the Conversation)
 - Appropriate prescription of daily low-dose aspirin









Primary and Secondary Endpoints– Extracted from Electronic Health Record (EHR)

Type of Data	Data Elements from EHR	Comments
Demographics	 Demographic/Registration File Date of Birth HIV Diagnosis Date Sex/Gender Identity Race Insurance Type (Medicaid, private, ADAP, Medicare, None, Other) Hispanic Ethnicity Patient Zip Code Has portal activated Language Marital Status Living Arrangement 	
Health Conditions	Problem list and with dates of entry	
Visit Codes	All ICD and CPT Codes and date for visits and provider name	 ICD-10: I10, E10, E11, etc CPT: 99212-99215, 99406, 99407
CDN		ADAP: AIDS Drug Assistance Program ICD: International Classification of Diseases CPT: Current Procedural Terminology









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Primary and Secondary Endpoints-Extracted from Electronic Health Record (EHR)

Type of Data	Data Elements from EHR	Comments
Vital File	• Systolic and Diastolic Blood Pressure & all recorded readings during visit: Height, Weight, BMI	
Behavioral Health	 Tobacco status (Current, Former [date of quit], Never) PHQ2/PHQ9 	
Laboratory File	All laboratory tests and dates	 HIV viral load Lipids (Total Cholesterol, LDL, HDL, TG) A1c, Creatinine COVID PCR, antigen
Medications	 Include all NDCs and dates when available 	 Aspirin Statins (Atorvastatin, Fluvastatin, Lovastatin, pravastatin Rosuvastatin, simvastatin, pitavastatin) Antihypertensives (all classes) Antismoking (Varenicline, Bupropion, Nicotine replacement including patches, inhalers, nasal spray and gum)
	BMI: Body Mass Index PHQ: Patient Health Questionnaire	LDL: Low-density Lipoprotein HDL: High-density Lipoprotein





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PCR: Polymerase Chain Reaction

NDC: National Drug Code

TG: Triglycerides



Characteristics of Clinicians and Patients*

PARTICIPANTS:	N (%)
<u>Clinicians</u>	
Enrolled	39 (100%)
Attended 1 AD session	29 (74%)
Attended 2 AD session	23 (59%)
<u>Patients</u>	
Total eligible	632
Eligible who enrolled	507 (100%)
Attended baseline & follow up 1 coaching session	477 (94%)
Enrolled in texting program	413 (82%)
Submitted at least one text response	337 (67%)
Text goal discussed	196 (39%)

*Categories are not mutually exclusive









Patient Demographics

Characteristic	Category	Total
Age Range		454
	40-54	128 (28%)
	55-64	240 (52%)
	>=65	86 (18%)
Gender at Birth		450
	Male	306 (68%)
	Female	143 (31%)
Gender Identity		452
	Male	306 (67%)
	Female	144 (31%)
	Transgender man	1 (<1%)
	Transgender woman	1 (<1%)
Race/Ethnicity (Self-Described)		456
	Black or African American	257 (56%)
	White	124 (27%)
ODN	Other	50 (10%)
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Patient Demographics

Characteristic	Category	Total
Hispanic (Self-Described)		450
	Yes	90 (20%)
Country of Birth		451
	USA-born	361 (80%)
Language most comfortable speaking		452
	English	413 (91%)
	Spanish	38 (8%)
	Other	1 (<1%)
Highest Grade Level or Degree		448
	Less than High School	109 (24%)
	High School diploma/GED	141 (31%)
	Some College (no Degree)	89 (19%)
	Bachelor's Degree or Higher	55 (12%)









Patient Demographics

Characteristic	Category	Total
Monthly Income		437
	\$0 to \$999	214 (48%)
	\$1,000 to \$1,499	91 (20%)
	\$1,500 to \$1,999	55 (12%)
	\$2,000 to \$2,499	28 (6%)
	\$4,000 and Over	24 (5%)
	\$3,000 to \$3,499	12 (2%)
	\$2,500 to \$2,999	9 (2%)
	\$3,500 to \$3,999	4 (<1%)
Marital Status		441
	Single	187 (42%)
	Married	83 (18%)
	Divorced	48 (10%)
	Never married	46 (10%)
	Widowed	30 (6%)
	Living with partner	27 (6%)
	Separated	20 (4%)









ASCVD Risk Factors

Characteristic	Category	Total
ASCVD Risk		452
	<5% (Negligible)	(3%)
	5% to 7.4% (Borderline)	(14%)
	7.5% to 9.9% (Intermediate)	(17%)
	10% to 19.9% (High)	(39%)
	<u>></u> 20% (Very High)	(25%)
Currently Taking Aspirin		450
	Νο	343 (76%)
	Yes	107 (23%)
Blood Pressure (mmHg)		447
	<u>></u> 140/90	73 (16%)
	130/80 to <140/90	257 (57%)
	<130/80	117 (26%)









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ASCVD Risk Factors

Characteristic	Category	Total
Total Cholesterol (mg/dL)		455
	<u>></u> 240	41 (9%)
	200-239	97 (21%)
	<200	317 (69%)
LDL Cholesterol (mg/dL)		455
	<u>></u> 160	24 (5%)
	130-159	50 (10%)
	100-129	136 (29%)
	75-99	135 (29%)
	<75	110 (24%)
HDL Cholesterol (mg/dL)		455
	<u>></u> 60	130 (28%)
	50-59	80 (17%)
	40-49	131 (28%)
	<40	114 (25%)
Current Smoking Status		456
	Current Smoker	188 (41%)
	Never Smoked	143 (31%)
	Former Smoker	125 (27%)
Diabetes		456
	Yes	142 (31%)









ABCS Goal Choices

Characteristic	Category	Total
1st Goal		446
	Cholesterol	190 (42%)
	Blood Pressure	127 (28%)
	Smoking	112 (25%)
	Aspirin	17 (3%)
2nd Goal		407
	Cholesterol	170 (41%)
	Blood Pressure	136 (33%)
	Aspirin	64 (15%)
	Smoking	37 (9%)











Proportion of Patients taking Statins by ASCVD Risk Score (N=448)











Methodological Challenges involving COVID-19 Dynamics

• Repeated surges in COVID-19 across time and space

• Evolution in response to COVID-19 over time

 Potential confounding by time, surges, geography, and across and between wedges









Summary

- Participants were primarily middle-aged to older Black/African American men who are low-income (<\$999 per month) and with low educational attainment
- Participants primarily had an elevated risk for experiencing a heart attack or stroke within 10 years since nearly 40% had a "High" ASCVD risk score (range: 10%-19.9%)
- As ASCVD risk scores increase, the proportion of participants taking statins increases in a dose-response fashion
- During the initial coaching session, most participants were interested in lowering their cholesterol levels









Successful Research Staff Adaptations &

Lessons Learned

Adaptations

- Rapid development of remote recruitment procedures, IRB approval, and deployment of these procedures
- Coordinating study visits with virtual patient visits
- Use of practice phone numbers when feasible (eg, Doximity)

<u>Lessons</u>

- Teamwork based on durable personal relationships with participating practices
- **Open communication** among team members about successes and challenges
- Remote Activities
 - Virtual study meetings
 - Remote consent
 - Clinician Academic Detailing Sessions
 - Clinician Audit and Feedback reports
 - Patient pre-screening and recruitment
 - Patient Assessment and Coaching Sessions
 - Patient texting









Part 4: Discussion of Interest & Feasibility in Building a Learning Collaborative and Research Project Modeled on GREAT2-HIV/ABCS

Outcomes - Primary Endpoint



Primary Endpoint

Change in CVD risk (from baseline to 12 months) using the validated American College of Cardiology (ACC) ASCVD **Risk Estimator Plus**

Variables in Calculator

- Medical Records Data (via EHR)
 - Age
 - Sex
 - Diabetes (history of)
 - Systolic Blood Pressure
 - **Diastolic Blood Pressure**
 - Lipids (HDL, LDL, Total Cholesterol)
 - Medication Use (antihypertensives, statins)
- Pre- and post- Patient Surveys
 - Race
 - **Smoking Status**
 - Medication Use (Aspirin Intake)

ASCVD Risk Estimator Plus







Primary and Secondary Endpoints– Extracted from Electronic Health Record (EHR)

Type of Data	Data Elements from EHR	Comments
Demographics	 Demographic/Registration File Date of Birth HIV Diagnosis Date Sex/Gender Identity Race Insurance Type (Medicaid, private, ADAP, Medicare, None, Other) Hispanic Ethnicity Patient Zip Code Has portal activated Language Marital Status Living Arrangement 	
Health Conditions	Problem list and with dates of entry	
Visit Codes	All ICD and CPT Codes and date for visits and provider name	 ICD-10: I10, E10, E11, etc CPT: 99212-99215, 99406, 99407
		ADAP: AIDS Drug Assistance Program ICD: International Classification of Diseases







CPT: Current Procedural Terminology



Primary and Secondary Endpoints-Extracted from Electronic Health Record (EHR)

Type of Data	Data Elements from EHR	Comments
Vital File	 Systolic and Diastolic Blood Pressure & all recorded readings during visit: Height, Weight, BMI 	
Behavioral Health	 Tobacco status (Current, Former [date of quit], Never) PHQ2/PHQ9 	
Laboratory File	All laboratory tests and dates	 HIV viral load Lipids (Total Cholesterol, LDL, HDL, TG) A1c, Creatinine COVID PCR, antigen
Medications	 Include all NDCs and dates when available 	 Aspirin Statins (Atorvastatin, Fluvastatin, Lovastatin, pravastatin Rosuvastatin, simvastatin, pitavastatin) Antihypertensives (all classes) Antismoking (Varenicline, Bupropion, Nicotine replacement including patches, inhalers, nasal spray and gum)
	BMI: Body Mass Index PHQ: Patient Health Ouestionnaire	LDL: Low-density Lipoprotein HDL: High-density Lipoprotein





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PCR: Polymerase Chain Reaction

NDC: National Drug Code

TG: Triglycerides



Building Networks of Practice Based Research Networks From South Africa to the USA and back

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