



Integrating **HIV** and **hEART** health in **South Africa** (**iHEART-SA**) through Community Engagement

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health
Department:
Health
REPUBLIC OF SOUTH AFRICA



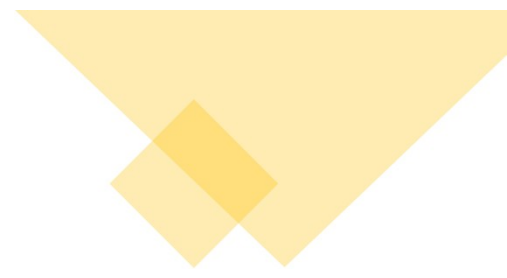
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German Research Center for Environmental Health



UMC Utrecht

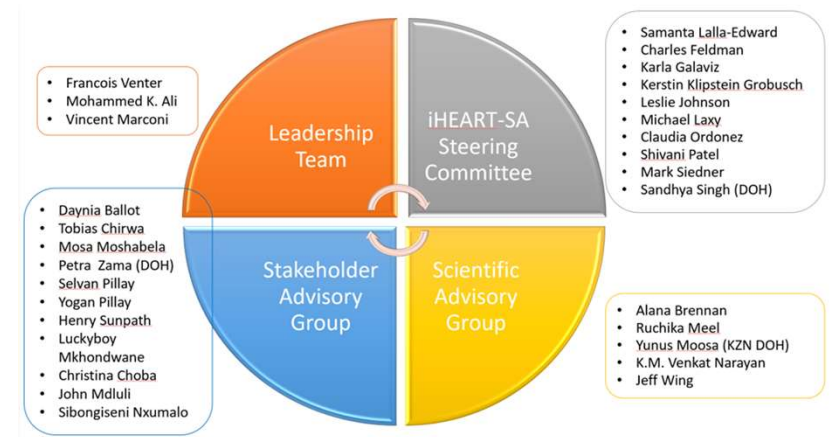


National Heart, Lung,
and Blood Institute



Community Summary

- Cardiovascular Disease (CVD) is a leading cause of death in South Africa
 - Hypertension is one of the main risk factors for CVD
 - Substantial gaps in hypertension care exist
 - Blood pressure monitoring increased in the clinics after the intervention
 - Partnership with Community was critical to study design, implementation, and success of iHEART-SA
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<https://www.iheart.ezintsha.org/>

iHEART-SA is supported by the National Heart, Lung, and Blood Institute of the National Institutes of Health under Award Number UG3HL156388. The content is solely the responsibility of iHEART-SA and does not necessarily represent the official views of the National Institutes of Health

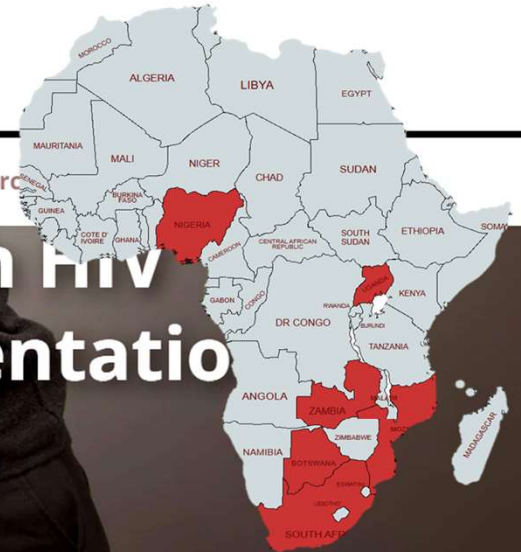


HLB-SIMPLe (www.hlbsimple.org)



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people living with HIV
through implementation
science



Our Mission

The HLB-SIMPLe research alliance aims to address critical gaps in heart disease prevention and treatment among individuals living with HIV through innovative strategies and collaborative efforts. Funded by the [US](#)

Background

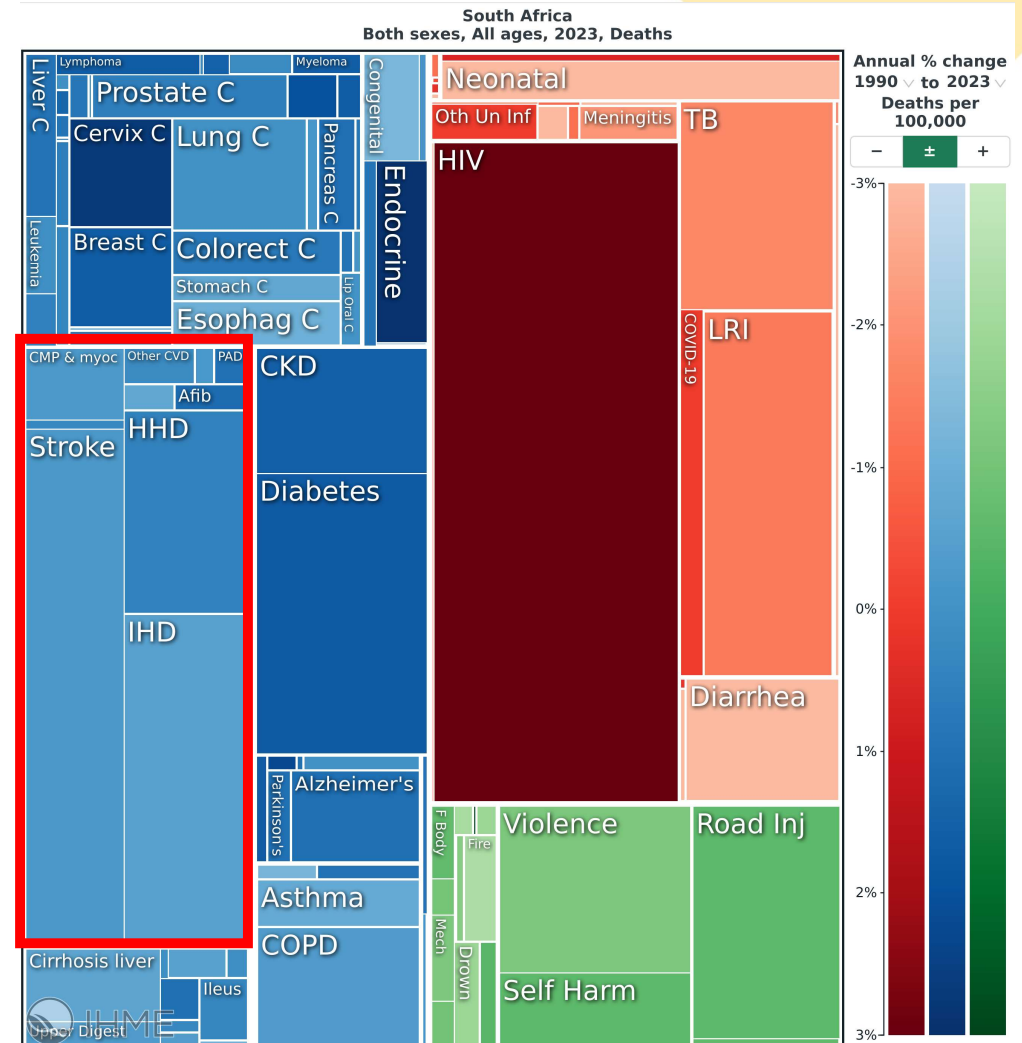


Cardiovascular Disease

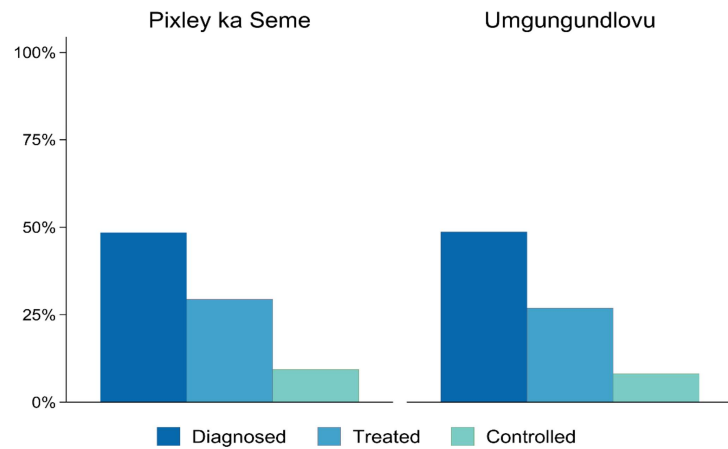
- Leading cause of death in South Africa comparable to HIV
- Independent associations shown between HIV and CVD in high income countries¹
- In South Africa, people with HIV appear to have no increased risk after accounting for traditional risk factors²

¹ Freiberg *JAMA IM* 2013

² Verstraeten *JAHA* 2024



GAPS IN CARE for Hypertension

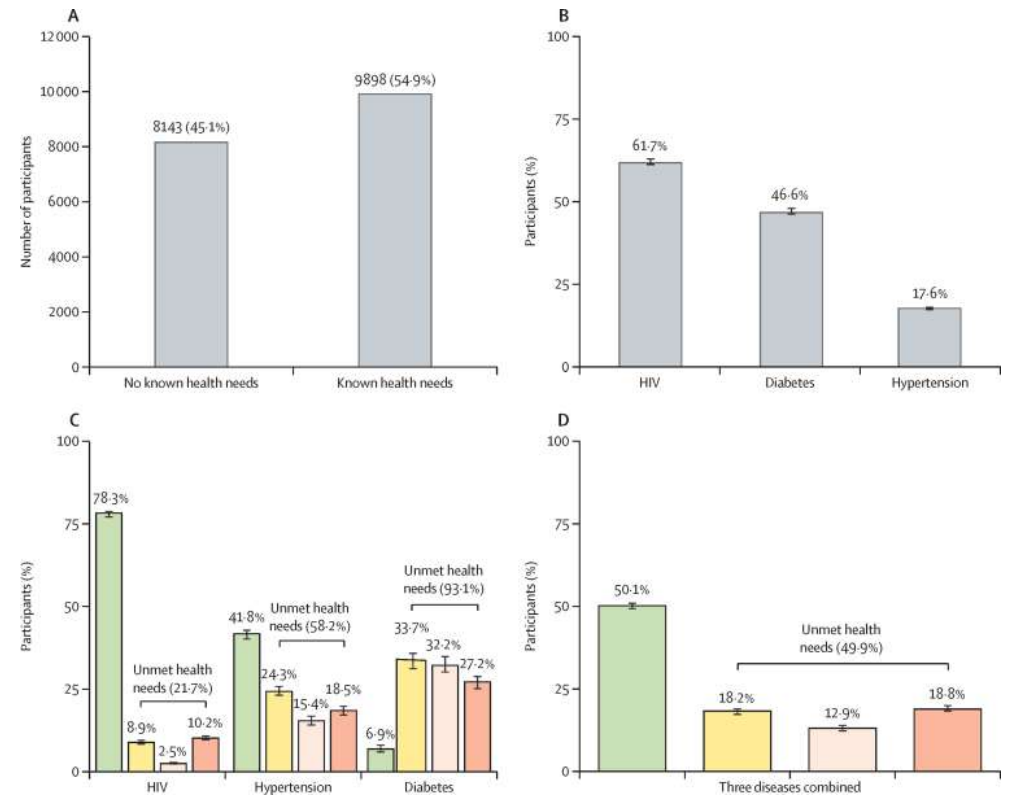
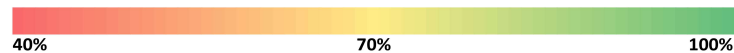


Umgungundlovu

	Hospital	CHC	PHC	Mobile Clinic	Private Doctor	Private Pharmacy
Pharmaceuticals	94	92	94	98	56	96
Testing Capacity	89	75	87	57	89	46
Guidelines	67	100	94	89	100	50

Pixley ka Seme

	Hospital	CHC	PHC	Satellite Clinic
Pharmaceuticals	100	90	98	100
Testing Capacity	83	96	98	92
Guidelines	100	100	96	100



OUR PREVIOUS TRIALS

ADVANCE



**INtegrating DEPrESSION and
Diabetes treatmENT study**



National Institutes
of Health



THE WORLD BANK



PEPFAR

U.S. President's Emergency Plan for AIDS Relief



USAID
FROM THE AMERICAN PEOPLE



TRIAL OBJECTIVES



Question 1 (IMPLEMENTATION)

Could we facilitate implementation of improved hypertension screening and management in the HIV care setting?

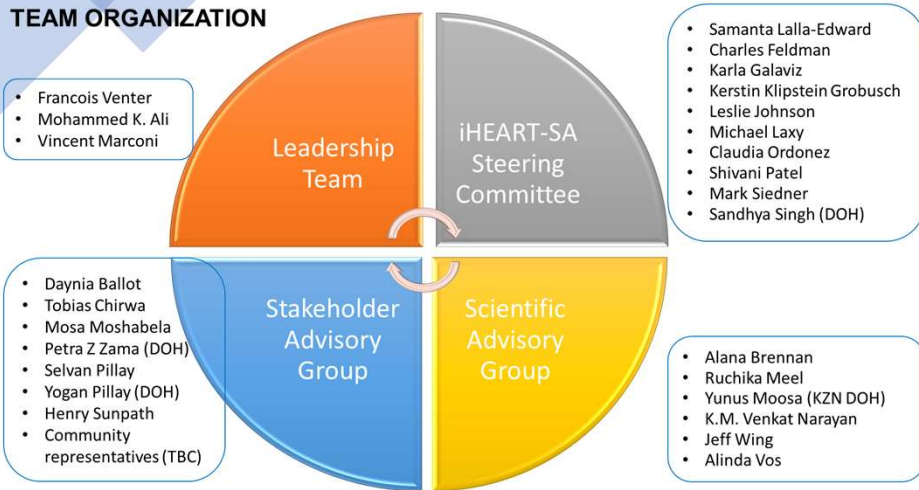
1. Task shifting
2. Audit and feedback
3. Healthcare worker education and training
4. Patient education and support

Question 2 (EFFECTIVENESS)

What are the short- and long-term effects on patient blood pressure control among adults with HIV and elevated BP?

TEAM and SPECIFIC AIMS

TEAM ORGANIZATION



UG Aim 1: Formalize stakeholder partnerships and tailor the intervention package for the local context.

UG Aim 2: Strengthen implementation science capacity among junior African scientists.

UH Aim 1: Evaluate reach, adoption, implementation, and effectiveness of the adapted intervention package.

UH Aim 2: Evaluate sustainability and costs of the intervention package.

UH Aim 3: Assess potential for scale-up.

Methods





CAB Structure



CAB Executive Committee:

Daynia Ballot (lead)
Samanta Lalla-Edward (co-lead)
Claudia Ordóñez (CE lead)
Steering Committee

Henry Sunpath (lead)
Selvan Pillay (co-lead)
Mohammed Ali (co-lead)
Leslie Johnson (qual)
Christina Koba
Prof Shabir Moosa
Yogan Pillay
Bilqees Sayed
Vincent Marconi
Jay Brijkumar
Yunus Moosa

Clinical
Advisory
Group

Tobias Chirwa (lead)
Mark Siedner (co-lead)
Karla Galaviz (qual)
Sandile Khumalo Mzikazi
Andile Madondile
Luckyboy Mkhondwane
Rainy Moukangwe
Leonard Mtshali
Nelly Williams
Daynia Ballot

Patient
Advisory
Group

Stakeholders
Advisory
Group

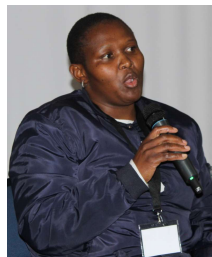
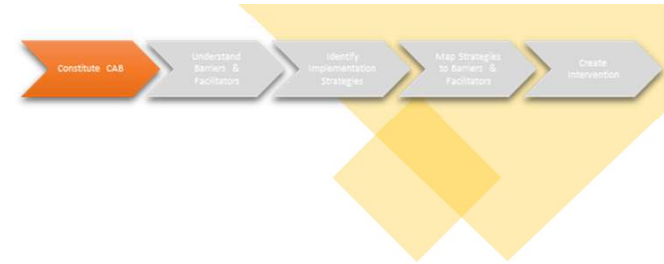
Community Advisory Board

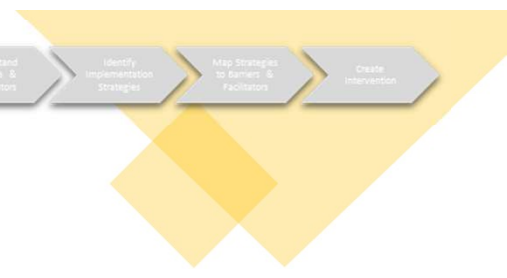
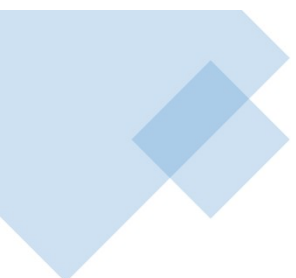
Community-
Based
Advisory
Group

Yogan Pillay (lead)
Vincent Marconi (co-lead)
Samanta Lalla-Edward (qual)
Daynia Ballot
Tobias Chirwa
Mosa Moshabella
Selvan Pillay
Henry Sunpath
Petra Zama
CAB Executive Committee
Qualitative Team

Petra Zama (lead)
Francois Venter (co-lead)
Claudia Ordóñez (qual)
Charles Feldman
John Mdluli
Sibongiseni
Luckyboy Mkhondwane
Mosa Moshabella
Sandhya Singh

Community Engagement

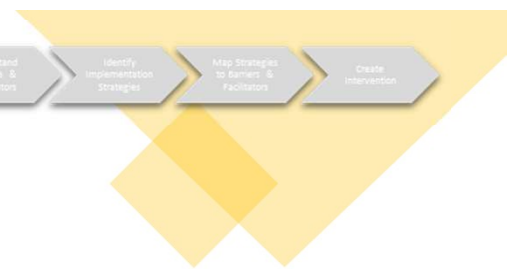




iHEART-SA Intervention Foci

Evidence-based and recommended by guidelines:

1. Measure Blood Pressure
 2. Manage hypertension with lifestyle modification or Blood Pressure-lowering medication as appropriate
- 
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iHEART-SA Intervention

Principles guiding intervention design:

- Aligns with feedback from patients, clinicians, clinic staff, clinic administrators, and broader health system shareholders (e.g., activists, patient advocates, healers)
 - Designed to remain responsive to the local context and current operating conditions of implementing clinics
 - Facilitates data management
 - Introduces a package of services into HIV clinics
 - Try to truly integrate HIV and hypertension care; not just inserting hypertension care onto routine HIV practice
 - Enable future expansion – e.g., add on a diabetes, depression, and other modules in subsequent studies
- 



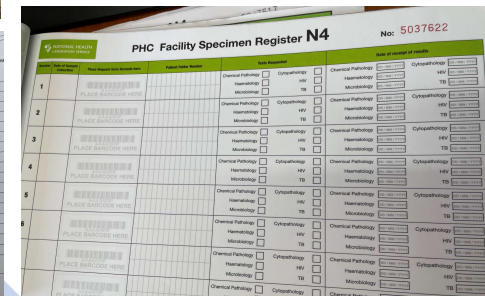
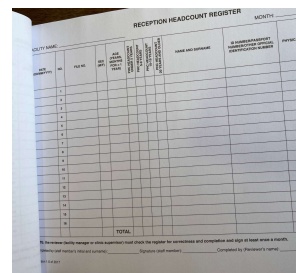
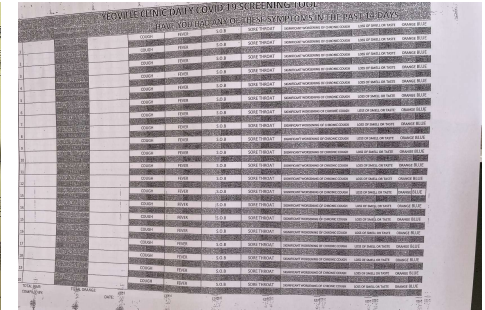
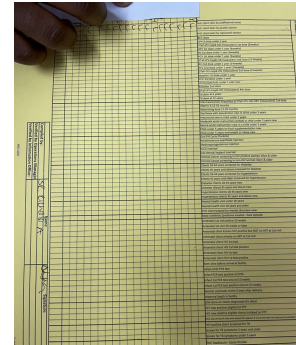
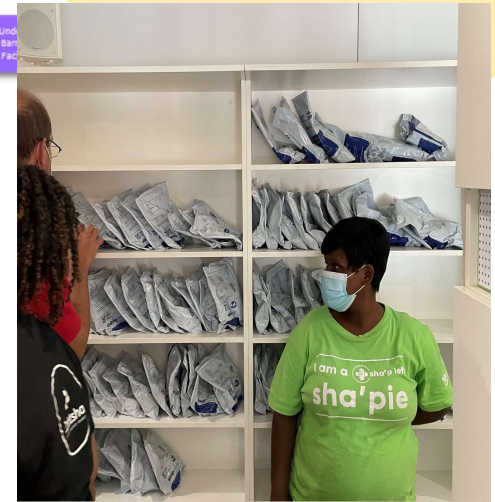
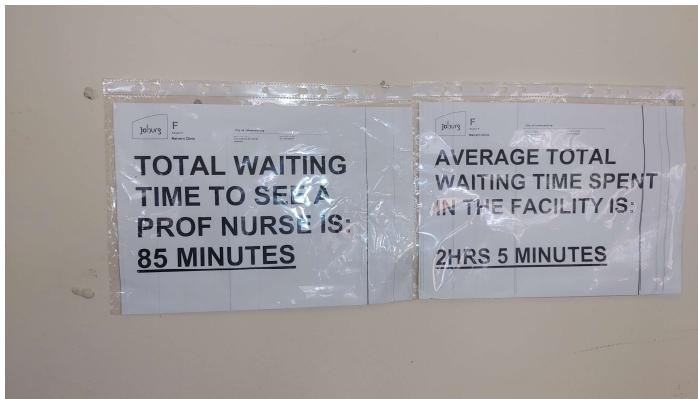
Interviews and Focus Group Discussions

Interview Type	Goal	Recording Complete	Transcript Complete	Analysis Complete
Patient IDI	45	46	46	46
Manager IDI	9	7*	6**	6
Provider FGD	9	9	9	9
Key Informant Interviews	5	3	3	3

* Data collection stopped due to saturation **1 interview with 2 managers

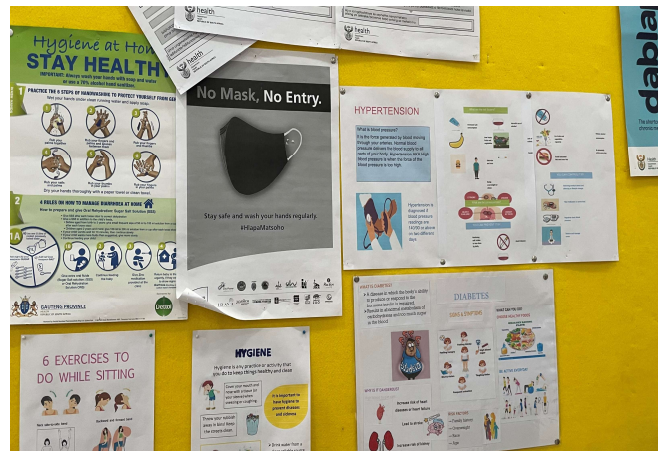
Barriers

- Long Wait times
- Missing Charts
- Unavailable/Faulty BP Machines
- Documentation Challenges
- COVID/Load Shedding/Security

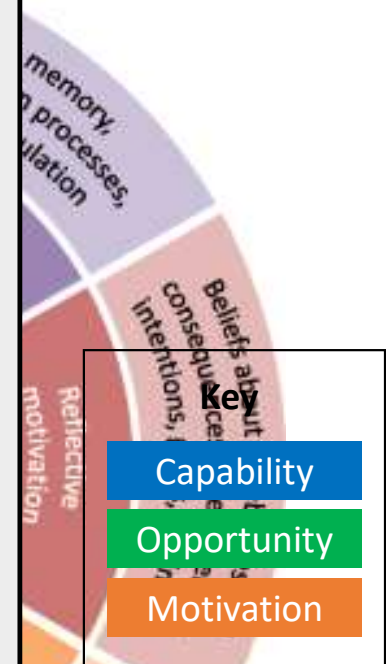
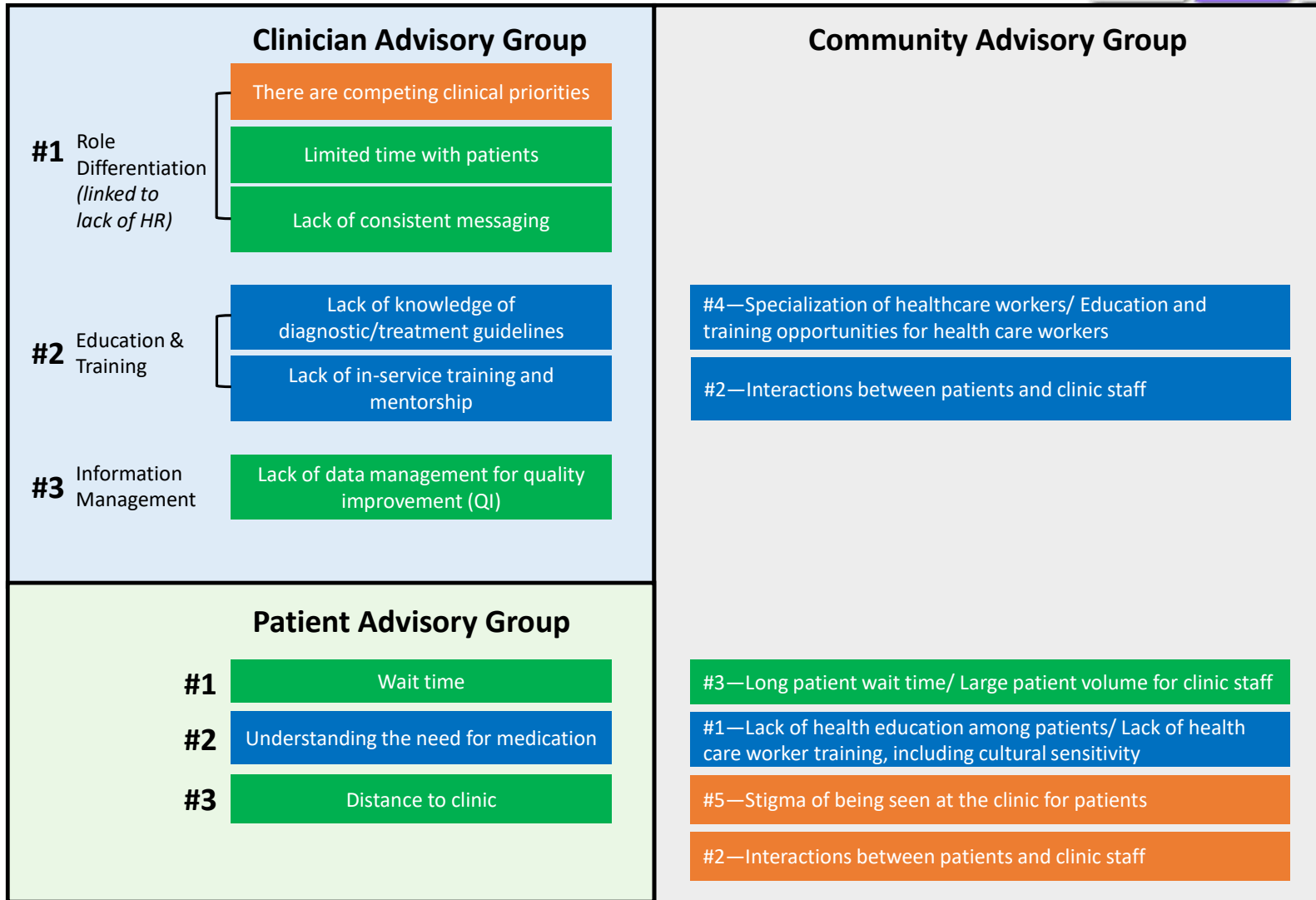


Facilitators

- Differentiated Service Delivery
 - Fast Tracking
 - CCMDD
 - Adherence Clubs
 - Pickup Points
 - Medication Lockers
- Video Information
- Health Messages
- Community Health Workers and Home-Based Care



Top Ranked Barriers to Promoting Care Integration



Implementation Strategies



Potential Barriers	Core Intervention Components	Intervention Function	Potential Adaptations
SYSTEM			
Limited Capability	Integration of decision support tools	• Training / Enablement	Electronic vs. paper guidelines
Limited Opportunity	Modification of organization workflow and culture	• Environmental restructuring • Persuasion	Modeling peer champions vs. passive training on utilization
Low Motivation	Audit / feedback meetings	• Enablement / Persuasion	Video conference vs. in-person
CLINICIAN			
Limited Capability	Training on HTN/ DM care guidelines	• Education / Training	Active vs. passive guideline training
Limited Opportunity	Care prompts and real-time feedback	• Enablement	Electronic vs. paper delivery, Real-time vs quarterly reports
Low Motivation	Support from care coordinator	• Persuasion / Enablement	Dashboard vs. in-person information
PATIENT			
Limited Capability	Counseling by care coordinator	• Education / Training	Individual vs family; phone vs. in-clinic
Limited Opportunity	Provision home BP and BG monitors	• Enablement	---
Low Motivation	Group-based behavioral activation	• Education / Persuasion	Behavior contracts vs. role playing

Patient Intervention Mapping

Target behavior: attending the clinic and taking medication



COM-B construct	Barrier	Intervention function	Behavior change technique	Mode of delivery
Capability (psychological)	-Lack of health education -Understanding the need for medication	Education	Information about health consequences	-Cellphone to deliver educational messages (SMS) -Short videos (TV)/Posters/Information Materials (e.g., pamphlets) for education
		Enablement		-Health promoter presentations -Sharing lab results (discuss/paper/electronic) -Phone patients to assess side effects from meds -Training on how to use self-monitoring devices (BP cuff, glucose, make it easy/accurate)
Opportunity (physical)	-Distance to clinic -Clinic wait time	Environmental restructuring	Prompts/cues	-sending reminders for patient appointments/medication pick up -Phone call to patients when appointment time is near (restaurant wait paging model)
			Action planning	-Have patients make a plan to attend and wait at the clinic
			Restructuring the physical environment	-Environmental improvements to clinics ——Entertainment for waiting (magazine, coffee) ——Toilet access, seating area, wifi -Mobile clinics (e.g. dental services) -Community based options (fairs, centers) -Telehealth (instead of in-person visit)
		Enablement	Self-monitoring of behavior	-Home setting care (provide self monitoring equipment) -create phone app for patients to enter data collected with at-home monitoring devices (incentivize patient health behavior and collect data for clinic staff) -Differentiated care -Less frequent if controlled -Urgent/walk-in (call ahead) if uncontrolled
Motivation (reflective)	Negative beliefs about what their clinic experience will be	Incentivization	Provide incentives	-Incentives for visits and outcomes control (credit card points [using gambling model])
		Persuasion	Feedback on outcomes of behavior	-Feedback on outcomes control (from clinician)

Clinician Intervention Mapping

Target behavior: taking vitals/blood work & following HTN/DM treatment guidelines



COM-B construct	Barrier	Intervention function	Behavior change technique	Mode of delivery
Capability (psychological)	-Guideline knowledge -In-service training/mentorship	Education	Instruction	-In-service sessions that cover topics on evidence-based NCD care -Trainings to enhance patient/provider communication -Include traditional health practitioner in offered trainings
		Training		
		Enablement	Social support	- Use WhatsApp/video consultation programs for remote specialist support for clinicians
Opportunity (social/physical)	-Limited time with patients -Lack of data management for QI -Lack of human resources -Lack of consistent messaging	Enablement	Social support	-create clinic WhatsApp group to facilitate staff communication
		Environmental restructuring	Adding to the clinic environment	-Attach flow sheets to individual patient files (reminders for upcoming deadlines) -Put up a chart with the timeline for follow-up care/ blood draws in the vitals/phlebotomy room -Lockers/vending machine or delivery for meds -establish a QI champion (i.e., train others on collecting/entering data into clinic registries)
			Prompts/cues	-App with prompts for evidence-based NCD treatment
Motivation (reflective)	Competing clinical priorities	Persuasion	Information from credible source	-monthly one-on-one meeting with manager to review target behaviors
			Feedback on outcomes of behavior	-Provide data on patient outcomes (providers typically see different patients each time) -Monthly meetings with clinic staff to review patient outcomes data (feedback on outcomes)
		Incentivization	Social reward	-praise at meetings for completing target behaviors



APEASE Survey Results

Who: Scientific Advisory Group ● Stakeholder Advisory Group ● Steering Committee

How potential interventions were assessed:

Affordability: Can it be delivered within an acceptable budget?

Practicability: Can it be delivered as designed and to scale?

Effectiveness/Cost-effectiveness: Does it work well and is it worth the cost?

Acceptability: Is it judged appropriate for relevant stakeholders?

Side effects/Safety: Does it avoid unintended consequences or unwanted side effects?

Equity: Will it reduce disparities in health/wellbeing/standard of living?

***Ratings from 1 (strongly disagree) to 5 (strongly agree)**



APEASE: Improve clinician's capacity for effective patient communication on self-management & institute patient nudges

Communication

	Patient f/up on med side effects	Training on pt-provider communication	Send patient reminders	Share lab Results w/ pts	Feedback to pts on outcomes control
<u>A</u> ffordability	4.1 4.05	4.1 4.13	4.1 4.17	3.9 3.65	4.2 4.23
<u>P</u> rac ^t icability	3.6	4.2	4.4	3.3	4.3
<u>E</u> ffectiveness	3.9	4.1	4.3	3.8	4.2
<u>A</u> cc ^e ptability	4.2	4.1	4.4	3.6	4.2
<u>S</u> ide effects/safety	4.4	4.3	3.9	3.8	4.3
<u>E</u> quity	4.1	4	3.9	3.5	4.2



Ranked Interventions according to overall score averages

1. Group mtgs to review patient outcomes
2. Feedback to patients on outcome control
3. Flow sheets
4. Send patient reminders
5. Tele-mentoring
6. Training on patient provider communication
7. Health promoter presentations
8. Chart w/follow up timeline
9. Patient f/up on med side effects
10. (tied) In service sessions
10. (tied) App with EBT prompts for NCD care
11. Educational materials
12. Provide clinicians with long-term patient outcomes data
13. Differentiated care
14. Include traditional healers in trainings
15. Share lab results with patients
16. Chart w/follow up timeline
17. Patient self-monitoring
18. Patient goal setting and action planning
19. Self-service med dispensing machines

Measuring Blood Pressure



Level	Barrier	Intervention Component
Patients	Wait times are long	Rework clinic workflow so that wait times used for obtaining BP, VLs, etc.
	Lack of understanding for need of medication	Waiting room posters / presentations / education materials on HTN/HIV and importance of screening and managing
	Distance to clinic for routine monitoring	Home BP monitor loan program** – purchase 10-20 per clinic / donated devices; integrate with data capture system. In appropriate circumstances, teach patients receiving them how to use and go over terms of use/return
Clinicians	Lack time and human resources	Task shifting: identify and support a clinic champion (nurse or allied health worker that is trained and wields respect from staff; paid for by the study for 12 months) to oversee conducting of BP measurements and recording in vitals room
	Lack information management for QI	Data capture system that tracks check-in at clinic, BP measured/not, BP treated/not, VL measured/not, time seen in clinic, home recordings
System	Maintenance of BP measuring tools	Incorporate into clinic champion's role*

*Critical to conducting the intervention but not identified by the formative data

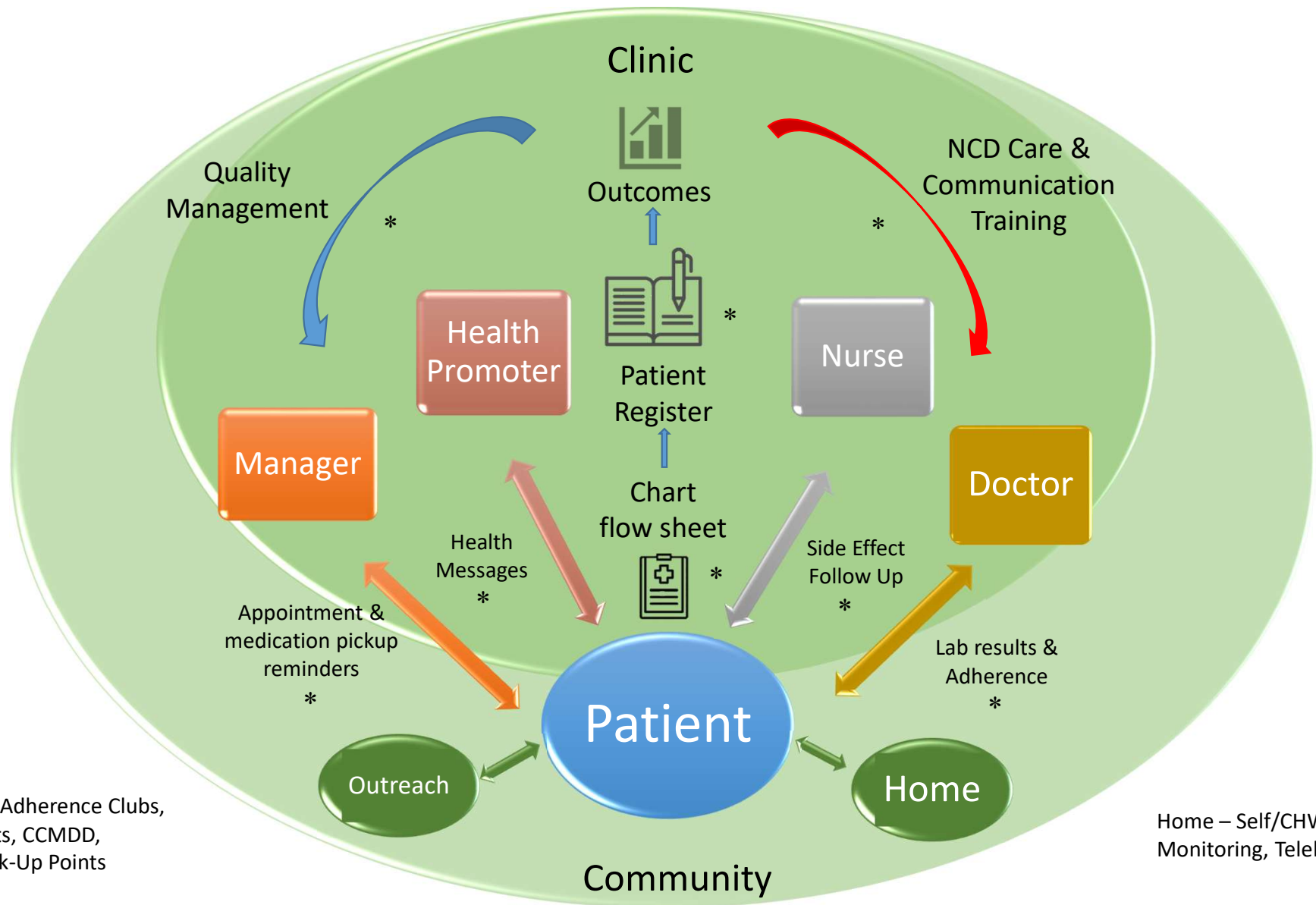
**See clarifications regarding use of home BP monitors

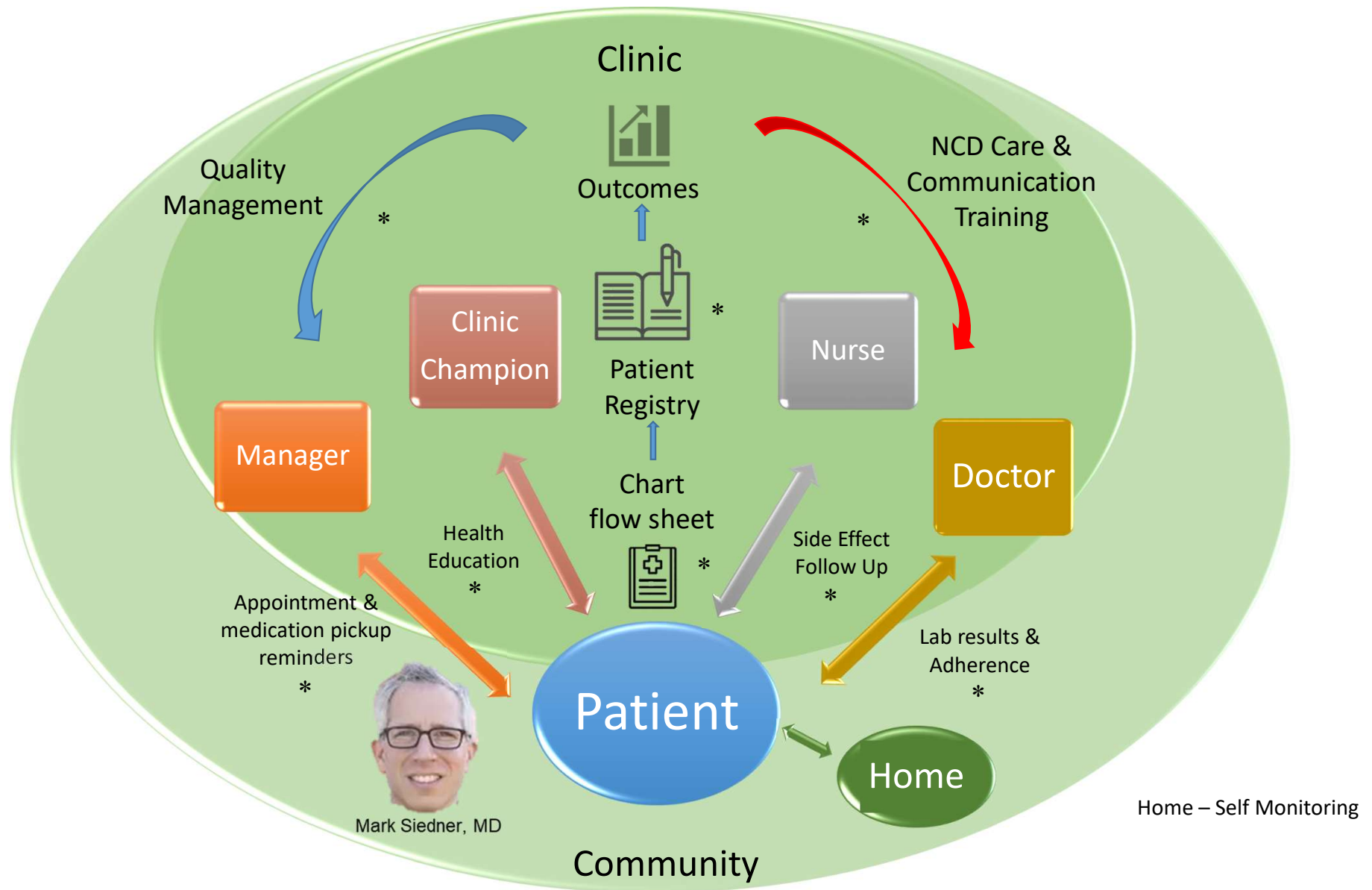


Managing Hypertension

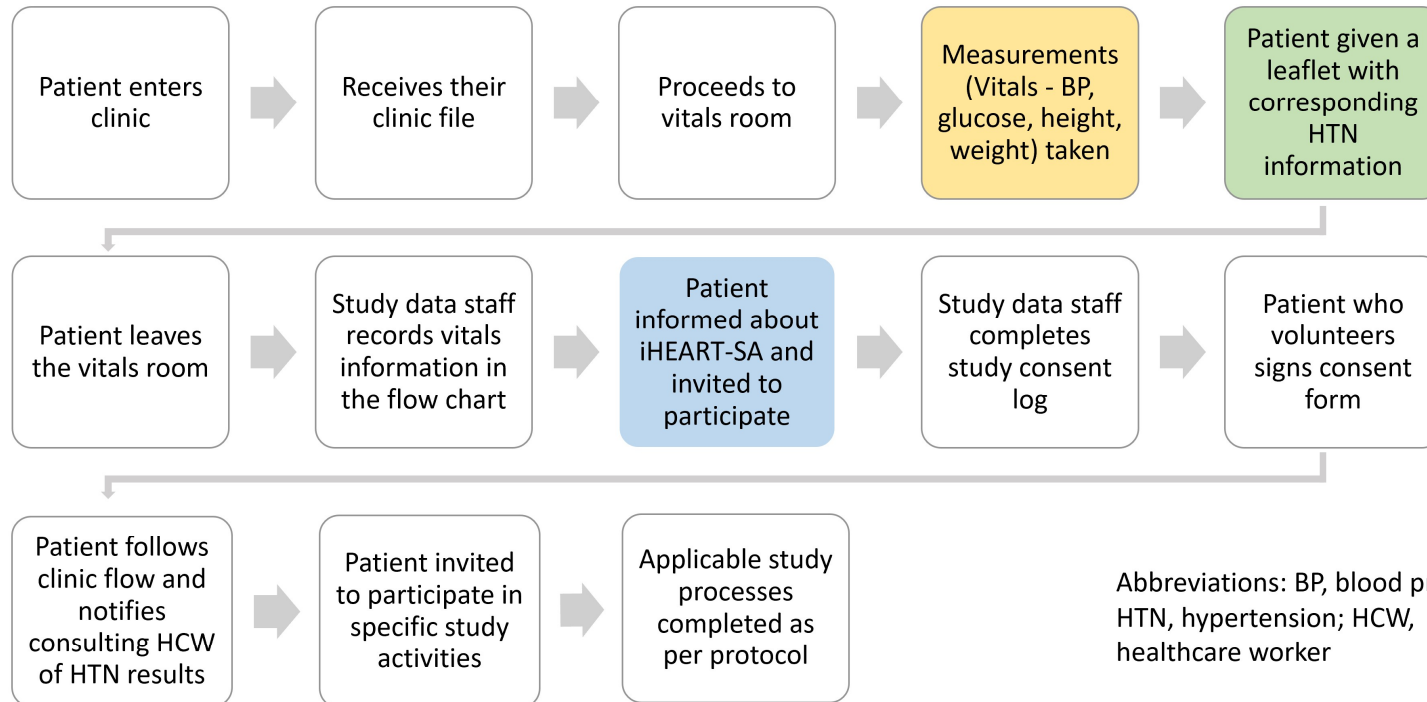
Level	Barrier	Implementation Strategy
Patients	Low understanding of HTN and treatment	Pamphlets and education on HTN/HIV including lifestyle and treatment
Clinicians	Lack information management for QI	Data capture system with home and clinic readings + built-in prompts for next visits, tests (<i>if electronic</i>)
	Lack of guidelines knowledge and in-service mentoring	Training – general + how to use data capture system Monthly case review meetings: - Audit and feedback that occurs outside the patient-clinician visit and uses the data capture system centrally to identify poorest controlled (<i>if electronic has menu of options / prompts to achieve improvement(s)</i>) - Opportunities to praise achievements - Opportunities for clinicians to learn and improve their practice
	Competing priorities	Data capture system and case reviews help keep accountability
System	Lack of BP-lowering meds	Incorporate into clinic champion's role to provide oversight*

*Critical to conducting the intervention but not identified by the formative data





Process Map



Abbreviations: BP, blood pressure; HTN, hypertension; HCW, healthcare worker



Type 2 Hybrid Implementation-Effectiveness Evaluation

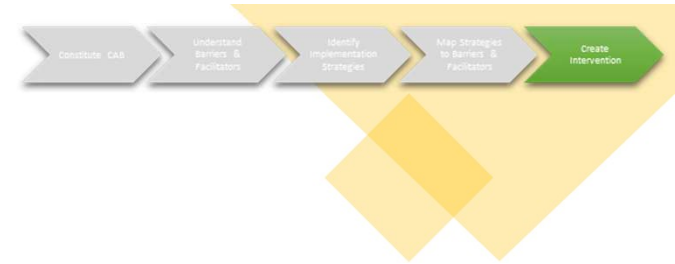


Stepped-wedge design showing time at which time clinics get iHEART-SA

	Pre-intervention observation period
	Active intervention period: Intervention implemented by study staff
	Offboarding transition: Study staff deliver the intervention while training clinic staff to take over
	Maintenance phase intervention period: intervention implemented by clinic staff
X	Data included in analyses of primary clinical effectiveness outcomes
+	Data collection for implementation science outcomes

		Period 1										Period 2			Period 3			Period 4			Period 5			Maintenance Period											
Step	Clinic Stratum	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32		
1	S	X	X	X	X	X	X	X	X	X	X			X	X	X	X	X	X	X	X	X	X	+	+	+	+	+	+	+	+	+	+		
	M	X	X	X	X	X	X	X	X	X	X			X	X	X	X	X	X	X	X	X	X	+	+	+	+	+	+	+	+	+	+		
	L	X	X	X	X	X	X	X	X	X	X			X	X	X	X	X	X	X	X	X	X	+	+	+	+	+	+	+	+	+	+		
2	S	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X	X	X	X	X	+	+	+	+	+	+	+	+	+	+		
	M	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X	X	X	X	X	+	+	+	+	+	+	+	+	+	+		
	L	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X	X	X	X	X	+	+	+	+	+	+	+	+	+	+		
3	S	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X	X	+	+	+	+	+	+	+	+	+	+		
	M	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X	X	+	+	+	+	+	+	+	+	+	+		
	L	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X	X	+	+	+	+	+	+	+	+	+	+		

OUTCOMES



Healthcare worker:

Difference in percentage of patient visits with recorded BP measurement between intervention and control clinics

Patient level:

Difference in mean systolic BP between the intervention and control conditions

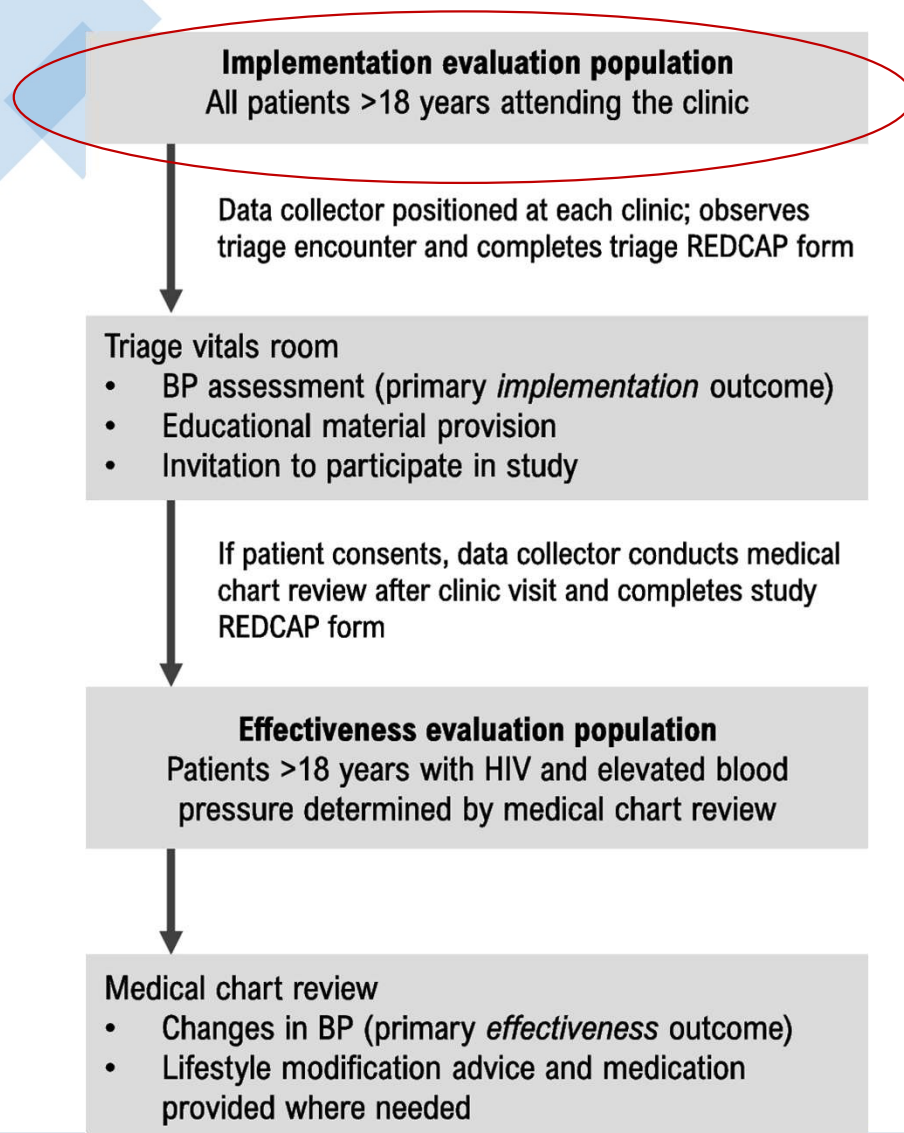
Table 3 RE-AIM outcome definitions, data sources and data collection time points

IMPLEMENTATION EVALUATION		
Outcome definitions	Time points	Data source
Adoption Participation rate and representativeness of clinics that initiate the blood pressure assessment intervention	At every initial study step (i.e., just the initial rollout step)	• Study REDCAP form
Implementation Fidelity Primary implementation outcome: extent to which the BP measurement protocol is implemented	All clinic visits in months 1–15, excluding the two months following intervention initiation (during research staff implementation phase)	• Medical charts • Study REDCAP form • Adaptations recorded by care coordinator / research staff
Cost Initial costs of implementation strategies and cost of implementing the BP measurement protocol	Control, intervention (months 1–15) and maintenance (months 16–27) periods	• Study records • Time and motion assessment
Clinic-level Maintenance Extent to which BP continues to be measured and is normalized after active intervention period	Months 16–27 (during clinic staff implementation)	• Medical charts • Healthcare worker normalization questionnaire
EFFECTIVENESS EVALUATION		
Outcome definitions	Time points	Data source
Reach Percentage and representativeness of patients with elevated blood pressure and HIV that receive the intervention	At the initial / enrollment study visit (months 1–15)	• Study REDCAP form • Medical charts
Effectiveness Primary clinical outcome: difference in mean systolic BP between the intervention and control periods	All visits in months 1–15, excluding the two months following intervention initiation	• Medical charts
Cost-effectiveness Health utility of the intervention and direct medical costs of additional patient visits and/or hospitalizations	Control, active intervention (months 1–15), and maintenance periods (months 16–27)	• Quality of life (EQ-5D) patient questionnaire • Patient-reported cost survey • Study records
Patient-level Maintenance Extent to which blood pressure improvements observed during the intervention phase are maintained	Active intervention (months 4–15) and maintenance (months 16–27) periods	• Medical charts • Study REDCAP form

BP blood pressure

Results





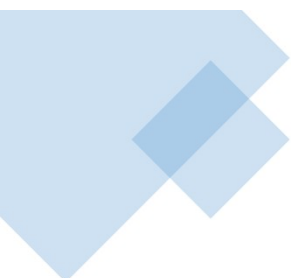
IMPLEMENTATION SAMPLE

Total patients: 37,557

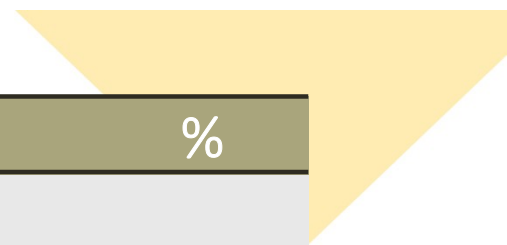
- First visit in the control period: 30,994
- First visit in the intervention period: 6,563

Total visits: 98,973

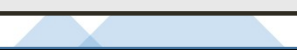
- Control visits: 52,360
- Intervention visits: 30,046
- Maintenance visits: 16,567



IMPLEMENTATION SAMPLE CHARACTERISTICS (37,557 PATIENTS)

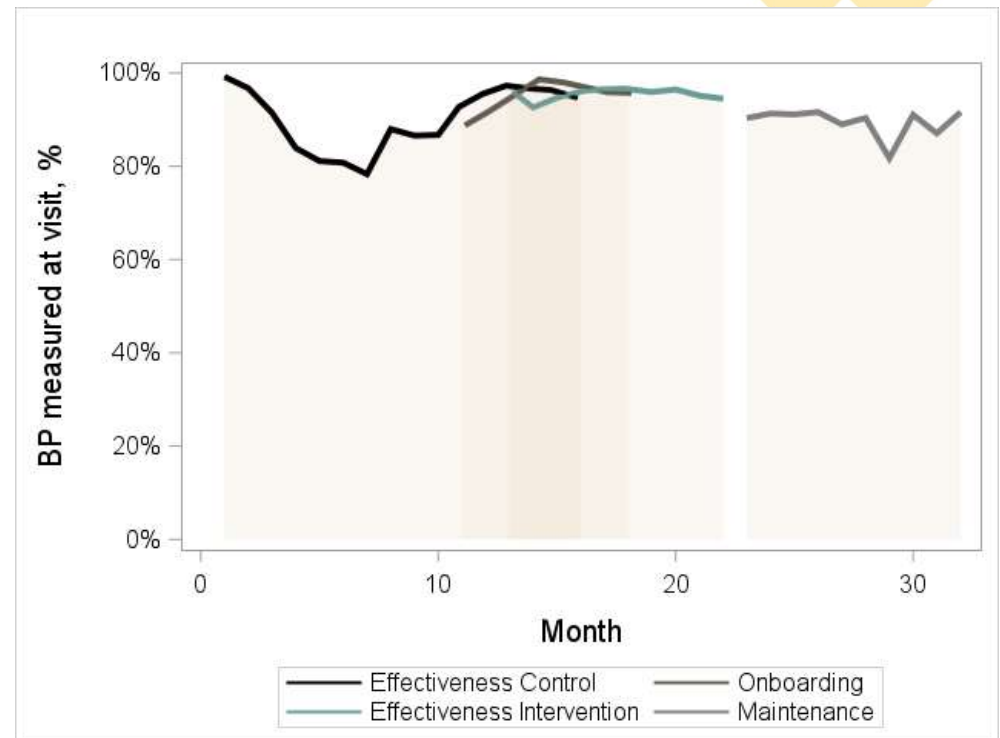


Characteristic	%
Sex	
Female	68
Male	32
Age group	
18–39	40
40–59	50
60–79	9
80+	<1
Nationality	
South African	68
Other	32
HIV status	
HIV +	60



Did Blood Pressure screening improve over time?

- Blood pressure screening peaked at the start of study control period
- Implementation of BP screening was **4.6%** points higher during intervention visits
- Blood pressure remained stable and high during the intervention period
- Reduced somewhat during the maintenance



SCREENING IN THE CONTROL VS INTERVENTION, BY DEMOGRAPHICS (98,973 VISITS)

BP screening improved in the intervention!
Especially in the groups that were lagging

% BP measured		
	Control	Intervention
Sex		
Female	98	99
Male	83	99
Age group		
18–39	90	95
40–59	89	96
60–79	89	97
80+	92	98
Nationality		
South African	84	95
Other	97	>99
HIV status		
HIV +	88	95

IMPLEMENTATION: EDUCATION DELIVERY TO ADULTS WITH HIGH BP

	%
BP booklet provided	99%
BP explained to patient	99%
BP recorded in chart	83%
Lifestyle discussed	3%
Lifestyle referral recorded	1%

Conclusions and Future Directions

1. CVD and Hypertension are among the leading causes of death for people in South Africa
2. Considerable gaps in HTN care exist
3. Ensuring blood pressure monitoring at every opportunity is a critical first step but insufficient to prevent disease without proper management
4. Successful implementation of clinical guidelines requires deep partnership with community and other shareholders
5. Plan to use of digital technologies and greater outreach to close integration gaps
6. Extend efforts to other NCDs
7. Expand HLB-SIMPLe Alliance



Questions?



<https://www.iheart.ezintsha.org/>

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