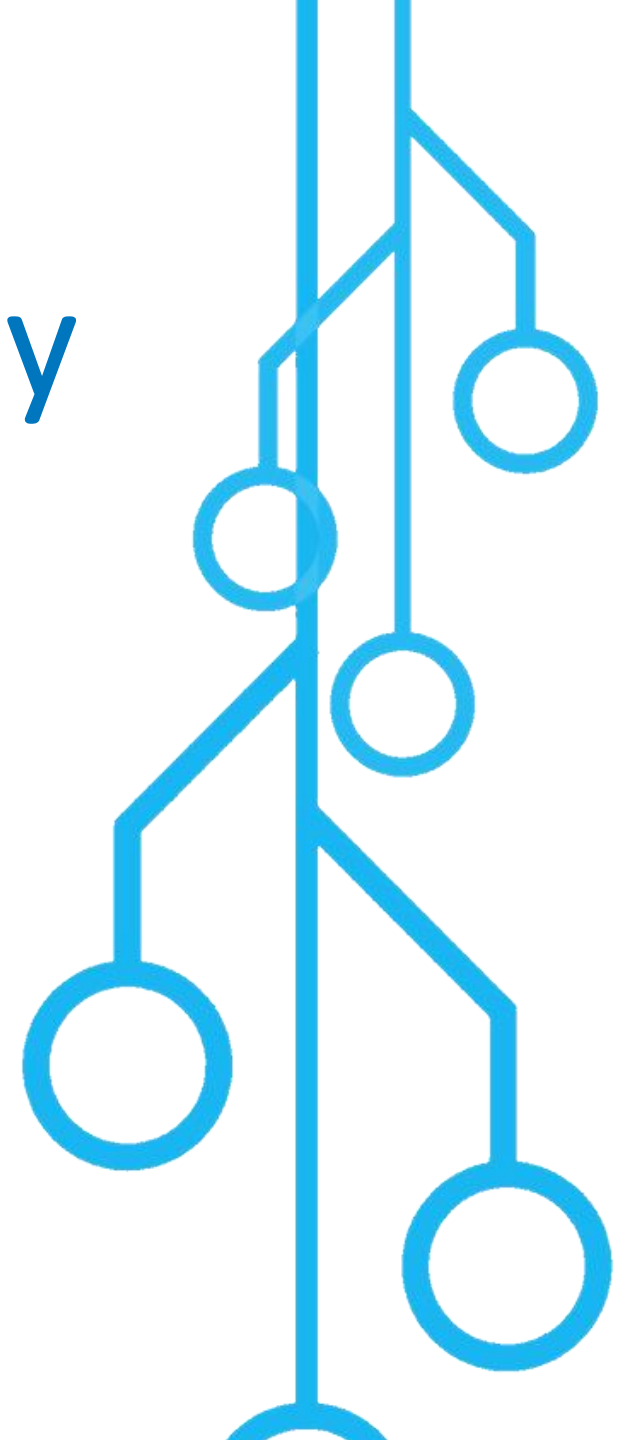


# The Positive Pathways Study

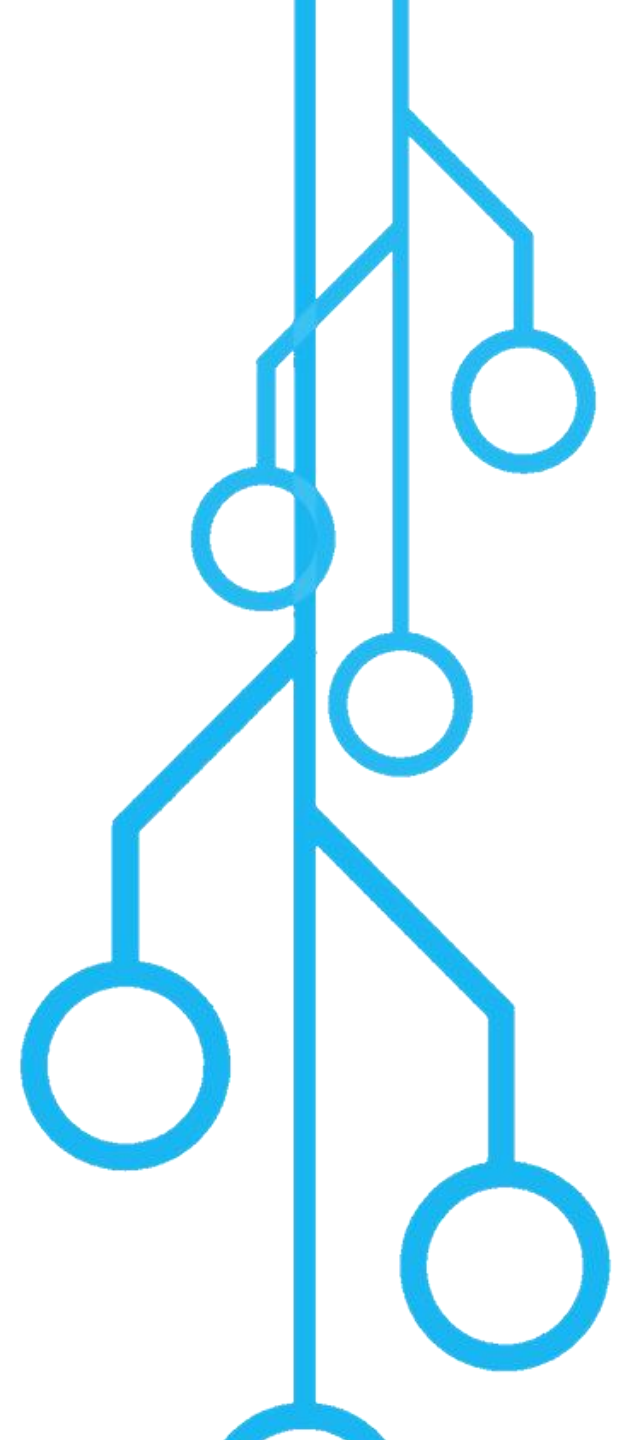
## AHF Retention in Care

Final Report Presentation  
November 1, 2021



# Study Objective

Is the CHORUS™ Retention in Care Module, plus enhanced contact, effective in re-engaging and retaining people living with HIV (PLWH) in care?



# Study Design: Parallel Cluster RCT

Group	# HCCs	2020			2021						
		Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
1	5	Intervention	Intervention	Intervention	Intervention	Intervention	Intervention	Intervention	Intervention	Intervention	Intervention
2	5	Control	Control	Intervention	Intervention	Intervention	Intervention	Intervention	Intervention	Intervention	Intervention
3	5	Control	Control	Control	Control	Control	Control	Control	Control	Control	Control
4	5	Control	Control	Control	Control	Control	Control	Control	Control	Control	Control






**Intervention**



**Control**

# Intervention & Control Arms

Retention in Care Effort	Intervention Arm	Control Arm
AHF 104-Day Report		
CHORUS™ Retention in Care Module Alerts + Enhanced Contact		

# Study Periods

Groups	2020			2021						
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
1 (Intervention) & 3 (Control)	Study Observation Period									
	Eligibility & Alerts Period									
2 (Intervention) & 4 (Control)	---		Study Observation Period							
	---		Eligibility & Alerts Period							

No clinical appointment in previous 4 months

&

No scheduled clinical appointment in next 2 months



Single clinical appointment in previous year, with a missed clinical appointment in previous month

&

No scheduled clinical appointment in next 2 months



Two missed sequential clinical appointments

&

No scheduled clinical appointment in next 7\* days



Lab result of >1000 copies/mL, >3 months ago, without any evidence of a subsequent viral load that is undetectable (<20\* copies/mL)

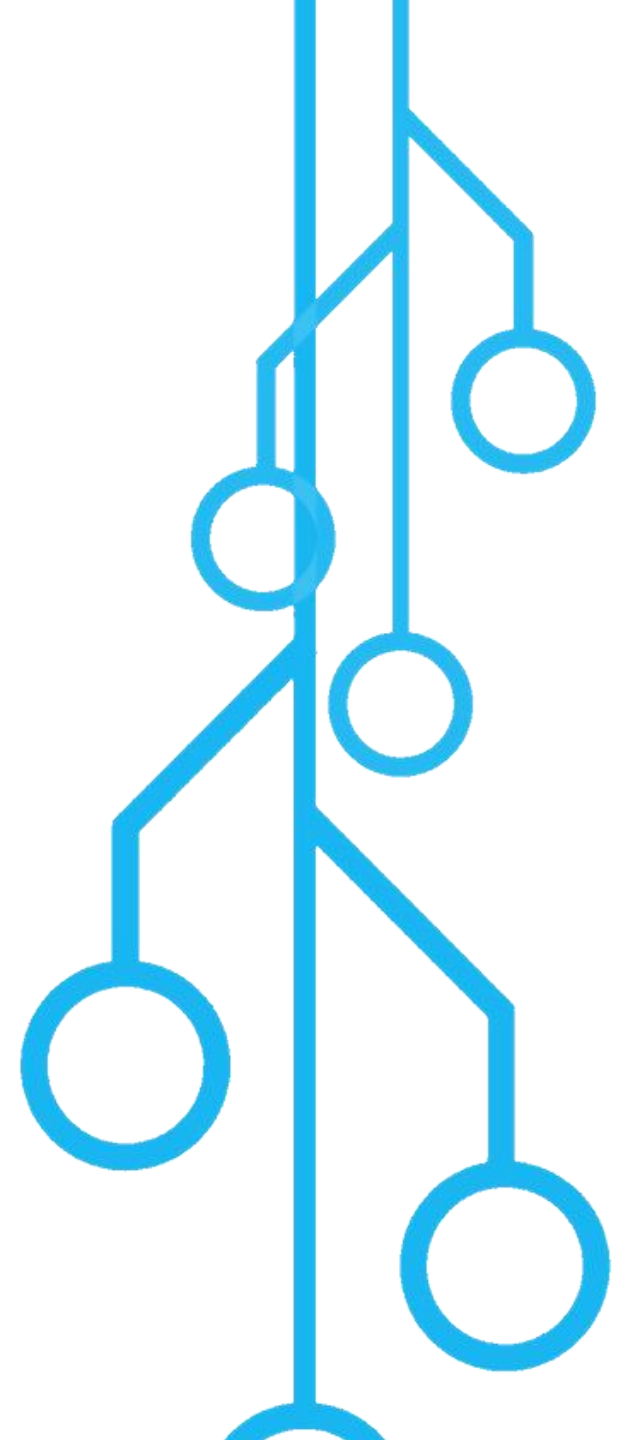
&

No scheduled clinical appointment in next 7\* days



# Clinic & Patient Populations

## Descriptive Statistics



# Characteristics of AHF HCCs in the Study



AHF Healthcare Center Characteristic at Baseline	AHF HCCs in the Intervention Arm (N = 10)	AHF HCCs in the Control Arm (N = 10)
US Census Region, n (%)		
Northeast	0 (0)	1 (10)
South	7 (70)	5 (50)
Midwest	1 (10)	2 (20)
West	2 (20)	2 (20)
Number of healthcare providers per HCC, median (IQR)	10 (4, 22)	8 (5, 11)
Medical Doctor/Doctor of Osteopathic Medicine	5 (3, 10)	4 (2, 7)
Physician Assistant/Nurse Practitioner	3 (1, 5)	4 (0, 5)
Psychologist/Psychiatrist	0 (0, 3)	0 (0, 0)
Social Worker	0 (0, 3)	0 (0, 0)
Proportion of active HIV+ patients per HCC, n (%)		
< 25% HIV+ patients	0 (0)	3 (30)
25-50% HIV+ patients	2 (20)	2 (20)
50-75% HIV+ patients	1 (10)	1 (10)
> 75% HIV+ patients	7 (70)	4 (40)
Number of active HIV+ patients per HCC		
Minimum, n	225	247
Maximum, n	2576	2201
Median (IQR)	1081 (621, 1812)	1018 (559, 1649)



# Characteristics of the Patients at the AHF HCCs in the Study



Patient Population Characteristic at Last Visit, Median % (IQR)	AHF HCCs in the Intervention Arm (N = 10)	AHF HCCs in the Control Arm (N = 10)
Proportion of patients age 50+ years	37 (31, 39)	41 (25, 49)
Proportion of female	13 (12, 18)	15 (10, 19)
Proportion of Black/African American	50 (34, 71)	43 (21, 65)
Proportion of Hispanic/Latino	18 (7, 34)	20 (9, 23)
Payer		
Proportion on Medicaid	17 (11, 42)	24 (12, 30)
Proportion on Medicare	7 (6, 10)	9 (7, 16)
Proportion on Commercial insurance	43 (25, 54)	41 (36, 53)
Proportion on ADAP/Ryan White	36 (23, 68)	28 (19, 42)
Proportion of patients with HIV viral load < 200 copies/ml	88 (86, 90)	87 (85, 92)
Proportion of patients with any mental health disorder	8 (7, 11)	11 (7, 13)
Proportion of patients with substance abuse	3 (2, 4)	4 (1, 5)

# All PLWH Eligible to Receive Alerts During the Study

Intervention Arm

N = 8,836

Control Arm

N = 7,039

Participating AHF HCCs	Eligible PLWH, N	Eligible PLWH with ≥1 Alert(s), n (%)	Eligible PLWH with 0 Alerts, n (%)
<b>Group 1 (Intervention Arm)</b>	<b>4,613</b>	<b>2,544 (55)</b>	<b>2,069 (45)</b>
HCC 1A	135	85 (63)	50 (37)
HCC 1B	1,380	625 (45)	755 (55)
HCC 1C	767	462 (60)	305 (40)
HCC 1D	1,543	874 (57)	669 (43)
HCC 1E	788	498 (63)	290 (37)
<b>Group 2 (Intervention Arm)</b>	<b>4,223</b>	<b>2,433 (58)</b>	<b>1,790 (42)</b>
HCC 2A	981	625 (64)	356 (36)
HCC 2B	249	129 (52)	120 (48)
HCC 2C	603	379 (63)	224 (37)
HCC 2D	1,629	798 (49)	831 (51)
HCC 2E	761	502 (66)	259 (34)
<b>Group 3 (Control Arm)</b>	<b>3,719</b>	<b>2,037 (55)</b>	<b>1,682 (45)</b>
HCC 3A	1,169	767 (66)	402 (34)
HCC 3B	211	125 (59)	86 (41)
HCC 3C	1,092	602 (55)	490 (45)
HCC 3D	416	200 (48)	216 (52)
HCC 3E	831	343 (41)	488 (59)
<b>Group 4 (Control Arm)</b>	<b>3,320</b>	<b>1,851 (56)</b>	<b>1,469 (44)</b>
HCC 4A	298	183 (61)	115 (39)
HCC 4B	1,035	650 (63)	385 (37)
HCC 4C	1,288	795 (62)	493 (38)
HCC 4D	544	177 (33)	367 (68)
HCC 4E	155	46 (30)	109 (70)
<b>Total Eligible PLWH</b>	<b>15,875</b>	<b>8,865 (56)</b>	<b>7,010 (44)</b>

# Eligible Patients: Select Baseline Characteristics

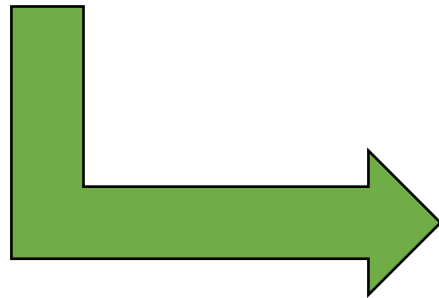
Different Between Patients with  $\geq 1$  Alert(s) and Patients with 0 Alerts

Characteristic	$\geq 1$ Alert(s)	0 Alerts
Median age	38 years	49 years
Black race	54%	37%
History of syphilis	48%	40%
Viral load <50 copies/mL	63%	87%
Any comorbidities	37%	42%
Cardiovascular	7%	11%
Endocrine	8%	12%
Substance abuse	5%	3%

# Eligible Patients: Select Baseline Characteristics

## Different Between HCCs in Intervention and Control Arms

Characteristic	Intervention Arm	Control Arm
Hispanic ethnicity	30%	18%
ADAP/Ryan White payer	49%	41%



### Statistical Models are Adjusted for the Following to Account for Differences Between HCCs

- Census region (Northeast, South, Midwest, West)
- Number of active PLWH at HCC
- Proportion of active PLWH that are Hispanic
- Proportion of active PLWH with a payer of ADAP/Ryan White

# Alerts, Annotations, Flags, and Visits

## Descriptive Statistics



# Total Alerts through 31MAY2021

	Intervention Arm	Control Arm
<b>Total Alerts, n</b>	<b>8,860</b>	<b>6,878</b>
<b>Alert #1: No clinical appointment in the previous 4 months and no scheduled clinical appointment in the next 2 months, n (%)</b>	2,412 (27)	1,817 (26)
<b>Alert #2: A single appointment in the previous year, with a missed clinical appointment in the previous month, and no scheduled appointment in the next 2 months, n (%)</b>	173 (2)	143 (2)
<b>Alert #3: Two missed sequential clinical appointments and no scheduled appointment in the next 14 days, n (%)</b>	3,820 (43)	3,063 (45)
<b>Alert #4: Lab result of &gt;1,000 copies/ml &gt;3 months ago without any evidence of a subsequent viral load &lt; 50 copies/mL and no scheduled appointment in the next 14 days, n (%)</b>	2,455 (28)	1,855 (27)

# Annotations by Role of Annotator

	<b>Intervention Group 1</b>	<b>Intervention Group 2</b>
	<b>01OCT2020 – 31JUL2021</b>	<b>01DEC2020 – 31JUL2021</b>
<b>Total Annotations, n</b>	<b>4,601</b>	<b>2,364</b>
<b>Medical Assistant, n (%)</b>	59 (1)	26 (1)
<b>Non-Clinical Staff, n (%)</b>	3,456 (75)	1,792 (76)
<b>Nursing, n (%)</b>	227 (5)	0 (0)
<b>Pharmacy, n (%)</b>	0 (0)	0 (0)
<b>Provider, n (%)</b>	488 (11)	457 (19)
<b>MD/DO, n (%)</b>	215 (44)	310 (68)
<b>PA/NP, n (%)</b>	273 (56)	147 (32)
<b>Psychotherapy/Social Work, n (%)</b>	7 (<1)	0 (0)
<b>Automatic Annotation, n (%)</b>	364 (8)	89 (4)

# Flags

A flag represents a continuous set of consecutive weeks during which a patient was receiving one or more alerts, regardless of which alert(s) were received

	<b>Group 1</b> <b>Intervention</b>	<b>Group 2</b> <b>Intervention</b>	<b>Group 3</b> <b>Control</b>	<b>Group 4</b> <b>Control</b>
<b>Eligible Patients, n</b>	<b>4,613</b>	<b>4,223</b>	<b>3,719</b>	<b>3,320</b>
<b>Eligible Patients with <math>\geq 1</math> Flag(s), n (%)</b>	2,544 (55)	2,433 (58)	2,037 (55)	1,851 (56)
<b>Eligible Patients with <math>\geq 2</math> Flags, n (%)</b>	833 (18)	708 (17)	736 (20)	485 (15)

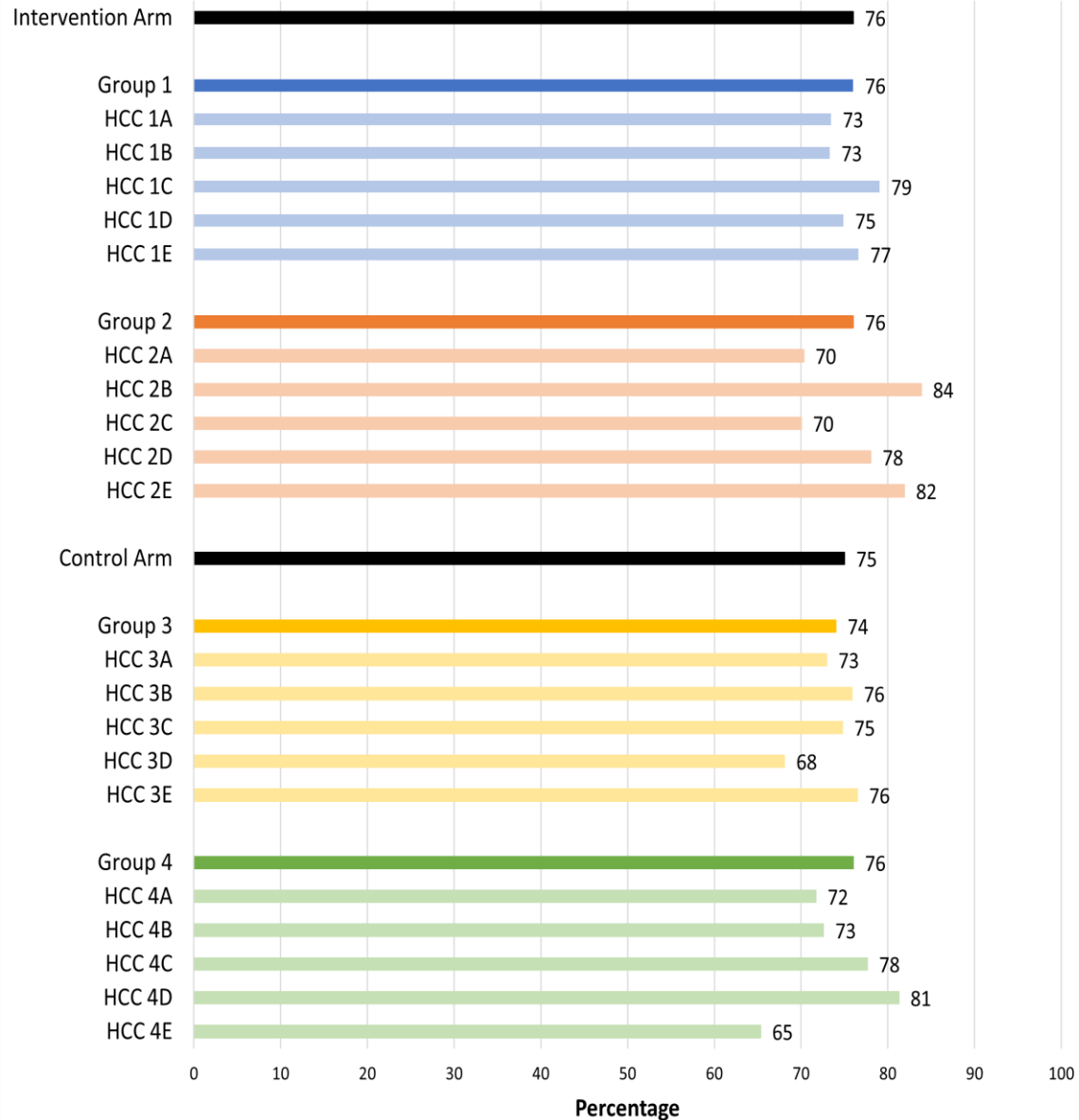


# Appointments & Visits After Flags

	Intervention Arm	Control Arm
<b>Number of Flags, n</b>	<b>7,355</b>	<b>5,649</b>
<b>Subsequent Appointments</b>		
Proportion of flags with subsequent appointment, n (%)	6,584 (90)	4,880 (86)
Time between start date of a flag and subsequent appointment, days		
Range (Min, Max), days	1 - 285	1 - 276
Median (IQR), days	4 (2, 16)	4 (2, 15)
<b>Subsequent Visits</b>		
Proportion of flags with subsequent completed visit, n (%)	5,580 (76)	4,249 (75)
Time between start date of a flag and subsequent completed visit, days		
Range (Min, Max), days	0 - 295	0 - 283
Median (IQR), days	32 (15, 60)	30 (12, 59)
Completed visit within 14 days, n (%)	1,361 (24)	1,093 (26)
Completed visit within 1 month, n (%)	2,668 (48)	2,127 (50)
Completed visit within 2 months, n (%)	4,200 (75)	3,246 (76)

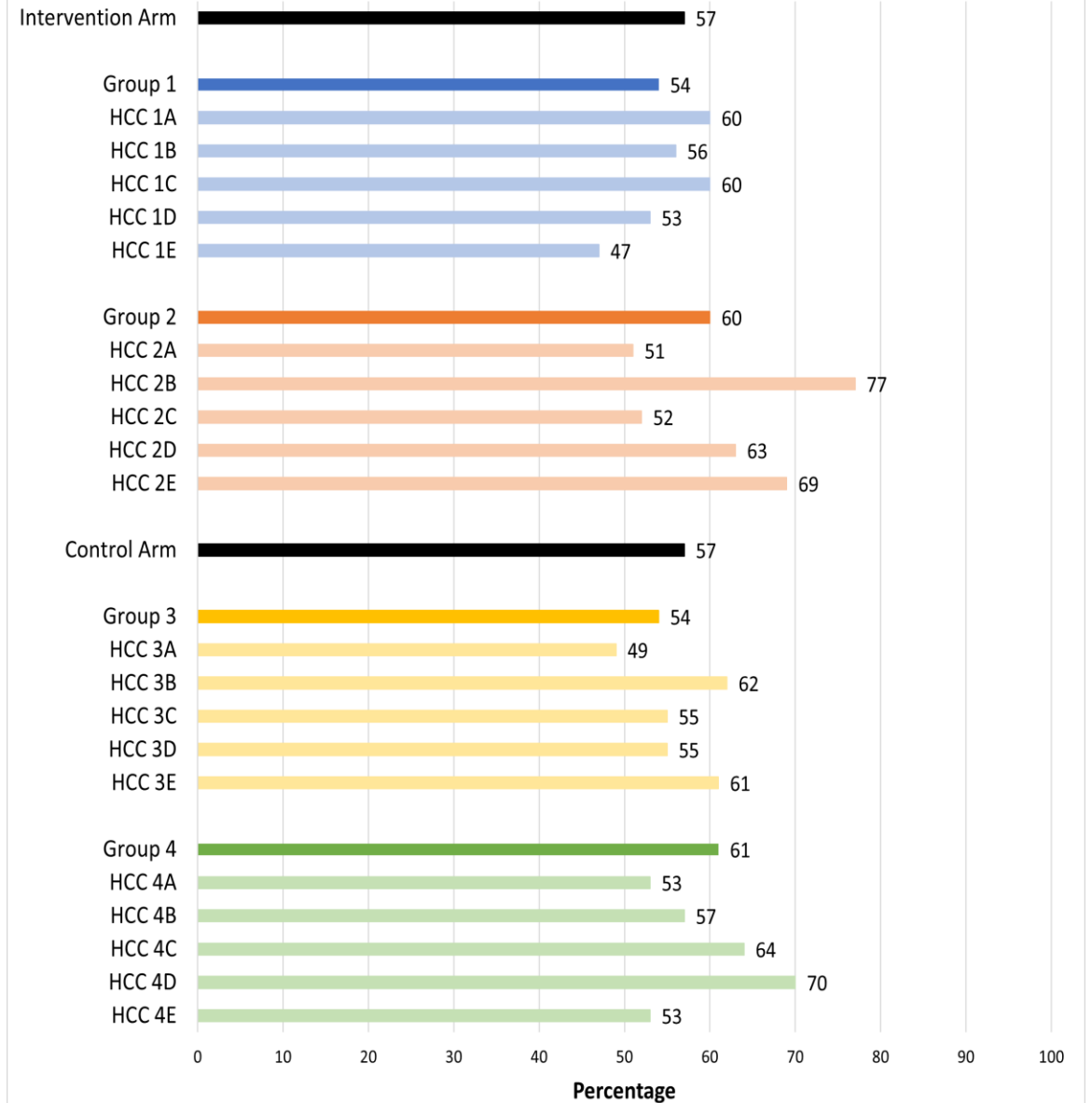
# Any Visit After Flag

Percent of Flags with Completed Visits During Study Period

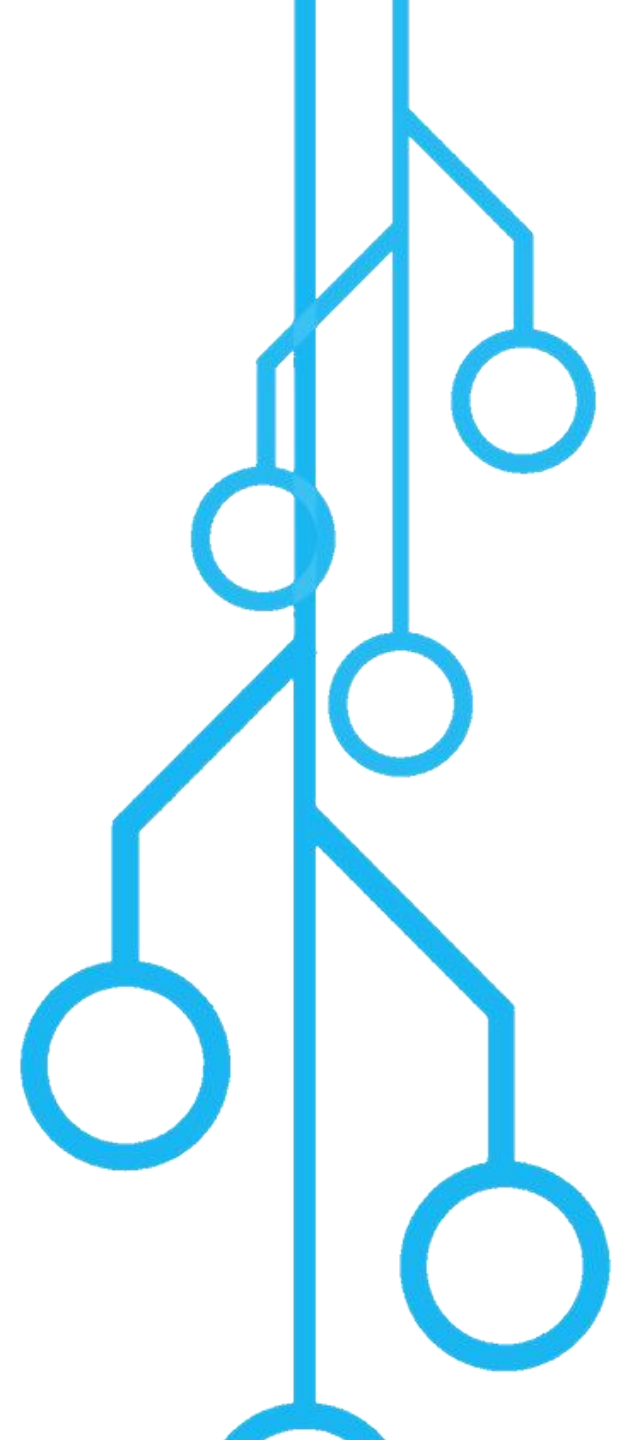


# Any Visit Within 2 Months After Flag

Percent of Flags with Completed Visits Within 2 Months of Flag



# Statistical Modelling



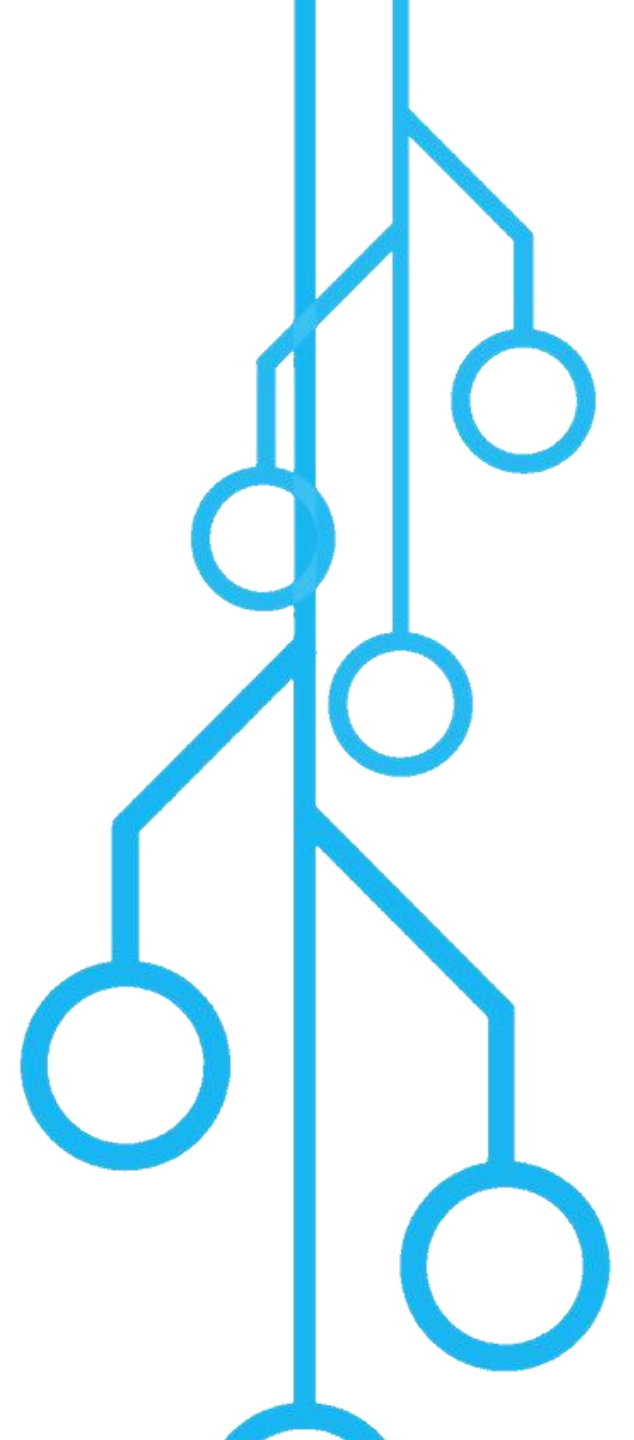
# Statistical Modelling

- Comparison of intervention versus control arm with respect to the odds of
  - Completing any visit after being flagged as being at-risk or at-high-risk of falling out of care
  - Completing any visit within 2 months of being flagged as being at-risk or at-high-risk of falling out of care
- Logistic regression fit with generalized estimating equations (GEE) with an independent correlation structure
  - Adjustment for similarities within HCCs and within patients who received more than 1 flag over the course of the study
- Adjustment for differences between HCCs
  - Census region (Northeast, South, Midwest, West)
  - Number of active PLWH at HCC
  - Proportion of active PLWH that are Hispanic
  - Proportion of active PLWH with a payer of ADAP/Ryan White

# Modelling Results

- ✓ Flags that occurred at HCCs in the intervention arm were **8% more likely** to result in any completed visit than flags that occurred in the control arm (adjusted odds ratio 1.08, 95% confidence interval: 0.97, 1.21)
- ✓ Flags that occurred at HCCs in the intervention arm were also **7% more likely** to result in any completed visit within 2 months of the flag than flags that occurred in the control arm (adjusted odds ratio 1.07, 95% confidence interval: 0.97, 1.17)

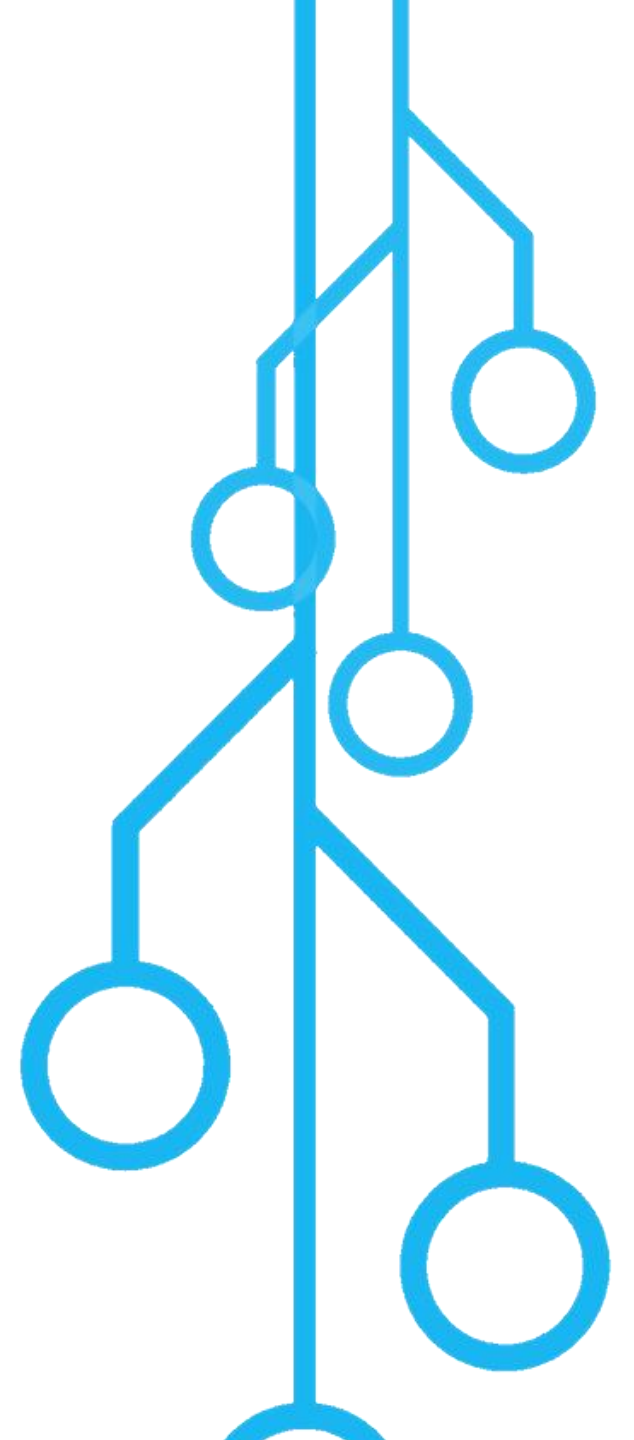
# Viral Suppression



# PLWH Who Received $\geq 1$ Alert

HIV Viral Load (copies/mL), n (%) unless otherwise described	Intervention Arm N = 2,951	Control Arm N = 2,300
<b>Baseline</b>		
Median (IQR)	20 (19, 150)	20 (19, 220)
< 50	<b>1,918 (65)</b>	<b>1,424 (62)</b>
50 to < 200	338 (12)	292 (13)
200 to < 1,000	109 (4)	103 (5)
1,000 to < 10,000	179 (6)	167 (7)
10,000 to < 100,000	264 (9)	194 (8)
$\geq 100,000$	143 (5)	120 (5)
<b>End of Follow-Up</b>		
Median (IQR)	19 (19, 50)	19 (19, 90)
< 50	<b>2,172 (74)</b>	<b>1,534 (67)</b>
50 to < 200	285 (10)	313 (14)
200 to < 1,000	121 (4)	115 (5)
1,000 to < 10,000	133 (5)	108 (5)
10,000 to < 100,000	158 (5)	144 (6)
$\geq 100,000$	82 (3)	86 (4)

# Surveys & Feedback

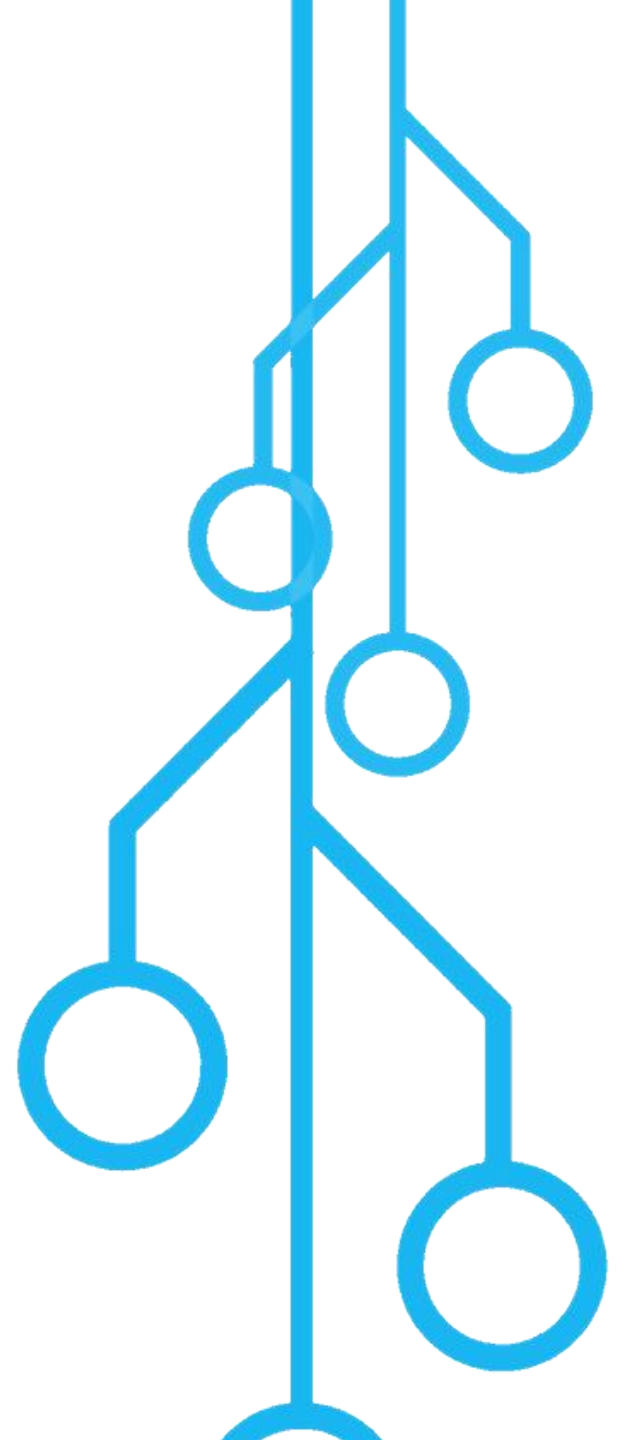




# Study Feedback

- Surveys via CHORUS™ App
  - 98 AHF workforce members provided signed, informed consent to receive surveys
  - 15 completed  $\geq 1$  survey(s) for a global response rate of 15%
- Overall feedback was positive
  - Liked/preferred CHORUS™
  - Duplication between CHORUS™ RIC Module and existing retention efforts was the largest barrier
- Based on feedback received, we made additional changes to the alerts

# Discussion

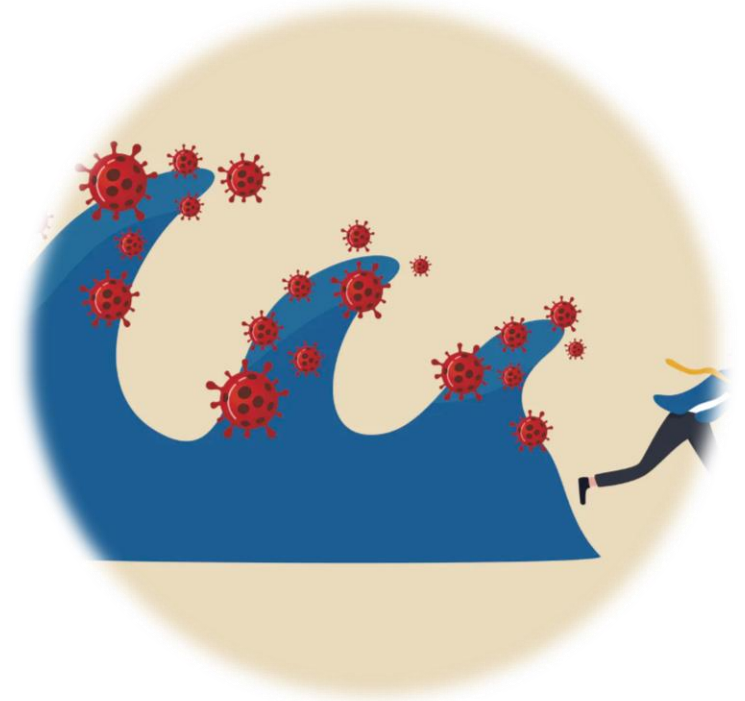
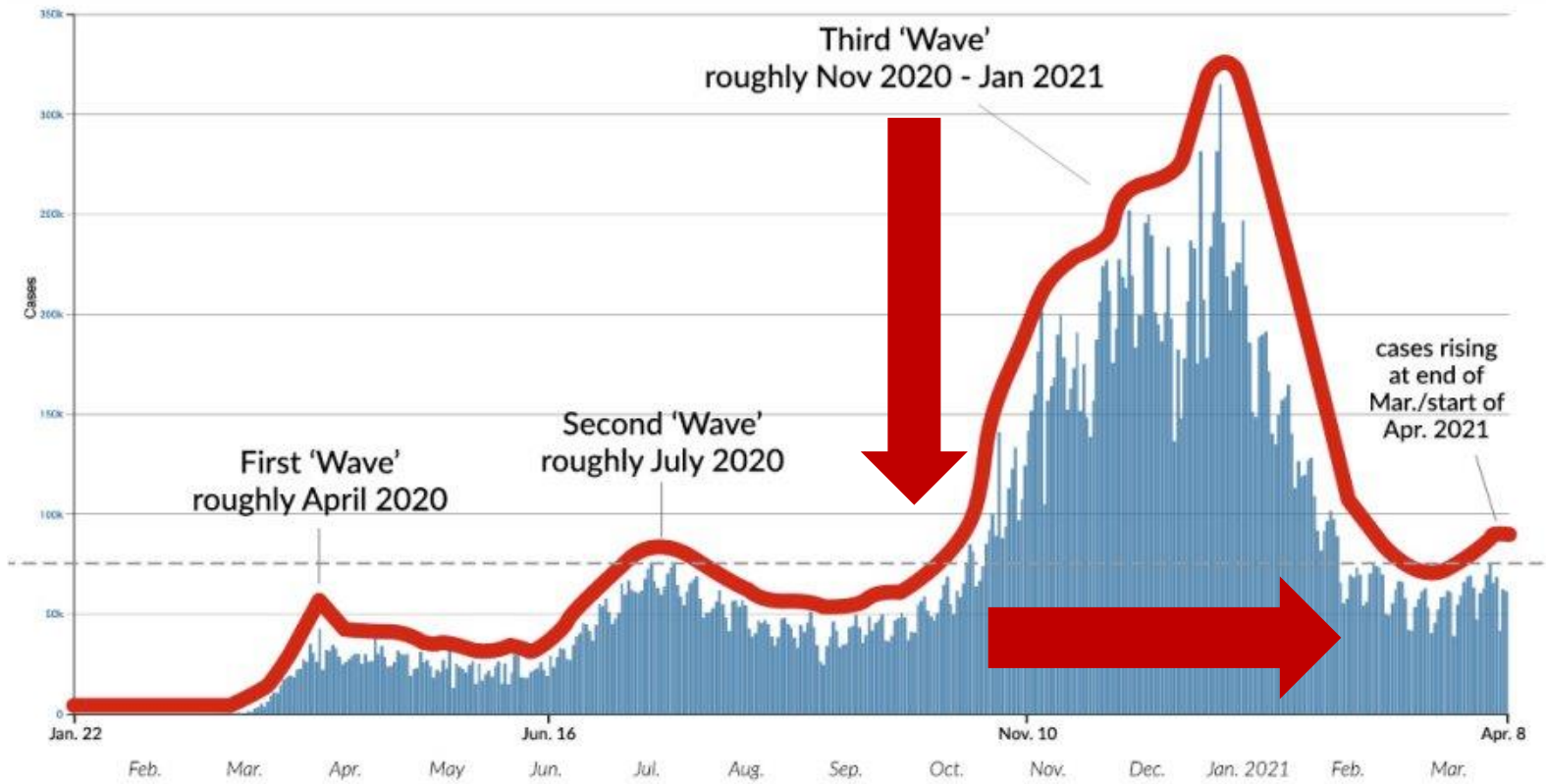


# Design Changes

- Stepped-Wedge Cluster → Parallel Cluster RCT
  - Training was time consuming and included entire HCC
  - Considerable time for HCCs to establish workflow and retention responsibilities
  - Power to detect differences between the groups was not diminished by this study design change
- Randomization (Once → Stepwise)
  - 6/10 initially selected control HCCs needed to be excluded from the study
  - Intervention and control HCCs were similar despite the *posteriori* modifications to the randomization procedures
  - Differences between the HCCs in the intervention and control arms were accounted for in the adjusted logistic regression models
- Intervention (RIC Module → RIC Module + Existing Retention Efforts)

# SARS-CoV-2 Global Pandemic

Daily Trends in Number of COVID-19 Cases in the United States Reported to CDC



# Plural Interventions

Retention in Care Effort	Intervention Arm	Control Arm
AHF 104-Day Report	✓	✓
CHORUS™ Retention in Care Module Alerts + Enhanced Contact	✓	



# Study Duration

## REMINDER: Behavior change takes time

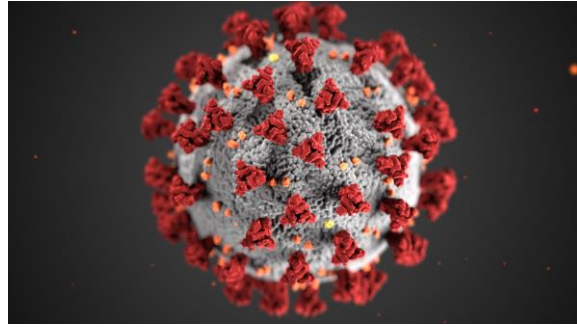
Change is difficult and it takes time. It is hard for people to change their own behavior, much less that of others. Change programs normally address attitudes, ideas, and rewards. But the behaviors of people in organizations are also strongly shaped by habits, routines, and social norms. Real change requires new power relationships, new work routines and new habits, not just intent.

— *Richard P. Rumelt* —

- The study duration was short (8 months for 2 groups and 10 months for 2 groups)
- A longer study would allow for a more comprehensive look at the potential for long-term behavior changes that could make a lasting impact on retention in care among patients
- Re-engagement of patients identified as at-risk or at-high-risk of falling out of care is not the same as sustained retention-in-care; future studies should evaluate interventions that aim to improve both over a longer period of time.

# Take Home Messages

Despite:



We Saw:

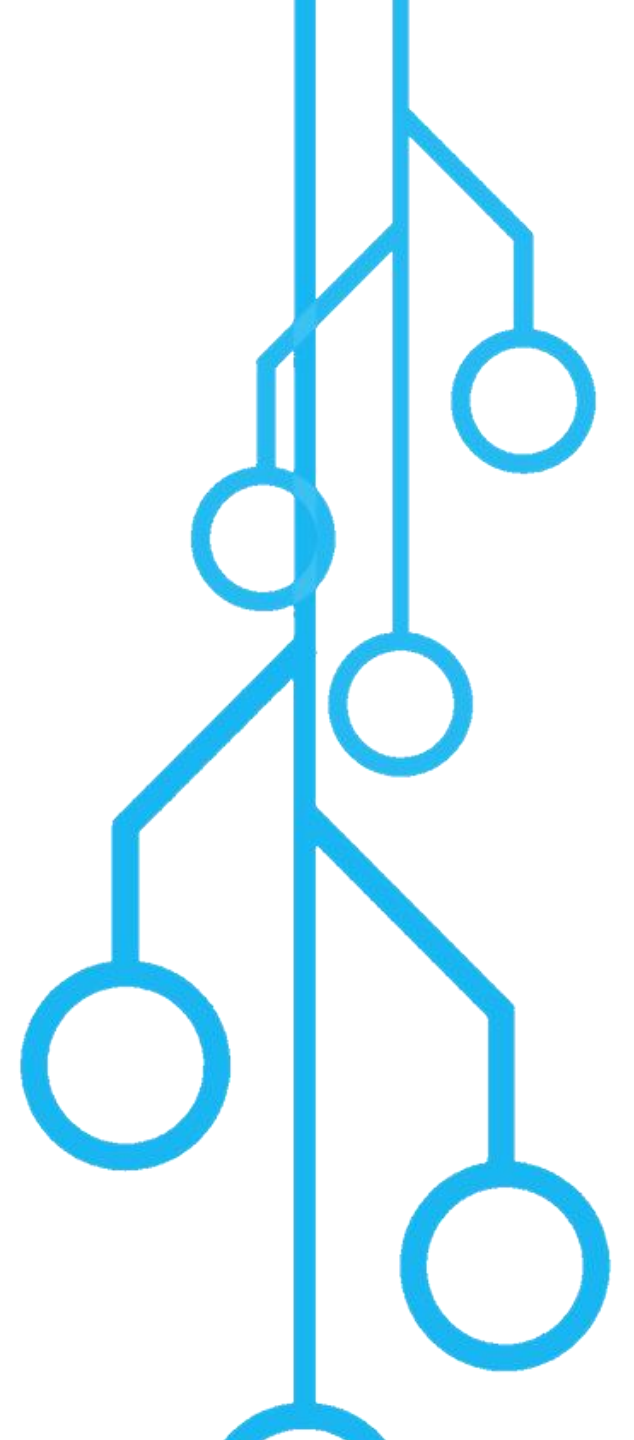
- ✓ It may be easy to increase the number of scheduled appointments, but it is not as easy to increase the number of completed visits
- ✓ Getting PLWH into the clinic takes time
- ✓ Flags at intervention HCC were more likely to result in any visit or any visit within 2 months than flags at control HCCs
- ✓ A greater proportion of at-risk PLWH who were retained in care during the study at the intervention HCCs achieved a viral load  $<50$  copies/mL, compared to the control HCCs







# Knowledge Transfer



# Conference Abstract

## Conference

February 12-16, 2022

Denver, Colorado

## Abstract Deadline

November 1, 2021



# Backup Conference

Anticipated Abstract Deadline: April 2022

16TH ANNUAL  
**ACTHIV**  
THE AMERICAN CONFERENCE  
FOR THE TREATMENT OF HIV  
2022



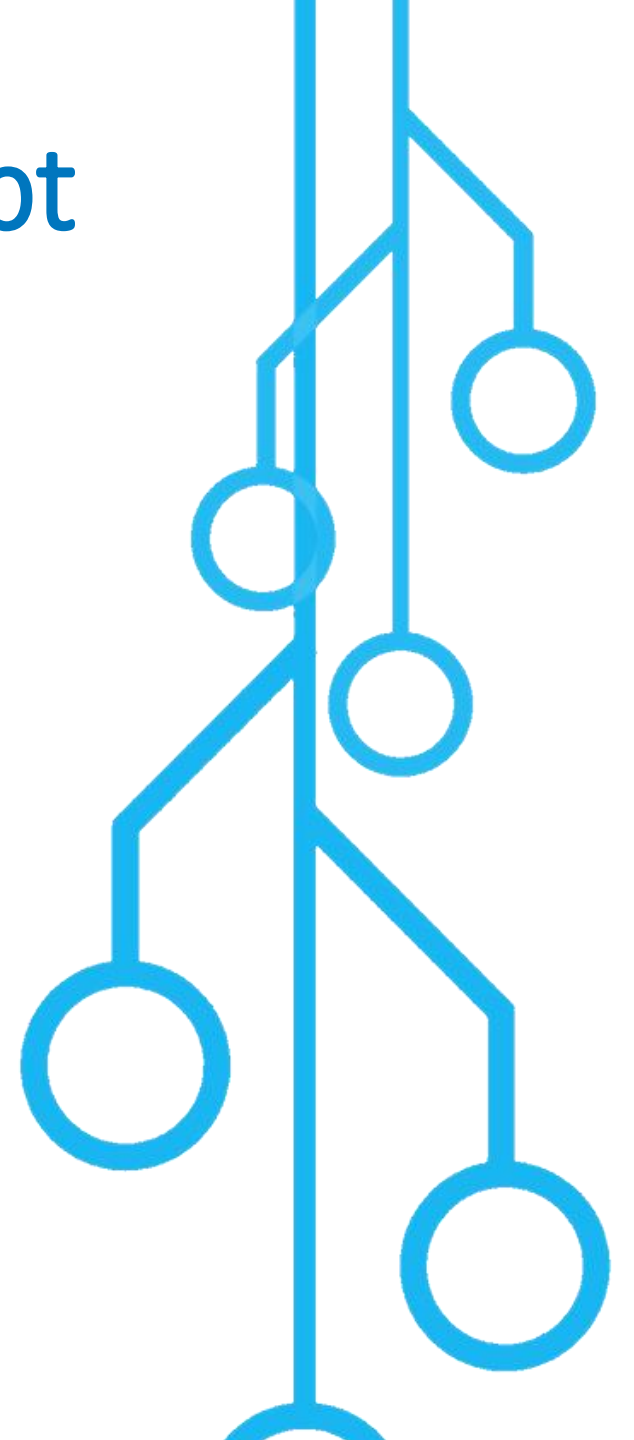
**DENVER, COLORADO**

MAY 5-8, 2022  
HYATT REGENCY DENVER

# Implementation Process Manuscript

## HIV Retention-in-Care

- Implementation science in the time of COVID-19
  - Lack of clinic resources
- Clinical Decision Support Systems (CDSS) using EHRs
- Behavior change (clinic operations, patient clinic attendance) takes time





# Potential Journals

## *Implementation Science Journal*

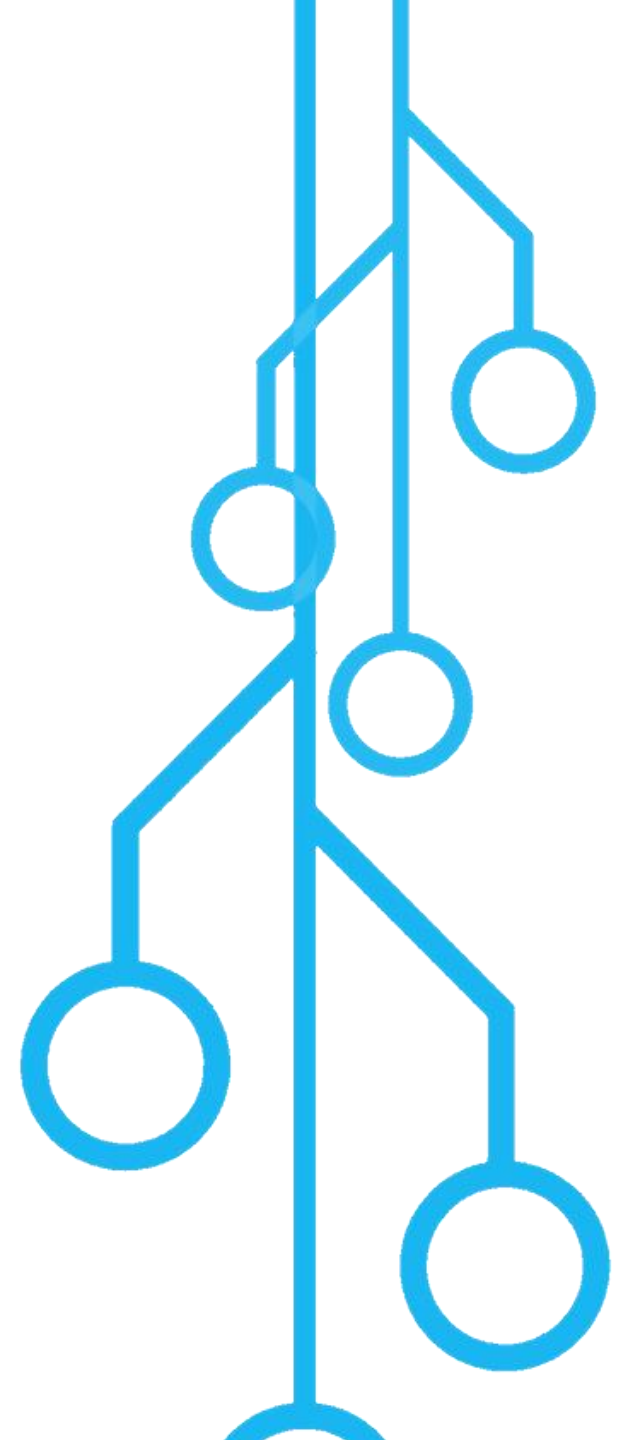
- Focus on implementation intervention development, process evaluations, economic evaluations, and theory-based studies
- Open Access (\$2890 APC)

## *Implementation Science Communications*

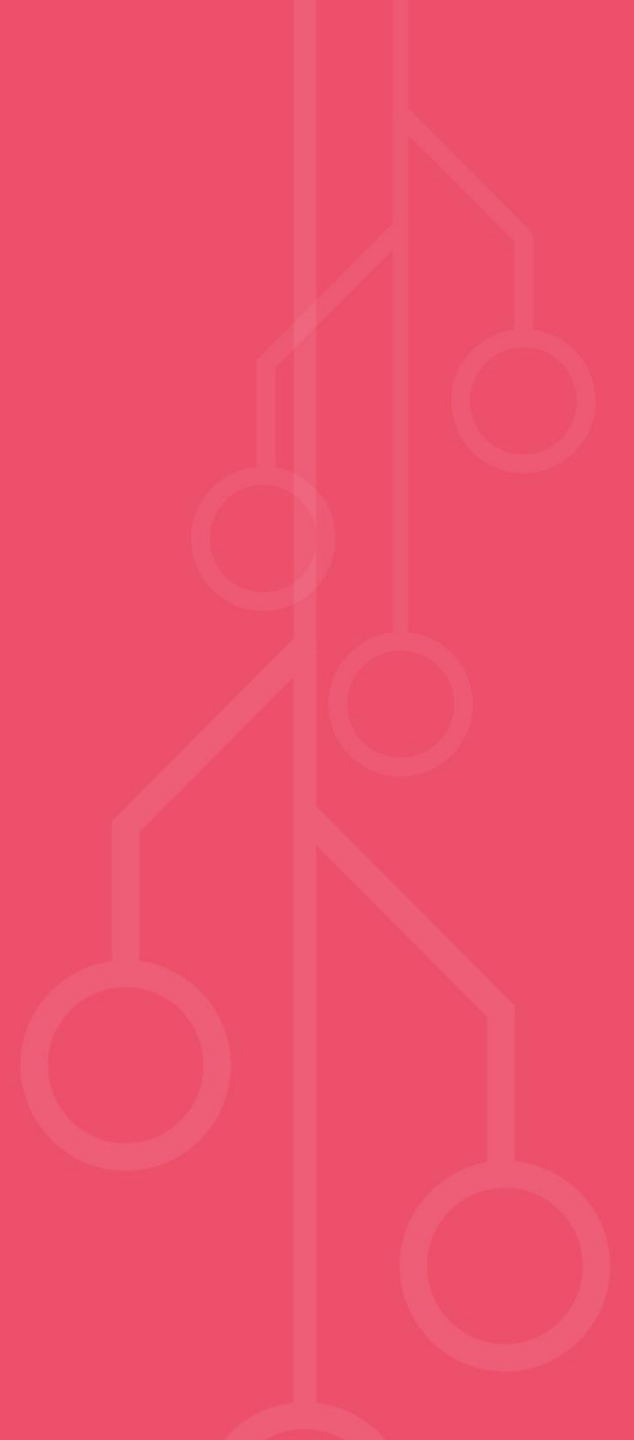
- Focus on implementation intervention development, process evaluations, economic evaluations, and theory-based studies
- Open Access (\$1875 APC)

## *BMC Health Services Research*

- Special focus on eHealth, governance, health policy, health system quality and safety, healthcare delivery and access to healthcare, healthcare financing and economics, implementing reform, and the health workforce
- Open Access (\$2570 APC)



# Extra Slides



# Appointments & Visits After Alert 1

No clinical appointment in the previous 4 months and no scheduled clinical appointment in the next 2 months

	<b>Intervention Arm</b>	<b>Control Arm</b>
<b>Number of Alert #1, n</b>	<b>1,679</b>	<b>1,118</b>
<b>Proportion of Alert #1 with subsequent appointment, n (%)</b>	1,560 (93)	994 (89)
<b>Time between alert and subsequent appointment, days</b>		
<b>Range (Min, Max)</b>	1 - 285	1 - 255
<b>Median (IQR)</b>	37 (10, 67)	38 (9, 73)
<b>Proportion of Alert #1 with subsequent completed visit, n (%)</b>	1,313 (78)	890 (80)
<b>Completed visit within 2 months, n (%)</b>	754 (57)	545 (61)
<b>Time between alert and subsequent completed visit, days</b>		
<b>Range (Min, Max)</b>	1 - 292	2 - 263
<b>Median (IQR)</b>	53 (32, 82)	50 (29, 86)

# Appointments & Visits After Alert 2

A single appointment in the previous year, with a missed clinical appointment in the previous month, and no scheduled appointment in the next 2 months

	<b>Intervention Arm</b>	<b>Control Arm</b>
<b>Number of Alert #2, n</b>	<b>159</b>	<b>134</b>
<b>Proportion of Alert #2 with subsequent appointment, n (%)</b>	158 (99)	134 (100)
<b>Time between alert and subsequent appointment, days</b>		
<b>Range (Min, Max)</b>	1 - 92	1 - 138
<b>Median (IQR)</b>	4 (2, 5)	4 (2, 5)
<b>Proportion of Alert #2 with subsequent completed visit, n (%)</b>	99 (62)	84 (63)
<b>Completed visit within 2 months, n (%)</b>	66 (67)	49 (58)
<b>Time between alert and subsequent completed visit, days</b>		
<b>Range (Min, Max)</b>	1 - 207	1 - 249
<b>Median (IQR)</b>	40 (25, 72)	46 (24, 90)



# Appointments & Visits After Alert 3

Two missed sequential clinical appointments and no scheduled appointment in the next 7 days

	<b>Intervention Arm</b>	<b>Control Arm</b>
<b>Number of Alert #3, n</b>	<b>3,773</b>	<b>2,982</b>
<b>Proportion of Alert #3 with subsequent appointment, n (%)</b>	3,758 (>99)	2,965 (99)
<b>Time between alert and subsequent appointment, days</b>		
<b>Range (Min, Max)</b>	1 - 236	1 - 212
<b>Median (IQR)</b>	3 (2, 5)	4 (2, 5)
<b>Proportion of Alert #3 with subsequent completed visit, n (%)</b>	3,041 (81)	2,441 (82)
<b>Completed visit within 14 days, n (%)</b>	371 (12)	312 (13)
<b>Completed visit within 1 month, n (%)</b>	1,297 (43)	1,063 (44)
<b>Completed visit within 2 months, n (%)</b>	2,287 (75)	1,811 (74)
<b>Time between alert and subsequent completed visit, days</b>		
<b>Range (Min, Max)</b>	0 - 295	0 - 257
<b>Median (IQR)</b>	36 (19, 60)	33 (21, 61)

# Appointments & Visits After Alert 4

Lab result of >1,000 copies/ml >3 months ago without any evidence of a subsequent viral load < 20 copies/mL and no scheduled appointment in the next 7 days

	<b>Intervention Arm</b>	<b>Control Arm</b>
<b>Number of Alert #4, n</b>	<b>2,371</b>	<b>1,779</b>
<b>Proportion of Alert #4 with subsequent appointment, n (%)</b>	2,359 (>99)	1,751 (98)
<b>Time between alert and subsequent appointment, days</b>		
<b>Range (Min, Max)</b>	1 - 261	1 - 276
<b>Median (IQR)</b>	4 (2, 11)	4 (2, 19)
<b>Proportion of Alert #4 with subsequent completed visit, n (%)</b>	1,984 (84)	1,537 (86)
<b>Completed visit within 14 days, n (%)</b>	964 (49)	770 (50)
<b>Completed visit within 1 month, n (%)</b>	1,304 (66)	1,015 (66)
<b>Completed visit within 2 months, n (%)</b>	1,659 (84)	1,276 (83)
<b>Time between alert and subsequent completed visit, days</b>		
<b>Range (Min, Max)</b>	0 - 264	0 - 283
<b>Median (IQR)</b>	16 (3, 44)	14 (3, 45)