



HIV, Retention in care and the MAX clinic

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Meena Ramchandani, MD MPH



Many slides courtesy of Dr. Julie Dombrowski

Disclosures

 Meena Ramchandani does not have relationships with a commercial interest related to the content of this educational activity.

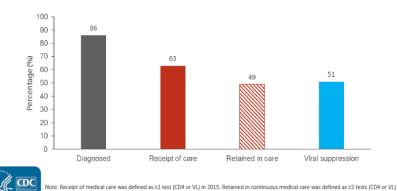
Outline

- Background: persons living with HIV (PLWH) in high resource settings
 - Who is out of care?
 - Why potentially they might be out of care?
 - What has been done to re-engage patients/retain patients in care?
- The MAX clinic: description and outcomes
- Key features of the MAX clinic that work well for this patient population

Background: Who is Out of Care and why does it matter?

Background: retention in care for persons living with HIV (PLWH)

- The CDC estimates as many as 40-50% of persons living with HIV (PLWH) who once were in HIV care are no longer in care
- Although all these patients might not be truly out of care, there are some PLWH are not consistently engaged in care and are not virologically suppressed
- Preventing the leaving of care and re-engaging PLWH with care are crucial if the HIV epidemic is to be brought under control
 - limits the potential of ART to improve health of PLWH and to prevent HIV transmission
 - Individuals who do not suppress their viral load are twenty times more likely to transmit HIV than those with suppressed virus
 - It is estimated that these individuals account for over 60% of HIV transmissions.
- Efforts from providers, clinics, public health on local, regional, national level. Good examples when these entities work together to jointly identify and seek PLWH who have left care and re-engage them with care.



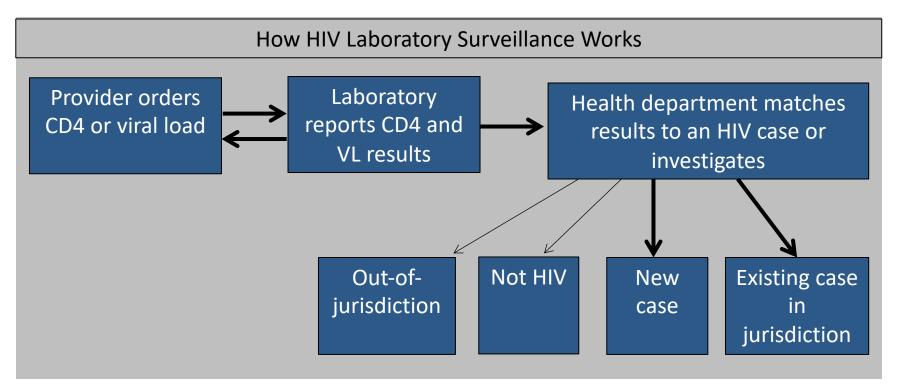
2015. Viral suppression was defined as <200 copies/mL on the most recent VL test in 2015

Persons Living with Diagnosed or Undiagnosed HIV Infection HIV Care Continuum Outcomes, 2015—United States

Data to Care



- Use of surveillance data to identify out-of-care individuals & re-link them to care
- CDC now requires for all health departments



- Data to Care concept:
 - No recent labs = out of care
 - Virally unsuppressed = inadequately engaged

Most PLWH who appear to be out of care are not actually out of care

Seattle - King County Surveillance Surveillance HIV Clinic Round 1 Round 2

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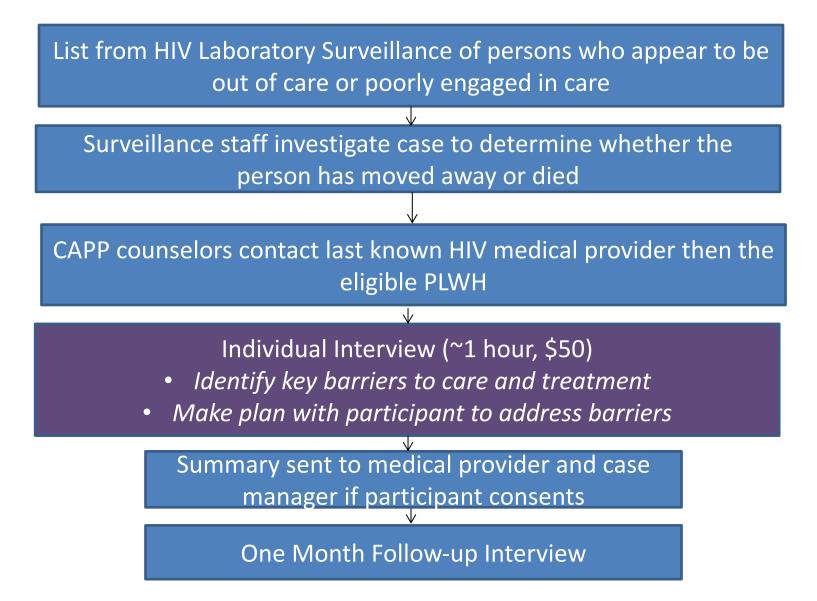
However, 28% of investigated cases in the region and a median of 30% (10%-57%) of investigated cases in each state had no evidence of care, migration, or death after investigation.

Findings replicated throughout the U.S. (MD, MA, MD, NY, TN, LA, 6 Northwestern States) : 47-88% of cases with no CD4 or VL for ≥12 months had an alternate explanation for the gap in lab reports

Buskin SB, et al STD 2014; Dombrowski JC et al, AIDS 2012, JAIDS 2014, JAIDS 2017; Bove J, JAIDS 2015 National HIV Prev. Conf (NHPC) 2016: Brantley #1910, Cassidy-Stewart #1650, Morrison #1503; Tesoriero J, JPMMP, 2017

Background: Why are they out of care?

The Care & Antiretroviral Promotion Program (CAPP): Seattle – King County HIV Care Relinkage Program



Barriers to Engagement in Care

Barriers to HIV Care (N=248)	
No insurance	123 (52%)
Forget appointments	88 (35%)
Trouble getting appointments	83 (32%)
No transportation	77 (31%)
Don't know how to find doctor	69 (27%)
Poor relationship with doctor	67 (26%)

Depression and substance abuse were both highly prevalent (69% and 54%, respectively), and methamphetamine was the most commonly abused substance.

Dombrowski JC et al. AIDS Patient Care STDS. 2015.

Factors Underlying & Interlinked with Poor Engagement in Care

- Poverty
- Food insecurity
- Unemployment
- Social instability
- Early life trauma
- Incarceration
- Domestic violence
- Health beliefs
- Stigma
- Cognitive impairment
- Untreated mental illness
- Unreliable transportation
- Insurance issues

Social determinants of health widely recognized

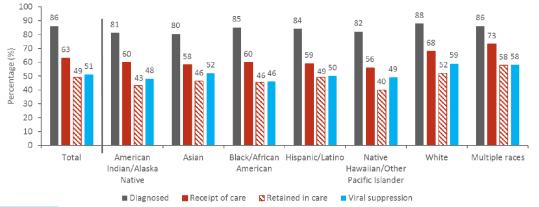
Gap in implementation & evaluation of programs that mitigate the impact of these factors

Sources: Bulsara, AIDS and Behavior, 2016; Aidala, AJPH 2016; Mautner, Population Health Management 2013, Dickson-Gomez, AIDS and Behavior 2016; Levison, AIDS Patient Care and STDs, 2016; O'Donnell, AIDS Care, 2017; Ports KA; J Urban Health, 2017; Yehia BMC Infect Dis 2015; Dombrowski AIDS Patient Care and STDs, 2015

Factors Associated with Poor Engagement in HIV Care

- Associated demographic factors
 - Younger age
 - US-Born Black
 - Female
- Key Barriers: The big 3
 - Substance use disorders
 - Mental health disorders
 - Unstable housing

Persons Living with Diagnosed or Undiagnosed HIV Infection HIV Care Continuum Outcomes, by Race/Ethnicity, 2015—United States





Note. Receipt of medical care was defined as ≥ 1 test (CD4 or VL) in 2015. Retained in continuous medical care was defined as ≥ 2 tests (CD4 or VL) ≥ 3 months apart in 2015. Viral suppression was defined as <200 copies/mL on the most recent VL test in 2015. Asian includes Asian/Pacific Islander legacy cases. Hispanics/Latinos can be of any race.

Other Potential Barriers for Some Patients

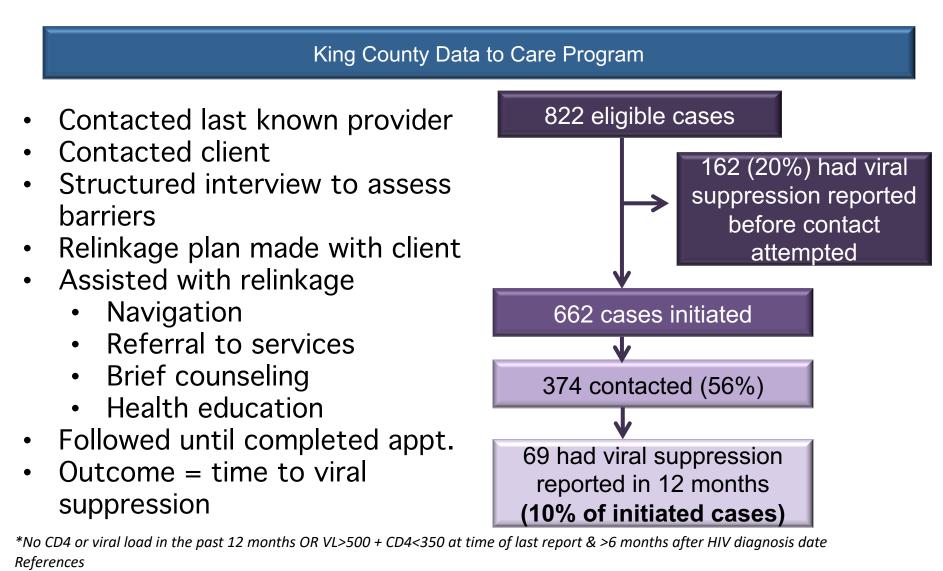
- Healthcare systems factors are commonly identified as barriers to HIV care
- Limited appointment availability
- The need for advanced scheduling
- Appointment start times with limited flexibility require patients to be organized and familiar with the healthcare system to navigate successfully.
- For some patients-
 - substance use disorders
 - unstable housing
 - inadequately treated mental illness—these barriers can be insurmountable, and engagement in HIV care as it is currently organized is simply not a realistic goal
- Goal is to create programs & health systems that mitigate the impact of social determinants of health

Re-engagement strategies in the literature

Key Strategies for Re-Engagement Studied to Date

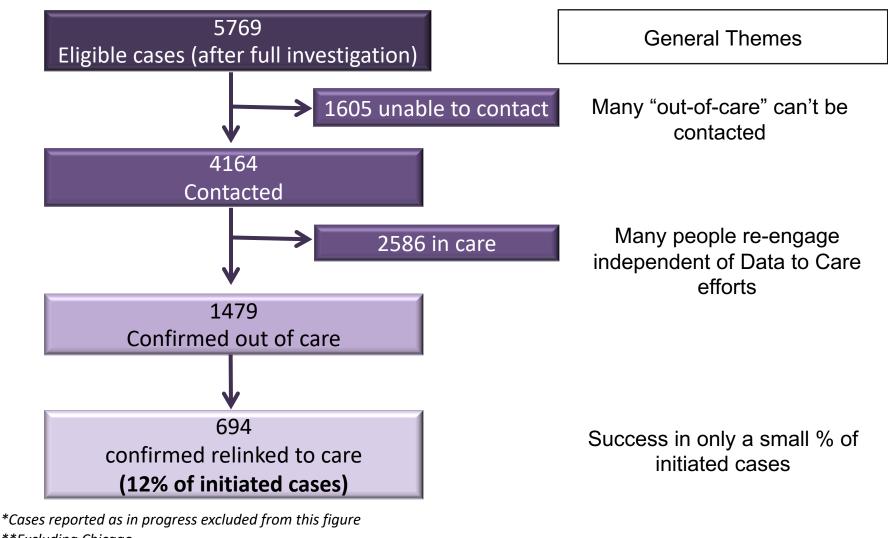
- Data to Care
- Peer navigation
- Financial incentives
- Care coordination

In most cases, our Data to Care efforts do not lead to successful re-engagement in HIV care



Source: Dombrowski et al. STD 2018.

Multisite Data to Care Evaluation^{*}: Illinois[±], Louisiana, Tennessee, Virginia



**Excluding Chicago Sweeney P et al. Public Health Reports, 2018

Interpretation

- The Data to Care strategy in and of itself does not appear to have a substantial public health impact
- Part of the problem is difficulty identifying and contacting poorly engaged individuals
 - This might get better as surveillance improves & with real-time health information exchanges



Peer Navigation



 Compelling rationale, little high-quality evidence of impact on viral suppression to date

Controlled studies of peer navigation in HIV					
Reference		Goal	% viral suppression		
(N)		Intervention	Control		
Metsch L, <i>JAMA</i> 2016 (N=801)	Hospitalized, virally unsuppressed, sub. use disorders	Engagement in care & substance use treatment	41%	39%	
Giordano T, <i>CID</i> 2016 (N=460)	Hospitalized, virally unsuppressed	HIV care engagement	28%	28%	
Cunningham WE, <i>JAMA IM</i> 2018 (N=356)	Incarcerated in LA County Jail	HIV care and medication adherence	50%	36%	

Images of peer navigators from Berry J. "Guiding Lights", Positively Aware, 2012. Systematic Review: Simoni JM, et al. AIDS Behav. 2011

Care Coordination

- Multicomponent intervention
- NYC Care Coordination Program includes
 - Outreach for case finding & after missed appts
 - Comprehensive case management services
 - Patient navigation & medical appointment support
 - Adherence support, including modified directly observed therapy (mDOT)
 - HIV self-management education

Outcomes among Care Coordination Clients (N=6812) vs. Matched Non-Enrolled Controls (N=6812)

	Ν	Intervention Pre	Intervention Post	Control Pre	Control Post
Viral suppression,12 months					
All clients	6812	31	60*	31	54
Consistently unsuppressed ¹	2833	0	43*	0	32
Durable viral suppression ² , 13-36 months					
All clients	6812		37		37
Consistently unsuppressed ¹	2833	0	21*	0	18

¹All VL >200 or no VL in 12 months prior to intervention ²All VL<200 in 13-36 months following intervention *p-value <0.05 for between-group post comparisons Sources: Nash D, *PLoS ONE*, 2018; Robertson MM, *JAIDS*, 2019

Viral Load Outcomes in the LA Medical Care Coordination (MCC) Program & NYC CCP

	Ν	Intervention Pre	Intervention Post	Control Pre	Control Post
NYC CCP All Clients (2009-13)	6812	31	60	31	54
Consistently unsuppressed	2833	0	43	0	32
LA MCC All Clients (2013)	1204	31	64		
High acuity ²	357	22	53		

¹All VL >200 or no VL in 12 months prior to intervention

²Based on score reflecting 12 life domains

Nash D, PLoS ONE, 2018

http://publichealth.lacounty.gov/dhsp/Reports/HIV/MCC_Year-1_EvaluationReport-FINAL.pdf

Financial Incentives: Project HOPE Trial

Randomized controlled trial	60
	ggest that <u>targeted</u> financial improve HIV outcomes on -
Int	es
Usuar treatment	10
Patient navigation Patient navigation +	
incentives	0 + 6 months 12 months
Source: Metsch LR et al, JAMA 2016	

Financial Incentives: HPTN 065

- Test & Treat study
- RCT in the Bronx, NY and Washington, DC
- Randomized HIV testing & care sites to standard of care or financial incentives
 - \$125 for linkage
 - \$70 quarterly for viral suppression
- No effect on linkage to care
 - 75% vs. 73%; RR 1.10 (0.73 1.67)
- Small increase in viral suppression (<400 c/ml)
 - Increased 11.5% vs. 3.7%; RR 3.8 (0.7 6.8)
- Greater effect among patients not consistently virally suppressed at baseline

El Sadr W, et al; JAMA Internal Medicine 2017

Summary including other models

Author	Intervention	Viral load suppression	Engagement
Bradford et al. 2007	Patient navigation for 12 months in OR, WA, MA and DC	Undetectable VL increased from 34% to 53% (no control)	2 or more visits in 6 months increased from 64% to 79%
Metsch et al. 2016	Patient navigation with financial incentives for 12 months. +control	viral suppression at 12 months: -39% in control -41% in navigation -44% in navigation + incentive	Visit with HIV provider in 12 m -59% in control -66% in navigation -75% in navigation + incentive
Simeone et al. 2017	Integration with methadone clinic	Undetectable VL -93% at methadone clinic (N=14) -79% at HIV clinic (N=31) -62% at community clinic (N=5)	Visit with provider Q6 m -93% at methadone clinic -74% at HIV clinic -62% at community clinic
El-Sadr et al. 2017	Financial incentives in NY and DC	Change in proportion w viral suppression (<400 c/ml) -11% for financial -3.7% for standard of care	Change in proportion continuity in care -16.5% for financial -neg 1.8% for standard of care
Sena et al. 2017	DIS Counselors for re- engagement (care coordination)	-did not say	-46% re-initated care within 90 days of referral -78% within 365 days
Brantley et al. 2018	Financial incentives in Louisiana	-VLS increased from 58% to 83%	-engagement increased from 70% to 99% at 12m and 96% 12-25m

However....

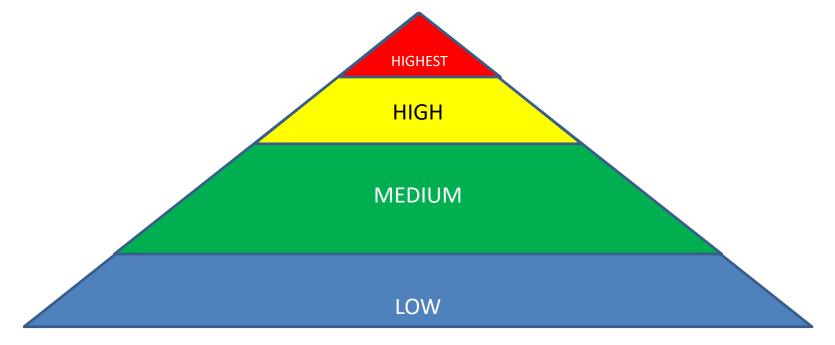
- Many studies have no control group
- Some persons entering/referred for the intervention already had evidence of care (virally suppressed or engaged at enrollment)
- Effects are modest
- Most don't include viral load suppression as outcome
- Interventions are brief
- Financial incentives might be too complicated
- We are spending a lot of effort trying to relink patients to the same system of care that failed to engage them in the first place

Summary of Evidence for Re-engagement Strategies

- Strategies with a one-time/short-term intervention to send patients back to the same system are minimally effective
- Care coordination strategies that provide ongoing enhanced support are more effective – Especially for the highest need clients
- Targeted financial incentives might have a role
- We still need something else to effectively and durably engage the hardest-to-reach

Ryan White-Funded Care: A System That Works

- Works for the <u>vast majority</u> of patients enrolled
- But not everyone
- Tiered strategy needed to match spectrum of support need among patients
- Need new approaches for people who cannot or do not engage in HIV care as it is traditionally organized



Can we change the structure of HIV care available for certain high risks persons who have difficulty navigating the medical system?

The MAX Clinic

MAX clinic

- Engage patients who have extensive barriers to HIV care
 - High-intensity
 - Low-threshold
 - Incentivized care model
 - Walk-in access to primary care
- Criteria:
 - Failed to engage in care
 - Not on ARVs
- Madison Clinic & Public Health Seattle & King County (PHSKC) STD clinic

The Max Clinic: HIV Care for the Hardestto-Reach Patients

MAX Clinic Components (Evolved Substantially Over First 2 Years, 2015-16)

Low-Threshold Care	Incentives	High Intensity Outreach Support	Coordinated Care & Case	
Walk-in access to	Snacks each visit,		Management	
 medical care 5 afternoons/wk 	\$10 meal vouchers 1x/wk	Non-medical case managers (Public	Jails	
 case managers 5 days/wk 	Cell phone	Health)	Housing & mental health case	
	Bus pass	Medical case		
Direct phone line to MAX case managers	\$25 - visit + blood draw q 2 months	managers (Madison)	management	
(no phone tree)	\$50 – VL<200 q 2			
Text message communication	months (previously \$100)			
Harm reduction				

Collaboration with multiple organizations

Bailey Boushay Adult Day Program

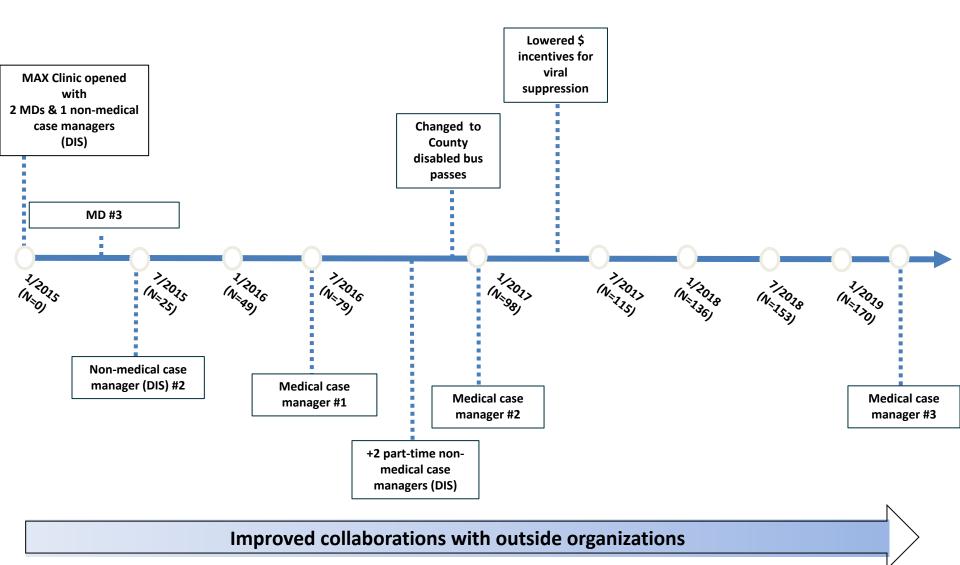
provides medication adherence support and other resources to high needs PLWH in King County;

Lifelong is a community-based AIDS Service Organization and Ryan White Part A recipient.

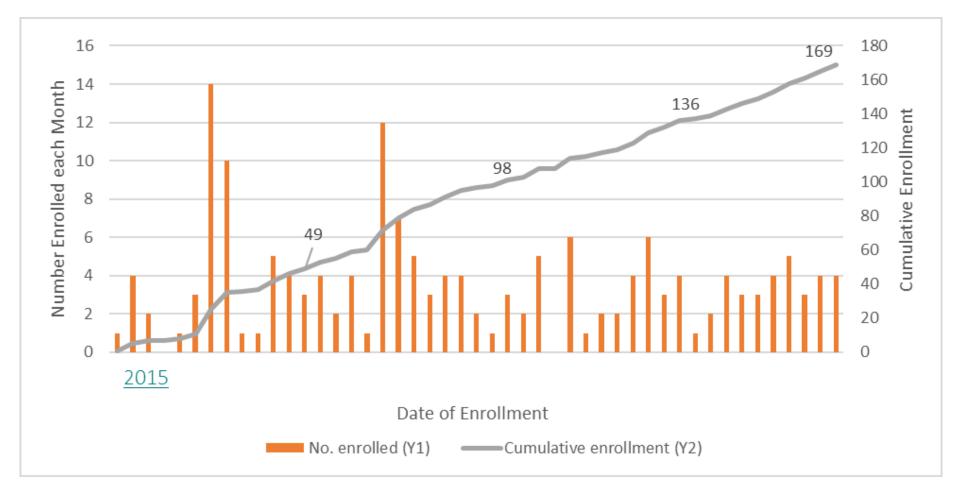
HEET provides intensive outreach support for PLWH who have substance use disorders, mental illness, and recent incarceration Other key collaborating organizations:

- King County jail release planning program
- Downtown Emergency
 Services Center
- Other organizations providing support services to homeless persons; and supportive housing facilities

Evolution of the MAX Clinic



Max Clinic Enrollment, Jan 2015-Nov 2018



PHSKC Surveillance Report 2018

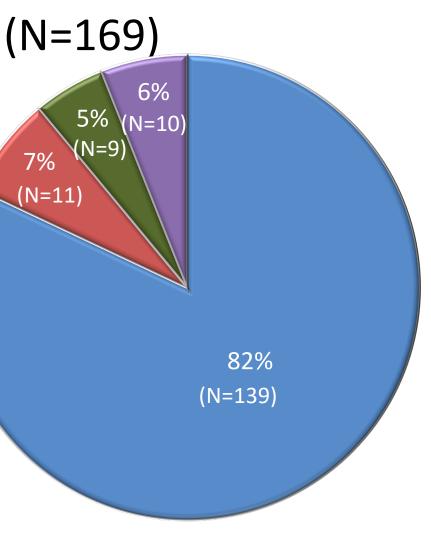
Status of Patients Ever Enrolled in Max (N=169)

Currently enrolled

- Transitioned to standard care
- Moved away or discharged

🛯 Died

- Of the 142 current enrollees, 70% were virally suppressed at most recent VL (< 200)
- ~95% ever virally suppressed
- Consistent >60% viral suppression every month

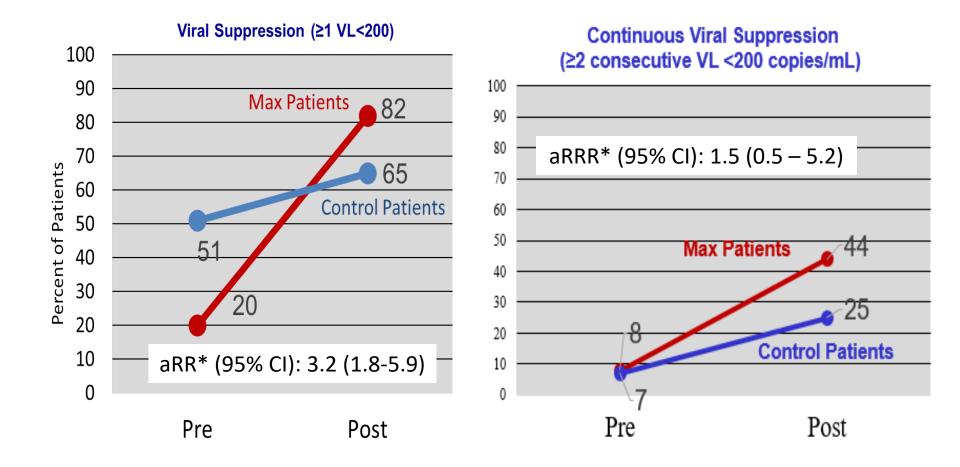


	Max Clinic (N=169)	HIV-Diagnosed, King County (N=6907)
Gender		
Male (cisgender)	70%	87%
Female (cisgender)	26%	12%
TG, NB, GQ	4%	1%
Race/ethnicity		
White, non-Hispanic	48%	56%
Black, non-Hispanic	31%	19%
Hispanic/Latinx	7%	13%
American Indian	5%	1%
Other	9%	11%
HIV Risk Factor		
MSM	31%	67%
IDU	22%	4%
MSM-IDU	21%	9%
Heterosexual	22%	10%

Characteristics of Patients Enrolled in the First Two Years of the MAX Clinic (N=95)

Characteristic	N (%)
CD4<200 cells/mm ³	44 (46%)
Illicit substance or unhealthy alcohol use	81 (86%)
Methamphetamine	56 (59%)
Mental illness	68 (71%)
Unstable Housing	62 (65%)
Sub use or mental illness or unstable housing	90 (95%)
Sub use + mental illness + unstable housing	43 (45%)
Documented history of incarceration	55 (58%)

Outcomes of Patients Enrolled in the Max Clinic (first 50) vs. Standard-of-Care Control (N=100) in the 12 months Pre- and Post-Baseline



*Relative Risk Ratio (RRR) Adjusted for substance use, psychiatric dx, housing status (aRRR)

John: A Story

	Viral Load (copies/mL	
2012	?	
2013	?	
2014	? ? ?	
2015	?	
10/2016	462,290	CD4 = 32
11/2016	104	
12/2016	<40	
3/2017	<40	
5/2017	64	
7/2017	<40	
10/2017	2106	
12/2017	90	
3/2018	181	
5/2018	<40	
7/2018	<40	
9/2018	<40	
11/2018	<40	
1/2019	<40	CD4 = 45

- Cisgender man born in mid-1960s
- 2012 Tested HIV+ in STD Clinic
- 2014 Contacted by Data to Care program
- Barriers to HIV Care:
 - Homelessness
 - IV meth use
 - Unclear psychiatric disorder (psychosis)
- 2014-16 Multiple visits to STD Clinic
 - Talked often with HIV care relinkage team
- 10/2016
 - Agreed to a lab draw for \$25!
 - Enrolled in Max Clinic

Qualitative Interviews: Themes & Quotes

• Key component is how patients feel they are treated at the clinic and how social circumstances are addressed

- Walk-in access to care is essential
 - Social circumstances make it hard to keep appointments
 - Past experience of showing up and being rushed

I'm grateful, forever grateful, to be here and for this program to be open for people like me, because I always used to tell every doctor, 'You don't understand, you don't understand, you don't understand. You can tell me all this and that, but you don't understand because you're not in my shoes to understand. But for me to have somebody that does understand, it helps."

"[I]t works out quite well. I don't have to worry, 'When is my next appointment? I forgot to ask this question last time I saw them and now I have to wait three months.' But instead, this way, I can remember and I can come back and say, 'Hey, this is what's going on.'....And that way, **they can deal** with the problem right then and there, instead of waiting for the problem to even get worse."

Qualitative Interviews: Themes & Quotes

• Financial incentives are valued, but not the most important for many....

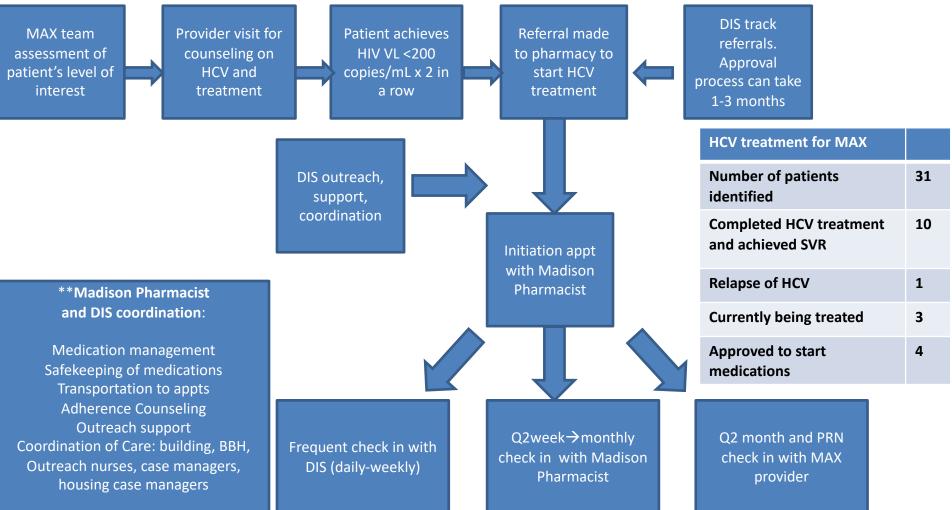
It's a great incentive for you to take your meds and get in the habit of taking your meds, so you know, even when....you're at the point where you leave this study and you stop getting cash for taking them, you're already in the habit of [taking them] and are already in a routine of taking them, so it's not that big of a deal for you to continue to take them, you know?" ...but make a crucial difference for others

"[W]hen they sent me here and they told me that that was one of the options if I get my blood drawn and I take my medicine more.....because I've always had problems taking my medication for my whole life.....a light bulb just clicked in my head and was like, 'I need that money. You need to take your medicine.' **So, that's what really helped me overcome the pills**."

"[I]t was important because **it made my spirits feel good....and it was like I got a surprise for even helping myself,** like I got a reward for doing something that I needed to do and once you get that, it makes you even feel better. Like, 'Oh, I did it!', and plus I get initiatives to do it, so it makes you keep on wanting to take your medicine."

HCV Treatment





What are the Essential Elements?

- Low-barrier access
 - walk-in visits
- Intensive support & care coordination

medical & non-medical

• Some sort of incentive to draw people in

Does not need to be cash

The Provider's Role in Retention in Care

- Assess the patient's perception of the time "out of care"
- Inquire about barriers (with attention to healthcare system barriers)
 - "What can we do to make this easier or better for you?"
- Make a concrete plan to address the barriers
- Consideration for restarting ART is key

 Don't create too high a threshold
- Practitioner behavior is a crucial piece of the engagement and retention
 - explain things in a way that they understand and take the time to get to know them as individuals

The Medical Provider's Role at the Time of Linkage

- Establish a timeline for care, and if the patient is unwell, return to physical and emotional health
- Visits are frequent and intense at first
- Anticipate a period where fewer appointments are necessary
- Patients can feel overwhelmed by requirements at beginning or experience spacing out of appointments as a personal rejection
- Harm-reduction approach to substance use, and abstinence is not required for any services

Christopoulos KA, et al, "Taking it a half day at a time": patient perspectives and the HIV engage continuum. AIDS Patient Care STDs, 2013.

Overall goals to help engagement: thinking about patient care in a different way

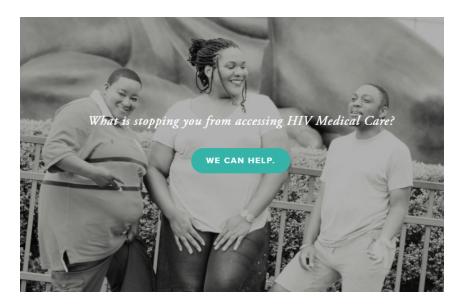
- Ease Structural barriers
 - Increasing clinic hours and ensuring availability
- Novel approaches for specific populations (youth, women, minority populations)
- Easy, low effort interventions
- Incentives: cash, cab/bus vouchers, grocery cards
- Use of peer navigators, care coordinators
- Medical homes (can provide med management)
- Multidisciplinary teams: case manager, social worker, pharmacist, nurse, and care practitioner.

Hightow-Weidman LB, et al. AIDS Patient Care STDs 2011. Gardner LI et al. CID 2012. Sitapati AM et al. J Health Care Poor Underserved 2012. Horberg MA, et al. JAIDS, 2012.

Emerging Models of HIV Care for High Need Individuals

Detroit

Link-Up Detroit (Data to Care program)



Wayne State University ID Clinic Homecare Program

- "Building an infrastructure to reach the last 20%"
- NP/MA team supervised by MD
- Care at home
- Patients can call direct cell phone
- Of first 28 enrolled:
 - 27 retained
 - 23 virally suppressed

Vancouver BC

Vancouver Native Health Society







- Street-front clinic
- Walk-in access
- Co-location of
 - HIV care
 - HCV care
 - Dental care
 - Pharmacy
 - Case mgmt, support groups
 - Hairstyling, food, TV

http://www.vnhs.net/programs-services/medical-clinic Pogue CAHR 2009, Prashar S et al, AIDS & Behavior, 2011

Maximally Assisted Therapy Program





BRITISH COLUMBIA CENTRE for EXCELLENCE in HIV/AIDS

- 86% active sub. use disorders
- 30% psychiatric disorders
- 81% hepatitis C co-infected
- 90% viral suppression

Future endeavors

- MOD clinic (Madison, here)
- Pierce County MAX (Tacoma, WA)
- Pop-up Clinic (UCSF, SF)

Conclusions

- We need to alter the medical system to meet the needs of the "hardest-to-reach" people living with HIV
- The current Ryan White funded care system works very well for the vast majority of PLWH, but not everyone
- The next increment of improvement in the HIV care continuum is going to be resource-intensive
- Intensive support & care coordination <u>coupled</u> <u>with</u> clinics specifically tailored for patients with complex medical & social needs is the most promising approach

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PHSKC HIV/STD Program

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HRSA – Ryan White Parts A, B, & C

CDC – esp. 12-1201 Category C demonstration grant

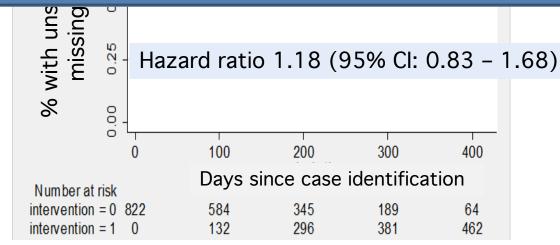
NIH – K23 MH090923 , R03 DA042668, and CFAR supplement & AIDS/STD T32

Thank You

Principal Finding of the Cluster RCT

Time to Viral Suppression According to Intervention vs. Control Period (excluding deaths and relocations, N=822)

About half of the individuals who achieved viral suppression did so before the Data to Care team attempted to contact them (N=161/301, 53%)



Source: Dombrowski JC, STD 2018