Development of a Rapid ART Initiative in San Francisco

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• Susa Coffey: None

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 - LINCS (Linkage Integration Navigation Comprehensive Services) Team
- UCSF HIV, Infectious Diseases and Global Medicine at SFGH
 - Diane Havlir
 - PHAST/RAPID (Positive Health Access to Services and Treatment) Team

Roadmap

- 1. Antecedents and what is Rapid?
- 2. Beginnings of Rapid in San Francisco: Pilot at Ward 86
- 3. Collective Impact to take Rapid Citywide: Getting to Zero-SF
- 4. Strategy
 - 1. Rapid Committee
 - 2. Adapting Ward 86 model, protocol for Citywide context
 - 3. Implementation
 - 4. Dissemination
 - 5. Metrics and accountability
- 5. Outcomes, next steps, lessons learned



RAPID ART: Definitions

- ART started as soon as possible after HIV diagnosis
 - On first clinic visit (before baseline test results are available...)
- AKA rapid start, same-day start, immediate ART, treatment on diagnosis
- There is no single accepted standard for what counts as immediate ART: 0 days from dx? 1 day? 7 days? 14 days?
- Compromise between aspirational and achievable



Rapid ART: Potential Benefits

- Provide immediate linkage to care
- Shorter time to virologic suppression, higher rates of retention with VS
- Community health benefit (decrease transmission)
- Equity address disparities (access to immediate ART for all)
- Potential psychological benefit/patient empowerment
- Patient/person expectation
- Decreased reservoir (in hyperacute infection)?







San Francisco RAPID – Brief History

- UCSF/SFGH Ward 86 RAPID: a pilot program initiated 2013
 - Safety-net population
 - Very successful; became standard of care in 2014
 - Goal: start ART as close to time of HIV diagnosis as possible, ideally same day



- Getting to Zero (GTZ) SF adopted RAPID <u>citywide</u> in 2014
 - Goals:
 - HIV diagnosis to 1st care visit ≤5 days
 - Start ART at first care visit
- Note: focus on people with new HIV diagnoses

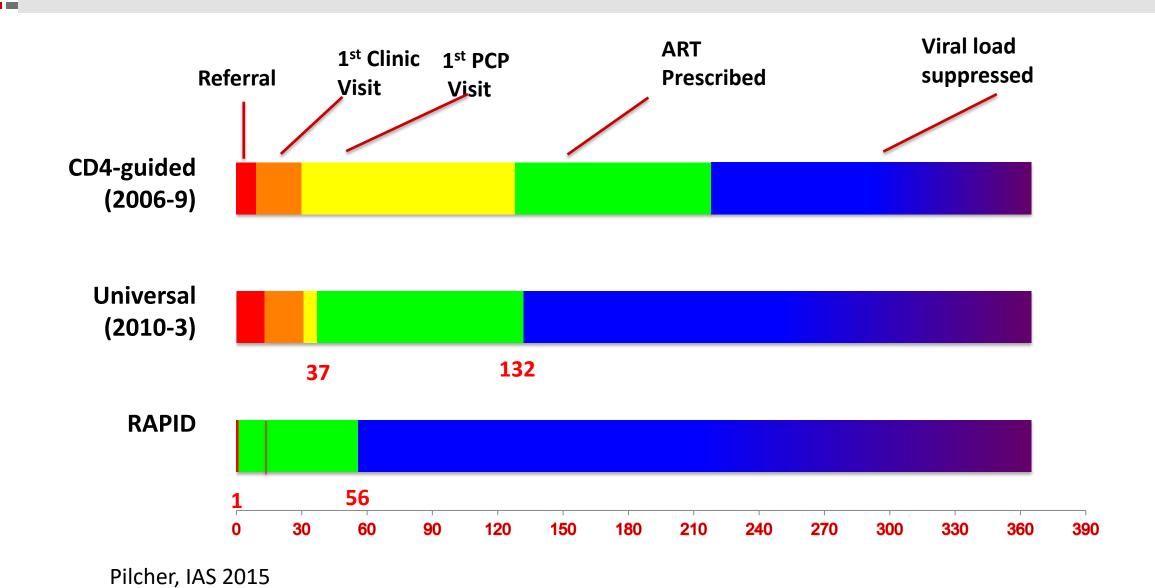


RAPID ART Pilot at Wd 86: Initial Clinic Visit

- Person referred from SFGH Testing Site or Clinical Lab
 - DPH navigators may be involved
 - Dedicated pager: single point of contact
- Multidisciplinary team sees person
 - SW intake, counseling, insurance/benefits activation/optimization (eg, emergency Medi-Cal)
 - Clinician intake, including education about ART
- Intake labs
- Start ART immediately, unless there is a clear contraindication or patient declines
 - ART starter pack, 1st dose in clinic; prescription sent to pharmacy
- F/u 1-2 days with SW or RN
 - Clinic visit (SW and clinician) 1-2 weeks; close f/u for weeks-months



Wd 86 RAPID Pilot: Shortened time to engagement, virologic suppression





Qualitative Lessons from Interviews with RAPID Pilot Team Members: Keys to Success

- 1. Single point-of-contact for referrals activates the team (e.g. PHAST Pager)
- 2. Committed team is essential (Counseling, Benefits Navigation, Clinical)
- 3. Avg. RAPID intake 2 hours
- 4. Minimize handoffs: Every handoff is a warm handoff
- 5. Have a plan for medication access
 - Emergency ADAP
 - Presumptive Medi-Cal
 - Pharma Patient Assistance Cards
 - Starter packs?
- 6. Schedule follow-up in 5-7 days and check in with patient in the 1-2 days after he/she leaves the appointment



Getting to Zero San Francisco

- Multi-sector independent consortium operates under principles of <u>collective</u> <u>impact:</u> "Commitment of groups from different sectors to a common agenda to solve a specific problem."
- Established in 2013
- Goals:
 - Zero new HIV transmissions
 - Zero HIV deaths
 - Zero stigma and discrimination



www.gettingtozerosf.org

Initial Signature Initiatives:

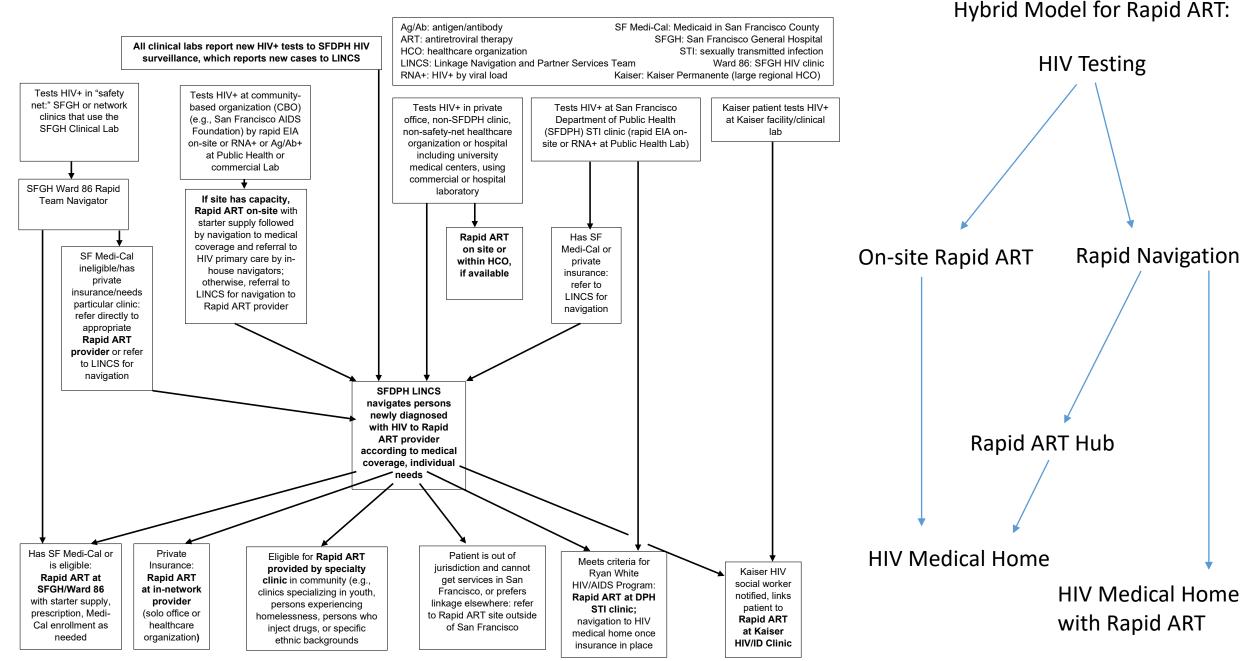
- 1. Citywide coordinated PrEP program
- 2. Rapid ART start
- 3. Patient-centered linkage, engagement, and retention in care
- 4. Ending stigma

Initial Challenges: multiple patient journeys from diagnosis to ART:

- Different test sites (clinic based, hospital based, community based)
- Different testing platforms
- Care site driven by insurance (or lack)
- Fragmented communication among parts of healthcare "system"
- Housing
- Mental health
- Substance use
- Accessibility and acceptability of healthcare to groups most at risk of HIV infection

Rapid Committee Membership

- Medicine: UCSF/SFGH; community providers; Kaiser Permanente
- SFDPH (Public Health): STI Clinic (high volume testing site, LINCS Navigation Team); HIV Surveillance Branch (ARCHES)
- CBOs: SF AIDS Foundation (high volume testing site, PrEP clinic, navigators); advocacy groups
- Met monthly
- Tasked with program design, dissemination/training, metrics, reporting
- Chair received salary support (Mayor's office through SFDPH);
 membership otherwise voluntary



Citywide Rapid Implementation: Clinical

Citywide RAPID Protocol:

- Definition: all new HIV diagnoses linked to care ≤ 5 working days; ART started ≤ 1 day of 1st care visit
- At 1st care visit: Baseline labs collected, counseling, medical/psychosocial assessment, ART started in almost all circumstances
- Consensus Rapid Regimens encouraged



Who is appropriate for immediate ART?

- Anyone with a new, confirmed HIV diagnosis unless there is a clear contraindication to starting immediate ART.
- Preliminary HIV+, confirmation pending, with high pretest probability of HIV infection
- Acute infection: Ab(-)/RNA(+)

Who is <u>not</u> appropriate for immediate ART?

- Patients for whom immediate ART might be medically dangerous and who should undergo a thorough evaluation and stabilization before ART:
 - Inflammatory OI in a closed space (untreated cryptococcal or TB meningitis)
 - Visceral KS

Who might be appropriate for immediate ART?

 Patients re-engaging in care with clear, uncomplicated ART history, low likelihood of resistance?

Attributes of a Rapid regimen (remember, lab results will generally not be available when starting):

- Minimal side effects
- Accessible/affordable
 - Minimal pill burden, once daily dosing (some preferred regimens for pregnancy may need BID)
 - If using insurance: no copay, or copay assistance available
 - If using Pharma assistance: easy to navigate, same-day enrollment
 - Starter packs helpful but not essential
- High potency, high genetic barrier to resistance
 - Viral loads >100,000 c/mL or 500,000 copies/mL
 - Active against virus with more common transmitted mutations (NNRTI mutations (12.8%), TAMs (6.7%)). Transmitted drug mutations K65R, M184V, and those conferring resistance to DRV are rare (<1%). ¹
 - Safe (liver, kidneys, hypersensitivity)
- Individual patient factors
 - Pregnancy
 - Life chaos and adherence
 - Lipids (boosted PIs?)
 - Weight gain (TAF vs TDF?)
 - Drug-drug interactions (cobicistat, ritonavir, PIs, statins, anticoagulants, rifamycins (for TB or staphylococcal osteomyelitis, endocarditis), divalent cations, antivirals for HCV......

¹Rhee et al, Trends in the Molecular Epidemiology and Genetic Mechanisms of Transmitted HIV type 1 Drug Resistance in a Large US Clinic Population. CID 2019:68

Preferred Rapid Regimens for Nonpregnant Adults

Option 1:

[DTG or BIC] + [TAF or TDF] + [FTC or 3TC]

• 1st generation INSTIs (RAL, EVG/cobi) less desirable due to lower barrier to resistance, multiclass resistance with failure

Option 2:

DRV + [rtv or cobicistat] + [TDF or TAF] + [FTC or 3TC]

ARVs <u>not</u> to use for Rapid Start in absence of lab data:

- Abacavir (example: DTG/ABC/3TC aka Triumeq®, ABC/3TC aka Epzicom®): potential for fatal hypersensitivity reaction
- NNRTIs: ART class with highest prevalence of transmitted resistance mutations; Rilpivirine less potent with VL>100,000 c/mL; neuropsychiatric SE with efavirenz
- DTG/3TC (Dovato®):
 - 2-drug regimen, potential for DTG monotherapy if M184V present
 - DTG monotherapy associated with acquisition of INSTI mutations, loss of this class in future regimens
 - Decreased potency in VL>500,000 c/mL, CD4<200
 - Potential for 3TC monotherapy if HIV/HBV coinfected

DHHS-preferred <u>initial</u> regimens for use in when <u>HIV diagnosed during pregnancy</u> (**excerpted**, **modified for Rapid start**)

- Preferred dual-NRTI backbones*:
 - ABC/3TC**
 - TDF*/FTC or TDF/3TC
- Preferred INSTI regimens*:
 - DTG/ABC/3TC (STR)
 - DTG + preferred dual-NRTI backbone
 - RAL BID + preferred dual-NRTI backbone
- Preferred PI regimens**:
 - ATV/r + preferred dual-NRTI backbone
 - DRV/r BID + preferred dual-NRTI backbone

Adapted from Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States. Available at https://clinicalinfo.hiv.gov/en/guidelines/perinatal/table-4-what-start-initial-combination-regimens-antiretroviral-naive-pregnant?view=full (accessed 5/13/2021

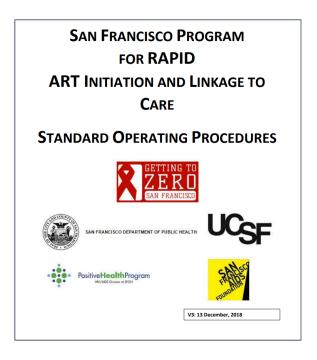
*data lacking on use of BIC in pregnancy; TAF now an accepted alternative for pregnant patients **cobicistat generally not recommended due to lower boosting effect vs rtv in 2nd, 3rd trimesters, however updated DHHS guidelines allow for cobicistat-boosted PI in pregnancy if patient, provider choose to do so with frequent viral load monitoring

Citywide Rapid Implementation: training, dissemination

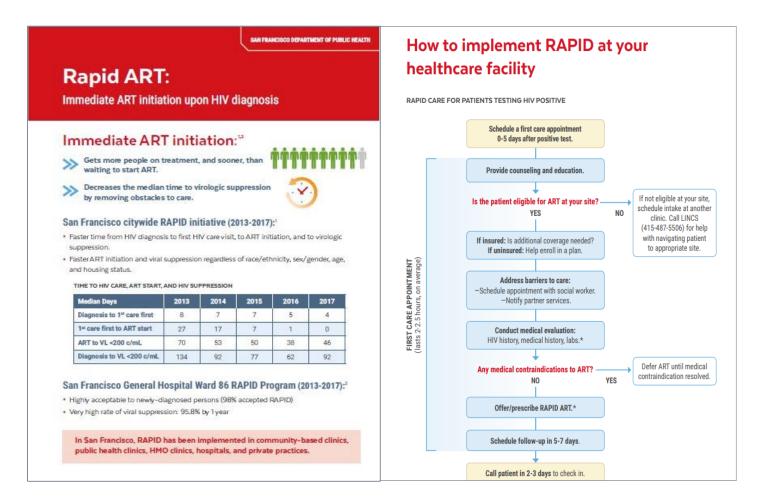
- **HIV clinics** identified using HIV surveillance data, trained on RAPID procedures by in-service; grand rounds, peer-to-peer (2015) and individual provider detailing (2016)
 - Clinics serving African Americans, Latinx, Youth, prioritized early
- Linkage navigators trained and given RAPID Provider Directory to identify optimal HIV clinic for each newly-diagnosed patient, by insurance coverage, psychosocial needs.
- Full protocol and RAPID detailing brochure for clinicians disseminated electronically at http://www.gettingtozerosf.org/rapid-committee/ and at open quarterly SFGTZ consortium meetings

Training/dissemination tools

Citywide protocol:



Public Health Detailing Brochure/Provider Guide:





The Rapid ART Program Ini	tiative for New HI	V Diagnoses	(RAPID) is a	city-wide e	ffort to of	ffer HIV
medication to everyone wit	hin 0-5 days of HI	V diagnosis r	egardless of	insurance	status.	
or: :						

Clinic	RAPID Contact	Insurance Info/Eligibility Requirements (bold
UCSF Positive Health Program Ward 86 San Francisco General Hospital 995 Potrero Ave, Bldg 80, Fl 6	Page PHAST team at 415-443-3892 Clinical staff can leave after- hours voicemail at 415-206-2460	Medi-Cal: SF Health Plan (23421) Medicare Healthy San Francisco Uninsured can enroll for ADAP or Medi-Cal
Larkin Street Youth Services 134 Golden Gate Ave	Page 415-257-6545	Age 12-24, low income, SF resident Medi-Cal: SF Health Plan (22096) Healthy San Francisco Uninsured (income less than \$16,395/yr)
Southeast Health Center 2401 Keith St	Gwen Smith 415-671-7057	Medi-Cal: SF Health Plan (21056) Healthy San Francisco Uninsured (income less than \$16,395/yr)
San Francisco City Clinic Early Care Clinic 356 7th St	Andy Scheer, MSW 415-487-5511	 Uninsured or currently not in HIV care, must be a SF resident Uninsured
HealthRight360 – Tenderloin Health Services Glide Memorial Church 330 Ellis St	Mike Wilk Program Manager 415-969-6530	Medi-Cal: SF Health Plan (25203) and Anthem Blue Cross (XXA) Medicare Health San Francisco
San Francisco Community Health Center (formerly API) 726 Polk St, Fl 4 1800 Market St, Suit 401	Jawon Jang, RN 415-292-3400 (x707)	Medi-Cal: SF Health Plan (25353) Medicare Uninsured (on sliding scale)
Kaiser Permanente 2238 Geary Blvd, Fl 4 West	Ed Chitty, RN Patient Care Coordinator 415-833-4258	Medicare and privately-attained plans CoveredCA: Kaiser Medi-Cal: If you've had Kaiser within 6 mo, enroll in SFHP and request Kaiser enrollmen
SF VA Medical Center 4150 Clement St, Blgd 203, Ward 1B	Elda Kong, NP 415-221-4810 (x23942) Mai Vu, PharmD 415-221-4810 (x24793)	 Active or eligibility for VA health coverage. For more info: https://www.sanfrancisco.va.qov/patients/eligbility
Mission Neighborhood Health Center—Clinica Esperanza 240 Shotwell St	Recruitment and Retention Coordinator 415-552-1013 (x2234) Treatment Linkage Specialist 415-552-1013 (x2319)	Eligibility documents expected to register (but not necessarily on first RAPID visit) Medi-Cal: SF Health Plan (21047) and Anthem Blue Cross (XK1000) Medicare and some privately-attained plans Healthy SF and uninsured (on sliding scale) Covered CA: Blue Shield, Health Net
Family Health Center 995 Potrero Ave, Bldg 80	Page PHAST team at 415-443-3892. The first appointment at W86 with ongoing care provided at FHC	Medi-Cal: SF Health Plan (21044) Medicare Health San Francisco Uninsured can in enroll in ADAP or Medi-Cal



Private Medical Doctors		
Dr. Charles Moser, MD, PhD	415-600-4900	Most PPO (commercial) plans. Call to make sure they accept Covered CA plan
Dr. Louis Cubba, MD / Dr. John Nienow, MD	415-621-4228	Most PPO (commercial) plans. Call to make sure they accept Covered CA plan
Dr. William Kapla, MD	415-600-4760	Most PPO (commercial) plans. Call to make sure they accept Covered CA plan
Dr. Lee Roy Liskey, MD	Israel Dedios 415-5642-2000 or 415-642-2001	Most PPO (commercial) plans. Call to make sure they accept Covered CA plan
Hyper-Acute HIV Patients		
Viiv Clinical Study San Francisco General Hospital 995 Potrero Ave, Bldg 80, Fl 4	Referral must be made by paging PHAST team at 415-443-3892. Project Coordinator Lisa Harms can be reached at 415-476-9296 (x325)	HIV antibody (-) but RNA (+). Can provide labs and medication but needs linkage to PCP Insurance does not matter. Helpful for individuals living outside SF or uninsured
Outside of SF		
East Bay AIDS Center (EBAC) 3100 Summit St, FI 2 Oakland, CA 94609	Call 510-655-4000 (x5065)	For individuals living in East Bay or wishing to receive treatment there Benefits navigators can work with public and private insurance options
RAPID Screening Questions		
Residency: Where do you!	ive?	

- SF resident (includes homeless in SF)
- Lives outside of SF. Which county?
- 2. Do you have insurance?
 - a. Yes
- ☐ MediCal in SF
- MediCare in SF
- □ Private Insurance via Covered CA, employer sponsored, or other commercial plan,
- Healthy SF (not insurance, but covers medical care in SF- good for undocumented patients who are NOT eligible for MediCal/MediCare)
- Select RAPID provider based on insurance, patient preference, location, special
- b. No
 - Are you eligible to enroll in MediCal, Covered CA, employer sponsored, etc?
- 3. What is your income?
 - If LESS THAN \$16,395/year or \$1,366/month (for a household of one- pre-tax gross), then
 - If MORE THAN \$16,395/year or \$1,366/month (for a household of one), then NOT MediCal eligible; will need commercial insurance (including Covered CA, Kaiser)
 - ☐ If NO income (eg just lost job, or has no unemployment benefits), then MediCal eligible
 - ☐ If below 500% of FPL, (e.g., \$59,400 for a household of one), then ADAP eligible
 - Select RAPID provider based on insurance, patient preference, location, special services
- Do you have a PCP?
 - If already insured, who is your PCP?
 - Do you have your insurance card to check provider network and active status?

Rapid Metrics: derived from routinely collected surveillance data

- Rapid start: First care visit ≤ 5 working days from dx and ART ≤ 1 day from first care visit
- "time to" outcomes:
 - Diagnosis to 1st care visit (linkage and intake)
 - 1st care visit to ART (provider dependent)
 - ART to VL<200 c/mL (ART and measurement interval)
 - Diagnosis to VL<200 c/mL (composite outcome)
- Stratified by sociodemographic variables
 - Who is benefiting?
 - Where do we need to improve?



San Francisco <u>Citywide</u> RAPID: Shortened time to care, ART, and HIV virologic suppression

Metric	2013	2014	2015	2016	2017	2018
Median Days						
HIV diagnosis to 1st care visit	8	7	7	5	4	2
1 st care visit to ART start	27	17	7	1	0	0
ART to VL <200	70	53	54	42	46	35
HIV Diagnosis to VL<200	134	92	79	65	65	46

VS w/in 6 and 12 mo.

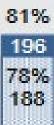
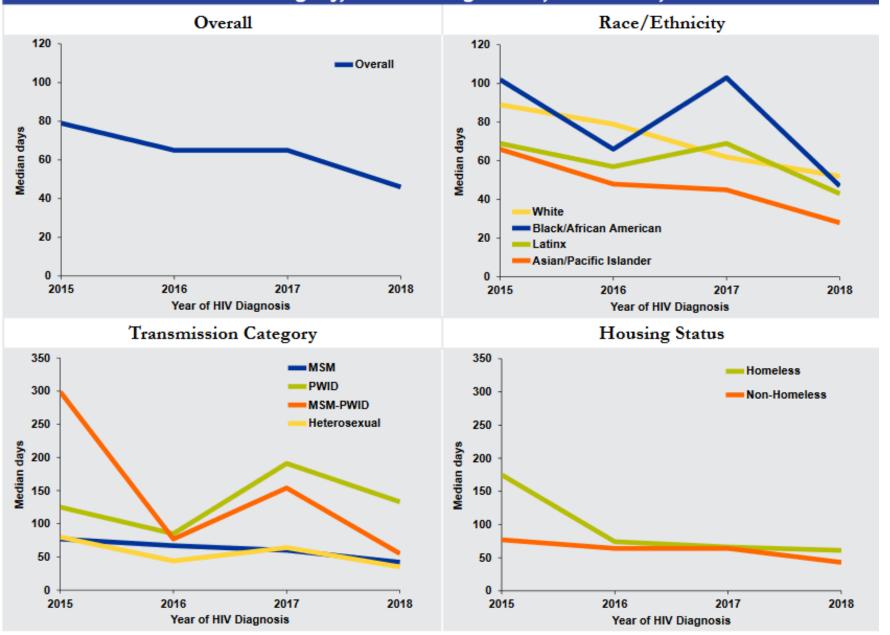


Figure 3.7 Median time from HIV diagnosis to viral suppression by race/ethnicity, transmission category, and housing status, 2015-2018, San Francisco



SFDPH Annual HIV Epidemiology report, 2019

Median Days from First Care Appointment to ART Initiation, New HIV Diagnoses, San Francisco						co	
	2013	2014	2015	2016	2017	P Value	% change
All	28	21	7	3	1		-96%
Male	28	21	7	3	0	<0.0001	100%
Female	72	20	21	3	3	<0.0001	96%
13-29	28	21	7	1	1	<0.0001	96%
30-39	28	18	8	3	0	<0.0001	-100%
>40	30	22	9	7	1	<0.0001	97%
White	27	27	8	7	1	<0.0001	96%
Black	41	48	7	6	0	<0.0001	100%
Latino	29	15	6	1	0	<0.0001	100%
Asian/PI	36	22	7	4	5	<0.0001	86%
MSM	27	21	7	1	0	<0.0001	-100%
PWID	98	20	31	6	2	<0.0001	98%
MSM-PWID	31	43	13	14	5	0.0006	-84%
Heterosexual	46	12	7	1	3	0.0003	-93%
Housed	28	21	7	2	0	<0.0001	-100%
Homeless	30	94	24	10	5	0.0041	83%

Adapted from: Bacon, Chin, Cohen, Sachdev, Coffey et al. Decreased Time from HIV Diagnosis to Care, ART Initiation, and Virologic Suppression during the Citywide RAPID Initiative in San Francisco. Clin Inf Dis., 2020

Rapid vs Non-Rapid ART starts, by year

Year of Diagnosis	Number of diagnoses	% started ART 0- 7 days after dx	% started ART 8-30d after dx	% started ART >30d after dx	% not known to have started ART
All Years	1211	34%	29%	30%	7%
2014	299	16%	29%	46%	9%
2015	272	25%	31%	36%	7%
2016	224	36%	29%	30%	5%
2017	215	46%	27%	20%	7%
2018	201	59%	26%	9%	6%

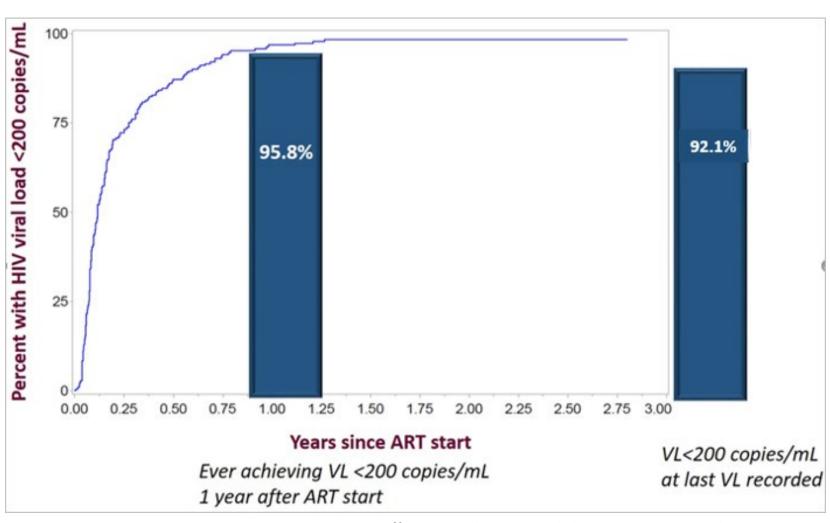
[&]quot;Left Shift" in time to ART: trend towards earlier start even if not meeting definition of Rapid start.



Ward 86 RAPID *Clinical* Program – HIV Suppression to <200 c/mL

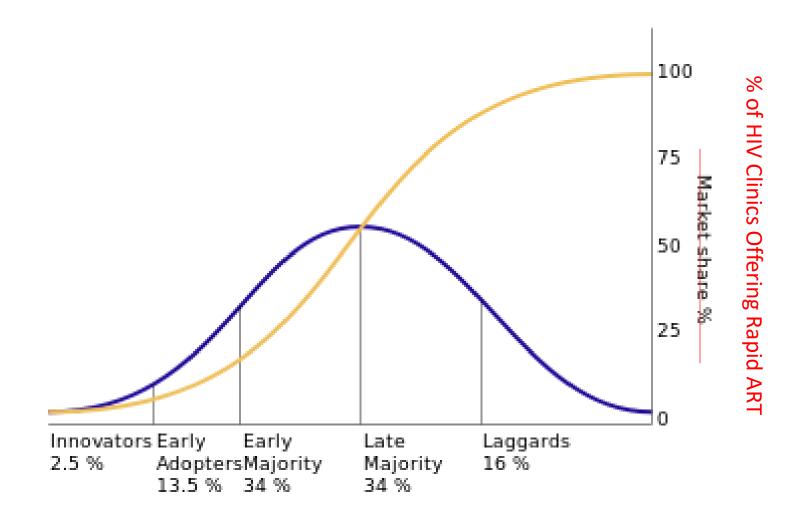
Median Age	30 yrs
Major substance use	51.4%
Major mental illness	48.1%
Homeless/unstable housing	30.6%

98% accepted RAPID ART



Citywide Rapid: Implementation and Diffusion

Rogers Everett - Based on Rogers, E. (1962) Diffusion of innovations. Free Press, London, NY, USA



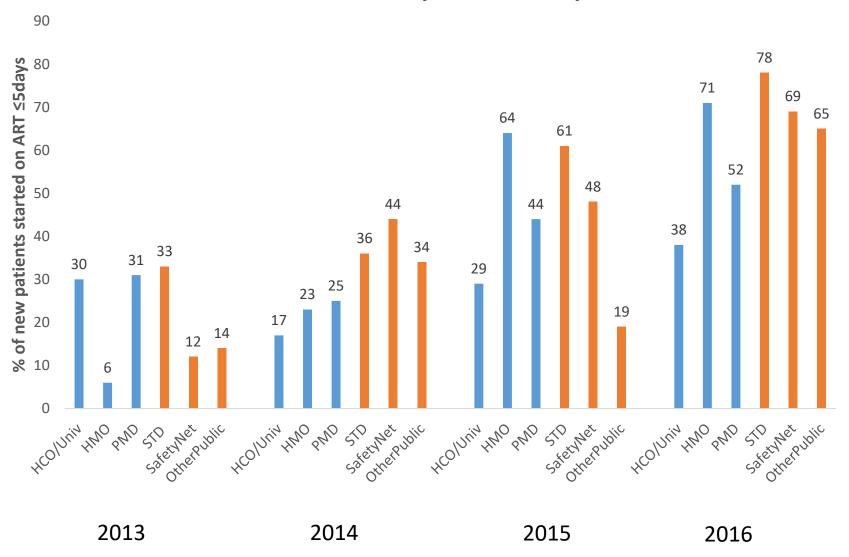


So how do you (did we) push the Rapid start curve (with variable degrees of intentionality)?

- Enlist local champions, opinion leaders early: Ward 86, Kaiser, DPH
- Outreach/dissemination: any way you can
 - Community level: public meetings (GTZ-SF Consortium quarterly mtgs)
 - Institutional level: Grand Rounds at HCOs
 - Provider Level: public health/academic "detailing" programs; peer-to-peer conversations
- Collaboration/collective effort: enlist allies
 - Public health
 - Academic and Community Medicine
 - Testing organizations
 - CBOs (HIV service organizations, advocacy groups)
 - Local press

Improvements in ART start reflect initial care sites prioritized for rapid

ART Initiation Within 5 days of 1st visit, by Care Site



Proportion of ART starts by Site, 2016				
Site	ART Starts(%)			
All	215			
HCO/Univ	24 (11)			
НМО	35 (16)			
PMD	29 (13)			
STD	18(8)			
Safety Net	83(39)			
Other Public	17(8)			
Out of Jurisdiction	9 (4)			

New(ish) Focus: Rapid Restart

RAPID Restart:

For persons re-engaging in care

Immediate ART restart (or initial start, if not previously treated) is appropriate for most persons with known HIV diagnoses who are not on ART, if:

- they are willing and there are no contraindications (see page 4),
- the ART and HIV resistance history is known or can be predicted (based on previous resistance testing, HIV viral load while on ART, and adherence history), and
- an appropriate ART regimen can be devised without information from current resistance test results
- Note that this includes nearly all persons who are re-engaging in care.
- ART restart is particularly urgent for persons with CD4 counts <200 cells/mm³.
- RAPID Restart can be done via Telehealth, if indicated.



Provide robust clinical supports to optimize successful re-engagement in care and ART adherence, e.g.:

Common objections to Rapid during Implementation

Challenge	Response
Patient readiness, need for preparation (often voiced by individual providers)	 Qualitative studies of patient, provider experience argue against this Making vulnerable populations wait to start ART only widens disparities RAPID is not mandatory
The Practice Transformation needed for RAPID is difficult (often voiced by larger clinics/HCOs)	 Easier than it seems Start slow RAPID Champion is crucial to success (SFGH, KPSF, Larkin Youth Clinic, Mission Neighborhood)
Systems barriers (finding a culturally appropriate clinic, insurance obstacles)	 Yes. They are real. Starter packs can bridge some delays (NYC, SFGH/Ward 86) Linkage/benefits navigators ESSENTIAL Tools: RAPID Provider Guide
Who is NOT benefitting from RAPID?	 IF underserved populations are prioritized from the start, outcomes can be more equitable Housing, substance use, mental illness remain obstacles: need low-barrier solutions



San Francisco RAPID – Take-Home Points

- Insurance coverage/systems of care
 - Need easier, consistent, access to (immediate) medications and clinical care
 - Statewide/national solutions
 - RAPID starter packs
 - Public benefits are county-based but people live multi-county lives (live in greater bay area but get their healthcare in SF): A multijurisdictional approach is needed.
- Ongoing efforts needed re improving HIV testing and retention in care
 - High acceptance of immediate ART, but keeping people on ART is more sensitive to social determinants of health: housing, mental illness, substance use
 - Rapid Restart emerging as an important issue
- Increase reporting of new HIV diagnoses by HCOs/hospitals directly to LINCS

Perspectives on RAPID ART in San Francisco

Ward 86 RAPID patient:

It's one of the best things to do to put your mind at ease, that it's not as devastating as it could be to be HIV-positive ... It made me feel great that I live in a time that doesn't take weeks or months to get treatment [instead of being] kept in doubt or guessing what are you going to do or ... dealing with the stress of that.

Community health clinic RAPID provider:

We talk all about the benefits to the client but we never talk about how much it makes it easier on the provider. I can't imagine ever disclosing again without being able to offer immediate treatment.

From a RAPID patient:

"You still have to work through the lifestyle adjustments: you have to disclose, stay healthy, but they are things you have to do as a responsible person, to make sure that no one else gets it. But the agony and depression of uncertainty about how you are going to be treated, is it (the medication) going to work or not, how do you organize yourself to take so many pills, it's going to be a ball and chain.... I looked at the two pills in my hand and said: ok, just two. And then you feel like you aren't sick. Taking the medication didn't make me feel like I was terminally ill. I was prepared for a lot worse, and it was very simple."