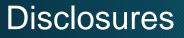




Optimizing STI Control with Clinical Services

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Last Updated: September 29, 2018

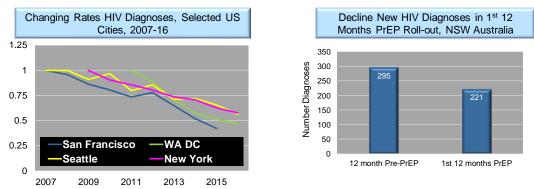


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Overview

- Contemporary epidemiology of HIV/STI – What are we up against?
- Specialized HIV/STI clinical care
- HIV/STI care in primary care
- Healthcare system change and caring for the needs of the most vulnerable patients

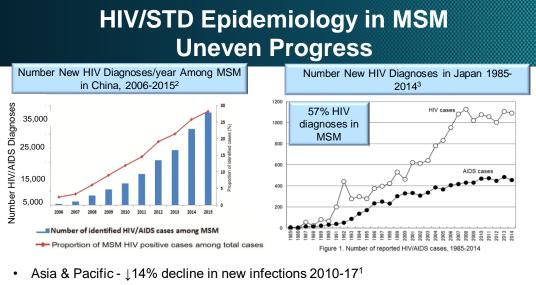




Declining rates of HIV infection in some areas

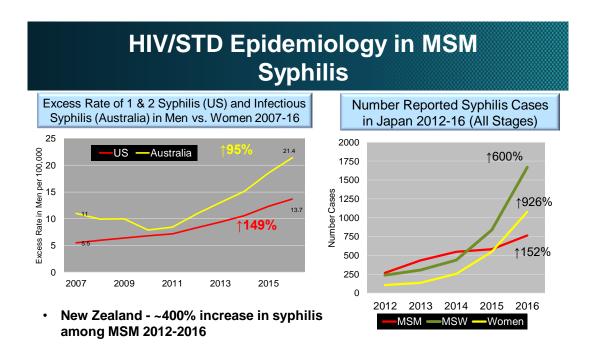
- ↓~40-50% over ~10 years in cities like San Francisco, Seattle, NYC,
- ↓25% NSW in first year following PrEP roll-out

Sources: 1 Grulich A. Lancet HIV 2018.



- 27% decline new HIV infections in India 2010-17
- Rising rate of new infections in Philippines, Pakistan and New Zealand
- Estimated annual incidence HIV among MSM in China and Thailand 4-7%^{3,4}

Sources: 1WHO HIV & AIDS in Asia and Pacific; 2Qun Q. CID 2017; Report to UNAIDS-HIV/AIDS Trends in Japan, 2016; 4van Griensven. Lancet HIV 2015.



Sources: ¹ UNSW Annual Surveillance Report 2017; ²Takahashi T. Sex Transm Dis 2018

STI Epidemiology Among Heterosexuals

High income nations

- Rising rates of gonorrhea & syphilis in many high income nations¹
- · Stable or slightly increasing rates of chlamydial infection
- Antimicrobial resistant gonorrhea
- · Persistent and profound racial and ethnic disparities
 - Australia aboriginal population
 - · New Zealand Maori, Pacific persons and MELAA
 - US African Americans, Latinos

LMIC

- · Trends often ill-defined and likely variable
 - · Rising rate of syphilis in China
- Syphilis seropositivity high in ANC some areas (e.g. Indonesia, Papua New Guinea)

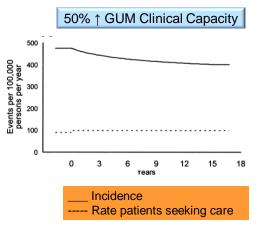
Sources: ¹CDC STD Surveillance Report 2017, UNSW Annual Surveillance Report 2017; ² Zhu B. Sustainability 2017

Role of Clinical Services



Principles in Using Clinical Services to Control HIV/STI

- Deterministic mathematical model of gonorrhea transmission in heterosexuals
- Varies GUM clinical capacity
 - Assumes that 5% of patients who want care abandon efforts to get it for every extra day of waiting
- Model suggests that expanding access to care creates a virtuous cycle of decreasing incidence and declining demand for services

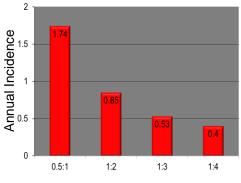


Source: White P. JID 2005

Core HIV/STI Control Interventions

- Treating symptomatic STIs
 - Critical first step
- Treating sex partners
- STI screening and rescreening
 - Higher risk persons every 3
 months
 - MSM all exposed anatomical sites
- Condoms
- PrEP/PEP HIV, ? STIs

Impact of HIV Testing Frequency on HIV Incidence



Number HIV Tests per year (Low and high sexual activity MSM)

5

Source: Cassels S. AIDS 2009

Fundamental Principle in Organizing Clinical Services to Control HIV/STI

- Success combating generalized epidemics (e.g. chlamydia, HPV) depends on intervention at the health system level
- Success combating concentrated epidemics (e.g. HIV, syphilis) requires an additional, dedicated and specialized infrastructure

Specialized Infrastructure



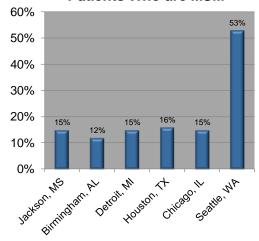
Rationale for Specialized STI Clinics

- Concentrate on priority STIs
 - HIV and syphilis
 - Rapid access to care
- Concentrate on vulnerable, highly affected populations
 - MSM, Transgender persons, Persons who exchange sex
 - Particularly critical in areas where stigma is greatest and where authoritarian governments pose a risk to individual liberties
- Specialized expertise
- Safety net clinics places without universal access to care

Features of Successful STD Clinics #1 Population Served

- Alignment of patient population served with public health priorities
- Dilemma:
 - Public health focus HIV, syphilis, MSM
 - Safety net provider Symptomatic people without adequate access to care – many do not have priority STIs
- Misalignment is common, particularly if the rest of the healthcare system has inadequate capacity
- Examples:
 - U.S. large number of women with vaginitis





Features of Successful STD Clinics #2 Focus on Patient Care Experience & Efficiency

- Simultaneously improves patient care experience AND improves efficiency (capacity)
 - Express visits
 - Online appointments block scheduling NOT instead of walk-in care
 - Rapid test results
 - No interaction with clinicians for patients who only need testing
- Increased HIV testing accomplished through the Dean St. credited with ~50% decline in new HIV diagnoses in Central London 2015-2017 (Lancet HIV 2017)



https://www.youtube.com/watch?v=JtCZG5ttD9k

Features of Successful STD Clinics #3 Promotion of Follow-up Care: Randomized Trials

Study	-	ents, Ev	ents,	%	
ID	OR 95% CI	latment Co	ntrol	Weight	Median Retested
Home Testing +/- phone	e				
Sparks		7/60 20	/62	9.90	(range)
Xu (STI clinic)	1.54 (1.11, 2.15) 10	09/408 77	/403	22.75	(C)
Xu (Family Planning clinic)	2.65 (1.70, 4.11) 80	0/196 43	/208	18.17	
Gotz+	2.78 (1.55, 4.99) 50	0/109 25	/107	13.40	
Cook -+	2.83 (1.78, 4.50) 16	61/197 11	7/191	17.28	
Subtotal (I-squared = 43.8%, p = 0.130)	2.2 (1.65-2.94) 42	27/970 28	2/971	81.50	45% (27-82)
Phone reminders					1070 (21 02)
Malotte (phone call)	14.00 (1.63, 120.09) 9/2	27 1/2	19	1.57	
Malotte (counselling +phone call)	2.50 (1.30, 4.80) 33	3/136 16	/141	11.70	
Subtotal (I-squared = 56.5%, p = 0.129)	4.3 (0.89-21.23) 42	2/163 17	/170	13.27	26% (11-33)
SMS reminders					20% (11-33)
Downing (SMS only)	5.87 (1.16, 29.83) 9/	32 2/3	12	2.65	
Downing (SMS +financial incentive)	5.45 (1.05, 28.24) 87	30 2/3	12	2.59	
Subtotal (I-squared = 0.0%, p = 0.950)	5.6 (1.78-17.99) 17	7/62 4/6	54	5.24	26% (26-27)
·					2070 (20-27)
Overall (I-squared = 37.5%, p = 0.119)	2.42 (1.84-3.19) 4	86/1195 30	3/1205	100.00	
NOTE: Weights are from random effects analysis				_	
.00833 1	120				

Source: Desai M. Sex Transm Infect 2015;91:314-323

Features of Successful STD Clinics

#3 Promotion of Follow-up Care: RCT SMS + Mailed Test Kits

- Randomized trial of STD clinic patients in Sydney, Australia
 - combination of SMS and mailed test kits
- **Dutch programmatic** evaluation of SMS/home testing
 - Only 22% of patients with CT tested

Percentage of Persons Retested and Diagnosed with 2nd Chlamydial Infection

	SMS Alone	SMS + Mailed Test Kit
Retesting		
All Participants (n=600)	39%	61%
Women	39%	64%
MSW	34%	56%
MSM	44%	62%
Diagnosis Repeat Infection	4%	10.3%

All outcomes statistically significant

Source:

Source: Smith KS, Am J Prev Med 2015: Dukers-Muijers NH, PLoS One 2015

Features of Successful STD Clinics #3 Promotion of Follow-up Care: MSM

Total Tests Facility-Based Tests Population Ν Home Facility Author (year) Facility **Home Testing** Testing **Testing Only Testing only** Arm (Control) Arm (Control) Jamil (2017) Sydney 362 1.9 4 1.9 1.7 Katz (2018) Seattle 230 3.6 5.3 3.6 1.4 Sullivan US - Internet 515 5.5 1.5 1.5 0.9

Randomized Trials of Home HIV Testing Among MSM

* Mean number tests, Difference between arms for total tests significant for all trials. Difference in number of facility-based tests statistically different in Katz and Sullivan studies only.

Home testing increases HIV testing frequency in MSM

In some studies, it decreases facility-based testing

Recruitment

(2018)

Oral fluid OraSure rapid test 75% sensitive in MSM STD clinic patients (Stekler J. J Clin Virol 2016)

Source: Jamil MS Lancet HIV 2017; Katz D. JAIDS 2018; Sullivan 2018 STD Conference

Retesting & Reminders: Where Do We Stand?

- Promoting retesting is the right thing to do!
 - Arranging SMS reminders is good if you can do it
 - · Alternative: Ask patient to put a reminder in their phone
- Heterosexuals with gonorrhea & chlamydia SMS & home testing seems best
- MSM
 - Home testing has a place in some populations
 - Main issue is sensitivity of home HIV tests and the absence of a good syphilis test
 - · Highlights need for better tests
 - Dried blood spots already doable for HIV
 - Finger stick microtube
 - New technologies

Features of Successful STD Clinics #4 Integrating New Interventions: PrEP

- Many US STD clinics are prescribing PrEP
- 962 patients initiated PrEP in PHSKC STD clinic since 2015 with 550 receiving ongoing PrEP
- Models vary widely
 - Seattle Manages patients in the clinic
 - San Francisco Tries to refer patients to primary care (14% do so)
 - NYC starts PrEP and refers patients to primary care to continue

STD Clinic Site	Number	Follow-up	Never Initiated PrEP or Discontinued
Seattle, WA* 2015-18	962	12 months	43%
San Francisco 9/14- 12/17*	1297	6 months	55%
New York City 2016-18**	2134	1-3 months	55%
Durham, NC	196	6 months	65%

 * 23% in San Francisco never start or stop after the initial visit; 34% in Seattle never started or stopped within 3 months

**NYC data – percent without documentation of link to a PrEP provider other than the STD clinic

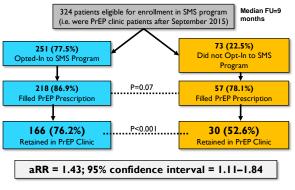
Sources: Dombrowski J STD 2018; Cohen S. 2018 STD Prevention Conference; Sena A, Holland D., Schillinger J (personal communication).

Features of Successful STD Clinics Integrating New Interventions: PrEP

- Limited involvement of clinicians – 1 visit/year
- Health educator arranges STI testing q3 months
- WELTEL 2-way texts used for adherence support & to arrange FU



Impact of Automated SMS Reminders on PrEP Retention



Source: Khosropour C. CROI 2016

PrEP in STC Clincs: Where Do We Stand?

- Providing PrEP in STD clinics is feasible and affects a high risk population
- Referring patients to receive PrEP through primary care is associated with high discontinuation rate in the U.S.
 - · Patients don't want to be referred out
 - Attrition is high in all circumstances
- Providing PrEP in STD clinics is a strain on the system
- Need to de-medicalize PrEP
 - PrEP is a very simple intervention
 - A health educator can manage PrEP with one-time per year medical follow-up
- · Models to improve retention are urgently needed

Care Through Primary Care

Improving STI care in Primary Care Settings

- Success combating generalized epidemics (e.g. chlamydia, HPV) depends on intervention at the health system level

Priority areas of STI care:

- HPV immunization
- HIV testing
- Chlamydia and gonorrhea screening and rescreening partner treatment (expedited partner therapy)
- Syphilis screening of pregnant women

Improving STI care in Primary Care Settings

- · Care is widely dispersed
 - Very difficult to change provider behavior on a large enough scale to make a difference
- · In some places, care is highly fragmented
 - U.S. Not one healthcare system each state is somewhat different – half the country has near universal health care and half does not

Increasing Chlamydial Screening in Clinical Settings: Randomized Trials

Author (year)	Intervention	Control	Intervention	
Walker (2010)	0) Prompt 10.6%*		12.2%	
Scholes (2006)		40.8%	42.6%	
Bilard (2010)	Incentives	8.8%	13.4%	
Morgan (2009)		13.2%*	16.8%	
Bowden (2008)	CT testing with PAPs	4.5%*	6.9%	
Verhoeven (2005)	Provider Education	67%	86%	
Allison (2005)		12.4%*	15.5%	
Schafer (2002)	Quality Improvement	15.6%*	43.8%	
Tebb (2005)		15.1%*	44.9%	
Scholes (2006)		40%	42%	
Hockings (2018)		17%*	24%	

Source: Modified from Guy R. BMC Infec Dis 2011

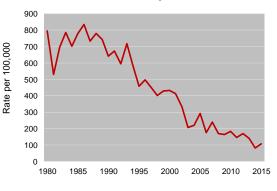
Why Are So Many Patients Tested if The Trial Results Are So Bad?

United States • ~14 million age 15-24	sexually active \bigcirc	Author	Population	Design	Proportion Women Tested	Limitations
 >33 million 	CT tests sold	Tao 2012	U.S. National	Self- Report	37.9%	Uncertain Validity
annually in	CDC 2009	U.S.	HEDIS	42%	Excludes	
largest co Coverage <u>Australia</u> Screening	Health system change often proceeds through gradual processes that are not					vomen who receive no are or out of plan care
	very amenable to study via RCT					Based on revalence &
				Estimation		# Reported Cases
		Golden	US 2017 ♀ age 15-24	Indirect Estimation	56%	Assumes 10% positivity
		Kirby Institute	Australia Women Age 15-29 2016	Medicare Rebated Tests	20% (30%)	Assumes All Young ♀ are Sexually Active

Success of STI Control Efforts In Primary Care

- Although uncertain, much of our effort to control STIs in primary care has probably worked
- Disconnect between CT diagnosis and positivity and morbidity trends
 - Morbidity data is limited
 - GC and CT effects hard to disentangle
 - The goal was never a sterile cervix
- Huge success with HPV immunization
 - Australia near elimination of vaccine covered HPV, including in indigenous population (Garland SM. Vaccine 2018; McGregor S Vaccine 2018)
 - U.S. 71% reduction in vaccine covered HPV among 14-17 year old girls 2003-2014 (Oliver SE. JID 2017)

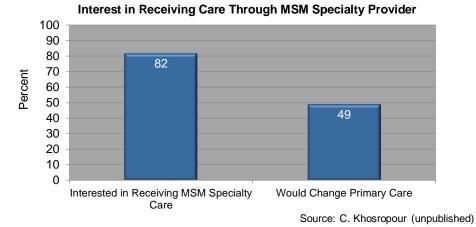
Rate of PID Among Women Age 14-44 in the U.S., 1980-2015



Source: CDC STD Surveillance Report 2016

Community Infrastructure LGBTQ Health

- 2014-15 Internet survey of 1413 MSM recruitment via Facebook
- Florida, Mississippi, North Carolina, Tennessee, WA State, Chicago, Philadelphia



Washington State BREE Collaborative

- Washington State initiative to improve medical care for LGBTQ patients
- 2018 Draft guidelines to improve the healthcare of LGBTQ persons
 - Standard questions about sexual behavior, orientation & gender identity – recorded in electronic medical record
 - Give patients greater access to medical providers interested in LGBTQ health
 - Develop practices to improve care
 - Implementation of PrEP & MSM/Trans STD Screening Guidelines
 - Monitoring standards
- 2019- Beginning work to promote change in major health care organizations statewide



BREE

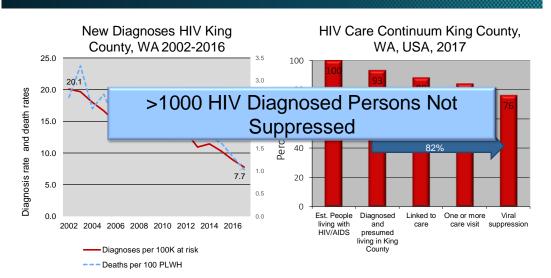
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Caring for the Most Vulnerable Patients



HIV Care Continuum and Trends in King County, WA



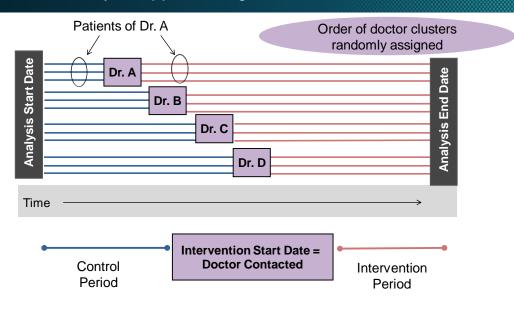
Data to Care (D2C)

- If our problem is that people are out of care, the solution is to find them and link them to care
- · HIV is reportable
 - Labs report all HIV RNA and CD4 results
 - We should know who is out of care
- D2C Use of surveillance data to promote increased engagement in care

CDC Centers for Disease Control and Prevention CDC 24/7 Saving Lives. Protecting Respis.**

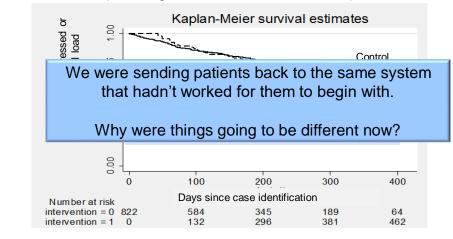


Implementation of Data to Care Program in Seattle-King County: Stepped Wedge Cluster Randomization



Principal Finding of Stepped Wedge Cluster Randomized Trial

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



Dombrowski J. Sex Transm Dis 2018

The MAX Clinic: HIV Care for the Hardest-to-Reach Patients

Components of the MAX Clinic (Evolved Substantially Over 2 Years)					
Low-Threshold Care	Incentives	High Intensity Outreach Support	Coordinated Care & Case Management		
Walk-in access to - medical care 5 afternoons/wk	Snacks each visit, \$10 meal vouchers 1x/wk	Non-medical case managers (Public Health)	Collaboration between university HIV clinic and public health STD Clinic		
- case managers 5 days/wk Direct phone line to MAX case managers (no phone tree)	Bus pass \$25 - visit + blood draw q 2 months \$50 - VL<200 q 2 months	Medical case managers (Madison)	Day Program with		
		managers (madison)	adherence support		
			Housing case managers & supportive housing facilities		
Text message communication	monuis		Jail release planners		
Harm reduction approach			Office-Based Opioid Treatment Team		

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%)
Documented history of incarceration	55 (58%)

MAX Clinic: Controlled Analysis

Viral suppression among the first 50 MAX patients and the Standard-of-Care Clinic (N=100) in the 12 months post-compared to 12 months pre-baseline

	MAX pre	MAX post	Control pre	Control post
Viral suppression, N%	10 (20)	41 (82)	51 (51)	65 (65)
Within group pre-post comparison, RR (95% CI)*	4.1 (2.3 – 7.2)		1.3 (1.0 – 1.6)	
Between group pre-post comparison, RR (95% CI)*	3.2 (1.8 – 5.9)			

*Generalized estimating equations controlling for housing status, substance use, and psychiatric diagnoses

Clinic now has 140 patients – 65% viral suppression

• Dombrowski J (unpublished)

Conclusions

- Clinical care is key to the control of HIV/STI
- A good system involves both specialized STD clinics and the broader healthcare system
 - · Two components play complementary roles
 - · In some instances, primary care should embrace specialization
 - Developing specialized infrastructure for marginalized populations is particularly important in places with stigma is greatest and where authoritarian governments pose a risk to individual liberty
- Efficiency plays a key role in improving access to care and the patient care experience, driving up screening rates
 - Contemporary communication technology
- · Better serving our most vulnerable patients require changes in the healthcare

We need to spend less time trying to change our patients to fit into our healthcare system, and more time changing our healthcare system to fit our patients

Acknowledgements

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PHSKC DIS & STD Clinic Clinicians

Thank You