



Public Health
England



The PROUD study


Creating desire for PrEP in the UK

Creating Desire for Microbicides 13-14May2014

Overview

- Context
 - Health care providers
 - Commissioners
- PROUD pilot study design
- Baseline results
 - Who is enrolling?
 - Sexual risk
- Public and Participant Involvement

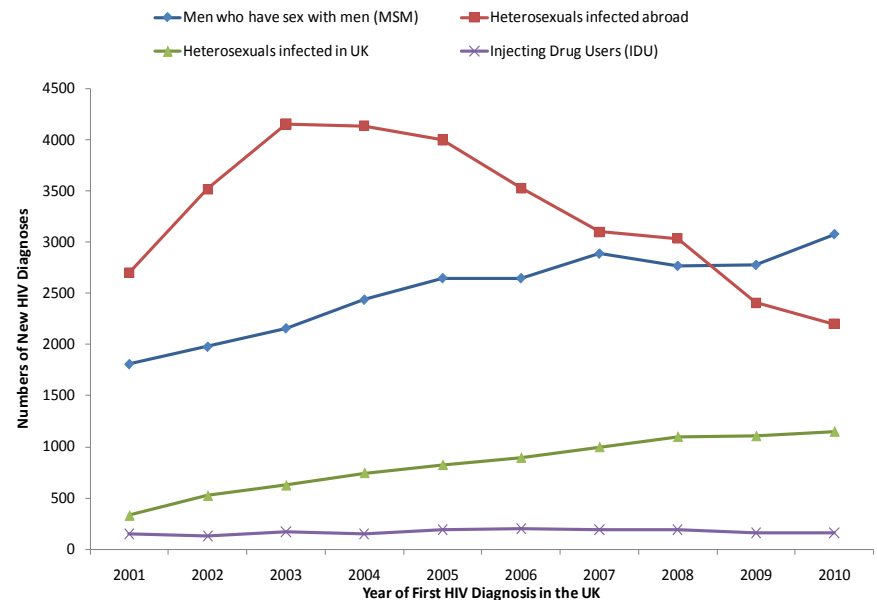
The UK clinic/public health network

- ~ 250 sexual health clinics reporting to 2 public health agencies
 - 27 participating in enhanced surveillance
- Walk-in service for HIV and STI screening
- HIV outpatients (not all; but all prescribe PEP)
- ~320 local authorities commission sexual health; National commissioning for HIV
- Standards set by two professional organisations
 - British HIV Association 
 - British Association for Sexual Health and HIV



The UK epidemic

- gradual increase in HIV in MSM since 2000
 - ~85% diagnosed in sexual health clinics
 - ~80% acquired in UK
- Fall in heterosexual HIV BUT rise in numbers acquired in UK



Preparing the ground

- iPrEx reports November 2010
- BASHH/BHIVA request Position Statement to enable HCW to discuss PrEP
- PrEP eGroup launched April 2011
- Proven biological efficacy of PrEP, but 'real world' effectiveness unknown

The British HIV Association/British Association for Sexual Health and HIV Position Statement on pre-exposure prophylaxis in the UK

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- PROUD designed to assess this
 - integrated into existing risk reduction package
 - must not undermine condoms

PROUD Pilot Study

PRe-exposure **O**ption for reducing
HIV in the **U**K: an open-label
randomisation to immediate or
Deferred daily Truvada for HIV
negative gay men

PROUD Pilot

Born male, reporting past, and intended, C₀AI
Willing to take a pill now or in 12M

Randomize 500 HIV negative eligible individuals
(exclude if on treatment for hepB)

Risk reduction includes
Truvada **NOW**

Risk reduction includes
Truvada **in 12M**

Follow **3 monthly** for up to 24 months

Main endpoints: **recruitment and retention**

Progress

- January 2012: funding for PROUD rejected
- March 2012: Public Health England/MRC Clinical Trials Unit/Gilead support Pilot
- BASHH/ASTDA debate, June 2012: supports limiting PrEP access to clinical research setting
- FDA approve Truvada as PrEP July 2012



Progress

- August 2012: Researchers meet with Commissioners
- August 2012: ethics review PROUD
- September-November 2013: HCW knowledge, attitudes and practices survey



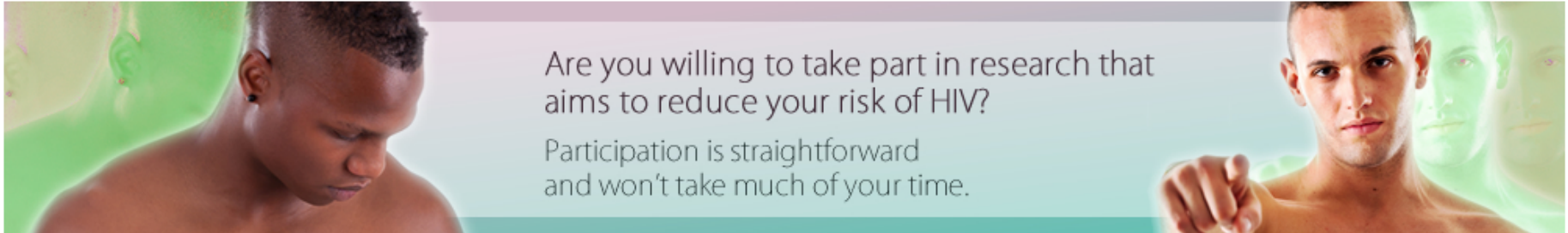
Examining the impact on gay men of using Pre-Exposure Prophylaxis (PrEP)



Friday, 20 September 2013

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Volunteers

Why take part?

The study will give us more information about how PrEP could be used to prevent new HIV infections amongst gay men.

By taking part, you could reduce your own risk of catching HIV.

Our team will help and support you to be healthy.

You can take part in the study if you:

- Are HIV negative
- Are 18 or older
- Have had anal sex without a condom in the last three months.
- Are likely to do this again in the next three months.
- Can visit the clinic for blood tests every three months.
- Are likely to do this again in the next three months.

Who is enrolling?

Data based on 494 enrolled, 443 baseline CRFs

Key demographics at baseline

		Number (N=439- 443)	Percentage (%)
Age	Median	35.5	IQR: 29.4- 42.3
Ethnicity	White	349	80%
	Black	14	4%
	S Asian	27	6%
	Other	48	10%
Maximum education	University degree or above	258	59%
	A-levels/equivalent	73	17%
	No qualifications	11	3%
	Other	97	23%
Enrolled as partners		17 (+1 triplet)	

Sexual risk at baseline

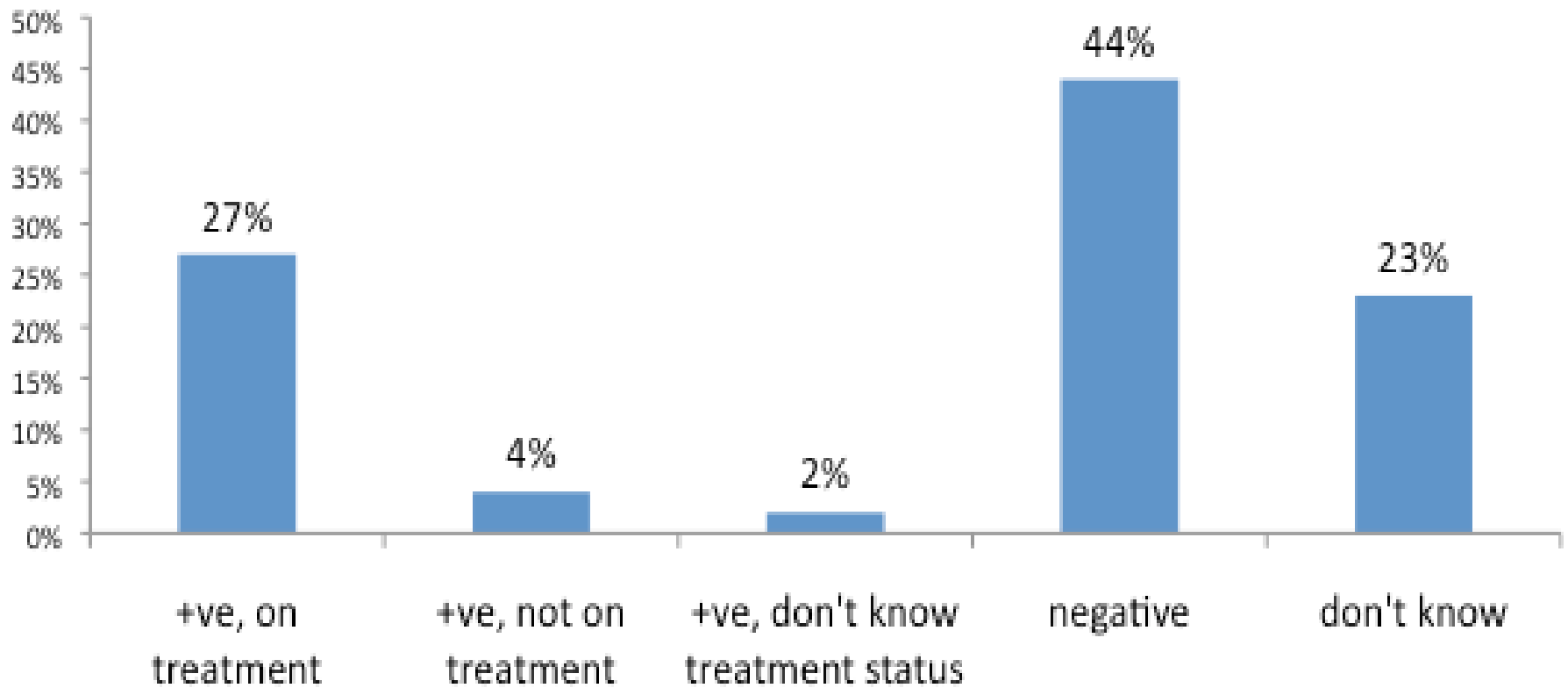
	Median	IQR
Sexual partners		
Total	10	4-20
Condomless receptive anal sex	2	1-5
Condomless insertive anal sex	3	1-6
	Number (N=440)	Percentage (%)
Partnerships		
In ongoing partnership	206	47%
Living with partner	138	31%

Reasons for no condoms

	Frequency of responses (N=1362)	Percentage of cases (%)
Reasons for no condom		
It's much more enjoyable without a condom	289	66%
I don't like using condoms	222	51%
He doesn't like using condoms	143	33%
Condoms weren't discussed	116	27%
Under the influence of drugs	102	23%
I don't consider myself at risk of HIV	98	22%
Under the influence of alcohol	94	22%
I was only dipping	81	19%
We don't use condoms with each other, but do with other partners	74	17%
Other less frequent reasons	143	33%

Partner serostatus at last anal sex

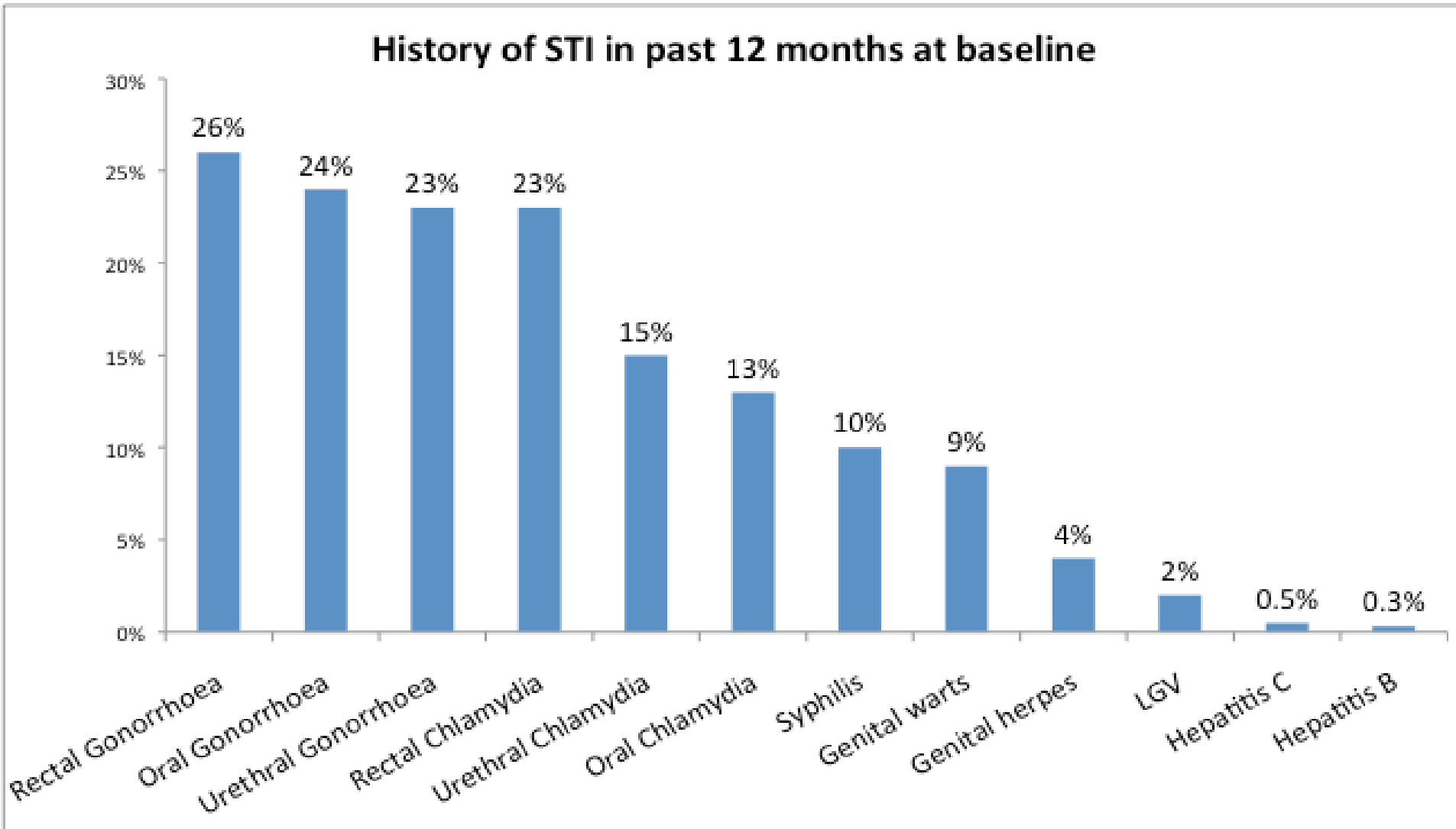
Partner serostatus at last anal sex



PEP use

	Number (N=420)	Percentage (%)
PEP use		
At least once in past 12 months	177	40%
>once in past 12 months	87	21%

Sexually transmitted infections



Comparison data: 1. Public Health England: STI data tables for England 2012; 2. Centers for Disease Control 2010 STDs in Men who have sex with men <http://www.cdc.gov/std/stats10/msm.htm>

Recreational drug use

- 322/434 (74%) report use of recreational drugs in past 12 months

Drug	Frequency of reports (N=957)	Percentage of cases
Poppers (amyl nitrate)	213	67%
Viagra	182	57%
Mephadrone	158	49%
GHB (liquid ecstasy)	136	43%
Cannabis	102	32%
Cocaine (coke)	113	35%
Ecstasy	84	26%
Crystal meth (methamphetamine)	78	24%

Public Involvement

- Community Engagement Group
 - To oversee launch
 - Designed promotional material and spread the word about PROUD
- Expanded meeting to address slow recruitment June 2013
 - Highlighted lack of awareness
 - Joint Community Statement supporting PrEP
 - Articles to raise awareness and promote PROUD
 - Bannered on internet dating sites

56 Dean Street — Chelsea and Westminster Hospital

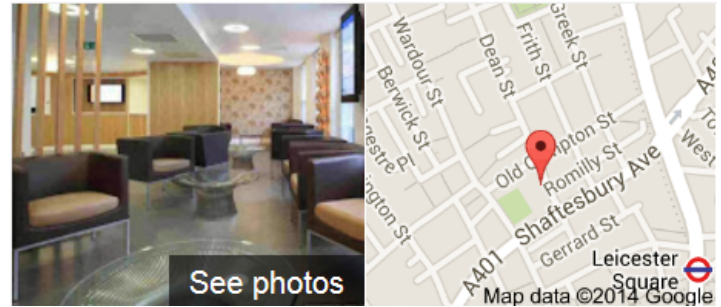
www.chelwest.nhs.uk/services/hiv-sexual.../56-dean-street/56-dean-street ▾

Your friendly convenient central London sexual health and HIV clinic based in Soho.

56 Dean Street offers convenient appointments for STD (STI) tests.

5.0 ★★★★★ 14 Google reviews · [Write a review](#) · [Google+ page](#)

📍 35 Dean St, London W1D 6AQ
020 3315 6699



See photos

Your visit to Dean Street Express



Chelsea and Westminster Hospital **NHS**
NHS Foundation Trust

Participant Involvement

- November 2013
 - Supported need for real-life effectiveness and proceeding to full scale trial
 - Did not like 'stereotypical images'
- March 2014
 - Endorsed daily dosing, and Truvada
 - Convenient, known efficacy, known safety
 - Willing to consider half a pill a day
 - Minority willing to test long acting injectables and rectal microbicides
 - All against placebo-controlled
 - Accept deferred option, but preference Truvada control

Summary

- Creating desire takes time – time to spread the knowledge
- Science has delivered new technology with terrible economic timing, and room for mixed messages
- Lucky in UK to have established and joined-up clinic and community network
- Gathering evidence – quantitative and qualitative – is the only way to counteract concerns and prejudice, and ensure the key messages are understood
- Dissemination of the evidence will need to be broad, deep and loud, and above all consistent

Acknowledgements (1)



Study participants

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Acknowledgements (2)



Trial Steering Committee

Independent members: Mike Adler (Co-Chair), Gus Cairns (Co-Chair), Dan Clutterbuck, Rob Cookson, Claire Foreman, Stephen Nicholson, Tariq Sadiq, Matthew Williams

Investigator members: Brian Gazzard, Noel Gill, Anne Johnson, Sheena McCormack, Andrew Phillips

Community Engagement Group

Alan McOwan (Lead), Yusef Azad (NAT), Anthony Bains, Gus Cairns (NAM), Rob Cookson (LGF), Tom Doyle (Mesmac), Mitzy Gafos (MRC CTU at UCL), Justin Harbottle (THT), Matthew Hodson (GMFA), Cary James (THT), Ben McClelland (THT), Sheena McCormack (MRC CTU at UCL), Francesa McNeil (PHE), Roger Pebody (NAM), Annabelle South (MRC CTU at UCL)

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Academia: Will Nutland (LSHTM)

Social media: Darren Clapich (Grindr), Simon Johnson (Gaydar)

Press: David Rowlands (Baseline), Robert Fieldhouse (Baseline), Chris O'Connor (Baseline), Patrick Cash (QX)