



Third Joint Conference  
of the  
British HIV Association (BHIVA)  
with the  
British Association for Sexual Health and HIV (BASHH)

**1-4 April 2014**

Arena and Convention Centre · Liverpool

THIRD JOINT CONFERENCE  
OF BHIVA AND BASHH 2014



**Dr Juan Tiraboschi**

Guy's and St Thomas' NHS Foundation Trust, London



Public Health  
England



MRC

Clinical  
Trials  
Unit

# Acute Hepatitis C in the PROUD pilot study

Juan Tiraboschi, Liz Brodnicki, Brady Michael, John  
Saunders, Schembri Gabriel, Mark Roche, Julie Fox on  
behalf of the **PROUD study**

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# PROUD Pilot Study

**PR**e-exposure **O**ption for reducing  
**HIV** in the **UK**: an open-label  
randomisation to immediate or  
**D**eferred daily Truvada for **HIV**  
negative gay men

# Background

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- Pre-exposure prophylaxis (PrEP) has proven biological efficacy to reduce the sexual acquisition of HIV<sup>1</sup>, but public health benefit is uncertain.
- Concerns about the effect of PrEP usage on risk behavior and acquisition of other STIs
- Excluding intravenous transmission, Hepatitis C (HCV) is almost exclusively found in HIV positive MSM. HCV testing is not routine in HIV negative MSM, so it is not included in the PROUD study

1. Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* 2010;363:2587-99. .

Interim guidance for clinicians considering the use of preexposure prophylaxis for the prevention of HIV infection in heterosexually active adults. [MMWR Morb Mortal Wkly Rep.](#) 2012;61:586-9

# Methods

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- ***Past history of STIs*** is collected at enrolment
- ***STI screens*** are conducted at six monthly intervals, but results from additional routine screens are collected at each visit (three monthly)
- HCV antibody and raised ALT were ***not exclusion criteria in PROUD***
- Acute HCV ***defined as:***
  - HCV RNA positive and anti HCV negative (with follow up)
  - HCV Ab/RNA positive with previous negative in 6 months

# Results

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- 393 participants enrolled by 31/12/2013
- 160 (41%) individuals had been tested on one or more occasion for HCV.
- HCV incidence in our cohort was 5/393:1.3%, and amongst those tested 5/160:3.1%.

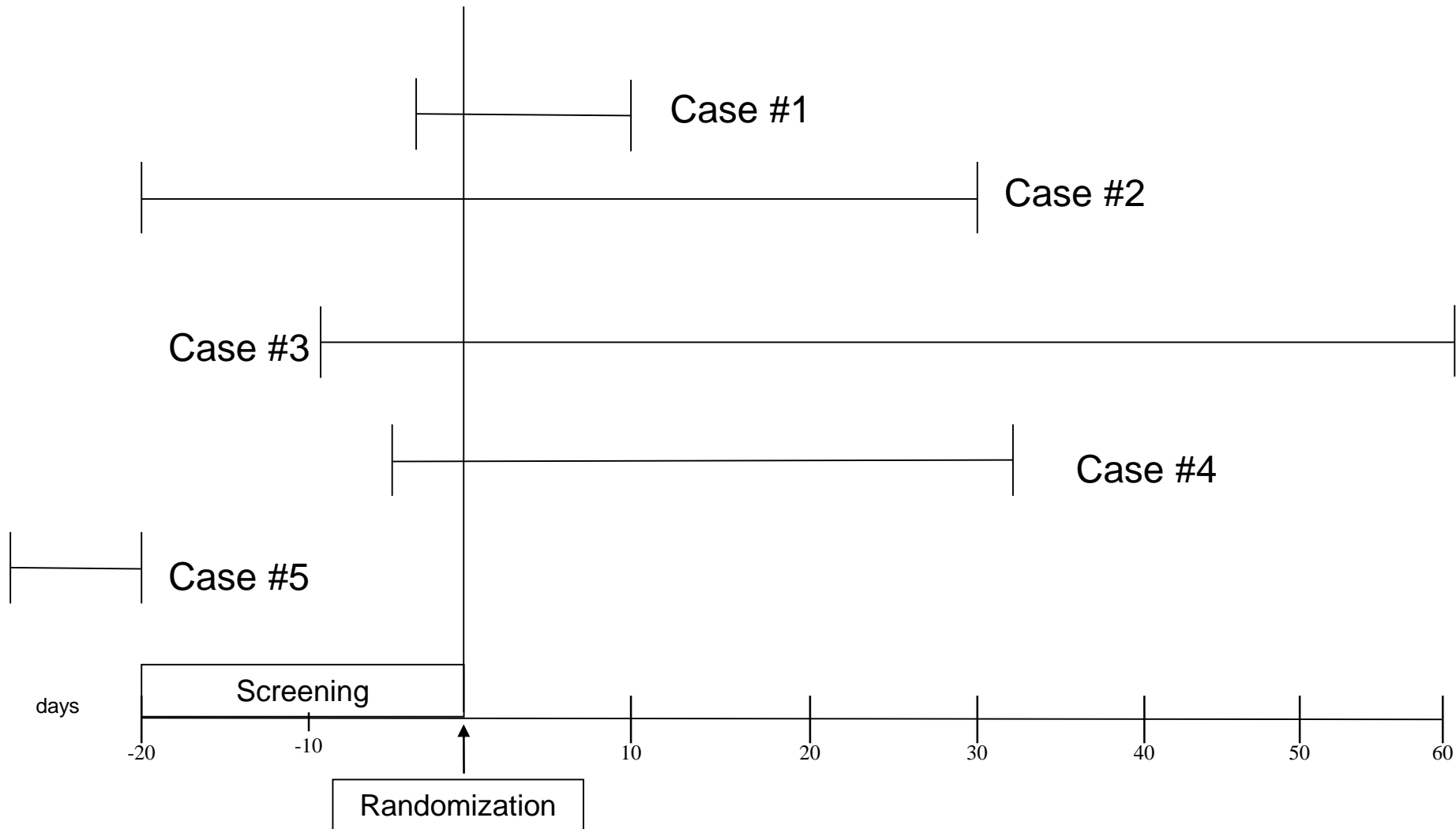
# Case characteristics

Site	Randomization ARM	Age	Time from enrollement to HCV diagnosis (Days)	HCV RNA Baseline	Indication for HCV Testing	Symptoms/ ALT	STI since enrollement
Brighton	Immediate	29	7	25897630	Risk Behaviour	NO	No
Barts	Immediate	39	28	11902147	Partner HCV (+)	NO	No
Manchester	Deferred	24	64	1684020	Symptoms	Jaundice/ Raised ALT	Yes
STH	Immediate	38	29	9003	Partner HCV (+)	NO	No
KLC	Deferred	64	-28	1,641,554	IDU	NO	Yes



# Time since last HCV negative to HCV diagnosis

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# Conclusions

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- There was an unexpected number of aHCV cases.
- HIV prevention studies should consider including HCV testing at baseline and follow-up as part of testing for other STIs.
- Undiagnosed acute HCV infection in MSM reporting high risk sex is a public health concern.
- Routine testing of HCV and ALT in the list of routine STIs should be considered for this group.

# Acknowledgements (1)

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## Study participants

### MRC CTU at UCL

David Dolling, David Dunn, Mitzy Gafos, Gemma Wood, Liz Brodnicki, Yolanda Collaco-Moraes, Sarah Banbury, Brendan Mauger, Yinka Sowunmi, Christina Chung, Monica Desai, Sheena McCormack

### HIV & STI Dept, PHE

Anthony Nardone, Noel Gill, Sarika Desai, Monica Desai, GUMCAD team, HIV team

### Clinics

Vanessa Apea (Barts Health NHS Trust), Nicola Mackie (St Mary's Hospital), Alan McOwan (56 Dean Street), Amanda Clarke (Claude Nichol Centre), Christine Bowman (Sheffield Teaching Hospitals NHS Foundation Trust), Charles Lacey (York Hospitals NHS Foundation Trust), Gabriel Schembri (Manchester Centre for Sexual Health), Richard Gilson (The Mortimer Market Centre), Ann Sullivan (John Hunter Clinic for Sexual Health), Iain Reeves (Homerton University Hospital NHS Foundation Trust), Michael Brady (Kings College Hospital NHS Foundation Trust), Julie Fox (Guy's and St Thomas's NHS Foundation Trust), Steve Taylor (Heart of England NHS Foundation Trust), Saye Khoo (University of Liverpool)

# Acknowledgements (2)



## Trial Steering Committee

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

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

## Community Engagement Group

**Clinics:** Alan McOwan (56 Dean St), Mark Roche (Brighton)

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

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

**Community:** Ben McClelland (THT), Matthew Hodson (GMFA), Cary James (THT), Tom Doyle (Mesmac), Yusef Azad (NAT), Justin Harbottle (THT), Roger Pebody (NAM)

**Academia:** Will Nutland (LSHTM)

**MRC CTU at UCL:** Sheena McCormack, Mitzy Gafos, Monica Desai, Annabelle South

**PHE:** Francesca McNeil

## Gilead

Jim Rooney, Rich Clarke, Matt Bosse, Murad Ruf



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