

Responses to the PROUD study results

From study participants:

Greg Mitchell, PROUD participant and writer, said: "This is the good news. PrEP allows us to take control of our own sexual health. It can eliminate the difference between positive and negative and we can become a community that is no longer split by our HIV status".

"PrEP is about taking responsibility for our own health, and those with whom we have sex. That's why we need PrEP – and we need it now!"

A longer speech by Greg about his views of PrEP is available at: <http://www.docdroid.net/q0kq/eatq-conference-speech.pdf.html>

Charlie Witzel, PROUD participant and research assistant said: "For me, PrEP has had a major and positive impact on both my anxiety levels around contracting HIV and my overall well-being. As a participant I'm thrilled to see that we have even more data showing how effective PrEP is when people know they are receiving it."

Stefan Laros, PROUD study participant and management consultant, said: "I am immensely pleased and overwhelmed - a little emotional even - as for the first time in 30 years I feel there is hope for people like me, who struggle with consistent condom use, but who want to protect themselves - and just as importantly - their sex partners against HIV infection."

Paul, PROUD study participant and lawyer, said: "PrEP has helped me relax around sex. After years of being used to sex leading to worry and regret, and wondering if every sore throat was the start of a seroconversion I now feel more in control. By participating in the study I also feel like I'm contributing something towards what could be one part of a wider strategy to really turn the tide of rising HIV infections. My optimism is tinged with some caution, but overall it seems like a real cause for hope."

Richard Rawlings, PROUD study participant and 26 year old health care advisor in HIV services, said: "PrEP has proven a controversial, though effective, way to prevent HIV. It would be easy to get lost in debates surrounding its controversy and the behaviours to which it relates. As an NHS sexual health and HIV worker and a PROUD study participant, I've been fortunate to follow the study in relation to my clinical and personal life. In my own opinion, the single most important thing PROUD has done is to increase discussion about HIV and sexual health. I've been catapulted into reflecting on, and discussing with others, both my own feelings surrounding HIV and where we are in facing the epidemic as a broader community. Whatever your standpoint on PrEP, I'm convinced that the open discussion and debate it's started around HIV can only be a good thing: In the UK, those who still get ill and die from AIDS do so because of silence and stigma, not lack of treatment options".

From researchers:

Sheena McCormack, Professor of Clinical Epidemiology at the MRC Clinical Trials Unit at UCL, and Chief Investigator of the PROUD study, said: "These results are extremely exciting and show PrEP is highly effective at preventing HIV infection in the real world. Concerns that PrEP would not work so

well in the real world were unfounded. These results show there is a need for PrEP, and offer hope of reversing the epidemic among men who have sex with men in this country. The findings we've presented today are going to be invaluable in informing discussions about making PrEP available through the NHS."

Professor Noel Gill, Head of HIV & STIs in PHE and PHE Lead for the PROUD study, said: "PHE estimates there are over 2,500 new HIV infections annually in gay men in the UK, a number that has not fallen over the past decade. This cutting edge work will help inform action in this area going forward."

David Dolling, MRC statistician on PROUD, said: "The PROUD study results demonstrate that Truvada PrEP can dramatically reduce the risk of HIV for gay and other men. It offered a significant benefit over existing tools in the HIV prevention toolkit. Our thanks to the MRC and PHE for continuing to fund this research, to the staff running study clinics and most importantly, to all the participants who are taking part."

Mitzy Gafos, Social Scientist on PROUD, said: "The PROUD results highlight the role PrEP can play to reduce the risk of HIV infection. However, sex is not just about risk, it is also about pleasure, intimacy and love. In the one-to-one interviews that we are conducting with study participants, the positive impact that PrEP has on people's sexual and emotional lives is evident. For many PrEP offers a HIV prevention option that men can incorporate into their lives and reduce the fear, anxiety and guilt which surrounds sex for many. PrEP is viewed as a tool to help prevent HIV during periods in people's lives when they may take more risks than at other times in their lives – and this is helping people reimagine their futures without feeling that HIV is *inevitable*".

From advisory committee members

Gus Cairns, Editor at Aidsmap.com and Co-chair of the PROUD Steering Committee, said: "PROUD has made me proud. As someone living with HIV for 30 years this year, I have seen the toll it has taken on the gay community and worldwide. As someone who once was a young gay man vulnerable to HIV, I want every young gay man these days to have protection. As a partner and ex-partner to HIV-negative men, I want relief for them from the anxiety I see them burdened with around sex. I first heard of PrEP at the CROI conference in Seattle in 2002, and it is fitting that this conference has heard data that clinch the position of PrEP as an important prevention resource for anyone at risk. I would also like to pay tribute to the researchers and especially Sheena McCormack for including community members every step of the way in the design, recruitment and monitoring of this trial. This is a major step in HIV prevention and I have been proud to play some part in it."

Mike Adler, Co-chair of the PROUD steering Committee, said: "The results of the PROUD study provide evidence that PrEP could play an important medical and public health role in the control of HIV transmission particularly in high risk individuals"

Justin Harbottle, programme officer with THT and member of the community engagement group, said: "The striking results from the PROUD trial brings important evidence from the UK to help complete the picture internationally; PrEP is an extremely effective tool in preventing HIV which we urgently need now. For those people who are most at risk of HIV infection, and who may struggle with existing methods of protecting themselves from HIV, PrEP is a real game-changer."

While the public health benefits of PrEP remain key, the personal benefits in providing people with a tool which can empower them to protect themselves from HIV, reduce anxiety and subsequently increase their sexual wellbeing, cannot be overstated enough. The task now remains to ensure that PrEP is made available as quickly as possible to those who most need it.

The passion and commitment of Professor McCormack and the PROUD team in realising the potential of PrEP, and proactively supporting the sexual health of men who have sex with men has been exemplary, and the success of this trial is a testament to everyone's hard work and dedication."

From clinicians on the study

Dr Richard Gilson, principal investigator for the PROUD study at the Mortimer Market Centre, a sexual health service run by Central and North West London NHS Foundation Trust, said: "Working at a central London sexual health clinic, it is clear to me that there are gay men attending sexual health clinics in the UK who are at high risk of catching HIV infection but who are willing and able to take tablets regularly, which can dramatically reduce their risk of becoming HIV positive. This will not suit everyone, and may not be needed indefinitely, but for at least some individuals for some of the time it should be considered as an important additional measure, that will help to reduce the persistently high rate of new infections that we are still seeing".

Dr Ann Sullivan, Consultant in Sexual Health Services at Chelsea and Westminster and lead NHS Investigator, said: "This is a very exciting result, demonstrating that if PrEP were made available to at risk individuals we could dramatically reduce the current high level of HIV infections being diagnosed in the UK in this group every year (almost 3000 last year). Within the study taking a tablet daily was combined with a wide range of other risk reduction strategies, including condoms, sexual health screens and behavioural and counselling interventions. Particularly encouraging was that the vast majority of participants took the medication regularly, and there was no evidence that taking the truvada resulted in more risky behaviour as the rates of STIs were the same in both groups. This is the first trial carried out in a 'real world' setting (i.e not a placebo controlled trial) and it offers another very useful tool for effective HIV prevention. "

Dr Michael Brady, Medical Director at Terrence Higgins Trust, said: "PrEP is, quite simply, a game-changer. We know that most gay men use condoms most of the time, and that this has prevented tens of thousands of HIV infections since the epidemic began in the UK. However, we also know that condomless sex vastly increases the risk of HIV being transmitted. This research shows just how effective PrEP can be in preventing transmission of the virus in groups at greatest risk; offering another line of defence alongside condoms and regular testing. It is not a vaccine and it won't be for everyone, but once approved, we expect it to significantly increase the momentum in our fight against the virus. Therefore, we urge the Government, NHS England and Local Authorities to make PrEP a key priority in the fight against HIV."

From the MRC

Dr Des Walsh, Head of Infections and Immunity at the Medical Research Council, said: "HIV remains a major public health concern, and gay, bisexual men and other men who have sex with men (MSM) continue to be the group most affected by HIV infection in the UK. An estimated 43, 500

(40,200-48,200) MSM were living with HIV in the UK in 2013; this is equivalent to 59 per 1,000 MSM aged 15-59 years, or one in 17 (HIV in the United Kingdom: 2014 Report). Over the last decade, an estimated 2,600 MSM acquired HIV infection each year. In 2013, the number of men who had acquired HIV remained high at 2,800.

Clearly, additional approaches are needed to tackle the HIV epidemic, particularly for populations at higher risk. As such, these results have addressed a very important question on the effectiveness of one such approach (PrEP), which appears to be both practical and promising.”