

TRANSFORMING
THE UK'S
RESPONSE
TO HIV



Report: May 2011

HIV treatment as prevention

Report of the NAT expert seminar, Towards a UK Consensus
on the Impact of ART on HIV Prevention Strategies.



Foreword

There is growing evidence that use of antiretroviral treatment (ART) can prevent HIV transmission. That evidence has been surrounded by much debate internationally, but we have not in the UK disentangled the arguments and agreed on the implications.

As this report goes to print we have heard the exciting news of the first randomised clinical trial into the preventive benefits of treatment. The HPTN052 trial of heterosexual couples was concluded early because the results were so conclusive - a 96% reduction in risk of HIV transmission when the HIV positive partner received ART. This latest finding is a further reminder that the UK must be prepared to respond to the possibilities of treatment as prevention.

NAT felt strongly that it was time for those involved in HIV prevention, treatment, care and support in the UK to pause and consider the significance of these findings. What we do know about the impact of ART on infectiousness is already sufficient to revolutionise how we consider HIV prevention.

Responding to this new potential requires us to think about HIV prevention in a different way. The message can no longer be simply about consistent condom use, important though that is, but about helping people choose and use the combination of prevention methods that is right for their individual circumstances. We will have to learn how to better communicate issues of risk, and risk reduction, in order to support people living with and at risk of HIV to make healthy and safer choices.

This report draws on the experience of a range of experts and stakeholders currently involved in HIV research, treatment, prevention, care and support in the UK who attended the NAT expert seminar *Towards a Consensus on the Impact of ART on HIV Prevention Strategies*. It does not contain advice for individuals living with or at risk of HIV on how to use ART for prevention, but it sets an agenda for the development of such advice.

There is more to know about how the use of HIV treatment may prevent new infections, but a UK response cannot wait for definitive answers to every possible question.

In this report we call for the development of a UK consensus on the evidence base as it currently stands, and for agreement on how this knowledge will inform our HIV prevention interventions at individual and population levels.



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Glossary

ART	Antiretroviral treatment – the drug treatment for people living with HIV. Sometimes also referred to as ARVs.
BASHH	British Association for Sexual Health and HIV
BHIVA	British HIV Association
BIS	British Infection Society
CD4 count	A measure of the impact of HIV on the immune system. A low CD4 count indicates that the patient is at risk of opportunistic infections and illness.
CHAPS	The English programme of HIV health promotion for men who have sex with men.
HIV incidence	The rate with which HIV infections occur in a particular population.
HIV prevalence	The number of HIV cases that are present in a particular population at a given time.
HPA	Health Protection Agency
NICE	National Institute for Health and Clinical Excellence
NPTs	New prevention technologies: used to describe in-development prevention tools such as microbicides, vaccines and PrEP.
PEP	Post-exposure prophylaxis: ART given to someone who has been exposed to HIV, to prevent them becoming infected.
PrEP	Pre-exposure prophylaxis: ART given to someone who is at risk of exposure to HIV, prior to the exposure, to prevent them becoming infected.
Sero-discordance	Used to describe sexual partners with different HIV status. Sometimes called 'sero-difference'.
SOPHID	Survey of Prevalent HIV Infections Diagnosed
STIs	Sexually transmitted infections
UNAIDS	The Joint United Nations Programme on HIV and AIDS
Viral load	The concentration of HIV in a bodily fluid (e.g. blood, semen)
WHO	World Health Organisation

1. Introduction

For a number of years, there has been a growing awareness that HIV treatment brings benefits for prevention. Infectiousness relates to viral load (a measure of the amount of virus in the body). By reducing viral load, antiretroviral treatment (ART) therefore also reduces infectiousness and risk of HIV transmission. But despite considerable international discussion in academic papers, publications, official ‘statements’ and conferences, the HIV sector in the UK had not previously engaged in a systematic way on the issue.

NAT considered it important to provide a forum where key stakeholders could discuss what is currently known and not known about the preventive impact of treatment, and then also address how we might integrate HIV treatment into our prevention strategies. We therefore organised an expert seminar in November 2010 – *Towards a Consensus on the Impact of ART on HIV Prevention Strategies*.

Participants at the expert seminar were a mix of people with HIV, community representatives, scientists, treatment experts, social researchers, health advisers, clinicians, and policy experts. The aim of the seminar was not to debate in detail the scientific and clinical studies, but rather to establish where consensus currently exists and what, on the basis of such consensus, we might do differently in our prevention work.

Likewise, the intention of this report is not to review the scientific evidence for and against, nor to critique any of these studies in detail. For a thorough literature review along these lines, NAT has also published a companion briefing paper by Edwin J Bernard, *Towards a UK Consensus on ART and HIV transmission risk*.¹

The Swiss Statement

Any discussion of this body of scientific evidence happens in the context of the ‘Swiss Statement’, the first statement of consensus on the impact of ART on infectiousness.

Released by the Swiss Federal Commission for HIV/AIDS and authored by four leading Swiss HIV experts, the Swiss Statement had international impact, by virtue of being the first such definitive statement of advice on the impact of treatment on transmission between sero-discordant couples:

An HIV-infected person on antiretroviral therapy with completely suppressed viraemia ("effective ART") is not sexually infectious i.e. cannot transmit HIV through sexual contact.

The statement specified that this was valid as long as:

- The person adheres to antiretroviral therapy, the effects of which must be evaluated regularly by the treating physician; and
- The viral load has been suppressed below the limits of detection (i.e. below 40 copies/ml) for at least six months; and
- There are no other sexually transmitted infections (STIs).

The Swiss Statement was followed by a range of other national consensus statements, but to date there has not been an equivalent response in the UK.

¹ The paper and the presentation slides from the speakers can be found on the NAT website: www.nat.org.uk

New HIV diagnoses of people infected in the UK remain high and are more than double what they were ten years ago. There is an international consensus that in order for HIV prevention to be most effective there must be a 'combination' approach which brings together behavioural, biomedical and structural interventions. Much of the discussion at the seminar thus focused on how to draw on the preventive benefits of treatment whilst not undermining condom use.

What is clear, given the prevention needs in the UK, is that we need to use every preventive tool at our disposal. "Just use a condom" is not enough to address the HIV epidemic.

The speakers

Transmission risk between individuals: the science

Dr Martin Fisher (Honorary Senior Clinical Lecturer, Consultant HIV/GUM, Brighton and Sussex University Hospitals NHS Trust and Lead for HIV/GUM Research)

Gus Cairns (Editor, HIV Treatment Update, NAM)

Transmission risk between individuals: information and advice

Dr Daniel Clutterbuck (HIV Consultant, NHS Lothian/NHS Borders)

Ceri Evans (Senior Sexual Health Adviser, Chelsea & Westminster Hospital)

Sanna Savolainen (Health Trainer, Terrence Higgins Trust)

Matthew Williams (Monument Trust)

What do models estimate to be the impacts on HIV incidence of various percentages of people with HIV on ART?

Prof. Andrew Phillips (Infection & Population Health, University College London)

The current efficacy of ART in keeping viral loads down – the population perspective

Alison Brown (Scientific Co-ordinator, Health Protection Agency)

When to start treatment? Balancing individual and public health benefits

Prof Brian Gazzard (HIV Consultant, Chelsea & Westminster Hospital)

Edwin J Bernard (Writer and advocate on HIV issues)

2. The Science

Dr Martin Fisher from Brighton and Sussex University Hospitals NHS Trust outlined the scientific basis for treatment as a preventive option. The two fundamental propositions Dr Fisher set out were that viral load determines risk of transmission and ART significantly reduces an individual's viral load.

Impact of viral load on transmission risk

Non-sexual transmission

There is convincing evidence in non-sexual contexts both of the relationship between viral load and infectiousness, and the impact of ART on viral load and thus on risk of transmission.

The impact of ART in preventing mother-to-child transmission is now well established. It has been shown that mothers with HIV are much less likely to transmit HIV to their babies if their viral load is less than 1,000 copies/ml.² Since the introduction of triple therapy³ in pregnancy, less than 1% of children born to HIV positive mothers are infected if appropriate interventions are taken.⁴ Moreover, considering mother-to-child transmission via breastfeeding, two studies of HIV positive mothers on triple therapy in Kenya and Uganda reported only one transmission among 613 cases where the baby was breast-fed.⁵

There is also evidence from occupational transmission. Dr Fisher presented a retrospective, case controlled study of healthcare workers infected with HIV through needle-stick injuries. It was shown that higher viral loads in the patients involved made transmission more likely.⁶

Sexual transmission

With respect to sexual transmission of HIV in sero-discordant couples, the subject of the Swiss Statement, a systematic review published in 2009 found no studies that fulfilled all the criteria of non-infectiousness set out in the statement. It did not, however, find in any of the relevant studies any instance of HIV being transmitted where the person with HIV had a viral load below 40 copies/ml (zero transmissions over 291 person years). Furthermore, there was a significant preventive benefit identified at low but still detectable viral loads. For example, amongst

1,000 HIV positive individuals with a viral load of below 400 copies/ml having sex with an HIV negative partner over one year, only one HIV transmission would be expected to occur.⁷ A more recent study found a 92% reduction in risk of HIV transmission from individuals on ART to their heterosexual partners, and no transmission among those with a viral load of less than 40 copies/ml.⁸

Dr Fisher also referred to a UK study of men who have sex with men in Brighton, which found an association between a higher viral load and a greater risk of HIV transmission.⁹ In particular, recent infection or co-infection with an STI significantly increased the risk of transmission. By contrast, amongst those on fully suppressive ART there were only two HIV transmissions in 3,556 person years of follow-up, and in one of those cases it was likely that transmission had in fact taken place when the viral load was still declining.

The preventive potential of ART is already being used for post-exposure prophylaxis (PEP), and in emerging new prevention technologies (NPTs) like microbicides and pre-exposure prophylaxis (PrEP). In the week of the expert seminar, the first proof of concept for PrEP in a

² Ioannidis J P et al. Perinatal transmission of human immunodeficiency virus type 1 by pregnant women with RNA virus loads <1000 copies/ml. *J Infect Dis* 183: 539-545, 2010

³ Also known as HAART, to distinguish from early single and dual ART.

⁴ von Linstow M L et al. Prevention of mother-to-child transmission of HIV in Denmark, 1994-2008. *HIV Medicine*- online edition, DOI: 10.1111/j.1468-1293.2009.00811x, 2010

⁵ Iilewo C et al. Prevention of mother to child transmission of HIV-1 through breastfeeding by treating mothers prophylactically with triple antiretroviral therapy in Dar es Salaam, Tanzania – the MITRA Plus study. Fourth International AIDS Society Conference on HIV Treatment and Pathogenesis, Sydney, abstract TuAX101, 2007.; Arendt V et al. AMATA study: effectiveness of antiretroviral therapy in breastfeeding mothers to prevent post-natal vertical transmission in Rwanda. Fourth International AIDS Society Conference on HIV Treatment and Pathogenesis, Sydney, abstract TuAX102, 2007.

⁶ Cardo D M et al. *New England Journal of Medicine* 337:1485, 1997.

⁷ Attia S et al. Sexual transmission of HIV according to viral load and antiretroviral therapy: systematic review and meta-analysis. *AIDS* 23:1397-1404, 2009.

⁸ Donnell D et al. Heterosexual HIV-1 transmission after initiation of antiretroviral therapy: a prospective cohort analysis. *Lancet* 375 (9731): 2092-2098, 2010.

⁹ Fisher M et al. Determinants of HIV- transmission in men who have sex with men: a combined clinical, epidemiological and phylogenetic approach. *AIDS* Jul 17;24(11):1739-47, 2010.

population of men who have sex with men was announced with the findings of the iPrEx study, which were discussed by Gus Cairns (NAM) in his presentation on key scientific studies about using ART for prevention.

The preventive effect of an undetectable viral load

There is no doubt that an undetectable viral load has a very significant impact on risk of HIV transmission. There are, however, both caveats and limitations to what we know and can confidently state.

It is first of all important to stress that the undetectable viral load is a measurement taken at one point in time of the amount of HIV in a blood sample. Relying on a past measurement of undetectable viral load must therefore take account of the possibility that viral load in blood now is not what it was when the measurement was taken.

Some individuals will experience a virological rebound or 'blips' at some point even after ART has effectively suppressed their viral load. This may be due to poor adherence, or may happen occasionally even if treatment is adhered to and successful.¹⁰

Brighton phylogenetic study Factors associated with transmission (Multivariable)			
Factor	Rate ratio	95% CI	p-value
Viral load (per log ₁₀ increase)	1.68	1.19 - 2.36	0.003
Recent Infection	3.43	1.52 - 7.73	0.003
STI during interval	5.64	2.65 - 12.02	0.0001
Age (per 5 years older)	0.68	0.54 - 0.85	0.0009
On HAART	0.28	0.05 - 1.44	0.13

Fisher M et al. AIDS 2010 Jul 17;24(11):1739-47

The presence of STIs appears to increase the viral load in the genital tract. When not taking ART, there seems to be an increase in the likelihood of increased viral load when co-infected with another STI - one study found this was up to 11 times more likely among those not taking treatment.¹¹ However, the extent to which STIs affect viral load when someone is taking ART is not entirely clear.

A further possible limitation is that viral load is measured routinely in the blood (for medical monitoring) but tests are not routinely available to measure viral load in the genital tract. Genital or rectum viral loads may sometimes be higher than the blood viral load, and detectable

even when the blood reading is 'undetectable'.¹² However, even though the penetration of ART into the genital tract may be relatively lower than that in the blood, it may still be at sufficient levels to be considered effective for prevention of HIV transmission. Nevertheless, the lack of research on the preventive impact of ART for anal sex and sex between men who have sex with men is a limitation which needs to be rectified.

An 'undetectable' viral load is one that is so low that it is not picked up. This viral load cut-off is normally at around 40 or 50 copies/ml. But it is worth emphasising that this threshold is a clinical artefact, not one pre-established by biology.

⁹ Fisher M et al. Determinants of HIV- transmission in men who have sex with men: a combined clinical, epidemiological and phylogenetic approach. AIDS 2010 Jul 17;24(11):1739-47.

¹⁰ The latter, however, may simply be the result of an error in the clinical measurement. <http://www.namlife.org/cms1254932.aspx>

¹¹ Winter A J et al. Asymptomatic urethritis and detection of HIV-1 RNA in seminal plasma. Sexually Transmitted Infections 75:261-263, 1999

¹² Zuckerman R et al. Higher concentration of HIV RNA in rectal mucosa secretions than in blood and seminal plasma, among men who have sex with men, independent of anti-retroviral therapy. Journal of Infectious Diseases July 1;190(1):156-61, 2004.

Whilst there is no doubt that at such undetectable levels transmission risk is becoming very low indeed, it is more difficult on the basis of current knowledge to exclude absolutely over an extended period of time the possibility, however remote, of HIV transmission taking place even if the viral load is undetectable. A few isolated possible cases of HIV transmission with an undetectable viral load were referred to at the seminar.

There is clearly a need for further research specifically into the impact of ART on viral load, alongside the broader need for studies specifically testing the impact of ART on transmission risk in sero-discordant couples of the same and opposite sex.

However, a theme at the seminar was the need to place such areas of doubt in context, and to focus on risk reduction rather than risk elimination, the latter of which is not possible during any kind of sexual intercourse. Participants agreed that there is already a significant body of evidence that ART dramatically reduces the risk of HIV transmission, even in the absence of condoms, and even more so when ART is used in combination with condoms and/or other risk reduction methods. This knowledge has already informed the development of new prevention technologies like microbicides and PrEP.

It was agreed that it is unrealistic to wait until all gaps in the scientific literature are addressed before advising individuals living with HIV and at risk of HIV, including men who have sex with men, about the preventive benefits of treatment.

Scientific and clinical studies have already made the preventive potential of ART clear, and a consensus UK response should be drafted on: the current state of scientific knowledge around ART's preventive benefit; those scientific/clinical issues which remain unclear; and how ART may be considered as a preventive tool alongside existing prevention options.

This UK statement should be drafted by a coalition of clinical and scientific experts, with the meaningful involvement of people living with HIV and HIV civil society.

There should be accompanying information to the UK statement elaborating on how it may be interpreted for use in individual advice and support on prevention.

Further research is needed on the impact of treatment on the risk of HIV transmission, in particular during sex between men and in relation to anal sex. It is also important to undertake more research on the impact treatment has on viral load in instances of STI co-infection.



3. Prevention Advice

The significant preventive impact of treatment raises questions as to how we should advise individuals to take account of this impact in their safer sex strategies. The debate on treatment as prevention 'went global' when the Swiss Federal AIDS Commission attempted to define the preventive benefit of treatment for individuals:

An HIV-infected person on antiretroviral therapy with completely suppressed viraemia ("effective ART") is not sexually infectious i.e. cannot transmit HIV through sexual contact.

The Swiss Statement went on to say that this was valid as long as:

- The person adheres to antiretroviral therapy, the effects of which must be evaluated regularly by the treating physician; and
- The viral load has been suppressed below the limits of detection (i.e. below 40 copies/ml) for at least six months; and
- There are no other STIs.

The Swiss Statement had been developed precisely to reflect the advice many clinicians in Switzerland were already providing to individual patients. It aimed to provide reassurance to sero-discordant couples. Whilst there may be reservations at the degree of certainty in the original wording ("not sexually infectious"), the Swiss Statement has been valuable not only in

focusing attention on the science but also on precisely how we advise individuals grappling with questions of intimacy and/or the desire to conceive, and how they can continue to have safer sex. The NAT seminar looked in some detail at the advice individuals should receive on the preventive benefits of treatment and how to apply them in safer sex.

It was clear at the seminar that advice to individuals had to be seen in the context of risk reduction rather than risk elimination. Whilst there are clearly worries amongst many at proposing alternative preventive approaches to condom use, it is well established that condoms do not entirely eliminate HIV transmission risk.

Dr Dan Clutterbuck (NHS Lothian/ NHS Borders) looked at the

evidence for the effectiveness of condoms in preventing HIV transmission. A meta-analysis of all previous studies found that at a population level condoms are 80% effective in preventing vaginal HIV transmission, with a range of 35-90%.¹³ He also noted that there are no similar analyses into the efficacy of condoms against rectal transmission of HIV. He suggested that the widespread perceptions among health professionals about the efficacy of condoms in preventing HIV transmission is not supported by a body of evidence equivalent to that we are seeking before making recommendations about using ART for prevention.

Matthew Williams (Monument Trust) illustrated this point in his comments to the seminar, by contrasting attitudes to risk of HIV transmission when relying on ART with that of relying on oral contraceptives to avoid pregnancy. He noted that the oral contraceptive is considered more effective than condoms to avoid pregnancy, even though it must be taken correctly and at specific times of the day. Many women become pregnant when taking the Pill, but this is considered 'user failure', rather than a problem with the medication. This demonstrates how differently people think about and live with risk.

¹³ Weller SC and Davis-Beatty K. Condom effectiveness in reducing heterosexual HIV transmission. Cochrane Database of Systematic Reviews Issue 1, 2002. These findings are drawn from population-level data, however, so not all individuals will enjoy an 80% preventive benefit – some will experience a greater benefit and others less, depending on whether they consistently use condoms correctly.

Reference was also made to the paper by Brian Gazzard and Geoff Garnett in *The Lancet* (2008) which suggests that reduction in transmission risk could be around 90% with ART alone where an undetectable viral load is achieved, which is equivalent to the protective benefit of a condom where the viral load is not undetectable. This benefit rises to close to 100% if undetectable viral load from ART is combined with condom use.¹⁴



Advice to couples

If the UK HIV sector comes to a consensus view that the protection offered by an undetectable viral load is equivalent to that of condoms, this will have significant implications for our prevention work and safer sex advice. How individuals respond will depend on the degree of risk they are prepared to live with - seminar participants agreed that it is not a question of the elimination of risk but rather the degree of risk that any of us feel it is reasonable to live with.

Some people living with, or at risk of, HIV may wish to combine reliance on undetectable viral load with consistent condom use to virtually eliminate the risk of transmission. Others may feel confident enough to

decide not to use condoms but rely instead on their HIV positive partner's undetectable viral load. There could be others who rely on an undetectable viral load occasionally, for example when trying to conceive. These are personal decisions but they need to be made by people living with, or at risk of HIV who are fully informed of the risks and benefits of such decisions.

It became clear at the seminar that in practice there will be complex personal factors which come into play when decisions around sole reliance on treatment for prevention are made. Ceri Evans, a Senior Sexual Health Adviser (Chelsea & Westminster Hospital), offered some case studies in her presentation which

gave participants insights on how personal dynamics come into play when choosing an HIV prevention strategy, and how the best possible prevention advice is that based on individual need.

The first case was a sero-discordant male couple who could be considered 'expert' in their knowledge of HIV and the impact of ART. As the HIV positive partner had an undetectable viral load, they had been having unprotected anal sex for some time. They made this decision prior to the publication of the Swiss Statement, and they were very happy with the arrangement.

The second involved a heterosexual couple, the man HIV positive, the woman negative.

¹⁴ Garnett GP and Gazzard B. Risk of HIV transmission in discordant couples. *Lancet* 372: 270-71, 2008.



Both partners were fully aware and informed on transmission issues. The female partner was not keen on having unprotected intercourse with her husband despite the fact he had an undetectable viral load. She was highly anxious about becoming infected despite her husband's keenness to have unprotected sex and assurances of extremely low risk of transmission. She started avoiding sex as she felt she was being emotionally pressured and felt a total lack of desire. The husband described himself as feeling neglected, unloved and unclear.

The third case by contrast concerned an HIV positive man very anxious around unprotected sex as he felt that if his negative partner were to become positive he would never forgive himself

– he felt he could not cope with the knowledge he had infected someone he loved even though the negative partner was fully aware of the risks and willing to take them.

It is clear that there will be significant advice required for individuals and couples, and expertise available in psychological and emotional counselling, as people come to grips with the preventive benefits of treatment and complex decisions around living with risk. Training and capacity will need to be in place to meet the sometimes complex needs around decisions over safer sex, condom use and viral load.

It should, however, be acknowledged that despite the equivalence of protection

offered by an undetectable viral load and condoms, in the real world they raise very different practical challenges. A condom is a visible and a shared technology and should it fail this is (usually) evident. By contrast, an undetectable viral load is invisible, has been measured at some point in the past and that information has been imparted to only one of the sexual partners. Very different issues of trust and disclosure are involved. In particular, co-infection with an STI may result in an increased transmission risk.

To rely only on HIV treatment for safer sex if one or both partners are not monogamous (and thus vulnerable to STI co-infection) is to accept an increased risk of HIV transmission when compared with the consistent and correct use of condoms (which are also protective against other STIs).

Advice to individuals

The application of the Swiss Statement was limited to people in monogamous relationships where the HIV positive partner was not infected with any other STI and had an undetectable viral load for at least six months.

It is clear, however, that there is still a significant preventive benefit of treatment even if viral loads are low but detectable.¹⁵ It is also probable that some

individuals outside monogamous relationships may well begin to take account of an undetectable viral load in their consideration of risk. Advice will also be necessary in such contexts to support people in assessing whether and how to take account of the preventive impact of treatment in their harm reduction strategies.

It does not seem likely that a UK consensus statement would consider treatment to be as effective as a properly used condom in reducing the risk of HIV transmission unless the HIV positive partner had an undetectable viral load. But even if condom use is still recommended, the protective benefit of treatment can be an additional harm reduction measure to support condom use. It is a further encouragement to commence treatment as recommended, adhere, attend for viral load monitoring, attempt to avoid STIs and have STI check-ups, all of which will reduce the risk of transmission.

We are moving irreversibly away from a time when the only prevention option advocated was condom use, which was often inaccurately described as effectively eliminating the risk of HIV transmission.

Discussion of treatment as prevention must also be considered in the context of research and interest in the use of PrEP. The recent iPrEX trial demonstrated in men who have sex with men at risk of HIV infection a greater preventive effect (42% reduction in risk of infection) for those who took one pill¹⁶ daily compared to a placebo. The preventive impact was even greater amongst those in the trial who adhered as recommended.

The CDC (Centre for Disease Control) in the USA has now published interim guidance for PrEP to patients who request it.¹⁷ The likely development of PrEP as a preventive option will only reinforce awareness more generally of the use of ART to reduce transmission risk.

There was debate at the seminar on the extent to which people with HIV and those in affected communities are already incorporating treatment's preventive effect into their safer sex strategies. A piece of qualitative work by Sigma Research found little evidence of this occurring amongst the men who have sex with men interviewed, but the study took place only just after the publication of the Swiss Statement.¹⁸

However, Sanna Savolainen, a Health Trainer (Terrence Higgins Trust), noted in her presentation that the Swiss Statement had been raised in discussions by service users, particularly in the context of sero-discordant heterosexual couples who wanted to conceive naturally.

Seminar participants discussed the possibility that knowledge of the preventive impact of ART may lead to 'risk compensation' among people living with and at risk of HIV, in particular decreased or less consistent use of condoms. There was no evidence or specific examples of this occurring to date. However, the possibility that there would be such an effect further indicates the need for clear and accessible information on the use of ART as part of HIV prevention strategies, including potential limits to the preventive benefit.

As clinics begin to incorporate information on the preventive benefit of treatment into their safer sex advice, there will be a need for clear, accessible and consistent information both to answer the many questions people have, and to ensure healthcare workers and health promoters advise accurately and consistently around complex questions of risk.

¹⁵ below 1500 copies/ml.

¹⁶ Truvada (tenofovir/FTC).

¹⁷ See CDC Factsheet 'Pre-exposure Prophylaxis for HIV Prevention' February 2011, <http://www.cdc.gov/hiv/prep/pdf/PrEPfactsheet.pdf>

¹⁸ Bourne A. et al. Relative Safety II: risk and unprotected anal intercourse among gay men with diagnosed HIV, Sigma Research 2009. By contrast, at the 2011 CHAPS conference there was a view that some men who have sex with men were taking viral load into account.

Further interventions should be funded and provided to people with HIV and affected communities with the aim of increasing 'literacy' around prevention and risk. Simplistic messages around risk elimination via condom use need to be replaced by accurate information on the range of preventive options available, continuing risk and uncertainty, and how to combine prevention approaches to reduce risk of HIV transmission.

Resources need to be available for healthcare workers, health promoters, people with HIV and those at risk of HIV, outlining clearly how the preventive benefits of ART can be taken into account in decisions around safer sex. Such material should not be limited to those in monogamous relationships, though of course the advice will vary depending on a person's sexual behaviours and relationships.

Those who provide advice and support to people with HIV will need to be trained in new skills so as to provide advice about the impact of ART on HIV transmission. This will include greater understanding of the importance of clinical issues such as viral load monitoring as well as psychological

and emotional well-being. Increasingly, advice will be sought not just by people with HIV but also by their partners, either separately or as a couple. This underlines the need for adequate resources and capacity for HIV clinics and other HIV support services to meet these complex prevention needs.

Early commencement of ART

Knowledge around the potential of ART may lead some individuals to seek earlier commencement of treatment for preventive purposes. BHIVA Treatment Guidelines currently recommend that ART is begun at a CD4 count of 350 cells/mm³. This contrasts with the USA where ART should be considered from a CD4 count of 500 cells/mm³. Even in current UK guidance, however, it is acknowledged that there will be occasions where transmission concerns can justify earlier commencement:

It is likely that successful antiretroviral treatment, by reducing viral load, reduces infectivity irrespective of the current CD4 cell count, and this may be taken into account in deciding on the timing of starting treatment, particularly in discordant couples where

the infected partner has a high viral load. This is likely to be an issue in a very small number of patients, and it must be stressed that antiretroviral treatment in this context would be an adjunct rather than an alternative to safer sex.¹⁹

There was agreement at the seminar that earlier commencement was justifiable in certain circumstances, and that some clinicians do currently recommend earlier treatment for precisely this reason. However, there was awareness that there is variation in willingness and capacity to do this between clinics, especially when the cost implications of early commencement are considered.

It was clear that for such early commencement to be effective and equitable, further guidance to clinicians is needed on:

- the circumstances in which early commencement might be discussed with the patient;
- how benefits and possible risks should be addressed;
- the importance of informed consent and the primacy of the well-being of the patient; and
- communication of the extent and limitations of preventive benefit.

Even for those who start only when treatment guidelines

¹⁹ BHIVA Guidelines for the treatment of HIV-1-infected adults with antiretroviral therapy 2008.

recommend, there can be challenges for adherence which risk drug resistance and may lead to treatment (and prevention) failure. Earlier commencement only extends the period for such risks. The desire to protect a loved one from HIV transmission may well be an added incentive to adhere. On the other hand, the absence for the patient of a clinical benefit to taking treatment now as opposed to later could conceivably undermine for some people the importance of adherence, particularly when experiencing treatment-related side-effects.

Earlier commencement may be relevant to monogamous couples who wish to have sex without condoms for reasons of trust and intimacy, and/or for heterosexual couples in order to conceive. But it may be as relevant, and more significant for public health, for those people who have a number of partners but who have great difficulty using condoms consistently. In instances where ART should be relied on in combination with other preventive measures (for example condom use, reduction in partner numbers, avoidance of STIs) it may be necessary to consider earlier commencement as part of a 'package' of support to meet the prevention needs of the individual and his or her partners.

For anyone considering earlier treatment commencement, there will need to be clear advice on the benefits and limitations of treatment as a preventive strategy, the

importance of adherence and risks of discontinuation, as well as advice on legal issues around criminal liability for reckless HIV transmission.

The role of treatment in new BASHH/BHIVA Safer Sex Guidelines

At the seminar, Dr Daniel Clutterbuck led a discussion with the group on how future BASHH/BHIVA safer sex guidelines may approach the potential of ART for prevention.

The draft guidelines, out for consultation at the time of publishing (May 2011), recommend discussing using ART for prevention with people with HIV and those at risk of HIV:

“Advice to people living with HIV, their sexual partners and those from groups with higher incidence of HIV infection should include:

- Taking effective ART and having a quantitative plasma viral load below the limit of detection of currently available assays significantly reduces the risk of HIV transmission
- Despite routine undetectable plasma viral load measurements a residual risk of transmission is likely to exist; this is likely to be higher for anal sex than for vaginal or oral sex
- The risks are increased with reduced ART adherence or the presence of STIs in either partner. The risks can be reduced by using condoms and having regular sexual health check ups.”

The guidelines also address the question of early commencement of ART, which was discussed at the seminar. They note that “the early initiation of treatment to reduce the risk of onward transmission may be appropriate as part of a risk reduction approach for some individuals” and that “discussion regarding the early initiation of antiretroviral therapy to reduce the risk of HIV transmission should be considered as part of safer sex counselling for some people living with HIV”. No further details have been provided as to how such a decision should be made, but NAT recommends that additional guidance is provided on this point.

Detailed guidance from BHIVA is necessary for clinicians and patients when considering whether to start HIV treatment earlier than usually recommended in order to prevent onward transmission. Whilst always an individual decision, it is important to achieve a degree of consistency across the country on grounds of equity.

Monitoring viral load

As has been discussed, one difficulty about relying on an undetectable viral load is that it has been measured in the past – the longer the interval, the longer for things possibly to change. Currently viral load monitoring tends to take place three or four times a year but BHIVA have recently consulted on reducing the frequency of such monitoring for stable patients since there seems little clinical need or benefit and thus unnecessary costs.

Conclusions on frequency of viral load monitoring for the stable patient need to consider whether and how any baseline frequency should vary for those who are relying on their viral load as part of their safer sex strategies. Once a patient is established and stable on treatment the main

risks for a viral load becoming detectable in the genital tract are suboptimal adherence, co-infection with an STI, or (in women) menstruation.

As viral load becomes a key consideration in prevention strategies, there will be an increased need to identify factors which affect adherence and monitor nationally the proportion of patients whose viral load remains undetectable over time. As important will be the need to reduce the burden of undiagnosed and/or untreated STIs amongst people living with HIV.

Recommendations should be agreed by BHIVA on routine regular viral load monitoring for individuals relying on ART's preventive effects – it may be that greater frequency is needed than for others.

Identifying and treating any STIs as soon as possible is crucial to the success of ART in reducing infectiousness. Regular STI screening must become a routine part of HIV clinical management, and should be offered to both HIV positive and HIV negative partners who rely on ART as an HIV prevention tool.

Implications for re-infection

It is possible that people living with HIV who engage in sex with others living with HIV (sero-sorting), or who are in a stable relationship with another HIV positive person, will have concerns about the possibility of HIV re-infection if they do not use condoms. This question was raised by participants at the seminar.

However, the evidence suggests that the risk of re-infection is also virtually eliminated if at least one partner is adhering to ART, has an undetectable viral load and no other STIs.²⁰

The potential to protect against re-infection among HIV positive sexual partners is an important aspect of the message about the impact of ART on infectiousness and HIV transmission risk.

²⁰ UK guidelines for the management of sexual and reproductive health (SRH) of people living with HIV infection 2008. Produced jointly by the British HIV Association (BHIVA), the British Association for Sexual Health & HIV (BASHH) and the Faculty of Sexual and Reproductive Healthcare of the Royal College of Obstetricians and Gynaecologists (FSRH).

4. Population Prevention

So far this report has focused on how knowledge about the impact of ART on individual viral load and infectiousness may affect the prevention strategies adopted by individuals. But there is another perspective on treatment and its preventive potential, which looks at the public health benefits of treatment for the population as a whole. Population prevention does not focus on advice to individuals, but on wider public health policies which could maximise the preventive benefit of ART.

A number of attempts have been made to model the impact of HIV treatment on HIV incidence.

One of the most well known, and most disputed, has been that of Granich et al published in *The Lancet* (2009) which predicted a precipitous drop in incidence in a southern African context if there was universal voluntary testing followed by immediate commencement of ART.²¹ There would be immense challenges associated with a roll-out of HIV testing as envisaged, and to then provide treatment to all diagnosed HIV positive sustainably over time. More recently, UNAIDS has advanced a new strategy known as Treatment 2.0, with 'Treatment as prevention' as one of its five pillars. UNAIDS concludes that "treating everyone in need of treatment according to current treatment guidelines could result

in a one third reduction in new infections globally".²²

Professor Andrew Phillips (UCL) presented at the NAT seminar on how mathematical models have been used to estimate the impact of ART on the incidence of new HIV infections. On a population level, there have been a number of approaches to interrogating the treatment as prevention thesis. This includes looking at the association between the number of HIV positive people on ART and new diagnoses;²³ the association between community viral load and new diagnoses;²⁴ and the relationship between testing rates and new diagnoses.²⁵

Professor Phillips explained that the predicted effects of ART on HIV incidence would depend on assumptions about several

issues:

- Uptake and frequency of testing
- The effect of early commencement of ART on individual health
- The likelihood that HIV positive people are diagnosed during primary infection
- Adherence to ART
- Durability of viral load suppression on ART
- The development and transmission of drug resistant virus strains
- Changes in unprotected sex due to HIV diagnosis
- Changes in unprotected sex due to viral suppression
- The extent to which infectiousness does reduce with ART.

He presented a synthesis model he and colleagues had developed drawing on southern African observational data to create a model dataset for a group of simulated individual patients. A range of testing and treatment scenarios can then be applied, for example treatment commencement at CD4 of 200 cells/mm³, or 350 cells/mm³ or immediately on diagnosis. In the southern African model Professor Phillips had developed, the great benefit to reducing HIV incidence was from a significant increase in the proportion of people with

²¹ Granich RM et al. Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model *Lancet* 373 (9657): 48-57, 2009.

²² UNAIDS. 'Treatment 2.0'. July 2010.

²³ Montaner J S G et al. Association of highly active antiretroviral therapy coverage, population viral load, and yearly new HIV diagnoses in British Columbia, Canada: a population-based study. *The Lancet*, Volume 376, Issue 9740, Pages 532 - 539, 14 August 2010.

²⁴ Das M et al. Decreases in Community Viral Load Are Accompanied by Reductions in New HIV Infections in San Francisco. *PLOS One* June 10, 2010.

²⁵ Wand H et al. Increasing HIV transmission through male homosexual and heterosexual contact in Australia: results from an extended back-projection approach. *HIV Medicine* 11(6):395-403, 2010; Prestage G et al. Trends in HIV testing among homosexual and bisexual men in eastern Australian states. *Sex Health* 5:119-23, 2008.

HIV who are diagnosed. This of course is understandable given the extremely low rates of diagnosis (< 20%) in this region. The model does, however, show a benefit (though a comparatively lesser one) from earlier ART commencement, which could justify the additional costs of earlier treatment commencement.

Professor Phillips explained that work was underway on applying a similar model to the UK epidemic. This would be very useful. Of course some treatment as prevention interventions, such as reducing the proportion of people undiagnosed or increasing treatment uptake and adherence as clinically recommended, are important in any event for treatment and care. But modelling would enable us to advocate with greater confidence for the preventive benefit, weight our advocacy in terms of greatest envisaged benefit, as well as discuss any advantages to earlier commencement at the population level.

Further modelling is needed of the preventive benefits of treatment in a UK context and amongst different populations, for example men who have sex with men and African communities.

A number of possible approaches around treatment and population

prevention are relevant and have been considered nationally and internationally:

- Increase the proportion of those diagnosed with HIV who commence treatment when clinically recommended and then adhere
- Improve HIV testing efforts to reduce the proportion of people undiagnosed and increase the number of those with HIV who can access treatment when clinically recommended
- Introduce earlier commencement of treatment to that currently recommended in clinical guidelines so as to increase the proportion of people with HIV with an undetectable viral load
- Universal voluntary testing and treatment at any CD4 count.

All of these approaches were discussed during the course of the NAT seminar.

Improving treatment uptake and adherence

Alison Brown, Scientific Co-ordinator at the Health Protection Agency (HPA), gave a presentation on current ART uptake and adherence in the UK. She drew chiefly upon SOPHID (Survey of Prevalent HIV

Infections Diagnosed) data.²⁶

SOPHID shows that around 78% of all people with diagnosed HIV are currently receiving ART, with no significant differences between populations of men who have sex with men and heterosexual women and men. But in 2009, 17% of people with HIV with a CD4 count below 350 cells/mm³ were not receiving treatment. Of this group, there was a fairly even split between those diagnosed for less than one year, and those diagnosed longer. This suggests there is still some room for improvement in more rapidly assessing patients after diagnosis and recommending commencement of ART as appropriate, as well as finding ways to support patients to continue attending their clinic and adhering to treatment.

Analysis of the 2009 statistics did not show a significant relationship between ART uptake and factors such as ethnicity, HIV exposure route or residential deprivation.²⁷ However, there is a relationship with the age of the patient - young people are more likely not to be taking ART when clinically indicated. SOPHID shows that of 15-24 year olds with a CD4 count of less than 350 cells/mm³ who have been diagnosed less than a year, more than half (54%) are not on treatment; for those diagnosed more than one year,

²⁶ SOPHID data may be accessed from the Health Protection Agency website. www.hpa.org.uk

that figure is a third (33%). By comparison, the proportion not on treatment less than a year after diagnosis is 28% in the 25-49 age group, and is 25% in the over 50s.

An important question to consider alongside ART uptake is the rate at which people living with HIV discontinue their treatment. In 2009, 5% of those who had previously commenced ART had stopped taking it within one year of commencement.²⁸ Again, age appears to have an impact on discontinuation of treatment. For the age group 15-24, 9% had discontinued ART within a year, compared to 4% of those aged over 55.

Crucially for consideration of the possibility of commencing ART earlier for preventive purposes, the 2009 data shows that there is also a relationship between higher CD4 count at commencement and discontinuation of treatment within a year. Individual patients will not normally be recommended to commence ART until their CD4 is around 350 cells/mm³. The rates of cessation were 10% for those commencing on a CD4 count of over 500 cells/mm³, compared to 5% for those with a CD4 count of under 200 cells/mm³.²⁹ There is no data available on why these individuals have discontinued their treatment.

Finally, Alison Brown noted

that almost 1 in 7 patients who commence ART do not achieve a viral load of less than 50 copies/ml within one year of treatment. This is an important reminder that the impact of ART on infectiousness is neither instantaneous nor inevitable, and people living with HIV, and their partners, will need a full range of HIV support services, even if increased uptake of ART does reduce new HIV infections on a population level.

Improved monitoring of adherence to ART and research into the factors affecting adherence is needed to learn how to support people living with HIV in achieving and maintaining an undetectable viral load.

The relationship between age at commencement of ART and discontinuation, and early commencement and discontinuation need further exploration, as do the reasons for the significant percentage of people in the UK with low CD4 counts who are not on ART, as well as those on ART who do not achieve an undetectable viral load.

Whilst further research is needed on its extent, there can be no doubt of the preventive benefit of maximising the proportion of people with

HIV on treatment and with an undetectable viral load. Across the UK, outcomes should be monitored and published on the proportion of people with HIV who commence treatment when clinically recommended, numbers lost to follow-up, the proportion of people who have an undetectable viral load one year after commencement of treatment, and the overall proportion of people on treatment who have an undetectable viral load.

The NHS Outcomes Framework needs to reflect the importance of achieving and maintaining an undetectable viral load for people living with HIV.

Improving HIV testing efforts

In her presentation, Alison Brown noted that overall it is estimated that one in four people with HIV in the UK are undiagnosed. Of these, half are estimated to have a CD4 count of 350 cells/mm³ or less and thus are people who, if diagnosed, would see their viral load significantly reduced if they started treatment as recommended. Recent years have seen significant momentum in improving HIV testing offer and take-up. Key policy documents have included the UK National Guidelines on HIV Testing,

²⁷ Although other research has found that African men and Caribbean men were more likely to not be accessing treatment than white gay men. <http://www.aidsmap.com/One-in-five-patients-at-London-clinic-are-lost-to-follow-up-and-do-not-attend-elsewhere-in-the-UK/page/1431308/>

²⁸ This figure excludes pregnant women, who may commence ART to prevent mother-to-child transmission, and then discontinue as clinically advised.

²⁹ Pregnant women were excluded from this figure.

produced in 2008 by BHIVA, BASHH and BIS, and more recently the NICE Public Health Guidance on HIV Testing amongst men who have sex with men and amongst African communities.

There was consensus at the NAT seminar that HIV testing had to be intensified but with differing emphases among participants - some highlighting the value of routine testing in high prevalence areas,³⁰ others of more targeted testing initiatives in communities most at risk. Some argued for greater HIV testing in community settings including, for example, gay saunas, and others for increased use of home sampling tests.

This is not the place to discuss in detail the optimum strategy to increase HIV testing and reduce undiagnosed HIV. But two issues were raised at the seminar which are relevant to the place of testing in treatment as prevention. The first was the relative 'contribution' of primary HIV infection to new HIV infections. Estimates vary as to what proportion of HIV transmissions emanate from people within this early and brief sero-conversion stage, but within communities with very high partner change it could be as high as 50%.³¹ Thus significant preventive benefit from reducing the numbers undiagnosed would depend not just on increasing

diagnoses but on the more difficult proposition of increasing diagnoses during this early and highly infectious primary infection stage.

The second issue, which also emerged during discussion of Professor Phillips' model, was precisely how improved testing had a preventive benefit. In particular: the extent to which the benefit is a result of those diagnosed changing their risk-taking behaviour; and the extent to which it is a result of those diagnosed beginning treatment and seeing their viral load decline. More consideration is needed of behaviour change post-diagnosis and the extent to which it is sustained over time. This point was also raised by Edwin J Bernard, in his closing remarks to the seminar. He noted that HIV testing is the gateway to treatment. But it is unrealistic to expect that as soon as someone tests HIV positive they automatically have the knowledge and are suitably empowered to always engage in safer sex.

The relative contribution of behaviour change and treatment commencement post-diagnosis does not of course alter the main message - that reducing the proportion of people with HIV who are undiagnosed will have a preventive benefit. Both behaviour change and treatment

adherence need to be supported for preventive and clinical reasons.

Recent progress in reducing the proportion of people with HIV who are undiagnosed needs to be maintained and intensified. In particular, the recommendations of the UK National Guidance on HIV Testing and the NICE Public Health Guidance on HIV Testing for men who have sex with men and for African communities need to be consistently implemented across the country.

Greater efforts are needed to increase the proportion of people with HIV who are diagnosed during the period of primary HIV infection.

Research is needed to further understand how HIV diagnosis affects individual behaviour, and how people living with HIV can be supported to make healthy choices.

Early treatment commencement for population prevention

There was discussion at the seminar as to whether clinical guidelines should be changed to an earlier threshold for commencement for population

³⁰ Where more than 2 in every 1000 people has diagnosed HIV infection.

³¹ Brenner B G et al. High rates of forward transmission events after acute/early HIV-1 infection. *J Infect Dis* 195; 951-959, 2007.

prevention reasons, not just for individuals who request or are specifically recommended this option.

At present, guidelines on treatment commencement draw on the best available data about individual benefit of commencement at different CD4 counts. A 2009 addendum to the BHIVA Treatment Guidelines notes that observational studies now suggest there may be a benefit to commencing at 500 CD4 cells/mm³. However, as a major, randomised study, the Strategic Timing of ART (START) study had begun by this point, the recommendation is that BHIVA "encourage recruitment into this trial where appropriate so that a more definitive answer to this important question can be obtained". At the time of writing BHIVA is again reviewing its treatment guidelines.

The suggestion of routine earlier HIV treatment for population prevention reasons raises some important ethical questions. Treatment should always primarily be provided for the benefit of the patient. If earlier commencement brings with it the possibility of a greater risk of longer-term ill-health for the patient, it does not seem right to recommend earlier treatment simply for the benefit of wider public health. Even if we admit an individual has a right to

Test and Treat?

Granich et al proposed for southern Africa what has become known as a 'Test and Treat' model - universal voluntary HIV testing with immediate commencement of ART for those diagnosed HIV positive. In San Francisco such an approach has in fact already been adopted. Gay men are being encouraged to have an HIV test every six months with those diagnosed as HIV positive recommended to start treatment immediately. The approach is based on a mathematical model of a 91% reduction in new infections over ten years if implemented.³² Evidence of early impacts is still awaited but its introduction has been controversial. In particular, it has been claimed that gay men diagnosed HIV positive are being recommended immediate ART in terms of the benefits to their personal health without clarity that timing of commencement has been determined also by public health considerations. Clearly the ethical concerns raised in relation to changing treatment guidelines for preventive reasons apply to 'Test and Treat' as well. It is crucial that individuals are told honestly about all of the factors relevant to the decision to start treatment.

discuss possible risks and weigh them against prevention benefits (as discussed earlier in the section on individual prevention), considerations are very different in relation to treatment guidelines which will be recommended by clinicians for all people with an HIV positive diagnosis. Whilst concerns over pill burden, side-effects and longer term toxicities have declined over time as treatment has advanced, there remain uncertainties over the longer-term impact of life-long ART, which for an individual diagnosed in their early 20s would mean more than fifty years on treatment.

Even where there is not considered to be any harm to the patient from earlier commencement, this issue should be seen in the context of the evidence presented by the HPA of a greater proportion of those who start treatment early or young discontinuing their treatment. There would also need to be clear evidence of the cost benefit of earlier commencement in terms of reduced incidence when compared with increased treatment costs.

Any change in treatment guidelines should be justified in terms of a clear net clinical benefit to the patient.

³² Das-Douglas M et al. 'Decreases in Community Viral Load Are Associated with a Reduction in New HIV Diagnoses in San Francisco.' Seventeenth Conference on Retroviruses and Opportunistic Infections, San Francisco, abstract 33, Feb 2010.

5. NAT Recommendations

The Science

Scientific and clinical studies have already made the preventive potential of ART clear, and a consensus UK response should be drafted on: the current state of scientific knowledge around ART's preventive benefit; those scientific/clinical issues which remain unclear; and how ART may be considered as a preventive tool alongside existing prevention options.

This UK statement should be drafted by a coalition of clinical and scientific experts, with the meaningful involvement of people living with HIV and HIV civil society.

There should be accompanying information to the UK statement elaborating on how it may be interpreted for use in individual advice and support on prevention.

Further research is needed on the impact of treatment on the risk of HIV transmission, in particular during sex between men and in relation to anal sex. It is also important to undertake more research on the impact treatment has on viral load in instances of STI co-infection.

Prevention Advice

Further interventions should be funded and provided to people with HIV and affected communities with the aim of increasing 'literacy' around prevention and risk. Simplistic messages around risk elimination

via condom use need to be replaced by accurate information on the range of preventive options available, continuing risk and uncertainty, and how to combine prevention approaches to reduce risk of HIV transmission.

Resources need to be available for healthcare workers, health promoters, people with HIV and those at risk of HIV, outlining clearly how the preventive benefits of ART can be taken into account in decisions around safer sex. Such material should not be limited to those in monogamous relationships, though of course the advice will vary depending on a person's sexual behaviours and relationships.

Those who provide advice and support to people with HIV will need to be trained in new skills so as to provide advice about the impact of ART on HIV transmission. This will include greater understanding of the importance of clinical issues such as viral load monitoring as well as psychological and emotional well-being. Increasingly, advice will be

sought not just by people with HIV but also by their partners, either separately or as a couple. This underlines the need for adequate resources and capacity for HIV clinics and other HIV support services to meet these complex prevention needs.

Detailed guidance from BHIVA is necessary for clinicians and patients when considering whether to start HIV treatment earlier than usually recommended in order to prevent onward transmission. Whilst always an individual decision, it is important to achieve a degree of consistency across the country on grounds of equity.

Recommendations should be agreed by BHIVA on routine regular viral load monitoring for individuals relying on ART's preventive effects – it may be that greater frequency is needed than for others.

Identifying and treating any STIs as soon as possible is crucial to the success of ART in reducing infectiousness. Regular STI screening must become a routine part of HIV clinical management, and should be offered to both HIV positive and HIV negative partners who rely on ART as an HIV prevention tool.

The potential to protect against re-infection among HIV positive sexual partners is an important aspect of the message about the impact of ART on infectiousness and HIV transmission risk.

Population Prevention

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Improved monitoring of adherence to ART and research into the factors affecting adherence is needed to learn how to support people living with HIV in achieving and maintaining an undetectable viral load.

The relationship between age at commencement of ART and discontinuation, and early commencement and discontinuation need further exploration, as do the reasons for the significant percentage of people in the UK with low CD4 counts who are not on ART, as well as those on ART who do not achieve an undetectable viral load.

Whilst further research is needed on its extent, there can be no doubt of the preventive benefit of maximising the proportion of people with HIV on treatment and with an undetectable viral load. Across the UK, outcomes should be monitored and published on the proportion of people with HIV who commence treatment when clinically recommended, numbers lost to follow-up, the proportion of people who have an undetectable viral load one year after commencement of treatment, and the overall proportion of people on treatment who have an undetectable viral load.

The NHS Outcomes Framework needs to reflect the importance of achieving and maintaining an undetectable viral load for people living with HIV.

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particular, the recommendations of the UK National Guidance on HIV Testing and the NICE Public Health Guidance on HIV Testing for men who have sex with men and for African communities need to be consistently implemented across the country.

Greater efforts are needed to increase the proportion of people with HIV who are diagnosed during the period of primary HIV infection.

Research is needed to further understand how HIV diagnosis affects individual behaviour, and how people living with HIV can be supported to make healthy choices.

Any change in treatment guidelines should be justified in terms of a clear net clinical benefit to the patient.

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