Undetectable = Untransmittable
(U = U)
Criminalisation and Conditional Consent

Dr Michael Brady
Consultant in HIV & Sexual Health
King’s College Hospital

U=U: Building the evidence

• The evidence, experience and expert opinion to support the U=U message has been increasing over two decades

• Viral load is the single biggest determinant of HIV transmission risk

• The Partner study was the ‘tipping point’ in our understanding and our approach to messaging

• The results of Partner 2 gives us the confidence to be definitive about the messaging and language around U=U

3. Rodger AJ et al. HIV transmission risk through condomless sex in gay couples with suppressive ART: The PARTNER2 Study extended results in gay men. IAS 2018
**U=U: Building the evidence**

Rakai study of 415 HIV serodifferent heterosexual couples in Uganda

No cases of transmission to sexual partners observed for patients with VL <1,500 copies/mL

RNA, ribonucleic acid; VL, viral load.

**U=U: Building the evidence**

HPTN 052: Study design

Stable, healthy, HIV serodifferent, sexually active couples
CD4 count: 350–550 cells/mm³

Randomisation

Immediate ART
CD4 350–550 cells/mm³

Delayed ART
Initiated when CD4 ≤250 cells/mm³

Primary transmission endpoint
Virologically-linked transmission events

Primary clinical endpoint
WHO stage 4 clinical events, pulmonary tuberculosis, severe bacterial infection and/or death

ART, antiretroviral therapy; CD4, cluster of differentiation 4; HPTN, HIV Prevention Trials Network; WHO, World Health Organization.
**U=U: Building the evidence**

Total HIV-1 transmission events: 78

- Linked transmissions: 46
- Unlinked transmissions: 26

93% reduction in HIV transmission
Hazard Ratio 0.07% (0.02 – 0.22)

P<0.05

**Partner Study**

**Design:**
- 888 HIV serodifferent couples (548 heterosexual and 340 MSM)
- HIV-positive partner on ART with a viral load <200 copies/mL
- 75 European clinical sites

**Primary aim:**
- To study the risk of HIV transmission through anal and vaginal sex in the absence of condom use for people with an undetectable viral load

ART, antiretroviral therapy; MSM, men who have sex with men; PLWHIV, people living with HIV.
**U=U: Building the evidence**

**Partner Study: Results**

<table>
<thead>
<tr>
<th>1,238</th>
<th>58,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>eligible CYFU</td>
<td>condomless sex acts</td>
</tr>
</tbody>
</table>

11% of the initially HIV-negative partners became HIV-1 infected

8 (73%) reported recent condomless sex with others apart from their study partner

ZERO transmissions linked to their HIV positive partner

18% of MSM and 6% of heterosexuals reported STIs

Overall transmission risk was zero (95% CI 0–0.3/100 CYFU)

---

**U=U: Building the evidence**

**Partner Study: Rate of HIV transmission according to sexual behaviour reported by the HIV- partner (All couples)**

<table>
<thead>
<tr>
<th>Sexual behaviour</th>
<th>% of eligible couples reporting specific sex act</th>
<th>Couple-years of follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any sex</td>
<td>99.7</td>
<td>1,238</td>
</tr>
<tr>
<td>Vaginal sex</td>
<td>60.6</td>
<td>629</td>
</tr>
<tr>
<td>Anal sex</td>
<td>52.9</td>
<td>522</td>
</tr>
<tr>
<td>Insertive anal sex</td>
<td>42.1</td>
<td>417</td>
</tr>
<tr>
<td>Receptive anal sex with ejaculation</td>
<td>21.4</td>
<td>166</td>
</tr>
</tbody>
</table>

Rate of within-couple transmission, per 100 couple-years of follow-up

U=U: Building the evidence

Partner Study: Rate of HIV transmission according to sexual behaviour reported by the HIV- partner (All couples)

<table>
<thead>
<tr>
<th></th>
<th>% of eligible couples reporting specific sex act</th>
<th>Couple-years of follow-up</th>
<th>Upper 95% confidence limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any sex</td>
<td>99.7</td>
<td>1,238</td>
<td>0.30</td>
</tr>
<tr>
<td>Vaginal sex</td>
<td>60.6</td>
<td>629</td>
<td>0.59</td>
</tr>
<tr>
<td>Anal sex</td>
<td>52.9</td>
<td>522</td>
<td>0.71</td>
</tr>
<tr>
<td>Insertive anal sex</td>
<td>42.1</td>
<td>417</td>
<td>0.88</td>
</tr>
<tr>
<td>Receptive anal sex with ejaculation</td>
<td>21.4</td>
<td>166</td>
<td>2.23</td>
</tr>
</tbody>
</table>


U=U: Building the evidence

Opposites Attract

- 343 serodifferent gay couples
- HIV+ partner undetectable on ART
- 16,889 condomless anal sex acts
- HIV transmissions:
  - None from primary partner
  - 3 from partner outside of study

Opposites Attract + Partner Studies $\approx 40,000$ CLAI acts in MSM

- No HIV transmission despite other STI:
  - Opposites Attract: Participants had STI from 6% of anal sex acts
  - PARTNER: Up to 18% of participants had an STI at some point

ART, antiretroviral therapy; CLAI, condomless anal intercourse; MSM, men who have sex with men; STI, sexually transmitted infection.

U=U: Building the evidence

Partner 2 Study

Design:
• 972 HIV serodifferent MSM couples
• 783 couples contributed to the analysis
• HIV-positive partner on ART with a viral load <200 copies/mL

Primary aim:
• To follow serodifferent partnerships that have penetrative sex without using condoms where the HIV-positive partner is on ART with a plasma HIV-1 RNA load <200 copies/mL to study risk of HIV transmission through anal sex in the absence of condom use

ART, antiretroviral therapy; MSM, men who have sex with men; PLWHIV, people living with HIV.

Rodger AJ et al. HIV transmission risk through condomless sex in gay couples with suppressive ART: The PARTNER2 Study extended results in gay men. IAS 2018

Partner 2 Study: Results

1,596 eligible CYFU

77,000 condomless sex acts

15 of the initially HIV-negative partners became HIV-1 infected

11 (73%) reported recent condomless sex with others apart from their study partner

ZERO transmissions linked to their HIV positive partner

24% of HIV-ve partners and

27% of HIV +ve partners reported STIs

Overall transmission for MSM in Partner 1 and 2 was zero (95% CI 0–0.23/100 CYFU)

CI, confidence interval; CYFU, couple years of follow-up; MSM, men who have sex with men; STI, sexually transmitted infection.

Rodger AJ et al. HIV transmission risk through condomless sex in gay couples with suppressive ART: The PARTNER2 Study extended results in gay men. IAS 2018
Why this is important

• Removes the shame and fear of sexual transmission

• Simplifies the possibility for conception

• Tackles HIV stigma

• Encourages people to test, engage in care and to start and stay on treatment

• Simplifies the issue of disclosure, criminilisation and ‘reckless transmission’

The language we use
If you believe it, so will they....

• Understanding the message has significant impact for individuals living with HIV

• Healthcare professionals need to adopt a consistency of message around U=U

• The language we use makes a difference:

  - “Could”
  - “Might”
  - “Low risk”

  - “Can’t”
  - “Won’t”
  - “No risk”

While effective viral suppression with antiretroviral therapy has been proven to substantially reduce the risk of sexual transmission, a residual risk cannot be excluded. Precautions to prevent transmission should be taken in accordance with national guidelines.
Putting this into practice

Communicating U = U with patients

Your approach

In the context of U=U, when someone has a sustained undetectable viral load, what would you advise about disclosure to a ‘casual’ sexual partner?

A. There is no need to disclose unless or until you want to
B. It is important to disclose your HIV status as soon as possible
C. It is important to disclose your HIV status immediately
D. Other
HIV and Criminalisation

HIV transmission and criminalisation

“People who have been diagnosed HIV positive should be made aware of the legal position in relation to HIV transmission and how to protect themselves from prosecution; this should occur (and be documented) at the time of their initial diagnosis and subsequently as indicated.”

• Do you routinely discuss criminalisation with PLWHIV?

• Does the U=U message change these discussions?

BHIVA Standards of care for people living with HIV (2018)
HIV transmission and criminalisation

Offences Against the Person Act 1861 sections 18 and 20

Section 18
*Intention* to cause serious harm + *Infliction of GBH*
*Consent is not a defence*

2 prosecutions to date
Maximum sentence 25 years

Section 20
“*Reckless*” about causing serious harm + *Infliction of GBH*
*Consent is a defence (if HIV status us disclosed)*

Most prosecutions to date
Maximum sentence 5 years

---

HIV transmission and criminalisation

- Recklessness: “.......a defendant foresaw that the complainant might contract the infection via unprotected sexual activity but still went on to take that risk”.

- Prosecution has to demonstrate that: “.......the defendant recklessly and actually transmitted the infection to the complainant”.

- “Evidence that the suspect took appropriate safeguards to prevent the transmission of their infection throughout the entire period of sexual activity, and evidence that those safeguards satisfy medical experts as reasonable...........will mean that it will be highly unlikely that the prosecution will be able to demonstrate that the suspect was reckless”.

Intentional or reckless sexual transmission of infection. Crown Prosecution Service.
https://www.cps.gov.uk/legal-guidance/intentional-or-reckless-sexual-transmission-infection
**U = U and HIV crimiplisation**

You can be prosecuted for reckless HIV transmission in E&W if all of the points below applied in relation to the alleged offence:

- You knew you had HIV
- You understood how HIV is transmitted
- You had sex which risked transmission
- You transmitted HIV to the sexual partner
- That sexual partner did not know you had HIV when the HIV was transmitted

---

**U = U and HIV crimiplisation**

If U=U means transmissions don’t happen, then reckless transmission convictions can’t happen either

- But investigations might .. you may be asked to confirm viral load of accused at relevant time
- You may need to explain U=U to police/CPS
- Are we clear at what point we can advise patients there is no risk of transmission?
- Do we also talk about low risk of transmission as viral load approaches undetectable?
HIV transmission and criminalisation

• “Where someone is receiving treatment, one of the effects is a reduction of the amount of the virus in their system (in some cases this may result in an undetectable viral load). In these circumstances, the prospect of the infection being transmitted to another is potentially significantly reduced.

• “It may be argued that taking medication may, in some circumstances, be as effective a safeguard as, for example, the use of a condom in reducing risk and therefore negating recklessness”

• To avoid transmission and/or a charge or recklessness an individual needs to demonstrate they actively took measures to reduce transmission risk:
  - Disclosure
  - Condoms
  - PEP
  - TasP


U = U and HIV criminilisation

In Scotland exposure to the risk of HIV transmission can also be charged, as well as transmission itself

• Scotland prosecution body says will only prosecute for exposure ‘in exceptional circumstances’ though in fact of five prosecutions to date, two involved additional charges of exposure to those of transmission

• Prosecute where ‘flagrant course of conduct’ or where helps make the case of reckless behaviour in relation to an additional transmission charge
U = U and HIV criminilisation

- Need to understand U=U and relevance to law in your nation – to advise both patients (reassurance) and possibly police/prosecutors

- ‘Prosecutable’ people increasingly those with adherence problems – already vulnerable – can we identify in clinic those at risk of breaking the law? How can we support them?

The law and consent to sex

- **Sexual Offences Act 2003**: ‘A person consents if he agrees by choice, and has the freedom and capacity to make that choice’ (section74)

- **Freedom**: no coercion, exploitation, threats/fear

- **Capacity**: may lack capacity to choose or be unable to communicate choice

- **Moment in time**: Consent must be ongoing and can be withdrawn at any time, and must be for every sexual act
The law and consent to sex

- **Reasonable belief:** Offence also requires that ‘A does not reasonably believe that B consents … Whether a belief is reasonable is to be determined having regard to all the circumstances, including any steps A has taken to ascertain whether B consents.’

The law and consent to sex

**Evidential presumptions around consent (s.75):**

- Consent/reasonable belief in consent assumed not to be present in certain defined circumstances, 'unless sufficient evidence is adduced' to raise an issue pointing the other way

- Circumstances – violence/fear of violence (including against a third party); unlawful detention; asleep/unconscious; consent not communicable because of physical disability; complainant had substance administered to them without consent which stupefied or overpowered them
The law and consent to sex

- Conclusive presumptions around consent (s.76):
  - Conclusive proof of no consent/no reasonable belief in consent if:
  - “(a) the defendant intentionally deceived the complainant as to the nature and purpose of the relevant act
  - (b) the defendant intentionally induced the complainant to consent to the relevant act by impersonating a person known personally to the complainant.”

The law and consent to sex

- Consent and chemsex:
  - Disinhibition, passing out on ‘G’, loss of awareness of ‘what happened’
  - Is reasonable belief in consent possible in a chemsex context? Questions of capacity
  - Lack of understanding of law on consent – ‘if you’re here you consent’
  - NB even though both parties may lack capacity, the rape/assault by penetration is committed by the ‘active’ sexual partner
The law and consent to sex

- Consent and chemsex:
  - Assaults may occur even if unintended
  - Fears of disclosing to police (e.g. illicit drug use, salacious investigation, ‘betrayal of community’)
  - Urgent need to inform gay community of law around consent and sexual assault
  - If chems are going to be used in sex, how maintain consent whilst enjoying sexual pleasure?
  - Law enforcement also needs to be educated in sensitivity around these cases

Disclosure and consent

CPS Legal Guidance on Intentional or Reckless Sexual Transmission of Infection:

- **Disclosure:** There is no legal obligation to disclose STI/HIV status before having sex, even where that sex carries a risk of transmission
- BUT it is a crime to transmit STIs/HIV to a sexual partner recklessly (i.e. through sex considered ‘risky’)
- UNLESS that sexual partner knew in advance you had the STI/HIV
- SO disclosure in advance of sex can be a defence against prosecution/conviction
Disclosure and consent

CPS Legal Guidance on Intentional or Reckless Sexual Transmission of Infection:

- **Rape:** A person who does not disclose the fact that they have a STI and then has consensual sexual intercourse with another without informing that person of their infectious state, is not guilty of rape (R v B [2006] EWCA Crim 2945, CA).

Disclosure and consent

- R v B [2006] EWCA Crim 2945, CA - rape case – is HIV status relevant to consent to sex? S.76 of Sexual Offences Act 2003 relevant? (‘Conclusive presumptions about consent’)
- The judgment relates to non-disclosure (‘implied deception’) of HIV positive status – (but might the law be different with regard to positive deception? – a ‘matter which requires debate not in a court of law but as a matter of public and social policy ..’)

Developing case law on consent

- R v F [2013] EWHC 945 (Admin) –
  - Defendant guilty of rape where having agreed not to ejaculate inside his wife, he did so in the context of aggressive and abusive sex, thus vitiating consent under s74 of the Act.
  - The judge said “The evidence relating to ‘choice’ and the ‘freedom’ to make any particular choice must be approached in a board commonsense way.”

Developing case law on consent

- R v Mc Nally [2013] EWHC Crim 1051 –
  - Young person born biologically female but identifying as a trans male, began online relationship, presenting as a male, with a girl. After some time met and penetrative sex occurred. Girl’s mother confronted young person over their gender. Prosecuted and found guilty of sexual assault by penetration.
  - Highly controversial judgment, esp in context of trans rights
HIV disclosure post-McNally

- 2013 CPS interest in allowing prosecutions for rape in cases of HIV status deception – NAT/THT/BHIVA protested – CPS backs down with promise to consult if case law develops further
- 2016 NAT hear by chance of CPS attempt to charge with rape for HIV status deception – further protest and roundtable with CPS – charge dropped
- 2018 CPS share draft revised Legal Guidance which speaks of rape charge for HIV status deception – currently being challenged

HIV disclosure post-McNally

- “In reality some deceptions (such as, for example, in relation to wealth) will obviously not be sufficient to vitiate consent.” *R v F*
- Roundtable participants in 2016 challenged whether HIV status deception made sex non-consensual
- What if no risk of transmission? But complainant nevertheless says would not have had sex if known status?
- What if lie about sexual history? When last tested? Number of partners?
Conclusions

- There is no legal requirement for people with HIV to disclose their status before sex
- However, in a case of reckless HIV transmission, the fact that your sexual partner knew your status because you had disclosed it is an effective defence
- There is debate as to whether positive deception about your HIV status makes sex non-consensual and criminal
- Where the HIV positive person is undetectable or uses a condom consistently it is extremely unlikely that positive deception would be prosecuted
- It is unclear whether positive deception would be successfully prosecuted as rape/sexual assault where there is a risk of transmission – it is safer not to deceive the sexual partner as to your HIV status

Conclusions

- Law on consent in sex is developing via case law and there has been CPS interest in prosecuting HIV status deception as vitiating consent
- Be aware of any local moves to charge re rape/sexual assault for status deception/non-disclosure and let NAT know
- We need to do more to communicate what the actual law is around sex and consent
Zero risk, Zero excuses

UNDETECTABLE = UNTRANSMITTABLE

#CantPassItOn
#UequalsU

www.tht.org.uk accessed August 2018
www.preventionaccess.org accessed August 2018