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Implementing TasP in your clinic

" Far from being tacitly compliant with the move towards TasP there are many practical and ethical challenges faced by front-line service providers turned implementers"

- Dodds et al, Sigma Research 2013; Professional ambivalence: the views of HIV service providers about ARVs for prevention in 3 settings *IAPAC Controlling the HIV Epidemic with Anti-retrovirals, London, 22-24 September 2013 (Poster).*

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Implementing TasP in your clinic

1} Where are we at now?
2} Challenges to implementing TasP in routine practice
3} Overcoming the obstacles
4} Some case studies
5} Summary and conclusion
6} Questions?

1] Where are we at now?

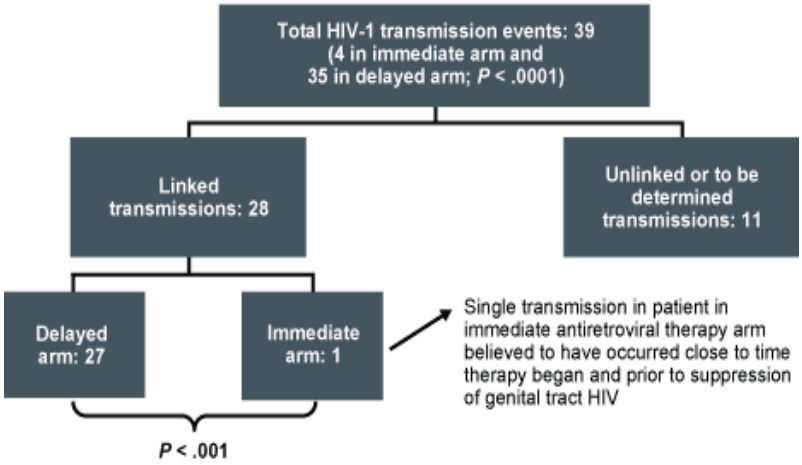
Swiss statement

- One of the first things we heard about the concept of TasP for sexual transmission was the Swiss statement (Swiss National AIDS Commission, 2008)
- ***An HIV-infected person on antiretroviral therapy with completely suppressed viraemia (effective ART) is not sexually infectious, ie cannot transmit through sexual contact***
- There was no change in treatment policy – however, our patients became increasingly aware of this statement

HPTN 052 study

- A multi-continent, randomised control trial set out to compare early ART versus delayed ART
- Patients were recruited who had CD4 counts between 350 and 500 cells/mL and were in a stable relationship
- Those in the immediate ART arm started therapy at enrolment.
- The delayed arm started ART once they had two consecutive CD4 counts of 250 cells/mL or less, or had an illness related to AIDS
- In July 2011, the results of the HPTN 052 study were released; this was the pivotal study relating to TasP

HPTN 052 study



PARTNER study

- Results presented at CROI 2014 reported that no linked transmissions have so far occurred {after almost 900 couple years of follow-up}.
- By November 2013, PARTNER had enrolled 1,110 couples.
- Follow-up results included almost 44,500 times when sex was without condoms and over 21,000 times when this was anal sex.

EAGA / BHIVA guidance

- The risk of a person living with HIV, who is taking effective ART, passing HIV on to sexual partners through vaginal intercourse is extremely low, provided the following conditions are fulfilled:

1. there are no other STIs in either partner.
2. the person who is HIV positive has a sustained v/load below 50 HIV RNA copies/mL for more than 6 months and below 50 copies/mL on the most recent test.
3. viral load testing to support the strategic use of ART as prevention should be undertaken regularly (3–4-monthly)

START study May 2015

- 'Early therapy conveys a double benefit, not only improving the health of individuals but … reducing the risk they will transmit HIV to others'. [1]
- 'Global implications for the treatment of HIV.' [1]
- 'These results support treating everyone irrespective of CD4+ T-cell count.' [2]

Refs ;1] Anthony Fauci, Director US National Institute of Allergy and Infectious Disease (NIAID). NIH Press Release May 27th 2015
2] Jens Lundgren, M.D., University of Copenhagen , co-chairs START study.

Perhaps we are late with our message?

- 2008 – Swiss statement
- 2011 – HPTN 052 release data
- 2012 – Joint BHIVA / EAGA position statement released
- Partner study 2014
- START study May 2015

Are we widely promoting TasP to our patients?

2] Challenges & complexity in implementation

Where to start?

- Understand the complexity
- Find out what the potential barriers are locally
  - Use focus groups
  - Meet and brainstorm with the team
  - Devise a questionnaire
  - Talk to key/influential individuals
  - Observe clinical practice

Complexity

For TasP to work there needs to be high rates of success in the following…
Four critical requirements

1} Testing
High rates of testing and sufficiently frequent

2} Linkage to care
Minimising numbers 'lost to follow up'

3} Proportion on therapy
A high proportion need to be on ART if treatment is to have an effect on onward transmission.

4} Proportion failing therapy
Optimal regimens and clinical outcomes needed

Potential obstacles to implementing change in practice &/or a new service

1} Acceptability and beliefs of both Clinicians and PLWHIV

2} Knowledge & skills

3} Motivation to implement new practice

4} Practicalities

5} Barriers beyond our control

Clinician acceptability

Lots of ambivalence revealed

- Will those who don't opt to take TasP risk further stigmatisation?
- Does this put excessive responsibility on PLWHIV for life long medication and transmission?
- Individual health priority – transmission should be a secondary concern
- Increased pressure on HCPS and PLWHIV to start ART earlier with implications for individuals' health
- Fears around drug availability/shortages in some countries
- Fears around impact on adherence long term

Ref] Dodds C et al Sigma Research]http://sigmaresearch.org.uk/presentation/hiv/tlak2013]

More questions…

- Potential to disrupt strong and uncomplicated HP message advocating condom use?
- Greater public good should not come at the sacrifice of the well being of individual PLWHIV
- Will there be an impact on risk-taking behaviours by people believing they, or their partners, to be non-infectious?
- How practical and cost effective is widespread up-scaling of testing and treatment?
- Human rights - Is there a danger of compulsory or coercive testing and treatment ?

Acceptability and knowledge; PLWHIV

- 12 different HIV prevention methods were listed.
- HIV testing was, and remained, the HIV prevention method accorded by far the highest priority.
- Condoms came second.
- However TasP and PrEP received the biggest *increase* in prioritisation.

Ref . NAM European HIV prevention survey 2014; The Lancet 382(9907):1795-1806, 2013.

PLWHIV acceptability/ reservations

- Concern regarding the importance of people being able to decide for themselves whether or not they took TasP
- Concern about people seeing being virally undetectable as a "*get out of jail free card*"
- People find the different ways of using ARVs for prevention, complex and confusing
- Varied ideas about the efficacy of different techniques and how effective different combinations of prevention methods might be.
- Ref; NAM prevention survey

Clinician knowledge & expertise

- NHIVNA TasP study {2013} revealed considerable gaps in the knowledge and confidence of many nurses working in the specialty.
- & a lack of clarity in relation to the logistics of how of how the initiative could be rolled out and funded.
- And ongoing clinical questions about…

- efficacy especially in clinically complex cases?
- nature of exposure -variability of infection risk?
- drug penetration variability?
- drug resistance and tolerability?
- reliability of plasma HIV RNA as an accurate marker for V/L in genital tract?

Clinician motivation

- Concerns around cost/limited resources including consultation time.
- Concern that expanding treatment might take attention away from research into, and advocacy for, other HIV-prevention methods and programmes?
- Concern about impact on patient-clinician relationship/pressure, perceived policing, judgements etc.
- What will be the rewards?

Infrastructure requirements

- A robust & effective MDT who communicate well and strive for common goals
- A supportive environment - Management Team/Trust backing
- Effective IT, documentation/record- keeping systems
- An embedded system for evaluation/audit and governance
- Backed by policy and 'user- friendly ' guidelines
- Sufficient resources, e.g. time and funding!

3} Overcoming the obstacles

- Remedying ambivalence
- Enhancing acceptability
- Improving knowledge and skills
- Motivating the team
- Building infrastructure

Remedying ambivalence & enhancing acceptability

- Organise workshops to facilitate MDT discussion regarding the evidence for /against TasP -involve a well-regarded opinion leader.
- Use patient mediated strategies;
  - empowering patients into proactive & shared decision making. [1]
  - knowledgeable patients are more likely to adhere to treatments with better outcomes, which in turn motivates HCPs. [1]
  - engage service users in implementing new initiatives that genuinely meet their needs.

- Ref 1] NICE How to Change Practice, 2007, available at www.nice.org.uk

Enhancing acceptability; continued

- HCPs like clinically 'rich' data and evidence.
- Need to see the benefit /improved patient outcomes.
- Ensure new service/policy is regularly evaluated and audited & get staff involved in the process.
- Feedback findings to demonstrate value – delivered by respected person in timely fashion, combined with educational materials and meetings.

Enhancing skills and confidence

- Team knowledge needs to be up- to -date & evidence-based – so effective dissemination of knowledge is essential
- Training where required – e.g. to enhance communication skills in relation to facilitating discussion on sexual relationships and behaviours, transmission risks etc
- Opinion Leaders- use people of influence who are respected
- Clear policy and procedure guidelines are required to back-up decision making
- Try peer- to peer coaching
- Embed clinical audit and feedback mechanisms

Infrastructure

- Draw up robust policy and procedure guidelines.
- Ensure training and education is a rolling programme.
- Embed prompts, reminder systems, audit & evaluation.
- Ensure IT supports practice.
- Prioritise effective communication channels.
- Maintain patient- centred working, proactively facilitating patient empowerment.
- Generate data that demonstrates VFM, including enhanced clinical outcomes.

4 } Case discussion A

- Jay, 33-year-old MSM
- Diagnosed April 2012
- CD4 – 678; VL – 42,000 (CD4 has always been around 600)
- Single
- Previous STIs (since HIV diagnosis) – Chlamydia/syphilis
- Sexual history – 7 partners in last 4 months. UPAI – receptive
  - He does disclose his HIV status to partners
- Jay attends for a 6-month review in your nurse-led clinic

Would you discuss ART as a prevention option with Jay?

Case discussion B

- Marie, 34 year old heterosexual
- Diagnosed March 2014
- CD4 – 788; VL – 110,000 (CD4 has always been around 800)
- Long term partner for 6 years, he is HIV negative and test regularly. They currently use condoms, he has taken PEP once
- Marie is currently taking combined oral contraception, they are planning to start a family.
- They both come in to clinic to discuss their options

Would you discuss ART with Marie and her partner?
What issues would your discussion include?

Case discussion C

- Angie, 39 year old heterosexual
- Diagnosed January 2015 after partner died of PCP
- CD4 – 540; VL – 80,000 (CD4 has always been around 500)
- New partner of 6 months, he does not like using condoms and has read about TaSP
- Angie and her partner come to clinic to discuss TaSP

What would you discuss in this consultation and would you consider TaSP appropriate?

5} Summary & conclusions

- Acknowledged the complexity of the issue and the need to support & guide each other.
- Provided some guidance in bringing about new practice and policy and the specific challenges of TasP.
- "Full incorporation of the such issues into the heart of policy and planning for TasP will be essential if such an intervention is to be successful." [1]
- Have we been slow off the mark in rolling out TasP ?
- If so what can we learn from this?
- New revelations from the START study may mean TasP is a 'given' for the majority of PLWHIV?

Ref 1] Dodds et al, 2013, Sigma Research

- Thank you!
- Questions?