Treatment as prevention (T4P)

The views of high risk patients attending a GUM outpatient service.

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Background: HPTN 052¹ demonstrated a 96% reduction of HIV transmission among sero-discordant couples and draft BHIVA treatment guidelines² suggest discussion of treatment for prevention (T4P) in patients with CD4 counts >350. Mathematical modelling has suggested that T4P may have a significant impact on HIV transmission at a community level³, however this requires testing within a clinical trial. The acceptability of T4P approaches among high risk populations is unknown.

Aim: To assess whether 'high risk' patients attending for HIV testing at a Genito-urinary medicine (GUM) clinic would consider taking T4P should they be diagnosed with HIV.

Methods: Men who have sex with men (MSM), injecting drug users (IDU) and patients with endemic risk attending the Jefferiss Wing (Imperial College Healthcare NHS trust) were invited to participate in an NIHR-CLAHRC funded HIV point of care testing validation study. All participants were asked to self complete a cross-sectional survey prior to HIV test results. The survey examined past HIV testing, prior sexually transmitted infections (STIs), sexual history (last 3 months) and history of PEP. Survey responses were linked to STI results at attendance. Responses to the hypothetical T4P question were regrouped into a binary variable comparing the characteristics of 'yes' responders to 'no' / 'not sure' responders. Univariable and multivariable logistic regression was performed to examine variables associated with T4P responses. Data analysis was in STATA12.

All participants were asked to read this statement and answer the following question.

"HIV is a highly treatable infection. Treatment does not cure the infection but controls it. Not every patient diagnosed with HIV requires treatment for their own health and many patients may have a number of years off treatment before they need to start. Currently the decision to start treatment is based on the health of the patient with HIV alone. However in some circumstances treatment is used to prevent passing on the virus e.g. in pregnant women to prevent transmission to their child. Treatment may also reduce the infectiousness of HIV to sexual partners. This does not replace the need for condom use and safe sex. It is not current practice for treatment to be started for this reason alone. We are therefore very interested in your views on this research idea."

Q - If you were diagnosed with HIV would you consider taking treatment to reduce the risk of passing on infection (even if you did not need to take treatment for your own health)?

Response options: Yes / No / Not sure

Results: 1001 participants were recruited to the validation study of whom 647 returned questionnaires. 606/647 (93.6%) respondents answered the T4P question of whom 537 (88.6%) were men. Overall 490 (80.9%) responded 'yes', 104 (17.2%) were 'not sure' and 12 (2%) said 'no'.

In univariable analysis (table 1) comparing factors associated with a 'yes' response compared to 'no / not sure' responses, age over 40, a past history of STI and a history of PEP were associated with decreased odds of a 'yes' response to T4P.

Among men that reported recent unprotected anal intercourse (UAI) with other men there was a trend towards increased odds of a 'yes' response (p=0.08). No association was observed with recent partners HIV status.

<u>Table 1 – Univariable analysis</u>

Multivariable analysis: In multivariable analysis (table 2), history of STI, past PEP use and men reporting recent UAI (3 months) remained associated with T4P responses.

After controlling for the other variables age-group was no longer associated with T4P responses (p value = 0.148) and was therefore not included in the final multivariable model.

Table 2 – Multivariable analysis

		Adjusted Odds ratio of 'Yes' response (95% CI)	P value
History of STI	No	1	
	Yes	0.57 (0.34 – 0.95)	0.032
PEP history	Never	1	
	PEP in the past	0.55 (0.31 – 0.98)	0.041
Men reporting UAI with other men - last 3 months	No	1	
	Yes	1.71 (1.04 – 2.80)	0.033

		Number of	Number	Odds ratio of a	p value
		Participants	"Yes"	'Yes' response	
			response (%)	(95% CI)	
Sex	Female	69	59 (85.5)	1	
	Male	537	431 (80.3)	0.69 (0.34-1.39)	0.297
Age group	<30	282	237 (84.0)	1	
	30-40	178	147 (82.6)	0.90 (0.54-1.49)	0.682
	>40	146	106 (72.6)	0.50 (0.31-0.82)	0.005
Risk factor	Endemic risk, IDU	90	75 (83.3)	1	
	MSM	511	410 (80.2)	0.81 (0.45-1.47)	0.493
PEP	Never	488	405 (83.0)	1	
History	PEP in the past	93	67 (72.0)	0.53 (0.32–0.88)	0.013
STI in the past	No	244	208 (85.3)	1	
	Yes	358	278 (77.7)	0.60 (0.39–0.93)	0.021
STI diagnosed at	No	528	424 (80.3)	1	
participation	Yes	63	55 (87.3)	1.69 (0.78-3.66)	0.181
Tested for HIV in	No	49	43 (87.8)	1	
the past	Yes	557	447 (80.3)	0.57 (0.23-1.37)	0.201
Partner HIV status	Negative / Unknown	457	371 (81.2)	1	
last 3 months	Positive	43	34 (79.1)	0.88 (0.40-1.90)	0.736
Men reporting UAI with other men -	No	286	221 (77.3)	1	
last 3 months	Yes	197	165 (83.8)	1.51 (0.95-2.43)	0.081
Unprotected sex between men and	No	165	136 (82.4)	1	
women - last 3 months	Yes	72	59 (81.9)	0.97 (0.47-2.00)	0.929
Any unprotected sex	No	310	244 (78.7)	1	
– 3 months	Yes	265	220 (83.0)	1.32 (0.87-2.02)	0.192

Summary T4P appears to an acceptable strategy in the majority of both male and female participants (80.3% and 95.5% respectively). In this analysis we ask a hypothetical question prior to HIV test results. Responses should therefore be interpreted with caution as they may not reflect participants' choices should they be diagnosed HIV positive.

Participants that had taken PEP had a decreased odds of a 'yes' response and this trend persisted in multivariable analysis. We speculate that this association is due to participants having experienced side effects from anti-retrovirals during PEP. It is however important to note that of those participants who had taken PEP 72% would still consider T4P should they be diagnosed.

Men reporting UAI with other men within the last three months had an increased odds of a 'yes' response. This differential acceptability is reassuring as it appears to suggest increased acceptability among the 'riskier' subgroup. The observation that participants with a past history of an STI had decreased odds of a 'yes' response requires further investigation and we postulate that this may reflect past experience of partner notification.

Conclusions

in this survey 80.9% of respondents reported potential acceptability of T4P as a concept. This is in keeping with the modelling projections³ which assumed an acceptability of >75% of those testing HIV positive to observe a significant effect on HIV incidence at a population level.

However, whilst the results of this survey are encouraging it remains critical to examine the *actual* acceptability, deliverability and sustainability of the T4P strategy in order to truly examine the population level impact of such an intervention.

References

- 1. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. 2011 Aug 11;365(6):493-505.
- Draft: BHIVA guidelines for the treatment of HIV-1 infected adults with antiretroviral therapy. 2012; Available from: <u>http://www.bhiva.org/documents/Guidelines/Treatment%20Guidelines/2012/formatted__ART_guidelines_04022012_v3_IW.pdf</u>
- 3. Granich R, Gilks C, Dye C, Decock K, Williams B. Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model. The Lancet. 2009;373(9657):48-57.

