

DBS Study in Bristol – aiming to increase the uptake of HCV antibody testing in IDU

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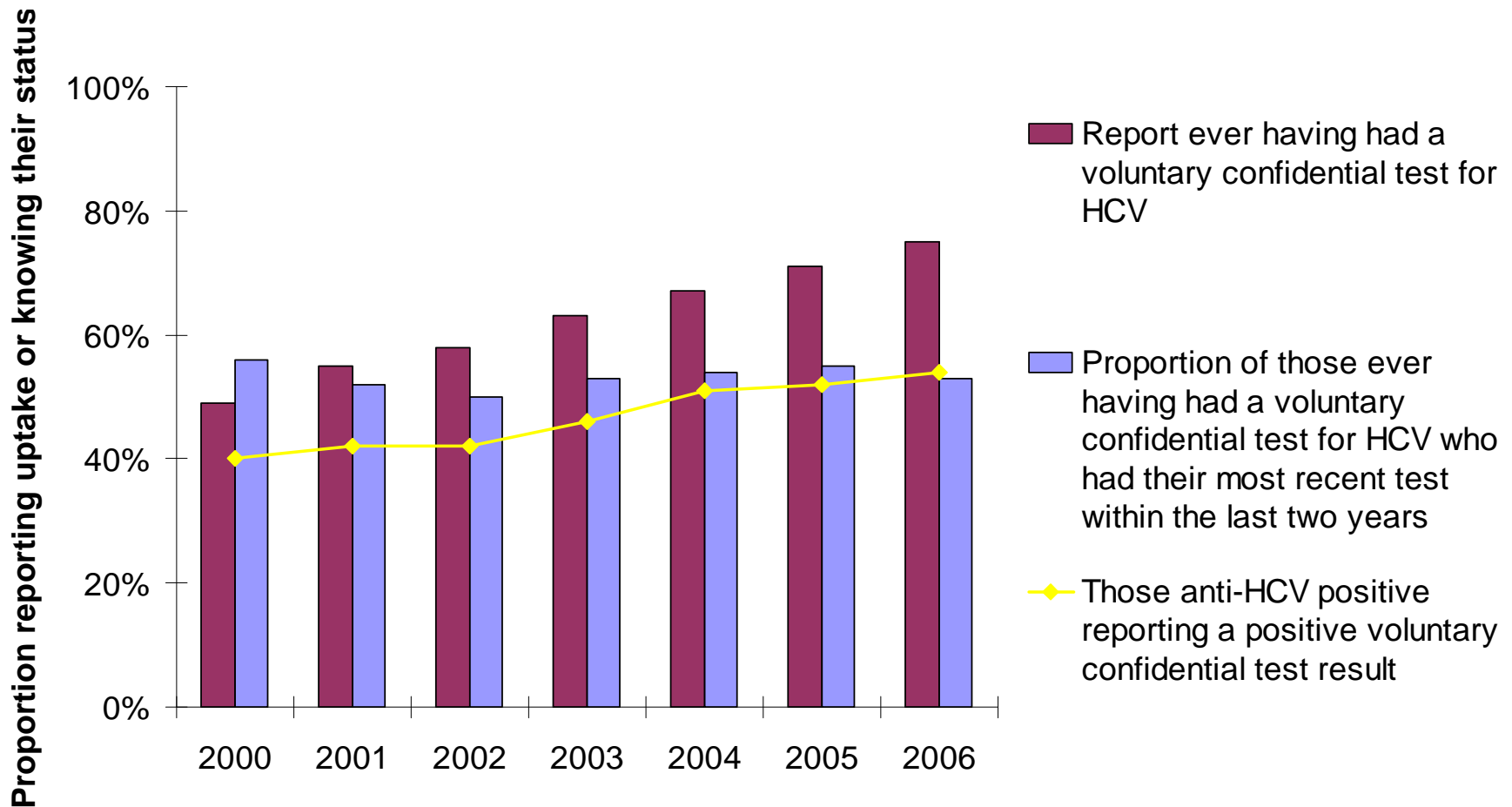
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Hepatitis C

- Public health problem
 - ~200,000 with HCV in England and Wales
 - ~40% current IDU; 45% ex-IDU
- Majority remain undiagnosed
- Vulnerable groups at highest risk
 - >85% diagnosed infections IDU
 - 20-60% IDU HCV positive
- Uptake of testing
 - Poor (e.g. 8.5% uptake reported from prisons *Skipper; Gut. 2003;52:1500-4;*
 - HCV Strategy Target to increase HCV testing
 - NTA Harm minimisation targets 100% testing

% IDU ever HCV tested increasing but < 1/2 aware HCV positive



*Self reports of voluntary confidential test for HCV and the results of the last test.

Trends in uptake of voluntary confidential testing for hepatitis C, and the proportion of those with hepatitis C aware of their infection: IDU England, 2000-2006. Source: Unlinked anonymous survey

Blood borne viruses in Intravenous Drug Users (IDUs)

- DBS in epidemiology:-
- Ongoing high risk/ Incidence of HCV
 - Evidence of recent infection: HCV antibody-ve and PCR+ve
 - In Bristol RDS Study: 14/115 HCV antibody-ve specimens
 - Incidence of 31 to 54 per 100 person years
 - Phylogenetic analysis showed 9/14 sero-converters in same cluster with four anti-HCV-positive specimens: outbreak/ recent transmission among IDU
- Likely to be high number of infections among current and ex-IDU in Bristol
 - estimate 1,900 to 3,350

Can use of dried blood spots provide technological solution, and increase uptake of HCV antibody testing?

- Is poor “regular” uptake of HCV testing among IDU due to
 - problems of venous access?
 - availability or willingness of staff to take blood?
- Propose DBS
 - 99.6% sensitive
 - 100% specific
- Other advantages
 - PCR available April
 - HIV and HBV (antiHBc HBsAG)

Judd et al. Evaluation of a modified commercial assay in detecting antibody to hepatitis C virus in oral fluids and dried blood spots. *Journal of Medical Virology* 2003;71(1):49-55

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Instructions for Use

The Lancet



1 After cleaning the puncture site, **PULL OFF** indicator as directed on tab and place in disposal.

2 Position safety lancet firmly against puncture site as illustrated. Hold lancet between fingers and place thumb on white activation button.

3 To activate, press white activation button **FIRMLY** into colored housing with thumb. Button should lock into housing and should not recoil. **DO NOT** pull lancet away from puncture site until after activation.

4 Gently massage from the hand to near the puncture site, holding hand below elbow level to obtain the required blood volume.

The Needle Lancet



1 After cleaning the puncture site, **TWIST OFF** indicator as directed on tab and place in disposal.

2 Position safety lancet firmly against puncture site as illustrated. Hold lancet between fingers and place thumb on white activation button.

3 To activate, press white activation button **FIRMLY** into colored housing with thumb. Button should lock into housing and should not recoil. **DO NOT** pull lancet away from puncture site until after activation.

4 Gently massage from the hand to near the puncture site, holding hand below elbow level to obtain the required blood volume.

Handle all biologic samples and blood collection "sharps" (lancets, needles, luer adapters and blood collection sets) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury) since they may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-in used needle protector if the blood collection device provides one. Becton Dickinson does not recommend reusing used needles, but the policies and procedures of your facility may differ and must always be followed. Discard any blood collection "sharps" in biohazard containers approved for their disposal.

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Trial Results

SITES	No. of pat's	INTERVENTION % HCV Tested			No. of pat's	CONTROL % HCV Tested			Outcome (% difference): <i>Intervention - control</i>	
		6 mnth< intervention	6 mnth during intervention	% difference		6 mnth< intervention	6 mnth during intervention	% difference		
Drug clinic pairs	1	160	34.0%	29.3%	-4.6%	200	37.1%	15.6%	-21.5%	16.9%
	2	1290	2.3%	3.1%	0.8%	110	0.0%	0.0%	0.0%	0.8%
	3	340	6.0%	12.4%	6.4%	290	6.1%	4.5%	-1.6%	8.0%
	4	420	18.3%	22.1%	3.8%	310	0.0%	0.0%	0.0%	3.8%
	5	250	0.0%	10.4%	10.4%	700	2.5%	2.4%	-0.1%	10.5%
	6	50	27.1%	85.0%	57.9%	60	15.9%	8.5%	-7.4%	65.2%
	7	210	0.0%	2.9%	2.9%	470	6.3%	4.2%	-2.1%	5.0%
	8	410	2.9%	5.4%	2.4%	180	3.8%	1.4%	-2.4%	4.8%
	9	320	1.3%	10.0%	8.6%	1150	1.7%	2.2%	0.5%	8.1%
	10	430	0.0%	5.8%	5.8%	490	0.0%	0.0%	0.0%	5.8%
	11	840	7.1%	8.6%	1.5%	180	2.3%	4.3%	2.0%	-0.5%
Prison pairs	1	920	2.9%	6.6%	3.7%	400	15.4%	18.7%	3.3%	0.4%
	2	270	3.7%	73.3%	69.6%	1000	1.4%	1.6%	0.2%	69.4%
	3	640	12.0%	13.9%	1.9%	260	15.3%	12.5%	-2.7%	4.6%
Average			8.4%	20.6%	12.2%		7.7%	5.4%	-2.3%	14.5%

Intervention sites: Total HCV before intervention 383; After Intervention 791 (DBS 529, 67%)

Control sites: Total HCV before intervention 292; After Intervention 243

Summary Trial Results

- Initial trial - 22 drug clinics 6 prisons
- Corroborate that uptake is low
 - Before trial 8% of patients at control/intervention sites tested for HCV
 - 95% of HCV tests at participating laboratories HCV-ve
- Evidence in support of H_0 that DBS may increase the uptake of HCV diagnostic testing
 - Average % difference - 14.5% (95% CI 1.3% to 28%) paired t-test, $p=0.03$
 - 13/ 14 pairs contribute to positive effect of the intervention - Wilcoxon matched-pairs signed-rank test, $p=0.002$
- Considerable heterogeneity in treatment effect
 - 0 - 34% tested at baseline; 3 – 85% tested after intervention; -0.5% to 69% risk difference
- What else needs to be done?

Hickman et al. Increasing the uptake of hepatitis C virus testing among IDU: a cluster randomised controlled trial. J Viral Hepatitis (in press)

New Study/ Intervention

- Need to strengthen evidence
- NHS NCCRCO funded study to introduce DBS in selected sites to support laboratory development
 - Grant funds testing at HPA Colindale
 - Introduce in selected sites that manage IDU: GP Shared Care, BSDS, BDP
 - Test kits and specimen transport managed by Bristol lab
 - If successful, Bristol lab will be able to take on testing
- Bristol AHR Recommendation: increase HCV testing – pilot use of DBS
- Ethics Informed consent and Patient Information Form to allow lab to use residual sample
- Other
 - Propose larger trial/study in IDTS prisons

