



HepCATT (Hepatitis C Assessment to Treatment Trial) in Primary Care: a cluster RCT of whether a complex intervention based on risk prediction algorithm tool and education can increase testing and diagnosis of HCV in primary care

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HepCATT Trial Team

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🔥 Is targeted case finding cost-effective


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- GPs and practice nurses should offer testing for hepatitis B and C to adults and children at increased risk of infection, particularly migrants from medium- or high-prevalence countries and people who inject or have injected drugs

Hepatitis B and C: ways to promote and offer testing to people at increased risk of infection

Issued: December 2012 last modified: March 2013

NICE public health guidance 43
guidance.nice.org.uk/ph43

- Evidence – weak – no robust trial evidence of interventions to increase uptake of HCV testing
- One small study suggests can increase uptake – and if so likely to be cost-effective



Nice 2012. Cullen J Public Health 2012

🔥 HepCATT trial

HepCATT

Cluster randomised controlled trial. Practices randomised to usual care or receive complex intervention of:

- Training for clinical staff
- Risk prediction algorithm run on AUDIT⁺ software (*Informatica Systems*) Patient invite for testing by letter.
- Reminder “pop-ups” on high risk patients
- Posters/ leaflets in waiting rooms, encourage on-going educational HCV training for practice
- [Request information on injecting history for new patients]



Roberts, K et al. Hepatitis C - Assessment to Treatment Trial (HepCATT) in primary care: Study protocol for a cluster randomised controlled trial. *Trials* 2016; 17:-

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🔥 Outcome measures

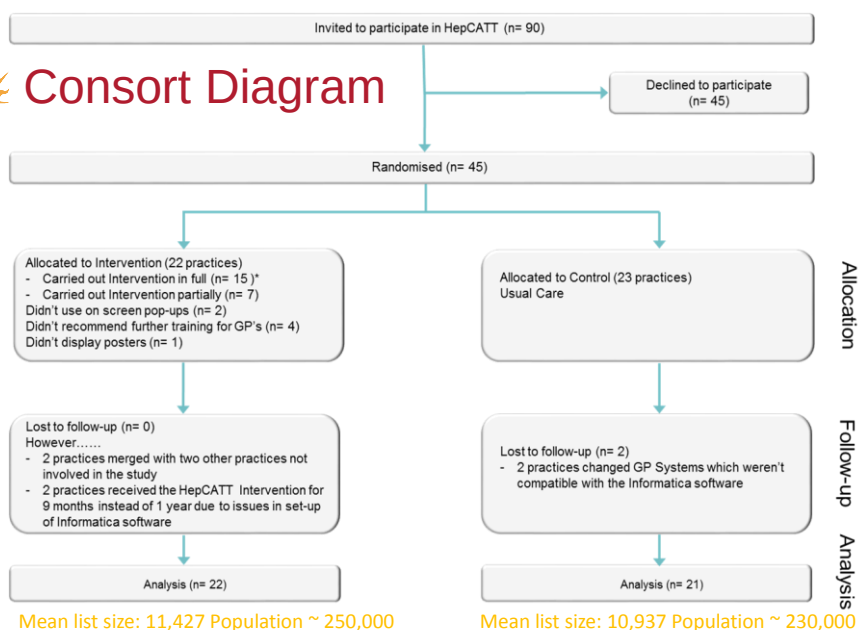
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- Data extracted via AUDIT+ in both intervention and control practices
- In patients identified as high risk over a year the number and proportion of patients
 - tested for HCV (primary outcome)
 - Referred to and engaging with hepatology as evidenced by request for viral load test in linked PHE data (secondary outcome)
- Nested Health Economic and Qualitative studies



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🔥 Consort Diagram



🔥 Risk algorithm

Criteria:	Intervention (n=13,097) Risk criteria+ (%)	Control (n=11,376) Risk criteria+ (%)
History of HCV exposure or testing	8295 (63.3)	6476 (56.9)
History of injecting drug use	2930 (22.4)	3315 (28.8)
History of HIV or HBV infection	971 (7.4)	829 (7.3)
History of blood transfusion <1991	423 (3.2)	378 (3.3)
History of prison/ childhood in care	899 (6.9)	1024 (9.0)
Altered ALT level	5120 (39.1)	3895 (34.2)

🔥 HCV Antibody testing during Intervention

	Intervention (n=13097)	Control (n=11376)			
	Tested (%)	Tested (%)	Rate ratio	95% CI	P-value
Crude	2071 (15.8%)	1163 (10.2%)	1.57	(1.18, 2.09)	0.002
Adjusted ^a			1.59	(1.21, 2.08)	0.001
			Relative RR ^c		
PWID/ Opioid ^b	189/2930 (6.45%)	80/3315 (2.41%)	1.91	(1.45, 2.52)	<0.001^c
Other	1882/10167 (18.51%)	1083/8061 (13.44%)			

a. Adjusted for prior infection and HCV testing rate (low versus high, as indicated by PHE)

b. Subgroups defined by a history of opioid use, injecting OAT. c. Estimated ratio of rate ratios in the two subgroups, with interaction test p-value

🔥 Increase in HCV testing in community

- Background testing of people previously tested for HCV increased
- Potential dilution of intervention effect/contamination?

Practice	Six-month pre-study period Antibody test (%)	Twelve-month study period Antibody test (%)
A (901)	23 (2.55)	86 (9.54)
B (311)	1 (0.32)	33 (10.61)
C (539)	29 (5.38)	43 (7.98)
D (337)	3 (0.89)	33 (9.79)
E (510)	9 (1.76)	27 (5.29)
F (474)	13 (2.74)	71 (14.98)
G (1159)	76 (6.56)	90 (7.77)
H (518)	12 (2.32)	61 (11.78)
I (286)	11 (3.85)	33 (11.54)
J (491)	23 (4.68)	89 (18.13)
K (503)	19 (3.78)	61 (12.13)
L (561)	27 (4.81)	87 (15.51)
M (10)	0	4 (40.00)
N (456)	37 (8.11)	79 (17.32)
O (624)	5 (0.80)	24 (3.85)
P (698)	3 (0.43)	60 (8.60)
Q (713)	14 (1.96)	67 (9.40)
R (1001)	18 (1.80)	54 (5.39)
S (220)	3 (1.36)	40 (18.18)
T (689)	47 (6.82)	101 (14.66)
U (375)	7 (1.87)	20 (5.33)
Overall (11376)	380 (3.34)	1163 (10.22)

🔥 Positive antibody tests and PCR

- Weak evidence that intervention had higher yield
 - 6.2% (129/2071) in intervention vs 4.4% (51/1163) in control (p=0.088)
- Comparatively low yield of chronic HCV cases
 - Intervention: 120/ 129 PCR; 43 Chronic HCV, 60 cleared, 17 insufficient
 - Control: 50/51 PCR; 13 Chronic HCV, 23 cleared, 14 insufficient

🔥 HCV treatment assessment

Group	Yes	Total
Control	3 (0.03%)	11,376
	2.6 per 10,000	
Intervention	20 (0.15%)	13,097
	15 per 10,000	
TOTAL	23 (0.9%)	24,473

Adjusted Risk Ratio: 5.78 (95% CI 1.5 - 21.6) p=0.009

Risk Difference = 1.3 HCV treatments per 1,000 i.e. 792 people flagged as high risk for every additional HCV treatment in primary care



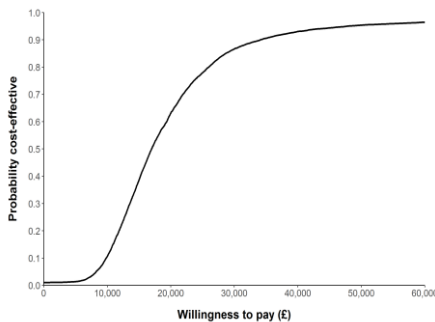
🔥 Is HEPCATT in Primary Care Cost-effective?

Task (per patient)	Intervention	Control	Difference (95% CI)
Training cost	£1.22	£0	
Screening cost	£2.06	£0	
Mean HCV antibody test cost	£5.50	£4.69	£0.81 (£0.58 to £1.05)
Mean HCV PCR test cost	£1.37	£1.01	£0.37 (£0.10 to £0.63)
HCV-related consultation - No - Yes	12,187 (94%) 735 (6%)	10,467 (95%) 507 (5%)	
Mean HCV-related consultation	£2.27	£2.10	£0.17 (-£0.09 to £0.44)
Mean hepatology referral	£0.34	£0.06	£0.28 (£0.11 to £0.45)
Total mean case finding cost	£12.42	£7.80	£6.65 (£4.36 to £8.93)*
HCV Treatment Assessment	0.15%	0.03%	
Cost per additional patient in HCV treatment			£5,214

Excluding training & software installation costs: cost of case finding was £3.50 (£1.76 to £5.23); mean additional HCV treatment assessment £2,746



🔥 Preliminary ICER



Conservative Base case results: ICER of £16,140 per QALY

- Sensitivity analyses all below £20,000 per QALY
- Excluding training - ICER ~£13,000 per QALY
- Incorporating greater linkage to care - ~£6,000 per QALY.

🔥 Summary Qualitative Assessment

- Semi-structured interviews 15 practice staff (GPs, Nurses, practice managers and IT managers). Practices expressed:
 - interest in finding out whether there were any patients at the practice at higher risk of HCV not previously identified.
 - improved knowledge of risk factors for HCV
 - benefits of the audit tool were offset by the time and resources needed to screen patients.
 - some 'Pop-up fatigue'
- Overall practices willing to engage with a complex intervention to identify and test patients – but careful implementation of the intervention needed

🔥 Preliminary Conclusions

HepCATT

- Mixed Methods Cluster RCT
- Strong evidence that intervention increases testing for Hepatitis C amongst high risk patients
 - Largest group identified people with previous HCV test
 - Testing increased in people with opioid/injecting history
 - Even though some “contamination” – increase in HCV testing in controls during intervention



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🔥 Preliminary Conclusions

HepCATT

- Strong evidence for increase in people assessed for HCV treatment. But Modest effect size
 - Risk difference: 1.3 per 1,000 i.e. 1 extra HCV treatment per 792 people flagged
- Low cost intervention highly likely to be CE
 - £6.65 or £3.50 per patient - mean additional HCV treatment assessment ~£5000 or £2,750
 - Baseline ICER ~£16,000 and could be £6,000
- Support from participating practices
- Warrants implementation/ scale-up



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END

🔥 Study Background

- Hepatitis C (HCV) is a blood-borne viral infection - 75% develop chronic infection
- PHE estimate 160,000 individuals in England and Wales with chronic HCV
- 100,000 positive tests – 28% treated
- Treatment is effective
- 30% of all HCV tests (31% positive tests) from GPs
- Some evidence that risk factor based case finding may increase testing



Cullen BL, Hutchinson SJ, Cameron SO, et al. Identifying former injecting drug users infected with hepatitis C: an evaluation of a general practice-based case-finding intervention. *Journal of Public Health* 2012;34:14-23

🔥 HepCATT trial: practices



	Intervention Practices	Control Practices
Total number recruited	22	23
Large practice population list* ¹	7	4
Small practice population list	15	19
High HCV testing rate* ²	4	6
Low HCV testing rate	18	17

*¹ High practice population list: $\geq 13,000$

*² High HCV testing rate: $\geq 1\%$



🔥 HCV Antibody testing during Intervention

Group	No	Yes	Total
Control	10,213 (89.78)	1,163 (10.22)	11,376
Intervention	11,026 (84.19)	2,071 (15.81)	13,097
TOTAL	21,239 (86.79)	3,234 (13.21)	24,473

Rate ratio 1.58 (95% confidence interval 1.25, 1.98) $p < 0.001$



✦ HCV Antibody positive tests

Group	Negative	Positive	Total
Control	1,112 (95.61)	51 (4.39)	1,163
Intervention	1,942 (93.77)	129 (6.23)	2,071
TOTAL	3,054 (94.43)	180 (5.57)	3,234

Risk ratio 1.42 (95% confidence interval: 1.04, 1.95) p = 0.028



✦ Secondary care assessment

Group	No	Yes	Total
Control	11,373 (99.7)	3 (0.03)	11,376
Intervention	13,077 (99.85)	20 (0.15)	13,097
TOTAL	24,450 (99.91)	23 (0.09)	24,473

Risk Difference = 1.3 viral load tests per 1,000, and 792 people identified as high risk for every additional viral load test due to the intervention

