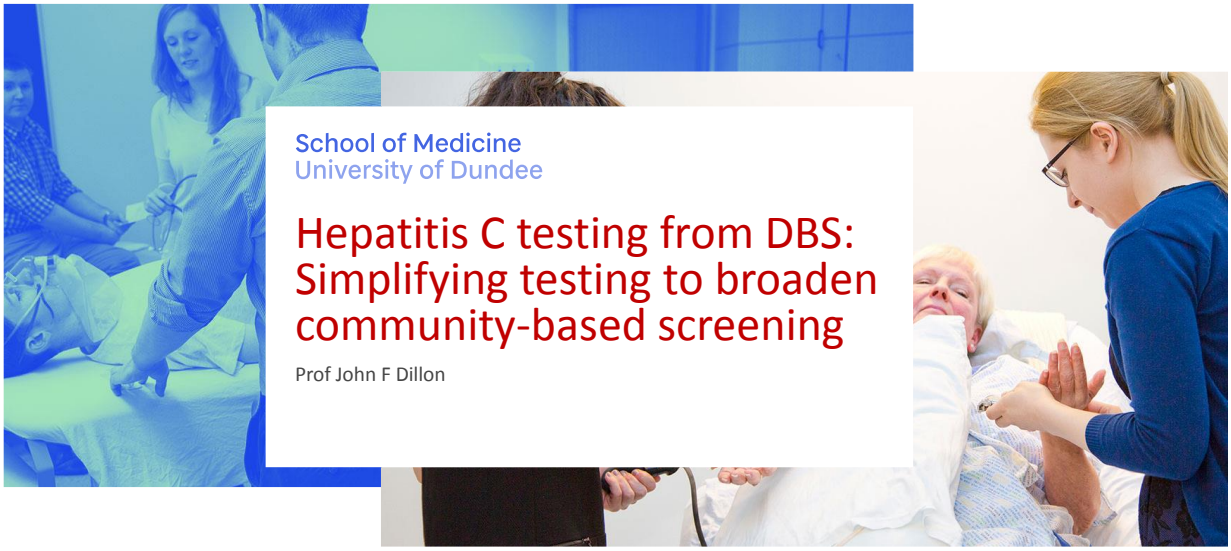
Scottish University of the Year 2017



School of Medicine
University of Dundee

Hepatitis C testing from DBS: Simplifying testing to broaden community-based screening

Prof John F Dillon

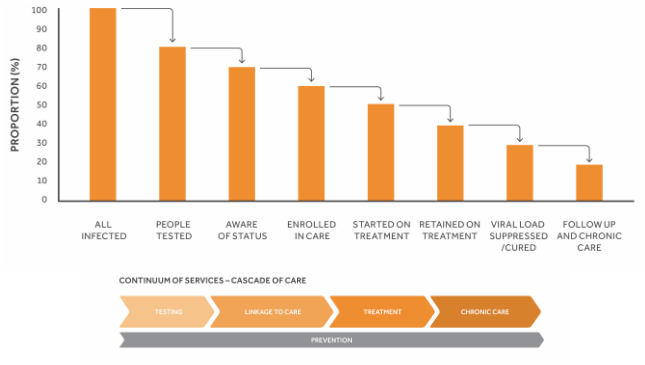
Declaration of Financial Interests or Relationships

Speaker Name: Prof John F Dillon

I have the following financial interest or relationships to disclose with regard to the subject matter of this presentation:

- Grant/research support: AbbVie, Bristol-Myers Squibb, Boehringer Ingelheim, Gilead Sciences, GlaxoSmithKline, Janssen, Merck Sharp & Dohme, Roche, Genedrive
- Speakers Bureau: AbbVie, Bristol-Myers Squibb, Boehringer Ingelheim, Gilead Sciences, GlaxoSmithKline, Janssen, Merck Sharp & Dohme, Roche

The continuum of viral hepatitis services and the retention cascade



Source: WHO Global Hepatitis Report, 2017. Available at www.who.int/hepatitis/publications/global-hepatitis-report2017/en/ (accessed May 2017).

Stigma, Barriers, fear, inflexibility, distance, travel costs, lack of self worth, nihilistic view of future, Ignorance

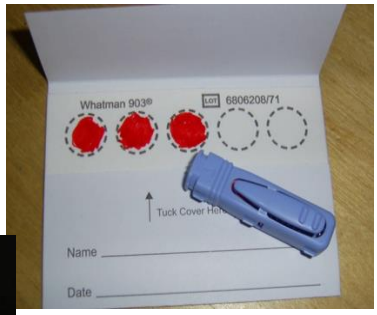
Loss of the benefits of HCV treatment engagement beyond liver health

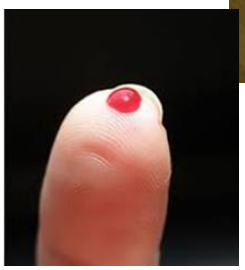
Hook

or

whole package of treatment

What is dried blood spot testing





Conventional testing with elution step

→ It gets sent to the lab

→ It goes in the same machine

→ You get the result back like venepuncture

HCV ab, HIV ab, HCV-PCR & HBsAg

Works where venepuncture difficult, but is more expensive.

Requires little skill and a bit of common sense

Anybody could do it

The legal stuff

Dried Blood spot testing for HCV antibody and PCR validated in over 50 academically lead published studies, plus 100s of lab based validations.

- → It works
- → No doubt about it
  - → If you are positive it is correct
  - → If you are negative your are negative

Not a licensed substrate for the laboratory machines

- → So the companies cannot promote
- → Payers can decide not to fund it
  - → Quality control
  - → Avoiding "quack" tests
  - → Cost control
- → So large problem in countries with a purchaser provider split.
  - → UK widely used
- → To obtain a license for a substrate is expensive

So local negotiation may be the solution

Integrating DBS into clinical care

What were the challenges in terms of getting people (both clients and providers) to accept this as a testing strategy?

- → Clients
  - → Right there, Right then no problem
  - → With a trusted and or known worker
- → Providers
  - → "Why should we do your job"
    - → It makes your outcomes better
    - → It builds your therapeutic relationship
    - → It is the right thing to do for your client
  - → Costs
    - → Covered from HCV services
    - → Training provided by HCV services

PREFERENCES FOR HEPATITIS C TESTING: APPLICATION OF A DISCRETE CHOICE EXPERIMENT WITH METHADONE USERS IN TAYSIDE, SCOTLAND

Preference	Willing to Wait
Own rather than other pharmacy	4.25 weeks
Own pharmacy rather than GP	2.11 weeks
Own pharmacy rather than drug worker	0.08 weeks
Treated with respect	7.42 weeks

Simplifying the technology
Dried Blood Spot test Roll out for HCV in Tayside

Conventional testing with elution step

HCV ab, HIV ab

HCV-PCR & HBsAg

Works where venepuncture difficult

Over 250 staff trained in Blood spot testing, mainly 3rd sector

HCV testing has become embedded in clinical practice (centres across Tayside)

→ Drug problem centres

→ Drug Testing and Treatment Order

If you can test or read a test result you can refer

→ Prisons

→ Needle exchanges

→ Addaction

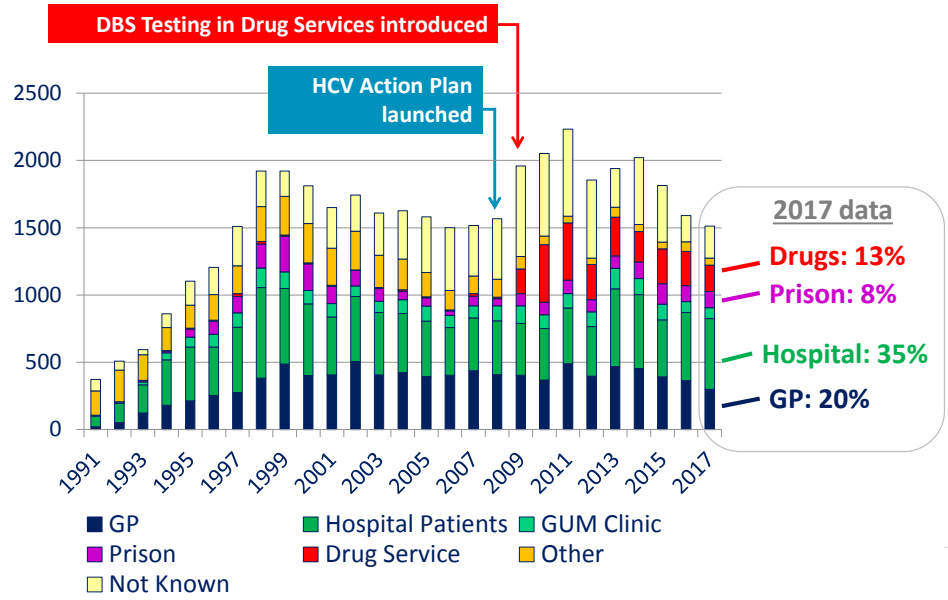
81% of tests are carried out by support workers, without clinical qualifications

Does dried-blood spot testing enhance HCV screening and linkage to care

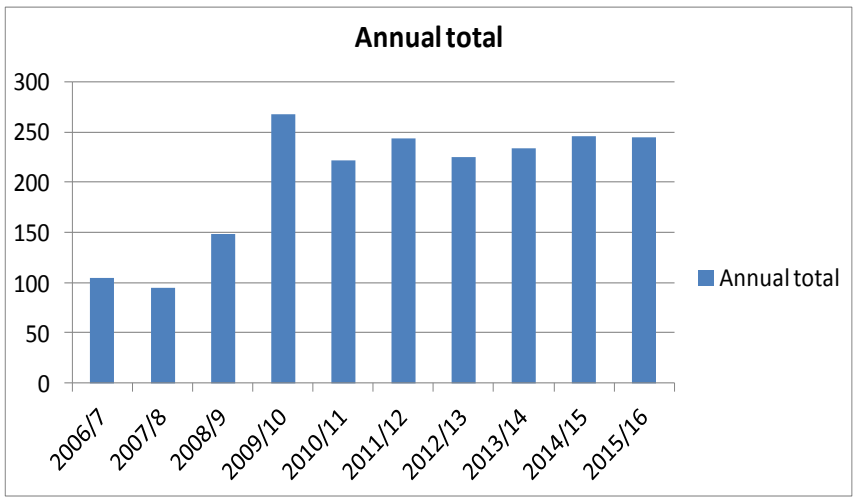
A systematic review of DBS testing

Title	*Study type*	*Population*	*Risk factors for HCV infection*	*Intervention*	*Results*
Craine et al 2014	Stepped-wedge cluster-randomised controlled trial	UK prison population across 5 prison sites	Prison inmate, other risk factors unknown.	Introduction of DBS testing for HCV, HBV and HIV with staff training.	No significant increase in testing on intention-to-treat analysis **OR 0.84 (95% CI 0.68-1.03) P = 0.088**.
Hickman et al, 2008	Cluster-randomised controlled trial	Clients of 28 substance misuse clinics and 6 prison inmates	Attendance at substance misuse clinic or prison inmates.	Introduction of DBS testing for HCV with staff training.	**Mean 14.5% (95% CI 1.3-28%) P=0.033 increase** in testing across all sites.
Craine et al, 2009	Clinical audit	All attendees at a single substance misuse service	History of injection drug use.	Introduction of DBS testing for HCV, HBV and HIV with staff training.	**Increase in testing from 35 in year 2006/07 to 202 by 2007/08**
Tait et al, 2013	Prospective cohort study	Substance misuse clinics and needle exchanges	Access needle exchange or drug treatment services.	Introduction of DBS testing for HCV and HIV and later also HBV with staff training.	**Increase in new diagnoses of HCV from 32.1/100,000 to 68.5/100,000.**
Abou-Saleh et al, 2013	Prospective cohort study	Substance misuse clinics, needle exchanges, and prison.	90.3% had injected in the past,	Introduction of DBS testing and self-administered DBS testing.	Average rate of client testing per 3 months **increased from 1.75 to 52.** Prison inmate testing rate per 3 months **increased from 0.5 to 43 clients**.
McLeod et al, 2014	regression analysis of retrospective testing data	Four largest Scottish health boards.	Not available.	Introduction of DBS testing alongside nationwide action plan.	Following introduction of DBS testing 3 fold increase in testing **(RR=3.5 P<0.001)** and 12 fold increase in positive anti-HCV antibody results **(RR=12.1 P<0.001)**

Annual number of persons newly diagnosed with anti-HCV in Scotland, by year and setting



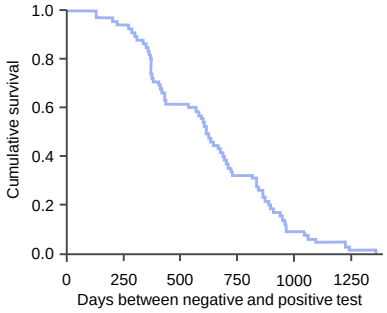
Impact of DBS on new HCV diagnosis



Data Source: Locally held data from NHS Tayside

Infection in a needle exchange
The First Requirement of Elimination

HCV-free survival in a needle exchange programme: the unexpected benefits!



Know who your patients are

Know where to find them

Have easy diagnostic tests

Develop easy pathways of care

Make treatment easy

Audit data, BBV MCN, NHS Tayside

What do you need to treat HCV?

What do you really need to cure HCV?
With simple pan genotypic drugs

DBS only

Current Tayside practice
But can be varied to suit the patient

1. Diagnosis made on DBS (HCV ab and PCR, HIV, HBV) or venepuncture by non specialist, referred by who ever did the test
2. Visit 1 Seen by Nurse specialist (or the Community Pharmacist who did the DBS)
    1. Protocol history (age and alcohol history)
    2. Bloods for FBC, LFTs, Fib 4, HCV PCR if not possible before,
        1. Genotype (only if cost difference)
        2. Start treatment
3. Virtual review of results, decide if ultrasound/fibroscan/duration of treatment/follow up
4. Visit 2 SVR

Integrating Community pharmacy into HCV treatment

A key role in opioid substitution therapy and a local community resource

Specialist prescribing or GP prescribing

→ Drug treatment centres specialist assessment

→ Some dispensing

→ Especially for early or unstable patients

Dispensing in community pharmacy

→ Daily

→ Twice or thrice weekly

→ Weekly

Local

→ Distance 0.5 km average Scottish urban location

→ Across Scotland, average 20 minutes travelling time

→ Normally 'in the high street'

→ Wide range of medical and personnel care products

→ Contractual payments for care

→ 'Prescription for Excellence'

Highly trained healthcare professional on site

Dried blood spot testing in Tayside, Scotland

A quasi-experimental evaluation of DBST through community pharmacies in the Tayside region of Scotland

Pharmacy site	Number of eligible patients	Number of tests taken (% of eligible patients)	Number of positive tests
A	23	13 (57)	3
B	22	11 (50)	4
C	30	5 (17)	3
D	26	10 (38)	1
E	26	3 (12)	1
F	16	1 (6)	0
Totals	**143**	**43 (30)**	**12**

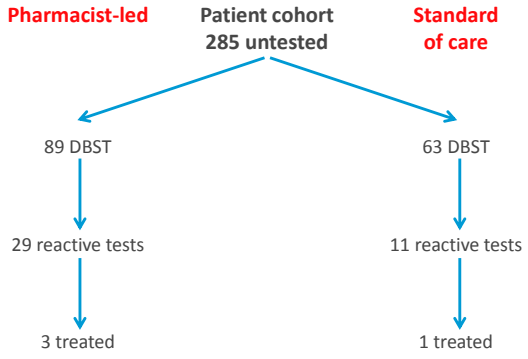
The OR for increased uptake of testing within the 6 pharmacies was 2.25 (95% CI 1.48 to 3.41, Z statistic = 3.81 p = <0.0001) in comparison to the other services

Radley A, et al. Frontline Gastroenterol 2017;0:1–8

CI: confidence interval; DBST: dried blood spot testing; OR: odds ratio

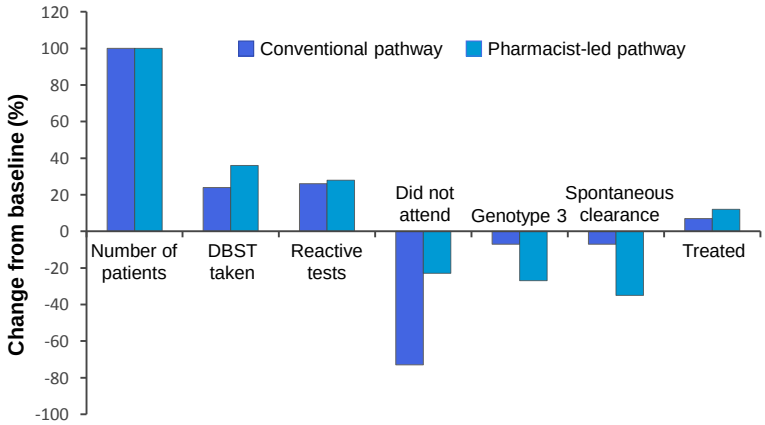
HCV testing and treatment in 8 community pharmacies

DOT-C: A pilot cluster randomised controlled trial



Radley A, et al. Unpublished data (manuscript under review)

DOT-C: waterfall plot of treatment attrition



Radley A, et al. Unpublished data (manuscript under review)

- DBS works, find a way to use it
- It reaches the parts other tests can't
- Its simple anyone can do it
  - Let them do it
- Make sure it links to treatment and cure
- It Saves Lives

Acknowledgements

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