

A Quasi-Experimental Evaluation of Dried Blood Spot Testing through Community Pharmacies in the Tayside Region of Scotland.

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Running Head:

Dried Blood Spot Testing in Community Pharmacies

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A Quasi-Experimental Evaluation of Dried Blood Spot Testing through Community Pharmacies in the Tayside Region of Scotland.

Abstract:

Objective: Comparison of uptake of dried blood spot testing (DBST) for Hepatitis C infection (HCV) between community pharmacies and established services.

Design: Quantitative evaluation of a service development with qualitative process evaluation undertaken in parallel.

Setting: Six pharmacies from 36 community pharmacies within Dundee City, a large urban settlement with high levels of socioeconomic deprivation.

Participants: Patients in receipt of Opioid Substitution Therapy (OST) not tested for Hepatitis C within 12 months. The 6 pharmacies provided OST for approximately 363 patients from a cohort of 1,385 patients within Dundee City.

Intervention: Provision of DBST by pharmacists.

Main Outcome Measure: Receipt of DBST between January and December 2014

Results: 43 of 143 service users with no record of testing from the 6 community pharmacies accepted a DBST. Of 561 from remaining 1022 service users with no record of testing, 75 were tested for HCV (30% Vs 13%). 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 $p = <0.0001$) compared to other services. The DBST taken by the pharmacies provided 12 patients with a reactive test. The process evaluation identified key themes important to staff and recipients of the service. A logic model was constructed.

Limitations: Non-experimental service evaluation performed in community pharmacies records service activity in one location across single time period.

Interpretation: Some evidence that DBST from community pharmacies may be feasible. Service users received the service positively. Staff reported that DBST was straightforward and achievable.

Background

Hepatitis C (HCV) is a blood-borne viral infection causing liver disease. Around 1% of the population may be infected with HCV and around 0.8% are chronically infected¹. The greatest risk of acquiring the virus in the UK is through injecting drug use. Patient outcomes from HCV infection vary, with 25% clearing the infection spontaneously and the remainder becoming chronically infected, risking development of cirrhosis and hepatocellular carcinoma. People infected with HCV may show no symptoms, presenting with incurable, end-stage disease. A recent Public Health England report highlighted that less than 3% of those known to be infected with HCV are being treated and less than half of those infected are known². The largest single infected group are those on opiate substitution therapy (OST)³. Research suggests around 40% of people receiving OST have HCV^{4,5}.

The conventional NHS pathway of care is that patients with a history of intravenous drug use or those currently prescribed OST should be offered HCV testing¹. Testing is commonly available from a range of primary care and third sector providers. Once diagnosed, patients may be referred to nurse led treatment pathways, based around hepatology or infectious disease teams in secondary care.

In current pathways, less than 10% of the OST population are tested for HCV. Of those tested, at very best 25% start treatment in one of the dedicated centres, with 70-80% successfully completing. This means that only 2-3% of this vulnerable population receive adequate treatment². The new highly effective Directly Acting Antiviral (DAA) drugs achieve cure rates in excess of 90%, with once or twice daily tablets for 8-12 weeks and few side-effects⁶.

The use of Dried Blood Spot Testing (DBST) in non-traditional environments has dramatically increased detection of HCV^{7,8}. DBST has been shown to be a reliable alternative to taking venous blood samples and determining HCV status in drug injectors. With appropriate training it can be carried out by all staff. Several practice-based projects have sought to implement DBST into pharmacy practice⁹.

Pharmacists have daily interactions with patients receiving methadone and we hypothesised that this relationship could be wielded to deliver increases in rates of testing using a DBST approach. To test this we employed a quasi-experimental design¹⁰ to compare the uptake of DBST for HCV in a small group of community pharmacies, with uptake in established services (those in substance misuse services, general practices and in third sector organisations).

Methods

A quasi-experimental design was chosen as a pragmatic route to evaluate the feasibility and scalability of a service development in community pharmacy, because of uncertainties about the effect size and nature of the intervention ¹¹.

This study was carried out in the city of Dundee, within the Tayside region of Scotland, a large urban settlement with significant socio-economic deprivation ¹². There are 36 community pharmacies that provide OST for approximately 1,385 patients, within a total population of 148,000 ¹³. Six pharmacies were trained to offer DBST. Pharmacies were selected if they provided OST supervision for at least 30 patients and staff were willing to participate. Patients in the comparator group were prescribed OST and attended a community pharmacy that did not offer DBST.

Design of the Intervention

Focus group interviews

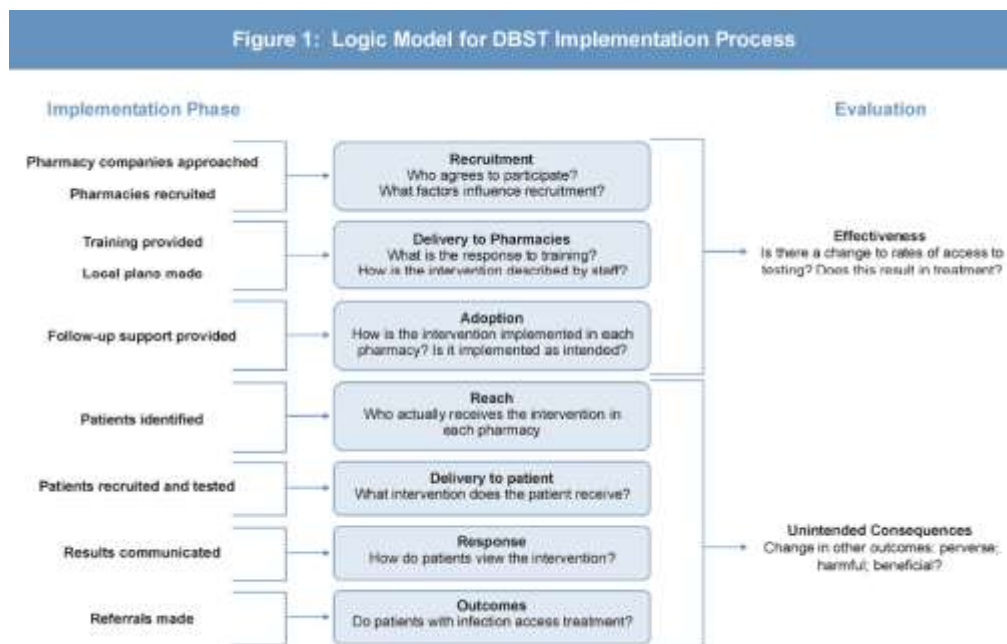
A focus group series was undertaken before implementation to identify service user responses to the offer of testing, utilising a co-production approach ¹⁴. A purposive sampling strategy recruited 41 participants in 7 focus groups, to gain a diversity of views (Table 1). All interviews and focus group discussions were recorded as digital audio files and transcribed in full for thematic analysis ¹⁵. Analysis drew on the constant comparison method, operationalised within a general thematic approach ¹⁶.

Table 1: Focus Group Participant details

		Number of Participants
Age group at participation	Less than 35 years	17
	35 – 44 years	5
	45 – 54 years	6
	Over 55 years	4
	Did not disclose	9
Sex	Male	31
	Female	10
Participant category	Service User	38
	Carer	3
Focus Group Venue	Large Urban Settlement	10
	Other Urban Settlement	10
	Accessible Rural Town	6
	Prison Educational Centre	7
	Women's Group	4
	Peer Mentor's Group	4

Development of Programme Theory

Figure 1 describes a logic model that was constructed to explicitly identify targets for evaluation and data collection. The process evaluation took cognisance of Normalisation Process Theory¹⁷ using the core constructs of coherence, cognitive participation, collective action and reflexive monitoring to conceptualise the processes involved with effectiveness of implementation.



Implementation of DBST

Staff from the six community pharmacies were trained to perform DBST to consenting patients¹⁸. DBST employs a finger prick of blood, spotted onto protein saving paper. The sample was tested by Medical Microbiology for HCV, HIV and Hepatitis B antibodies⁷. Fourteen staff members from the pharmacies attended a 2 hour interactive teaching session. The six pharmacies were notified which of their OST patients had no history of HCV testing, as identified by the central virology laboratory. Testing for HCV was offered to each of these individuals. All individuals with a reactive antibody HCV test were offered referral to the specialist hepatitis service.

Participants' comments during the training were noted and each pharmacy was visited several times to discuss progress. Notes of these interactions and e-mails from participants were retained for analysis. Testing took place during the last quarter of 2014.

Post-Testing Interviews

Semi-structured interviews were conducted with (i) 8 service users and (ii) 10 professionals taking part in the study, with all 6 pharmacies represented. The interviews were conducted using two topic guides developed in line with the research aims and programme theory. All interviews were recorded as digital audio files and transcribed in full for thematic analysis^{15, 19}. These data contributed to assessment of feasibility and acceptability (including barriers and facilitators); identifying any unintended consequences of participation. Transcripts were inductively analysed to identify themes emergent from the interviews. A deductive analysis was also undertaken to compare findings with programme theory.

Quantitative Data collection and analysis

Data on demographic information, risk factors, laboratory tests, referral, follow-up and treatment were collected. The age structures of the intervention and comparator groups were compared by t-test, as were data on DBST taken by the pharmacies. An odds ratio was calculated for the numbers of service users undertaking testing at pharmacies compared to non-pharmacy services.

Ethics Approval

Study documents were submitted to the East of Scotland Research Ethics Service, who confirmed that this work did not require Ethical Approval under its terms of the Governance. Caldicott permission was gained to enable access to and analysis of patient information.

Results

The age structure of the 143 service users (26% of all OST users) with no record of testing from the 6 pharmacies, together with the 1022 service users of the comparator group are presented in Table 2.

Table 2: Age structure of service users prescribed OST in Dundee

Age	Intervention Cohort	Intervention Cohort (%)	Comparison Cohort	Comparison Cohort (%)	Total Population	Total Population (%)
<19	0	~	0	~	0	~
20-24	14	4%	23	2%	37	3%
25-29	51	14%	133	13%	184	13%
30-34	112	31%	256	25%	368	27%
35-39	86	24%	239	23%	325	23%
40-44	61	17%	185	18%	246	18%
45-49	26	7%	120	12%	146	11%
50-54	10	3%	48	5%	58	4%
55-59	3	1%	16	2%	19	1%
60-64	0	0%	2	0%	2	0%
65-69	0	0%	1	0%	1	0%
	363	100%	1023	100%	1386	100%

Analysis of the age structure of intervention and comparator groups was undertaken. A significant difference between the two groups was detected using the two-sided t-test ($p < 0.05$). The intervention group were younger by 1.75 years (mean age of 35.6 years) compared to the comparison group (mean age of 37.4 years). The study design meant that intervention and comparison groups were not randomised, and therefore equal mean ages of the two groups were not expected.

During the test period, 43 (30%) of the 143 service users from the six community pharmacies accepted a DBST. Within the comparator group 561 from 1022 service users had no history of DBST and a total of 75 (13%) patients were tested for HCV by other providers of DBST (30% Vs 13%). The OR for increased uptake of testing within the six pharmacies was 2.25 (95% CI 1.48 to 3.41, Z statistic = 3.81 $p = < 0.0001$) in comparison to the other services (Table 2). The six pharmacies identified 12 patients with a reactive test. The uptake of DBST by each of the six pharmacies is presented in Table 3. No significant difference in uptake between the sites could be detected at the $p < 0.05$ level using two-sided t-testing.

Table 3: Uptake of testing by pharmacy site

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

Understanding of context for delivery

Themes identified from transcript analysis of the focus groups provided information about the context for delivery²⁰. Focus groups discussions demonstrated an understanding of HCV including latency and effects on general health (Figure 2). Participants could talk about cirrhosis and cancer. Participants knew about the burden of treatment of interferon-based regimes. Several clients knew about the cost of the new treatments.

Hepatitis C was viewed as a “dirty disease” caught from sharing needles. It was unacceptable to admit to having HCV and participants feared social exclusion if found out. Participants described the shame they expected to feel if their family discovered they had HCV and spoke about “letting them down”. The fear of being found out contributed to reticence about testing.

What factors influenced client recruitment and participation?

The transcripts from the post-test interviews demonstrated that service users had both positive and negative perceptions of testing. Interviewees clearly thought that pharmacies were a good place to be tested and valued this service and the positive relationships built with pharmacy staff. Lack of money meant travelling to a local hospital was a barrier to clinic attendance. Service users talked vividly about their diminished horizons: they felt this was due to their dependence on drugs and lack of money. Pharmacies however were viewed as part of the local community.

Some service users’ previous experiences of stigma and discrimination when attending a pharmacy led to caution and suspicion when they were offered testing. One client complained that they were offered DBST stood at the dispensary counter, rather than in the private consultation room. Clients with negative experiences suggested staff would need intensive training before offering the service. Some clients expressed the wish for a better explanation about how the test worked and what the results might mean. Clients with positive experiences raised no issues for service improvement.

Several interviewees distinguished themselves from other “junkies”. These interviewees would describe their plans for recovery and would describe their relationship with a partner or young family. These individuals believed that service users with more chaotic lives were less likely to be tested.

What feedback on staff training and implementation was received?

Staff interviewees had clear views about successful implementation. Staff considered that strong leadership and involving all the team were necessary. Comments such as “a great opportunity”, “an obvious thing to do” and “a no brainer” were made. The degree of enthusiasm for new roles and positive relationships with patients were important. Only one individual viewed the development “as a step beyond what pharmacies do”. There were some initial anxieties expressed about potential contact with infected blood. Some staff viewed DBST as a pharmacist’s role, whereas others thought it was a team role.

The training was evaluated positively, with comments received about the simplicity of DBST. Several teams took lancets and protein-saving cards with them to practice the technique. Implementation was viewed as most successful where all the team were involved.

Some staff expressed concern about offering DBST when prescription dispensing workload was high. An identified solution was to use time slots when workload was less. Time barriers were most important where DBST was seen as a pharmacist role

Figure 2: Examples of focus group quotations

What do service users understand by hepatitis C infection and how they obtain testing and treatment?
<p>Perceptions of disease</p> <p><i>“my daughter and partner have it. It can lie dormant. it makes you feel very tired and you have no appetite” (Participant 5, Carer, December 11)</i></p> <p><i>“You could have hepatitis even though, you could be stable on methadone for years then find out you’ve got hepatitis” (Participant 35, 22 April)</i></p> <p>Perceptions of testing and treatment</p> <p><i>I think more people have got it done since they started doing that ‘cause it’s easier (DBST) (Participant 37, 22 April)</i></p> <p><i>“What they do is they have a look at your white blood cells count and things like that and how your system is reacting to it and whether or not. See, when you get the finger prick test for Hepatitis it’ll, if you have been exposed to the Hepatitis virus at all, it will come back positive. That doesn’t</i></p>

necessarily mean to say that you have got Hepatitis, so what they then is they will do a blood test and start talking about counts and things like that as its really confusing” (Participant 19, 25 February)

You see my partner is really skinny as it is and I think he will loose, everybody;s different are they, I think he will loose a lot of weight and I think it affects them mentally as well (Participant 33, 7 March)

Preferences for obtaining treatment

It would have tae be someplace where dinnae have tae travel everywhere where its gonnae cost them money that they have nae always got that’s, that’s what I feel is a big thing having tae travel tae Ninewells all the time (Participant 27, 5 March)

I think that’s one of the things that’s gonnae be down tae the individual, it depends on how chaotic their lifestyle is otherwise there’s gonnae be a lot of money wasted there. And I take it this new stuff isnae cheap coz it never is when its first introduced. (Participant 22, 5 March)

“Well I say your pharmacy because like I say you’re there every day, you’re only, some people dinna even go to the DPC once a month. So and then you forget your appointment, some people forget their appointment at the DPC but you’re guaranteed to go for your methadone every day so” (Participant 36, 22 April)

Aye but you could be going tae the pharmacy for anything you see, so this again de-stigmatising. Nobody knows what they’re in there for, it could be a drug problem it could be... anything (Participant 19, 25 February)

Discussion

Key findings

This study provides some evidence that pharmacies may be a feasible site from which to offer DBST. People receiving OST were more likely to accept a DBST from a pharmacy than from other local providers. The evaluation of the implementation provides some evidence of the context for delivery and the mechanisms that may lie behind the outcomes observed²⁰. Contextual factors included: expectations and experiences of stigma and discrimination; fears about confidentiality; the limited horizons of people receiving OST and the poverty they experience. Identified mechanisms that may influence uptake included the presence of established relationships with pharmacy staff; a pre-existing reason for attending the pharmacy for OST and the proximity of the pharmacy within the local community.

Review of programme theory

The programme theory provided a useful structure from which to consider the process evaluation and enabled a series of insights into the barriers and facilitators to effective implementation. In particular, we valued insights into the context that testing in pharmacies created for service users and the meaning that such testing may have. The evaluation also provided an indication about how the attitudes and behaviours of staff towards the intervention contributed to success or otherwise.

A number of barriers to uptake of testing and treatment including fear of blood tests²¹, adverse socioeconomic and family circumstances, as well as fear of treatment side-effects were identified in other studies as well as being identified in this study²². Evidence suggests that offering DBST may increase the uptake of HCV testing, when compared to venepuncture, although this finding may also reflect increased availability and access when a DBST technique is used^{7, 23, 24}. Community-based settings for HCV services may also increase acceptance and uptake of testing^{25, 26, 27, 28}. Provision of on-site testing may also have positive effects on uptake, due to the proximity of the testing offer²³.

Different settings have been used to increase the uptake of testing and treatment including testing from methadone maintenance services^{29, 30}, in city homeless shelters²³ and mental health sites²⁶. Little work has utilised the daily interaction with community pharmacists to increase testing, follow-up and treatment adherence. A pilot project introducing DBST in a community pharmacy was undertaken in England in 2009^{31, 32}. The pilot concluded that community pharmacies provide a useful route to diagnosing HCV patients and could successfully reach at-risk groups. The pilot service was most successful when pharmacists worked closely with local drug services and where pharmacists were proactive in discussing risks with clients. Several limitations were noted, including the availability of consultation rooms in pharmacies, the provision of adequate staffing to manage the normal workload of a pharmacy and also the motivation and commitment of the pharmacist to support this new activity. Similar factors were identified in this current study. The provision of clinical standard consultation rooms is now very common in Scotland.

The stigma associated with both OST prescription and HCV infection was strongly recognised in this study. A systematic review of qualitative research into Hepatitis testing, recommended framing the positive outcomes of testing in terms of responsibility for individual health and the health of family and community, building positive relationships and targeting stigmatising attitudes²³.

Limitations

The primary limitation of the current feasibility study is the small group of pilot pharmacies. Further work is now required to establish stronger evidence that pharmacies can positively influence uptake in a greater variety of locations.

The intervention group had a slightly lower average age than the comparator group. Since patients on OST undertake a pathway to recovery, a younger patient group may be expected to have a less stable situation than an older group and be less motivated to engage in healthcare interventions.

Some variance in service delivery is common place in pharmacies and in health services generally. The variance may be explained by a range of factors including staffing levels, building configuration, profile of the client group, as well as staff attitudes. With more experience of delivering training for and services, as well as role acceptance, it is expected that some of the variance will diminish.

Interpretation

The study design provided a rapid and simple method of demonstrating that the systems required for DBST testing can be established successfully in community pharmacies. The daily attendance at the pharmacy provides an unexploited opportunity to deliver health interventions. OST recipients usually lived a short walk from their pharmacy

An increase proportion of OST service users accessed DBST from a pharmacy, compared to other providers. Knowledge of potential issues with implementation should assist with creation of effective service delivery. Further work to evaluate the outcomes associated with this service configuration is required³⁴. The identified barriers to the uptake of testing in this study were overcome by local availability of the pharmacies and positive relationships with pharmacy staff.

Reporting guideline: Trend Statement –

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Competing Interests:

Andrew Radley

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