Original research

Are all blood-based postal sampling kits the same? A comparative service evaluation of the performance of dried blood spot and mini tube sample collection systems for postal HIV and syphilis testing

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ABSTRACT

Objectives We comparatively evaluated two HIV and syphilis blood sampling kits (dried blood spot (DBS) and mini tube (MT)) as part of an online STI postal sampling service that included tests for chlamydia and gonorrhoea. We aimed to see how the blood collection systems compared regarding sample return rates and result rates. Additionally, we aimed to observe differences in false-positive results and describe a request-to-result ratio (RRR)—the required number of kit requests needed to obtain one successful result.

Methods We reviewed data from an online postal STI kit requesting service for a client transitioning from MT to DBS blood collection systems. We described service user baseline characteristics and compared kit requests, kit and blood sample return rates, and the successful resulting rates for HIV and syphilis for MT and DBS. Pearson's χ^2 and Fisher's exact test were used to determine statistical differences, and statistical formulae were applied to produce CIs for differences in proportions.

Results 5670 STI postal kit requests from a Midlands region were reviewed from 6 September 2016–2 January 2019 (1515 MT and 4155 DBS). Baseline characteristics between the two groups were comparable (68.0% female, 74.0% white British and 87.5% heterosexual, median age 26 years). Successful processing rates for DBS were 94.6% and 54.4% for MT (p<0.001) with a percentage difference of 40.2% (95% CI 36.9% to 43.4%). The RRR for MT was 2.9 cf. 1.6 for DBS. False-positive results for MT samples were 5.2% (HIV) and 0.4% (syphilis), and those for DBS were 0.4% (HIV) and 0.0% (syphilis).

Conclusions This comparative analysis demonstrated the superior successful processing rates for postal DBS collection systems compared with MT. Reasons for this included insufficient volumes, high false-positive rates and degradation of blood quality in MT samples. A postal sampling service using DBS to screen for HIV, syphilis and other blood-borne viruses could be a viable alternative.

INTRODUCTION

The landscape for HIV and STI testing is changing, with postal sampling kits being increasingly adopted as part of eHealth.[1] In England, there remains a large effort to increase the uptake of HIV testing and to expand accessibility to HIV testing, without increasing demands on staff.[2 3] Expanded HIV testing has been recommended by Public Health England (PHE) and the National Institute for Health and Care Excellence (NICE) for individuals who reside in areas where the local HIV prevalence is considered high (2–5 per 1000 people) or extremely high (>5 per 1000 people).[4]

A national HIV self-sampling postal service was available in England for key populations, and between November 2015 and October 2017, this service was routinely commissioned by 55% of local authorities, distributing over 122 000 kits with a 57% return rate.[5] The need for remote ways to access STI and HIV tests intensified during the 2020 COVID-19 pandemic. The impact of COVID-19 on sexual health provision was assessed by the British Association of Sexual Health and HIV (BASHH) via a sexual health survey, which found a number of STI services had a significantly reduced footfall.[6] Some responders identified that there was a need for, '…affordable (or free) online STI/blood-borne virus (BBV) testing services (without age limitations)'.[7]

There are two methods of postal blood-based STI/HIV collection in England, which both use capillary blood sampling. Mini tubes (MTs) are the most common postal blood collection device, typically requiring 500 µL of serum to process samples for HIV and syphilis, compared with ~200 µL for dried blood spot (DBS). DBS uses a specialised filter paper, where sampled blood is absorbed and can remain stable for months until it is processed.[8] The processing of DBS samples requires an additional sample resuspension step prior to analysis, making them more costly, with fewer laboratories accredited to analyse them.[9]

Despite the availability of many postal sampling services for STIs and HIV, there are very little data on the effectiveness of the multistep processes undertaken to get from an online kit request to the user being provided with a meaningful result.

In 2018, we published a comparative evaluation of the processing successes for DBS and MT blood sample collection kits for HIV testing within a North-West (NW) of England sexual health clinic.[10]

We concluded that DBS collection for HIV had significantly better processing and analysis rates, owing largely to insufficient volumes of blood obtained by the users when using MT.[10] We acknowledged that it was a small study (a total of 550 kits: 275 MT and 275 DBS) and identified that a similar larger-scale study in a different location was required to confirm our findings.[10]

We now present a similar comparative service evaluation for a Midlands-based sexual health service, where we additionally include syphilis antibody testing as part of the processing analysis. We aimed to ascertain how DBS HIV antigen/antibody and syphilis antibody sampling kits compared with MT kits for this postal testing service. We worked with the HIV and sexual health awareness charity, Saving Lives, who had developed a postal STI and HIV sampling service (TakeATestUK.com) in collaboration with their partners and PHE Birmingham laboratories.

The primary objectives were to record the STI kit request and subsequent return rates, and to determine the proportion of blood samples successfully processed and analysed for MT and DBS kits. Secondary objectives were to describe the request-to-result ratio (RRR) (the required number of kit requests to obtain one successfully processed result) and the proportion of false-positive results for DBS and MT.

METHODS

Design

This real-world evaluation compared MT and DBS blood collection kits, focusing on its processing performance as part of an STI postal sampling kit which additionally contained kit for chlamydia and gonorrhoea sampling. All kits contained identical capillary lancets with instructions, were requested and dispatched from the same provider, and analysed in the same accredited laboratory for both HIV and syphilis. The only differences between the kits were the blood collection modalities included. The kits contained MT for the first 14 months, which were then replaced with DBS for the subsequent 14 months. This evaluation is reported in accordance with Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. See online supplemental appendix STROBE checklist.

The online requests, returns, processing and analysis rates of the HIV and syphilis blood collection components were calculated from users ordering a free (at point of access) STI self-sampling kit from a single service from an online platform.

The study was conducted in a Midlands-based sexual health clinic with a local diagnosed HIV prevalence of 2.2 per 1000 people, and a new HIV diagnosis rate of 5.3 per 100 000 population.[11] The local new syphilis diagnostic rate per 100 000 population was 5.4, 10.3 and 10.7 for years 2016, 2017 and 2018, respectively.[12] This centre had been using Saving Lives STI postal self-sampling service as part of their online STI kit requesting service, and had noted a high blood sample rejection rate with the MT kits. As a consequence, they were motivated to try the DBS blood collection system in hope of better results.

Retrospective anonymised data collected for the purpose of routine clinical care from the Saving Lives database were used for this service evaluation. The data were required as part of the standard clinical service provided to local sexual health services. Patients had electronically consented for their anonymised data to be shared by a third-party organisation (Saving Lives).

Laboratory methodology

Laboratory methodologies for HIV and syphilis testing remained the same throughout the study (from 2016 to 2019). The laboratory used the ARCHITECT HIV (Ag/Ab) combo assay (chemiluminescent microparticle immunoassay (CMIA)) to test samples for HIV, and the ARCHITECT Syphilis (IgM/IgG) assay (CMIA) for the qualitative detection of syphilis antibodies. Please see online supplemental appendix 1 for further details of the laboratory methodologies.

Statistical analysis

Data were extracted from the Saving Lives charity database and transferred into a spreadsheet where data management was conducted.

User baseline characteristics, STI kit and blood sample return rates, in addition to processing and analysis rates of the MT and DBS, were compared using Pearson's χ^2 test and Fisher's exact test, where values were ≤5. Differences in proportions between MT and DBS were analysed using a difference in proportions calculation with 95% CIs for the observed differences in proportions. Where Fisher's exact test has been used to calculate the p value, the 95% CIs around the proportional difference will not be presented due to the differing distribution models both statistical tests use (hypergeometric and normal distribution respectively). The RRR was calculated by dividing the kit request number by the number of generated meaningful test results. All analyses were conducted using Microsoft Excel 2016.

RESULTS

Baseline characteristics

Between 6 September 2016 and 2 January 2019, 5670 STI postal kit requests (1515 MT and 4155 DBS) from a Midlands sexual health clinic were reviewed. From 6 September 2016 to 1 November 2017, the kits contained MT for HIV and syphilis blood collection. From 3 November 2017 to 2 January 2019, kits contained DBS for HIV and syphilis blood collection. The recorded baseline characteristics between the two groups (MT and DBS) were comparable (69.4% vs 67.1% female, 75.7% vs 73.2% white British, and 64.5% vs 63.0% heterosexual female, with a median age of 26). A statistical significant difference was noted between the two collection modalities for exclusive women who have sex with women (p<0.001) and bisexual women (p=0.009), but the magnitude of this difference was minimal (1.9%, 95% CI 0.8% to 2.9%, and 1.1%, 95% CI 0.4% to 1.8%, respectively). See table 1 for full baseline characteristics.

Kit return and processing rates

The blood samples were analysed for both HIV and syphilis. In some instances, processing failures affected only one of the two results and were subsequently excluded from the main analysis. For data describing the successful processing of HIV and syphilis tests independently, please refer to online supplemental appendix 3.

Although a statistically significant difference in favour of DBS samples was observed for kit return rates (p<0.001), the magnitude of this difference was modest (4.6%, 95% CI 2.0% to 7.3%) and likely to not be practically relevant. Of the returned STI kits, blood sample return rates between MT and DBS were comparable (88.2% vs 87.0%, p=0.340). The DBS samples demonstrated significantly higher successful HIV and syphilis sample processing rates than the MT (94.6% vs 54.4%, p<0.001), with 40.2% (95% CI 36.9% to 43.4%) more DBS samples being successfully resulted. This study demonstrated that the RRR values for MT and DBS were 2.9 and 1.6 respectively. See table 2 for a summary of comparisons of MT and DBS for complete results of HIV and syphilis blood sampling.

Table 1 Baseline characteristics

Requesting dates	6 September 2016–1 November 2017	3 November 2017–2 January 2019	6 September 2016–2 January 2019	p value (MT vs DBS)
5670 Datasets	EDTA MT kit (1515), n (%)*	DBS kit (4155), n (%)*	Combined kits (5670), n (%)*	
Sex				
Male	460 (30.4)	1357 (32.6)	1817 (32.0)	0.100
Female	1051 (69.4)	2788 (67.1)	3839 (67.7)	0.110
Transgender	0 (0.0)	2 (0.05)†	2 (0.04)†	1.000
Other gender identity	4 (0.2)	8 (0.2)	12 (0.2)	0.540
Age (years), mean (95% CI)	27.4 (27.1 to 27.8)	27.3 (27.1 to 27.5)	27.3 (27.1 to 27.5)	–
Age (years), median (IQR)	26 (22–31)	26 (22–31)	26 (22–31)	–
Ethnicity				
Any other Asian background	2 (0.1)	5 (0.1)	7 (0.1)	1.000
Any other black background	6 (0.4)	21 (0.5)	27 (0.5)	0.600
Any other mixed background	11 (0.7)	30 (0.7)	41 (0.7)	0.990
Any other white background	41 (2.7)	105 (2.5)	146 (2.6)	0.710
Bangladeshi	6 (0.4)	12 (0.3)	18 (0.3)	0.530
Black African	25 (1.6)	104 (2.5)	129 (2.3)	0.570
Black Caribbean	81 (5.3)	246 (5.9)	327 (5.7)	0.410
Chinese	1 (0.06)†	7 (0.2)	8 (0.1)	0.690
Indian	51 (3.4)	111 (2.7)	162 (2.9)	0.160
Pakistani	13 (0.9)	45 (1.1)	58 (1.0)	0.460
Unknown/not specified	26 (1.7)	78 (1.9)	104 (1.8)	0.690
White and Asian	17 (1.1)	51 (1.2)	68 (1.2)	0.750
White and black African	2 (0.1)	9 (0.2)	11 (0.2)	0.740
White and black Caribbean	79 (5.2)	271 (6.5)	350 (6.2)	0.700
White British	1147 (75.7)	3044 (73.2)	4191 (74.0)	0.630
White Irish	7 (0.5)	16 (0.4)	23 (0.4)	0.690
Sexuality				
Heterosexual man	353 (23.3)	1012 (24.3)	1365 (24.1)	0.410
Heterosexual woman	977 (64.5)	2617 (63.0)	3594 (63.4)	0.300
Bisexual man	20 (1.3)	67 (1.6)	87 (1.5)	0.430
Bisexual woman Percentage difference (95% CI)*	18 (1.2)	95 (2.3)	113 (2.0)	**0.009** **1.1 (0.4 to 1.8)**
MSM exclusive	87 (5.7)	278 (6.7)	365 (6.4)	0.200
WSW exclusive Percentage difference (95% CI)*	56 (3.7)	76 (1.8)	132 (2.3)	**<0.001** **−1.9 (−2.9 to −0.8)**
Heterosexual TG woman	0 (0.0)	2 (0.05)†	2 (0.04)†	1.000
Unknown/not specified	4 (0.2)	8 (0.2)	12 (0.2)	0.600

p values in bold typeface denote statistical significance; p values rounded to three decimal places.
For proportion percentage differences with 95% CI; negative values favour MT, positive values favour DBS.
*Rounded to one decimal place.
†Rounded to two decimal places for representation.
DBS, dried blood spot; MSM, men who have sex with men; MT, mini tube; TG, transgender; WSW, women who have sex with women.

Sample processing failures

We considered potential reasons why blood samples did not generate a test result once received in the laboratory. Some samples were returned without the required request form and therefore were not processed. This occurred equally for both MT and DBS kits. A statistically significant difference (p<0.001) was seen with the labelling of the samples, with 1.6% of DBS samples being unlabelled compared with 0.0% for MT (1.6% difference).

Table 2 Summary of comparisons of MT and DBS for complete results of HIV and STS blood sampling

Blood collection system	STI kit return/request, n (%)	HIV/STS sample returns/STI kit return, n (%)	Successful HIV/STS sample processing and analysis/blood sample return, n (%)	Overall HIV/STS result obtained/STI kits requested, n (%)	RRR, n (ratio)
MT	1072/1515 (*70.8*)	945/1072 (*88.2*)	514/945 (*54.4*)	514/1515 (*33.9*)	2.9
DBS	3133/4155 (*75.4*)	2727/3133 (*87.0*)	2578/2727 (*94.6*)	2578/4155 (*62.0*)	1.6
p value Percentage difference (95% CI)	**<0.001** **4.6 (2.0 to 7.3)**	0.340 −1.2 (−3.3 to 1.2)	***<0.001*** **40.2 (36.9 to 43.4)**	***<0.001*** **28.1 (25.3 to 30.9)**	--

P values in bold typeface denote statistical significance; p values rounded to three decimal places, RRR value rounded to two decimal places.
For proportion percentage differences with 95% CI, negative values favour MT and positive values favour DBS.
DBS, dried blood spot; MT, mini tube; RRR, request-to-result ratio; STS, serological test for syphilis.

An inadequate volume of blood was provided for 32.3% of returned MT compared with 2.0% of DBS samples (p<0.001). The magnitude of this difference was statistically significant (30.3%, 95% CI 27.2% to 33.3%). Inadequate blood volumes often led to only one of the two tests being processed—with HIV being the more favoured test for processing. Haemolysis (as defined by analyser instrument rejection) accounted for 7.2% of returned MT samples and 0.0% of returned DBS samples (p<0.001), giving a difference of 7.2%. See online supplemental appendix 4 for table of reasons why returned samples did not generate a meaningful test result.

False-positive results for HIV and syphilis

Of the successfully analysed blood samples, 6.2%, of MT samples were reactive for HIV compared with 1.1% for DBS samples. The magnitude of this difference was statistically significant (p<0.001; 5.7%, 95% CI 3.7% to 7.8%). Reactive HIV results with confirmatory venous samples revealed that 5.2% of all successfully processed MT samples for HIV were falsely positive compared with 0.4% for DBS samples. This was statistically significant (p<0.001), with the magnitude of this difference being 4.8% (95% CI 3.0% to 6.7%).

For syphilis, 1.1% of MT samples were reactive, compared with 0.7% of samples using DBS (p=0.271). Reactive syphilis results with confirmatory venous samples revealed that 0.4% of all successfully processed MT samples for syphilis were falsely positive compared with 0.0% for DBS samples (p=0.030). The magnitude of this difference, however, was small (0.4%).

We could not verify all reactive results due to the absence of a confirmatory test recorded by the service provider or the users general practitioner (GP). For HIV reactive tests, evidence of confirmatory testing was available for 30/35 MT users and for 11/13 DBS users. For syphilis antibody reactive tests, evidence of confirmatory testing was available for all MT users and for 16/17 DBS users (table 3).

DISCUSSION

This comparative evaluation of two blood collection methods demonstrates DBS blood collection for HIV and syphilis has significantly better processing and analysis rates than MT. Almost a third of MT samples had an inadequate volume of blood to produce results for both tests and was likely responsible for the large discrepancies within the MT samples between HIV and syphilis result numbers. Haemolysed (degraded) samples accounted for 7.2% of MT samples compared with 0.0% of DBS samples, supporting the literature about the stability of DBS blood samples.

PHE recently published a 2-year report (from November 2015 to October 2017) on the National HIV self-sampling service, which used MT. Of the 44 791 HIV self-sampling kits returned, they found that 5.04% of the samples haemolysed, and that 2.05% had an insufficient volume of blood.[5] Their additional study, from November 2017 to October 2018, recorded 24 591 returned HIV self-sampling kits with reduced processing failures: 2.68% haemolysed and 2.87% with insufficient volumes of blood.[2] The PHE report noted reductions in the incidence of haemolysis in the self-sampling HIV kits and cited procedural changes as the reason for this. Our study demonstrates, however, that DBS collection eradicates this issue entirely. MT samples in our study appear more likely to haemolyse than the ones used for the national HIV self-sampling service. Percentages of insufficient volumes reported in the PHE 2 year report were similar to those of our DBS samples and were significantly better than those seen for the MT in our study. It is worth noting that the National HIV self-sampling service only analysed blood for HIV, which requires a minimum serum volume of 200 µL, while serum volumes for MT for our study required a 500 µL minimum in order to process the sample for both HIV and syphilis. This is likely to account for discrepancies seen between the percentages of insufficient MT volumes in our study and the ones reported in the PHE 2-year report.

Our study acknowledges the notable differences in kit request numbers for MT-containing and DBS-containing kits (1515 vs 4155) despite each kit type being evaluated over a 14-month time period. At the start of this evaluation, the set-up of the postal STI service was brand new to the service provider, which was the time when the STI kits contained MT. By the time of switch to DBS-containing kits due to the high number of unprocessed and false-positive results, the service had become established to the local population and, through continued advertising, resulted in an increased uptake of the postal service. This may also explain the very modest increased kit return rate for the DBS-containing kits compared with MT.

A number of returned DBS samples were unlabelled and therefore were not processed (1.6% compared with 0% for the MT kits). This is most likely due to the pre-labelling of MT containers prior to their dispatch to the user. Logistical reasons meant that on switching to DBS, kit users were required to attach the label themselves, creating the possibility of this step being omitted.

False-positive results for HIV and syphilis in the MT samples were high compared with DBS samples. The quality of the blood sample received in the MT containers may be an explanation for this. Blood collected by this method is very time sensitive and can degrade if left for extended periods of time before posting

Table 3 False-positive results for HIV and STS for MT and DBS

Blood collection system	STI tested	Reactive tests, n (%)	Confirmed reactive tests, n (%)	False positive, n (%)
MT	HIV	35/561 (6.2)	1/30* (3.3)	29/556* (5.2)
DBS	HIV	13/2583 (0.5)	1/11* (9.1)	10/2582* (0.4)
p value *Percentage difference (95% CI)*	–	***<0.001*** ***–5.7 (–7.8 to –3.7)***	*0.470* *5.8 (n/a)*	***<0.001*** ***–4.8 (–6.7 to –3.0)***
MT	STS	6/544 (1.1)	4/6 (66.7)	2/544 (0.4)
DBS	STS	17/2579 (0.7)	16/16* (100.0)	0/2578* (0.0)
p value *Percentage difference (95% CI)*	--	*0.271* *–0.4 (–1.4 to 0.5)*	*0.065* *33.3(n/a)*	***0.030*** ***–0.4 (n/a)***

p values in bold typeface denote statistical significance; p values rounded to three decimal places.
For proportion percentage differences with 95%CI, negative values favour MT, and positive values favour DBS.
*Numerical reductions due to no evidence of confirmatory test by service provider or general practitioner.
DBS, dried blood spot; MT, mini tube; n/a, not applicable; STS, serological test for syphilis.

back or if the sample is exposed to extremes of temperatures. This may affect sample analysis.

Comparison to previous study in NW of England

Baseline characteristics were similar between this study and our earlier study using data from the NW of England, although participants were less likely to be white British (74.0% vs 90.0%). MT and DBS kit return rates were slightly higher than those in the NW of England (70.8% and 75.4% vs 68.7 and 66.5%, respectively).[10]

Successful processing rates were slightly higher in our previous study for for both MT and DBS (54.4% and 94.6% vs 55.7% and 98.8%, respectively), but DBS demonstrated higher processing success than MT in both studies with more favourable RRR values (Midlands: MT 2.9, DBS 1.6, and NW England: MT 3.0, DBS 1.7).

False-positive rates for HIV were consistent across both Midlands and NW England studies (MT, 5.2% and 5.4%, respectively, and for DBS, 0.4% and 0.0%, respectively). Further information on comparisons between the two studies can be found in online supplemental appendices 5A–C.

Limitations

Due to the practicalities of a service provision, the study was conducted consecutively (MT followed by DBS), when a randomised parallel comparison would have been best. Selection bias is minimised by the similarities of baseline characteristics between the users of the different blood collection modalities. Samples received were processed in the same laboratory with all staff receiving the same standardised training. As no paired venous blood samples were taken for those who tested negative, we were unable to produce real-world sensitivity or specificity data as a measure of test accuracy. The laboratory used in this study had previously conducted (under laboratory conditions) sensitivity and specificity studies to which they validated the DBS and MT assays. These were directly compared with known HIV-positive and syphilis antibody-positive whole blood samples.

This postal testing system could only test for the presence of syphilis IgM/G antibody in the serum, and not treponema pallidum particle agglutination assay/treponema pallidum haemagglutination assay (TPPA/TPHA) or rapid plasma reagin (RPR). For this reason, the test was unable to differentiate between those with previously treated syphilis and those who were re-infected with syphilis.

This evaluation would have benefitted from qualitative methodologies to provide insight into the acceptability of each blood collection system.

CONCLUSIONS

This large dataset highlights the superior successful processing rates of postal DBS collection systems compared with MT. It builds on our previous paper by replicating its findings. Insufficient volumes and haemolysis of samples remained an issue for MT samples, which were the lead causes for the DBS samples' superiority. The RRR nicely summarises the efficiency of the postal STI kit service and would make a good unit of measure to compare with other similar services. The false-positive rates for MT samples were again high, even with a cohort 10 times the size of the previous study. This may be suggestive of an intrinsic problem with the stability and quality of blood samples collected by MT. This further comparative evaluation supports the notion that not all postal blood collection modalities are equal. The clinical implications of this are potentially major, and explorations into other infections requiring blood-based testing (such as hepatitis B and C) are warranted. This is of particular interest at a time where in the UK, expansion of hepatitis B and C testing is needed to help achieve the WHO hepatitis B and C elimination targets by 2030.[13] A postal sampling service using DBS to screen for HIV, syphilis and potentially other BBVs could be a viable option in a post-COVID era.

Key messages

- Dried blood spot (DBS) postal blood samples are more likely to be successfully processed than mini-tube (MT) blood samples.
- DBS postal blood collection systems have fewer incidences of false-positive results compared with MTs.
- Postal DBS samples can be processed for multiple blood-based tests more successfully than postal MT samples, with a lower blood volume requirement.
- Fewer STI kit requests are needed to generate a blood-based test result when using DBS postal blood collection systems compared with MT.

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Patient consent for publication Not required.

Ethics approval We used the Medical Research Council (MRC) 'Is my study research?' toolkit (http://www.hra-decisiontools.org.uk/research/), which considered the study as research. We consequently used the MRC 'Do I need NHS REC review?' decision toolkit (http://www.hra-decisiontools.org.uk/ethics/), which stated that research ethics committee approval was not required. Details on information governance for the online IT systems can be found in supplemental appendix 2 and online supplemental file 1).

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