Are all HIV postal sampling kits the same?

Dried blood spots significantly outperform conventional mini-tube sampling in a real world comparative review

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Public Health England

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NHS
University Hospitals Birmingham
NHS Foundation Trust

Declarations

I have received educational, research and travel grants and personal fees from Gilead Sciences, ViiV Healthcare and MSD

Postal HIV kits: Context

- HIV testing remains a vital element in confronting the HIV epidemic

- There is a need to close the HIV undiagnosed gap
  - UNAIDS 90:90:90 target
  - Achieving this requires comprehensive testing programs

- There is a need to expand and simplify access to HIV/STI testing
  - Reduce barriers to testing

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Postal HIV kits: Context

- Postal HIV/STI self-sampling is one way which this can be achieved
- Different blood collection systems for HIV postal kits
  - Have been validated
  - At variable costs to the suppliers
- In England, micro-containers (MT) for capillary blood sample collection are currently the most widely used system for postal blood sampling
- Dried blood spot (DBS) systems are becoming a popular alternative

A Unique Opportunity

- Access to an established postal STI sampling kit service – through the Saving Lives Charity
  - Charity provided both MT and DBS collection systems in their kits

- A clinical service with motivation to move away from MT blood collection systems for their STI postal kits
  - Due to;
    - Sample rejections because of inadequate blood volumes/ suboptimal quality samples
    - A number of false positive results requiring patient recall to clinic
    - The option to trial a move to DBS

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Pictorial representation of blood collection system

>500µl of blood

Micro-containers (MT)

Pre-paid addressed envelope with rest of STI kit

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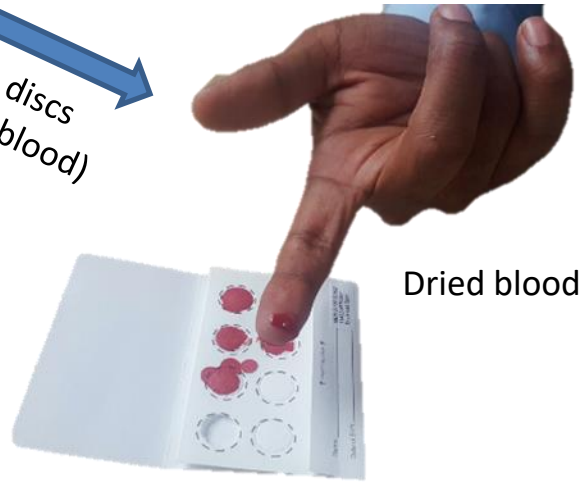
Pictorial representation of blood collection system

>500µl of blood

Micro-containers (MT)

≥4 10mm discs
(≥ 50µl of blood)



Dried blood spot (DBS)

Pre-paid addressed envelope with rest of STI kit

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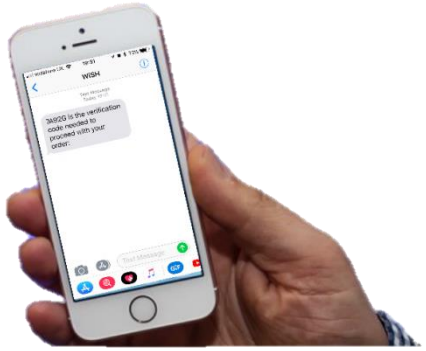
Simplified pictorial representation of blood collection system processes

NHS

Text message if negative results



Call from local clinic for “non-negative” results (reactive or processing issues)

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Aims

- To ascertain how DBS and MT HIV collection systems compared as part of an online postal STI testing service

- **Primary outcomes:**
  - Kit return rates (any component of the kit)
  - Blood sample return rates
  - Successful processing/analysis rates of returned blood samples

- We also aimed to calculate the HIV **Request-to-Result Ratio (RRR):**
  - the number of online kit requests required to produce one successfully analysed HIV result

Methods

- North-West of England clinical service
  - Started using MT containing STI postal kits on 13/06/17
  - By 04/08/17 they had switched to DBS
  - Collected data until 22/09/17

- Retrospective review of data extracted from system database from 13/06/17 – 22/09/17
  - Baseline characteristics of kit requesters
  - STI kit return rates (any component of the kit)
  - Blood sample return rates
  - Successful processing rates of returned blood samples
  - Reactive results

Results: Baseline Demographics

550 results extracted
- 275 were MT
- 275 were DBS

No statistical diff. between MT & DBS w.r.t. sex or age

550 data sets	Mini-tube, n(%)* n=275	Dried Blood Spot, n(%)* n=275	COMBINED, n(%)* n=550	p-value (MT vs DBS)
Sex				
-Male	106 (38.5)	94 (34.2)	200 (36.4)	*0.29*
-Female	166 (60.4)	181 (65.8)	347 (63.1)	*0.19*
-Transgender	2 (0.7)	0 (0)	2 (0.4)	*n/a*
-Unspecified	1 (0.4)	0 (0)	1 (0.2)	*n/a*
Age, yrs [Median, (IQR)]	26 (22, 31)**	25 (22, 30)	26 (22, 31)**	*n/a*
Age, yrs [Mean, (95%CI)]	28 (27, 29)**	28 (27, 29)	28 (27, 29)**	*n/a*

Results: Baseline Demographics

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No statistical diff. between MT & DBS w.r.t. ethnicity

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Ethnicity[¥]				
-Any other mixed background	2 (0.7)	2 (0.7)	4 (0.7)	*1*
-Any other white background	7 (2.5)	5 (1.8)	12 (2.2)	*0.56*
-Unknown/not spec.	3 (1.1)	1 (0.4)	4 (0.7)	*0.62*
-White & Asian	4 (1.5)	3 (1.1)	7 (1.3)	*1*
-White and black Caribbean	3 (1.1)	1 (0.4)	4 (0.7)	*0.62*
-White British	242 (88)	253 (92)	495 (90)	*0.12*
-White Irish	10 (3.6)	6 (2.2)	16 (2.9)	*0.31*

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No statistical diff. between MT & DBS w.r.t. ethnicity

No statistical diff. between MT & DBS w.r.t. sexuality

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Sexuality				
-Heterosexual Male	86 (31.3)	66 (24)	152 (27.6)	*0.06*
-Heterosexual Female[ǂ]	152 (27.6)	167 (60.7)	319 (58)	*0.20*
-MSM[ǂ]	20 (7.3)	28 (10.2)	48 (8.7)	*0.23*
-WSW[ǂ]	16 (5.8)	14 (5.1)	30 (5.5)	*0.71*

*95%CI rounded to nearest whole number, *to one decimal place, **x1 data missing ǂ inclusive of transgender female, ǂ inclusive of bisexual. ¥Omissions of ethnicity for Bangladeshi, Black African, Black Caribbean, Chinese, Indian, and white & black African due to extremely low numbers (in many cases zero) and unable to calculate p-values for these*

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Results: Returns & Processing – MT vs DBS

Test type	STI Kit Return/Request n (%)	HIV Sample Return/STI kit return n (%)	Successful HIV sample processing & analysis/HIV sample return n (%)	Overall HIV result obtained/ STI kits requested n (%)	Request-to-result Ratio (RRR) n (ratio)
Mini Tube	189/275 (68.7)	167/189 (88.4)	93/167 (55.7)	93/275 (33.8)	275/93 (2.96)
Dry Blood Spot	183/275 (66.5)	164/183 (89.6)	162/164 (98.8)	162/275 (58.9)	275/162 (1.70)
p-value	0.58	0.70	<0.001	<0.001	<0.001

No differences between kit and blood sample return rates

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Significant differences between processing/analysis rates

3 MT Kits required/ 1 successful HIV result vs **1.7** for DBS – **statistically significant**

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Results: Reasons why samples not analysed– MT vs DBS

Test Type	Reason why sample not processed for analysis n (%)				
	Number of blood samples not analysed	*No specimen returned*	*Insuff. sample*	*Significantly haemolysed or sample >4 days old*	*No request form*
Mini Tube	**96**	21/96 (21.9%)	62/96 (64.6%)	12/96 (12.5%)	1/96 (1%)
Dried Blood Spot	**21**	19/21 (90.5%)	2/21 (9.5%)	0/21 (0%)	0/21 (0%)

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Dried Blood Spot	**21**	19/21 (90.5%)	2/21 (9.5%)	0/21 (0%)	0/21 (0%)

Results: False positives – MT vs DBS

Test Type	Reactive results (%)	Positive result confirmation* (%)	False positivity rate (%)
Mini Tube	5/93 (5.4)	0/93 (0)	5/93 (5.4)
Dried Blood Spot	0/162 (0)	0/162 (0)	0/162 (0)

*Confirmed by venous blood sample

Demographics of the 5 false positive;

- All Caucasian
- Age range 19-30years old
- Four females (HT), One male (MSM)

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Limitations

- Pragmatic review
  - MT & DBS comparison conducted consecutively rather than in parallel
  - Relatively small numbers over a short period of time
  - ?Regionally specific

- Lack of patient feedback on experience of both kits

Conclusions

Key points

- Significant differences between performance of postal MT and DBS samples
- High proportion of inadequate blood volumes associated with MT
- MT HIV blood samples yielded a higher than expected false positive rate compared to DBS
- Request-to-result ratio (RRR) provides a way to show the effectiveness of a postal testing system

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Acknowledgements

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