Supplementary Material

Appendix 1: Information Governance

The Saving Lives self-sampling postal kit request system consists of a database housed on a secure N3-compatible server. A request module is called into a client clinic's website via a simple iFrame. Patients complete a demographic questionnaire which enables them to select an appropriate kit, and the database system generates unique identifiers which monitor both patient and sample through each stage of the system: request, kit despatch, sample receipt, laboratory analysis and resulting. Each stage of this process is information governance (IG) compatible, and is fully compliant with all current and pending requirements of the IG toolkit programme. All data is recorded in real time and stored within an N3-compliant environment, and can be anonymised for all necessary applications.

Appendix 2: Laboratory Methodology

All postal samples received in the laboratory were unpackaged, date-stamped, barcoded and booked onto the laboratory data management system. At this stage any samples failing to meet the minimum testing requirements (e.g.: insufficient sample [<500µl for MT, 4 or less spots for DBS], no sample, no patient details, excessively haemolysed or leaking MT samples), were rejected and reported as such with relevant details. Prior to testing, MT samples were microcentrifuged for 10 minutes at 13,000 rpm and the supernatant transferred to a fresh barcoded 2ml tube. For DBS testing four 10mm discs, each containing at least50 µl of dried blood was required from each patient. The four discs were eluted in 1.5ml elution buffer (0.05% phosphate buffered saline with Tween®) and left on a shaker at room temperature. The eluate was then microfuged for 10 minutes at 10,000 rpm and the supernatant was then transferred to a second barcoded 2ml tube.

All samples were tested on an Abbott ARCHITECT serological analyser using the ARCHITECT HIV antigen/antibody (Ag/Ab) Combo assay. This is a chemiluminescent microparticle immunoassay (CMIA) that allows the simultaneous qualitative detection of HIV p24 antigen and antibodies to HIV type 1 and/or type 2. Abbott claim an HIV-1 p24 antigen sensitivity of 0.87 IU/ml, as assessed using the WHO first international reference reagent (NIBSC code 90/636). This was confirmed during local verification of the assay, where an average sensitivity of 0.78 IU/ml was achieved in serum samples, although due to the dilution of samples during DBS processing, the observed sensitivity for blood spots was reduced approximately 8-fold to 0.625 IU/ml. This reduction in sensitivity is unlikely to be of clinical significance for a screening assay in which HIV antibody levels would be expected to be high in sera and/or plasma. The 'off-label' use of the ARCHITECT HIV Ag/Ab combo assay for DBS samples was validated locally and the process has been accredited for routine use following a successful United Kingdom Accreditation Service [UKAS] inspection). Both DBS filter paper and MT are CE marked.

All results were automatically downloaded into the laboratory data management system and released to the Saving Lives server following relevant technical and clinical checks. Reactive postal HIV results were checked by repeat HIV testing at the local genitourinary clinic using a 4th generation (Ag/Ab) venous HIV blood test (Roche Cobas 6000 platform).

Appendix 3: Baseline Characteristics

Baseline Characteristics

Dates	13/06/17 – 04/08/17	04/08/17 – 22/09/17	13/06/17 – 22/09/17	
550 data sets	Mini-tube, n(%)* n=275	Dried Blood Spot, n(%)* n=275	COMBINED, n(%)* n=550	p-value (MTvsDBS)
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*
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*
-Bangladeshi	1 (0.4)	0 (0)	1 (0.2)	*n/a*
-Black African	0 (0)	1 (0.4)	1 (0.2)	*n/a*
-Black Caribbean	0 (0)	1 (0.4)	1 (0.2)	*n/a*
-Chinese	0 (0)	2 (0.7)	2 (0.4)	*n/a*
-Indian	1 (0.4)	0 (0)	1 (0.2)	*n/a*
-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 African	2 (0.7)	0 (0)	2 (0.4)	*n/a*
-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*
Sexuality				
-Heterosexual Male	86 (31.3)	66 (24)	152 (27.6)	*0.06*
-Heterosexual Female[ŧ]	152 (27.6)	167 (60.7)	319 (58)	*0.20*
-MSM[‡]	20 (7.3)	28 (10.2)	48 (8.7)	*0.23*
-WSW[‡]	16 (5.8)	14 (5.1)	30 (5.5)	*0.71*
Unknown/not spec.	1 (0.4)	0 (0)	1 (0.2)	*n/a*

95%CI rounded to nearest whole number, *to one decimal place, **x1 data missing, [ŧ]inclusive of transgender female, [‡]inclusive of bisexual

Appendix 4: Reasons for samples not being analysed

Reasons for samples not being analysed

Test Type	**Reason why sample not processed for analysis n** *(MT n=96, DBS n=21)*			
	No specimen returned	***No request form***	***Insuff. sample***	***Sample >4 days old or a significantly haemolysed sample***
Mini-tube	21	1	62	12
Dried Blood Spot	19	0	2	0