



Public Health
England

Protecting and improving
the nation's health



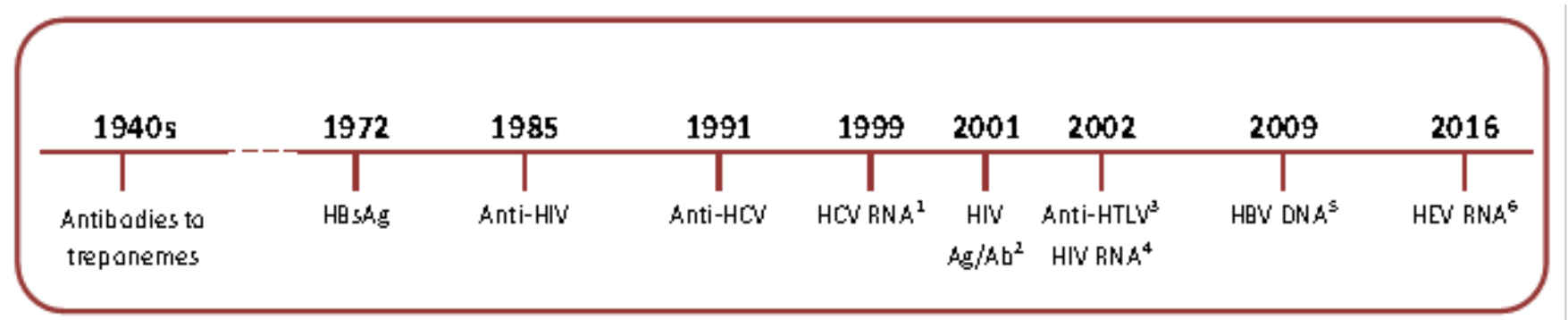
Blood and Transplant

Transfusion-transmitted HIV from seroconverted blood donors has not been identified in England since the introduction of HIV NAT screening

Bhavita Vishram

Caring Expert Quality

Timeline of introduction of microbiological tests for blood donations, UK



Window period

Parameter	1996	2013
OBSERVED incidence repeat donors excl. occult		
Estimated incidence new donors (multiplier)		
HBV WP	80 d	30 d
HCV WP	59 d	4 d
HIV WP	15 d	9 d
Seroconversion	10 yrs	3 yrs
IDI	estimated	observed
HCV infectivity		
HBsAg transience		
Testing error- false negative	✓	x
Sampling/processing/issue errors	✓	x
95% confidence interval simulation		

Developed from Schriber et al NEJM 1996

by Soldan et al Vox Sang 2003; Eurosurveillance 2005

Risk due to window period		HBV ¹	HCV ²	HIV ³
Number of potentially infectious window period donations in 1 million donations entering the blood supply (95% CI). This is equal to risk x 1,000,000	All donations ⁴	0.63 (0.17 – 1.19)	0.038 (0.015 – 0.100)	0.16 (0.10 – 0.23)
	Donations from new donors	1.51 (0.35 – 3.66)	0.117 (0.017 – 0.707)	0.041 (0.03 – 0.06)
	Donations from repeat donors	0.56 (0.15 – 0.99)	0.033 (0.014 – 0.053)	0.17 (0.11 – 0.23)
Number of donations (millions) entering the blood supply before 1 of those donations can be expected to be a potentially infectious donation. This is equal to 1/(risk x 1,000,000)	All donations ⁴	1.6	25.3	6.2
	Donations from new donors	0.7	8.5	24.2
	Donations from repeat donors	1.80	30.4	5.9

1. HBV testing assumed all donations were tested for markers of HBsAg and HBV DNA using NAT with a window period of 30 days.

2. Anti-HCV testing and HCV RNA testing with a window period 4 days.

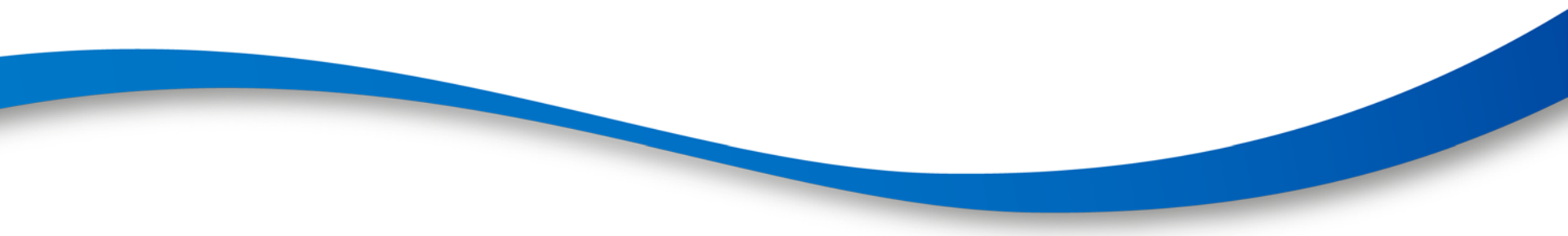
3. Combined HIV antigen/antibody testing and HIV NAT with a window period 9 days.

4. The risk due to WP among all donations was calculated as the weighted average of the risk among new and repeat donors, weighted according to the number of donations made from new and repeat donors.

All NAT testing was on pooled samples of 24 donations.

The current risk of not detecting an HIV infectious donation is much less than 1 per million donations.

Lookback investigations I

- HIV positive repeat blood donor – most recent previous negative donation (MRPD)
 - possibility that previous donation was infectious but not detected – donated in window period or false negative.
 - lookback – testing archives, tracing fate of components made from MRPD and arranging notification of living recipients.
 - introduction of NAT screening and Ab/Ag assays – reduced chance of false negative.
- 

Lookback investigations II

- positive repeat donor –donor contacted and offered a post test discussion with a NHSBT clinician.
- stored archive sample (kept for 3 years) tested– in an individual sample HIV PCR test.
- irrespective of the result, a lookback is often carried out to determine fate of blood components.
- lookback may not be carried out where other information points to the infection having being acquired a later date.
 - clear history of seroconversion illness
 - credible risk for infection in the donor with postdates the MRPD.
- the results of all lookbacks are collated by the NHSBT/PHE Epidemiology unit.

Case 1

- male donor - late 20's
- donation in November 2016- previous donation March 2016
- avidity – seroconversion may have occurred within 4 months of donation
- archive sample HIV PCR negative.
- history of new female partner after MRPD
- seroconversion illness in June with high fever, diarrhoea, vomiting and night sweats.

–NO LOOKBACK CONDUCTED

Case 2

- male - Mid 40's
- donation in January 2015 - previous donation September 2014.
- one off sexual contact with another male – no clear history
- archive sample was HIV PCR negative

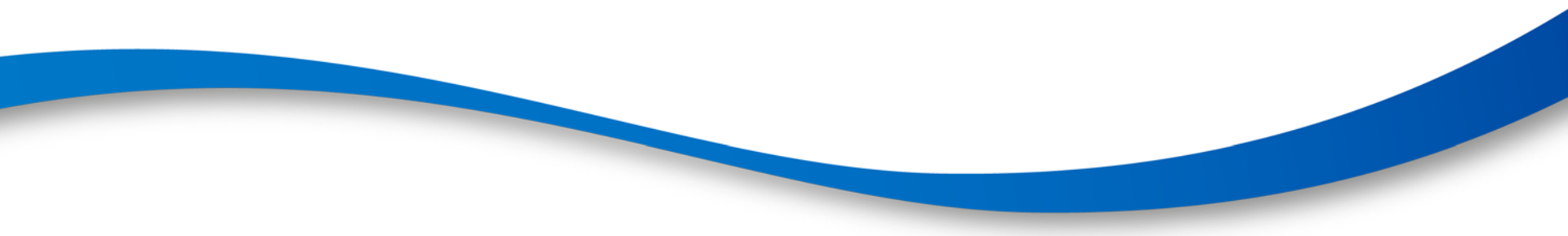
LOOKBACK CONDUCTED

- Red cells transfused - recipient identified, tested HIV negative
- Platelets transfused – recipient identified – deceased before lookback conducted

**Where archive samples test negative
on singleton PCR – do we need to
continue HIV lookback
investigations?**

A thick, solid blue line that curves across the bottom of the slide, starting from the left edge, dipping down, and then rising towards the right edge.

Data from 1995 to 2008



Data from 1995 to 2008

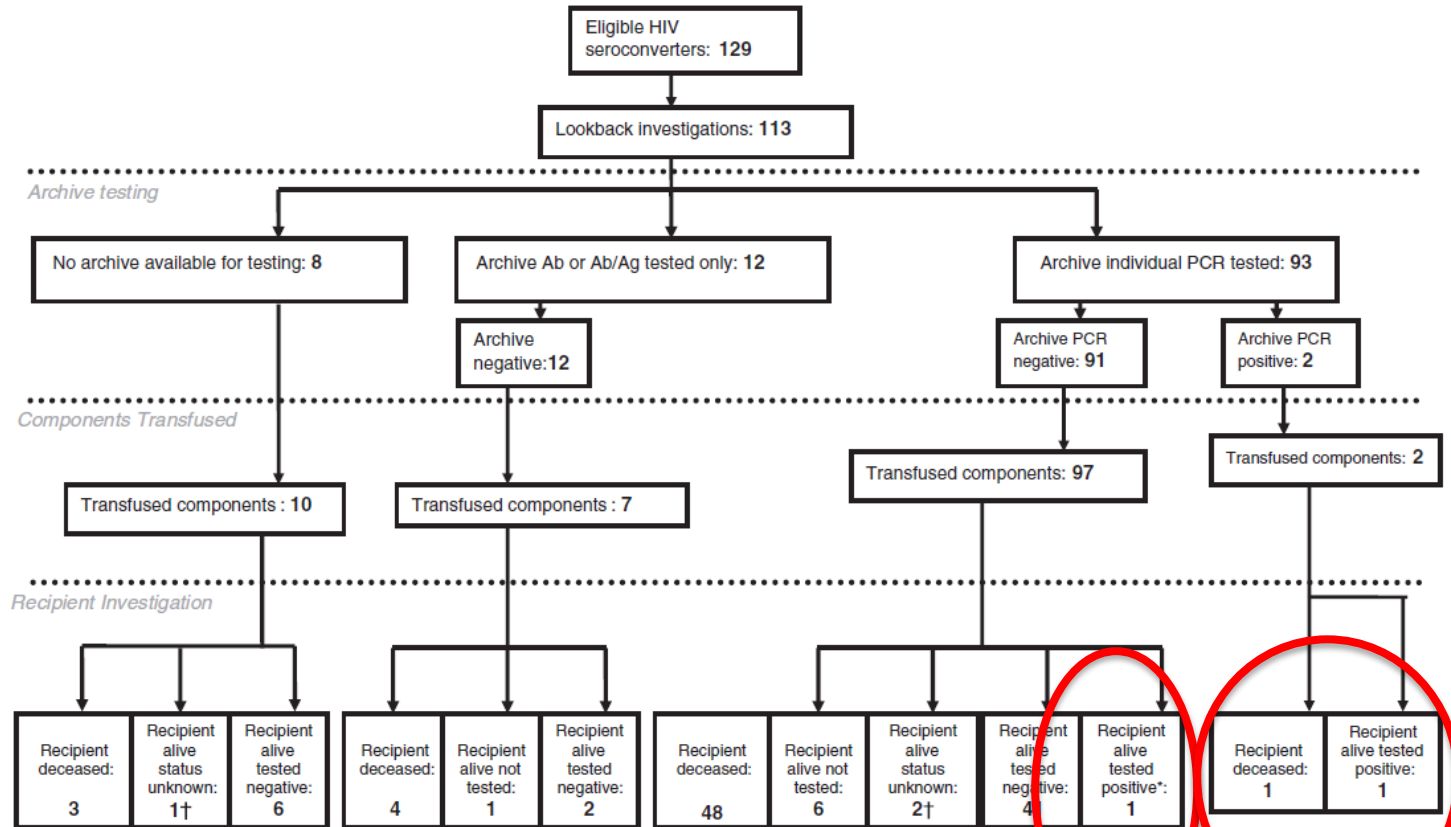
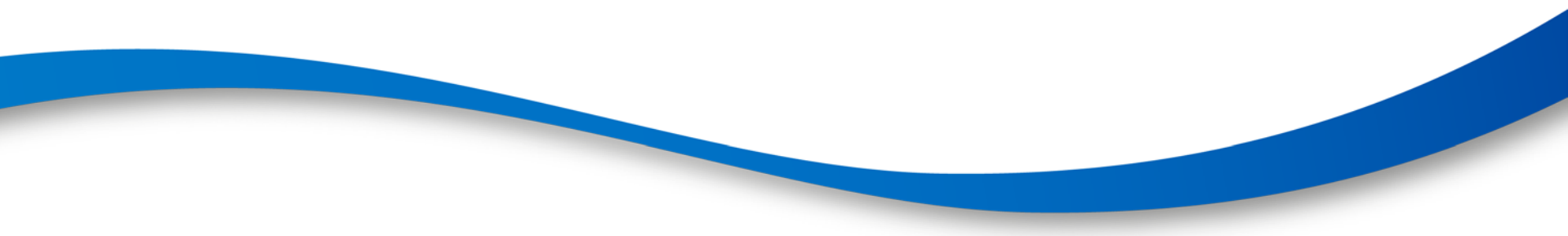
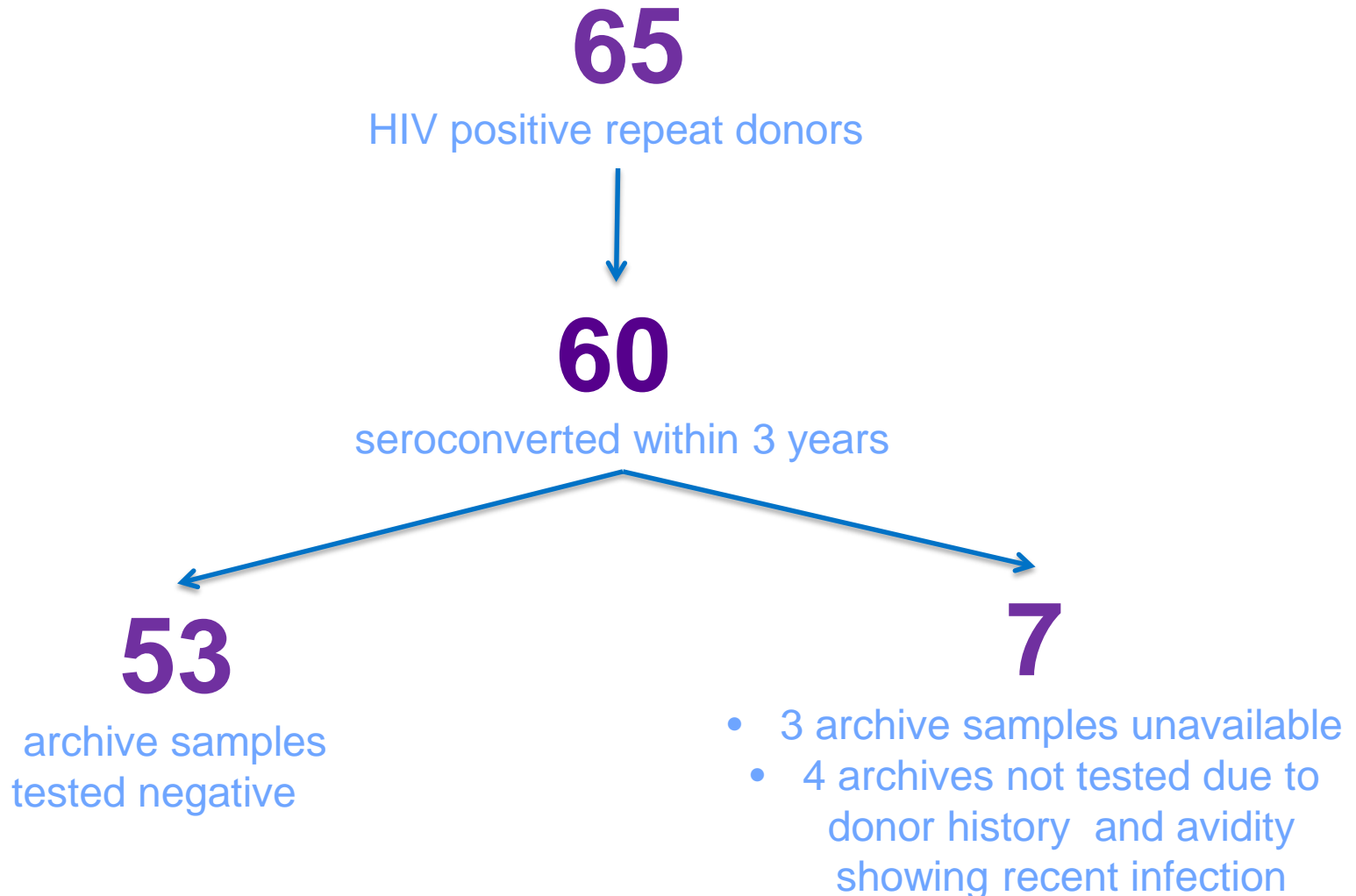


Fig. 1. Summary of HIV lookback investigations, England and Wales, October 1995 through December 2008. * This figure includes one recipient who was known to be positive before transfusion. Recipient testing before and after transfusion confirmed no transmission from the blood donation. The recipient was antibody positive only. † Status unknown as it was not reported back to the blood services despite repeated requests.

Data from 2009 to 2016

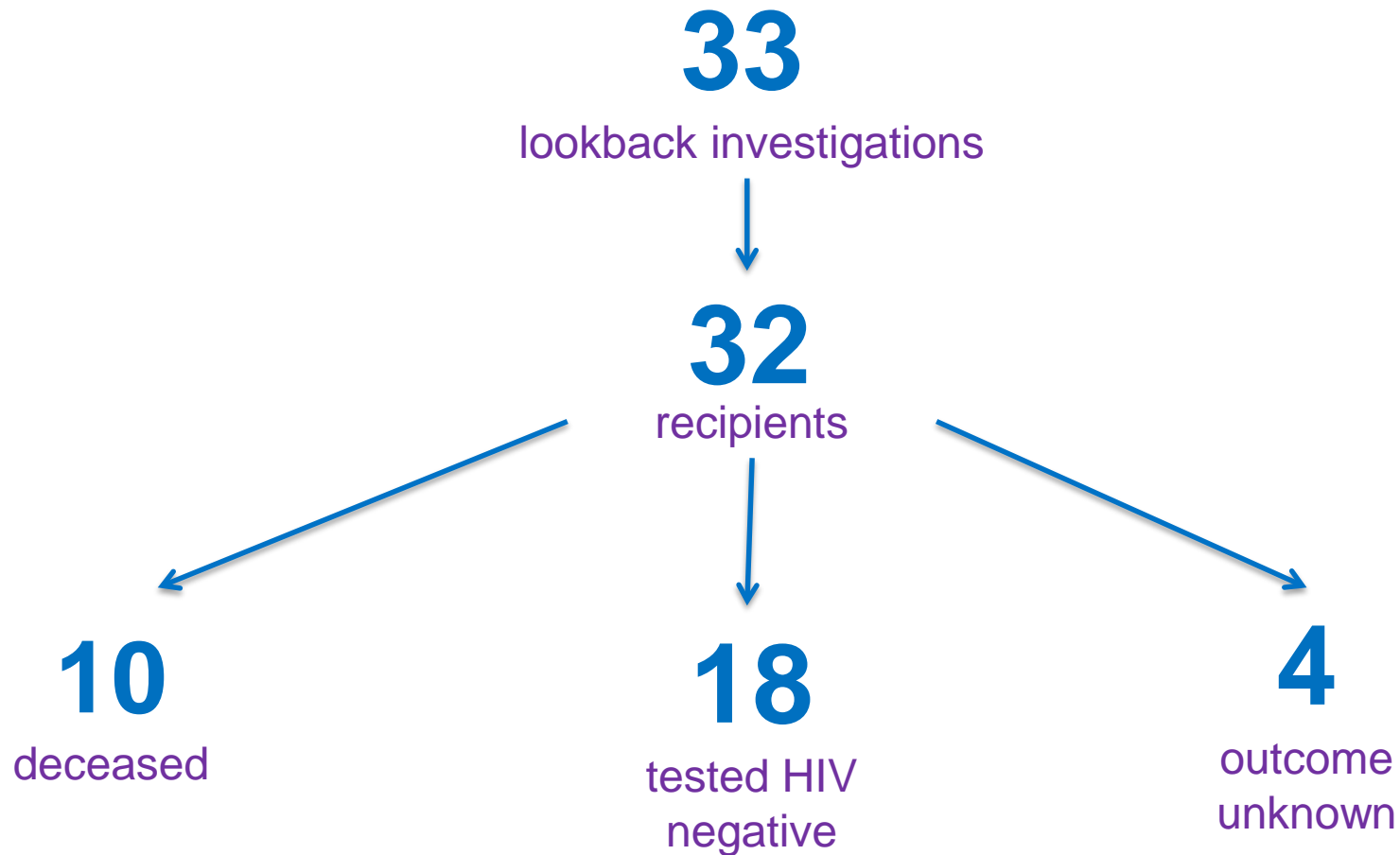


Results – archive samples



Results – lookback investigations

Blood and Transplant



NO HIV TRANSMISSIONS WERE IDENTIFIED

since the introduction of pooled HIV NAT screening in 2003:

4 HIV window period donations (NAT pick ups) detected by screening; negative on HIV serology but reactive on pooled HIV NAT screening.

no cases of HIV transmission detected by lookback investigations since routine NAT screening was introduced within NHSBT.

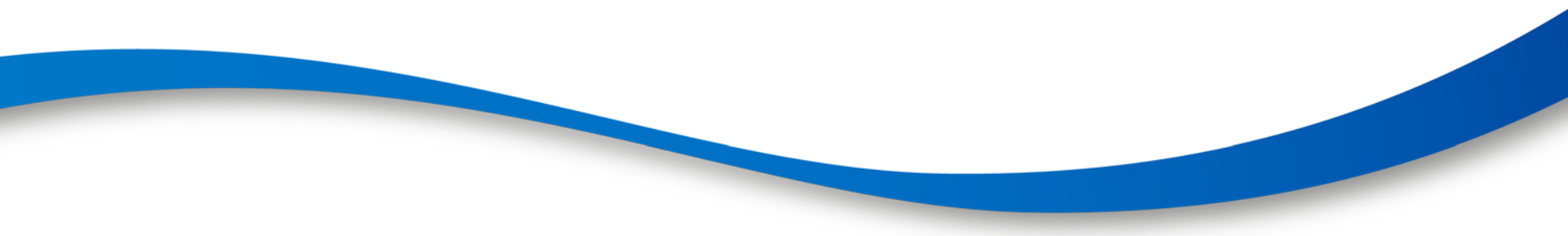
**Where archive samples test negative
on singleton PCR – do we need to
continue HIV lookback
investigations?**

A thick, solid blue line that curves across the bottom of the slide, starting from the left edge, dipping down, and then rising towards the right edge.

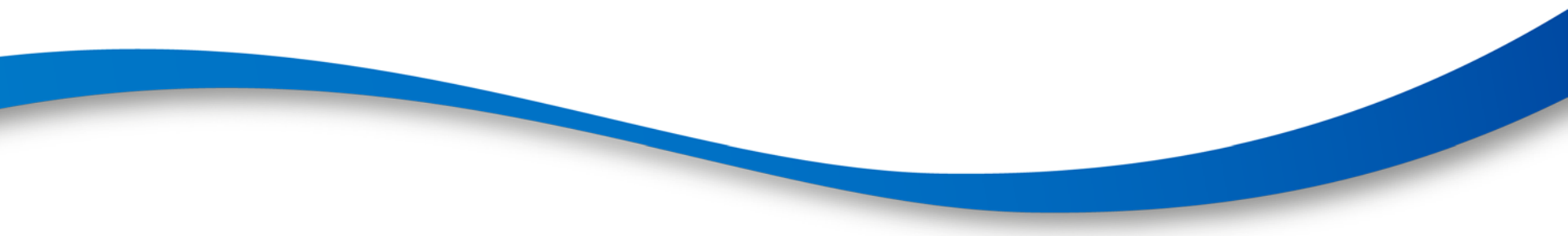
**NHSBT governance committee
recently approved no lookback is
needed where archive samples test
HIV PCR negative.**

A thick, solid blue line that curves from the left side of the bottom of the slide, dips down in the center, and then curves back up towards the right side.

Conclusion

- HIV screening has improved in sensitivity over the last 20 years.
 - 4 window period donations have been detected through screening of 21 million donations from 2003-2016.
 - number of window period donations **not detected** through the use of pooled HIV NAT screening will be vanishingly small and lookback has failed to detect any.
 - discontinue lookback investigations where archive samples HIV PCR negative.
- 

Acknowledgements

- Dr Patricia Hewitt
 - Dr Su Brailsford
 - Claire Reynolds
 - Katy Davison
 - All staff in hospitals who have helped in collecting information.
- 
- A thick blue wavy line that curves across the bottom of the slide, starting from the left edge, dipping down, and then rising towards the right edge.