



ST VINCENT'S
CENTRE FOR APPLIED
MEDICAL RESEARCH

A DIVISION OF ST VINCENT'S HOSPITAL SYDNEY

Point of care, near patient testing, of blood borne viruses – *issues with design and implementation of programs*

Philip Cunningham

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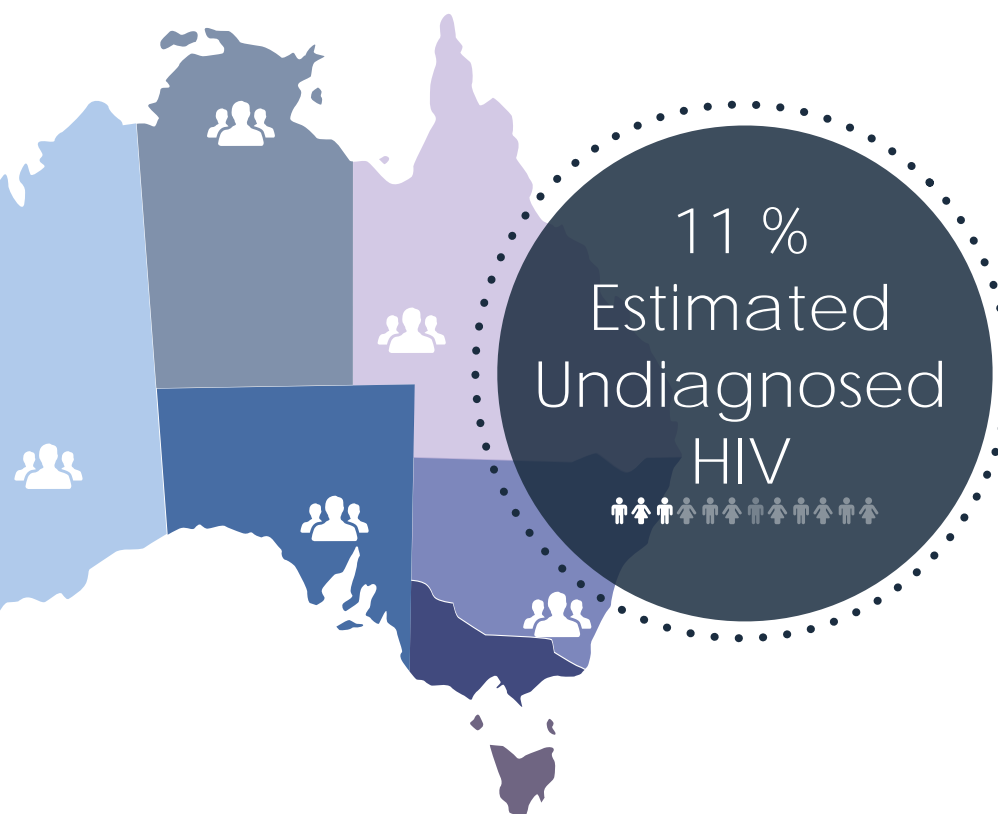
NSW State Reference Laboratory for HIV

WHO Regional Reference Laboratory for HIV Drug Resistance *HIVResNet*

St Vincent's Hospital Sydney



NSW HIV STRATEGY 2020



- Undiagnosed HIV infections contribute disproportionately to new cases
- Frequency of testing within gay & MSM groups not being met
- New initiatives to remove barriers to testing

$$[\text{TEST MORE}] + [\text{TREAT EARLY}] + [\text{STAY SAFE}] = \text{ENDING HIV}$$

Background – *why innovate testing?*

- NSW HIV strategy 2016-2020 identifies GBM and CALD as priority populations for testing
- HIV testing frequency in GBM is below recommended guidelines (STIGMA)
- Reducing time from test to treatment is desirable for public health
- GBM are interested in self testing however currently not available
- Those from CALD communities are more likely to be diagnosed late

Reasons for not testing - GBM



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	n = 1129	%
I haven't done anything risky	412	36.5
I don't want to know the result	143	12.7
I don't want to be seen getting a sexual health checkup	77	6.8
I don't want my family or other people to know	90	8.0
The process of getting tested is too much hassle	190	16.8
My doctor doesn't bulk bill	76	6.7
I don't like having to return for the results	191	16.9
I don't want to go to the doctor about this	80	7.1
I don't want to have to discuss my sex life	124	11.0
I don't like needles	99	8.8
I haven't had any symptoms or an illness that made me worry	187	16.6
Nothing – I never put off getting tested	414	36.7
Some other reason	118	10.5

Improving 'test and treat'

EXPERT REVIEW OF MOLECULAR DIAGNOSTICS, 2017
VOL. 17, NO. 12, 1109-1115
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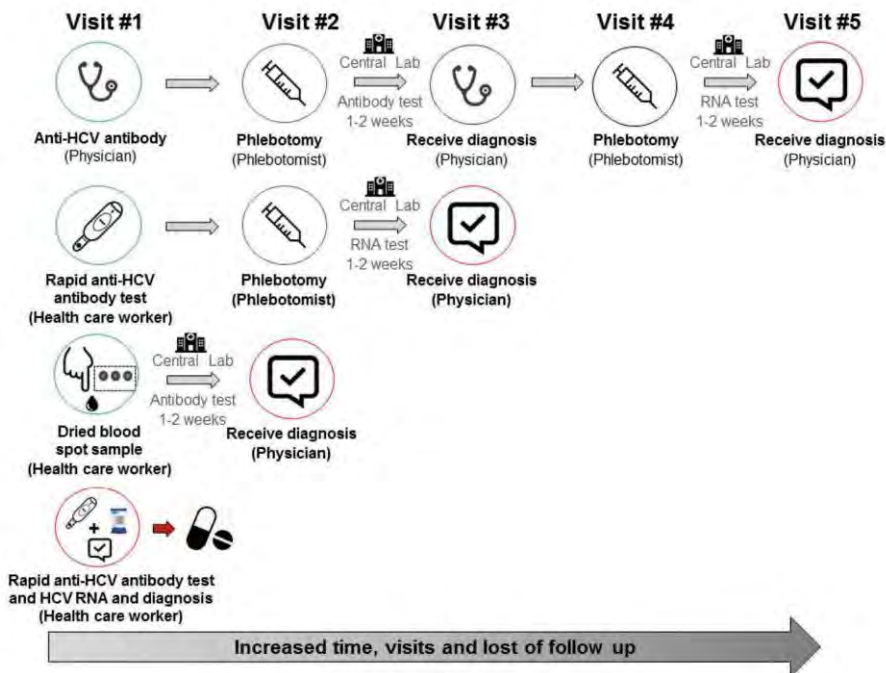
Check for updates

REVIEW

Hepatitis C point-of-care diagnostics: in search of a single visit diagnosis

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We need to do things differently

- **Conventional laboratory testing must be efficient**
 - Package full STI screen and increase TAT
- **Contemporary programs that take testing to people**
- **Point of care testing or near patient testing**
- **Peer led testing programs in community based settings**
- **Home sampling (eg. postal DBS programs)**
- **Home testing**

NSW HIV Strategy 2012-2015: A New Era



3.4 Promote HIV testing, making HIV testing easier to have a test

- Increasing access and increase frequency
- Remove barriers to testing – returning for results, cost barriers, recommended frequency
- Introduce rapid testing
- Reduce late diagnosis of HIV



BBV POCT considerations

- **Regulatory – are tests ATRG registered and meet TGA conditions**
- **Most BBV tests are class IV IVD (high public health risk)**
- **Quality management considerations**
 - Clinical governance
 - QC and participation in EQAS
 - Equipment maintenance and calibration
 - Operator training and competency (including peer educators)
 - Delivery of and management of test results and test data
- **Laboratory confirmation of screening (presumptive) results**
- **De-linking POCT from other laboratory tests (eg. HIV from STI screening)**
- **Linkage to care and loss to follow-up**
- **Costs – who pays ?**

TGA Conditions of approval

- HIV PoCT are classified as Class 4 in-vitro diagnostic devices (IVD)
- Any commercially available HIV PoCT must be registered on the Australian Register of Therapeutic Goods (ARTG)
- There are currently 3 approved HIV PoCT available in Australia

Device can only be supplied for use by:

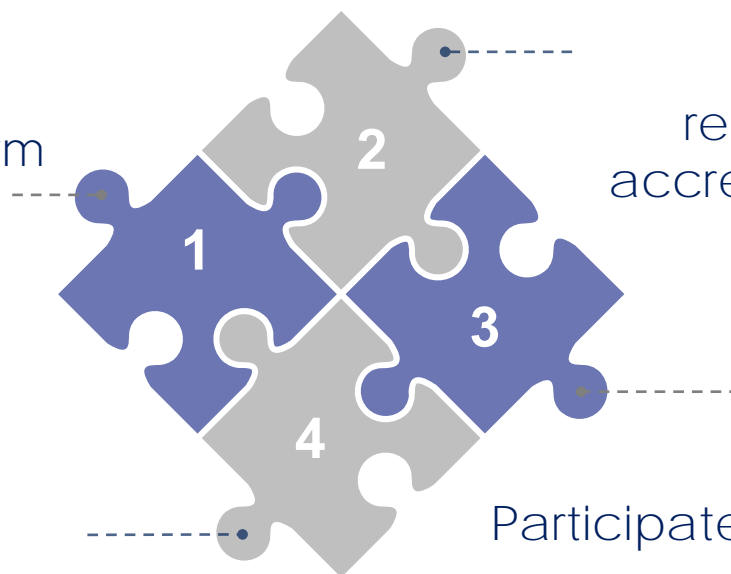
- a. NATA accredited laboratory
- b. Organisations that:
 - i. employ health professionals who perform or supervise performance of PoCT
 - ii. Have an established relationship with NATA accredited medical testing laboratory
 - iii. Participate in a recognised HIV PoCT quality assurance program
 - iv. Ensure PoCT operators are *comprehensively* trained

Sponsors (manufacturers) have reporting obligations to TGA in regard to compliance with conditions of registration

SITE REQUIREMENTS

Staff

Employ and train health professionals who perform or supervise HIV POCT



NATA Laboratory
Have an established relationship with a NATA accredited medical testing laboratory

Declaration

Provide to the sponser & TGA every 12 months evidence of compliance

EQAS
Participate in an external quality assurance proram

HIV PoCT **DEVICE'S** IN AUSTRALIA



Trinity Uni-Gold

ARTG Entry: 240814

Result time: 10 mins

HIV-1/2 antibody

Capillary sample

Preferred PoCT NSW



Alere Combo

ARTG Entry: 232957

Result time: 20 mins

HIV antibody/antigen

Capillary sample

Not used in NSW



OraQuick Advance

ARTG Entry: 240813

Result time: 20 mins

HIV-1/2 antibody

Capillary or oral fluid

1 location: oral fluid

FRAMEWORK AND STANDARD OPERATING PROCEDURE

FOR THE PROVISION OF POINT OF CARE TESTING FOR HIV IN CLINICAL AND NON-CLINICAL SETTINGS



Health

RAPID HIV TESTING

WHAT IS A RAPID HIV TEST?

Rapid HIV tests are used to get a result quickly (often within 30 minutes). Rapid tests use blood from a small prick of your finger collected by a specially trained health professional or care provider. The testing is conducted on-site. These tests are sometimes referred to as Point of Care Tests.

If your rapid test is reactive, there is a chance that you might be HIV positive but that is not certain – you will need a laboratory test to confirm the result. Laboratory HIV tests take longer – a few days to a week. They involve us collecting some of your blood with a needle, and sending it to the laboratory for testing by a technician.

WHO CAN HAVE A RAPID HIV TEST?

Rapid HIV tests are appropriate for groups of people who are at higher risk of HIV infection such as gay men and other men who have sex with men.

For other groups of people, laboratory testing is more suitable and we can refer you to other HIV testing services (please ask us for a list of local services). If you have a doctor you normally see, you could ask him or her about HIV testing.

If you have had a recent risk exposure or if you might be experiencing symptoms of a recent HIV infection (e.g. flu-like symptoms including fever, rash, headache, loss of appetite, muscle aches and swollen lymph nodes), please discuss this with the provider, as a laboratory test may be better for you.

WHICH RAPID HIV TEST IS USED AT THIS SITE?

The Determine Combo test is used at this site. It is the only rapid HIV test that has been approved for use in Australia at this time.

What are the possible results and what do they mean?

There are three possible results:

- Non-reactive (no evidence of HIV infection)
- Reactive (potential evidence of HIV infection, but a laboratory test is needed to confirm if correct; we will arrange a laboratory test today if you have a reactive result)
- Invalid (the test did not work so another test needs to be done)

HOW ACCURATE IS THE RAPID HIV TEST?

Overall, rapid HIV tests are very accurate, however a very small number of rapid HIV tests can give a false reactive result (around 6 in every 1,000 tests). This means the test reacts even though HIV is not present. Confirmation with a laboratory test is used to check whether the rapid test result is correct.

If a rapid test is conducted during the window period (i.e. the period after infection but before the test can detect the presence of the virus), the test may give a false-negative result. A non-reactive test today tells you that you were HIV negative three months ago.

Laboratory HIV tests can detect a recent HIV infection sooner than rapid HIV tests. Some laboratory tests can detect infections within approximately 3-6 weeks. If you have had a very recent risk that you are concerned about, please let us know so we can advise you about the best test for you.

HEALTH.NSW.GOV.AU

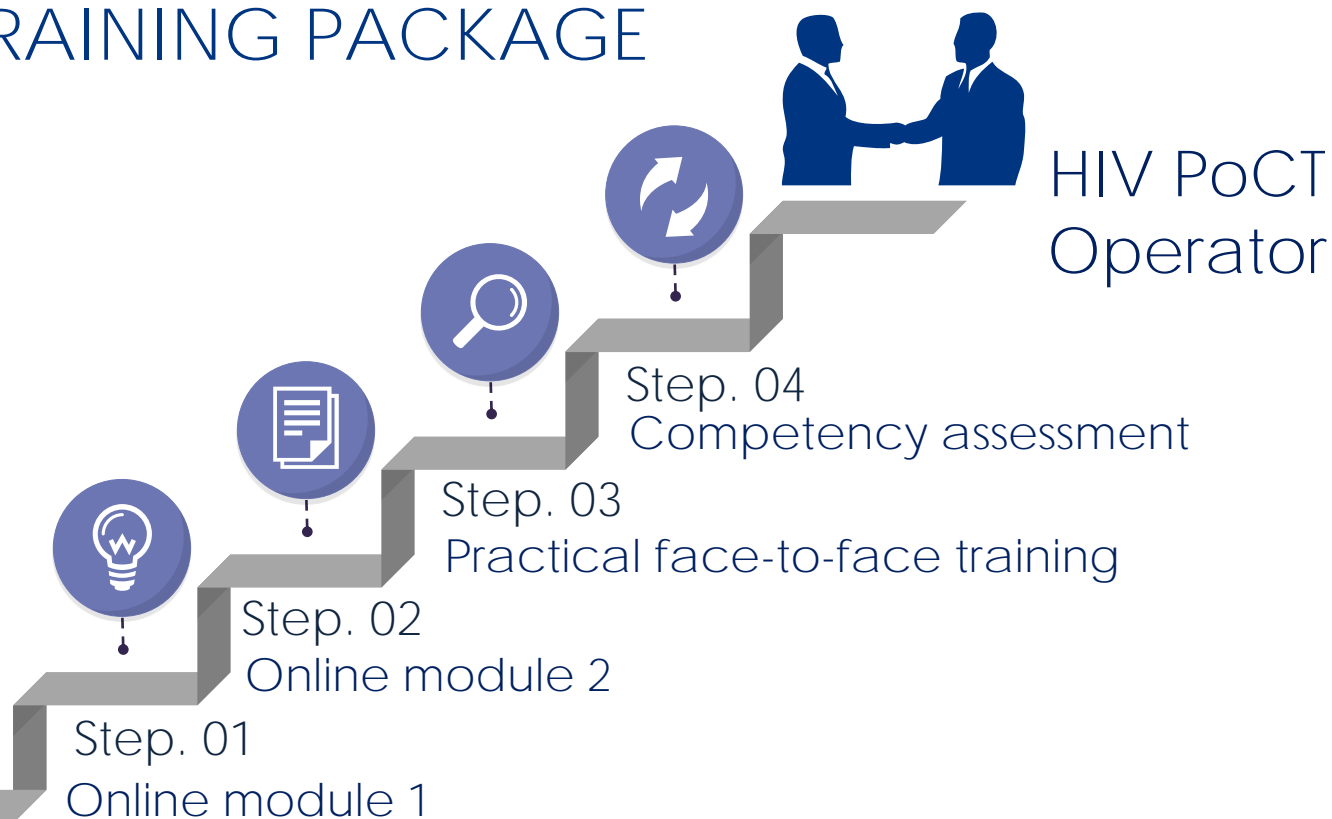
Comprehensive operator training



Most quality issues relate to adequate sample collection and training

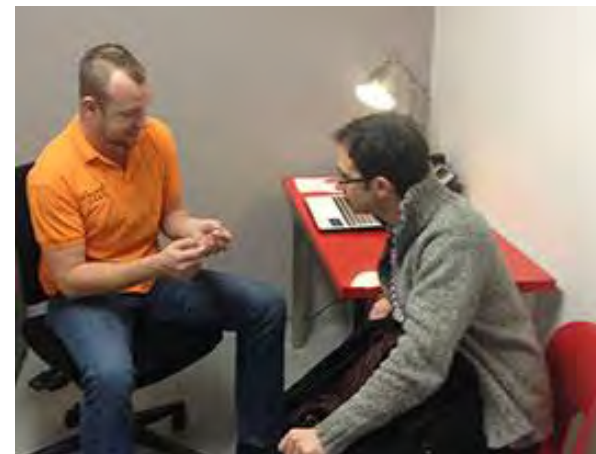


ASHM TRAINING PACKAGE



Implementation

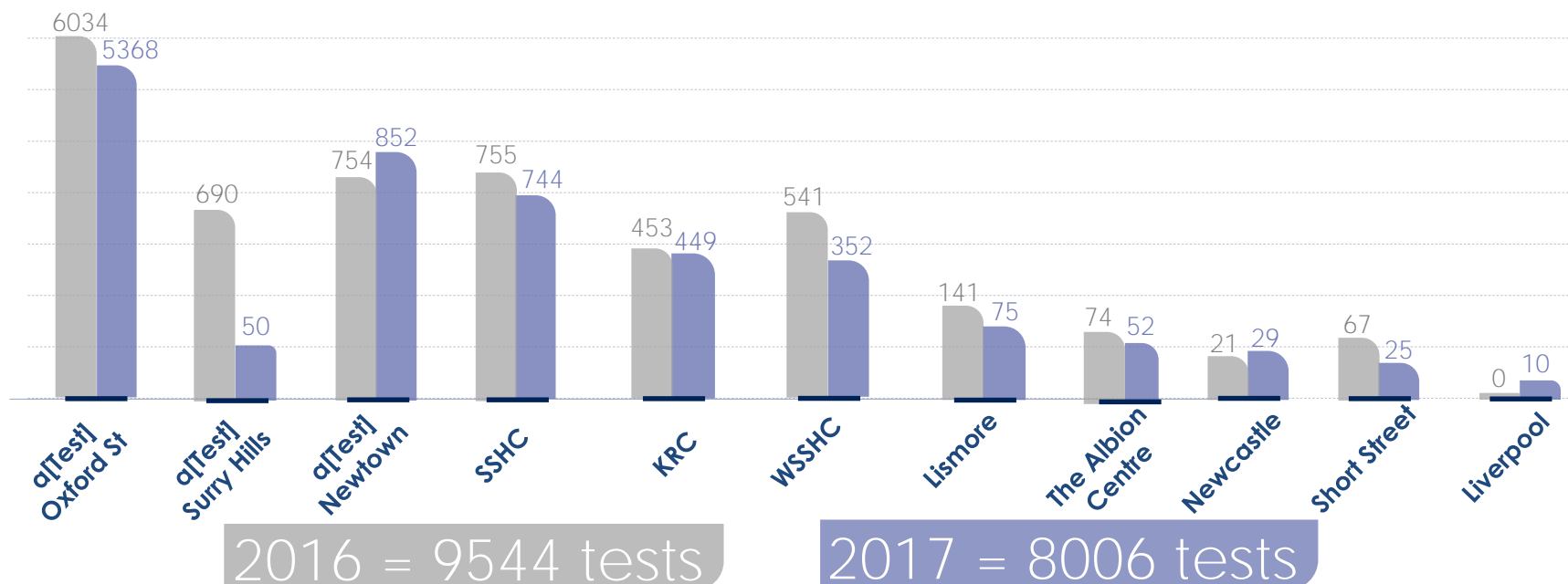
with a focus on community settings

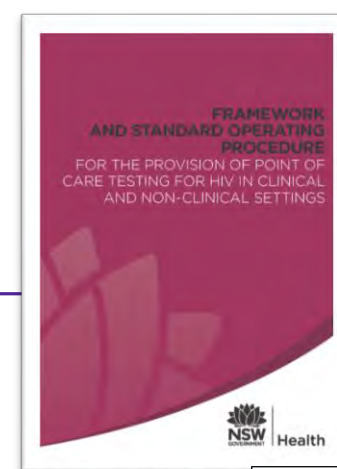


FAST, FREE & CONVENIENT

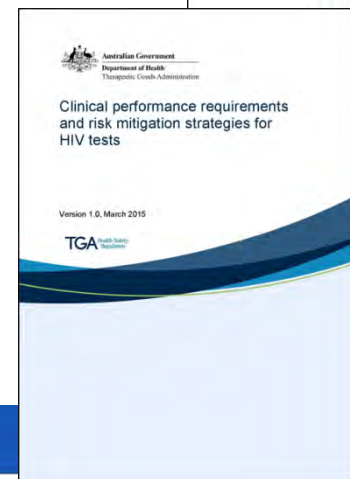
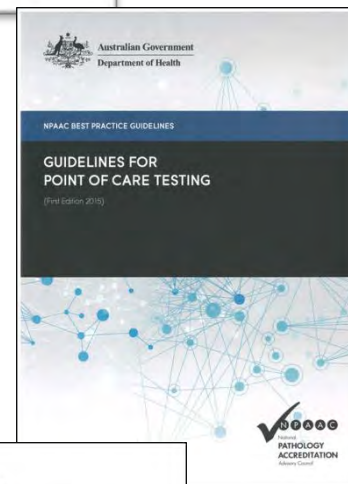
SITE ACTIVITY

Number of **PoCT's** per annum





NT'S
FOR APPLIED
RESEARCH



Who pays for POCT ?

Medicare benefits are only payable for pathology services if conducted within the Australian Pathology Accreditation framework

- 1. approved services are performed in a laboratory within an appropriate Accredited Pathology Laboratory (APL) category**
- 2. the service is rendered by or on behalf of an Approved Pathology Practitioner (APP)**
- 3. the proprietor of the laboratory is an Approved Pathology Authority (APA)**

Five laboratory categories :

- Category GX (general)**
 - Category GY (general)**
 - Category B (branch)**
 - Category M (medical practice)**
 - Category S (specialised)**
-
- Registered medical practitioner orders the test with approved request form**
 - Testing outside the framework maybe**
 - funded by health service or private arrangements**

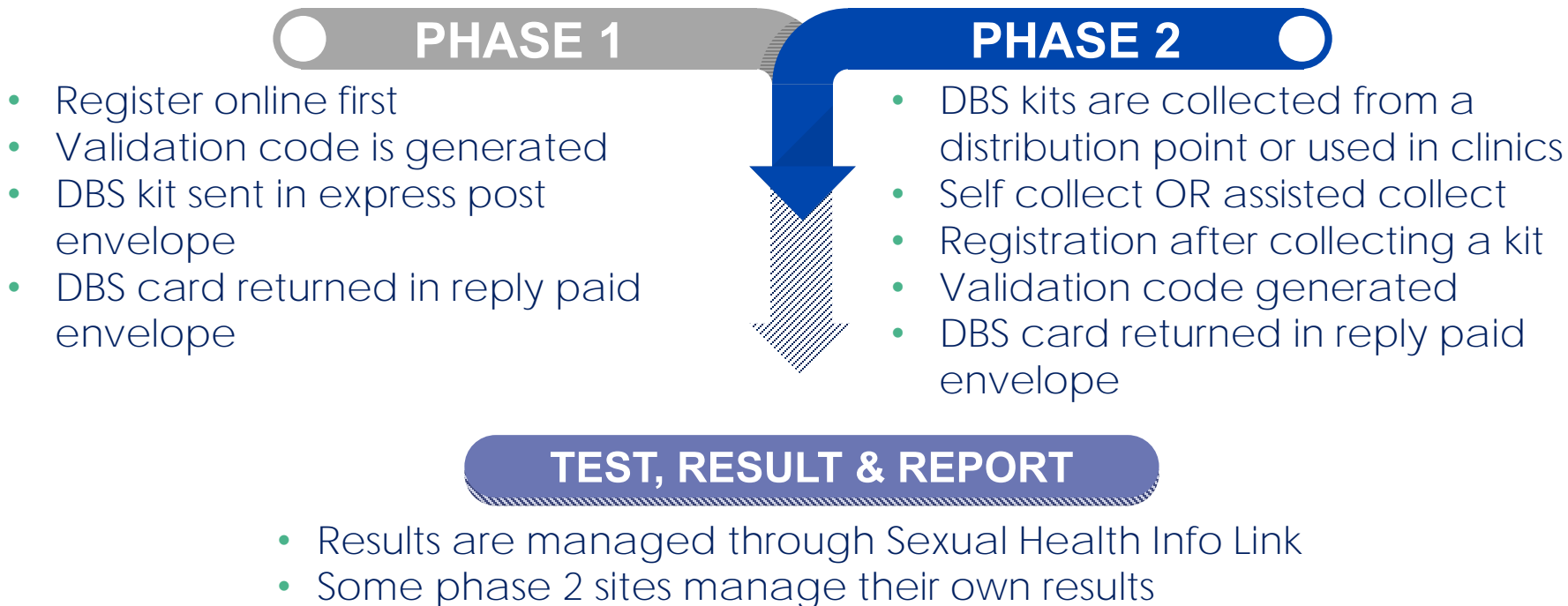
Home collection – Postal HIV Test HIV self-sampling pilot program (DBS)



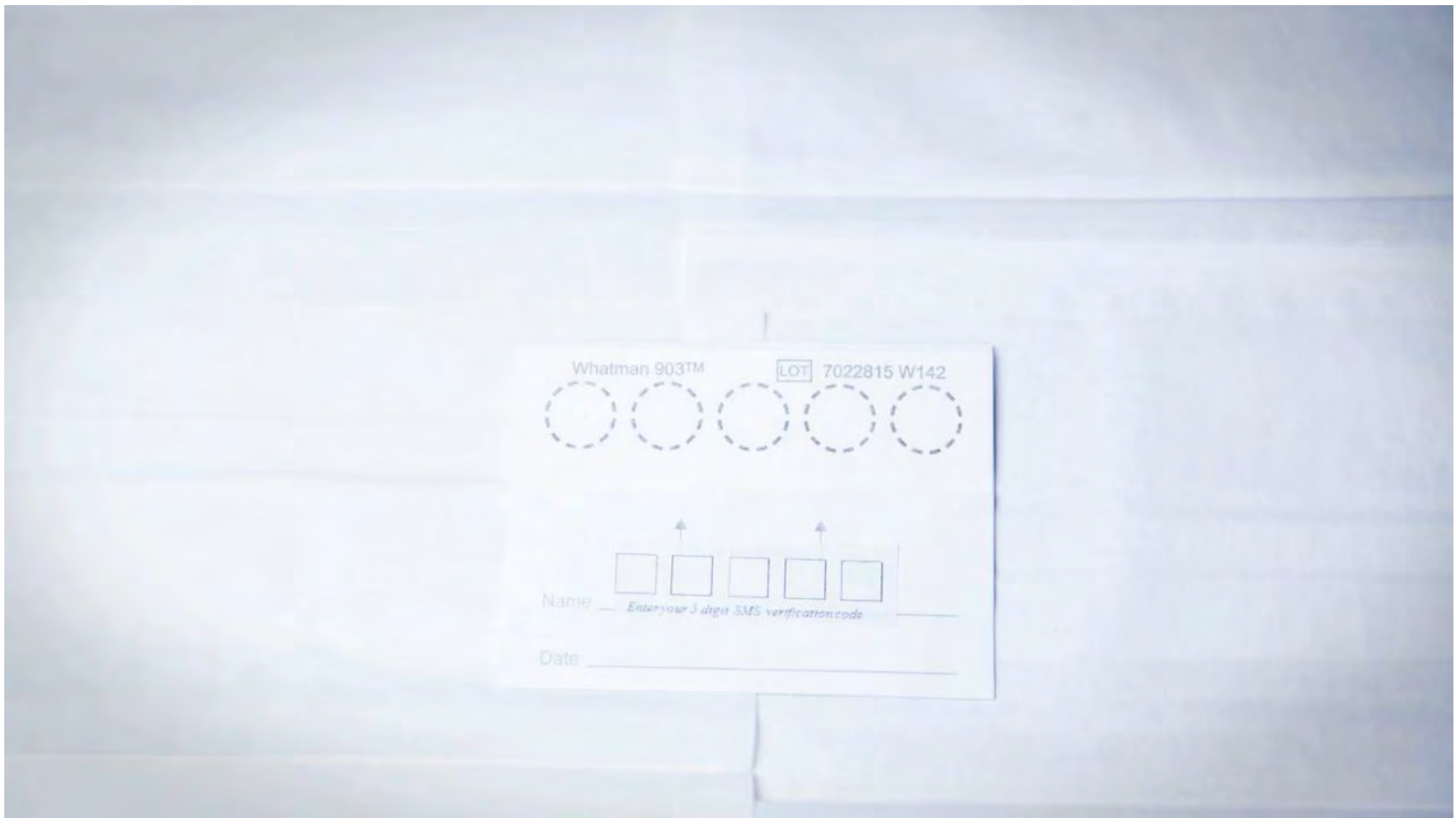
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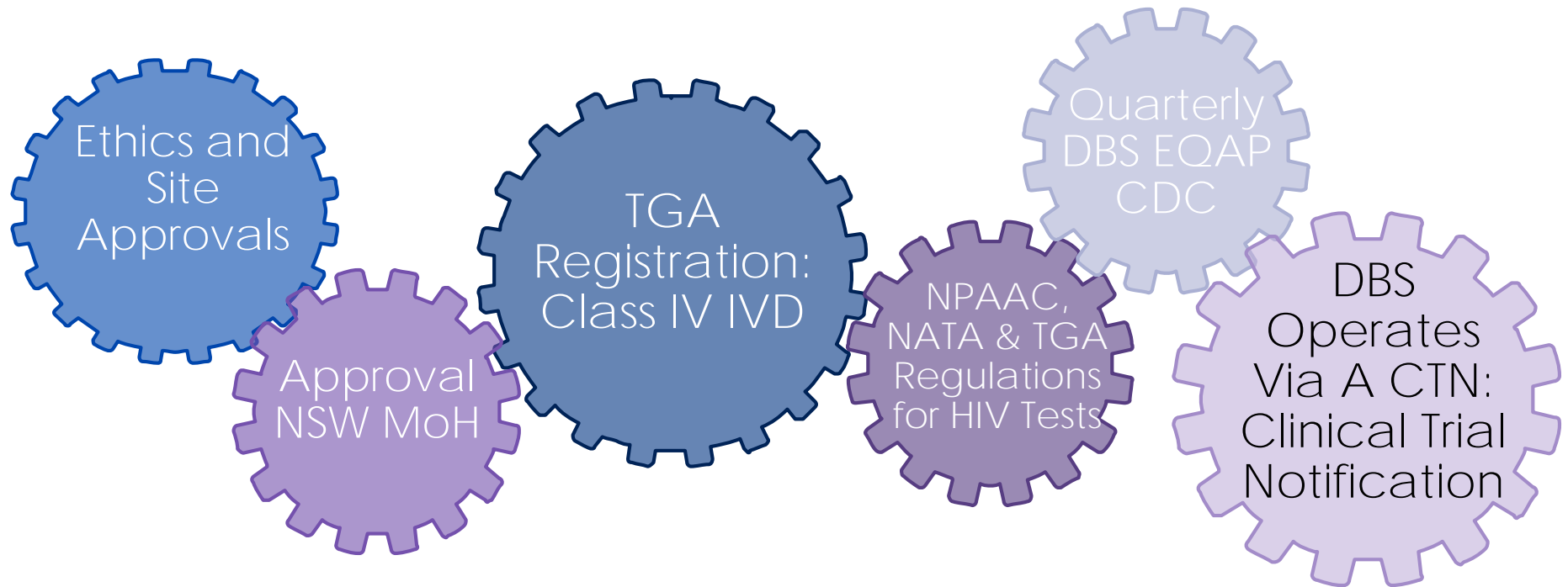
DBS PROJECT SET-UP



Postal HIV test – Dried Blood Spot



Governance

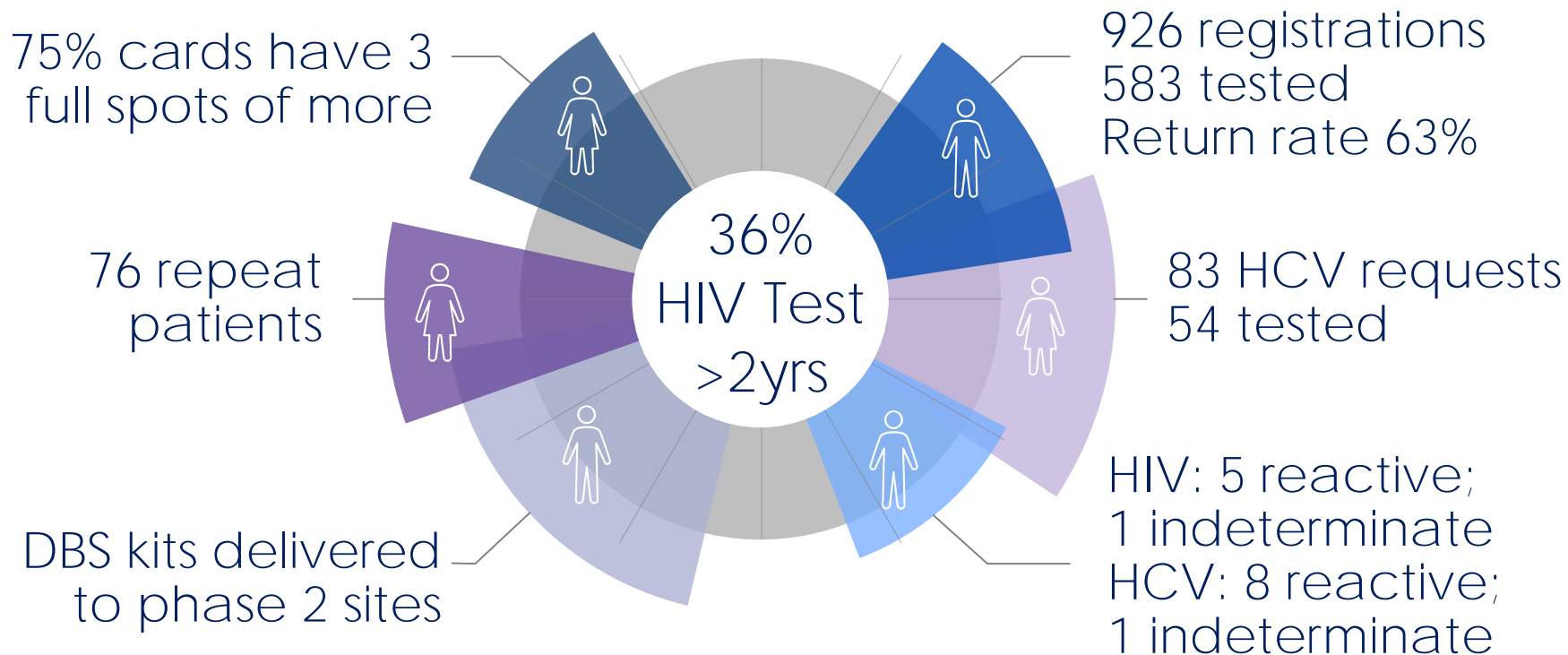


Program awareness

- Promoted through social media and local initiatives
- Translated into 10 languages



NOVEMBER 2016 - TODAY



Demographic data for registrations

HIV and Hepatitis C DBS Testing Pilot, 1 Nov 2016 to 31 March 2018



Target population	
	1 Nov 2016 – 31 March 2018
Aboriginal people*	44 (5%)
MSM	637 (72%)
Ever injected drugs*	71 (8%)
From Asia/Africa	231 (26%)
Partners from Asia/Africa	283 (32%)

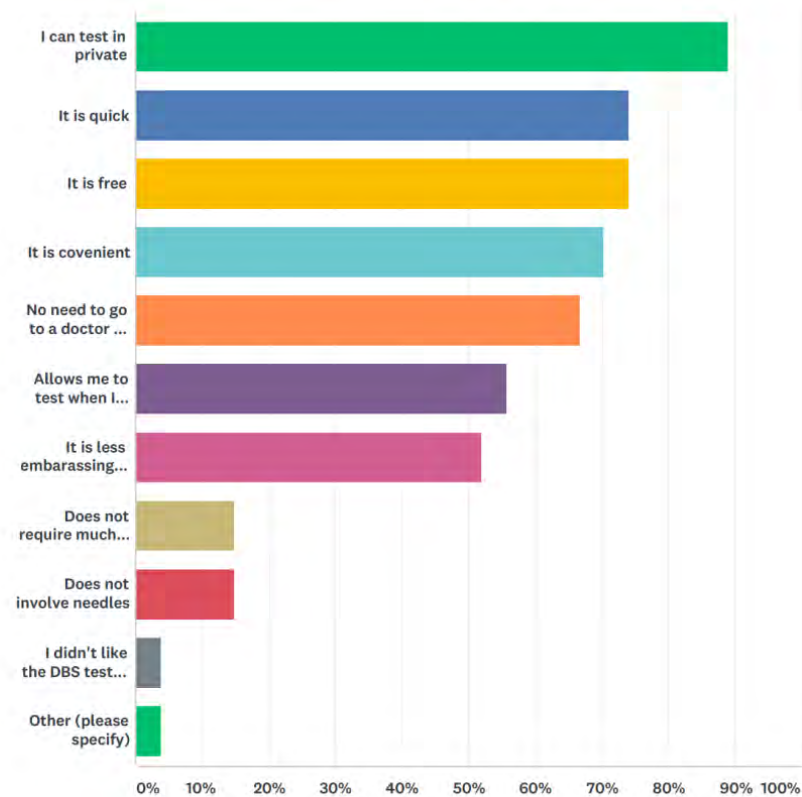
*Aboriginal people and people who have ever injected drugs included from September 2017.

Results

Post test survey

Q1 What did you like about using DBS HIV test? (Tick as many as you wish)

Answered: 27 Skipped: 0



Conclusions

- Embedded into the mix of the testing options in NSW
- New programs do improve HIV testing rates
- High rates of acceptability
- False negative POC in acute infection (as high as 50%)
- Importance of Quality Framework
- Ongoing regulatory issues
- Funding issues
- Sustainability of some programs
- Role of labs in support of community based testing programs

