

Biomedical Scientist Leading Innovation in Blood- Borne Virus Testing within Novel Community Settings across Wales

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1. Introduction

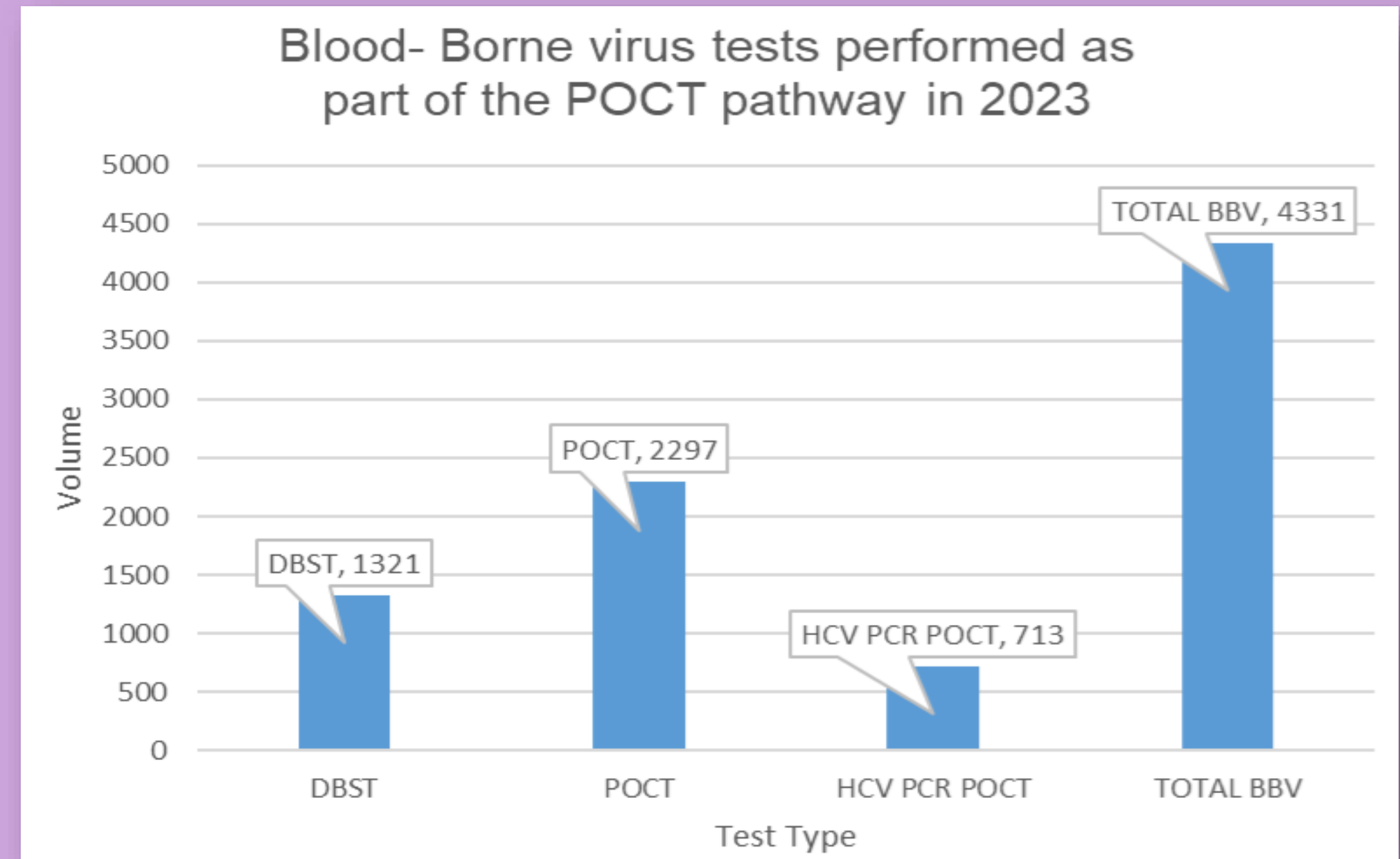
In 2016, the World Health Organisation (WHO) announced a global health sector strategy on viral hepatitis which sets out to eliminate hepatitis B (HBV) and hepatitis C (HCV) as significant public health threats by 2030.

In Wales, an innovative approach has been developed with a Biomedical Scientist (BMS) and Point of Care (POCT) Practitioners establishing a key role in the expansion of Blood-Borne Virus (BBV) testing.

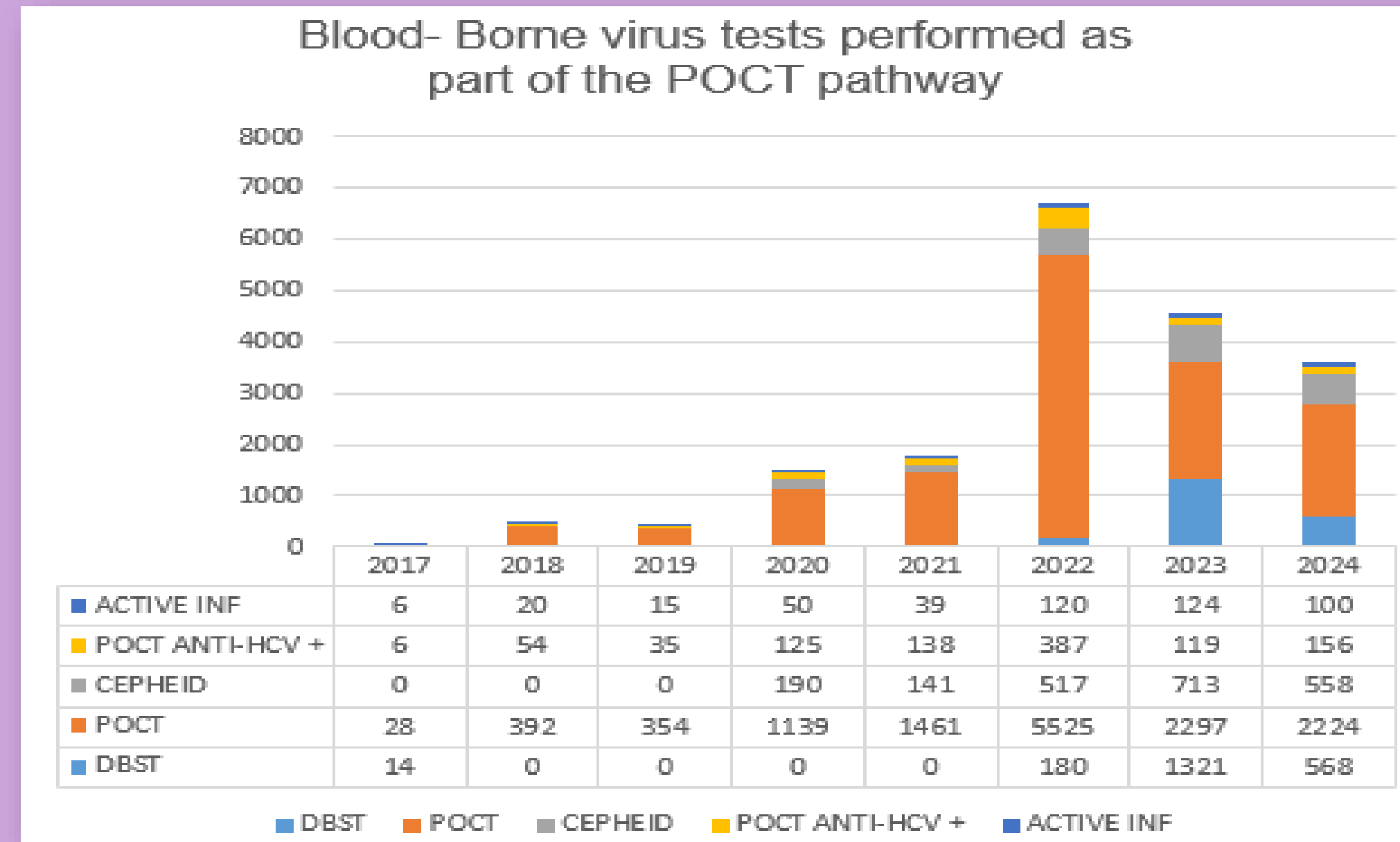
The team of three laboratory trained professionals set about implementing POCT services, organising clinic sessions and high intensity test and treat (HITT) initiatives in a range of settings using advanced diagnostic tools to diagnose BBV infections.

Particular focus was directed towards settings attended by 'high-risk' individuals in locations such as prisons, probation delivery units, substance misuse services, homeless shelters and mobile community-based outreach.

3. Results



Graph 1.



Graph 2.

In 2023 a team of three laboratory trained professionals held screening events at 35 different sites across Wales. The results of which are show in Graph 1. In some clinic sessions >30 patients were tested per day.

HCV POCT services came in to existence in Wales back in 2017. Graph 2 details the number of clinical tests performed across Wales since 2017.

>90% diagnosed with active infection as part of the POCT pathways have started treatment.

2. BBV testing method and strategy

As part of the BBV screening initiatives, patients were offered the following tests:

Test	Examine	Method	Description
Orasure, OraQuick®	HCV antibody	POCT	Finger-prick or oral swab providing result in 20-40 minutes
Cepheid, GeneXpert® *	HCV RNA (PCR) (Detection and quantification of HCV)	POCT	EDTA Micro-capillary blood sample (finger-prick) collection providing result in 60 minutes (100µl blood used for analysis)
Dried blood spot test (DBST)	Hepatitis C Virus Hepatitis B Virus HIV Syphilis	Sent to NHS laboratory	Capillary blood sample (finger prick) sent to laboratory for analysis. Results returned to requestor

Table.1 Description of clinical tests

* Only HCV antibody positive patients were tested on the Cepheid, GeneXpert.

Steps taken to plan each High Intensity Test and Treat session (HITS):

- Establish working groups; multidisciplinary approach to design bespoke pathways for each service.
- Assess environment to ensure there were adequate facilities available for testing.
- 'BBV look back exercises' undertaken to identify client history to ensure correct diagnostic tests were used.
- Appointment systems established to offer efficient access to testing for all clients.
- Staffing capacity plan actioned to create rosters to ensure sufficient staff cover and adequate time to perform testing and offer all clients a test at each service.
- Exit plans were developed with services to enhance sustainability of testing when the initiatives were complete.
- Robust result reporting mechanisms were established for clinical governance and epidemiological purposes.
- Workable treatment pathways were established, ensuring patients requiring intervention were treated.



Figure .1 Demonstrates the seven pillars of clinical Governance.

Clinical governance is a systematic approach to maintaining and improving the quality of patient care within the National Health Service.

4. Discussions

BMS and other laboratory trained staff are highly skilled professionals with an advanced knowledge of diagnostic techniques. In addition, they have knowledge of how testing strategies should be considered to ensure quality assurance (see figure.1) and patient safety.

Scientists understand the value of a diagnostic test, the importance of selecting the correct test method and undertake validation and verification procedures to evaluate manufacturers claims. They also appreciate the analytical factors to consider when performing and selecting diagnostic tests.

BMS staff recognise that test accuracy can be attributed to the sensitivity and specificity i.e the probability of a test identifying a true positive/negative. They are aware that tests have a lower limit of detection (LOD) and that some low-level infections might not be identified. They have expert knowledge of factors that can cause interference and generate limitations with the testing process which can lead to misleading results. On these occasions, the need for performing confirmatory tests is understood. Their appreciation of the importance of obtaining a good quality sample and correct timing of the test ensures validity of both the test and result.

Laboratory trained professionals work in a procedure-driven, systematic way appreciating the need to follow Standard Operating Procedures, so ensuring that testing practises are performed to the highest quality with accurate and meaningful results obtained. Their knowledge of quality control processes enables early identification of errors allowing prompt corrective measures to be applied. BMS are analytically minded and strive for evidence based continuous service improvement and possess the analytical skills to evaluate the outcomes of clinical sessions.

5. Conclusions

Testing across Wales is offered through a range of professionals and organisations which include substance use key workers, BBV nurses, third sector organisations and peers. However, BMS staff working in a patient-facing role, setting up clinical services to rapidly diagnose Hepatitis C and other BBV is an exciting and new concept.

BMS and other laboratory trained professionals leading high intensity BBV screening has proven to be highly effective. They have proven to possess the key attributes, skills and expertise to establish an enhanced, high-quality clinical BBV testing service. The logical, rational and methodical working practices along with adherence to quality assurance processes ensures accuracy of test performance. The team have led high intensity testing initiatives in a range of settings across Wales, which has demonstrated enhancement of diagnostic and treatment outcomes.



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