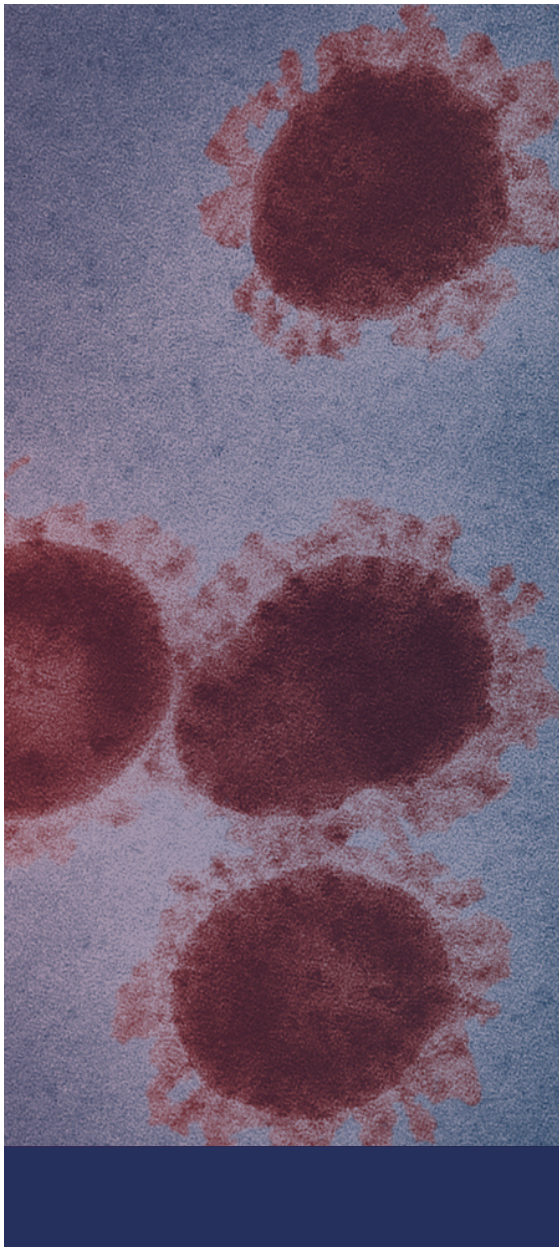
NRL WORKSHOP ABSTRACTS

MONDAY 9 OCTOBER

2023



Title: The sustainability, clinical effectiveness, and quality of a large, decentralised point-of-care testing network for STIs in rural and remote primary care clinics in Australia

Author: Dr Louise Causer

[1]. Kirby Institute, UNSW, Sydney, NSW, Australia

Abstract: Following a world-first cluster-randomised controlled trial (called TTANGO – Test, Treat and Go), molecular point-of-care testing (POCT) for Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG) and Trichomonas vaginalis (TV) has been programmatically scaled-up to regional and remote primary health clinics across Australia since 2016 during which time clinics could offer laboratory testing and POCT. This presentation will share findings and key lesson learnt from a recent evaluation assessing clinical effectiveness, sustainability, and quality of POCT for CT/NG and TV delivered through this program using routinely collected clinic and program testing data from participating clinics.

Title: LIFEBLOOD – MORE THAN A BLOOD BANK: SEROSURVEILLANCE FOR SARS-COV-2, JEV, AND OTHER PATHOGENS IN BLOOD DONORS

Authors: Gosbell, Iain B; [1], [2] Hirani, Rena;[3],[4] Hoad, Veronica C.;[1] Irving, David O.[3] [5]

Affiliation(s):

[1]Pathology & Clinical Governance, Australian Red Cross Lifeblood, West Melbourne; [2] School of Medicine, Western Sydney University, Penrith; [3]Research & Development, Australian Red Cross Lifeblood, West Melbourne; [4]Department of Molecular Sciences, Macquarie University, Sydney; [5]Australia Faculty of Health, University of Technology, Sydney, Australia.

Text of abstract:

The Australian Red Cross Lifeblood is a national organisation that not only supplies blood and plasma products but also provides products such as serum eye drops, human milk, and FMT, and provides services to transplantation, an extensive educative program to hospitals, and a major Research and Development unit, and has links to all governments and some regulators.

Lifeblood responded to the COVID-19 emergency by establishing immediately the blood supply would not transmit SARS-CoV-2, and we ensured supply was never jeopardised. We instituted infection prevention policy, procedure and education aligning with current public health requirements. Lifeblood decided to contribute what it could to the national COVID-19 response, including participating in several serosurveillance projects to help governments track how transmission and immunity evolved geographically and temporally. The various public health manoeuvres kept SARS-CoV-2 infection to very low levels, and immunity (presence of anti-S antibodies) rose in parallel with vaccination roll-out, until the Omicron Variant of Concern arrived, most of the population got infected and composite immunity from vaccination and infection became almost universal.

The connections with multiple researchers and organisations developed with the COVID-19 works came to the fore when Japanese encephalitis virus emerged in Australia, and there was rapid development and execution of various JEV seroprevalence projects including one involving blood donors. We found a low level of immunity in regions where JEV was detected, so this as combined with other data to inform public health decisions.

It was recognised internationally and by Lifeblood management that blood donors are a valuable source of specimens that can be tested for certain pathogens to inform public health responses, noting blood donors are healthy people >18 years of age without deferrals for specified infection risks. This culminated in serosurveillance being included in the new business plan, Lifeblood Unlocked, with new collaborative projects being developed.

Title: Using routine laboratory testing data to enhance surveillance of HTLV-1

Author: Nicolas Legrand - Kirby Institute

Human T-lymphotropic virus type 1 (HTLV-1) is estimated to affect 5 to 10 million people globally and can cause severe disease, including adult T-cell leukemia/lymphoma (ATL) and HTLV-1-associated myelopathy/tropical spastic paraparesis (HAM/TSP). Globally, the burden of HTLV-1 infection is not distributed uniformly, with higher prevalence in discrete regions and populations. In Australia, existing data indicate a significantly higher HTLV-1 prevalence among Aboriginal communities in Central Australia compared to other regions, with rates 1,000 to 10,000 times greater than those among blood donors. Gathering representative prevalence data through community-based surveys is the gold standard, however these surveys can be logistically challenging across extensive regions. To address this gap, we are undertaking an expanded surveillance study to enhance our understanding of HTLV-1 epidemiology in Australia. Using routine HTLV-1 laboratory testing data from Qld, NT, WA, and SA, in combination with notifications data from the NT, our objective is to compile systematic information on HTLV-1 testing practices. This will provide insight into how testing coverage has evolved over time, and identify factors associated with test positivity.

Title: Access and Opportunity

Authors: Jacky Thomas, Skye McGregor, Lise Lafferty, Handan Wand, Rebecca Guy, Caroline Watts, Robert Monaghan

Background

Access: Many Aboriginal-led organisations conduct health promotion activities targeting young people, but rarely are they rigorously evaluated. The opportunity to enhance an innovative health promotion program called Walkabout, and then evaluate its impact on sexual health. Established in 2018, the Walkabout Barber/Beautiful (Walkabout) is led by Aboriginal and/or Torres Strait Islander men and women and provides haircuts, beauty services. Mental health and sexual health and two of the key health issues for young people, thus expanding this novel interface to integrate sexual health promotion and STI testing is a natural next step. The addition of sexual health to the Walkabout program provided a unique opportunity to engage people, facilitate discussions, breakdown stigma with the objective of improving access to sexual health information and access to sexual health clinical services.

Opportunity: The Medicare Benefits Schedule item 715 is designed to provide a comprehensive annual health check for Aboriginal and/or Torres Strait Islander people. The 715 includes a detailed medical history, a medical examination, and relevant pathology, including sexually transmitted infections (STI) and blood borne viruses (BBV) testing, as per guidelines. The check provides an important opportunity to normalise STI /BBV testing and reduce stigma.

Innovative models are being used to increase the uptake of 715s but have not been formally evaluated. A variety of health promotion initiatives have been used to encourage young people to come forward for a 715, such as the 'Deadly Choices' program (and comparable less costly versions), where Aboriginal Community Control Health Services (ACCHS) or Aboriginal Medical Services (AMSs) can purchase a package of incentives (e.g. t-shirts, celebrity visits) and deliver them in the community. However, none of these programs have been formally evaluated. There is urgent need to optimise, evaluate and scale up the use of these models as AIHW data show that only 28% of the Aboriginal population received at least one 715 Health Check in the 12-month period to June 2020.

Title: Evaluation of a program providing operator training, quality assurance, and quality control for point-of-care testing for hepatitis C infection

Author: Jae Williams

Robust training and compliance with standard operating procedures underpin point-of-care (POC) testing quality, thus minimising patient harm. At the time of this evaluation, the National Australian HCV POC Testing Program had delivered standardised training to 31 health services (of 89 planned). As part of continual quality improvement, this study evaluated HCV POC testing operator competence and error rates during initial Program scale-up. Standardised training for GeneXpert HCV Viral Load Fingerstick POC testing was developed and delivered to staff at enrolled services. Pre- and post- training competency improvement surveys were completed for specimen collection, quality control, RNA testing and result interpretation. Ninety-seven operators completed HCV POC training, with 23% having previous GeneXpert experience. Staff performing HCV POC testing recognise the importance of robust training, standard operating procedure compliance and ongoing skill acquisition for GeneXpert competency. Supplementary training can further reduce test errors and cartridge wastage. Comprehensive training with competency assessment and embedded continual quality improvement are essential for scale-up and delivery of high-quality POC testing.

Title: Safety and Feasibility of a Repeat Testing Algorithm for Initial Reactive Samples in Nucleic Acid Testing of Blood Donations: A Retrospective Analysis for Occult Hepatitis B Infection (OBI) Profiling

Authors: Mohd Hazwan Ab Halim[1], Mohd Azam Mohd Nor[1], Murniwati Mat Radzi[1], Norazyan Ahmad[1], Lailatul Binti Mohd Yuso[1]

[1]. TRANSFUSION MICROBIOLOGY DIVISION, PUSAT DARAH NEGARA, KUALA LUMPUR, Malaysia

Background

Ensuring the safety of blood components necessitates a highly sensitive and specific nucleic acid test (NAT) capable of detecting blood-borne viruses. Over the past two decades, individual-donation NAT screening of blood donations has been widely adopted as a standard practice in developed countries,. Despite the efficacy of this method, confirming the accuracy of initial reactive (IR) NAT samples remains challenging. To address this issue, various algorithms are currently employed to mitigate false reactive results. This study aims to substantiate the safety and feasibility of the algorithm implemented in 2011, which involves triplicate runs of repeat testing for IR samples. Extensive analysis of data from 2013 to 2015 was performed, focusing on cases where subsequent donation data were available.

Methods

Between December 2013 and November 2019, ID-NAT screening utilized the Procleix Ultrio Plus assay on a Procleix Tigris system. The screening process involved subjecting all IR samples to repeat testing in triplicate independent runs for NAT Only reactive case. Only when all three results yielded non-reactive outcomes (designated as Repeatedly Non-Reactive = RNR) was the donor allowed to return to the donor pool for future donations. Retrospective data analysis from the period 2013 to 2015 was conducted to identify instances where an initial reactive result reoccurred in subsequent donations following the initial RNR result. Additionally, Anti-HBc and Anti-HBs testing was performed to develop an occult hepatitis B (OBI) profile.

Results

Among the 1,079,066 donations tested, 180 samples were identified as Repeat Non Reactive (RNR), making up only 0.04% of the total donations. Due to certain limitations, donor information was available for only 159 of these donations, and out of these, 108 donors returned for their next donation. With the exception of six donors, all others were found to be ID-NAT non-reactive. Five of the returning donors showed Anti-HBc reactivity.

Regarding the OBI profile, 51 samples exhibited Anti-HBc reactivity, and among them, 35 had an unprotective level of Anti-HBs (<100 IU/ml).

Discussion/Conclusion:

Prior to 2011, all RNR cases underwent Anti-HBc testing, and only those with non-reactive results were permitted to make future donations but the all blood products were discard. If the same algorithm were used today, it would result in 51 donors being deferred for future donation, causing donor loss. The current algorithm is considered safe since 94.4% of RNR donors do not show a recurrence of RNR results in subsequent donations, with only six exceptions. Among them, only one donor fell into the window period category, but there is no evidence of any seroconversion taking place in the follow-up sample. Considering the donor profile, it would be beneficial to subject any recurrent RNR case to Anti-HBc and Anti-HBs testing before the donor can return to the donor pool.

Title: Three years experience in NAT Testing of Blood Donor using Procleix Ultrio Elite at National Blood Center of Malaysia

Authors: Mohd Hazwan Ab Halim[1], Mohd Azam Mohd Nor[1], Murniwati Mat Radzi[1], Elizebeth Mah[1], Noor Afidah Abd Majid[1], Aishah Farliani Shirat[1], Malisanurhidayu Yaacob[1], Mohd Izar Omar[1], Norazyan Ahmad[1], Hana Najian Mokhtardin[1], Mohd Adib Taha[1]

[1]. TRANSFUSION MICROBIOLOGY DIVISION, PUSAT DARAH NEGARA, KUALA LUMPUR, Malaysia

Introduction:

Nucleic acid amplification testing (NAT) is a highly sensitive and specific method for detecting viral nucleic acids, particularly useful in reducing the window period for virus detection. Since 2020, National Blood Center of Malaysia has used Procleix Ultrio Elite assay for routine screening. This study aims to assess the outcomes of NAT testing over three years of using this new assay.

Materials and Methods:

A retrospective analysis of TTI-reactive units from January 2020 to December 2022 was carried out. Blood units underwent screening using the Procleix Ultrio Elite assay on the Panther System, and the NAT yield for Hepatitis B, C, and HIV was calculated.

Results:

Among the 546,098 collected blood units, 94 units were found to be NAT yields which attribute to 0.017 %. With ID-NAT, we have identified six HIV WP Nat yields (1:91,016), one HCV WP Nat yields (1:546,098), 66 HBV WP Nat yields (1:8,274) and 21 non discriminate NAT yields (1:26,004)

Conclusion:

Our findings indicate that NAT is more sensitive than chemiluminescence in detecting Hepatitis B infections, including both the window period and occult infections. The implementation of NAT has significantly contributed to safer blood transfusions by reducing the risk of window period transmissions of Hepatitis B.

Title: LESSONS LEARNT FROM EXTERNAL QUALITY ASSESSMENT SCHEME IN POCT SETTING

Authors: Imasha IA Amarasuriya[1], Liza LC Cabuang[1], Wayne WD Dimech[1]

[1]. NRL, Fitzroy, VIC, Australia

Background: COVID-19 is a respiratory disease that continues to be a serious global health threat. The Foundation for Innovative New Diagnostics (FIND) funded NRL to provide COVID-19 External Quality Assessment Scheme (EQAS) to point-of-care (POC) settings to increase access to testing in low-and middle-income countries. EQAS was introduced to first time users at POC sites, allowing NRL to perform comparisons of assay and operator performance.

Method: Six panel configurations were created using different dilutions of the original Type B strain, and delta and omicron variants. Each panel had five vials with randomly generated code labels, linked to a sample name. Participant data was analysed to determine "true reactive" rates of each dilution and to collect data on performance of operators using different rapid diagnostic tests (RDT).

Results: Sixty-one sites submitted results (from eight countries); however, five sites only submitted results for less than two samples in the panel. The highest true reactive rate with 47.45% was observed in the omicron variant. The same concentration of the Type B strain and delta variant had true reactive rates of 37.93% and 31.03%, respectively. The participants identified the COVID-19 negative sample with an accuracy of 87.80%. Participants used nine different RDT, with the majority using the Panbio covid-19 rapid test device (nasal) and standard Q COVID-19Ag test.

Discussion: We provided different variants because most of the RDT were designed to detect Type B, which may impact on the detection of other strains. Equally, the testing was performed by non-clinical operators in POC settings which could lead in result transcriptional and performance errors.

Conclusion: Our EQA shows what the advantages of subscribing are to POC sites. We can use these data to address concerns related to operator training components, performance of RDT and concentrations of panel samples to optimise EQA schemes in future.

Title: Evaluation of the Cepheid Xpert® HIV-1 Viral Load for use with Dried Blood Spot Samples; And an Evaluation of the Xpert® HIV-1 Qual XC

Authors: LP McNally[1], I Hanafi[1], M Starr[1], J Nonweiler[2], PH Cunningham[1,3]

[1]NSW State Reference Laboratory for HIV/AIDS, St. Vincent's Hospital, Sydney [2]Cepheid Holdings Pty. Ltd., Macquarie Park, Sydney [3]Kirby Institute, University of New South Wales, Sydney

The use of Dried Blood Spot (DBS) specimens for HIV testing is well established in many settings. This includes resource-limited settings, for collecting and transporting early infant diagnosis (EID) specimens for nucleic acid testing primarily in centralized laboratories. This includes HIV-1 qualitative and quantitative testing and for the determination of HIV-1 drug resistance profiles. DBS samples offer an advantage over more routine whole blood collection procedures in that they can be collected from a finger or heel prick and do not require any specialized equipment such as centrifuges or refrigeration at the collection site and can be easily transported and stored at 2-25 °C or -15 °C or colder for up to 12 weeks.

The GeneXpert® system is in use in many resource-limited settings and offers a rapid time to result without the requirement for batch testing and enables consultation of the patient in other health related assessments whilst testing is in progress and the ability to issue results and therefore initiate treatment in cases where the patient may otherwise be lost to follow-up.

We are currently undertaking a small feasibility study to evaluate the use of DBS specimens on the Cepheid Xpert® HIV-1 Viral Load assay, which has a claim for plasma samples only. Initial results have shown that HIV-1 viral load can be quantified following the DBS protocol used for the Cepheid Xpert® HIV-1 Qual which has a claim for DBS as a suitable specimen type. Further correlation studies will be performed with plasma HIV-1.

A further small evaluation of the recently released Xpert® HIV-1 Qual XC (Extended Claims) assay in comparison to the original Xpert® HIV-1 Qual assay will also be presented. The Xpert® HIV-1 Qual assay is in routine use in our laboratory as part of our HIV Confirmatory testing algorithm and has proven to be beneficial in clarifying indeterminate/inconclusive reference serology results, in HIV-1 seroconversion and EID. The Xpert® HIV-1 Qual XC assay provides a simplified workflow for both EDTA whole blood and DBS samples, with an improved time to result, and a lower limit of detection for whole blood specimens.

FIND
Diagnosis for all

DxConnect

Virtual Biobank

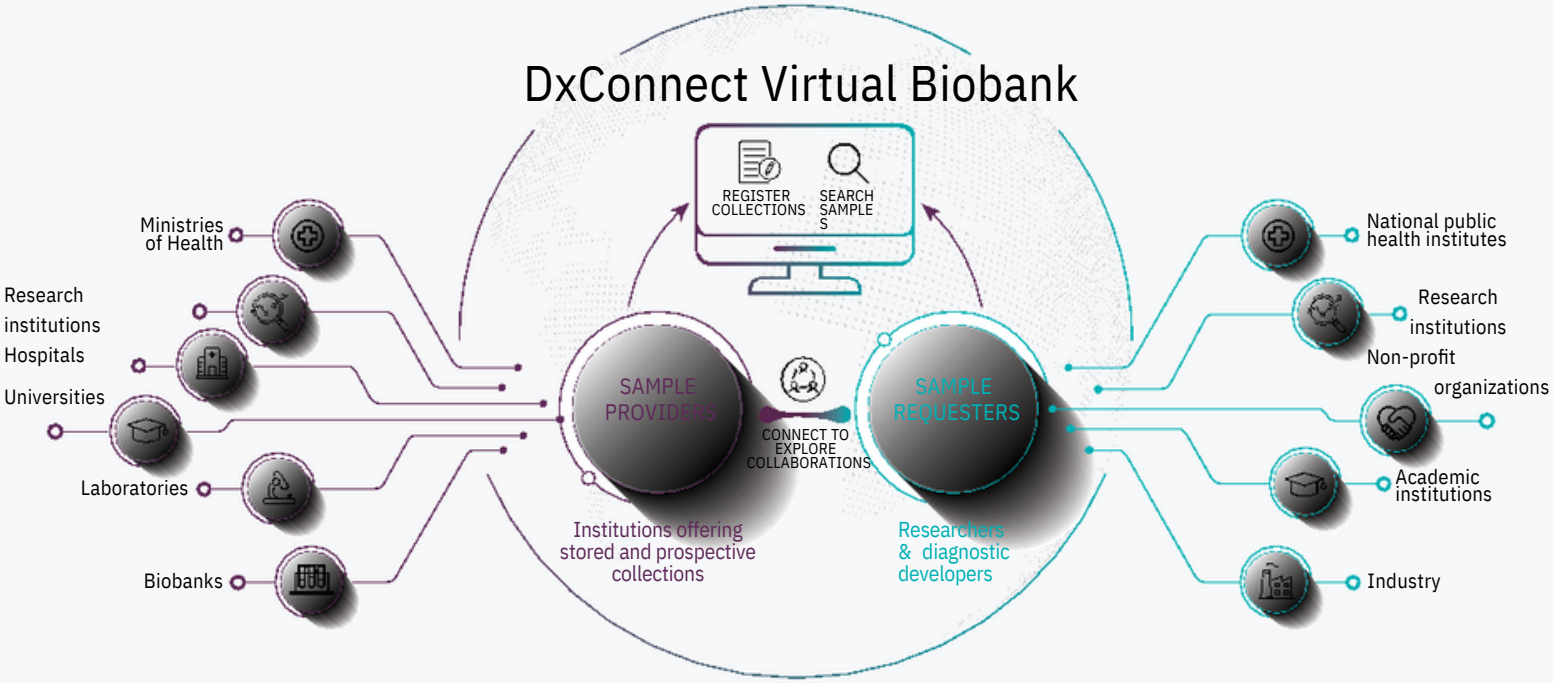
An open-access platform providing a global view of infectious disease sample collections available worldwide

Why a Virtual Biobank?

Access to a wide range of well-characterized samples relevant to the intended use is critical for developing diagnostic tests. But difficulties finding and acquiring biological samples, particularly of infectious diseases create a real barrier to diagnostic development. Meanwhile, samples that have been ethically collected worldwide are stored in repositories but remain difficult to access for researchers.

The DxConnect Virtual Biobank connects institutions holding infectious disease samples with the researchers who need them for developing diagnostic tests, addressing the challenge of sample procurement from dispersed collections. The open-access platform exhibits and helps to locate samples from multiple repositories, without registration or use fee.

DxConnect Virtual Biobank



SAMPLE PROVIDERS

Increase the visibility of your samples to maximize their use, value and impact

REGISTER your institution and sample collections on the directory to make them visible to researchers and engage in new research collaborations.

- Increase discoverability of your collections and prospective collection capabilities.
- Maintain full control of your physical collections while displaying them on a virtual platform.
- Explore research collaborations and co-authoring opportunities for benefit sharing.

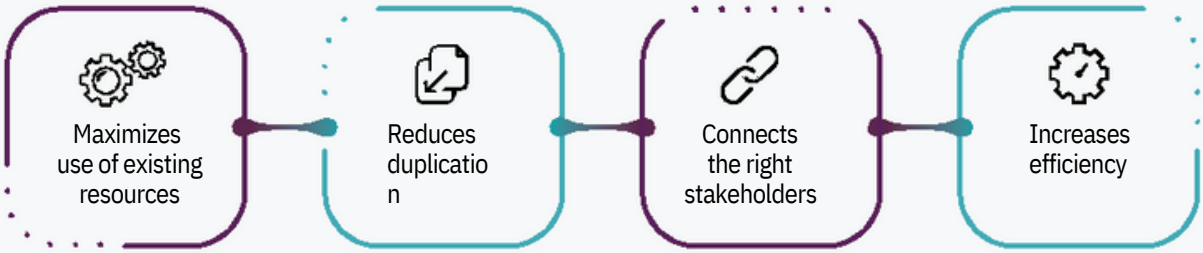
SAMPLE REQUESTERS

Easily locate samples on a central platform designed to support your research

SEARCH sample collections from institutions globally to quickly procure relevant high-quality samples, vital to develop, validate and assess diagnostic tests.

- Fulfil your sample requirements through a streamlined search on a global platform.
- Locate stored samples and find partners to prospectively collect the samples you need.
- Discuss specific requirements and research collaboration opportunities with providers.

The DxConnect Virtual Biobank goal is one of collective action and collaboration



Collaborative data and sample exchange are key to advancing research. Together, we can have a greater impact on infectious disease control and elimination by accelerating the development of high-priority diagnostic tools.

MORE INFORMATION

CONTACT US

Driven by researchers' needs and designed to overcome the difficulty of accessing suitable samples for diagnostic development, the platform will continue to evolve to serve its users. Contact us to share your feedback or engage a collaboration.

The DxConnect Virtual Biobank is hosted by FIND, the global alliance for diagnostics, supported by grants from the Bill & Melinda Gates Foundation and Unitaid and made possible by the valuable contribution of a network of institutions that have registered their sample collections. The software platform is developed in collaboration with the Digital Research Service department at the University of Nottingham.

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Title: Prevalence and Trends of Blood-Borne Viral Infections Among Blood Donors in Malaysia: An 6-Year Retrospective Analysis

Authors: Mohd Hazwan Ab Halim[1], Mohd Azam Mohd Nor[1], Balkis Mohd Amin[1], Lailatul Zuraida Mohd Yusof[1], Hafidzah binti Mond Nor[1], Mohd Nor Fazil[1]

1. TRANSFUSION MICROBIOLOGY DIVISION, PUSAT DARAH NEGARA, KUALA LUMPUR, Malaysia

Background: Blood transfusion-associated blood-borne viral infections, such as hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), pose significant public health concerns. The repercussions of transmitting infected blood extend beyond the recipients to encompass their families, communities, and society at large.

Aims: The purpose of this study was to evaluate the trends and prevalence of hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) among blood donors in Malaysia.

Materials and Methods: Employing a retrospective cross-sectional design, data spanning six consecutive years (2017 to 2022) were collected. Analysis encompassed total blood collections and the prevalence of HBV, HCV, and HIV infections among donors.

Results: Comprehensive seroprevalence rates of 0.033% for HIV, 0.06% for HCV, and 0.136% for HBV were unveiled by the study, signifying the presence of these viral infections within the donor population. The incident rates within the donor cohort were determined to be 32.09, 52.57, and 102.83 for HIV, HCV, and HBV, respectively, spotlighting the substantial burden imposed by these infections.

Notably, data analysis revealed a remarkable trend characterized by a consistent reduction in seroprevalence rates across all markers, with this downward trajectory becoming especially pronounced from 2017 onwards. This observed trend highlights a commendable shift towards diminished infection rates within the donor group, implying the successful implementation of preventive measures or shifts in risk behaviors over the passage of time.

These findings collectively emphasize the persistent importance of vigilant surveillance and intervention strategies to effectively mitigate the impact of these bloodborne infections on both donor and recipient safety and well-being.

Conclusion: This study not only provides current prevalence insights into three potentially life-threatening bloodborne pathogens but also serves as a catalyst for effective clinical risk management. Furthermore, the prospect of heightened systematic surveillance of the donor population in the future holds the promise of enriching our understanding of epidemiology, evaluating the frequency trends of key bloodborne infections, and continually assessing the efficacy of donor recruitment and selection protocols. This ongoing surveillance additionally facilitates the monitoring of residual transmission risks associated with blood transfusion, ensuring an ever-evolving commitment to blood safety.

Keywords: seroprevalence rates, incident rates, bloodborne infections, HIV, HCV, HBV, trend analysis, surveillance, intervention strategies, donor recruitment, blood safety.

Title: Assessing Quantitative Values in EQAS for Infectious Diseases Serology across different assays

Authors: Kirsten Muscat[1], Bernadette Portelli[1]

1. NRL Quality, Fitzroy, VIC, Australia

At NRL's 38th Workshop on Infectious Disease Testing, EQAS presented quantitative data for molecular viral load assays which displayed comparable values and tight ranges. This presentation will focus on the quantitative values submitted for several serology analytes such as HBsAg, HBsAb, Rub IgG and CMV IgG across different assays. We will examine if these values are comparable, both amongst their peer groups and against the WHO international standard.