AIMS NSM 2024
ABSTRACT BOOK

'TRANSFUSION LABORATORY ESSENTIALS': BUILDING TRANSFUSION KNOWLEDGE FOR NEW AND RETURNING LABORATORY SCIENTISTS

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Introduction

Australian Red Cross Lifeblood's Clinical Education Team (CET) is creating an e-learning course of microcredentials called 'Transfusion Laboratory Essentials'. It is designed for new and returning laboratory scientists to build their knowledge of transfusion laboratory practice.
The course has been developed to complement existing laboratory training programs and will be in the form of online interactive modules, utilising contemporary instructional design and adult learning techniques. By completing the course, the learner will have gained the background knowledge to understand their role in providing safe and appropriate transfusions.

Method

Lifeblood commenced the development of this course in 2022 after a gap analysis identified a need for transfusion education resources for new scientists. The concept was supported by laboratory managers who acknowledged this would assist with training new staff members.
The multi-disciplinary project team consists of laboratory and clinical transfusion subject matter experts, an instructional and graphic designer, and communications experts and is overseen by a transfusion medicine specialist.
There are three modules currently available: 'The Australian Transfusion Community', 'Pretransfusion testing', and 'Pretransfusion labelling requirements'. Upcoming modules include: 'Blood group systems', 'ABO and Rh discrepancies', and 'Antibody investigations'.
Each module will cover an essential laboratory element of the transfusion process. Downloadable resources will be available for learners to use as job aids. A series of assessment questions concludes each module, with a certificate being provided on successful completion.
Future modules will cover crossmatching, blood components and storage, massive transfusions, and adverse transfusion reactions.

Results

The course has so far been positively received by participants, with enrolment numbers at a pleasing number of 324 (as of 6/5/24).

Conclusion

This online course aims to provide new and returning laboratory scientists with essential knowledge to confidently undertake transfusion-related laboratory activities.

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This case study describes a Babesia sp infection in a 60-year-old woman who had travelled to North America and Canada. On her return she presented with fevers, headaches and myalgia. Tests were performed for respiratory viruses and influenza and a full blood count (FBC) and electrolytes and liver function tests (ELFTs) were also requested.

Abnormalities were detected in the ELFT results and the FBC gave an abnormal lymphocyte flag and high monocyte count. On examination of the blood film, intra- and extracellular parasites were seen and these were then diagnosed as Babesia sp. She was also found to have either an active or past Lyme disease (borreliosis) infection.

She was hospitalised and treated but went into respiratory distress. After further treatment, she was cleared of the infection and discharged.

ADVANCEMENTS IN LABORATORY OPERATIONAL CAPABILITIES FOR EMERGENCY MEDICAL TEAMS (EMT's)

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Introduction

The National Critical Care and Trauma Response Centre (NCCTRC) plays a vital role in the Australian Government's disaster and emergency medical preparedness and response capability framework. At the core of this capability is the Australian Medical Assistance Team (AUSMAT), a multi-disciplinary medical team that deploys to health emergencies of national and international significance.

Integral to AUSMAT's effectiveness is its laboratory component, designed to operate in austere environments, where resources are limited and conditions are unpredictable, aligning to the World Health Organization's (WHO) Classification and Minimum Standards for Emergency Medical Teams.

The aim was to pinpoint the areas for improvement in compliance with WHO EMT Minimum standards.

Method

A comprehensive assessment focusing on policy, technology, capability and capacity was conducted to evaluate the operational effectiveness of the AUSMAT laboratory.

Results

A multidisciplinary pathology technical working group was established to provide expert advice and recommendations. Key areas of enhancement for WHO EMT operation were identified including the development of specialised protocols tailored to the challenges of austere environments, implementation of quality control measures, and improvement in laboratory design and infrastructure. To address the future health emergency demands, initiatives such as immersive simulation platforms for realistic training scenarios, utilisation of innovative technologies like BioFire, and the establishment of a walking blood bank were recommended.

Conclusion

Through continuous innovation and adaptation, AUSMAT has attained re-verification as a WHO EMT Type 1 Mobile, Type 1 Fixed, and Type 2 Surgical deployable hospital. The NCCTRC and AUSMAT remain committed to advancing laboratory capabilities, ensuring readiness for evolving health emergencies.

ANALYZING LIPAEMIC SPECIMENS IN A HOSPITAL LABORATORY – A CASE STUDY

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Introduction

Lipaemia is a well-known interference that affects testing across different disciplines. In a hospital laboratory, various techniques are employed for the correction or removal of interfering lipids. We report a case of lipaemia and describe methods to circumvent this interference.
A 47-year-old female with immune-mediated thrombocytopenia, currently treated with steroids, presents for a routine check-up. Her medical history is otherwise unremarkable.

Method

Biochemistry results were obtained from the analysis of serum on the Abbott Alinity C and Abbott Architect c16000. Hematology results obtained from the analysis of whole EDTA blood on the Siemens XN1000. Coagulation results were obtained from the analysis of sodium citrate plasma on the Siemens CN3000 and Stago STart Max. Ultracentrifugation was performed using the Beckman Coulter Airfuge.
The referring haematologist was interviewed for additional medical history and treatment details.

Results

Lipaemic index of 8 on the Abbott Alinity C. Haemoglobin (Hb) corrected by 24%. (29g/L) There was no significant difference in Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) between using spectrophotometric and electromagnetic detection methods. Total protein corrected by 24%. (26 g/L) Sodium corrected by 4%. (5 mmol/L)

Conclusion

This case illustrates the effective application of multiple analytical techniques to overcome the challenges posed by lipaemia in a hospital laboratory setting.

Biochip immunofluorescence as a new diagnostic tool for autoimmune blistering skin diseases

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Abstract

Autoimmune blistering skin diseases are a heterogenous group of disorders characterised by autoantibodies targeting the important structural proteins in the skin that mediate cell-cell or cell-matrix adhesion. The conventional method for diagnosing autoimmune bullous disorders is a multi-step procedure, involving histopathology and direct immunofluorescence, followed by indirect immunofluorescence and enzyme-linked immunosorbent assay (ELISA). Indirect immunofluorescence uses patient's serum and a substrate to visualize circulating autoantibodies. Recently, the Biochip mosaic-based indirect immunofluorescence technique has been made available to allow polyvalent immunofluorescence tests and provide antibody profiles in a single incubation, Sera from patients with provisional diagnoses of autoimmune blistering skin diseases were collected prospectively and sent to the pathology laboratory for indirect immunofluorescence using the Biochip method. The Biochip mosaic contained 6 test substrates which included monkey oesophagus, human salt-split skin, bullous pemphigoid (BP)180, desmoglein (Dsg) 1, Dsg 3, and BP230. The results showed The BIOCHIP mosaic showed a sensitivity and specificity of 86.8%, 85% for BP180 or BP230 being positive in BP and 75%, 97.7% for Dsg1 in PF and 60.9%,73.6% for Dsg3 in PV.
The BIOCHIP mosaic-based immunofluorescence technique presents a novel and faster way of diagnosing autoimmune blistering skin diseases. This test potentially a simple, time and effort saving test that can aid in the diagnosis and screening of BP, PV and PF. Our preliminary results showed that the Biochip method has a high diagnostic accuracy for PV and BP. However, more studies need to be carried out to minimise interpretation error.

Biography

Doctor Wei Melbourne (MSc) has been a snr hospital scientist at immunohistochemistry Anatomical pathology St. George Hospital (Sydney, Australia) since 1997. Wei graduated in Medicine at An Hui Medical College in China, trained as a surgeon and plastic surgeon in Shanghai, and went on to study medical science in Australia; graduated Degree in Health Science 1997; Masters of Public Health in 2006; Master of Science in Medicine at UNSW Australia in 2013. Wei has worked in diagnostic EB laboratory since 2000.

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FAST? NORMAL? SLOW? CASE STUDIES INVOLVING A PARTICULARLY TOUGH TEST; ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT). THE SPECIALISED HAEMOSTASIS LAB PERSPECTIVE.

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APTT: Fast? Normal? Slow?
Join me for a discussion on some fascinating ‘bleeding and clotting’ case studies from our laboratory in Adelaide. We’ve all heard of it, but have you ever wondered what testing is involved when this ‘screening’ test requires investigation? This presentation will take you on a journey from the patient’s arm (preanalytical variables), to specialised haemostasis lab testing ‘logic’ (including factor assays and interpretation) and end with clinical interpretation and relevance.

Title: CHALLENGE ACCEPTED - NAVIGATING A NEW NON-PARALLEL UNIVERSE

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Abstract:
Introduction:
Traditionally, one-stage coagulation factor assays are performed at multiple dilutions to assess for the presence of non-parallelism, a phenomenon linked to the presence of inhibitors including Lupus anticoagulant and some anticoagulant medications. In a 2022 Research and Practice in Thrombosis and Haemostasis Forum, a challenge to this practice was issued by Emmanuel J. Favaloro and Leonardo Pasalic. In the interest of moving forward and not resting on tradition when better practices are available, a study was conducted assessing the frequency, causes and clinical impact on non-parallelism in our patient population to construct a model that combines single and multi-dilution testing that maximises cost savings and maintains diagnostic accuracy.
Methods:
1324 routine factor levels performed with multi-dilution analysis (MDA) in a single laboratory were retrospectively reviewed. 50 samples with known lupus anticoagulant (LAC) and 50 samples with known rivaroxaban use were analysed. An optimal pathway for reflex MDA testing was developed by examining different thresholds for MDA and their impact on efficiency and diagnosis.
Results:
Non-parallelism is rare, and is most common in Factor XI assays. The most common causes are unknown, drug and LAC. The degree of non-parallelism is strongly related to rivaroxaban concentration but showed low correlation to LAC. A model that only performs MDA on levels outside of a predetermined threshold results in significant cost savings, does not impact lab efficiency, and retains diagnostic accuracy.
Conclusion:
Utilising single dilution factor levels, with reflex MDA in select patients, represents a feasible and cost-effective alternative that could allow laboratories to move forward from the traditional paradigm of universal MDA, whilst still identifying patients with clinically significant pathology.

DEVELOPMENT OF AN ONLINE LEARNING MODULE TO ENHANCE MEDICAL LABORATORY SCIENCE UNDERGRADUATE STUDENTS' PROFESSIONAL CONNECTEDNESS AND IDENTITY

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Introduction

Graduate employment metrics, used to measure student and institutional success, puts pressure on higher education providers to explore opportunities for better preparing students for the workforce. The demand for flexible education platforms has introduced further challenges in designing a curriculum that promotes connectedness with profession. The aim of the study was to understand student perceptions of their future profession and related continuing professional development (CPD) activities, and to identify opportunities that improve student connectedness to the workforce.

Methods

The study consisted of three phases. An anonymous survey was advertised to undergraduate students enrolled in AIMS accredited programs (phase 1) to understand their perception of workforce. These results assisted in developing an online learning module (phase 2) that attempted to consolidate key areas of workforce connectedness. Usefulness of the module was evaluated through an anonymous questionnaire (phase 3).

Results

The majority (79%) of participants noted that they were not members of any professional organisation, 59% were not aware of CPD activities and 41% noted that it would be useful to have a module that hosts job advertisements, information about professional bodies and associated CPD activities. Therefore, in phase 2, a free online module was developed using Brightspace learning management system. The questionnaire in phase 3 highlighted the importance of the module in presenting information in a user-friendly platform.

Conclusion

Many professional bodies offer memberships and CPD activities that undergraduate students are often not aware of. The module provided an easy to access platform, consolidated key information that promotes workforce integration, enhancing students' sense of professional identity.

Embedding Employability in Medical Laboratory Science (MLS) Programs: Rationale and Protocol

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Aim and Rationale: Accredited pathology laboratory services periodically undergo a paradigm shift. This imposes challenges to medical laboratory scientists because they are required to embrace, cope with, and effectively manage these changes to meet the dynamic nature of the pathology industry. To overcome the challenges, medical laboratory scientists must engage in life-long learning and develop career-building skills. Hence, it is important that undergraduate medical laboratory science (MLS) programs embed employability best practice into their curriculum. Employability best practice not only enables the graduates to seek a desired career but, more importantly, recognises and promotes those attributes that are required to engage in life-long learning and career development. Currently, there is a lack of research regarding best employability practice in MLS program curricula. As a result, MLS program curricula often lacks an appropriate employability framework and may not necessarily meet industry demands. Hence, this project aims to address this gap by investigating the perceptions of MLS students, graduates, academics, and employers on employability best practice, employability framework and essential graduate attributes.

Method: This is a cross sectional mixed methods study utilising data collection via a survey tool and collaborative workshop. The questions within the survey are adapted from the DkIT Embedding Employability study with some modifications. The proposed research will be undertaken by UniSQ in collaboration with CDU. However, UniSQ researchers are willing to extend this collaboration to all interested AIMS accredited universities. The study will be rolled out from September this year.

Outcomes: The findings will be used to develop and incorporate employability best practice into MLS pedagogy and curriculum.

ENHANCING EMPLOYABILITY OF MEDICAL LABORATORY SCIENCE GRADUATES

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Introduction: Griffith University (GU) is in the south-east Queensland region with an enrolment of approximately 46,000 students. Its major campus at the Gold Coast is the site of the Medical Laboratory Science (MLS) program. The GU-MLS program was developed collaboratively with industry professionals with a breadth of disciplines that are valuable in regional multidisciplinary laboratories. The curriculum includes all diagnostic MLS disciplines as well as genetics and molecular diagnostics and is accredited with the Australian Institute of Medical and Clinical Scientists (AIMS) and the UK Institute of Biomedical Sciences. Students attend a mandatory 560-hour placement in their fourth year and undertake two research projects. To increase student preparedness for placement the GU-MLS program has delivered the Enhancing Employability Workshop (EEW) in 2022 (2), 2023 (1) and 2024 (1). The micro-credentialled EEW focuses on industry specialist material such as pre-analytical error training, 3D virtual pathology simulations, telepathology, understanding NATA requirements and ISO15189 standards.

Aims & Approach: This study aimed to (i) assess the student experience and respond to student evaluation and (ii) assess the experience of industry supervisors of placement students regarding student preparedness. Students were surveyed before and after completion of the EEW. Industry supervisors were surveyed at the mid-placement meeting during student placement.

Results & Conclusions: Specific EEW topics were laboratory information systems, central specimen reception and pre-analytical errors, work-based competencies, compliance with NATA standards, discipline-specific automation tasks as well as employability training. Analysis of survey data indicated a positive impact of the EEW on student preparedness for placement from both student and industry supervisor responses.

We acknowledge funding of this project by AIMS grant REGS-29704-2022.

Enhancing Rural Diabetes Management: Evaluating the Impact of HbA1C Point-of-Care Testing (POCT) on Clinical Outcomes

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Introduction

This study examines the agreement between Point of Care Testing (POCT) and conventional pathology for HbA1c levels in rural diabetes management. Additionally, the study evaluated whether POCT can streamline clinical pathways while maintaining precision and accuracy of traditional pathology, ultimately improving outcomes for patients with TDM-1 and TDM-2, as well as those with impaired fasting glucose.

Methods

A multi-centre evaluation involved 243 HbA1c tests across four rural centres using the Cobas b101 device. Healthcare professionals received training. Patient demographics, test platform, and clinical outcomes were collected. The precision and accuracy were compared using statistical tests, including the Shapiro-Wilk test for data normality, Mann-Whitney U test for significance, and logistic regression to assess predictor variables.

Results

The Bland-Altman plot revealed strong agreement between POCT and conventional pathology, with only one outlier attributed to medication changes. Both datasets exhibited non-normal distributions ($p < 0.001$). Despite this, there was no significant difference between POCT and conventional pathology ($p > 0.05$). Additionally, logistic regression analysis identified HbA1c as a significant predictor for changes in care plans, with 12% of patients undergoing treatment adjustments. Furthermore, 97% of patients expressed satisfaction with the POCT intervention.

Conclusion

POCT demonstrates comparable results to conventional pathology, facilitating timely clinical decisions and improving diabetes management in rural areas. Its use can enhance patient engagement, streamline processes, and promote health equity, especially in regions with limited healthcare access.

Title: ERYTHROCYTE MICROVESICULATION HEALTH AND DISEASES.

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Aim: To demonstrate (using Guava Easy flow-cytometer) that micro vesicles are released from erythrocyte membrane naturally in normal and disease conditions, without inducing with calcium chloride; and also, to know how many erythrocytes makes a micro vesicle.
Methods: 15mls of blood samples from the stored in CPDA or SAG-M was provided by NHS blood and transplant, and 10 ml of this blood were mixed thoroughly with 30ml of phosphate buffered saline in a 50ml centrifuge tube, and centrifuge immediately at 600 x g at 4 degrees centigrade for 10 minutes to remove soluble plasma proteins. The supernatant was removed and discarded after centrifugation. This process was repeated three times in order to remove any erythrocyte bound plasma proteins. Erythrocytes were then counted with haemocytometer using x10 objective lenses and x40 for magnification). The number of red blood cells countered were recorded and documented. Flow cytometry analysis was conducted using 10ul of the eMV stock sample which were diluted in 190ul (1:20) of phosphate buffer saline.Biuret protein assay and Agarose gel electrophoresis were performed. Haemolysed red blood cell was used as a negative control method.
Results: Erythrocyte cell counts was performed using haematology cell counting chamber and analysed with Guava flow cytometer on three consecutive times. The number of cells counted was greater than 400cells. About 3446666 million of micro vesicles were released by 1ml of the isolated erythrocyte. The unknown protein component of micro vesicles was determined as 2.5mg/ml and the protein bands separation were identified using agarose gel electrophoresis.
Conclusion: The isolated micro vesicles were analysed using Guava Easy flow cytometer. The protein concentration was quantified using Biuret assay method, and the protein band separation was analysed using Agarose gel electrophoresis.

EVALUATING CLINICAL EQUIVALENCE BETWEEN DIFFERENT CENTRIFUGAL CONDITIONS

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Introduction

To improve the turnaround for analyte testing, we investigated if the centrifugal speed and time of the Rotina 380 Benchtop Centrifuge at 1680 RCF for 8 minutes can achieve equivalent performance as its recommended setting of 1000-1300 RCF for 10 minutes.

Method

22 sets of donor blood samples were collected in BD Vacutainer Gel Serum Separator Tube (SST) with one evaluation and one control sample each. After standing at room temperature for 45 to 70 minutes, each donor evaluation sample was centrifuged at 1680 RCF for 8 minutes while control sample was centrifuged at 1300 RCF for 10 minutes concurrently using the same slot position. Platelet counts, gamma-glutamyltransferase, creatinine, sodium, lipase, urea, hemolysis index, icterus index, lipemic index, lactate dehydrogenase, potassium and high sensitivity troponin I were subsequently analysed on the Sysmex XN-10 and Abbott Alinity ci platforms.

Results

Platelet counts of all 22 evaluation samples were within acceptable range of 0-1 x 10^9/L (Clinical and Laboratory Standards Institute (CLSI) guidelines). Result differences between the evaluation and control samples of 19 donors passed the Royal College of Pathologists Australian's (RCPA) 2021 Analytical Performance Specifications (APS) criteria for all analytes. Differences in potassium levels obtained for three donor samples were out of acceptable criteria and two of the samples contained presence of fibrin strands that could have led to the differences.

Conclusion

For the eight routine chemistry analytes, clinical equivalence was demonstrated between the evaluated centrifugal condition of 1680 RCF for 8 minutes and the recommended centrifugal condition of 1300 RCF for 10 minutes. Therefore, the evaluated centrifugal condition can be used for analyte testing without compromising its accuracy while improving turnaround time.

Evaluating Point-of-Care CRP Testing for Antibiotic Prescription Guidance in Regional and Remote South Australian General Practices

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Introduction

The study objective was to investigate the primary reason for antibiotics prescription when using Point of Care testing (POCT) in rural and remote medical centres in South Australia, focusing on the potential roles of CRP levels, reasons for GP visits, and other contributing factors.

Methods

The study involved 273 CRP tests conducted with the Cobas b101 device at four different rural centres. The multi-centre evaluation included healthcare professionals at these centres, each receiving training on using the device. During the study period, the following data was recorded: CRP results, patient demographics, reasons for GP visits, the need for antibiotic prescriptions, subsequent hospitalizations, and patient satisfaction.

Results

The results showed that 67% of participants were female, with ages ranging from 9-97 years. CRP levels varied widely, with a mean of 23 mg/L and a median of 6 mg/L. Among the participants, 37% received immediate antibiotics, while 38% required hospitalization.
The thematic analysis revealed that conditions such as respiratory issues, gastrointestinal problems, and infection and inflammatory diseases had higher rates of antibiotic prescriptions at elevated CRP levels. This suggests that CRP levels can be a determinant for antibiotics in certain contexts, but reasons for GP visits still play a critical role in guiding treatment decisions.

Conclusion

CRP measurements using POCT can indicate when antibiotics are needed, particularly if other clinical signs support it. However, GP visit reasons still play a significant role in guiding medical interventions. The results underscore the importance of effective CRP screening while considering other clinical factors to avoid overprescribing antibiotics and to combat antibiotic resistance.

Evaluation of Helena Cascade Abrazo Point-of-Care PT/INR and APTT testing.

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The Prothrombin Time/ International Normalised Ratio (PT/INR) and Activated Partial Thromboplastin Time (aPTT) are global screening tests used to detect coagulation factor deficiencies and monitor anticoagulant therapy. The Cascade Abrazo Point-of-care (POC) PT/INR (human placental thromboplastin) and aPTT (ellagic acid activator) tests citrated whole blood and has a fibrinogen clot endpoint.

We evaluated POC precision using provided QC material and compared patient results to plasma tests using our routine laboratory (LAB) Stago STA R-MAX analyser with reagents Neoptimal (rabbit brain thromboplastin) and TriniCLOT aPTT S (micronized silica activator). Spare blood from unselected samples was used for POC tests and included patients on anticoagulants and for thrombophilia screening.

Using Normal (L1) and Abnormal (L2) QC material over the study days, the between-run CV% of PT L1 and L2 was 1.71% and 6.72% respectively. The aPTT L1 between-run CV was 2.84%; an aPTT L2 QC material was not available.
The POC-PT compared well to the LAB-PT (n 35, 6 on warfarin) with r^2 0.88 and a Passing Bablok (PB) slope 0.99. Similarly, POC-INR compared to LAB-INR had an acceptable r^2 0.89, PB slope 1.00 and mean bias 0.05. aPTT results were sorted into two categories – All (n 41) and aPTT <40 sec (n 29, most on Direct Oral Anticoagulant therapy). The correlation was moderate with PB slopes 1.19, 1.43; r^2 0.81, 0.58; mean bias 2.93, 2.56 seconds respectively. However, as the POC-aPTT had a reported normal reference range of 22-40 seconds, slightly higher than the LAB-aPTT of 24-38 seconds, this was consistent and diagnostic agreement was 88%.

These results show that the Cascade Abrazo has potential as a suitable device to measure POC PT/INR and aPTT. Further studies are required to compare to other reagents/analysers and to assess the sensitivity and specificity to detect factor deficiencies and monitor warfarin therapy.

EXAMINATION OF PHOTOPERIOD AND GLUCOSE CONTROL IN AUSTRALIAN ADULTS: A PILOT STUDY

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Introduction

Photoperiod, a principal regulator of circadian rhythms, is the duration of light exposure each day. Naturally it is limited to a daylength, however, exposure to artificial light at night has extended photoperiod in humans. Long photoperiod impairs circadian rhythm leading to poor glucose control in animals. This study aims to examine the photoperiod and its association with glycosylated haemoglobin (HbA1c) in Australian adults.

Methods

Participants wore ActLumus wristband (Condor Instruments, Brazil) for seven days to record light exposure, body temperature, activity, and sleep in real time. Anthropometric measurements were taken, HbA1c was measured by point of care device (A1cNow®, PTS Diagnostics, USA), and participants completed Pittsburgh sleep quality index and depression anxiety sleep questionnaires during first clinic visit. Photoperiod was calculated as duration between first and last (>5 lux) light exposure in the day.

Results

This pilot study is still recruiting until May 2024. Interim analysis showed that the participants had mean±SD age 30.7±4.9 years, SBP 112±11 mmHg, DBP 75±9 mmHg, BMI 25.8±6.1 kg/m^2, waist-hip ratio 0.88±0.11, and HbA1c 5.1±0.5%. Participants spent 58-73% duration of their day during the light condition and artificial light accounted for 28.9±5.1% of total photoperiod. As the study is still ongoing, statistical analyses have not yet been performed; results will be available in August 2024.

Conclusions

Photoperiod accounted for nearly 2/3rd of the day and nearly 1/3rd of which was artificial light after sunset. Extended exposure of artificial light after sunset may delay circadian rhythm which may impact glucose control in long-term.

HAEMOGLOBINOPATHY DETECTION ON ROUTINE HBA_{1C} TESTING

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Introduction

HbA_{1c} testing is routinely used to both monitor and diagnose diabetes mellitus. Haemoglobin separation techniques, such as high-performance liquid chromatography and capillary zone electrophoresis, are commonly used to determine HbA_{1c} concentrations. The presence of a variant haemoglobin, or elevated levels of HbA_2 and/or HbF are often an incidental finding on HbA_{1c} testing. Some authors have suggested that HbA_{1c} testing may be a method of screening for haemoglobinopathies in the general patient population.

Methods

Retrospective case study and literature review.

Results

The HbA1c results from a single week of testing were reviewed for the presence of variant peaks, or elevated HbA_2 and/or HbF. Of the 18820 results obtained, 124 results showed either an elevated HbA_2/HbF, or a variant peak. Presumptive identification of variant peaks performed based on review of electrophoregram data. No further identification of peaks was performed on these samples. Of the 63 patients with a variant peak identified, 40 patients demonstrated the presence of presumed HbS, HbE, HbD or HbS. An elevated HbA_2 peak, characterised as a HbA_2 > 3.3%, was the sole abnormality in 50 cases. A combined elevated HbA_2/elevated HbF was identified in 3 patients, and 7 patients demonstrated an elevated HbF.

Conclusions

While some authors have suggested that HbA_{1c} testing could be used to screen for haemoglobinopathies, there are some important ethical considerations which should be considered, the most important of which is patient consent for screening of a genetic disorder. However, with appropriate laboratory guidance, HbA_{1c} testing may highlight those patients who require further follow-up testing for haemoglobinopathy diagnosis.

IDENTIFICATION OF GENETIC VARIANTS ASSOCIATED WITH DEEP VEIN THROMBOSIS (DVT) IN A COHORT OF PATIENTS AFFECTED WITH DVT IN SRI LANKA.

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Introduction:
Deep Vein Thrombosis (DVT) is a thromboembolic manifestation that occurs due to various genetic and non-genetic etiologies. The aim of this study was to design and implement a molecular assay to identify genetic variants suggestive of causing DVT in a cohort of patients affected with DVT in Sri Lanka.
Methods:
A comprehensive literature review was conducted to identify genetic variants associated with DVT. Using online tools Tetra-Amplification-Refractory-Mutation-System Polymerase Chain Reaction (T-ARMS-PCR) protocols were designed, developed and optimized to genotype the extracted DNA samples of the subjects with prior informed consent. The genotype results were validated by gold-standard Sanger sequencing for accuracy before sample genotyping.
Results:
110 subjects comprising 62 (56.4%) females and 48 (43.6%) males ranging 2 to 73 years of age were genotyped. There were 14 (12.7%) normal for the variant (CC), 39 (35.5%) heterozygotes (CA) and 57 (51.8%) homozygotes (AA) for *CYP4V2* c.775C>A (rs13146272) variant, with an ancestral (C) allele frequency of 0.3045 and variant (A) allele frequency of 0.6955 at Hardy Weinberg's equilibrium. For *F5* c.2573A>G (rs4524) variant 37 (33.6%) were normal for the variant (AA) while 73 (66.4%) heterozygotes (AC) and nil homozygotes (GG) were detected with a calculated allele frequency of 0.6651 and 0.3349 for both ancestral (A) allele and variant (G) allele respectively.
Conclusion:
The developed and optimized T-ARMS-PCR assay of this study can be implemented to screen the *CYP4V2* c.775C>A (rs13146272) variant in DVT diagnosed patients. Allele frequencies of both *CYP4V2* and *F5* variants were consistent with published South-Asian population allele frequencies suggesting the reliability of our finding.

INVESTIGATING THE IMPACT OF GUIDELINE ADHERENCE AND COVID-19 ON THE MANAGEMENT OF TYPE 2 DIABETES IN REGIONAL QUEENSLAND

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Background: Guidelines for the management and treatment of Type 2 Diabetes Mellitus (T2DM), a chronic metabolic disorder, were introduced in Australian health care system to optimize health outcomes for individuals with T2DM. These guidelines include lifestyle modifications, pharmacotherapy, and regular monitoring. Adherence to clinical practice guidelines stresses the importance of routinely monitoring glycated haemoglobin A1c (HbA1c) levels in patients with T2DM, typically recommending testing every six months. However, there is a scarcity of comprehensive research assessing the clinical consequences of the suggested testing frequency. This gap in the literature underscores the need for in-depth studies to establish the significance of adhering to these guidelines.
Methods: This retrospective cohort pilot study utilized the data gathered from January 2019 - December 2021 from general practice in Gold Coast, Queensland, Australia. Guideline adherence rates for each patient were determined by the proportion of HbA1c tests conducted within the intervals recommended by Australian guidelines. Adherence levels were then categorized as low (≤41%), moderate (42%–64%) and high (>65%). To evaluate the impact of COVID 19 on patient health parameters repeated measures one way ANOVA with Tukey's post hoc test used.
Results & Discussion: The results from this study have shown that Patients with low adherence may have a gradual or sustained poorly controlled HbA1c levels, while those with high adherence maintained or improved levels. High guideline adherence group correlated with 100% of patients showing improved lipid profile over three years, indicating the reduced risk factors for cardiovascular risk when compared to low adherence.
Conclusion: Greater guideline adherence and frequency of testing for HbA1c was associated with improved health outcomes for individuals with T2DM. The results from this study may provide further evidence to support the use and adherence to T2DM clinical guidelines.

Urinary Nephrin: Potential to become a predictor for early Glomerular Injury During Pregnancy

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Introduction: Pregnancy-related medical complications (gestational diabetes and preeclampsia) may cause renal damage. Urinary nephrin has previously been shown to provide early identification of PE in high-risk pregnancies, however, the role of urinary nephrin for determining early glomerular injury is yet to be explored. This study aimed to investigate the use of urinary nephrin as a predictor for early glomerular injury in a large cohort study (KIDMIN) conducted at the Townville University Hospital.
Methods and Materials: Pregnant women (n=273) were classified into 3 categories according to urinary albumin/creatinine ratio (ACR): normo, micro and macroalbuminuria. The urinary nephrin/creatinine ratio (NCR) cutoff value which could predict the stage of albuminuria was determined as an indirect indicator of early glomerular injury. The percentages of pregnant women with elevated nephrinuria were calculated for each of the ACR categories.
Results: NCR positively correlated with urinary ACR ($r=0.29$, $p<0.0001$) and women with PE had markedly higher NCR. NCR increased comparably in women with normo, micro and macroalbuminuria. Using a cutoff value of 14ng/mg, nephrinuria was detected in 64.9% of women with normoalbuminuria, 94.7% with microalbuminuria, and 100% with macroalbuminuria. Of the women in the normoalbuminuric group demonstrating nephrinuria; 77.8% had a hypertensive disorder and 62.7% had diabetes in pregnancy. NCR was able to predict glomerular injury with a sensitivity and specificity of 93% and 42% respectively when related to PE and 97% and 36% respectively when related to all pregnancy complications.
Conclusion: This study found that NCR was elevated in the absence of albuminuria and may indicate early glomerular injury. NCR for early detection of glomerular injury could become a useful tool for monitoring renal function during pregnancy.

LOCAL VALIDATION OF A METHOD TO MEASURE EMICIZUMAB IN BLOOD.

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Emicizumab (Hemlibra) is a novel drug therapy for prophylaxis in haemophilia A. It is a monoclonal antibody which mimics factor VIII (FVIII), serving as a co-factor for human factor IXa to activate factor X. In clinical trials and in real-world experience, emicizumab significantly reduces annual bleeding rates in severe haemophilia A including in those patients with FVIII inhibitors. The drug is given by subcutaneous injection in standard doses and is expected to reach a steady-state level of 22 to 85 ug/mL. There is no requirement to monitor emicizumab, but a drug level is helpful 1. to confirm the expected steady-state level is achieved; 2. to check compliance especially if bleeding; 3. to assess when the patient is also treated with FVIII for surgery; 4. to determine if emicizumab is unexpectedly low, raising suspicion of an anti-drug antibody.
An activity assay for emicizumab is available based on the 1-stage FVIII clotting protocol and using a commercial standard, control material and test samples at a starting dilution of 1/40. This has been set up at SA Pathology and shows satisfactory between-run precision (CV 7.5% - 8.0%), wide linear range (9-125 ug/mL), good accuracy in a between-laboratory comparison (<2% difference to therapeutic targets), and within acceptance in external Quality Assurance surveys. Thirty-nine patients on emicizumab have had steady-state levels measured, with the majority of results 20-76 ug/mL (93 samples tested). The assay has been helpful during surgery when FVIII therapy is also given, although high plasma FVIII can interfere with drug measurement. Emicizumab can interfere with the 1-stage FVIII assay, and if FVIII measurement is also needed it must be measured by a chromogenic method with bovine factors IXa and X. In our experience the emicizumab assay is robust and assists clinical decisions, making it of value to haemophilia treatment centres.

Modification of an experiential, learning-by-doing approach to clinical flow cytometry training at The University of Western Australia

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We developed a pedagogical approach to flow cytometry training, grounded in experiential, problem-based learning-by-doing. In this approach, students perform compensation, calculate staining index, and collaboratively design a gating strategy to analyse clinical flow cytometry data sets using FlowJo software. The approach is implemented in postgraduate programs designed to train specialist medical scientists, including the Master of Infectious Disease and the AIMS accredited Master of Clinical Pathology, where it leverages unique active and collaborative eLearning spaces at The University of Western Australia. The approach allows students to achieve learning outcomes not previously possible with traditional teaching formats, with favourable perceptions and improved student confidence in performance of cytometry data analysis and interpretation.
Since it was first implemented and published in 2016, our approach has been modified to include a self-directed offering (adapting to restrictions on face-to-face learning during the pandemic), updated for changes in consensus guidelines for clinical flow cytometry published by the Australasian Cytometry Society, and modified to accommodate changes in audiovisual, information technology and software licensing agreements as part of a switch to Bring Your Own Device (BYOD) approaches at The University of Western Australia.
We will present data and reflections on how our approach has been adapted in the changing landscape of medical scientist training in the pandemic and post-pandemic setting. We will present data on how these adaptations have impacted student confidence and competence in the analysis and interpretation of clinical cytometry data.

Multicentre Evaluation of Point-of-Care NT-ProBNP Testing for Cardiac Risk Assessment and Clinical Outcomes in Rural South Australia

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Introduction

This research seeks to assess the effectiveness of Point-of-Care NT-ProBNP testing in evaluating cardiac risk, and how its incorporation affects clinical pathways for cardiac care in rural South Australia. The study specifically explores variations in NT-ProBNP levels based on demographic factors and patient history.

Methods

A multicentre evaluation of the Cobas h232 for NT-ProBNP was conducted at four general practice clinics in rural South Australia. NT-ProBNP levels were cross-analysed with themes emerging from a thematic analysis. The study examined demographic data, trends in NT-ProBNP, and the relationship between NT-ProBNP levels, patient demographics, and clinical outcomes.

Results

Data from 84 tests were analysed, with a mean age of 79 years and a median age of 82 years. The mean NT-ProBNP level was 1,554 pg/mL, with a median of 671 pg/mL. 71% of the of patients tested for NT-ProBNP with unknown history of heart failure met the criteria for specialists follow up due to NT-ProBNP >300 pg/mL. The remaining 29% triggered a cardiologist referral or ECHO referral for unknown reasons.

The linear regression analysis suggests that NT-proBNP levels increase with age in both genders, more noticeably in males. This suggests a need for further research and supports age and gender-stratified clinical guidelines.

Conclusion

Point-of-care NT-ProBNP testing is valuable for cardiac risk assessment in rural settings. Considering clinical themes, gender, and age in NT-ProBNP thresholds enhances clinical pathways and patient satisfaction, supporting the broader adoption of POCT NT-ProBNP testing for comprehensive cardiac risk assessment and tailored treatment strategies.

Multidisciplinary Cases – Expect the Unexpected

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Many patients with immunological and inflammatory conditions present with symptoms and signs which require testing across many of the disciplines of pathology.
Several cases of immunology and inflammatory conditions are presented which required testing across chemistry, haematology, immunology, and microbiology to arrive at a diagnosis. Not infrequently the testing in one specialty will only go so far in obtaining a diagnosis and it is only by putting all tests altogether that appropriate management based on testing can be achieved.
The final diagnosis in each of these cases was somewhat unexpected.

PERSPECTIVES AND EXPERIENCES OF STUDENTS AND STAFF OF A MICROSESSION MEDICAL LABORATORY SCIENCE (PATHOLOGY) UNDERGRADUATE COURSE.

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Introduction

In 2021, a microsession model was implemented for the Bachelor of Medical Laboratory Science (Pathology) course at Charles Sturt University. This condensed course allows a student to graduate within 3 years full-time (via six 8-week microsession blocks per year) instead of the usual 3.5-years (in a conventional 16-week block trimester per year).

Method

An anonymous, cross-sectional online survey was disseminated to all enrolled students and teaching staff within the program. Likert-scale questions relating to student & staff satisfaction and overall learning and teaching experience was collected and analysed using *SPSS* (v.29). Open-ended comment questions regarding facilitators and barriers to student success were thematically analysed using *Nvivo* (v.13) software.

Results

Overall themes included whether students felt disadvantaged in a condensed mode of learning compared to the conventional course. Would students report higher stress in this format? Would this be balanced by certain benefits such as quicker completion, and a more efficient intensive school for practical classes? Academics had experience of both types of programs, and although they might have individual preferences, were staff readily able to adapt? Were they able to implement their pedagogical strategies optimally in a condensed session?

Conclusion

Our study provides a unique insight into our student population and teaching staff, by highlighting the needs and priorities that students and staff valued in their educational experience. This data is useful for both educators and policy makers in subject and course design. Although certain adaptations in pedagogical methods have to be considered when teaching in a microsession model, both staff and students alike have expressed numerous benefits.

PRE-ANALYTICAL ERRORS AND THEIR PREVENTION IN AN EMERGENCY DEPARTMENT SETTING

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Introduction: The pathology laboratory plays a key role in a patient's healthcare journey and the results from pathology testing can influence medication, hospital admission status and differential diagnoses. Errors in the pre-analytical phase may negatively impact the total testing process (TTP) and therefore patient outcomes. The pre-analytical phase involves multiple healthcare professionals from different disciplines and departments.
Methods: An observational study of pre-analytical errors was conducted over two months at an Australian hospital emergency department (ED) and associated laboratory. This study was used to assess the type and number of pre-analytical errors occurring at this site. A Likert-Like survey targeting the ED staff was used to form a basis for the intervention phase of the experiment which aimed to reduce the overall number of pre-analytical errors occurring at this site. An intervention study focusing on educating the ED staff on pre-analytical errors from four bases (request-based, specimen-based, transport-based, and laboratory-based) was conducted over two months.
Results: The observational study found 12159 unique pre-analytical errors over four different categories. The intervention was not successful in significantly reducing the number of pre-analytical errors at this site; however multiple suggestions have been made to help reduce the number of pre-analytical errors in the future. These include introducing a pneumatic tube system, running a monthly/bi-monthly training program, and implementing a training program targeting laboratory staff.
Conclusion: An extended study with more frequent interventions is needed to assess the benefits of running an intervention training program focusing on pre-analytical errors.

Recombinant protein technology applied to investigate whether alloantibodies to a novel Rh variant in maternal serum, associated with HDFN, bound to a an RHCE construct

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Introduction A discordant pairing between maternal blood group and the fetal blood group is associated with risk of the formation of alloantibodies and Haemolytic Disease of the Fetus and Newborn (HDFN) in future pregnancies. The RBC panels used to detect antibodies to RBC in the maternal circulation are designed for variants found in Mendelian ratios mainly in European population,s low-frequency variants and variants found in other ethnic groups will not be detected. A novel low-frequency variant, CETW (c.486C>G), in the Rh blood group system has been reported to be associated with HDFN. As cells of this phenotype are rare the use of recombinant technology to express the antigen was investigated.

Methods Full length WT (RHCE*Ce) and CETW (RHCE*CeTW; c.486C>G) RHCE gene constructs were cloned into a mammalian expression vector (pEGFPn1) with a linked C-terminal fluorescent protein (GFP). Following transfection and antibiotic selection, a stable pool of RHCE expressing clones was selected using fluorescence activated cell sorting (FACS). RHCE expression in stable pools was investigated using a commercially available anti-Rh antibody (BRIC69) via flow cytometry. Binding of maternal serum, reported to contain anti-CETW, against these stable pools was also investigated using flow cytometry.

Results While an expressed RhCE protein (expressing C and e variants) was detected using the developed method, alloantibodies specific to the CETW variant RhCE protein did not react differentially between the CETW variant and wild type RhCe construct at the concentrations tested.

Conclusion While recombinant technology presents an alternative to standard red blood cell serology, further work is required to optimise presentation of these constructs particularly those with single nucleotide variants.

SKILLS DEVELOPMENT PATHWAY

Maureen Jacobsen, Tony Woods, Robyn Wells, Sarah Just
Australian Institute of Medical and Clinical Scientists

Introduction

Part of being a professional is taking responsibility for your own skills, recognising when they need to be improved and updated and then undertaking formal or other learning pathways. These enhanced skills and knowledge must be applied and shared. Continuing professional development (CPD) is ongoing, career long, systematic and planned.

Aim

This presentation will outline some of the pathways for all working in the laboratory to undertake CPD, be enrolled in a CPD program such as APACE, increase the range of CPD activities and be recognised through certification for that continuing education and professional development.

A/Prof Tony Woods, AIMS Fellowship Committee, will outline the prerequisites and the process of obtaining the formal qualification of the AIMS Fellowship.

Ms Robyn Wells, Editor of AJMS, will present on passing on your knowledge by publishing your case studies, work projects and dissertations.

The medical laboratory science profession in Australia now has its own national professional certification scheme, CMLS. The CEO of AIMS, Sarah Just, will outline the requirements and how to apply for CMLS

Conclusion

By actively engaging in CPD, being enrolled in a CPD program, either certified or are working towards CMLS certification, a medical scientist will not only develop skills and knowledge but enhance their career prospects.

Thrombotic Microangiopathy Induced by the Exposure to Oxaliplatin: A case report.

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Introduction

Oxaliplatin is a platinum-based chemotherapy that is widely used as part of standard treatment for metastatic colorectal cancer. Although rare, the occurrence of thrombotic microangiopathy (TMA) due to the exposure of this agent has been previously reported and may present as a life-threatening event. Timely diagnosis is critical for the administration of appropriate clinical management. Here, we present a case of acute TMA development after oxaliplatin infusion.

Method

Clinical data and pathology results were obtained through institutional electronic medical records and laboratory information systems. Data collection spans from pre-chemotherapy until 25 days after the onset of symptoms. Results were reviewed and compared to other reported cases in the literature.

Results

Post oxaliplatin treatment, the patient exhibited symptoms of TMA with microangiopathic haemolytic anaemia, thrombocytopenia and acute kidney injury. These were demonstrated by the precipitous drop of haemoglobin from 129g/L to 88g/L. Haptoglobin was critically low at >0.1g/L with serum creatinine and lactate dehydrogenase elevated at 306 umol/L and 908 U/L respectively. Within 24 hours, platelets fell from 120×10^9/L to 45×10^9/L. Haemoglobin and platelet count normalised 7 days after the incident while creatinine took about 25 days to reach normal levels. Coagulation profile of the patient remained normal except for D-Dimer at >20 mg/L. Normal ADAMST-13 activity and the absence of history of gastrointestinal infection further guided the diagnosis of this TMA towards atypical haemolytic uraemic syndrome (aHUS).

Conclusion

Through various laboratory testings and clinical observations, the rapid onset of TMA development post chemotherapy was demonstrated in this case. As the patient was undergoing haemolysis, this further substantiated the need for efficient and prompt care. The role of timely and reliable laboratory testings and efficient supportive clinical care resulted in the recovery of the patient. Oxaliplatin was excluded from patient's future chemotherapy regiments.

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Introduction

In monochorionic diamniotic (MCDA) gestations the twins share a placenta within which there are multiple vascular anastomoses, which run on the surface of the chorionic plate, and allow the blood to flow between the twins in foetal life or during delivery. Although the blood flow is balanced in most cases, in up to 15% of cases[1], net blood flow is toward one of the twins. When this occurs before birth, this is known as either twin to twin transfusion (TTTS) or twin anaemia polycythaemia sequence (TAPS), depending on the size of the vascular anastomoses and associated clinical symptoms. TTTS is caused by imbalanced blood flow through relatively large placental anastomoses from donor to recipient, while TAPS is caused by unbalanced slow transfusion of red blood cells through a few small placental ateriovenous anastomoses. When bleeding between the twins occurs during delivery, it is known as peri partum or acute TTTS. In both TTTS and TAPS, this can lead to large intertwin haemoglobin differences resulting in anaemia of donor twin and polycythaemia in recipient twin. In this case presentation of TAPS, we reviewed clinical and laboratory features of Twin 1 (Donor Twin) and Twin 2 (Recipient twin).

Method

Haematology results were obtained using Sysmex haematology XN10 analyser, and pre transfusion testing from Bio-Rad IH500 analyser.

Results

Donor twin showed a haemoglobin of 66g/L, reticulocyte 22.9% and recipient twin showed a haemoglobin of 247 g/L and reticulocyte count of 4.01% which correlates with the diagnosis of TAPS, in addition to an abnormal ultrasound showing selective intrauterine growth restriction and TAPS leading to emergency Caesarean delivery.

Conclusion

Antenatal ultrasound, postnatal laboratory results, placental pathology play a key role in the diagnosis of TAPS.

1. Tollenaar Lisanne S.A. et al. 2021. TAPS Knowledge and insights after 15 years of research. MFM Maternal-Fetal Medicine 3(1):p 33-41 January 2021

The utility of molecular testing in cytology

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ABSTRACT

It is the era of personalised medicine for cancer diagnosis, management and treatment. This is largely due to rapid development of molecular techniques, such as Next Generation Sequencing, and understanding of cancer genomics. Molecular testing plays a part in diagnosis, treatment and prognosis of cancer with histology and cytology specimens routinely used for testing. Cytology specimens are an ideal specimen as they are obtained via minimally invasive methods and offer a reduced turnaround time for diagnosis. Specimens include fine needle aspiration and serous cavity effusions. Cellular material can either be fresh, alcohol-fixed or formalin-fixed providing multiple options for preparation and laboratory protocols. Cell blocks (formalin-fixed paraffin embedded) are often the specimen of choice.

Molecular testing can be used to identify a wide range of somatic mutations in solid tumours and haematological malignancies, as well as infectious agents. Commonly encountered tumours for molecular testing include malignant melanoma and non-small cell lung carcinoma (NSCLC). More than 50% of malignant melanomas contain BRAF mutations, with the most common variant V600E (up to 90% of cases). Melanoma patients with tumours harbouring mutations in BRAF may benefit from BRAF kinase inhibitor testing. NSCLC is the most common type of lung cancer with diagnosis, management and treatment options rapidly evolving. It is a heterogeneous disease with numerous genomic subtypes. Molecular testing is the standard of care for advanced stage NSCLC.

Cytology is a useful and efficient tool as a source of material to aid in the diagnosis of malignancies and identification of molecular mutations. The identification of molecular markers for diagnosis, prognosis and treatment is an evolving landscape and highlights the importance of a multi-disciplinary approach to patient management.

VERIFICATION OF THE ABBOTT ALINITY HQ ANALYSER FLAGGING (VERSION 5.6)

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Introduction

Analyser flagging is an essential technology that alerts the laboratory that abnormal scatter plots are present and is suspicious of atypical cells. Version 5.6 will enable us to set the flagging sensitivity, from level 1 through to 4, for Blasts (BL) and Variant Lymphocytes (VL). Flagging must ensure abnormalities are identified but non-specific flagging is minimalised.

Methods

A 3-step process was adopted for flag setting determination and confirmation. Fresh patient samples (N=13) with true positive BL or VL flags were selected, the gating level was adjusted to determine at what point the sample ceased to flag.
Then further samples (N=24) which flagged were correlated with the blood film report. The flagging setting was adjusted as above.
Finally, a larger cohort of samples (N=100) with the flagging from step-2 were locked in and correlated with the blood film.

Results

The patients were separated as Lymphoid or Myeloid or non-haematological disease cohorts. Sensitivity, specificity and accuracy truth tables were compiled.

The flagging settings with V5.6 software upgrade have shown a slight improvement. However, the sensitivity and specificity were still sub-optimal, especially the degree of False positivity for non-haematological patients.

The frequency with which a blood film review is mandated is based on the diagnosis. Initial investigations with the Alinity, at installation, required our review frequency to be reduced for lymphoid diseases. Version 5.6 has enabled a review of these criteria.

Conclusion

The flagging settings has not substantially reduced the number of blood films requiring review. Together with the implementation of a lower frequency of a blood film review, as determined by diagnosis, and with the frequency of review requirements from the reoccurrence of flagging, morphology efficiencies will be achieved. Additionally, our “Rules based” middleware algorithms (AMS) provide us with confidence that patients with significant changes are reviewed.