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Implementation of a New Diagnostic Algorithm for Anti-Neutrophil Cytoplasmic Antibody (ANCA) Testing
Maria Pasic (Presenter), St. Joseph's Health Centre
Adriana Krizova, St. Michael's Hospital
Jeffrey Companion, St. Joseph's Health Centre
Cathy Streutker, St. Michael's Hospital
Drake Yip, St. Michael's Hospital
Jeff Zaltzman, St. Michael's Hospital
Daniel Beriault, St. Michael's Hospital
Malgorzata Kisiel, St. Michael's Hospital

Abstract:

Beverley Young, St. Michael's Hospital

Dawn-Marie King, St. Michael's Hospital

Objectives: Anti-neutrophil cytoplasmic antibodies (ANCAs) are an important diagnostic tool for ANCA-associated vasculitides. The dominant autoantigens in these conditions are proteinase 3 (PR3) and myeloperoxidase (MPO). ANCA testing also has a role in diagnosis of inflammatory bowel diseases (IBD) and autoimmune liver diseases. Historically, the gold-standard test for ANCA vasculitis screening has been indirect immunofluorescence (IIF), with subsequent antigen-specific immunoassay/ELISA for MPO and PR3. Recent evidence suggests that ELISA is as effective as the two-step algorithm previously proposed. For labs that do not perform these specialized tests on-site, turnaround times may be prolonged due to send-out and batch testing restraints. Furthermore, performing multiple manual tests can be costly and potentially unnecessary. In order to ensure that the appropriate patients are being tested and results are received in a timely manner, we aimed to: 1) restrict ordering to subspecialties that treat ANCA vasculitis/IBD/ hepatitis; and 2) optimize the diagnostic algorithm for ordering ANCAs. Design: Based on new developments in methodologies and discussions with clinical colleagues, we created two types of orders: ANCA vasculitis (to be tested by ELISA), and ANCA IBD/hepatitis (to be tested by IIF, with no reflex to MPO/PR3). As 99% of ANCA orders at our institutions are for ANCA vasculitis, we decided to restrict ordering of ANCA IBD/ hepatitis to gastroenterologists and hepatologists.

Results: The expected outcomes are a reduction in inappropriate ANCA ordering, faster turnaround times, and improved usage of lab resources. These changes have been implemented (January 2018) and will be followed-up prospectively to observe if the expected outcomes are met.

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A quest for quality improvement in healthcare and laboratory management: a six sigma approach

Jawahar (Jay) Kalra, University of Saskatchewan Ashish Kopargaonkar (**Presenter**), University of Saskatchewan Abstract:

Objective: The healthcare quality debate is centered on innovative processes to achieve better outcomes. Our objective was to review the error rate in clinical diagnostic laboratories in sigma levels to understand causes of errors and opportunities for improvement in the process.

Design / **Methods:** Six-sigma is a valuable guideline in achieving quality goals. A sigma value indicates the frequency of defects occurring in a process. We conducted a review of studies that investigated the rate of errors in clinical laboratory and process improvement strategies using six sigma.

Results: The present day healthcare services are only functioning at three-sigma and, in some cases, four-sigma levels. Despite low error rates, the magnitude of usage of clinical laboratories is so high that even the low variances translate into a very high number of defects. The results from studies on errors in clinical diagnostic laboratories give a wide range of rate of errors, varying from 0.1% to 9.36%. Various reasons like variability in the process itself or imperfect error detection methods, may be attributed to this difference in the rates of error.

Conclusion: Quality in clinical laboratories is driven by application of data driven approaches and evidence based practices. This approach aids in setting up professional quality standards, coupled with education and training which helps transform a laboratory culture into a 'Quality Conscious' setting. A six-sigma concept aims at an overall improvement in the quality of the process as a fundamental goal in healthcare services thereby improving the performance of the process exponentially.

Keywords- Six-sigma, quality healthcare, quality standards, clinical laboratories, culture of safety.

Invitation Status: I accept

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Demographics of cannabinoid use pre-cannabis legalization in Canada: a retrospective review of urine drug screening positivity rates from 2014 to 2017

Hui Li (**Presenter**), Dynacare Dana Bailey, Dynacare Peter Catomeris, Dynacare Adam S. Ptolemy, Dynacare

Abstract

Objective: Identify age- and gender-specific trends in cannabinoid use amongst community-based patients in Ontario, Canada by reviewing the liquid chromatography tandem mass spectrometry-based (LC-MS/MS) urine drug screening positivity rates for 11?nor?9?carboxy??9?tetrahydrocannabinol (THCA).

Design and Method: All LC-MS/MS urine drug screening results from

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2014 (N=136,864), 2015 (N=153,329), 2016 (N=106,687) and 2017 (N=75,774) were retrospectively reviewed. THCA had a positive/negative screening cut-off concentration of 40 ng/mL. Positivity rates were calculated annually and partitioned by gender and age (?19 y, 20 to 29 y, 30 to 39 y, 40 to 49 y, 50 to 59 y, 60 to 69 y, 70 to 79 y and ?80 y).

Results: Overall THCA positivity rates in 2014, 2015, 2016 and 2017 were 29.6%, 28.9%, 29.4% and 28.6%, respectively. With the exception of the ?80 y cohort, males had relatively higher THCA positivity rates than females in all age partitions. THCA positivity rates for both genders were highest amongst 20 to 29 y (46.4% and 34.1% in all males and females tested from 2014 to 2017, respectively) and steadily decreased with age. This trend was consistent in each of the testing years examined. From 2014 to 2017, the THCA positivity rates for males and females ?19 y were 39.0% and 30.6%, respectively.

Conclusions: Age and gender specific information on cannabinoid use was obtained through a multi-year retrospective review of THCA urine drug screening positivity rates. This study may be used to evaluate the relative impact of cannabis legalization in Canada on cannabinoid use within this population.

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Alkaline Phosphatase Isoenzymes (isoALP) Prevalence in Community-based Patients with Elevated Total ALP Levels in Ontario

Hui Li (Presenter), Dynacare Adam S. Ptolemy, Dynacare William Hui, Dynacare Dana Bailey, Dynacare Jay Healey, Dynacare

Peter Catomeris, Dynacare

Objective: To identify prevalence of ALP isoenzymes in community-based patients with elevated total ALP levels in Ontario.

Design and Method: ALP isoenzymes results from 2937 patients (n=1911 females, aged 5 to 101 yrs; n=1026 males, aged 1 to 104 yrs) with elevated ALP (>120 U/L) between January 2015 to November 2017 were retrospectively reviewed.

Results: Seven patterns of elevated isoALP were routinely recognized and reported. The prevalence of these patterns in descending order: liver isoALP (64%), bone (18%), liver +bone (10%), liver +intestine (7%), bone + intestine (4%), and intestine (3%). Similar prevalence of each isoALP was observed in female and male patients, with the exception of two cases of placental isoALP and two cases of macro liver isoALP being observed in females only. Highest average total ALP levels was observed with macro liver isoALP (342 U/L), followed by placental (320 U/L), bone (252 U/L), liver + bone (220 U/L), liver (214 U/L), intestine (175 U/L), liver+intestine (174 U/L), and bone+intestine (172 U/L). Highest average patient age was associated with the macro liver isoALP (77), followed by liver (65), liver + intestine (65), liver +bone (63), intestine (61), bone + intestine (56), bone (55) and placental (34). In these patients, a positive correlation was observed between concentrations of total ALP and GGT, but not ALT or AST. Higher phosphorus levels were observed in samples with Bone isoALP, but no difference in calcium levels was noted in samples with different

Conclusions: This study may provide useful information to assist laboratory scientists and clinicians to interpret elevated ALP and isoALP patterns.

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VALIDATION of BD Barricor plasma tube on Beckman-Coulter AU5800 and DXI under different centrifugation conditions.

Tan Paul, Centre hospitalier de l'université de Montréal Fabien Magne, Centre hospitalier de l'université de Montréal Pierre-Olivier Hétu, CHUM Notre-Dame Belanger Marie-Claire (Presenter), Centre hospitalier de l'université de

Montréal

Abstract:

Objectives: Routine and STAT orders are often processed on the same system, which increases the turnaround time. To optimize laboratory automation efficiency, a shorter centrifugation time is warranted. Although the recommended centrifugation parameters are 10 minutes at 1890 to 2500xg, we evaluated performance of BD BarricorTM tubes for high volume chemistry analytes on the Beckman-Coulter Power Express centrifuged 5 minutes at 1952xg.

Design and methods: Fifty paired specimens (BarricorTM) were obtained from healthy subjects. First set of samples were centrifuged 10 minutes and the second set 5 minutes at the same speed (1952xg) Each plasma sample was analysed on AU 5800 and DXI for selected routine chemistry analytes and immunoassays. Data were analyzed using weighed Deming regression analysis and comparison acceptability criteria was based on mean bias (clinical acceptance limits) and correlation coefficient (r ? 0.975).

Results: Biochemistry panel including Na, K, Cl, creatinine, urea, glucose, ALT, ALP, TBIL, calcium, phosphorus, albumin, total CO2, Mg, CK, LD, GGT, AMY, total proteins, cholesterol, HDL-C, Tg, lipase, uric acid, CRP (> 1 mg/L), iron, transferrin, IgG and IgA showed mean bias less than 5%. Immunoassays including TSH, T4, T3, FSH, LH, cortisol and prolactin showed bias less than 7%. Lipemia, icterious and hemolysis index remained unchanged. All the parameters examined were judged clinically acceptable.

Conclusion: Alternative centrifugation time of BD BarricorTM tube showed clinically equivalent results compared to the recommended 10 minutes while improving total automation time.

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COMPARISON of the BD Barricor Tube with BD serum separator tube(SST) for selected chemistry analytes on Beckman-Coulter AU 5800 and DXI.

Tan Paul, Centre hospitalier de l'université de Montréal Fabien Magne, Centre hospitalier de l'université de Montréal Pierre-Olivier Hétu, CHUM Notre-Dame

Belanger Marie-Claire **(Presenter)**, Centre hospitalier de l'université de Montréal

Abstract:

Objectives: The use of plasma has important advantages for laboratory professionals: among them reduced turnaround time and no interference induced by microfibrin. Moreover, it is desirable to consolidate a number of analytes on the same tube. The aim of this study is to evaluate the performance of the BD BarricorTM tube in comparison with the BD SSTTM tube for selected chemistry analytes.

Design and methods: Samples from 119 volunteers were collected in the two different tubes (SSTTM and BarricorTM). Each sample was analysed on AU 5800 and DXI for selected routine chemistry analytes and immunoassays. Data were analyzed using weighed Deming regression analysis and comparison acceptability criteria was based on mean bias (clinical acceptance limits) and correlation coefficient (r ? 0.975).

Results: A total of 34 routine biochemical analytes, 14 endocrinology analytes and 7 tumour markers were tested. The correlation data were good with r>0.975 for all the tested parameters except for some analytes, such as calcium, electrolytes and free T4. However, all the tested analytes were deemed clinically acceptable, even when the correlation coefficient was below 0.975.

Conclusion: The use of BD BarricorTM tube showed clinically acceptable equivalence to the SST tube for the studied parameters resulting in an shorter turnaround time and an improved analytes consolidation.

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Reference laboratory-controlled interventions are successful in reducing unnecessary test ordering: AST and folate testing in Ontario, Canada

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