

Valuable Hospital and Laboratory Practice in an Integrated Medical System for HIV Infection Prevention Interventions at a Veteran Affairs Medical Center (VAMC)

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Introduction/Objective: Patient focused integrated health systems have been described in the literature as being more likely to obtain positive health outcomes in their patient populations. This has particularly been the case for screenings with follow-up interventions as necessary. The usefulness of an Integrated Medical System in optimizing quality medical care for HIV infection and in monitoring patients already on Pre-Exposure Prophylaxis (PrEP) has been previously discussed in the literature. However, when it comes to the screening and initial identification of HIV-negative patients who may benefit from HIV preventive therapies such as PrEP, the literature is sparse. Here we report the useful initial identification of potential patients in a VAMC.

Methods: As part of a quality assurance/improvement project, a search in Vista/Fileman from June 2018 to February 2020 was performed for all patients with a positive sexually transmitted disease (STD) test result - PCR testing for gonorrhea/chlamydia and RPR - during this time period. A medical chart review was performed to determine the HIV status of the patient, and if negative for HIV, whether PrEP was discussed with the patient by the clinical primary care team or the infectious disease consult. The number of patients who ultimately began PrEP as a result of this initial identification was tabulated.

Results: A total of 58 unique patients who tested positive for an STD were successfully identified as being potential candidates for PrEP by the clinical primary care teams or the infectious disease consult in the Integrated Medical System, and as a result the possibility of PrEP was discussed with all 58. In the end, 28 of these patients started PrEP interventions after discussion with their clinical providers. In all patients, these patients were initially identified by a positive STD test result. This is out of a total of 220 HIV negative patients that had been reviewed by their respective clinical providers upon being alerted by the computerized patient record system.

Conclusion: The Integrated Medical System at the VAMC successfully screened and identified patients who may benefit from PrEP. This is a significant example of an integrated medical system successfully screening and providing quality care for identified patients who otherwise would not have had this health preserving intervention.

Leading Laboratory Testing through a Viral Pandemic

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Introduction/Objective: In March, thrown into the 2019 Novel Coronavirus pandemic the first test result was returned on the first suspected of this virus. Since, we implemented numerous plans of action, control measures, test procedures and managed the flow of accurate information to the entire facility.

Methods: Control and leadership engagement were key to our success. Control of collection process, creating collection “kits”, methods of shipment, results reporting and regulated distribution. Key players maintained order and track all samples on a spreadsheet. The spreadsheet utilized was the most vital tool in weeks to come. Daily updates for both supplies and samples. Simultaneously, researching test capabilities with current analyzers. Daily huddles and group meetings to coordinate all efforts which included manning.

Results: Supply counts three times a day at the start and collection “kits” weekly. This measured the capabilities initially. Counting errors lead to numerous redundancies. This was a burden and abandoned. Reference laboratory instructions were verified for all transport media allowed and was as a starting point. Daily usage was subtracted. Patient management was populated with sample specificities, patient demographics and testing locations. Every result called to provider, public health, infectious disease, and a sanitized report to hospital management. This data became “the” source and used as a check against other methods. Later only positives were notified. In April, microbiology implemented Cepheid GeneXpert (Sunnyvale, Ca.). Protocols established changed rapidly. Confusion drove subpar test utilization this created processing errors. Multiple shifts were trained previously and no lag was noted. A back-up, BioFire Torch (Salt Lake City, Utah), was validated.

Conclusion: After eight weeks, over 900 tests, 800 patients and two systems brought online. Overall, a dedicated white board specific to COVID news was established. The “normalcy” phase has hit. Some early protocols have been established as working methods and new members were brought into the fold.

Validation/Verification of Abbott RealTime SARS-CoV-2 Assay on the Abbott m2000 System: The Veteran Affairs Medical Center (VAMC) Experience

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Introduction/Objective: The extraordinary circumstances of the highly contagious SARS-CoV-2 pandemic have led the FDA to approve diagnostic assays with emergency use authorizations (EUA). One of these assays is the Abbott RealTime SARS-CoV-2 assay (Abbott Park, Ill.). However, the literature is sparse on the validation of EUA assays for SARS-CoV-2 assays for this crisis; therefore, we present the Veteran Affairs Medical Center (VAMC) experience in validating/verifying this test for clinical use.

Methods: Validation/verification was performed in three parts as part of quality assurance/quality improvement; 1) sample/patient correlation, 2) precision, and 3) validation/verification of accuracy at the lower limit of detection (LOD). The results from these studies was compiled, reviewed by the laboratory, and after performance was deemed satisfactory, the test would be put for clinical use.

Results: For the sample/patient correlation, a total of 68 known positive and 59 known negative samples were run; these included 56 positive contrived samples or controls, 12 known positive patient samples, 31 negative contrived or controls, and 28 known negative patient samples. All results from the assay were as expected with 100% positive and negative percent agreement except for one sample that was quantity not sufficient for testing. The precision study with 4 known positive and 4 known negative samples run once per day for 5 days yielded perfect 100% precision for both the positive and negative samples. Replicates to determine accuracy at the lower LOD (100 virus copies/ml per instructions for use of the assay) demonstrated accuracy even with dilutions down to 50 virus copies/ml. For this third step, 3 replicates each had been performed at 1000, 500, 250, 70, 60 and 50 virus copies/ml. As 100 virus copies/ml was the provided manufacturer LOD, 7 replicates were performed at 100 virus copies/ml.

Conclusion: The validation/verification indicated that the Abbott RealTime SARS-CoV-2 assay performed with expectations including with real patient samples and could be put into clinical use at the VAMC. After this validation/verification, the assay has been very successfully used for in-house testing for SARS-CoV-2. In fact, the validation demonstrated an LOD as low as 50 virus copies/ml, suggesting the assay may be even more sensitive to low levels of viremia than is stated in the EUA.

Microbiology

Rat-Bite Fever: Updated Recommendations For Culture And Isolation Of Streptobacillus Moniliformis Using An Automated Continuous Blood Culture Instrument In A Clinical Setting

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Introduction/Objective: Rat-bite fever and Haverhill fever are difficult to diagnose in a clinical setting due mostly to clinicians and laboratory professionals being unable to culture the causative agent-Streptobacillus moniliformis. SPS in blood culture bottles has historically been implicated as the complicating factor.

Methods: Utilizing the BDFX40 automated continuous blood culture bottle system and novel quantitative PCR data, we present how blood volume is critical in order to consistently detect, isolate and grow the organism in the presence of SPS using modern laboratory instrumentation in a clinical setting.

Results: We demonstrate here that 10ml of blood was determined to provide optimal results for detection and growth of *S. moniliformis* in 0.05% SPS. For all isolates tested, 100% (n=56) were detected or alerted as positive by the instrument, with the longest time required for detection being 102 hours (n=1) and the fastest time to detection being recorded at 13.4 hours. (n=1) with an average time of 26.5 hours (n=56).

Conclusion: During the course of this study, we determined that blood inoculum volume played a significant role in organism growth and detection. We found that in 100% of the isolates tested (and all the variations of testing within), SPS (up to a concentration of 0.05% w/v) in blood culture media appeared to be counteracted, allowing for the growth detection and culturing of *S. moniliformis* using an automated continuous blood culture system when 10ml of blood was used as an inoculum. This is the first study to report and suggest that a specific blood volume is critical when utilizing a closed commercial blood culture system to detect *S. moniliformis*, this research is the largest study of *Streptobacillus moniliformis* isolates to date.

Microbiologic Proof-Of-Concept: A Novel Device Combining UV Light And Ozone For Human Skin Antisepsis

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Introduction/Objective: Hand hygiene (HH) decreases healthcare-associated infections (HAI). Available products include alcohol-based gels, foams, wipes, and “gold-standard” hand-washing with soap and water. We tested an investigational device (HyLuxO3; GMI, LLC, patent pending) for antimicrobial effect (AME). HyLuxO3 was