Diagnostic stewardship implementation and impact of Filmarray Meningitis/ Encephalitis (FA-ME) panel in a tertiary care setting in Karachi, Pakistan

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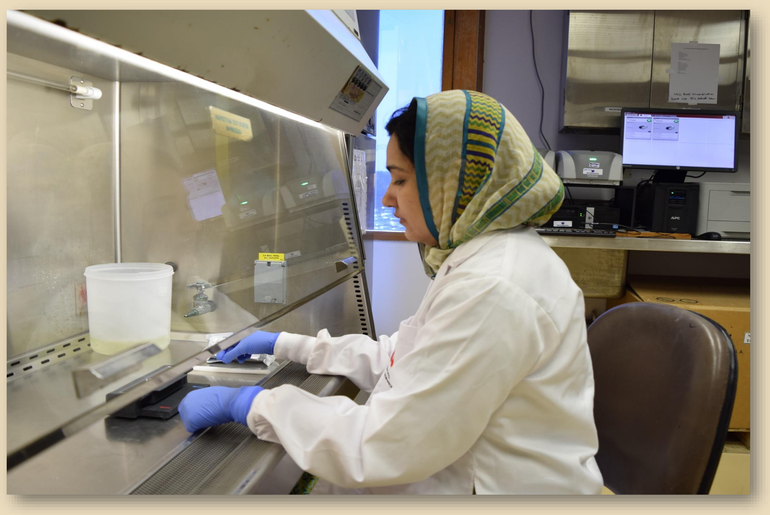
Introduction:

Filmarray Meningitis-Encephalitis® (FA-ME) provides rapid, reliable Community-Acquired Meningitis/Encephalitis (CA-ME) diagnosis, maximizing early, pathogen-directed clinical decision support and stewardship goals. We implemented FA-ME diagnostic stewardship (DS) in a tertiary care hospital in Karachi, Pakistan and report on process activities and antimicrobial de-escalation impact.



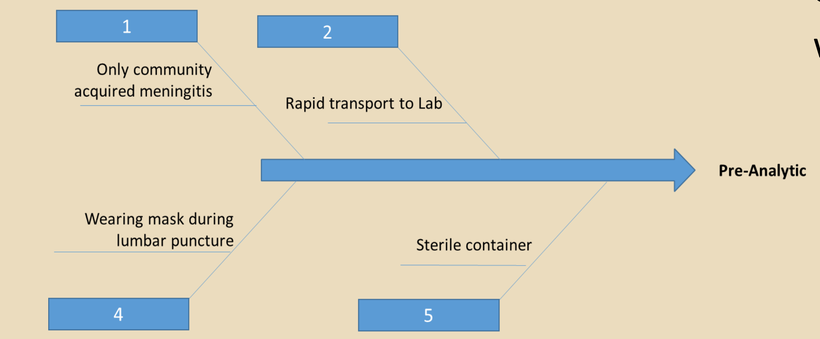
Processing of Filmarray specimen in biosafety cabinet

Methods:

FA-ME was implemented in May 2017 for CA-ME patients admitted to Aga Khan University Hospital. Strategies were implemented in pre-analytic (exclusion of nosocomial and shunt meningitis), analytic (backup culture, wet mounts and Xpert MTB/RIF®), and post-analytic (clinical correlation to reduce false positives, antimicrobial advice) phases to improve reliability and stewardship outcomes. Antimicrobial de-escalation at 24 hours was determined for FA-ME negative, and enterovirus positive patients.

Results:

From May 2017 to July 2018, FA-ME was requested on 600 patients. Pre-analytic assessment led to deferral of 6 (1%) tests. Mean laboratory turnaround time was 3.6±3.6 hours (95% CI 3.379-3.908). Backup microbiological cultures, wet mounts, and Xpert yielded additional diagnoses in 1.2% (n=7), 0.7% (n=4) and 1.3% (n=8) patients respectively. Two HSV-2 false-positives and 1 Cryptococcus false-negative test were identified, re-tested, and corrected on post-analytic assessment. Antimicrobials were de-escalated in 63.2% (12/19) patients with enterovirus meningitis, and in 51% (n=218) adults and 53.8% (n=40) children ≤18 years (infants excluded) with negative FA-ME results.



Conclusions:

Diagnostic utility of FA-ME was improved through application of DS strategies. Although we did not perform a before-after study to evaluate percent reduction in antimicrobial use, antimicrobials were discontinued in 50-60% of patients with results warranting de-escalation. Physician education can further increase compliance with de-escalation.

Filmarray 2.0 FilmArray Meningitis/Encephalitis (ME) IQCP Risk Assessment Quality Plan

			Required Element Key			Team Leader				
IQCP Name	Filmarray ME	Specimen				Team Members				
IQCP Implementation	5/1/2017	Reagent								
Revision Number	1	Environment				Date/Month/Year:				
Revision Date	N/A	Testing Personnel								
Retirement Date		Test System								
Lab Section	Microbiology					Director Approval				
Form #						Director Approval	3/5/2017			
Instrument Name/Serial #										
Process	Failure Mode	Effect of Failure	Potential Cause(s)/ Mechanism of Failure	Risk Level	Mitigation	Responsibility & Target Completion Date	Update and New Actions	New Problem	New Risk Level	New strategy
Pre Analytic										
Sample collection	Sample contamination	False positive results for contaminating respiratory colonizers	Contamination of sample during collection or processing	2	1. Instruction to staff to wear surgical mask whe performing Lumbar Punctures 2. Sample containers with tightly closing lids to avoid contamination udring transport 3. Leaking containers not accepted 4. Staff wearing masks when handling samples during processing stage		No False positive results for contaminating respiratory colonizers were detected			
Staff Training & Competence	Staff not adequately trained on Filmarray ME instrument and procedure	Incorrect Results Reported	1. Competency assessment and sign off by trainer of all staff before carrying out procedure on clinical specimens Filmarray ME test checklist signed off by staff after each test performed.	1	Staff must complete procedure training checklist and checklist signed by tech and supervisor before they can perform testing	1. Yearly competency checklist signed by tech and supervisor 2. Compliance monitored by supervisor.	Staff performing test are adequately trained on Filmarray ME instrument and procedure and competency assesment are signed off by the trainer	Invalid Quality control results were obtained	1	Retraining of Staff is done
Supply Procurement	Filmarray ME cartridges not received/ shipment delayed	Discontinue/ suspend test reporting	Unexpected increase in test volumes/ unacceptable lot received/ shipment delayed	1	1. Ordering of FA ME cartridges as routine our base supplies 2. Revision of ordering based on test volumes every 6 months		Filmarray ME cartridges received within time, no shipment delayed			
Lot Performance	Lot does not produce expected results	Lot Performance Compromised, Incorrect Results Reported	1.Manufacturer fault 2. Shipment subject to excessive temperatures in transit or after delivery	1	Perform **external** (Zeptometrix) QC on each new lot to verify kit performance	Policy to check each new lot / shipment as soon as received (ensure tested before patient testing)	Lot verified and lot produce expected results			
					Do not use pouch if upon					**Added new item to IQCP**
Sample types	CSF from shunt infections or body fluids other than CSF accepted for FA ME test	Incorrect Results Reported	a) Medical receptionist training for acceptable specimen types b) ILMS failure to show acceptable specimen types	1	Only cerebrospinal fluid acceptable sample type in system (ILMS) 2. Test update and literature distributed to hospitals/ physicians show shint associated CSF to be unacceptable		CSF from only lumbar puncture were accepted for FA ME test	**Second sample of same patient was sent to lab within**	1	**no samples will be flagged if same test is charged within the same**
Sample Volume	Low/sample volumes received where unexpected results cannot be rechecked and/ or backup cultures cannot be performed	Results will nt be rechecked/ reconfirmed bg culture	Insufficient CSF received	0	Reporting consultant to communicate with requesting physician to prioritize tests requested and performed for optimal management		Sample volumes received with adequate volume where unexpected results can be rechecked and/ or backup cultures can be performed			
Patient ID Issues	Orders for wrong patient	Test performed on incorrect patient, erroneous results	Failure to follow patient ID protocol	1	Pre-Analytic Verification of patient ID	Clinical laboratory and hospital policy (head nurses, managers)	All Test performed on correct patient, no erroneous results were obtained			
Patient ID Issues	Incorrect patient ID entered in ILMS	Test performed on incorrect patient, erroneous results	Failure to follow patient ID protocol	1	Pre-Analytic Verification Process of patient ID and barcoding of results 2. direct communication of results to ILMS	Clinical laboratory and hospital policy (managers)	No Incorrect patient ID entered in ILMS			
Analytic										
Instrument ambient temperature	Ambient airconditioning fails	QC failure/ Incorrect Results may be Reported	Failure of engineering controls over airconditioning	1	Centrally controlled airconditioned environemnt and humidity control optimal for instrument function	Engineering Department servicing laboratory	No Ambient airconditioning fails			
Specimen with interfering substances	"Error/ Invalid" result	Test repeated/ specimen rejected	1. Specimen inherent factors 2. May occur when incorrect specimen type accepted or inadequate patient preparation before collection	1	Built-in internal control		No "Error/ Invalid" result obtained			
Specimen backup culture for culturable pathogens	Backup culture not performed/ missed inoculation	Culturable non-FA ME pathogens for meningitis not recovered; failure of diagnosis	1. Specimen insufficient; 2. Sample inoculation missed/ culture plates missing or not followed up on bench	1	1. Sample log sheet printed each morning to follow up on culture and results of samples received		New process introduced			
Internal QC	Internal procedural controls (Schizosaccharomyces pombe) included in every testing device fail to amplify	Misinterpretation of test results when invalid. Test must be repeated.	Sample inherent factors	0	Test SOP requires all invalid/ rejected control results to be repeated		Internal procedural controls (Schizosaccharomyces pombe) included in every testing device was amplified and all controls were passed			
External QC	Weekly external positive and negative controls to ensure well-functioning test system	Module error requiring instrument maintenance	Inadequate QC material used	0	1. Controlled environment 2. Well-characterized external controls (Zeptometrix external control pools as positive and nuclease free water as negative controls)		Weekly external positive and negative controls are performed to ensure well-functioning test system			
Patient/ Pouch	Pouch (Cartridge) not	Results Reported on incorrect	Failure to follow procedure	1	1. SOP requires double ID check 2. Emphasized in		No Results were reported			

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Poster number: 250