



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

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.

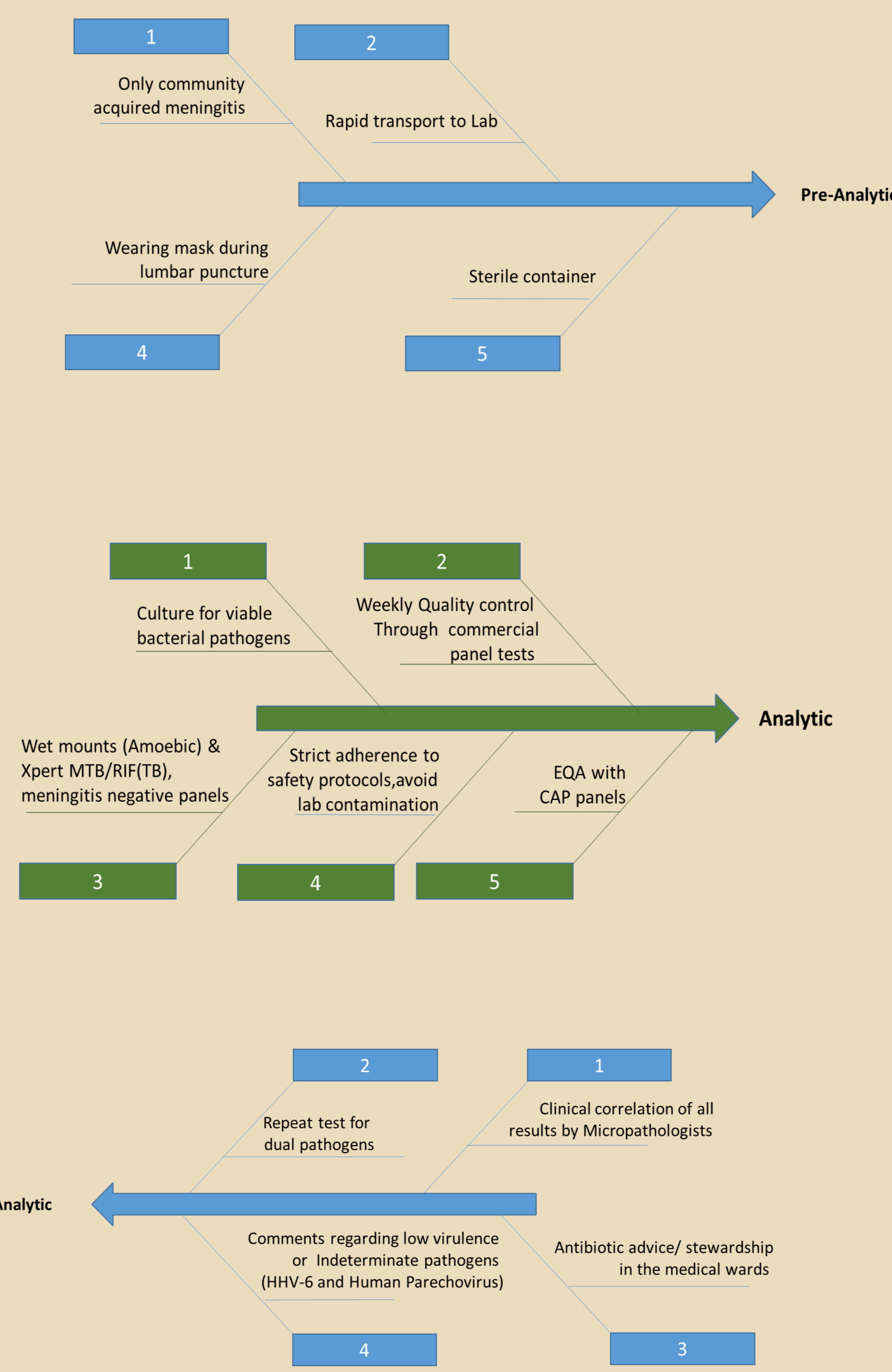


Conclusions:

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.

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.



Process	Failure Mode	Effect of Failure	Potential Cause(s) of Failure	Risk Level	Mitigation	Responsibility & Target Completion Date	Update and New Actions	New Process	New Policy	New Strategy
Pre-Analytic	Sample contamination	False positive results for contaminating respiratory colonizers	Contamination of sample during collection or processing	2	1. Limitation on staff who perform tasks that require opening the Filmarray ME instrument. 2. Staff must complete process training, checklist and supervisor before they can perform testing. 3. Staff wearing masks when handling samples during processing stage.	1. Director of FA-ME, 2. Infection control nurse and supervisor	No false positive results for contaminating respiratory colonizers were detected			
Pre-Analytic	Staff Training & Compliance	Staff not adequately trained on Filmarray ME instrument and procedure	Incomplete training	1	1. Competency assessment and sign-off by supervisor of all staff before carrying out procedure on clinical staff after each test. 2. Filmarray ME test checklist signed off by staff after each test.	1. Director of FA-ME, 2. Infection control nurse and supervisor	1. Yearly competency checklist signed by supervisor and compliance monitoring by supervisor.	Staff performing test are adequately trained on Filmarray ME instrument and procedure and competency assessment are signed off by the staff.		Forming of Staff to do
Analytic	Supply Procurement	Filmarray ME cartridges not received or shipment delayed	1. Discontinued supply of reagents. 2. Shipment subject to excessive temperature in transit or after delivery.	1	1. Order of FA-ME cartridges in advance and have regular 2. Position of ordering based on test volumes every 6 months.	1. Director of FA-ME, 2. Infection control nurse and supervisor	Filmarray ME cartridges received within time, no shipment delayed.			
Analytic	Lot Performance	Lot does not produce expected results	1. Manufacturer fault. 2. Filmarray ME instrument not calibrated.	1	1. Perform external QC on each lot of reagents before patient testing.	1. Director of FA-ME, 2. Infection control nurse and supervisor	Lot verified and lot produce expected results.			Add a new item to EQA samples will be shipped if same patient was changed within the same
Analytic	Sample Input	CSF from shunt, pleurocentesis or body fluids other than CSF accepted for FA-ME test	1. Media not specifically testing for acceptable specimen types. 2. EMS failure to show acceptable specimen types.	1	1. Do not use open if open. 2. Daily observational test acceptable sample type in system (EMS). 3. Test setup and for patient CSF samples to hospital physicians who must ensure CSF is not unacceptable.	1. Director of FA-ME, 2. Infection control nurse and supervisor	CSF from only lumbar puncture was accepted for FA-ME test.			
Analytic	Sample Volume	Low sample volume received where unexpected results reported to be included in backup culture cannot be performed	1. Incomplete CSF received.	0	1. Reporting consultant to requesting physician to provide test to be performed and performed for optimal management.	1. Director of FA-ME, 2. Infection control nurse and supervisor	Sample volumes received with adequate volume where unexpected results can be included and backup culture can be performed.			
Analytic	Patient ID Error	Orders to wrong patient	1. Failure to follow patient ID protocol.	1	1. Pre-Analytic Verification of patient ID.	1. Director of FA-ME, 2. Infection control nurse and supervisor	All test performed on correct patient, no incorrect results were obtained.			
Analytic	Patient ID Error	Incorrect patient ID entered in LIS	1. Failure to follow patient ID protocol.	1	1. Pre-Analytic Verification of patient ID and barcoding of results. 2. Direct communication of results to LIS.	1. Director of FA-ME, 2. Infection control nurse and supervisor	No incorrect patient ID entered in LIS.			
Analytic	Instrument ambient temperature	Ambient air conditioning fails	1. Failure of engineering controls over air conditioning.	1	1. Centrally controlled air conditioning and humidity control system for instrument function.	1. Director of FA-ME, 2. Infection control nurse and supervisor	No ambient air conditioning fails.			
Analytic	Specimen not receiving calibration	'Error' result	1. Test reagent expired.	1	1. Batch in internal control.	1. Director of FA-ME, 2. Infection control nurse and supervisor	No 'Error result' result obtained.			
Analytic	Specimen backup culture not performed on all patients	Backup culture not performed on all patients	1. Specimen not received. 2. Sample not received or not followed up on bench.	1	1. Sample log sheet provided weekly to be followed up on culture and results of sample received.	1. Director of FA-ME, 2. Infection control nurse and supervisor	New process involved.			
Analytic	Internal QC control	Internal QC control (E-test) not included in every testing device and all controls were passed	1. Sample inherent factors.	0	1. Test SOP requires all internal control results to be reported.	1. Director of FA-ME, 2. Infection control nurse and supervisor	Internal QC control (E-test) included in every testing device and all controls were passed.			
Analytic	External QC	Weekly external positive and negative controls are performed to ensure test functioning test system	1. Module error requiring instrument maintenance. 2. Inadequate QC material used.	0	1. Controlled environment. 2. Verify external control results are reported to LIS.	1. Director of FA-ME, 2. Infection control nurse and supervisor	Weekly external positive and negative controls are performed to ensure test functioning test system.			
Analytic	Patented Process	Results Reported on incorrect	1. Failure to follow procedure.	1	1. SOP requires double check. 2. Engineering	1. Director of FA-ME, 2. Infection control nurse and supervisor	No Results were reported			