Association of the FilmArray Meningitis/Encephalitis Panel With Clinical Management

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ABSTRACT

OBJECTIVES: To determine the association of the use of the multiplex assay meningitis/encephalitis panel with clinical management of suspected meningitis.

METHODS: A cross-sectional study was conducted with children 0 to 18 years of age who received a lumbar puncture within 48 hours of admission for an infectious workup. Patient demographic and presenting information, laboratory studies, and medication administration were collected. The primary measure was length of stay (LOS) with secondary measures: time on antibiotics, time to narrowing antibiotics, and acyclovir doses. LOS and antibiotic times were stratified for outcomes occurring before 36 hours. Logistic regression analysis was used to account for potential confounding factors associated with both the primary and secondary outcomes. A value of \( P < .05 \) was considered statistically significant.

RESULTS: Meningitis panel use was associated with a higher likelihood of a patient LOS <36 hours (\( P = .04; \) odds ratio = 1.7; 95% confidence interval [CI]: 1.03–2.87), a time to narrowing antibiotics <36 hours (\( P = .008; \) odds ratio = 1.89; 95% CI: 1.18–2.87), and doses of acyclovir (\( P < .001; \) incidence rate ratio = 0.37; 95% CI: 0.26–0.53). When controlling for potential confounding factors, these associations persisted.

CONCLUSIONS: Use of the meningitis panel was associated with a decreased LOS, time to narrowing of antibiotics, and fewer acyclovir doses. This likely is a result of the rapid turnaround time as compared with cerebrospinal fluid cultures. Additional studies to examine the outcomes related to this change in management are warranted.

www.hospitalpediatrics.org
DOI:https://doi.org/10.1542/hpeds.2019-0064
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HOSPITAL PEDIATRICS (ISSN Numbers: Print, 2154-1663; Online, 2154-1671).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: Funded by the University of Nebraska Medical Center Pediatric Research grant.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

Dr Nabower conceptualized and designed the study, participated in data collection, and drafted the initial manuscript; Ms Miller and Mr Biewen participated in data collection and reviewed and revised the manuscript; Ms Lyden conducted the initial analyses and reviewed and revised the manuscript; Drs Goodrich, Miller, Gollehon, Skar, and Snowden designed the study and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.
There are >72,000 admissions for suspected meningitis in the United States annually, averaging $12,000 per case. Bacterial meningitis can have severe consequences if not appropriately treated; however, viral meningitis tends to be self-limited. Until recently, the ability to rapidly distinguish between the 2 was limited. Real-time polymerase chain reaction (PCR) testing rapidly distinguishes between viral and bacterial meningitis, which may lead to decreased length of stay (LOS) and cost savings.

In October 2015, the Food and Drug Administration approved the FilmArray Meningitis/Encephalitis (ME) Panel. This was the first real-time PCR-based cerebrospinal fluid (CSF) assay capable of detecting 14 pathogens simultaneously (Supplemental Table 5) with an 85% sensitivity for human herpesvirus 6 (HHV-6), 96% sensitivity for enterovirus, and 100% sensitivity for the other pathogens and a specificity >98% for all organisms. However, positive sample results have been limited in previous studies. Potential ME panel benefits include quicker turnaround time (TAT) and increased sensitivity in pretreated CSF samples than culture. Previous studies have been limited by sample size (no positive bacterial pathogen results) as well as longer TAT due to using a reference laboratory.

In this study, our aim was to compare management practices in patients who had CSF ME panels performed versus those who had CSF cultures with enterovirus and/or herpes simplex virus (HSV) PCR.

**METHODS**

This was a cross-sectional study at a 150-bed freestanding children’s hospital from June 2015 to July 2017. The ME panel was introduced at the hospital in July 2016. The decision to obtain the assay was provider dependent because the institution has no policy addressing its obtainment or interpretation. This study was approved by the relevant institutional review board with a waiver of consent.

**Subjects**

Children 0 to 18 years old who had a CSF culture or ME panel obtained within 48 hours of admission were included. Subjects were identified through a search of the e-health records. Exclusion criteria included patients who died during hospitalization because of a noninfectious cause, who never received antibiotics, who had lumbar puncture (LP) to evaluate a noninfectious etiology, who had a repeat LP in known meningitis, or who had a history of central nervous system surgery. LP to evaluate a noninfectious cause was determined through review of the history and physical (H&P). If no infectious etiology was listed in the assessment in addition to no antimicrobial agents started, the patient was excluded. Excluded conditions included malignancy, pseudotumor cerebri, intractable epilepsy, maternal syphilis, autoimmune encephalitis, and Guillain Barré syndrome.

**Data Collection**

Manual chart review included the attending physician’s initial H&P or consult notes, laboratories, imaging, and medication administration record using a standardized form among 3 reviewers. The lead author reviewed 10% of other reviewers’ charts to assess for agreement in coding. If a diagnostic study was not performed, it was assumed that the provider did not base clinical management on the study, and therefore it was classified as a negative result. Presenting symptoms were presumed to be negative results if not listed in documentation.

**Outcomes**

The primary outcome measure was LOS measured in hours on the basis of encounter start and end times. Secondary outcome measures included total time on antibiotics in hours from the time the first antibiotic dose was administered at our institution to the last dose administered, including antibiotics prescribed at discharge. For antibiotics prescribed at discharge, the duration was estimated on the basis of dosing instructions. Antibiotics were coded by class. Time to narrowing antibiotics was defined as the time from the first antibiotic dose at our institution to the time at which monotherapy or dual therapy for a specific organism was initiated. If patients were continued on the same monotherapy throughout their course, they were excluded from the time to narrowing analysis. Acyclovir was measured in intravenous or oral doses received at our institution or at discharge. This method was used to avoid creating artificial differences in hours on therapy due to different dosing regimes. Prophylactic dosing of antimicrobial agents was not included.

**Covariates**

Age was stratified into <30, 30 to 90, and >90 day groups. The admission department was noted, as were illness markers, including prematurity (birth before 37 weeks’ gestation); Streptococcus agalactiae status; non-neurologic focal symptoms (respiratory, acute otitis media, pharyngitis, vomiting, diarrhea, dysuria, or skin infection); neurologic symptoms (altered mental status, seizure, or abnormal neurologic examination); sick contacts; and HSV concern (concerning lesions on examination or HSV exposure). The presence of renal dysfunction as noted in the problem list or admission laboratories was noted. Immunosuppression, including immunodeficiency, neutropenia, and active chemotherapy or immunomodulator use, were recorded. All brain imaging reports during the admission were reviewed for changes consistent with an infectious process, including dural enhancement or thickening; leptomeningeal enhancement; restricted diffusion; or multifocal T2 weighted MRI image hyperintensities concerning for encephalitis, lenticulostriate vasculopathy, mastoiditis, empyema, or abscess. Pediatric Risk of Mortality (PRISM) III scores were collected for all PICU admissions.

**Laboratories**

Initial serum white blood cells (WBCs), bands, creatinine, blood urea nitrogen, liver function tests, C-reactive protein (CRP), and procalcitonin were noted. Serum WBCs were classified as normal or abnormal by using age-specific guidelines. Less than one-third of patients had bands, CRP, or procalcitonin reported, so these were excluded in final analysis. CSF studies included WBCs, neutrophil percentage, red blood cells (RBCs), glucose, protein, Gram-stain, culture, enterovirus PCR, HSV PCR, and the ME panel. HSV PCR was performed via
sendout laboratory during business hours by using a Simplexa Direct Kit. CSF culture, ME panel, and enterovirus PCR were performed 24 hours per day every day at our institution.

The LP was classified as bloody if it had >1000 RBCs based on laboratory-reported cutoffs. Other infectious workup recorded included urine, blood, and respiratory cultures within 48 hours of admission as well as respiratory PCR panel results. Bacterial cultures obtained at outside facilities and recorded within the H&P were also included. Urine cultures with colony count <10,000 or multiple flora and blood cultures with coagulase-negative *Staphylococcus* and *Bacillus* species results were categorized as likely contaminants.11 Bacterial meningitis was classified by the presence of CSF culture or ME panel result positive for a bacterial pathogen.

**Statistical Analysis**

Descriptive statistics were used to define the study groups. Fisher’s exact test was used to compare categorical measures, and the Mann-Whitney U test was used for nonparametric continuous variables. Because of the extreme skewness of LOS and antibiotic times, model assumptions were not met when the outcomes were considered as count or time to event data. Thus, LOS was dichotomized into <36 and ≥36 hours on the basis of data that most true-positive bacterial culture results are identified within 36 hours; thus being a likely critical time point if the management decision was based solely on cultures.12,13 Accordingly, antibiotic time was categorized as 0 (single dose), 1 to 35, and ≥36 hours. Logistic regression was used to model LOS and time to narrowing antibiotics. A cumulative logit model was used to analyze antibiotic time. Univariate analyses were done of possible covariates on the basis of clinical judgement to evaluate for association with longer LOS or antibiotic time. Age group, previous antibiotic use, neurologic symptoms, abnormal serum WBCs, admission location, and positive culture results were evaluated as possible confounders. No immunocompromised patients and only 1 patient with abnormal imaging stayed <36 hours, limiting their inclusion in the model. Year was not included in the model as a result of multicollinearity concerns because it was strongly associated with ME panel obtainment but not outcome measures. Negative binomial regression was selected to model acyclovir dose because it is a count variable with a large number of 0 values. Age group, HSV concern, admission location, abnormal serum WBCs, neurologic symptoms, and positive culture results were evaluated as possible confounders. A 2-sided value of P < .05 was considered statistically significant.

**RESULTS**

**Presenting Characteristics**

CSF cultures were obtained in 910 patients, with 571 remaining after exclusion criteria (Fig 1). Patient presentation data are in Table 1. A higher proportion of non-ME panel patients were admitted to the NICU than ME panel patients (P = .0009). There was no difference between the study groups for abnormal WBCs or imaging, neurologic symptoms, immunosuppression, PRISM III scores, or antibiotic pretreatment (Table 1).

**CSF Pathogen Identification**

Detected CSF pathogens are summarized in Table 2. Median TAT for HSV PCR was 23.2 hours. Median TAT of bacterial identification from CSF culture was 34.0 hours, whereas that of the ME panel was 2.2 hours and that of the enterovirus PCR was 4.8 hours. Fifty-one patients in the non-ME panel group had a CSF sample result that was positive for viral or bacterial organisms. Forty-six (90%) results were positive for a virus: 44 enterovirus and 2 HSV. Of the 5 patients with culture results positive for bacteria, 3 had organisms not detected by the ME panel: *Staphylococcus capitus*, *Group A Streptococcus*, and *Micrococcus luteus*.

Forty-nine patients in the ME panel group had a CSF evaluation result that was

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**FIGURE 1** Multiplex assay study inclusion pathway.
Eight patients had ME panel results discordant with culture results (Table 3). One patient’s ME panel result was positive for Haemophilus influenzae. There was no antibiotic pretreatment; however, the patient was treated for presumptive meningitis on the basis of pleocytosis. Another patient’s ME panel result was positive for Streptococcus pneumoniae, and blood culture results were positive for methicillin-susceptible Staphylococcus aureus. He was treated for presumptive meningitis on the basis of pleocytosis and positive ME results. Three other patients had ME panel results positive for S pneumoniae with negative pretreated CSF culture results. All were presumptively managed as meningitis. One ME panel result was positive for Cryptococcus neoformans/gatti without pleocytosis or corroborating separate PCR testing. This was considered a false-positive result (Supplemental Table 6).

In 2 cases, the ME panel result was negative with a positive bacterial culture result. However, both results were treated as contaminants without adverse advents (Enterococcus casseliflavus without pleocytosis and Bacillus nonanthracis with mild pleocytosis and otherwise normal CSF studies; Supplemental Table 6). Ten patients had both an ME panel and enterovirus PCR; 1 had a positive result on the enterovirus PCR but a negative result on the ME panel.

**Clinical Outcomes**

**LOS**

Median LOS in the ME panel group was 59 vs 68 hours in the non-ME panel ($P = .049$). In the multivariate analysis, patients who had an ME panel were 1.75 (95% confidence interval [CI]: 1.03–2.91) times as likely to have been discharged within 36 hours ($P = .04$; Table 4). There was no interaction between ME panel and age group for LOS ($P = .48$). There was no difference in LOS between ME panel results positive for a viral pathogen and positive enterovirus PCR results or between patients with negative CSF study results in both groups. However, identification of a virus on either platform was associated with a shorter LOS ($P < .0001$). The presence of abnormal brain imaging, immunosuppression, or neurologic symptoms was associated with a longer LOS ($P = .002, P = .05, P = .001$; Supplemental Table 7).
Antibiotic Exposures

Median antibiotic time was 42.1 hours in the ME panel group and 45.9 hours in the non-ME panel group with median time to narrowing 23.7 and 34.7 hours, respectively ($P = .14; P = .053$). In multivariate analysis, ME panel patients were 1.46 (95% CI: 1.00–2.13) times more likely to have an antibiotic time <36 hours compared with non-ME panel patients but this did not reach significance ($P = .05$). Patients who had an ME panel were 1.89 (95% CI: 1.20–2.97) times more likely to have quicker narrowing of antibiotics than the non-ME panel group ($P = .008$; Table 4). The effect of ME panel testing on antibiotic exposure was not influenced by age group ($P = .61$) or admission location ($P = .87$). When comparing ME panel results positive for any virus versus enterovirus PCR positive results or completely negative CSF results, there were no differences in antibiotic time. However, the identification of a virus was associated with shorter antibiotic time ($P < .0001$). Abnormal serum WBCs or imaging were associated with longer antibiotic duration ($P = .02; P < .001$; Supplemental Table 7).

Acyclovir Exposures

The number of acyclovir doses administered in the ME panel group was 0.36 (95% CI: 0.25–0.51) times that of the HSV PCR group ($P < .001$). The model predicted that ME panel patients would receive an average of 1 acyclovir dose versus 3 doses in the HSV PCR group. A total of 70.4% in the ME panel group received no acyclovir versus 48.3% in HSV PCR group (Table 4).

DISCUSSION

We found that ME panel use was associated with a decrease in LOS and antibiotic narrowing time in the evaluation of suspected pediatric meningitis. However, multiple instances of discordant results between the ME panel and CSF cultures were noted. Although the ME panel was associated with a high negative predictive value for bacterial organisms when compared with the current standard of CSF cultures, its positive predictive value is lower.

The ME panel is reported to be more sensitive for infectious meningitis than older techniques. Studying its sensitivity and specificity in actual clinical practice has been limited by the relatively low prevalence of positive bacterial results. In this study, there were multiple positive ME panel results without corresponding pleocytosis; however, studies have revealed viral and bacterial meningitis can lack pleocytosis, thus making it difficult to fully interpret these results without additional testing. Additionally, HHV-6 results may remain positive, indicating a previous infection but not accounting for the acute illness. Three of 5 patients with positive ME panel results for bacteria with negative culture results received antibiotics before testing, which also has been reported in other cohorts. The remaining 2 patients with positive ME panel results but negative culture results were clinically treated as having meningitis. This is consistent with the 1.4% of unverified positives in previous studies. Conversely, 5 pathogens cultured in the current study would not be tested for by the ME panel. Discrepant results will continue to require clinical judgement to guide treatment in each situation.

ME panel use was associated with a decreased LOS and antibiotic narrowing time, with a trend toward decreased total antibiotic duration. Decreased LOS is consistent with previous studies. Unsurprisingly, because of the relatively rapid results of enterovirus PCR, there was no difference for LOS or antibiotic duration for children with results positive for enterovirus on either platform. Thus, it seems that the detection of other viruses is driving the change in practice. The importance of a positive viral result is supported by authors of a German study that noted decreased antibiotic time for children with positive virus results in comparison with children with a negative ME panel result in addition to results from this study showing detection of a virus is associated with both a shorter LOS and antibiotic time.

Our findings provide additional insight into the potential role of multiplex assay testing on clinical practice. Authors of previous studies with prolonged TAT likely underestimated the potential benefit of this diagnostic tool, as opposed to our study with a 2-hour TAT. Still, both studies

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**TABLE 3** Diagnostic Accuracy of ME Panel Using CSF Culture Results as a Reference

<table>
<thead>
<tr>
<th>Positive CSF Culture Result</th>
<th>Negative CSF Culture Result</th>
<th>Total panels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive ME panel result for bacteria</td>
<td>3</td>
<td>5$^*$</td>
</tr>
<tr>
<td>Negative ME panel result for bacteria</td>
<td>2$^a$</td>
<td>213</td>
</tr>
<tr>
<td>Total panels</td>
<td>5 $^b$</td>
<td>218</td>
</tr>
</tbody>
</table>

NPV, negative predictive value; PPV, positive predictive value.
$^a$ Indicated samples that had negative CSF culture results but clinically were thought to be true-positive results on the ME panel given antibiotic pretreatment and the presence of pleocytosis. Adjusting for these, PPVs would be 63% for bacterial organisms.
$^b$ Both positive culture results were clinically thought to be false-positive results and were treated as such. Adjusting for these, the panel would have an NPV of 100% for the detection of bacterial organisms tested on the ME panel.
revealed a decreased LOS among patients who received the ME panel. Because the ME panel TAT was much shorter than both median antibiotic time and LOS, we propose that the positive viral result population is contributing to the changes seen when examining the group as a whole and that additional studies with increased samples of positive results are warranted. We did not find a significant decrease in total antibiotic duration. This could be due to multiple ME panel results positive for bacteria in our study as opposed to other studies. This is further supported by the findings that antibiotic narrowing time was decreased in this study.

Although the decrease in LOS is beneficial from a resources perspective, the decreased antibiotic duration may also decrease some of the short-term adverse effects of antibiotic exposure such as ototoxicity and diarrhea and long-term outcomes such as increased rates of obesity, asthma, and inflammatory bowel disease. The ME panel also offers a potential source of antibiotic stewardship because narrowing coverage sooner could help with antibiotic resistance.

ME panel use was also associated with decreased acyclovir dosing in this study. This is likely due to the more rapid TAT with ME panel testing compared with HSV PCR (2.2 vs 23.2 hours). The TAT of the ME panel is even faster than that published for rapid HSV testing, thus, it may be a valuable alternative to HSV PCR testing. However, additional study is needed to evaluate the application of the ME panel to HSV infections because the current studies have limited patients with active infection and limited follow-up.

A limitation of this study is that the non-ME panel and ME panel groups were largely separated by time (before and after June 2016), with 275 overlapping. Thus, an overall practice change during this time could also influence results. For example, our institution participated in a national practice standardization project starting in January 2017, with which we aimed to discharge low-risk febrile infants in <36 hours. This is likely due to the more rapid TAT with ME panel testing compared with HSV PCR (2.2 vs 23.2 hours). The TAT of the ME panel is even faster than that published for rapid HSV testing, thus, it may be a valuable alternative to HSV PCR testing. However, additional study is needed to evaluate the application of the ME panel to HSV infections because the current studies have limited patients with active infection and limited follow-up.

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Authors of future studies evaluating rates of discordant results as well as the risk of having a concurrent bacterial infection with the less commonly detected viral pathogens are needed. Although we found a decreased LOS, the ME panel is more expensive than routine testing; a cost analysis is needed to determine the value of the ME panel. Additionally, researchers examining the long-term outcomes of early discharge (<36 hours) could ensure this practice change is occurring safely.

### Table 4

<table>
<thead>
<tr>
<th>Clinical Outcome</th>
<th>ME Panel (%, n = 223)</th>
<th>Non-ME Panel (%, n = 348)</th>
<th>P (Univariate Analysis)</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOS, h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>36</td>
<td>39 (17.5)</td>
<td>37 (10.6)</td>
<td>.04* Multivariate analysis: 1.73 (1.03–2.91)</td>
<td></td>
</tr>
<tr>
<td>≥36</td>
<td>184 (82.5)</td>
<td>311 (89.4)</td>
<td>—</td>
<td></td>
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<tr>
<td>Antibiotics time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 dose</td>
<td>31 (13.9)</td>
<td>29 (8.3)</td>
<td>(.053) Univariate analysis: 1.41 (1.00–2.01)</td>
<td></td>
</tr>
<tr>
<td>≥36 h</td>
<td>53 (23.8)</td>
<td>74 (21.3)</td>
<td>—</td>
<td></td>
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<tr>
<td>Antibiotic narrowing, h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>36</td>
<td>140 (62.8)</td>
<td>187 (53.7)</td>
<td>(.02) Univariate analysis: 1.63 (1.07–2.47)</td>
<td></td>
</tr>
<tr>
<td>≥36</td>
<td>83 (37.2)</td>
<td>161 (46.3)</td>
<td>—</td>
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<tr>
<td>Vancomycin exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>12 (16)</td>
<td>16 (10.6)</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Median doses</td>
<td>6</td>
<td>6</td>
<td>.42</td>
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<tr>
<td>Acyclovir doses</td>
<td>&lt;.001* Multivariate analysis: IRR = 0.36 (0.25–0.51)</td>
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<tr>
<td>0</td>
<td>157 (70.4)</td>
<td>168 (48.3)</td>
<td>(&lt;.001)*</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>58 (26.0)</td>
<td>116 (33.3)</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>≥5</td>
<td>8 (3.6)</td>
<td>64 (18.4)</td>
<td>—</td>
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<tr>
<td>Deaths</td>
<td>1 (0.4)</td>
<td>2 (0.6)</td>
<td>.99</td>
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Multivariate model for antibiotic exposure and LOS included age group, previous antibiotic use, neurologic symptoms, abnormal serum WBCs, admission location, and positive culture results. Multivariate model for HSV exposure included age group, HSV concern, admission location, abnormal serum WBCs, neurologic symptoms, and positive culture results. IRR, incidence rate ratio; —, not applicable.

* Denotes statistically significant at P < .05.
CONCLUSIONS
The ME panel is associated with a decreased LOS and antibiotic narrowing time as well as fewer acyclovir doses. These results are likely due to the rapid TAT. Additional multisite studies are required to evaluate the potential role of multiplex CSF PCR testing in the management of pediatric meningitis.

Acknowledgments
The authors thank Russell McCulloh, MD for his contribution.

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*Hospital Pediatrics* 2019;9;763
DOI: 10.1542/hpeds.2019-0064 originally published online September 11, 2019;

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