Poster Board #2099

Impact of the BioFire FilmArray® Gastrointestinal Panel in Children Hospitalized for Acute Gastroenteritis

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ABSTRACT (REVISED)

Background: Molecular assays can improve the diagnosis of acute gastroenteritis (GE) by increasing detection of pathogens, timeliness of results, and appropriate patient management. This study assessed the impact of the FilmArray® Gastrointestinal (GI) Panel on patients hospitalized with GE.
Methods: A pre-/post-intervention study was conducted on patients < 18 years presenting to 5 pediatric EDs with chief complaints of GE. During the pre-intervention period (PRE), clinicians ordered standard of care (SOC) testing at their discretion. In contrast, FilmArray GI Panel was performed and results reported in real time in the post-intervention period (POST). The impact of the FilmArray GI Panel on the clinical management of inpatients was determined.
Results: Of the 1158 subjects enrolled in the study to date (572 PRE and 586 POST), 177 (15.3%; 81 PRE and 96 POST) were hospitalized for management of GE symptoms. 36.7% patients hospitalized (HOSP) had an underlying condition compared to 24.3% of patients discharged (DC) ($p = 0.018$). In the PRE period, 20 (24.7%) HOSP had SOC testing ordered and 5 (6.2%) were positive for pathogens including, *E. coli* O157:H7, rotavirus, *C. difficile* and norovirus. In contrast, 68 (70.8%) HOSP had at least 1 pathogen detected on FilmArray GI Panel in the POST period (25 cases with ≥ 2 pathogen). The most common pathogens detected were norovirus (28), adenovirus (9) and *C. difficile* (21). SOC testing ordered by clinicians would have missed 33 positive cases in the POST period. The mean turn around time decreased by 32.3 h (46.5 h vs 14.2 h, $p < 0.001$) using FilmArray GI Panel during POST period. In the PRE period, antibiotics were initiated in 13 (16.0%) patients upon admission despite SOC testing ordered on only 5 (45.5%). Antibiotics were not discontinued in 2 patients despite detection of *E. coli* O157:H7 and norovirus. Of the 13 (13.5%) treated in the POST period, antibiotics were discontinued in 8 and appropriately initiated in 2 patients in < 24 h of FilmArray GI Panel result. 13 patients had *C. difficile* and virus detected and none were treated for *C. difficile* infection.
Conclusions: The FilmArray GI Panel enabled rapid and definitive diagnosis in the majority of patients admitted with GE. This may allow for prompt but appropriate use of antibiotics.

BACKGROUND

✧Acute gastroenteritis (GE) is a significant cause of morbidity and mortality worldwide. In the United States, GE accounts for 1.5 million outpatient visits, 200,000 hospitalizations and 300 deaths annually.

✧The advent of multiplex molecular assays can improved diagnosis of GE by increasing detection of infectious pathogens and time to result, allowing clinician's to appropriately manage patients.

✧The FilmArray® Gastrointestinal (GI) Panel is a fully automated ~1 hr sample-to-answer PCR-based test for identication of 22 different pathogens, including bacteria, diarrheagenic *E. coli*, parasites, and viruses from stool specimens.

✧It is unknown if more rapid and comprehensive diagnosis will improve patient management and outcome.

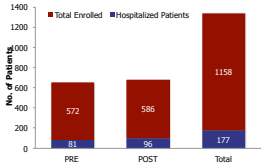
This study assessed the impact of the FilmArray GI Panel on pediatric patients admitted upon presentation at five pediatric emergency department (ED):

- ✧ Nationwide Children's Hospital
- ✧ Primary Children's Medical Center
- ✧ Children's Mercy Hospital
- ✧ Children's Hospital of Los Angeles
- ✧ Rhode Island Hospital.

METHODS

- ✧ Pre-intervention period (PRE):
  - ✧ Clinicians ordered standard of care (SOC) testing at their discretion
- ✧ Post-intervention period (POST):
  - ✧ FilmArray GI panel performed and reported in real-time to the hospital information system.
- ✧ Patients admitted for further management PRE and POST were assessed for positive results by SOC and FilmArray GI panel
- ✧ Antimicrobial therapy were evaluated to determine the impact of testing results on optimization or discontinuation of antimicrobial therapy.
- ✧ Statistical significance was calculated using t-test and all *P* values < .05 were considered statistically significant.

Figure 1. Patient Enrollment Distribution



RESULTS

- ✧ A total of 1158 pediatric patients were enrolled in the study and 177 of patients were hospitalized (Figure 1).
- ✧ Co-morbidities: 36.7% hospitalized patients vs. 24.3% discharged patients ($p = 0.018$).
- ✧ SOC testing were evaluated in 24.7% (20) and 42.7% (41) hospitalized patients in the PRE and POST period, respectively.
- ✧ **PRE:** only 5 (5.2%) positives by SOC testing
- ✧ **POST:** 12 (12.5%) and 68 (70.8%) were positive by SOC testing and FilmArray GI panel, respectively
- ✧ 25/68 patients (36.8%) polymicrobial infections in the POST period (Figure 4).
- ✧ In the POST period, the most common pathogens detected by FilmArray GI panel were Norovirus (28) and *C. difficile* (21).
- ✧ In contrast, based on SOC testing, the most common pathogen identified in the POST group was *Salmonella* species and *C. difficile* (4 positives each).
- ✧ 33 positive patients would have been missed in the POST period if only SOC testing was available, including all cases of Norovirus.

Figure 2. Testing and Positivity Distribution

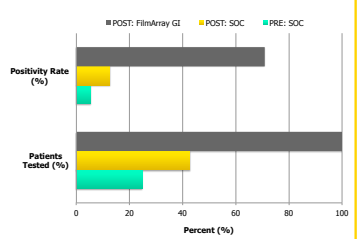
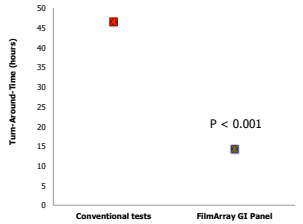


Figure 3. PRE and POST Turn-Around-Time



RESULTS

- ✧ 13 (14.8% PRE; 13.5% POST) patients each were treated with antimicrobial agents for GE presentation (Table 1 and 2).
- ✧ PRE:
  - ✧ Despite treatment in 13 patients, SOC testing were only ordered on 5 patients and 3 patients were positive for: Norovirus/Adenovirus/Rotavirus, *C. difficile* and *E. coli* O157:H7.
  - ✧ Antibiotics were discontinued once *C. difficile* results were back (4 days of Vancomycin therapy). In contrast, antibiotics were continued in the Norovirus positive patient and initiated 48 hours after *E. coli* O157:H7 result.
- ✧ POST:
  - ✧ Of the 13 patients treated, 9 were positive by FilmArray GI Panel and the most common pathogen detected was *C. difficile*.
  - ✧ Antibiotics were appropriately discontinued in 8 patients and appropriately initiated or continued in 4 patients with *Salmonella*, *Shigella*, and *C. difficile*.

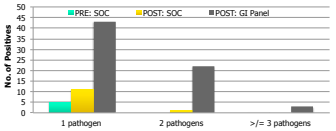
Table 1. Patients Treated With Antibiotics in PRE Period

Patient	SOC Result	Antibiotic Selection	Antibiotic duration	Antibiotic Change
1	*E. coli* O157	piperacillin-tazobactam, metronidazole, vancomycin, ciprofloxacin	24 h; > 2 weeks	Initiated within 48 hours after result
2	Adenovirus; Norovirus; Rotavirus	metronidazole	10 - 11 days	Continued for ~7 days
3	*C. difficile*	metronidazole	96 hours	Discontinued
4	Negative	ceftriaxone	< 24 hours	NA
5	Negative	amoxicillin	< 24 hours	NA
6	Negative	cefuroxime	24 - 48 hours	NA
7	Negative	piperacillin-tazobactam	unknown	NA
8	Negative	metronidazole	24 - 48 hours	NA
9	Negative	metronidazole	24 - 48 hours	NA
10	Negative	ceftriaxone	< 24 hours	NA
11	Negative	ceftriaxone	24 - 48 hours	NA
12	Negative	ceftriaxone	< 24 hours	NA
13	Negative	ceftriaxone	24 - 48 hours	NA

Table 2. Patients Treated With Antibiotics in POST Period

Patient	FilmArray GI Panel	Antibiotic Selection	Antibiotic duration	Antibiotic Change
1	STEC; Astrovirus	ciprofloxacin, piperacillin-tazobactam	14 days	Initiated 72 hours after
2	*C. difficile*	metronidazole	> 2 weeks	Initiated same day as result
3	*C. difficile*; Norovirus	metronidazole	< 24 hours	Discontinued
4	*Salmonella*	ceftriaxone	72 hours	Continued
5	C. difficile	metronidazole	9 days	Initiated same day as result
6	Sapovirus	ceftriaxone, vancomycin	< 24 hours	Discontinued
7	*C. difficile*; Norovirus	metronidazole	< 24 hours	Discontinued based on SOC testing
8	*C. difficile*; EPEC	metronidazole	48 hours	Discontinued based on SOC testing
9	*Shigella*/EIEC	azithromycin	72 hours	Antibiotic started 48 hours later
10	Negative	amoxicillin	< 24 hours	Discontinued
11	Negative	ciprofloxacin	< 24 hours	Discontinued
12	Negative	cefazolin	< 24 hours	Discontinued
13	Negative	ceftriaxone	< 24 hours	Discontinued

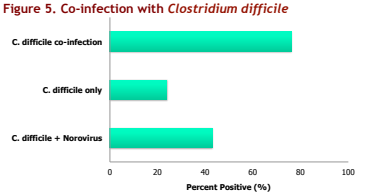
Figure 4. Pathogen Distribution Between PRE and POST Period



RESULTS

- ✧ There were 16 (76.2%) co-infections with *C. difficile* in the POST period; 13 with viral etiologies and 3 with bacteria or toxin (Figure 5).
  - ✧ Norovirus was the most common with 9 (56.3%) patients
  - ✧ Antibiotics were discontinued in 2 patients (> 10 y); antibiotics were not initiated in the 7 patients (all < 2 y)
- ✧ The 2 patients that were treated for *C. difficile* infection were 1 and 13 years old (table 1). *C. difficile* was the only pathogen detected.
- ✧ This highlights the benefit of broad-panel testing to identify true pathogens versus *C. difficile* colonization.

Figure 5. Co-infection with *Clostridium difficile*



CONCLUSIONS

- ✧ An significant increase in number of pathogens were detected using the FilmArray GI Panel on patients admitted to the hospital for further management of GE.
- ✧ The FilmArray GI panel results led to early discontinuation or initiation of antibiotics in 8/13 patients.
- ✧ The ability to detect additional pathogens alongside *C. difficile* prevented unnecessary treatment of patients colonized with *C. difficile*.
- ✧ Overall, the FilmArray GI Panel enabled rapid and definitive diagnosis in the majority of patients admitted with GE. This may allow for prompt but appropriate use of antibiotics.

ACKNOWLEDGEMENT

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