Evaluation of a PCR-based gastrointestinal panel at UF Health Shands Hospital

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OBJECTIVE

The aim of this study is to determine the clinical impact of a new comprehensive molecular test, the FilmArray® Gastrointestinal (GI) panel which tests for nearly all known agents of infectious diarrhea in approximately one hour.

It is hypothesized that use of the GI panel will result in more cost-effective care and improved resource stewardship through shorter length of stay and a decreased need for other, more invasive and expensive tests, such as abdominal imaging studies.

INTRODUCTION

- Diarrheal diseases are a major cause of emergency department visits and hospitalization.
- Conventional methods for identification of gastrointestinal pathogens are time consuming, expensive, and have limited sensitivity.
- Patients may not receive antibiotics in a timely manner, may undergo unnecessary diagnostic testing, and incur excessive healthcare costs.

METHODS

- Following approval from the UF Health Institutional Review Board, patients with stool cultures submitted 6/1/16 to 12/31/16 were additionally processed via the BioFire GI Panel (Figure 1).
- A historical control group was obtained from the same time period a year prior, 6/1/15 to 12/31/15.
- Both the cases and controls were filtered to include only patients with a length of stay (LOS) that was 14 days or fewer. This helped adjust for patient acuity and morbidity.
- An extensive chart review was performed to collect information on diagnostic testing, procedures, medications, and recurrent admissions.
- Data were managed using the methodology shown in Figure 2.
- Statistical analyses were performed using SAS 9.3 and Microsoft Excel.

METHODS

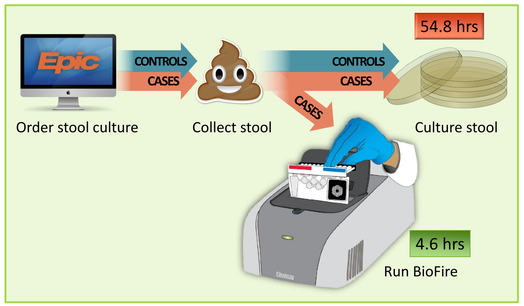


Figure 1. Current stool testing process. Standard of care did not change for cases vs. controls. We simply added an additional step for cases via the BioFire.

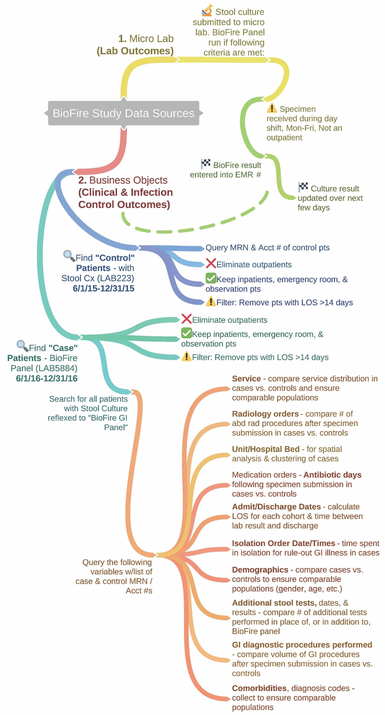


Figure 2. Data collection and management methodology, using Coggle Mind Mapping https://coggle.it/.

RESULTS

Organism	Cases (2016) BioFire GI Panel # positive / # tested (%)	Controls (2015) Standard of Care # positive / # tested (%)
Any Pathogen	30/123 (24.4)	41/594 (6.9)
BACTERIAL PATHOGENS*		
Campylobacter spp.	2/123 (1.6)	7/594 (1.2)
Plesiomonas shigelloides	0/123 (0)	0/594 (0)
Salmonella spp.	7/123 (5.7)	41/594 (6.9)
Vibrio spp.	1/123 (0.8)	1/27 (3.7)
Yersinia enterocolitica	0/123 (0)	0/46 (0)
DIARRHEAGENIC E.COLI/ SHIGELLA		
E. coli O157	0/123 (0)	0/41 (0)
Enteroaggregative *E. coli* (EAEC)	1/123 (0.8)	NT
Enteropathogenic *E. coli* (EPEC)	6/123 (4.9)	NT
Enterotoxigenic *E. coli* (ETEC)	1/123 (0.8)	NT
Shigella/Enteroinvasive *E. coli* (EIEC)	2/123 (1.6)	3/594 (0.5)
Shiga-like toxin-producing *E. coli* (STEC) stx1/stx2	0/123 (0)	1/41 (2.4)
VIRAL PATHOGENS		
Adenovirus F40/41	1/123 (0.8)	NT
Astrovirus	0/123 (0)	NT
Norovirus GI/GII	10/123 (8.13)	NT
Rotavirus A	1/123 (0.8)	0/27 (0)
Sapovirus	3/123 (2.4)	NT
PARASITIC PATHOGENS		
Cryptosporidium spp.	0/123 (0)	2/59 (3.4)
Cyclospora cayetanensis	1/123 (0.8)	0/28 (0)
Entamoeba histolytica	0/123 (0)	0/274 (0)
Giardia lamblia	2/123 (1.6)	1/146 (0.7)

Table 1. Traditional laboratory methods versus the BioFire GI Panel.

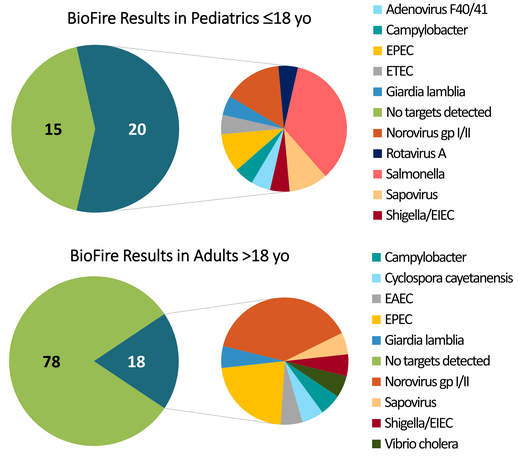
NT = Not tested. **C. difficile* is included on the BioFire GI Panel, but was not included in our study.

Variable	Cases (n=123)	Controls (n=594)	*p*-value
Sex, Male (%)	61 (49.6%)	286 (48.2%)	
Age, Mean (range)	42.95 (0-93)	41.66 (0-102)	
BMI, Mean (range)	25.97 (13.52-48.04)	25.22 (11.08-85.58)	
Addtl Stool Tests (95% CL)	2.60 (2.38-2.82)	3.02 (2.89-3.14)	0.004
Antibiotic Days (95% CL)	1.59 (1.20-1.98)	2.12 (1.89-2.35)	0.023
Radiologic Procs (95% CL)	0.35 (0.19-0.51)	0.39 (0.31-0.48)	0.670
Turnaround Time (hrs)	4.6 (1.92-11.04)	54.75 (30.48-209.52)	<0.0001
Admit to Result (days)	2.12 (1.81-2.43)	3.67 (3.52-3.82)	<0.0001

Table 2. Comparison of BioFire cases to controls.

BMI = Body mass index; CL = Confidence limit; LOS = Length of stay; Additional stool tests = Ova & parasite testing, Giardia/Cryptosporidium antigen, Microsporidia stain, Cyclospora stain, Rotavirus antigen, Shiga-like toxin antigen assay, Yersinia culture, Vibrio culture; Radiologic procedures = Computed tomography (CT), Magnetic resonance imaging (MRI), ultrasound, and/or x-ray, of the abdomen or pelvis.

RESULTS



- 25 of 123 BioFire patients were found to have an unsuspected pathogen that would have went undiagnosed without use of the GI panel.
- Co-infections were identified in 4.9% (n=6) of GI panel patients, but no co-infections were found in our control population.
- BioFire co-infections included:
  - Norovirus gp I/II, EPEC
  - Norovirus gp I/II, *Giardia lamblia*
  - Salmonella, Adenovirus F40/41
  - Salmonella, EPEC, ETEC
  - Salmonella, Rotavirus A
  - Salmonella, Sapovirus, EPEC

CONCLUSIONS

- The GI panel has the potential to improve patient care by rapidly identifying a broad range of pathogens, reducing the need for other diagnostic tests – thereby improving resource utilization, reducing unnecessary use of antibiotics, and leading to a reduction in hospital length of stay.
- The GI panel can provide a significant improvement in quality of care, delivery efficiency, and an increase in value per healthcare dollar.
- The GI panel identified numerous pathogens that would not have been identified by conventional methods.