C. Difficile “Time Out”: To Test or Not To Test
Purpose

➢ Decrease hospital onset infections through correct identification, testing, and reporting.
➢ Higher than expected rates of hospital onset C. difficile yet the lowest antibiotic usage
➢ Current testing identifies presence of toxigenic C. difficile-unable to differentiate between infection and colonization
➢ 10-15% patients are asymptptomatically colonized with C. difficile on admission
➢ Need to reduce inappropriate testing for C. diff

➢ Reclassification of Clostridium difficile as Clostridioides difficile still known as C. diff
What is Diagnostic Stewardship?

♦ Appropriate use of laboratory testing to guide patient management
♦ “The right test, for the right patient, at the right time.”
♦ Identify “true “ infection to optimize management and prevent overtreatment

Benefits  Diagnostic Stewardship
♦ Reduce cost of lab tests
♦ Prevent hospital penalties
♦ Reduces cost of treatment-unnecessary antibiotic treatment
♦ Improves quality of care
♦ Decreases length of stay
♦ Reduces risk of antimicrobial resistance

Madden, G.R., et al. (2018). Reduced Clostridium difficile tests and lab-identified events with a computerized clinical decision support tool and financial incentive. Infection Control Hospital Epidemiology. 1-4.
Background

CDC Upgrade: Condition urgent

- Most common cause of healthcare associated infection in the U. S.
  - ~500,000 incidents (CDC, 2015)
  - ~15,000 deaths (CDC, 2015)
  - Emergence of more virulent strain (NAP1)

Changing Epidemiology in Hospitals

- Increased morbidity
- Increased mortality
- Increased costs to healthcare-additional $17,260 per case
In 2014, NHSN required all healthcare facilities to report all positive C. diff tests. Any positive C. diff test collected on or after day 4 is counted as hospital onset C. diff infection—regardless if symptoms were present on admission. Current lab tests cannot differentiate between infection and colonization. At RSFH, higher than expected rates of hospital onset C. diff yet the lowest antibiotic usage. The positive C. diff tests likely included colonized patients.
What is the difference between C. diff colonization and C. diff infection?

**Clostridioides difficile colonization**
- Exhibits **NO** clinical symptoms
- Tests positive for *C. diff* organism
- More common than *C. diff* infection

**Clostridioides difficile infection**
- Exhibits **clinical symptoms (diarrhea)**
- Tests positive for the *C. diff* organism and/or its toxin
- Requires treatment
- After treatment, repeat *C. diff* testing is not recommended if the patient is asymptomatic as patients may remain colonized and will test positive

Source: www.cdc.gov/hai/organisms/cdiff/cdiff_infect.html
Clinicians and laboratory personnel agree at the institutional level to not submit stool specimens on patients receiving laxatives and to submit stool specimens only from patients with unexplained and new onset ≥ 3 unformed stools in 24 h for testing for CDI.

Stool toxin test* as part of a multiple step algorithm (i.e. GDH plus toxin; GDH plus toxin, arbitrated by NAAT; or NAAT plus toxin) rather than a nucleic acid amplification test (NAAT) alone.

Diagnostic Stewardship

NAAT alone OR stool toxin test* as part of a multiple step algorithm (i.e. GDH plus toxin; GDH plus toxin, arbitrated by NAAT; or NAAT plus toxin) rather than a toxin test alone.

*Approved stool EIA toxin tests vary widely in sensitivity. Laboratories should choose a toxin test with sensitivity in the upper range of sensitivity as reported in the literature [146-149, 156].
Strategy and Implementation

C. *diff* Testing Decision Tree
≥ 18 years old

**Step 1**
Does the patient have ONE of the following:
- At least 3 loose watery stools in the past 24 hours;
- OR
  - A significant increase in baseline loose watery stool in the last 24 hours
- Specimen must be Type 6/7 on the Bristol Stool Chart
- Significant increase in ostomy output in the last 24 hours

AND

**Step 2**

Does your patient have ONE of these exclusion criteria?
- C difficile diagnosis or treatment THIS admission
- Loose watery stools associated with clinical diagnosis, medications (i.e. laxatives), or enteral feedings given within the last 24 hours

If patients meets criteria:
- Order for C. *diff* stool specimen and a task for Contact Enteric Isolation will automatically fire.
- Place patient on Contact Enteric Isolation with C. *diff* Bundle Bag
- Collect Stool Specimen within 48 hours

STOP
Screen again if patient has onset of symptoms.

Implemented April 24, 2018
Testing Algorithm

C. diff Testing “Timeout”

Hospital Day 1, 2, 3 (Day 1 is Admission Day) 3 or more loose/watery stools in last 24 hours
plus any one of the 3 clinical signs of C. diff infection below:

- WBC>10.6K
- Abdominal tenderness/cramping/distention
- Fever>38°C

Yes - Send specimen
No - continue daily screening

Hospital Day 4 or AFTER:

- 3 or more loose watery stools in the last 24 hours?
  - If No - Do Not send
  - Yes - Go to the next question

- Any Laxatives, Lactulose, bowel prep, tube feeding, or enema given in the last 24 hours? OR
  - Diarrhea associated with a clinical diagnosis: Crohn’s disease, IBS, colitis
    - If Yes - DO NOT SEND
    - No - Go to next question

- Has patient been tested for C. diff in the past 7 days?
  - If Yes - DO NOT SEND specimen
  - No - Go to next question

- Does the patient have CLINICAL SIGNS of C. diff infection? (any one of the 3 below)
  - WBC>10.6K
  - Abdominal tenderness/cramping/distention
  - Fever>38°C

Yes - Do SEND specimen
No - DO NOT Send

Hospital Day 4 or AFTER:

NOTE: If a specimen is sent for testing, initiate CONTACT ENTERIC PRECAUTIONS immediately and utilize the C. diff bundle bag.

Do NOT wait for a test result.
Strategy and Implementation

Re-education of staff

Critical Thinking

- Colonized patients VS Infected Patients
- Assess for laxative use within 24 hours
- Identify clinical diagnosis consistent with loose stool (Crohn’s, IBS)
- Identify one sign of clinical illness

Both colonized and infected patients can shed spores
Reduction in Testing

Testing Data 2018-2019

# Test Ordered/# Test Positive

Diagnostic Stewardship Initiative started 5/1/2018

Changes Live In Cerner Feb 12 2019

% Test ordered positive

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>13%</td>
<td>18%</td>
<td>15%</td>
<td>14%</td>
<td>18%</td>
<td>15%</td>
<td>11%</td>
<td>15%</td>
<td>20%</td>
<td>18%</td>
<td>15%</td>
<td>20%</td>
<td>18%</td>
<td>15%</td>
<td>12%</td>
<td>15%</td>
<td>17%</td>
<td>15%</td>
<td>11%</td>
<td>15%</td>
<td>17%</td>
<td>15%</td>
<td>11%</td>
<td>15%</td>
<td>17%</td>
<td>15%</td>
<td></td>
</tr>
</tbody>
</table>
Reduction in SIR- Standard Infection Ratio
How we measure how we are doing

7 Variables Required to Calculate Number of Predicted Infections
- Inpatient Community Onset Prevalence Rate
- CDI Test Type
- Medical School Affiliation
- Number of ICU Beds
- Total Number of Inpatient beds
- Facility Type
- Reporting CDI From an ED or 24 Hour Observation Unit

<table>
<thead>
<tr>
<th>C Diff HO (Lab ID) RSFH</th>
<th>Standard Infection Ratio (SIR) 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018Q1</td>
<td>1.595</td>
</tr>
<tr>
<td>2018Q2</td>
<td>1.030</td>
</tr>
<tr>
<td>2018Q3</td>
<td>1.034</td>
</tr>
<tr>
<td>2018Q4</td>
<td>1.012</td>
</tr>
<tr>
<td>YTD</td>
<td>1.179</td>
</tr>
</tbody>
</table>

Number of infections (calculated by the 7 variables)
Goal: SIR less than 1

<table>
<thead>
<tr>
<th>Actual # HO C Diff RSFH</th>
<th>2018Q1</th>
<th>2018Q2</th>
<th>2018Q3</th>
<th>2018Q4</th>
<th>YTD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>31</td>
<td>20</td>
<td>17</td>
<td>17</td>
<td>85</td>
</tr>
<tr>
<td>Expected # HO C Diff RSFH</td>
<td>19.435</td>
<td>19.411</td>
<td>16.440</td>
<td>16.798</td>
<td>72.084</td>
</tr>
</tbody>
</table>
Surveillance is done to examine laxative use within 24 hours of testing revealed up to 67% had laxative use

In December, 2018, all testing was reviewed by Infectious Disease MDs for appropriateness before testing before the test was done. There was 1 HO onset C. diff reported!
Statistical Analysis Tested Our Hypothesis

Data subjected to statistical analysis and we found:

✓ The # HO increases with the number of tests performed (significant)

✓ The # positive by PCR increases with the number of tests performed (significant)

✓ The more nursing protocol is responsible for the order, the more HOs (significant)

✓ Not significant due to the small numbers, MD testing higher positive predictive value

✓ The use of laxatives increases the number of tests performed and therefore increases the number of HO positive tests
Pearson’s Correlation Coefficient | Coefficient of determination | P value
--- | --- | ---
0.5926 | 0.3512 | 0.0255
Testing Data
2017-2018

CD Positive Test

Diagnostic Stewardship initiative started 5/1/2018
Changes Live In Cerner Feb 12 2019

<table>
<thead>
<tr>
<th>Month</th>
<th>Positive by EIH/GDH only</th>
<th>Positive by PCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-18</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Feb-18</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Mar-18</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Apr-18</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>May-18</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Jun-18</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Jul-18</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Aug-18</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Sep-18</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Oct-18</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Nov-18</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Dec-18</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Jan-19</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Feb-19</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Mar-19</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Apr-19</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>May-19</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Jun-19</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Jul-19</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Aug-19</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Sep-19</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Oct-19</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Nov-19</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Dec-19</td>
<td>4</td>
<td>6</td>
</tr>
</tbody>
</table>

Diagnostic Stewardship initiative started 5/1/2018
Changes Live In Cerner Feb 12 2019

<table>
<thead>
<tr>
<th>Series1</th>
<th>Pearson's Correlation Coefficient</th>
<th>Coefficient of determination</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.7647</td>
<td>0.5848</td>
<td>0.0014</td>
</tr>
</tbody>
</table>
Testing Data
2017-2018

<table>
<thead>
<tr>
<th># non-RN proto</th>
<th># HO-C diff</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>20</td>
<td>80</td>
</tr>
<tr>
<td>40</td>
<td>60</td>
</tr>
<tr>
<td>60</td>
<td>40</td>
</tr>
<tr>
<td>80</td>
<td>20</td>
</tr>
<tr>
<td>100</td>
<td>0</td>
</tr>
</tbody>
</table>

Pearson's Correlation Coefficient | Coefficient of determination | P value
0.1329 | 0.0177 | 0.6506

HO-RSFH
# non-RN proto

Series1
Linear (Series1)
Testing Data
2017-2018

<table>
<thead>
<tr>
<th>Pearson’s Correlation Coefficient</th>
<th>Coefficient of determination</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5369</td>
<td>0.2883</td>
<td>0.0477</td>
</tr>
</tbody>
</table>
Conclusion and Next Steps

Conclusion: Statistical Data indicates that testing should be ordered by MDs only and the Nurse protocol/C. diff daily screen should be eliminated

➢ Assessment for clinical signs of infection
➢ Accurate history of laxative use
➢ Proposal for a “hard stop” protocol was considered, but not to be implemented at this time.
➢ Testing stewardship is critical to minimize frequency of false positive results
➢ Physician and nursing re-education
Thank you!