

ABSTRACT

Flu season adds many challenges for healthcare organizations. Emergency departments experience a sharp increase in patients with flu or influenza-like-illnesses that are indistinguishable from the flu. Bed management, workforce shortages, antiviral shortages, and antimicrobial stewardship are especially challenging during the viral season. Rapid and accurate laboratory results are necessary to overcome these issues. To alleviate these challenges and to support pandemic preparedness, we designed the FluWorks program. As part of the program we implemented Flu/RSV testing, using the Cepheid Xpert® Flu/RSV XC and the Xpert® Xpress Flu/RSV cartridges, in 8 Geisinger Rapid Response Laboratories (RRLs) throughout central and northeastern PA.

The FluWorks program was launched during the 2016-2017 flu season. Given the limitations in space in our RRLs, dead-air boxes were designed and crafted by our facilities team. Doctoral staff and specialists from our core laboratory trained the RRL personnel on the basics of molecular testing, decontamination procedures, and amplicon control. Personnel from Cepheid trained the staff on the use of the Xpert® cartridges. Method verification was performed using Zeptomatrix controls (Buffalo, NY) tested for 20 days. Competency of the personnel was assessed with previously characterized blinded samples. Testing on site occurred from Nov 1st, 2016 to Jan 19th, 2017, after that date samples were transported by couriers to our core laboratory (Feb 25th to Apr 25th, 2017).

Our on-site and courier cohorts were gender-, age-, and virus- matched to minimize bias. The percent positivity for FluA/B samples 16.9% for samples tested on site vs 16.4% for samples transported by courier. During on-site testing, the collect-to-result time (CTR) was reduced by 70% using the Xpert® Flu/RSV XC cartridge, which provides results in ≤1h (p < 0.0001) with median CTR of 6.9 h for courier to 1.3 h for on-site). Over- or under-treatment for influenza A and B (measured by anti-viral prescription) was reduced by 15% when testing was performed on site (p < 0.0001). Antimicrobial prescription, was not affected by the faster CTR. The potential savings on antiviral prescription were calculated to be \$75K for the '16-'17 season. Of note, during the '17-'18 season increases in numbers of flu-negative cases increased the potential antiviral savings to \$186K/season.

The pilot for the FluWorks program showed a significant reduction in CTR and antiviral prescriptions and presents an opportunity for antibacterial stewardship for future flu seasons. The 2016 launch of FluWorks as standard of care for the Geisinger community allowed us to better respond to the harsher flu season experienced in 2017-2018 by balancing the workload between RRLs and our core laboratories. By offering highly accurate molecular technology, geographically close to patients, has an impact on flu season challenges as should impact patient and provider satisfaction.

METHODS



2016-2017: Phase I, in house verification of Xpert® Flu/RSV XC (60 min) and at RRL:
Objective: To verify Xpert® Flu/RSV tests with clinical specimens in 8 RRLs and assess competency of personnel to perform the assay.



Testing on-site: Nov 1st, 2016 to Jan 19th, 2017.

Courier transport: Feb 25th, 2017 to Apr 26th, 2017.

RRL sites marked by pins, central laboratory by star.



2017-2018 Phase II, Near POCT Roll-out, Xpert® Xpress Flu/RSV (30 min):
Objective: Patient-centered care for Geisinger FluWorks with live testing for rapid diagnostics and treatment. Retrospective comparison with previous Flu seasons.

RESULTS



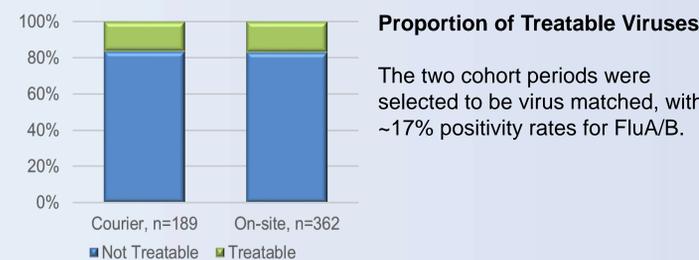
Training and Validation

Evaluation of space requirements occurred prior to training, Geisinger on-site facilities custom-designed, and built dead-air boxes, optimized for small spaces. Training included four molecular education sessions were molecular testing principles, contamination control, decontamination, weekly swabs, etc. were reviewed by laboratory technical specialists. Cepheid personnel trained RRL staff on testing procedures. No contamination events were observed throughout the study. Standardization across all sites allowed for rapid 20 d verification of both Xpert® XC and Xpert® Xpress cartridges, with ~98% precision. Competency samples (known samples tested with Biofire FilmArray Respiratory Panel at central laboratory) were tested by all operators; personnel were blinded to previous results. 100% concordance for competency samples was observed.



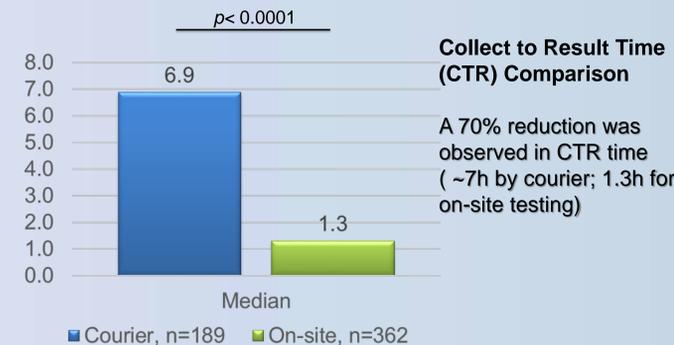
Demographics

When comparing gender between cohorts, samples tested on site vs samples transported by courier, the same proportion of males to females was observed, even though absolute numbers were higher for on-site testing. When substratified by age, no significant age differences were noted between cohorts; however, the sample set was disproportionately skewed to age < 5y. A potential bias was documented for children < 5y.



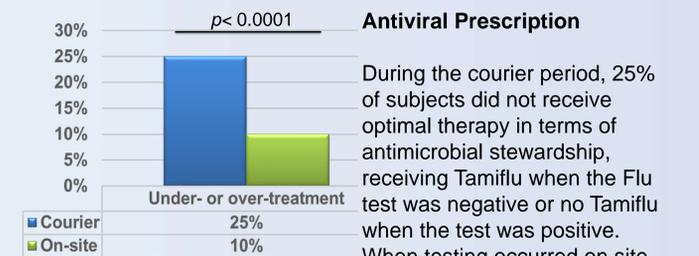
Proportion of Treatable Viruses

The two cohort periods were selected to be virus matched, with ~17% positivity rates for FluA/B.



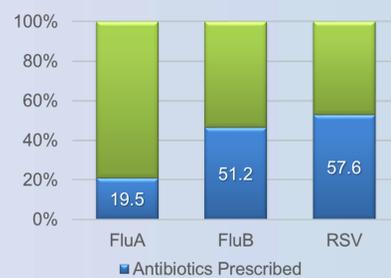
Collect to Result Time (CTR) Comparison

A 70% reduction was observed in CTR time (~7h by courier; 1.3h for on-site testing)



Antiviral Prescription

During the courier period, 25% of subjects did not receive optimal therapy in terms of antimicrobial stewardship, receiving Tamiflu when the Flu test was negative or no Tamiflu when the test was positive. When testing occurred on site, the proportion of under- or over-treated subjects was reduced to 10% (p < 0.0001).



Antimicrobial Prescription

Despite no clinical symptoms of bacterial infection, 20-60% of subjects were prescribed antibiotics. Data labels in percentage. The shorter CTR had no impact on antimicrobial prescription.

CONCLUSIONS

- ❑ Near POCT technology was deployed to 8 RRL sites, bringing leading edge technology closer to patients.
- ❑ Dead-air boxes for small spaces were custom-designed, built, and deployed.
- ❑ Training of personnel for molecular testing was completed.
- ❑ Two tests (Xpert® XC and Xpert® Xpress) were verified, and competency of personnel was assessed.
- ❑ On-site testing balanced core laboratory workload and created infrastructure for future pandemics.
- ❑ Statistical differences were observed in collect to result time (CTR) and in antiviral stewardship.
- ❑ During the test period, 311 patients could have avoided antiviral therapy for potential savings of ~\$75K and return on investment (ROI) of 3.3y.
- ❑ Opportunities for antibiotic stewardship and associated recovered costs remain despite on-site testing.

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