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Evaluation of pharmacist guided intervention using procalcitonin and respiratory virus testing

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Abstract

Background: Acute respiratory infections make up a sizable percentage of emergency department (ED) visits and many result in antibiotics being prescribed. Procalcitonin has been found to reduce antibiotic use in both outpatient and critical care settings, yet remains underused in the ED.

Objective: To evaluate whether point of care molecular influenza and Respiratory Syncytial Virus (RSV) testing, procalcitonin, and a pharmacist driven educational intervention in aggregate optimizes antibiotic and antiviral prescribing in the ED setting.

Methods: A randomized trial of the Cobas Liat Flu/RSV Assay, procalcitonin, and the use of pharmacist-led education in patients 0–50 years of age being seen in the ED for Influenza Like Illness (ILI) or acute respiratory illness. The study enrolled 200 ED patients between March 2018 and April 2022 at the University of California Davis Medical Results: There was little difference in antibiotic or antiviral prescribing between the intervention and control groups in this study (39% - 32% = 7.0%, 95% CI: −6.2, 20.2, P=0.30). However, a post-hoc analysis of the use of PCT showed PCT results were used as indicated in the ED (P=0.001).

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Declaration of Competing Interest

Roche Diagnostics US Medical and Scientific Affairs sponsored this study though had no role in protocol development.
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Conclusion: Procalcitonin can be used in both adult and pediatric populations to help guide the decision of whether to treat with antibiotics in the ED setting. Pharmacist guided education may not be a driving factor.

Keywords

influenza; procalcitonin; emergency department; antibiotic stewardship; ILI; RSV

1. Introduction

Influenza and RSV pose a significant disease burden in terms of morbidity and mortality worldwide. Acute respiratory tract infections account for 12.2% of all emergency department (ED) visits, and antibiotics are prescribed in 61% of these encounters (Donnelly et al., 2014). Access to rapid diagnostic testing in the ED is one strategy to reduce inappropriate antibiotic use for respiratory infections. Among the diagnostics tests used, procalcitonin tests (PCT) have the potential to significantly reduce the length of antibiotic therapy, (Morris et al., 2016), as well as decrease antibiotic side effects (Morris et al., 2016, Scheutz 2018). Procalcitonin in adults have been linked to a reduction in antibiotic use in primary care (Briel et al., 2000, Burkhardt et al., 2010, Morris et al., 2016), inpatient units (Bouadma et al., 2010, Kristofferson et al., 2009, Morris et al., 2016), and emergency departments (Christ-Crain et al., 2004, Schuetz et al., 2009, Morris et al., 2016) yet remain understudied in pediatric ED patients and as part of a concerted antimicrobial stewardship intervention.

There is a need to develop additional strategies to address inappropriate antibiotic prescribing for respiratory illnesses in the ED (Donnelly et al., 2014, Yadav et al., 2019). Implementing antibiotic stewardship programs in outpatient settings has become a national priority, with the goal of reducing adverse events, opportunistic infections including *C. difficile*, antibiotic resistance, hospital costs, and lengths of stay (CDC, 2021, Antibiotic Stewardship, Fridkin et al., 2014).

2. Methods

We conducted a prospective, pilot randomized clinical trial to evaluate both the use of the point of care (POC) Flu/RSV Assay, procalcitonin, and pharmacist-led result-based education for physicians in aggregate compared to usual care. The study took place at a an urban-rural quaternary level 1 trauma medical center with 625 hospital beds with an annual ED volume of 85,000. The UC Davis Institutional Review Board approved this trial, and it was registered on clinicaltrials.gov https://clinicaltrials.gov/show/NCT02899065

From March 2018 to February 2019, we enrolled patients <21 years old, who were evaluated by the clinician for suspected influenza like illness or non-specific URI for whom the clinician ordered a POC flu/RSV assay. Enrollment during this period was lower than expected, and as a result of this in March 2019 we opened enrollment to patients <50 years old and removed the requirement of having a POC flu/RSV assay ordered to be eligible. The inclusion criteria were updated to include patients who were evaluated by the clinician for suspected influenza, including symptoms of ILI (fever, cough, sore throat) or

non-specific URI for whom the clinician suspected RSV or influenza or lower respiratory infections (with or without x-ray). Exclusion criteria during the study included patients who were pregnant, prisoners, or unable to give informed consent in English or Spanish. We also excluded patients for whom the physician was unwilling to wait for a procalcitonin result. Having a PCT test ordered as part of the clinical care plan did not exclude a patient from participation. Because of the COVID-19 pandemic and institutional research pause, the study closed for enrollment between March 14, 2020, and November 19, 2020. When enrollment resumed, the study excluded patients who tested positive for COVID-19. Excluding COVID-19 positive patients was not a protocol change but reflects a workflow modification to follow university policy. Screening occurred when research coordinators (RCs) was available and during ED pharmacist hours 7am-1am Monday through Friday, and 1pm-1am Saturday and Sunday.

Consented patients in the ED were randomized into one of two arms. The patient, research coordinator, and treating physician were not blinded to the patient's allocation.

Patients randomized to the intervention arm received procalcitonin testing with a patient specific stewardship intervention. The stewardship intervention was pharmacist-led guidance about antibiotic and antiviral prescribing recommendations to the treating physician. Figure 1 displays the PCT algorithm used. Patients randomized to this arm had 1mL of blood drawn for the PCT to identify bacterial infections. Whenever possible, the blood draw was timed with standard clinical labs, or from an IV if one was in place. If no blood draw was ordered for standard of care and/or no IV was placed, the patients were given the option to consent to an additional blood draw for the purpose of research if both the clinician and the patient agreed to wait for the test.

The control arm received usual care. Prior to March 2019, POC molecular testing for influenza and/or RSV was the usual care for our institution.

All enrolled patients were asked to participate in a 7-day follow-up phone call and a 4-week follow-up phone call. All patients had a 30-day chart review to evaluate outcomes.

The (co-)primary outcome is the rates of Antibiotic and Antiviral prescriptions in the ED for influenza positive and negative patients.

The secondary outcome measures included symptoms resolution, number missed school days of the patient, and number of missed workdays all were assessed at 7-days and 4-weeks.

Study data were collected and managed using REDCap electronic data capture tools hosted at UC Davis. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources (Harris et al., 2009, 2019).

We used standard descriptive statistics to summarize patient characteristics at randomization; mean and standard deviation (SD) for continuous variables and frequency and proportion for categorical variables. We indicated the count of missing data for each variable. For the comparison of the primary outcomes, we used frequency and proportions by arm, and computed a point estimate of the difference along with 95% confidence interval (CI) and p-value. We did not adjust p-values for multiple comparisons but presented all outcomes analyzed (without selective reporting). Furthermore, we conducted a stratified analysis based on flu status. For primary (unstratified) analyses, we used Chi-square test (and Fisher exact test), and for stratified analyses, we used Mantel-Haenszel method. Secondary outcomes and post-hoc exploratory analyses were performed similarly. During statistical analyses, statisticians and other investigators were blinded to treatment identity (e.g., data analyses with A/B coding). All CIs and p-values are two-sided and unadjusted for multiple testing (e.g., for 2 primary outcomes). For all analyses, we used SAS 9.4 (SAS Institute, Cary, NC).

3. Results

We enrolled 200 patients over the 4-year enrollment period including breaks in enrollment during the summer months and in 2020 for institutional research restrictions due to COVID-19. See Figure 2 for the CONSORT diagram.

Out of the 200 patients enrolled 51 were found to be positive for Influenza A, B, or RSV. 28 positives were in the intervention group and 23 positives were in the usual care group. Patient demographics are shown in Table 1. Overall, the intervention of PCT testing with pharmacist led intervention did not have a statistically significant effect on the rate of antibiotic prescribing compared to the control group (39% - 32% = 7.0%, 95% CI: −6.2, 20.2, P=0.30 from Chi-square and 0.38 from Fisher exact) on Table 2. When stratified by influenza and RSV status, there was also no difference in antibiotic (94% (−4.5, 23.2), P=0.18) and antiviral (1.0% (−7.6, 9.2), P=0.81) prescribing between the two groups (Table 3).

Also, we performed a post hoc analysis to investigate whether the procalcitonin results themselves drove provider prescribing of antibiotics. Table 5 lists results stratified by PCT. ED physicians were likely to follow PCT guidelines when prescribing antibiotics for patients with PCT >0.25 and not prescribing when <0.25 (P=0.001) as presented in Table 6 with results stratified by pediatric and adult populations in Table 7.

Our 7-day survey completion rate was 85.5% versus a 4-week follow-up completion rate of 77.0%. Out of our secondary outcomes, symptom resolution by day 7 (P=0.09) is the only one trending in the direction of a difference with more patients in the intervention group reporting symptom resolution than the control one week after ED visit. See Table 3 for secondary outcome analyses.

4. Discussion

In this study, pharmacist targeted provider education at the bedside to optimize antibiotic and antiviral prescribing did not appear to impact ED clinician decision making in following

the guidelines. Nonetheless, a post hoc analysis showed that physicians do use procalcitonin to guide antibiotic use with or without pharmacist intervention. We suspect that the small sample size (which may be reasonable for pilot trials) and PCT becoming more common as a part of the usual care in our institution contributed to us not seeing a statistically significant difference in antibiotic prescribing between these two groups. Yet, clinical meaningfulness of the observed point estimates of differences (7–10%) along with corresponding CIs may warrant consideration (ref: JAMA stat) and could inform future study/trial designs.

Research on the use of rapid respiratory panels (RRP) in the ED have shown mixed results with respect to decreasing antibiotic prescribing in the ED, with one study finding an association between RRP use and decreased antibiotic use for both pediatric and adult patients (May et al., 2019), and two studies on pediatric patients showing no/little decrease (Rao et al., 2021, Rogers et al., 2014).

Procalcitonin in pediatric populations could likely be a tool, to reduce inappropriate antibiotic prescribing but research is thin with respect to pediatrics. Even in adult's workflow considerations and heuristics are critical to the use of PCT in adult ED patients with acute respiratory tract infection. For example, a patient-level RCT of PCT in US hospitals published by Huang et al in 2018, found that there was no significant difference between a procalcitonin group and a control group regarding antibiotic use, treatment duration, and adverse outcomes, although this could be due to increased antibiotic stewardship efforts in recent years and a lower number of patients with pneumonia enrolled compared to other studies, or to biased selection of a population of subjects being admitted with lower respiratory tract infection for whom the decision to prescribe an antibiotic had already been made prior to the PCT result. Thus, implementation of PCT within clinical workflow, appropriate populations, and the stewardship context are critical to successful use in clinical decision making.

Additional study limitations included challenges to enrollment over 4 influenza seasons, interrupted by COVID-19. In particular, institutional closure of research during the early part of the pandemic stopped enrollment temporarily. Furthermore, concerns around transmission of COVID-19 delayed restarting enrollment, and a subsequent need to wait for COVID-19 test to result and confirm negative COVID-19 prior to enrollment. Thus, the latter half of the study enrolled a higher acuity population. At the end of the study, more patients had procalcitonin ordered in the control group as compared to the beginning of the study. This was likely related to waiting for COVID-19 test to enroll patients which delayed consent and mildly ill patients were more likely to be discharged, while more critically ill patients stayed in the ED for further testing. In addition, particularly in pediatric patients, there was a shift in practice to more commonly ordering procalcitonin in patients being admitted and in adults being evaluated for respiratory illness. The UC Davis Medical Center introduced PCT testing in December 2014; this early adoption may also be a contributing factor in why we did not see a difference it is possible our early adoption made physicians more willing to enroll and follow PCT results as part of their clinical decision making and aligns with the results of our ad hoc analysis.

5. Conclusion

Procalcitonin can be used to guide antibiotic prescribing in adults and pediatric patients. There does not appear to be a significant impact of direct patient specific education and guideline provision in decision making around antibiotic use for respiratory tract infection patients in the ED; however, additional research is needed on the role of targeted interventions that incorporate PCT and point of care molecular tests in improving antimicrobial stewardship.

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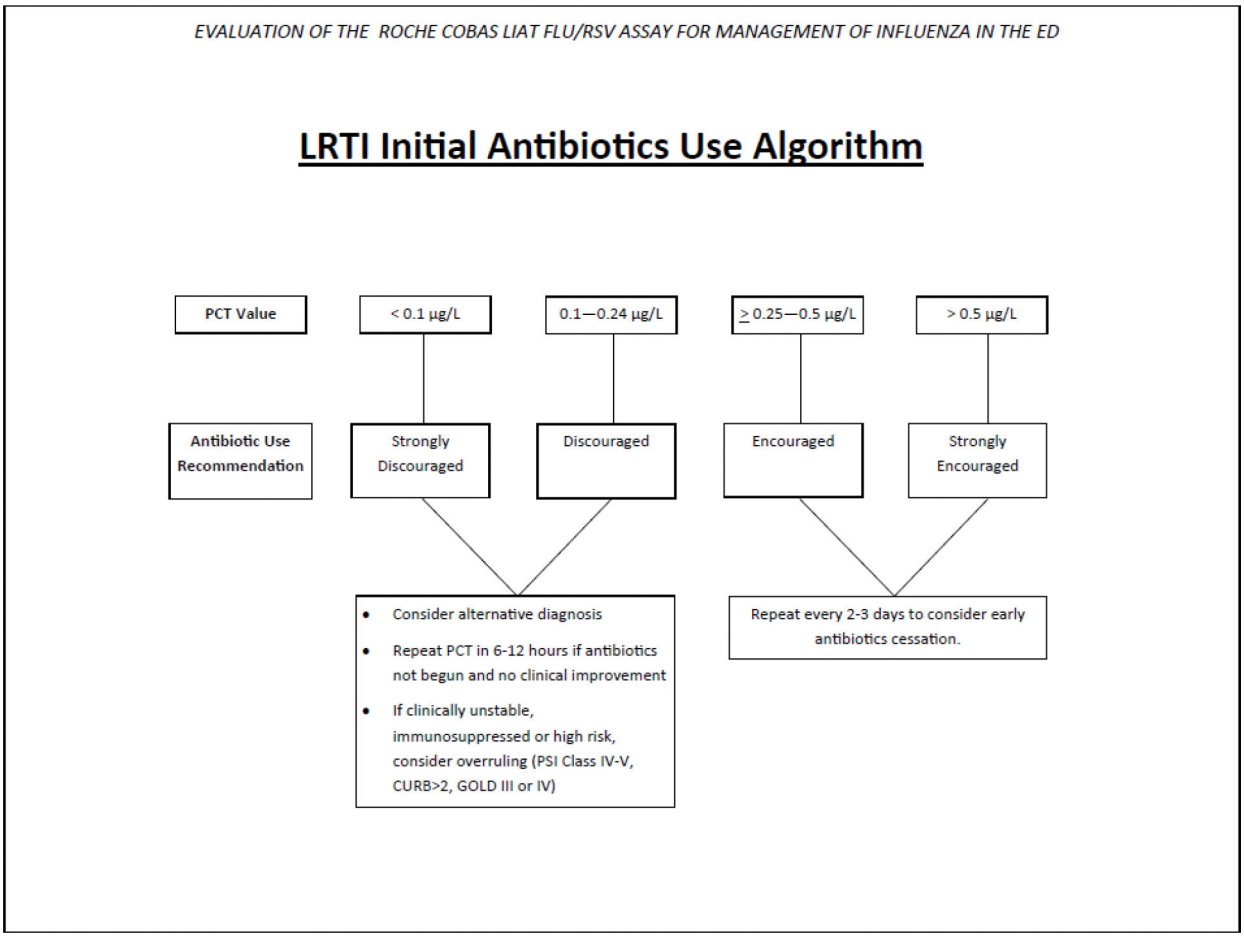

Figure 1:
PCT Algorithm

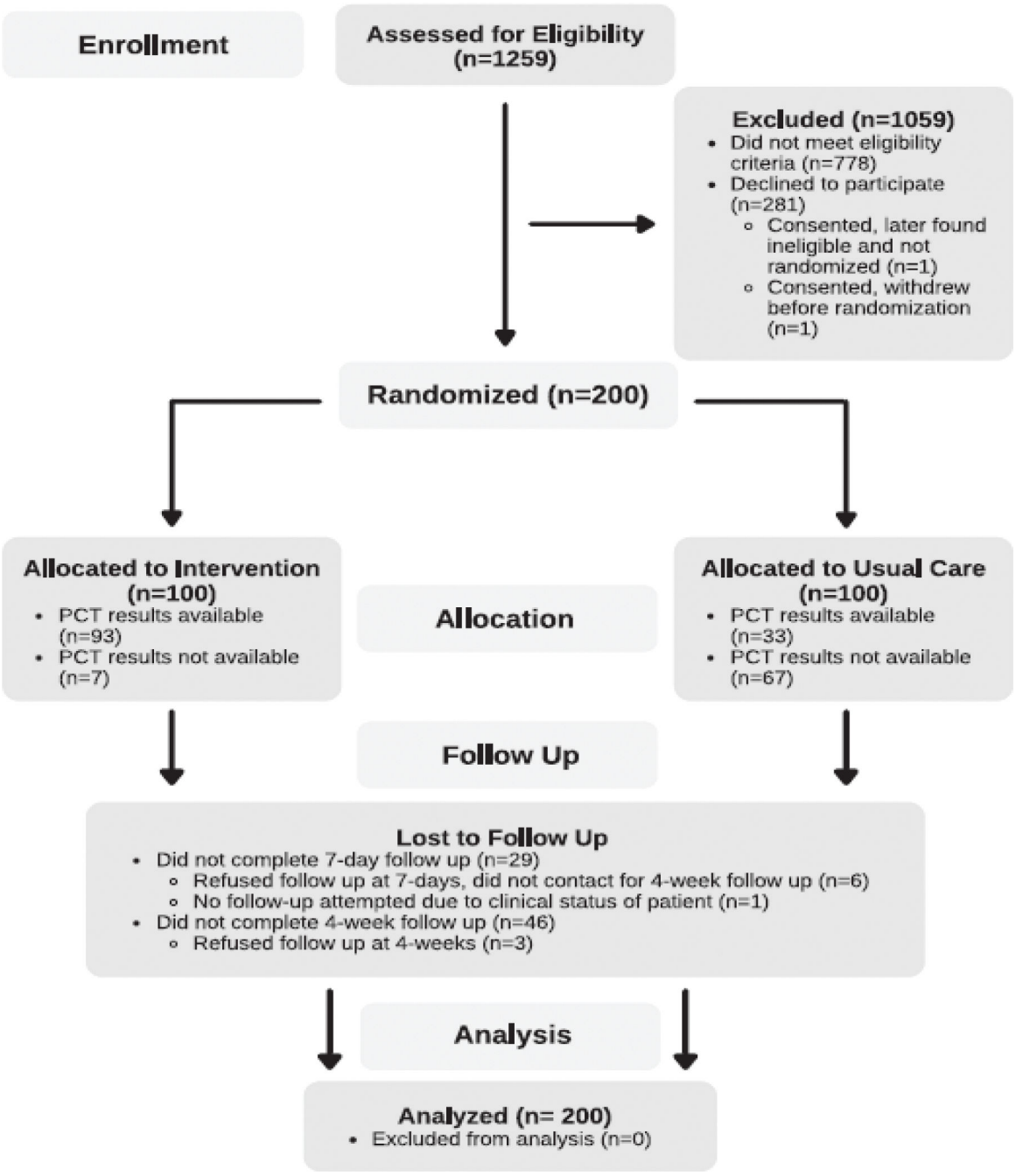

Figure 2:
Consort Diagram

Table 1.

Patient characteristics at randomization (N=200)

	Intervention (N=100)	Usual Care (N=100)
Age, in month, mean (SD)	149 (157)	124 (140)
Gender, n Female	44	47
Race, n Black	18	18
White	46 (N=74)	42 (N=73)
Ethnicity, n Hispanic	49 (N=99)	46
Education, n Some college	16 (N=98)	11 (N=98)
Height, in inches, mean (SD)	50.5 (16.5) (N=80)	50.8 (14.9) (N=77)
Weight, in kg, mean (SD)	40.0 (33.7) (N=99)	38.7 (34.6) (N=97)
Temperature, in Celsius mean (SD)	37.7 (1.1)	37.6 (1.0) (N=99)
Influenza A, n	13	11
B, n	8	5
RSV, n	7	7

Sample size (N) is indicated when missing data are present.

Table 2.

Primary outcomes analyses

Outcome	Intervention (N=100)	Usual Care (N=100)	Difference in proportions (95% CI), P-value*
Antibiotics, yes	39	32	7.0% (−6.2, 20.2), P=0.30/0.38
Antivirals, yes	12	10	2.0% (−6.7, 10.7), P=0.65/0.82

* For overall (combined, primary outcome), Chi-square/Fisher exact test was used for P-value.

Table 3.

Stratified by flu status

	Intervention		Usual Care		Difference in proportions (95% CI), P-value**
	Flu A/B/RSV + (N=31)	**Flu/RSV − (N=58)**	**Flu A/B/RSV + (N=25)**	**Flu/RSV − (N=65)**	
Antibiotics, yes	6	28	7	20	9.4% (−4.5, 23.2), P=0.18
Antivirals, yes	11	1	9	0	1.0% (−7.2, 9.2), P=0.81

** For stratified analyses, patients with unknown flu status were excluded. Mantel-Haenszel method was used for CI and P-value.

Table 4.

Secondary outcomes analyses

Outcome	Intervention	Usual Care	P-value
	n/N	n/N	
Return to ED	19/100	16/100	0.71
Symptoms resolved by 7-days?	66/87	52/82	0.09
Symptoms resolved by 4-weeks?	62/76	61/77	0.84
	N, mean (SD), median	N, mean (SD), median	
School days missed by child at 7-days	N=100, 2.6 (3.0), 0	N=100, 2.6 (3.1), 0	0.91
Workdays missed at 7-days	N=100, 2.5 (2.7), 2	N=100, 3.1 (3.1), 2	0.24
School days missed by child at 4-weeks	N=72, 1.8 (3.7), 0	N=70, 1.4 (4.1), 0	0.16
Workdays missed at 4-weeks	N=75, 0.9 (1.7), 0	N=77, 1.2 (3.6), 0	0.43

P-values were not adjusted for multiplicity. Data with unknown status were excluded in total n.

For continuous variables, Wilcoxon test was used for p-values.

Table 5.

Post-hoc exploratory analyses stratified by PCT status

	Intervention		Usual Care		P-value
	PCT ≥ 0.25 (N=26)	**PCT < 0.25 (N=67)**	**PCT ≥ 0.25 (N=9)**	**PCT < 0.25 (N=24)**	
Antibiotics yes	17	21	7	11	0.15
Antivirals yes	3	7	1	1	0.44

Table 6.

Post-hoc Exploratory Analysis PCT & outcomes

	PCT ≥ 0.25 (N=35)	**PCT < 0.25 (N=91)**	**P-value**
Antibiotics yes	24	32	0.001
Antivirals yes	4	8	0.74

Table 7.

Post-hoc exploratory analysis stratified by pediatric vs. adult

	Intervention		Usual Care		P-value
	Ped (N=69)	Adult (N=31)	Ped (N=80)	Adult (N=20)	
Antibiotics yes	28	11	24	8	0.32
Antivirals yes	6	6	8	2	0.77

PCT was missing for 7 patients in arm A and 67 patients in arm B.