collaborating physician support and inclusion, are identified as significant areas of improvement. The establishment of APP-specific training programs and educational courses will create more opportunities for APPs and further expand the ID workforce.

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629. Understanding the Effects of Social Determinants of Health on Outcome When Discharging Veterans on Parenteral Antibiotic Therapy

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Session: P-23. Clinical Practice Issues

Background: Social determinants of health are conditions in which people live, including aspects of both social environments and physical environments, and how these conditions affect their health. Examples of social determinants include access to health care, social support, culture, etc. These factors are often considered when discharging a patient on IV antibiotics. The purpose of this study was to determine if social determinants of health are related to outcomes for veterans discharged from the Zablocki VA on outpatient parenteral antibiotic therapy (OPAT).

Methods: This retrospective chart review evaluated veterans discharged home from the Zablocki VA on OPAT between the years of 2013 and 2017. Variables of social determinants of health included: race/ethnicity, co-habitants, mental health diagnosis, employment, use of illicit drugs, use of tobacco, and use of alcohol. The primary outcome analyzed was completion of therapy with or without complication. Complication is defined as antibiotic change/dose adjustment, PICC line complication, or additional clinic/hospital visit.

Results: Overall, 294 veterans' charts were reviewed. Of these patients, 188 (63.95%) had no complication and 106 (36.05%) had a complication. Univariate analyses of social determinants are summarized in Table 1. Tobacco use was the only factor significantly associated with OPAT complication (p= 0.008).

Table 1.

Table 1. Social determinants of patients receiving OPAT at Zablocki VA 2013-2017.

Determinant	No Complication N= 188; N(%)	Complication N= 106; N (%)	p-value
Sex			
Male	181 (96.28)	105 (99.06)	0.124
Female	7 (3.72)	1 (0.94)	
Race/ethnicity			
White	167 (88.83)	88 (83.02)	0.3671
Black	16 (8.51)	14 (13.21)	
Other	5 (2.66)	4 (3.77)	
Co-inhabitants			
Alone	50 (26.60)	23 (21.70)	0.6338
Not Alone[a]	127 (67.55)	77 (72.64)	
Unavailable	11 (5.85)	6 (5.66)	
Mental Health Diagnosis			
No	99 (52.66)	56 (52.83)	0.2333
Yes[b]	89 (47.34)	50 (47.17)	
Employment			
Employed	37 (19.68)	18 (16.98)	0.8947
Retired	80 (42.55)	46 (43.40)	
Unemployed	22 (11.70)	15 (14.15)	
Unavailable	49 (26.06)	27 (25.47)	
Illicit Drug Use			
Current IV	0	0	0.698
Former IV	1 (0.53)	2 (1.89)	
Current Non-IV	5 (2.66)	4 (3.77)	
Former non-IV	13 (6.91)	5 (4.72)	
Denied	162 (86.17)	90 (84.91)	
Unavailable	7 (3.72)	5 (4.72)	
Tobacco Use			
Yes	38 (20.21)	39 (36.79)	0.0088
No	58 (30.85)	21 (19.81)	
Former	90 (47.87)	46 (43.40)	
Unavailable	2 (1.06)	0	
Alcohol Use			
Yes	73 (38.83)	39 (36.79)	0.585
No	80 (42.55)	48 (45.28)	
Former	26 (13.83)	17 (16.04)	
Unavailable	9 (4.79)	2 (1.89)	

Abbreviations: OPAT, Outpatient Parenteral Antimicrobial Therapy; VA, Veterans Affairs

[a] Spouse, family, or roommate

[b] Depression, anxiety, bipolar, schizophrenia, and/or PTSD

Conclusion: This analysis suggests that many social determinants thought to potentially impact OPAT outcomes, such as race/ethnicity, co-inhabitants, mental health diagnosis, employment status, and use of illicit drugs or alcohol were not significant contributions to OPAT complications in the Milwaukee VA population; although, veterans who were current smokers were more likely to have an OPAT complication. These results may speak to the VA's integral social support provided to veterans upon discharge, and perhaps, the above social determinants should not be as heavily considered when deciding if a veteran can perform OPAT. However, it is important to consider that these results may reflect the careful selection of Milwaukee veterans discharged on OPAT, as questionable cases can be treated as an inpatient.

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630. A 5-mRNA host response whole-blood classifier trained using patients with non-COVID-19 viral infections accurately predicts severity of COVID-19

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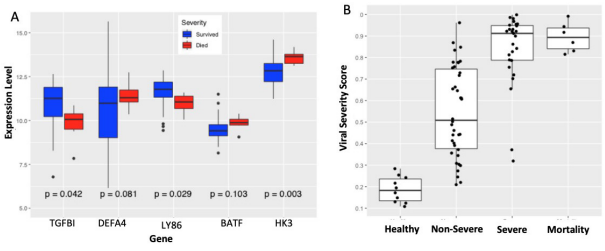
Session: P-24. Clinical Trials

Background: While major progress has been made to establish diagnostic tools for the diagnosis of SARS-CoV-2 infection, determining the severity of COVID-19 remains an unmet medical need. With limited hospital resources, gauging severity would allow for some patients to safely recover in home quarantine while ensuring sicker patients get needed care. We discovered a 5 host mRNA-based classifier for the severity of influenza and other acute viral infections and validated the classifier in COVID-19 patients from Greece.

Methods: We used training data (N=705) from 21 retrospective clinical studies of influenza and other viral illnesses. Five host mRNAs from a preselected panel were applied to train a logistic regression classifier for predicting 30-day mortality in influenza and other viral illnesses. We then applied this classifier, with fixed weights, to an independent cohort of subjects with confirmed COVID-19 from Athens, Greece (N=71) using NanoString nCounter. Finally, we developed a proof-of-concept rapid, isothermal qRT-LAMP assay for the 5-mRNA host signature using the QuantStudio 6 qPCR platform.

Results: In 71 patients with COVID-19, the 5 mRNA classifier had an AUROC of 0.88 (95% CI 0.80-0.97) for identifying patients with severe respiratory failure and/or 30-day mortality (Figure 1). Applying a preset cutoff based on training data, the 5-mRNA classifier had 100% sensitivity and 46% specificity for identifying mortality, and 88% sensitivity and 68% specificity for identifying severe respiratory failure. Finally, our proof-of-concept qRT-LAMP assay showed high correlation with the reference NanoString 5-mRNA classifier (r=0.95).

Figure 1. Validation of the 5-mRNA classifier in the COVID-19 cohort. (A) Expression of the 5 genes used in the logistic regression model in patients with (red) and without (blue) mortality. (B) The 5-mRNA classifier accurately distinguishes non-severe and severe patients with COVID-19 as well as those at risk of death.



Conclusion: Our 5-mRNA classifier demonstrated very high accuracy for the prediction of COVID-19 severity and could assist in the rapid, point-of-impact assessment of patients with confirmed COVID-19 to determine level of care thereby improving patient management and healthcare burden.

Disclosures: ljubomir Buturovic, PhD, Inflammatix Inc. (Employee, Shareholder) Purvesh Khatri, PhD, Inflammatix Inc. (Shareholder) Oliver Liesenfeld, MD, Inflammatix Inc. (Employee, Shareholder) James Wacker, n/a, Inflammatix Inc.

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631. Preliminary safety and pharmacokinetic profile of VIR-2482: a monoclonal antibody for the prevention of influenza A illness

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Session: P-24. Clinical Trials

Background: VIR-2482 is a fully human immunoglobulin G1(IgG) monoclonal antibody (mAb) directed against a highly-conserved epitope in the influenza A hemagglutinin stem region and is in clinical development for the prevention of influenza A illness. The Fc region of VIR-2482 has been modified to provide an extended half-life.

Methods: This is a randomized, placebo-controlled, Phase 1/2 study of VIR-2482 administered intramuscularly (IM) to healthy adult volunteers aged 18-64 years old who have not received a current influenza vaccine. The Phase 1 portion of the study will evaluate the safety, tolerability, pharmacokinetic (PK), and immunogenicity profile of VIR-2482 following single (Part A) or multiple doses (Part B). The Phase 2 study will evaluate the efficacy of VIR-2482 in the prevention of influenza A illness as well as safety, tolerability, and PK. Part A is ongoing and consists of four single dose cohorts (N=25/cohort) randomized (4:1) to a single dose of VIR-2482 or placebo at 60, 300, 1200, or 1800 mg. Safety, tolerability, PK and immunogenicity will be evaluated for at least 52 weeks post-dose.

Results: In Part A, all 100 subjects received a single dose of VIR-2482 (N=80) or placebo (N=20). Preliminary blinded safety data for all cohorts and PK data for the 300 and 1200 mg cohorts are reported here. Dosing was well tolerated; 6% (6/100) of subjects experienced mild injection site reactions, which generally resolved within 48 hrs. Through 12 weeks post-dosing, the majority (124/126; 98.4%) of adverse events (AEs) were mild to moderate in nature, no serious AEs were reported, and no subjects discontinued due to an AE. Based on available data, exposure (C_{max} and AUC) between 300 and 1200 mg of VIR-2482 increased in a dose proportional manner. The PK profile of VIR-2482 is consistent with a half-life extended IgG.

Conclusion: Based on available data, VIR-2482 has been well tolerated following single IM doses of up to 1800 mg in healthy subjects. The preliminary PK profile of VIR-2482 enables once per season dosing. Overall, these data support initiation of a Phase 2 study to evaluate efficacy of VIR-2482 for the prevention of influenza A illness.

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632. A Randomized, Placebo-Controlled, Double-Blind, Clinical Trial Evaluating Two Dose Regimens of Rifaximin (550mg daily or twice-daily) for Chemoprophylaxis Against Travelers' Diarrhea Among Deployed U.S. and U.K. Military Personnel (PREVENT TD)

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PREVENT-TD Study Team

Session: P-24. Clinical Trials

Background: Travelers' diarrhea (TD) is a leading threat to military readiness. Most trials of rifaximin chemoprophylaxis involve civilians or short-duration travel, whereas military travelers are exposed for longer periods at austere locations and are often physically taxed. We sought to assess efficacy of two regimens among military personnel deployed overseas.

Methods: This was a multi-site, double-blind, placebo-controlled trial of deployed military, randomized to placebo, rifaximin 550 mg daily, or rifaximin 550 mg twice-daily, for up to 42 days (1:1:1; 6 randomizations/block). Diaries were reviewed with subjects on return. Primary endpoint was time to first unformed stool (TFUS) in a TD episode. Other endpoints were assessed by intention to treat (ITT) and subgroups included incidence of any loose stool, meeting criteria for TD, safety, efficacy, adherence and impact to activity endpoints.

Results: 343 subjects were included in the ITT population. All UK travelers deployed to a single-site in Kenya; US travelers mostly deployed to various Asia-Pacific locations. Of 73 (21.2%) subjects reporting diarrhea, 42 (57.5%) met TD criteria. Among rifaximin-treated subjects, 15.9% (n=17) reported diarrhea in the twice-daily arm, 20.7% (n=25) in the daily arm, vs. 27.0% (n=31) of placebo recipients; p=.04 and 0.26 respectively. TD was reported by 10.3% (n=11) and 10.7% (n=13) in the daily and twice-daily arms, vs. 15.7% (n=18) among placebo recipients; p=0.24 vs. 0.26 respectively. Among UK personnel, a twice-daily regimen vs. placebo resulted in significantly fewer TD episodes (1.6% vs. 11.9%; p=0.03). Adverse events were similar between groups.

Table 1: Demographics, endpoints, and adverse events (Comparisons are across placebo vs. each dosing regimen. Intent-to-treat [ITT] population defined as subjects enrolled into the study, randomized, travelled and had follow-up. p-values calculated from chi-square or Fisher's exact test [categorical variables] and Wilcoxon-Mann-Whitney test [continuous variables]. Analyses performed on SAS v9.4. BID: twice-daily)

	Rifaximin 550mg BID	Rifaximin 550mg daily	Placebo	Total	p-value twice-daily	p-value daily
Total ITT population n (%)	107 (31.2)	121 (35.3)	115 (33.5)	343	NA	NA
Gender n (%)					0.786	0.291
Male	97 (90.6)	113 (93.4)	103 (89.6)	313 (91.2)		
Travel Duration (days)						
Median (IQR)	45 (39-50)	45 (38-50)	45 (40-50)	45 (38-50)	0.955	0.592
Subject Group n (%)					0.926	0.749
US	44 (41.1)	53 (43.8)	48 (41.7)	145 (42.3)		
UK	63 (58.9)	68 (56.2)	67 (58.3)	198 (57.7)		
Region n (%)					0.659	0.901
South America	1 (0.9)	1 (0.8)	1 (0.9)	3 (0.9)		
Sub-Saharan Africa	71 (66.4)	73 (60.8)	75 (65.2)	219 (64.0)		
South-East Asia	22 (20.6)	32 (26.7)	28 (24.4)	82 (24.0)		
East-North Asia	8 (7.5)	11 (9.2)	10 (8.7)	29 (8.5)		
Central America	2 (1.9)	0 (0)	0 (0)	2 (0.6)		
South-Central Asia	3 (2.8)	3 (2.5)	1 (0.9)	7 (2.0)		
Subjects Reporting any diarrhea (Loose stools)	17 (15.9)	25 (20.7)	31 (27.0)	73 (21.2)	0.045	0.256
Subjects Meeting TD Criteria	11 (10.3)	13 (10.7)	18 (15.7)	42 (12.2)	0.235	0.264
Subjects Reporting any Diarrhea (Loose stools – by UK Subject Group)	4 (6.4)	11 (16.2)	15 (22.4)	30 (15.2)	0.0097	0.360
Subjects Meeting TD Criteria (by UK Subject Group)	1 (1.6)	5 (7.4)	8 (11.9)	14 (7.1)	0.034	0.366
Subjects Reporting any Diarrhea (Loose stools – by US Subject Group)	14 (29.6)	14 (26.4)	16 (33.3)	43 (29.7)	0.696	0.441
Subjects Meeting TD Criteria (by US Subject Group)	10 (22.7)	8 (15.1)	10 (20.8)	28 (19.3)	0.826	0.452
TFUS						
Days: Median (IQR)	11.8 (5.3-50.6)	21.3 (12.9-30.3)	14.3 (5.9-34.9)		0.75	0.76
Adverse events					0.559	0.139
None	77 (72.0)	90 (74.4)	77 (67.0)	244 (71.1)		
Mild/Moderate	30 (28.0)	27 (74.4)	37 (32.2)	94 (27.4)		
Severe	0 (0)	4 (3.3)	1 (0.9)	5 (1.5)		

Conclusion: This is the first trial comparing two high-dose regimens of rifaximin prophylaxis in deployed personnel. Unlike prior reports, neither regimen was associated with an overall significant decrease in TD, potentially due to low overall TD incidence. However, the twice-daily regimen was associated with a numerically lower incidence of diarrheal stool, and in the UK subject group, there was a significant decrease of both TD and diarrheal stool. The impact of variability in regional TD risk, pathogen distribution and adherence in austere deployment environments on efficacy will be reviewed.

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633. Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) Efficacy in Participants with Pre-Existing Primary Integrase Inhibitor Resistance Through 48 Weeks of Phase 3 Clinical Trials

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