is developing an aluminum-adjuvanted RSV F nanoparticle vaccine for use in the third trimester of pregnancy, with the goal of preventing medically significant infant RSV LRTI in the first 3–6 months of life via transplacental transfer of maternal antibodies.

Method. After dose-finding studies in 1,050 women, we studied vaccine safety and immunogenicity in a Phase 2 trial in 50 healthy third trimester pregnant women. Safety was assessed in mothers and infants, focusing on pregnancy and peri-partum outcomes. We measured binding and functional RSV antibodies in mothers at baseline, day 14, delivery, and days 35 and 180 post-partum, in cord blood, and in infant sera on days 14, 35, 60, and 180 of life. Anti-F antibody specificities were probed with biolayer interferometry and monoclonal antibodies (mabs) to known epitopes.

Result. In Phase 2, RSV F nanoparticle vaccine was immunogenic, safe, and well-tolerated in pregnant women. Anti-F IgG and neutralizing antibodies were elicited. Increases in antibodies competitive with mabs to neutralizing epitope sites Ø, VIII, II, and IV, and also the p27 domain displayed by the pre-fusogenic F protein, were present in maternal and infant sera of vaccinated subject pairs. Transplacental transfer of RSV antibodies was more efficient (110 to 120%) in women immunized >30 days before delivery compared with those vaccinated later; RSV antibody $t_{1/2}$ ranged from 30 to 41 days in infants. We have subsequently enrolled 4,636 pregnant women and their infants in a global observer-blind, randomized, placebo-controlled Phase 3 trial assessing efficacy against medically significant RSV LRTI. In November 2017, an informational analysis performed by an independent statistician, the sponsor remaining blinded, yielded a posterior probability of ≥90% that efficacy was >0%.

Conclusion. RSV F nanoparticle vaccine is immunogenic in pregnancy, and neutralizing antibodies, including those competing for pre-and post-fusion F epitopes, are transferred efficiently transplacentally. An analysis of Phase 3 efficacy against medically signifcant infant RSV LRTI is projected for Q1, 2019.

Disclosures. **L. Fries**, Novavax: Employee and Shareholder, Salary. **D. N. Thomas**, Novavax: Employee, Salary. **G. Smith**, Novavax: Employee and Shareholder, Salary. **J. Plested**, Novavax: Employee, Salary. **P. Piedra**, Novavax: Collaborator, Consultant, Research Contractor and Scientific Advisor, Consulting fee, contract fees for immunologic assays and Research support. **N. Patel**, Novavax: Employee and Shareholder, Salary. **I. Cho**, Novavax: Employee and Shareholder, Salary. **G. Glenn**, Novavax: Employee and Shareholder, Salary.

LB20. Impact of School-Located Influenza Vaccination on Vaccination Coverage, School Absenteeism, and Influenza Hospitalization

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Session: 213. Late Breaker Oral Abstracts: Influenza and Vaccines
Saturday, October 6, 2018: 10:30 AM

Background. School-located influenza vaccination programs aim to increase influenza vaccination coverage and produce indirect effects by interrupting influenza transmission. We evaluated the impact of a program that delivered the inactivated influenza vaccine in 2016–2017 to elementary schools in a large, diverse urban school district in Oakland, California on vaccination coverage, school absenteeism, and influenza hospitalization.

Methods. We conducted a prospective cohort study and used pre-program data from the California Department of Education on school characteristics to identify a control school district with similar characteristics to the program district. We measured parent recall of student influenza vaccination in surveys in 2017 in 44 schools per district (N = 6,070). We obtained absence data from school districts and influenza hospitalization data for district catchment areas prior to and during the program. We used generalized linear models to estimate difference-in-differences (DIDs) in absence rates during influenza season adjusting for month, race, and grade to account for differences in pre-program rates. Standard errors accounted for school clusters. For influenza hospitalization, we estimated cumulative incidence rates using census data to obtain the population size and risk ratios (RR) using modified Poisson regression.

Results. Vaccination coverage was 56.7% in control schools and 63.9% in program schools (difference = 7.2%; 95% CI 3.6%, 10.8%). 24% of students in program schools were vaccinated at school. Absences per 100 days were 5.40 vs. 6.68 in program vs. control sites for all absences and 3.01 vs. 3.60 for illness-related absences; DIDs were statistically significant for illness absences. Among all ages, the risk ratio for influenza hospitalization in program vs. control districts was 0.65 (95% CI 0.55, 0.78) among all ages and 0.71 for adults 65 or older (95% CI 0.57, 0.89). Hospitalization was too rare among elementary aged students to estimate RRs in that group.

Conclusion. Elementary school-located influenza vaccination increased influenza vaccination and decreased school absence and influenza hospitalization. There was an indirect effect on hospitalization in the elderly and nonelementary aged groups.

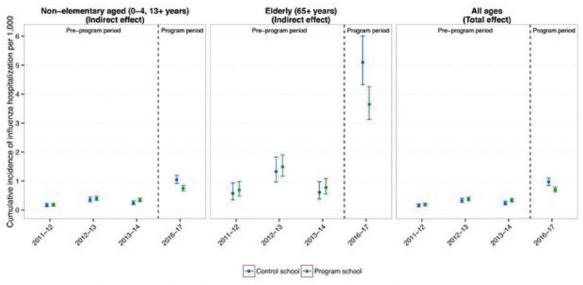

Figure caption: Influenza hospitalization rates per 1,000 in school-located influenza vaccine program and control schools prior to and during the program. Note: 2014-15 and 2015-16 are excluded from the figure because the program delivered the live attenuated influenza vaccine those years, which was later shown not to be effective. Thus, no effects on influenza hospitalization are expected in those years.

Disclosures. **All authors:** No reported disclosures.

LB21. Preemptive Therapy (PET) vs. Prophylaxis for Prevention of Cytomegalovirus (CMV) Disease in High-Risk Donor Seropositive/Recipient Seronegative (D+R−) Liver Transplant Recipients (LTR): A NIH-Sponsored, Randomized, Controlled, Multicenter Trial

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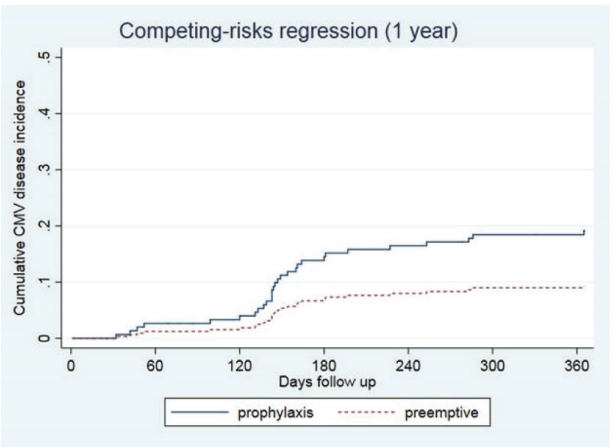
Session: 275. Featured Oral Abstract
Saturday, October 6, 2018: 4:05 PM

Background. Current guidelines preferentially recommend valganciclovir (VGCV) prophylaxis over PET in most D+R− organ transplant populations, but adequately powered direct comparative clinical trials are lacking.

Methods. D+R− LTR were randomly assigned (1:1, stratified by site and T-cell depleting induction) to receive either PET (weekly plasma CMV DNAemia at central laboratory for 100 days, with VGCV 900 mg bid for DNAemia at any level, until two consecutive negative weekly tests) or prophy (VGCV 900 mg qd for 100 days). The primary outcome was CMV disease by 12 months as adjudicated by an independent, blinded, endpoint committee in ITT population. Secondary outcomes were opportunistic infections (OIs) (invasive fungal and bacterial), neutropenia (ANC < 1000/μL), acute rejection, graft loss, and mortality assessed at12 months.

Results. From October 2012 to June 2017, 205 patients were randomized at six centers; 100 to PET, 105 to prophy. The incidence of CMV disease was 9% (9/100) in PET and 19% (20/105) in prophy (P = 0.039) with majority of difference due to post-prophylaxis disease: 6% in PET vs. 17% in prophy (P = 0.027). CMV disease included syndrome in 55% (16/29) and end-organ in 45% (13/29), with similar proportions in two groups. Secondary outcomes were not different for PET and prophy groups: OIs (19% vs. 21%), neutropenia (34% vs.. 28%), acute rejection (27% vs. 27%), graft loss (2% vs. 2%), and mortality (10% vs. 6%), respectively, P > 0.05 for all comparisons. Mortality at last follow-up (median 3.2 years) was not different for PET vs. prophy (14% vs. 18%, P = 0.43).

Conclusions. PET significantly reduced the incidence of CMV disease compared with prophy in D+R- LTR, and was associated with similar other clinical outcomes. Current guidelines should be revised to recommend PET over prophylaxis in this setting, and similar trials conducted in other D+R− transplant populations. (Funded by NIAID; ClinicalTrials.gov# NCT01552369.)



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