Table 1: Descriptive Statistics of Sample Population by Wave

	Ov	erall	Wave 1		Wave 2	
	n	%	n	%	n	%
Total	24,410	100.0%	6,149	100.0%	18,261	100.0%
Race						
White	12,271	50.3%	3,444	56.0%	8,827	48.3%
Black	5,551	22.7%	1,373	22.3%	4,178	22.9%
Asian	935	3.8%	166	2.7%	769	4.2%
Other	3,772	15.5%	769	12.5%	3,003	16.4%
Unknown	1,881	7.7%	397	6.5%	1,484	8.1%
Ethnicity						
Hispanic	3,264	13.4%	686	11.2%	2,578	14.1%
Non-Hispanic	18,845	77.2%	4,961	80.7%	13,884	76.0%
Unknown	2,301	9.4%	502	8.2%	1,799	9.9%
Language						
English	16,897	69.2%	4,575	74.4%	12,322	67.5%
Spanish	1,892	7.8%	533	8.7%	1,359	7.4%
Chinese	252	1.0%	< 10	-	244	1.3%
Russian	89	0.4%	< 10	-	74	0.4%
Other	2,230	9.1%	985	16.0%	1,245	6.8%
Unknown	3,050	12.5%	33	0.5%	3,017	16.5%
City						
Dorchester	2,462	10.1%	706	11.5%	1,756	9.6%
Other	21,948	89.9%	5,443	88.5%	16,505	90.4%
Vaccination Site						
BILH Site	6,712	27.5%	2,792	45.4%	3,920	21.5%
Other MA Site	8,613	35.3%	1,309	21.3%	7,304	40.0%
Not Vaccinated	9,085	37.2%	2,048	33.3%	7,037	38.5%

Table 2: Results by Wave and town of residents

The coefficient of interest is on Wave1*Dorchester, 0.094. This indicates that residents of Dorchester who were offered the vaccine in Wave 1 were 9.4 percentage points more likely to receive the vaccine at BILH, given that they were vaccinated, relative to patients living outside of Dorchester and offered the vaccine in Wave 2.

	Point estimate (95% CI)		
	Pr(Vaccinated at BILH Vaccinated)	Pr(Vaccinated At All)	
Wave1*Dorchester	0.094*	0.017	
	(0.039 to 0.149)	(-0.028 to 0.062)	
Dorchester	0.093*	0.02	
	(0.065 to 0.124)	(-0.004 to 0.043)	
Wave 1	0.311*	0.041*	
	(0.293 to 0.329)	(0.026 to 0.055)	

* denotes p-value < 0.001

Point estimates displayed with 95% confidence intervals in parentheses. Column 1 has the dependent variable of vaccinated at BILH vs. vaccinated elsewhere (sample limited to patients who were vaccinated).

Column 2 has the dependent variable vaccinated anywhere vs. unvaccinated.

The coefficient of interest is on Wave1*Dorchester, 0.094. This indicates that residents of Dorchester who were offered the vaccine in Wave 1 were 9.4 percentage points more likely to receive the vaccine at BILH, given that they were vaccinated, relative to patients living outside of Dorchester and offered the vaccine in Wave 2.

Conclusion. Patients residing in an urban community given prioritized access to vaccination had a higher likelihood of vaccination at our health system, given that they were vaccinated, than patients in other urban communities without prioritized access. We provide an example of a successful effort to move towards equity in access to COVID-19- vaccines, in contrast to larger national trends.^{2,3} Health systems can use a prioritization approach to improve vaccination equity.

Citations

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571. Safety and Immunogenicity of INO-4800, a COVID-19 DNA Vaccine as a Primary Series and Booster

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Session: P-25. COVID-19 Vaccines

Background. DNA vaccines are safe, tolerable, elicit humoral and cellular responses, allow for repeated dosing over time, are thermostable at room temperature, and are easy to manufacture. We present a compilation of Phase 1 and Phase 2 data of Inovio's US COVID-19 DNA Vaccine (INO-4800) targeting the full-length Spike antigen of SARS-CoV-2. A South Korean Phase 2 study is ongoing.

Methods. Participants in the open-label Phase 1 trial received 0.5 mg, 1.0 mg or 2.0 mg intradermally (ID) followed by electroporation (EP) at Days 0 and 28. An optional booster dose was administered >6 months post-dose 2. The Phase 2 further compared the 1.0 mg and 2.0 mg doses against placebo in a total of 401 participants randomized at a 3:3:1:1 ratio. ClinicalTrials.gov identifiers: NCT04336410 and NCT04642638

Results. The majority of adverse events (AEs) related to INO-4800 across both trials were mild in severity and did not increase in frequency with age and subsequent doses. In Phase 1, 78% (14/18) and 84% (16/19) of subjects generated neutralizing antibody responses with geometric mean titers (GMTs) of 17.4 (95%CI 8.3, 36.5) and 62.3 (95% CI 36.4, 106.7) in the 1.0 and 2.0 groups, respectively (Figure 1). By week 8, 74% (14/19) and 100% (19/19) subjects generated T cell responses by Th1- associated IFNy ELISPOT assay . Following a booster dose, neutralizing GMTs rose to 82.2 (95% CI 38.2, 176.9) and 124.7 (95% CI 62.8, 247.7) in the 1.0 mg and 2.0 mg groups, respectively, demonstrating the ability of INO-4800 to boost (Figure 2). In Phase 2, neutralizing antibody responses demonstrated GMTs of 93.6 (95%CI 77.3, 113.4) in the 1.0 mg dose group (Figure 3).

Pseudovirus Neutralization by Dose Group in Phase I

	1.0 mg INO-4800 + EP	2.0 mg INO-4800 + EP
Week 0 GMT Reciprocal Titer	n = 39	n=39
(95% CI)	3.3 (1.8, 6.1)	3.3 (1.8, 6.0)
Week 6 GMT Reciprocal Titer	n = 37	n=38
(95% CI)	17.4 (8.3, 36.5)	62.3 (36.4, 106.7)
	n=37	n=38
Geometric Mean Fold Rise (GMFR) (95% CI)	4.9 (2.2, 10.8)	18.4 (8.5, 39.6)

Pseudovirus Neutralization by Dose Group (all subjects who received booster dose) in Phase 1

	1.0 mg INO-4800 + EP	2.0 mg INO-4800 + EP
Pre-booster GMT Reciprocal	n = 23	n = 31
Titer (95% CI)	7.4 (2.8, 20.0)	14.3 (6.2, 33.1)
Post-booster GMT Reciprocal	n = 26	n = 32
Titer (95% CI)	82.2 (38.2, 176.9)	124.7 (62.8, 247.7)
	n = 22	n = 29
GMFR (95% CI)	8.1 (3.5, 18.3)	9.8 (5.0, 19.1)

<u>Pseudovirus</u> Neutralization by Dose Group in Phase 2

	1.0 mg INO-4800+ EP	Placebo for 1.0 mg group + EP	2.0 mg INO-4800+ EP	Placebo for 2.0 mg group + EP
Day 0 GMT Reciprocal	n = 124	n = 46	n = 114	n = 43
Titer (SD)	32.2 (0.38)	30.3 (0.40)	35.8 (0.45)	36.3 (0.43)
Week 6 GMT	n = 125	n = 45	n = 115	n = 43
Reciprocal Titer (SD)	93.6 (0.47)	32.5 (0.33)	150.6 (0.46)	35.3 (0.41)
GMFR (SD)	n = 124	n = 45	n = 113	n = 43
, ,	2.9 (0.45)	1.2 (0.32)	4.3 (0.53)	1.0 (0.34)

Conclusion. INO-4800 appears safe and tolerable as a primary series and as a booster with the induction of both humoral and cellular immune responses. In addition to eliciting neutralizing antibodies, INO-4800 also induced T cell immune responses as demonstrated by IFN γ ELISpot. Finally, as a homologous booster, INO-4800, when administered 6-10.5 months following the primary series, resulted in an increased immune response without increase in reactogenicity. The 2.0 mg dose was selected for Phase 3 evaluation.

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572. Real-world Effectiveness of COVID-19 mRNA Vaccines against Hospitalizations and Deaths in a Retrospective Cohort

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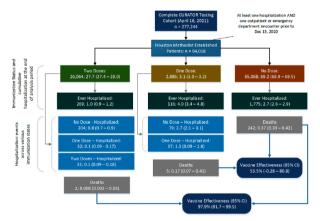
Session: P-25. COVID-19 Vaccines

Background. The effectiveness of Severe Acute Respiratory Syndrome Coronavirus 2 vaccines after two doses needs to be demonstrated beyond clinical trials. *Methods.* In a retrospective cohort assembled from a cross-institution comprehensive data repository, established patients of the health care system were categorized as having received no doses, one dose or two doses of SARS-CoV-2 mRNA vaccine through April 4, 2021. Outcomes were COVID-19 related hospitalization and death.

Results. Of 94,018 patients 27.7% had completed two doses and 3.1% had completed one dose of a COVID-19 mRNA vaccine. The two dose group was older with more comorbidities. 1.0% of the two dose group had a COVID-19 hospitalization, compared to 4.0% and 2.7% in the one dose and no dose groups respectively. The adjusted Cox proportional-hazards model based vaccine effectiveness after two doses (vs. no dose) was 96%(95% confidence interval(CI):95–97), compared to 78%(95%CI:76–82) after one dose. After two doses, vaccine effectiveness for COVID-19 mortality was 97.9%(95%CI:91.7–99.5), and 53.5%(95%CI:0.28–80.8) after one dose. Vaccine effectiveness at preventing hospitalization was conserved across age, race, ethnicity, Area Deprivation Index and Charlson Comorbidity Indices.

Cohort Enrollment and Distribution by Immunization Status and Vaccine effectiveness against mortality

Figure 1:



Cohort members are described by their immunization status and hospitalization at the end of the study period ending April 4th, 2021. Percentages compare this population to the total established patients. Each group is then divided into when hospitalized events occurred across immunization status. These percentages compare the number of events to the population in the immunization status at the end of the analysis period. Odds ratios for mortality were calculated and vaccine effectiveness calculated as 1 minus odds ratio times 100%.

Table : Hazard Ratios and Vaccine Effectiveness associated with COVID-19
Hospitalization Among the One and Two Dose Vaccine Cohorts with COVID-19 mRNA
vaccines

Two Doses 2 26,062 0.021 97.8 One Dose 5 2,881 0.465 53.8 Two or One Dose 7 28,943 0.065 93.8 (0.031 - 0.137) (86.3 - 9.38)					
Two doses		•		•	
One dose 0.22 (0.18 – 0.25) 78% (75 – 82) Adjusted ' Two Doses 0.04 (0.03 – 0.05) 96% (95 – 97) One Dose 0.22 (0.18 – 0.24) 78% (76 – 82) Two Doses 2 26,062 0.021 97.9 One Dose 5 2,881 0.465 53.5 Two or One Dose 7 28,943 0.065 93.5 Na Data 0.031 – 0.137) (86.3 – 9)	Unadjusted				
Adjusted Two Doses 0.04 (0.03 – 0.05) 96% (95 – 97) One Dose 0.22 (0.18 – 0.24) 78% (76 – 82) Death No Death OR (95% CI) VE (95% Two Doses 2 26,062 0.021 97.5 One Dose 5 2,881 0.465 53.5 (0.192 – 1.128) (-0.28 – 1.128) (-0.28 – 1.128) Two or One Dose 7 28,943 0.065 93.5	Two doses	0.05 (0.04 – 0.07)		95% (93 – 96)	
Two Doses 0.04 (0.03 – 0.05) 96% (95 – 97) One Dose 0.22 (0.18 – 0.24) 78% (76 – 82) Death No Death OR (95% CI) VE (95% Two Doses 2 26,062 0.021 97.9 One Dose 5 2,881 0.465 53.5 Two or One Dose 7 28,943 0.065 93.5 Na Data 0.031 – 0.137) (86.3 – 9)	One dose	0.22 (0.18 – 0.25)		78% (75 – 82)	
Death No Death OR (95% CI) VE (95% CI) Two Doses 2 26,062 0.021 (0.005 - 0.083) 91.7 - 10.005 (91.7 - 1.005) One Dose 5 2,881 0.465 (0.192 - 1.128) 53.5 (-0.28 - 1.128) Two or One Dose 7 28,943 0.065 (0.031 - 0.137) 93.5 (0.031 - 0.137)	Adjusted *				
Death No Death OR (95% CI) VE (95% CI) Two Doses 2 26,062 0.021 (0.005 - 0.083) (91.7 - 6.000) 97.5 (91.7 - 6.000) One Dose 5 2,881 (0.192 - 1.128) (-0.28 - 6.000) (-0.28 - 6.000) Two or One Dose 7 28,943 (0.031 - 0.137) (86.3 - 6.000) 93.5 (0.031 - 0.137) (86.3 - 6.000)	Two Doses	0.04 (0.03 – 0.05)		96% (95 – 97)	
Two Doses 2 26,062 0.021 97.9. One Dose 5 2,881 0.465 53.5 Two or One Dose 7 28,943 0.065 93.5 (0.031 - 0.137) (86.3 - 9.1)	One Dose	0.22 (0.18 – 0.24)		78% (76 – 82)	
2 26,062 (0.005 - 0.083) (91.7 - 9) One Dose 5 2,881 0.465 53.5 (0.192 - 1.128) (-0.28 - 1.128) Two or One Dose 7 28,943 0.065 93.5 (0.031 - 0.137) (86.3 - 9)		Death	No Death	OR (95% CI)	VE (95% CI)
5 2,881 (0.192 – 1.128) (-0.28 – Two or One Dose 7 28,943 (0.031 – 0.137) (86.3 – 9	Two Doses	2	26,062		97.9 (91.7 – 99.5)
7 28,943 (0.031 – 0.137) (86.3 – 9	One Dose	5	2,881		53.5 (-0.28 – 80.8)
No Dose	Two or One Dose	7	28,943		93.5 (86.3 – 96.9)
242 64,826	No Dose	242	64,826	-	-

Age, Sex, Race, Ethnicity, Area Deprivation Index (ADI), Charlson Comorbidity Index (CCI)

Conclusion. In a large, diverse US cohort, receipt of two doses of an mRNA vaccine was highly effective in the real-world at preventing COVID-19 related hospitalizations and deaths with a substantive difference in effectiveness between one and two doses.

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573. Digital Patient/Caregiver Education: A Tool to Improve COVID-19 Vaccination Rates and Confidence Among the Public

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Session: P-25, COVID-19 Vaccines

Background. Due to patient hesitancy surrounding the COVID-19 vaccination initiative, the public needs accurate and timely education that encourages partnership with medical professionals.

Methods. This study assessed the impact of online patient/caregiver education on knowledge, confidence and intent to act. The educational intervention consisted of 4 activities published on a dedicated COVID-19 learning center on WebMD Education portal from April-May, 2021. The activities were comprised of text and integrated visuals, with 3 of the activities being further customized with a patient or healthcare professional (HCP) video commentary. Demographic questions were asked prior to each activity. Knowledge questions were asked both before and after to assess learning gains. Intent to change and confidence questions were asked at the end of each activity. Absolute improvements were calculated for pre/post questions. An initial data pull was conducted on 6/7/2021 for the purpose of this abstract, and data for the complete analysis will be collected until approximately 8/7/21.

Results. To date, 14,911 learners (3,579) of which responded to the pre/post questions) have participated in the activities, and have demonstrated improvements in knowledge and high levels of confidence and intent to act (Figure). Activity 1: COVID-19 Vaccines: Covering the Basics. Demographics (n=155): 50% male; 41% White, non-Hispanic, 30% Asian; 52% over the age of 54. Activity 2: Understanding the Why, Who, and When of COVID-19 Vaccines. Demographics (n=2,325): 66% female; 51% White, non-Hispanic, 18% Asian; 54% over the age of 54. Activity 3: What to Expect When You Get the COVID-19 Vaccine. Demographics (n=500): 66% female; 49% White, non-Hispanic, 22% Asian; 56% over the age of 54. Activity 4: What Have You Heard about Herd Immunity and COVID-19. Demographics (n=599): 63% female; 53% White, non-Hispanic, 25% Asian; 53% over the age of 54.

Results.