Poster PCR36

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Vaccinate or Not Vaccinate? Comparative Patient Reported Outcomes on the Severity of Influenza-Like-Symptoms in an Australian Community Screening Program

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BACKGROUND

- Common endpoints in trials measuring the efficacy or effectiveness of influenza vaccination include the number of cases of infection and the reduction in influenza-related hospitalizations.
- Reports on the breadth of the protective effects of influenza vaccination suggest that vaccinated individuals also experience milder symptom severity[1,2].
- A Patient-Reported Outcome (PRO) is a report provided directly by a patient regarding their health condition, without external interpretation. PROs can track symptoms, disease severity, or changes over time; they are commonly used in clinical studies to evaluate the subjective effects of treatments[3].

OBJECTIVE

Using a disease-specific patient-reported-outcome (PRO), compare peak influenza-like-illness (ILI) symptoms among non-hospitalized adults with acute disease between those vaccinated or unvaccinated for influenza.

*Can vaccination prevent the most acute symptoms of **Influenza**?*

METHODS

- During the 2023 southern hemisphere influenza season, Australian adults with influenza-like-illness (ILI) were recruited through an existing community screening program study and remunerated for participating.
- Along with self-swabbing for disease diagnosis, participants self-reported symptoms, and its severity, using the Respiratory Infection, Intensity and Impact Questionnaire (RiiQ™) using digital or paper-based forms.
- RiiQ™ includes 6 respiratory and 7 systemic items which can be rated ‘none’, ‘mild’, ‘moderate’, or ‘severe’ (figure 1).

Figure 1: Sample RiiQ™ Questions

1. **During the past hours**, have you had the following symptoms?

	None	Mild	Moderate	Severe
a. Cough	☐	☐	☐	☐
b. Sore throat	☐	☐	☐	☐
c. Headache	☐	☐	☐	☐

Sample

- RiiQ™ was reported by participants daily for 14 days, starting at enrollment.
- Individual RiiQ™ items were grouped into two domains: Respiratory Symptoms and Systemic Symptoms. Domain scores are calculated by summing the individual items and dividing by the number of items in each domain.
- For vaccinated vs unvaccinated arms, the relative-risk (RR) of participants reporting the highest two possible response-scores (i.e. ‘moderate’ and ‘severe’) of RiiQ™ items during the most acute 5-days peak of symptoms was evaluated.

Table 2. Participant characteristics at baseline

	Vaccinated	Unvaccinated	All
Total *(%)*	28 *(47%)*	31 *(53%)*	59 *(100%)*
Lab-confirmed influenza *(%)*	2 *(7%)*	8 *(26%)*	10 *(17%)*
Gender female *(%)*	20 *(71%)*	18 *(58%)*	38 *(64%)*
Mean age *(sd)*	46,2 *(16)*	44 *(17,5)*	45 *(16,8)*
14 days compliance (%)	25,0 *(89%)*	25 *(81%)*	50 *(85%)*

CONFLICTS OF INTEREST:

Jose Bartelt-Hofer and Erica Dueger: Sanofi — employee, may hold stock and/or stock options in the company.

FUNDING:

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REFERENCES:

1. Osborne RH, et al. Journal of Patient Reported Outcomes. 2023;7:51
2. Van Essen, et al. Influenza and other Respiratory Viruses 2014;8(4)
3. FDA. Guidance for the Industry, Patient-Reported Outcome Measures 2009

RESULTS

- 59 ILI respondents, mean age 45 years, were enrolled. 47% self-reported being vaccinated. Compliance, as defined by 14 days of RiiQ™ daily filling, was achieved by 85% of participants (table 2).
- 27.3% (range 15.1-39.6) of vaccinated respondents experienced ‘moderate’ or ‘severe’ respiratory symptoms during the 5-day peak, compared to 33.5% (18.3-51.1) for those unvaccinated (RR=0.81 [95%CI 0.36-1.8]).
- For the systemic symptoms domain, 24.8% (11.3-40.9) vs 29.9% (20.0-45.6) reported ‘moderate’ or ‘severe’ scores for those vaccinated vs unvaccinated, respectively (RR =0.86 [0.36-2.04]).
- RR of all 6 respiratory items, and 6/7 systemic ones, favored the vaccinated arm.
- Analyses of severe cases (‘severe’ symptom scale only) revealed directionally similar findings for all items, with lower risk of symptoms for vaccinated patients in the 5-day peak (RR=0.52 [0.1-2.83] for respiratory and RR=0.46 [0.07-3.1] for systemic).
- Although analyses of LCI participants suggest greater benefits associated with vaccination, these results are not presented due to low number of cases limiting interpretation of such analyses.

Table 2. Relative-risk of vaccinated vs unvaccinated respondents to experience ‘moderate’ or ‘severe’ symptoms during the 5-day peak

		Vaccinated		Unvaccinated			
		N *(5-day mean)*	Cases *(5-day mean)*	N *(5-day mean)*	Cases *(5-day mean)*	RR	95% CI
Respiratory Symptoms	Cough	26	10	29	14	0,77	(0,41-1,44)
	Sore throat	26	6	29	8	0,75	(0,3-1,9)
	Nasal congestion	26	10	29	15	0,77	(0,43-1,38)
	Wheezing	26	4	29	5	0,89	(0,26-3,07)
	Coughing up phlegm	26	9	29	12	0,88	(0,44-1,73)
	Short of breath	26	4	29	5	0,87	(0,27-2,79)
	Mean Respiratory	**26**	**7**	**29**	**10**	**0,81**	**(0,36-1,8)**
Systemic Symptoms	Headache	26	7	29	11	0,70	(0,31-1,58)
	Feeling feverish	26	5	29	8	0,66	(0,24-1,78)
	Body aches	26	5	29	9	0,60	(0,22-1,63)
	Fatigue	26	13	29	15	0,97	(0,57-1,66)
	Neck pain	26	3	29	4	0,90	(0,23-3,54)
	Interrupted sleep	26	10	29	10	1,12	(0,55-2,29)
	Loss of appetite	26	4	29	6	0,76	(0,25-2,33)
	Mean Systemic	**26**	**7**	**29**	**9**	**0,86**	**(0,36-2,04)**

Strengths

To our knowledge, this is the first influenza community screening program to remotely engage and diagnose participants, incorporating RiiQ™ data collection.

Limitations

Larger cohorts with lab-confirmation of influenza are needed to overcome the limitations of this study.

CONCLUSIONS

- **Influenza vaccination may result in milder symptoms during the peak-stages of infection**
- **Complementing classical trial endpoints, disease-specific PROs such as the RiiQ™ can provide unique insights into severity of symptoms in non-hospitalized patients, denoting an additional benefit of vaccination, and bringing patient-centricity to the evaluation of vaccine effectiveness.**
- **Active patient follow-up, remuneration and availability of digital and paper-based forms contributed to excellent study compliance.**

Beyond protecting against infection, influenza vaccination likely reduces the severity of symptoms, offering an additional compelling reason for immunization

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