P-22

Implementing patient-reported outcomes in community screening programs: Results from the 2023 Southern Hemisphere influenza season

CSP-based RiiQ™ (PRO) implementation is a feasible approach to assess symptoms and QoL of individuals when comparing vaccination status or other participant differences

Jessie Edwards[1], Jocelyn Moyes[2], Erica Dueger[3], Nigel Stocks[1], Mvuyo Makhasi[2,4], Sheena Sullivan[5], Sibongile Walaza[2,4], Monique Chilver[1], Lana Allen[1], Daniel Blakeley[1], Fahima Moosa[2], Anne von Gottberg[2,4], Nicole Wolter[2,4], Mignon du Plessis[2], Cheryl Cohen[2,4], Richard Osborne[6], José Bartelt-Hofer[3]*

[1]Discipline of General Practice, University of Adelaide, Australia; [2]Centre for Respiratory Diseases and Meningitis, National Institute for Communicable Diseases (NICD) of the National Health Laboratory Service, Johannesburg, South Africa; [3]Sanofi Vaccines, Lyon, France; [4]Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa; [5]Department of Infectious Diseases, University of Melbourne; [6]Measured Solutions for Health Pty. Ltd., Alphington, Australia

***Presenting author.** Email: jose.bartelt-hofer@sanofi.com

BACKGROUND

- Vaccination against seasonal influenza can reduce the duration and severity of influenza symptoms and mitigate the negative impacts on quality of life (QoL)[1,2]
- To effectively assess the impact of disease development and vaccination from a patient's perspective, patient reported outcomes (PROs) are used[3]
- PROs provide important data on the infected individual's disease course[4]

OBJECTIVE

Assess the Respiratory Infection, Intensity, and Impact Questionnaire (RiiQ™) PRO, in the context of community screening programs (CSP), to measure symptoms and QoL in relation with Influenza vaccination status, and provide lessons for future implementation

METHODS

Data collection

- In 2023, two southern-hemisphere CSP - iSwab in Australia and Coughcheck in South Africa - offered free respiratory illness diagnoses for patients with influenza-like illness (ILI). This was done through self-swabbing with laboratory confirmation (laboratory-confirmed influenza [LCI])
- Patients were recruited via general practice sites
- They were invited to self-report the RiiQ™ daily for 14 days, starting at enrollment

RiiQ™ measures[4]

- Respiratory and systemic symptoms
- QoL (impact on daily activities, impact on emotions, and impact on others)

Higher RiiQ scores denote worse symptoms/health status

RiiQ™ implementation*

- iSwab responders: Completed digital - or paper-based forms and were remunerated
- Coughcheck responders: completed digital forms and were not remunerated

Analysis

- CSP data was pooled into a single southern hemisphere dataset
- Mean daily RiiQ™ scores per domain were separately calculated and plotted for vaccinated vs unvaccinated arms
- Results for each arm represent the Area Under the Curve (AUC), a higher AUC denote worst health status

*Differed between settings

RESULTS

- A total of 178 CSP respondents (iSwab, 59†; Coughcheck, 119‡) completed the RiiQ™ (**Table 1**)
  - Self-reported, vaccinated patients: 24%
  - Total LCI: 8.4%
- iSwab (Australia) respondents preferred paper surveys (**70%**) over digital and showed higher RiiQ™ compliance compared to Coughcheck (South Africa; **84.7% vs 16%**)

†The total PRO enrolment on Day 1 was N = 59, participation dropped to 88% (n=52) at day 5, and to 84.7% (n=50) at day 14
‡The total PRO enrolment on Day 1 was N = 119, participation dropped to 42% (n=50) at day 5, and to 16% (n=19) at day 14

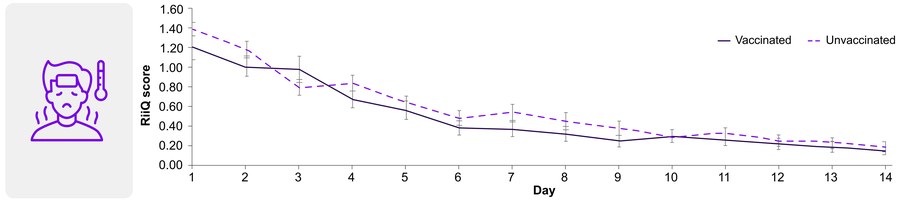
- Vaccinated ILI individuals reported milder symptoms and better QoL across all 5 RiiQTM domains (lower AUC) (**Table 2**)
- In most domains, AUC differences between vaccinated and unvaccinated individuals were higher in those older than 50 years
- The vaccinated individuals reported milder systemic symptoms than the unvaccinated individuals (**Figure 1**)
- The vaccinated individuals reported less impact on daily activities compared with unvaccinated individuals (**Figure 2**)

Table 1: Respondent characteristics

	Vaccinated	Unvaccinated	Total
Cohort size*, n (%)	34 (19.1)	144 (80.9)	100
LCI, %	1.7	6.7	8.4
Gender female, %	13.5†	55.6	69.1
Age, mean	42	50	46
Full 14-days compliance, %	14.6	24.4	38.8

*Characterizes patients that voluntarily enrolled in the PRO, by responding to ≥1 RiiQ™
†In the subset of South African vaccinated patients, females were misrepresented and skewed the total gender distribution
LCI, laboratory-confirmed influenza; PRO, patient-reported outcome; RiiQ, Respiratory Infection, Intensity, and Impact Questionnaire

Figure 1: Systemic symptoms*, vaccinated vs unvaccinated



Number of respondents														
Total (N)	178	129	106	114	102	93	90	86	83	80	71	69	69	69
Vaccinated (n)	34	31	26	31	27	26	25	26	25	26	26	26	26	26
Unvaccinated (n)	144	98	80	83	75	67	65	60	58	54	45	43	43	43

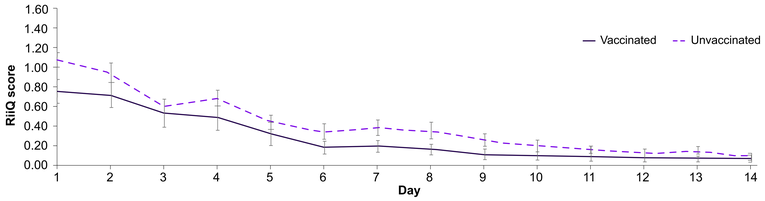
*Headache, fever, Body aches and pains, fatigue, neck pain, interrupted sleep, and loss of appetite

Table 2. Comparison of RiiQ™ results over 14 days among vaccinated and unvaccinated respondents (Area under the curve [AUC] analysis)

RiiQ™ domain	Vaccinated AUC		Unvaccinated AUC		AUC difference in vaccinated vs unvaccinated *p* value*	
	All patients	Patients 50+ years	All patients	Patients 50+ years	All patients	Patients 50+ years
Respiratory symptoms	8.11	7.55	9.18	9.10	-1.06 *p=0.63*	-1.56 *p=0.5*
Systemic symptoms	6.21	5.69	7.21	6.84	-0.99 *p=0.65*	-1.14 *p=0.6*
Impact on daily activities	3.45	2.57	5.20	2.92	-1.75 *p=0.36*	-0.34 *p=0.86*
Impact on emotions	3.85	2.06	6.85	5.53	-3.00 *p=0.09*	-3.47 *p=0.08*
Impact on others	2.27	0.61	4.10	1.99	-1.83 *p=0.25*	-1.38 *p=0.54*

*95% confidence (T-test)
AUC, area under the curve; RiiQ, Respiratory Infection, Intensity, and Impact Questionnaire

Figure 2: Impact on daily activities*, vaccinated vs unvaccinated



Number of respondents														
Total (N)	178	129	106	114	102	93	90	86	83	80	71	69	69	69
Vaccinated (n)	34	31	26	31	27	26	25	26	25	26	26	26	26	26
Unvaccinated (n)	144	98	80	83	75	67	65	60	58	54	45	43	43	43

*Activities include get out of bed, prepare meals / get the food, perform usual activities, leave the home, self care, and go out of the room

DISCUSSION

Strength

Despite a challenging setting to implement PRO, CSP achieved to maximize enrollment and compliance

Limitation

Low number of positive influenza cases does not allow a subanalysis of LCI or additional subgroup analyses

CONCLUSION

- CSP-based RiiQ™, linked to LCI, is feasible and can provide useful information about different symptoms and QoL when comparing vaccination status
- Participants remuneration, active follow-up, and the availability of paper surveys improved participation and compliance
- Larger LCI samples are needed to further confirm current RiiQ™ results in ILI and to achieve statistical relevance

REFERENCES

1. Pan Y, et al. *Public Health Nurs*. 2022;39:509-516; **2.** Yoshino Y, et al. *Int J Gen Med*. 2021;14:2095-2099; **3.** Curran D, et al. *Hum Vaccin Immunother*. 2022;18:1-8; **4.** Osborne RH, et al. *J Patient Rep Outcomes*. 2023;7:51

ABBREVIATIONS

AUC: area under the curve; CSP: community screening program; ILI: influenza-like illness; LCI: laboratory-confirmed influenza; PRO: patient-reported outcome; QoL: quality of life; RiiQ: Respiratory Infection, Intensity, and Impact Questionnaire

FUNDING STATEMENT

This study was funded by Sanofi

CONFLICT OF INTEREST

ED and JB are employees of Sanofi (a company that develops and commercializes influenza vaccines) and may own stocks of the company. RO is the author of the Respiratory Infection, Intensity, and Impact Questionnaire, licensed by Sanofi. JE, JM, NS, MM, SS, SW, MC, LA, DB, FM, AVG, NW, MP, and CC received Sanofi grant to conduct their respective studies

ACKNOWLEDGEMENTS

Medical writing support was provided by Ghungroo Saraswat, PhD (Sanofi). The authors would also like to thank Anirban Sanyal, PhD for editorial support and poster coordination on behalf of Sanofi