Burden of COVID-19 on health-related quality of life in immunocompromised adult participants from the EPIC-IC trial

PCR 250

Scan the QR code to view an electronic version of this poster

Ruth Mokgokong,[1] Paul Cislo,[2] Elena Tudone,[3] Edward Weinstein,[2] Joseph C. Cappelleri[4]

[1] Pfizer Ltd, Walton Oaks, Tadworth, KT20 7NS, UK; [2] Pfizer Inc, New York, NY, US; [3] Pfizer s.r.l, Milan, Italy; [4] Pfizer Inc, Groton, Connecticut, US

Introduction

- Immunocompromised populations are disproportionately affected by infection with SARS-CoV-2,[1–4] experiencing slower viral clearance[5] and worse clinical outcomes than the general population.[3] Some immunocompromised subpopulations also experience a substantial decline in health-related quality of life (HRQoL) over 12 months after SARS-CoV-2 infection.[6]
- A 5-day, twice-daily regimen of nirmatrelvir-ritonavir (NMV/r) antiviral therapy is approved to treat adults with mild–moderate COVID-19 who are at high risk for developing severe disease.[7]
- However, the approval of NMV/r was based on the EPIC-HR trial (NCT04960202),[7,8] which tested NMV/r vs. placebo in a broad sample of high-risk participants — <1% of whom were immunocompromised.[8]
- The Phase 2 EPIC-IC trial (NCT05438602) was conducted to explore the efficacy of NMV/r in immunocompromised individuals with mild–moderate COVID-19, addressing whether the approved 5-day NMV/r regimen is adequate and whether a longer regimen would provide additional benefit in this population.[9]
  - Immunocompromised participants (N=156) were randomized 1:1:1 to receive the approved 5-day NMV/r regimen or extended 10-day or 15-day NMV/r regimens.[9] Participants were randomized from August 03, 2022, to July 17, 2023,[9] during which time the Omicron variant was dominant.[10]
  - Clinical data from EPIC-IC show that similar proportions of participants in the 5-day, 10-day, and 15-day NMV/r arms achieved the primary endpoint of sustained viral clearance.[9]

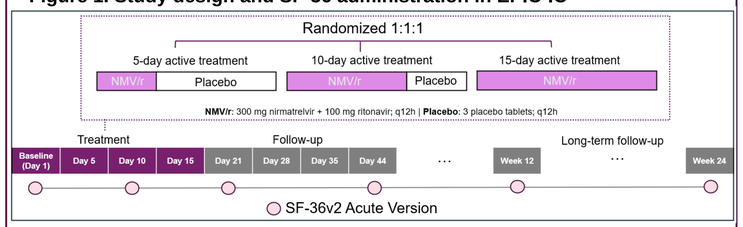
Aims

- In this study, we assessed HRQoL in immunocompromised adults from the EPIC-IC trial, comparing HRQoL across the 5-day, 10-day, and 15-day NMV/r arms and exploring differences in subpopulations with severe vs. non-severe immunocompromise.

Methods

- The 36-Item Short Form Health Survey version 2 – acute form (SF-36) comprises 36 questions that assess a participant's perceived functional health and wellbeing over a one-week recall period.[10]
- In EPIC-IC, immunocompromised participants aged ≥18 years at screening completed the SF-36 using an electronic study diary at Baseline and several post-Baseline visits (Figure 1).[9]

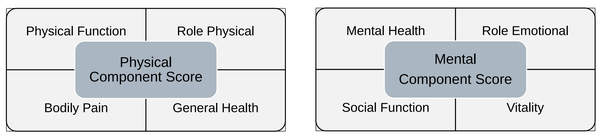
Figure 1. Study design and SF-36 administration in EPIC-IC



Abbreviations: NMV/r, nirmatrelvir-ritonavir; q12h, every 12 hours; SF-36, 36-Item Short Form Health Survey version 2 – acute form.

- SF-36 physical health component summary (PCS) scores and mental health component summary (MCS) scores were calculated from the relevant scale scores (Figure 2), following standard procedures.[11] Aggregated PCS and MCS scores were converted to norm-based T-scores (mean=50, standard definition [SD]=10). Missing data were not imputed.
- A mixed-effects model with repeated measures was implemented to assess the effect of treatment on PCS and MCS scores. Post hoc analyses were conducted to compare subgroups with severe vs. non-severe immunocompromise. Severe immunocompromise was defined to include participants with a hematologic malignancy or who had received chimeric antigen receptor T-cell therapy, B-cell–depleting therapies, or hematopoietic stem cell transplant.[9]

Figure 2. SF-36 Physical Component and Mental Component Scores



Abbreviations: SF-36, 36-Item Short Form Health Survey version 2 – acute form.

Participants

150 **immunocompromised adults with mild–moderate COVID-19**
(evaluable participants who received ≥1 dose of NMV/r)

52	48	50
5-day NMV/r	10-day NMV/r	15-day NMV/r

Demographic characteristics*

58 years median age | **54%** female

90% White | **65%** Hispanic or Latino

8 countries: **Spain** (33%), **US** (24%), **Slovakia** (16%), **Mexico** (15%)
Canada (7%), Brazil (3%), Australia (1%), and Bulgaria (1%)

Clinical characteristics*

87% vaccinated against SARS-CoV-2

37% with severe immunocompromise

Current infection at Baseline*

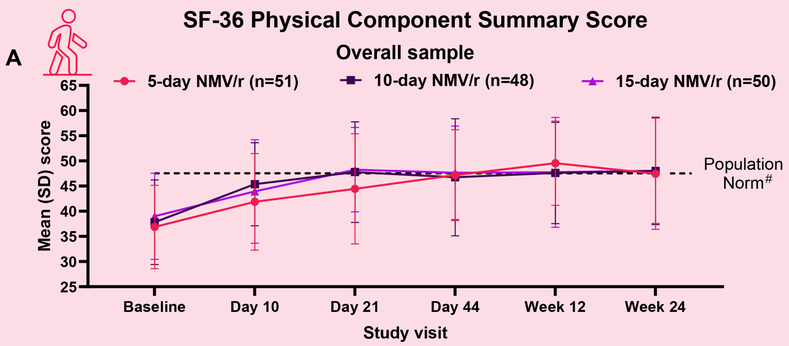
3 median days since first SARS-CoV-2 symptom

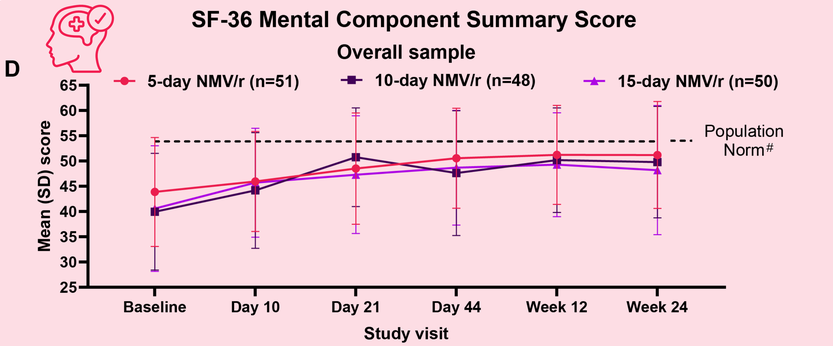
1 median day since initial SARS-CoV-2 diagnosis

*Participant information is based on the full randomized sample (N=156).

Results

Figure 3. SF-36 physical and mental component summary scores in immunocompromised participants treated with NMV/r





- Participants' mean PCS score at Baseline was significantly below the age-matched general population norm score# of 47.55[12] (Figure 3A), suggesting a severe impact of COVID-19 on participant's physical health.
- PCS scores increased up to Day 44 (~6.3 weeks) and remained stable through Week 24, falling within the range of age-specific general population scores (Figure 3A).
- Scores improved across follow-up in subgroups of participants with severe and non-severe immunocompromise (Figure 3B–C). However, participants with severe immunocompromise (Figure 3B) had numerically lower scores, on average, than those with non-severe immunocompromise (Figure 3C). In participants with severe immunocompromise, PCS was significantly lower at Day 10 and numerically lower at Day 21 in those treated with 5-day vs. 10-day NMV/r.

- Participants' mean MCS score at Baseline was substantially below the age-matched general population norm score# of 53.87[12] (Figure 3D), suggesting a severe impact of COVID-19 on participants' mental health.
- MCS scores increased up to Day 44 (~6.3 weeks) and remained stable through Week 24. At Week 24, scores were slightly below but within the range of age-specific general population scores (Figure 3D).
- Scores improved during follow-up in both subgroups of participants with severe and non-severe immunocompromise, but scores at Day 44 were numerically higher, on average, in those with non-severe immunocompromise (Figure 3E–F).

Mean score for US general population participants aged 55–64 in the National Health Measurement Study, calculated as the unweighted mean of male and female mean scores.[12]
Abbreviations: MCS, Mental Component Summary; PCS, Physical Component Summary; NMV/r, nirmatrelvir-ritonavir; SD, standard deviation; SF-36, 36-Item Short Form Survey version 2 acute form.

Conclusions

- COVID-19 had a substantial impact on physical and mental HRQoL in immunocompromised adults.
- Physical and mental HRQoL improved to general population norm ranges in participants treated with 5-day, 10-day, or 15-day NMV/r, with no significant longer-term decrements observed.
- Participants with severe immunocompromise trended towards worse physical and mental HRQoL than those with non-severe immunocompromise and may benefit from extended antiviral treatment.
- Larger studies are needed to further evaluate optimal dosing duration in severely immunocompromised populations.

Immunocompromised adults with mild–moderate COVID-19 who were treated with 5-day, 10-day, or 15-day NMV/r showed substantial improvements from baseline in physical and mental HRQoL.

References

1. Abbasi, J. *JAMA*. 2021;325(20):2033-5. **2.** Corey L, et al. *N Engl J Med*. 2021;385(6):562-6. **3.** Evans RA, et al. *Lancet Reg Health Eur*. 2023;35:100747. **4.** Antinori A, Bausch-Jurken M. *J Infect Dis*. 2023;228(Supplement_1):S4-S12. **5.** Li Y, et al. *Sci. Transl. Med*. 2024. **6.** Vergouwe M, et al. *Open Forum Infect Dis*. 2025; 12(2):ofaf055. **7.** PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets). Package insert. Pfizer; 2025. **8.** Hammond J, et al. *New Engl J Med*. 2022; 386(15):1397-1408. **9.** Weinstein E, et al. under review. **10.** Hodcroft, EB. https://covariants.org/. Accessed 09-Apr-2025. **11.** Ware JE, et al. QualityMetric, Incorporated; 2008. **12.** Maglinte GA, et al. *J Clin Epidemiol* 2012; 65(5):497-502.

Disclosures

This study was funded by Pfizer, Inc. (New York, NY, United States). RM, PC, ET, EW, and JCC are employees and minority shareholders of Pfizer, which funded this study. Medical writing was provided by Dr. Jacqueline Janowich Wasserott (PPD clinical research business of Thermo Fisher Scientific) in accordance with Good Publication Practice guidelines and was funded by Pfizer, Inc. (New York, NY, United States).

Poster presented at ISPOR 2025, Montreal, Canada; May 13–16, 2025.

Contact: Ruth Mokgokong - ruth.mokgokong@pfizer.com