

ORIGINAL ARTICLE

COVID-19 Quality of Life (CO-19_QoL) Questionnaire for Investigation of Health-Related Quality of Life of COVID-19 Patients in Selangor: A Translation and Validation Study

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ABSTRAK

Kesan Penyakit Koronavirus 2019 (COVID-19) terhadap kualiti hidup (QoL) masih sering dipandang remeh. Di Malaysia, Selangor merupakan antara negeri yang mencatatkan jumlah kes COVID-19 tertinggi. Instrumen ukuran generik lazimnya tidak memberi tumpuan khusus kepada kesan sesuatu penyakit, sebaliknya merangkumi dimensi QoL yang lebih luas seperti kesejahteraan mental, fungsi fizikal, fungsi sosial dan tahap kesakitan sebagai aspek yang boleh terjejas akibat pelbagai jenis penyakit. Oleh itu, instrumen khusus bagi sesuatu penyakit adalah lebih sensitif dalam mengenal pasti perubahan status klinikal atau membezakan pesakit berdasarkan tahap keterukan penyakit. Kajian ini bertujuan untuk menilai kesahan dan kebolehpercayaan versi Bahasa Melayu soal selidik COVID-19 Quality of Life (CO-19_QoL) bagi kegunaan dalam konteks Malaysia. Kajian keratan rentas ini melibatkan 330 orang pesakit dewasa COVID-19 di Selangor. Soal selidik ini telah diterjemahkan dan diadaptasi mengikut kesesuaian budaya berdasarkan garis panduan International Society for Pharmacoeconomics and Outcomes Research (ISPOR), yang merangkumi proses terjemahan hadapan (forward translation), terjemahan balik (backward translation), serta semakan oleh panel pakar bagi memastikan kesetaraan konsep dan linguistik dengan versi asal. Hasil analisis menunjukkan kesahan kandungan yang sangat baik ($Kappa > 0.8$), membuktikan bahawa setiap item adalah relevan dengan simptom COVID-19 dan diterjemahkan dengan tepat. Pekali konsistensi dalaman (Cronbach's alpha) adalah tinggi pada 0.919, manakala ujian ulangan (test-retest) menunjukkan kebolehpercayaan yang sangat baik ["Intraclass Correlation Coefficient" (ICC) = 0.896, $p < 0.001$]. Bagi kesahan konstruk, satu domain tunggal dengan 15 item didapati sah dan boleh dipercayai untuk mengukur QoL pesakit COVID-19. Instrumen CO-19_QoL ini mempunyai potensi besar sebagai alat pengukuran khusus penyakit yang mudah digunakan, diterima baik oleh pesakit dan memenuhi kriteria ketat dari segi kebolehpercayaan serta kesahan. Selain itu, penggunaan instrumen ini bersama ukuran QoL generik mampu memberikan analisis yang lebih menyeluruh terhadap HRQoL pesakit COVID-19 di Selangor.

Kata kunci: COVID-19; kualiti hidup; kualiti hidup berkaitan kesihatan; terjemahan; validasi

ABSTRACT

The impact of Coronavirus Disease 2019 (COVID-19) on quality of life (QoL) appears to be substantially underestimated. In Malaysia, Selangor consistently ranked among the states with the highest reported COVID-19 cases. Generic QoL instruments typically assessed broad domains such as mental well-being, physical function, social function and pain, which can all be impacted by any disease. Hence, disease-specific tools are more sensitive in detecting clinical changes or differentiating patients according to disease severity. This study aims to assess the validity and reliability of the Malay version of the COVID-19 Quality of Life (CO-19_QoL) questionnaire for the use in the Malaysian context. A cross-sectional study involving 330 adult COVID-19 patients was conducted in the state of Selangor. The questionnaire was translated and culturally adapted following International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines, including forward backward translation and expert review to ensure conceptual and linguistic equivalence. It demonstrated excellent content validity ($Kappa > 0.8$), confirming that the items are relevant to COVID-19 symptoms and accurately translated. Internal consistency was high (Cronbach's $\alpha = 0.919$), while test-retest showed excellent reliability [Intraclass Correlation Coefficient (ICC) = 0.896, $p < 0.001$]. Construct validity analyses identified a single 15-item domain to be reliable and valid to measure the QoL of COVID-19 patients. The CO-19_QoL is a promising new instrument for measuring disease-specific QoL. It is easy to use, acceptable to patients, and meets rigorous reliability and validity standards. Also, CO-19_QoL enables a more thorough evaluation of HRQoL among COVID-19 patients in Selangor when used together with a generic QoL instrument.

Keywords: COVID-19; health-related quality of life; quality of life; translation; validation

INTRODUCTION

The Coronavirus Disease 2019 (COVID-19) pandemic has caused an unparalleled global health crisis, with over 777.4 million confirmed cases and more than 7 million deaths reported globally as of December 31st, 2024 (World Health Organisation 2024). Along with many other countries, Malaysia has been heavily impacted, with more than 5.23 million cases and over 37, 000 deaths, affecting nearly one in seven Malaysians at the height of the pandemic (World Health Organisation 2020).

While initial strategies focused on minimising the transmission of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and managing acutely ill patients, attention has increasingly turned to the long-term health of survivors (Sharma et al. 2020). It is now evident that COVID-19 extends beyond acute infection, affecting not only physical health but also mental, cognitive and social well-being of patients. These impacts are observed in both severe and mild cases of COVID-19 (Hui et al. 2005; Simpson & Robinson 2020). This health status impairment potentially reduces the health-related quality

of life (HRQoL) and health state utility scores of COVID-19 patients (Barani et al. 2022)

HRQoL has emerged as an important dimension for understanding the broader burden of COVID-19. HRQoL is defined as a multidimensional concept, that includes physical, psychological and social well-being, and is best assessed through patient-reported outcome measures (PROMs) (Bjordal & Kaasa 1992). HRQoL can vary throughout a patient's life and is influenced by a number of factors, such as disease severity, responses to treatment, existing comorbidities, as well as sociodemographic and socioeconomic status (Chen et al. 2020).

The impact of COVID-19 on HRQoL appears to be highly underestimated (Poudel et al. 2021). Beyond its direct health effects, the COVID-19 pandemic has generated profound socioeconomic consequences. Lockdowns and movement restrictions, while necessary for infection control, disrupted economies worldwide, disproportionately affecting vulnerable groups and widening inequalities as reported by Valentino-DeVries et al. (2020) and Bonaccorsi et al. (2020). In Malaysia,

prolonged movement control orders (MCOs) led to job losses, financial hardship and long-term impacts on family livelihoods (Lim 2020). These challenges in turn negatively influenced health outcomes, contributing to reduced HRQoL and increased psychological distress. In response, the Malaysian government pledged significant financial resources to support healthcare delivery and mitigate socioeconomic damage (Karim 2020; Ministry of Finance 2020). This resource allocation highlights the need for evidence-based assessments of HRQoL to guide policy decisions, particularly in evaluating the cost-effectiveness of treatments, vaccines and rehabilitation services (Payakachat et al. 2015).

Patient-reported outcome measures (PROMs), such as the EuroQol five-dimensional (EQ-5D) instrument, have been instrumental in assessing HRQoL globally (EuroQol 2019). However, while generic HRQoL tools like EQ-5D are valuable, they do not focus on the specific impacts of diseases like COVID-19. Combining generic and disease-specific HRQoL measures can provide a comprehensive analysis of the health impacts on COVID-19 patients in Malaysia (Jandhyala 2021). Given the limitations of generic instruments, disease-specific measures are urgently needed to evaluate the actual impact of COVID-19 on patients' lives. Although few such tools exist globally at the time of this study, the COVID-19 quality of life (CO-19_QoL) questionnaire represents one of the earliest efforts to develop a COVID-19-specific PROM. Its focus on respiratory symptoms and post-acute manifestations making it a suitable and contextually relevant instrument for this study. This is because it was initially developed to evaluate HRQoL associated with community acquired pneumonia-related symptoms and covers 18 symptoms which are also commonly present in COVID-19 patients (Bhatraju et al. 2020; Chan et al. 2020; Keller et al. 2020). One of the most important complications seen in COVID-19 patients is pneumonia, therefore it would stand a reason that this questionnaire should be able to reflect the HRQoL of COVID-19 patients (Kim et al. 2020; Wang et al. 2020; Yang et al. 2020). However, the

CO-19_QoL tool has yet to be validated in the Malaysian context, where cultural and linguistic adaptation is necessary to ensure its reliability and applicability.

Therefore, this study focused on translating and validating the Malay version of the CO-19_QoL questionnaire for use among COVID-19 patients in Selangor, Malaysia. Establishing a reliable disease-specific PROM allows a more accurate assessment of HRQoL, supports clinical management, enables robust health economic evaluations and informs future pandemic preparedness and response.

MATERIALS AND METHODS

Participants and Study Design

This study was part of a larger study conducted under the COVID-19 Epidemiological Analysis and Strategies (CEASe) research project funded by Malaysia's Ministry of Science, Technology & Innovation (MOSTI). COVID-19 patients were recruited from the state of Selangor between 1st March 2021 to 30th June 2021, when MCOs and active case surges were still ongoing. Selangor was selected as the study setting because it consistently recorded among the highest COVID-19 caseloads in Malaysia, had a large and demographically diverse population that closely reflected the nation's ethnic distribution, and therefore provided a representative setting for HRQoL assessment (Department of Statistics Malaysia 2020b). The participants must be able to communicate in Malay to be included in the study, be above 18 years old and was infected with SARS-CoV-2 within the last three months. Participants were excluded if they had cognitive impairment, were illiterate and/or having mental illness. Data was collected via an online Google Form and telephone interviews by trained interviewers in compliance with social distancing measures in Malaysia. The translation, pilot testing and main validation were conducted sequentially. The main validation began promptly after translation and pilot testing.

Sample Size and Sampling Method

For confirmatory factor analysis (CFA), the recommended minimum sample size was 10 subjects per item (10:1) (Arifin 2013). Given that there were 15 items in the adapted CO-19_QoL questionnaire, a minimum of 150 participants were required for the exploratory factor analysis (EFA) and CFA, respectively, amounting to a total of 300 participants. Participants were selected using simple random sampling from the Ministry of Health's COVID-19 line-listing, which was a continuously updated registry of confirmed COVID-19 cases maintained by the National Crisis Preparedness and Response Centre (CPRC). The random selection was performed using a random number generator in Microsoft Excel, Version 16.111.2 (Microsoft Corporation, Redmond, WA, USA). A separate convenience sample of 30 COVID-19 patients aged 24 to 78 years old years (mean 49.35 ± 11.69 years) was selected to from the same line listing of COVID-19 patients to participate in the test-retest reliability analysis. Ethics approval was obtained from the Ministry of Health's Medical Research and Ethics Committee (MREC) (NMRR-20-865-54823 (IIR)) and all participants gave their informed consent.

CO-19_QoL

The original English version of the questionnaire comprised 18 items, asking participants to recall the extent to which community-acquired pneumonia symptoms had bothered them in the preceding 24 hours. Responses were recorded on a six-point Likert scale, ranging from 0 ("no symptom") to 5 ("extremely bothersome"), with intermediate points indicating increasing levels of discomfort (1-not at all, 2 -a little, 3-moderately, 4-quite a bit). The total score was obtained by summing all 18 items, yielding a possible range from 0 to 90, with higher scores reflecting poorer outcomes or greater symptom burden. The instrument's reliability and validity had been well established, and it had been translated into 12 other languages, including French, Spanish, Italian, Portuguese, Swedish, Norwegian, German

(for use in Germany and Switzerland), Polish, Hungarian, Hebrew, Afrikaans (for use in South Africa) and Russian (for use in Israel) (Lamping et al. 2002).

After obtaining permission from the authors, the questionnaire was first translated into Malay by a native speaker and then back into English by another, following the guideline recommended by the International Society for Pharmacoeconomics and Outcomes Research's (ISPOR's) Task Force for Translation and Cultural Adaptation, to ensure conceptual and linguistic equivalence with the original version. Only one item in the questionnaire had to undergo minor modification after the back translation. The Malay equivalent of coughing was changed from 'batuk-batuk' to 'batuk' after expert panel review. It is more common for Malaysians to describe coughing as 'batuk' instead of 'batuk-batuk' to their health practitioners. Hence, 'batuk' was chosen as the most adequate equivalent of 'coughing' to describe one of the most common symptoms of COVID-19. Another commonly reported COVID-19 symptom, 'anosmia' was included to increase content validity. The Malay equivalent of anosmia was 'hilang deria bau', underwent the same cognitive debriefing procedures as the other translated items, confirming that it was easily understood and culturally appropriate. The translation was then adjusted, and the Malay version of the initial 19-item COVID-19 symptoms questionnaire was pretested.

Data Collection

For the validity study, all eligible patients were contacted by phone by trained interviewers from the research team within three months of COVID-19 infection. Their phone numbers were obtained from the line-listing of COVID-19 patients kept by the national CPRC, Ministry of Health Malaysia, Putrajaya. The study participants were allowed sufficient time to consider their participation in the study. Once they had agreed to participate (after reading the patient information sheet and consent form), a Google Form (Google LLC, Mountain View, CA,

USA) link to the questionnaire was then sent via WhatsApp (WhatsApp LLC, Menlo Park, CA, USA) or Telegram (Telegram Messenger LLP, Dubai, United Arab Emirates) application. This was done to be in compliance with social distancing measures in Malaysia at the time of the movement control order. If the respondent did not have either WhatsApp or Telegram, the questionnaire was read to them. Data confidentiality was maintained by ensuring that only the trained interviewers from the research team had access to the Google Forms account in which all responses were stored. The account was password-protected and restricted to the research team only. WhatsApp and Telegram were used solely as delivery channels to send the questionnaire link through private, individual messages, and no study data were stored on these platforms.

In the reliability study, a separate set of 30 participants were contacted by phone. They were asked to complete a second set of the questionnaire again two weeks later. This interval was chosen because the questions referred to COVID-19 symptoms at a specific point in time, and recall accuracy tends to decline over time.

Statistical Analysis

A total of 300 completed questionnaires were included in the analysis, and no missing data were observed in the test-retest reliability sample. Data management and analyses were conducted using Statistical Package for the Social Science (SPSS), version 29 (IBM, Armonk, NY, USA).

This study assessed the psychometric characteristics of the Malay version of the questionnaire. Content validity was evaluated by an expert committee using the Item-Content Validity Index (I-CVI). Items with I-CVI values ≥ 0.79 were considered relevant, those scoring between 0.70 and 0.79 required revision, and items scoring < 0.70 were eliminated. The final selection of the 15 items was based not only on the I-CVI results but also on expert consensus to ensure both statistical adequacy and clinical relevance (Tsang et al. 2017).

Internal consistency and test-retest reliability were examined using Cronbach's alpha and the intraclass correlation coefficient (ICC), respectively. Newly developed measures can be accepted if they had a Cronbach's alpha of > 0.5 , otherwise 0.7 should be used as the threshold (Koo & Li 2016). The ICC values were classified as poor (< 0.40), moderate (0.40–0.75), and excellent (> 0.75) to reflect different levels of reliability (Arifin & Yusoff 2016).

Construct validity was examined using EFA and CFA. EFA was conducted with principal component analysis and varimax rotation. Sampling adequacy was measured using Kaiser-Meyer-Olkin (KMO), which values varied from 0 to 1. The KMO values between 0.8 to 1.0 indicated that the sampling was adequate, whereby values between 0.7 to 0.79 were middling and values between 0.6 to 0.69 were mediocre. KMO values less than 0.6 indicated inadequate sampling requiring remedial action (Hair et al. 2019). Factor retention was determined based on eigenvalues > 1.0 , scree plot inspection and parallel analysis (Patil et al. 2017).

CFA was conducted using partial least squares structural equation modelling (PLS-SEM) with SmartPLS, version 4 software (SmartPLS GmbH, Oststeinbek, Germany). PLS-SEM was chosen because this study involved the adaptation and validation of a newly translated instrument, for which the primary goal was to establish the measurement model rather than to test a well-established theoretical structure (Hair et al. 2019). Factor loadings > 0.50 , composite reliability > 0.70 , average variance extracted (AVE) > 0.50 , and Heterotrait-Monotrait ratio (HTMT) < 0.90 were considered evidence of good construct validity and reliability (Hair et al. 2012; Henseler et al. 2015).

RESULTS

The pilot and main validation studies were conducted on distinctly different participants. Thirty participants were recruited for the pilot study and 300 participants for the main validation study. All participants had access to

either WhatsApp or Telegram and completed the questionnaire independently through the online link. Consequently, no interviewer-administered responses were required, reducing the possibility of interviewer-induced bias. In Table 1, the sociodemographic characteristics of this study were shown. The questionnaire took about five minutes to complete.

Translation and Cross-Cultural Adaptation

Out of the 18 items in the questionnaire, only one item underwent minor modification after the back translation. The Malay equivalent of coughing was changed from ‘batuk-batuk’ to ‘batuk’. It was understood that ‘batuk’ were more commonly used by Malaysians to describe their symptom to their health practitioners. A team of six experts evaluated the 18 items original questionnaire and two of them proposed the inclusion of an additional question to evaluate the presence of anosmia, resulting in a total of 19 items in the new questionnaire.

Content validity as assessed by the I-CVI showed that four items had values of less than 0.75, indicating lower relevance to COVID-19 symptoms, and were subsequently removed. These items were ‘batuk berkahak’, ‘batuk

berdarah’, ‘kurang selera makan’ and ‘sukar untuk berfikir’. The remaining items achieved I-CVI 0.79 and Kappa values > 0.4, indicating moderate to excellent inter-rater agreement, yielding a 15-item questionnaire.

Internal Consistency and Test-retest Reliability

A preliminary 15-item version of the questionnaire was pilot tested among 30 patients from the state of Selangor. Internal consistency (Cronbach’s alpha) for the 15 items questionnaire was 0.919. The mean score derived from the Community Acquired Pneumonia Symptom 15 questionnaire for the first and second administrations were 20.0 ± 15.57 and 16.4 ± 15.74 respectively. The test-retest reliability was high and showed good reliability (ICC = 0.896).

Construct Validity

EFA and CFA were conducted to assess the underlying factor structure. Prior to performing EFA, the Kaiser–Meyer–Olkin (KMO) measure and Bartlett’s test of sphericity were applied to verify sampling adequacy. The overall KMO value was 0.88 with all individual KMO values exceeding 0.8, which was considered meritorious according to Kaiser (1974). Based on Kaiser’s criterion, four factors with eigenvalues > 1 were identified, cumulatively explaining 71.71% of the total variance, as presented in Table 2. Factor 3 and 4 had an eigenvalue of close to one, declaring it not to be meaningful to retain. The two factors solution explained more than 50% (57.80%) of the total variance.

The scree plot supported the retention of the first two factors, as illustrated in Figure 1. The factor loadings following varimax rotation for these two factors were presented in Table 3. Eigenvalues obtained from parallel analysis compared to factor analysis also reaffirmed the retention of two factors as factor three onwards were dropped from the analysis. Taken together, the scree plot, eigenvalue comparison and poor conceptual interpretability supported the

TABLE 1: Sociodemographic characteristics of participants included in the CO-19_QoL validation study

Sociodemographic Characteristics	n	%
Total	300	100.0
Gender		
Male	172	57.3
Female	128	42.7
Age		
< 60 years old	219	73.0
≥ 60 years old	81	27.0
Ethnicity		
Malay	195	65.0
Chinese	60	20.0
Indian	20	6.7
Bumiputera Sabah & Sarawak	25	8.3

TABLE 2: Eigenvalues and percentage of variance explained from exploratory factor analysis before rotation

Component	Extraction Sums of Squared Loadings		
	Total	% of Variance	% Cumulative Variance
1	7.34	48.96	48.96
2	1.33	8.85	57.80*
3	1.08	7.20	65.0
4	1.01	6.71	71.71

*Percentage of cumulative variance more than 50% = acceptable

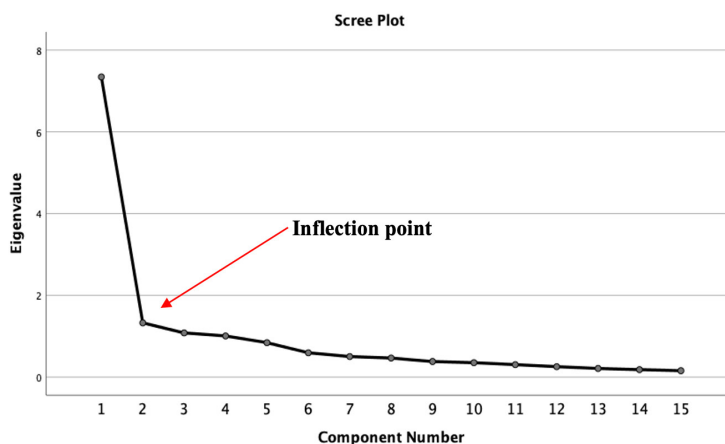


FIGURE 1: Scree plot for 15-item CO-19_QoL questionnaire

TABLE 3: Rotated factor loadings from the exploratory factor analysis (PCA with varimax rotation) for the two-component solution

Items	Rotated Component Coefficients		
	Component 1	Component 2	Communalities
Q1	0.622	0.402	0.548
Q2	[†] 0.844	0.084	0.720
Q3	[†] 0.806	0.181	0.683
Q4	0.358	0.576	0.460
Q5	0.571	0.525	0.601
Q6	0.333	[†] 0.759	0.687
Q7	0.226	[†] 0.804	0.697
Q8	0.184	0.619	0.417
Q9	0.335	0.503	0.365
Q10	0.455	0.428	0.390
Q11	0.533	0.588	0.595
Q12	0.460	0.692	0.690
Q13	[†] 0.773	0.289	0.681
Q14	[†] 0.733	0.357	0.665
Q15	0.034	0.686	0.471

[†]Major loadings are bolded.

Extraction method: Principal Component Analysis; Rotation method: Varimax with Kaiser normalisation; Component coefficients were set to 0.3.

decision to retain only the first two factors. Factor loadings from both factors were fair to excellent (0.503 – 0.844) except for Q7 (0.226) and Q8 (0.184). “Loya” and “Muntah-muntah” were retained due to its clinical significance.

The two component, 15-item questionnaire instrument then underwent CFA to confirm that a single factor was the most parsimonious model for the 15-item questionnaire. The two domains (physical & mental health) were considered reflective as shown in Figure 2. Table 4 showed the domains had a factor loading exceeding 0.50 indicating that the construct was reliable. The physical health domain had an average variant extracted (AVE) value of 0.469 while the mental health domain had an AVE value of 0.712. Composite reliability (CR) value for physical and mental health domains was 0.902 and 0.797 respectively which had good internal consistency. The Cronbach’s Alpha value was above 0.7 for all domains as shown in Table 5. The HTMT ratio (1.018) and cross loadings on

each of the 15 items indicated poor discriminant validity and high multicollinearity. Therefore, the domains were merged into a single construct and renamed as 15-item CO-19_QoL survey. Overall, no notable floor or ceiling effects was observed in this study.

DISCUSSION

The National Institute for Health and Care Excellence (NICE) currently recommends the EQ-5D-5L questionnaire for measuring HRQoL, although this instrument has been widely criticised for several reasons (Turner et al. 2013). The main challenge with using generic measures such as EQ-5D-5L and similarly, other generic tools available in Malay such as the World Health Organization Quality of Life - Brief Version (WHOQOL-BREF), is their limited sensitivity in detecting clinically meaningful changes in disease-specific symptom burden. In the context of COVID-19, these limitations are particularly

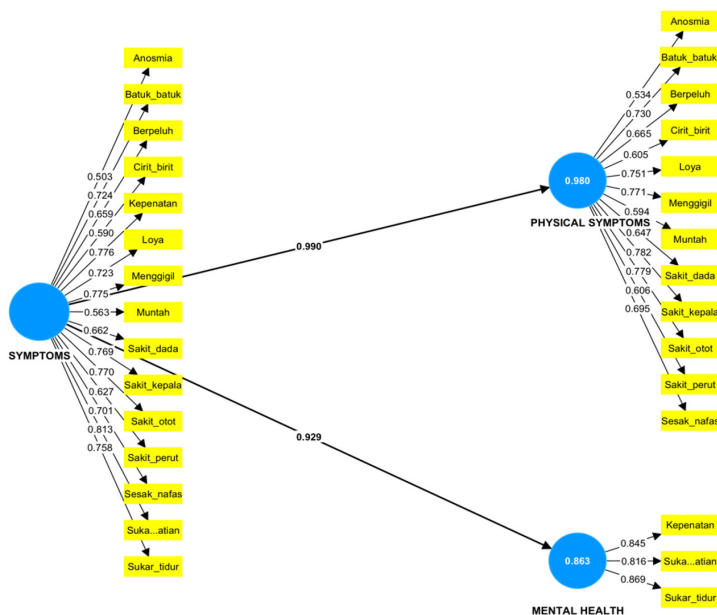


FIGURE 2: Confirmatory factor analysis model using partial least square-structural equation modelling (PLSSEM) approach for the CO-19_QoL Questionnaire

TABLE 4: Confirmatory Factor Analysis loadings for the physical and mental health domains of the 15-Item CO-19_QoL questionnaire

Domain	Items	Physical Health Domain	Mental Health Domain
Physical Health	Batuk batuk (Cough)	0.730	
	Sakit dada (Chest pain)	0.647	
	Sesak nafas (Shortness of breath)	0.695	
	Berpeluh (Sweating)	0.665	
	Menggigil (Shivering)	0.771	
	Sakit kepala (Headache)	0.782	
	Loya (Nausea)	0.751	
	Muntah (Vomiting)	0.594	
	Cirit birit (Diarrhoea)	0.605	
	Sakit perut (Stomach pain)	0.606	
	Sakit otot (Muscle pain)	0.779	
	Anosmia	0.534	
Mental Health	Sukar menumpukan perhatian (Concentration problems)		0.816
	Sukar untuk tidur (Sleeping problems)		0.869
	Kepenatan (Tiredness/fatigue)		0.845

TABLE 5: Measurement model assessment of the physical and mental health domains from confirmatory factor analysis

Domain	Number of items	Cronbach's Alpha	Composite Reliability	Average Variance Extracted
Physical Health	12	0.895	0.902	0.469
Mental Health	3	0.797	0.797	0.712

important, as the disease presents with a wide spectrum of acute respiratory and systemic manifestations that generic HRQoL measures may not adequately capture. This highlights the need for a disease-specific instrument in Malay capable of assessing symptom severity, especially during the early and acute phases of COVID-19.

When this study was designed in 2020, no validated COVID-19-specific HRQoL instrument was yet available. Most early tools were symptom checklists without established psychometric properties. Several respiratory-specific questionnaires such as the American Thoracic Society (ATS) Dyspnoea Scale, the Horsley Respiratory Symptoms Questionnaire, and the St. George's Respiratory Questionnaire (SGRQ) were considered at the time; however, these instruments were developed for chronic respiratory conditions like chronic obstructive

pulmonary disease, asthma, or chronic bronchitis and focused mainly on long-term functional impairment. As such, they did not adequately reflect the acute pneumonia-like symptom burden characteristic of early COVID-19. In contrast, the CAP-Sym 18 provided a validated, responsive and clinically relevant measure originally developed for community-acquired pneumonia, which closely resembled the respiratory manifestations observed in COVID-19 during the early waves. Its robust psychometric foundation and applicability across diverse settings made it the most appropriate instrument for adaptation into Malay and subsequent validation as the CO-19_QoL.

This study offers preliminary evidence supporting the reliability and cross-cultural validity of the Malay CO-19_QoL questionnaire, which was adapted from the CAP-Sym 18

questionnaire to assess disease-specific quality of life among patients with COVID-19. A key strength of this study lies in the validation process of the Malay version of CAP-Sym, which extended beyond simple translation to ensure semantic, linguistic and contextual equivalence. Furthermore, the instrument was validated using a cohort representative of the target population for which it was intended. The Malay version of this instrument has been shown to be potentially useful among Malaysian population.

The Malay CO-19_QoL demonstrated excellent internal consistency with a Cronbach's alpha of 0.92, exceeding the commonly accepted threshold for new instruments ($\alpha > 0.70$) and surpassing the reliability reported for the original version of the CAP-Sym 18 ($\alpha = 0.82$). The test-retest reliability was high with an ICC value of 0.90, comparable to the original version's value of 0.96, indicating strong temporal stability (Lamping et al. 2002). These findings confirm that the adapted questionnaire consistently measures the intended construct across time.

Construct validity is essential for evaluating latent constructs that cannot be directly observed or measured, such as HRQoL (Tavakol & Wetzell 2020). The CO-19_QoL questionnaire seeks to capture these unobservable dimensions by assessing patients' self-reported physical, psychological and social symptoms associated with COVID-19. In this study, construct validity assessment through factor analysis indicated that while two domains (physical and mental health) were initially identified, poor discriminant validity and high multicollinearity suggested that these domains were not statistically distinct, as measured by the HTMT ratio. Therefore, the domains were merged into a single construct. This unidimensional structure also provides a more conceptually accurate representation of COVID-19 symptom burden, given that physical and psychological manifestations are highly interdependent in this disease (Taquet et al. 2021). This finding was similar to the original study conducted by Lamping et al. (2002), where only a single construct was found to best represent the measured symptoms.

While the factor structure ultimately converged into a single construct, the performance of individual items within this construct provided additional insights. All retained items met the recommended factor loading threshold (> 0.50) with the exception of "loya" (nausea) and "muntah-muntah" (vomiting). Although these items demonstrated lower loadings, they were preserved due to their clinical significance in COVID-19. According to Amdal et al. (2021) gastrointestinal symptoms were reported in patients with COVID-19, specifically, nausea and vomiting were the second most reported gastrointestinal symptoms after diarrhoea. Retaining these items, despite weaker statistical performance, ensures that the questionnaire remains clinically comprehensive and sensitive to the full range of symptoms experienced by patients. This decision strengthens the tool's content validity by acknowledging symptom domains that may be less common but are nonetheless impactful to patients lived experiences and quality of life.

The adapted CO-19_QoL questionnaire offers both psychometric and practical advantages. Psychometrically, all item-total correlations (ITC) met the minimum threshold, whereas one item in the original CAP-Sym-18 failed to do so. Practically, the shorter 15-item format reduces respondent burden while retaining comprehensive coverage of relevant symptoms (Rolstad et al. 2011).

The validated Malay CO-19_QoL questionnaire has the potential to play a pivotal role in both clinical practice and public health surveillance in Malaysia. The CO-19_QoL, just like its parent instrument, the CAP-Sym, is intended to function as a continuous measure of symptom burden. In practice, higher scores indicate greater symptom severity, and changes in scores over time may be more informative than absolute values. Clinicians may therefore use the CO-19_QoL to monitor symptom trajectories, identify patients who show minimal improvement, or flag those with persistently elevated scores who may require further evaluation or rehabilitation.

In clinical practice, the CO-19_QoL can

support outpatient follow-up by monitoring residual symptoms, recognising individuals at risk of prolonged recovery or long COVID, and informing referral decisions for rehabilitation or specialist care. The instrument also has potential applications in public health surveillance, where it could be integrated into existing digital reporting systems such as MySejahtera or district health office monitoring platforms to generate population-level insights on post-COVID functional outcomes. Incorporating symptom-specific HRQoL data into routine monitoring would enhance the Ministry of Health's capacity to detect emerging trends in post-acute sequelae, optimise the allocation of rehabilitation services and evaluate the long-term impact of COVID-19 interventions. The study findings can also be submitted to the Ministry of Health for their consideration, particularly for integration into future follow-up protocols or pandemic evaluation frameworks. The CO-19_QoL may contribute valuable symptom-specific HRQoL data to support national planning and recovery assessments.

By providing a disease-specific assessment of HRQoL, it offers clinicians a sensitive tool to monitor recovery trajectories, identify residual symptom burdens and tailor rehabilitation strategies for COVID-19 patients, particularly those with lingering symptoms or long COVID manifestations. From a policy-making perspective, the tool enables health planners to generate patient-centred data critical for evaluating post-COVID care programmes, cost-effectiveness of interventions and resource prioritisation. In the Malaysian context, where COVID-19 has disproportionately affected economically vulnerable and ethnically diverse populations, the availability of a culturally adapted PROM empowers more equitable care delivery by ensuring that patient-reported outcomes are contextually meaningful as well as locally actionable (Lim et al. 2023).

Unlike widely used generic instruments such as EQ-5D or SF-36, the CO-19_QoL was originally designed to reflect the symptomatology of respiratory illnesses like community-acquired

pneumonia and subsequently adapted for COVID-19 contexts. Its focus on symptom bothersomeness, rather than functional limitation or broad well-being, enables it to detect nuanced changes in symptom severity and patient burden—features often underrepresented in generic tools (Chen et al. 2020; Jandhyala 2021). The translation and cultural adaptation process undertaken in this study followed ISPOR guidelines, ensuring semantic equivalence while also accommodating local linguistic norms, as demonstrated in the modification of “batuk-batuk” to “batuk.” This attention to cultural specificity enhances the tool's face validity and acceptability, ensuring that items resonate with Malaysian patients and reflect their symptom expression more accurately. Such adaptation is crucial in multicultural settings where language and cultural nuances significantly shape health communication and patient experience (Wild et al. 2005).

There are a few limitations in this study. It is possible that the psychometric properties of the CO-19_QoL questionnaire observed in this sample may not fully represent the broader Malaysian population. This study was conducted solely in Selangor, and while it is the most populous and demographically diverse state in Malaysia, Selangor comprises a multi-ethnic population including Malays, Chinese, Indians and other minority groups distributed across both urban and semi-urban settings. It also demonstrates a wide socioeconomic spectrum, ranging from affluent urban centres to lower-income communities, making it a representative site for studying the varied health-related quality of life (HRQoL) outcomes among COVID-19 patients in Malaysia (Department of Statistics Malaysia 2020a).

However, the exclusion of respondents from other states may limit the generalisability of the findings. Cultural and linguistic variations across states could influence how certain items are interpreted. Moreover, the evaluation was also cross-sectional, without longitudinal follow-up, thus precluding assessment of responsiveness or changes in HRQoL over time. Future

validation efforts should aim to include a more diverse demographic sample and incorporate longitudinal assessments to strengthen the applicability and clinical utility of the CO-19_QoL across different contexts.

Another limitation is that participants for test-retest were recruited through convenience sampling, which may introduce selection bias and limit the representativeness of this subgroup. Convenience sampling was chosen because test-retest was not so easy to sample randomly as time was a constraint during the data collection period.

CONCLUSION

This study established that the Malay version of the CO-19_QoL questionnaire as a reliable and valid disease-specific patient-reported outcome measure suitable for use in Malaysia. The instrument exhibited strong psychometric properties, including excellent internal consistency, high test-retest reliability and acceptable construct validity among COVID-19 patients in Selangor. These findings confirm its suitability for assessing the health-related quality of life (HRQoL) of individuals affected by COVID-19 within the Malaysian healthcare context.

The validated CO-19_QoL addresses a critical need for culturally adapted tools capable of capturing the specific physical and psychological effects of COVID-19, beyond the scope of generic measures. Its application can enhance clinical management, guide rehabilitation and long COVID care, and support health policy planning and resource allocation. Future research should examine the longitudinal responsiveness of this tool across different time points, disease severities and geographic regions in Malaysia. Establishing a minimal clinically important difference would further strengthen its interpretability and clinical applicability. Cross-cultural adaptations of the CO-19_QoL in other languages may also enhance regional and international comparisons, as well as support broader efforts toward equitable and patient-informed pandemic recovery strategies.

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REFERENCES

- Amdal, C.D., Pe, M., Falk, R.S., Piccinin, C., Bottomley, A., Arraras, J.L., Darlington, A.S., Hofso, K., Holzner, B., Jørgensen, N.M.H. 2021. Health-related quality of life issues, including symptoms, in patients with active COVID-19 or post COVID-19; A systematic literature review. *Qual Life Res* 30(12): 3367-81. <https://doi.org/10.1007/s11136-021-02908-z>
- Arifin, W.N. 2013. Sample size for questionnaire validation studies. https://wnarifin.github.io/workshop/qvw2017/Sample%20size%20for%20questionnaire%20validation%20studies%20v1_1.pdf [Accessed on 12th April 2024]
- Arifin, W.N., Yusoff, M.S.B. 2016. Confirmatory factor analysis of the Universiti Sains Malaysia emotional quotient inventory among medical students in Malaysia. *SAGE Open* 6(2): 2158244016650240. <https://doi.org/10.1177/2158244016650240>
- Barani, S., Bhatnagar, T., Natarajan, M., Gayathri, K., Sonekar, H.B., Sasidharan, A., Selvavinayagam, T., Bagepally, B.S. 2022. Health-related quality of life among COVID-19 individuals: A cross-sectional study in Tamil Nadu, India. *Clin Epidemiol Global Health* 13: 100943. <https://doi.org/10.1016/j.cegh.2021.100943>
- Bhatraju, P.K., Ghassemieh, B.J., Nichols, M., Kim, R., Jerome, K.R., Nalla, A.K., Greninger, A.L., Pipavath, S., Wurfel, M.M., Evans, L. 2020. Covid-19 in critically ill patients in the Seattle region-case series. *New England J Med* 382(21): 2012-22. <https://doi.org/10.1056/NEJMoa2004500>
- Bjoridal, K., Kaasa, S. 1992. Psychometric validation of the EORTC Core Quality of Life Questionnaire,

- 30-item version and a diagnosis-specific module for head and neck cancer patients. *Acta Oncologica* 31(3): 311-20. <https://doi.org/10.3109/02841869209108178>
- Bonaccorsi, G., Pierri, F., Cinelli, M., Flori, A., Galeazzi, A., Porcelli, F., Schmidt, A.L., Valensise, C.M., Scala, A., Quattrocioni, W. 2020. Economic and social consequences of human mobility restrictions under COVID-19. *Proc Natl Acad Sci USA* 117(27): 15530-5. <https://doi.org/10.1073/pnas.2007658117>
- Chan, J.F.W., Yuan, S., Kok, K.H., To, K. K.W., Chu, H., Yang, J., Xing, F., Liu, J., Yip, C.C.Y., Poon, R.W.S. 2020. A familial cluster of pneumonia associated with the 2019 novel coronavirus indicating person-to-person transmission: A study of a family cluster. *Lancet* 395(10223): 514-23. [https://doi.org/10.1016/S0140-6736\(20\)30154-9](https://doi.org/10.1016/S0140-6736(20)30154-9)
- Chen, K.Y., Li, T., Gong, F., Zhang, J.S., Li, X.K. 2020. Predictors of health-related quality of life and influencing factors for COVID-19 patients, a follow-up at one month. *Front Psychiatry* 11: 668. <https://doi.org/10.3389/fpsy.2020.00668>
- Department of Statistics Malaysia. 2020a. Average Incidence Rate of COVID-19 Cases per 100,000 Population October 13-26 2020. <https://www.dosm.gov.my/portal-main/article/covid-19> [Accessed on 19 October 2024]
- Department of Statistics, Malaysia. 2020b. Population by ethnic group, SELANGOR, 2020. <https://pqj.stats.gov.my/searchBI.php?tahun=2020&kodD ata=2&kodJadual=1&kodCiri=7&kodNegeri=10> [Accessed on 2 April 2024]
- EuroQol, R.F. 2019. EQ-5D-5L User Guide. <https://euroqol.org/information-and-support/documentation/user-guides/> [Accessed on 3 May 2024]
- Hair, J.F., Risher, J.J., Sarstedt, M., Ringle, C.M. 2019. When to use and how to report the results of PLS-SEM. *Eur Bus Rev* 31(1): 2-24. <https://doi.org/https://doi.org/10.1108/EBR-11-2018-0203>
- Hair, J.F., Sarstedt, M., Ringle, C.M., Mena, J.A. 2012. An assessment of the use of partial least squares structural equation modeling in marketing research. *J Acad Marketing Sci* 40(3): 414-33. <https://doi.org/10.1007/s11747-011-0261-6>
- Henseler, J., Ringle, C.M., Sarstedt, M. 2015. A new criterion for assessing discriminant validity in variance-based structural equation modeling. *J Acad Marketing Sci* 43(1): 115-35. <https://doi.org/10.1007/s11747-014-0403-8>
- Hui, D., Joynt, G., Wong, K. T., Gomersall, C., Li, T., Antonio, G., Ko, F., Chan, M., Chan, D., Tong, M. 2005. Impact of severe acute respiratory syndrome (SARS) on pulmonary function, functional capacity and quality of life in a cohort of survivors. *Thorax* 60(5): 401-9. <https://doi.org/10.1136/thx.2004.03020>
- Jandhyala, R. 2021. Neutral theory: Applicability and neutrality of using generic health-related quality of life tools in diseases or conditions where specific tools are available. *BMC Med Res Method* 21(1): 1-8. <https://doi.org/10.1186/s12874-021-01279-w>
- Kaiser, H.F. 1974. An index of factorial simplicity. *Psychometrika*. 39(1):31-36. <https://doi.org/10.1007/BF02291575>
- Karim, K.N. 2020. Health Ministry gets extra RM1bil allocation under stimulus package. New Straits Times. <https://www.nst.com.my/news/nation/2020/03/578723/health-ministry-gets-extra-rm1bil-allocation-under-stimulus-package> [Accessed on 23 June 2021]
- Keller, K.G., Reangsing, C., Schneider, J.K. 2020. Clinical presentation and outcomes of hospitalized adults with COVID-19: A systematic review. *J Adv Nurs* 76(12): 3235-57. <https://doi.org/10.1111/jan.14558>
- Kim, E.S., Chin, B.S., Kang, C.K., Kim, N.J., Kang, Y.M., Choi, J.P., Oh, D.H., Kim, J.H., Koh, B., Kim, S.E. 2020. Clinical course and outcomes of patients with severe acute respiratory syndrome coronavirus 2 infection: A preliminary report of the first 28 patients from the Korean cohort study on COVID-19. *J Korean Med Sci* 35(13): e142. <https://doi.org/10.3346/jkms.2020.35.e142>
- Koo, T.K., Li, M.Y. 2016. A Guideline of selecting and reporting intraclass correlation coefficients for reliability research. *J Chiropractic Med* 15(2): 155-63. <https://doi.org/10.1016/j.jcm.2016.02.012>
- Lamping, D.L., Schroter, S., Marquis, P., Marrel, A., Duprat-Lomon, I., Sagnier, P.P. 2002. The community-acquired pneumonia symptom questionnaire: A new, patient-based outcome measure to evaluate symptoms in patients with community-acquired pneumonia. *Chest* 122(3): 920-9. <https://doi.org/10.1378/chest.122.3.920>
- Lim, J., Park, S., Park, C., Kim, B. 2023. Survey instrument for related to the use of outcome measures in physical therapy: A systematic review. *J Int Acad Phys Ther Res* 14(3): 2923-30. <https://doi.org/https://doi.org/10.20540/JIAPTR.2023.14.3.2923>
- Lim, L.L. 2020. The socioeconomic impacts of COVID-19 in Malaysia: Policy review and guidance for protecting the most vulnerable and supporting enterprises. International Labour Organization. <https://share.google/KZmQnY5YWFHreSwOR> [Accessed on 9 February 2024]
- Ministry of Finance, Malaysia. 2020. Budget 2021 Speech. <https://www.mof.gov.my/portal/arkib/budget/2021/bs21.pdf> [Accessed on 19 March 2023]

- Patil, V.H., Singh, S.N., Mishra, S., Donovan, D.T. 2017. Parallel analysis engine to aid in determining number of factors to retain using R. <https://analytics.gonzaga.edu/parallelenigne> [Accessed on 31 September 2024]
- Payakachat, N., Ali, M.M., Tilford, J.M. 2015. Can the EQ-5D detect meaningful change? A systematic review. *Pharmacoeconomics* 33: 1137-54. <https://doi.org/10.1007/s40273-015-0295-6>
- Poudel, A.N., Zhu, S., Cooper, N., Roderick, P., Alwan, N., Tarrant, C., Ziauddeen, N., Yao, G.L. 2021. Impact of COVID-19 on health-related quality of life of patients: A structured review. *PLoS One* 16(10): e0259164. <https://doi.org/10.1371/journal.pone.0259164>
- Rolstad, S., Adler, J., Rydén, A. 2011. Response burden and questionnaire length: is shorter better? A review and meta-analysis. *Value Health* 14(8): 1101-8. <https://doi.org/10.1016/j.jval.2011.06.003>
- Sharma, A., Tiwari, S., Deb, M.K., Marty, J.L. 2020. Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2): A global pandemic and treatment strategies. *Int J Antimicrob Agents* 56(2): 106054. <https://doi.org/10.1016/j.ijantimicag.2020.106054>
- Simpson, R., Robinson, L. 2020. Rehabilitation after critical illness in people with COVID-19 infection. *Am J Physical Med Rehabil* 99(6): 470. <https://doi.org/10.1097/PHM.0000000000001443>
- Taquet, M., Luciano, S., Geddes, J.R., Harrison, P.J. 2021. Bidirectional associations between COVID-19 and psychiatric disorder: Retrospective cohort studies of 62 354 COVID-19 cases in the USA. *The Lancet Psychiatry* 8(2): 130-40. [https://doi.org/10.1016/S2215-0366\(20\)30462-4](https://doi.org/10.1016/S2215-0366(20)30462-4)
- Tavakol, M., Wetzel, A. 2020. Factor analysis: A means for theory and instrument development in support of construct validity. *Int J Med Educ* 11: 245-7. <https://doi.org/10.5116/ijme.5f96.0f4a>
- Tsang, S., Royse, C.F., Terkawi, A.S. 2017. Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine. *Saudi J Anaesthesia* 11(Suppl 1): S80. https://doi.org/10.4103/sja.SJA_203_17
- Turner, N., Campbell, J., Peters, T.J., Wiles, N., Hollinghurst, S. 2013. A comparison of four different approaches to measuring health utility in depressed patients. *Health Qual Life Outcomes* 11(1): 1-10. <https://doi.org/https://doi.org/10.1186/1477-7525-11-81>
- Valentino-DeVries, J., Lu, D., Dance, G.J.X. 2020. Location data says it all: Staying at home during coronavirus is a luxury. The New York Times. <https://www.nytimes.com/interactive/2020/04/03/us/coronavirus-stay-home-rich-poor.html> [Accessed on 4 January 2023]
- Wang, D., Hu, B., Hu, C., Zhu, F., Liu, X., Zhang, J., Wang, B., Xiang, H., Cheng, Z., Xiong, Y. (2020). Clinical characteristics of 138 hospitalized patients with 2019 novel coronavirus-infected pneumonia in Wuhan, China. *JAMA* 323(11): 1061-9. <https://doi.org/10.1001/jama.2020.1585>
- Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A., Erikson, P. 2005. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. *Value in Health* 8(2), 94–104. <https://doi.org/10.1111/j.1524-4733.2005.04054.x>
- World Health Organization. 2020. COVID-19 Weekly Epidemiological Update. <https://www.who.int/publications/m/item/weekly-epidemiological-update---29-december-2020> [30 December 2020]
- World Health Organization. 2024. WHO Coronavirus (COVID-19) dashboard <https://data.who.int/dashboards/covid19/cases?n=o> [Accessed on 7 August 2024]
- Yang, X., Yu, Y., Xu, J., Shu, H., Liu, H., Wu, Y., Zhang, L., Yu, Z., Fang, M., Yu, T., Wang, Y., Pan, S., Zou, X., Yuan, S., Shang, Y. 2020. Clinical course and outcomes of critically ill patients with SARS-CoV-2 pneumonia in Wuhan, China: A single-centered, retrospective, observational study. *Lancet Respir Med* 8(5): 475-81. [https://doi.org/10.1016/S2213-2600\(20\)30103-X](https://doi.org/10.1016/S2213-2600(20)30103-X)