

# Validity and Reliability of the Pfizer Booster Vaccine Effectiveness Questionnaire

Raihan Fadhil Muhammad<sup>1</sup>, Diana Laila Ramatillah<sup>1</sup> <sup>1</sup>Faculty of Pharmacy, Universitas 17 Agustus 1945 Jakarta

Email corespondence: raihanfadhilmuhammad777@gmail.com

#### Abstract

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Vaccination is the right method to deal with the increasing number of infections due to COVID-19. One method for assessing the effectiveness of a vaccine is by using a questionnaire. This pilot study was conducted to assess the validity and reliability of the Pfizer booster vaccine effectiveness questionnaire in Indonesia. The pilot study was carried out cross-sectionally using a new questionnaire that had not been tested for validity and reliability. The validity test of the questionnaire was carried out using the modified Delphi method which 3 professional will determine whether the questionnaire is valid to be used while in reliability analysis using inter reliability consistency analysis with score not less than < 0.3. Based on the collected data, there are 25 (62.5%) female respondents and 15 (37.5%) male respondents. With the age of majority <30 years as many as 37 (92.5%) respondents, <45 as many as 2 (5%) respondents and >45 as many as 1 (2.5%) person. In the validity test, 3 experts stated that the questionnaire is considered to be valid and suitable for use in research. Before checking the inter reliability consistency there were 50 questions but after the analysis only 12 questions were considered reliable to be used with Cronbach's alpha score 0.797. Of the 12 questions, there were 3 questions on sociodemography, 3 questions on side effects, 4 questions on allergy history, and 2 questions on data regarding history of COVID-19 infection. It can be concluded that the questions are considered valid by 3 experts and has 12 reliable questions in this questionnaire with Cronbach's alpha of 0.797. Although it functions as a pilot study for questionnaire development, its significance lies in the potential to enhance our understanding of the various factors that impact the effectivness of the pfizer booster vaccine, specifically within the Indonesian population.

Keyword: Cronbach's Alpha, Pfizer, Reliability, Vaccines, Validity

## **INTRODUCTION**

To reduce the infection rate due to COVID-19, vaccination is the right method to overcome this problem by injecting to the body several doses of either 2, 3 or 4 doses given for a certain period of time such as several weeks or months an inactive or weakened part of an organism that is put into a liquid to form the immune system (Kemenkes RI, 2021; Speiser & Bachmann, 2020). Until 2023, there are many COVID-19 vaccines that are used by many nations and one of them is the Pfizer-BioNTech vaccine. Pfizer-BioNTech vaccine or Pfizer vaccine is one of is the most popular COVID-19 vaccine due to it's 95% of efficacy which also can be proven through many research. In a research, there was a difference in the number of cases of infection due to COVID-19 where 39 cases of COVID-19 were found in the Pfizer vaccine group and 82 cases in the placebo group. Vaccine efficacy between the first and second doses was 52% (95% credible interval 29.5% to 68.4%). Vaccine efficacy then increased to 95% (90.3% to 97.6%) seven or more days after the second dose proving the importance of vaccine (Mahase, 2020). Similar research also found to have the same result, where in vaccine

participants who had never been infected with COVID-19 or were currently infected with COVID-19 had an efficacy of 95% while in 9 participants who were infected with COVID-19 after at least 7 days of giving the second dose the efficacy changed to 94.6% (Polack et al., 2020).

In current time as most first and second dose had already distributed to people all over the world, the use booster Pfizer becomes an option to gives more protection the body againts new variants of COVID-19. In a research Pfizer booster shown to have significant efficacy to protect it's receiver from the COVID-19 infection by having 95.3% efficacy (Chi et al., 2022). This can be proven where in a specific research that study the efficacy of booster vaccine of the 21,707 recipients of booster types of mRNA-based COVID-19 vaccine, only 11.2% were infected with the omicron variant, 3.1% were infected with the delta variant and 85.6% were negative for SARS-CoV-2, different from the number that only received the vaccine until the second dose where 31,271 participants 23.2%, 14 .6% and 62.2% were infected with omicron, delta and SARS-CoV-2 negative variants (Accorsi et al., 2022). In other study, revealed that young individuals (40.7%), women (62.8%), Malays (63.8%), Muslims (72.3%), married individuals (52.9%), highly educated individuals (86.8%), and those in good health comprised the majority of respondents (85%) have concerns about the COVID-19 vaccine because of the side effects (95.8%), safety (84.7%), lack of knowledge (80.9%), effectiveness (63.6%), and cultural and religious considerations (20.8%) were the primary reasons for hesitancy.

Safety is a critical criterion when assessing the use of a vaccine by monitoring it's safety. The monitoring of system safety involves gathering information about medical issues and complications that occur following the administration of these pharmaceutical products, including both expected side effects and any unexpected adverse reactions (Medicines gency, 2022). When a drug is administered to a significant population, there is always a risk of side effects. Therefore, it is crucial to closely monitor for any signs of direct or indirect consequences that may arise as a result (Ahamad et al., 2023). Out of the 370 participants surveyed, 20 individuals reported experiencing symptoms of nausea and vomiting (Al-Matouq et al., 2022). These results are consistent with a separate study that investigated the side effects of the Pfizer vaccine, which identified gastrointestinal symptoms in 10 cases of mild side effects and 1 case of severe side effects out of a sample of 46 individuals (Lee et al., 2022).

Although Pfizer booster vaccine proves to be safe and effective, there are many people in Indonesia that stills too afraid or believe it is better to not get vaccinated. In a population study, it was found that out of 11,611 participants who filled out the survey, 201 and 209 participants preferred not to vaccinate because of fear of needles and personal beliefs (Hidayana et al., 2022). Doubts on the effectiveness of booster vaccine also can be affected also by news media. In Malaysia itself, there are 38.5% that very much agree news media could affect their decisions on getting vaccinated (Kyaw et al., 2022).

There are many methods to prove the effectiveness of booster vaccine and of them is by using a questionnaire. Questionnaires are a data collection method where research participants are presented with a series of questions to answer. This approach involves engaging individuals from the target population to ensure that the questionnaire accurately represents their perspective. The goal is to create a questionnaire that is acceptable, comprehensive, and relevant to their specific circumstances. (Ricci et al., 2019).

While the Pfizer booster vaccine demonstrates high efficacy, it is not a guarantee that individuals will be completely immune to COVID-19 infection or hold the belief in the benefits of receiving the Pfizer booster vaccine. Variations in sociodemographic factors and geographic locations in Indonesia may contribute to the differing incidence of side effects and Covid-19 infections following the administration of the Pfizer booster vaccine and until now, there are still few studies that analyze the instrument of the research's instrument especially instrument that analyze the effectiveness of the Pfizer booster vaccine in Indonesia using a questionnaire.

Therefore this pilot study was conducted to assess the validity and reliability of the questionnaire used to assess the effectiveness of the Pfizer booster vaccine in Indonesia which will provide better insight on what variables and questions that can be used to assess the effectiveness of pfizer booster vaccine in indonesia and provide basic info of pfizer booster vaccine effectiveness on a small group of samples.

#### **METHODS**

A cross-sectional study model with a questionnaire as a tool was conducted for 2-3 months to obtained the needed data of the first 40 respondents. The main method of collecting primary data in this study involved distributing questionnaires on various social media platforms such as Twitter, Facebook, WhatsApp, Line, and Instagram with the population and sample of this study was sorted out with convenience sampling so therefore the obtained population of this study is Indonesian citizen, while the samples in this study include people who have received the Pfizer booster vaccine on the third dose and aged >18 years. Participants who has autoimmune, cancer, HIV/AIDS or hepatitis and also pregnant women are excluded. Prior to completing the questionnaire, the researcher provided a clear explanation to the respondents regarding the research aims and objectives. But before the questionnaires were distributed an ethical approval was made. Based on ethical approval, this research was

approved by the Health Research Ethics Committee of the University of 17 August 1945 Jakarta with reference number No.58/KEPK-UTA45JKT/EC/EXE/01/2023 and was declared ethically feasible according to 7 (seven) WHO Standards 2011.

Data in this pilot study were divided into 4, namely sociodemographic data, vaccine side effects, history of allergies and data on the history of COVID-19 infection in respondents. The data that has been obtained will be sorted according to the predefined inclusions and exclusions. After sorting, the data from the questionnaires were analyzed for validity using a modified Delphi study and for reliability by asess the result of internal reliability consistency analysis In the final results of the analysis, the questionnaire was declared valid if declared appropriate by three experts through an expert judgment letter and declared reliable if Cronbach Alpha > 0.07 and Corrected item-total correlation >0.3.

### RESULTS

In the validity test, the researcher makes an assessment table which will later be ticked by the expert who is the tester for the validity of the questionnaire. Based on the reviews provided, the questionnaire that has been made is stated to be representative, relevant, and clear or unbiased.

1	Gender			
	Male	15 (37.5%)		
	Female	25 (62.5%)		
2	Age			
	<30	37 (92.5%)		
	<45	2 (5%)		
	>45	1 (2.5%)		

Table 1 Characteristics of Respondents (n=40)

In the pilot test, reliability and validity analysis was carried out on as many as 40 respondents. There are 25 (62.5%) female respondents and 15 (37.5%) male respondents. With the age of majority <30 years as many as 37 (92.5%) respondents, <45 as many as 2 (5%) respondents and >45 as many as 1 (2.5%) person.

#### Table 2. Internal reliability consistency test

Instrumen	Total item	Scale mean if item deleted	Scale varience if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
Sosiodemography					
What is your gender?	-	19.17	22.282	0.355	0.790
What was the first dose of vaccine you received?	3	18.23	14.668	0.671	0.768
What second dose of vaccine did you receive?	-	18.23	13.978	0.789	0.741
Side effects					
Do you feel headache / dizziness after receiving the booster vaccine?	-	19.13	21.223	0.589	0.774
Do you feel chills after receiving the booster vaccine?	3	19.40	21.697	0.589	0.778
Do you feel nauseous / vomit after receiving the booster vaccine?	-	19.00	22.414	0.342	0.791
Allergy history					
After the booster vaccine, have you ever had an allergy?	-	18.90	21.955	0.494	0.783
After the booster vaccine, do you feel itching after consuming peanuts?	- 4	18.70	23.321	0.349	0.795
After the booster vaccine, do you feel itching after consuming fish?	- 4	18.77	22.530	0.485	0.787
If you had allergies before the vaccine, what allergic condition do you feel now?	-	18.90	22.369	0.392	0.788
Data regarding history of COVID- 19 infection					
Have you ever experienced fever symptoms after getting the second dose of vaccine?	2	19.40	22.179	0.463	0.785
How long have you had fever symptoms?	-	19.13	20.326	0.409	0.786

In testing internal reliability consistency which can be seen in table 2, it was found that from the 50 questions tested, there are only 12 questions that are considered valid based on the corrected item-total correlation score with a score of > 0.3. The reliable questions consist of; 3 (three) sociodemographic instrument questions, 3 (three) side effect instrument questions, 4 (four) allergy history questions and 2 (two) data instrument questions regarding the history of COVID-19 infection.

Table 3. Reliability analysis

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
0.797	0.834	12

From the results of the reliability analysis of the questionnaire in table 1, there are 12 reliable items with a Cronbach alpha value for 12 items of 0.797.

# DISCUSSION

Pfizer is an mRNA-based vaccine that can enhance the immune response against the Covid-19 virus. The vaccine utilizes mRNA extracted from the SARS-CoV-2 virus, specifically targeting the spike protein found on its surface. This mRNA is encapsulated within lipid nanoparticles. Upon intramuscular injection, these nanoparticles attach to host cells and release the mRNA into the cytoplasm. Ribosomes within the cells utilize the mRNA to synthesize the viral spike protein. The resulting proteins, including MHC-2 found in antigen-presenting cells and MHC-1 present in all nucleated cells of the body, are then expressed on the cell membrane. This mechanism stimulates the immune system to recognize and mount a response against the Covid-19 virus (Mascellino et al., 2021).

To asses the effectiveness of pfizer booster vaccine a pilot research is needed as it is the first step before the primary research to assess the clarity and comprehensibility of scale items and evaluate the scale's reliability through the calculation of internal consistency. Questionnaires are commonly used to accomodate data collection. In a research that investigate the COVID-19 the initial efficacy of the primary vaccine series, its gradual decline over time, and the safety and effectiveness of administering booster doses within a community in the United Kingdom they were able to find a conclusion of booster dose could restore the primary vaccine effectiveness notably the pfizer booster vaccine by using questionnaire as their tool of data collection (Menni et al., 2022; Yilmaz et al., 2018).

There are mainly 2 setting of questions that can be used in a survey such as close ended and open ended question. The type of question that is used in this study is a combination of open ended and close ended question because to collect data from the selected population it is better to use an open ended or close ended questions or by combining both where open-ended questions empower respondents to express themselves in their own terms, fostering rich and diverse responses. Open ended questions are proveen to be beneficial when researchers are uncertain about how participants may answer, as well as for creating fresh response choices for closed-ended questions (Story & Tait, 2019). Conversely, close-ended questions restrict the range of potential answers by offering predefined choices, potentially constraining the accuracy and depth of responses (Taherdoost, 2022). Combined method is also can be found in a similar study to obtain the participants opinion on post-vaccination experienced (Sultana et al., 2023).

In contemporary research, validity and reliability are fundamental concepts that play a pivotal role in improving the exactness and dependability of evaluating and appraising a research endeavor. Validation is an integral component of quality management procedures, yet it remains less prevalent in pharmacy practice and research, necessitating education and training during its incorporation into pharmaceutical research. Reliability, on the other hand, denotes that a scale or test is dependable, yielding consistent results with repeated measurements under consistent conditions (Ahmed Alomi, 2020; Ahmed & Ishtiaq, 2021).

The validation of questionnaire was done using a modified Delphi method by collecting the opinions of three clinical pharmacists. The data validation process is critical to ensure that the survey questionnaire is filled in accurately and represents reliable response data. The Delphi technique is a systematic and collaborative approach to forecasting, utilizing the combined opinions of a panel of experts. This structured method of consensus-building among panel members has been widely embraced across various medical disciplines. In recent decades, the Delphi methodology has played a crucial role in developing best practice guidelines by leveraging collective intelligence. It is particularly valuable in situations where research is scarce, ethical or logistical challenges exist, or when available evidence presents conflicting information (Nasa et al., 2021). Delphi panels are typically formed through a purposive or convenience sampling approach, which involves selecting experts based on specific qualifications (Plaiasu et al., 2023). In consensus methods, there are not strict guidelines regarding the inclusion of participants, except that each participant should be considered an expert in the relevant subject matter and be representative of their profession. Additionally, participants may be selected based on their ability to implement the findings or their status as unchallenged experts in the field (Taylor, 2020). Based on the validity test, the three panelists approved the questions from this questionnaire to be use to collect data of participants.

Reliability test is a test used to prove whether the tests performed are reliable or not and to test the reliability of the questionnaire. One of the most common method to asses the reliability is by the result of the internal reliability consistency test. The internal reliability consistency test is a test that measures the degree of relatedness between the items included in the test. To assess the reliability of the scale, the most commonly used statistic is Cronbach's coefficient  $\alpha$ . (Bornstein, 2018). Cronbach's alpha is a statistical measure used to evaluate internal consistency and reliability of a measurement scale. A Cronbach's alpha score above

1191

0.7 indicates acceptable consistency, above 0.8 indicates good consistency, and above 0.9 indicates excellent consistency (Wilson et al., 2022). From the result of this study, The reliability analysis of the questionnaire in table 1, there are 12 reliable items with a Cronbach alpha value for 12 items of 0.797.

In this study, an issue arises in the Reliability analysis. Validity and reliability analyses are interconnected. While a question may be deemed valid according to expert opinion, it may lack reliability as per the reliability analysis. Same as validity, Even if a test or measurement demonstrates high reliability, indicating consistent results when applied repeatedly, it does not necessarily mean that the test accurately assesses the desired behavior or quality it intends to measure (Surucu & Maslakci, 2020). This issue becomes evident when out of 50 questions in this study, only 12 demonstrate reliable internal consistency exceeding 0.3. To tackle internal reliability concerns, researchers should ask themselves: Can another researcher readily replicate this study based on the provided description? How probable are similar results and analyses if the study were conducted anew? (Rose & Johnson, 2020).

Additional investigation is required, involving another group of sample, in order to know whether are there more questions that are reliable from the 50 questions. This study have the potential to offer further understanding of the elements that play a role in the effectiveness pfizer booster vaccine, especially among Indonesians citizens.

### CONCLUSIONS

Based on this pilot test, it has been determined that the survey questions validated by three experts are both valid and reliable, as indicated by a Cronbach's alpha coefficient of 0.797 for the 12 questions, determined through an internal reliability consistency test. It's important to note that this research represents an initial investigation into the effectiveness of the Pfizer Booster vaccine in Indonesia. While it serves as a pilot study for questionnair, This study holds the potential to provide a deeper comprehension of the factors influencing the effectiveness of the Pfizer booster vaccine, particularly within the context of Indonesian citizens.

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