Development and validation of a functional health literacy instrument in the Philippines

Ma. Carmen C. Tolabing[1], Kim Carmela D. Co[1], Martin Aaron M. Mamangon[2]
[1]Department of Epidemiology and Biostatistics, College of Public Health, University of the Philippines Manila, Manila, Philippines
[2]College of Public Health, University of the Philippines Manila, Manila, Philippines

Article Info	ABSTRACT
	Functional health literacy (FHL) involves skills in writing, reading, oral expression, comprehension, and numerical calculations to successfully function and complete health-related tasks. This study aimed to develop and validate an instrument for measuring FHL in the Philippines using a mixed-method design. FHL-5TEST is an instrument consisting of five questions developed in consultation with local experts, translated to major Philippine languages, and underwent translation analysis, pretesting, cultural adaptation, and validation. A cross-sectional study was conducted in a random sample of 15-70-year-old Filipino residents to validate the instrument. The FHL-5TEST demonstrated high internal consistency, with a Cronbach's alpha of 0.7690. Across different cut-off values, the sensitivity and specificity of the instrument in detecting limited FHL ranged from 60.9% to 86.0% and from 61.6% to 97.2%, respectively. The study demonstrated that the FHL-5TEST is a valid and reliable instrument to measure functional health literacy in the Philippines. *This is an open access article under the CC BY-SA license.*

Corresponding Author:

Ma. Carmen C. Tolabing
Department of Epidemiology and Biostatistics, College of Public Health
University of the Philippines Manila, Manila, Philippines
Email: mctolabing@up.edu.ph

1. INTRODUCTION

Health literacy is broadly defined as the "knowledge, motivation, and competencies to access, understand, appraise, and apply health information in order to make judgments and take decisions concerning health care, disease prevention, and health promotion" [1]. Its close link with utilization of health services and health outcomes has drawn recognition to its importance in health care [2], [3]. Low health literacy has been shown to be associated with poor health-related knowledge [4], high-risk health behaviors [5], [6], underuse of preventive services [7], increased hospitalizations [8], more health care expenditures [9], and higher mortality risk [8].

Health literacy is a complex and evolving concept encompassing different cognitive and social skills [10]. This spectrum of relevant skills can be categorized into multiple types of health literacy, one of which is functional health literacy [2]. Functional health literacy (FHL) involves skills in writing, reading, oral expression, comprehension, and numerical calculations so as to successfully function and complete health-related tasks [11]. FHL enables transmission of information and facilitates engagement, autonomy, and empowerment in health-related settings [12]. FHL has three domains: prose literacy, document literacy, and numeracy [10]. Prose literacy is needed to understand and use information from sentences or paragraphs, while document literacy is needed to locate and use information from noncontinuous texts in various formats.

Lastly, numeracy corresponds to identifying and performing computations using numbers from printed materials [13].

The increasing attention on the importance of FHL warrants an instrument to accurately measure FHL in order to facilitate health literacy interventions when needed. Various instruments have been developed to measure FHL, such as the test of functional health literacy in adults (TOFHLA), the rapid estimate of adult literacy in medicine (REALM), and the newest vital sign (NVS). NVS is a brief instrument that can assess prose literacy, document literacy, and numeracy and can be administered in about three minutes [14]. It contains six questions based on an ice cream nutrition label, wherein each correct response is given one point. A score of 4-6 indicates adequate health literacy, while a score of 0-3 suggests limited health literacy. Its quick and accurate assessment of FHL led to its adaptation and utilization in several countries [7], [15]–[18] and application in primary care clinics [19], hospitals [7], and communities [15].

Ideally, measurement tools should be specific to the population to account for cultural and institutional differences. Localized instruments for measuring FHL have been developed and validated in other countries [20]–[23]. The instruments covered different health topics depending on relevance to the target population. However, while instruments for measuring general health literacy have recently been validated in the Philippines [24], [25], no such instrument for FHL has been developed yet in the country based on a review of available literature. In the absence of a localized instrument, FHL cannot be accurately identified to enable implementation of tailored interventions [23], [26]. Further, a locally validated instrument is needed to produce accurate population estimates of the local magnitude of limited FHL that can support evidence-based health policy and programs for improving FHL [27], [28]. This study aimed to develop and validate an instrument for measuring FHL in the Philippines that is adapted to local context using a health topic widely familiar within the population.

2. RESEARCH METHOD

This study was part of the national health literacy survey (NHLS) conducted in 2018, which had a general objective of describing the level of health literacy of Filipinos aged 15 to 70 years old. A mixed-method design was employed for this study, with qualitative methods for the development of the instrument and quantitative methods for the validation of the instrument. The main steps in the methodology for this study is illustrated in Figure 1.
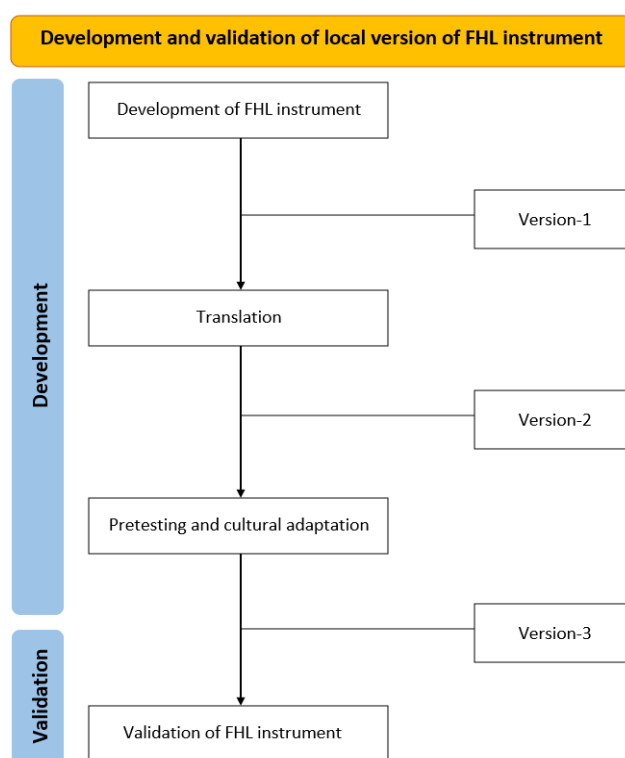

Figure 1. Process of developing and validating the local version of FHL instrument

2.1. Development and translation of FHL instrument

An expert panel consisting of public health practitioners and specialists in health promotion and in health literacy developed a local version of an instrument to measure FHL patterned on the newest vital sign, with questions based on a specific health education material. This was conducted through a workshop and the output was the first version of the instrument. Content validity of the instrument was examined by determining whether the questions covered the three domains of FHL.

The instrument underwent forward and backward translation to seven major Philippine languages. Forward translation to each language was done by the Commission on Philippine Languages, while backward translation of each version to English was done by native speakers of each respective language. This was followed by translation analysis using the scheme developed by Hall *et al.* [29] to assess semantic equivalence between the original and back-translated versions and ensure that the original meaning was not lost in translation. Items assessed as having no agreement were modified at the local level with local language experts.

2.2. Pretesting and cultural adaptation

One city or municipality was randomly selected in areas that speak each language to which the instrument was translated. In each sampled location, a focus group discussion (FGD) was conducted to assess the clarity and cultural appropriateness of the instrument and refine specific items as needed. Participants of each FGD included 8-12 residents of the selected city or municipality, one local expert in research methods, and one local language expert.

2.3. Validation study

A cross-sectional study was employed to validate the instrument among Filipino residents 15 to 70 years old using the newest vital sign (NVS) as the reference test [14]. NVS is a brief instrument that can assess prose literacy, document literacy, and numeracy. It contains six questions based on an ice cream nutrition label, wherein each correct response is given one point. The validation process took place during the pilot testing of the national health literacy survey (NHLS).

2.4. Sampling method and sample size

Respondents were recruited from the NHLS study sites which were selected using multiple-stage random sampling. The sampling methodology for NHLS has been previously described in another paper [25]. Specific barangays (the smallest political unit in the Philippines) were randomly selected to represent areas that speak each language the instrument was translated and adapted to. Households were randomly chosen in each barangay and one respondent was randomly selected from among the eligible members of the household. Exclusion criteria included being illiterate, having self-reported poor vision, having prior knowledge of the information in the health education material from memory, and having cognitive impairment determined using Mini-Cog© administered during recruitment. The recommended sample size in validation studies is to use a respondent-to-item ratio of at least 10:1, with an absolute minimum of 100 respondents [30], [31]. For this study, a total of 240 residents were recruited from eight barangays.

2.5. Data collection

Individual interviews were carried out using the Computer-Assisted Personal Interviewing (CAPI) method in December 2018. Informed consent was obtained from each respondent prior to participation in the validation of the FHL-5TEST. Demographic information, including sex, age, marital status, religion, educational attainment, and occupation, were collected. Afterwards, the newly developed instrument (FHL-5TEST) and the reference instrument (NVS) were administered. Data collectors were trained in the administration of the newly developed instrument and carried with them the 1-page protocol for administering the instrument.

2.6. Data analysis

The collected data were initially processed in Microsoft Excel® 2010 and were subsequently analyzed using Stata® 12 IC version. Categorical variables were presented using frequencies and proportions, while numerical variables were presented using mean and standard deviation as appropriate. Analyses were conducted to describe the reliability and validity of the FHL-5TEST, including Cronbach's alpha to estimate the internal consistency of items and Spearman's rank correlation between the FHL-5TEST score and NVS score. In addition, sensitivity, specificity, and areas under the receiver operating characteristic curve (AUC) were computed with the corresponding 95% confidence intervals to determine the ability of FHL-5TEST to correctly classify people as with adequate or with limited functional health literacy using NVS as the reference test. The NVS instrument categorizes FHL level into adequate (score of 4-6) and limited (score of 0-3).

2.7. Ethics clearance

The study was granted technical clearance by the Philippine Statistics Authority and the Philippine Council for Health Research and Development (DOH-1840) and was given ethics clearance by the National Ethics Committee (NEC Code:2018-013 Tolabing-Literacy). Participation in the study was voluntary and written informed consent was obtained from individuals who signified their agreement to participate in the study. For minors (15-17 years old), assent was obtained in addition to the consent signed by the parents.

3.   RESULTS AND DISCUSSION

3.1. Development, translation, pretesting, and cultural adaptation

FHL-5TEST was developed as an instrument to measure functional health literacy in the Philippines based on a health education material of an immunization schedule created by the Philippine Department of Health as shown in Figure 2 [32]. Vaccination was selected as the subject matter of the instrument since vaccination is one of the most common health services utilized in the country. The instrument consisted of five test items which the respondents answered while referring to the immunization schedule that was handed to them: i) Which vaccines may be given to infants immediately after birth?; ii) How many types of vaccines should have been received by a child who is one year old?; iii) In total, how many doses of all the recommended vaccines should be given to infants?; iv) Which vaccine(s) can protect against pneumonia?; v) Assume that you have a child who was born on January 1, 2017, when should he/she receive the first dose of the measles-mumps-rubella (MMR) vaccine?

Each item is scored "1" for correct answer and "0" for incorrect answer. The total score may range from 0 to 5, with higher scores indicating higher FHL. The questions were constructed to test the FHL skills of prose literacy, document literacy, and numeracy. Numeracy is measured by items 2, 3, and 5; prose literacy is assessed by item 5, while document literacy is incorporated in all items. During instrument development, experts carefully considered the relevance and comprehensiveness of the items as these were being constructed [33].

Figure 2. Health education material used for the FHL5-TEST [32]

The Figure 2 describes the schedule of routine immunization for infants according to the age of the child when each vaccine should be administered. A similar version of this immunization schedule table in English is available elsewhere [34]. The multi-step process of translation was designed to maintain the faithfulness of different language versions to the original without substantial change in the meaning and difficulty of the items. Across several language translations of the instrument, majority of the items were classified as having good semantic equivalence between the original and the backtranslated versions as

shown in Table 1. Only the Ilocano language version had two items assessed as having no agreement at all. Items assessed as having no agreement underwent an iterative process of forward and backward translation until all items preserved the meaning of the original version.

Table 1. Semantic equivalence of the back-translated and source versions of the FHL-5TEST

Rating on semantic equivalence[1]	Number of items under each rating (out of total 5 items)						
	Bicolano	Filipino	Hiligaynon	Ilocano	Kapampangan	Sebuano	Waray
A	1	1	1	1	1	2	4
B	1	3	2	1	3	2	0
C	2	1	1	1	0	1	0
D	1	0	1	2	1	0	1

[1]A- perfect semantic equivalence and good literal and semantic parallels between the back-translated and source versions; B - satisfactory semantic equivalence but have one or two different words; C- meaning of the original has been preserved but without a satisfactory semantic equivalence; and D- no agreement.

In the majority of language versions, all items were deemed clear and culturally appropriate and were retained as they did not require further revision. For Waray, Bisaya, and Hiligaynon language versions, one to two items were modified for clarity and cultural sensitivity. No major challenges were identified in administering and in answering the instrument during the pretesting phase. Pretesting and cultural adaptation were done to establish the conformity to local usage and context. These phases were essential to maximize the quality and comparability of data from an instrument applied across varying languages and cultures [35].

3.2. Validity and reliability measures

Evidence for validity of research instruments include content validity, face validity, construct validity, and criterion validity [36]. Content validity, referring to the extent to which items in an instrument are reflective of the content universe it is supposed to measure, was ensured during the development of the instrument through extensive literature review and expert panel consultations. Meanwhile, face validity as the subjective judgment of non-experts on the presentation and relevance of the instrument was examined through focus group discussions during the pretesting [36].

A total of 215 participants were included in the validation study after applying the inclusion and exclusion criteria. Majority were females, between ages 15-35 years, and had no occupation. Using the FHL reference test (NVS), 83.3% of the respondents were classified as having limited FHL as revealed in Table 2.

Table 2. Characteristics of the respondents (n=215)

Variable	Freq.	Percent
Age group (n=209)		
15-35years	105	50.24
36-60 years	82	39.23
61-70 years	22	10.53
Sex		
Male	62	28.84
Female	153	71.16
Educational attainment (n=212)		
Primary school level	20	9.43
High school level	81	38.21
Senior high/vocational	32	15.09
College level	79	37.26
Type of occupation (n=214)		
None	129	60.28
Managerial/Professional	18	8.41
Others	67	31.31
FHL classification using NVS		
Limited	179	83.26
Adequate	36	16.74

The distributions of scores using the FHL-5TEST and the NVS are shown in Table 3. Using FHL-5TEST, the mean score was 2.57 (±1.77), while the median score was 2. The proportions in each score ranged from 13-22%, with a perfect score (5 out of 5 items correct) being the most frequent. In comparison, using NVS, the mean score was 1.62 (±1.60), while the median score was 1. The most frequent score was having zero correct items.

Table 3. Distribution of participants according to total FHL scores obtained using FHL-5TEST and NVS

Total FHL score obtained	FHL-5TEST		NVS	
Score	n	%	n	%
0	36	16.7	76	35.4
1	32	14.9	36	16.7
2	42	19.5	46	21.4
3	30	14.0	21	9.8
4	28	13.0	24	11.2
5	47	21.9	10	4.7
6			2	0.9

Among the five items of FHL-5TEST, item 4 was the most correctly answered, whereas item 2 was the least correctly answered as displayed in Table 4. Reliability of the FHL-5TEST was assessed in terms of internal consistency, which is concerned with the similarity of items in measuring the same construct [37]. FHL-5TEST was demonstrated to have high internal consistency, with a Cronbach's alpha of 0.769, supporting that the five items were all measuring the same construct of FHL level. This was higher compared to the observed internal consistency when any of the items is removed as shown in Table 4. Thus, the instrument was retained as a 5-item questionnaire.

Table 4. Proportion of correct answers and internal consistency of items

FHL-5TEST item	Correct		Cronbach's alpha when item is removed
	n	%	
1. Which vaccines may be given to infants immediately after birth?	110	51.2	0.709
2. How many types of vaccines should have been received by a child who is one year old?	81	37.7	0.759
3. In total, how many doses of all the recommended vaccines should be given to infants?	95	44.2	0.707
4. Which vaccine(s) can protect against pneumonia?	140	65.1	0.759
5. Assume that you have a child who was born on January 1, 2017, when should he/she receive the first dose of the measles-mumps-rubella (MMR) vaccine?	127	59.1	0.694
Cronbach's alpha of FHL-5TEST			0.769

Criterion validity is concerned with the extent to which a measure is related to an outcome. One way of demonstrating this is through correspondence between the test and a previously established measure for the same construct [36]. The results showed that the FHL-5TEST score was moderately correlated with the NVS score (Spearman's rho=0.457, p-value<0.0001).

Three cut-off values were explored for classifying a respondent as having limited FHL–having a score below 60%, 80%, or 100%. The classifications of respondents with limited and adequate FHL according to NVS and FHL-5TEST using different cut-off values are shown in Table 5. The corresponding sensitivity and specificity values for detecting a respondent with limited FHL using NVS classification as the reference test are shown in Table 6. A cut-off value of 100% resulted in the highest sensitivity, wherein 86% of those with limited FHL based on NVS were similarly classified as having limited FHL (95% CI: 0.801–0.908). Meanwhile, a cut-off value of 60% resulted in the highest specificity, wherein 97% of those classified as having adequate FHL based on NVS were similarly classified as having adequate FHL. Among the three values, a cut-off score of 60% resulted in the highest area under the receiver operating characteristic curve (AUC=0.796, 95% CI: 0.746–0.836). Using NVS category as the reference, the analysis revealed that the cutoff scores of 60%, 80%, and 100% all had acceptable performance in discriminating between populations with adequate and limited FHL [38].

Researchers intending to use the FHL-5TEST should then select the most appropriate cutoff score based on the objective of their studies. The cut-off score of 60% showed the greatest area under the curve, with high specificity of 97.2% (2.8% false positive) but low sensitivity of 60.9% (39.1% false negative). Since it demonstrated the best discriminatory property, it may be the most optimal for prevalence surveys. However, this cut-off may miss to identify a substantial proportion of individuals with limited FHL–with as high as 39.1% being misclassified as having adequate FHL (i.e. false negatives). Misclassifying those with limited FHL as having adequate FHL is considered more serious than incorrectly labelling those with adequate FHL as having limited FHL (i.e. false positives) due to the significant burden of having limited FHL on the individual and on the health care system [8], [9].

Table 5. Distribution of participants according to FHL level using NVS and using different cut-off points of the FHL-5TEST

| FHL-5TEST Cut-off points | NVS classification | | | |
| | Limited (n=179) | | Adequate (n=36) | |
	n	Column%	n	Column%
FHL-5TEST 60%				
Limited	109	60.9	1	2.8
Adequate	70	39.1	35	97.2
FHL-5TEST 80%				
Limited	133	74.3	7	19.4
Adequate	46	25.7	29	80.6
FHL-5TEST 100%				
Limited	154	86.0	14	38.9
Adequate	25	14.0	22	61.1

Table 6. Comparison of the areas under the curve, sensitivity, and specificity of different cut-off points of the FHL-5TEST

Cut-off point	n	Area under the curve	95% CI	Sensitivity	95% CI	Specificity	95% CI
60%	215	0.791	0.746-0.836	0.609	0.533-0.681	0.972	0.855-0.999
80%	215	0.774	0.701-0.847	0.743	0.672-0.805	0.806	0.640-0.918
100%	215	0.736	0.651-0.820	0.860	0.801-0.908	0.611	0.435-0.769

Among the three cut-off scores, the score of 100% was able to identify the most number of individuals with limited FHL. Although it did not exhibit the highest overall diagnostic accuracy, it minimized the proportion of those with limited FHL incorrectly classified as having adequate FHL. This cut-off score may be more useful for FHL intervention studies based on a reasonable assumption that more individuals with limited FHL would better gain an opportunity to improve their FHL levels. Moreover, health literacy interventions are not expected to pose significant adverse consequences to those with adequate FHL if they are erroneously labelled to have limited FHL. Ultimately, the relative importance attributed to false-positive and false-negative results should direct the choice of cut-off score [39].

The observed validity measures for FHL-5TEST were comparable to previous instruments. NVS, the reference test used in this study, was reported to have an area under the curve (AUC) of 0.88 (95% CI, 0.84-0.93; p<0.001), a sensitivity of 100% and a specificity of 64% for predicting limited FHL using TOFHLA as the reference test [14]. Other instruments developed to measure FHL used NVS or TOFHLA as the reference test and reported a range of values for AUC (0.65-0.80), sensitivity (18%-81%), and specificity (62%-94%) [40]–[42]. Majority of instruments previously developed had a higher number of items [23], which will take a longer time to administer. The FHL-5TEST was developed with only five items so that it can be administered in a short amount of time, allowing ease of use in different types of settings, including clinical and research settings.

Half of the participants in this study population scored lower than 60% using the FHL-5TEST, while a high proportion was assessed to have limited health literacy using NVS, indicating potential floor effects. Floor or ceiling effects exist in an instrument if a high proportion of the respondents obtained the lowest or highest possible scores, respectively [43]. Validation of the NVS in North America found no significant floor effect (6.8% with a score of zero) [14]. In contrast, using NVS among the study respondents revealed a marked floor effect (35.4% with a score of zero), as opposed to using the FHL-5TEST in which the distribution of scores was more spread out. A high floor or ceiling effect may lead to a reduced ability of the instrument to differentiate respondents from each other and to detect changes in FHL among respondents at the end of the score range [43]. One explanation for the result of NVS in this study may be the less familiarity of Filipinos to nutrition labels which are the material used in NVS [44]. A national survey reported that only 53.6% of the Filipino adult population read product labels, and of these, only 19.9% read the nutrition facts [45]. This proportion is notably lower than those reported in other countries [46]–[48]. It further highlights the challenges in using instruments validated in other countries, and the importance of considering local context and culture when developing or adapting instruments to measure health literacy level more accurately and implement responsive interventions accordingly.

The strengths of this study are the following: firstly, the translation process was rigorous and included translation analysis that ensured semantic equivalence of the original and the back-translated versions; and secondly, possible influence of prior knowledge about immunization in the assessment of FHL was addressed by excluding those with prior knowledge about the concepts covered in the FHL-5TEST. This study, however, had several limitations. The data for the validation of FHL-5TEST was collected during the pilot-testing phase of the NHLS, during which the main objective was to finalize the instruments and

methods for NHLS. The sample selection during this phase was not designed to be representative of the population of the Philippines, and it may have affected the demographic distribution of the study population. Therefore, the estimates of FHL level reported in this study may not be generalizable to the whole country. The results pertaining to the validation of the instrument do not require a random sample and thus may still be utilized and interpreted. In the administration of instruments during data collection, the respondents always answered the FHL-5TEST first and the NVS second. Hence, it is possible that the participants may have become fatigued by the time the NVS was administered, potentially leading to poor performance on the NVS. However, the data collectors were trained to give the participants sufficient breaks as needed during the interview to avoid this, and as such, this is not expected to have influenced the result significantly.

4. CONCLUSION

The FHL-5TEST is the first locally developed and validated instrument to measure FHL. It consists of five questions based on an immunization schedule flyer. In comparison to the reference test (NVS), FHL-5TEST was observed to have acceptable sensitivity and specificity in detecting limited functional health literacy. The study demonstrated that the FHL-5TEST is a potential valid and reliable instrument that can be used to measure functional health literacy in the Philippines. The instrument is short and can be administered quickly, so it can be used to measure FHL in different settings. It also has the added benefit of reminding individuals of the importance and the timeline of childhood vaccination that may subtly promote vaccine uptake. Future studies may seek an external review of the instrument translation and adaptation, consider standardizing scores across cultures, and assess other aspects of the instrument, including the duration of administration. Further research may include information on health outcomes to provide additional evidence of validity of the FHL-5TEST in measuring FHL, to identify the most appropriate cut-off score to use in classifying FHL level, and to determine utility in primary care clinics and hospitals.

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BIOGRAPHIES OF AUTHORS

Ma. Carmen Cornelia-Tolabing 🆔 🇬 SC Ⓟ is a Public Health professional with specialization in Epidemiology. She teaches Epidemiology, Biostatistics, and Research in the University of the Philippines, College of Public Health. She obtained her undergraduate and graduate degrees in Public Health (BSPH, MPH, DrPH) with graduate specialization in Epidemiology from the University of the Philippines. Carmen's research interests include health information system, health human resources, evaluation of public health programs/interventions, and health literacy. She served as Principal Investigator of the first National Health Literacy Survey that was completed in mid-2019. She is Vice President of the Asia Health Literacy Association (AHLA) and Deputy Director of the AHLA Country Office in the Philippines. She can be contacted at email: mctolabing@up.edu.ph.
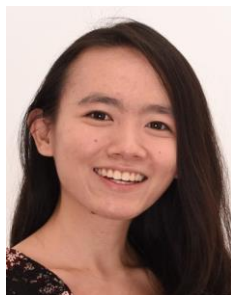
Kim Carmela Co 🆔 🇬 SC Ⓟ is an epidemiologist, previously teaching epidemiology, biostatistics, and research at the University of the Philippines, College of Public Health. Currently, she is working as a public health epidemiologist supporting preparedness and response to health emergencies in Laos. She can be contacted at email: kimcarmelaco@up.edu.ph.

Martin Aaron M. Mamangon 🆔 🇬 SC Ⓟ holds a Bachelor of Science degree in Public Health and is currently pursuing Doctor of Medicine at the University of the Philippines Manila. He worked as a research assistant in projects related to health literacy and was inducted as a member of the Royal Society for Public Health. He can be contacted at email: mmmamangon@up.edu.ph.