Study Protocol

A Community-based Intervention to Improve Measles Immunization Status Among the Marginalized Population in Kota Kinabalu, Sabah

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ABSTRACT

Background: Measles disease continues to be a problem in Sabah despite the existence of a measles vaccination programme. Cases and outbreaks of measles continue to be recorded. Children from marginalised communities are particularly vulnerable, owing to insufficient vaccine coverage. To address this issue, improvisation of the immunisation effort through community-based engagement is required.

Objective: The aim of this study is to supplement the current service, a community-based intervention will be implemented and evaluated to see how it affects measles immunisation rates.

Methods: The community-based intervention will be implemented using a cluster randomised control trial design. The intervention's impact on measles immunisation status, as well as the community's acceptability and satisfaction with the intervention, are then evaluated. To assess community acceptance and satisfaction, as well as the intervention's influence on measles immunisation status, a descriptive, univariate, and bivariate analysis will be conducted using IBM Statistical Package for Social Science (SPSS).

Significance: This study will increase the comprehension of the marginalized population's perception of measles immunization and community-based participation. The intervention can then empower the community to get their children vaccinated, increase health literacy, enhance health care services, reduce health disparities and measles incidence in Sabah.

INTRODUCTION

Research Background

The Measles Morbillivirus (MeV) is the causative agent of a highly contagious disease known as measles. When a person coughs or sneezes, it spreads swiftly via respiratory droplets, and transmission can occur through personal touch or direct contact with the secretions. Fever, maculopapular rash, coryza, cough, and conjunctivitis are all symptoms of measles infection. When someone comes into contact with this virus, they have a 90% probability of contracting measles. Upon contracting the infection, the individual is capable of transmitting the disease for a period of four days prior to and four days subsequent to the manifestation of the maculopapular rash. Because humans are the virus's natural host, measles can be reduced, eliminated, and eradicated. Numerous governments have made a commitment to decrease childhood morbidity and mortality rates by striving to achieve immunisation coverage for more than 95% of the population.

The administration of the measles, mumps and rubella (MMR) vaccine serves to impede the transmission of the measles virus and provides safeguarding to individuals who have not received the vaccination. Measles immunisation is effective, as evidenced by a decline from 145 cases per million individuals in 2000 to 49 cases per million individuals in 2018, and the annual mortality rate attributed to measles was observed to have decreased by 73% during the period spanning from 2000 to 2018, effectively averting approximately 23.2 million fatalities on a global scale [1]

Nevertheless, despite the availability of the measles vaccination, there are ongoing reports of measles cases worldwide. Between the year 2000 and 2018, there was an increase in the incidence of measles in five nations, namely Liberia, Madagascar, Somalia, the Democratic Republic of Congo, and Ukraine. The aforementioned nations constituted 45% of the total documented instances of measles across the globe, exhibiting a prevalence exceeding 600 cases per million. **Figure 1.1** showed that the reported measles incidence per 1 million persons worldwide in 2000, 2016, and 2018 [1]. Then, in 2019, there were a delay in routine vaccination during the COVID-19 pandemic which placed many children at risk [2]. As such, measles outbreak were reported post-COVID 19 pandemic in several countries including the neighbouring country, Indonesia [3].

In Malaysia, the number of measles cases similarly increased from 2014 until 2018 where 1,985 cases with 133 clusters of measles outbreaks reported **(Figure 1.2)** [4]. Then, a measles outbreak involving the nomadic indigenous people in Kelantan involving 110 cases and 11 deaths were reported at Kuala Koh, Gua Musang Kelantan in 2019 [5]. In the year 2021, due to COVID 19 pandemic, the measles incidence decreased with no measles deaths reported [6]. However, based on the measles immunisation coverage for the measles-vaccine first-dose (MCV-1) and measles-vaccine second-dose (MCV-2), the immunisation coverage for both doses were less than the targeted 95 percent to achieve the herd immunity during and after the pandemic **(Table 1.1)** [7]. Therefore, optimising the immunisation coverage is important for this country to achieve locally transmitted measles cases by 2023. This target then needs to be sustained for three (3) consecutive years for Malaysia to successfully attain measles elimination status by 2025.

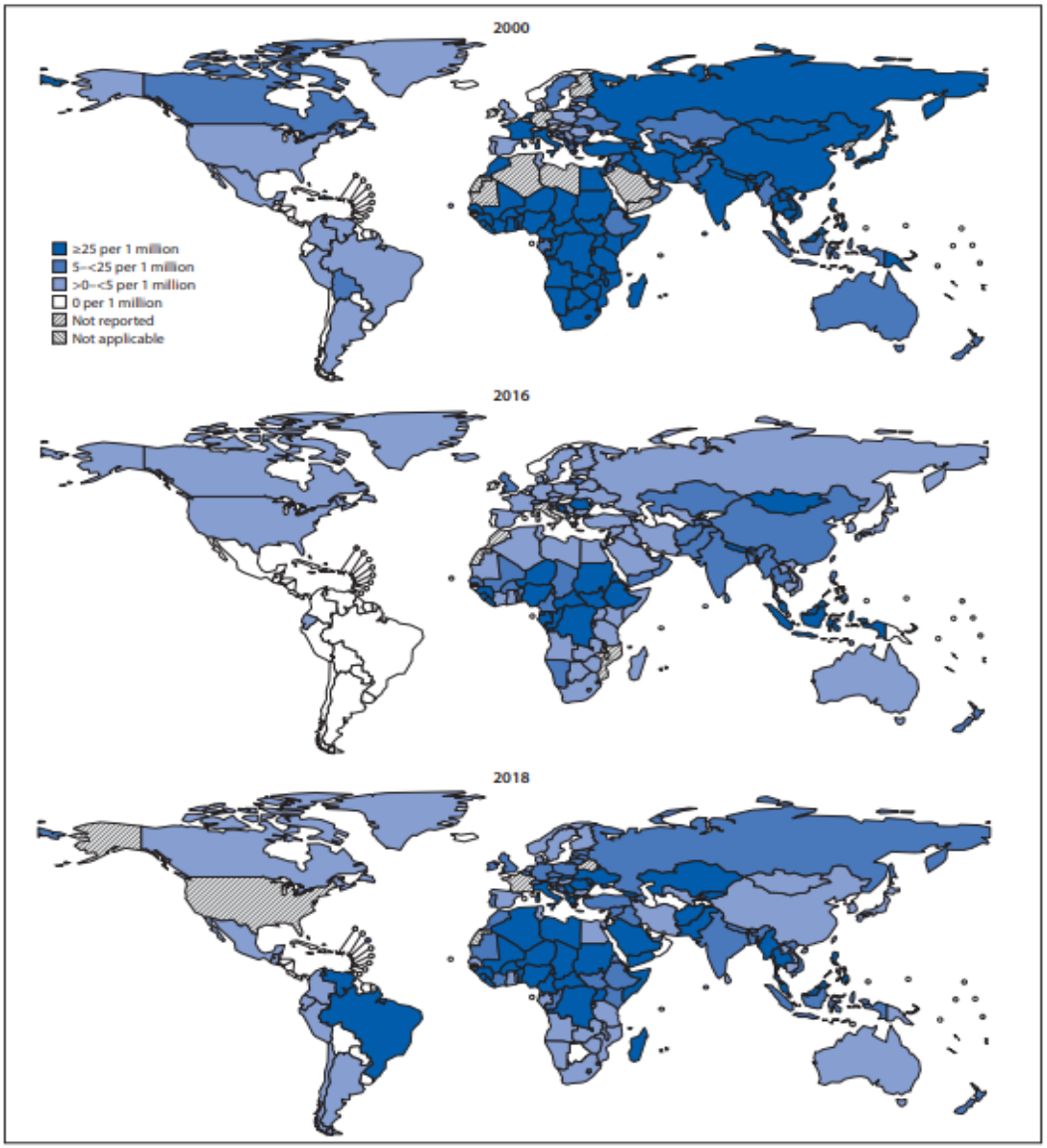


Figure 1.1: Reported measles incidence per 1 million worldwide – 2000, 2016, 2018

Source: Adapted from [1]

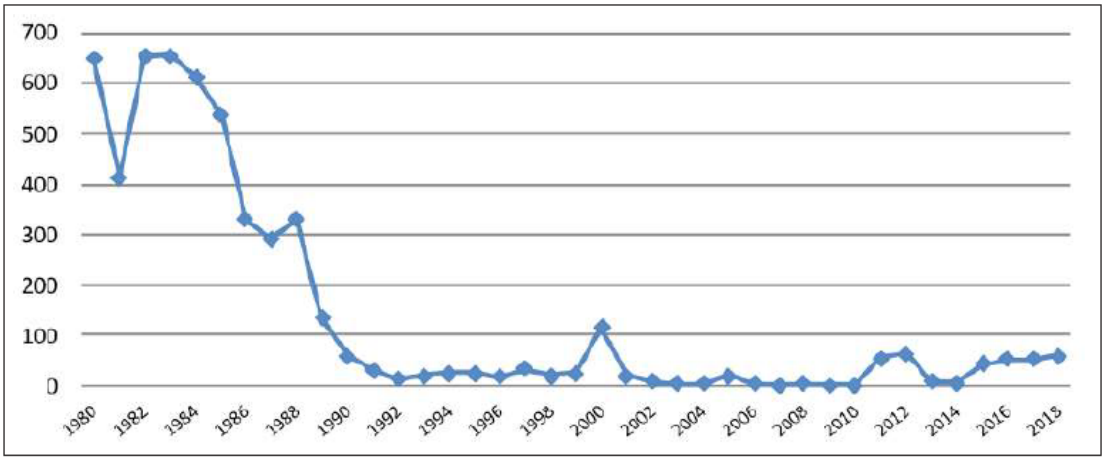


Figure 1.2: Reported measles incidence per 1 million people in Malaysia – 1980 to 2018

Source: Disease Control Division (Ministry of Health, Malaysia).

Table 1.1: Measles Immunization Coverage in Malaysia – 2019 to 2022

Country / Region	Antigen	Data source	2022	2021	2020	2019
Malaysia	Measles-containing vaccine, 1st dose	ADMIN	103.46%	98.69%	97%	96.64%
		OFFICIAL		96%	95%	97%
		WUENIC		96%	95%	97%
	Measles-containing vaccine, 2nd dose	ADMIN	102.24%	97.52%	83.99%	86.68%
		OFFICIAL			84%	87%
		WUENIC		84%	84%	87%

Source: World Health Organisation (WHO).

Attaining the target of 95 percent measles immunisation coverage is important to achieve herd immunity to protect the population against measles disease. Although the coverage is less than the targeted 95 percent, the impact may not be seen immediately especially during the COVID-19 pandemic where preventive measures also reduced the spread of measles virus such as social distancing, wearing facial mask, and travel restrictions [8]. However, measles outbreaks do occurred at low and middle income countries like India, Yemen, Pakistan, Indonesia, Ethiopia, Cameroon, Nigeria, Turkey, Somalia, and Democratic Republic of Congo due to low first dose of measles immunisation coverage [3]. Measles

outbreaks also occurred in high-income countries like the Unites States of America, due to the presence of antivaxxers who caused low immunisation rates [9].

Therefore, the eradication of measles necessitates global partnerships and collaborative efforts. One of the initiatives that exist is the Global Measles and Rubella Initiative, which comprises the World Health Organisation, the United Nations Foundation, the US Centres for Disease Control and Prevention, and the American Red Cross. The aforementioned programme aims to augment measles vaccine coverage in countries by extending financial and technical support to those who require it. The Global Measles and Rubella Strategic Plan outlines strategies aimed at mitigating the morbidity and mortality associated with the measles virus [10]. The strategy under consideration places significant importance on immunisation as a crucial element. It is imperative to uphold regular immunisation practises, as certain nations continue to document occurrences resulting from the importation of cases, despite having attained the eradication stage. Consequently, there are still a number of nations that have not succeeded in eliminating measles.

In Malaysia, the monovalent measles vaccine was introduced into the National Immunisation Program (NIP) in 1982. Then, in 2004, children at the age of nine and 12 months were introduced with the trivalent measles-mumps-rubella (MMR) vaccine. In addition, children residing in the state of Sabah are provided with their first dose of the measles vaccine at the age of six months due to the presence of unvaccinated population in the state [11]. Furthermore, other strategies used by the Ministry of Health, Malaysia includes laboratory-based and case-based measles surveillance [12], where notification of reported cases and outbreaks were done through the e Notification and SM2 e Measles online systems for standardisation purposes [13]. There is also measles preparedness and measles outbreak management and supplementary immunisation activity (SIA) done to ensure that the measles disease do not spread and is managed timely and effectively.

Problem statement

Despite having a good measles immunization program, measles disease is still a problem in the state of Sabah. The low measles immunization coverage in this state contributes to the prevalence of measles cases and outbreaks, which commonly occur among the marginalized population. According to the WHO, the measles coverage in Malaysia for MCV1 was 97%, and MCV2 was 87%. Thus, incomplete immunization occurred during the second MMR dose, where not all the children received it at 12 months.

There are extensive researches that studied measles disease in the past. In Sabah, a measles outbreak occurred among the Sea Gypsies in the district of Kudat [14]. The marginalized children have difficulty getting vaccinated, especially those who live in remote rural areas, undocumented, refugee,

migrant, or stateless people [15]. Therefore, they contribute to the cause of low immunization coverage, and there is a need for better approaches for these underserved children [16].

Currently, routine immunization (RI) activity and supplementary immunization activity (SIA) are instrumental in achieving the targeted immunization coverage. However, they can still be delayed and disrupted [17], especially during this COVID 19 pandemic. There is also the issue of sustaining immunization activities among these marginalized populations since the impact is not as expected. Those with poor access to health services or who live in urban slums with social and geographical issues may have difficulty getting routine immunization. They may only get immunized after an outbreak occurs through SIA [18]. Hence, the immunization delivery and acceptance of the intervention program is something that we want to explore to improve immunization activities.

Furthermore, there is a lack of literature that studied community interventions to improve measles immunization coverage among the marginalized population. Chopra et al., in their article, suggested incorporating a behavioural change program with effective communication strategies for further improvement. There is also an emphasis on community engagement, as well as intersectoral and intragovernmental collaboration.

Thus, due to the disperse and limited studies on this area, we will conduct a comprehensive qualitative assessment on the marginalized community in Sabah to explore the community's perception of measles immunization and community-based participation. Then we will design, implement and evaluate a community-based intervention to see its impact on measles immunization and the community itself.

Research questions

1) What is the outcome of implementing community-based intervention towards measles immunization coverage?
2) How is the community's acceptance and satisfaction on the community-based intervention implemented?

Research justification

In view of the above problem, this study aimed to implement and evaluate a community-based intervention to improve measles immunisation status among the marginalised population. Through this research, the effectiveness of the intervention towards improving the completion of measles immunisation could be determined.

Similar with other public health program organised, combination of strategies is required to achieve measles elimination in the country, and this include having targeted approach on the high-risk population. Testing the effectiveness of such intervention required direct implementation on the specific community so that evidence-based findings could guide future actions to improve measles immunisation in this country. However, in contrast with other community-based programs done, the intervention integrates the community's own suggestion to assist their own people in obtaining measles vaccine which could empower the marginalised community at the same time. Hence, from a health provider's point of view, this study added to the body of knowledge as more information are obtained in relation to the targeted people's needs and concerns, as well as the gaps that could occurred on the ground when the intervention is executed. This is important as solution towards the problems could be suggested and provided when the intervention is done at other settings.

Meanwhile, from a policy maker's point of view, this study offered the insight on the parent's experience which guide them towards their decision in utilising immunisation services. The result served as an evidence-based for policy makers to see whether the intervention is able to achieve its goals or not, and whether the intervention could be extrapolated to other district or other healthcare programs.

Therefore, this study highlighted the needs for a targeted sustainable intervention through the marginalised community empowerment and involvement. This could then improve measles immunisation coverage and prevent future measles outbreak that could occurred.

Research objectives

General objectives

To implement and evaluate a community-based intervention to improve measles immunisation status among the marginalised population.

Specific objectives

a. To determine the effectiveness of the intervention in improving immunisation status or completeness.

b. To identify and compare the community's perceived satisfaction between the community-based intervention with the routine healthcare services that they received.

c. To identify the community's perceived acceptability towards the community-based intervention they received.

Research Hypothesis

a) The community-based intervention is acceptable to the marginalized population.

b) The community-based intervention satisfies the marginalized population.

c) The community-based intervention improves immunization status.

d) When compared to standard healthcare follow-up, the community-based intervention improves measles immunisation status.

METHODOLOGY

Study design

This research is a cluster randomised control trial that study the effectiveness of community-based intervention towards improving measles immunisation coverage through the involvement of community volunteers. The study will be conducted in ten (10) urban slums and settlement areas of the marginalised population in Kota Kinabalu from March 2022 to March 2023. It is hypothesized that the community-based intervention implemented could improve the completion of three (3) measles immunisation doses among the children of the marginalised population. The intervention was conducted in collaboration with clinics under the management of Kota Kinabalu district health office and the community living in the areas. The acceptance and the perception of the community living in the study areas regarding the intervention program will be conducted prior to the study [19]. Thus, the conduct, analysis, and reporting of trial will be done in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines adapted for cluster-randomised trials [20].

Randomisation

The clusters in this study will be the ten (10) urban slums and settlement areas of the marginalised population, and they were randomly assigned and evenly allocated to two groups. The settlements will be chosen based on five (5) criteria: (i) Community which include legal and illegal migrants; (ii) Majority of the community were socially excluded (iii) Majority of the community have difficulties in getting access to healthcare; (iv) Live in urban slums; and (v) Have low immunisation coverage. They were excluded from the trial if they had ongoing community health programs that could bias the study outcome. There will be a total of 10 urban slums and settlements, where 5 settlements will receive the community-based intervention, while 5 settlements will receive no intervention and only routine immunisation services. A cluster-randomised approach is preferred compared to an individually randomised approach to avoid potential contamination of intervention activities between neighbouring villages.

The ten villages in this trial will be divided into intervention and control group through simple random allocation. The simple randomisation process was done using R software to designate cluster assignment. The allocation sequence was concealed from the researcher as the villages were numbered from one to ten prior to being input into the software. They were then randomly allocated into either the intervention or control group. Randomisation was done to balance known and unknown risk variables (Matts & Lachin, 1988) while allocation concealment technique was done to prevent selection

bias (Kim & Shin, 2014). There was no stratification or matching. Both intervention and control arm location were also identifiable to the researcher, participants, and community volunteers.

Study population and setting

The participants in this study will be the children who lived in the 10 settlements in Kota Kinabalu. The eligibility criteria for the children to be included in this study are: (i) born from October 2021 to March 2022; and (ii) parents consented to join the study (iii) parents living long term in the village of six months or more. While children who will be excluded from the study include: (i) contraindicated towards measles vaccination, and (ii) parents were community volunteers in the village which was to avoid bias in the study. The participant's parents or caretakers needed to have access to a mobile phone in which the intervention could be done. For those participants did not own a phone, the enrolment was paused until the participant confirmed with the owner of the shared phone that text messages and incentives, as applicable, could be sent to the mobile phone. Other than that, the immunisation status of the children was determined through medical record review and irrespective of the group allocation, all the children could get the routine immunisation services provided at the health clinics.

Control

The participants in the control group continued to receive the available routine immunisation healthcare services at the health clinics. In this group, the nurses also remind the participants regarding their immunisation and do the home visits **(Figure 1.3)**. However, these activities were done depending on the workload and available free time that the nurses have and many did not receive such care.

Intervention

The community-based intervention in this study is a reminder and recall strategy which seek to improve the completion of measles immunisation doses among the children of the marginalised population. This intervention will be done to address the barriers that was found on the same community prior to the study [19]. The participants allocated to the intervention groups will receive messages sent by the community volunteers whom were recruited from the same village to remind them regarding their appointments to get their three doses of measles vaccines at the health clinics. The immunisation appointment dates will be relayed to the community volunteers by the principal researcher. Then, the community volunteers relayed the intervention message via SMS informing the need for the participant to go to the health clinic to receive their measles vaccination at the scheduled date.

Basically, for the intervention group, SMS reminders will be delivered seven (7) days before the scheduled measles immunisation date at ages 6 months, 9 months and 12 months **(Figure 1.4)**. If the parents or caretakers did not respond and the participants missed their vaccination appointments, the community volunteers then will do a home visit three days after that to assist them so that the participants could get their vaccinations. The participant's immunisation status will then documented in the maternal and child health (MCH) booklet. If the MCH booklet is not available, a verbal report of immunisation history will be taken.

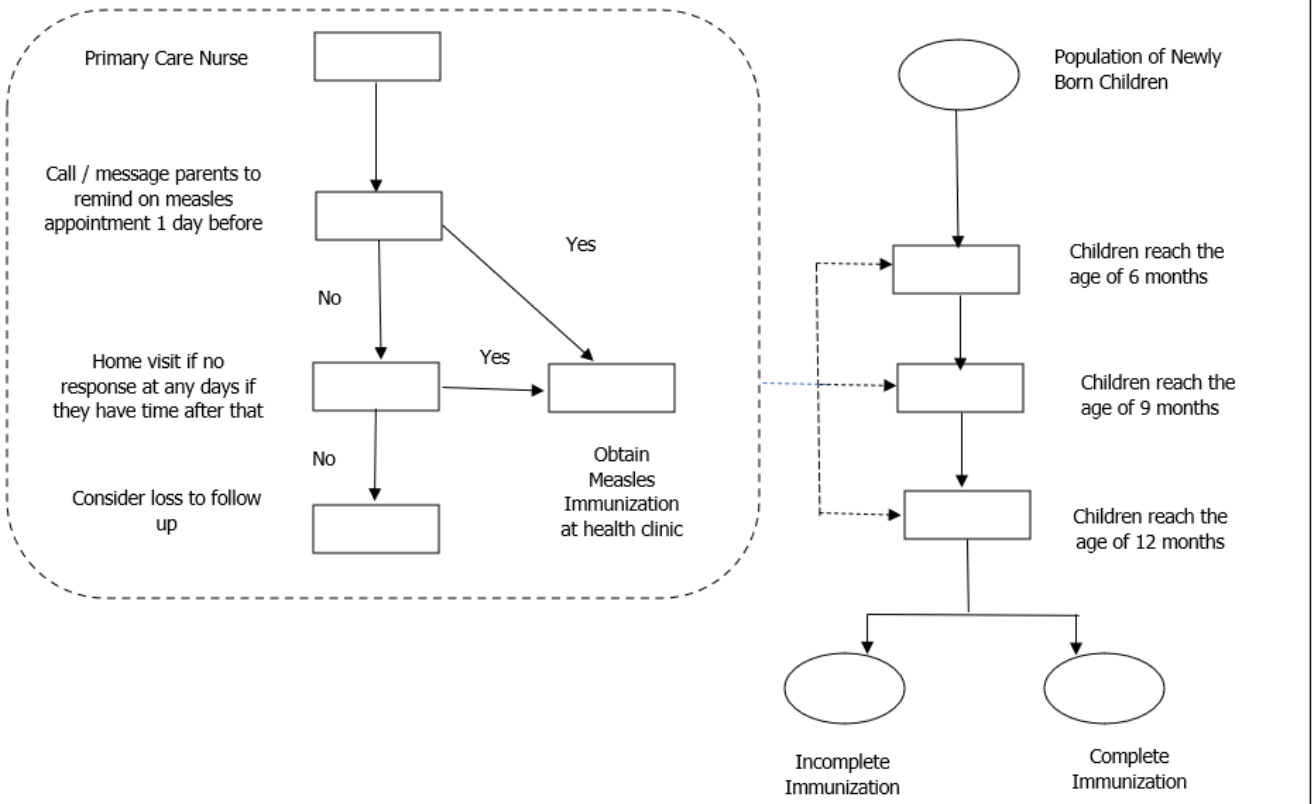
Person in charge	Activities	Routine Healthcare Services Flowchart
Primary Care Nurse	Obtain the number of newly born in the locality every month Remind parents/ caretakers regarding measles vaccination appointment 1 day prior to visit Do outreach by visiting parents/ caretakers' home or locate where they are if no answer at any time available if no response. Only do this once.	

Figure 1.3: Routine Immunisation Healthcare Service Flowchart

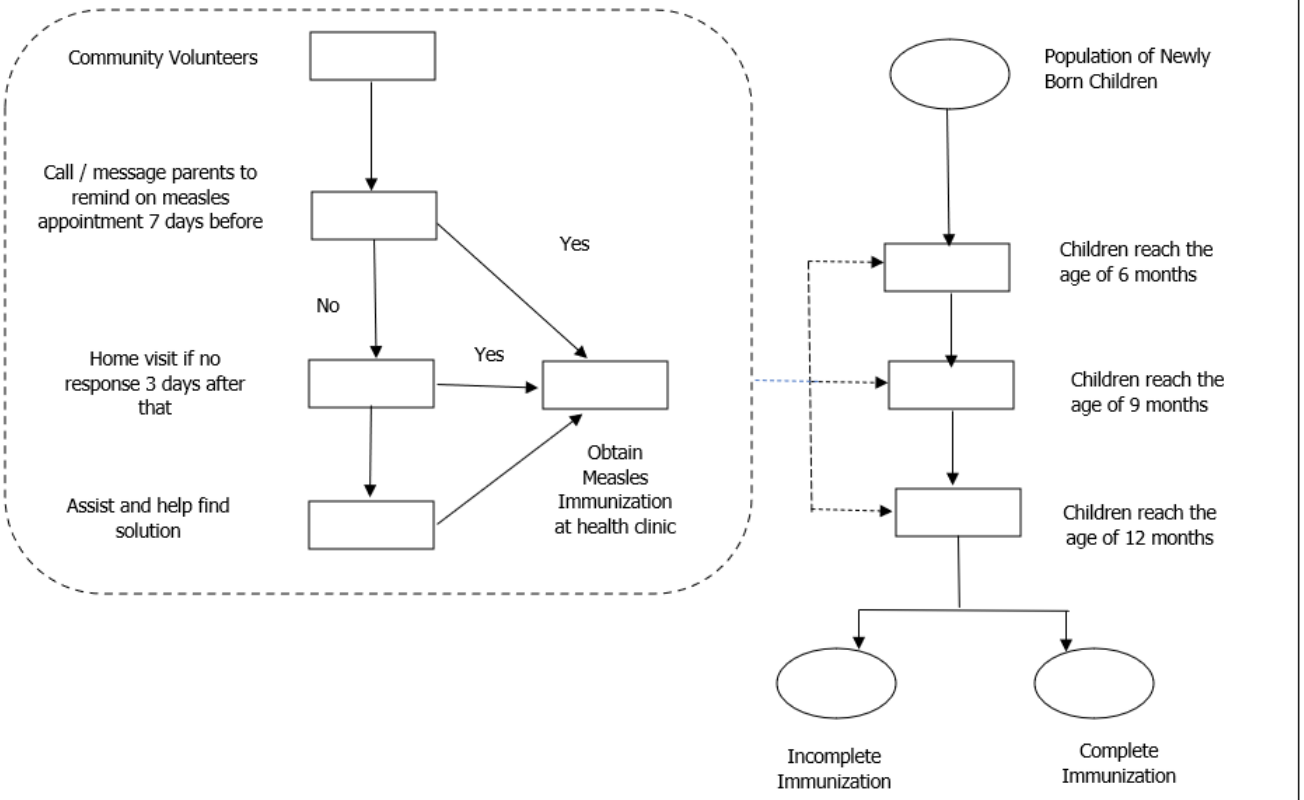
Person in charge	Activities	Community Intervention Activities Flowchart
Main researcher (health clinic, village leader)	Obtain the number of newly born in the locality every month	
Team of Community volunteer	Remind parents/ caretakers regarding measles vaccination appointment 7 days prior to visit	
	Do outreach by visiting parents/ caretakers' home or locate where they are if no answer after 3 days if no response	
Team of Community Volunteer with The Village Committee	Assist and find solution if some of the parents have difficulty in bringing their children to get immunization	

Figure 1.4: Community-based Intervention Activity Flowchart

Planning and development of MIICA program

In the initial planning stages, we paid advocacy visits and convened planning meetings with the community leaders of every settlement, local politicians, and representatives of the Kota Kinabalu district health clinics to embrace and support the hard-to-reach project. We conducted qualitative study to understand the perspectives of the community regarding the program. From the prior study, knowledge regarding the barriers faced by the marginalised population were acquired and discussed. The community volunteers were recruited by the village committee and they were mobilized and trained to assist in the program. A team of community volunteer was created per settlement with 10 volunteers in each team. Training session for the community volunteers were planned and organised based on the input of the community leaders. During the session, the barriers faced by the community were provided as a scenario to the volunteers, and they discussed and provided solution on how to assist the participants in obtaining their measles immunisation.

Monitoring and follow-up

Supervisory support and monitoring visits were done by the principal researcher. Due to the hard-to-reach settlements, monitoring visits were limited but constant communication were maintained with the community volunteers throughout the study via WhatsApp. After each SMS reminders were conveyed to the participants, the volunteers updated them in their WhatsApp group. The volunteers also shared their successes and failures for the participants who needed home visits and assistance to obtain measles vaccination at the health clinics. The principal researcher monitors and recorded the information updated in the WhatsApp group to make sure every participant in the intervention group received the intervention needed.

Outcome measures

The primary outcome was the proportion of complete measles immunised children by 12 months of age. The participants met the outcome definition when they received all the three doses of measles vaccine. Those who missed any one of the vaccine doses were considered as having incomplete immunisation. Data for the primary outcomes came from the written immunisation records found on the child's MCH booklet and was collected at the end of the 12-month follow-up. There were two copies of MCH booklets where one is kept by the parents or caretakers while another booklet was kept by the health clinics. The MCH booklet from the health clinics was chosen as the primary source document because it was a formal record of the vaccines received. Verbal reports of immunisation at 12-month

follow-up, in the absence of written documentation, were considered as not receiving the measles vaccine. Meanwhile, the secondary outcome was the parents or caretaker's satisfaction and acceptability towards the intervention that they received. The outcome was measured using CSQ-8 and AIM-IAM-FIM questionnaire at the end of the study.

Sample Size

Current statistics indicate measles vaccine coverage of approximately 70% at 12 months of age for children living in Kota Kinabalu. A target of 10% improvement in the immunisation status was set within the population based on other study implementing SMS reminders [21]. An intra-cluster correlation (ICC) of 0.20 with 20 clusters per arm was considered since cluster sampling was used [22]. The primary outcome will be binary; yes or no as to whether the community-based intervention is able to improve measles immunisation status. Therefore, the formula for the standard parallel-group, two-armed design with binary outcomes were applied and there was a total of 470 participants needed to be enrolled in this study. Among the ten settlements, 5 settlements with 235 participants received the community-based intervention, while another 5 settlements with 235 participants received the routine healthcare services.

Statistical analysis

The primary analysis for this study used the intention to treat analysis (ITT) which include all the study participants from the randomised clusters who provided the 12-month followed-up data on immunisation. The categorical variables pertaining to sociodemographic data were characterised using frequency and percentage. The primary outcome which was the effectiveness of the community-based intervention in improving measles immunisation status or completeness was analysed using multilevel logistic regression analysis to take into account the cluster design effect. It was then adjusted to the individual sociodemographic effect characteristics of the study participants. The findings were presented using Odds Ratio with 95% Confidence Interval and p values.

While for the secondary outcome, a descriptive study of the community's satisfaction and acceptability of the intervention was performed using mean. The scores were then classified according to percentile (Quartiles). In addition, the analysis for the satisfaction was compared between the study arms using multilevel linear regression analysis with the same reason of taking into account the cluster design effect. It was then adjusted to the individual sociodemographic characteristics of the study participants. Furthermore, adjustment for multiple comparison was made using Bonferroni method. The study utilised the control group as the reference group for all analyses. The statistical significance level was established at 0.05, and the SPSS software was employed for data analysis.

Study Intervention Procedures

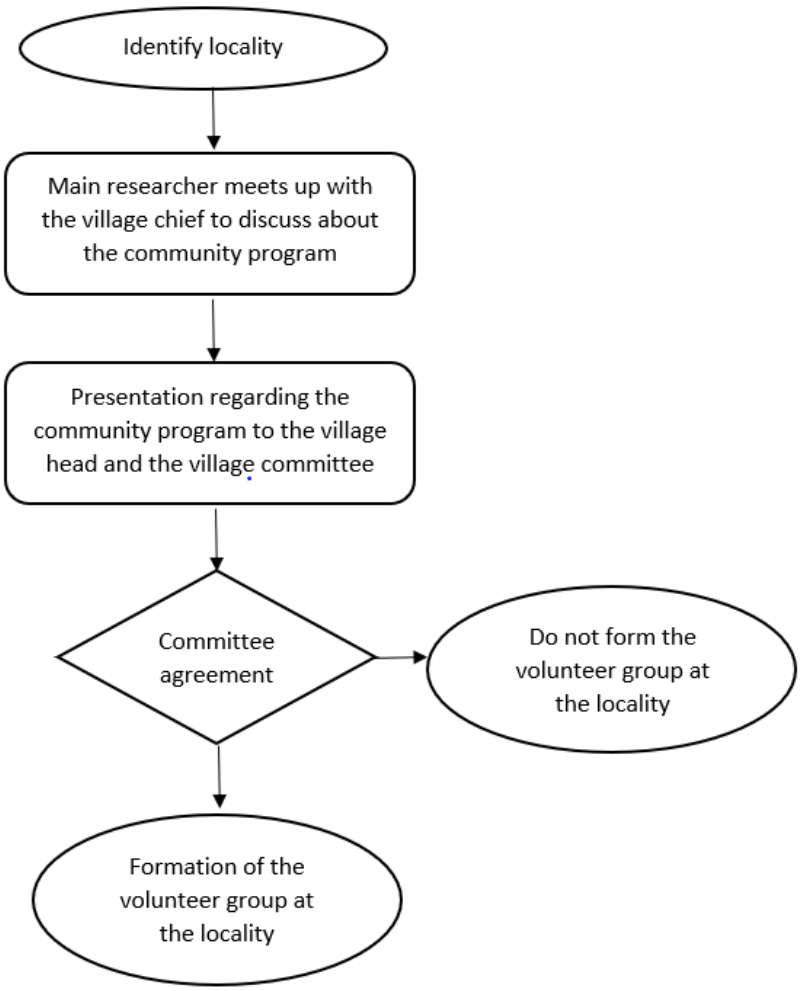
a) Community-based intervention

The community-based intervention in this study will begin with the development of community volunteer organisations in the selected communities. The local community head and the village committee will be the primary stakeholders with whom this study will be discussed. Once approval has been obtained, community volunteers who meet the specified requirements will be chosen. The criteria for the community volunteers include:

(i)Committed to become a volunteer

(ii)Is a permanent residence in the village

A minimum of 7 to 10 volunteers will be assigned to each town. The volunteers will work together as a team and can divide their responsibilities as needed. To maintain effective communication between the volunteers and the researcher, each village will have a community volunteer leader.



Next, the activities and duties that the community volunteers have to do throughout the study period will be explained to them. A list of children within the village will be provided to the community volunteer teams together with the phone numbers or address of their parents within the village. The duties of the community volunteers will be: -

(i) To educate the parents regarding measles disease and measles immunization. Researcher will educate the volunteers first and leaflets and health education information on the topic will be provided to them.

(ii) To remind parents on their measles vaccination appointment date

(iii) To do home visit if needed and encourage parents to go vaccinate their children.

(iv) To assist and find solution together with the village committee for parents who may need help in getting measles immunization for their children

The specific steps for each of the duties are as below: -

i.	Education	-A meeting with the team of community volunteers will be organized. -Researcher will teach and explain to the team regarding measles disease and measles immunization using the leaflets and information sheet. -Leaflets and information sheet on measles disease is as seen in Appendix. -The community volunteers will then educate the parents based on the information given. -Education and sharing of information can be done through phone calls or home visits or as an organized village activity.
ii.	Reminder activities	-The team community volunteer will be provided with list of children in the village that needs measles immunization. -This list will also include the parents phone numbers and/ or address. -The team is responsible to arrange a volunteer to call, educate and get the appointment dates given by the health clinic for child's measles immunization from the parents. -The team will then remind parents regarding their incoming measles immunization appointment at the health clinic at any time 1 week prior to the date.

		-They can also SMS or WhatsApp reminders regarding the visit at any time 1 week before. -If the parents did not answer the phone calls or message three days after that, the community volunteer team will then proceed to home visit. -After the date of the children visit for measles immunization, the team can contact the parents at anytime to get the next measles immunization date until the children complete getting their 3 doses of measles vaccination.
iii.	Home Visit	-The community volunteer team will do home visit to the children's home when they have unanswered calls and phone messages. -They will do this on the next day after the supposed measles immunization appointment date. -During the home visit, the community volunteer team will then find out the reason for the lack of response. -The reasons for non-response will then be filled up in the form. -Any difficulties for the children to get vaccination can be discussed with the village committee for assist and solution
iv.	Assist and Find Solution	-The parents who face difficulties in bringing their children to the clinic to get measles immunization could be assisted -The team of community volunteers could discussed this with the village committee to help in ensuring the children get the immunization -Any solution or non-solution will be informed to the nurses in charge of the locality.

For data management, aall the record of the follow up activities and the children's vaccinations will be recorded in the form and monitored by the main researcher. All the children in the locality will be followed up on their measles vaccination routine. Meanwhile, researcher will also maintained village profile where the contents include: -

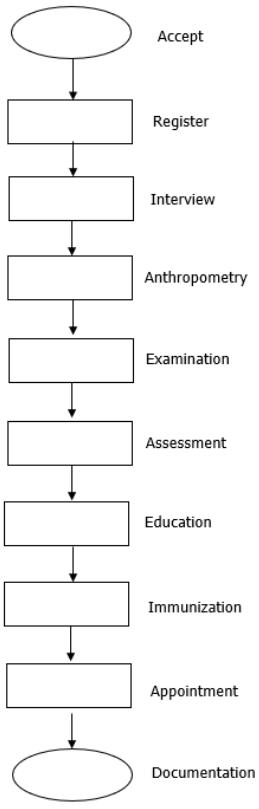
(i)The number of volunteers per locality

(ii)The number of children age 0 to 1 year old

(iii)The map of the village

b) Routine Health care for Immunization

For the control group, the village chosen will continue following the routine health care services provided. It will be based upon the Mother and Child Service Manual produced by the Family Health Development Division, Ministry of Health Malaysia. The services flowchart for child immunisation is as followed: -



When a child defaulted appointment, the nurses in charge will call the parents and try to locate the child until he or she gets the measles immunisation. However, for the marginalized population especially for illegal citizens, the attempt to locate the child will only be done one time before it is considered that the child already move somewhere that is non locatable. No attempt will be done to find the child for immunization.

Operational Definitions

a) Marginalize

Refer to the processes and conditions by which specific populations are impacted by structural, avoidable, and unnecessary inequities which result in disproportionate illness and hardship (Browne et al., 2012). For this study, the marginalized population would refer to the urban poor people who live in the slum and squatter areas in Kota Kinabalu. It will include both legal and illegal populations.

b) Incomplete measles vaccination

Incomplete immunization is defined as missing any of the listed vaccines among children aged six months to 12 months or did not take any vaccination at all

c) Defaulter

A person who defaults or fails to fulfil an obligation of getting measles immunization

3.2.9 Study Instruments

The study instruments applied in this study include the consent form, and questionnaire.

(i)Consent Form

Before conducting the study using a questionnaire, written consent from the participants will be obtained before they can proceed to fill in the questionnaire form. An information sheet regarding this study will be provided.

(ii)Questionnaire

A self-administered questionnaire will be disseminated to the parents/ caregivers via the health clinic nurses. It will consist of 3 sections in which each of them will cover different topicsThe sociodemographic section and the health care service section would be answered when the recruited children are at the age of 2 months. The intervention acceptability section would be given to be

answered when the children are at the age of 12 months.

i. Section A

Sociodemographic questionnaire included detailed information of the respondents such as age, gender, ethnicity, level of education, literacy status, marital status, household income, citizenship, spoken language, number of children, and employment status.

ii. Section B

Health service factors will be asked in this segment, including the type of health care facility the participants choose to get their measles immunization, the cost for the immunization, mode of transport to reach the clinic, and the distance from their village to the respective health facility.

iii. Section C

We will use a questionnaire adapted from the Computerized Therapy Questionnaire- Patient Version (PCTQ-P), a self-report questionnaire for potential customers based on the Diffusion of Innovations theory developed by Carper et al. [23]. This is a 15-item instrument to assess participant's perceptions of the acceptability of the community-based intervention. The subscales include the parents/ caregiver's perception regarding their satisfaction, the intervention's complexity, compatibility, relative advantage, and future use intention. The items are measured using the Likert scale (Strongly disagree – Strongly agree). The measure is scored by calculating the subscale mean.

Nevertheless, the Computerized Therapy Questionnaire- Patient Version (PCTQ-P) is in English. There is no validated Malay version at the moment; PCTQ-P will be translated into Malay version based on the ISPOR Guideline for Translation and Cultural Adaptation Process [24].

a. Preparation

This is the initial work that will be carried out before the translation works begin. The work includes obtaining permission from the instrument developer to use the instrument, inviting the developer to be involved in this process, and developing explanations of concepts in using the tool. All these are done for copyright purposes and able to clarify the idea behind the instruments.

b. Forward translation

This is translating the instrument from the original language into another language, commonly called the target language. There need to be two or more independent bilingual translators who are also native speakers of the target country. The translations can then be compared to detect

errors and identify ambiguous items that can result in bias. We will have translators from the Language Faculty from University Malaysia Sabah to assist in this process.

c. Reconciliation

This is when more than one forward translation is compared and merged into a single forward translation. Here, a consensus needs to be reached based on the two or more forward translators. This can be done via discussion between the forward translators and the principal researcher, or an independent translator can be used to perform the reconciliation.

d. Back translation

This is the process of translating the new language version back into the original language. Two or more independent bilingual translators with English as their native language will do this process. This function as a quality control step demonstrates that the exact meaning is derived when the translation is moved back to the original language.

e. Back translation review

In this process, we will compare the back-translated version of the instrument with the original to highlight and investigate the differences between the original and the translated version. The revision will be made to resolve any issues found. The rationale for this process is to ensure that there is conceptual equivalence from the translation.

f. Harmonization

It compares two or more back translations of different language versions with each other and the original instrument to highlight the discrepancies between them. This can be done via a meeting chaired by the principal researcher with the two or more back translators to achieve a consistent approach in dealing with the translation problems.

g. Cognitive debriefing

This is the process of testing out the instrument on the relevant people and, for this study, the marginalized population. This is done to test the wording and check the understandability, interpretation, and cultural relevance of the translation. For the pre-test, we will do on 10% of the marginalized population for our study. Then, we will do a pilot test to test the reliability of the questionnaire. For this process, we would test on at least 10 participants per item on the scale.

h. Review of cognitive debriefing results and finalization

Here, we will compare the lay's people interpretation of the translation with the original version to highlight and amend any discrepancies. Modification is made on any items that need to be reworded where the respondent's comments justified such change.

i. Proofreading

This is the final review of the translation, where any typographic, grammatical, and other errors will be corrected.

j. Final report

It is a report written at the end of the process to document the development of each translation. It will clearly explain the reasons for the wording choices made throughout the translation. This is essential for future translations of the instruments, which will be harmonized with the other language versions developed previously.

3.2.10 Data Collection

The data collections duration will take twelve months. For the secondary data on measles immunization coverage, it will be obtained from the Kota Kinabalu District Health Office. Data on the community intervention's follow up meanwhile will be continuously obtained from the community volunteer team monthly. The data will be collected by the principal researcher assisted by health clinic nurses who are trained in collecting field data.

For the questionnaire, participants will be briefed by the principal researcher to explain the purpose, process, and benefit of this study. After obtaining verbal consent, the questionnaires will be given to the participants. There may be a need for the researcher and enumerator to assist the participants in filling the questionnaire. The estimated time to fill up the questionnaire will be around 30 minutes.

3.2.11 Data Analysis

The initial data obtained will be entered and arranged using Microsoft excel. The data will then be analyzed using IBM Statistically Package for Social Sciences (SPSS) version 26. All the analyses will be based on the intention to treat. First descriptive analysis will be done where the continuous data will be expressed as mean, median, mode, and standard deviation. The categorical data will be represented as frequency and percentage. In addition, descriptive statistics were used to describe the characteristics of the participants and the distribution of the interventions. We will also do a descriptive analysis of the

community's perception on the intervention's acceptability and satisfaction.

The primary outcome will be the proportion of measles immunization status. We will compare the proportion of immunization status between the community-based intervention group and the routine healthcare follow-up, the control group. Comparison can be made using the Chi-square test. Then we will use logistic regression to adjust the association with other factors.

3.2.12 Data Storage and Ethical Consideration

The ethical approval for this study will be obtained from the Ethical Committee of University Malaysia Sabah (UMS) and the Medical Research Ethics Committee (MREC). Once the MREC, the approval letter will be sent to the Sabah State Health Director to request permission to conduct the study among the health investigators at the health department. Then the approval of the letter from the Sabah State Health Department will be sent to the Kota Kinabalu District Health officer in charge.

In addition, all the information gathered from the respondents will be kept confidential. Subjects will not be identifiable, and no personal data will be revealed.

3.2.13 Control of Bias

Bias in any trend or deviation from the truth in data collection, data analysis, interpretation, and publication can cause false conclusions. In this study, the clusters will be randomly assigned, and all the targeted children in the clusters will also be included in this study. Thus, there will be no selection bias. We would also recruit all the parents/ caregivers who consented to join this study regardless of their opinion on vaccination, whether anti-vaccine or pro-vaccine. This study is also not done exclusively in one cluster, but it will be done in several clusters in different areas of Kota Kinabalu.

Other than that, during data collection, the researcher will guide and train the nurses on the details of the questionnaire. Clarification and confirmation of the answers will be done during the submission of the questionnaire to the researcher. To control non-response bias in this study, a confirmation date will be given and informed one week before visiting day.

Informed Consent

The health staff will be interviewed at their workplace. Those who are willing to be participate will sign the consent form and dated.

Privacy and Confidentiality

Subject's names will be kept on a password-protected database and will be linked only with a study identification number for this research. The identification number instead of patient identifiers will be used on subject data sheets. All data will be entered into a computer that is password protected. On completion of study, data in the computer will be copied to a hard drive and the data in the computer erased. The hard drive and any hardcopy data will be stored in a locked office of the investigators and maintained for a minimum of three years after the completion of the study. The hard drive and data will be destroyed after that period of storage. Subjects will not be allowed to view their personal study data, as the data will be consolidated into a database. Subjects can write to the investigators to request access to study findings.

Conflict of Interest

The investigator declares that there is no conflict of interests.

Publication Policy

No personal information will be disclosed and subjects will not be identified when the findings of the survey are published.

Termination of Study

The investigator may decide to terminate the study at any time. Subjects will be informed if the study is terminated and follow-up visits will be arranged if needed.

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