Assessing readiness to implement routine immunization among patent and proprietary medicine vendors in Kano, Nigeria: a theory-informed cross-sectional study

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ABSTRACT

Background

Patent and proprietary medicine vendors (PPMVs) are widespread in communities and can potentially be used to expand access to routine immunization especially in underserved communities. In this study, we aimed to assess their readiness to implement routine immunization in Kano, Nigeria, and identified factors associated with it.

Methods

We conducted a cross-sectional survey of PPMVs aged 18 years and above in Kano metropolis, Nigeria, using cluster sampling technique. A 10-item Likert scale-based measure was used to estimate readiness score. The relationship between selected factors and readiness score was examined using multilevel linear modeling technique.

Results

A total of 455 PPMVs with median age of 36 years participated in the study. The median raw score for readiness was 4.7 (IQR: 4.3 – 4-8) (maximum obtainable was 5). The mean readiness score (obtained through factor analysis) was 5.28 (SD: 0.58). Readiness score was associated with factors such as knowledge of immunization and task demand, engagement by other public health programmes among others.

Conclusion

This study demonstrated the feasibility of measuring the level of readiness for implementing routine immunization among PPMVs. Given the high level of readiness, policy makers should consider the possibility of expanding access to immunization through PPMV.

Keywords: patent and proprietary medicine vendors, readiness, immunization, systems thinking, causal loop diagram

1.0 INTRODUCTION

Ever since the World Health Organization (WHO) launched the Expanded Programme on Immunization (EPI) in 1974 [1], universal access to vaccines for children has remained an important global health agenda [2]. Although several initiatives have emerged over time to improve the availability of vaccines [3,4], several African countries including Nigeria are still lagging behind in the set benchmark for routine childhood immunization coverage [5]. Coverage rate of third dose of diphtheria-tetanus-pertussis containing vaccine (DTP3) is a surrogate indicator of immunization programme performance for which countries are expected to reach at least 90% national coverage [6]. According to the WHO, coverage with DTP3 in the African region has remained between 70% and 76% since 2013, with a stagnation at 76% since 2016 [5]. This means that approximately one child out of every four children are missed out by the immunization system in the region [5]. In Nigeria, the coverage estimates are even lower than regional averages, as DTP3 coverage were 45%, 33% and 58% in 2016, 2017 and 2018 respectively [7]. Epidemiologically, such coverage levels are not sufficient for herd immunity against vaccine-preventable diseases [8–10]. As the post-2020 era approaches, strengthening routine immunization through innovative and purposeful service expansion should be a key goal for national immunization programmes.

A potential private health sector group that could be used to further expand access to routine childhood immunization are patent and proprietary medicine vendors (PPMVs) in patent medicine stores (PMS) [11]. A PPMV is an individual who do not possess formal pharmacy qualification but engages in the sales of medicines [12]. They are an important source of essential child healthcare because they are often the first (and sometimes sole) point of contact for many sick children in communities with fragile health systems [13]. It is estimated that between 15% - 83% of caregivers in sub-Saharan African countries visit PPMVs for health services when their child is sick [13]. There are several reasons for this high patronage. Firstly, PPMV are widespread in rural areas, urban slums and underserved hard-to-reach communities [14–16]. Secondly, their closeness to where people live makes it more convenient to seek health care from them [15]. Even when free services are offered in health facilities, people sometimes prefer to seek care

from a PPMV to avoid the indirect costs of travel and time that are associated with attending formal health facilities [17]. Furthermore, their services are fast and opening hours are usually longer and more flexible than that of a typical health centre [18]. Finally, since PPMVs do not typically charge consultation fees, their services are often cheaper [16,19]. For these reasons, several public health programmes in Nigeria have already began to engage PPMVs to expand access to family planning commodities [20] and quality services for malaria and diarrhea diseases treatment [21].

Given their wide patronage for child health services, PPMVs can also be incorporated into the immunization system to complement already existing structures. But an important precursor to such engagement is to establish their readiness to implement such services in the first place [22]. Routine immunization is complex [23] and involving PPMVs in the service delivery framework will entail system redesign that have implications for both service providers and government stakeholders. If the PPMVs, who will be responsible for providing the services, are not psychologically and behaviorally prepared to implement it, the programme could fail [24]. Several studies have already highlighted the link between lack of readiness and poor performance of health programmes [22,25,26]. Readiness is important because it determines the extent to which a change is adopted and the level of effort that is put in to ensure implementation success [27].

Several frameworks for readiness exists [28–30]. However, the organizational readiness for change framework is distinct as it regards readiness as a shared psychological state among a group of people [22]. This framework conceptualizes readiness as both a multi-level and multi-faceted concept [22]. Readiness is multilevel because it can be present to varying degrees at individual, group, organizational or even societal level [22]. It is multi-faceted because it has two constructs; change commitment and change efficacy [22]. Change commitment refers to the shared decision of members of an organization or group to implement change [22]. On the other hand, change efficacy refers to an organization's confidence in their capability to implement change [22]. Based on this framework, the organizational readiness for implementing change (ORIC) tool was developed [31]. This tool provides a valid and reliable measure of

organizational readiness that can be used in health care settings [31]. The tool is brief such that it can be used in busy settings [31].

Despite the availability of a simplified tool for measuring readiness [31], there is still a dearth of research evidence on organizational readiness for implementing change in health-care settings in sub-Saharan Africa. Particularly, the level of readiness of PPMVs to implement routine immunization services is not fully understood. Furthermore, readiness is complex as it can be influenced by several factors [31]. As such, a full understanding of this complexity can provide further insights on how to maximize the potentials of PPMVs within the immunization system. Most often, linear models are used to explore the relationship between variables, but they are unable to account for feedbacks loops which are an integral part of the dynamics of a real-world system [32]. The emerging field of systems science provides additional tools for exploring such dynamic relationships [33]. Therefore, in this study, we aimed to quantitatively assess readiness to implement routine immunization among PPMVs in Kano metropolis, Nigeria, at individual and district level. In addition, systems thinking was integrated after using a multilevel modeling approach to identify the factors that are associated with readiness to implement routine immunization to enable a more nuanced understanding of their interrelationship.

1.1 Conceptual framework

In this study, we drew on Weiner's theory of organizational readiness for change and the organizational readiness for implementing change (ORIC) to assess the level of readiness to implement routine immunization services among PPMVs in Kano metropolis, Nigeria [22,31]. This framework was adopted because engaging PPMVs for immunization services will entail group-level behavior change [31]. To ensure that the assessment reflects supra-individual views, group-reference (the people) rather than self-reference (I) was used [31]. The two constructs; change commitment and change efficacy, were also represented in this study. Change commitment was defined as the shared resolve of PPMVs to implement routine immunization activities, while change efficacy was defined as PPMVs' shared belief in their collective capabilities to implement routine immunization activities. It was hypothesized that factors such

as sociodemographic characteristics, participation in other public health programmes, knowledge of immunization, perceived awareness of task, willingness to cooperate with supervision and availability of incentives can be related to PPMV readiness to implement routine childhood immunization services.

2.0 METHODOLOGY

2.1 Study design

A cross-sectional survey design was used for this study [34].

2.2 Study setting

This study was conducted in six Local Government Areas (LGAs) of Kano metropolis, Nigeria, which included Dala, Fagge, Tarauni, Nassarawa, Kano Municipal, and Gwale. The trade associations of PPMVs further subdivided these LGAs into 16 trade associations districts to enable better coordination. The estimated number of PPMVs in these districts are between 1500 to 1800. It is difficult to ascertain the exact number of PPMVs across these districts because of their rapid proliferation.

2.3 Study population

Any PPMV aged 18 years and above that was met in a patent medicine store was included. In case more than one PPMV was met in the store at the time of this study, only the owner or most senior personnel was selected to avoid overrepresentation.

2.4 Sampling

A one-stage cluster sampling technique was used for this study. A list of all the 16 trade association districts in the six LGAs was obtained. Then simple random sampling was used to select 12 districts. Within each of the selected districts, all eligible and consenting PPMVs were included.

2.5 Sample size

A total of 455 PPMVs were included in the study. Cochran's equation was used to compute the minimum sample size [35]. Confidence limit specified was 95% (z=1.96) with a precision level of ±5%. A proportion of 50% was used as no previous study or estimate was found. Design effect (DEFF) of 2 was considered.

2.6 Data collection

Data was collected using semi-structured, interviewer administered questionnaire. The questionnaire was built using Research Electronic Data Capture (REDCap) and administered through mobile tablets by three trained field data collectors [36]. Data collection was conducted in October 2019. These field data collectors were trained for one day prior to commencement of data collection. During their training, several dry runs were conducted to enhance flow and familiarity. All the three data collectors were fluent in both Hausa and English languages. During the field work, if a patent medicine store was found to be closed during morning or afternoon hours, the data collector would return in the evening to check for their availability and conduct the interview. Advocacy was paid to the PPMV trade association leadership across the districts to obtain their buy-in and ensure participation from their members.

2.7 Variables

Outcome variable: readiness for implementing routine childhood immunization

To measure readiness for implementing routine childhood immunization services among PPMVs, a 10-item, Likert scale-based tool was used. The Likert scale were based on five points ranging from strongly disagree (1) to strongly agree (5). The 10-item tool (five each for change commitment and change efficacy) was based on a previously developed ORIC tool [31]. All items with factor loadings greater than 0.6 in the ORIC tool were used in this study [31]. Also, these items had factor loadings of less than 0.35 on other factors [31]. The items began with "people who work in this patent medicine store…" and "implementing this change" in the ORIC tool was replaced with "implement childhood routine immunization services" [31]. For change commitment, the five-items were: '*people who work in this patent medicine store are committed to implementing childhood routine immunization services*', '*people who work in this patent medicine store are determined to implement childhood routine immunization services*', '*people who work in this patent medicine store are motivated to implement childhood routine immunization services*', '*people who work in this patent medicine store will do whatever it takes to*

implement childhood routine immunization services', and '*people who work in this patent medicine store want to implement childhood routine immunization services*'. While for change efficacy, the five-item were: '*people who work in this patent medicine store feel confident that they can manage the politics of implementing childhood routine immunization services*', '*people who work in this patent medicine store feel confident that the association can support people as they adjust to implementing childhood routine immunization services*', '*people who work in this patent medicine store feel confident that they can coordinate tasks so that implementation of childhood routine immunization services goes smoothly*', '*people who work in this patent medicine store feel confident that they can keep track of progress in implementing childhood routine immunization services*', and '*people who work in this patent medicine store feel confident that they can handle the challenges that might arise in implementing childhood routine immunization services*'.

Explanatory Variables

Sociodemographic characteristics include age, sex, level of education, formal health-related training (this was defined as possession of a health-related qualification), ever involved in immunization activities, currently working in a health facility, type of health facility and currently involved in immunization activities.

Characteristics of operations and services provided by the PPMV include ownership of the store, time of operation, staff strength, number of children less than one year who are brought to the store per day, administer injections in the store, engagement to offer counseling and referral for family planning services, engaged to offer zinc and oral rehydration salts for diarrheal diseases in children and engaged to offer malaria rapid diagnostic test.

Perceptions regarding knowledge of vaccines, task demand and incentive requirement were based on 5-point Likert scales.

2.8 Data analysis

The sociodemographic characteristics of the PPMVs, characteristics of the operation of patent medicine store and services provided, perceptions regarding knowledge, task demand and incentives were summarized using frequencies and percentages. Cronbach's alpha was calculated for the 10-item tool that was used to assess PPMV readiness to implement routine immunization. To establish that the 10-item tool measured any latent construct(s), factor analysis was performed [37]. Bartlett's test of sphericity was determined to test whether the correlation matrix of the data had an identity and Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was calculated to estimate the proportion of variance in all the 10 items in the tool that was as a result of an underlying construct [38,39]. A polychoric correlation matrix was fitted and subsequently used for the factor analysis. The factor with eigen values above one was retained. For the retained factor, the factor loadings for each of the ten items were calculated. Based on the 5-point responses on the Likert scale of each of the 10 items, raw scores calculated for individual PPMVs. The calculated raw scores were then categorized into high readiness if the PPMV scored four (4) and above (out of a maximum obtainable score of five), and low readiness of they scored less than 4. In addition, the retained factor was used to generate more refined scores using regression-based factor scoring method [40]. The average readiness score with its corresponding standard deviation for PPMVs was then calculated. Before aggregating this readiness for each PPMV trade association district, three within-group agreement indices; $r_{wg(j)}$ [41], $r^*_{wg(j)}$ [42] and a_{wg} index [43] were calculated to establish the validity of the 10-item tool. The $r_{wg(j)}$ was calculated by subtracting observed group variance divided by expected random variance from one. The $r^*_{wg(j)}$ was calculated by replacing the denominator of the $r_{wg(j)}$ with the average variance of the items. The a_{wg} is similar to Cohen's kappa. The expected random variance was set at two since all the Likert scales had five points. To ascertain the reliability of using individual PPMV readiness score as a reflection of readiness at district level, intraclass correlation coefficient one and two (ICC(1) and ICC(2) were calculated using one way random effect analysis of variance (ANOVA) [44]. ICC(1) measures the extent to which raters can represent each other [45], so the

larger the ICC(1), the more similar the PPMVs are within their trade association districts. ICC(2) is a function of ICC(1) [44], and it measured the reliability of the district level mean readiness score. Mean and standard deviation of the readiness score for each PPMV trade association district were then calculated. The factors associated with readiness score were explored using a multilevel linear regression model which was based on maximum likelihood estimation method [46]. This modeling approach accounted for the non-independence in responses from the PPMVs as they were nested within their trade districts. Two models were fitted. The first model was a null (empty) model, which included only the readiness score. This model was used to estimate the between-district variation in the readiness score. In the second model, which was the full model, predictor variables were then specified. Both were varying intercept models. For the fixed effect component, coefficients with their corresponding 95% confidence intervals (CI) were reported. For the random component, standard deviations at district level and intraclass correlation coefficients (ICC) were reported. The log likelihood for each model was also reported. A likelihood ratio test was then used to check for model fit by comparing the two models. The predictors of readiness score were used to build a descriptive causal loop diagram to illustrate the feedback mechanisms that exists between them [47]. The linkage between variables were depicted using arrows and the direction of influence were denoted using plus (+) and minus (-) signs [47]. When the linkage between variables is additive, then it's tagged a reinforcing loop, otherwise, it's tagged as a balancing loop [47]. The authors validated the causal loop diagram as such the conceptual assumptions reflect their views. Data analysis was performed in Stata 14.2 and R using the multilevel and *nlme* package. Causal loop diagram was built using Vensim PLE 8.0.6.

2.9 Ethical consideration

Ethical clearance was obtained. An information sheet was read out to each participant to state the purpose of the study. Participants were informed that participation is voluntary and that they can leave the study anytime they want to or decline response to any of the questions. Informed consent was obtained from all participants.

3.0 RESULTS

The 445 PPMVs included in this study had a median age of 36 years with an interquartile range (IQR) of 30 – 43. About 50.11% of the PPMVs were aged between 21 – 36 years. Majority of the PPMVs possessed post-secondary education and were males. A total of 240 (52.75%) had formal health-related training and 75.06% have previously been involved in immunization activities. Other sociodemographic characteristics are presented on **Table 1**.

Among the PPMVs, 73.19% reported that they were the owners of the patent medicine stores. Majority of them reported that they are already providing counseling and referrals for family planning services, selling zinc and oral rehydration salts for diarrheal diseases in children or offering malaria rapid diagnostic test in their stores. About 81.32% reported that they attend to more than five children below the age of one per day. Other characteristics are shown on **Table 2**.

A total of 280 (61.67%) PPMVs responded they strongly agreed that the knowledge of the people in their store regarding vaccines and immunization is adequate. Also, 57.05% strongly agreed that they will require some form of incentives to provide routine immunization services. The frequency and percentages of other responses are provided on **Table 3**.

The 10-item tool for assessing readiness for implementing routine immunization services among PPMVs had a scale reliability coefficient of 0.92. The KMO measure of sampling adequacy was 0.96 and Bartlett's test of sphericity yielded a Chi-square of 2568.99 at p-value of 0.00. Factor analysis yielded one factor with an eigenvalue of 6.14. The proportion of variation explained by this factor was 99%. Eigenvalues and proportions for other factors are shown on **Table 4**.

As shown on **Table 5**, all the 10 items in the retained factor (factor 1) had factor loadings greater than 0.6. The median raw score for readiness to implement routine immunization services among PPMVs was 4.7 (with an IQR of 4.3 – 4.8). A total of 444 (97.58%) had high level of readiness while 2.42% had low readiness.

The median $r_{wg(j)}$ value among PPMVs within districts was 0.99 which was above the conventional values of 0.7. The median r^*_{wgj} was 0.90. In addition, the a_{wg} was 0.629 which also suggests substantial strength of agreement within districts. Details of the indices are shown on **Table 6**.

The ICC (1) and ICC (2) were 0.29 and 0.94 respectively. ICC (1) suggests that 29% of the variance in PPMV readiness score can be explained by the trade association district they are located in. While the ICC2 of 0.94 indicates that trade association districts can be reliably distinguished in terms of their mean readiness score.

The mean readiness score to implement routine immunization services among PPMVs was 5.28 (with standard deviation of 0.58). District level mean readiness score vary across districts and it ranged from 4.68 (with standard deviation of 0.11) in the first district to 5.59 (with standard deviation of 0.12) in the sixth district. The mean readiness score for other districts are shown on **Table 7**.

Factors such as ever involved in immunization activities, administering injections in patent medicine store, offering counseling and referral for family planning services, offering malaria rapid diagnostic tests, perception regarding adequacy of knowledge on immunization, awareness that immunization services involves completing registers and forms, willingness to cooperate with supervision and requiring incentives were found to be positive predictors of readiness score among PPMVs. The average readiness score was higher by 0.17 units among PPMVs who had ever been involved in immunization activities compared to those who had never being involved, after controlling for other factors (coef. = 0.17, 95%CI: 0.04 to 0.29). Among PPMVs who administer injections in their patent medicine stores, the average readiness score was higher by 0.17 units compared to those who don't, after controlling for other factors (coef. = 0.17, 95%CI: 0.05 to 0.30). Readiness score on average was higher by 0.22 units among PPMV who currently offered malaria rapid diagnostic test compared to those who don't, after controlling for other factors (coef. = 0.22, 95%CI: 0.07 to 0.38). The coefficients for other variables are presented on **Table 8**.

Dynamics of factors that are related to readiness for implementing routine immunization among patent and proprietary medicine vendors

Involvement in immunization activities, administration of injection, and provision of family planning services as well as malaria rapid diagnostic test were linked to readiness with positive polarity. The link between knowledge of routine immunization, awareness of task, and readiness was a reinforcing loop because they all had positive polarity. The interrelationship between the variables revealed three balancing loops and one reinforcing loop. Other links are shown in **Figure 1**.

4.0 DISCUSSION

In this study, we used the organizational readiness for change framework to inform an assessment of readiness to implement routine immunization services among PPMVs in Kano metropolis, Nigeria. A total of 455 PPMVs were included in the study and majority of them had post-secondary education. Most of the PPMVs are already engaged by other public health programmes to offer counseling and referral services for family planning, conduct malaria rapid diagnostic test and dispense zinc and oral rehydration salts for diarrheal diseases in children. Majority of PPMVs had high level of readiness but the mean readiness score varied across districts. The positive predictors of readiness were previous involvement in immunization activities, administering injections in patent medicine store, providing counseling and referral service for family planning, offering malaria rapid diagnostic tests in the store, perceived adequacy of knowledge regarding immunization, awareness that immunization services involves completing registers and forms, willingness to cooperate with supervision and expressed desire for some form of incentives to provide immunization.

To reach the remaining unvaccinated and under immunized children in communities, one key strategy that should be explored by health policy makers is expanding routine immunization through already existing health care delivery platforms that caregivers of children in areas with low coverage commonly utilize when their children are sick [11]. One of such platforms are PPMVs [11]. They are widespread in communities, trusted, and have flexible work hours [11]. Incorporating PPMVs into the immunization system can complement existing immunization facilities and ease access to vaccines especially on weekends, evenings and public holidays, and even for children that are delivered at home. Such engagement can form part of a broader strategy to harness the potentials of PPMVs to improve primary health care. However, before implementation, decision makers should have a good understanding of their level of readiness to provide such complex services. In this study, we found that the level of readiness to implement routine immunization was high among PPMVs in Kano metropolis, thus suggesting that they are psychologically and behaviorally prepared to implement the services if engaged properly.

The readiness score among PPMVs in Kano metropolis are associated with several factors. As expected, perceived knowledge of vaccines and immunization as obtainable in the country and awareness of key expected tasks like completion of registers and forms were found to be positive predictors of readiness score. This is consistent with what was postulated in the theoretical framework that was used in this study [22]. Furthermore, engagement in services like counseling and referral for family planning and malaria rapid diagnostic test by other public health programmes were also found to be positive predictors. These are important situational factors as hypothesize in the framework [31] and are also shown in the causal loop diagram (CLD). Logically, such engagements will improve the confidence of the PPMV to venture into more programmes. Similarly, administration of injection in patent medicine store is linked with readiness and denoted with a positive polarity in the CLD. Since some antigens are administered through injections, it was not unexpected that PPMV who already administered injections in their stores had higher readiness score on average compared to those who were not.

In this setting, an assessment like this is important because PPMVs are part of the private health sector and they are autonomous [11], as such, they cannot easily be mandated to provide public health-related services like immunization. At district level, the mean readiness score was high across board although some between-district variations were noticed. If PPMVs will be engaged for routine immunization, group-level behavior change will be needed. This was why district-level analysis was necessary necessary in this study. Since the PPMVs already have a coordination mechanism – trade associations – they should be leveraged upon by the immunization system to engineer a more collective action. Moreover, established readiness needs to be sustained and working with these trade associations can foster peer support and experience sharing as well as enhancing information sharing [22].

Surprisingly, the factor analysis showed that the 10-item tool that was used to measure readiness fitted into a single underlying construct. This is an important finding as the results contrast the theoretical framework which posits organizational readiness for change as a multifaceted concept, with change commitment and change efficacy representing two different constructs [22]. However, it is important to

note that the conceptual definition of change commitment and change efficacy in this framework are in psychological terms, as such, how they are perceived across settings might be prone to the influence of social context including culture [22,48]. In this study setting, it is possible that for contextual reasons, perceived shared resolve to start providing routine immunization and perceived shared belief in capabilities to provide quality immunization services among PPMVs overlapped.

This study had some limitations. Readiness assessment did not evaluate structural readiness such as power supply and cold-chain capacities of patent medicine stores. Studies assessing the capacity of drug storage facilities in patent medicine stores have shown that while most stores could properly store drugs and commodities like malaria medicines, contraceptives and oral rehydration salts, they often lack the cold-chain capacity to store those that require stricter temperature controls, such as vaccines [11,49]. This is particularly the case in Nigeria, where power supply is enormously challenging [49]. Since this study was a cross-sectional survey, assuming causal relationship might not be appropriate. Also, the Likert-scale responses obtained are prone to social desirability bias [50] and 'anchor effect' (a phenomenon in which the extremes of a Likert-type response tend to get less responses than the more central choices) [51].

However, the study also had some important strengths. The readiness assessment was based on empirically-sound conceptual and theoretical frameworks [22,31], and an already validated tool was adapted [31]. The validity and reliability of the tool was assessed before estimating district-level readiness score. The effect estimates produced are adjusted for the study design using multilevel modeling approach.

4.1 Implications for policy

Based on the findings from this study, PPMVs demonstrated high level of readiness to implement routine immunization services. This is influenced by some key factors (as shown in **Figure 2**) which can be leveraged by health policy makers.

Using systems thinking lens, the potential feedback loops between the factors that influence readiness to implement routine immunization becomes more apparent and explicit. Knowledge of immunization can be linked to readiness directly and also through awareness of task that are required in the immunization systems like use of registers. In the causal loop diagram, the reinforcing loop suggests that good knowledge of routine immunization can improve knowledge of tasks that are involved in the provision of routine immunization which also increases readiness. In turn, an increase in readiness will encourage policy makers to purposefully engage more PPMV which can lead to an improvement in their knowledge of immunization. Thus, this knowledge loop is a potentially useful leverage point for policy makers. There is also a balance between supervision and readiness to implement routine immunization among PPMVs. If the frequency of supervision increases, readiness will increase and vice versa.

However, routine immunization is complex and requires tightly controlled mechanisms in order to sustain quality services and avoid vaccine wastage. So, we recommend that policies to scale up routine immunization to patent medicine stores should be gradual and systematic. Given the high level of readiness across districts, all patent medicine stores with PPMVs should be linked to existing immunization sites that are close to them through a hub-spoke model, with the stores serving as the spokes. Those PPMVs who had ever been involved in immunization activities, currently engaged by other health programmes, and can administer injections should be assessed and converted into an immunization site (fixed). Additionally, criteria such as possession of health-related qualifications and current or previous experience as a health worker should be considered. To ensure optimal quality of service, they should be trained as vaccinators and provided additional trainings on injection safety among others. The finding that many PPMVs strongly agreed that they will require some form of incentives to provide routine immunization services necessitates considerations for incentivizing their engagement through performance-based approaches. The interrelationship between incentives and readiness is illustrated in the third balancing loop (B3) of the causal loop diagram. High readiness can serve as a motivation for the performance incentives schemes to sustain the interest and motivation of PPMVs to provide routine

immunization services. In turn, an absence of incentives can also lead to a decline in readiness to implement routine immunization among them.

Due to the enormous challenges of power supply in Nigeria, and because vaccines often require cold-storage with strict temperature controls, many PPMVs with high readiness may not have adequate power supply to maintain optimal vaccine cold-storage [11,49]. As such, it is imperative to deploy innovative, energy-efficient vaccine cold-chain strategies when engaging PPMVs in immunization service delivery [52]. This can be managed through the hub facilities. The trade associations should be incorporated into government supervisory team to ensure optimal compliance with guidelines at district level. Those patent medicine stores that are operated by PPMVs who do not meet these criteria should be engaged as referral-only sites.

4.2 Implications for future research

In this study, the adapted ORIC tool that was used to measure readiness for implementing routine immunization among PPMVs revealed only one latent construct instead of two as suggested in the theoretical framework [22]. As such, there is a need to conduct further assessments in this setting using other tools to see if similar findings will be seen. Although longer, the organizational readiness to change assessment (ORCA) tool could be useful [53]. In addition, further studies can extend the tool that was used in this study by introducing other distinct yet related constructs like resource adequacy (such as cold storage capacity) and organizational climate to check whether they will be differentiated. This study was conducted in an urban setting, as such, future studies should include PPMVs in rural areas.

5.0 CONCLUSION

This study demonstrated the feasibility of measuring the level of readiness for implementing routine immunization among PPMVs. Given the high readiness that was observed in this study, policy makers in the immunization system should begin to consider strongly the possibility of using PPMVs to expand access to immunization services.

6.0 REFERENCES

[1] Keja K, Chan C, Hayden G, Henderson RH. Expanded programme on immunization. World Health Statistics Quarterly Rapport Trimestriel de Statistiques Sanitaires Mondiales 1988;41:59–63.

[2] Greenwood B, Salisbury D, Hill AV. Vaccines and global health. The Royal Society; 2011.

[3] Wittet S. Introducing GAVI and the Global Fund for children's vaccines. Vaccine 2000;4:385–6.

[4] Gilchrist SA, Nanni A. Lessons learned in shaping vaccine markets in low-income countries: a review of the vaccine market segment supported by the GAVI Alliance. Health Policy and Planning 2012;28:838–46.

[5] World Health Organization. Global Vaccine Action Plan. 2019 Regional Reports on Progress Towards GVAP-RVAP goals. Annex to the GVAP review and lessons learned report. 2019.

[6] VanderEnde K, Gacic-Dobo M, Diallo MS, Conklin LM, Wallace AS. Global routine vaccination coverage—2017. Morbidity and Mortality Weekly Report 2018;67:1261.

[7] World Health Organization. WHO UNICEF coverage estimates. Vaccine preventable diseases monitoring system 2019 Global Summary Reference. Time Series: DTP3 2019. http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragedtp3.html (accessed January 28, 2020).

[8] Anderson RM. Mathematical models of transmission and control. Oxford Textbook of Public Health 1991;2:225–52.

[9] Black FL. The role of herd immunity in control of measles. The Yale Journal of Biology and Medicine 1982;55:351.

[10] Plans-Rubió P. Evaluation of the establishment of herd immunity in the population by means of serological surveys and vaccination coverage. Human Vaccines & Immunotherapeutics 2012;8:184–8.

[11] Beyeler N, Liu J, Sieverding M. A systematic review of the role of proprietary and patent medicine vendors in healthcare provision in Nigeria. PLoS One 2015;10:e0117165.** **(provided overview of the role of PPMVs in Nigeria)**

[12] Brieger WR, Osamor PE, Salami KK, Oladepo O, Otusanya SA. Interactions between patent medicine vendors and customers in urban and rural Nigeria. Health Policy and Planning 2004;19:177–82.

[13] Goodman C, Brieger W, Unwin A, Mills A, Meek S, Greer G. Medicine sellers and malaria treatment in sub-Saharan Africa: what do they do and how can their practice be improved? The American Journal of Tropical Medicine and Hygiene 2007;77:203–18. ** **(provided overview of PPMVs involvement in malaria services)**

[14] Van Der Geest S. Self-care and the informal sale of drugs in South Cameroon. Social Science & Medicine 1987;25:293–305.

[15] Molyneux CS, Mung'ala-Odera V, Harpham T, Snow RW. Maternal responses to childhood fevers: a comparison of rural and urban residents in coastal Kenya. Tropical Medicine & International Health 1999;4:836–45.

[16] Adome RO, Whyte SR, Hardon A. Popular pills: community drug use in Uganda. vol. 1. Het Spinhuis; 1996.

[17] Williams HA, Jones CO. A critical review of behavioral issues related to malaria control in sub-Saharan Africa:: what contributions have social scientists made? Social Science & Medicine 2004;59:501–23.

[18] Goodman CA. An economic analysis of the retail market for fever and malaria treatment in rural Tanzania. London School of Hygiene & Tropical Medicine, 2005.

[19] Amin AA, Marsh V, Noor AM, Ochola SA, Snow RW. The use of formal and informal curative services in the management of paediatric fevers in four districts in Kenya. Tropical Medicine & International Health 2003;8:1143–52.
[20] Chace Dwyer S, Ishaku SM, Okunade F, Reichenbach L, Jain A. Feasibility of patent and proprietary medicine vendor provision of injectable contraceptives: preliminary results from implementation science research in Oyo and Nasarawa, Nigeria. Contraception 2018;98:460–2. https://doi.org/10.1016/j.contraception.2018.08.015.
[21] Iheoma C. Impact of Patent and Proprietary Medicine Vendors Training on the Delivery of Malaria, Diarrhoea, and Family Planning Services in Nigeria. Open Access Library Journal 2016;3:1.
[22] Weiner BJ. A theory of organizational readiness for change. Implementation Science 2009;4:67. ** **(provided the conceptual framework for the study)**
[23] Shen AK, Fields R, McQuestion M. The future of routine immunization in the developing world: challenges and opportunities. Global Health: Science and Practice 2014;2:381–94.
[24] Weiner BJ, Amick H, Lee S-YD. Conceptualization and measurement of organizational readiness for change: a review of the literature in health services research and other fields. Medical Care Research and Review 2008;65:379–436.
[25] Kotter JP. Leading change. Boston, MA: Harvard Business School Press. Kouzes, JM, & Posner, BZ (2002). The Leadership Challenge San Francisco, CA 1996.
[26] Jennett P, Yeo M, Pauls M, Graham J. Organizational readiness for telemedicine: implications for success and failure. Journal of Telemedicine and Telecare 2003;9:27–30.
[27] Weiner BJ, Lewis MA, Linnan LA. Using organization theory to understand the determinants of effective implementation of worksite health promotion programs. Health Education Research 2009;24:292–305.
[28] Lewin K. Field theory in social science: selected theoretical papers (edited by dorwin cartwright.). 1951.
[29] Armenakis AA, Harris SG. Crafting a change message to create transformational readiness. Journal of Organizational Change Management 2002.
[30] Levesque DA, Prochaska JM, Prochaska JO. Stages of change and integrated service delivery. Consulting Psychology Journal: Practice and Research 1999;51:226.
[31] Shea CM, Jacobs SR, Esserman DA, Bruce K, Weiner BJ. Organizational readiness for implementing change: a psychometric assessment of a new measure. Implementation Science 2014;9:7. ** **(provided the ORIC measure)**
[32] Hargrove JL. Dynamic modeling in the health sciences. Springer Science & Business Media; 2012.
[33] Peters DH. The application of systems thinking in health: why use systems thinking? Health Research Policy and Systems 2014;12:51.
[34] Levin KA. Study design III: Cross-sectional studies. Evidence-Based Dentistry 2006;7:24.
[35] Naing L, Winn T, Rusli B. Practical issues in calculating the sample size for prevalence studies. Archives of Orofacial Sciences 2006;1:9–14.
[36] Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. Journal of Biomedical Informatics 2009;42:377–81.
[37] Bryant FB, Yarnold PR. Principal-components analysis and exploratory and confirmatory factor analysis. 1995.
[38] Tobias S, Carlson JE. Brief report: Bartlett's test of sphericity and chance findings in factor analysis. Multivariate Behavioral Research 1969;4:375–7.
[39] Trujillo-Ortiz A, Hernandez-Walls R, Castro-Perez A, Barba-Rojo K, Otero-Limon A. kmo: Kaiser-Meyer-Olkin Measure of Sampling Adequacy. A MATLAB File[WWW Document] URL Http://Www Mathworks Com/Matlabcentral/Fileexchange/LoadFile Do 2006.

[40] DiStefano C, Zhu M, Mindrila D. Understanding and using factor scores: Considerations for the applied researcher. Practical Assessment, Research, and Evaluation 2009;14:20.
[41] James LR, Demaree RG, Wolf G. Estimating within-group interrater reliability with and without response bias. Journal of Applied Psychology 1984;69:85.
[42] Lindell MK, Brandt CJ. Measuring interrater agreement for ratings of a single target. Applied Psychological Measurement 1997;21:271–8.
[43] Brown RD, Hauenstein NM. Interrater agreement reconsidered: An alternative to the rwg indices. Organizational Research Methods 2005;8:165–84.
[44] Bliese PD. Within-group agreement, non-independence, and reliability: Implications for data aggregation and analysis. 2000.
[45] Klein KJ, Kozlowski SW. From micro to meso: Critical steps in conceptualizing and conducting multilevel research. Organizational Research Methods 2000;3:211–36.
[46] Gelman A, Hill J. Data analysis using regression and multilevel/hierarchical models. Cambridge university press; 2006.
[47] Tip T. Guidelines for drawing causal loop diagrams. Systems Thinker 2011;22.
[48] Gergen KJ, Gulerce A, Lock A, Misra G. Psychological science in cultural context. American Psychologist 1996;51:496.
[49] Obitte NC, Chukwu A, Odimegwu DC, Nwoke VC. Survey of drug storage practice in homes, hospitals and patent medicine stores in Nsukka Nigeria. Sci Res Essay 2009;4:1354–9.
[50] Nederhof AJ. Methods of coping with social desirability bias: A review. European Journal of Social Psychology 1985;15:263–80.
[51] Bishop PA, Herron RL. Use and misuse of the Likert item responses and other ordinal measures. International Journal of Exercise Science 2015;8:297.
[52] Robertson J, Franzel L, Maire D. Innovations in cold chain equipment for immunization supply chains. Vaccine 2017;35:2252–9.
[53] Helfrich CD, Li Y-F, Sharp ND, Sales AE. Organizational readiness to change assessment (ORCA): development of an instrument based on the Promoting Action on Research in Health Services (PARIHS) framework. Implementation Science 2009;4:38.

Table 1: Sociodemographic characteristics of patent and proprietary medicine vendors in Kano metropolis, Nigeria

Variables	Frequency	Percentage
Age group		
21 - 36 years	228	50.11
Above 36 years	227	49.89
Sex		
Male	372	81.76
Female	83	18.24
Level of education		
Tertiary education	437	96.47
No tertiary education	16	3.53
Formal health training		
No	215	47.25
Yes	240	52.75
Ever involved in immunization activities		
No	113	24.94
Yes	340	75.06
Currently work in a health facility		
No	159	34.95
Yes	296	65.05
Type of health facility where PPMV is currently working		
Primary health care	183	61.82
Others	113	38.18
Currently involved in immunization activities in the health facility		
No	57	19.26
Yes	239	80.74

Table 2: Characteristics of operations and services provided by patent and proprietary medicine vendors in Kano metropolis, Nigeria

Variables	Frequency	Percentage
Owner of patent medicine store		
No	112	26.81
Yes	333	73.19
Time of operation		
Full time	313	68.79
Part time	142	31.21
Staff strength		
1 - 2	266	58.46
Above 2	189	41.54
Number of children less than one year of age per day		
5 or below	85	18.68
More than 5	370	81.32
Administer injections in this patent medicine store		
No	66	14.54
Yes	388	85.46
Offer counseling and referral for family planning services		
No	62	13.66
Yes	392	86.34
Offer zinc and oral rehydration salts for the management of diarrheal diseases		
No	70	15.42
Yes	384	84.58
Offer malaria rapid diagnostic test		
No	41	9.05
Yes	412	90.95

Table 3: Perception regarding knowledge of immunization, task demand and incentive requirement among patent and proprietary medicine vendors in Kano, Nigeria

Variables	Strongly disagree n (%)	Disagree n (%)	Neutral n (%)	Agree n (%)	Strongly agree n (%)
The knowledge of the people in this patent medicine store on vaccines and immunization as obtainable in Nigeria is adequate.	0 (0)	3 (0.66)	1 (0.22)	170 (37.44)	280 (61.67)
The people in this patent medicine store are aware that childhood immunization services involves completing several registers and forms.	0 (0)	0 (0)	3 (0.66)	234 (51.43)	218 (47.91)
The people in this patent medicine store are willing to cooperate with regular supervision from government agencies and their partners that are involved in routine immunization	3 (0.66)	2 (0.44)	2 (0.44)	208 (45.81)	239 (52.64)
The people in this patent medicine store will require some form of incentives to provide childhood routine immunization services.	3 (0.66)	0	2 (0.44)	190 (41.85)	259 (57.05)

Table 4: Factor analysis of the ten-item tool for assessing readiness for implementing routine immunization services among patent and proprietary medicine vendors in Kano, Nigeria

Factor	Eigenvalue	Difference	Proportion	Cumulative
Factor1	6.14	5.89	0.99	0.99
Factor2	0.24	0.09	0.04	1.03
Factor3	0.15	0.08	0.02	1.06
Factor4	0.07	0.08	0.01	1.07
Factor5	-0.01	0.03	0.00	1.07
Factor6	-0.04	0.01	-0.01	1.06
Factor7	-0.04	0.04	-0.01	1.05
Factor8	-0.08	0.03	-0.01	1.04
Factor9	-0.11	0.03	-0.02	1.02
Factor10	-0.14	.	-0.02	1.00

Table 5: Factor loadings of each of the items in the tool for assessing readiness for implementing routine immunization services among patent and proprietary medicine vendors in Kano, Nigeria

Item	Factor 1	Uniqueness
People who work in this patent medicine store are committed to implementing childhood routine immunization services.	0.92	0.16
People who work in this patent medicine store are determined to implement childhood routine immunization services.	0.76	0.42
People who work in this patent medicine store are motivated to implement childhood routine immunization services.	0.70	0.52
People who work in this patent medicine store will do whatever it takes to implement childhood routine immunization services.	0.73	0.47
People who work in this patent medicine store want to implement childhood routine immunization services.	0.75	0.44
people who work in this patent medicine store feel confident that they can manage the politics of implementing childhood routine immunization services	0.76	0.41
people who work in this patent medicine store feel confident that the association can support people as they adjust to implementing childhood routine immunization services	0.74	0.45
people who work in this patent medicine store feel confident that they can coordinate tasks so that implementation of childhood routine immunization services goes smoothly	0.75	0.44
people who work in this patent medicine store feel confident that they can keep track of progress in implementing childhood routine immunization services	0.86	0.27
people who work in this patent medicine store feel confident that they can handle the challenges that might arise in implementing childhood routine immunization services	0.84	0.29

Table 6: Inter-rater agreement on readiness to implement routine immunization services among patent and proprietary medicine vendors within trade association districts

Indices	Median	Minimum	Maximum	1st quartile	3rd quartile
rwg(j)	0.99	0.73	1.00	0.99	0.99
r*wg(j)	0.90	0.21	0.97	0.87	0.92
awg	0.63	-0.42	0.96	0.56	0.86

Table 7: Readiness score to implement routine immunization services across trade association districts for patent and proprietary medicine vendors in Kano metropolis, Nigeria

PPMV trade district	Number of PPMVs	Mean Score	Standard Deviation
1	24	4.68	0.11
2	25	4.74	0.15
3	58	4.90	0.33
4	70	5.46	0.14
5	12	4.88	0.28
6	45	5.59	0.12
7	69	5.51	0.14
8	50	5.50	0.14
9	25	5.46	0.40
10	23	5.45	0.63
11	29	4.95	1.40
12	25	5.35	1.07

Table 8: Factors associated with readiness score for implementing routine immunization services among patent and proprietary medicine vendors in Kano metropolis, Nigeria

Variables	Model 1 Coef. (95%CI)	P-Value	Model 2 Coef. (95%CI)	P-Value
Fixed effect				
Age group				
21 - 36 years			ref	
Above 36 years			0.01(-0.07 to 0.09)	0.78
Sex				
Male			ref	
Female			-0.03 (-0.13 to 0.08)	0.58
Level of education				
Tertiary education			ref	
No tertiary education			-0.18(-0.43 to 0.06)	0.14
Formal health training				
No			ref	
Yes			-0.06 (-0.15 to 0.03)	0.21
Ever involved in immunization activities				
No			ref	
Yes			0.17 (0.04 to 0.29)	0.01
Currently work in a health facility				
No			ref	
Yes			-0.08 (-0.22 to 0.06)	0.26
Currently involved in immunization activities in the health facility				
No			ref	
Yes			0.05 (-0.08 to 0.17)	0.46
Time of operation				
Part time			ref	
Full time			-0.05 (-0.15 to 0.05)	0.31
Staff strength				
1 - 2			ref	
Above 2			0.03 (-0.07 to 0.12)	0.58
Number of children less than one year of age per day				
5 or below			ref	
More than 5			0.04 (-0.07 to 0.15)	0.47
Administer injections in this patent medicine store				
No			ref	
Yes			0.17 (0.05 to 0.30)	0.01
Offer counseling and referral for family planning services				
No			ref	
Yes			0.17 (0.05 to 0.29)	0.01
Offer zinc and oral rehydration salts for the management of diarrheal diseases				

Variables	Model 1 Coef. (95%CI)	P-Value	Model 2 Coef. (95%CI)	P-Value
No			ref	
Yes			-0.03 (-0.15 to 0.09)	0.66
Offer malaria rapid diagnostic test				
No			ref	
Yes			0.22 (0.07 to 0.38)	0.00
The knowledge of the people in this patent medicine store on vaccines and immunization as obtainable in Nigeria is adequate.				
Other responses			ref	
Strongly agree			0.43 (0.34 to 0.53)	0.00
The people in this patent medicine store are aware that childhood immunization services involves completing several registers and forms.				
Other responses			ref	
Strongly agree			0.13 (0.05 to 0.21)	0.00
The people in this patent medicine store are willing to cooperate with regular supervision from government agencies and their partners that are involved in routine immunization				
Other responses			ref	
Strongly agree			0.26 (0.18 to 0.35)	0.00
The people in this patent medicine store will require some form of incentives to provide childhood routine immunization services.				
Other responses			ref	
Strongly agree			0.14 (0.05 to 0.23)	0.00
Random effect				
Standard deviation (District level)	0.31 (0.20 to 0.49)		0.06 (0.01 to 0.28)	
ICC	0.29		0.02	
Model fit				
Log likelihood	-339.25		-232.23	
Likelihood ratio test $X^2 = 214.04$, p-value 0.00				

Model 1 = Empty model
Model 2 = Full model
ICC = Intraclass correlation coefficient
X^2 = Chi-square
Coef. = Coefficient
CI = Confidence Interval

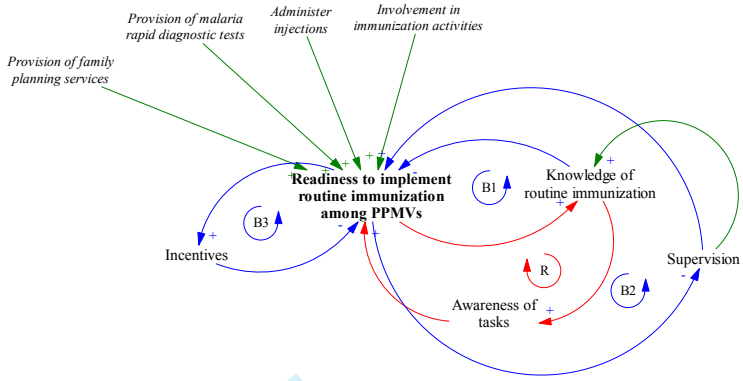

Figure 1: Causal loop diagram of the factors that influence readiness to implement routine immunization among patent and proprietary medicine vendors in Kano metropolis, Nigeria

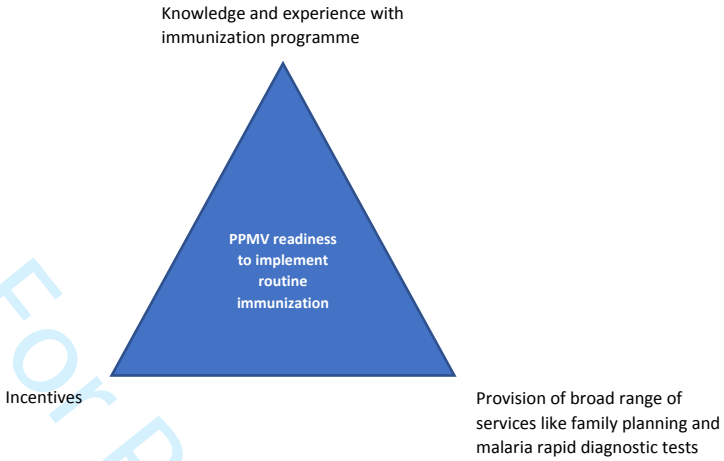

Figure 2: Triad of determinants of readiness to implement routine immunization among patient and proprietary medicine vendors in Kano metropolis, Nigeria

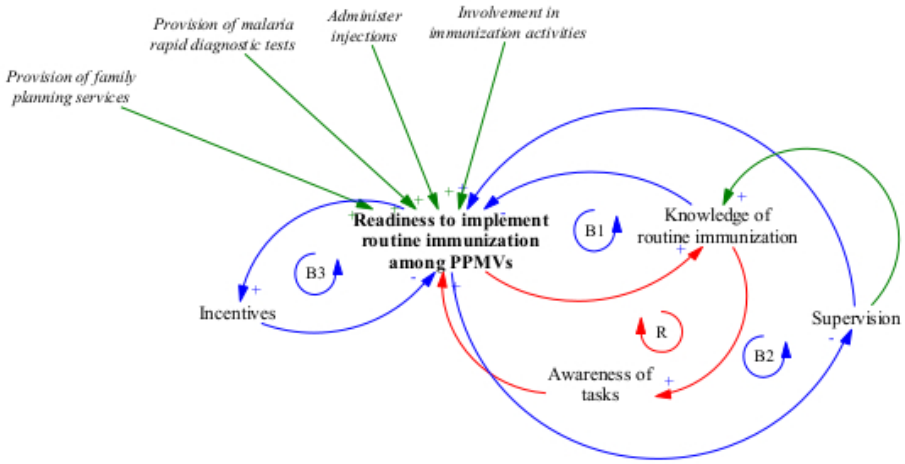

Figure 1: Causal loop diagram of the factors that influence readiness to implement routine immunization among patent and proprietary medicine vendors in Kano metropolis, Nigeria

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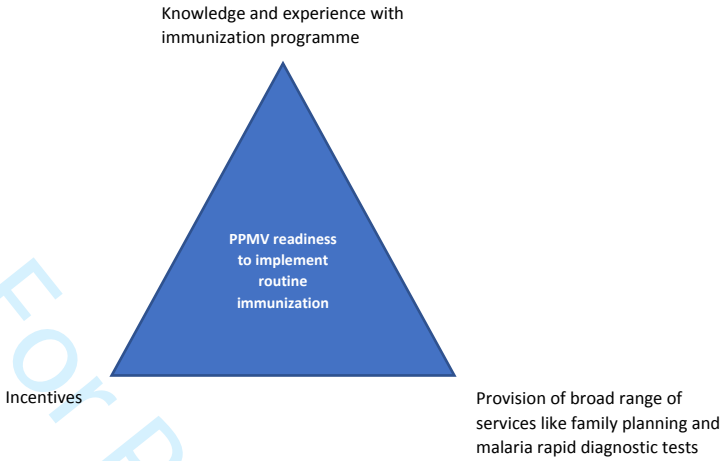

Figure 2: Triad of determinants of readiness to implement routine immunization among patient and proprietary medicine vendors in Kano metropolis, Nigeria