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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 (PPMV) 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

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3 from a PPMV to avoid the indirect costs of travel and time that are associated with attending formal
4 health facilities [17]. Furthermore, their services are fast and opening hours are usually longer and more
5 flexible than that of a typical health centre [18]. Finally, since PPMVs do not typically charge
6 consultation fees, their services are often cheaper [16,19]. For these reasons, several public health
7 programmes in Nigeria have already begun to engage PPMVs to expand access to family planning
8 commodities [20] and quality services for malaria and diarrhea diseases treatment [21].
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16 Given their wide patronage for child health services, PPMVs can also be incorporated into the
17 immunization system to complement already existing structures. But an important precursor to such
18 engagement is to establish their readiness to implement such services in the first place [22]. Routine
19 immunization is complex [23] and involving PPMVs in the service delivery framework will entail system
20 redesign that have implications for both service providers and government stakeholders. If the PPMVs,
21 who will be responsible for providing the services, are not psychologically and behaviorally prepared to
22 implement it, the programme could fail [24]. Several studies have already highlighted the link between
23 lack of readiness and poor performance of health programmes [22,25,26]. Readiness is important because
24 it determines the extent to which a change is adopted and the level of effort that is put in to ensure
25 implementation success [27].
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38 Several frameworks for readiness exists [28–30]. However, the organizational readiness for change
39 framework is distinct as it regards readiness as a shared psychological state among a group of people [22].
40 This framework conceptualizes readiness as both a multi-level and multi-faceted concept [22]. Readiness
41 is multilevel because it can be present to varying degrees at individual, group, organizational or even
42 societal level [22]. It is multi-faceted because it has two constructs; change commitment and change
43 efficacy [22]. Change commitment refers to the shared decision of members of an organization or group
44 to implement change [22]. On the other hand, change efficacy refers to an organization's confidence in
45 their capability to implement change [22]. Based on this framework, the organizational readiness for
46 implementing change (ORIC) tool was developed [31]. This tool provides a valid and reliable measure of
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3 organizational readiness that can be used in health care settings [31]. The tool is brief such that it can be
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5 used in busy settings [31].
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8 Despite the availability of a simplified tool for measuring readiness [31], there is still a dearth of research
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10 evidence on organizational readiness for implementing change in health-care settings in sub-Saharan
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12 Africa. Particularly, the level of readiness of PPMVs to implement routine immunization services is not
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14 fully understood. Furthermore, readiness is complex as it can be influenced by several factors [31]. As
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16 such, a full understanding of this complexity can provide further insights on how to maximize the
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18 potentials of PPMVs within the immunization system. Most often, linear models are used to explore the
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20 relationship between variables, but they are unable to account for feedbacks loops which are an integral
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22 part of the dynamics of a real-world system [32]. The emerging field of systems science provides
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24 additional tools for exploring such dynamic relationships [33]. Therefore, in this study, we aimed to
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26 quantitatively assess readiness to implement routine immunization among PPMVs in Kano metropolis,
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28 Nigeria, at individual and district level. In addition, systems thinking was integrated after using a
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30 multilevel modeling approach to identify the factors that are associated with readiness to implement
31
32 routine immunization to enable a more nuanced understanding of their interrelationship.
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36 **1.1 Conceptual framework**

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38 In this study, we drew on Weiner's theory of organizational readiness for change and the organizational
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40 readiness for implementing change (ORIC) to assess the level of readiness to implement routine
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42 immunization services among PPMVs in Kano metropolis, Nigeria [22,31]. This framework was adopted
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44 because engaging PPMVs for immunization services will entail group-level behavior change [31]. To
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46 ensure that the assessment reflects supra-individual views, group-reference (the people) rather than self-
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48 reference (I) was used [31]. The two constructs; change commitment and change efficacy, were also
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50 represented in this study. Change commitment was defined as the shared resolve of PPMVs to implement
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52 routine immunization activities, while change efficacy was defined as PPMVs' shared belief in their
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54 collective capabilities to implement routine immunization activities. It was hypothesized that factors such
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3 as sociodemographic characteristics, participation in other public health programmes, knowledge of
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5 immunization, perceived awareness of task, willingness to cooperate with supervision and availability of
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7 incentives can be related to PPMV readiness to implement routine childhood immunization services.
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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 $\pm 5\%$. 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*

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

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28 Sociodemographic characteristics include age, sex, level of education, formal health-related training (this
29 was defined as possession of a health-related qualification), ever involved in immunization activities,
30 currently working in a health facility, type of health facility and currently involved in immunization
31 activities.
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37 Characteristics of operations and services provided by the PPMV include ownership of the store, time of
38 operation, staff strength, number of children less than one year who are brought to the store per day,
39 administer injections in the store, engagement to offer counseling and referral for family planning
40 services, engaged to offer zinc and oral rehydration salts for diarrheal diseases in children and engaged to
41 offer malaria rapid diagnostic test.
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48 Perceptions regarding knowledge of vaccines, task demand and incentive requirement were based on 5-
49 point Likert scales.
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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 if 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.

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3 The median $r_{wg(j)}$ value among PPMVs within districts was 0.99 which was above the conventional values
4 of 0.7. The median r^*_{wgj} was 0.90. In addition, the a_{wg} was 0.629 which also suggests substantial strength
5 of agreement within districts. Details of the indices are shown on **Table 6**.
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10 The ICC (1) and ICC (2) were 0.29 and 0.94 respectively. ICC (1) suggests that 29% of the variance in
11 PPMV readiness score can be explained by the trade association district they are located in. While the
12 ICC2 of 0.94 indicates that trade association districts can be reliably distinguished in terms of their mean
13 readiness score.
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19 The mean readiness score to implement routine immunization services among PPMVs was 5.28 (with
20 standard deviation of 0.58). District level mean readiness score vary across districts and it ranged from
21 4.68 (with standard deviation of 0.11) in the first district to 5.59 (with standard deviation of 0.12) in the
22 sixth district. The mean readiness score for other districts are shown on **Table 7**.
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28 Factors such as ever involved in immunization activities, administering injections in patent medicine
29 store, offering counseling and referral for family planning services, offering malaria rapid diagnostic tests,
30 perception regarding adequacy of knowledge on immunization, awareness that immunization services
31 involves completing registers and forms, willingness to cooperate with supervision and requiring
32 incentives were found to be positive predictors of readiness score among PPMVs. The average readiness
33 score was higher by 0.17 units among PPMVs who had ever been involved in immunization activities
34 compared to those who had never being involved, after controlling for other factors (coef. = 0.17, 95%CI:
35 0.04 to 0.29). Among PPMVs who administer injections in their patent medicine stores, the average
36 readiness score was higher by 0.17 units compared to those who don't, after controlling for other factors
37 (coef. = 0.17, 95%CI: 0.05 to 0.30). Readiness score on average was higher by 0.22 units among PPMV
38 who currently offered malaria rapid diagnostic test compared to those who don't, after controlling for
39 other factors (coef. = 0.22, 95%CI: 0.07 to 0.38). The coefficients for other variables are presented on
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54 **Table 8**.
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3 **Dynamics of factors that are related to readiness for implementing routine immunization among**
4 **patent and proprietary medicine vendors**
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7 Involvement in immunization activities, administration of injection, and provision of family planning
8 services as well as malaria rapid diagnostic test were linked to readiness with positive polarity. The link
9 between knowledge of routine immunization, awareness of task, and readiness was a reinforcing loop
10 because they all had positive polarity. The interrelationship between the variables revealed three
11 balancing loops and one reinforcing loop. Other links are shown in **Figure 1**.
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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.

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3 The readiness score among PPMVs in Kano metropolis are associated with several factors. As expected,
4 perceived knowledge of vaccines and immunization as obtainable in the country and awareness of key
5 expected tasks like completion of registers and forms were found to be positive predictors of readiness
6 score. This is consistent with what was postulated in the theoretical framework that was used in this study
7 [22]. Furthermore, engagement in services like counseling and referral for family planning and malaria
8 rapid diagnostic test by other public health programmes were also found to be positive predictors. These
9 are important situational factors as hypothesized in the framework [31] and are also shown in the causal
10 loop diagram (CLD). Logically, such engagements will improve the confidence of the PPMV to venture
11 into more programmes. Similarly, administration of injection in patent medicine store is linked with
12 readiness and denoted with a positive polarity in the CLD. Since some antigens are administered through
13 injections, it was not unexpected that PPMV who already administered injections in their stores had
14 higher readiness score on average compared to those who were not.
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29 In this setting, an assessment like this is important because PPMVs are part of the private health sector
30 and they are autonomous [11], as such, they cannot easily be mandated to provide public health-related
31 services like immunization. At district level, the mean readiness score was high across board although
32 some between-district variations were noticed. If PPMVs will be engaged for routine immunization,
33 group-level behavior change will be needed. This was why district-level analysis was necessary
34 in this study. Since the PPMVs already have a coordination mechanism – trade associations – they should
35 be leveraged upon by the immunization system to engineer a more collective action. Moreover,
36 established readiness needs to be sustained and working with these trade associations can foster peer
37 support and experience sharing as well as enhancing information sharing [22].
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49 Surprisingly, the factor analysis showed that the 10-item tool that was used to measure readiness fitted
50 into a single underlying construct. This is an important finding as the results contrast the theoretical
51 framework which posits organizational readiness for change as a multifaceted concept, with change
52 commitment and change efficacy representing two different constructs [22]. However, it is important to
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3 note that the conceptual definition of change commitment and change efficacy in this framework are in
4 psychological terms, as such, how they are perceived across settings might be prone to the influence of
5 social context including culture [22,48]. In this study setting, it is possible that for contextual reasons,
6 perceived shared resolve to start providing routine immunization and perceived shared belief in
7 capabilities to provide quality immunization services among PPMVs overlapped.
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14 This study had some limitations. Readiness assessment did not evaluate structural readiness such as
15 power supply and cold-chain capacities of patent medicine stores. Studies assessing the capacity of drug
16 storage facilities in patent medicine stores have shown that while most stores could properly store drugs
17 and commodities like malaria medicines, contraceptives and oral rehydration salts, they often lack the
18 cold-chain capacity to store those that require stricter temperature controls, such as vaccines [11,49]. This
19 is particularly the case in Nigeria, where power supply is enormously challenging [49]. Since this study
20 was a cross-sectional survey, assuming causal relationship might not be appropriate. Also, the Likert-
21 scale responses obtained are prone to social desirability bias [50] and ‘anchor effect’ (a phenomenon in
22 which the extremes of a Likert-type response tend to get less responses than the more central choices)
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37 However, the study also had some important strengths. The readiness assessment was based on
38 empirically-sound conceptual and theoretical frameworks [22,31], and an already validated tool was
39 adapted [31]. The validity and reliability of the tool was assessed before estimating district-level readiness
40 score. The effect estimates produced are adjusted for the study design using multilevel modeling
41 approach.
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48 **4.1 Implications for policy**

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50 Based on the findings from this study, PPMVs demonstrated high level of readiness to implement routine
51 immunization services. This is influenced by some key factors (as shown in **Figure 2**) which can be
52 leveraged by health policy makers.
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3 Using systems thinking lens, the potential feedback loops between the factors that influence readiness to
4 implement routine immunization becomes more apparent and explicit. Knowledge of immunization can
5 be linked to readiness directly and also through awareness of task that are required in the immunization
6 systems like use of registers. In the causal loop diagram, the reinforcing loop suggests that good
7 knowledge of routine immunization can improve knowledge of tasks that are involved in the provision of
8 routine immunization which also increases readiness. In turn, an increase in readiness will encourage
9 policy makers to purposefully engage more PPMV which can lead to an improvement in their knowledge
10 of immunization. Thus, this knowledge loop is a potentially useful leverage point for policy makers.
11
12 There is also a balance between supervision and readiness to implement routine immunization among
13 PPMVs. If the frequency of supervision increases, readiness will increase and vice versa.
14
15 However, routine immunization is complex and requires tightly controlled mechanisms in order to sustain
16 quality services and avoid vaccine wastage. So, we recommend that policies to scale up routine
17 immunization to patent medicine stores should be gradual and systematic. Given the high level of
18 readiness across districts, all patent medicine stores with PPMVs should be linked to existing
19 immunization sites that are close to them through a hub-spoke model, with the stores serving as the
20 spokes. Those PPMVs who had ever been involved in immunization activities, currently engaged by other
21 health programmes, and can administer injections should be assessed and converted into an immunization
22 site (fixed). Additionally, criteria such as possession of health-related qualifications and current or
23 previous experience as a health worker should be considered. To ensure optimal quality of service, they
24 should be trained as vaccinators and provided additional trainings on injection safety among others. The
25 finding that many PPMVs strongly agreed that they will require some form of incentives to provide
26 routine immunization services necessitates considerations for incentivizing their engagement through
27 performance-based approaches. The interrelationship between incentives and readiness is illustrated in the
28 third balancing loop (B3) of the causal loop diagram. High readiness can serve as a motivation for the
29 performance incentives schemes to sustain the interest and motivation of PPMVs to provide routine
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3 immunization services. In turn, an absence of incentives can also lead to a decline in readiness to
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5 implement routine immunization among them.
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8 Due to the enormous challenges of power supply in Nigeria, and because vaccines often require cold-
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10 storage with strict temperature controls, many PPMVs with high readiness may not have adequate power
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12 supply to maintain optimal vaccine cold-storage [11,49]. As such, it is imperative to deploy innovative,
13
14 energy-efficient vaccine cold-chain strategies when engaging PPMVs in immunization service delivery
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16 [52]. This can be managed through the hub facilities. The trade associations should be incorporated into
17
18 government supervisory team to ensure optimal compliance with guidelines at district level. Those patent
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20 medicine stores that are operated by PPMVs who do not meet these criteria should be engaged as referral-
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22 only sites.
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25 26 **4.2 Implications for future research**

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28 In this study, the adapted ORIC tool that was used to measure readiness for implementing routine
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30 immunization among PPMVs revealed only one latent construct instead of two as suggested in the
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32 theoretical framework [22]. As such, there is a need to conduct further assessments in this setting using
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34 other tools to see if similar findings will be seen. Although longer, the organizational readiness to change
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36 assessment (ORCA) tool could be useful [53]. In addition, further studies can extend the tool that was
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38 used in this study by introducing other distinct yet related constructs like resource adequacy (such as cold
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40 storage capacity) and organizational climate to check whether they will be differentiated. This study was
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42 conducted in an urban setting, as such, future studies should include PPMVs in rural areas.
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46 **5.0 CONCLUSION**

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

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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

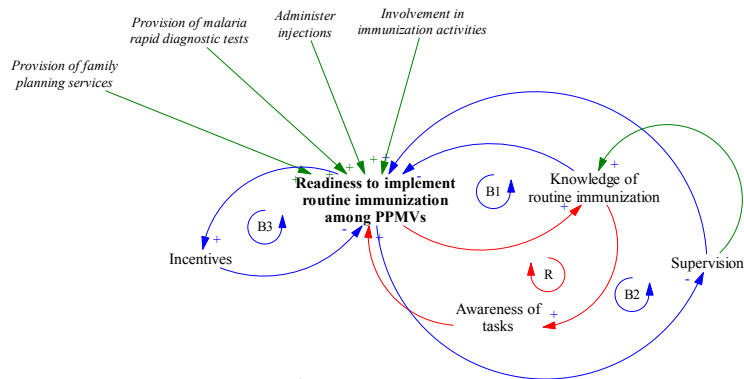


Figure 1: Causal loop diagram of the factors that influence readiness to implement routine immunization among patent and proprietary medicine vendors in Kano metropolis, Nigeria

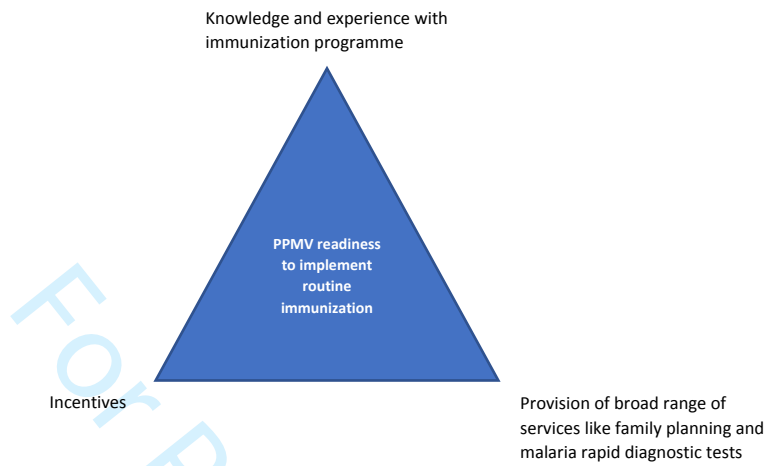


Figure 2: Triad of determinants of readiness to implement routine immunization among patient and proprietary medicine vendors in Kano metropolis, Nigeria

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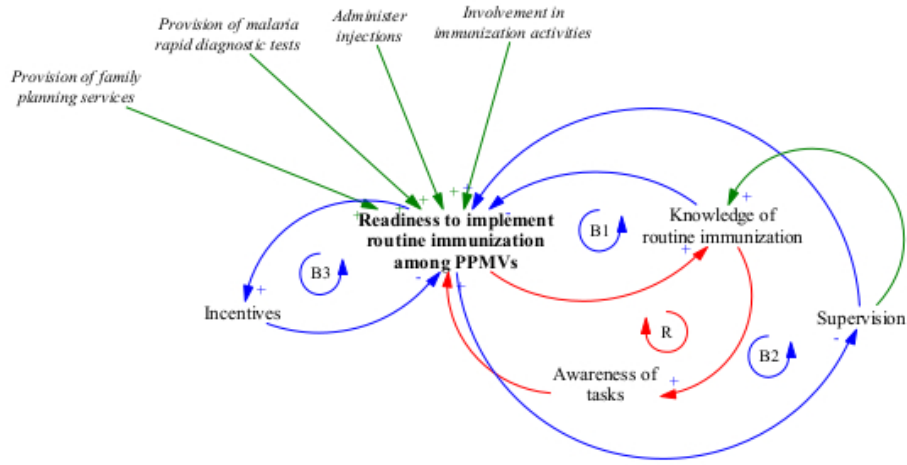


Figure 1: Causal loop diagram of the factors that influence readiness to implement routine immunization among patent and proprietary medicine vendors in Kano metropolis, Nigeria

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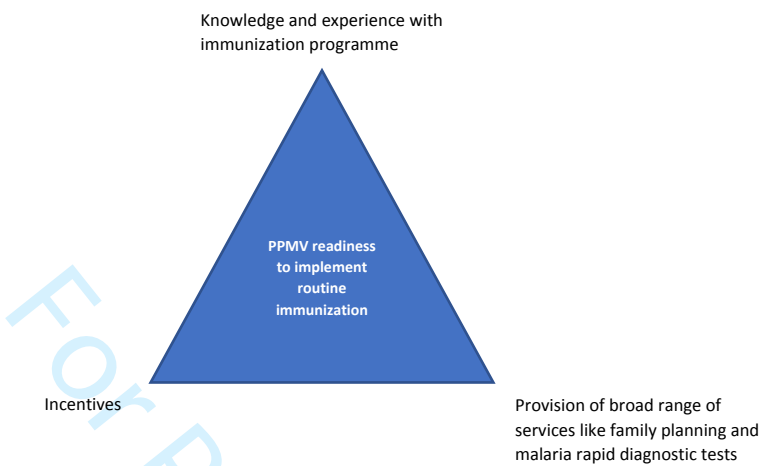


Figure 2: Triad of determinants of readiness to implement routine immunization among patient and proprietary medicine vendors in Kano metropolis, Nigeria