Assessment of quality assurance capability for medicines in community pharmacies in two cities in Nigeria

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ABSTRACT

Background: Medicine quality is a global concern and lack of reliable quality assurance (QA) system for medicines may be contributory to the high level of spurious medicines in many developing countries. Objectives: The study evaluated the level of institutionalization of QA components for medicine inventory in community pharmacies in two cities of Osun State in Nigeria as a measure of QA capability and explored for factors influencing QA capability.

Methods: A set of pretested semi-structured questionnaire was administered to community pharmacists practicing in Oshogbo and Ile-Ife. The instrument sought information on the level of institutionalization of essential components of QA, and explored for factors influencing QA, both on ordinal scales with weighting scores of 1-5 and 0-4 respectively. Descriptive statistics were used to summarize the data. Chi square, Spearman's rank correlation as well as multiple and ordinal regressions were used to evaluate the respondents' opinions at 5% level of significance.

Results: Only two (12.5%) of the essential components of QA had been implemented (WA≈ 4) and none institutionalised (WA≈5). The three most prominent factors influencing QA capability were management commitment, suppliers and government regulatory control all with median score of 4.

Conclusion: Quality assurance capability for medicine inventory in the community pharmacies was low.

Key words: Medicine quality, counterfeit medicine, quality assurance, quality assurance capability, community pharmacy.

Évaluation de la capacité d'assurance de la qualité des médicaments dans les pharmacies communautaires dans deux villes du Nigeria

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RESUME

Contexte : La qualité des médicaments est une préoccupation mondiale et l'absence de système d'assurance qualité fiable (QA) pour les médicaments peuvent être contributive au niveau élevé des faux médicaments dans de nombreux pays en développement.

Objectives: The study evaluated the level of institutionalization of QA components for medicine inventory in community pharmacies in two cities of Osun State in Nigeria as a measure of QA capability and explored for factors influencing QA capability.

Objectifs: L'étude a évalué le niveau d'institutionnalisation des composantes de l'AQ pour l'inventaire des médicaments dans les pharmacies communautaires dans deux villes de l'Etat d'Osun au Nigeria en tant que mesure de la capacité d'AQ et a exploré les facteurs qui influent sur la capacité de l'AQ.

Méthodes: Un ensemble de questionnaire semi-structuré prétesté a été administré à des pharmaciens communautaires exerçant à Oshogbo et Ile-Ife. L'instrument a recueilli des informations sur le niveau d'institutionnalisation des composantes essentielles de l'AQ, et a exploré les facteurs qui influent sur l'AQ, à la fois sur des échelles ordinales avec des scores de pondération de 1-5 et 0-4 respectivement. Les statistiques descriptives ont été utilisées pour faire le bilan des données. Le Chi carré, le rang de corrélation de Spearman, ainsi que des régressions multiples et ordinales ont été utilisés pour évaluer les opinions des répondants au niveau de signification de 5%.

Résultats: Seulement deux (12,5%) des composantes essentielles de l'AQ avaient été mises en œuvre (WA≈4) et aucune n'a été institutionnalisé (WA≈5). Les trois facteurs les plus importants qui influent sur la capacité de l''AQ étaient engagement de la direction, les fournisseurs et le contrôle réglementaire du gouvernement, tout avec un score médian de 4.

Conclusion: la capacité d'assurance de la qualité pour l'inventaire des médicaments dans les pharmacies communautaires était faible.

Mots clés: qualité des médicaments, médicaments contrefaits, assurance qualité, capacité d'assurance de la qualité, pharmacie communautaire.

INTRODUCTION

Medicines are vital to successful health care and medicine supply is the backbone of community pharmacy practice. Unfortunately, there is a growing challenge posed by proliferation of counterfeit and substandard medicines especially in Sub-Saharan Africa. It is believed that although consistent detection of counterfeit drugs is difficult, pharmacists can take several reasonable measures to lessen the chances they are dispensing counterfeit drugs. It is of key importance that quality and integrity of medicines are maintained through the entire supply chain and the overall strategy for achieving this goal is effective quality assurance. 6-9

Quality assurance (QA) is a vital part of the whole supply chain and especially so for medicines in community pharmacy practice, which is the last point for medicines before they get to end-users. The ultimate goal of QA of medicines is to protect the health of the consumers by ensuring that medicines stocked and distributed by suppliers within the entire supply chain are of expected standards of safety, quality and cost effectiveness. There are several definitions of QA. There are several definitions of QA. However, two basic goals of QA are that products are "fit for purpose" which implies suitability for intended purpose and "right first time" implying that mistakes should be eliminated.

Quality assurance of medicines is a major public health challenge not only in developing countries but all over the world. 16,17,11 Quality Assurance Project (QAP), a program of the US government Agency for International Development (USAID), employed quality management principles used in industry to develop tools and methods for QA in the context of developing country health systems. According to QAP, effective QA can be achieved through institutionalization of four core principles and eight essential elements grouped into three categories. 12,18 The four principles comprise focus on customer/client, focus on systems and processes, focus on measurement and focus on teamwork. The eight essential elements are policy, leadership, core values, resources, structure, capacity building, communication and reward for improving quality while the three categories are internal enabling environment, structure, and support functions. 12 The categories are internal enabling environment, structure, and support functions. Institutionalization is an ongoing process in which a set of activities, structures, and values becomes an integral and sustainable part of an organization.¹² The above principles and elements (which form the essential components of QA capability) can be adapted

in the study of QA of medicines in community pharmacies.

QA institutionalization is a continuous process which requires sustained commitment from the leadership of an organisation and can have a lasting positive impact on the organisation's culture. 12 The QAP institutionalization model appears to be related to Roger's innovation decision process theory model.¹⁹ Rogers describes the process of adoption of innovations as a progress through five stages or levels namely 1. knowledge - when a potential adopter becomes aware of an innovation and has some idea of how it functions, 2. persuasion - when the potential adopter forms a favourable or unfavourable attitude toward the innovation; 3. decision - when the potential adopter engages in activities that lead to a choice to adopt or reject the innovation. At the systemic level, the decision stage can be viewed as 'trial stage'20 when majority of potential adopters are yet to cross to the implementation stage; 4. Implementation - when an adopter puts an innovation into use; and 5. confirmation - when the adopter evaluates the results of an innovation-decision already made and finalizes his/her decision to continue to use the innovation with or without its modification.

Dividing the institutionalization process into stages or levels reflects the recognition that there is a progression in the extent to which a system can assure the quality of its product. This we call QA capability. Thus for a community pharmacy, QA capability for medicines can be defined as the degree to which quality of the medicine inventory in the community pharmacy can be assured. It is the degree to which the essential components of QA are institutionalized. This we describe as a five stage process beginning with 1. Awareness of need for the element, 2. Planning to use/practice; 3. Practised but not supported with work records; 4. Existing with work records but without policy statements and/or SOPs; and 5. Existing and supported with policy statements and SOPs.

A number of factors have been identified as influencing the implementation of quality assurance of medicines stocked and distributed in CPs and can be internal or external.^{4,21-23} An example is the reported lack of knowledge and resources as barriers to detecting the presence of counterfeits by pharmacists.²¹ Other factors are government regulatory control, suppliers and economy.⁴ There is limited report in literature on the framework put in place in community pharmacies to assure the quality of their medicine inventory and on factors influencing the effectiveness of their QA

framework. The specific objectives of the study therefore were to assess the extent of institutionalization of QA components in the selected community pharmacies and determine the factors influencing their QA capability.

METHODS

The study was carried out in community pharmacies in two cities, Ile-Ife and Oshogbo, in Osun State of Nigeria. The criteria for inclusion of participants were those registered and licensed to practise as pharmacists in Nigeria for the year of study and were practising in community pharmacies registered for the year. Only primary source was employed for data and responses were obtained with the aid of a set of questionnaire. A draft of the questionnaire was developed based on the QAP institutionalisation model¹² and Rogers' innovation decision process theory.¹⁹ The instrument was pretested on two community pharmacists in one of the cities using test - retest method within a two-week interval and gave a test-retest reliability coefficient of 0.91. The result of the pre-test was used to make necessary modifications on the questionnaire and only items rated as comprehensible and relevant were retained in the final version. The questionnaire was divided into three sections. The first section included items seeking information on demographic variables. The second section, adapting the QAP model, 12 had items that sought information on the core principles and essential elements of QA. The level of institutionalisation of QA principles and elements (components) was employed as indicator of QA capability. 12,19 The QA capability's components were measured with responses to statements on a five-point Likert-type scale ranging from 'Aware of need for the 'Already planning to use/practice' 'Used/practised but not supported with work records' 'Existing with work records but without policy statements and/or SOPs' and 'Existing with work records and supported with policy statements and/or SOPs' with assigned values of 1-5 respectively. Weighted average (WA) score for each item rounded off to whole number was taken as indicator of the level of institutionalisation. Responses of 'Aware of the item' (WA=1) and 'Already planning to use/practice' (WA=2) were taken to imply levels of mere knowledge and persuasion respectively. Responses of 'Used/practised but not supported with work records' (WA=3), 'Existing with work records but without policy statements and/or SOPs' (WA=4) and 'Existing with work records and supported with policy statements and/or SOPs' (WA=5) were taken to indicate 'trial' 'implementation'

and 'institutionalisation' respectively. Only items with weighted average (WA) scores of 4-5 on the scale of institutionalisation were taken as contributing to QA capability. The mean of the weighted averages (MWA) for all the items was computed as an indicator of overall QA capability. MWA values of 1-2 were taken to imply lack of QA capability while MWA values of 3, 4 and 5 were taken to imply low, moderate and high QA capability respectively. The third section of the questionnaire had items that sought information on the factors that influence QA capability on a five-point Likert-type scale ranging from 'Undecided', 'Not important', 'Slightly important', 'Important' and 'Very important' with allotted weights of 0-4 respectively. Median score (Mdn) for each factor was taken as indicator of the level of importance.

The calculated sample size was 29 of the 31 community pharmacists using Yaro Yamane's formula for finite population.²⁴ The instrument was administered to the participants in their practice premises and the completed instrument collected immediately or during return visit. However, 23 of them were retrieved by the close of data collection period for a return rate of 73.9%. The obtained responses were fed into computer with the aid of SPSS application package version 21. Descriptive statistical measures such as frequencies, percentages, weighted averages and mean of weighted averages were used to summarise the data while inferential statistics including chi square, Spearman's rank correlation as well as multiple and ordinal regressions, were used to determine significant relationships between variables at 5% level of significance. The various items of QA components were computed into composite mean score as dependent variable (which distribution was normal) and each of the item responses was collapsed from ordinal to dichotomous data for independent variables before subjecting them to hierarchical multiple regressions. For the factors, composite QA capability median score was computed as dependent variable and the factors influencing QA were collapsed from the five level scale of importance to dichotomous scale of 'Influencing QA capability' and 'Not influencing QA capability ' before performing an ordinal regression analysis of the factors' influence on QA capability.

RESULTS

Table 1 shows the demographic data of the respondents.

Table 1: The community pharmacists' demographic data

Item	Values	N	Percent
Age (years)	20 to 30	6	28.57
	31 to 40	7	33.33
	41 to 50	3	14.29
	51 and above	5	23.81
Gender	Male	18	78.26
	Female	5	21.74
Marital status	Single	5	21.74
	Married	18	78.26
Location	Ile-Ife	8	34.78
	Osogbo	15	65.22
Head of pharmacy	Yes	22	95.65
	No	1	4.35
Bachelor Degree	B.Pharm./BSc. Pharm.	22	95.65
	Pharm. D.	1	4.35
Other qualification(s)	MBA	1	50.00
	Postgraduate Fellowship in Clinical Pharmacy	1	50.00
Job status	Locum pharmacist	1	4.55
	Full-time pharmacist	21	95.45
Experience in Community Pharmacy Practice (years)	0 to 5	13	56.52
marmaey ractice (years)	6 to 10	3	13.04
	11 to 15	0	0.00
	16 to 20	1	4.35
	21 to 25	4	17.39
	26 to 30	2	8.70
Superintendent Pharmacist	Yes	21	95.45
	No	1	4.55
Proprietor	Yes	15	68.18
	No	7	31.82

Majority of the respondents were males (78.3%), married (78.3%) and head of the pharmacy premises (95.7%). Most (95.7%) of the participants had Bachelor of Pharmacy degree as their qualification. Majority (69.6%) had 0 to 10 years of experience in community pharmacy practice while most (91.3%) of them were full-time pharmacists. Most (91.3%) of them were the superintendent pharmacists and majority (65.2%) were the proprietors. Chi-square (χ^2) tests show that there was significant association between age and marital status (χ^2 (1) = 6.562, P = .010), and marital status and being proprietor (χ^2 (1) = 6.609, P = .021) as well as being proprietor and years of experience in community practice (χ^2 (1) = 4.669, P = .031) whereas tests of relationship show that there was correlation between age and experience in community practice (r = .869, P = .000).

Table 2 presents 16 essential components of quality assurance in community pharmacy practice covering the core principles and essential elements and their levels of institutionalization expressed as weighted averages (WA) of the respondents' scores. The results show that only two components were reported by respondents to be at the fourth level of 'existing with work records but without policy statements and/or SOPs' (WA≈ 4). The two were 'Apparent leadership commitment to quality' (WA=3.6) and 'Quality improvement procedures' (WA=3.5). The items having their weighted average scores in the third stage of the institutionalisation process in which the items were practised but not supported with work records (WA≈3) include 'Pharmacy having definition/standard of "quality of medicines", 'Expression of QA as a core value', 'Available quality control procedures for medicines', 'Use of procedural documents and work 'Pharmacy having customers' records', definition/standard of quality of medicines', 'Available officer/unit responsible for quality management of medicines', 'Policy statement on desired quality of medicines dispensed', 'Recording improvement and changes in quality achievement', 'Sharing quality achievement amongst staff', 'Defined roles and responsibilities for QA' and 'Using results of quality achievement to advocate policy changes'. Items that were at the second ('planning to use/practise') stage of

the institutionalisation process (W \approx 2), included 'Staff time allocated for QA', 'Capacity building/staff training' and 'Presence of a QA team'. The computed mean of weighted averages was 2.97 (MWA \approx 3) showing that overall level of QA capability of the community pharmacies was at the 'decision' (or 'trial') stage.

The result of multiple regression analysis showing QA components that significantly influence QA capability is presented in Table 3. The result indicated that four of the components, 'Policy statement on desired quality of medicines dispensed in this community pharmacy', 'Using results of Quality achievement to advocate policy changes and resource allocation from management', 'Apparent leadership commitment to quality' and 'Customers' definition/standard of the phrase "quality of medicines" explained 84% of the variations in QA capability ($R^2 = .835, F(4, 18) = 21.22, P = .000$).

The result of correlation analysis that shows the strength and directions of the relationships between the various components and QA capability is presented in Table 4. Only community pharmacists' understanding of 'Customer's definition/standard of the phrase "quality of medicines", Staff time allocated for QA initiatives' and 'Capacity building/staff training for QA' are not significantly correlated with overall QA capability. Inferential statistics show association between ages of the participants and their perception of the level of QA capability ($\chi^2(2) = 6.562$, P = .010).

Table 2: Essential components of quality assurance capability in community pharmacies

S/N.	Elements / Components of Quality Assurance (N=23)		Aware of need for it	Already planning to use/practise	but not	Existing with work records but no policy statements and/or SOPs	supported with	Weighted average (WA)	Mean of Weighted Averages (MWA)
			x 1	2	3	4	5		
1	Apparent leadership commitment to	f	2	2	6	7	6		
	quality	% 8.7 8.7 26.09 30.43 ₂₆	26.09	3.57					
2	Available quality improvement	f	1	2	7	10	3	2.52	
	procedures/activities	%	4.35	8.7	30.43	43.48	13.04	3.52	
3	Pharmacy's definition/standard of "quality	f	3	0	8	8	4	2.42	
	of medicines"	%	13.04	0	34.78	34.78	17.39	3.43	
4	Expression of QA as a core value in the	f	3	4	3	7	6	3.39	
	community pharmacy	%	13.04	17.39	13.04	30.43	26.09	3.39	
5	Available Quality Control (QC)	f	0	4	11	4	4		
	procedures/activities for medicines	%	0	17.39	47.83	17.39	17.39	3.35	
6	Use of procedural documents and work	f	3	3	7	3	7		
	records	%	13.04	13.04	30.43	13.04	30.43	3.35	
7	Customer's definition/standard of "quality	f							
	of medicines"	%	17.39	4.35	47.83	8.7	21.74	3.13	
8	Available unit/officer responsible for	f	2	7	5	5	4	3.09	
	quality management	%	8.7	30.43	21.74	21.74	17.39		
9	Policy statement on desired quality of	f	3	6	4	7	3		2.97
	medicines dispensed	%	13.04	26.09	17.39	30.43	13.04	3.04	2.37
10	Recording improvements and changes in	f	4	6	3	6	4		
	Quality achievements	%	17.39	26.09	13.04	26.09	17.39	3	
11	Sharing Quality Achievement amongst staff	f	7	2	8	3	3		
	members	%	30.43	8.7	34.78	13.04	13.04	2.7	
12	Defined roles, responsibilities and	f	6	4	8	3	2		
	accountability for QA	0/	20.00	17.20	24.70	12.04	8.7	2.61	
12	Using results of Quality achievement to	% f	26.09 8	17.39	34.78	13.04			
13	Using results of Quality achievement to advocate policy changes and resource	т %	8 34.78	2 8.7	8 34.78	3 13.04	2	2 52	
	allocation	/0	34.70	0.7	J4./0	13.04	8.7	2.52	
14	Staff time allocated for QA activities	f	8	4	5	4	2	0.45	
		%	34.78	17.39	21.74	17.39	8.7	2.48	
15	Capacity building/staff training for QA	f	9	6	4	2	2	2 2.22	
		%	39.13	26.09	17.39	8.7	8.7	2.22	
16	Presence of a QA team	f	11	6	3	3	0	2.04	
		%	47.83	26.09	13.04	13.04	0	2.04	

Key for table 2:

1 - Aware of need for the element. 2 – Already planning to use/practice.3 - Practised but not supported with work records. 4 - Existing with work records but no policy statements and/or SOPs. 5 - Existing and supported with policy statements and SOPs

However, there were no significant effects of gender, location, years of experience, job status, being superintendent pharmacist and being proprietor on participants' assessment of QA capability. Table 5 presents the factors influencing QA capability while Table 6 shows significant correlations between the factors.

The factors perceived by the respondents as 'very important' in determining QA capability were 'management commitment', 'suppliers', 'government

regulatory control', 'funding', 'qualification of staff' and 'attitude of staff' all with median score (Mdn) of 4 while those perceived as 'important' (Mdn = 3) factors influencing QA capability were, 'capacity building/training on the job', 'inexperience of managers/policy makers', 'technology', 'economy' and 'shortage of staff'.

Table 3: Multiple regression result showing QA components that significantly influence QA capability

Variables	Unstandardized Coefficients		Standardized Coefficients				onfidence al for B
	В	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound
(Constant)	2.211	.112		19.762	.000	1.976	2.446
Policy statement on desired quality of medicines dispensed in this community pharmacy	.479	.165	.344	2.900	.010	.132	.826
Using results of Quality achievement to advocate policy changes and resource allocation from management	.689	.172	.412	3.995	.001	.327	1.051
Apparent leadership commitment to quality	.452	.152	.325	2.978	.008	.133	.772
Customers' definition/standard of the phrase "quality of medicines"	.403	.167	.278	2.416	.027	.052	.753

Dependent Variable: Quality Assurance (QA) Capability

DISCUSSION

This study has sought to assess the QA capability for medicines in the selected community pharmacies and explore for factors influencing this QA capability. The importance of QA in pharmaceutical service delivery particularly in community pharmacies cannot be over flogged. With the well-known menace of spurious medicines in pharmaceutical supply chain and the attendant torrential loss of lives especially in developing countries,^{3-5,17} the need for effective means to stem the tide and assure the quality of medicines in the supply chain has become imperative. 14,15 Community pharmacists have a key role to play in combating this challenge since medicine supply remain an essential part of their practice. 1,2,6 The level of institutionalization of components (core principles and essential elements) of QA could serve as an indication of the QA capability of the community pharmacies for their medicine inventory.

Table 4: Spearman's rank correlation of QA components with QA capability

QA Capability components	Correlation with QA capability (r)	<i>P</i> -value
Our pharmacy's definition/standard of the phrase "quality of medicines" (N=23)	.607**	.002
Our customers' definition/standard of the phrase "quality of medicines"	.271	.211
Section/Unit/The officer responsible for quality management of medicines in this pharmacy	.636**	.001
Quality Control (QC) procedures/activities for medicines	.509*	.013
Quality improvement procedures/activities like our pharmacy's (Self) Inspection for Quality	.452 [*]	.031
Policy statement on desired quality of medicines dispensed in this community pharmacy	.730**	.000
Apparent leadership commitment to quality	.605**	.002
Expression of Quality Assurance (QA) as a core value in the community pharmacy	.652**	.001
Staff time allocated for QA initiatives/activities (e.g. having committee or team on Quality issues like Tender analysis in Procurement	.303	.161
Capacity building/staff training for QA	.383	.071
Defined roles, responsibilities and accountability for QA	.578**	.004
Sharing Quality Achievement amongst staff members for learning and motivation	.689**	.000
Using results of Quality achievement to advocate policy changes and resource allocation from management	.656**	.001
Presence of a QA team/committee/officer in this community pharmacy	.417*	.048
Use of procedural documents and work records in this community pharmacy	.438 [*]	.036
Recording improvements and changes in Quality achievements	.576**	.004

^{**.} Correlation is significant at the 0.01 level (2-tailed)

The fact that from the results obtained in this study, none of the essential components of QA institutionalisation framework investigated had been adopted to the fifth and ultimate level of institutionalisation in which the component is 'existing and supported with policy statement and/or SOPs' implies that none of them had been entrenched in the CPs.

^{*.} Correlation is significant at the 0.05 level (2-tailed)

Omoniyi J. Ola-Olorun and Akeem A. Tijani

Table 5: Factors influencing QA capability in the community pharmacies

			Undecided	Not important	Slightly important	Important	Very important	Median Value
S/N.	Factors (N=23)	x	0	1	2	3	4	
1	Management commitment	f	0	0	1	4	18	4
		%	0	0	4.35	17.39	78.26	
2	Suppliers	f	0	0	1	5	17	4
		%	0	0	4.35	5	73.91	
3	Government regulatory control	F	0	0	1	7	15	4
		%	0	0	4.35	30.43	65.22	
4	Funding	f	0	1	0	7	15	4
	-	%	0	4.35	0	30.43	65.22	
5	Qualification of staff	f	0	1	0	8	14	4
		%	0	4.35	0	34.78	60.87	
6	Attitude of staff	f	1	0	0	10	12	4
		%	4.35	0	0	43.48	52.17	
7	Capacity building on the job	f	0	0	2	10	11	3
		%	0	0	8.7	43.48	47.83	
8	Experience of managers	f	0	1	1	10	11	3
		%	0	4.35	4.35	43.48	47.83	
9	Technology	f	0	1	1	11	10	3
		%	0	4.35	4.35	47.83	43.48	
10	Economy	f	0	1	1	12	9	3
	,	%	0	4.35	4.35	52.17	39.13	-
11	Shortage of staff	f	0	0	3	12	8	3
	9	%	0	0	13.04	52.17	34.78	

The issue of medicines quality is a global concern, and lack of reliable medicine quality assurance systems along supply chain in many developing countries has been reported as contributing to avoidable loss of lives

that result from use of counterfeit and substandard medicines.³⁻⁵ The absence of effective quality assurance encourages the reported distribution of spurious (counterfeit and substandard) medicines.²

Table 6: Significant Spearman's rank correlations between factors influencing QA capability

Factor	r	<i>P</i> -value	
Poor capacity building/training on the job	Inexperience of managers/policy makers	.414	.05
Poor capacity building/training on the job	Shortage of staff	.506	.014
Attitude of staff	Suppliers	.431	.040
Management commitment	Poor/inadequate technology	.416	.048
Economy	Poor/inadequate technology	.434	.038

From the obtained results, only two of the sixteen items were perceived by the respondents to have been adopted up to the fourth stage of 'existing with work records but without any policy statements and /or SOPs on them' (WA≈4) in the institutionalisation process. The two items were 'Apparent leadership commitment to quality' and 'Quality improvement procedures'. With the lack of policy statements on them, they could be abandoned easily if and when situation was unfavourable. They had not been entrenched in the system. 12,19 Majority of the items had their scores in the third stage (WA≈3) of the institutionalisation process in which the item is 'used/practiced but not supported with work record'. The legal principle of documentation is applicable in this context; "if it was not documented, it was not done".25 Thus it is taken that they were not implemented. They could be said to be at the trial stage from which they may or may not become implemented and entrenched in near future. Two of the items were scored in the second, 'already planning to use/practise' stage (WA≈ 2) of the institutionalisation process. This implies the two items 'capacity building/staff training for QA' and 'Presence of a QA team' were totally lacking in the QA framework of the community pharmacies. The fact that none of the items was scored in the first stage (WA≈1) shows that the community pharmacists did not lack awareness of any of the items.

With none of the essential components of QA institutionalized and only 12.5% of them implemented and the MWA \approx 3, the level QA capability is, on the overall, low, and is at the trial stage and not yet implemented. The low level of QA capability may explain in part why distribution of spurious medicines

with the resultant death in tens of victims has continued over decades in developing countries, 4,5 and the situation may continue to be a major challenge until meaningful intervention is implemented. The factors influencing QA capability provide insight into areas of focus for remedial actions. 4,21,22,23

Four of the six identified 'very important' factors namely 'management commitment', 'funding', 'qualification of staff' and 'attitude of staff' which are internal factors²¹ fall within the control of the organisation and the community pharmacist. Thus management of CPs need to be more committed to issues of QA. They should be ready to allocate part of their budget to QA and improve their QA proficiency. This can be achieved through education and training.21,26 The two external factors, 'suppliers' and 'government regulatory control' project some implications. Community pharmacists need to be more critical of their suppliers and form relationship with them.²⁶ Unknown suppliers should be avoided. With respect to Government regulatory control, a number of calls had been made earlier on for heavier regulation of medicine production and distribution since errors often lead to severe, even fatal, consequences. 7,27 There is an imperative need for those responsible at the international, national or regional levels to rise up and enforce the laws for QA in community pharmacies.

The 'important' factors which include 'attitude of staff', 'capacity building/training on the job', 'inexperience of managers/policy makers', 'technology', 'economy' and 'shortage of staff' implies there is need for community pharmacists to be more positive in their attitude to QA of their medicine inventory. Majority of the respondents are green with 56% of them having less

than five years experience in community pharmacy practice and 70% having less than ten years. There is need for personal development on the job and to share experiences with themselves and more experienced colleagues. This could be enhanced through organised professional association trainings. Community pharmacists should also take advantage of new information and communication technologies to read more about QA in their practice and engage in online training.23 'Economy' has been identified as one of the important factors and one cannot lose sight of the financial implication of all these suggestions but the net payoff will be positive. This will result from better customer service, reduction in loss from spurious medicines, increase in profitability resulting from better customer service and more professional satisfaction. The obtained correlation between 'poor capacity building/training on the job' and 'inexperience of managers/policy makers', though weakly significant, implies that managers which are inexperienced do not get trained on the job. This may have been due to financial reasons as inexperienced managers who in most cases are also the owner of the business may not yet be financially stable to sponsor themselves for training. This financial reason could also explain why 'shortage of staff' correlates with 'poor capacity building/training on the job' since financially yet-to-bestable managers who could not sponsor themselves for training would most likely not be able to employ more hand to join the staff. The correlation of 'attitude of staff' to 'suppliers' appears to show that suppliers' effect on QA capability has a lot to do with attitude of staff. If managers are critical of suppliers and form relationship with them before trusting them to supply medicines and do not purchase medicines from just any source, QA capability will likely receive a boost. The correlation of 'poor/inadequate technology' with 'management commitment' and 'economy' can also be explained as only managers with positive attitude towards technology adoption and those who are financially buoyant would not be constrained from adopting technology to improve operations. However, there is need for managers of community pharmacies to view adoption of technology as a necessity for operations in this age, especially for supporting online access to clinical practice information and possibly telepharmacy. The net payoff will likely be positive with more job satisfaction for the community pharmacists. The main limitation to this study is that probability sampling was not achieved. This is as a result of challenges in retrieving dispatched questionnaire

provides an insight into current status of quality assurance capability for medicines in a Nigerian environment, and can serve as a template for similar studies with wider coverage.

CONCLUSION

The quality assurance capability for medicine inventory in the studied community pharmacies was low. The most important factors influencing QA were management commitment, suppliers, attitude of staff, funding and qualification of staff, among others. However, quality assurance capability for medicines in community pharmacies could be improved through more positive attitude of community pharmacists to QA in their practice, personal development through education, training and reading especially by taking advantage of rich online resources now readily available; better government regulatory control and advocacy by organised professional associations.

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REFERENCES

- Schommer JC, Pedersen CA, Doucette WR, Gaither CA, Mott DA (2002). Community Pharmacists' Work Activities in the United States during 2000. Journal of the American Pharmacists Association 42(3): 399-406.
- Ziance, RJ (2008). Roles for pharmacy in 2. combating counterfeit drugs. JAPHA 48(4): e71-
- 3. Gautam CS, Utreja A, Singal GL (2009). Spurious and counterfeit drugs: a growing industry in the developing world. Postgraduate Medical Journal 85:251-256.
- Bah-Traore N (2012). Quality Assurance and 4. Safety issue of Pharmaceutical Products marketed in Developing countries. Published Ph.D. Thesis on the internet, Available at: http://hss.ulb.unibonn.de/2012/3056/3056.pdf. Accessed January 25, 2013.
- 5. Erhun WO (2012). Poverty, Disease and Drugs in Regional Development. West African Journal of *Pharmacy* 23 (2) 3 -13.
- FIP. (1997). Standards for quality of Pharmacy 6. Services - Good Pharmacy Practice. Available at:

within the allotted project duration. However, the study

- http://www.fip.org/good pharmacy practice. Accessed May 7, 2014.
- 7. Amin AA Kokwaro GO (2007). Antimalarial drug quality in Africa. Journal of Clinical Pharmacy and *Therapeutics* 32: 429–440.
- World Health Organization (2011). WHO good 8. distribution practices for pharmaceutical products: WHO Technical Report Series, No. 957. Available at: http://www.who.int/medicinesAA. Accessed May 8, 2014. A Accessed May 8, 2014.
- 9. Federal Government of Nigeria (2012). National Drug Distribution Guidelines. Federal Ministry of Health. Second Edition. Abuja. Available at http://nascp.gov.ng/demo/wpcontent/uploads/2014/02/National-Drug-Distribution-Guidelines.pdf. Accessed June 10, 2014.
- 10. Federal Government of Nigeria (2005). National Drug Policy. 1st Revision. Abuja: Federal Ministry of Health Publications. Available at: http://collections.infocollections.org/whocount ry/en/d/Js6865e/. Accessed February 3, 2015.
- World Health Organization (1999). Quality 11. Assurance of pharmaceuticals: A compendium of guidelines & related materials GMP & inspection. Geneva, 2: 19-27. Available at: http://www.who.int/quality assurance/Quality Assurance Pharm. Accessed June 1, 2014.
- 12. Silimperi DR, Franco LM, Zanten TVV, Macaulay C (2002). A Framework for Institutionalizing Quality Assurance. International journal of healthcare quality assurance 14(1): 67–73.
- 13. Mannu T, Priyavrat T (2007). The Quality Brilliance through Brilliant People; Quality World 4(2): 1-10.
- 14. Defoe JA, Juran JM. Juran's Quality Handbook: The Complete Guide to Performance Excellence. New York: McGraw-Hill, 2010
- 15. Hackman JR, Wageman R (1995). Total Quality Management: Empirical, Conceptual, and Practical Issues. Administrative Science Quarterly 40(2): 309-342
- 16. Caudron JM, Ford N, Henkens M, Macé C, Kiddle-Monroe R, Pinel J (2008). Substandard medicines in resource-poor settings: a problem that can no longer be ignored. Tropical Medicine and International Health 13:1062-72.
- 17. Wertheimer AI, Santella TM (2005). Counterfeit drugs: defining the problem and finding solutions. *Expert Opinion on Drug Safety* 4(4):

- 619-622.
- 18. Brown LD (1995). Lessons learned in institutionalization of quality assurance programs: an international perspective. International Journal for Quality in Health Care 7: 419-425.
- Rogers EM. Diffusion of Innovations. 5th Edn. 19. Glencoe: Free Press, 1995. Available at: http://books.simonandschuster.com/Diffusionof-Innovations-5th-Edition/Everett-— Rogers/9780743222099. Accessed June 5, 2014.
- 20. Nwalieji AH, Ajayi AR (2009). Farmers' adoption of improved vegetable production practices under the National Fadama Phase One Development Project in Anambra State of Nigeria. African Journal of Biotechnology 8(18): 4895-4406.
- 21. Law E and Youmans SL (2011). Combating Counterfeit Medications: The California Pharmacist Perspective. Journal of Pharmacy Practice 24(1): 114-121.
- Ongoagchai S, Harun-Or-Rashid M, Sakamoto J 22. (2011). Factors Affecting Drug Quality Problems in Thailand. Quality Assurance Journal 14: 9-17.
- Storey J (2013). Factors affecting the adoption of 23. quality assurance technologies in healthcare. Journal of Health Organisation and Management 27(4):498-519.
- Yamane Y. Statistics: An introductory analysis. 24. New York: Hamper, 1964
- 25. Hafter JL, Fedor VL (2004). Emergency Medical Services and the Law: EMS continuing education series. ISBN 0763720682, 9780763720681. eBook: Jones & Bartlett Learning. Available at: https://books.google.com.ng/books?isbn=0763 720682. Accessed May 8, 2014.
- Black SA, Porter LJ (1996). Identification of the 26. Critical Factors of TQM. Decision Sciences 27(1):1-21.
- Singh SB, Dhalla RS (2010). Effect of Total Quality 27. Management on Performance of Indian Pharmaceutical Industries. Proceedings of the 2010 International Conference on Industrial Engineering and Operations Management Dhaka, Bangladesh. Available at: http://www.iieom.org/index-3.htm. Accessed July 18, 2014.