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CONTEMPORARY CHALLENGES OF PHARMACEUTICAL COMPOUNDING IN SOUTHERN NIGERIA: RESULTS OF SURVEY

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In the past decade the pharmacy practice worldwide has witness a trend shift from product-orientation to patient-orientation. This and other reasons encouraged the Nigerian government and its institutions to systematically de-emphasized through its budget, funding for the development of compounding unit.
Aim: *The aim of given article was to examine the challenges facing compounding pharmacists in hospital pharmacies, cost estimating of extemporaneous preparations and searching of solutions.*
Methods: *A closed and open-ended format questionnaire was distributed to 50 compounding pharmacists in Rivers State of Nigeria. The questionnaire comprised of a cover letter and 10 items which cut across personnel training, staffing, premise and equipment, logistics, cost of compounding, national reference standards on compounding, in-pharmacy control.*
Results: *From the survey results, challenges of compounding pharmacies in southern Nigeria such as inadequate manpower, absence of electronic documentation, facilities and funding; lack of national formulary on extemporaneous formulations and locally conducted stability tests were revealed. Cost of extemporaneous preparations ranged from 1–15 US dollars.*
Conclusions: *Development and implementation of easily accessible national formulary on extemporaneous formulations and their stability study, development of standard operating procedures for all activities in the pharmacy and staff training on recent technologies in compounding preparations are recommended*
Keywords: *compounded preparations, hospital pharmacy, questionnaire, standard operating procedure, national formulary, stability*

За останнє десятиліття в фармацевтичній практиці в усьому світі спостерігається тенденція переходу від продуктової орієнтації на орієнтацію на пацієнта. Через дану та інші причини уряд Нігерії та його інституції систематично скорочують бюджетні кошти на розвиток блоку аптечного виготовлення.
Метою *даної статті було визначення проблем, що постають перед фармацевтичними працівниками госпітальних аптек, оцінка вартості екстемпоральних лікарських засобів та пошук рішень.*
Матеріали і методи: *Анкета, що включала в себе закриті і відкриті питання, була поширена серед 50 фармацевтів виробничих аптек в штаті Ріверс, Нігерія. Анкета складалася з пояснювальної записки і 10 питань, які стосувалися навчання персоналу, кадрового забезпечення, приміщення та обладнання, логістики, вартості виготовлення, національних стандартів виготовлення, внутрішньоаптечного контролю якості.*
Результати: *Виходячи з результатів анкетування, проблемами виробничих аптек у південній Нігерії є неналежна кількість персоналу, відсутність електронного документування, обладнання і фінансування; було виявлено відсутність національного формуляру екстемпоральних лікарських засобів та проведених досліджень на стабільність. Вартість екстемпоральних лікарських засобів коливається в межах від 1–15 доларів США.*
Висновки: *Рекомендуються розробка та впровадження легко доступного національного формуляру на екстемпоральні лікарські засоби і їх вивчення стабільності, розробка стандартних операційних процедур для всіх видів діяльності в аптеці і підвищення кваліфікації персоналу про новітні технології виготовлення лікарських засобів в аптеках*
Ключові слова: *лікарські засоби аптечного виготовлення, госпітальна аптека, анкета, стандартна операційна процедура, національний формуляр, стабільність*

1. Introduction

In the past decade the pharmacy practice worldwide has experienced a shift from product-orientation to patient-orientation [1–3]. Compounding is the preparation (mixing, altering, assembling), under the supervision of a licenced pharmacist, of a medication that is not commercially available in the concentration or form needed for a specific patient pursuant to a prescription [4]. Products of compounding are called compounded preparations, extemporaneous formulations and compounded medications. The British pharmacopoeia refers to them as unlicensed medicines [5].

2. Formulation of the problem in a general way, the relevance of the theme and its connection with important scientific and practical issues

At the present stage of development of pharmaceutical industry there is a need to preserve the compounding of medicines in pharmacies. The Nigerian government and its institutions also have over the years, systematically de-emphasized through its budget, funding for the compounding unit. Today the compounding of medicines usually involves a small number of state and hospital pharmacies. In this regard, the majority of the population is limited acquisition opportunities in extemporaneous preparations.

3. Analysis of recent studies and publications in which a solution of the problem and which draws on the author

Organizational and economic problems of pharmaceutical compounding and its preservation for a long time are discussed by the pharmaceutical community [6–9]. Usually these problems are due to insufficient development of the pharmaceutical legislation in the absence of adequate funding.

4. Allocation of unsolved parts of the general problem, which is dedicated to the article

Study of problems of pharmaceutical compounding and dynamics of main economic indicators are relevant today. These include compliance to good compounding and pharmacy practices such as standard operating procedures, accessible harmonized national formulary and updates on local stability tests for extemporaneous formulations, quality control, and cost of extemporaneous preparations, logistics and adequate facilities.

5. Formulation of goals (tasks) of article

The aim of this study is to examine challenges facing compounding pharmacists in hospital pharmacies in southern Nigeria, cost of extemporaneous preparations and proffer solutions.

6. Statement of the basic material of the study (methods and objects) with the justification of the results

A closed and open-ended format questionnaire was distributed to 50 compounding pharmacists. The survey was conducted in River State (southern Nigeria) within the period of October – December 2015. The questionnaire comprised of a cover letter and 10 items which cut across personnel training, staffing, premise and equipment, logistics, cost of compounding, national reference standards on compounding, in-pharmacy control. The statement was considered accepted if it is affirmed by 50 % of the respondents. Data from questionnaire were analysed into Microsoft Excel 2010 and summarized below.

Out of the 50 distributed questionnaires, a total of 48 were returned, representing a 96 % response rate of the sample size. Mean scores were determined for each item and the summarized data presented below.

Table 1

Relevant responses from administered questionnaire

#	Questions	Scales (responses)					
1	Do you believe a biennial seminar/workshop for compounding pharmacists on recent scientific research is necessary?	Yes		No			
		100 %		0%			
2	Type of API used during compounding	Pure		API, as part of commercial drug (tablet, capsule, injection etc)			
		7.1 %		92.9 %			
3	Vehicles/bases used	Imported(ORA-Plus, ORA-Sweet etc)	Locally available (Vit C, Vit BCo etc)	Both		Abstained from answering question	
		47.6 %	38.1 %	11.9 %		2.4 %	
4	What determines the cost of a R_x	API	Base/Vehicle	Both		Abstained from answering question	
		16.7 %	23.8 %	52.4 %		7.1 %	
5	Possible high cost for a compounded preparation ($)	1 USD	1–3 USD	3–5 USD	5–15 USD	>15 USD	Abstained from answering question
		2.4 %	16.7 %	61.9 %	4.8 %	7.1 %	7.1 %
6	Possible low cost for a compounded preparation ($)	<0.5 USD	<1 USD	1–3 USD	3–5 USD	Abstained from answering question	
		9.6 %	14.3 %	61.9 %	7.1 %	7.1 %	
7	Awareness/existence of Nig. Ref. standards on compounding or quality control	Aware		Not aware		Abstained from answering question	
		2.4 %		95.2 %		2.4 %	
8	Existence/awareness of stability tests conducted in/for the country	Aware		Not aware		Abstained from answering question	
		35.7 %		61.9 %		2.4 %	
9	Adequacy of quality control lab	Adequate		Inadequate		Abstained from answering question	
		21.4 %		76.2 %		2.4 %	
10	Who should equip the Q.C. Lab?	Hospital	Government	Private firms	H+G	All stakeholders	
		33.3 %	42.9 %	–	11.9 %	11.9 %	

Cost: Compounding in Nigeria is done mainly in government-owned hospital pharmacies, where the cost of extemporaneous preparations is highly subsidized. Whilst 61.9 % of respondents pegged the possible high cost of a compounded prescription to be in the range of 3–5 USD, extemporaneous formulations in the pharmacy could go for as high as 15 USD. 61.9 % of respondents pegged the lowest possible cost of a compounded prescription to be in the range of 3-5 USD. 52.4 % of respondents agree that the cost of both APIs and vehicles/bases determine the final cost of the extemporaneous medication. The cost of APIs is subsidized if they are included in the National health insurance scheme (NHIS) drug list [10]. A fee (maybe fixed) for compounding service as proposed and obtainable in some countries should be stipulated to enable the pharmacist place the patient as the primary focus and the cost of the product as a secondary in priority [11].

Personnel and training: 100.0 % of the respondents approved a biennial seminar/workshop on recent scientific development on compounding; the curriculum should include the course of quality assurance of compounding preparations [12].

Staffing: The ratio of compounding pharmacists to population is very low [13]. This poses a threat of wear-out, prescription errors and less time devoted to patient counselling on medications. Compounding is done mainly by pharmacists.

Documentation: Thanks to routine preparation of monthly reports the practice of documentation has being strong. However, only 30.9 % of respondents had switched to electronic (computer-based) documentation of compounded formulations. Their reasons bothered on time constraint as a result of understaffing.

Logistics: availability of required APIs and excipients (vehicle/bases) is an important aspect of compounding. Although use of pure substances is preferable, 92.9 % use commercial drugs (tablet, capsules etc.) as APIs for compounding. Vehicles/bases utilised include ORA-Plus, ORA-Sweet, cherry syrup, simple syrup USP. A staggering 50 % of the respondents said there was difficulty accessing required ingredients for compounding. The problem of logistics is being tackled by both the Nigerian government and the Pharmaceutical Society of Nigeria through a proposed Mega drug distribution System [14, 15].

Premises and equipment: Until recently, the pharmacy unit as a whole was planned and designed by doctors. Pharmacists made no input. As a result compounding units are poorly planned. Head of Hospitals and clinics (doctors) are forced to make readjustments of the pharmacy premises to meet a required specification recommended by the NHIS [16], when they apply for accreditation to join the scheme. Since compounding units is not a compulsory requirement for registration of hospital pharmacies with the scheme, pharmacists are forced to make a strong case for its inclusion. Compounding unit specifications should be stipulated and included in the requirements for setup of a hospital.

Quality Control: 76.2 % complain of inadequately equipped compounding units. 33.3 % and 42.9 % ascribe responsibility of an adequately equipped compounding unit on the hospital itself and government respectively. 11.9 % place the responsibility on both while the same percentage believes all (including private firms) stakeholders share the responsibility. All respondents (100 %) acceded to the need for development and implementation of standard operating procedures (SOP) for all activities in the pharmacy, including all stages of compounding, routine cleaning procedures, compounding equipment and environmental conditions under which products are prepared to enhance quality assurance [17].

In-pharmacy control: 100 % of the participants (respondents) confirmed in-pharmacy control. Prescriptions are vetted before compounding. Calculations and technology of production are checked by the supervising pharmacist before compounding. The compounded formulation is checked by another pharmacist before dispensing. Stocks are checked monthly. Erring pharmacists are retrained on the job. Raw materials are examined on reception, before storage and before use. Inspection of compounding by regulatory bodies is less frequent.

Reference standard: the reference standards used within the pharmacy include the British Pharmaceutical Codex, British Pharmacopoeia, United States Pharmacopoeia, the American Society of Health System Pharmacists Drug Information, Information from the International Journal of Pharmaceutical Compounding and other available sources that provide information on stability studies or recent updates relating to drug compounding. From the survey, 95.2 % of respondents are not aware of the existence of a national reference standard. Neither is 61.9 % aware of any stability tests being conducted in/for the country (Nigeria). A template for national formulary for compounded drugs is therefore proposed in Fig. 1, similar to existing/proposed formats in other countries [18–20].

This should be in a database form, containing readily accessible formulary to pharmacists nationwide. The formulary should include formula magistrals and medicines prepared by a hospital or community pharmacy in accordance with instructions in a compendium, pharmacopoeia or a formulary and dispensed by a pharmacy to patients [21, 22].

It should be subject to regular updates and a channel (or forum) [23] be created for inputs on new formulas/recipe. The advantages include access to locally usable information, increased quality assurance, inputs from academic and practicing pharmacists, and a harmonised national formulary of suitable formulations [24]. Stability tests should be made using products readily available in the country. Since generics of the same drug may produce different stability results due to the use of different excipients, it becomes necessary that the specific company producing the generic be mentioned.

Formulation Record

Name/Strength/Dosage form: Propranolol 1 mg/ml Suspension

Route of Administration: Oral

Ingredients	Strength	Quantity
Propranolol Tablets	40 mg	6 tablets
Distilled water(wetting agent)		4.8 ml
Citric acid Solution	25 %	1 ml
Simple Syrup	qs	240 ml

Procedure:

1. Crush tablets in a mortar to a fine powder.
2. Levigate the powder with distilled water until a smooth paste.
3. Add a small amount of simple syrup to form a smooth paste. Add more syrup until a liquid is formed and transfer the contents into a graduated cylinder. Use additional simple syrup to rinse the remaining drug from the mortar.
4. Add citric acid to the suspension in the graduate. Mix well.
5. QS to final volume with simple syrup.
6. Transfer the suspension into amber bottle
7. Shake well and label

Storage requirements: Refrigerate. Keep in amber bottle. Protect from light.

Stability: 45 days

Reference:

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Fig. 1. Proposed format for compounding preparation formulary

7. Conclusion

The survey reveals challenges of compounding pharmacists in southern Nigeria such as inadequate manpower, electronic documentation, facilities and funding, access to a comprehensive national formulary on extemporaneous formulations and locally conducted stability tests.

Full electronic documentation, increased government funding for quality assurance conditions, logistics, adequate equipment of the compounding and quality control units, recruitment of more pharmacists is advocated.

An easily accessible national formulary on extemporaneous formulations and their stability study, development and implementation of SOP for all activities in the pharmacy and staff training on recent technologies in compounding preparation are recommended.

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DEVELOPMENT OF METHODS FOR DETERMINATION OF PHENOLIC ACIDS AND FLAVONOIDS IN CAPSULES CONTAINING CORYLUS AVELLANA L. DRY EXTRACT

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The questions of standardization and quality control of both herbs and herbal remedies remain relevant, because it is well-known that product quality standards are essential, whether consumer using herbs or drugs. The necessity of the standardization methods development for the initial herbal material and capsule dosage form for the further quality control under manufacturing conditions remains relevant.

Aim. *The aim of our research was to develop simple, specific, accurate and reproducible methods for identification of flavonoids and phenolic acids in capsule dosage form containing Corylus avellana L. dry extract.*

Methods. *The samples of gelatine capsules containing Corylus avellana L. dry extract for oral administration were analyzed. The analysis was carried out using Camag HPTLC system.*

The absorption spectroscopy determination of the sum of flavonoids was carried out using THERMO Scientific Evolution 60S Spectroscope in wavelength range of 300–600 nm.

Results. *As a result of HPTLC research rutine and quercitrine have been identified in capsule dosage form containing Corylus avellana L. dry extract. Among phenolic acids, neochlorogenic and chlorogenic acids have been identified.*

Under the given conditions, the spectrum of the test solution had a maximum absorption at wavelength 406 nm. The analysis of flavonoids total content in gelatine capsules containing Corylus avellana L. dry extract calculated as rutine has shown the content of 1,7 %.

Conclusion. *Effective HPTLC and absorption spectroscopy methods for determination of flavonoids and phenolic acids in capsule dosage form containing Corylus avellana L. dry extract have been developed. It has been found that described methods are promising enough for standardization of capsules with Corylus avellana L. dry extract and may be suggested for the quality control of the dosage form under manufacturing conditions*

Keywords: *capsules, Corylus avellana L., extract, HPTLC, absorption spectroscopy, phenolic acids, flavonoids*

Питання стандартизації та контролю якості як рослин, так і лікарських засобів рослинного походження набуває актуальності, враховуючи той факт, що стандарти якості продукції є вкрай важливими, незалежно від того, чи вживає споживач лікарські рослини або лікарські засоби. Необхідність розробки методик стандартизації для вихідної рослинної сировини та капсульовано лікарської форми для подальшого контролю якості в умовах виробництва залишається актуальною.

Мета. *Метою нашого дослідження була розробка простої, специфічної, точної та відтворюваної методики ідентифікації флавоноїдів та фенольних кислот у капсульованій лікарській формі з сухим екстрактом Corylus avellana L.*

Методи. *Для дослідження використовували зразки желатинових капсул з сухим екстрактом Corylus avellana L. для орального застосування. Аналіз проводили з використанням системи Camag для ВЕТСХ.*

Визначення вмісту суми флавоноїдів методом абсорбційної спектроскопії здійснювали за допомогою спектрометра THERMO Scientific Evolution 60S у діапазоні хвиль 300–600 нм.

Результати. *В результаті ВЕТСХ аналізу у капсульованій лікарській формі з сухим екстрактом Corylus avellana L. були ідентифіковані рутин та кверцитрин. Серед фенольних кислот були ідентифіковані неохлорогенова та хлорогенова кислоти.*

В умовах проведення спектрофотометричного дослідження спектр випробовуваного розчину мав максимум поглинання за довжини хвилі 406 нм. Вміст суми флавоноїдів у желатинових капсулах з сухим екстрактом Corylus avellana L. у перерахунку на рутин становив 1,7 %.