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## Drug Production in Tertiary Health Institutions - Needs, Constraints and Prospects

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### SUMMARY

This study was carried out to investigate the needs, problems and prospects of drug production in tertiary health institutions using Lagos University Teaching Hospital as a case study and to recommend solutions to the problems so identified.

The use of questionnaires was employed in the study covering all pharmacists in the pharmaceutical services department, pharmacy technicians and quality control technologists in the Drug Production unit of the hospital. It was unanimously agreed by the respondents that local drug production was necessary in tertiary hospitals. About two third of the respondents considered the current performance of the Drug production unit to be at most, average. The major problems were identified to be lack of adequate funding, inadequate support and commitment by the hospital management and absence of maintenance culture leading to breakdown and collapse of equipment and machinery.

It was realized that the prospect of drug production in tertiary health institutions was very bright and that success could be achieved, but only through very careful planning and execution of the project, adequate funding, strong commitment from the management of the institution, well trained and motivated staff.

**Key Words:** Drug Production, Constraints, Prospects.

### INTRODUCTION

Pharmacy practice in tertiary hospital involves supplying of medications for in-patients and outpatients, bulk compounding, preparation of certain sterile medications, research, drug information service and all other aspects of clinical pharmacy services.

Drug production is an essential function of pharmacy practice in a tertiary hospital though there is hardly any manufacturing activity in place in many of our hospitals currently.

In the historical developments of pharmacy in Nigeria, manufacturing activities did not take-off on time in hospitals. This has been traced to the fact that early dispensers of 1887 - 1923 were trained by medical doctors and that the medicines used in those early days were concentrated mixtures and decoctions imported from overseas<sup>1</sup>. It has also been inferred that pharmaceutical service was not

established on the basis of self-reliance, hence the importation of all preparations and that the nature of training given to the early pharmacists was such that the idea of procuring finished drugs from overseas or from outside the hospital environment was deeply rooted<sup>2</sup>. The lower level of manufacturing activity in the tertiary hospitals can also be traced to the fact that planning of Nigerian health policies had always been influenced by medical practitioners and drug production was not reckoned with in the design of hospital pharmacy planning<sup>2</sup>. Although interest in local production has grown considerably in recent years, statements about self-sufficiency, are largely meaningless in the pharmaceutical arena since there will still be needs to buy some ingredients from external sources. Self-sufficiency is almost utopian and unattainable.

Pharmaceutical production is a complex activity in which many interdependent manufacturing enterprises contribute to the production of a variety of pharmaceutical dosage forms. Production may be viewed in three essential phases viz. primary manufacture, secondary manufacture and packaging<sup>3,4</sup>. At the level of drug production in hospitals, the phase of interest is the secondary manufacture which is concerned with the production of pharmaceutical dosage forms by processing of active medicinal substances in admixture with pharmaceutical excipients<sup>4</sup>.

Small scale production can be divided into sterile and non-sterile production. Depending on the availability of qualified staff, adequate facilities, sufficient equipment and fund. Production can be very simple or quite sophisticated. Sterile production is the most demanding type and it must be carried out in strict compliance with current good manufacturing practices. Depending on need and capacity, sterile products that can be manufactured include eye drop, water for injection and parental products e.g. Intravenous fluids<sup>5</sup>.

### Drug Production Unit (LUTH)

The Management Board of Lagos University Teaching Hospital (LUTH) first decided to embark on local production in 1984. With the technical support of DPI medical Ltd, UK, the intravenous fluid production plant was commissioned in 1991 with few personnel staff comprising Pharmacists, Pharmacy technicians, Porters and Engineering personnel. The quality control section was manned by a Pharmacist and two technologists serving as analysts and one microbiologist. Production of the intravenous fluids and



haemodialysis concentrates lasted till 1994 when the steam-generating unit developed problem.

Since the cessation of Haemodialysis concentrate and intravenous fluid production in 1994, the unit has concentrated its attention on the production of liquid dosage forms (oral and external), semi solid preparations, e.g. Salicylic acid in Sulphur ointment and Whitfield ointment; Ophthalmic preparations e.g. Pilocarpine eye drops (4%)

and Sodium chloride eye drops (5%) and special preparations e.g. Shohl's solution, Brompton's cocktail and Podophyllum paint. From 1995 – 1997, the period immediately following the collapse of the boiler unit, the contribution of the unit to total drug consumption in LUTH ranged from 1.65 – 1.83% annually (Table 1). After 1997, the services rendered by the Drug Production Unit became seriously hampered.

**Table I**

**Contribution of Drug Production Unit (DPU) to total drug consumption in LUTH**

Year	Total cost of drugs issued from Pharmacy main store	Cost of Drugs issued to Pharmacy main store by drug production unit	% Contribution of DPU to total drug consumption
Jan 1st - Dec. 31st 1995	N37,378,757.03	N683,906.00	1.83%
Jan 1st - Dec. 31st 1996	N57,194,154.72	N1,013,476.00	1.77%
Jan 1st - Dec. 31st 1997	N59,979,202.00	N988,741.50	1.65%

**METHODS**

The use of questionnaire was employed in the study and this was complemented with observation of the system and some selected records of the organisation. The records include reports of committees, information regarding procedures and policies of the unit as all these could provide useful sources of facts about the unit's activities. Observation of the system involves visiting the unit to observe the totality of the procedure operating there for assessment. This is advantageous in the sense that first hand and verified facts are obtained and shortcomings in the observed procedures will be revealed.

The questionnaire was designed for all Pharmacists in the hospital, Pharmacy technicians working with Drug Production Unit and the Quality control Technologists in the unit. Other health professionals like Doctors and Nurses were not covered because of the technicality of the issue at stake and that majority of these professionals hardly knew much about the existence of the unit and its contribution to the hospital drug supply. Only a very few Medical specialists have had the cause to order special products from the unit. The data obtained from the study were analyzed using simple frequency distribution.

**RESULTS**

59 questionnaires were sent out and 49 were returned (83.1%). Question was asked as to whether or not drug production in hospital was necessary. All the respondents (100%) were of the opinion that there was a need for drug production in tertiary Hospitals.

**Table II**

**The Needs of 'In-house' Drug Production in Hospitals**

Need	No. of Respondents (%)
(a) Provision of some drug Products which are unavailable in community pharmacy outlets.	47 (95.9)
(b) Provision of high quality products of proven therapeutic efficacy	38 (77.6)
(c) Possibility of individualizing dosage forms	46 (93.9)
(d) Cost effectiveness of health care budget	30 (61.2)
(e) Creation of Employment	35 (71.4)
(f) Ensuring continuity of drug supplies	36 (73.5)
(g) Others	14 (28.6)

**Table III**

**Problems militating against drug Production in LUTH**

Problem	No. of Respondents(%)
1 Lack of cooperation and support from hospital management	37 (75.5)
2 Lack of cooperation and understanding from pharmacy colleagues	23 (46.9)
3 Manpower shortage	24 (49.0)
4 Absence of maintenance culture	42 (85.7)
5 Non - availability of skilled technical staff	22 (44.9)
6 Non - availability of up-to-date equipment	43 (87.8)
7 Infrastructural deficiencies	40 (81.6)
8 Space / Location constraints	27 (55.1)
9 Quality assurance problems	25 (51.0)
10 Others	8 (16.3)



Respondents were asked to assess the drug production unit on performance and ability to attain the desired objectives for which it was set up (Table IV). Reasons were adduced for the performance rating.

**Table IV**  
**Assessment of Performance of Drug Production Unit in LUTH**

Performance Rating	No. of Respondents (%)
Excellent	4 (8.5)
Good	10 (21.3)
Average	22 (46.8)
Poor	11 (23.4)

Question was asked as to whether or not there was a prospect for drug production in tertiary hospitals. Here, 79.6% of the respondents were of the opinion that there was a prospect for drug production while 6.1% claimed there was no prospect and 14.3% were undecided.

**Table V**  
**Potential Benefits of Drug Production in the Hospitals**

	No. of Respondents (%)
(i) Better patient care in terms of drug management	36 (73.5)
(ii) Enhancement of Research and Development	35 (71.4)
(iii) Better and improved interaction between members of health care team	27 (57.5)
(iv) Enhancement of the image of the hospital and professional image of the pharmacists in particular	20 (81.6)
(v) Expansion of activities in the production unit can serve as source of genuine, unstable and non-commercially available drug products to other hospitals	35 (71.4)
(vi) Others	6 (12.2)

## DISCUSSION

All the respondents agreed that drug production in tertiary hospitals is a necessity. The respondents were of the opinion that there were several benefits to be derived from local drug production (Table II). Above all, there are many products that are not available in the community pharmacy outlets either because of low demand (and it is uneconomical for manufacturers to produce such items) or because of stability problems e.g. Brompton's cocktail, Isoniazid Elixir. Hospital drug production also affords the opportunity to individualize dosage forms. Thus, drugs can be prepared for individual patient such as in diseased states such as renal and hepatic dysfunctions where drug dosages may need to be adjusted; in patients that cannot swallow

drugs, and for children (where paediatric formulations are not readily available) e.g. Potassium chloride elixir, Rifampicin HCl preparations for children. The latter has been presented for children by applying the knowledge of divided powders.

In this era of faking and adulteration, drug production in the hospitals provides the opportunity for producing high quality drugs with proven therapeutic efficacy. Apart from quality consideration, continuity of drug supply is also assured, since the drugs are produced in-house in the hospital. Drug production leads to job creation for Pharmacists and Pharmacy technicians, Laboratory scientists and technical staff. It also leads to savings in the cost of health care services and scarce fund can be channeled to other areas of health care delivery system. Other benefits to be derived include improvement of skills and specialization of Pharmacy personnel. It gives room for research into products and formulation science and complements the effort of pharmaceutical services unit to provide comprehensive pharmaceutical care to patients.

As shown in Table III, 87.8% of the respondents believed that non-availability of up-to-date equipment is a major problem confronting the production of drugs in the tertiary hospitals, particularly LUTH. Inspire of the fact that most of the equipment and machinery are obsolete and cannot meet the challenges of modern production, the maintenance culture is poor. The equipments are not taken care of due to shortage of fund and lack of support from the management of the hospital. Another problem is infrastructural deficiencies. The location of the plant is inadequate and unsuitable. Most of the time, supply of water and electricity is epileptic. Manpower could be an obstacle in drug production but in LUTH, the unit is effectively manned by experienced pharmacists and pharmacy technicians and skilled technical staff. The only problem that can be associated with manpower is the absence of training opportunities and incentives for the staff of the unit. In LUTH, one of the most important constraints is the lack of support from the management of the hospital. There is no annual subvention for the unit, and money is not always transferred on time from Drug Revolving Fund Account for sourcing of raw material or payment of suppliers. Equipments are left unmaintained and members of staff are not motivated. About 16.3% of the respondents highlighted some other problems such as inadequate funding by the government; lack of suitable storage condition due to absence of or non-maintenance of air conditioners at the storage area. All these factors have conspired to keep the level of capacity utilization very low.

In Table IV, it can be deduced that 70% of the respondents considered the current performance of drug production unit as not good enough. Almost a quarter of the respondents believed the performance was poor and about half of the respondents felt the unit's performance was average. For the average performance rating, reasons adduced were as follows; poor quality assurance, low range of products, under utilization of production capacity; bureaucratic tendencies leading to unsteady supply of certain preparations, time lag between supply and demand was large and lack of promptness in delivery of preparations requested for by the service unit. The lack of



promptness in delivery of preparations was observed to be due to management's requirement that intra-departmental transfer of products (from the production unit to the pharmacy main store) had to wait for approval by the chief medical director of the hospital.

Table V gives a listing of potential gains of local drug production. About 12% of the respondents listed some other potential gains. These are the development of skill of pharmacists and provision of training opportunity for pharmacy students; the unit can serve as a centre for consultancy services, which can generate revenue for the hospital. By embarking on local drug production, research and development issues will have to be tackled to improve on production techniques. Problems arising in production will have to be addressed e.g. shedding of particles into intravenous fluid solution by rubber bungs resulting in the failure to satisfy particulate matter analysis requirement. Occasionally there may be a need to formulate an unstable preparation in a form that will be of therapeutic benefit to the patient. When solutions are then found to some of these technical and formulation problems, there will be a great contribution to knowledge and better patient care.

Drug production can also lead to the enhancement of the image of the hospitals and the professional image of the pharmacists. Pharmacists have been seen as not contributing much to patient care in hospitals. Production is an area where their impact can be felt. There is also a better and improved interaction between Pharmacists, Medical specialists and Nurses. Many medical specialists have had cause to request for special products from the unit. (E.g. EDTA eye drops and 5% sodium chloride eye drops, Brompton's cocktail, glucose powder for OGTT) and the unit had been meeting such challenges despite all the constraints confronting it. Drug production has important contributions to make in providing health care and in lowering the cost of health care in our tertiary health institutions.

Several solutions were suggested by the respondents to the problems faced by the Drug production unit. These are:

- (i) Proper and regular funding of the unit by the Government via Hospital Management
- (ii) Supportive policies by the Hospital Management
- (iii) Availability of skilled manpower.
- (iv) Utility services like Electricity and water supply should be augmented and complemented with private and alternative supply.
- (v) Investment in manpower development, training and updating opportunities for the staff of the unit.
- (vi) Motivation and incentive for staff
- (vii) Privatization or commercialization of the unit to remove bureaucracy and instill efficiency.
- (viii) Presentation of seminar or workshop to the management of the hospital and all stakeholders in the hospital to enhance the image of the unit and draw attention to the problems of the unit and the

roles the unit can perform to further the patient and pharmaceutical care.

- (ix) Development of good maintenance culture and regular servicing of equipment and machinery.
- (x) Full autonomy for the drug production unit with separate budgetary allocation and to be directly responsible to the management of the hospital.
- (xi) Understanding and cooperation from pharmacists and all staffers of the pharmacy department.
- (xii) Timely and adequate sourcing of raw materials and galenicals and provisions of good storage facilities.

## CONCLUSION

This work has made an attempt to study the gains, constraints and prospects of drug production in tertiary health institutions. There are many benefits to be derived from drug production. These include savings on overall cost of drug purchases to health services and savings in foreign exchange, thus more funds is available to be channeled to other areas of health care that can benefit the patients. It can also serve as a training tool for pharmacy students, interneer pharmacists and qualified pharmacists on the production and quality control of drugs. It also satisfies the needs of the patient in the supply of drug products (which may not be commercially available) thus enhancing pharmaceutical care.

Though local drug production is highly beneficial, it is not without constraints, the major ones are poor funding, absence of good maintenance culture and lack of commitment and support on the part of the management of the hospital.

For success in the production venture, a prime requirement is an enthusiastic and competent managerial and technical staff and conditions of employment must be such that staff remains enthusiastic and motivated to continue to provide upper and middle management that is essential for the smooth running of operations.

It can be stressed that the prospect of drug production in tertiary health institutions is bright and success can be achieved, but only through very careful planning and execution of the project.

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