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Health Systems Research

Health care delivery is an overwhelming challenge area of Kenya’s health care systems. In this Journal issue, a review article by Dr. Christine Sadia looks at factual evidence to describe the main challenges facing health care delivery in Kenya, including inefficiency and mismanagement. The review paper articulates that public health professionals and operations research practitioners are not prominently or effectively playing their role and concludes that evidence based analysis and data can help in the health reforms. Furthermore, another article, in this journal issue, on dispensing practices by Mugiira et al endeavors to provide a baseline from which intervention programs could be designed to improve dispensing practices in the hospital studied. Although dispensing is just one aspect of healthcare delivery system, it is the last point of visit in a health facility and also most critical for the patient to get the correct information that impact on rational use of medicines. The manuscript has thus provided useful information to inform policy formulation on appropriate healthcare delivery. Effectiveness of medicines also depends on availability of quality medicines. The pharmaceutical industry needs to play its part. To achieve this, it could not have been better described by the article on Pharmaceutical Operational Excellence by Friedli et al which has given a definition of the concept of Operational excellence (OPEX) as constituting the continuous pursuit of improvement of a production plant in all dimensions.

I shall briefly deliberate on what and how research can help address some major issues to improve healthcare delivery.

What is a health system?

A health system is the set of resources and activities that work together to improve the health of populations. Elements of a health system include:

» **health facilities**, beginning with local clinics all the way up to specialty-care referral hospitals

» a **health workforce** made up of the right mix of well-trained clinical providers

» **laboratory and pharmacy** products and services, and the related procurement and transport systems

» a **health information system** that enables health officials to analyze how the system is functioning and whether health outcomes are being achieved

» **health financing** that raises funds for health and protects people from the financial risk of catastrophic health costs

» **leadership and governance** structures and policies that ensure all parts of the system work together and are accountable to the populations they serve

» **linkages to the community**

When one or more of these elements are weak, the health system suffers, and so do the people it serves. Crucial and expensive vaccines can sit useless and expensive in a warehouse if there are not enough trained health workers to deliver them. Understanding what works and improving health services requires a reliable central database, accurate data and the ability to analyze the information and make decisions.
Health Systems Research

Health systems research (sometimes called “implementation science”, “operations research” or “translational research”) is a growing area of work that looks at how interventions or services are delivered in real life, and how they can be improved. It attempts to understand and evaluate how health systems function and how they can be strengthened, including how to develop and implement policies in ways that strengthen, rather than undermine, health systems. The main purpose of health systems research is to conduct research to develop and improve the organization, efficiency, effectiveness and impact of health systems on population health. Through this kind of research, governments can see what is working and where gaps exist so they can make more informed management decisions. The goal is to make sure that innovations in healthcare can be brought from theory into practice, and reach the people who need them. Health Systems research in the context of the developing countries works towards finding best ways to improve access, affordability and quality of health services for the poor while building robust health systems for the future.

A number of development partners are currently working together in support of research to improve health systems in developing countries. They are committed to strengthening the evidence base for improving health in low- and middle-income countries by investing millions of dollars to fund research aimed at providing evidence to strengthen health systems and improve health outcomes. Health systems research in the context of the developing countries works towards finding best ways to improve access, affordability and quality of health services for the poor while building robust health systems for the future.

Translating Evidence into Practice

How can public health agencies and their partners most effectively and efficiently keep people healthy and safe, particularly in this era of fewer dollars and people to support public health services? Health services research (HSR) a multidisciplinary scientific field that examines how people get access to health care practitioners and health care services, how much care costs, and what happens to patients as a result of this care, is able to find these answers. Studies in HSR investigate how social factors, financing systems, organizational structures and processes, medical technology, and personal behaviors affect access to health care, the quality and cost of health care, and quantity and quality of life. Primary goals of HSR are to identify the most effective ways to organize, manage, finance, and deliver high quality care; reduce medical errors; and improve patient safety. HSR is more concerned with delivery and access to care, in contrast to medical research, which focuses on the development and evaluation of clinical treatments. It is grounded in theory, its underlying aim being to perform research that can be applied by physicians, nurses, health managers and administrators, and other people who make decisions or deliver care in the health care system.

Further reading


Dispensing Practices at Mbagathi District Hospital

Mugiira M. K, 1Orwa J. A, 2Namasaka, M. P. 
1Institute of Tropical Medicine and Infectious Diseases, Jomo Kenyatta University of Agriculture and Technology P.O Box 62000-00200 Nairobi, Kenya. Email: martin.mugiira@gmail.com, 2Centre for Traditional Medicine and Drug Research, Kenya Medical Research Institute, P.O Box P.O. Box 54840 Nairobi, Kenya. Email: jorwa@kemri.org, 1Jomo Kenyatta University of agriculture and technology P.O BOX 6200-00200 Nairobi Email pmnamasaka@gmail.com/philnamasaka@yahoo.com.

Corresponding author: Martin Mugiira, Institute of Tropical Medicine and Infectious Diseases, Jomo Kenyatta University of Agriculture and Technology P.O Box 62000-00200 Nairobi, Kenya. Tel: Office: 254 (20) 6999 272 Mob: 254 722 799 695 Email: martin.mugiira@gmail.com

Abstract

Inappropriate use of drugs is a major public health concern of present day pharmaceutical practice. It is associated with several consequences all leading to decreased quality of health care to the population. This study was to establish the dispensing practices in Mbagathi District Hospital. The study was a Cross-sectional study carried out at the outpatient Pharmacy. Using simple random sampling, records were reviewed retrospectively and prospective interviews done to dispensing staff and patients using a semi-structured questionnaire. Average dispensing time was 61 (CI 52.2-69.8) seconds per patient. The hospital was able to dispense 68 % (CI 61.7-73.2) of the prescribed drugs. Ninety five percent (CI 89%-98%) of the dispensed drugs were adequately labeled and 92% (CI 85%-96%) of the patients correctly described the dosage of the drugs. The pharmacy had 80% (CI 52%-96%) of the key drugs used to treat common ailments during the study period. This study provides a baseline from which intervention programmes could be designed to improve dispensing practices in the hospital.

Key words: Dispensing practices; Mbagathi District Hospital; Irrational drug utilization

Introduction

Since we entered the 21st century, it has been a matter of great concern that inappropriate and irrational dispensing is still common in most countries. Although the problem is undoubtedly more serious in the developing countries, which also has to operate under minimal health budgets, the developed world is also prone to unscientific dispensing habits and practices 1. Significantly, the rapid advances in technology and the use of modern education methods in health have failed to remedy the situation. In the developing countries, where the resources for the health sector are scarce, this inappropriate use of drugs makes the situation even worse as squandering of the lean provisions invariably affects the overall quality of care adversely, leading to serious consequences for the general population 2.

Since 1981, the World Health Organization, through the Action Program of Essential Drugs (DAP), the Nairobi Conference of Experts and the International Network for Rational Use of Drugs (INRUD) has been supporting and assisting developing countries in addressing this problem. Their technical assistance is mainly in the field of research, development of intervention strategies and promoting the rational use of drugs while also providing forums and tools of expertise 1, 3, 4. Several factors are generally believed to contribute in varying degrees to inappropriate drug use. These factors greatly influence the behavior of the health care practitioners, and include their training (or lack of it), influence of sales representative of pharmaceutical companies, peer pressure, social and cultural pressure, emulating prescribing habits of senior health care providers, availability of drugs, procurement, selection irregularities and demands of patients for certain medications, supervision, level of training among others 5. These irrational drug use practices cause wastage of scare resources, produce resistance to various commonly used antibiotics, and go against the ethics of the medical profession 6.

In Kenya, irrational dispensing practices are likely to be prevalent at all levels in the government health facilities as well as by the private practitioners 7. The public health sector, which serves more than 90% of the general population, is likely to have more of this problem 8. Currently, small scale interventions are in place to address the problem but no scientific studies have been carried out in Kenya to evaluate the effectiveness of such policies and correlate them to the actual drug use practices 9. Baseline studies are necessary to establish the current dispensing practices before interventional campaign programmes are designed. This study achieves the first step in improving the practice by examining the current dispensing practice at Mbagathi District Hospital.

Materials and Methods

Mbagathi District Hospital’s outpatient Pharmacy is mainly managed by Pharmaceutical technologists with a few pharmacists available. The facility is very busy attending to more than 100 patients a day. The hospital’s outpatient pharmacy formed the unit of study for this research. The design of this study was cross-sectional, mainly quantitative and descriptive. Quantitative data was collected retrospectively from prescriptions while Patient care data was collected prospectively according to standardized guidelines by World Health Organization (WHO) 10. A questionnaire was used to collect data prospectively from patients and health care providers, using open and close-ended questions.
**Retrospective data**

In order to produce representative and comparable statistics of appropriate dispensing, the indicators defined by WHO in How to investigate drug use in health facilities: selected drug use indicators were used to form the dependent variables. The World Health Organization (WHO) “core drug indicators” used included: average dispensing time, percentage number of drugs actually dispensed, percentage of patients with adequate prescription knowledge of correct dosage, and percentage of adequately labeled drug packages. Adequate patient knowledge of dosage schedule included adequate report of “how to take the medication” to the investigator of drug regimen, for all the drugs in the patients’ hands.

In order to determine if drug supply contributed to inappropriate drug dispensing, i.e. if the appropriate drug was unavailable, and a less appropriate drug would be prescribed in lieu, the World Health Organization (WHO) “core health facility indicator” (an inventory of key essential drugs) was also completed.

**Prospective data**

Standardized methods of investigating drug use indicators were used in conducting the study. These methods as published by World Health Organization (WHO) recommend a study of 100 patient records in a single large health facility. Therefore 100 prospective records were collected from the facility’s outpatient department. The sample size of 100 patient interviews and all dispenser encounters at the hospital on the visit days were based upon World Health Organization (WHO) recommendations.

The quantitative data was analyzed descriptively and proportions and percentages of each dispensing and patient care indicator parameter calculated. Analytical tests used were odds ratio to measure magnitude of effect between binary and continuous variables and student’s independent t-test to test the difference of independent variables means. The ethical considerations in this study focused specifically on ethical aspects that have posed particular problems in epidemiological studies of communities in developing countries. At both national and institutional levels, approval for this study was sought and granted from the Ethics Review Committee (ERC) at Kenya Medical Research Institute (KEMRI) and from hospital Medical Superintendent.

**Results**

On average, dispensing staff at Mbagathi District Hospital spends an average of 61 seconds only interpreting the prescription, issuing out the drugs and educating the patient on how to correctly take and store the medication. The study also found out that the hospital was able to dispense only 68% of the drugs prescribed to the patients. Patients were sent out to the private pharmacies to buy the rest of the unavailable prescribed medicines. This translates to a mean of 2.7 prescribed medicines compared to a mean of 1.8 that were actually dispensed (P-Value < 0.0001).

![Fig 1: Average Comparison of prescribed and dispensed drugs](image1)

Out of the surveyed 100 prospective samples, 95% of the total dispensed drugs were adequately labeled with essential information on the drug package. This included at least the patient name, drug name and when the drug should be taken. Further to the packaging labeling, 92% of all patients interviewed had good knowledge of the drugs they were prescribed. These patients were able to know the drug and dosage schedule of the drugs they had as shown in the graph below:

![Fig 2: Percentage of Adequately labeled drugs and patients with good knowledge of dosage](image2)

On measuring the availability of key drugs in the outpatient pharmacy of the Mbagathi district hospital, this study found out that 80% of the Essential medicines for treatment of common community diseases were available at the time of data collection.

**Discussion**

While there may not be a gold standard to measure against on what is the ideal threshold for each of the parameters, other studies in the country and in the region provide an important comparative basis for planning interventions to improve drug use practice by both prescribing and dispensing staff. Patient care indicators demonstrate an effort to quantify the dispensing process between a Health Care Provider and a patient. The rationale is that the more the time a Health Care Provider spends with a patient, the better they manage them and the better they prepare them on how to properly use the medicines prescribed. Similar studies done in some of the developing countries have shown that most of the countries dispensing time are in the same range as Mbagathi District Hospital except for Nigeria which is unusually short.
This parameter is however likely to vary depending on the number of patients visiting the institutions and the number of health workers available to see patients. It was worth noting that 95% of the sampled drugs were adequately labeled and this has a potential of greatly reducing misuse of drugs by patients as a result of poor labeling. A correlation that was statistically significant (Chi-square P-Value < 0.007) was also established between correct labeling of the drugs and patients ability to correctly describe how to take each of the drugs issued. According to the significant result of the study, patients attending the outpatient pharmacy are unlikely to get all the drugs prescribed from the hospital pharmacy. The drugs dispensed were less than the prescribed drugs by ~1(P-Value < 0.0001). This poses a problem because it is not easy to know whether the patient bought the prescribed medication from the private pharmacies or not. Usually, the cost of medication in private pharmacies is much more expensive than in the public hospitals and this may present a valid barrier for the patients not to buy the drugs not dispensed at the hospital.

**Conclusion and recommendations**

Drug dispensing is the end of the therapeutic consultation. This study suggests that there are key areas of improvement by the pharmacy department in the hospital. At the same time the hospital is doing fairly well on some measured parameters compared to other institutions in surveyed similar countries.

One area that requires immediate action is on availability of medicines at the pharmacy. Many patients are unable to get prescribed medicines form the hospital pharmacy. This greatly erodes the patient quality of care provided by hospital. This is because the hospital is unable to tell whether the patients bought the right medicines or not at all form the private pharmacies.

The study also shows that Mbagathi District Hospital is doing fairly well on labeling of drugs which greatly improves patient’s knowledge of correct dosage for the prescribed medicines. This best practice should be maintained and shared with other similar institutions. The hospital needs to set up a committee to regularly monitor dispensing and patient care practices while benchmarking with similar institutions in developing countries to ensure optimal care of patients by the dispensing staff. This will ultimately improve out-patients’ quality of care. Similar study needs to be carried out in the inpatient pharmacy to compare the findings with the outpatient pharmacy department.

**References:**


ABSTRACT.

Keywords: Giriama; Ethno-medicine; Deinbollia; Clerodendrum; Gardenia; herbal remedies; sustainability

Background: Though the Giriama people of Kenya rely mostly on ethno-medicine to manage human ailments, the indigenous knowledge remains largely undocumented. This study was set to survey, record and report some of the medicinal plant species they use to manage human ailments. The Main Objective of this study was to identify some of the indigenous medicinal plants used amongst the Giriama community of Kenya. Methodology: Observations and semi-structured interviews (see Appendix 1) were used to gather ethno-botanical data for each plant. About 3 Kg of suitable specimens were harvested, with leaves pressed and preserved for identification at SUDIC Herbarium. Voucher specimens were also deposited at SUDIC and excess material powdered and kept dry. The pressed specimens were dried at 200°C to 250°C using plant blower. Results: A total of 23 medicinal plants, belonging to 15 families, were harvested and identified. The families Lamiaceae, Malvaceae and Fabaceae were the most represented. The medicinal use of three of the plant species (Deinbollia borbonica Scheff., Clerodendrum incisum Klotzsch and Gardenia posoquerioides S. Moore) had hitherto not been documented and may be new records for treating various ailments. Conclusion and Suggestions: It is apparent that the Giriama of Basi are well endowed with knowledge on indigenous ethno-medicine and forest contours. Their passion and protection of the Kayas and medicinal plants help them in contributing not only to sustainable provision of community health care but also a potential to share this knowledge far beyond their Kilifi County. If nurtured well, this knowledge could empower the people economically. It could also be incorporated into key policies to guide conservation efforts for the rainforest and its biodiversity, to stave off over-utilization and loss of plant genetic reservoir. The ethno-medicinal knowledge needs to be well researched and recorded before it is irretrievably lost.

1.0 INTRODUCTION

1.1 Background

Plants have been the mainstay of sophisticated traditional medicines that have been used by mankind for thousands of years and continue to provide remedies. They produce an array of secondary metabolites that have been used throughout history as drugs, pesticides, pigments, flavors and fragrances [1]. Most drugs today are synthetic, but plants still occupy an important position in healthcare with about 119 drugs derived from plants still being produced commercially, accounting for about 25% of all prescription medicines [2]. Being pillars of culture and human socialization, traditional herbal remedies provide health services even in highly industrialized setups. Many plants used as herbal remedies also act as food supplements with vitamins, minerals and immune boosters.

The African continent is blessed with a unique biodiversity, accounting for almost 25% of the global pool of genetic plant resource. Yet, while the medicinal plant trade continues to grow globally, exports from Africa contribute little to the overall trade in natural products and generally only revolve around plant species of international interest that are indigenous to Africa [3]. African herbal medicine relies more on wild harvesting of plants whenever needed than on planned, economical and sustained sourcing. This has greatly threatened the sustainability of indigenous resources with an average annual loss of 1% as opposed to 0.6% at the global level [4]. The depth of knowledge of countless generations of traditional prospecting and medicinal application of plants in human and animal diseases is impossible to fathom, especially in the face of present day high technology global bio-prospecting activities.

East African ethnic communities have traditionally used plants to treat a whole range of human and animal diseases [5-10]. Kokwaro has recorded more than 1,200 Kenyan plant species as medicinal [7] out of a floral population of approximately 10,000 [11].

The Giriama people of Kenya, like other East African communities, have traditionally used plants to treat a variety of ailments, including those caused by microbial infections. They depend on the coastal forests for their supplies of medicine, food, etc. They use some plant species to prevent or treat diseases, including infections like boils, scabies, diarrhea, dysentery, gonorrhea, and syphilis.
1.2 Study Justification

Despite this confirmed widespread use of traditional herbal medicines at the community [7], it is quite clear that only a few of such uses are scientifically recorded, some with validated evidence of activity, many others without. Natural products are known to be as effective as the standard drugs of scientific medicine. However, the natural medicines are usually more affordable, more accessible, non-patented and much safer, often having zero to few toxic or significant adverse effects. This makes them quite appealing, appropriate and acceptable for use by the poor of the society [5]. There is enormous knowledge of the use of medicinal plants, especially in the underdeveloped Tropical countries, but if this traditional knowledge is not rapidly researched and recorded, indications are that it will be lost with succeeding generations [12]. First, there is a high rate of (plant) species extinction [13] due to over utilization, posing a great risk of losing a multitude of potentially useful plants. There is also a decline in authentic knowledge in traditional treatment, as a result of the death of many experienced healers. This vast lacuna of untapped knowledge requires continuous surveillance, identification, recording and validation of the ethno-medical claims to medicinal uses. Further, there is need to conserve and protect such plants before we lose them irrevocably.

1.3 The Giriama (Giryama) and their Kayas

The Giriama (Giryama) are one of the nine ethnic Bantu groups that make up the Mijikenda of the South Eastern (Geographical coordinates of centre point: 3° 48’ 0” South, 39° 35’ 0” East) Coast of Kenya [14]. The Mijikenda occupy the almost 300 km coastal strip extending from Lamu in the north to the Kenya/Tanzania border in the south, and approximately 30 km inland. The Giriama have their heritage within the Kilifi County, one of the 47 counties that make up Kenya, and are among the largest of the Mijikenda ethnic groups. They inhabit the area bordered by the Indian Ocean coastal cities of Mombasa and Malindi, and the inland towns of Mariakani and Kaloleni, and speak Kigiriama (Kigiryama) which is a sub-language of the Kimijikenda. The nine Mijikenda groups speak closely related languages which also includes Kiswahili [15].

Spiritual beliefs and magical practices are important aspects in Giriama life [14]. Each Mijikenda clan had their own sacred place known as Kaya, a shrine for prayer, sacrifices and other religious rituals. These Kayas were located deep in the forests and it was considered taboo to cut the trees and vegetation around them. The Kaya elders, often members of the oldest age-set, were deemed to posses supernatural powers including the ability to make rain. In the past, they used the kaya forests as protective premises [16], and as a resource base for wild plants. They developed a wealth of knowledge concerning the specific biological resources (flora and fauna) found in the region they inhabited. Over the centuries, they accumulated a wealth of concepts in traditional knowledge and associated practices and customs, related to the forest, the land and sea, and these formed their unique culture.

1.4 Objectives of the Study

1.4.1 Main Objective

The Main Objective of this study was to identify some of the indigenous medicinal plants used amongst the Giriama community of Basi in Kilifi County of Kenya.

1.4.2 Specific Objectives

The Specific Objectives of the study were to:

i. Identify the plants traditionally used by the Basi Community to treat human diseases by both local and scientific names

ii. Profile the parts of the plants used, how and for what conditions they are used

2.0 MATERIALS AND METHODS

2.1 Study site:

The plant materials and specimen were collected from Basi, Kilifi County (Figure 1 below), in July, 2011.

Figure 1: Map of Kenya showing the location of Kilifi County (Green) [19].
2.2 Ethnobotanical data collection Methodology:

The Research Team first held a meeting with the Basi community leader and an elder representing the Provincial Administration. They then brought in a 45 member (5 men and 40 women) group of farmers called Basi Mwangaza. The meeting was intended to:

i. explain the aims, objectives and importance of our research mission to mankind and to the community;

ii. get cooperation and permission to use their cultural heritage;

iii. collect information for structuring the interviews;

iv. give orientations for the selection of informants by age and gender; and

v. plan the field activities.

The meeting identified six informants (2 men and 4 women) as the best traditional knowledge holders. These six were well known and regarded Giriama herbal specialists, recognized and licensed by the community to access the Kayas for prospecting and collection of herbs. During our field trip, they operated between the Kaya and mutually acceptable collection sites since we were not authorized to access the Kaya. Wise counsel made us avoid witch-doctors due reasons related to beliefs and myths.

Standard methods of observations, structured and semi-structured interviews [20, 21] were used to gather ethnobotanical data in the local Kigiriama language. These included: common and local name of the plant, applications, parts of the plant used, and methods of preparation and administration. This was then translated into English by a Giriama-English linguist. Suitable specimens were harvested from each collection site, away from road sides to avoid samples covered in dust and fuel fumes. Harvesting was done by cutting aerial plant parts containing twigs, leaves and flower heads with garden secateurs. The bark and some roots were also harvested with garden mattock and, taking care not to damage the root and bark system, the plant materials were placed in paper bags, moved into the shade and transported on the same day. Plastic bags were avoided because the plants were mostly obtained from far distances. Plants in the study area were mainly collected in the morning and kept dry at room temperature.

3.0 RESULTS AND DISCUSSION

A total of 23 plants, reportedly of medicinal value to the locals, belonging to 15 families were harvested, identified, voucher specimen deposited at the herbarium and excess material powdered and kept dry. The families which produced the highest number of medicinal plant species were Lamiaceae, Malvaceae and Fabaceae, each with 3 species, 13.04% a piece (See Table 1). The current study has found three plant species (Deinbollia borbonica Scheff., Clerodendrum incisum Klotzsch and Gardenia posoqueroides S. Moore) whose medicinal use are undocumented and may be new records for treating various ailments. Except for those three, all the other species have already been reported as medicinal plants [7, 22-26].

The plants were collected at a central point protected by local Giriama herbalists. The collected plants were used for varied conditions (See Table 2) ranging from treating jiggers, stomachache, headache, dysmenorrhea, chest infection, high blood pressure, wound treatment, diabetes, diarrhea, and cancer and impotent in men. Many plants are boiled together for better results. The most used parts were roots (45.8%), leaves (27.1) and bark of the trees (14.6), in that order (See Table 3).

Some of the medicinal plants that could have been collected were extinct already, according to the herbalists, or were very rare and could only be found in specific inaccessible areas of the forested Kayas. Many other plants are endangered species, among them Uvaria acuminata Olivi., Lannea schweinfurthii Engl., Zanthoxylum chalybeum Engl., Terminalia spinosa Engl., Cassia afrofistula Brenan., Sena singueana Delile, and Hoslundia opposita Vahl. From the statistics most endangered species were collected plants. Some of the plants like Zanthroxyllum chelybeum Engl. are jealously guarded by the land owner. The Giriama do not cultivate the plants and the herbalists depend 100% on the plants from the wild, posing danger since they end up competing with the wild and domestic animals including among themselves. The region also suffers from deep gulley erosion which frequently wipes away the plants.

Decoctions prepared by boiling plant parts of a single plant species in water were the most preferred method of preparation among the Giriama. This finding was unusual because the use of more than one plant species (concoctions) is said to be useful in that the different species may act synergistically to enhance the activity of one another or neutralize the toxic effect of another plant species while allowing the active portion to alleviate illness. The medicinal use of plant leaves and roots in the management and treatment of diseases has been an age long practice [27].

Plants in the study area were mainly collected in the morning because the plants were mostly obtained from far distances. Secondly, because early in the morning snakes could not be encountered due to low temperatures and, finally, they were said to be effective only when collected in the mornings.
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Roots are invariably the most used plant parts, followed by the bark. These two have a high partitioning for the secondary metabolites or exudates [28] which act as toxins for protection against devourers and most of these are of medicinal value to the human body. However, compared to the bark, leaves or branches, the use of roots is an unsustainable utilization and is dangerous to the existence of individual plants. This requires conservation measures on the medicinal plants otherwise the plants get depleted through continual use.

Like in most traditional communities, water was the main medium for the Giriama medicinal preparations through decoction, maceration and infusion methods. They prepare their herbal remedies mostly as decoctions but the delicate parts of the plants; like leaves, flowers and stem buds are infused. Decoctions are used to prepare remedies from the hard parts of the plants (root, rhizome, seeds and stem barks). The advantage with infusion is that it is gentle, with many active principles extracted almost unaltered chemically, thus preserving almost all their properties.

The Giriama people use traditional remedies for a whole host of conditions (See Table 4). Gastrointestinal disorders have the highest number of species (20.8%), followed by respiratory disorders, HIV & Sexually Transmitted Infections and Circulatory disorders (all at 7.5%).

**Conclusion and Suggestions:**

It is evident that the Giriama people are well endowed with knowledge on indigenous ethno-medicine and forest contours. Their passion and protection of the Kayas and medicinal plants help them in contributing not only to sustainable provision of community health care but also a potential to share this knowledge far beyond Kilifi County. If nurtured well, this knowledge could empower the people economically. It could also be incorporated into key policies to guide conservation efforts for the rainforest and its biodiversity, to stave off over-utilization and loss of plant genetic reservoir. The ethno-medicinal knowledge needs to be well researched and recorded before it is irretrievably lost.

**ACKNOWLEDGEMENTS**

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**REFERENCES:**


APPENDIX

Table 1: A summary of the families of medicinal plants used by the Giriama

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<thead>
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<td>7</td>
<td>Boraginaceae</td>
<td>1</td>
<td>4.35</td>
</tr>
<tr>
<td>8</td>
<td>Combretaceae</td>
<td>1</td>
<td>4.35</td>
</tr>
<tr>
<td>9</td>
<td>Euphorbiaceae</td>
<td>1</td>
<td>4.35</td>
</tr>
<tr>
<td>10</td>
<td>Flacourtiaceae</td>
<td>1</td>
<td>4.35</td>
</tr>
<tr>
<td>11</td>
<td>Loganiaceae</td>
<td>1</td>
<td>4.35</td>
</tr>
<tr>
<td>12</td>
<td>Phyllanthaceae</td>
<td>1</td>
<td>4.35</td>
</tr>
<tr>
<td>13</td>
<td>Rubiaceae Juss.</td>
<td>1</td>
<td>4.35</td>
</tr>
<tr>
<td>14</td>
<td>Rutaceae</td>
<td>1</td>
<td>4.35</td>
</tr>
<tr>
<td>15</td>
<td>Tiliaceae</td>
<td>1</td>
<td>4.35</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td>23</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 2: Some medicinal plants used for Human treatment by the Giriama people of Kilifi County
<table>
<thead>
<tr>
<th>NO</th>
<th>Local (vernacular) name</th>
<th>Plant Botanical name</th>
<th>Family Name</th>
<th>Traditional use by the Giriama</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Mnyumbu</td>
<td><em>Lannea schweinfurthii</em> Engl.</td>
<td>Anacardiaceae</td>
<td>Leaves are used as bottle sterilizer. Bark boiled and taken to expel round worms in young children. Roots are boiled and used to treat stomach ulcers and stomachache.</td>
</tr>
<tr>
<td>2.</td>
<td>Mkithunga</td>
<td><em>Cassia afrofistula</em> Brenan.</td>
<td>Fabaceae (Subfamily: Caesalpinioideae)</td>
<td>Roots and bark are boiled and taken to suppress the proliferation of ovarian cancer cells and prostate cancer cells. Leaves are chewed or boiled and taken by men to increase dynamic activity of human sperm.</td>
</tr>
<tr>
<td>3.</td>
<td>Mkayukayu</td>
<td><em>Cordia sinensis</em> Lam.</td>
<td>Boraginaceae</td>
<td>Roots are boiled and taken to treat paralysis. Leaves are boiled and steam is inhaled under blanket cover by sick person, especially for shortness of breath.</td>
</tr>
<tr>
<td>4.</td>
<td>Mdungutundu</td>
<td><em>Dovyalis abyssinica</em> A. Rich.</td>
<td>Flacourtiaceae</td>
<td>Fruit is edible (eaten raw), but very acidic. It is used for making jam, and added to porridge as a flavor among the Giriama. Roots and stem are added to soup and taken to treat gonorrhea, bilharzia, stomach-ache and fever.</td>
</tr>
<tr>
<td>5.</td>
<td>Murori</td>
<td><em>Uvaria acuminate</em> Oliv.</td>
<td>Annonaceae</td>
<td>The plant roots and leaves are boiled and taken to treat drowsiness.</td>
</tr>
<tr>
<td>6.</td>
<td>Muhumbu</td>
<td><em>Senna singueana</em> Delile</td>
<td>Fabaceae</td>
<td>A hot water infusion of the leaves is drunk and the warm leaves applied as a compress to treat fever; and the leaf sap is drunk to cure malaria. The leaves in decoction or infusion or as dried powder are applied to wounds caused by leprosy and syphilis. An infusion of the flowers is used as an eye lotion. The fruit pulp soaked in water and cooked with a staple food is eaten by lactating women as it is considered lactogenic. The roots are used to treat venereal diseases, stomach disturbances and as a purgative, and to cure impotence caused by diabetes. The ash of burnt roots is eaten mixed with porridge to cure abdominal pain.</td>
</tr>
<tr>
<td>7.</td>
<td>Mudhungu</td>
<td><em>Zanthoxylum chalybeum</em> Engl.</td>
<td>Rutaceae</td>
<td>The plant bark, leaves and roots are boiled for the purpose of treating malaria, persistent headache, toothache and pancreatic disorder; and for treating nose and eye allergy.</td>
</tr>
<tr>
<td>8.</td>
<td>Mtserare</td>
<td><em>Hoslundia opposita</em> Vahl</td>
<td>Lamiaceae</td>
<td>The plant leaves and roots are boiled then taken for the purpose of treating heartburn, headache and help in blood clotting after a cut. It is also used to treat tonsillitis.</td>
</tr>
<tr>
<td>9.</td>
<td>Muchinjiri</td>
<td><em>Dichrostachys cinerea</em> L.</td>
<td>Fabaceae</td>
<td>The plant root is boiled and taken to treat diarrhea and stomachache especially in young children.</td>
</tr>
<tr>
<td>10.</td>
<td>Mfune</td>
<td><em>Sterculia appendiculata</em> K. Schum. (Sub-family Sterculiaceae)</td>
<td>Malvaceae</td>
<td>The plant root is boiled and taken three times per day to treat HIV/AIDS in the community. It also treats Sexually Transmitted Infections.</td>
</tr>
<tr>
<td>No.</td>
<td>Name</td>
<td>Scientific Name</td>
<td>Family</td>
<td>Description</td>
</tr>
<tr>
<td>-----</td>
<td>-----------</td>
<td>------------------------------------------------------</td>
<td>-------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>11</td>
<td>Mkasiri</td>
<td><em>Phyllanthus reticulatus</em> Poir.</td>
<td>Euphorbiaceae</td>
<td>The root is boiled and taken to treat yellow fever in young children and babies.</td>
</tr>
<tr>
<td>12</td>
<td>Mndalamwaka</td>
<td><em>Deinbollia borbonica</em> Scheff.</td>
<td>Sapindaceae</td>
<td>Plant root is boiled and taken to treat stomachache and is also chewed and retained in the mouth for toothache.</td>
</tr>
<tr>
<td>13</td>
<td>Mkwamba</td>
<td><em>Flueggea virosa</em> Willd.</td>
<td>Phyllanthaceae</td>
<td>The roots and leaves are boiled and taken to treat diseases of uterine wall.</td>
</tr>
<tr>
<td>14</td>
<td>Mwangakulu</td>
<td><em>Terminalia spinosa</em> Engl.</td>
<td>Combretaceae</td>
<td>Plant leaves, bark and roots are boiled for the purpose of treating malaria, persistent headache, toothache, pancreatic disorder and for treating nose and eye allergy.</td>
</tr>
<tr>
<td>15</td>
<td>Fula</td>
<td><em>Sclerocarya birrea</em> A.Rich</td>
<td>Anacardiaceae</td>
<td>The bark and root are boiled and taken to treat hypertension. It is also used to make wine.</td>
</tr>
<tr>
<td>16</td>
<td>Mkone</td>
<td><em>Grewia plagiophylla</em> K. Schum.</td>
<td>Tiliaceae</td>
<td>Decoction of root and leaves used for diarrhea and kidney trouble and stomachache. The fibres can also be immersed in water to form foam which is used for washing an eye affected by any irritating substance such as pepper.</td>
</tr>
<tr>
<td>17</td>
<td>Karusapungu</td>
<td><em>Clerodendrum incisum</em> Klotzsch</td>
<td>Lamiaceae</td>
<td>The leaves and bark are boiled and taken to treat babies with breathing difficulties. It also treats high blood pressure.</td>
</tr>
<tr>
<td>18</td>
<td>Mvuma</td>
<td><em>Premna chrysocladia</em> Gürke</td>
<td>Lamiaceae</td>
<td>The plant roots and leaves are boiled and taken by men and women to treat infertility.</td>
</tr>
<tr>
<td>19</td>
<td>Muhowe</td>
<td><em>Thespesia danis</em> Oliv.</td>
<td>Malvaceae</td>
<td>The plant roots and leaves are boiled then taken to treat pressure and diarrhea.</td>
</tr>
<tr>
<td>20</td>
<td>Mujaje</td>
<td><em>Strychnos spinosa</em> Lam.</td>
<td>Loganiaceae</td>
<td>The plant roots are dried and crashed, then the powder is mixed with Vaseline and smeared around the foot to kill and control the jiggers.</td>
</tr>
<tr>
<td>21</td>
<td>Mbangulamavi</td>
<td><em>Sida cordifolia</em> Linn.</td>
<td>Malvaceae</td>
<td>The plant bark is chewed by women to stimulate menstruation. The plant root and leaves are pounded and taken to treat diarrhea.</td>
</tr>
<tr>
<td>22</td>
<td>Kimwemwe</td>
<td><em>Gardenia posoqueroides</em> S. Moore.</td>
<td>Rubiaceae</td>
<td>A decoction of the root is taken as a remedy for syphilis.</td>
</tr>
<tr>
<td>23</td>
<td>Munywamadzi</td>
<td><em>Aporrhiza paniculata</em> Radlk.</td>
<td>Sapindaceae</td>
<td>A decoction of the root is taken as a remedy for gonorrhea. An infusion of the bark is taken as a remedy for tuberculosis.</td>
</tr>
</tbody>
</table>
Table 3: The frequency of usage of different plant parts

<table>
<thead>
<tr>
<th>Part of plant used</th>
<th>Frequency</th>
<th>% of plant species</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Roots</td>
<td>22</td>
<td>45.8</td>
</tr>
<tr>
<td>2 Leaves</td>
<td>13</td>
<td>27.1</td>
</tr>
<tr>
<td>3 Stem Bark</td>
<td>7</td>
<td>14.6</td>
</tr>
<tr>
<td>4 Pulp</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>5 Fibre</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>6 Fruits</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>7 Flowers</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>8 Sap</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>9 Stem</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>10 Root Bark</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>11 Tubers /Rhizomes</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12 Seeds</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>13 Whole plant</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>48</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

Table 4: The Human diseases treated by the medicinal plants used by the Giriama

<table>
<thead>
<tr>
<th>No.</th>
<th>Human Disease(s)</th>
<th>No. of plant species used</th>
<th>No. as a percentage of the total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Gastrointestinal disorders</td>
<td>11</td>
<td>20.8</td>
</tr>
<tr>
<td>2</td>
<td>Respiratory disorders</td>
<td>4</td>
<td>7.5</td>
</tr>
<tr>
<td>3</td>
<td>HIV and Sexually Transmitted Infections</td>
<td>4</td>
<td>7.5</td>
</tr>
<tr>
<td>4</td>
<td>Circulatory disorders</td>
<td>4</td>
<td>7.5</td>
</tr>
<tr>
<td>5</td>
<td>Obstetric &amp; Gynaecological disorders</td>
<td>3</td>
<td>5.7</td>
</tr>
<tr>
<td>6</td>
<td>Malaria</td>
<td>3</td>
<td>5.7</td>
</tr>
<tr>
<td>7</td>
<td>Irritation of the eye /Allergies</td>
<td>3</td>
<td>5.7</td>
</tr>
<tr>
<td>8</td>
<td>Male fertility</td>
<td>3</td>
<td>5.7</td>
</tr>
<tr>
<td>9</td>
<td>Headaches</td>
<td>3</td>
<td>5.7</td>
</tr>
<tr>
<td>10</td>
<td>Toothaches</td>
<td>3</td>
<td>5.7</td>
</tr>
<tr>
<td>11</td>
<td>Fever</td>
<td>2</td>
<td>3.7</td>
</tr>
<tr>
<td>12</td>
<td>Round worms</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>13</td>
<td>Ovarian and Prostate cancers</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>14</td>
<td>Muscle paralysis</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>15</td>
<td>Bilharzia</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>16</td>
<td>Drowsiness</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>17</td>
<td>Dermatological problems /ulcers</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>18</td>
<td>Poor lactation</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>19</td>
<td>Renal problems</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>20</td>
<td>Jigger infestation</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>21</td>
<td>Yellow fever</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>53</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>
Health Care Delivery and Management in Kenya: A Review from the Public Health Perspective

Sadia Christine, Public Health specialist
adhis1956@yahoo.co.uk

Background

Health care is supposed to be one of the high ranking domestic industries in Kenya and one of the largest industries in developing countries in the Sub-Sahara Africa. Health care systems present many complex problems that could benefit from operations research providing evidence-based information and data related to policies, programmes, institutional arrangements, clinical and preventive services including related operational arrangements and applications. The general administration of holistic health systems is generally under the purview of public health and in particular Public Health professionals supported by the evidence generated by Operations Research specialists. The public health practitioners and other health professionals are pivotal in assisting the country to enact progressive health statutes, develop policies and regulations that make health care delivery equitable, efficient, responsive and cost-effective; but aligned and harmonized with the goal of providing accessible and affordable quality health care for all Kenyans.

Anecdotal evidence and personal observations indicate that the health care delivery system in Kenya seldom use proven public approaches that is contextualized to local context in terms of epidemiology, geography, socioeconomic factors, health and demographic characteristics. Moreover, Public Health professionals and/or operations research practitioners are not prominently playing their role effectively for several reasons; among them lack of appreciation of their role by the appointing authority, wrong deployment in health sector, weak professional body to assert the community of practice by public health experts and some practitioners adopt and contend with the status quo in the health sector so long as they are not seen to antagonize the system for personal reasons or gains. Most practitioners are not given opportunity to assist in the development of health care policies and the design of appropriate health care interventions due to lack of recognition of their critical role in health care delivery system by the authorities (lack of political goodwill) either deliberately or because of ignorance; and/or the professionals themselves have generally neglected the field.

The majority of public health experts practicing in Kenya undertake health care administration, management and research if engaged in public service, some of them are in academia and others in private and non-profit organizations. Very few are engaged, categorized and/or designated as practitioner specialists or consultants in the health care delivery in Kenya and very few or none may be actually working at hospital level undertaking operational analysis on qualitative and quantitative monitoring and related continuous quality improvement of care delivery system. Many public health specialists have written documents and papers on health care or have been involved in health care projects and then moved out to international engagements or merely the enthusiasm/moral diminished as a result of several factors; mainly not being utilized effectively. Ideally one can correctly assume that the efficient operations in the field of public health care requires more public health practitioners and operational research specialists, as observed from the practice and experiences of many countries, but this is a rare practice in Kenya. The cadre does not exist in health sector establishment or staffing norms as a distinct entity with its own job profile. The cadre may exist in various designations performing some kind of public health mandates and operation research work as part of their other assignments.

The health care industry faces many of the same issues confronting other industries, but with some significant management and technical differences. If one tries working in the health care area without understanding the politics and technicalities behind the issues, then one is asking for frustration and some instance failure. At the same time, health care represents a huge opportunity in diverse segments of the economy and it truly requires and needs the skills, expertise and help of public health experts, epidemiologists or operational research specialists. The magic puzzle is why the health sector trains, but does not retain and deploy appropriately the public health experts.

Review of Health Care Delivery (Contextual Analysis)

“For too long the treatment of patients in our health services has had to conform to the needs of the system.” The creation of the county system of governance may offer opportunity for those who are innovative to chart a new discourse in health care delivery that would provide better and affordable care to county residents. It will allow innovation and real data to redesign the system and put the needs of the patient front and centre.

In Kenya Health Sector may be perceived as small industry when examined from public allocation and expenditure returns from exchequer. The statistics on health care spending is not readily available, as spending returns takes about 2 to 3 years to compute and more years to be put in public domain. Typically, it takes two to three years to collect, analyze and avail information on health care spending where the system is not well integrated and reporting is slow.
It may be available when the National Health Spending Assessment is done or where the National Health Account is established and maintained. However, it was still difficult to get accurate record of the actual national health expenditure and not allocations as a public document. Critically, the national figures would be less, factoring that the spending in health care from private financing and national health insurance, employment health benefit, community care financing, private medical insurance and other medical aid including out of pocket expenditures are currently not exhaustively captured. The total amount of national health care expenditure should represent a percent of the National Gross Domestic Product for the fiscal year being considered. The percent of GDP devoted to health care in Kenya is available and should be recorded, tracked and the trend analyzed. In my assumption it may have fluctuating due in part to GDP variations for the past 15 years and because the percentage of GDP to health care has not been fixed. As far as government spending is concerned, the Ministry of Finance sets three-year budget ceilings for each sector in Kenya. In practical terms this means that the Ministry of Health creates a budget based on what the Ministry of Finance has said it will allocate for health expenditures rather than submits a budget request based on actual needs.

Kenya has not attained the Abuja Commitment of -15% GDP allocations to health care. Kenya's total expenditure on health as a percentage of GDP was 4.6% in 2006, according to the 2009 World Health Statistics Report. In 2006 Kenya spent 29 USD per capita on health services. This was below the 34 USD which WHO recommends for African countries to spend on providing a minimum health package for their citizens. According to the WHO, the Government of Kenya covers about 38.7% of the overall expenditures on health, while private expenditures account for 61.3% of overall spending. In 2006 80% of private expenditures were out of pocket payments for health services. This transfers a burden for financing health care to individuals or households. Taking into consideration the percentage living below the poverty line, it is incomprehensible to figure out how they access health care.

In more personal terms, the per-capita annual expenditure for health care should be availed and the amount recorded, but also disaggregated by age, sex and regions or now by counties. This should be able to provide better information on disparities in health spending by various categories within the households and reveal the deficit in addressing the disease burden of certain groups requiring special attention. It is not easy to get per-capita health expenditure figures as part of the regular health statistics and information on public documents and most people are astounded by the per-capita expenditures. Individual health care costs are generally much lower than per-capita expenditures. As a matter of fact, the elderly should consume the bulk of health care expenditures during last few years of their lives. This may not be so in Kenya due to lack of national public system in health care delivery that is responsive and friendly to the needs of the elderly. The burden is borne by the families and may not directly be captured in health care spending. The quality of life and the onset of chronic illnesses which consume expensive medications is a factor worth considering in health care planning and management. This phenomenon is frightening news in Kenya as the majority of people facing retirement; already have their health care demands escalating or are already consuming a sizeable proportion of their income on health care; yet the expendable income is reduced with retirement; unless one has massive investment or alternative sources of income apart from that generated from direct employment this is a worrisome concern.

There seems to be little correlation between the amounts spent per person on health care compared to enjoyment of better health on average. Some nations with less per capita health expenditures may live longer on average than some with higher per capita health expenditures. This is influenced by a number of factors, but primarily by the organization and priorities of the health care delivery system, individual habits, care seeking practices and consumerism. Some health care delivery systems may opt to have more surgical procedures per capita, but it must also prioritize and may mean that clients also have to wait for perceived non-urgent services. It may also mean that preventive services get less percentage of per-capita expenditure as may be the case in Kenya. Of course, averages are deceptive; the issue is not the per capita expenditure, but getting full value for the investment at the national level that translates to quality of life for the individual level. The concern is how much of the national investment can actually be attributed to quality of life years for Kenyans. In my view this is a debate that must start if not already started so that the health managers can be held to account. Therefore getting to understand the epidemiology of diseases in terms of incidence, prevalence, including progression and prognosis; and striking a balance between clinical, preventive and other health-related care services using a rational investment framework is desirable. Moreover, the health care delivery system must avoid the current widespread inefficiencies. Some notable inefficiencies and wastages can be attributed to mismanagement, corruption and clinical malpractices which are widespread and showing a relative upward trend in Kenya.

Kenya faces a significant shortage of physicians, estimated only 4,500 in the entire country, according to the World Health Organization. This number is not adequate for the current population of Kenya. The doctor population ratio of Kenya is just one doctor per 10,000 residents, a ratio that is below average for the Africa region. More than 50% of Kenyan physicians practice in Nairobi serving estimated 4 million people, which only represents a small fraction of the country’s population. It is estimated that only 1,000 physicians work in the public sector, which serves the majority of Kenyans. The people working in health care delivery system are seemingly dedicated to providing the best possible service. However, the presence of so few health personnel in Kenya can make it difficult for the government to carry out adequate disease
surveillance, maintain accurate statistics regarding disease outbreaks and make reports. The problem may be the management of the health workforce and more importantly management that do not have the training or knowledge to make the best use of the available resources. The combination of these two factors is a recipe for inefficient and none responsive health care delivery service. The cost-benefit analysis of the service to be implemented is hardly done nor discussed in a broad stakeholder meeting or in a consultative participatory process. In my opinion, no private industry would survive with the level of wastage and inefficiencies commonly seen in most health care settings in Kenya. I am convinced, based on years of experience in health care practice and administration; that if a team of dedicated epidemiologists, biostatisticians, management specialists and public health professionals were to be put at the disposal of health sector, Kenya could easily cut down the real cost of health care by estimated 20 to 30 percent and vastly improve the health care delivery system within the timeframe of Vision 2030.

There are many reasons why public health specialists have not been more successful in the health care field, starting with a lack of interest and support on the part of health care managers. I doubt if top management appreciates what epidemiologists, biostatisticians or operational researchers and public health specialists have to offer. This may be probably the fault of the public health specialists and professionals for lack of marketing their role and place or their added value in the provision of health care delivery that benefits from a public health perspective. A clear understanding and introduction to operation research, epidemiology and public health approaches to health care delivery is not a common component of most training and curriculum of Health Administration programs let alone the general administration and management courses and training. Therefore its application tends to be forgotten or not at all factored in the health care delivery, policy planning and implementation of interventions in cases where such functions are performed by health administrators/managers who have limited capabilities in health care delivery system. Apparently, this seems to be the case in Kenya – health planning and administration at the top national echelon has predominantly those who have qualification in general management and administration or economics, but not public health or majoring in health planning and/or health economics. There is definitely a huge difference when the policies and planning is done by those who also understand the operational and technicalities in management of diseases or familiar with hospital or clinical settings.

There has been a protracted debate whether health sector should be managed by medical or non medical managers. The debate is immaterial as long as the manager can appreciate the limitations and marshal the necessary expertise and competencies to get the job done. The manager must also have a mechanism for quality assurance and control to ensure that the product being given to Kenyans is sound and beneficial. There is however, a general perception that public health approaches particularly the operations research aspect and even the experts themselves are diverting funds away from direct clinical care and disease specific research. It is difficult to convince managers, particularly in the health care system, to direct part of limited funding away from direct patient care into better planning, appropriate program design, implementation and quality improvement. The begging question is – do Kenyans have the best product health sector can offer if Kenya is to achieve national, continental and international indicators for health. Though a big proportion is still spent in health service administration, time is ripe for Kenya to examine seriously the value for money for each component and use business/investment framework model for cost-effectiveness. In my considered opinion the people with requisite expertise and skills are not engaged in their rightful slots in health service administration/management, health policy formulation, design and implementation, systems analysis and continuous quality improvement; and therefore this has rendered health sector prone to inefficiencies that can be eliminated or minimized by rational use of human resource for health in health service delivery.

Another major issue is the dreadful state of health care information systems and data. It is universally acknowledged that there is a dire need for reliable data and there is no good way to determine the effectiveness of any health care program or treatment intervention if sectors have no good tools to measure “health” and no information systems to record and assess a person’s “health status” over time. This information and data can be correlated with health expenditure trends to reveal additional information on health outcomes. Designing linear programming to maximize “health” is pretty difficult when people do not know and have a common understanding of what “health” means and have no way to determine the impact that expenditures have on “health”. So at the national policy level what is the desirable quality of health for the people of Kenya and the indicator to measure optimal level of perceived “health”? Even when the Constitution guarantees people health care, what do people expect and that which when lacking or not attained then accountability is demanded.

We may know what the constraints in health care delivery system are, but a common understanding of the objective function is still not very clear to many citizens. Health care management research is not usually viewed as a core research area by medical or social science funding agencies. Little attention is given to the performance evaluation of health care management and the politics of health care including the big pharmaceutical companies. The trends in political climate and appointments should also be studied. It is assumed that once a person is holding a political office, that management leadership functions and acumen would translate to better health care benefits to beneficiaries and in effect enjoyment of quality health care by the populace. It becomes more difficult to hold one accountable if the concept of health is not clearly defined or a shared understanding is lacking between the duty holders and consumers or beneficiaries.
Health care is a business like no other; it requires meticulous planning based on real evidence. It has multiple decision making points as well as players with conflicting goals and objectives. Therefore continuous reviews and research must be undertaken to produce new or update existing protocols, frameworks and matrices to ensure relevance and help explain why the entire health care system both at the national and decentralized levels may have failed or pass the test of being efficiently managed to avoid what has proven to be virtually classified by most as unsatisfactory management, inefficiency and poor quality of service.

Let us consider the acute care hospital or Accident and Emergency Unit for this hypothetical management analysis. Whereas it seems that Kenya public health care system is larger than the private and non-profit hospitals in relative terms; when critically analyzed most Kenyans access acute hospital health care in private hospitals, teaching referral hospitals, nursing homes and non-governmental or independent institutions. Distinctly one can identify four management groups that can be broadly categorized within a hospital as follows:

- Doctors and nurses manage the clinical operations because of their focus on patient treatment and care
- Managers and trustees manage resources, operations and those who use and control or fund the institution
- Moreover, employees (managers, few doctors and nurses) practice some management “in” the institution
- While some doctors and trustees manage “out” of the hospital, since they are technically not employees and are thus independent of its formal authority. In the case of doctors, there are those who are given rights to practice and others are employed on special arrangements in the case of private institutions and are therefore regarded as staff or vendors providing a service.

According to the current structure, these are distinct features of the health care system. The major one is the world of curative care which is characterized by short, intensive and (mostly) non-personal medical interventions. Most specialized doctors typically work for several hospitals even when permanently employed in one or in academic setting. They are therefore private entrepreneurs who have admission privileges at some hospital. (Some doctors are salaried hospital employees, but the majority of consultant specialists work on a fee-for-service basis). To maximize their income, doctors make brief appearances when the patient needs intervention (treatment) and then they move on.

Then there is the world of care. This is mostly represented by nurses and others, the providers who work directly for a hospital on salary and typically account for the largest component of its personnel recurrent operating budget. They work in their own internal management hierarchy and have a unique relationship with patients. They are the only providers who actually perform direct clinical care or indirectly get involved with patients procedures and care issues. Managers perform technical, operational oversight and control. They are employed by the hospital and are normally removed from direct involvement in clinical operations, but are responsible for its control. There are two categories; some are clinical managers and others are operational. Clinical managers understand clinical operations, but are not usually involved directly with patients. Most other managers lack the knowledge to understand clinical operations, but all managers exercise oversight and control over what they are responsible for, which is costs and quality of care. The beneficiary or community normally represented by the trustees or Board of Directors and is often composed of those representing business interests and/or community members’ interests. The Board is responsible for setting hospital policies and appointing senior managers. However, in most cases, they are usually people who generally know the least about health care or its delivery, since they neither work for the institution nor do they provide direct clinical services.

In this fractured environment, doctors, clinical officers and nurses form what is called the “Clinical Team.” They form a coalition, based on the objective of delivering patient care, usually as a common front as patient advocates. The nurses and managers make up the “Insider Team.” since they are the ones who actually work for the hospital and have concerns about the day-to-day operations of the organization. They form a coalition against the outsiders to preserve their hospital and their jobs. The managers and the Board of Directors form the “Containment Coalition.” They form a coalition on the basis of strong concerns about leadership, managerial and operations, expansion and development including financing and budgetary concerns. Finally, the Board and the doctors make up the “Status Coalition.” They share the prestige of being part of the institution, and yet still, they are at the top of its status symbol and pecking order.

Unlike any private sector business with clear hierarchical lines from the Board, the health set-up has many accountability lines and no one is really in charge of a hospital or enterprise. Managers whether doctors or non-medical make resource allocation decisions, but doctors or clinicians, nurses and other care providers decide what the hospital does with those resources. A horizontal cleavage divides the clinical workers from the containment sector and there is little harmonization between the two. It has been observed that both doctors and managers tend to turn to the nurses for coordination and conflict resolution. Nurses become the hospital managers. This puts them in an awkward situation, since they may not have the ultimate delegated authority to truly manage.

The same template can be applied to the overall social health system. In this case, the acute care hospital itself represents cure. Patients go to the hospital when they are really sick and then get quickly discharged back to the community (home care, family doctor) where they receive basic long-term care. The hospital is somewhat beyond direct public control and thus “out” of the day-to-day community participation and
Rationalization

In health care situations, typically the objective is to minimize cost or maximize quality or some combination of these two. On the surface, this sounds pretty straightforward, but if we look closer, even the definition of these terms; “cost” and “quality” is open to various interpretations. Which aspect if cost is our concern? The cost could be at hospital, the government or sectors, the patient or the doctor. Whose cost are we minimizing? Do we want to minimize the cost per hospital visit (minimize care and length of stay) or do we want to minimize the overall annual cost? In the latter case, efforts need to be directed towards systems that spend more on prevention, as more tests now may mean avoiding a much more expensive episode later. When we minimize hospital costs, we often simply transfer those costs from hospital to family who must provide support and care. In other words, there is need for the government to spend money on prevention programs that save social costs later, but these costs may not translate into government direct savings, which makes it difficult to justify, as most allocations and costs are derived from treatment and care services provided. This is a dire reason why cost-benefit analysis is critical in health planning and management to assist in the justification of savings and social benefits.

The notion of balancing cost and quality can be taken out of context. One may argue that it is better to have people smoke and then get their lungs damaged and then die quickly without spending too much funding in hospital care when they die at relatively young or in middle age to avoid costs related to old age and chronic illnesses. This ridiculous argument completely stretches the discussion of cost too far without due consideration to quality of health care and years of life lost. It does not consider the public health approaches which is based on right to health by all and right based approaches. The early loss of life has effect on socio-economic development and its impact on human development and wellbeing. But how does health sector maximize quality? Quality is real patient outcomes and is hard to measure. The one time hospital intervention is difficult to measure once a client leaves the hospital. When the client is gone home, there is no tracer or monitoring mechanisms in place to gauge the outcome resulting out of hospital intervention overtime. There is no mechanism for hospitals to have information on what happened to patients once they walk out the door, unless outcomes are so bad that they are re-admitted within a short period due to deterioration or complications. The lack of reliable outcome measurement is a common problem in health care. Most hospitals or programs do not track the patient’s health status after they have received care. Lack of data is even more pronounced in home care and nursing homes where data is typically manual and not standardized. Therefore the aggregate measurement indicators that indirectly capture the individual outcomes must be deployed nationally. I actually have no idea when the quality adjusted life years or days adjusted lost years by Kenyans ever been mentioned health care setting, yet these indicators are taught during training in academic settings.

Doctors are the gatekeepers, but they seem not to care about cost. They are required to be the patient’s advocate and safeguard patient’s health care and wellness interest. It has been observed that patients either, do not have the expertise to know what they need as a patient or are too reserved, timid or afraid to express their desires based on doctor-patient perceptions and relationships. Nearly all rely on the doctors to decide if they need more tests. Majority will consent to any suggestion from health providers and would say yes to the tests and ignore the cost, especially if they do not have to pay for them directly. So where are the safeguards, standards, accountability and ethical considerations in health costs and care? Someone may be benefitting unethical in the absence of patient safeguards and patient literacy. Health is an issue of equity and fairness. Individuals must be better engaged in making decisions about their own health. Everyone should have an equal opportunity to live a healthy life and improving the health literacy of everyone is a proven path toward that goal. To achieve this worthy and critically necessary goal, our nation needs information to flow quickly and openly among the relevant regulatory agencies, researchers, the pharmaceutical industry, hospitals and health care professionals, and an informed and engaged public. Health literacy is the tool that can break down the walls that currently exist in the health sector.

Maximizing quality is also quite ambiguous. There is a need to be clear on the following; does one maximize the quality of the outcome for a particular episode of care or try to maximize the patient’s quality of life? One particular measure receiving a lot of attention is the concept of “Quality Adjusted Life Years.” The idea behind Quality Adjusted Life Years is similar to asking oneself when faced with a fatal illness and
an option of a medical intervention, “Would I rather live for two additional years in a hospital bed as compared to living normally for three months and then dying?” Sometimes surgery can have negative impact on quality of life. How can people pick between complex and risky options like these? The notion behind patient consent is based on thorough information disclosure on part of the care provider including possible risks and prognosis. Furthermore, doctors are “rewarded” for good “outcomes,” which sometimes has little to do with a patient’s well-being. A patient may have undergone surgery, then surgeon could prescribe a very powerful medication to assist some function of an organ to be performed, but the drugs may be causing some negative side effects. The drugs obviously may have very negative impact on the person’s quality of life, but taking him off the drugs could have a negative impact on the surgeon’s outcomes. The issue may be that the surgeon is perceived to have given a patient good outcome, but the reality is that the drugs are compromising quality of life. These decisions need to be communicated and patient informed to be aware of the ultimate long-term expected outcome. Confidential patients’ Exist interviews and follow up case studies points to: a trend that is emerging which seems to indicate that in many care settings in Kenya; full disclosure by most care providers is minimal and patient participation seems passive. A knowledgeable and literate patient who asks for more/explorative information gets a negative perception from care providers and is termed as difficult or uncooperative patient.

One of the reasons for the delayed reaction in health care has been the reluctance on the part of the medical community to acknowledge and report errors and problems. Health care providers especially clinicians are often reluctant to even have their results tracked and benchmarked. There is a culture of silence in health care; the public do not report violations and malpractices, medical practitioners do not want to admit that mistakes do occur and the various Boards and Councils are more protective of their members. The public and even medical colleagues who report adverse events find it difficult to have for example Medical Practitioners and Dentist Board (MP&DB) to admit that an adverse event happened from its members. The various investigative and redress committees are made up of colleagues who do not act transparently and accountably; but protect their colleagues for various reasons. The professionals have influence over the Board employees and this does not uphold independence resulting in rampant unethical and corrupt practices including collusion to distort facts to arrive at favourable outcomes on the part of practitioners. Therefore the Board in most cases does not act fairly and just. The Board should be made more accountable and independent, so that public participation and reporting can improve not only as a redress mechanism, but also to try and improve on standards and minimize medical adverse events. Some operations of the Board are sustained by the fees paid by professionals and this has inherent conflict of interest.

The Harvard Medical Practice Study (Brennan et al [1991]) reviewed more than 30,000 hospital records in New York State and found injuries care itself (adverse events) to occur in 3.7 percent of admissions, more than half of which were preventable and 13.6 percent of which led to death. If these figures can be extrapolated to the 33.6 million admissions to American hospitals in 1997, then more than 98,000 Americans die each year as a result of preventable errors in their hospital care (Kohn et al [2000]). By comparison, 97,860 people died in 1999 due to all unintentional accidents, which would make medical error the fifth highest cause of death (from the U.S. National Centre for Health Statistics, www.cdc.gov/nchs). The U.S. study provides a good pointer to Kenya situation. In terms of medical equipment and facilities including post intervention support U.S. is definitely superior to Kenya, if we replicate the study in our setting, what would be the outcome. My guess is that Kenya would have more medical adverse events and more deaths as a result of preventable errors in Kenyan hospitals. The analysis and prevention of adverse medical events has become a major focus of attention. In many situations, redesigning the processes can prevent errors.

**Emerging Approaches for Improving Health Management (Issues)**

In my experience, one of the major causes of inefficiency in the health care system is what I call “compartmentalized mentality”. People working in the health care system are very knowledgeable about their routine operational area of work, but have relatively little understanding of what goes on in the next department, yet the next department may be a critical support for their work. Doctors and nurses in the Accident and Emergency Department or in operating rooms do not really understand or sympathize with the problems faced by ward staff. People in hospitals have little appreciation for issues in long-term and home care. More often, it is simply too difficult for people to get a real handle on the whole “system.” This is where public health practitioners or operational researcher/analyst can play an important role. The health service can benefit a great deal from the advancement made in ICT which challenges the origin compartmentalization mentality.

Take hypothetical case where in one hospital a review was done. Operating room management team had to decide how to allocate available time in the operating rooms over the course of a week. The team included nurses, managers and surgeons. They were very careful to be fair to each service and each surgeon. However, they did not consider the impact their decisions were having on the rest of the hospital. The allocation of surgeon time in operating rooms has dramatic effects on staff requirements in recovery rooms, wards, labs, medical imaging and administrative time. In particular, at this hospital, it was discovered that the nursing workload in one of the wards was almost double on Wednesday compared to every other day of the week due to the weekly surgical schedule. By simply switching a few surgeons, it was possible to effectively level the workload in all wards. Operating room
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planners did not have the tools to evaluate the impact that their decisions had on the rest of the hospital. In this case, the reviewers used simulation, but simpler tools could easily be designed. In the current health care delivery system in Kenya, ICT applications can vastly be exploited to improve efficiency and better health outcomes at the point of care. Obviously, one of the major issues in health care is waiting times (waiting for surgery, wait lists for transplants, location of emergency services, etc.), and most health care queuing problems are too complex to be analyzed theoretically. Therefore, simulation is a popular alternative. Simulation also helps people visualize the impact of local decisions on the whole system. One problem with using simulation in health care is the difficulty of collecting data. One cannot really follow patients around with a stopwatch. The health care environment also frequently involves multi-tasking; doctors and nurses look after several patients at once and it is challenging to determine how to model their time.

**Linear Programming and Goal Programming.** LP has been used in a number of applications including staff scheduling, budget allocation and case mix management among others. Case mix is similar to the basic product mix example problem in every introductory LP text, except that it contains a few twists. The problem lies in deciding which set of procedures a hospital should perform to meet performance targets and stay within budget. One major obstacle in this process is that the hospital administration, unlike private industry, cannot dictate the case mix. As discussed earlier in the worlds of health care, doctors are the gatekeepers. They decide what the hospital does and they are generally more concerned about patient care than they are about the hospital’s case mix issues. Hospitals are usually divided into a “medical” and a “surgical” side. There is not much that we can do about the medical side; patients typically arrive with a variety of symptoms and must be treated promptly. However, the surgical side is primarily concerned with “elective” procedures. They are not elective in the sense that the patient has a choice about having them performed, but the patient and doctor will schedule them for some future date unless it is emergency surgical procedure. Usually patients are on waiting list or appointments. Since one cannot dictate the “optimal” case mix, one simply determines whether or not a given hospital policy is feasible and hospital bookings and appointments is feasible.

**Queuing Models.** There has been some work on managing hospital waiting lists and allocating beds in a hospital to various services. One interesting aspect of health care waiting lists, particularly for home care and long-term care, is the dynamic nature of the problem: as the queue increases, the backlog or waiting time is also increasing. People on the list either look elsewhere for service, become more seriously ill and go to a hospital for emergency or perhaps die waiting.

**Data Envelopment Analysis.** There have been dozens of DEA papers published in the health care sector. Kooreman [1994] used DEA to compare the 320 nursing homes in the Netherlands. The homes were funded based on the number of beds and days of treatment. The author noted that it is hard to measure real health outcomes like “improved health status” or “improved quality of life,” so he just used the output “number of patients treated” divided into four treatment groups. This becomes a real challenge when patients demand for discharge from hospitals due to worry about escalating cost and fear of detention in hospitals as is the case in most hospitals in Kenya if medical bills are not fully paid. Therefore the outcome measure is not based on clinical consideration by the expert, but is influenced by other considerations.

**Integer Programming:** There have been several papers published describing integer-programming applications, primarily for facility location and staff (nurse and physician) scheduling problems. A number of these describe locating emergency medical services and ambulance location in particular. Repede & Bernardo [1994] developed a system for locating ambulances in Louisville, Ky. According to U.S. standards, “95 percent of all (urban) ambulance calls should be served within 10 minutes.” In their model, Repede and Bernardo assumed that the fleet size and the demand pattern changes over time. They provide a decision-support tool to help EMS planners relocate ambulances to maximize the total expected demand that can be served within 10 minutes. One of the distinguishing features of this type of facility location problem is that, once an ambulance is dispatched, it is no longer available to cover calls and it could be out of service for an hour or more. Therefore, the fleet size is constantly shifting. This is a tricky problem that requires more attention and quick decision making as well as monitoring the fleet movement. I am convinced that the emergency service can benefit from use of ICT as a tool to model its efficiency especially in areas where traffic movement is a challenge and unpredictable as is the case of Nairobi and others.

**AIDS Epidemic Modeling.** This may be more known and widely used in most countries, Kenya included. Much of the modeling in AIDS research is systems dynamics in nature. The HIV epidemic is a serious, growing public health problem worldwide, but resources for treating HIV-infected patients and for combating the spread of the virus is limited. Governments, public-health agencies and healthcare providers must determine how best to allocate scarce resources for HIV treatment and prevention among different programs and populations. Operation Research based models have influenced—and can influence—AIDS policy decisions. Mathematical modeling has had an effect on AIDS policy in a number of areas, including estimating HIV prevalence and incidence, understanding the pathophysiology of HIV, evaluating costs and benefits of HIV-screening programs, evaluating the effects of prevention interventions such as needle-exchange programs and determining policies for HIV/AIDS care. Further work is needed to model a range of programs using comparable methods, to model overall epidemic control strategy and to improve the usefulness of research based models for policymaking.
Quality Management. In North America in the early to mid-1990s, hospitals were just beginning to do quality assurance using tools like statistical process control to monitor (immediate) outcomes. Manufacturing was at this stage in 1975, and other service industries were there in the 1980s. Other components of the health care industry (home care, nursing homes) are further behind. In contrast, the pharmaceutical industry was probably more in line with other manufacturing sectors.

One of the reasons for the delayed reaction in health care has been reluctance on the part of the medical community to acknowledge and report errors and problems. Physicians are often reluctant to even have their results tracked and benchmarked. There is a culture of silence in health care; they do not want to admit that mistakes can happen. Therefore the analysis and prevention of adverse medical events including transparent, open public discussion of medical malpractices should take a major focus of attention in Kenya health service delivery. The public and institutions of public protection should demand for review or enactment of laws to address health service delivery. The public and institutions of public protection should demand for review or enactment of laws and policies that are more protective to patients/clients. This should culminate and facilitate redesigning of systems and processes that can withstand test of accountability and responsiveness to prevent unwarranted medical errors and deaths in care settings.

Conclusion

Peoples’ Involvement and Participation: Whenever Operations Research in health care is discussed, some people are eager and excited about trying to do something. They want to know how to start. My advice is that there is a dire need for awareness and information sharing with policy makers and health managers and they are known. That is how to start; simply chat with people and tell them about what Operations Research and the experts can do and have done when engaged and when relevant policies are in place. Start by giving practical examples can be changed positively in health care settings in Kenya. Do not expect people to immediately embrace these concepts. However, I guarantee that you will quickly find someone who is frustrated with the inefficiency of health care delivery and very willing to take action by trying models that work, including quantitative methods. The recommendation is to start simple and demonstrate positive result and success. I may even go further to encourage a collective approach where Public Health Professional Associations and other experts team up to bring this realization to bear among policy makers and the beneficiaries. Given a chance, public health experts especially those involved with operational research can make a big difference; but do not start with complex mathematical model that has little chance of being implemented or that which may take too long to implement before tangible result can be demonstrated. We need to demonstrate to people in the industry that we can make a difference. Academia should get their staff and students involved in projects at hospitals not only in clinical areas, but also in practical systemic and operational models for problem solving and improving efficiency of the system. Experienced professionals should play proactive role or volunteer their services as consultants/advisers on their local hospital boards to add value and improve efficiency. The difficulty, however, lies in the culture of most managers in Kenya who will be very suspicious of volunteers and reluctant to team up with professionals with the zeal to improve systems. It has always left me wonder, if the kind of inefficiencies we encounter in health sector, is not deliberate.

Frequently, when I read various newspapers, magazines of sorts, listen to media of every kind and listen to people talk either in public transport or personal communications; I come across various complaints relating to health care system inefficiencies and dissatisfaction. One can feel the desperation and a people who have surrendered to situation that their fate is already decided, sealed and there is no way out except by divine intervention. I wonder what this means if reviewed critically and if we direct our minds to it. Politicians complain that government cannot afford the increase in taxation that go towards basic social sectors including health care; but has health care to the public received public mention and attention it deserves in terms of cost, quality, equity and access. People complain that health insurance costs are out of control. Well, the bottom line is that people are going to pay for it, either in taxes or insurance premiums or out of your pocket. The problem is not going to go away. The culture in Kenya and most countries in SSA is that we do not act until we have a real crisis. I hope you realize that we are in a health care crisis. Population explosion is going to strain the system beyond its limits and the escalating costs of drugs and related medical diagnostics and point of care technologies are going to bring the system to its knees. I believe that evidence based analysis and data can help in the health reforms and rationalization; but it will take some years to make the significant changes and adjustments required to get through the current crisis. What are we waiting for? It seems to me that inaction means that more people will miss out on affordable, accessible, acceptable and available quality health care or more will continue dying or compromise on quality of life.

Bibliography


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Abstract

Introduction: Microbial Culture and Sensitivity is still the gold standard procedure for diagnosis of infectious diseases and, in certain cases, the only method that can be reliably used for the diagnosis of these diseases. Although there is a gradual shift towards molecular diagnosis in developed countries, it will take longer for this to happen in the developing countries. Ready-to-Use (RTU) culture media can be imported from developed countries but they have short shelf lives.

Objective: To find out the need to develop local capacity to sustainably produce quality-assured and cost effective culture media.

Methodology: Market research was conducted, using a questionnaire to survey and collect data from regional public health facilities. Random Sampling method was employed in selecting the health facilities visited, 71 of them in total. The questionnaires were filled on spot by respondents and some information gathered by observation. The collated primary data was hence entered in Ms Excel and analyzed by SPSS.

Results: A good majority of the respondents (83.6%) indicated they regularly make their own culture media. Most consider ‘High Quality Media’ as the most important factor when choosing culture media.

Conclusion and Recommendation: Formulation of viable, affordable and sustainable products that will serve the large market in Kenya and Eastern Africa in general. It is advisable to establish an integrated working committee to facilitate the effective planning and implementation of this project(s).

Declaration

This survey was wholly sponsored by CDC-Foundation, with technical support by the KEMRI Production Team and the Marketing Team under the guidance and supervision of the Head of Production Unit.

Abbreviations & Acronyms

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<tr>
<th>Acronym</th>
<th>Full Form</th>
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<tr>
<td>BP</td>
<td>British Pharmacopoeia</td>
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<tr>
<td>CDC</td>
<td>US Centres for Disease Control &amp; Prevention</td>
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<tr>
<td>CDC-F</td>
<td>Centre for Disease Control- Foundation</td>
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<tr>
<td>COMESA</td>
<td>Common Market of Eastern and Southern Africa</td>
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<tr>
<td>DCA</td>
<td>Sabouraud Dextrose Agar</td>
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<td>ECO WAS</td>
<td>Economic Community of West African States</td>
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<td>EMP</td>
<td>Eliava Media Production</td>
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<td>GLI</td>
<td>Global Laboratory Initiative</td>
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<td>GMP</td>
<td>Good Manufacturing Practices</td>
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<td>GoK</td>
<td>Government of Kenya</td>
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<tr>
<td>HEA</td>
<td>Hektoen enteric agar dehydrated powder</td>
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<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>KEMRI</td>
<td>Kenya Medical Research Institute</td>
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<td>KEMSA</td>
<td>Kenya Medical Supplies Agency</td>
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<td>KPD</td>
<td>KEMRI Production Department</td>
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<tr>
<td>MOH</td>
<td>Ministry Of Health</td>
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<tr>
<td>QC</td>
<td>Quality Control</td>
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<tr>
<td>RTU</td>
<td>Ready-to-Use</td>
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<tr>
<td>SCMS</td>
<td>Supply Chain Management System</td>
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<tr>
<td>TCBS</td>
<td>Thiosulfate-citrate-bile salts-sucrose agar</td>
</tr>
<tr>
<td>U.S.DTRA</td>
<td>United States Defense Threat Reduction Agency</td>
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<tr>
<td>USP</td>
<td>United State Pharmacopoeia</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>XLD</td>
<td>Xylose Lysine Deoxycholate agar</td>
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Introduction

Microbial Culture and Sensitivity is still the gold standard procedure for diagnosis of infectious diseases and, in certain cases, the only method that can be used reliably for diagnosis of these diseases. Only in exceptional cases can an organism be identified on the basis of its morphological characteristics alone. Although there is a gradual shift towards molecular diagnosis in developed countries, it will take longer for this to happen in the developing countries.

Studies have shown that some microbial diseases are best diagnosed through Microbial Culture & Sensitivity. Widal testing, for example, was banned in Kenya in 2011 and bacterial culture is now the expected mode of typhoid diagnosis. Unfortunately, Widal test kits are still found in use in Kenya, mainly because of unavailability of culture media. While culture is the gold standard for tuberculosis diagnosis globally, most high burden countries like Kenya rely on microscopy (sensitivity <65% c.f. culture). In 2009, WHO called for universal access to TB culture by 2015 and the STOP TB partnership set up the Global Laboratory Initiative (GLI) to help facilitate this. Vibrio cholerae is confirmed through culture from stool or rectal swabs by use of selective media like thiosulfate-citrate-bile salts agar. Confirmation is serologically done by O1- or O139-specific antisera. Rapid test kits of these are commercially available but do not yield an isolate for antimicrobial susceptibility testing or sub typing. In other countries, rapid test kits are not used for routine diagnosis.

The role of suitable quality CM cannot be over emphasized, as the success of isolation of aetiological agents depends on it. Due to increasing quality standards, regulatory scrutiny and efficiency pressure in the world market, the demand for CM is shifting quickly to ready-to-use culture media.

Globally, there are companies specialized in Media production. Such companies include Eliava Media Production (EMP), a member of Eliava Institute of Georgia (the oldest Scientific research Institute in the former Soviet Union). EMP employs modern technologies and equipment, experienced scientists, standardized production process and strict quality control, which make it the unique media production facility in the region.

Other companies that manufacture ready-to-use Culture Media include Merk Chemicals, LIP Diagnostics of UK, Hardy Diagnostics (3rd largest producer in USA) and Cherwell Laboratories, among others.

Kenya Snapshot

Kenya has an estimated population of 40 million, majority of who live in rural and sub-urban areas. Traditionally, donor funding has gone to the development budget of the Ministry of Health, which for many years has amounted to 60–90% of budget support. HIV/AIDS and malaria pose the greatest disease burden on the healthcare system.

There is currently unmet demand for quality culture media in Kenya and the region. Most public facilities in Kenya, laboratories included, suffer from limited quality infrastructure, equipment/supplies and human resources. Constant supply of CM is hampered due to high cost and, sometimes, expertise to prepare them. Quality control of the prepared media is a challenge, compromising the integrity of the results obtained using the prepared media. There is a need to enhance the capacity of CM productivity in, say, KEMRI Production facility which has basic infrastructure and expertise, to produce cost-effective culture media to serve the region and help Kenya to achieve her Vision 2030 health goals and MDGs. It was envisaged that the KEMRI Ready-to-use Culture Media Project, supported by partners like Bienmoyo Foundation, could serve not only Kenya but also the larger Common Market of Eastern and Southern Africa (COMESA).

Weak Healthcare System

There are over 5,000 health facilities across the country 41% of which are run by the government, 15% by non-governmental organizations (NGOs) and 43% are for profit private businesses.

The Kenyan healthcare sector faces four major challenges that augment the need for local capacity to develop and manufacture culture media. First, population and economic growth that has outpaced the service capacity of the existing healthcare infrastructure. Secondly, there is the increasing incidence of non-communicable diseases. Thirdly, a “vicious circle” of poor services in remote and rural areas due to insufficient supply of qualified health professionals and the limited number and inconsistent quality of facilities and equipment. Lastly, there is the growing headache of antimicrobial resistance (AMR) and microbial threats that is beginning to retard healthcare growth, and even take us back to the pre-penicillin era.

Besides, the cost of various reagents for use in the medical laboratories in Kenya and neighboring countries are high due to their high costs of shipment that results from their bulk. Generally, ready-to-use culture media have short shelf lives (e.g. Nutrient Agar Plates have a shelf life of less than 7 - 90 days) so that by the time the shipments arrive in the country, substantial parts of their shelf lives are normally gone. Many of them tend to expire on the shelf, heightening their costs.

Aim /Objective

The objective of the study was to quantify the demand for Bacteriological Culture Media in Kenya with a view to developing local capacity to Sustainably Produce Quality-assured and cost effective culture media.

Methodology

A marketing research schedule and questionnaire were developed to ensure relevant data was collected from target
health facilities from around the country by field visits. The first field visits targeted the KEMRI Centers in Nairobi and environs. The second circuit of visits covered randomly selected Regional hospitals, reference laboratories and other health facilities in Central and Eastern Kenya. Thereafter, Coastal Region followed by the Western and Nyanza circuit was visited hence finalizing the survey. In the initial circuit, 8 KEMRI centers and the 16 health facilities in Nairobi and environs were visited between 2nd May and 17th May 2012 and questionnaires administered. In Central and Eastern Kenya Circuit, the field visits were conducted from 11th -15th June 2012. In total 14 health facilities were visited in North Eastern and questionnaires administered. The Coastal Strip was visited from 25th June to 30th June 2012. In total 13 facilities were visited. The Western and Nyanza regions were the last circuit of the market research and were visited from 8th July 2012 to 15th July 2012 with 20 facilities in total visited. Random Sampling method was employed in selecting the health facilities visited. The questionnaires were filled on spot by respondents and some information gathered by observation. The collated primary data was hence entered in Ms Excel and analyzed by SPSS.

Results and Discussion

A total of 61 participants in various health facilities in Kenya were engaged on the use of culture media with the aim of identifying and quantifying the target market. The 61 participants were selected randomly from the eight regions in Kenya, with ten health facilities targeted for each. Majority of the participants in this study were Laboratory Technicians in Charge, 21(34.4%), followed by Laboratory Technicians, 20(32.0%). The least were the Research Scientists. Out of all the personnel interviewed, 51 (83.6%) stated that they prepared bacteriological culture media for their facility, 7 (11.5%) did not know if bacteriological culture media was prepared in their facility and only 3(4.9%) stated that culture media was not prepared in their facility. The laboratory personnel interviewed prepared several types of media which indicated the type of experiments they performed and the types of bacterial pathogens they handled. The media ranged from the general media (non-specific) to specific bacteriological media. The media also varied from enriched to non-enriched. In general, majority of the laboratories used Mac-Conkey Agar (65.6%), followed by Blood Agar and CLED media with 59.0% and 57.3% respectively. The lowest proportion was that of Chocolate Blood Agar (CBA) and Muller Hinton (MH) media, with 19.7% and 37.7% respectively as shown in (Figure 2.0).

Figure 2.0: Types of media prepared by the participants

The other types of CM prepared included; XLD, DCA, Urea broth and Lowenstein Jansen. All these media had a proportion of less than 5% out of the total laboratories.

Eastern and Central regions had a higher proportion of participants who prepared Blood Agar, Mac-Conkey and CLED media for their routine work (33.3%, 31.4% and 27.5% respectively). They were closely followed by Nyanza and Western regions (see table 2.1). Majority in Coast and Nairobi regions did not prepare Blood Agar, Mac-Conkey and CLED media. However, CLED media was prepared by all ten participants at the coast which represented 25.0% of the 40 participants who used CLED. In all the regions, Nairobi had highest proportion of participants who did not prepare the media: Blood agar (44.4%), Mac-Conkey (42.3%) and CLED (57.1) (Table 2.1(a)).

The trend was different for the three other media; majority did not prepare Chocolate Blood Agar (CBA) and Muller Hinton Agar and there was no big difference observed in proportions of those who prepared other media and those who were using the media discussed.

Majority of the laboratory facilities (82.3%) performed 1 to 50 cultures per day (Fig. 2.1) and among these the District hospitals perfomed the highest number of tests (38.1%).
They were followed by the Medical Research Institute with 19.0% and Private hospitals (16.7%). Least were the Referral Hospitals and Religion based hospitals. Very few facilities performed more than 50 cultures per day. The few that performed more than 50 tests included Medical Research Institute that performed between 51-100 tests and of referral and the District hospital respectively. It was the Medical Research Institute that performed all ranges of tests up to above 500 tests per day as per the chart below.

The culture media purchased locally were 66.7% while in-house produced media stood at (11.8%). However, other participants imported the culture media (7.8%) while some were given as a donation (3.9%) from their project donors. Depending on the nature of the test, some participants combined two or more sources of obtaining the culture media. In this combination there were an equal proportion of those who combined locally purchased and in house and those who locally purchased and imported (both at 3.9%). Only one laboratory combined all the three (2.0%) (Table 2.4).

<table>
<thead>
<tr>
<th>Source of Media</th>
<th>Frequency(n)</th>
<th>Percentage(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locally purchased</td>
<td>34</td>
<td>66.7</td>
</tr>
<tr>
<td>In-house produced</td>
<td>6</td>
<td>11.8</td>
</tr>
<tr>
<td>Imported</td>
<td>4</td>
<td>7.8</td>
</tr>
<tr>
<td>Donation</td>
<td>2</td>
<td>3.9</td>
</tr>
<tr>
<td>Both In-house and Locally purchased</td>
<td>2</td>
<td>3.9</td>
</tr>
<tr>
<td>Both Locally purchased and Imported</td>
<td>2</td>
<td>3.9</td>
</tr>
<tr>
<td>Both In-house and Locally purchased</td>
<td>1</td>
<td>2.0</td>
</tr>
<tr>
<td>All In-house, Locally purchased and Imported</td>
<td>1</td>
<td>2.0</td>
</tr>
<tr>
<td>Total</td>
<td>51</td>
<td>100</td>
</tr>
</tbody>
</table>

The frequency of making orders varied from one laboratory to the other, majority of the laboratories ordered their culture media quarterly (66.7%) and bi-annually (19.6%). Only 4/51 ordered monthly (Table 2.7). Some participants (5.9%) did not know how the culture media was ordered. There was a direct relationship between the number of tests performed per day and the capacity ordered. The District hospitals that performed higher number of tests ordered above 2kg of the media. The highest capacity cited was 5kg of each medium. On average, the District hospitals ordered 500grams to 1kg of each media.

Once the culture media was ordered, 18/47 (38.3%) took between two months to three months to be delivered, while in 13/47 (27.7%) took less than a week. Other media took 1-3months (23.4%) (Table 2.8). Most of those that took longer period to be delivered were those that were imported.

<table>
<thead>
<tr>
<th>Order Frequency</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly</td>
<td>34</td>
<td>66.7</td>
</tr>
<tr>
<td>Bi-annually</td>
<td>10</td>
<td>19.6</td>
</tr>
<tr>
<td>Monthly</td>
<td>4</td>
<td>7.8</td>
</tr>
<tr>
<td>Did not know</td>
<td>3</td>
<td>5.9</td>
</tr>
<tr>
<td>Total</td>
<td>51</td>
<td>100</td>
</tr>
</tbody>
</table>

There were various factors considered when choosing culture media for use in the laboratory, but top in the list of most respondents was “High Quality Media” 44/52 (86.6%). This factor was closely followed by “Best Performance” 82.7% (43/52) and lastly in the top three factors was “Affordability” 51.9% (27/52). Other factors included the Value of the media (26.9%), Broad product selection (26.9%) and Recognized brand name (13.5%). Least amongst the factors was Good marketing or Sales representatives 1/52 (1.9%) and being given a Discount when purchasing the media 2/52 (3.8%) (Figure 2.2). These factors were evenly distributed in all types of health facilities selected in all regions and among the target professional groups.

<table>
<thead>
<tr>
<th>Time taken to deliver</th>
<th>Frequency (%)</th>
<th>Percentage(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than a week</td>
<td>13</td>
<td>27.7</td>
</tr>
<tr>
<td>2 to 3 months</td>
<td>18</td>
<td>38.3</td>
</tr>
<tr>
<td>1month to 3 months</td>
<td>11</td>
<td>23.4</td>
</tr>
<tr>
<td>More than 3 months</td>
<td>5</td>
<td>10.6</td>
</tr>
<tr>
<td>Total</td>
<td>47</td>
<td>100</td>
</tr>
</tbody>
</table>

![Figure 2.2: Factors considered when choosing culture media for the laboratory](image)
Research Institute 5/14 (35.7%) and 5/11 (45.5%) respectively. Discount provision was mentioned only at the district hospital and Good marketing and Sales representative was only mentioned at Regional hospital.

A higher proportion (53.1%) of the respondents agreed and 39.7% strongly agreed that locally produced microbial CM would save them on time and cost, only 2/49 (4.1%) were of the contrary opinion. On the other hand, majority (63.2%) of the respondents strongly agreed and another 28.6% agreed that standardized media would improve disease diagnosis in their facility (Table 2.9).

On RTU media, a higher proportion strongly agreed (49.0%) while 42.9% agreed that these would save them time for their core activity i.e. diagnosis. However, 18.4% of them were of the contrary opinion on whether RTU packed culture media would improve on short shelf life of the product (Table 2.9). In general, a higher proportion felt that locally produced media would save them on cost and time and that standardized media would improve disease diagnosis in their facility.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>Don’t Know</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locally produced microbial culture media will save us on time and cost</td>
<td>0%</td>
<td>4.1%</td>
<td>53.1%</td>
<td>39.7%</td>
<td>6.1%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Standardized media will improve disease diagnosis in my facility</td>
<td>0%</td>
<td>4.1%</td>
<td>28.6%</td>
<td>63.2%</td>
<td>4.1%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Ready to use media will save us on our core activity i.e. diagnosis</td>
<td>0%</td>
<td>6.1%</td>
<td>42.9%</td>
<td>49.0%</td>
<td>2.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Ready to use packed culture media will improve on short shelf life for the product</td>
<td>4.1%</td>
<td>14.3%</td>
<td>46.9%</td>
<td>28.6%</td>
<td>4.1%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

From the data analysis above the culture media and haematological project are viable. From the 61 facilities that were visited 83.6% of the respondents agreed that they prepared bacteriological culture media in their facilities although Quality Control remained the main challenge. Majority of the facilities utilized Mac-Conkey Agar (65.6%) followed by Blood Agar (59.0%) and CLED Media (57.0%). Other media categorised as ‘Other’ including XLD, DCA, Urea Broth and Lowenstein Jansen must be equally considered since a lot of such media is utilized by research and learning institutions.

It is important to note that priority must be given to the commonly utilized media but this will depend on the niche KPD chooses to focus on. Referral hospitals were in all four circuits visited while the research institute centres were also geographically located in Nairobi, Coast, Nyanza and Western Region in Busia. These may be chosen as areas to start with incrementally spreading to other key areas of interest.

Majority of the respondents consider ‘High Quality Media’ as the most important factor when choosing culture media. Best Performance came second followed by ‘Affordability’ of the media. KPD is at an advantage considering that it is in the process of acquiring ISO 9001-2008, ISO 17043 and ISO 13847. These standards will ensure that all products emanating from the facility including the culture media are of the highest international standards. Additionally, having a local base will ensure that the prices of the culture media are priced competitively compared to the imported products hence giving the customers value for their money. This is further supported by the fact that, generally, a higher proportion of the respondents felt that locally produced media will save them on cost and time which means that the lead time between imported supplies shall be drastically reduced. They also believed that standardized media would improve disease diagnosis in their facility thus making them focus more on their core activity which is diagnosis rather than media preparation.

From the statistics, KPD should mainly target the Medical Research Institute, Referral Hospitals and District Hospitals as a niche market then afterwards consider the other laboratories. This is due to the numerous cases they handle everyday for either research purpose, first-hand patients or due to referrals.

Frequency of ordering culture media has a major impact on which market segment KPD should focus on. There was a direct relationship between the number of tests performed per day and the capacity ordered. Those District Hospital laboratories that performed higher number of tests ordered above 2kg of the media. The highest capacity cited was 5kg of each medium. On average the laboratories ordered a capacity of 500grams to 1kg of each media. Current shelf life of ready- to- use media is 7 to 14 days thus translating to either daily, weekly or after every two weeks deliveries by KPD (a much shorter time than quarterly deliveries). With a high capacity commercial autoclave installed, KPD would be able to meet high demand of ready-to-use culture media. In fact the higher number of orders the more economic it would be for the commercial autoclave.

Based on the findings, a lot of awareness must therefore be carried out by the marketing team to ensure the target market get to know of the RTU media that will be offered by KPD.
Relevant promotional strategies such as product brochures and catalogues must be distributed to target markets.

It is evident that were KPD to engage in the production of RTU media, the greatest competition would be from the imported media; quality products would be necessary given the short shelf life of ready-made media. KPD would have to manufacture media in strict conformity with the ISO 9001:2003 specifications then deliver under strict cold-chain. Since most imported CM come in powder for reconstitution just before use, KPD would have to consider the best selling proposition to counter this challenge.

Conclusion and Recommendations

For production of affordable and sustainable culture media products the following interventions should be in place: Establishment of viable, affordable and sustainable products that will serve our target markets. Formulation of an integrated working committee to facilitate the effective planning and implementation of this project. Allocation of both human and financial resources including capacity building of key players in both production and marketing. The Marketing Team be fully supported so as to create adequate awareness of KPD products to target markets to solicit positive purchase response from them. Encouraging local (in-house) procurement by linking the KEMRI centers and projects to consume the RTU media products. Strengthen collaboration between the Ministries of Health, NGOs and other relevant stakeholders for prosperity and posterity. Strengthen and make regular the sensitization programs for medical personnel and other prospective users of the KPD products and services. Lastly, conduct regular needs assessment to identify key issues impacting on implementation of this project.

References

Pharmaceutical Operational Excellence– A suitable concept for Kenya?

Friedli, Thomas; Lembke, Nikolaus; Bellm, Daniel

1Prof. of Production Management, Vice Director Institute of Technology Management, University of St. Gallen, Switzerland
2Research Associate at the Institute of Technology Management, University of St.Gallen, Switzerland
3Research Associate at the Institute of Technology Management, University of St.Gallen, Switzerland

Key words: Operational Excellence, Pharmaceutical Industry, Kenya

Introduction

The pharmaceutical environment

The global pharmaceutical industry currently faces a great upheaval that poses severe challenges to organizations of all sizes. Companies which were blessed with success until yesterday are now confronted with patent expirations, R&D pipelines running dry and considerable overcapacities. A constantly increasing competition and complexity within pharmaceutical manufacturing make pharma a tough business [1].

The current situation which pharma endures came, however, not out of the blue. Moreover, especially large research driven and generic manufacturers, working on margins’ edge, searched for and developed their own defence mechanisms to sustain in global business. One of the most promising approaches to improve a company’s situation that hit pharma agenda at the turn of the century is the relentless effort to achieve operational excellence (OPEX).

Operational excellence defined

Operational excellence in particular “[…] constitutes the continuous pursuit of improvement of a production plant in all dimensions. Improvement is measured by balanced performance metrics comprising efficiency and effectiveness, thus providing a mutual basis for an improvement evaluation”. [2] The philosophy of operational excellence traces back to approaches of World Class Manufacturing [3], or even earlier to all those well-known Japanese manufacturing concepts, most impressively publicized in conjunction with the Toyota Production System [4, 5]. Based on the work of Cua et al. [6], the Institute of Technology Management of the University of St. Gallen, Switzerland, developed a framework for the structured discussion of operational excellence in a pharmaceutical context which was officially published [7].

Figure 1: The St. Gallen model for operational excellence [2]

TPM aims to maximize the effectiveness of used equipment in production, all at moderate costs. Therefore, the main focus of TPM optimization does not lie in short-term reduction of costs for equipment and maintenance; rather, TPM is concerned with the optimal support of production processes based on stable and reliable equipment. Thus, TPM provides the basis for improvements in efficiency. TPM does not only focus on technical aspects such as equipment reliability, but also involves engaging all employees in maintenance-related activities. TQM is a holistic quality philosophy involving all employees from top management (role model) to the shop-floor with the objective of continuously improving the quality of products and processes. Activities are based on the assumption that costs for correcting quality activities are higher than for preventive quality activities like process management, customer integration or an adequate supplier management. JIT is a crucial element to increase flexibility by avoiding excessive inventories. It provides the customer with goods in the right quality and quantity when he needs...
it. Furthermore, focused on manufacturing site’s internal processes, it supports the continuous reduction and ultimate elimination of waste like inventory and overproduction [8].

The basic elements ‘Standardization’ and ‘Visual Management’ are crucial to realizing the full potential of TPM, TQM, and JIT. Methods like 5S and Visual Management are not limited to the production and shop-floor area, but can equally be applied in the laboratories and offices.

EMS represents the social aspect of operational excellence and emphasizes the importance of top management commitment, company culture and a broad employee involvement in order to realize a sustainable success of any operational excellence initiative [8].

The evolution of operational excellence in pharma

Over the last decade the role and perception of pharmaceutical operational excellence has changed significantly. Whereas single and stand-alone approaches of operational excellence were first introduced by large companies, they realized quickly that a mere copy and paste from successful automotive organizations would not fit the pharmaceutical requirements in the long run [9]. Today, almost all pharmaceutical manufacturers apply selected concepts and approaches from the OPEX tool box in order to increase their efficiency [10]. However, the evolution of operational excellence in pharma showed that reaching operational excellence is far more than solely applying tools. Especially large research driven organizations started their transformation with broad trainings of their entire workforce. The provision of basic trainings to drive efficiency and effectiveness had several advantages: first, training people in tools like problem solving or process mapping increase the know-how and awareness of employees for their daily challenges within operations. Secondly, providing large scale training is a signal by management that starting the transformation towards operational excellence is more than just fad – it is the ignition of a changing mindset to drive responsibility and empowerment of people. Thirdly, these basic trainings equip people on shop-floor with the skills to create and maintain a pharmaceutical environment which meets the basic requirements of cGMP1.

OPEX in Kenya – it is about people

The philosophy of operational excellence is suitable for all cultures [9]. Besides, transforming a manufacturing site to an operationally excellent environment is neither dependent on state-of-the-art equipment [11] nor is it restricted to a certain industry, product mix or business model [12]. Nevertheless, prevailing manufacturing challenges in Kenya as described by UNIDO [13] might deter some managers from exuberant optimism and, rather, lead them to treat operational excellence with reserve.

In 2013, in a joint cooperation with UNIDO, a research team of the University of St. Gallen visited several manufacturing sites in Nairobi, Kenya. Though the companies belong to some of the most advanced pharma companies of the country, they represented varying levels of pharmaceutical manufacturing capabilities. The research team held several interviews with the site leadership teams and people on shop-floor in order to become familiar with the Kenyan manufacturing environment.

In general, the findings support Liker’s proposition [3] that the concept of operational excellence is applicable everywhere. More precisely, every system requires stability which is all the more demanding to realize in a volatile environment such as Sub-Saharan Africa. Following the lessons from the St. Gallen model for operational excellence, the first step for Kenyan pharmaceutical companies towards OPEX is recommended as a broad engagement with TPM. Introduced top-down and supported by the site’s entire leadership team, a training program needs to be set up to train people in housekeeping approaches. In such cases 5S is not limited to the shop-floor but embraces all facets of a manufacturing site, e.g. storage, utilities, laboratories, etc. People need to be encouraged and empowered by management to strive for improvement and pharmaceutical cleanliness of their workplace which includes the meticulous care of all equipment time and again. Moreover, management has to actively involve people from all hierarchies in improving the site’s operations. Since it is the people in areas like dispensing, tableting, packaging, QA/QC or at the storage etc. who daily work in their processes, who are valuable experts for the company, and who are the ones who produce quality, management has to listen to their opinions and suggestions for improvement. To achieve this, people need to be encouraged and managers have to follow a long-term strategy in order to realize such potential.

Conclusion

As the pharmaceutical industry is facing increasing challenges, like a rising complexity, the time has come to realize the potential of sustainably implementing OPEX. Because of the complex and interconnected nature of integrated production systems, adjustments of one sub-system affect all of the other sub-systems. Starting with TPM and then TQM will lead to the needed stability to also strive for the elimination of all kinds of waste (addressing JIT). One of the most important steps which have been taken in the previous years is an expansion of measuring activities and the use of tools such as Statistical Process Control. The knowledge which can be derived from precise measuring is essential in terms of quality and fosters a science of manufacturing. According to Ishikawa [15] data should not be collected to provide the basis for nice figures but to create a basis for action and the development of processes. Collecting the right data and using it as an objective performance indicator in a continuous improvement process will prove to be highly beneficial to pharmaceutical companies [14].

1 See Friedli et al. [14] for an overview of the most important tools and their application in pharmaceutical operational excellence.
References


INSPECTIONS

Scope
The Authority pharmacists are authorised to inspect pharmacies to ascertain whether provisions of the Pharmacy Regulation Act 2010 are being met. They are required to gather information with reference to the Act, the Guidelines and other relevant legislation and standards in order for the Authority to be satisfied that premises comply with good pharmacy practice. Relevant legislation includes:

- Pharmacy Regulation Act 2010
- Drugs, Poisons and Controlled Substances Act 1981
- Drugs, Poisons and Controlled Substances Regulations 2006
- Health Practitioner Regulation National Law (Victoria) Act 2009

The Authority’s Guidelines represent the current policies of the Authority and any departure from them must be justified on a case by case basis.

The Authority recognises the registration standards, guidelines, codes and policies issued by the Pharmacy Board of Australia. The Authority has regard to the standards, codes and guidelines issued by the Pharmaceutical Society of Australia and the Society of Hospital Pharmacists of Australia.

Procedure
Inspections are intended to be informative and not punitive, aiding in the early identification and rectification of matters of concern. Inspectors examine security, workload, privacy, equipment, fittings, compliance with legislation and pharmacy practice standards, and pay particular attention to opioid replacement therapy and dose administration aids. The inspectors may gather evidence during inspections, for example by taking photographs.

Outcome
The Authority may investigate a matter relating to a licence or a premises registration resulting from an inspection. In the case of an investigation, a licensee may be required to respond to the Authority detailing steps taken to rectify deficiencies before any further action is taken. A panel may be convened by the Authority to hear a matter which has been the subject of an investigation. Panel decisions may result in:

- a condition(s) being placed on a licence and/or premises registration
- a licence and/or premises registration being revoked
- cautioning or reprimanding of the licensee or registration holder
- the licence or premises registration continuing

The Authority may direct that a site re-inspection be undertaken. In such cases a fee (currently $299.40) shall be billed to the pharmacy.

MATTERS COMMONLY NOTED AT INSPECTIONS

1. Dispensary activities
Non-dispensary staff members are frequently observed carrying out activities in the dispensary contrary to VPA Guideline 3.3.3.4.1. Dispensary access should be restricted to dispensary staff only. The dispensary is a private area dedicated to the dispensing of medicines and the secure storage of patients’ records. All other activities are to be carried out away from the dispensary. These include non-dispensary clerical work such as POS data entry, storage of personal belongings for non-dispensary staff, and meal or tea break activities.

2. Privacy
It is frequently noted that many pharmacists are still not making adequate arrangements for consumer privacy in their pharmacies. The identity of a medicine being supplied or dispensed cannot be known by another client of the pharmacy or pharmacy department, and where this occurs pharmacies are operating in contravention of the Pharmacy...
Regulation Act 2010 (refer Schedule to the Act, clause 9(h)). Adequate arrangements must be in place to (a) ensure that confidential discussions can occur between pharmacists and their clients in privacy, and that third parties do not see a patient’s medicines, and (b) the identity of patients’ medicines is kept private during transit to, and at the cash and wrap counter. Privacy-related complaints now comprise a significant proportion of complaints to AHPRA. Pharmacists should frequently put themselves in the place of the consumer as they move around their pharmacies in order to identify where privacy breaches may be occurring. Refer to VPA Guideline 3.3.3.3 for details regarding privacy and privacy screens.

Although improvements have been observed in recent inspections there are still instances where the carrying of open baskets containing dispensed medicines to a remote cash register enables other people to identify a patient’s medication. As a statutory condition of the licence, arrangements must be in place to prevent inadvertent disclosure of this kind.

If the dispensed medicines are to be transferred to the final bag at the cash register, arrangements are necessary to maintain privacy.

When PBS prescription duplicates older than 12 months are to be disposed of, no personal information is to be disclosed. Shredders can be used but the quantity is often beyond their capacity. In this case, a confidential document destruction firm should be contacted.

Pharmacists should also ensure that adequate procedures are in place to ensure that confidential waste is not disposed of in general waste. Inspectors frequently find unwanted repeat authorisations, dispensing labels and dose administration aid material and header cards amongst general waste.

3. Workloads

A pharmacy or pharmacy department should be staffed to meet the expected workload. Pharmacists are encouraged to monitor workloads to ensure that they are within limits specified by the Authority. Inspectors frequently visit pharmacies in which workload limits are being breached. The Authority takes excessive workloads very seriously as both the public and pharmacists are put at risk. VPA workload limits are summarised below:

- The minimum staffing level allows for one pharmacist to dispense 150 prescriptions over a 9am to 6pm day or pro rata at weekends
- The preparation of each dose of pharmacotherapy medication (administered and taken away) is counted as being the equivalent of one prescription
- A trained dispensary assistant (DA) and/or intern pharmacist may assist the pharmacist if dispensing 150-200 prescriptions per day; a second DA may be used if dispensing 200-220 prescriptions per day
- When workload is in excess of 220 prescriptions per day a second pharmacist will be required for at least part of the day
- A pharmacist can supervise up to two DAs involved in dispensing tasks requiring direct supervision
- Attention should be paid to predictable spikes in activity during specific times, days or weeks

Reference should be made to the VPA Guidelines and Pharmacy Board of Australia Guidelines for Dispensing of Medicines.

4. Storage of S8 medicines

Inspectors continue to note instances where pharmacists have failed to comply with S8 storage requirements. In these instances licensee/s have been required to attend panel hearings at which conditions may have been imposed on their licence and/or premises registration. S8 poisons must be stored in accordance with the DPCS Regulations 2006.

- It is never acceptable to store excess S8 stock in drawers or cupboards. Recent cases have involved general S8 and pharmacotherapy medicines. The increased prescribing of S8 poisons has required pharmacies to carry larger stocks than in the past. Storing surplus stock out of the regulation safes is an offence.
- S8 safes should be large enough to store all S8 poisons on hand and facilitate their accurate selection.
- Safes must meet the specifications and installation requirements prescribed under the DPCS Regulations 2006 (refer also to the Guide to the DPCS Regulations 2006).
- S8 keys must never be kept on the premises overnight unless they are stored in a safe of equivalent security to the S8 safe. It is unacceptable to leave the keys in the door of the safe, on a hook or shelf, or in a drawer in the dispensary.

Authority staff estimate that in over 30 per cent of pharmacies, there is inadequate security of keys to the Schedule 8 safe. Either the keys go home with the pharmacist(s) or they are stored in a safe of at least equivalent security to the drug safe.

- The regulations governing the attachment of Schedule 8 safes to the wall or floor have been unchanged since the 1970s. There must be four expanding bolts (DynaBolts or Loxins), each 10 mm x 50 mm minimum. See the Guide to the Drugs, Poisons and Controlled Substances Regulations 2006. All too often, wood screws or fewer than four bolts are evident.
- Negative balances in the Schedule 8 Register are not permitted. You either have stock or you do not. Where a part supply is made, appropriate entries must be made to reflect actuality.
- When labelling methadone takeaways, follow the wording in the APF22 (page 210). Do not state “Methadone 5mg/mL” on the label as this is the strength of the concentrate.
• Do not store in use methadone concentrate in tea mugs! This has been observed several times recently.

• Alprazolam will be rescheduled to S8 on 1 February 2014 which will require more stock to be stored in the controlled drug safe. An examination of safe space and the possible need to obtain another or larger safe needs to be made.

These matters may also be referred to the Drugs and Poisons Regulation Group which may consider prosecution through the Magistrates Court.

5. Continuous temperature monitoring of drug refrigerators

Drug refrigerators are required to be equipped with a continuous temperature monitoring device (e.g. a data logger), in addition to daily maximum/minimum temperature monitoring. Data loggers provide useful information detailing the duration medications have been subject to temperatures outside the required 2° Celsius to 8° Celsius range. Data loggers can be downloaded when a potential cold chain breach is noted so that the effect of a breach on the integrity of drugs can be assessed. Data loggers may be purchased from vaccine refrigerator companies and can provide proof should an insurance claim be necessary.

6. Recycling of dispensed medicines

Clause 9(b) of the Schedule to the Pharmacy Regulation Act 2010 states that adequate arrangements must be in place to ensure that medicines are not re-used after dispensing and after they have left the pharmacy or pharmacy department. There have been numerous cases where labelled, previously dispensed medicines from other pharmacies are found on pharmacy shelves for the purpose of filling dose administration aids (DAAs). Patients’ own medicines supplied for filling that patient’s DAA should be stored in a container clearly labeled with the patient’s name. Medicines are not to be used after dispensing to fill dose administration aids for persons other than the person to whom the medicine was dispensed. Returned/expired medicines should be quarantined in a secure manner and disposed of regularly using the Return of Unwanted Medicines (RUM) service.

7. Security

Pharmacy perimeter doors and locks are required to be substantial in accordance with VPA Guideline 3.3.3.1. Perimeter doors to secluded areas (e.g. rear doors to carparks, laneways or adjoining tenancies) are required to be solid core and have metal sheeting or a substantial metal security door fitted, and windows should be fitted with metal bars/grills. Perimeter doors are often found to be constructed of timber which would require little effort to break into.

8. Mandatory reference Books

Reference should be made to the Pharmacy Board of Australia’s Guidelines on practice-specific issues – Guideline 1 (List of References) to ensure that current editions of mandatory references are immediately available in the pharmacy. It is never acceptable to hold only editions that are several years out of date, or for references to be unavailable because they have been taken home for study purposes.

9. Supply of S3 Medicines

A pharmacist is required to personally ensure that a therapeutic need exists before a Pharmacist Only Medicine (S3) is sold or supplied in the pharmacy. Refer DPCS Regulations Part 4 and Guide to DPCS Regulations. Inspectors have observed cases in which S3 poisons have been supplied without any involvement of a pharmacist. S3 Medicines should not be displayed with multiple facings or in a manner which draws undue attention.

Pseudoephedrine continues to be a major reason for break-ins into pharmacies and the previous statements referring to only stocking one week’s supply and for that stock to not be visible still applies.

10. Schedule 8 Registers for Pharmacotherapy medicines

Records for S8 poisons must comply with the requirements of Regulation 41 of the DPCS Regulations 2006. The Department of Health’s Guide to the DPCS Regulations 2006, and Which Software May Be Used By Health Practitioners in Victoria should be consulted to confirm that electronic or written S8 records comply with Regulation 41.

Inspectors have noted cases where, particularly for methadone registers, records do not comply with Regulation 41 (e.g. they do not show a true and accurate balance and they do not show the name of the person carrying out the transaction).

11. Banner/franchise groups

Inspectors are frequently advised that “Head Office” has required particular stock to be displayed in a certain location eg. Scheduled paediatric medicines in the baby goods area outside of the Professional Services Area. Similarly the “Store Manager” or “Area Manager” has directed that certain medicines are to be recommended or they have set substitution targets.

The layout including the placement of privacy screens always remains the responsibility of the proprietor/s.

Incitement

Such directions may contravene legislation. Section 136 of the Health Practitioner Regulation National Law (Victoria) Act 2009 provides as follows:

(1) A person must not direct or incite a registered health practitioner to do anything, in the course of the practitioner’s practice of the health profession, that amounts to unprofessional conduct or professional misconduct.

Maximum penalty—

(a) in the case of an individual—$30,000; or

(b) in the case of a body corporate—$60,000.

Undue influence
Similarly agreements designed to permit this to happen may contravene Section 11 of the Pharmacy Regulation Act 2010 which provides as follows:

A provision in a bill of sale, mortgage, lease or in any other commercial arrangement in respect of a pharmacy or pharmacy business that gives to any person other than the person licensed under section 38 to carry on the pharmacy business—

a. the right to control the manner in which the pharmacy business is carried on; or

b. the right of access to books of accounts or records kept in respect of that business, otherwise than for the purpose of determining whether or not the conditions of the relevant document are being complied with; or

c. the right to receive any consideration that varies according to the profits or takings in respect of the business—is void.

12. Display and sale of codeine-containing medicines in Schedule 3

The health risks associated with the taking of large quantities of over-the-counter medicines that contain codeine have been documented. The risks include dependency on codeine and gastrointestinal, kidney and liver damage caused by accompanying ibuprofen or paracetamol.

The Drugs, Poisons and Controlled Substances Regulations 2006 require that Schedule 3 poisons must not be stored or displayed in a manner which will promote their sale or draw undue attention to them. It is also an offence to supply a Schedule 3 poison to a person merely to support that person’s dependency.

New Guideline

Only one package of codeine containing medicine is to be supplied at a time unless there are exceptional circumstances.

Only one shelf-facing of the smallest commercial package of each product may be displayed. All other stocks are to be out of the public’s view.

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Dear E-drug readers,

I would like to bring your attention to a press release that we have just issued:

PRESS RELEASE by PRESCRIRE - 19 FEBRUARY 2014

Domperidone (Motilium° or other brands) has modest efficacy against nausea and vomiting. It increases the risk of heart rhythm disorders and sudden death. Based on data on reimbursements paid by the French health insurance system and the incidence of sudden death in France, Prescrire has shown that it is a likely hypothesis that as many as 25 to 120 sudden deaths were linked to domperidone in 2012 in France. It is high time the European health authorities withdrew this drug from the market.

Domperidone (Motilium° or other brands) is a neuroleptic used to treat the symptoms of common nausea and vomiting, with modest efficacy. Neuroleptics are known to expose patients to the risk of heart rhythm disorders. Since 2005, several epidemiological studies, conducted in the Netherlands and Canada, have shown that sudden cardiac death is about 1.6 to 3.7 times more frequent in patients exposed to domperidone.

In late 2011, the French drug regulatory agency and the main drug company that markets domperidone informed doctors and pharmacists about the risk of sudden death. The European Medicines Agency (EMA) is due to issue an opinion on domperidone in March 2014, but there is a chance it will simply recommend lower dosages or shorter treatment durations. These measures are insufficient to fully protect patients and would just shift the responsibility from drug regulatory agencies onto healthcare professionals, who have enough to do without having to explain to patients that a particular drug is authorised but should not be used.

Against this background, on Wednesday 19 February, Prescrire is publishing a study conducted by its editorial team using data from the French health insurance system. According to these data, domperidone was dispensed at least once to about 7% of French adults in 2012, i.e. about 3 million adults. Based on these data and the incidence of sudden death in France, using conservative assumptions, it is likely that about 25 to 120 sudden deaths were attributable to domperidone in France in 2012.

It is high time to stop the use of this drug that can easily be replaced by better solutions for patients. In practice, the disorders for which domperidone is prescribed are often self-limiting or resolve with dietary measures. For patients who nevertheless want drug therapy, one option is a truly harm-free placebo. For patients with gastroesophageal reflux disease, a proton pump inhibitor such as omeprazole is preferable to domperidone. And in the rare situations in which a gastric “motility modifier” appears justified, metoclopramide can be discussed, but used with great caution: at the lowest effective dose, monitoring very closely for its adverse effects, given that this drug is also a neuroleptic. Metopimazine and alizapride offer no demonstrated advantages over metoclopramide.

For more information, please contact: Press relations Pierre Chirac - Tel: +33 (0)1 49 23 72 63
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Kind Regards,

Teresa Leonardo Alves
International Policy Adviser
La Revue Prescrire
Email: talves@prescrire.org

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Papers which have been submitted and accepted but not yet published may be included in the list of references with the name of the journal and indicated as “In press”. Use of abstracts as references should be avoided. The “unpublished observations” and “personal communications” may not be used as references but may be inserted (in parentheses) in the text. The Reference list should begin on a new page and typed double spaced in the Vancouver style.

2.0 Right to Reject Article: The editors reserve the right to reject an article for publication if it does not meet the requirements of the Pharmaceutical Journal of Kenya. If an Article is adjudged suitable and publishable in PJK, the editors will have the final say on the Journal number and Section in which it will appear.

3.0 Articles should be submitted to:
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