DRUGS VERIFICATION AND MANAGEMENT SYSTEM

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ABSTRACT

This research is based on the order for consumers to make effective decisions when using drugs, there is the need to make certain information available. The use of drug verification system to provide information on registered pharmaceutical drugs will be of immense help to the country and the world. With the help of this system, the user can search if a prescribed drug is registered. This system is a web-based application developed using Hypertext Pre-processor (PHP) and MYSQL database, the methodology used in the implementation of the system is V-shaped model of System Development Life Cycle (SDLC). This system integrates with registered drugs and their respective details from National Agency for Food and Drug Administration and Control (NAFDAC) and the software developed for the implementation of this research can be used by any drug enforcement agency other than NAFDAC. It also provides solution to help in the fight against counterfeit drugs and majorly unregistered drugs by allowing users to verify the authenticity of the drugs and to report otherwise.

Keywords: Verification, Pharmacy, Drug, Management, Counterfeit

1. INTRODUCTION

With the majority of the world’s population seeking medications for various illness and medical conditions, there is a need for appropriate pharmaceutical drugs. Counterfeited drugs are unauthentic drugs that have been manufactured using wrong quantities or wrong ingredients to either reduce the capacity or invalidate the capacity of drugs. This addition of harmful ingredients leads to drug counterfeiting. Drug counterfeiting has become an economic and social problem for decades as it directly affects human beings due to the unavoidable importance of drugs to life. The World Health Organization (W.H.O) has discovered a terrific growth rate in food and drug faking especially in the developing nations (P-ORC, 2012) which have caused increasing rate of ill-health and death among all level of human development.

Drugs verification and reporting agencies and establishments like National Agency for Food and Drug Administration and Control (NAFDAC) require efficient and effective system for proper drugs management. Their main objective is to safe guard the public health by ensuring that only the right drugs and other regulated products are manufactured, advertised, sold and used. Hence, there is the need to build an application that will help achieve their objectives (National Agency for Food and Drug Administration and Control, 2013). This research will be of paramount importance as it will be designed to address most of the challenges faced by such agencies.

2. STATEMENT OF THE PROBLEM

The major reason that gave rise to this research is the fact that fake drugs have led to treatment failures and death of so many citizens, hence, the need to resolve this by developing a secure and reliable system. It uncovers some of the problems with drugs reporting and access to registered pharmaceutical companies. The aim of this researchis to design and implement drugs verification and management system. Thus the objectives are:

- Register pharmaceutical company with respective trademark and register drugs produced by the pharmaceutical companies.
- Register drugs verification code and verify drugs.
- Handle fake drugs report files and automate the process of drug authentication using appreciated channel.

3. OPERATIONAL DEFINITION OF TERMS

- Database: A collection of related data that can be accessed managed and updated.
- DBMS: Database Management Software that enable the user to define, maintain and control the database.
- Drug: It is referred to as a medicine or chemical substance that is administered to Patients for curative measures.
- Pharmacy: A place where medicine or chemical substances are kept stored and prepared.
- Flow diagram: A diagram that shows connection between different stages of the process of a system.
- Relation: A relation is a named table with columns and rows.
- PHP: Hypertext Preprocessor used as server-side scripting language to link the interface and the database.
- MYSQL: A type of relational Database.
- SDLC: System Development Life Cycle is a set of procedures which serve as a template for generating an individual design process.
4. LITERATURE REVIEW

Counterfeit products threaten public health and safety, reduce jobs and tax bases, and inhibit corporate innovativeness and profitability. The production, distribution, and consumption of counterfeit pharmaceuticals represent a particularly dangerous public health risk; estimates of the numbers of counterfeit pharmaceuticals range from 10 to 15 percent of the world drug supply. Counterfeit drugs indirectly and directly adversely affect health. Indirectly, false drugs hasten the illness and death of consumers who do not receive the appropriate active agent or dosage to treat their conditions, and sub-potent pharmaceuticals that do not kill a disease-causing pathogen can eventually lead to the development of drug-resistant strains, making even the authentic drugs useless. More directly, toxic ingredients in counterfeit pharmaceuticals can cause serious health problems (Fenoff & Wilson, 2009).

Among the factors that encourage drug faking worldwide is corruption and conflict of interests. Corruption is a driving force for poor regulation, which encourages drug faking/counterfeiting. The Management of NAFDAC has resolved that counterfeit medicines must be brought to the barest minimum in the shortest possible time. They have a clear vision, goals and strategies. Their vision is to safeguard public health by ensuring that only the right quality products are manufactured, imported, exported, advertised, distributed, sold and used in Nigeria (Akunyili D. N., 2005).

The World Health Organization (WHO) defines counterfeit drugs as “drugs that have been deliberately or fraudulently mislabeled with respect to identity and/or source”(Akinyandenu, 2013). Counterfeit medications have been defined as "products deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product” (Chambiss, et al., 2012). Examples include medications that contain no active ingredient, an incorrect amount of active ingredient, an inferior-quality active ingredient, a wrong active ingredient, contaminants, and repackaged expired products (Ziance, 2008). Falsified and substandard medicines provide little protection from disease and, worse, can expose consumers to major harms. Bad drugs pose potential threats around the world, but the nature of the risk varies by country, with higher risks in countries with minimal or non-existent regulatory oversight (Countereting the Problem of Falsified and Substandard Drugs, 2013).

5. Health and Economic Consequences of Drug Counterfeiting

The problem of counterfeit drugs has embarrassed the Nigerian healthcare providers and denied the confidence of the public in the nation’s healthcare delivery system. The result of fake drug proliferation has led to treatment failures, organ dysfunction or damage, worsening of chronic disease conditions and death of many Nigerians. Even when patients are treated with genuine drugs, no response is seen due to resistance caused by the previous intake of fake drugs (Akunyili D . , 2005). Counterfeit drugs pose great threats to the attainment of the millennium development goals 4, 5 and 6 which hopes for a reduction in infant mortality, improved maternal health and combating HIV/AIDS, malaria and other diseases (Akinyandenu, 2013).

It denies the Nigerian people the right to safe, effective and quality medicines. Counterfeit drugs rob the country of valued man power resources and economic benefits. Laxity of an ineffective judicial system and widespread corruption are reasons behind the easy production and sale of fake drugs in Nigeria. It enables counterfeit drug producers sell their products cheap to vendors who in turn sell to the consumers. The major factors facilitating the preponderance of fake drugs in Nigeria have been reported to include: the ineffective enforcement of existing laws, non-professionals in drug business, lose control systems, high cost of genuine drugs, greed, ignorance, corruption, illegal drug importation, chaotic drug distribution network, demand exceeding supply amongst many others (Chinwendu, 2008).

6. Reasons behind the Successful Market of Counterfeit Drugs

The reason for why medicines are targeted by counterfeiters has a lot to do with the fact that fakes can now be made relatively easy. The profitability may therefore be at least as good as for narcotics, while the risk is lower due to lack of rules, law enforcement and global cooperation. Even in developed countries, however, the risk of prosecution and penalties for counterfeiting are still inadequate with the exception of the US. It is also relatively easy to sell the drugs on the internet, or in developing countries where the real drugs are expensive, potential consumers are plenty and there is limited regulation and enforcement.

The way medicines are traditionally sold also contributes to their potential to be targeted by counterfeiters. The end-user has little or no knowledge of the product and therefore entirely trusts pharmacies, companies and hospitals. The evolution of social security systems in the western world must also take some responsibility for the success of the market in counterfeit drugs (Wright, 2006).

As states seek to reduce the cost of provision of social security services individuals, particularly those on lower income levels, can see themselves facing increasing drug bills for which they receive less than adequate support. It is almost inevitable that they turn to other, apparently more economical, sources to fulfill their pharmaceutical needs. The evolution of social security systems in the western world must also take some responsibility for the success of the market in counterfeit drugs. As states seek to reduce the cost of provision of social security services individuals, particularly those on lower income levels, can see themselves facing increasing drug bills for which they receive less than adequate support. It is almost inevitable that they turn to other, apparently more economical, sources to fulfill their pharmaceutical needs (Wright, 2006).

7. Roles of Pharmacist in Preventing Distribution of Counterfeit Drugs

Although any product can be counterfeited, an increased ability to enter the supply chain drives counterfeiters to target high-demand, high-priced medications. Medications sold via non-traditional distribution channels such as the Internet, the gray market, and clinics have a higher risk of being counterfeit. Up to 60% of medications purchased online could be counterfeit or substandard (Howard, 2010), and more than 50% of medications purchased online from sites that concealed their actual physical address were found to be counterfeit (Assembly and the Working Groups, 2006-2010).

Nonetheless, thousands of websites sell unapproved and/or counterfeit medications, including the sale of prescription medications without requiring a prescription (Report, Counterfeit
Pharmaceutical Inter-agency Working Group, 2011). The National Association of Boards of Pharmacy (NABP) created a database (i.e., Verified Internet Pharmacy Practice Sites) of online pharmacies that are legitimately licensed and operating on the Internet (National Assembly of Boards of Pharmacy, 2011). The White House announced the formation of a nonprofit organization to educate the public on the risks of purchasing medications on the Internet (Report, Counterfeit Pharmaceutical Inter-agency Working Group, 2011).

A "perfect storm" exists when legitimate suppliers of a high demand, expensive medication are unable to supply the market needs and counterfeiters break into the supply chain because pharmacists are searching for alternative suppliers. Pharmacists can help ensure the integrity of the supply chain by purchasing medications from known, reliable sources, warning patients of the dangers of purchasing medications over the Internet, affirming that distributors purchased the product from the manufacturer or another reliable source, and monitoring counterfeit product alerts. Pharmacists, technicians, student pharmacists, and patients need to be educated about counterfeit medications (Chambliss, et al., 2012).

8. The Fight against Fake Drugs by NAFDAC in Nigeria

National Agency for Food and Drug Administration and Control (NAFDAC) is a Nigerian government agency responsible for regulating and controlling the manufacture, importation, exportation, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, chemicals and pre-packaged water. Its creation was inspired by a 1988 World Health Assembly resolution requesting countries help in combating the global health threat posed by counterfeit pharmaceuticals and amidst growing concerns about the growing problem of fake and poorly regulated drugs in Nigeria. In December 1992, NAFDAC's first governing council was formed. In January 1993, supporting legislation was approved as legislative Decree No. 15 of 1993, and January 1, 1994, NAFDAC was officially established, as a “parastatal of the Federal Ministry of Health”. NAFDAC replaced an earlier Federal Ministry of Health body, the Directorate of Food and Drug Administration and Control, which had been deemed ineffective, largely due to a lack of laws concerning fake drugs and political issues(National Agency for Food and Drug Administration and Control, 2013).

The objective of any drug regulatory agency is the protection and promotion of public health. The enforcement directorate arm of NAFDAC established under the provisions of the counterfeit and fake drugs (miscellaneous provision) act is charged with the responsibility of enforcing the provisions of the counterfeit and fake drug decree, which includes:

- Conducting surveillance on companies and persons suspected to be violating NAFDAC regulations and carrying out investigations on such persons and companies.
- Paying unscheduled visits to all ports of entry and border posts and interrogation of suspects.
- Sampling of NAFDAC regulated products to the laboratory and compilation of case files.
- Raiding of drug hawkers and destruction of fake and spurious regulated products.
- Coordination of activities of state task force.

The establishment of the task force in Nigeria was seen as a welcomed development for the fight against fake drugs (Chinwendu, 2008).

9. The New Drug Distribution Guidelines and Responsibilities

The drug distribution guidelines have erected pillars and clearly delineated channels of distribution with roles and responsibilities. The manufacturers and importers occupy the apex of the ladder. Their role is to make drugs available and sell only to Mega Drug Distribution Centers (MDDC), State Drug Distribution Centers (SDDC), and National Health Programs. The next Level below this position is occupied by the MDDC and SDDC. While the MDDC is private sector-driven, the SDDC is meant to service the public sector at the state level. The SDDC will cater for all public health facilities in the state and is allowed to sell to National Health Programs (where indicated) and to wholesalers (Federal Ministry of Health, 2012).

The MDDC is allowed to sell to wholesalers only. Wholesalers occupy a pivotal position in the value chain. Purchases could be made from MDDC or SDDC but not from the manufacturers or importers. The wholesalers can sell to community pharmacies, public and primary healthcare facilities, and private health institutions. With this functions clearly spelled out, there is really no need for a wholesaler to engage in retailing as it is now. At the bottom of the distribution ladder, we have community pharmacies, public and private health institutions who sell directly to the consumers. The community pharmacies are allowed to sell to private health facilities. Other provisions that affect pharmacists directly include all drug retailing institutions and facilities (Federal Ministry of Health, 2012).

The Pharmacist Council of Nigeria (PCN) is mandated to register private hospitals, local government clinics and any facility that directly or indirectly make use of drugs, poisons, and related products. The law to register and operate community pharmacy outlets mandates only pharmacists. It is a clear departure from the previous system where anything goes. To be a superintendent pharmacist, one must have at least five years post qualification experience to qualify for retail and ten years for wholesale. The position and importance of pharmacists are clearly spelled out in the new structure in addition to the operations of the MDDC and the SDDC. The guidelines are being operated based on the existing PCN and NAFDAC laws. This is necessary to bring sanity to the system plagued by activities of charlatans and non-professionals in the sector (Federal Ministry of Health, 2012).

The current guideline will change the concept of distributors from glorified retailers with limited resources and coverage to big organizations with solid asset base, wide coverage and state of the art logistic information technology and management systems. It will make distributors to be specialized and formidable with huge capital and technology to meet the ever-increasing need for drugs and pharmaceuticals (Onyebuchi, 2015).

10. Analysis of the Existing System

Conventional drug systems are generally limited to information and management systems. The systems consist of data entry, retrieval, monitoring the facility and generating of reports among others (Bint Muhammad, 2010). The system only allows retrieval and review of decisions previously made on a drug item. Another system allows the user to browse for registered pharmaceutical
drugs and also verify if the drug is authentic, the administrator has the admin window to sign in to the backend (Kester, Owusu, & Hatsu, 2015) but does not register pharmaceutical companies. A system was also developed to download as a file, which helps users to know when to take their drugs but it lets the user to order drugs which may promote addiction. Although the interface is fluid and fast, it may not be simple enough for users and it does not verify drugs for authentication (Onuiri, Oyebanji, Fayehun, & Chukwujioke, 2016). More efforts should be put into researching the safety of drugs. In daily practice, many signals of potential counterfeit drugs are not followed by a systematic process of verification. The medical literature is probably by far the most effective system for initial detection of fake drugs. The current emphasis on the costly procedures of mandatory reporting should shift towards studies for testing a hypothesis (Stricker & Psaty, 2006).

11. Drug Management and Information System
Drug management and Information System consists of a database of approved drug products and other medical related items or devices in a market place set up by a recognized regulating body. Approval from the regulating body must be obtained by drug merchants and retailers before a new product can be allowed to be traded in the market place. This often serves as a reference used for tracking, detection and reporting of counterfeit drugs.

12. Working With MYSQL Database
SQL simply stands for Structured Query Language which is a database sublanguage used in querying, updating and managing relational database. Derived from an IBM research project that created Structured English Query Language (SEQUEL) in the 1970s, SQL is an accepted standard in database products. Although it is not a programming language in the same sense as C or PASCAL, SQL can be used in formulating interactive queries or be embedded in an application as instructions for handling data. The SQL standard also contains components for defining, altering and controlling data. MYSQL is a fast, easy to use RDMS being used for many small and big businesses.

13. System Development Life Cycle (SDLC)
There are many definitions for well-known term Life Cycle. They diverge according to the branch. A life cycle is a description of the distinct phases through which each product passes during its product life. This includes phases such as requirements definition, concept design, production, operation, maintenance, etc. A life cycle is a plan, composed of several phases, aimed at maximizing the efficient development of a quality, usable product. A life cycle is a set of procedures, some required and others optional, which serve as a template for generating an individual design process. The plan is not meant to be a strict step by step process, but rather a flexible process ensuring that users, designers, and management are directly involved in the development of the final product (Pavel, 2004)

14. Waterfall Model
It is plan-driven model with separate and distinct phases of specification and development. There are separate identified phases in the waterfall model: Requirements analysis and definition, System and software design, Implementation and unit testing, Integration and system testing. Operation and maintenance. The main drawback of the waterfall model is the difficulty of accommodating change after the process is underway. In principle, a phase has to be completed before moving onto the next phase (Sommerville, Software Engineering, 2011). Fig 2.1 illustrates the waterfall model as shown by (Sommerville, Software Engineering, 2011).

15. Incremental Development Model
Specification, development and validation are interleaved. It may be plan-driven or agile. The amount of analysis and documentation that has to be redone is much less than is required with the waterfall model; the main phases are specification, development and validation (Sommerville, Software Engineering, 2011). This process is characterized with flexibility and revision whenever necessary in all phases. The process will begin in an initial plan and concluded with interaction among the various phases and component. Fig 2.1 illustrates the waterfall model as shown by (Sommerville, Software Engineering, 2011).

16. Evaluation
Evaluation indicates a judgment of how well the system strengths correspond with respect to the action of verifying drugs in a fast and efficient way. The main objective of this project is to create a system which will be beneficial to all stakeholders for identifying authentic drug products, using PHP as the front end and MYSQL as the back end. The system should be able to handle pharmaceutical companies in Nigeria, such as reporting of fake drugs, verification of fake drugs and drugs confirmation code under the case study of National Agency for Food and Drug Administration and Control (NAFDAC). The system will include a feedback layout for drug confirmation.

17. System Development Life Cycle
V-shaped model is technically appropriate in solving complex solutions; a convenient and simple approach may be used though. V-shaped model is suitable for project having well-defined requirements that are unlikely to change significantly over the life of the project. In this methodology, the requirements were first listed, then the software was written, and finally it was tested and delivered. It also permits testing in three stages; these are unit testing, integration testing and acceptance testing. A typical V-lifecycle consists of the following phases being executed sequentially:

- Requirements
- System Specification
- Unit design
- System design
- Development
- Unit testing
- Integration testing
- Acceptance testing

17.1 Requirement Specification
In order to design and implement an efficient system, there are basic requirements that should be considered; the requirements of this system are as follows:

- The system should have security access control that enforces users to sign in before accessing any feature of the system.
- For any member to access the system he/she should be registered as a user on this platform.
The system should have a staff management page through which the system admin can administrate the entire system. The system should have a list of all users on its database. The system should provide an easy search window for easy reporting of drug case.

17.2 Software Specification
This system will be a web-based application and will be implemented on:
- MYSQL: Relational Database
- HTML (Hypertext Markup Language)
- Bootstrap: A CSS framework
- PHP (Hypertext Preprocessor): Will be used as server-side scripting language to link the interface and the database.
- WAMP Server: To be used as the local host.

17.3 System Design
The implementation stage of software development is the process of converting a system specification into an executable system. It always involves processes of software design and programming but, if an incremental approach to development is used, it may also involve refinement of the software specification. A software design is a description of the structure of the software to be implemented, the data models and structures used by the system, the interfaces between system components and the algorithms used. (Sommerville, Software Engineering, 2011).

Figure 1 Use case diagram

The Figure 1 Use case diagram sequence above represents objects interacting with one another and it shows how each process interacts with the other and the order in which they interact. This illustrates how the system user (actor) interacts with the system.

When the actor launches the application, the actor is taken to the index page, i.e. the Home page of the application. The actor can then navigate to other pages to retrieve required information.

17.4 Implementation
After a complete development of the system, this chapter presents the result of the work. The design specification in chapter three was used to develop the system. The system developed was tested, ran on a local server. In the implementation of this project, PHP (Hypertext Pre-processor) and MYSQL database were used. PHP is a general purpose server side scripting language originally designed for web development to produce dynamic web pages. It has also evolved to include a command line interface capability and can be used in stand-alone graphical applications. MYSQL is a relational database management system written in C and C++ that runs as a server providing multi user access to a number of databases. MYSQL is used basically to create a relational database structure on a server in order to store data or automate procedures. Figure 2 is the Admin dashboard page which shows various action that take place on this framework. While Figure 3 is the Report form, for submitting reports on the framework.
18. CONCLUSION

The main objective of this project was to register drugs verification code and verify drugs, as well as register pharmaceutical companies with respective trademark and register drugs produced by the pharmaceutical companies. These objectives were achieved. The third objective was to handle fake drugs report file which was also achieved. The system also has reasonable response time which is another objective that was also achieved.

The system is a web-based application running on a local host, this method therefore has all the strengths and weaknesses associated with a web-based system. One of the weaknesses of this system is that the admin cannot view the location in which the report was sent from, because the system is an offline system.

The strengths of the system lies in the speed of the system, as the system only requires a certain number of codes before giving out the output. Another strength is not only verification of drugs but report filing which will make drug verification by drug enforcement agencies more flexible and reliable, and also the user interface (UI) is very easy to use. The administrative application was tested on the major browser platforms (Mozilla Firefox, Google chrome, Microsoft internet explorer, and opera) to ensure that the user experience is uniform throughout the different browsers. The software developed for the implementation of this research can be used by any drug enforcement agency other than NAFDAC, which was used as a case study.

RECOMMENDATION

In order to cover up the system’s weaknesses, several steps can be taken to further improve upon it. Some of these steps taken can complement the system. For instance, system users should ensure safe keeping of password since it provides access to the system. System client should login from time to time to see update on drugs report. Places with no access to network will not have access to the system, hence the need to further develop a mobile application for the system. After users have sent in complaints about unverified drugs, there should be a view location page where the admin can view the location in which the report was sent from, to help locate pharmacies or hospitals that market or sell these counterfeited or unregistered drugs.

This system can be enhanced by adding features, capabilities and functions in response to new technologies, upgrades, new requirements or new problems. Since the environment in which the application would be running is dynamic, it has been made to suit whatever requirements that may change in the long run. Based on the results produced, the system is shown to be effective at verifying drugs and filing reports which makes drug verification more effective and reliable. The existing types of a drugs verification management were discussed and it was narrowed down to a drug verification and reporting system which is the main aim of this project.

The resulting software would be of benefit to individuals who wish to verify drugs by typing the drug verification code on the system. The software has been able to meet its objectives and will make drug verification and report management more successful. When a good relationship is developed between drug manufacturers, retailers, consumers and the government, it would lead to a successful implementation of drug verification systems.

With the global counterfeit problem on the rise, the system is designed to be beneficial to all stakeholders and hence, the need for it to be standardized for identifying drug products.

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