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User Satisfaction and Acceptability of Dialogue Systems for Detecting Counterfeit Drugs

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Abstract**—**The menace of counterfeiting pharmaceuticals/drugs has become a major threat to consumers, healthcare providers, drug manufacturers and governments. It is a source of public health concern both in the developed and developing nations. Several solutions for detecting and authenticating counterfeit drugs have been adopted by different nations of the world. In this article, a dialogue system-based drug counterfeiting detection system was developed and the results of the user satisfaction and acceptability of the system are presented. The results show that the users were satisfied with the system and the system was widely accepted as a means of fighting counterfeited drugs.

Keywords**—**Counterfeiting, dialogue system, drugs, voice application.

I. Introduction

WHAT constitutes a counterfeit/fake drug differs from one nation to the other [1]. However, according to the World Health Organization (WHO), "A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging" [2]. According to the Nigerian Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions), a fake drug is [3]:

- Any drug product which is purported to be; or
- Any drug or drug product which is so coloured, coated, powdered or polished that the damage is concealed or which is made to appear to be better or of greater therapeutic value than it really is, which is not labeled in the prescribed manner or which label or container or anything accompanying the drug bears any statement, design, or device which makes a false claim for the drug or which is false or misleading; or
- Any drug or drug product whose container is so made, formed or filled as to be misleading; or
- Any drug product whose label does not bear adequate directions for use and such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of use; or
- Any drug product which is not registered by the Agency in accordance with the provisions of the Food, Drugs and Related Products (Registration, etc) Decree 1993, as amended.

This monster, if not checked using a combination of methods, portends a grave danger to the entire world population. Consumers, healthcare providers, drug manufacturers and governments all have one or more things at stake if the menace is not tackled with all armories.

However, there have been several detection and authentication methods used in curtailing and mitigating the effects of counterfeit drugs. Some of these methods, however, require specialized equipment and expertise, and some are not easily accessible by the masses. This paper presents a dialogue-based method to augment the existing ones. The results of the user satisfaction carried out on the system are also presented. The proposed method has the advantage of being usable by the non-literates in Africa where the level of literacy is very low [4], [5]. It is also suitable for the visually impaired and can be implemented in the various indigenous languages of Africa. In addition, it can provide eyes-free interaction, and serve as a great aid for the physically challenged. The approach also exploits the ubiquitous and widespread availability of mobile phones to reach a vast majority of the world population, Nigerians inclusive.

II. Technologies Developed Against Counterfeiting

Several technologies have been developed to detect and control counterfeit drugs. Among them are the following [6]:

Sanofi-Aventis Security Label (SASL): Developed exclusively for sanofi-aventis by one of the world's leading manufacturers of security paper (bank notes). This security label is a tamper-proof security label, measuring 25x15 mm, attached to the packaging of high-risk products.

Traceability Technology Based on Bar Codes (Datamatrix): The objective for setting up this code is to ensure traceability of each box in its supply chain to the pharmacist until the end-user, the patient.

Other methods are [1]:

Simple Chemical Approaches: These are simple and low-cost approaches to rapidly identify counterfeit drugs in developing countries. The techniques applied here are thin layer chromatography (TLC) and colorimetry. TLC allows the active ingredient to be recognized by comparison with a known drug standard. This approach is cheap, specific and sensitive. Similarly, colorimetry is rapid and highly specific [7].

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Bulk Property Testing: Bulk properties of matter include weight, density, solubility, viscosity, refractive index and optical rotation, as well as physical description of the tablets. These can be easily measured by low cost, rugged equipment and can provide simple tests for detecting counterfeit drugs [8].

The GPHF Mini-lab: This is an initiative of German Pharma Health Fund (GPHF). This consists of four stages used to test the quality of drugs [9]:

(a) Visual inspection of solid dosage forms and packaging material;

(b) Tablet and capsule-disintegration test for a preliminary assessment of any deficiencies related to drug solubility;

(c) Simple colour reactions to identify drugs; and

(d) Semi-quantitative TLC to check for quantities of drug.

Chromatography: The methods used include gas chromatography (GC), High-performance liquid chromatography (HPLC), Thin layer chromatography (TLC) and capillary electrophoresis (CE).

Hyphenated Techniques: The methods used under this technique are: gas chromatography-mass spectrometry (GC-MS), liquid chromatography-mass spectrometry (LC-MS) and ICP-MS (inductively-coupled plasma-mass spectrometry).

Raman Spectroscopy: Raman spectra are obtained by irradiating a sample with a powerful laser source of visible or infrared monochromatic radiation. During the irradiation process, the spectrum of the scattered radiation is measured at an angle, usually 90u, with a spectrometer [10].

Tensiography: In this method, a forming pendant drop is illuminated from within by an optic fibre generator and receiver.

Another method is that of isotopic characterization.

A. Categories of Measures for Authenticating Counterfeit Pharmaceuticals by Consumers at the Point of Sale

These measures used for authenticating counterfeit pharmaceuticals can be categorized into three [11]:

i. **Overt Security Features:** These security features are noticeable and visible and do not require instruments to detect them.

ii. **Covert Security Features:** These security features are hidden, not directly noticeable and need a simple instrument (e.g. UV lamp, magnifier) to identify them.

iii. **Forensic Security Features:** These are very secretive measures. They are available on a 'need to know' basis only. They may include the addition of a taggant material or changes to a substrate or print which requires specialized instrumentation to detect them.

III. National Agency For Food and Drug Administration and Control (NAFDAC)

The National Agency for Food and Drug Administration and Control (NAFDAC), regulates and controls the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals/detergents and medical devices [12] in Nigeria. The agency was established with Decree No. 15 of 1993. According to Erhun et al. the agency performs the following functions [13]:

a) Regulate and control the importation, exportation, manufacture, advertisement, distribution, sale, and use of food, drugs, cosmetics, medical devices, bottled water and chemicals;
b) Conduct appropriate tests and ensure compliance with standard specifications designated and approved by the council for the effective control of the quality of food, drugs, etc., as well as their raw materials and production, including processes in factories and other establishments;
c) Undertake appropriate investigations into the production premises and raw materials for food, drugs, etc. and establish relevant quality assurance systems, including certification of the production sites and regulated products. (d) Undertake inspection of food, drugs, etc;
d) Compile standard specifications and regulations and guidelines for the production, importation, exportation, sale and distribution of food, drugs, etc;
e) Undertake registration of food, drugs, etc; and
f) Establish and maintain relevant laboratory or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions.

A. Measures and Interventions by NAFDAC at Controlling Fake Drugs

The following are the measures and interventions by NAFDAC in controlling fake drugs in Nigeria [3]:

Drug Inspection: The rationale behind drugs inspection is to ensure that quality is built into the product and not just tested for, in the finished product. It is also seen as a vital component for control of pharmaceuticals.

Drug Product Registration: This is a mechanism for checking drug faking and adulteration. It is a valuable means used by government to control the ways products are manufactured and offered for sale in Nigeria to ensure safety and good quality of the products.

Enforcement Activities: NAFDAC has an enforcement directorate that makes sure that standards are followed by drug manufacturers. The directorate ensures that drugs manufactured are according to standards. The directorate also ensures that fake drugs are confiscated and destroyed.

Public Enlightenment: The agency also carries out public enlightenment in a bid to sensitize the consumers about the menace of fake drugs. This consists of "dialoguing, educating as well as persuasion through different means such as jingles on television, prints and electronic media, alert notices for consumers, use of billboards, publications of the lists of all

identified fake regulated products in the media, use of workshops, seminars and advocacy to stakeholders.

Another recent effort by NAFDAC is the use of short message service (SMS).

Use of Short Message System: NAFDAC, in collaboration with telecommunications service providers in Nigeria provides a short message system of authenticating drugs. When a consumer wants to buy a drug, he/she would need to look for the NAFDAC assigned pin and send it to "35383". A message will then be sent back indicating whether the product is original or not [14].

IV. Dialogue System/Voice Application

According to Bickmore and Giorgino, "dialogue is discourse between two or more parties, with the quintessential example being a conversation between two people or, between a person and a computer" [15]. Alan et al. also define dialogue as a conversation between two or more parties [16]. A dialogue system or a voice application can therefore, be defined as a computer system that communicates with a human.

A. Voice Application and How It Works

1. Voice Application

A voice application is a collection of one or more VoiceXML documents. A VoiceXML document is composed of one or more dialogues and a single VoiceXML document serves as the application entry point [17]. The components of VoiceXML application are [18]:

Mobile or Land Line Phone: The user places a call to application using any mobile phone or a land line phone.

The Voice Gateway: A VoiceXML gateway is an operational platform on which VoiceXML services run. As a gateway, it bridges the world of telephony to other networks such as Internet and data networks. It ensures the correct development of services in terms of usability, operability and maintenance. The VoiceXML gateway is responsible for:

• **Processing calls:**

* It accepts/rejects incoming calls.
* It initiates outgoing calls.
* It transfers calls.

• I**nteracting with speech related resources**: ASR, TTS, DTMF

* Engaging users through audio prompts that are either prerecorded or synthesized from text (TTS – Text To Speech)
* Collecting and validating responses either through DTMF or through voice (ASR – Automatic Speech Recognition)

• Retrieving the VoiceXML pages and fetching associated sub-components

• **Interpreting VoiceXML content**: Interpretation of VoiceXML content is done by a voice browser. A voice browser is composed of an interpreter which parses VoiceXML documents and interfaces to access to external resources (Automatic speech recognition (ASR), Text-to-speech (TTS), DTMF recognition, Call handling). The interpretation of VoiceXML pages is done using the form interpretation algorithm (FIA). The form interpretation algorithm determines the order of execution in a VoiceXML form or menu. The FIA cycles through all of the fields in the form, asking the caller to supply values for each unfilled field. The FIA provides the default sequence of processing fields within a form; and thus hides the procedural aspects of form processing from the dialogue designer.

- The VoiceXML language supports a speech grammar format, namely the XML form of the W3C Speech Recognition Grammar Specification. In VoiceXML terminology, grammar consists of list of words and sentences recognized by the ASR engine as valid inputs.
- Caching frequently used resources.
- The VoiceXML gateway usually interacts with other software components such as the Database, Application servers, and Web servers.

Application Server: The application server actually hosts the application. It accepts the HTTP request from the voice browser and sends response. The response is dynamically generated VoiceXML pages. The application server is responsible for implementing the business logic, accessing the database and providing the data to the voice browser in form of VoiceXML.

2. How a Voice Application Works

Just as HTML is used to create visual application, VoiceXML is a markup language used to create voice application. With a traditional webpage, a Web browser will make a request to a Web server which in turn will send an HTML document to the browser to be displayed visually to the user. With a voice application, it is the VoiceXML Interpreter that sends the request to the Web server, which will return a VoiceXML document to be presented as a voice application via a telephone [19].

V. Architectural Diagram for VoiceXML Application

A VoiceXML platform is the foundation for developing and operating voice automation applications. During human-computer interaction, it executes the commands and logic specified by applications written in VoiceXML. It also provides the speech processing capabilities (speech recognition, speech synthesis, voice authentication, etc). VoiceXML platform architecture is based on HTTP protocol and uses both phone and Internet networks. The Web server is often connected to a database which the user can question and update.

A critical look at the VoiceXML gateway in Figure 1 shows that the computer is equipped with a telephone card that is able to manage incoming and outgoing calls, a connection with Internet network, and a VoiceXML interpreter charged to carry out all the orders programmed in this language. Just as a Web browser renders HTML document visually, a VoiceXML Interpreter renders VoiceXML documents audibly. VoiceXML Interpreter can be thought of as a telephone-based voice

browser. Automatic Speech Recognition (ASR) engine, recording of audio files and Dual Tone Multi Frequency (DTMF) telephone keyboard are the inputs users interact with. Text-to-Speech (TTS) voice synthesis and restitution of pre-recorded audio files are the outputs the machine can use ([20], [21]).

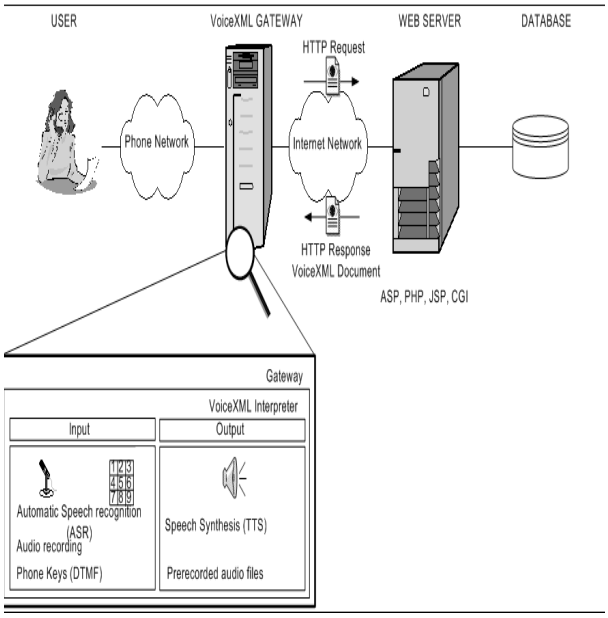

Fig. 1 VoiceXML Platform Architecture [20]

VI. Methods

The system was developed using Voice Objects Desktop for Eclipse 11 integrated development environment (IDE). Voxeo Prophecy 10 was used as the implementation platform, while MySQL was used as the relational database management system (RDBMS) that houses the numbers that uniquely identify the drugs available for selection by the user of the drugs. MySQL also stores information about the name of the drugs and the producer of the drugs. X-lite soft phone, was used for calling the application for testing. In measuring the user satisfaction and acceptability of the prototype system developed, a questionnaire used in a related study by Kwan and Jennifer [22] and user satisfaction survey used in Marilyn et al. [23] were adopted. "The measures used in the questionnaire have both face and content validities. In terms of face validity, all measures were constructed by experts who have more than 10 years of experience in usability tests of mobile and speech user interface (SUI) applications. In terms of content validity, the measures cover all dimensions of usability in telephony applications as defined by the European Telecommunications Standard Institute (ETSI)" [22]. Usability in telephony applications is defined as the level of effectiveness, efficiency, and user satisfaction with which a specific user achieves specific goals in a particular environment [24]. Effectiveness is how well a goal is achieved in the sense of absolute quality. Efficiency is the amount of resources and efforts that are used to achieve the specific goal, while satisfaction is the degree of users' approval of a specific system [22]. The only modification done to the questionnaire by Kwan and Jennifer [22] was the changing of certain adjectives to their simpler synonyms so as to aid the subjects' understanding.

VII. Subjects

Twenty nine subjects participated in the evaluation. This is more than 16 used by Kwan and Jennifer [22]. Seventeen or 58.6% are females while 12 or 41.4% are males. Thirteen or 44.8% are within 15-20 age range. Eleven or 37.9% lie between 21-30 age range, three or 10.3% are between the age range of 31-40 while two or 6.9% are between 41-50 age range. 10% rated themselves as 'novice' in terms of experience/skill in the use of computer software while 24% rated themselves as average. 52% rated their experience/skill as 'good' while 14% rated themselves as 'experts'. 14% use cellphone/PDA to enhance their work while 69% use laptop/notebook. 7% use desktop/PC while 10% did not respond to this question. 93% own a mobile phone/PDA while 7% did not respond to the question. 21% have owned a mobile phone/PDA for the past 6 months during the time of evaluation. 7% have owned their devices for 1 year, 10% for 2 years and 62% for more than 2 years. 3% make calls 1-2 times a day, 14% 3-4 times a day, 17% 5-6 times a day and 66% more than 7 times a day.

VIII. Dialogue Flow of the Prototype System

The snapshot below shows part of the dialogue flow of the prototype system generated from VoiceObjects. The system welcomes the user and relays information about the functionality it provides. The user can either choose to verify the genuineness of a drug or get other information relating to NAFDAC activities and offices in Nigeria. If the user picks the option of validating a drug, he/she would be required to enter the registration number of the drug assigned to it by NAFDAC by pressing the keys on the telephone keypad. Once that is done, the system will access the database to see if the information entered is available. If not, the system relays information to the user about the non-existence of the particular drug information in the database. If the information is available, the system responds by outputting the drug information and lets the user know whether the drug is a counterfeit of a genuine one.

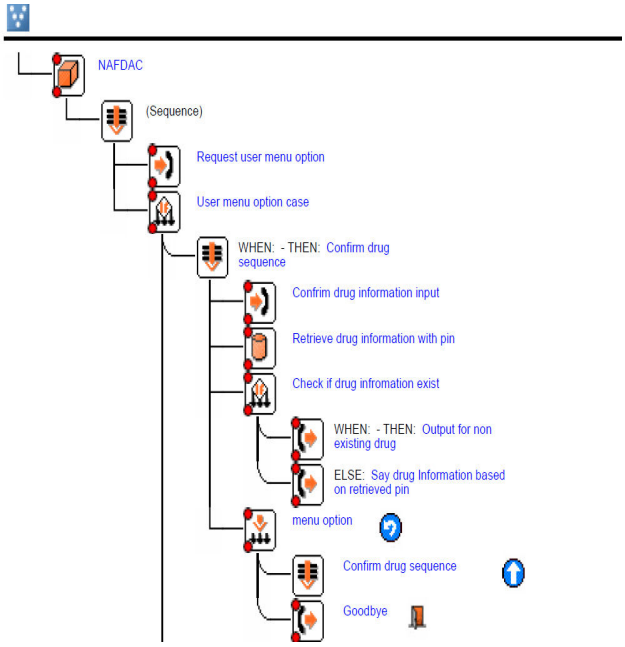

Fig. 2 Dialogue Flow of the Prototype System

Fig. 3 below shows how the prototype system is called with Prophecy in-built soft phone.

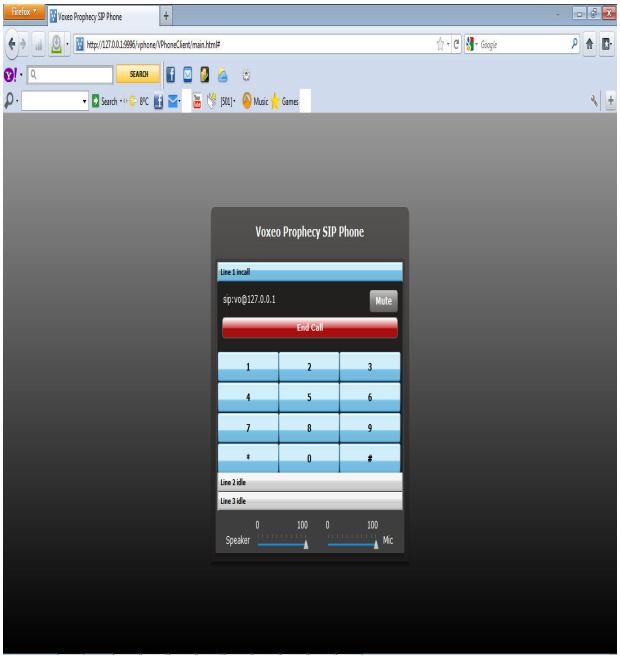

Fig. 3 Calling the Prototype System With Prophecy In-built Soft Phone

IX. Results

97% supported the use of cell phone/PDA in healthcare delivery while 3% did not, giving inadequate training as their reason. Numerous usability studies suggest that system with good usability should have a mean rating of 4 on a 1-5 scale and 5.6 on a 1-7 scale [25]. In this work, the questionnaire was scaled on 1-5 and the mean rating was 4.18 which is higher than 4 suggested for good usability studies. This result suggests that the users were satisfied with the system. In response to the question "Would you support the use of cell phone/PDA n healthcare delivery?", 97% responded in the affirmative while only 3% disapproved of it. In response to the question "Would you like NAFDAC to provide this kind of system to verify the genuineness of drugs you often buy?", 28 (96.5%) replied in the positive while only 1 (3.5%) replied in the negative and no reason was given. Those that reported in the positive gave reasons such as:

i. Because it is instant unlike text messages that may not be instant at times.
ii. The ease of use.
iii. It will help save lives.

X. Conclusion

Counterfeited drugs have been identified to be a source of concern to consumers, healthcare providers, drug manufacturers and governments both in the developed and developing nations. Although several approaches have been adopted to fight the menace, this article has presented a dialogue system-based approach that exploits the increase in the usage of telephones, especially mobile phones worldwide. The user satisfaction and acceptability of the system were also carried out, and based on the results; it is quite clear that the users were satisfied with the system and the system was widely accepted as a means of fighting counterfeited drugs. This system will provide a cost-effective and ubiquitous means of detecting counterfeited drugs and compliments the existing ones. It is also suitable for the visually impaired and can be implemented in the various indigenous languages of Africa. In addition, it will provide eyes-free interaction and serve as a great aid for the physically challenged.

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