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Usability of home cholesterol test kits and their impact on patients' decision

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USABILITY OF HOME CHOLESTEROL TEST KITS AND THEIR IMPACT ON PATIENTS' DECISION

A Thesis

Submitted to the Graduate Faculty of the
Louisiana State University and
Agricultural and Mechanical College
in partial fulfillment of the
requirements for the degree of
Master of Science in Industrial Engineering

in

The Department of Industrial Engineering

By
Deepti Surabattula
B.E., Andhra University, 2002
May 2005

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TABLE OF CONTENTS

ACKNOWLEDGEMENTS	ii
LIST OF TABLES.....	v
LIST OF FIGURES.....	vi
ABSTRACT.....	vii
1 INTRODUCTION.....	1
2 LITERATURE REVIEW	3
2.1 Home Health Tests.....	3
2.2 Cholesterol Tests and Their Functions.....	5
2.3 Human Factors in FDA.....	8
2.4 Usability: Definition.....	12
2.5 Problems Faced by the Aged Population while Using Home Testing Devices	14
2.6 Heart Attack Risk: Women Vs Men.....	17
3 RESEARCH OBJECTIVES AND HYPOTHESES.....	20
3.1 Research Objectives.....	20
3.2 Conceptual Model... ..	20
3.3 Research Hypotheses.....	23
4 METHOD	25
4.1 Experimental Design.....	25
4.2 Participants.....	25
4.3 Testing Materials and Tools.....	25
4.4 Procedure.....	26
5 RESULTS	28
5.1 Hypothesis 1	30
5.1.1 Case 1.....	31
5.1.2 Case 2	32
5.1.3 Correlation between Laboratory Results and Test Results	33
5.2 Hypothesis 2	35
5.3 Hypothesis 3.....	37
5.3.1 Usability Questionnaire	38
5.3.2 Comparison Questionnaire	39
5.3.3 Post – Questionnaire	41
5.3.4 Video Analysis.....	42
5.3.4.1 Video Analysis Results.....	43
5.4 Post Hoc Analysis.....	46

5.4.1 Correlation between the Significant Errors Committed while Using the Test Kits and the Difference between the Laboratory Results and Test Kit Results.....	46
5.5 Subjective Comments from Users	47
6 DISCUSSION	49
7 CONCLUSIONS AND RECOMMENDATIONS.....	56
7.1 Conclusions.....	56
7.2 Recommendations.....	57
REFERENCES.....	58
APPENDIX	
A DEMOGRAPHIC QUESTIONNAIRE.....	62
B USABILITY QUESTIONNAIRE – AccucheK® <i>Instant plus</i> ® (DIGITAL DISPLAY).....	64
C USABILITY QUESTIONNAIRE – HOME ACCESS® INSTANT CHOLESTEROL TEST (METER BASED TEST).....	66
D COMPARISON QUESTIONNAIRE.....	68
E POST – TEST QUESTIONNAIRE.....	71
F VIDEO – ANALYSIS WORKSHEET.....	75
G RESULTS OF KRUSKAL WALLIS TEST.....	76
H DATA USED FOR STATISTICAL ANALYSIS.....	77
I DISCRETE ACTION CLASSIFICATION – SWAIN & GUTTMAN (1983).....	91
J ACCUCHEK® <i>INSTANT PLUS</i> ® INSTRUCTION CARD.....	92
VITA	95

LIST OF TABLES

2.1	Important cholesterol numbers.....	6
5.1	Demographic Statistics.....	29
5.2	Case 1: <150 = 149mg/dL and <120 = 119mg/dL.....	32
5.3	Case 2: <150 and <120 = laboratory results or 149/119 whichever is closer.....	32
5.4	Correlation between Laboratory results and test kit results.....	34
5.5	Results of Wald test for individual effects – considering gender as an effect.....	35
5.6	Predicted P values for each option when the cholesterol level is in the range of 119 mg/dL and 254 mg/dL.....	36
5.7	Results of ANOVA – Usability questionnaire.....	39
5.8	Results of ANOVA – Comparison questionnaire.....	40
5.9	Results of ANOVA – Post questionnaire.....	41
5.10	Significant errors in each of the test kits.....	43
5.11	Results of correlation Analysis for video analysis validation.....	43
5.12	Results of paired T-Test for total errors and total significant errors.....	44
5.13	Results of paired T-tests for the different categories of errors.....	44
5.14	Correlation analyses between the significant errors and errors in test results.....	46

LIST OF FIGURES

2.1	New 510(k) paradigm as given by the FDA.....	11
2.2	Flow chart showing the various divisions of system acceptability.....	13
2.3	Factors defining the usability of home health devices.....	15
3.1	Conceptual model of the usage of home cholesterol test kit.....	23
4.1	Flow chart of the experimental procedure.....	27
5.1	Graph showing the predicted P values for men and women.....	36
6.1	Instruction card for Accuchek.....	51
6.2	The ‘STOP’ sign as in the instructions for Instant cholesterol.....	52

ABSTRACT

Release of home health testing kits into the market has enabled people to take care of their own health. Misinterpretation of results and delays in treatments are the major concerns of the doctors. In the present study, two cholesterol test kits, Accucheck® *Instant plus*® and Home Access® Instant Cholesterol Test, were compared on the basis of user performance, accuracy, and the patient's future medical decisions based on the test results. The study was conducted with 30 participants, 15 men and 15 women. Participants tested their overall cholesterol level with both kits. In addition, a clinical cholesterol evaluation, the medical gold standard, was performed. The usability of both test kits was evaluated through questionnaires, user task performance, and comparison with the clinical evaluation. Participants were questioned on how they would use the information once they had seen the result from the first test kit.

Results of the study found that regardless of the kit used, participants always found the first kit used as the more usable kit. Use of both kits resulted in participants committing a number of errors. In both cases, errors were primarily attributed to poorly written procedural instructions. Since the literature raises the question of test kit accuracy, the home health test kit results were compared to the clinical results. Inaccuracy of the test kit results did not depend on the type of the test kit used; however, the Accucheck® *Instant plus*® resulted in a greater correlation between the clinical results and test kit results regardless of the number of user errors. When participants were asked to provide a decision on future health care, predominate number of participants said they would change their lifestyle rather than visit a doctor regardless of their cholesterol level. A nominal logistic statistical prediction profiler test found that as the cholesterol level

increased, participants only changed their decision from that of doing nothing to just changing their lifestyle. This finding highlights physicians' concerns that patients may delay treatment for potentially serious conditions even when they have the available results. Further studies with larger sample sizes are needed to further evaluate these initial findings.

1. INTRODUCTION

A home health test kit is a medical test approved by the United States Food and Drug Administration that can be purchased without a prescription and used in the privacy of the individual's home. These tests first appeared in the 1940s for testing glucose level in Diabetic patients. At that point, home health testing was primarily used for monitoring the status of medical ailments rather than for patient self-diagnosis and treatment (Gimino & Liang, 1998). Today, the FDA states there are approximately 500 approved at home tests and this does not include tests available on the Internet that have not been approved (Sims,2003). The most popular home health test is the pregnancy test which was introduced in the 1970s (Valanis & Perlman, 1982). Presently, test kits are available for testing blood glucose, pregnancy, total cholesterol, ovulation, drugs of abuse, colorectal disease, HIV and others.

Home tests are being used for monitoring medical ailments as well as to diagnose health conditions. According to Lynne T. Shuster, M.D, a general internist and associate medical editor for Mayo Clinic Women's health source newsletter, these tests help people have a better knowledge about their health condition and take better care about themselves (Shelton, 1999). It is also potentially a less expensive alternative to visiting the doctor's clinic. Home health tests are generally used for doctor recommended monitoring, detecting health conditions when there are no physical signs or noted symptoms or for detecting a health condition when physical signs and symptoms exist.

According to United States Home Diagnostics and Monitoring, a publication of Frost and Sullivan's, a market research, consulting and training company, these home diagnostic products and monitoring devices generated \$1.89 billion in manufacturer's revenue in 1998. This trend is expected to reach \$3.5 billion in five years (Shelton,

1999). Many doctors fear that this trend could change the relation between the patients and doctor drastically. Misinterpretation of results, delays in treatments and increase in demand for medication without the patient being examined first are the major concerns of the doctors. The growing popularity of these home health tests is mainly due to the increasing cost of professional health care. But in some situations like regular monitoring of the blood glucose level in Diabetic patients and monitoring of cholesterol level in patients at high heart risk, few doctors are recommending the use of these tests. Doctors recommending the tests believe they are cost-effective for the patients and time-effective for both the patients and the doctors.

2. LITERATURE REVIEW

2.1 Home Health Tests

The first home health test kit was introduced in the 1940s (Gimino & Liang, 1998). At that time home health kits were primarily used for monitoring health conditions rather than diagnosis and treatment. Home health tests that measure blood glucose, cholesterol level and blood pressure can augment a physician's treatment by providing information about patient's condition 24 hours a day. Home health tests are designed for perform one of the three major purposes: 1) to detect a specific disorder or condition (like pregnancy or ovulation), 2) to detect the presence of a health condition whose symptoms are not predisposing (blood cholesterol level for high cholesterol, occult blood in stool for colon or rectal cancer); or 3) to monitor an existing health condition so as to change diet or medication according to the severity of the situation (blood pressure for hypertension or blood glucose for diabetes) (Gossel, 1988). The most important development that led to the revolutionizing of these home health tests is the discovery of monoclonal antibodies and development of methods of producing them in almost limitless supply. The monoclonal antibodies combine with the specific chemical substance of intent and can then detect a substance in extremely small quantities (Gossel, 1988). This has enabled the manufacturers to develop inexpensive, easy to use and reproducible tests. All home health tests sold to the public are to be approved by the Food and Drug Administration. To be approved by the FDA the test must show an accuracy of 95%-99% and should be easy to use (Gossel, 1988). There are more than 500 approved home health tests in the market apart from the tests sold on the internet which have not been approved (Sims, 2003). The conditions for approval and exemption have been discussed in the section "Human Factors in FDA."

Several terms are used to describe a home health test. Sensitivity refers to how well the test can detect the target substance at a level that permits accurate assessment of the condition. Specificity is a measure of how accurately the home health test measures only the substance that it has to measure (it should not detect any of the other substances). Accuracy is the ability of the test to give consistent results. The wrong interpretation of the test results are classified into two categories. The false-positive result occurs when the test results indicate the presence of a condition that does not exist. The false-negative result occurs when the test result does not show a condition that does exist. If the majority of the test results fall into these two categories the reliability of the home health testing kit is questionable (Gossel, 1988).

Since the first appearance of these tests in the market, a large number of home health tests have been launched in the market. The categories of tests cleared by the Food Drug Administration for home use are:

- Cholesterol – for assessing risk of heart attack
- Glucose and fructosamine – for monitoring Diabetes
- hCG – for detecting pregnancy
- HIV antibody – for determining HIV infection
- Fecal occult blood – to screen colo-rectal cancer
- Luteinizing hormone – to predict ovulation
- Presence of illegal drugs and drugs of abuse
- Prothrombin time – for monitoring blood thinning and clotting.

(Glenn, 2001)

Apart from the above tests, other tests approved by the FDA are the home health tests for testing Asthma, Urinary tract infection, Blood pressure, Hepatitis C, Sulphite,

Calcium and vision. All home health testing products need FDA approval before they can be marketed to the public (Gossel, 1988).

The popularity of home health test kits as a substitute to a physician can be attributed to several factors. Factors that affect the medical care received by people can influence the market of these home health kits. The level of utilization of health care services gives a clear picture of its accessibility. Ensuring equal accessibility to health care services is difficult as the demand for service differs from person to person. The known barriers to this utilization are geographic factors, socio-economic factors, cost of medical care, education, ethnicity/race and religious beliefs (Field, Cart & Briggs, 2001). Other factors like ease of use and confidentiality, which are the characteristics of the test kits, can also to be considered as influential factors. The home health test kits are simple to perform, economical and time saving. Because of the differences in health care services received, distance of health care services and requirement of privacy and confidentiality, the market for these products is fast expanding. For older citizens living on fixed income, these kits may substitute for a physician. An individual can check his/her cholesterol and blood glucose in the privacy of his/her home which saves him/her time, money and stress.

2.2 Cholesterol Tests and Their Functions

Cholesterol is a soft, waxy substance present in the bloodstream in the form of lipids or fats. It also forms the cell membranes, some hormones and parts of tissues. A small amount of cholesterol is essential for the proper functioning of the body. A high level of cholesterol in the blood, also known as hypercholesterolemia, is a major risk factor for coronary heart disease. There are different kinds of lipoproteins in the body but the two kinds which indicate the risk of heart attack are “Low Density Lipoproteins” or LDL and “High Density Lipoproteins” or HDL (Medical

Encyclopedia, 2004; Cholesterol, 2004a; Cholesterol, 2004b; Cholesterol 2004d). Low density Lipoprotein is the major cholesterol carrier in the blood. It is also known as the “bad” cholesterol. HDL cholesterol also known as the “good” cholesterol carries the cholesterol from other parts of the body back to the liver. The liver removes cholesterol from the body. Triglyceride is a form of fat which is made in the body and also comes from the food that people eat. People having a high level of Triglyceride (>200 mg/dL) have a tendency to have high total cholesterol (> 240 mg/dL), high LDL cholesterol (>160 mg/dL) and low HDL cholesterol (<40 mg/dL). Cholesterol is usually measured in milligrams (mg) of cholesterol per deciliter (dL) of blood. Some of the important cholesterol numbers are explained in Table 2.1.

Table 2.1: Important cholesterol numbers

Total Cholesterol Level	Total Cholesterol Category
less than 200 mg/dL	Desirable
200-239 mg/dL	Borderline high
240 mg/dL and above	High
LDL Cholesterol Level	LDL Cholesterol Category
less than 100 mg/dL	Optimal
100-129 mg/dL	Near optimal / above optimal
130-159 mg/dL	Borderline high
160-189 mg/dL	High
190 mg/dL and above	Very high
HDL Cholesterol Level	HDL Cholesterol Category
less than 40 mg/dL(men < 37 mg/dL, Women <47 mg/dL)	A major risk factor for heart disease
40-59 mg/dL	The higher the better
60 mg/dL and above	Considered protective against heart disease
Triglyceride Level	Triglyceride Category
less than 150 mg/dL	Desirable
150-199 mg/dL	Borderline high
200 mg/dL -399mg/dL	High
400 mg/dL and above	Very high

The cholesterol numbers and their classifying categories have been taken from the third report of the National Cholesterol Education Program (NCEP) expert panel on

detection, evaluation and treatment of high blood cholesterol in adults (Adult treatment panel III) (Cleeman, 2001), official website of National Heart, Lung and Blood Institute, Diseases and Conditions Index (Cholesterol, 2004e), NIH-National Cholesterol Education Program-2001 recommendations (Hall, 2003) and (Medical Encyclopedia, 2002).

Cholesterol is one of the major risk factors for heart disease. Studies show that a 1% decrease in cholesterol level leads to 2% decrease in risk for heart disease (Cholesterol, 2004c). In the third report of the National Cholesterol Education Program (NCEP) expert panel on detection, evaluation and treatment of high blood cholesterol in adults (Adult treatment panel III), the members have updated clinical guidelines for cholesterol testing and management. They claim that adults above the age of 20 years should have a fasting lipoprotein profile (total cholesterol, high density lipoprotein, low-density lipoprotein and triglycerides) done every five years (Cleeman, 2001).

Due to the high demand to constant check on the cholesterol level and the increasing cost of medical care, the usage of home cholesterol testing kits is increasing. According to Pal (1998), the home cholesterol test kits had the highest sale growth rate of 28% in the year 1996. These cholesterol testing kits are cheap and easy to use. Different types of cholesterol testing kits are available in the market. They can be broadly divided into two main categories – the laboratory based test and the home based tests. In the laboratory based test the user collects two to three drops of his blood using a lancet and places the blood on a special collection card to dry. The special collection card is then mailed to a laboratory for analysis. Results are mailed back within 4-5 days. Some of the tests give the total cholesterol/HDL level/LDL level and the Triglyceride level also (Cholesterol monitors, 2004c). Most

of the tests that are performed at home give the total cholesterol level only. There are three types of home based tests – the meter based tests, the direct reading tests and the color comparison tests. In the meter based tests, a single drop of blood is collected using a lancet and placed on the cartridge. After two minutes the side tab is pulled to start the reaction. The results are read after 10-15 minutes as in a calibrated scale which resembles a thermometer. The results are compared to a chart to get the total cholesterol level (Cholesterol monitors, 2004d). In the direct reading cholesterol kits a chip is inserted to turn on the instrument. The test strip is inserted in to the instrument. A drop of blood is placed on a test strip using a capillary blood collector. The test results are displayed on the monitor (Cholesterol monitors, 2004a). In the color comparison tests the blood drop is collected using a lancet. A single drop of blood is placed on the small circular test pad. The test pad is left for three minutes for the chemical reaction and development of color to take place. After three minutes the entire tab area on the test pad is discarded. The drop of blood changes color. What we see is the changed drop of blood in the centre of a circular sliding chart or a color wheel. The color of the blood sample is compared to the colors in the chart to get the cholesterol level (Cholesterol monitors, 2004b).

2.3 Human Factors in FDA

The FDA has taken aggressive steps to approach human Factors in Medical devices. It is encouraging manufacturers to apply Human Factors during design and development and is verifying this by evaluating the manufacturer's design validation document as required by the Quality System Regulation. The FDA is working with manufacturers and distributors to help them in applying Human Factors in the design of new products. FDA's Human Factors Program and Human Factors Engineering

Group are making efforts in this direction. The main goals of these programs are (FDA, 2003a);

- To evaluate manufacturers' design validation documents required by the Quality System Regulation
- To develop Guidance documents to help manufacturers understand and use human factors engineering
- To educate manufacturers about the need for human factors programs;
- To provide training and guidance for other FDA personnel about the importance of human factors in product design
- To input human factors principles into medical device standards
- Collaborate with professional organizations to educate the public about human factors and
- To encourage users and manufacturers to report serious adverse incidents

All the medical devices released in the market need to have pre-market approvals and pre-market notification 510(k). There are three main steps for obtaining market clearance from the Center for Devices and Radiological Health (CDRH). The first step is to ensure that the product to be marketed is a medical device according to the definition of a medical device in section 210(h) of federal Food Drug and Cosmetic Act (FD&C Act). In the second step, the manufacturer needs to determine how the FDA will classify the device. Unless exempted, FDA will classify the medical device. FDA classifies a device according to the amount of regulations necessary for reasonable assurance of safety and effectiveness. The three categories into which the FDA divides all the non-exempted medical devices are:

- Class I (General controls) – A device is classified under this category if there is evidence that the general controls of the device are sufficient to assure safety and effectiveness, example- elastic bandages, elastic gloves, hand held surgical instruments
- Class II (Special controls) - A device is classified under this category if general controls alone cannot provide reasonable assurance of safety and effectiveness but has sufficient information to establish special controls to provide this assurance , example- powered wheel chairs, infusion pumps, surgical drapes
- Class III (Pre-market Approval) – A device is classified under this category if the information about the device is insufficient to classify the device into Class I or Class II. A device is classified under this category if it is a life-sustaining or life-supporting device or it is used for preventing impairment of human health or presents potential unreasonable risk of illness or injury, example- implantable pacemaker pulse generators and endosseous implants (FDA, 2002a ; Schultz, 1998).

The third step is to development of data for submitting a marketing application to obtain clearance from FDA. For certain devices clinical performance data is required and the trial should be conducted according to FDA’s Investigational Device Exemption (IDE) regulation in addition to marketing clearance (FDA, 2003d). The flow chart in Figure 2.1 shows the process to be followed according to the new 510(k) (FDA, 2004a).

Most Class I and a few Class II devices are exempted from pre-market notification [510(k)] subjected to certain limitations. This decision has been taken in order to meet the requirements the Food and Drug Administration Modernization Act

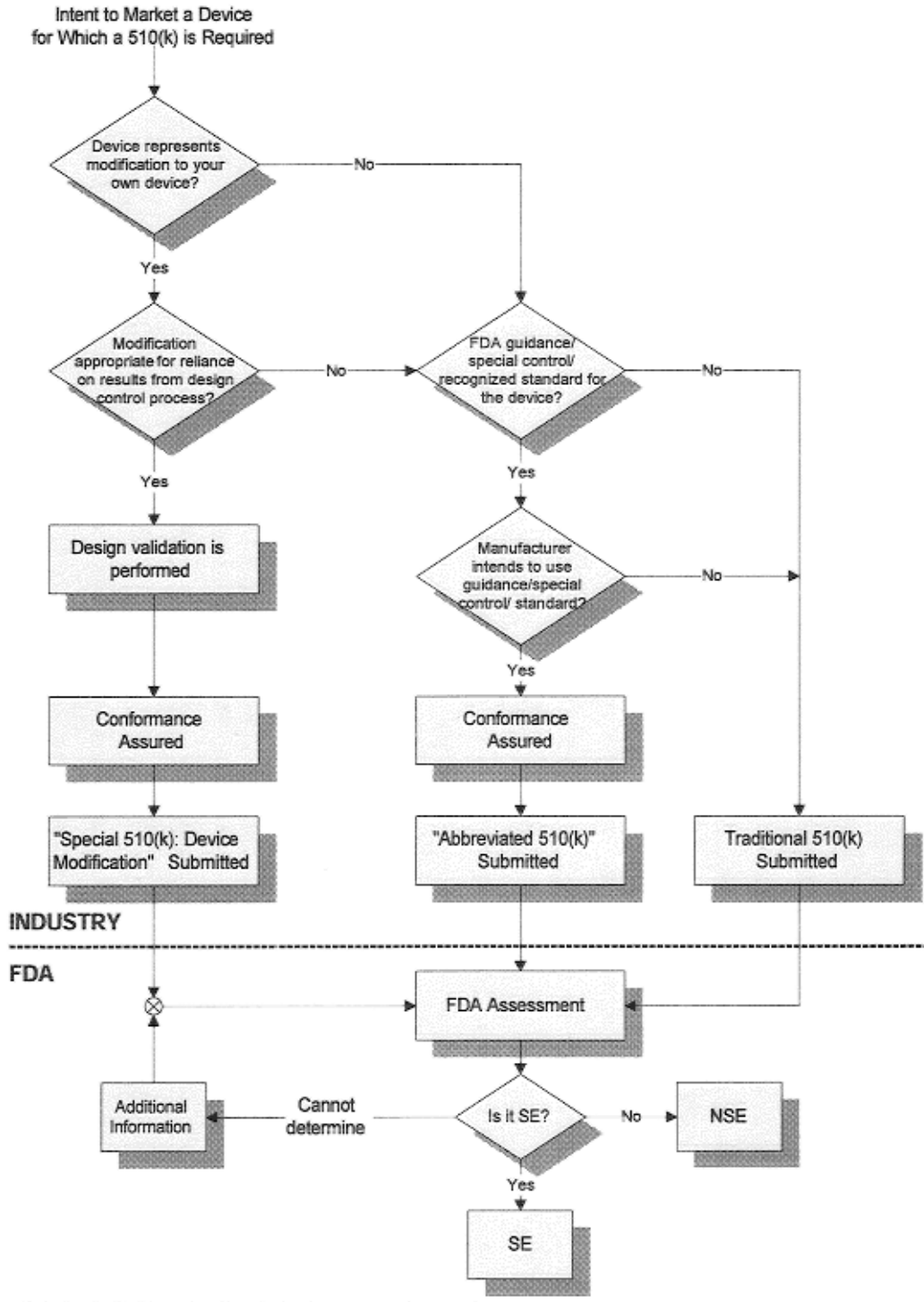


Figure 2.1: New 510(k) paradigm as given by the FDA (FDA, 2004a)

of 1997 (FDAMA). The FDA has exempted over 800 generic types of Class I devices and 60 Class II devices from pre-market notification requirements. Devices exempted from 510(k) pre-market notification are:

- Preamendment devices not significantly changed or modified, or
- Class I/II devices specifically exempted by regulation (FDA, 2000).

Though the exempted devices need not file a pre-market notification 510(k), they still need to meet other requirements for marketing which include Establishment Registration, Medical device listing, Labeling requirements and to fulfill Good Manufacturing Practices (GMP)/Quality System (QS) Regulation.

2.4 Usability: Definition

When a new product/ system is designed, the main concern for the manufacturer is its acceptability. The product/system acceptability is defined as the ability of the system to fulfill the needs and requirements of the users. It is a combination of social acceptability and practical acceptability. The practical acceptability can be analyzed within various categories- cost, compatibility, reliability usefulness etc. usefulness can be defined as the extent to which the system can be used to achieve specific goal. It can be broken down into utility and usability. Utility is whether the functionality of the system can do what is needed and usability is how well the users use the functionality. The various considerations of usability are ease of use, efficient to use, few errors, ease to remember etc (Nielsen, 1993). The system acceptability can be better understood from the model shown in Figure 2.2. Usability is defined as the effectiveness, efficiency, and satisfaction with which specified users achieve specified goals in particular environments.

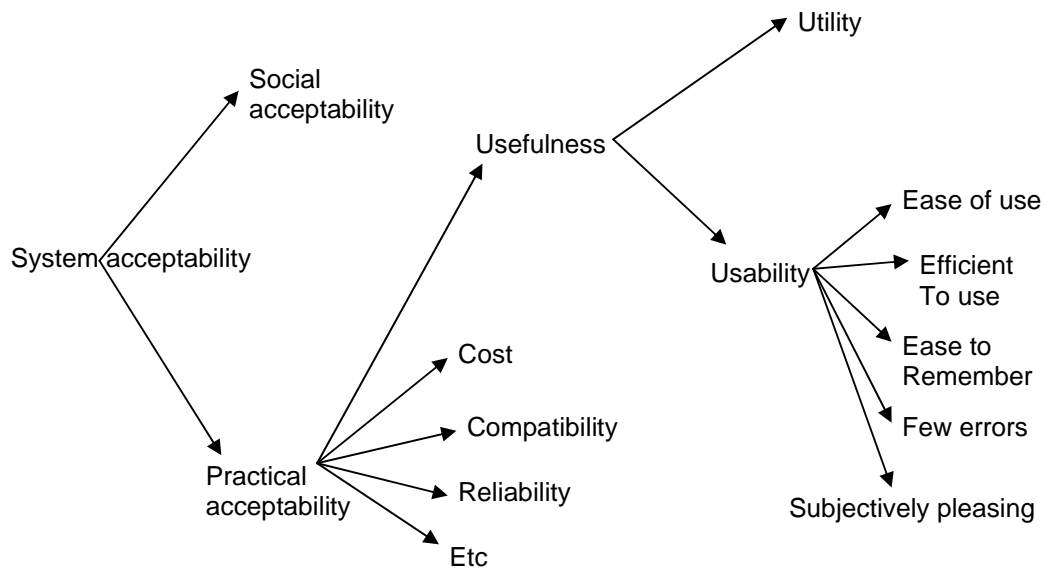


Figure 2.2: Flow chart showing the various divisions of system acceptability (Nielsen, 1993)

Each of the terms effectiveness, efficiency, and satisfaction can be further defined as:

Effectiveness: The accuracy and completeness with which specified users can achieve specified goals in particular environments.

Efficiency: The resources expended in relation to the accuracy and completeness of goals achieved.

Satisfaction: The comfort and acceptability of the work system to its users and other people affected by its use (Dix et al, 1998).

Usability is not a single, one-dimensional property of a product. It has multiple components and is associated with five attributes- learnability, efficiency, memorability, errors and satisfaction (Nielsen, 1993).

Several changes have been occurring in the design of systems and devices for the elderly. The efficiency and safety of the health devices depends on their usability.

The factors defining the usability of these home health devices can be divided into three main categories-user characteristics, health care device characteristics and environmental conditions. The first consideration is the environmental conditions. Before designing a healthcare device the environment in which they will be used must be understood properly. For example, a home health testing kit for testing blood glucose or cholesterol will be used in the privacy of the house, offices, workplaces etc. Hence it should be considered as a portable device and size is an essential factor to be considered. The second consideration should be the user characteristics. It is always essential to define the characteristics of the users before thinking about the design specification of the medical device. The physical abilities and limitations, personal preference and cultural/ethnic background are few of the important aspects to be considered. Third, the device characteristics should be considered. Ease of use, size of device, appeal, cost, functionality and maintainability are few of the factors that come under this category. In the midst of satisfying all the usability factors the main purpose for which the device is being designed must not be lost (Garden-Bonneau & Gosbee, 1997). The usability of a medical device can be better interpreted by Figure 2.3.

2.5 Problems Faced by the Aged Population while Using Home Testing Devices

The Institute of Medicine states that as a result of the change in the mortality patterns, the populations of older adults (above the age of 65) constitute a major proportion of the American population (Sainfort et al., 2002). Lonergan & Krevans (1991) as quoted by Garden-Bonneau & Gosbee (1997) found that around \$160 million was spent on healthcare for older adults suffering from chronic disorders and disabilities. The primary goal of many older adults is to maintain an independent life.

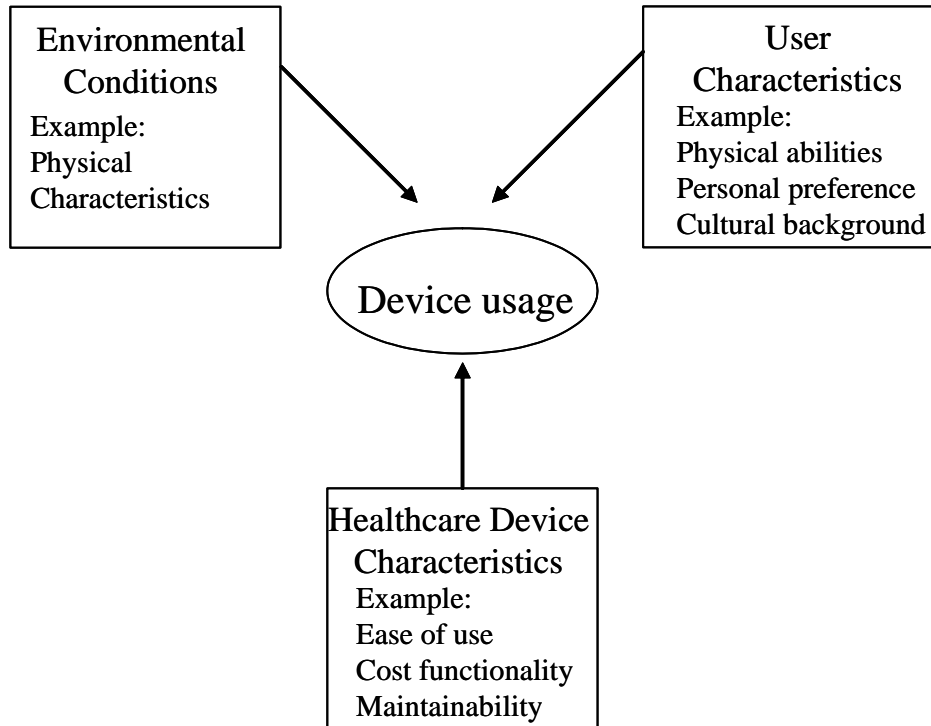


Figure 2.3: Factors defining the usability of home health devices (Garden-Bonneau & Gosbee, 1997)

Research shows that as people age their movement control performance decreases. They take longer time to perform specific movements which are easily performed by younger adults. For example most of the cholesterol tests state “prick your finger, put a drop of blood on the test strip”. This may be easy for a young adult but older adults suffering from severe arthritis may find this task very difficult to perform (Fisk, 1999). Researchers have also found that elderly people do not understand or remember information that is essential for using devices efficiently (Morrow et al., 1988). They also have more difficulty in performing dual tasks than younger adults. For example, if an older adult needs to read instructions and perform the cholesterol test or blood glucose test simultaneously, he/she may skip instructions, repeat instructions, use the instructions in the wrong place or perform the test

incorrectly (Sit & Fisk, 1999). Vision and audition are the two primary modes of communicating information. Researchers have identified a variety of changes in the visual system (acuity, contrast, sensitivity and color discrimination) and cognitive function (working memory, symbol comprehension, language comprehension and prospective memory). Due to a decrease in the cognitive capacity there is a decrease in comprehension and compliance (Rousseau et al., 1998). Even though the home health testing kits may be designed for the older population considering their cognitive disabilities and physical limitations, the end result of the test depends on the correct interpretation of the instructions given to perform the test. Generally older adults try to match the instructions of a new device with their mental models of similar devices and hence try to put both of them together (instructions for the new device and their mental model of a similar device used) to use the novice device (Morrow et al., 1988). People better understand a step-by-step representation of the task being accomplished. The language used to write these instructions should be simple, explicit and unambiguous for better understanding. According to Wright (1981), instructions are usable only when they match the capabilities and limitations of the user.

The mode of instructions is also important. In a study done by Mykityshyn et al. (2002), it was found that the older adults who received video instructions had more knowledge about the device as compared to the older adults who received instructions through a written manual. They were faster, experienced lesser workload and the accuracy of performing the test was higher than the older adults who were trained using a manual. According to Kelly et al. (1991), with an advance in vitro diagnostic testing technology, there has been a reduction in the number of procedural steps. But this does not necessarily improve the overall effectiveness. They claim that

automating an easily learned task like wiping the extra blood from the test strip will not improve the effectiveness of the user-device system. On the other hand automating tasks such as blood sampling which are techniques-dependent and require training may improve the effectiveness of the user-device system. Performance testing is a useful method to detect procedural errors.

Though designers may design the home health kits by taking into consideration all the usability aspects and the user limitations and disabilities, the reaction of the user after interpretation of the results can never be predicted. This depends on how much the user trusts his ability to perform the test and interpret the results and his confidence on the reliability of the test kit.

2.6 Heart Attack Risk: Women Vs Men

Heart disease is by far the leading cause of death in men as well as in women. According to the American Heart Association, each year cardiovascular disease claims the lives of about 448,000 men and 478,000 women. Nearly twice as many women die of heart disease and stroke as from all forms of cancer (Broad issues in women's health, 2003). According to the Cholesterol Statistics of American Heart Association, (Cholesterol, 2004f), studies done on people aged 20 years and older showed that from the age of 50, a higher percentage of women than men have cholesterol level greater than 200 mg/dL (borderline high- 200 mg/dL to 239 mg/dL). In spite of this proportion, women fear most that they will die of breast cancer. Although women develop heart disease 10 years later than men, they typically have more severe first strokes and remain more disabled. At the time of heart attack they are most likely to have other conditions like diabetes and high blood pressure which makes their recovery even more difficult. Women are not the only ones to overlook this serious problem. Even the physicians tend to overlook this problem in women.

The Centre for Disease Control and Prevention states that physicians often wait until women have a heart attack to advise them about preventive care though women are less likely to survive a first attack than men (Women and heart attack, 1999). Around 35% of the heart attacks in women go unnoticed or unreported (Giardina, 2000). In the past, most of the studies done in this field have been concentrated on men and the gender difference has been ignored completely. The studies that have included women as subjects suggest that most of the diagnosis, treatment and prevention of heart disease in men may not apply to women (Patlak, 1994).

The most common and the most important sign/symptom of heart disease is chest pain or angina, occurring while a physically demanding task is being done. But chest pain is not a good diagnostic clue for heart disease in women as in men. Women are more susceptible to conditions such as heartburn or spasms of the esophagus or heart arteries which cause chest pain similar to angina. So, most of the chest pains complained by women are dismissed as heartburn. According to Dr. Weese, he once had a patient who complained of pain in the ear canal and once diagnosed, required a bypass surgery (Women and heart attack, 2002). Even though men and women are given the same treatment, women are less likely to survive. The main reasons for this difference is that the treatments and the medicines have been tested using the male subjects only. There have not been any studies to prove that the same treatments and medicines are effective for both genders. Few of the treatments cannot be performed on women because of their small size (small blood vessels and arteries). According to Dr. Ruth Merkatz of FDA, commonly used heart medications may not be as effective in women as they are in men because of their smaller body size, hormones and the fat content present in their body (Patlak, 1994).

Following a low cholesterol diet will reduce the heart risk in women”- this statement is debatable as all the studies supporting low cholesterol diet have been done primarily using male subjects. Lowering the cholesterol lowers the HDL level as well as the LDL level. High HDL levels are much more protective in women than low LDL levels. It is not very clear whether lowering the total cholesterol is a good preventive measure in women with heart risk. (Patlak, 1994). According to Dr. Ashish K. Jha, M.D. (a general medical fellow at Brigham and women hospital and the Harvard School of Health in Boston), heart disease is the biggest cause of death for women and there is a large gap between black and white women. According to a report from the American Heart Association, black women are more likely to have a coronary heart disease than white women. Black women have higher blood pressure, diabetes and high cholesterol. Poor control of cardiovascular disease could be one of the reasons for this difference. This cannot be attributed to economic status as in a study done by Dr Ashish K Jha, he found that black women used more expensive drugs than white women. He also found that women under higher risk were being under treated. Studies need to be done to narrow this gap between black and white women (Jha, 2003).

The answers to many of the questions concerning women and their heart attack risk remain unanswered. Research in heart disease in women started around 25 years after research started on men. Hence research is still being done in this field. The FDA is also insisting that the new drugs and treatments being tested should represent the female population properly so that the drugs and treatments can be applied to both the genders.

3. RESEARCH OBJECTIVES AND HYPOTHESIS

3.1 Research Objectives

From the conclusions drawn from the literature review, two research objectives have been framed.

1. To find whether the instructions, procedure of the test and the ergonomic design of the cholesterol test kit affect the results (cholesterol numbers).
2. To study differences in the future actions of people based on their gender and cholesterol results.

3.2 Conceptual Model

The popularity of home health testing kits has been increasing since their introduction in the 1940s. This increase in popularity may be influenced by several factors like the cost of the kit, cost of medical care, accessibility of health care, acceptance of the accuracy of the test results, ease of use features of the kit and the action of the patient after conducting the test and interpreting the results, refer to Figure 3.1: Conceptual model. These factors can influence the usage of any home health test kit irrespective of what it is testing. In a study done by Pal in 1998, he found that the sale growth rate of home cholesterol testing was the highest at 28%. Since then, the popularity of the home cholesterol test kits has been increasing. According to the cholesterol statistics published by the American Heart Association (Cholesterol, 2004f), an estimated 105 million American adults have total blood cholesterol value of 200 mg/dL and above. Of these, 42 million Americans have level of 240 mg/dL and above. In adults, the total blood cholesterol levels of 200mg/dL-239mg/dL is considered as borderline risk and 240mg/dL and above are considered as high risk cholesterol numbers. Based on these statistics, the present study concentrates on the home cholesterol test kits only.

Instructions using the home health test kits directly influence the accuracy in performing the test and hence the results obtained by performing the test. The wrong interpretation of instructions can give different results and hence put the health of the patient at risk. The correct interpretation of the instructions also depends on the age and education of the person. Vision and audition are the two primary modes of communicating information. Researchers have identified a variety of changes in the visual system (acuity, contrast, sensitivity and color discrimination) and cognitive function (working memory, symbol comprehension, language comprehension and prospective memory) as a person ages. Due to a decrease in the cognitive capacity there is a decrease in comprehension and compliance (Rousseau et al., 1998). The education level of the users may be less than the readability level of the instructions. Even though the instructions maybe interpreted correctly the design of the kit may hinder the performance of the test. For better portability these home health test kits are often made as small as possible and as such there is a possibility that the patient pushes the wrong buttons. Hence the ergonomic design of the kit also influences the outcome or result of the test. Interpretation of results is another major factor to be considered. In the direct display test kits, the cholesterol numbers are displayed on the digital display screen but in the color comparison and meter based test kits, the cholesterol number is interpreted by comparing the length of the colored solution or the color on the card (like in Chemcard) to get the cholesterol numbers. In a study done by the manufacturers of Chemcard, it was found that more than 50% of the participants wrongly interpreted the cholesterol numbers (Chemcard, 2004).

According to the National health and nutrition examination survey III (NHANES III) 1988-94, conducted by The Centers for Disease Control/National Center for Health Statistics, the risk of Coronary Heart Disease due to high blood

cholesterol differs according to race and ethnicity. It was found that among the non-Hispanic blacks ages 20-74, the age adjusted prevalence of total blood cholesterol levels over 200 mg/dL was 45 percent of men and 46 percent of women. They also found that 15 percent of men and 18 percent of women had blood cholesterol levels of 240 mg/dL or higher (total blood cholesterol levels of 200 – 239 mg/dL are considered as borderline risk cholesterol numbers and 240 mg/dL and above are considered as high risk cholesterol numbers). The results of the survey also stated that the non-Hispanic blacks were a high CHD risk population next to the Mexican Americans (Cholesterol, 2004f). If non-Hispanic blacks from lower socio-economic background with lower levels of education are considered, the risk of high cholesterol maybe more.

The home health testing kits were introduced in the market to help people take better care of their health and also reduce the cost of health care. After performing the test and interpreting the results the question that now arises is, “What do patients do with these results?” If the result shows that their health is at risk do they visit a doctor or take home curative measures like controlling their diet or do they simply ignore the results. If the results show that they are fine and do not have any health problems, do they trust the results and accept that they are healthy or do they still go and visit the doctor regularly. This is a question which does not have a single answer. The psychology of the person plays a very important role here. The knowledge of the patient about their risk factors is also important here. For example women in general do not consider heart attack as a women’s disease. So if they get a test result showing that they have a high risk of heart attack what will be their reaction? Similarly it has been found that African-American women are more prone to heart attack than white American women. Will they react differently than their counterparts? Another

question that can be asked in this context is whether men and women will react in the same manner when they get similar results. This is one of the major factors that influence the usage of home health test kits which cannot be physically measured.

The conceptual model of the factors affecting the usage of home health testing kits and their interdependence has been graphically represented in Figure 3.1.

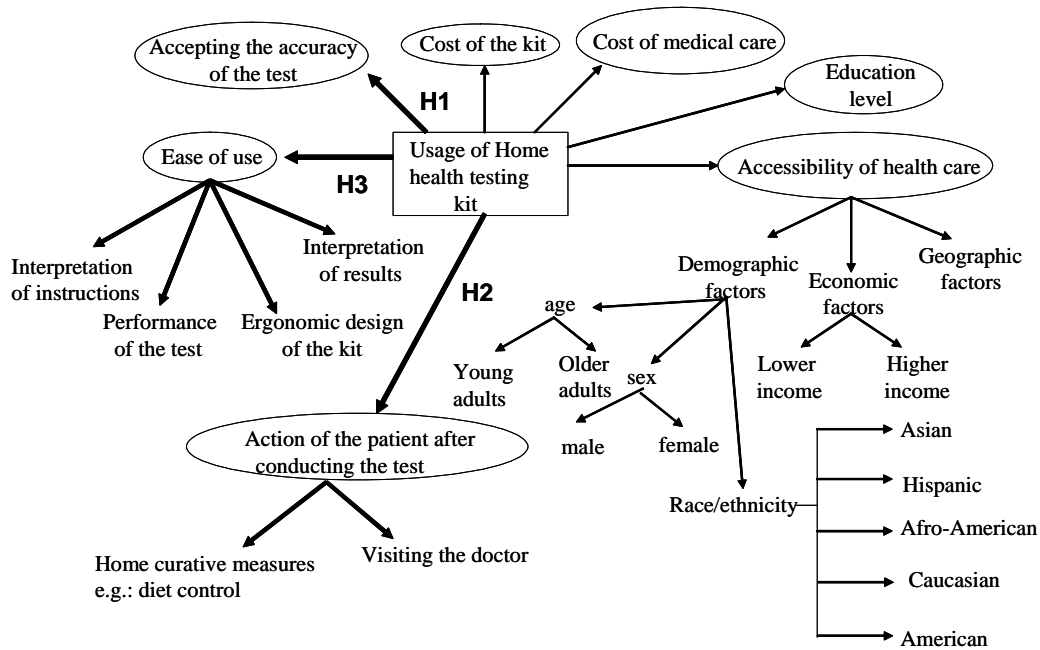


Figure 3.1: Conceptual model of the usage of home cholesterol test kit

This research project will investigate ease of use factors for the home cholesterol tests actions of patients upon receipt of the results, and clinical accuracy of the kits. Each of the hypotheses have been highlighted in Figure 3.1.

3.3 Research Hypothesis

From the literature and the conceptual model the following three hypotheses have been defined.

H1: No difference exists in the cholesterol reading between the two test kits and the clinical laboratory results.

H2: No difference exists in use of information from cholesterol test kit results by gender.

H3: No difference exists between the user performance of cholesterol digital test and cholesterol meter based test.

4. METHOD

4.1 Experimental Design

A study was conducted at Louisiana State University in Baton Rouge. Factors measured were usability questionnaire scores for each test kit, the number and type of errors committed by participants while using the cholesterol test kits, future healthcare decision of the participants based on the cholesterol test results, and the accuracy of the test kits results when compared to clinical laboratory results.

4.2 Participants

Thirty individuals consisting of 15 males and 15 females from different economic backgrounds and different education levels employed by Louisiana State University participated in the study. The only basis for excluding people from the study was their unwillingness to participate in the study.

4.3 Testing Materials and Tools

The tools used in the study are the demographic questionnaire (Appendix A), Usability questionnaire (Appendix B and Appendix C), Comparison Questionnaire (appendix D), the post test questionnaire (Appendix E) and Video analysis worksheet (Appendix F). The demographic questionnaire included questions on age, gender, education level, annual income, type of medical insurance and information on the knowledge and usage of the home health test kits. The usability questionnaire includes questions on the test kit instructional material, the experience of the patient while using the test kit and subjective comments of the patient on the test kit. In the comparison questionnaire, the patients were asked to rate each of the two kits on the given criteria. In the post test questionnaire, participants were asked their about future health decisions they would make based on the tests results and their willingness to use the home cholesterol test kit in the future. Additionally, participants were asked

(Part –B) to compare the home cholesterol test and the laboratory results. The change in the future medical decision of the patient due to the availability of the laboratory results was studied through the questionnaire. The Video analysis worksheet includes the step-by-step procedure to be followed to perform the home cholesterol test, the time taken to perform each step, and the errors committed while performing the test. Accucheck® *Instant plus*® cholesterol test kit manufactured by Roche Diagnostics and Home Access® Instant Cholesterol Test kit manufactured by Home Access will be used as the two cholesterol test kits to be compared.

4.4 Procedure

All the participants were asked to complete the demographic questionnaire (Appendix A). The participants were randomly assigned one of the two home cholesterol test kits and asked to check their cholesterol level. No instruction was provided as this was an out-of-the-box experiment. Their interaction with the cholesterol test kits was recorded using a Video Camcorder. After checking their cholesterol level they were asked to answer the Usability questionnaire (Appendix B or Appendix C) based on the cholesterol test they used. Participants were later asked to complete the post results questionnaire (Appendix E) to assess their future healthcare decision based on the cholesterol results of the first test they used. The participants were given the other cholesterol test kit and were asked to check their cholesterol level again. Once again, they answered the usability questionnaire for the cholesterol test kit used. After they checked their cholesterol level using both kits, the participants were asked to complete the comparison questionnaire (Appendix D). The participants were taken to the LSU student health center where a blood sample was drawn by the medical technician in the laboratory. This blood sample was then transported to Pennington Biomedical Research Center for analysis. Laboratory

cholesterol levels were obtained which included the complete cholesterol value along with the HDL and LDL values. After the participants receive their cholesterol numbers from the Pennington, a follow on study was conducted. The participants were asked to complete Part-B of the post results questionnaire to evaluate the accuracy of the home cholesterol test results, change in their future health plan, and any change in their opinion on the home cholesterol test kits. The step by step procedure of the study is represented in the Figure 4.1.

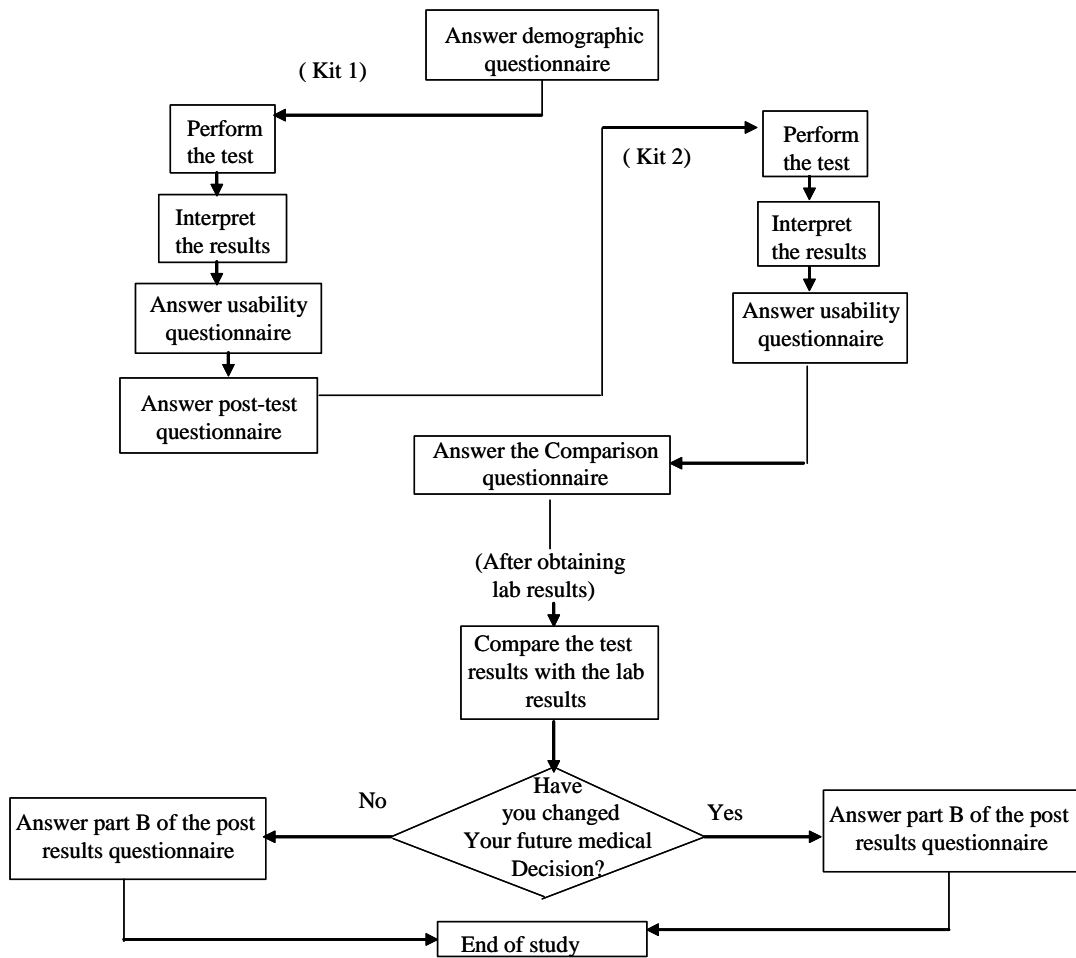


Figure 4.1: Flow chart of the experimental procedure

5. RESULTS

Experimental analysis was conducted using SAS 9.1.2 and JMP (version 5). Analysis of variance (ANOVA), T-tests and Nominal logistic regression were performed on the data using a significance level of $\alpha = 0.05$. Correlation studies were conducted to compare the laboratory cholesterol results and the home cholesterol test results and also to compare the total significant errors committed while using each of the test kits and the error in the test kit reading.

As discussed in the procedure section, thirty participants, fifteen male and fifteen female, participated in the study. The interaction of the participants with the test kits was video-taped to compute the number of errors and the type of errors committed by them while using each of the test kits. During the study, two participants refused to use the Accucheck® *Instant plus*® (digital) test kit as they found the procedure to be very complicated. One Home Access® Instant Cholesterol Test kit did not work although the participant followed the instructions and performed the test as per the instructions. Three participants did not use enough blood for the Home Access® Instant Cholesterol Test kit and their test results failed completely. The two participants who refused to use the Accucheck® *Instant plus*® test kit did not rate the meter in the post questionnaire. They were deleted from the analysis. For the analysis of future healthcare decision based on the cholesterol test kit results, all the participants who were already visiting a doctor were excluded. Demographic statistics of the study are shown in Table 5.1.

Appropriate parametric and non-parametric analyses were performed on the data. Before conducting parametric analysis, test for normality and homogeneity of variance were performed to check the normality of the data. According to Neter, Wasserman & Kutner (1985), “the F test for equality of factor level means is but little

Table 5.1: Demographic Statistics

Demographics	Number
Number of participants	30
Number of male participants	15
Number of female participants	15
Number of participants between	
Below 30 years	1
31 – 40 years	4
41 – 50 years	12
51 – 60 years	10
61 – 70 years	3
Number of participants used AccucheK® <i>Instant plus</i> ® first	16
Male	8
Female	8
Number of participants used Home Access® Instant Cholesterol Test first	14
Male	7
Female	7
Number of participants quit AccucheK® <i>Instant plus</i> ®	2
Number of participants quit Home Access® Instant Cholesterol Test	0
Number of test kits failed to give results	1
AccucheK® <i>Instant plus</i> ®	0
Home Access® Instant Cholesterol Test	1
Number of times kits yielded no results	3
AccucheK® <i>Instant plus</i> ®	1
Home Access® Instant Cholesterol Test	2
Number of participants answered usability questionnaires	30
AccucheK® <i>Instant plus</i> ®	30
Home Access® Instant Cholesterol Test	30
Number of participants answered comparison questionnaire	30
Number of participants answered post usability questionnaire	28

effected by lack of normality. The F-test is a robust test against departures from normality.” Hence, normality is not a major concern. However, homogeneity of variance is essential for testing ANOVA (Neter et. al, 1985). All data as will be discussed was found to be homogeneous. Even though the ANOVA test is robust to non-normality, if the data failed the normality test, the nonparametric Kruskal Wallis test was also performed. In all cases, the conclusion between the ANOVA and nonparametric ANOVA yielded the same conclusion. Thus, only the parametric analysis is reported. All non-parametric results are included in Appendix G. A nominal logistic regression was performed for the analysis for the evaluation of the future healthcare decision.

5.1 Hypothesis 1

The first hypothesis states that no difference exists in the cholesterol reading between the two test kits and the clinical laboratory results.

A stepwise selection was performed to determine which factors (e.g., gender, kit) should be included in the analysis. At a reduced $\alpha=0.1$ level of significance, where the model accepted a variable, it was concluded that gender should not be included in the model, thus gender was excluded as a variable and the data collapsed to evaluate the errors between test kit results and laboratory results irrespective of gender. The Accucheck® *Instant plus*® test kit displays all the cholesterol results between 150 mg/dL and 300 mg/dL. If the cholesterol level is <150 mg/dL it displays “Low” and if the cholesterol level is higher than 300 mg/dL it displays “high”. Similarly, Home Access® Instant Cholesterol Test cannot measure cholesterol levels lower than 120. A few of the participants had very low cholesterol, lower than 120. Their test kit results showed “low” in the case of Accucheck® *Instant plus*® and <120 for Home Access® Instant Cholesterol Test. The accuracy of such results for

Accucheck® *Instant plus*® and Home Access® Instant Cholesterol Test cannot be determined as the test results can vary from 149 and 119 respectively to their actual cholesterol level. Two cases have been considered for such data. In the first case (case 1), all the “<150” values have been approximated to 149 mg/dL and “<120” to 119 mg/dL. In the second case (case 2), “<150” and “<120” have been approximated to the laboratory values or 149/119 whichever is closer. A two sample one way ANOVA was performed. The independent variable was the type of test kit and the dependent variable was the error between the test kit results and the laboratory results. The sample size was 54. Participants who did not have a test result were excluded from the study. The results of both cases for evaluation follow.

5.1.1 Case 1

- Model Assumptions

Tests for normality, Shapiro-Wilkes’ test, and homogeneity of variance, Levene’s test, were conducted. Shapiro-Wilkes found the data to be non-normal ($W = 0.739197$, $p < 0.001$). Levene’s test showed that the homogeneity of variance can be assumed ($F(1, 52) = 2.19$, $p = 0.1453$). As discussed earlier, parametric tests were used since homogeneity of variance was found to exist regardless of the non-normality.

- Analysis of Variance (ANOVA)

The results of the ANOVA are tabulated in Table 5.2. The mean error in cholesterol reading while using the Accucheck® *Instant plus*® test kit is 25.14815 and the mean error in cholesterol reading while using Home Access® Instant Cholesterol Test kit is 35.59259. The results show that there is no relationship between the type of test kit used and the errors between the test kits results and the laboratory results in case 1. Thus, there does not

appear to be a relationship between the type of test kit used and the errors between the test kit and the laboratory results.

Table 5.2: Case 1: <150 = 149 mg/dL and <120 = 119 mg/dL

Source	DF	Sum of squares	Mean square	F – value	Pr > F
Model	1	1472.66667	1472.66667	1.23	0.2721
Error	52	62145.92593	1195.11396		
Corrected total	53	63618.59259			

Kruskal Wallis test, ANOVA for non-parametric data, was performed as the data set failed the normality test. The results (Appendix G) of the Kruskal Wallis test gave the same conclusion as the ANOVA.

5.1.2 Case 2

- Model Assumption

Tests for normality, Shapiro-Wilkes' test, and homogeneity of variance, Levene's test, were conducted. Shapiro-Wilkes found the data to be non-normal ($W = 0.722185$, $p < 0.001$). Levene's test showed that the homogeneity of variance can be assumed ($F(1, 52) = 2.25$, $Pr > F = 0.1396$).

- Analysis of Variance (ANOVA)

The results of ANOVA are tabulated in Table 5.3.

Table 5.3: Case 2: <150 and <120 = laboratory results or 149/119 whichever is closer.

Source	DF	Sum of squares	Mean square	F – value	Pr > F
Model	1	2802.24074	2802.24074	2.29	0.1366
Error	52	63749.18519	1225.94587		
Corrected total	53	66551.42593			

The mean error in cholesterol reading while using the Accuchek® *Instant plus*® test kit is 20.33334 and the mean error in cholesterol reading while using Home Access® Instant Cholesterol Test kit is 34.74074. The results show that there is no relationship between the type of test kit used and the errors between the test kit results and the laboratory results.

Equating <150 to 149 mg/dL and <120 to 119 mg/dL or equating them to the laboratory values does not effect the results of the ANOVA or the Kruskal Wallis. The end result was the same; there appears to be no relation between the type of test kit used and the error between the test kit and the laboratory results. From the results of the statistical analysis, there is strong evidence supporting hypothesis 1.

5.1.3 Correlation between Laboratory Results and Test Results

A correlation analysis was performed between the laboratory test results and test kit results, and between the two test kit results. The Accuchek® *Instant plus*® test kit displays all the cholesterol results between 150 mg/dL and 300 mg/dL. If the cholesterol level is <150 mg/dL it displays “Low” and if the cholesterol level is higher than 300 mg/dL it displays “high”. Similarly, Home Access® Instant Cholesterol Test cannot measure cholesterol levels lower than 120. A few of the participants had very low cholesterol, lower than 120. Their test kit results showed “low” in the case of Accuchek® *Instant plus*® and <120 for Home Access® Instant Cholesterol Test. The accuracy of such results cannot be determined as the test results can vary from 149 to their actual cholesterol level. Two cases have been considered for such data. In the first case, all the <150 values have been approximated to 149 mg/dL and <120 to 119 mg/dL. In the second case, <150 and <120 have been approximated to the laboratory values or 149/119 whichever is closer. The correlation analysis was performed for both the cases to see if there is a difference in the Pearson correlation for the two

cases. The correlation analysis was conducted by gender and also ignoring gender. The correlations are tabulated in Table 5.4.

From the results of the correlation analysis, the laboratory results and AccucheK® *Instant plus*® test results are highly correlated for both male and female subjects. Even if the gender is ignored the laboratory results and the AccucheK® *Instant plus*® results are highly correlated.

Table 5.4: Correlation between Laboratory results and test kit results.

	b/w lab results and individual test kit				b/w test kits	
	AccucheK® <i>Instant plus</i> ® & Laboratory results		Home Access® Instant Cholesterol Test & Laboratory results		AccucheK® <i>Instant plus</i> ® & Home Access® Instant Cholesterol Test	
	<150=149	<140=lab or 149	<120=119	<120=lab or 119	<150=149 & <120=119	<150 & <120 = lab or 149/119
Female	0.71938 (p=0.0037)	0.80990 (p=0.0004)	0.54219 (p=0.0452)	0.58021 (p=0.0296)	0.22019 (p=0.4699)	0.36195 (p=0.2243)
Male	0.81107 (p=0.0008)	0.91533 (p=<0.0001)	0.28840 (p=0.3393)	0.31361 (p=0.2968)	-0.15217 (p=0.6551)	0.07287 (p=0.8314)
Total	0.73752 (p=<0.0001)	0.84110 (p=<0.0001)	0.38881 (p=0.0450)	0.42055 (p=0.0289)	0.11322 (p=0.5984)	0.27500 (p=0.1934)

For the laboratory and the Home Access® Instant Cholesterol Test results, there is significant correlation for female subjects for both the cases. There is no significant correlation for male subjects for both the cases. When the gender is ignored, once again the test kits and the laboratory results are significantly correlated.

5.2 Hypothesis 2

The second hypothesis states that no differences exist in use of information from cholesterol test kit results by gender.

For the purpose of analysis, all the subjects who were already visiting a doctor were excluded from the data set. Participants were given three options: (1) change in lifestyle, (2) visit a doctor and (3) no change in lifestyle/ not visiting a doctor for their response to the future healthcare decision, the dependent variable. Their decision was based on the results of the first test kit used. The independent variables were gender, test results and their interaction. Since the response variable, future health care decision, is nominal, a nominal logistic regression was performed. The analysis was performed on eleven male and eleven female subjects. A whole model test was performed to check the validity of the test. The results of the test (χ^2 (0.05, 6) = 18.7164, $\text{Pr} > \chi^2 = 0.0047$) show that the model is a good fit for the data. Wald test for individual effects was performed. The results are tabulated in Table 5.5 below

Table 5.5: Results of Wald test for individual effects – gender is considered as an effect.

Source	Nparm	DF	Wald Chi-square	Pr > ChiSq
Gender	2	2	0.29473882	0.8630
Test results	2	2	0.66394332	0.7175
Gender*test results	2	2	0.36012879	0.8352

The p values for each of the independent variables show that there is no effect on any of the individual variables on the future healthcare decision by themselves and thus the whole model is the best description of the effect. A Table for the predicted P value for each option when the cholesterol level is in the range of 119 mg/dL and 254 mg/dL was drawn to find the probability of the subject choosing a specific future

healthcare plan on the basis of his/her gender and test results. The probabilities are tabulated in Table 5.6 and plotted in Figure 5.1 below.

Table 5.6: Predicted P values for each option when the cholesterol level is in the range of 119 mg/dL and 254 mg/dL

Gender	Test results	change in lifestyle	visit a doctor	no change in lifestyle/ not visiting a doctor
female	119	2.5937E-49	0.03802754	0.96197246
female	152.75	4.48E-30	0.12841984	0.87158016
female	186.5	6.3252E-11	0.35449685	0.64550315
female	220.25	1	1.0958E-09	5.3533E-10
female	254	1	2.1424E-28	2.8081E-29
male	119	0.14075929	0.30011077	0.55912994
male	152.75	0.37415823	0.24806484	0.37777693
male	186.5	0.68361797	0.14093822	0.17544381
male	220.25	0.88547097	0.05676688	0.05776215
male	254	0.96476992	0.01923313	0.01599695

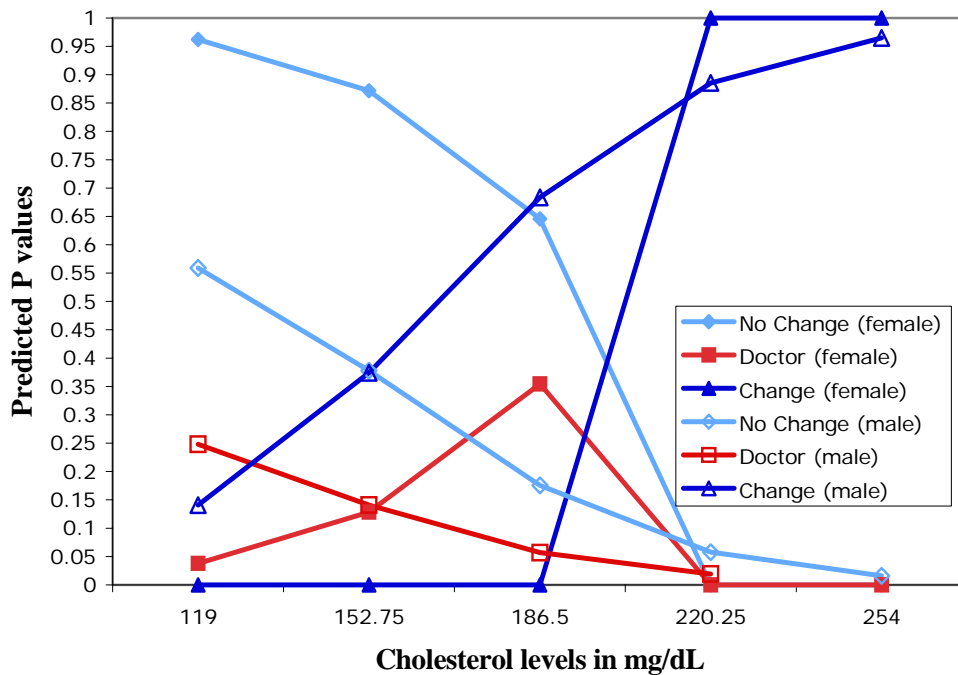


Figure 5.1: Graph showing the predicted P values for men and women

From Table 5.6 it is observed that regardless of the cholesterol level of the participant, there is a relatively low probability that a patient would chose to visit a doctor. By looking at the predicted P values one sees a trend in the probabilities associated with the decision. As the cholesterol increases, the decision tends to move from a do nothing decision to a change in lifestyle. The percentage choosing to visit a physician stays relatively constant across all levels of cholesterol.

From Figure 5.1 it is observed that the trend in the predicted P values is different for male and female subjects. Both men and women said they preferred not to change their lifestyle at lower cholesterol levels. As the cholesterol level increases the predicted probabilities decreases steadily. A sharper decline is observed in women when compared to men. Both men and women have low predicted probabilities for choosing to visit a doctor regardless of the cholesterol level. Infact, for men the probabilities decline as the cholesterol level increases. As the cholesterol level increases, men and women said they preferred to change their lifestyle. A gradual increase in predicted probabilities is observed for men. At 186.5 mg/dL the predicted probability for men is 0.68361797 and at 220.25 mg/dL it is 0.88547097. The predicted probability for women sharply increases from 6.3252E-11 to 1 as the cholesterol level increases from 186.5 mg/dL to 220.25 mg/dL. From Figure 5.1 it is observed that men and women have different opinions on their future healthcare decision.

5.3 Hypothesis 3

The third hypothesis states that no differences exist between the user performance of cholesterol digital test and cholesterol meter based test.

The user performance was assessed with the aid of questionnaires and video analysis. Responses were collected through three different questionnaires – usability questionnaire, comparison questionnaire and post result questionnaire.

5.3.1 Usability Questionnaire

The participants answered a usability questionnaire after using each of the test kits. A stepwise selection was performed to see whether order of test kit used and gender of the participant had an effect on the responses. At $\alpha=0.1$ level of significance, where the model accepted variable, it was found that order had an effect on the response ($p= 0.0144$), but gender did not have an effect. For analysis, the scores of those subjects who used the respective test kits, Accucheck® *Instant plus*® and Home Access® Instant Cholesterol Test, first were considered. The usability scores were compared irrespective of gender, for each test kit. The dependent variable is the response score and the independent variable is the type of meter. The sample size was 30. A two-sample set-up one way ANOVA was performed

- Model Assumption

A normality test was conducted to check the normality of the data set. The Value of Shapiro-Wilkes was very insignificant at $W = 0.78318$ and $p = <0.001$. A Levene's test for homogeneity of variance was performed. The test results show that the homogeneity of variance exists ($F (1, 28) = 1.87$, $Pr > F = 0.1826$).

- Analysis of Variance (ANOVA)

The results have been tabulated in Table 5.7. The mean usability score for Accucheck® *Instant plus*® test kit is 30.9375 and the mean usability score for Home Access® Instant Cholesterol Test kit is 33.14286. The results show

that the response of the usability questionnaire does not depend on the type of test kit being rated.

Table 5.7: Results of ANOVA – Usability questionnaire results.

Source	DF	Sum of squares	Mean square	F - value	Pr > F
Model	1	36.314881	36.314881	0.30	0.5873
Error	28	3372.651786	120.451849		
Corrected total	29	3408.966667			

Kruskal Wallis test, ANOVA for non-parametric data, was performed as the data set failed the normality test. The results (Appendix G) of the Kruskal Wallis test gave the same conclusion as the ANOVA. There is no relation between the type of test kit being rated and the response of the usability questionnaire.

5.3.2 Comparison Questionnaire

After testing their cholesterol using both the test kits, the participants answered a comparison questionnaire in which they were asked to rate the two test kits against each other. A stepwise selection was performed to see whether order of test kit used and gender of the participant had an effect on the responses. At $\alpha=0.15$ level of significance it was found that order had an effect on the response ($p= 0.1136$) but gender did not have an effect. For the analysis, the scores of those subjects who used the respective test kits, Accuchek® *Instant plus*® and Home Access® Instant Cholesterol Test, first were considered. The usability scores were compared irrespective of gender, for each test kit. The dependent variable is the response score and the independent variable is the type of meter. The sample size was 30. A two-sample set-up one way ANOVA was performed.

- Model Assumptions

A normality test was conducted to check the normality of the data set. The Value of Shapiro-Wilkes was very insignificant at $W = 0.760658$ and $p = <0.001$. A Levene’s test for homogeneity of variance was performed. The test results show that the homogeneity of variance exists ($F(1, 28) = 1.93, Pr > F = 0.1755$).

- Analysis of Variance (ANOVA)

The results have been tabulated in Table 5.8.

Table 5.8: Results of ANOVA – comparison questionnaire results

Source	DF	Sum of squares	Mean square	F - value	Pr > F
Model	1	221.488095	221.488095	1.70	0.2032
Error	28	3652.678571	130.452806		
Corrected total	29	3874.166667			

The mean usability score for Accucheck® *Instant plus*® test kit is 28.625 and the mean usability score for Home Access® Instant Cholesterol Test kit is 34.07143. The results show that the response of the comparison questionnaire does not depend on the type of test kit being rated. Kruskal Wallis test, ANOVA for non-parametric data, was performed as the data set failed the normality test. The results (Appendix G) of the Kruskal Wallis test gave the same conclusion as the ANOVA. There is no relation between the type of test kit being rated and the response of the comparison questionnaire.

5.3.3 Post – Questionnaire

After getting the laboratory test results, the participants were again asked to answer a usability questionnaire. A stepwise selection was performed to see whether order of test kit used, and gender of the participant had an effect on the responses. At $\alpha=0.15$ level of significance it was found that neither order nor gender had an effect on the response. For the analysis, the scores of all the participants irrespective of the order of use and the gender of the participant, was considered. The dependent variable is the response score and the independent variable is the type of meter. Two participants did not rate the Accucheck® *Instant plus*® meter as they quit the test. The sample size was 58. A two-sample set-up one way ANOVA was performed.

- Model Assumptions

A normality test was conducted to check the normality of the data set. The Value of Shapiro-Wilkes was very insignificant at $W = 0.947175$ and $p = 0.0135$. A Levene’s test for homogeneity of variance was performed. The test results show that the homogeneity of variance exists ($F(1, 56) = 0.11, Pr > F = 0.7453$).

- Analysis of Variance (ANOVA)

The results have been tabulated in Table 5.9.

Table 5.9: Results of ANOVA – post questionnaire results

Source	DF	Sum of squares	Mean square	F - value	Pr > F
Model	1	52.155172	52.155172	2.21	0.1423
Error	56	1318.965517	23.552956		
Corrected total	57	1371.120690			

The mean usability score for Accuchek® *Instant plus*® test kit is 11.7931 and the mean usability score for Home Access® Instant Cholesterol Test kit is 13.68966. The results show that the response of the post - questionnaire does not depend on the type of test kit being rated. Kruskal Wallis test, ANOVA for non-parametric data, was performed as the data set failed the normality test. The results (Appendix G) of the Kruskal Wallis test gave the same conclusion as the ANOVA.

There is no relation between the type of test kit being rated and the response of the post questionnaire. From the statistical analysis of the three questionnaire studies there is strong evidence supporting hypothesis 3.

5.3.4 Video – Analysis

The interaction of the participants with the test kits was also recorded to assess the number of errors and the type of errors committed during the interaction. Errors have been classified into four different categories – commission errors, omission errors, timing errors and sequence errors based on Swain and Guttman's (1983) error taxonomy (Appendix I). Errors were also classified as significant and non-significant errors. Errors which influence the test result are called as significant errors and the errors which do not influence the test results are called non-significant errors. A list of significant errors for each of the test kits is given in Table 5.10. To validate the video analysis, 30 random data points were selected. Each data point consisted of a 5 minute randomly generated interval. The videos were re-run and the errors committed during this time interval were tabulated. The errors committed during the total video analysis and the validation video analysis was compared using Pearson correlation.

Table 5.10 Significant errors in each of the test kits

Accuchek® <i>Instant plus</i> ®	Home Access® Instant Cholesterol Test
Not wiping off the first drop of blood	Not wiping off the first drop of blood
Improper application of blood on the yellow test pad of the test strip	Improper application of blood in the well. The well should be filled with blood until the black circle is completely covered
Not closing the protective cover within 5 seconds	Not completing the application of blood in the well within 5 minutes
	Not waiting for at least 2 minutes and not more than 4 minutes before pulling the plastic tab
	Improper tapping of the test meter after pulling the plastic tab.

The results of the correlation analysis are tabulated in Table 5.11.

Table 5.11: Results of correlation Analysis for video analysis validation.

	Total	Commission	Omission	Timing
Correlation	0.85466	0.91700	0.82916	0.74536
(p-value)	(<0.0001)	(<0.0001)	(<0.0001)	(<0.0001)

The results of the Pearson correlation show that there is a significant correlation between the two analyses results. As a result of the correlation of 0.70 or greater, the researcher is confident in the findings.

5.3.4.1 Video Analysis Results

A paired t- test was performed to compare the total errors committed by each participant while using each kit. The results of the t-tests are tabulated in Table 5.12.

Comparing the total errors committed while using each of the two test kits, the mean errors committed while using the Accuchek® *Instant plus*® test kit is 3.5334 and the mean errors committed while using Home Access® Instant Cholesterol Test kit is 1.9667.

Table 5.12: Results of paired T-Test for total errors and total significant errors.

Difference	DF	Total Errors		Total Significant errors	
		t Value	Pr > t	t Value	Pr > t
acct - inst	29	3.91	0.0005	-3.46	0.0017

There is strong evidence that the two means are not equal. Hence, the number of errors committed while using AccucheK® *Instant plus*® were significantly more than the number of errors committed while using Home Access® Instant Cholesterol Test. Comparing the total significant errors committed while using each of the two test kits, the mean errors committed while using the AccucheK® *Instant plus*® test kit is 1.0667 and the mean errors committed while using Home Access® Instant Cholesterol Test kit is 1.9667. There is strong evidence that the two means are not equal. Hence, the number of errors committed while using Home Access® Instant Cholesterol Test is significantly more than the number of errors committed while using AccucheK® *Instant plus*®.

Paired t-tests were performed to compare the commission errors, omission errors and the timing errors committed while using each of the two test kits. The results of the T-tests are tabulated in Table 5.13.

Table 5.13: Results of paired T-tests for the different categories of errors

Difference	DF	Commission		Omission		Timing	
		t Value	Pr > t	t Value	Pr > t	t Value	Pr > t
acct - inst	29	6.29	<0.0001	-1.72	0.0960	-3.79	0.0007

- Commission Errors

The mean errors committed while using the Accucheck® *Instant plus*® test kit is 2.9 and the mean errors committed while using Home Access® Instant Cholesterol Test kit is 0.8334. There is highly significant evidence that the two means are not equal. Hence, the number of commission errors committed while using Accucheck® *Instant plus*® significantly more than the number of commission errors committed while using Home Access® Instant Cholesterol Test.

- Omission Errors

Comparing the omission errors committed while using each of the two test kits, the mean errors committed while using the Accucheck® *Instant plus*® test kit is 0.334 and the mean errors committed while using Home Access® Instant Cholesterol Test kit is 0.5. There is slightly significant evidence that the two means are not equal. Hence, the number of omission errors committed while using Accucheck® *Instant plus*® were weakly significantly less than using Home Access® Instant Cholesterol Test.

- Timing Errors

Comparing the timing errors committed while using each of the two test kits, the mean errors committed while using the Accucheck® *Instant plus*® test kit is 0.2 and the mean errors committed while using Home Access® Instant Cholesterol Test kit is 0.6334. There is highly significant evidence that the two means are not equal.

Hence, the number of commission errors committed while using Accucheck® *Instant plus*® significantly less than the number of commission errors committed while using Home Access® Instant Cholesterol Test.

5.4 Post Hoc Analysis

5.4.1 Correlation between the Significant Errors Committed while Using the Test Kits and the Difference Between the Laboratory Results and Test Kit Results

A correlation analysis was performed between the significant errors committed while using each of the test kits and the difference between the laboratory results and each of the test kit results. Two different cases were considered for each kit. For Accucheck® *Instant plus*®:

- Case 1 – All “<150” values have been approximated to 149
- Case 2 – All “<150” values have been approximated to either the laboratory results or 149, whichever is closer.

For Home Access® Instant Cholesterol Test:

- Case 1 – All “<120” values have been approximated to 119
- Case 2 – All “<120” values have been approximated to either the laboratory results or 119, whichever is closer.

The results of the correlation analysis are tabulated in Table 5.14 below.

Table 5.14 Correlation analyses between the significant errors and errors in test results

	Accucheck® <i>Instant plus</i> ®		Home Access® Instant Cholesterol Test	
	<150 = 149	<150 = lab value or 149	<120 = 119	<120 = lab value or 119
Correlation	0.09451	0.18170	0.17248	0.16717
(p-value)	(0.6392)	(0.3644)	(0.3896)	(0.4646)

From the results of the correlation analysis it is no evidence of a correlation between the significant errors committed and the errors in test results. While no correlation existed between the significant errors committed and the errors in test results, one

cannot assume that errors in user operation of the kits might not ultimately result in poor test results.

5.5 Subjective Comments from Users

After using both the test kits the participants were asked whether they were willing to use the home cholesterol test kits again. This question was asked to get their opinion on cholesterol test kit for future use. Price was a major factor that effected their decision. Most of the participants were not willing to spend more that \$20 to \$40 on these test kits. Ease of use and speed of results also effected their decision. Some of the participants felt that the home cholesterol test kits would be really helpful in keeping constant check on their cholesterol between the annual check-ups at the doctor's clinic. They also felt that the using these test kits was easier than visiting a doctor. Few of the participants wanted to know the accuracy of the home test kits results when compared to the laboratory test results before making a decision. A few people felt that the Home Access® Instant Cholesterol Test required too much blood to give accurate results. Few of the participants, who were already seeing a doctor, were suffering from high LDL. They wanted a test kit that would give them the LDL value. It was a new experience for all the participants as none of them had ever heard of home cholesterol test kit until they participated in the study.

After getting the laboratory cholesterol results from Pennington Medical Center, the laboratory test results were given to all the participants. They were asked their future healthcare plan based on the laboratory results to see if there was a change in the future healthcare plan when their cholesterol level increased or decreased as compared to the home test kit results. A few of the participants had far higher cholesterol as compared to the home test kit results. All the participants who had a cholesterol level higher than 220 mg/dL chose to change their lifestyle. The

laboratory test results consisted of total cholesterol, HDL, LDL and triglycerides value. Some of the participants were suffering from high LDL and chose to see a doctor at the earliest convenience.

After getting the laboratory results the participants were given the error for each of the test kits they used. They were again asked their opinion on using the home cholesterol test kits for future use. This question was asked to see if the difference between the laboratory results and the test results affected their opinion on using the home test kits in future. Most of the participants whose test kit results differed greatly when compared to the laboratory results, changed their opinion on using the test kits. Most of them felt that the tests were not accurate and they were not willing to spend money on test kits when they were not confident of getting correct results.

6. DISCUSSION

From the results of the ANOVA for hypothesis 1, it was observed that there is no relation between the type of test kit and the error in the test results when the test results of each test kit were compared to the laboratory results. A correlation analysis was performed to determine the correlation between the test results for each test kit and the laboratory results. The results of the correlation differ from the results of the ANOVA. The results of the correlation analysis showed that the Accuchek® *Instant plus*® test results and the laboratory test results were highly correlated but the Home Access® Instant Cholesterol Test results were marginally correlated to the laboratory test results. A paired t-test was performed to check whether the number of significant errors committed while using each of the test kits affected the test results. The results of the t-test show highly significant evidence that the participants committed more significant errors while using Home Access® Instant Cholesterol Test than while using Accuchek® *Instant plus*®. The results of the correlation analysis can be explained by the results of the paired t-test. As the number of significant errors committed while using Home Access® Instant Cholesterol Test is higher than those committed while using Accuchek® *Instant plus*®, the results of Accuchek® *Instant plus*® are highly correlated to the laboratory results when compared to the Home Access® Instant Cholesterol Test results. Irrespective of the number of significant errors committed, the contribution of the errors might have been equal. The results of ANOVA support the above statement. Hence, we have significant evidence to accept hypothesis 1.

A correlation analysis was performed to check whether, the number of significant errors committed while using each of the test kits affected the error between the test results and the laboratory results. The results of the correlation

analysis show that there was no correlation between the number of errors committed and the errors in the test results. Hence, we can state that though the participants committed more significant errors while using Home Access® Instant Cholesterol Test than Accucheck® *Instant plus*®, it did not affect the end result. While no correlation existed between the significant errors committed and the errors in test results, one cannot assume that errors in user operation of the kits might not ultimately result in poor test results. This is the same conclusion drawn from the results of the ANOVA.

Some of the participants in the study were already seeing a doctor so the test results did not effect their future healthcare decision. Among the 30 participants, 22 (11 men and 11 women) of them were not seeing a doctor. These 22 participants were considered for the statistical analysis of hypothesis 2. From the predictor P values for male and female subjects (table 5.6 and figure 5.1), it was observed that irrespective of the gender of the participant, as the cholesterol level of the participant increased from 119 mg/dL to 254mg/dL the participants said that they were more likely to change their lifestyle rather than visit a doctor. As the cholesterol level increased, the predicted probability to choose not to change ones lifestyle decreased and the predicted probability to change ones lifestyle increased. Men said that they would change their lifestyle at a lower cholesterol level than women. For women, there was a sharp increase in the predicted probability to change ones lifestyle between 186.5 mg/dL and 220 mg/dL. According to the National Cholesterol Education Program (NCEP) expert panel, cholesterol levels between 200 mg/dL and 238 mg/dL are considered to be borderline high (refer table 2.1 in the literature review section). It can be stated that women tend to worry when their cholesterol levels are

neering the borderline high category. Hence, we have significant evidence to reject hypothesis 2.

It was strange to note that as the cholesterol level increased, there was a slight decrease in the predicted probability to see a doctor. The change in the predicted probability to visit a doctor was negligible regardless of the increase in cholesterol level. This is a matter of concern. People having cholesterol higher than 238 mg/dL are at a high risk of heart attack and their cholesterol should be brought down as soon as possible. But, if they neglect going to the doctor and try to reduce their cholesterol by changing their lifestyle, the remedy may not be very effective. The purpose of home cholesterol test kits is completely reversed. The home cholesterol test kits were manufactured to help people have better knowledge of their cholesterol level and help them go to the doctor at the right time before it is too late. From the results of the statistical analysis, it can be seen that this purpose is not being served.

In hypothesis 3 we are comparing the usability of the two test kits used. Though the end result of the two test kits was the same, the procedure followed to get the result was completely different. Figure 6.1 shows the instruction card that was used by the participants to perform the test. The Accucheck® *Instant plus*®, digital test kit, was found to have major flaws in its instruction card.

Most of the participants were not able to insert the test strip in their first attempt. The instruction card had no picture showing the correct side of the test strip that should be inserted (Figure 6.1, refer Appendix J for larger view). The error card also gave very little information as to how to rectify the error committed. The procedure to remove the test strip was also not specified in the error card. After inserting the test strip the next instruction stated “open the protective cover”. The instruction card did not give a picture of the protective cover. Even on the test meter,

there was no sign to direct the users to the protective cover. All the participants had to search for the protective cover before they managed to open it. Two of the participants got frustrated searching for the protective cover and quit the test.

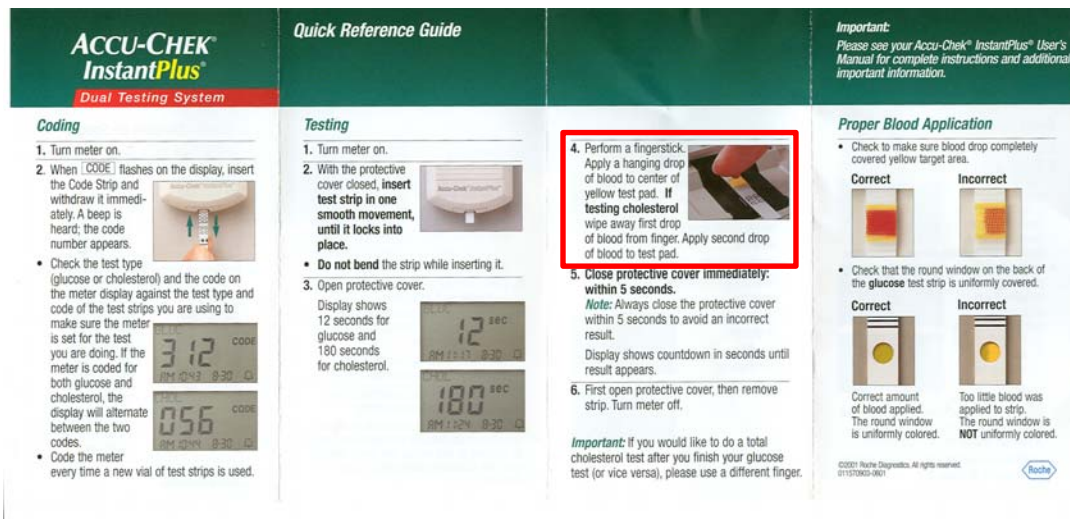


Figure 6.1: Instruction card for Accuchek® Instant plus®

After performing a finger stick the users are asked to apply a hanging drop of blood at the center of the test strip. After this instruction, the instruction stated that “if testing for cholesterol, wipe off the first drop of blood. Apply second drop of blood to test pad” (refer to the box in Figure 6.1). Most of the participants read this instruction after applying blood on the test pad. The amount of blood to be applied on the test pad is shown in a picture at the end of the test. By the time the participants looked at the picture they had already finished applying blood and closed the protective cover. The participants were also given the Accuchek® Instant plus® user manual for reference if they were unclear with any of the instructions in the instructions card “quick reference guide”. Around 28 of the 30 participants were not interested in reading the user manual to perform the test. They stated that they did not have time to read through a manual to perform the test although they were not given any instructions that limited their time to complete the test. Most of the errors committed while using

the Accucheck® *Instant plus*® meter were commission errors (i.e., incorrect insertion of test strip and improper blood application on the test pad). The Accucheck® *Instant plus*® test kit gets switched off in 3 minutes after it is switched on. This information is not given in the user manual or in the quick reference guide. Some of the participants switched on the meter first and then continued reading the instructions. By the time they inserted the test strip, opened the protective cover and applied blood on the test pad, the meter would get switched off. The participants had to repeat the test again. They were quite frustrated at that time and were not able to do the test as well as they had done the first time. The different errors committed by participants while using Accucheck® *Instant plus*® were improper insertion of test strip, not wiping off the first drop of blood not closing the protective cover within 5 second of applying blood to the test pad and insufficient amount of blood on the test strip. Improper insertion of test strip would not have affected the test result but all the other errors are significant errors which would have affected the test results.

All the participants felt that the instructions for the Home Access® Instant Cholesterol Test kit were better organized and helpful as compared to the Accucheck® *Instant plus*® test kit. The pictorial presentation of the instructions helped in better user performance. A stop sign was given and the instruction “use the gauze pad to wipe off the first sign of blood from your finger, Failure to do so may affect your result” was stated in red as show in Figure 6.2.

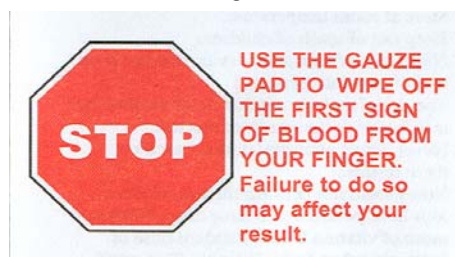


Figure 6.2: The ‘STOP’ sign as in the instructions for Home Access® Instant Cholesterol Test

Though the instruction was specified clearly, some of the participants failed to follow the instruction. The major problem with this test kit was the amount of blood required to perform the test. The participants had to fill a well till the black circle was completely covered. A large amount of blood was to be applied to complete this step. Most of the participants were unable to squeeze out enough blood to complete the step. The participants had to wait for 2 to 4 minutes before performing the next step. Some of the participants did not wait the required amount of time and proceeded to the next step. After the tab is pulled completely the test meter is to be tapped 2 to 3 times to activate the test. If the test meter is not tapped properly, the result is affected. The test result is read after the “end” indicator turns green. The very tip of the purple color bar is to be read, even if it is fuzzy and faint. Most of the participants were not sure if they were reading their result correctly. The very tip of the purple fuzzy bar was difficult to determine. There might have been an error in reading the purple bar which might have contributed to the error in the test result. The different errors committed while using the Home Access® Instant Cholesterol Test kit are not wiping off the first drop of blood, insufficient amount of blood in the well, pulling the tab before 2 minutes or after 4 minutes and not tapping the meter properly. All the above mentioned errors can be classified as significant errors which may affect the end result.

When the total number of errors committed while using each of the test kits was compared, it was found that the participants committed significantly more errors while using the Accucheck® *Instant plus*® meter than the Home Access® Instant Cholesterol Test kit. Participants committed significantly more commission errors while using Accucheck® *Instant plus*® than while using the Home Access® Instant Cholesterol Test kit but they committed significantly more timing errors while using

Home Access® Instant Cholesterol Test than while using the AccucheK® *Instant plus*® meter. When the number of omission errors committed while using each of the two test kits were compared, they were not significantly different from each other. Results of the paired t-test for significant errors showed that significantly more errors were committed while using Home Access® Instant Cholesterol Test than while using the AccucheK® *Instant plus*® meter. There is evidence rejecting hypothesis 3. The results of the usability questionnaire, comparison questionnaire and the post questionnaire show that the participants rated the test kits equally on the basis of usability.

The attitude of the participants on using the cholesterol tests kits to keep a constant check on their cholesterol, changed after they received their laboratory test results. The accuracy of the test kit was a major concern. The cost of the testing kit also played a major role in this change of decision. Most of the participants were unwilling to spend even \$20 on test kits if they did not have the assurance of its accuracy. It can be concluded the decision to use the test kits in future depends on the cost of the test kit, the accuracy of the test results and the ease with which it can be used.

7. CONCLUSIONS AND RECOMMENDATIONS

7.1 Conclusions

Usability analysis was conducted on home cholesterol testing kits using two different types of meters. It was found that the procedural instructions needed to be in a proper sequential manner for the successful completion of the test.

Statistical analysis revealed that the error in the test result when compared to the laboratory result did not depend on the type of the test kit. There is room for error in both the testing kits and from the results of the video analysis it can be concluded that the participants did commit number of significant errors irrespective of the testing kit used. From the nominal logistic analysis it was concluded that men and women differed on health care decision point for transition to a changing lifestyle. As the cholesterol levels increased it was noticed that the participants said they would change their life style rather than visit the doctor. It was strange to note that regardless of the cholesterol level the participants never preferred to visit a doctor. This was observed for both men and women alike.

From the video analysis it can be concluded that the user performance depended on the type of test kit being used. Significantly more errors were committed while using Accucheck® *Instant plus*® than Home Access® Instant Cholesterol Test. From the statistical analysis of the questionnaire study it was found that both the kits were rated equally when they were first used. There was an ordering effect on the usability score. From the post results study it can be concluded the decision to use the test kits in future depends on the cost of the test kit, the accuracy of the test results and the ease with which it can be used.

7.2 Recommendations

Better design of the testing kit by providing sequential procedural instructions could improve the accuracy of these testing kits. It is also recommended that these instructions provided in a stepwise pictorial manner could yield better results. The variation in results while performing statistical analysis can be attributed to the variation in sample size for each analysis. A larger sample size is recommended for more stabilized results. A matter of concern is the decision of the participants to change their lifestyle rather than visiting a doctor regardless of their cholesterol level. This aspect needs further investigation. The participants in this study represented employees from the Louisiana State University. When using larger sample sizes, it is recommended that participants should be chosen from a larger population.

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APPENDIX A
DEMOGRAPHIC QUESTIONNAIRE

Subject Number: _____

1. Which category best describes your age?
 - a) below 30
 - b) 30-40
 - c) 40-50
 - d) 50-60
 - e) 60-70
 - f) 70-80
 - g) 80 and above

2. What is your gender?
 - a) Male
 - b) Female

3. What category best describes your income?
 - a) \$0-\$14,999
 - b) \$15,000-\$29,999
 - c) \$30,000-\$44,999
 - d) \$45,000-\$59,999
 - e) \$60,000-\$74,999
 - f) \$75,000-\$89,999
 - g) \$90,000 and above

4. Which category best describes your educational status?
 - a) Below middle school
 - b) Middle school/ Jr High
 - c) High school
 - d) Some college
 - e) 2-year degree
 - f) 4-year degree
 - g) Masters degree and higher

5. Which category best describes your ethnicity?
 - a) African American
 - b) Caucasian
 - c) Asian
 - d) Hispanic
 - e) Pacific Islander
 - f) Native American
 - g) European

6. What kind of medical insurance do you have?
 - a) Medicare
 - b) Private insurance

7. Have you ever had your cholesterol numbers checked?

- a) Yes
- b) No

8. How often do you get your cholesterol checked?

- a) Once a week
- b) Once in two weeks
- c) Once in a month
- d) Never checked

9. Have you ever heard of home cholesterol test kits?

- a) Yes
- b) No

9. Have you ever used a home cholesterol test kit?

- a) Yes
- b) No

10. If the answer to the above question is 'yes', what is the name of the product and how much does it cost?

Name of product: _____

Cost of the product: _____

11. How much money are you willing to spend on the home health testing kits?

- a) none
- b) less than \$20
- c) \$20 to 40
- d) \$ 40 to \$60
- e) \$60 to \$150
- f) \$150 to \$250
- g) more than \$250

APPENDIX B
USABILITY QUESTIONNAIRE – Accuchek® Instant plus®
(DIGITAL DISPLAY)

Subject Number: _____

Please circle the response that best represents your opinion to the following questions.

1. Is it easy to learn the procedure of the test?

1	2	3	4	5
Very Easy	Easy	Borderline	Hard	Very Hard

2. Is it easy to remember how to perform the test?

1	2	3	4	5
Very Easy	Easy	Borderline	Hard	Very Hard

3. Is the amount of effort required to learn the test procedure acceptable?

1	2	3	4	5
Very Acceptable	Acceptable	Borderline	Unacceptable	Very Unacceptable

4. Is the amount of time taken to learn the test acceptable?

1	2	3	4	5
Very Acceptable	Acceptable	Borderline	Unacceptable	Very Unacceptable

5. How helpful are the instructions in performing the test?

1	2	3	4	5
Very Helpful	Helpful	Borderline	Unhelpful	Very Unhelpful

6. Are the instructions presented in a proper step-by-step manner?

1	2	3	4	5
Strongly Agree	Agree	Borderline	Disagree	Strongly Disagree

7. Are the instructions legible and clear?

1	2	3	4	5
Strongly Agree	Agree	Borderline	Disagree	Strongly Disagree

8. How easy is it to insert the test strip?

1	2	3	4	5
Very Easy	Easy	Borderline	Hard	Very Hard

9. How easy is it to draw blood using the lancet?

1	2	3	4	5
Very Easy	Easy	Borderline	Hard	Very Hard

10. Are you satisfied with the size of the test strip you used?

1	2	3	4	5
Very Satisfied	Satisfied	Borderline	Unsatisfied	Very Unsatisfied

11. How do you rate the design of the kit?

1	2	3	4	5
Excellent	Good	Borderline	Bad	Very Bad

12. How do you rate your interaction with the kit?

1	2	3	4	5
Excellent	Good	Borderline	Bad	Very Bad

13. How satisfied are you with your performance of completing the test?

1	2	3	4	5
Very Satisfied	Satisfied	Borderline	Unsatisfied	Very Unsatisfied

14. Are you satisfied with the time taken to perform the test?

1	2	3	4	5
Very Satisfied	Satisfied	Borderline	Unsatisfied	Very Unsatisfied

15. Are you satisfied with the way you were presented the test results?

1	2	3	4	5
Very Satisfied	Satisfied	Borderline	Unsatisfied	Very Unsatisfied

16. Do you believe that the test results are a true representation of your cholesterol numbers?

1	2	3	4	5
Strongly Agree	Agree	Borderline	Disagree	Strongly Disagree

APPENDIX C
USABILITY QUESTIONNAIRE – HOME ACCESS® INSTANT
CHOLESTEROL TEST (METER BASED TEST)

Subject Number: _____

Please circle the response that best represents your opinion to the following questions.

1. Is it easy to learn the procedure of the test?

1	2	3	4	5
Very Easy	Easy	Borderline	Hard	Very Hard

2. Is it easy to remember how to perform the test?

1	2	3	4	5
Very Easy	Easy	Borderline	Hard	Very Hard

3. Is the amount of effort required to learn the test procedure acceptable?

1	2	3	4	5
Very Acceptable	Acceptable	Borderline	Unacceptable	Very Unacceptable

4. Is the amount of time taken to learn the test acceptable?

1	2	3	4	5
Very Acceptable	Acceptable	Borderline	Unacceptable	Very Unacceptable

5. How helpful are the instructions in performing the test?

1	2	3	4	5
Very Helpful	Helpful	Borderline	Unhelpful	Very Unhelpful

6. Are the instructions presented in a proper step-by-step manner?

1	2	3	4	5
Strongly Agree	Agree	Borderline	Disagree	Strongly Disagree

7. Are the instructions legible and clear?

1	2	3	4	5
Strongly Agree	Agree	Borderline	Disagree	Strongly Disagree

8. How easy is it to draw blood using the lancet?

1	2	3	4	5
Very Easy	Easy	Borderline	Hard	Very Hard

9. Is it easy to place blood on the region given on the test kit to place the blood?

1	2	3	4	5
Very Easy	Easy	Borderline	Hard	Very Hard

10. How do you rate the design of the kit?

1	2	3	4	5
Excellent	Good	Borderline	Bad	Very Bad

11. How do you rate your interaction with the kit?

1	2	3	4	5
Excellent	Good	Borderline	Bad	Very Bad

12. How satisfied are you with your performance of completing the test?

1	2	3	4	5
Very Satisfied	Satisfied	Borderline	Unsatisfied	Very Unsatisfied

13. Are you satisfied with the time taken to perform the test?

1	2	3	4	5
Very Satisfied	Satisfied	Borderline	Unsatisfied	Very Unsatisfied

14. Are you satisfied with the way you were presented the test results?

1	2	3	4	5
Very Satisfied	Satisfied	Borderline	Unsatisfied	Very Unsatisfied

15. Is it easy to interpret the test results?

1	2	3	4	5
Very Easy	Easy	Borderline	Hard	Very Hard

16. Do you believe that the test results are a true representation of your cholesterol numbers?

1	2	3	4	5
Strongly Agree	Agree	Borderline	Disagree	Strongly Disagree

APPENDIX D
COMPARISON QUESTIONNAIRE

Subject Number: _____

Please circle the response that best represents your opinion to the following questions.

1	2	3	4	5
Strongly Agree	Agree	Borderline	Disagree	Strongly Disagree

1. It is easy to learn the procedure of the test.

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

2. It is easy to remember how to perform the test.

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

3. The amount of effort required to learn the test procedure is acceptable.

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

4. The amount of time taken to learn the test is acceptable.

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

5. The instructions given with the test kit are helpful in performing the test.

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

6. The instructions are presented in a proper step-by-step manner.

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

7. The instructions are legible and clear.

AccucheK® *Instant plus*®

Home Access® Instant Cholesterol Test

1 2 3 4 5

1 2 3 4 5

8. It is easy to draw blood using the lancet given in the kit.

AccucheK® *Instant plus*®

Home Access® Instant Cholesterol Test

1 2 3 4 5

1 2 3 4 5

9. It is easy to place blood on the test (strip) or the region given on the test kit to place the blood.

AccucheK® *Instant plus*®

Home Access® Instant Cholesterol Test

1 2 3 4 5

1 2 3 4 5

10. The design of the kit is apt for this kind of test.

AccucheK® *Instant plus*®

Home Access® Instant Cholesterol Test

1 2 3 4 5

1 2 3 4 5

11. It is easy to interact with the kit.

AccucheK® *Instant plus*®

Home Access® Instant Cholesterol Test

1 2 3 4 5

1 2 3 4 5

12. How satisfied are you with your performance of completing the test?

AccucheK® *Instant plus*®

Home Access® Instant Cholesterol Test

1 2 3 4 5

1 2 3 4 5

13. The time taken to perform the test is sufficient.

AccucheK® *Instant plus*®

Home Access® Instant Cholesterol Test

1 2 3 4 5

1 2 3 4 5

14. The presentation of the test results is easy to understand.

AccucheK® *Instant plus*®

Home Access® Instant Cholesterol Test

1 2 3 4 5

1 2 3 4 5

15. It easy to interpret the test results.

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

16. The test results are a true representation of your cholesterol numbers.

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

APPENDIX E
POST -TEST QUESTIONNAIRE

Subject Number: _____

PART A

1. Do you think the results of the home cholesterol test kit are accurate and represent your true cholesterol numbers?

1	2	3	4	5
Highly Inaccurate	Accurate	borderline	Inaccurate	Highly Accurate

2. According to your test results, what is your cholesterol level?

Total Cholesterol

(Accucheck® Instant plus®)

(Home Access® Instant Cholesterol test)

Value: _____

Value: _____

- a) Desirable (less than 200 mg/dL)
- b) Borderline high (200-239 mg/dL)
- c) High (240 mg/dL or above)

- a) Desirable (less than 200 mg/dL)
- b) Borderline high (200-239 mg/dL)
- c) High (240 mg/dL or above)

3. Are you willing to use the home cholesterol test kit again, to test your cholesterol level?

1	2	3	4	5
Strongly Agree	Agree	Borderline	Disagree	Strongly Disagree

4. Why would/ wouldn't you use the home cholesterol test kit again?

5. What is your future health care plan based on the cholesterol numbers for the home cholesterol test?

- a) Visit a doctor
- b) Change in lifestyle
- c) No change in lifestyle or visit to a doctor
- d) Others

If others, state your future health care plan.

PART B – (comparison with Laboratory results) – Follow on study

1. According to your laboratory results, what are your cholesterol levels?

Total Cholesterol

Value: _____

- a) Desirable (less than 200 mg/dL)
- b) Borderline high (200-239 mg/dL)
- c) High (240 mg/dL or above)

2. How do your lab results differ from your home cholesterol test results?

Total Cholesterol (Home Access® Instant Cholesterol Test)

- a) Exactly equal
- b) Different but in the same range

Lab results are greater by _____ mg/dL

Lab results are less by _____ mg/dL

- c) Entirely in a different range
- Lab results are greater by _____ mg/dL
- Lab results are less by _____ mg/dL

Total Cholesterol (Accucheck® Instant plus®)

- a) Exactly equal
- b) Different but in the same range

Lab results are greater by _____ mg/dL

Lab results are less by _____ mg/dL

- c) Entirely in a different range
- Lab results are greater by _____ mg/dL
- Lab results are less by _____ mg/dL

3. How would you rate the home cholesterol test kits on the basis of the following?

(Please circle the response that best represents your opinion)

1	2	3	4	5
Strongly Disagree	Agree	Borderline	Disagree	Strongly Agree

a) The results are accurate and show my correct cholesterol level

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

b) The test is reliable

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

c) The test results depend on the procedure followed to perform the test.

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

d) The results depend on the design of the test kit.

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

e) The price of the kit is within my range

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

f) I would use the kit to keep a constant check on my cholesterol level

AccucheK® *Instant plus*®

1 2 3 4 5

Home Access® Instant Cholesterol Test

1 2 3 4 5

4. Did you change your decision on your future health care plan after comparing your laboratory results with the home cholesterol test results?

- a) Yes
- b) No

5. Reasons for changing /not changing your decision on your future medical plan?

6. Are you willing to use the home cholesterol test kit again, to test your cholesterol level?

- | | | | | |
|----------|-------|------------|----------|----------|
| 1 | 2 | 3 | 4 | 5 |
| Strongly | Agree | Borderline | Disagree | Strongly |
| Agree | | | | Disagree |

7. Has your decision on using the home cholesterol test kit for testing your cholesterol levels in future, changed?

- a) Yes
- b) No

8. Reasons for changing/ not changing your decision on using the home cholesterol test kit for testing your cholesterol levels in future.

APPENDIX F

VIDEO ANALYSIS WORKSHEET

Subject	Run	Procedure No.	Procedure	HH	M	SS	TT	Begin	HH	M	SS	TT	end dec	Response	Error	Gender
	1		read instructions													
	ACC		turn meter on													
			insert test strip													
			open protective cover													
			wipe finger with alcohol swabs													
			stick your finger													
			wipe off first drop of blood													
			apply blood on the yellow pad of the test strip													
			the yellow test pad must be filled with blood													
			close protective cover within 5 sec													
			countdown begins													
			read results													
	2		read instructions													
	IC		place the contents on the table													
			warm your hands													
			wipe hands using alcohol swabs													
			place lancet on the table													
			stick your finger by pushing your finger firmly													
			wipe off first drop of blood													
			apply hanging drop of blood to the well till black													
			wait for 2 to 4 minutes													
			pull the plastic tab till completely arrow appears													
			tap the device on the table 2-3 times													
			OK' indicator turns purple - test starts													
			END' turns green in 10-12 minutes													
			read results													

APPENDIX G
RESULTS OF KRUSKAL WALLIS TEST

Hypothesis 1

1. Case 1: <150=149 and <120=119

Chi-Square	0.4215
DF	1
Pr > Chi-Square	0.5162

2. Case 2: <150 and <120 are equal to lab value or 149/119 whichever is closer

Chi-Square	1.7330
DF	1
Pr > Chi-Square	0.1880

Hypothesis 3

1. Usability Questionnaire analysis

Chi-Square	0.0004
DF	1
Pr > Chi-Square	0.9834

2. Comparison Questionnaire analysis

Chi-Square	0.5653
DF	1
Pr > Chi-Square	0.4521

3. Post Questionnaire analysis

Chi-Square	2.1975
DF	1
Pr > Chi-Square	0.1382

APPENDIX H
EXCEL TABLES USED FOR STATISTICAL ANALYSIS

Hypothesis 1

1. Tables for ANOVA

a. Approximating all <150 to 149 and <120 to 119

Meter	Error
Accuchek	6
Accuchek	57
Accuchek	6
Accuchek	43
Accuchek	7
Accuchek	3
Accuchek	66
Accuchek	49
Accuchek	9
Accuchek	38
Accuchek	13
Accuchek	47
Accuchek	35
Accuchek	40
Accuchek	0
Accuchek	2
Accuchek	1
Accuchek	4
Accuchek	23
Accuchek	4
Accuchek	21
Accuchek	5
Accuchek	47
Accuchek	23
Accuchek	78
Accuchek	4
Accuchek	48

Meter	Error
instant	13
instant	39
instant	4
instant	13
instant	21
instant	39
instant	34
instant	17
instant	8
instant	39
instant	5
instant	181
instant	129
instant	10
instant	30
instant	45
instant	2
instant	13
instant	128
instant	11
instant	55
instant	18
instant	20
instant	23
instant	2
instant	18
instant	44

b. Approximating <150 and <120 to either the lab values or to 149/119 whichever is closer

Meter	Error
Accuchek	6
Accuchek	57
Accuchek	6
Accuchek	0
Accuchek	7
Accuchek	3
Accuchek	66
Accuchek	49
Accuchek	9
Accuchek	38
Accuchek	13
Accuchek	47
Accuchek	35
Accuchek	0
Accuchek	0
Accuchek	2
Accuchek	1
Accuchek	4
Accuchek	23
Accuchek	4
Accuchek	21
Accuchek	5
Accuchek	0
Accuchek	23
Accuchek	78
Accuchek	4
Accuchek	48

Meter	Error
instant	13
instant	39
instant	4
instant	0
instant	21
instant	39
instant	34
instant	17
instant	8
instant	39
instant	5
instant	181
instant	129
instant	0
instant	30
instant	45
instant	2
instant	13
instant	128
instant	11
instant	55
instant	18
instant	20
instant	23
instant	2
instant	18
instant	44

2. Tables used for correlation

a. Correlation between Laboratory results and test results by test kit type and gender

(i) Approximating all <150 to 149 and <120 to 119

Gender	Meter	Lab results	Test results
female	Accuchek	209	215
female	Accuchek	220	163
female	Accuchek	148	154
female	Accuchek	106	149
female	Accuchek	241	248
female	Accuchek	216	213
female	Accuchek	215	149
female	Accuchek	198	149
female	Accuchek	168	167
female	Accuchek	202	198
female	Accuchek	247	270
female	Accuchek	185	189
female	Accuchek	251	230
female	Accuchek	162	157
female	Instant	209	196
female	Instant	220	181
female	Instant	148	144
female	Instant	106	119
female	Instant	241	220
female	Instant	216	177
female	Instant	215	181
female	Instant	198	181
female	Instant	168	166
female	Instant	202	189
female	Instant	247	119
female	Instant	185	196
female	Instant	251	196
female	Instant	162	144

Gender	Meter	Lab results	Test results
male	Accuchek	196	187
male	Accuchek	190	152
male	Accuchek	182	169
male	Accuchek	301	254
male	Accuchek	248	213
male	Accuchek	109	149
male	Accuchek	149	149
male	Accuchek	171	169
male	Accuchek	102	149
male	Accuchek	172	149
male	Accuchek	238	160
male	Accuchek	153	149
male	Accuchek	209	161
male	instant	196	204
male	instant	190	151
male	instant	182	177
male	instant	301	120
male	instant	248	119
male	instant	109	119
male	instant	149	119
male	instant	171	126
male	instant	102	122
male	instant	174	151
male	instant	222	220
male	instant	238	220
male	instant	209	165

(ii) Approximating <150 and <120 to either the lab values or to 149/119 whichever is closer

Gender	Meter	Lab results	Test results
female	Accuchek	209	215
female	Accuchek	220	163
female	Accuchek	148	154
female	Accuchek	106	106
female	Accuchek	241	248
female	Accuchek	216	213
female	Accuchek	215	149
female	Accuchek	198	149
female	Accuchek	168	167
female	Accuchek	202	198
female	Accuchek	247	270
female	Accuchek	185	189
female	Accuchek	251	230
female	Accuchek	162	157
female	Instant	209	196
female	Instant	220	181
female	Instant	148	144
female	Instant	106	106
female	Instant	241	220
female	Instant	216	177
female	Instant	215	181
female	Instant	198	181
female	Instant	168	166
female	Instant	202	189
female	Instant	247	119
female	Instant	185	196
female	Instant	251	196
female	Instant	162	144

Gender	Meter	Lab results	Test results
male	Accuchek	196	187
male	Accuchek	190	152
male	Accuchek	182	169
male	Accuchek	301	254
male	Accuchek	248	213
male	Accuchek	109	109
male	Accuchek	149	149
male	Accuchek	171	169
male	Accuchek	102	102
male	Accuchek	172	149
male	Accuchek	238	160
male	Accuchek	153	149
male	Accuchek	209	161
male	instant	196	204
male	instant	190	151
male	instant	182	177
male	instant	301	120
male	instant	248	119
male	instant	109	109
male	instant	149	119
male	instant	171	126
male	instant	102	122
male	instant	174	151
male	instant	222	220
male	instant	238	220
male	instant	209	165

b. Correlation between the two test kits results (Accuchek® *Instant plus*® and Home Access® Instant Cholesterol Test)

(i) Approximating all <150 to 149 and <120 to 119

(ii) Approximating <150 and <120 to either the lab values or to 149/119 whichever is closer

Table (i)

Gender	Accuchek® <i>Instant plus</i>®	Home Access® Instant Cholesterol Test
female	215	196
female	163	181
female	154	144
female	149	119
female	248	220
female	213	177
female	149	181
female	149	181
female	167	166
female	270	119
female	189	196
female	230	196
female	157	144
male	187	204
male	152	151
male	169	177
male	254	120
male	213	119
male	149	119
male	149	119
male	169	126
male	149	122
male	160	220
male	161	165

Table (ii)

Gender	Accuchek® <i>Instant plus</i>®	Home Access® Instant Cholesterol Test
female	215	196
female	163	181
female	154	144
female	106	106
female	248	220
female	213	177
female	149	181
female	149	181
female	167	166
female	270	119
female	189	196
female	230	196
female	157	144
male	187	204
male	152	151
male	169	177
male	254	120
male	213	119
male	109	109
male	149	119
male	169	126
male	102	122
male	160	220
male	161	165

Hypothesis 2

Table for Nominal logistic regression

gender	result	Decision	decision
female	119	3	No change in lifestyle/visit a doctor
male	122	3	No change in lifestyle/visit a doctor
female	144	3	No change in lifestyle/visit a doctor
female	149	3	No change in lifestyle/visit a doctor
female	149	3	No change in lifestyle/visit a doctor
male	149	1	Change in lifestyle
male	151	2	Change in lifestyle
male	152	3	Change in lifestyle
female	163	1	Change in lifestyle
male	165	1	visit a doctor
female	166	3	No change in lifestyle/visit a doctor
male	169	2	visit a doctor
male	187	3	No change in lifestyle/visit a doctor
female	189	3	No change in lifestyle/visit a doctor
female	196	1	visit a doctor
female	196	3	No change in lifestyle/visit a doctor
female	213	2	No change in lifestyle/visit a doctor
male	213	2	visit a doctor
female	215	2	visit a doctor
male	220	2	Change in lifestyle
male	220	2	Change in lifestyle
male	254	2	Change in lifestyle

Hypothesis 3

1. Usability Questionnaire table

Meter	Score
Accuchek	24
Accuchek	30
Accuchek	43
Accuchek	34
Accuchek	41
Accuchek	32
Accuchek	26
Accuchek	23
Accuchek	31
Accuchek	27
Accuchek	34
Accuchek	28
Accuchek	33
Accuchek	26
Accuchek	37
Accuchek	26
Instant	32
Instant	30
Instant	29
Instant	24
Instant	42
Instant	30
Instant	34
Instant	17
Instant	21
Instant	34
Instant	44
Instant	31
Instant	77
Instant	19

2. Comparison questionnaire table

Meter	Score
Accuchek	23
Accuchek	32
Accuchek	32
Accuchek	29
Accuchek	32
Accuchek	32
Accuchek	22
Accuchek	23
Accuchek	16
Accuchek	34
Accuchek	33
Accuchek	22
Accuchek	32
Accuchek	25
Accuchek	36
Accuchek	35
Instant	33
Instant	33
Instant	24
Instant	41
Instant	45
Instant	27
Instant	31
Instant	25
Instant	20
Instant	27
Instant	42
Instant	32
Instant	80
Instant	17

3. Post Questionnaire table

Meter	Score
Accuchek	15
Accuchek	23
Accuchek	9
Accuchek	6
Accuchek	14
Accuchek	10
Accuchek	17
Accuchek	18
Accuchek	6
Accuchek	11
Accuchek	10
Accuchek	12
Accuchek	13
Accuchek	9
Accuchek	6
Accuchek	11
Accuchek	6
Accuchek	6
Accuchek	11
Accuchek	9
Accuchek	16
Accuchek	6
Accuchek	12
Accuchek	9
Accuchek	22
Accuchek	12
Accuchek	13
Accuchek	11
Accuchek	19

Meter	Score
Instant	9
Instant	9
Instant	16
Instant	16
Instant	22
Instant	13
Instant	18
Instant	23
Instant	12
Instant	8
Instant	12
Instant	14
Instant	16
Instant	12
Instant	10
Instant	9
Instant	5
Instant	11
Instant	10
Instant	21
Instant	19
Instant	7
Instant	12
Instant	7
Instant	21
Instant	14
Instant	21
Instant	16
Instant	14

4. Video analysis tables

- a. Table for paired T-test for total errors and different types of errors

Where,

C = Commission

O = Omission

S = Sequence

T = Timing

1 represents Accucheck® *Instant plus*®

2 represents Home Access® Instant Cholesterol Test

C1	O1	T1	S1	Total	C2	O2	T2	S2	Total
0	0	0	0	0	0	0	0	0	0
5	0	0	0	5	1	0	1	0	2
2	0	1	1	4	0	1	2	0	3
4	0	0	0	4	1	0	1	0	2
5	0	0	0	5	2	0	1	0	3
5	0	0	0	5	1	1	0	0	2
3	1	0	0	4	1	1	1	0	3
4	1	0	0	5	0	0	0	0	0
1	0	1	0	2	0	0	1	0	1
2	1	0	0	3	1	1	1	0	3
1	0	0	0	1	0	0	1	0	1
1	0	0	0	1	0	0	1	0	1
1	0	0	0	1	0	1	1	0	2
1	0	0	0	1	0	1	1	0	2
5	0	1	0	6	1	1	1	0	3
9	0	0	2	11	2	0	0	0	2
7	1	0	0	8	4	1	0	0	5
4	0	0	0	4	5	0	1	0	6
2	0	0	0	2	0	0	0	0	0
3	0	0	0	3	1	0	1	0	2
4	1	0	0	5	1	1	0	0	2
2	1	1	0	4	0	1	0	0	1
2	0	0	0	2	1	0	1	0	2
3	2	1	0	6	1	2	1	0	4
0	0	0	0	0	0	1	0	0	1
0	0	1	0	1	0	0	0	0	0
2	1	0	0	3	0	0	0	0	0
6	0	0	0	6	0	1	1	0	2
3	0	0	0	3	2	0	1	0	3
0	1	0	0	1	0	1	0	0	1

b. Table for validation of video analysis

Where,

C = Commission

O = Omission

S = Sequence

T = Timing

1 represents first analysis

2 represents second analysis

C2	O2	T2	S2	Total	C1	O1	T1	S1	Total
0	0	0	0	0	0	0	0	0	0
2	0	0	0	2	5	0	0	0	5
0	0	0	0	0	0	0	0	0	0
1	0	0	0	1	1	0	1	0	2
3	0	0	0	3	3	0	0	0	3
1	1	0	0	2	1	1	0	0	2
0	0	0	0	0	0	0	0	0	0
3	1	0	0	4	3	1	0	0	4
0	0	1	0	1	0	0	1	0	1
1	0	1	0	2	1	1	1	0	3
1	0	0	0	1	1	0	0	0	1
0	0	0	0	0	0	0	1	0	1
0	1	0	0	1	0	1	0	0	1
0	0	0	0	0	1	0	0	0	1
2	0	0	0	2	3	0	0	0	3
3	0	0	0	3	5	0	0	1	6
2	0	0	0	2	2	0	0	0	2
3	0	0	0	3	3	0	0	0	3
2	0	0	0	2	2	0	0	0	2
1	0	0	0	1	1	0	0	0	1
3	0	0	0	3	4	1	0	0	5
0	1	0	0	1	0	1	0	0	1
2	0	0	0	2	2	0	0	0	2
3	0	0	0	3	3	0	0	0	3
0	1	0	0	1	0	1	0	0	1
0	0	1	0	1	0	0	1	0	1
1	0	0	0	1	1	0	0	0	1
4	0	0	0	4	5	0	0	0	5
2	0	0	0	2	2	0	0	0	2
0	1	0	0	1	0	1	0	0	1

c. Table for paired T-test for significant errors

Accuchek® Instant plus®	Home Access® Instant Cholesterol Test
0	0
0	2
2	3
1	2
1	3
1	2
1	3
2	0
1	1
2	3
0	1
1	1
0	2
0	2
2	3
3	2
2	5
1	6
0	0
1	2
2	2
2	1
0	2
3	4
0	1
1	0
1	0
0	2
1	3
1	1

Post Hoc Analysis

1. Correlation between significant errors and the difference between test results and laboratory results

(a) Accucheck® *Instant plus*®

(i). All '<150' value are approximated to 149.

(ii). All '<150' values are approximated to 149 or the laboratory value, which ever is closer

Table (i)

Error in results	Error in performance
9	0
38	0
13	2
47	1
35	1
40	1
0	1
2	2
6	1
57	2
1	0
47	1
6	0
43	0
7	3
23	1
3	0
66	1
49	2
4	2
23	3
4	0
78	1
21	1
5	0
4	1
48	1

Table (ii)

Error in results	Error in performance
9	0
38	0
13	2
47	1
35	1
0	1
0	1
2	2
6	1
57	2
1	0
0	1
6	0
0	0
7	3
23	1
3	0
66	1
49	2
4	2
23	3
4	0
78	1
21	1
5	0
4	1
48	1

(b) Home Access® Instant Cholesterol Test

(i). All '<120' value are approximated to 119.

(ii). All '<120' values are approximated to 119 or the laboratory value, which ever is closer

Table (i)

Error in results	Error in performance
8	0
39	2
5	3
181	2
129	3
10	2
30	3
45	0
13	1
39	3
2	1
20	1
4	2
13	2
23	3
21	2
2	5
39	0
34	2
17	2
13	2
128	4
11	1
18	0
55	0
18	2
44	1

Table (ii)

Error in results	Error in performance
8	0
39	2
5	3
181	2
129	3
0	2
30	3
45	0
13	1
39	3
2	1
20	1
4	2
0	2
23	3
21	2
2	5
39	0
34	2
17	2
13	2
128	4
11	1
18	0
55	0
18	2
44	1

APPENDIX I
DISCRETE ACTION CLASSIFICATION – SWAIN & GUTTMANN
(1983)

Type of error	Definition
Commission	Involve performing an act incorrectly
Omission	Involve the failure to do something
Sequence	(subclass of errors of commission) occurs when a person performs a task, or step in a task, out of sequence
Timing	(subclass of errors of commission) occurs when a person fails to perform an action within the allotted time, either performing too fast or too slowly.

APPENDIX J
Accucheck® Instant plus® INSTRUCTION CARD

Testing

1. Turn meter on.
2. With the protective cover closed, **insert test strip in one smooth movement, until it locks into place.**

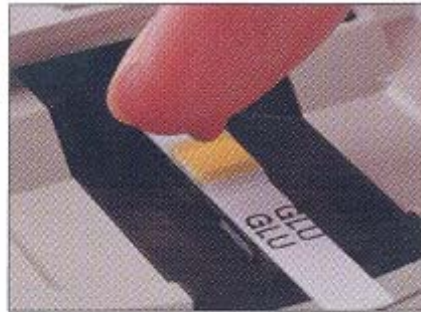


- **Do not bend** the strip while inserting it.
3. Open protective cover.

Display shows
12 seconds for
glucose and
180 seconds
for cholesterol.



-
4. Perform a fingerstick. Apply a hanging drop of blood to center of yellow test pad. **If testing cholesterol** wipe away first drop of blood from finger. Apply second drop of blood to test pad.



5. **Close protective cover immediately: within 5 seconds.**

Note: Always close the protective cover within 5 seconds to avoid an incorrect result.

Display shows countdown in seconds until result appears.

6. First open protective cover, then remove strip. Turn meter off.

Important: If you would like to do a total cholesterol test after you finish your glucose test (or vice versa), please use a different finger.

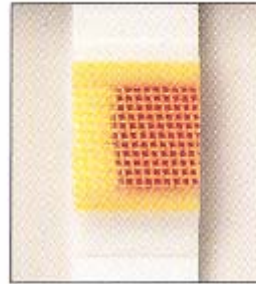
Proper Blood Application

- Check to make sure blood drop completely covered yellow target area.

Correct



Incorrect

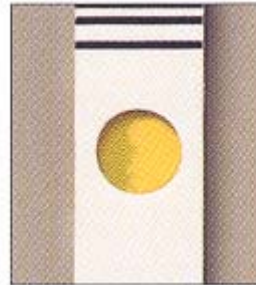


- Check that the round window on the back of the **glucose** test strip is uniformly covered.

Correct



Incorrect



Correct amount of blood applied. The round window is uniformly colored.

Too little blood was applied to strip. The round window is **NOT** uniformly colored.

VITA

Deepti Surabattula was born on 21st October, 1979, in Rourkela, India. She finished her high school education in first class with distinction from Delhi Public School, Visakhapatnam, in 1996. She joined the Gandhi Institute of Technology and Management, affiliated to Andhra University, Visakhapatnam, in 1998 for a Bachelor of Engineering degree in the Department of Mechanical Engineering. She received the best student award for the year 2002 in the Department of Mechanical Engineering. She graduated with distinction in 2002. She joined Louisiana State University in Spring 2003 and enrolled in a master's degree program in industrial engineering. She is currently working in the area of usability analysis and human computer interaction under the guidance of Dr. Craig Harvey, Assistant Professor, Department of Industrial Engineering.