Teleconsultation for diagnosis and care of burn injuries in the Western Cape:

Evaluation of healthcare providers' intention to use mHealth technology.

By

Ken Ngoy Diango

MMed Emergency Medicine
University of Cape Town

Student number: DNGKEN002

This study is in partial fulfilment of the requirements for the degree Masters of Medicine in the Faculty of Health Sciences at the University of Cape Town

Supervisor: Professor Lee A Wallis

Head of Division
Emergency Medicine

June 2017

Declaration

I, **Ken Ngoy Diango** , hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.
I authorise the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

I further declare the following:

1. I know that plagiarism is a serious form of academic dishonesty.

2. I have read the document about avoiding plagiarism. I am familiar with its contents and have avoided all forms of plagiarism mentioned there.

3. Where I have used the words of others, I have indicated this by the use of quotation marks.

4. I have referenced all quotations and properly acknowledged other ideas borrowed from others.

5. I have not and shall not allow others to plagiarise my work.

6. I declare that this is my own work.

7. I am attaching the summary of the Turnitin match overview.

Signature:. Signed by candidate Date: 10/03/2017

TABLE OF CONTENTS

I. ABSTRACT

Background: Burn care in resource-constrained settings represents a significant challenge. Mobile health (mHealth) could have useful advantages by providing timely expert advice. As part of a larger study on teleconsultation in burn care, a mobile application – the Vula App – was developed and tested in the Western Cape. This study gauges healthcare providers' intention to use this mHealth technology and factors influencing its adoption.

Methods: 48 healthcare providers working in Emergency Centres of three health facilities answered a questionnaire immediately after being trained in the use of the app. The survey was based on the Technology Acceptance Model of Davis and included the constructs of ***ease of use, usefulness, design quality, impact on care, compatibility, and behavioural intention to adopt***. Descriptive statistics were used for data analysis.

Results: The mean age of participants was 29.5 years old and the male-to-female ratio was 1:2. 73.9% of respondents were doctors and the remainder nurses. 93.4% of them already owned and used smartphones, with 76% using them in medical practice. 93% of respondents thought the app was easy to use and 91.3% found it useful. 17.8% found it incompatible with their routine work. 84.8% of participants expressed their intention to adopt and use the system. 4.3% of participants rejected it and 10.9%remained undecided.

Conclusion: The majority of participants already used smartphones and found the Vula app useful, easy to use, well designed, beneficial in burn care and compatible with their routine work. These factors led them to express the intention to use the app. This significantly predicts actual future use and is essential to the successful implementation of mHealth.

II. INTRODUCTION

Trauma is responsible for more than five million deaths each year, and accounts for around 11% of Disability-Adjusted Life Years (DALYs) globally (1). The majority of this burden is in low and middle-income countries (2), with more than 90% of global deaths from injuries occurring in these regions (3). Despites being classified as an upper middle income country with the highest GDP in Sub-Saharan Africa (4), South Africa faces significant challenges and its healthcare system is overwhelmed (5). The country's trauma burden is one of the highest in the world, with injury-related mortality rates as high as six times the global average (6). Approximately one-third of all admissions to Emergency Centres are due to injuries (7). While there is no national database and the exact incidence is unknown, several studies indicate that a significant proportion of these cases are burn injuries (6, 8). Further estimates suggest that 3.2% of South Africa's population suffer burns annually (8), with a mortality rate as high as 6.9% (6). Poor communities are the most vulnerable, with a study on paediatric burns in Cape Town finding that most hospitalised burned children were from informal settlements (9). The picture is similar in the African continent where burns account for over 18% of the world's burden, with clinical outcomes noticeably poorer than in rich countries (10).

Management of burns in poor resource settings is challenging for many reasons, mainly due to under-resourced health care systems and lack of clinical expertise in burn care. It has been shown for example that the burn size is often estimated incorrectly by inexperienced physicians (10); some tend to err on the side of caution and frequently overestimate burn size, while some will inappropriately underestimate it, to the detriment of patient care (10). Difficulty accessing to adequate care, lack of clinical proficiency in burn care and lack of prompt expert advice can greatly be palliated by the use of mobile health technology. Its feasibility and benefits have been demonstrated by several studies and well summarized in a recent systematic review (11).

Mobile health in burn care

Telemedicine projects have recently flourished worldwide, from just a handful of projects at its inception in the 1990s to numerous systems now running in many countries (12). Telemedicine is particularly compelling for service delivery in poor resources areas characterized by deficiencies in medical personnel, medical institutions, medical equipment, and even medications (13). Previous research already proved its value in radiology, pathology, cardiology (14), with clear advantages compared to alternatives approaches: referrals are reduced (15) and costs cut (16, 17). Furthermore,

professional isolation is diminished, recruitment and retention to rural areas is promoted (14,15). Smartphones have amplified the above advantages by enhancing further productivity in healthcare and increasing information access as well as communication.

However, many projects related to information and communication technologies (ICTs) in general and mHealth in particular start promisingly but are not sustained, leading to loss in both potential, and set up outlay (12, 18, 19). Research on both their acceptance into practice and the subsequent health outcomes is essential for successful implementation, sustainability and expansion. Not only success but also areas for concern and improvement need to be documented on scientific grounds.

Systems evaluation must extend to all users, including patients, medical staff and experts providing remote consultation and advice (20, 21). Little is known about how the clinical front line users relate to information and communication technology systems such as mHealth and how, in turn, this form of consultation influences the perception of their role. Nevertheless, the benefits of these teleconsultation tools are numerous, particularly in under-resourced and poorly accessible settings.

In light of the above, a research team from the Division of Emergency Medicine and the Karolinska Institutet (Stockholm) implemented and evaluated the Vula mobile application, a mHealth system that can facilitate timely and equitable access of acute burn patients to high quality care. The long-term objective of the system was to improve burn injuries management and outcomes in poor and marginalized communities of poor resource settings. Through it, visual and textual information are captured via a mobile phone application and transmitted from an emergency care worker to a tele-expert who provides prompt management advice. (Appendix 2)

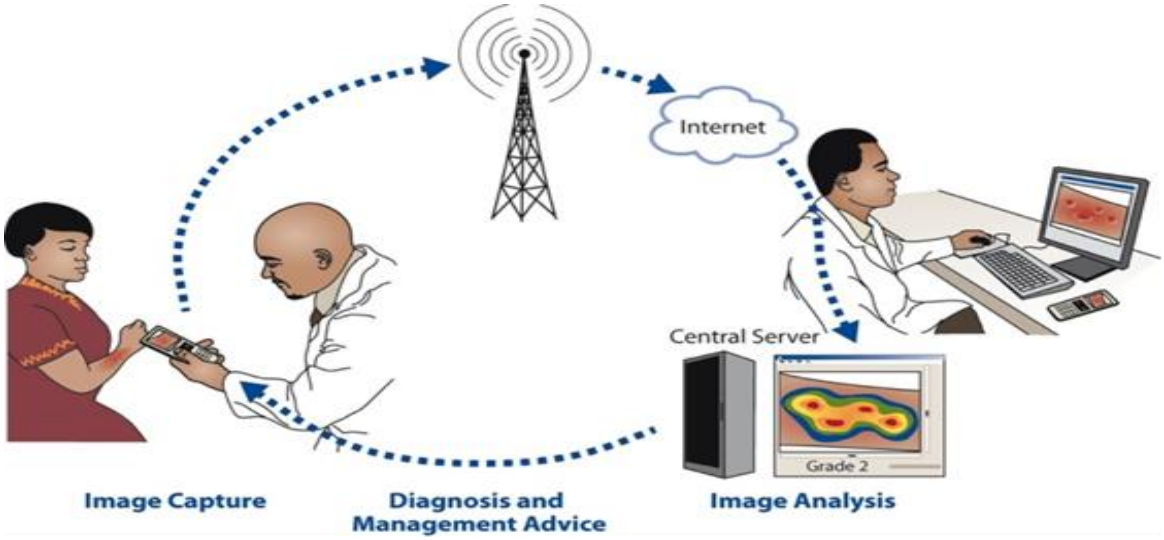


Figure 1. *Diagnostic and decision support system developed in the Western Cape*

This mobile application specifically designed for burn care was integrated in a large pre-existing mHealth platform – Vula Mobile – already providing similar teleconsultation in ophthalmology, orthopaedics, dermatology and cardiology. Vula is the brainchild of Dr William Mapham, an ophthalmologist who conceived the idea for the app while working at the Vula Emehlo Eye Clinic in rural Swaziland. He experienced first-hand the difficulties faced by rural health workers when they need specialist advice. The launch of the app initially designed to provide ophthalmology teleconsultation took place in July 2014 and, as it quickly became evident that the functionality provided by Vula was widely needed for other specialities, it progressively expanded to include the burn teleconsultation module in late 2015.

The overall project on teleconsultation for diagnosis and burn care in the Western Cape includes five broad phases of different length, each consisting in a series of studies:

1) System development;
2) Recruitment of tele-experts and set up of targets;
3) Understanding of clinical user perspectives (at point of care and among tele-experts);
4) System uptake and clinical outcomes;
5) System patient/public health outcome.

Additionally, investigators plan to interrogate the diagnostic accuracy and validity of the system compared to the gold standard of on-site clinical care. Lastly, the effect of the system on patient management will be reviewed.
This sub-study relates to the third phase of the project with regard to healthcare providers' perspectives at point of care and analyses the perceptions of doctors and nurses on the app, as well as their intention to use it.

Acceptance of information and communication technologies by healthcare professionals

In the context of Information and Communication Technologies (ICTs), acceptance is defined as a demonstrable willingness within a user group to employ an information technology tool for the tasks it is designed to support (22). It is a pivotal factor in determining the success or failure of any information system project (23). For example, physicians' rejection of novel technology is one of the reasons that telemedicine implementations have failed (13). Adoption of ICTs by individuals has been studied following two approaches. The first approach emphasizes on rationalistic goal-oriented

behaviour while the other focuses on poignant forces that influence an individual's reaction to new ICTs. The individuals' acceptance and subsequent usage of new ICTs is predicated in both (22). Another way of presenting factors influencing a user's adoption of a new technology is to group them in innate factors (emotive factors specific to a user based on his/her familiarity with ICTs, his/her perceived ease of use, usefulness, etc.) and external factors (organisational, cultural, financial, etc.) (22).

In his Technology Acceptance Model (23), Davis put forward four key components, namely:

- External stimulus: systems features design,
- User cognitive response: perceived usefulness and ease to use,
- User affective response: attitude toward using,
- Behavioural response: actual system use.

It is therefore of vital importance to understand individual decision-making behaviour with respect to acceptance (and its corollary resistance), and how this behaviour influences the successful transfer of ICTs into organizations located within poor resource environments (13). The Vula app was designed to this effect in the Western Cape and was set to be assessed for its technical and clinical quality, its clinical outcomes as well as cost-benefits aspects. Capturing the perspectives of all users was identified as an essential subject to be studied. Our sub-study focused on the evaluation of healthcare providers' intention to adopt the Vula app in the specific setting of the Western Cape.

III. METHODOLOGY

i. Setting

Surveys were conducted in the Emergency Centres of three health facilities located in predominantly economically disadvantaged townships in the City of Cape Town, namely Gugulethu Community Health Centre, Khayelitsha Site B Community Health Centre and Khayelitsha District Hospital.
The first two facilities are primary care institutions and represent the first access point for basic healthcare for many poor residents, most of whom live in informal settlements. They are open twenty-four hours a day, seven days a week, and record high patient attendance.

They are primarily staffed by nurses with basic training and junior medical staff who must provide emergency care. Patients requiring higher level of care (like severe, full thickness or chemical burns) are transferred out to the district or referral hospitals.

Khayelitsha District Hospital caters for a drainage area with up to a million residents, and receives referrals from several clinics in the area, including patients with severe burns. Limited specialised care is provided in Emergency Medicine, General Surgery, Obstetrics and Paediatrics. Cases requiring further advanced care are transferred to the tertiary academic hospital.

Poverty, high illiteracy and poor housing make burn injuries an endemic reality in these areas, with high incidence peaks during winter.

ii. Training

During April and May 2015, doctors and nurses working in Emergency Centres at the designated sites received a predesigned training in the use of the system. The staff was contacted beforehand to arrange suitable dates. The training was piloted at the outset and standardized so that all participants receive the same information. To minimise service disruption and provide an accurate representation of workplace environments, training sessions took place at each healthcare facility. There was a maximum instructor per trainee ratio of 1:4.

Participants had the option to be provided a smartphone with the Vula application installed on it, or to have it directly installed on their personal smartphones. Simulated cases were undertaken to practice using the App before users applied the system with live patients.

iii. Sample

The study target of surveying at least 70% of healthcare professionals trained in the use of the App was reached. In each selected facility, all the medical and nursing staff on duty in the Emergency Centre the morning of the training was invited and all responded positively.

Forty-eight doctors and nurses completed a questionnaire on paper. Medical doctors included interns, community service doctors, medical officers and specialists, while nurses were represented by nurse practitioners, professional nurses and nurses' assistants.

All fully trained participants who signed the consent form (Appendix 1) and completed the survey were included. Those who did not identify themselves, did not complete the full training session or declined to complete the survey were excluded.

iv. Post-training questionnaire

A previously validated questionnaire – the Kifle et al questionnaire in the Ethiopia study – was adapted to the South African context (Appendix 2). The survey was written in English and on paper. It included constructs from the Technology Acceptance Model of Davis, namely perceived ease of use, perceived usefulness, compatibility with routine of care, anxiety to use, impact on quality of care and behavioural intention to adopt.
Users' background information and questions related to the training itself were included.

v. Data collection and analysis

Responses on paper were entered into a password protected Excel spreadsheet. Data accuracy was assured by a second investigator who checked a random 10% sample. This is a descriptive study; missing data points (unanswered questions) were left out from data entry and simple descriptive statistics were used. Regarding cut-offs that were used in the handling of data, answers 1 and 2 were regarded as bad or negative while answers 4 and 5 were regarded as good/positive.

vi. Ethical considerations

Several parts of the bigger study on teleconsultation for the diagnosis and care of burn injuries in the Western Cape project received approval from the Health Research Ethics Committee of the University of Stellenbosch, including the consent form and questionnaire.
This sub-study related to the evaluation of healthcare providers' intention to use mHealth technology received approval from the Health Research Ethics Committee of the University of Cape Town ((UCT HREC ref 198/2015) (Appendix 3).
All the data collected were de-identified prior to database entry; only demographic information was retained. Data were stored on a password protected work computer.

IV. RESULTS

Table 1. **Demographics and smartphone use [(n) [%]]**

Age	20-29 (29) [63.0%]	30-39 (8) [17.4%]	40-49 (6) [13.0%]	≥50 (0) [0.0%]	No answer (3) [6.5%]
Gender	Males (15) [32.6%]	Females (31) [67.4%]			No answer (0) [0.0%]
Current occupation	Nurse (12) [26.1%]	Intern (4) [8.7%]	Medical officer (28) [61.0%]	Specialist (2) [4.3%]	Other (0) [0.0%]
Year post-graduation	1-2 (18) [39.1%]	3-4 (12) [26.1%]	5-10 (10) [21.7%]	>10 (6) [13.0%]	No answer (0) [0.0%]
Experience in burn care	Extensive (4) [8.7%]	Moderate (21) [45.6%]	Minimal (18) [39.1%]	None (0) [0.0%]	No answer (3) [6.5%]
Smartphone ownership	Yes (43) [93.5%]	No (3) [6.5%]			No answer (0)[0.0%]
Smartphone clinical use	Yes (35) [76.1%]	No (10) [21.7%]			No answer (1) [2.2%]
Purpose of clinical use	Look up guide-lines (18)	Send images (10)	Discuss referral (9)	Other reason (6)	No answer (5)
Frequency of use	Every day (0) [0%]	A few times a week(9)[19%]	A few times a month(19)[42%]	A few times a year (7) [15%]	Never(9)[19%] No answer [4%]

Table 2. **Responses regarding the Vula app [(n) [%]]**

	Completely disagree (1) – Completely agree (5)					
	1 Completely disagree	**2**	**3** Neither disagree nor agree	**4**	**5** Completely agree	No answer
I was satisfied with the way I was taught how to use the App.	(1) [2.1%]	(0) [0.0%]	(0) [0.0%]	(13)[28.3%]	(31)[67.4%]	(1) [2.1%]
I have the knowledge to use the burns App system after this training.	(1) [2.1%]	(1) [2.1%]	(0) [0.0%]	(15)[32.6%]	(29)[63.0%]	(0) [0.0%]
I'm sufficiently comfortable with smartphones and their Apps, therefore training wasn't necessary for me	18)[39.1%]	(24)[52.2%	(0) [0.0%]	(0) [0.0%]	3) [6.5%]	(1) [2.1%]
I found the various functions in this App were well integrated.	(4) [8.9%]	(0) [0.0%]	(4)[8.9%]	(25)[54.3%]	(12)[26.1%]	(1) [2.1%]
I thought there was too much inconsistencies in this App.	(22)[47.8%	(11)[23.9%	(4)[8.7%]	(6)[13.0%]	(1) [2.1%]	(3) [6.5%]
I feel apprehensive about using this App.	(28)[60.9%]	(8)[17.4%]	(1)[2.1%]	(3)[6.5%]	(4)[8.7%]	(2) [4.3%]
It scares me to think that I could lose a lot of information using this App by hitting the wrong key.	(30)[65.2%	(9)[19.6%]	(0)[0.0%]	(4)[8.7%]	(3)[6.5%]	(0)[0.0%]
I thought the App was easy to use.	(1)[2.1%]	(0)[0.0%]	(2) [4.2%]	(20)[43.5%]	(22)[47.8%]	(1) [2.1%]
Using this App may improve the care I give to my patients.	(0)[0.0%]	(0)[0.0%]	(3) [6.5%]	(16)[34.8%]	(27)[58.7%]	(0)[0.0%]
This system is not compatible with other routines within the unit.	(13)[28.3]	(11)[24%]	(13)[28%]	(4)[8.7%]	(4)[8.7%]	(1) [2.1%]
I will find this system useful in my job.	(0)[0.0%]	(1)[2.1%]	(3) [6.5%]	(22)[47.8%]	(19)[41.3%]	(3)[6.5%]
Using this system for burn emergency care is a good idea.	(2)[4.3%]	(0)[0.0%]	(7)[15.2%]	(20)[43.5%]	(17) [36.9%]	(0)[0.0%]
I think I will use this App frequently.	(1)[2.1%]	(1)[2.1%]	(5) [10.8%]	(23)[50.0%]	(16)[34.7%]	(0)[0.0%]

48 participants were surveyed, but two were excluded: one due to lack of identity and the other for lack of signed consent. The average age of respondents was 29.5 years old and the male-to-female ratio was 1:2. 73.9% of participants were doctors and the remainder nurses. The average post-graduation experience of participants was 3.1 year, with up to 39.1% of respondents practising for only two years or less.

Regarding experience in burn care, 45.6% thought it was moderate, 39.1% minimal and 8.7% extensive. 93.5% of participants owned and already used smartphones for their private communication, except three nurses who didn't own any mobile phone. 76.1% of participants already used their smartphones in medical practice, all of whom were doctors. 19% did so few times a week, 42% a few times a month and 15% just a few times a year. None of the providers used his smartphone in clinical practice on a daily basis. The main reasons for the clinical use of smartphones were to look up treatment guidelines or protocols, to send images or pictures (ECGs and X-rays) and to discuss patient referral with a consultant.

95.7% of respondents were satisfied with the way they were taught how to use the app and believed they gained the knowledge to use it. Only 6.5% of participants thought they were sufficiently comfortable with smartphones and their Apps to the point that training was not necessary for them. 80.4% of surveyed health providers thought that the app functions were well integrated while 15.1% found inconsistencies. 15.2%% of participants reported that they felt apprehensive about using this App, with a similar proportion revealing that it scared them to think that they could hit the wrong key in the app and lose a lot of information.

Noticeably, 91.3% believed the app was easy to use; three participants (6.5%) said that using the App might not improve the care given to their burn patients. 17.4% of respondents found that using the new mHealth tool was incompatible with their routine work within the unit. However, 91.3% believed in the usefulness of the system in their work while 80.4% of affirmed that using the new system of teleconsultation for burn emergency care was a good idea.

84.8% of healthcare providers surveyed expressed their intention to adopt and regularly use this system. Two respondents (4.3%) rejected it and five (10.9%) remained undecided.

V. DISCUSSION

MHealth systems have shown undeniable advantages in burn care in resource-constrained settings. This study set out to obtain a detailed understanding of a sample Western Cape healthcare providers' intention to adopt a new telemedicine system in a poor resource environment. The results provide an insight into the acceptance behaviour of doctors and nurses by identifying the factors influencing their intention to use mHealth technology. The majority of participants found the app useful, easy to use, valuable in burn care, and expressed the intention to use it. Key factors associated with positive or negative views on the app were identified.

Age and gender

Our participants were relatively young (average of 29.5). Several studies identified the effect of age on ICT usage. Morris et al showed clear differences with age in the importance of various factors in technology adoption (24); younger users found attitude towards using a new technology to be more prominent than the older workers who, conversely, weighed the importance of subjective norm and perceived behavioural control more strongly in determining usage of a new technology in the short term (24). Neves found that older people were in general poor technology consumers (computer, internet and mobile phone) compared to the young (25). Though our study wasn't powered to measure the impact of age, we believe the relative young age of most of our subjects played a key role in the positive perception of the app.

Our respondents were predominantly females (female-to-male ratio of 2:1), in keeping with the gender ratio in the healthcare sector in South Africa (26). A South African study found that ICTs access and usage was structured along gender lines (27).The influence of gender on adoption of ICTs has been well documented. Gilwald et al noted that men and women adopt and use technology differently (28). When compared to women's decisions, the decisions of men are strongly influenced by their attitude toward using the new technology (29). In contrast, women are strongly influenced by subjective norm and perceived behavioural control components of the planned behaviour model of Ajzen (29). We could not establish if the female predominance of our population contributed to a more positive perception of the app.

Participants' profession: Doctors versus Nurses

73.9% of participants were doctors and the remainder were nurses. Doctors included interns

(doctors in their first or second year post-graduation), community service medical officers (in their third year post-graduation), medical officers as well as a Family Physician and an Emergency Physician.

The twelve nurses were represented by nurse practitioners, professional nurses and enrolled nurses' assistants. There are fundamental differences between doctors and nurses, not only with regard to the core of their duties, but also their education background, way of life, familiarity with ICTs, etc. These differences undeniably influence their perceptions of a mHealth tool.

Although our study wasn't set up to ascertain the impact of these differences, mainly the core of their duties, we believe they played a key role. The two participants who didn't express the intention to use the app were all nurses, and three more were undecided. However, the majority of nurses - seven out of twelve - had a positive view on the app. This topic will be discussed further in the paragraph regarding compatibility of the app with routine of work.

Burn care experience:

Our respondents were mostly inexperienced providers (post-graduation experience average of 3.1 years. The experience in burn care was minimal for 45.6% respondents and moderate for 39.1 %. This finding further highlights the need to test a new system which allows timely expert advice. Pilot mHealth projects have shown that, particularly in low and middle income countries, mobile phones improve healthcare delivery (30). Regarding teleconsultation in burn care, we hypothesized that the necessity of an effective and efficient system would enhance the perception of the app usefulness, and in so doing, ultimately have a positive impact on acceptance. This narrative is discussed further in the paragraph on usefulness.

User familiarity with ICTs:

93.4% of respondents already owned and regularly used smartphones. This indicates prior familiarity with general processes and mobile application functions of smartphones, which positively affects the perceived ease of use and makes it easier for an individual to embrace a tool with similar applications. In a study conducted in Ethiopia, Kifle et al found that prior computer ownership and internet connection were factors affecting acceptance of telemedicine (13). Similarly, Gagnon et al found that issues regarding familiarity with ICTs as well as design and technical concerns were the most frequent limiting factors in ICT adoption among healthcare providers (31). Moreover, pre-existing familiarity in most of our respondents greatly aided our training in the use of the Vula app, resulting in a great post-training satisfaction and knowledge acquisition (95.6%). This most probably

affected adoption. In our study, the three participants who didn't own and regularly use a smartphone generally had a negative view of the app, with two eventually rejecting it.

App design

The design and technical aspects of an information and communication technology tool influence adoption amongst healthcare providers (31). The main purpose of ICT design is to increase utility through combining aesthetics, functionality and usability dimensions (31). 8.9% of respondents thought the various functions of the app were not well integrated and 15.1% found many inconsistencies in the design. The majority of doctors and nurses surveyed found the app to be user-friendly and well designed. This aspect also certainly impacted positively the perceived ease of use of the app. The two participants who eventually didn't intend to use the app also had a negative view on its technical aspects.

Perceived ease of use and usefulness

91.3% of respondents found the Vula app easy to use. The same proportion of respondents also found it useful in their work. In a systematic review of factors influencing the adoption of information and communication technologies by healthcare providers, Gagnon et al found that system usefulness and perceived ease of use were respectively the first and second most frequent adoption factors encountered (31).

Ease of use refers to the degree to which an individual believes that using a particular system would be free of physical and mental effort (23). It is understood to have a significant direct effect on perceived usefulness which is defined as the degree to which an individual believes that using a particular system would enhance his or her job performance (23). Kifle established that physicians' perceptions about the system's perceived ease of use were also found to have a noteworthy influence on their perceptions about the system's usefulness (13).

In his Technology Acceptance Model, Davis argued that the powerful effect of usefulness on actual use through attitude was perhaps the most striking result (23). The fact that usefulness exerts more than double the direct influence on use than does attitude towards using underscores its importance as an acceptance factor (23). In addition, usefulness was found to exert more than four times as much direct influence on attitude as did ease of use (23). Several other studies on mHealth acceptance have highlighted the impact of perceived usefulness (33, 34, 35). Our study wasn't set up to quantify the amplitude of the effect of factors such as perceived usefulness and usefulness on the

intention to use. However, in the light of the compelling findings in studies mentioned above, it is likely that the high intention to use was greatly influenced by the high proportion of respondents who found the app to be useful and easy to use. The two participants who rejected the app in the end didn't find it useful.

Compatibility with routine work

52.3% of respondents found that using the new mHealth tool was compatible with their routine work; 28.0% were unsure and 17.6% didn't think so. Kifle et al indicated that compatibility of a system to the physician's work practices was a significant determinant of its usefulness (13), hence its acceptance. Gichoya found the implementation of information and communication technologies projects without due regard to compatibility issues is one of the reasons they fail (36). To be adopted, a new mHealth tool must not only be well designed, easy to use and useful; it must smoothly fit in the routine of HCPs. The two respondents who revealed their intention not to use the Vula app found it incompatible with their routine work.

Furthermore, nine out the twelve professional nurses who completed our survey didn't find the app compatible with their routine nursing duties. Compared to doctors, nurses generally had a reserved or negative view on the app, probably because the majority of them didn't think the app fitted in their day-to-day nursing duties. This could be explained by the difference in the nature of the duties of a nurse from one setting to another. In rural areas where medical practitioners are scarce, nurses are at the forefront of healthcare, examining and treating patients with diverse illnesses including burns. It makes sense that a mHealth tool designed to provide timely remote expert advice would be welcome by to this category of nurses. On the other hand, the majority of nurses whose usual duties routinely involve executing the care plan directed by a medical officer would find an app primarily used in patient assessment and management incompatible with their duties, hence are less incline to adopt the app.

Clinical benefit

All but three respondents believed the app would improve burn care they provided to their patients. The perceived clinical benefit of a mHealth tool is a key aspect of its usefulness. Healthcare providers tend to adopt an ICT if they see its clinical added value. This could be in the form of increased efficiency, reduction of errors and the alteration of professional roles and responsibilities in a

manner which allows improvement in the delivery of patient care (38). It would indeed be a futile endeavour to try to introduce a new system or tool with unproven substantial benefits in patient care.

In the context of under resourced settings, such an initiative would actually be detrimental to the delivery of patient care by putting additional strain on an already overwhelmed system. Additionally, any potential improvement a mHealth system can bring in patient management must to be appraised through the prism of cost-benefits soundness.

Intention to use

84.8% of respondents expressed their intention to ultimately use the app. It is noteworthy that an intention to use is just an intention. Although it gives good insight into users' behavioural attitude towards new ICTs, it doesn't confirm actual use. A study by Tao on Intention to Use and Actual Use of Electronic Information Resources found that the determinants of intention-to-use significantly predict actual use behaviour (39); but there is always an intention-behaviour gap which needs to be bridged (40).

Sheeran described the extent to which four groups of variables—behaviour type, intention type, properties of intention, and cognitive and personality variables— moderate intention–behaviour relations (40). Several social psychological models converge on the proposal that the most immediate and important predictor of a person's behaviour is his/her intention to perform it. This means that a healthcare provider who expressed the intention to adopt and use a mHealth technology system is likely to do as he stated. It is unusual – but not surprising – for a user who initially expressed the intention to adopt a new ICT system to end up not using it and vice versa.

The intention of an individual to use an information and communication technology system is multifactorial. Several influences come into play: individual factors (emotive elements specific to a user based on his/her familiarity with ICTs, his/her perceived ease of use, usefulness, etc.) and external factors such as cultural differences, the type of organisation one works at, the financial considerations, etc.) (22).

VI. LIMITATIONS

Our study population size was smaller than originally planned. Training and data collection took place in a limited number of sites, namely three high burn burden emergency centres representative of Cape Town Metropole. However, it would have been ideal to include participants from rural sites as well as other sites with a different profile in order to capture a variety of users' perceptions on the app. Nonetheless, the analysis of responses from our population gives a comprehensive insight on participants' perceptions and is an accurate reflection of views of healthcare providers in LMIC.
It would have been interesting to measure the impact of each factor influencing mobile health technology acceptance, and determine if they play a greater or smaller role compared to previous studies. However, this would have required a study design specifically set out to that effect.

VII. CONCLUSION

Mobile health systems have shown undeniable advantages in burn care in resource-constrained settings. A mobile application was developed and tested in the Western Cape. Our study analysed perceptions of healthcare providers on the app and their intention to use it. The main constructs of the Technology Acceptance Model of Davis were included in a post-training survey.
The majority of participants found the app useful, easy to use, valuable in burn care, and expressed the intention to use it. Key features associated with positive or negative views on the app were identified. The typical Vula app opponent appeared to be a healthcare provider who didn't own or already use a smartphone. He/she also did not believe that the training provided for the use of the app was satisfactory or enabled him/her to confidently use it. More importantly, he/she typically did not find the app easy to use, useful or compatible with his routine work.

Overall, the behavioural attitude towards adoption was similar to observations made in previous studies. There were however nuances that could be explained by the particular traits of our study setting and population profile. Further research is needed to understand the magnitude of individual factors in the bigger scheme of implementation of mHealth projects in poor resource settings.

VIII. REFERENCES

1. Global Burden of Disease Data [Internet]. Seattle: Institute for Health Metrics and Evaluation. 2010 [Accessed in 2016 Dec 6]. Available from: http://www.healthdata.org/gbd/data

2. Gosselin R. Injuries: the neglected burden in developing countries. Bull World Health Organ. 2009; 87(4):246–246.

3. Hoffman K, Primack A, Keusch G, Hrynkow S. Addressing the growing burden of trauma and injury in low-and-middle-income countries. Am J Public Health. 2005; 95(1):13–17.

4. World Bank data: South Africa. http://data.worldbank.org/country/south-africa. Accessed on December 15 2016.

5. Coovadia H, Jewkes R, Barron P, Sanders D, McIntyre D. The health and health system of South Africa: historical roots of current public health challenges. Lancet 2009; 374: 817–34.

6. Norman R, Matzopoulos R, Groenewald P, Bradshaw D. The high burden of injuries in South Africa. Bull World Health Organ 2007; 85(9):695-702

7. Wallis L, Garach SR, Kropman A. State of Emergency Medicine in South Africa. Int J Emerg Med 2008; 1(2):69–71.

8. Rode H, Berg AM, Rogers A. Burn care in South Africa. Annals of Burns and Fire Disasters. 2011; Vol XXIV (March):7–8.

9. Parbhoo A, Louw Q, Grimmer-Somers K. A profile of hospital-admitted paediatric burns in South Africa. BMC Research Notes. 2010, 3:165.

10. Saffle JR, Edelman L, Theurer L, Morris SE, Cochran A. Telemedicine evaluation of acute burns is accurate and cost-effective. J Trauma. 2009 [Accessed 2016 Nov 29]; 67(2):358–65.

11. Dunne JA, Rawlin JM. A Systematic Review of Telemedicine in Burn Care. Available from: http://www.cdesign.com.au/anzba2013/posters/anzba2013asm1final00038.pdf

12. Whitten P, Love B. Patient and provider satisfaction with the use of telemedicine: Overview and rationale for cautious enthusiasm. J Postgrad Med 2005; 51:294-300.

13.Kifle M, Payton F, Mbarika V, Meso P. Transfer and adoption of advanced information technology solutions in resource-poor environments: The case of Telemedicine Systems adoption in Ethiopia. Telemed and e-Health.2010, 16(3):327-43

14. Kim YS. Telemedicine in the U.S.A. with focus on clinical applications and issues. Yonsei Med J. 2004; Vol 45(5):761-75.

15. Van der Heijden JP, De Keizer NF, Voorbraak FP et al. A pilot study on tertiary teledermatology: Feasibility and acceptance of telecommunication among dermatologists. J Telemed Telecare. 2010; 16(8):447–53.

16. Bashshur R, Telemedicine Effects: cost, quality and access. Journal of medical systems, Vol 19 No2, 1995;

17. Bachman RE. Telehealth and Patient-centered Care. 2015. Georgia Public Policy. Accessed on http://www.ncpa.org/sub/dpd/index.php on Dec 02n 2015

18. Hendy J, Chrysanthaki T, Barlow J et al. An organisational analysis of the implementation of telecare and telehealth: The whole systems demonstrator. BMC Health Serv Res. 2012; 12(1):403.

19. Van Dyk L. A review of telehealth service implementation frameworks. Int J Environ Res Public Health 2014; 11(2):1279–98.

20. Catwell L, Sheikh A. Evaluating eHealth interventions: The need for continuous systemic evaluation. PLoS Med. 2009. Accessed 2016 Nov 22.

21. World Health Organisation. Telemedicine: Opportunities and Developments in Member States. Report on the Third Survey on eHealth. 2015. [Accessed on 13 Oct 2016]

22. Dillon A. and Morris M. User acceptance of new information technology: theories and models. Annual Review of Information Science and Technology, 1996 Vol. 31, 3-32.

23. Davis F. User acceptance of information technology: systems characteristics, user perception and behavioural impacts. Int. J. Man- Machines Studies. 1993 (38), 475-87.

24. Morris M, Venkatesh V. Age differences in technology adoption decisions: Implications for a changing work force. Personnel Psychology; 2000; 53 (2); 375-404.

25. Neves B., Amaro B. Too Old For Technology? How The Elderly Of Lisbon Use And Perceive ICT. The Journal of Community Informatics, North America 2014 (Accessed: 17 Sep 2016.)

26. Statistics SA. Gender statistics in South Africa: 2011, 45-48. Statistics South Africa. (Accessed on 12 September 2016).

27. Maleka M. Gender-based analysis of ICT adoption and usage in South Africa. 2012. (Accessed 17 Nov 2016.)

28. Gilwald A. Gender assessment of ICT access and usage in Africa. 2010. Policy Paper 5

29. Venkatesh V, Morris M, Ackermann P. A Longitudinal Field Investigation of Gender Differences in Individual Technology Adoption Decision-Making Processes. Organizational Behavior and Human Decision Processes, Vol. 83, No. 1, 2000. 33–60.

30. Chib A, Van Velthoven MH, Car J. mHealth Adoption in Low-Resource Environments: A Review of the Use of Mobile Healthcare in Developing Countries. Journ of Health Comm Vol. 20, 2015.

31. Gagnon M-P, Desmartis M, Labrecque M et al. Systematic Review of Factors Influencing the Adoption of Information and Communication Technologies by Healthcare Professionals. J Med Syst. 2012 Feb; 36(1): 241–77.

32. Bardici M, Lilijenfors R. ICT design and users' affect cognition and creativity.2010. http://www.diva-portal.se/smash/get/diva2:833411/FULLTEXT01.pdf (Accessed: 17 Sep. 2016.)
33. Hu P.J., Chau P.Y., Sheng O.R.L. and Tam K.Y. Examining the technology acceptance model using physician acceptance of telemedicine technology. Journal of Management Information Systems, 1999, Vol. 16, No. 2: 91-112,
34. Bhattacherjee, A., Hikmet, N. Physicians' Resistance toward Healthcare Information Technology: A Theoretical Model and Empirical Test. Euro Journ of Inform Systems, 2007. Vol. 16, No. 6: 725-37.
35. Moores T.T. Towards an integrated model of IT acceptance in healthcare. Decision Support Systems. 2012. Vol. 53, No 3: 507-16.
36. Gichoya D. Factors affecting the successful implementation of ICT projects in Government. Journal of e-Government. 2015. Vol 3 Issue 4.
37. Gagnon MP, Legare F, Labrecque M, Fremont P, Pluye P et al. Interventions for promoting information and communication technologies adoption in healthcare professionals. Cochrane Database Syst Rev. 2009.
38. Li J. A sociotechnical approach to evaluating the impact of ICT on clinical care environments. Open Med Informatics Journ. 2010 Vol 10. 202-05.
39.Tao D. Intention to Use and Actual Use of Electronic Information Resources: Further Exploring Technology Acceptance Model .AMIA Annu Symp Proc. 2009; 2009: 629–33.
40. Sheeran P. Intention—Behavior Relations: A Conceptual and Empirical Review. European Review of Social Psychology Vol. 12, Iss. 1, 2012.
41. Aranda-Jan C, Mohutsiwa-Dibe M, Loukanova S. Systematic review on implementation of mobile health projects in Africa: What works? What doesn't work and why. 2014.
42. Davis FD. Perceived usefulness, perceived ease of use and user acceptance of information technology. 1999 Sep;13(3):319–40

IX. APPENDICES

Appendix 1. Consent and questionnaire

CONSENT TO PARTICIPATE IN RESEARCH

Treating burns patients in emergency care:
Post-training questionnaire on perception of the App for tele-consultation on burns injury care and intention to use

(Continued on next page)

You are asked to participate in a research project conducted by researchers at Stellenbosch University and Karolinska Institutet in Stockholm, Sweden. The results of this questionnaire-based investigation will be used to inform the implementation of a smartphone application (App) for expert consultation for burn injuries in the Western Cape Province. You were selected as a possible participant in this study because you have just received the training required to start using the App in your health care facility.

1. PURPOSE OF THE STUDY

The primary aim of this study is to increase knowledge about factors that influence the adoption of a mHealth system for burn care as a means of communication between emergency staff and specialists.

mHealth is defined as mobile technology used to assist or aid in healthcare services. The mHealth technology in question allows a trained healthcare provider to upload relevant pictures of burn injuries taken via smartphone cameras (coded and after informed consent by the patient) onto a customised burns application on the phone. The pictures, along with circumstantial information about the injury, will be transmitted wirelessly to a central server. From the server, a burns specialist will access the images over the web, view and classify the images visually, and provide appropriate diagnostic and treatment information back to the treating care provider.

2. PROCEDURES

If you volunteer to fill in this questionnaire, we would ask you to do the following things:

Answer a few short questions about yourself background, how you experienced the training, what you think about the App, and whether and how you plan to use it.

You are asked to respond honestly to all the questions presented.

It is anticipated that this questionnaire will take no more than 15 minutes of your time.

3. POTENTIAL RISKS AND DISCOMFORTS

There are no foreseeable risks, discomforts, or inconveniences envisaged due to participation.

4. POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY

There are no direct benefits to the participant envisaged, however the answers provided through this questionnaire will be used to inform how we can improve the training, the App and the manner in which it is being implemented.

5. PAYMENT FOR PARTICIPATION

Participants will receive no payment for completing this questionnaire; however we thank you for your time.

6. CONFIDENTIALITY

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. The only item that shall retain your name is this consent form. The actual questionnaire used for research purposes will not contain your name or any identifying information. The consent forms will be kept separately from the questionnaires, so no indication may be made as to which participant completed which questionnaire. All collected documents will be kept in the Investigator's office at Stellenbosch University, in a locked cabinet. Only the Investigator and researchers involved in the study will have access to the key. The data will be transcribed into an Excel database and will be password protected and stored in a computer in the Investigator's office at Stellenbosch University.

The results of the questionnaire will be shared with international collaborators via telephonic communication; however no personal data will be disclosed without your permission. It is not foreseen that this will be necessary. The results of the questionnaire will also be published in a peer-reviewed academic journal; however no identifiable personal details of the participants whatsoever will be included.

7. PARTICIPATION AND WITHDRAWAL

You can choose whether to be in this study or not, your decision regarding this will not affect your working conditions. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

8. IDENTIFICATION OF INVESTIGATORS

Professor Lee A. Wallis, MBChB, MD from the Division of Emergency Medicine, Department of Interdisciplinary Health Sciences at Stellenbosch University, South Africa;

Associate Professor Marie Hasselberg, PhD and

Professor Lucie Laflamme, MSc PhD from the Division of Global Health, Department of Public Health Sciences at Karolinska Institutet, Sweden.

If you have any questions or concerns about the research, please feel free to contact:

Local Investigator: Lee Wallis
Division of Emergency Medicine
Department of Interdisciplinary Health Sciences
Faculty of Medicine and Health Sciences
Stellenbosch University
Tygerberg Campus
021 938 9804
leew@sun.ac.za

9. RIGHTS OF RESEARCH PARTICIPANTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research participant, contact Ms Maléne Fouché [mfouche@sun.ac.za; 021 808 4622] at the Division for Research Development. The study has been approved by the Health Research Ethics Committee.

SIGNATURE OF RESEARCH PARTICIPANT OR LEGAL REPRESENTATIVE

The information above was described to [me/the participant] by [name of relevant person] in [Afrikaans/English/Xhosa/other] and [I am/the participant is] in command of this language or it was satisfactorily translated to [me/him/her]. [I/the participant] was given the opportunity to ask questions and these questions were answered to [my/his/her] satisfaction.
[I hereby consent to voluntarily participate in this study/I hereby consent that the participant may participate in this study.] I have been given a copy of this form.

Name of Participant

Name of Legal Representative (if applicable)

Signature of Participant or Legal Representative Date

SIGNATURE OF INVESTIGATOR

I declare that I explained the information given in this document to .....
[*name of the participant]* and/or [his/her] representative ……....
[*name of the representative]*. *[*He/she] was encouraged and given ample time to ask me any questions. This conversation was conducted in [*Afrikaans/English/Xhosa/Other*] and [no translator was used/this conversation was translated into .....by .....]

Signature of Investigator Date

Background information

1. Age .....

2. Sex ……

3. Highest level of training/education completed .....

4. Current occupation:

   ☐ SPECIALIST ☐ REGISTRAR ☐ PHYSICIAN ☐ INTERN ☐ PROFESSIONAL NURSE

   ☐ OTHER, please specify .....

5. Experience in emergency care:

   a) At current facility ……☐ Weeks ☐ Months ☐ Years

   b) In total (since graduating) ……☐ Weeks ☐ Months ☐ Years

6. How would you describe your experience with acute burn care?

   ☐ EXTENSIVE ☐ MODERATE ☐ MINIMAL ☐ NONE

8. Do you use a mobile phone for private use? If no, go directly to question nr. 10. ☐ YES ☐ NO

9. If yes, is your private phone a smartphone? ☐ YES ☐ NO

10. Do you use have any experience of using smartphones for work purposes? ☐ YES ☐ NO

11. If yes, please clarify the purpose(s)? .....

.....

12. How often do you use a smartphone to look at clinical images in your current work?

☐ EVERY DAY ☐ A FEW TIMES A WEEK ☐ ONCE A WEEK
☐ A FEW TIMES A MONTH ☐ ONCE A MONTH ☐ A FEW TIMES A YEAR
☐ NEVER

13. How often do you use a smartphone to take and send clinical images for clinical consultation?

☐ EVERY DAY ☐ A FEW TIMES A WEEK ☐ ONCE A WEEK
☐ A FEW TIMES A MONTH ☐ ONCE A MONTH ☐ A FEW TIMES A YEAR
☐ NEVER

Feedback about the training	**Completely disagree (1) – completely agree (5)**				
For each statement below, please place an "X" in the box that best represents your view about the training	**1** Completely disagree	**2**	**3** Neither disagree nor agree	**4**	**5** Completely agree
The length of the training session was appropriate					
The following subjects were satisfactorily explained:					
• Introduction of the application					
• Why I would use the application					
• How to use the application					
The trainers were able to support my learning during the training					
I am sufficiently comfortable with smartphones and their Apps, therefore training was not necessary for me					
I have the knowledge to use the burns App system after this training session					
I have the resources necessary to use the system					
I have the relevant practical and professional skills to use the App					

Please add comment(s) about the training if you wish……

……..…….

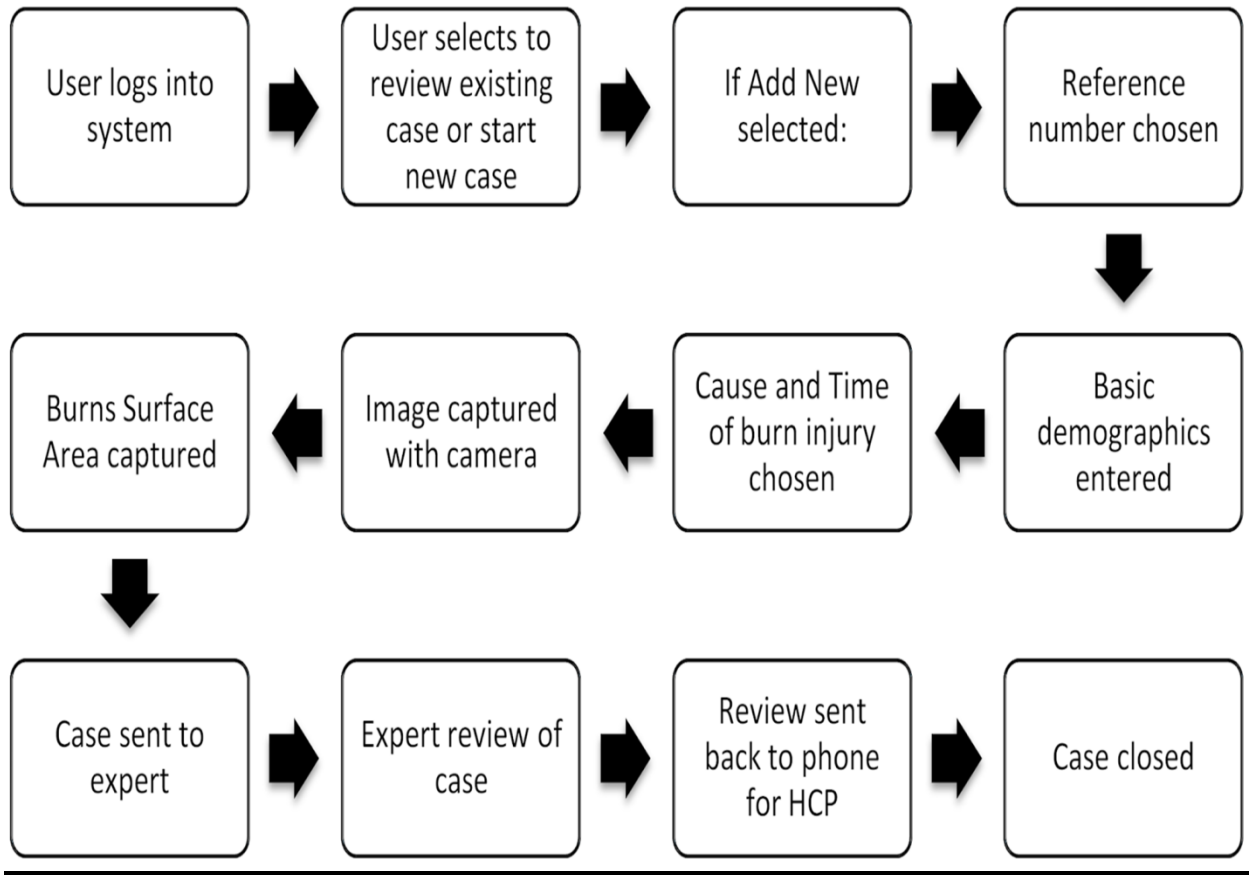
Feedback about the APP	**Completely disagree (1) – completely agree (5)**				
For each statement below, please place an "X" in the box that best represents your view about the App	**1** Completely disagree	**2**	**3** Neither disagree nor agree	**4**	**5** Completely agree
I found the App unnecessarily difficult to use					
I found the various functions in this App were well integrated					
I thought there was too much inconsistency in this App					
I thought the App was easy to use					
I felt very confident using the App					
I found the App very cumbersome to use					
Over the next few months, I plan to use the App regularly with burn patients					
I think I would use this App frequently					
I feel apprehensive about using this App					
It scares me to think that I could lose a lot of information using this App by hitting the wrong key					
This system is not compatible with other routines within the unit					
Using this system for burn emergency care is a good idea					
It will be easy for me to become skilful at using this system					
Using this App may improve the care I give to my patients					
I will find this system useful in my job					

Please add comment(s) about the training if you wish……

……..…….

THANK YOU

Appendix 2. FLOWCHART : STEPS OF BURN APP USE



Appendix 3. Ethics approval letters

1. Original Stellenbosch University Human Research Ethics Committee (SUN HREC) approval letter.

2. Original University of Cape Town Human Research Ethics Committee (UCT HREC) approval letter.

UNIVERSITEIT·STELLENBOSCH·UNIVERSITY
Jou kennisvennoot • your knowledge partner

Approval Notice
Response to Modifications- (New Application)

04-Sep-2013
Wallis, Lee LA

Ethics Reference #: N13/02/024
Title: Teleconsultation for diagnosis and care of burn injuries in the Western Cape clinical Feasibility and Potential Benefit.

Dear Professor Lee Wallis,

The **Response to Modifications -** ***(New Application)*** received on **28-Aug-2013**, was reviewed by members of **Health Research Ethics Committee 2** via Expedited review procedures on **28-Aug-2013** and was approved.
Please note the following information about your approved research protocol:

Protocol Approval Period: **28-Aug-2013 -28-Aug-2014**

Please remember to use your **protocol number** (**N13/02/024**) on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:
Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired.
The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.
Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.
For standard HREC forms and documents please visit: www.sun.ac.za/rds

If you have any questions or need further assistance, please contact the HREC office at 0219389207.

Included Documents:
Investigators Supervisors declaration
Cv's
Protocol
Checklist
Consent Forms
Training Description
Synopsis
Application Form

Sincerely,

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

13 May 2015

HREC REF: 198/2015

Prof L Wallis
Emergency Medicine
Surgery
OMB

Dear Prof Wallis

PROJECT TITLE: TELECONSULTATION FOR DIAGNOSIS AND CARE OF BURN INJURIES IN THE WESTERN CAPE: EVALUATION OF HEALTH CARE PROVIDERS' INTENTION TO USE MHEALTH TECHNOLOGY (MMed candidate - Dr K Diango)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th May 2016.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the student, Dr Ken Diango will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH