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### The Importance of the Preceptor-Preceptee Relationship in Creating Well Prepared Professionals: A Make or Break Experience

Tagwa Yusuf Omer<sup>1</sup> & Shehnaaz Mohamed Moola<sup>2</sup>

Correspondence: Shehnaaz Mohamed Moola, Department of Nursing Science, School of Healthcare Sciences, Faculty of Health Sciences, University of Pretoria, Private Bag X323, Arcadia 0008, South Africa.

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#### Abstract

**Objectives:** In this study, we explore the 'make or break' challenges faced in the preceptor-preceptee relationship. The preceptor-preceptee relationship needs to evolve from a teacher-student dynamic to a collegial partnership.

**Methods:** This qualitative study used focus group interviews which explored challenges experienced by preceptors and preceptees. The preceptors included ten clinical teaching assistants and 14 clinical professionals. The preceptees included ten student nurses. In total, we interviewed 34 participants. The interviews were audio recorded, transcribed verbatim and thematically analyzed.

**Results:** Both preceptors and preceptees experienced challenges in developing healthy relationships. Preceptors felt that they were committed and trained to teach, and that fulfilling an extended role was beyond their reach. Preceptees had difficulty realizing nursing practice and transitioning from a student to a professional role. Both parties identified strategies for developing healthy professional relationships. Preceptors could extend their professional role to include a mentorship facet. Preceptees could be exposed to diverse clinical environments with guided transitioning to facilitate the change from student to professional.

**Conclusion:** Student nurses need a caring environment to transition from a student role to a professional role. The relationship based care model undoubtedly influences the teaching and learning process by fostering a caring attitude and commitment to teaching and learning. Preceptees develop a sense of belonging and are motivated to accept and adapt to practical realities.

Keywords: preceptor, preceptee, relationship, student nurse, clinical professionals, clinical teaching assistants

#### 1. Introduction

Most health and educational programs depend on preceptors to facilitate the transition of the preceptee from student to professional nurse. Although experience and proficiency are important, the preceptorship relationship has a considerable caring component. The relationship between preceptor and preceptee symbolizes caring expressed in humane actions and words. A caring and supportive preceptor workforce may help to transition student nurses into professionals by enhancing students' sense of belonging in the nursing profession.

Preceptorship is defined as a 'teaching-learning' model where an experienced preceptor guides an inexperienced preceptee through their practical training (Moyet & Wittmann-Price, 2008; deWolfe et al., 2010; Park et al., 2011). Student nurses or preceptees are in the process of learning the 'culture or way' and internalizing group norms and professional values as they develop in the nursing profession (Wilkens, 2003). Students acquire knowledge, skills, competence, confidence, values, ethics and a multitude of attributes to transition into the role of professional nurse. The transition process also has a socialization component, which occurs through observation and role-modeling behavior within the learning environment (Lai & Lim, 2012). While few studies have explored the relationship between preceptors and preceptees in the nursing profession, many have explored unsuccessful transition from student to professional nurse, which is often accompanied by low productivity, low morale, lack of job satisfaction, increased absenteeism, increased errors and near misses, burnout syndrome and finally an end to a nursing career. Effective preceptorship programs have reduced turnover by 186.102% in a six month period and led to neophyte nurses making almost no medication errors (Lee et al., 2009).

<sup>&</sup>lt;sup>1</sup> King Saud bin Abdulaziz University for Health Sciences-Jeddah, Kingdom of Saudi Arabia

<sup>&</sup>lt;sup>2</sup> Department of Nursing Science, School of Healthcare Sciences, Faculty of Health Sciences, University of Pretoria, Arcadia, South Africa

Preceptor relationships are fluid, and can assume a collaborative, integrative, team approach, or take on the form of a one to one relationship. Although one-to-one relationships have resulted in positive experiences, leading to expanded knowledge, skills acquisition and theory-practice integration, several aspects on the dynamics of one to one preceptor relationships need to be explored. These aspects include understanding how the culture of support and challenges experienced affect commitment to the preceptorship relationship. The commitment of the preceptor may affect the sense of belonging of the student, who may expect different outcomes from the preceptorship relationship. A lack of professional comportment may also negatively affect the transition from student to professional. The preceptor role has to adapt to diverse learning needs, the complex health environment and needs to recognize that ongoing support is crucial to a preceptorship relationship. Students feel a need to belong and to be seen as part of a nursing community (Andrew et al., 2009). Nurse preceptors facilitate students towards becoming a part of the professional team (Sedgwick & Yonge, 2008). A positive preceptorship relationship is a crucial step in exploring and discovering the professional role (Bremmer & O'Brian, 2007). For student nurses, preceptorships facilitate a structured process of internalizing soft skills, practical skills, theory, ethics, values and professional comportment in transitioning from student to well adapted nurse practitioner.

In the nursing profession, preceptorship relationships are intricately tied in with patient care. According to Kolouritis (2004) the relationship-based care model aims to protect the patient as well as those providing the care through mindfulness and understanding of emotional responses of the 'self' in order to connect with professional others, the patient and family. Caring brings us to our basic purpose, namely, caring for and connecting with other human beings. In the nursing profession, the teaching and learning environment should foster caring and healing. A well supported nurse from a caring environment will be better prepared to render quality patient care in a changing clinical environment (Koloroutis, 2004).

In this study, we consider the caring aspect of the preceptorship relationship and explore the perceptions of both preceptors and preceptees regarding possible barriers and facilitators of a successful preceptorship relationship. We used the relationship-based care model of Kolouritis, (2004) as a conceptual framework to clarify our findings.

#### 2. Methods

We explored the lived experiences of preceptors and preceptees using a qualitative approach. Focus group interviews explore real life situations and interactions of people, revealing attitudes, feelings, a range of experiences, values and views. Information may be disclosed more effectively during focus group interviews and enhance interaction (Krueger, 1994). We purposively sampled participants, who included nursing students, clinical teaching assistances and clinical preceptors.

#### 2.1 Setting

The study was conducted in a nursing college in Saudi Arabia affiliated to a 900 bed teaching hospital, where clinical training takes place.

#### 2.2 Participants

The sample included ten student nurses who are in their undergraduate Baccalaureate program and ten registered nurses who are referred to as clinical teaching assistants, as well as fourteen clinical preceptors from the clinical areas of the hospital, who hold a Baccalaureate degree in nursing.

#### 2.3 Data Collection

We conducted three focus group interviews (Krueger, 1994), one with student nurses, one with clinical teaching assistants and one with the clinical preceptors. The focus group sessions were arranged to ensure confidentiality and privacy. Researchers facilitated the focus group interviews, which were moderated by co-facilitators. Each focus group interview was held at one of two designated locations, either the hospital or the nursing college. Participants were informed about the study and asked to sign informed consent if they agreed to participate. Participants were able to withdraw from the study at any point. In appreciation of their time, knowledge and experiences shared, participants were indulged in a refresher at the start and a light lunch after concluding. Table 1 explains how the researchers' maintained trustworthiness.

The focus group interviews were semi-structured. The researchers asked a key question at the start of the interviews, which stimulated further discussion. The researchers ask the preceptors, "How do you provide a suitable learning environment whilst students are in the process of becoming professional nurses?" The researchers asked the students, "How are you provided with a suitable clinical learning environment while you are in the process of becoming a professional nurse?"

The study was approved by the ethics committee of the associated university and hospital review boards for IRB

approval and consent to conduct the study.

Table 1. Measures for ensuring trustworthiness

Strategy	Criteria	Applicability
Credibility	Prolonged engagement	The researchers interacted and worked closely with the participants from 2013.
Triangulation	Multiple investigators	The researchers used independent researchers, a facilitator and a joint facilitator from the initial planning phase to the final report. A co-analyst confirmed findings using the computer software, NUDIST 4-0.
	Multiple sources	Focus group interviews, field notes and audio-recordings were used.
	Member checks	Participants validated information as their own, from verbatim quotes and in-field notes and further supported by a literature review.
	Peer examination	The study was discussed with peer researchers.
	Authority of the researchers	The researchers have conducted qualitative methods during their PhD studies and are experienced in qualitative research. Attend workshops frequently.
Applicability and Transferability	Sample	A purposive sampling method was used.  The findings of this study can be applied to other populations groups, cultures and religions.
	Peer evaluation	Peer checking by colleagues and supervised by experts.  Independent checking by colleagues and supervised by experts.
	Code-recode procedure	Consensus discussion between the researchers and the independent coder. The researchers used the raw data from the focus group interviews with students (preceptees) and preceptors.
Neutrality	Bracketing	The researchers recognized their own biases and intentions, which were bracketed during the interviews.
Consistency and dependability	Audit trail	Verbatim quotes were checked by listening to the audio-taped recordings.
Confirming the data	Audit trail	The researchers used the raw data from the focus group interviews with students (preceptees) and preceptors.  Data analyses and conclusions were formulated.

Guba and Lincoln (1985: 306) and Hallet, 1995; Taylor, 1995 and Beech, 1999.

#### 2.4 Data Analysis

All the focus group interviews were recorded on at least two audio cassette recorders, in the event of a technical error. The researchers used tapes of 90 minute duration. References to gesturing or remarks made were indicated in field notes. Audio-tapes were transcribed verbatim. The researchers listened to the audio-tapes repeatedly to ensure that data saturation was reached (Krueger, 1994). Researchers read transcripts and field notes independently. Transcripts were analyzed and open coded into key themes, further analyzed into sub-themes until no new themes emerged. Table 2 gives an overview of the themes and sub-themes.

Table 2. Important themes and sub-themes that emerged from focus group interviews exploring the preceptorship relationship

Theme	Sub-theme
Being committed and trained for the preceptor role	1.1 diversity in transitioning 1.2 the preceptor eases the transition
2. The student realizes nursing practice	2.1 the student gives meaning to the clinical practice
3. The student integrates a student role into a professional role	3.1 the student internalizes norms, values, culture and ethics
4. The extended roles of the preceptor	<ul> <li>4.1 role model</li> <li>4.2 educator role</li> <li>4.3 facilitator role</li> <li>4.4. protector role</li> <li>4.5. socialization role</li> <li>4.6. motivator role</li> </ul>

#### 3. Results

#### 3.1 Demographic Characteristics

Preceptees (student nurses, SN) were female and on average 23 (20-25) years old. Preceptors included clinical teaching assistants working at the nursing college. The clinical teaching assistants (CTAs) were all female and on average 35 (40–58) years old. Clinical preceptors from the health service (hospital staff, HS) were female and on average age of 35 (30–47) years old. The mean experience of precepting was in range of 0–6 years.

#### 3.2 Theme 1 Being Committed and Trained for the Preceptor Role

Preceptors felt that an effective preceptorship relationship depended on the 'commitment and training of the preceptor' (CTA3) and that preceptors not committed to the role experienced problems with students. Clinical teaching assistants described the characteristics and qualities needed to be a preceptor using the following words, 'the heart to teach', 'compassion and passion' (CTA3) 'committed' (CTA 10) 'manage people in difficult situations is important' (CTA5), 'everyone must be seen as an individual (CTA 9, 7, 10). Hospital staff (2, 1, 14, 12) mentioned the need to be 'flexible', 'intellectually strong', 'experienced', 'skilled', 'dedicated, 'approachable' (HS5), 'deal with differences in people' (HS4), 'patient' (HS11) and 'knowledgeable' (HS7). Hospital staff stated the following, 'that if you don't have the heart of being a preceptor, even if you teach and are knowledgeable' (HS 9,10).

The literature supports that commitment to the preceptor role is enhanced by interested students (Monareng et al., 2009), positive self-awareness, self-confidence, having a mature age, experience and being formally trained as a preceptor (Hallin & Danielson, 2009). Preceptors who receive training are more willing, committed, and capable of mentoring student nurses (Donley et al., 2014).

#### Sub-theme 1.1 Diversity in transitioning

Student nurses shared that language and cultural barriers that made it difficult to follow preceptors. In a preceptorship relationships 'one has to deal with differences in people' (SN4). Students found that preceptors of the same culture were more empathetic, 'who guides, teaches and recognizes weaknesses, she's polite, they trust us more' (SN7). Similarly 'the language between the student and preceptor should be the same' (SN 2, 9, 5), or 'they (SNs) should be given a course in Arabic' (SN 10, HS 6). Most clinical preceptors mentioned that they had to accommodate other cultures (HS 2, 6, 8, 12).

Differences in cultural and educational backgrounds are possible stressors in the teaching/learning environment that may make or break a professional relationship. Individuals are unique beings and should be treated respectfully (Johnstone & Mohide, 2009). A preceptor may require the assistance of faculty or an interpreter for students whose first language is not English (San Miguel et al., 2006).

#### Sub-theme 1.2 The preceptor eases transition

Student nurses mentioned that they were dependent on preceptors for their guidance in easing transition to a professional role. According to the preceptees, their preceptors were their 'medium for understanding the culture of nursing in the clinic' (SN 1, 2, 5). According to the CTAs 'it is very important for us to be around, because they are following our footsteps' (CTA 1, 4, 2, 5, 6) and 'that a role model means what you teach, you should know

especially personality wise, like this simple thing as 'dress code' the students sees how you move, how you talk how you greet, how you consider the team in nursing and the role of professional nurse nursing practice' (CTA 7). In contrast, hospital staff had little time for dealing with students due to lack of 'support from the higher management' (HS1), lack of 'financial support' (HS1), lack of 'support from colleagues' (HS7), 'time constraints (HS6), heavy 'work load' (HS 11), lack of 'open communications' (HS 12) and 'refusal to do unrelated work' (HS 13).

Students were adversely affected by the attitude of preceptors and were unable to learn in a hostile environment. Some preceptors had outbursts in front of patients and emphasized that 'shouting' (SN 5) makes them feel 'nervous, frustrated and confused' (SN 7) and 'she (HS) behaves 'aggressively' when procedures are not done competently' (SN 4, 5). Student nurses felt that HS must learn to 'control her mood' (SN 3), 'not humiliate, but respect others' (SN 6). One SN mentioned 'I feel like I have 'committed a crime' (SN 2). Student nurses had a need for more advanced training in the clinical setting, rather than 'from scratch' (SN 5) and as preceptors 'they (HS) should not be teaching the basics, but show them the routine, 'experience, work preparation' (SN 7), 'support from colleague' (NS 5), 'dedication skills' (SN 10), 'knowledge, commitment' (SN 7), 'time management, good interrelationship' (SN 5, 10, 7).

(Horton et al., 2012) supports that if preceptees are expected to be able to practice caring, then they must be shown caring within the preceptor-preceptee relationship. Clinical preceptors need to have a lower patient workload to be effective in the role (Horton, 2012). Precepting can cause significant stress and preceptors are advised to reflect on their immediate actions, to highlight educational experience and clinical decision making in developing themselves professionally for future situations (Fidelindo et al., 2016).

#### 3.3 Theme 2. Realizes Nursing Practice

The second theme concerned the feelings of SNs experiencing the clinical environment for the first time, which were mainly feelings of overwhelm. Educational objectives for SNs were not perceived as realistic to practice realities. The CTAs mentioned that the clinical environment is an 'anonymous, mysterious world for the girls' (CTA3); 'a different world' (CTA 7), 'it is not only giving medication to your patient, since we are nurses we deal with human beings, not only their physical illnesses, but also their emotional' (CTA 4, 10). When dealing with patients, 'it is not only the knowledge, the skills' (CTA 8) 'but it is how you try to understand or treat your patient as a human being' (CTA 9). Furthermore, human beings are holistic beings (CTA 2, 5). Hospital staff were also concerned with 'time management' and 'interpersonal relationships' (HS 7).

Preceptees felt that preceptors were unable to communicate professionally and caused more distress being unsupportive and uncaring. 'Students need guidance in training, does not require humiliating...it is more than critiquing...and evaluation of performance' (HS 4), another stated that when 'I am questioned I am made to feel like a criminal, because I don't know something' (HS 8).

Students coming to practice experience a gap between what they have in their minds and what is experienced in reality (Dimitriadou et al., 2013). Theory and practice within realistic expectations reduces the 'reality of shock' when students enter the practice environment for the first time (Duteau, 2012). A caring student-preceptor relationship enhances a caring and safe environment (Hilli et al., 2014).

Sub theme 2.1 The students give meaning to the clinical environment

Student nurses give meaning to the clinical environment and explored uncomfortable feelings. The verbatim quotes revealed how distressed and uncomfortable SNs felt interacting with patients in the real life setting. The feelings of SNs are described as the 'first time in the 'reality of the clinical environment' (SN 3), 'first time to deal with patients and to do a job' (SN 5). They 'felt discomfort and fears' (SN 8), 'horrible for me' (SN 3) 'it was the first time experience' (SN 4), 'the environment was not comfortable for me' (SN 2), 'it was a strange place' (SN 7, 1). A few responders nodded approval.

Students perceive the practical environment whilst "learning the ropes" (Messersmith, 2008). Students entering the practice environment need to learn their professional role. Students need to adapt to inter-professional pressures, conforming to the behaviors and expectations of the professional role (Dimitriadou, 2013). Preceptors who are overloaded and lack time cannot fulfill student needs and challenges (Broadbent et al., 2014). Preceptors who are overly critical, unsupportive and lacked commitment, are not perceived as role models (O'Mara et al., 2014). Socialization of students in the practice environment enhances feelings of belonging, confidence and trust (Carlson, 2013).

#### 3.4 Theme 3 the Student Role Is Integrated Into a Professional Role

Some students perceived transitioning from student to professional as overwhelming but others found the experience less intimidating. Some students emphasized that they must be 'perceived as students' (SN 4, 5), 'I want to be seen as a student and not as a professional' (SN 10), 'from the first day, we should learn and they should teach' (SN 6). Some students reflected positively 'it puts responsibility on us, but I did not feel it was horrible, I feel it was very interesting' (SN 7), 'teach, give guidance and training' (SN 9). Students emphasized that 'the teaching style should focus on teaching/training mostly', it is more than critiquing, 'but evaluation of performance'.

When moving from theory to clinical practice; clear, realistic learning objectives need to be stated (Charleston & Happell, 2005). New knowledge, facts and skills, values and norms are internalized through interaction with others (Shiyanski et al., 2006). Students need to be proactive rather than reactive or passive learners (DinMohammadi et al., 2013; Price, 2009). A positive experience with an experienced preceptor is a crucial step in assuming the professional role (McIntosh cited in Price, 2008). For students, preceptors who are mostly concerned with competencies are perceived as uncaring and harsh and do not reflect their ideal role models (Mcintosh cited in Price, 2008). Nursing practice is a practical wisdom, which is fostered by being sensitive and human in the preceptor-preceptee relationship (Myrick et al., 2012).

Sub-theme 3.1 The student internalizes norms, values, culture and ethics.

In the nursing college, student nurses internalize the culture of nursing, values, norms and ethics. Clinical preceptors felt that 'students must have the willingness to learn' simple objectives, compare with policy and system in the hospital' (HS 4, 9, 10, 13), 'compares the learning objectives of what was attained at the end of the day' (HS 2, 5, 10), 'teaching a person your routine is not hard but are they willing to learn or how eager are they to learn is the question' (HS 2). The clinical teaching assistants stated that 'I involve them, with endorsements and identify if learning objectives have been met' (CTA 8), ensure that 'feedback is given on time' (CTA 8), 'orient our students, orientation is very important based on the course syllabus or on the course outline or objectives and ethical code' (CTA 6). Clinical teaching assistants also highlighted 'the art of motivating', 'I think for me it is the art of motivating the students, because if you don't have the art of motivating then I don't think you will have a successful outcome' (CTA 7, 9).

Students struggled to internalize their professional role and stated 'we are not professional yet, and are in the working environment for the first time' (SN 1, 2, 6) and 'being in the hospital for the first time is a scary experience' (SN 4).

Information is internalized when observing role models or mentors in their professional capacity (Shiyanski et al., 2006). Students are inducted into the culture of nursing, establishing social roles in a social structure through interaction with others (Shinyaski et al., 2006). Nurses have a distinct body of knowledge, a responsibility to society by an ethical code of standards to uphold (ANA, 2010b). Nurses are socialized into nursing by learning how to relate to patients and are in the process of developing a professional identity (Price, 2009). Whilst developing a professional identity, student nurses need a culture of safety during all phases of learning. In the nursing profession, students do better when they care and have an interest in nursing without being induced to learn (Kristan Ho & Reed, 2013), this caring is further developed if student nurses feel cared for and appreciated.

#### 3.5 Theme 4 The Extended Roles and Responsibilities of the Preceptor

#### Sub-theme 4.1 Role model

Student nurses are socialized easily when they perceive preceptors as role models. They copy professional comportment, and strive for competence. Not perceiving the preceptor as a role model may obstruct a successful relationship. In this study, the preceptors knew the qualities of a good role model, but the preceptees did not perceive these qualities in their existing relationships. Clinical preceptors expressed that a role model means what you teach and demonstrate, including 'clinical competence' gives 'feedback', be a 'good role model' (HS 3, 4, 8, 12) and model professional behavior (HS 1, 2). The CTAs mentioned that they should have 'effective communication skills' (CTA 2), learn to 'control her mood' (CTA 13) and 'but respect others' (CTA 14). Students found these qualities lacking and had negative experiences, 'feel 'nervous, frustrated and confused' and makes 'facial expressions', behaves 'aggressively' when procedures are not done competently (SN 6, 8, 9).

Nurses are socialized into their professional roles in two phases, firstly through education and training and, secondly through agents in the work environment who influence, guide, support, protect and nurture (Shiyanski et al., 2006). Student nurses are continuously internalizing information and behavior by careful listening and observing role models/mentors and role modeling professional behavior themselves (Shiyanski et al., 2006).

#### Sub-theme 4.2 Protector role

A culture of safety is important for quality practice and, students should internalize and exercise safety during all phases of learning. Healthcare workers need to exercise transparency for a safe environment. Quality and safety should be ensured by CTAs and HS. Student nurses depend on the CTS and the HS for guidance, for example NS 2 is assigned a patient and 'competence is assessed' (NS 2, 10) and agreed that 'the CTA adds to my information' (NS 10, 2, 4), and 'they give us objectives and the time to ask questions' (NS 3, 4). Clinical preceptors are responsible for giving constructive feedback, modelling capability and clinical judgment by assigning the most appropriate patient to the student for effective learning' (HS 1, 3). One CTA expressed 'so you need to have outcomes, so you also have to assess your students, how the students have come up with competency skill' (CTA 8).

The preceptor protects the preceptee and the patient and, facilitates a rich learning non-human practical environment ensured by safe, competent, practice (AACN, 2008). Safe practice is the focus on social competence in academic and practical environments (Sedgwick & Harris, 2012). Preceptors who are supported and instill a sense of importance to the role are better able to transition student nurses into the clinical environment effectively (Happel, 2009). Patients are better informed and expect professional, safe, competent and satisfied nurse practitioners to care for them.

#### Sub-theme 4.3 Educator role

The educator aims to narrow the gap between theory and practice. To maintain an effective learning environment, preceptors need to use their time to apply learning objectives to feel committed in the role, without feeling overloaded. Students agreed that 'the clinical preceptor adds to my information', she provides opportunity for 'learning, guides, teaches and recognizes weaknesses' (SN 4, 1, 5, 6), 'she (CTA and HS) accommodates me, teaches me and asks me to follow her' (SN 2), and 'even though she is overloaded with her own work she accommodates me' (SN 6, 10). As educators, CTAs stated 'so you need to have outcomes, so you also have to assess your students' (CTA 1) and felt 'that if your student can't get you...for example, you are using terms which can't be understood by students' (CTA 4, 6) and 'the ideal preceptor is the level of understanding of the student should also be considered' (CTA 10). Hospital staff felt that the 'hospital is a good learning experience and the hardships encountered' (HS 12), 'students must have the willingness to learn' (HS 14), nursing is continuous learning process and through teaching you are also learning (HS 9). Preceptors also valued the opportunity 'increase your knowledge through explaining to that person the process and procedures' (HS 6).

Preceptors face challenges, including overload (Hurley & Snowden, 2008), lack of support, inadequate preparation of the preceptor role, barriers in communication with faculty and being held accountable for student success or failures. Theory to practice inconsistencies of students leads to perceived lack of knowledge and unhealthy preceptor-preceptee relationships (Matua, 2014)

#### Sub-theme 4.4 Facilitator role

Preceptors have to facilitate the transitioning of student nurses to professional nurse. According to CTAs, they have to 'involves them (SNs), with endorsements and identify if learning objectives have been met' (CTA 8) and ensure that 'feedback is given on time' (CTA 8), to help them become professional. The clinical preceptors have to 'follow policy and procedure' (HS 4), 'students must have the willingness to learn' (HS 12), 'give guidance and training' (HS 12).

The student should adopt an independent role while being facilitated and guided (Franklin et al., 2014). Matua et al. (2014) indicated that treating students as colleagues created a harmonious relationship of mutual respect, open communication and trust.

#### Sub-theme 4.5 Socialization role

Students are socialized into the clinical environment and are introduced to the professional team during the orientation period. Student nurses described 'In the first day we establish a rapport not only with students but with Nurse' (SN 3), 'collaborative learning with other nurses, managers or supervisors and communicate with them' (SN 7), 'how you consider the team in nursing and the role of professional nurse nursing practice' (SN 10).

Sedgwick, Yonge (2008) showed that nurse preceptors assist students to become members of the team. Students feel they want to belong and to be seen as part of a nursing community (Andrew et al., 2009). Student nurses who are exposed to collaborative relations are better prepared and confident individuals who will adapt to the realities of the clinical practice. Preceptors who are supported and instill a sense of importance to the role are better able to cope with student nurses.

#### Sub-theme 4.6 The Evaluator role

Preceptors need to evaluate students and provide prompt feedback. Students need to self-evaluate by reflecting on the task at hand. According to the CTA 1 'So you need to have outcomes, so you also have to assess how the students have come up with competency skills'. Evaluation is also important for students, 'she asks me to do a task and checks on my competency' (SN 6). In the hospital, clinical preceptors need to 'confirms, critiques, modifies and adds to knowledge' (HS 12), 'gives feedback (HS 14), timeously' (HS 4). Evaluators also need to 'simplify the objective, compare with the policy or system involve' (HS 9), 'give assignments' (SN 10), 'make them (SNs) involve' (HS 11) and 'set base line expectation' (HS 8).

Helminem et al., (2014) emphasized that preceptors must be skilled in assessing student nurses. Constructive critique is aimed at encouraging students to improve their competencies and cognitive abilities (Omer et al., 2015). The student should be cognizant of deficits, able to reflects and improve and progress towards becoming a professional (McIntosh, 2003).

#### Sub-theme 4.7 The motivator role

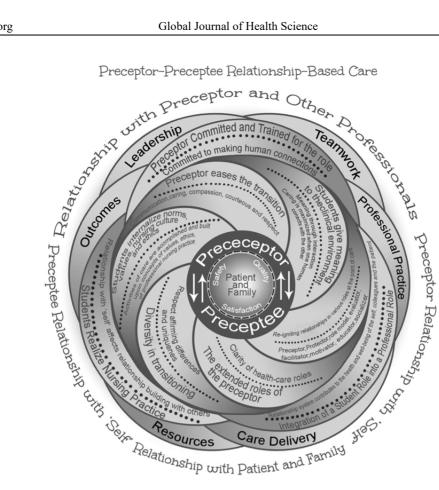
The concept the 'art of motivating' emerged from the content when CTA's stated, 'I think for me it is the art of motivating the students....because if you don't have the art of motivating than I don't think you will have a successful outcome' (CTS 7, 9)."

Unmotivated students' may negatively influence other students. Because caring is an intrinsic motivator, nurses may transition into their professional role quite easily, without being coerced. Unmotivated students need to be extrinsically motivated, encouraged and guided (Kristan et al., 2013).

#### 4. Discussion

In this study, we identified challenges and strategies to encourage and enhance relationship building between preceptors and preceptees. We discuss our findings using a conceptual framework, the Relationship Based Care model of Koloroutis (2004), adapted for this study in Figure 1. Linking various roles and relationships between the preceptor and the preceptee. Mutual respect is imperative and confidence and trust is enhanced when learning outcomes have been achieved. Preceptors have multiple roles, all of which are enhanced when there is a caring relationship between the preceptor and preceptee.

#### Preceptor-Preceptee Relationship-Based Care



outis, M (2004), Relationship Based Care, A Model for Transforming Practic

Figure 1. A conceptual framework of (Kolouriris, 2004), is adapted for this study, linking various roles and relationships between the preceptor and the preceptee

The RBC model of Koloroutis (2004) considers three relationships, namely establishing a therapeutic relationship between patients, co-workers and self. There are six essential dimensions that interact, namely, teamwork, leadership, professional nursing practice, care delivery, resource driven care and outcome measures. The clinical experience of students is determined by the physical environment and patient care needs. We adapt the RBC model and assume that nursing students (preceptees) are inspired when teaching and learning is displayed by professional roles integrated within caring relationships. Universities are responsible for the cognitive and theoretical application of RBC on simulated patients while clinical practice provides a 'live' experience on 'real' patients (Happell, 2009). In our study, preceptors and preceptees face challenges, centered around human connections in a 'make or break; relationship. Preceptors identified that commitment and preparation for the role were a challenge. Interpersonal relationships and teamwork are based on deep commitment and caring attitudes and behaviors, rather than compliance in the role. Preceptors who are trained are able to skillfully connect with preceptees. The student gives meaning through interaction and relationship building.

Another challenge that affected interpersonal relationships was the effect of diversity on transitioning. In a RBC, cultural relationships are enhanced when there is respect in affirming differences and uniqueness. The shortage of staff worldwide leads to students being educated by diverse cultures and religions. Preceptors should ease the transition from student nurse to a professional role. Preceptors should strive towards being culturally competent and sensitive. The preceptorship relationship is also affected by the experiences of student nurses as they realize nursing practice. According to the RBC model, the patient and family should be the central focus (Koloroutis, 2004), and preceptors and preceptees are responsible for patient care. All activities and relationships should result in safe patient care and family satisfaction. Caring relationships between preceptors, preceptees and patients can be limited if students are overwhelmed by the realities of the clinical environment, or if they are unsupported. Professional preceptorships and caring patient relationship can be fostered by engaging in open communication on expectations, responding to adversities, prompt feedback, validating, reassuring and being respectful. Respect and

courtesy are essential components of the RBC model, where the relationship with 'self' affects relationship building with others (Koloroutis, 2004)

In the nursing profession, student nurses have to transition to nursing professional. The process is daunting for young, inexperienced student nurses who have never had to deal with the realities of clinical practice. The formation of knowledgeable, competent and caring student nurses into well prepared professional nurses is a shared responsibility, in which the student internalizes norms, values, culture and ethics. Implementing a RBC model of care provides a collective belief in defining caring attitudes towards the delivery of care, professional development and in an ongoing improvement of the patient, nurse and organizational outcomes (Koloroutis, 2004).

In the preceptorship relationship, preceptors have to fulfill extended roles. Organizations should be responsible for the skills development and training of preceptors. The RBC model of Koloroutis (2004) implements role clarity and work alignment as a process which enhances the clarity of health care worker roles, professional practice, teamwork and delegation of tasks. The outcomes are based on the alignment of patient-centered care using the most skilled health care worker, with the best possible resources. In extending the preceptor role to a protector, role model, evaluator, facilitator, motivator, educator and socializer, both the preceptee and the patient form the foundation of the precepting role. Teaching by example as a role model educates by being supportive and motivates by demonstrating commitment. Students seek preceptors who are committed in the role, who give regular feedback and reflect on practice as a dual process of care and education. This allows the preceptee to give meaning to the clinical environment and even if the preceptee is overwhelmed by clinical realities, support from the preceptor and inter-professionals will facilitate the student into a professional role. The success of a professional relationship must reflect realistic expectations of the clinical environment and in which Happell, (2009) viewed preceptorship as an essential element of high quality nursing education. This inevitably leads to high quality patient care established through an interactive process of professional relationships. Nursing education and the clinical practice environment cannot be viewed in isolation and merging these recognized the importance of the preceptorship relationship in nursing education. A conceptual framework of (Kolouriris, 2004) in Figure 1, is adapted for this study, linking various roles and relationships between the preceptor and the preceptee.

#### 4.1 Limitations

The responses gathered from the focus groups were from one health and academic organization and thus may not be representative of other organizations. The focus group size ideally stipulates 6–10 respondents (Beech, 1999, p. 56) but in this study it extended to 14 clinical preceptors from the health facility, which might have influenced the findings. The intricacies of the collective perceptions have illuminated 4 themes, which could be differently perceived in another study. Preceptors of diverse cultures could have influenced the findings. Students perceived Saudi preceptors as more caring and accommodating. It is worthwhile to mention that the authors do not suggest that 'caring' and a 'sense of belonging' are the most significant concepts in relationship building, but that there are many factors, or hidden in the curriculum. However despite these limitations the authors are of the view that the results of this study offers a significant awareness and comprehension of a 'make or break' preceptor-preceptee relationship.

#### 5. Conclusions

Through real lived experiences, rich, meaningful perceptions emerged when preceptors and student nurses explored the efficacy of teaching and learning in the process of building a relationship. We identified four significant themes, namely commitment in the preceptor role, the students realizes nursing practice, the student integrates a student role into a professional role and the extended roles of the preceptor. Highlighting a caring environment in the process of teaching and learning is significant for the sustainability of the relationship based care model between preceptor and preceptee in nursing education. The relationship based care model undoubtedly influences the teaching and learning process in preceptorship, and ultimately had implications for patient care. The findings of this study can be used in the preparation of preceptors and preceptees to display caring, commitment to teaching and learning and motivate students' in accepting and adapting to practical realities and applying congruent theory to practice learning objectives. The relationship-based care model supports the importance of the acquisition of knowledge and skills in a 'caring' collaborative learning environment.

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#### **Competing Interests Statement**

The authors declare no conflicts of interest that may have influenced this research study.

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#### Patient Satisfaction With Caring at a District Hospital in Malawi

Brian Nkwinda<sup>1</sup>, Wanda Jacobs<sup>2</sup> & Charlene Downing<sup>3</sup>

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#### **Abstract**

**Purpose:** The purpose of this study was to investigate and understand patient satisfaction with caring at a district hospital in Malawi.

**Materials and Methods:** The study used a mixed methods design, employing the sequential explanatory strategy. A total of 120 adult patients completed a survey questionnaire (phase one), and of these, two patients were followed up with individual interviews (phase two).

**Results:** Data were analyzed using statistical procedures, thematic analysis and an integration process of quantitative and qualitative findings. Highest patient satisfaction (90.6%; M=4.53; SD=0.879) occurred with nurses' presence; while lowest satisfaction (37.4%; M=1.87; SD=1.710) was seen with patient teaching. Patients' lived experiences revealed that nurses' demonstration of presence and professional proficiency were critical to caring.

**Unique Contribution to Theory, Practice and Policy:** To enhance improved caring, there was a need for nurses to increase personal presence, promote patient involvement in decision-making, and demonstrate competent confidence.

Keywords: caring, district hospital, Malawi, mixed methods, patient satisfaction

#### 1. Introduction

Caring is the core of nursing (Qiuting, 2013; Watson, 1979) and forms the basis for an inter-subjective relationship between the patient and the nurse (Wu & Volker, 2012). Failure to provide optimum care diminishes quality and negatively impacts on patient outcomes including patient satisfaction (Kim et al., 2017). Patients' satisfaction is regarded as a major determinant of healthcare quality (Kvist, Voutilainen, Mäntynen, & Vehviläinen-Julkunen, 2014), and a clear insight into patients' self-reports of their satisfaction with care may help in efforts to improve the care (Aiken et al., 2012).

#### 1.1 Literature Overview

#### 1.1.1 Attributes of Caring

Caring is described with reference to cognitive actions, behaviors, techniques, processes, or patterns that are culturally learned to help an individual, family or community improve or maintain a healthy condition (Smith, 2013). When quality of care is good, patients tend to be satisfied with it (Kim et al., 2017). Three attributes have been identified as being key to caring: professional knowledge and skills, trusting nurse-patient relationship, and promotion of human dignity.

#### 1.1.2 Professional Knowledge and Skills

Professional knowledge and skills comprise the theory, practice and experience of the nurse, (Sumner, 2012). They are the authority that mandates the nurse to render care (Papastavrou et al., 2012). Professional knowledge and skills demonstrate the nurse's competence (Shrestha, Petrini & Turale, 2013), and when intertwined with positive personality characters, they help the nurse demonstrate professional maturity by conveying caring, loving kindness, and equanimity (Smith, 2013). Knowledge deficit and lack of skills among nurses were found to be the cause for unwarranted changes of filters, removal of machines, and failure to troubleshoot equipment in continuous renal

<sup>&</sup>lt;sup>1</sup> Post graduate student (MCur), Department of Nursing, University of Johannesburg, South Africa

<sup>&</sup>lt;sup>2</sup> Lecturer and supervisor (DCur), Department of Nursing, University of Johannesburg, South Africa

<sup>&</sup>lt;sup>3</sup> Senior lecturer and co-supervisor (DCur), Department of Nursing, University of Johannesburg, South Africa Correspondence: Charlene Downing, Department of Nursing, Faculty of Health Sciences, University of Johannesburg, Johannesburg, South Africa. Tel: 27-011-559-9063. E-mail: charlened@uj.ac.za

replacement therapy (Przybyl, Androwich, & Evans, 2015), not knowing what to do or say to patients (Baillie, Cox, & Merritt, 2012), and development of a negative attitude towards nursing (Baillie et al., 2012; Nguyen, Yates, & Osborne, 2014).

#### 1.1.3 Trusting Nurse-Patient Relationship

Building a trusting nurse-patient relationship is vital to securing the patient's active engagement with the healthcare experience (Phillips-Salimi, Haase, & Kooken, 2011). Patients who are actively involved in a trusting nurse-patient relationship have been found to experience increased adherence to treatment protocols (Elder et al., 2012; Blackstock, Addison, Brennam, & Alao, 2012), increased likelihood of lifestyle and behavioral change (Jones, Carson, Bleich, & Cooper, 2012), and higher patient satisfaction with care (Shan et al., 2016; Bohnert, Zivin, Welsh, & Kilbourne, 2011), leading to improved healthcare outcomes. In addition, Brumpton et al., (2013) ascertained the therapeutic effect of a trusting nurse-patient relationship. They found that chronic stress acted as a pathologic trigger in asthma incidents among adult patients, and by controlling stress through the trusting nurse-patient relationship, asthma incidents were reduced. Winning patients' trust, however, takes deliberate effort by the provider (Murray & McCrone, 2015). Meyer, Ward and Jiwa (2012) posit that morals and ethics are critically important to offset power imbalances associated with the patient's vulnerability.

#### 1.1.4 Promoting Human Dignity

Humans have a desire to maintain dignity at all cost, however, vulnerability from illness occasionally demeans their will and predisposes them to a loss of their dignity (Ferri, Muzzalupo, & Lorenzo, 2015). Studies indicate that patients who are treated with dignity experience reduced stress (Warner, Saxton, Indig, Fahy, & Hovart, 2012), greater satisfaction (Lin & Lin, 2011), increased comfort, and enhanced recovery (Baillie & Gallagher, 2011). Dignity is, therefore, an essential element in healthcare. Perceptions of care quality do not simply depend on treatment outcomes, but also on the manner in which care is delivered (Ferri et al., 2015). In caring, dignity as a concept has been associated with respect, privacy, justice, autonomy, respectful communication and emotional support conferred upon humans (Ferri et al., 2015; Lin & Tsai, 2011; Tadd et al., 2011). In contrast, undignified care is characterized by individual dehumanization and objectification, the use of humiliating and abusive language, lack of focus, and the promotion of individual invisibility and disempowerment (Tadd et al., 2011). Respecting patients involves honoring their beliefs, aspirations, commitments and choices, understanding their abilities and limits, and promptly attending to their needs and priorities (Lin, Tsai, & Chen, 2011; Tadd et al., 2011). Respect for patients promotes patients' autonomy and active participation in nursing care. Therefore, respecting and maintaining human dignity in patient care is a way of demonstrating a caring attitude (Ferri et al., 2015).

#### 1.1.5 Patient Satisfaction

Patient satisfaction is described as the patient's attitude, perceptions or feelings towards care and the extent to which their expectations of ideal care are met when compared with the actual care received (Iftikhar et al., 2011; Rama & Kanagaluru, 2011). Patient satisfaction has recently become a very useful outcome indicator for quality of care (Aiken et al., 2012; Kvist et al., 2014) since it represents patients' actual views on care (Al-Abri & Al-Balushi, 2014). Also, the increasing awareness of patients' rights among healthcare users due to advancements in information and technology services has strengthened the healthcare consumerism attitude which calls for incorporating patients' views in healthcare decision-making (Souliotis et al., 2016). Despite that, however, Bjertnaes, Sjetne and Iversen (2012) posit that it would be misleading to use patients' opinions as a sole basis for subjective evaluation of care quality. Likewise, Zgierska, Rabago and Miller (2014) found that physicians under pressure to satisfy patients were lured into writing out unnecessary prescriptions, conducting needless tests, and admitting patients unnecessarily. Meanwhile, studies have shown that patients who are satisfied with care experience several positive healthcare outcomes, including increased treatment compliance (Elder et al., 2012; Blackstock et al., 2012), increased likelihood for a positive behavioral change (Jones et al., 2012), longer survival periods (Gupta, Markman, Rodeghier, & Lis, 2012), and increased trust in healthcare providers (Bohnert et al., 2011).

Several factors have been identified that influence patient satisfaction. Among them the nature of patient-provider interaction, the level of support from the care-providers, and the nature and extent of care continuity (Kobayashi, Takemura, & Kanda, 2011; Balfe et al., 2013; Liljeroos, Agren, Jaarsma, & Strömberg, 2014). In the out-patient department, Carlucci, Renna and Schiuma (2013) found that provision of complete and clear medical information, attentiveness, and respecting the patient's privacy were the main factors associated with patient satisfaction. In addition, Higgins and Prigerson (2013) found that in end-of-life care, patient and care giver satisfaction were influenced by active patient and care giver involvement in decision-making, prolonging the patient's life, and preparing the patient and care givers for the patient's impending death. In Nigeria, despite being satisfied with

overall healthcare, patients reported dissatisfaction with long waiting times, complicated hospital bureaucracy, and the high cost of services (Iloh et al., 2013). Similarly, in South Africa, patients on antiretroviral therapy (ART) reported dissatisfaction with prolonged physical examinations and insufficient HIV transmission and prevention counselling (Finkel, Adelekan, Marcus, & Wolvaardt, 2012).

Inconsistencies have been observed regarding findings on studies investigating the influence of patient demographic variables (gender, education, age and socioeconomic status) on satisfaction with care. In Kuwait, Rouhi, Asayesh, Rahmani and Abbasi (2011) found that male patients in general- and special wards reported higher satisfaction with care than female patients. Regarding education, patients who were university graduates reported higher satisfaction than those with other qualifications. Consistent with these findings, Azizi-Fini, Mousavi Mazroui-Sabdani and Adib-Hajbaghery (2012) discovered that patient education, coupled with nurses' caring behaviors, increased patients' satisfaction. In contrast, age, gender and patients' level of education were not found to have any significant predictive value on patient satisfaction in a study by Taheri, Jahromi and Hojat (2015). These contradictory findings of various studies were an indication that more research may be required in the area of patient satisfaction and demographic variables.

#### 1.2 Research Problem

However, the issues that affect patient satisfaction, the level at which patients are satisfied with nursing care, and the extent to which nurses were reported to be caring during their interactions with patients at a district hospital in Malawi, had never been documented.

#### 2. Methods

The study design was mixed methods (quantitative and qualitative methods) using a sequential explanatory strategy (Creswell, 2014).

#### 3. Phase One (Quantitative Phase)

In this phase, the core method was applied. It was descriptive and correlational in nature (Gray, Grove, & Sutherland, 2017). It focused on surveying patients' satisfaction with caring. Caring nurse-patient interactions were assessed, analyzed and described in relation to patients' satisfaction (Ivankova, 2015).

#### 3.1 Study Participants and Setting

Stratified sampling was used to recruit respondents. A total of 120 adult patients (18 years and older, both female and male) were recruited from four wards (female, male, TB, maternity) at the participating district hospital in Malawi. All respondents were hospitalized for at least two days prior to recruitment and volunteered to complete the questionnaire.

#### 3.2 Measuring Instrument and Data Collection

Data were collected using a 58-item questionnaire divided into four sections. Section A contained five items (1-5) designed to collect respondent demographic information: gender, age, marital status, occupation, and level of education. Section B consisted of 24 items (6-29) adopted from the Caring Nurse-Patient Interactions (CNPI-23P) (Cossette et al., 2006: 198-214), scale. The CNPI-23P is divided into four dimensions namely clinical, relational, humanistic, and comforting care. Items in these four dimensions assess nurse caring from the perspective of nurse-patient interactions as evaluated by the patient. A 5-point Likert scale was used with frequency response categories 'never' (1), 'rarely' (2), 'sometimes' (3), 'often' (4), and 'always' (5). Section C comprised 25 items (30-54) adapted from the patient satisfaction instrument (PSI). The PSI has three dimensions: trust, technical-professional care, and education. The response category with the PSI was the level of agreement using the 5-point Likert scale which ranged from 'strongly disagree' (1), 'disagree' (2), 'neutral' (3), 'agree' (4), to 'strongly agree' (5). Although the PSI was developed in 1975, its usability across patient satisfaction studies is still applicable to date (Freitas, Silva, Minamaisava, Bezerra, & Sousa, 2014). The last four questions in Section D elicited information on the general evaluation of the quality of care received by the respondents. Visual analogues (circles, emoticons and thumbs) were used across all response items. This was done in consideration of the low literacy level within the target population, and to facilitate easy understanding of the response categories among respondents.

#### 3.3 Reliability and Validity

All factors of the CNPI-23P and the PSI demonstrated acceptable levels of internal consistency. Cronbach's alpha coefficient scores for CNPI-23P ranged from 0.710 to 0.905 and from 0.712 to 0.918 for the PSI. In addition, despite being multidimensional, each dimension of the CNPI-23P and the PSI were unique and no single dimension demonstrated bi-dimensionality. Conclusions derived from the study were based on patterns observed

in the data.

#### 3.4 Data Analysis

Statistical analysis procedures included descriptives, factor analysis, correlation analysis, and reliabilities.

#### 3.5 Findings

#### 3.5.1 Respondents' Characteristics

Table 1 shows respondents' characteristics in terms of gender, age and marital status.

Table 1. Participants' characteristics: gender, age and marital status

	Number	0/0
Gender		
Female	105	87.5
Male	15	12.5
Age		
Average age	31.72	
Standard deviation	12.23	
Marital status		
Divorced	11	9.2
Married	88	73.3
Separated	3	2.5
Single	13	10.8
Widowed	5	4.2

Of all 120 respondents, 87.5% (n=105) were women and 12.5% (n=15) were men. The age distribution of all respondents ranged from 18 to 70. The majority of respondents, 73.3% (n=88), were married, 10.8% (n=13) were single, 9.2% (n=11) were divorced, 4.2% (n=5) were widowed, and 2.5% (n=3) were separated.

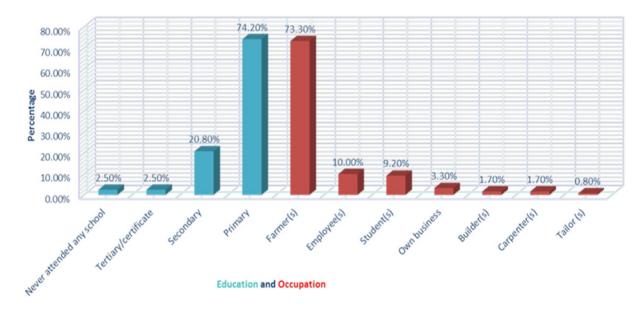


Figure 1. Depicts respondents' characteristics in terms of level of education and occupation

Of the total number of respondents (n=120), the majority, 73.3% (n=88), were farmers. Few others, 10.0% (n=12), were business people, 9.2% (n=11) were students, and 3.3% (n=4) were technical professional employees. Craft workmanship was very low with only 1.7% (n=2) builders, 1.7% (n=2) tailors, and 0.8% (n=1) carpenters. Consequently, it was observed that while the majority of respondents were farmers, the highest level of education attended by the majority of respondents, 74.2% (n=89), was primary school. The rest were secondary school leavers at 20.8% (n=25), respondents with tertiary certificates at 2.5% (n=3), and those that who attended any formal school at 2.5% (n=3).

#### 3.5.2 Caring and Satisfaction Rating

Across the caring and satisfaction dimensions, the highest rated caring attribute was respect for patients' privacy of comfort dimension (88.6%; M=4.43; SD=1.301), while the lowest rated caring attribute was patient teaching of clinical care dimension (40.6%; M=2.03; SD=0.898). Highest patient satisfaction was observed with the attribute of trust dimension (90.6%; M=4.53; SD=0.879), and lowest patient satisfaction occurred with the patient teaching aspect of education dimension (37.4%; M=1.87; SD=1.710). Table 2 shows detailed frequency results for caring and satisfaction.

Table 2. Frequencies for caring and satisfaction

Range of standard deviation and mean scores for caring and satisfaction						
Lowest mean score Standard deviation Highest mean score Standard deviation						
Caring	2.03	0.898	4.43	1.301		
Satisfaction 1.87 1.710 4.53 0.879						

#### 3.5.3 Overall Rating of Quality of Care

Table 3 tabulates the detailed frequency results for overall rating of caring quality.

Table 3. Frequencies for quality of care rating

	Number	%	
Quality of care rating			
Very good	23	19.2	
Good	67	55.8	
Average	25	20.8	
Poor	5	2.5	
Very poor	2	1.7	

#### 3.5.4 Correlation Between Caring and Patient Satisfaction

Pearson product moment correlation revealed positive correlation of moderate strength between caring and patient satisfaction with the majority of correlations (68%; n=17) statistically significant (r=.260 to .475; p<.005 {2 tailed}; N=120). Table 4 shows details of the correlation results between caring and patient satisfaction.

Table 4. Pearson correlation among caring and patient satisfaction dimensions

		Satisfaction				
		1. Nurse's professional skills	2. Respect for patients autonomy	3. Promotion of patient trust	4. Nature of nurse-patient communication	5. Professional proficiency
	1. Personal presence of the nurse	.45**	.4**	.3**	.34**	.28**
	2. Caring by nurse's creative use of self	.38**	.3**	.22*	.14*	.21*
Caring	3. Caring by competence and with confidence	.47**	.15*	.23*	.34**	.36**
S	4. Presence and being present partner in patient care	.41**	.23*	.26**	.30**	.47**
	5. Caring by promotion of human dignity	.40**	02*	.17*	.27**	.38**

<sup>\*\*</sup> p < .005 (2 tailed) N=120; \* p > .005 (2 tailed) N= 120.

#### 3.6 Influence of Participants' Demographic Characteristics on Caring and Satisfaction

#### 3.6.1 Age

Pearson product moment correlation coefficient showed a negative correlation between age and caring (r=-.231, p < .05, N=120), and age and satisfaction (r=-.248, p < .05, n=120). Thus, the older a respondent was in the sample, the less they were satisfied with caring.

#### 3.6.2 Gender

Independent sample t-test showed that female respondents were more satisfied than male respondents, with statistically significant difference in satisfaction for female (M=19.57, SD=2.812), against male (M=17.81, SD=5.493), t (118) = -1.970, p = <.005, 2-tailed. Mean difference = -1.766, 95% CI: -3.541 to .009; eta squared = 0.03. For caring, no significant difference in caring rating was observed between male and female respondents.

#### 3.6.3 Marital Status

The independent sample t-test found that unmarried respondents rated caring higher than married respondents, with statistically significant difference in caring rating for the unmarried (M=18.88, SD=3.626), against the married (M=17.96, SD=3.401), t (118) = -1.286, p = <.005, 2-tailed. Mean difference = -.919, 95% CI: -2.334 to .496; eta squared = 0.01. For satisfaction, there was no significant difference in the rating between married and unmarried respondents.

#### 3.6.4 Education

Independent sample t-test showed that more educated respondents (secondary/higher) rated caring higher than the less educated respondents (primary/lower), with statistically significant difference in caring rating for the more educated (M=18.95, SD=3.558), against the less educated (M=17.98, SD=3.431), t (118) = -1.302, p = <.005, 2-tailed. Mean difference = -.972, 95% CI: -2.451 to .507), eta squared = 0.01. However, for satisfaction, there was no significant difference in the rating between the less educated and the more educated.

#### 4. Phase Two (Qualitative Phase)

This was a follow-up supplementary phase. The phenomenological approach (Denzin & Lincoln, 2013) was used to explore and describe patients' experiences of care. Kerwin-Boudreau and Butler-Kisber (2016) explain that the phenomenological approach involves verbal extraction of important statements from participants, through the researcher's interpretation, making meanings out of them, organizing the meanings into themes, then clarifying the themes in a rich written description.

#### 4.1 Study Participants and Setting

Two participants (highest and lowest satisfied participants) who participated in the initial survey were purposively selected and followed up with semi-structured individual interviews. Both interviews were conducted in places chosen by the participants. A small sample was used as the qualitative data and results to elaborate on or explain the initial quantitative findings (Creswell, 2015: 37-9; Ivankova, 2015: 133; Morgan, 2014: 157-161).

#### 4.2 Data Collection

An interview guide was used. The first key question asked, 'How was nursing care like for you during the last hospitalization?' Probes and follow-up questions were used to encourage the participants to clarify points, say more, or to re-focus the direction of the interview. With the participants' consent, the interviews were audio-taped. Each interview lasted 30 minutes (Grove, Burns, & Gray, 2013).

#### 4.3 Data Analysis

Data were analyzed by theming process as described by Giorgi (2009). The method seeks to explore the meaning of a phenomenon by identifying themes from the participants' lived experiences. By using this approach, the transcripts were first read through several times to get a sense of the whole. Next, the transcripts were re-read to discriminate meaning units and clarify them in relation to the caring phenomenon. Then, the identified meaning units were transformed into nursing language with emphasis on caring phenomenon.

#### 4.4 Findings

One central theme was identified: *perceived quality of caring was experienced by patients when nurses demonstrated presence and professional proficiency*. It appeared that such a caring quality perception occurred as a result of trust that patients developed towards nurses. A lack of such trust was identified by Shan *et al.*, (2016) as a cause for patient dissatisfaction. By being present with the patients and demonstrating proficiency when intervening with them, the nurses instilled a sense of trust in the patients, leading to high perceptions towards nurses' care. Similarly, patients lost trust in nurses and perceived them as uncaring when the nurses demonstrated absence, a lack of empathy, and emotional disconnectedness. The quotes below attest to these observations as narrated by the participants:

- "...the care was very nice... I was given bed immediately I arrived in the ward. Perhaps just almost five minutes, everything was going well." No doubt, they knew what they were doing... 257 ...that is why I did not bother to ask why they took my blood samples, or deny them the 261 samples..."
- "...For me, the nurses were not reliable. I did not trust them...<sup>542</sup>...because I saw that what they did to me was somehow cruel. ...during the night shift, they could not be seen. For sure they went to sleep because throughout the night, they could not be<sup>435</sup> seen in the ward. They only came when a new patient arrived...<sup>436</sup> ...not for patients already in the ward. For those already in the ward, once they give you<sup>440</sup> medicine in the evening, you won't see them again until the next morning.<sup>441</sup>...'

A patient's experiences during a caring moment are critical for the patient to develop trust. Murray and McCrone (2015: 3-23) suggest that conscious effort by the nurse may be necessary to help the patient develop trust. Morals and ethics might be critical to offset power imbalances associated with patients' exposure (Meyer et al., 2012). Creating an enabling caring environment might be essential to promote flourishing antecedents that foster development and trust. Such antecedents include, but are not limited to, demonstrations of professional expertise (McCabe & Sambrook, 2014; Chowdhurry, 2012), good reputation (Nilsson & Mattes, 2015), demonstrations of integrity through honesty, loyalty, fairness and reliability (McCabe & Sambrook, 2014), communication (Nilsson & Mattes, 2015; McCabe & Sambrook, 2014; Chowdhurry, 2012), personality traits (Nilsson & Mattes, 2015), and shared values (Chowdhurry, 2012).

#### 4.5 Demonstration of Caring Presence by Nurses Was Experienced by Patients as an Expression of Caring

Watson (2008: 34) describes caring presence in line with a caring moment. It involves enabling and sustaining the nurses' own beliefs and those of the patient, being present to meet the patients' needs, thereby instilling hope and trust in the patients. The nurse invokes special competencies such as nurse-patient connection (Watson, 2008: 34; Kostovich, 2012: 169), therapeutic silence (Watson, 2008: 34; Hooper, 2013), nurse-patient sharing of stories and experiences (Kostovich, 2012: 169; Hooper, 2013), appropriate eye contact (Watson, 2008: 34; Kostovich, 2012: 169), respecting life, incorporating patients' values and beliefs in the care plan, promoting patients' growth, avoiding objectifying patients (Watson, 2008: 34), therapeutic touch, attentiveness, smiling, sense of humor, centering, and positive body posture (Kostovich, 2012: 169). These competencies make caring presence an integral aspect of nursing care (Mohammadipour, Atashzadeh-Shoorideh, Parvizy, & Hosseini, 2017). Narratives

from participants' experiences in this study show that when the nurses were present in the ward, patients were promptly attended to. The following participants' narratives attest to these observations:

- '... I was well received  $^{44}$  ... to the extent that the nurses showed eagerness to assist me and actually they assisted  $me^{48}$  to the best of how they knew their job.  $^{49}$  ...
- '...When they spoke, they had manners. They spoke well enough making sure that I should<sup>376</sup> understand...<sup>377</sup> You know how a person behaves when sick...<sup>381</sup> If you shout at him/her, he/she wouldn't care...<sup>385</sup> ...but the nurses might know what they are doing, while the patient might not know.<sup>389</sup> Sometimes as a patient you act abnormally. The nurses tried their best to make sure that I<sup>390</sup> understood...<sup>391</sup>

Demonstrating respect towards patients is an important aspect of patient care (Chadwick, 2012: 187-191). Respect for patients involves protecting their physical privacy (Warner et al., 2012: 86-92). Unnecessary exposure of patients during intimate procedures constitutes a breach of patient privacy (Lin et al., 2013: 168-177). It is dehumanizing and embarrassing. Careless behaviors and humiliating actions that compromise patients' respect and dignity have been reported within the healthcare profession. Findings in a study by Willassen, Blomberg, Von-Post and Lindwall (2015: 688) showed that healthcare providers demonstrate humiliating behavior that strip patients of their dignity. These included rendering the patients invisible, ignoring the patients' complaints, treating the patients as objects, speaking negatively to and about the patients, and blaming the patients for their health situation.

- 4.6 Demonstration of Professional Proficiency by Nurses Was Experienced by Patients as an Expression of Caring Participants' narratives show that when nurses demonstrated competence, the patients perceived a quality of care. Nurses' demonstration of professional knowledge and skills was an indication of proficiency and quality caring (Chang, Yang, & Yuan, 2014: 124). In other studies, an inability to demonstrate competence in healthcare delivery accounted for about 12% of total patients who expressed dissatisfaction with healthcare (Shan et al. 2016). Regarding nurses' demonstration of knowledge and skills, participants' statements in this study showed that patients found nurses to be knowledgeable and skillful.
- '...No doubt, they knew what they were doing.  $^{257}$  That is why I did not bother to ask why they took my blood samples, or deny them the  $^{261}$  samples. After all, the treatment came after the tests and my aim was to be treated and  $^{262}$  get better. That's what I was interested in...  $^{263}$

Those equipments, no I was not put on oxygen...<sup>552</sup> but thermometer, yes! They were coming to measure my temperature in my armpits...<sup>556</sup> She could look at the readings...<sup>560</sup> and then leave without saying anything...

Clinical competence is an essential element of quality caring, but it would not exist without professional knowledge and skills (Shrestha et al., 2013: 205-212). Professional knowledge and skills were found to correlate positively with competence, resulting in improved practice among nurses caring for children in Nepal (Shrestha et al., 2013: 205-212), diabetic patients in Jordan (Yacoub et al., 2014: 255-262), and oncology care in Vietnam (Nguyen et al., 2014: 448-456). The patients' perceptions of the improved care might have resulted from their trust in the nurses (Cross, Roe & Wang, 2014: 560-565). In critical care settings, clinical competence is vital for monitoring a patient's condition (Atkinson, 2013), as well as operating specialized medical equipment. Inadequate clinical competence in continuous renal replacement therapy, for example, was found to be the cause for unwarranted change of filters, removal of machines, and failure to troubleshoot equipment; resulting in adverse effects for the patients (Przybyl et al., 2015: 135-147). Nurses' demonstration of competence in various clinical skills, including operating medical equipment, was a good indication of the quality of care they rendered to patients.

#### 5. Phase Three: Interpretation, Integration and Discussion of Results

Results obtained in the quantitative phase suggest that the majority of patients were highly satisfied. Nurses' respect for patients' privacy and the nurses' presence were scored highly. Patient education (explanation and information giving) was poorly rated in both caring and satisfaction. These findings are consistent with previous studies where nurses were rated high at caring for respecting patient privacy, and low for not giving treatment-related information (Carlucci et al., 2013; Finkel et al., 2012). Respecting patient privacy is a critical step towards delivering dignified patient care. According to Li et al., (2013), unnecessary patient exposure during physical examination causes a lot of embarrassment to the patient, thereby undermining patient dignity. Safeguarding patient privacy is not only a caring issue; it is also a constitutional provision.

The nurses' physical presence in the ward reassures patients of prompt attention (Okoro & Odedina, 2016). However, the nurses' presence as a caring concept goes beyond their mere physical presence. It entails emotional and spiritual connectedness between the nurse and the patient (Watson 2008: 34; Kostovich, 2012: 169). This

connectedness propels the nurses' intentionality to caring and the patients' participatory willingness towards care interventions. In this study, it was found that the majority of patients were highly satisfied with caring with regard to the nurses' presence. This could be attributed to the fact that the nurses were well connected with patients, or that the patients had few expectations from the nurses.

#### 6. Conclusion: Caring and Satisfaction

In conclusion, the findings of this study have shown that in general, quality of caring was high at the district hospital and patients were highly satisfied with the caring. Critical to influencing the patients' satisfaction were nurses' presence and professional proficiency. By using the mixed methods design, the study has broadened and deepened our understanding of patient satisfaction with caring at the district hospital in Malawi more than a single method alone would have done.

#### 7. Ethical Considerations

Ethical clearance was obtained from the Research Ethics Committee (REC: 01-246-2015) and the Higher Degrees Committee (HDC: 01-164-2015) of the Faculty of Health Sciences at the University of Johannesburg. Permission to conduct the study was obtained from the National Health Sciences Research Committee (NHSRC) at the Ministry of Health of the Malawi government (protocol # 15/12/1520), and from the district health officer. Further permission to gain access to the wards and participants was granted by nurses-in-charge in the participating wards. Participants' rights regarding their voluntary participation, withdrawal, privacy and confidentiality in the study were firmly upheld.

#### 8. Limitations of the Study

The main limitation of this study was the underrepresentation of male participants. The use of two participants as part of the qualitative exploratory part can be seen as a further limitation.

#### **Competing Interests Statement**

The authors declare that there are no competing or potential conflicts of interest.

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## Second Generation Antipsychotics (SGAs) in Schizophrenic Patients and Bipolar Disorder: Correlation With Metabolic Syndrome (NCEP ATP III(a))

Consuelo Roldan Menco<sup>1</sup>, Anderson Díaz-Pérez<sup>1, 2</sup> & Zoraida Barrios Puerta<sup>1</sup>

Correspondence: Consuelo Roldan-Menco, Faculty of Health Sciences, University Corporation Rafael Núñez, Cartagena, Colombia. Tel: 57-313-562-2595. E-mail: consueloroldan@curnvirtual.edu.co

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#### **Abstract**

**Introduction:** The Metabolic Syndrome is a set of diverse clinical situations such as diabetes mellitus, hypertension and dyslipidemia. Patients with mental illnesses such as schizophrenia or bipolar disorder have a higher mortality than the general population attributable in 60% to somatic diseases and metabolic syndrome, where second generation antipsychotics increase the risk of weight gain and insulin resistance. **Objectives**. Correlate the treatment with second generation antipsychotics (SGAs) as a possible predictor for Metabolic Syndrome according to the NCEP ATP III (a) classification.

**Methods:** Descriptive, cross-sectional correlational study. The sample was of 92 patients, applying an open and convenience sampling due to the mental state of the patients in order to determine their degree of acceptance to the study (Informed Assent) and consent to the legal guardian as the main inclusion criterion. For the analysis, the following variables were considered: blood pressure, weight, height, abdominal circumference, serum levels of triglycerides, glucose and high density lipoproteins. The SPSS 20.0 ® program was used logistic regression analysis with a p-value <0.05 and a confidence level of 95%.

**Results:** SGAs most used was clozapine (54.3%). The correlation analysis showed that sociodemographic aspects such as personal history, habits, physical activity and paraclinical and anthropometric records correlated with the possible diagnosis of metabolic syndrome (p < 0.05), but not with SGAs (p > 0.05).

**Conclusion:** No correlation was found between the presence of the metabolic syndrome and the type of antipsychotic treatment.

**Keywords:** second generation antipsychotics, schizophrenic patients, bipolar disorder, metabolic syndrome

#### 1. Introduction

The Metabolic Syndrome (MS) is a current disscusion and issue in the medical community; Its approach is essential because it is related to the diseases that cause the highest mortality worldwide, and its incidence is increasing, characterized by the presence of a set of risk factors such as insulin resistance and compensatory hyperinsulinism associated with disorders of the metabolism of carbohydrates and lipids, high blood pressure levels, and obesity (Menco & Pérez, 2011; Pineda, 2008)

The adoption of behavioral patterns such as unhealthy diet and lack of physical activity have contributed to the high prevalence of hypertension, hypercholesterolemia, diabetes, obesity, and, with this, that cardiovascular diseases are the leading cause of death, disability and premature mortality (Lakka et al., 2002; Park & Lee, 2018). The National Cholesterol Education Program Adult Treatment Panel III (ATPIII), implemented some parameters where three or more of the following criteria must be met: high abdominal perimeter (> 102 cm in men and> 88 cm in women) TG> 150 mg/dl , Low HDL (men <40 mg/dl and women HDL <50 mg/dl), BP> 130/85 mm Hg or receive antihypertensive therapy, glycemia> 110 mg/dl including DM, but in 2004 with the update of the American Diabetes Association, glycemia was modified to 100 mg/dL (Expert Panel on Detection, 2001; Kavey et al., 2003; Grundy et al., 2004). The updated definition of ATPIII (ATPIIIa) is used as the limit of abdominal perimeter the same proposed in the guidelines of the International Diabetes Federation (IDF) for South Americans, that is, 90 cm

<sup>&</sup>lt;sup>1</sup> Faculty of Health Sciences, Corporación Universitaria Rafael Núñez, Cartagena de Indias, Colombia

<sup>&</sup>lt;sup>2</sup> Faculty of Health Sciences, Universidad Popular del César, Valledupar, Colombia

for men and 80 cm for women (Alberti, Zimmet, & Shaw, 2006).

Patients with severe mental illnesses such as schizophrenia or bipolar disorder have a higher mortality 2-3 than the general population (Atun et al., 2015; De Hert, Dekker, Wood, Kahl, & Möller, 2009; Levav, Lima, Somoza Lennon, Kramer, & Salvatierra-González, 1989), where according to Newcomer, it is 60% attributable to somatic diseases and metabolic syndrome (Newcomer, 2007a, 2007b). Regarding the metabolic syndrome, the prevalences are two to four times higher than the rest of the population, in the United States, it has been calculated that the average number of years potentially lost in patients with mental illness ranges from 25 to 30 years, compared with the general population where the main cause of death was coronary heart disease (McEvoy et al., 2005; Cortés Morales, 2011; Vancampfort et al., 2015). It is clear that genetic factors and lifestyle have an influence at mental illnesses as well as the presence of metabolic syndrome, where it has not been possible to elucidate in how the interaction of antipsychotic drugs interact with each other, which Somehow, it would explain the differences in the fact that people with mental illness have a greater predisposition to this type of metabolic diseases (Firmann et al., 2008; De Hert et al., 2009; García-García et al., 2008; McEvoy et al., 2005; Muñoz-Calero Franco et al., 2015; Ortiz Lobo & Ibáñez Rojo, 2011; Rojo, Mesa, & Martínez-Ortega, 2014; Lakka et al., 2002).

Second generation antipsychotics (SGAs), as a group can reduce the risk of producing extrapyramidal side effects and hyperprolactinemia when compared with first generation antipsychotics (FGAs) (Martínez, León, Torres, & Crossley, 2017; Cortés Morales, 2011; Pato, Rodríguez, & Valverde, 2017). However, there is scientific evidence suggesting that the interaction of these may increase the risk of significant weight, insulin resistance metabolic homeostasis, hyperglycemia, diabetes mellitus (DM) type 2 and dyslipidemia which could reduce life expectancy in patients who need these drugs as schizophrenic patients and with bipolar disorder (Cortés Morales, 2011).

MS is very frequent in patients with severe mental illnesses, several studies have raised the relationship of schizophrenia with MS, consequently in 240 Canadian subjects showed figures of 42.6% for men and 48.5% for women using the criteria of the National Cholesterol Education Program ATP (ATP III) (Cortés Morales, 2011). In another study conducted with 430 chronic schizophrenic patients in Belgium the presence of MS reached prevalences of 28.4%, and 36%, according to the diagnostic criteria of the ATP III and the International Diabetes Federation, respectively, being more prevalent in female patients (Moreno, González, Fleta, & Pérez, 2006). In Latin America, a study conducted in Brazil also found a higher proportion of women using the criteria of the ATP III (Cortés Morales, 2011).

The objective of the study is correlate the treatment with second generation antipsychotics (SGAs) as a possible predictor for Metabolic Syndrome according to the NCEP ATP III (a) classification.

Objetivo del estudio es correlacionar el tratamiento con antipsicóticos de segunda generación (AP2G) como posible factor predictor para Síndrome Metabólico según la clasificación NCEP ATP III(a).

#### 2. Methods

Descriptive study with a cross-sectional correlational component. The population was 200 inpatients and outpatients of a psychiatric center of the City of Cartagena de Indias/Colombia. The method of sample selection was opened for convenience, for a (n = 92) outcome of patients with schizophrenia and bipolar disorder.

The participating patients gave their informed consent as a way to contribute to their moral development (Autonomy), informed consent was given to the tutors and to patients who demonstrated maturity and independence in the adherence of the treatment as the main inclusion criterion, as a suggestion of the ethics committee of the Corporación Universitaria Rafael Núñez, in addition the patient's data was processed and safeguarded subject to Resolution 8430 of 1993 of Colombia and to the declaration of Helsinki. As exclusion criteria, patients who were not medicated with (SGAs) and patients under 18 years of age did not participate due to the conditions of their mental capacity in relation to the type of pathology.

An instrument validated by experts was applied, in order to obtain sociodemographic, clinical and risk factors information, antipsychotic treatment, cardiovascular and family risk history, among others. Anthropometric parameters were taken, as well as blood sampling. The body mass index (BMI) was calculated by using the measured anthropometric parameters: weight in kilograms and height in meters (Kg/m²). Likewise, the measurement of the abdominal and hip circumference was made in centimeters with a tape measure, the blood pressure measurement was made using a mercury sphygmomanometer with the patient sitting after five minutes of rest according to the indications of the British Hypertension Society (Williams et al., 2004; Stergiou et al., 2018).

Within the paraclinical studies venipuncture was performed, with a fasting period of 12 hours, to evaluate glucose, total cholesterol, HDL cholesterol and triglycerides. LDL cholesterol was determined by the Friedewald formula. The determinations were made using Fotometer Humalyzer primus (HUMAN), with human serum control level I

and II. For the analysis of the metabolic syndrome, the criteria of (NCEP ATP-III (a)) were considered, considering three or more of the following criteria: abdominal obesity (waist circumference  $\geq$ 90 cm in men and  $\geq$ 80 cm in women; 2) Triglyceride values greater than or equal to 150 mg/dl, c-HDL values <40 mg/dl in men and <50 mg/dl in women; 3) values of blood pressure greater than or equal to 130/85 mmHg or carry hypertensive treatment; 4) values of plasma glucose of greater than or equal to 100 mg/dl in the fasted state (including diabetes mellitus) (Thomas et al., 2005; Heng et al., 2006). Through the SPSS 20.0® for Windows, the univariate and multivariate logistic regression analysis was performed. All calculations were made with a 95% confidence level and p-value <0.05.

#### 3. Results

The population was constituted by women (n = 44) and men (n = 48) in equal proportion, between ages of 18 to 76 years with an average of 35.5 years, the great majority are young adults with ages of 23 years (7.6%). (Table 1)

Table 1. Age

Sample	92
Mean	38,62
Standard error of the mean	1,590
Median	35,50
Mode	23
Standard deviation	15,252
Variance	232,634
Rank	58
Minimum	18
Maximum	76

In women, a greater distribution of mental illnesses was found in relation to bipolar disorder in a (36.4%). In men the highest percentage was found in schizophrenia compared to women in a (72.9%), however no statistical significance was found between the distribution of the disease between the sexes (P-value> 0.05). (Table 2)

Table 2. Gender versus Diagnosis

		Diagnosis	Diagnosis						
		Schizophrenia n (%)	Asperger Syndrome n (%)	Bipolar Disorder n (%)	Mental disorder (Behavior) n (%)	Mixed Disorder n (%)	Acute Psychotic Disorder n (%)	Total n (%)	P Value
C 1	Female	24 (54,5)	0 (0,00)	16 (36,4)	0 (0,00)	2 (4,5)	0 (0,00)	44 (100)	
Gender	Male	35 (72,9)	1 (2,1)	8 (16,7)	2 (4,2)	0 (0,00)	1 (2,1)	48 (100)	0,94*
Total		59 (64,1)	1 (1,1)	24 (26,1)	2 (2,2)	2 (2,2)	1 (1,1)	92 (100)	_

Pearson Chi-square\*.

In patients diagnosed with Schizophrenia and Bipolar Disorder, it was found a prevalence of sedentary lifestyle, with a high rate of increasing their tendency to obesity, added to the consumption of alcohol and smoking, which also increases the probability of suffering from hypertension at medium term. (Table 3)

Table 3. Habits and Concomitant Diseases versus Schizophrenia and Bipolar Disorder

			Pathologies				
Damaanal History	Schizophrenia		Bipolar D	isorder	Total		
Personal History $n = 67 (\%)$			n = 25 (%)		n = 92 (%)		
	Yes	No	Yes	No	Yes	No	
Hypertension	8 (11.9)	59 (88.1)	5 (20)	20 (80)	13 (14.1)	79 (85.9)	
Obesity	13 (19.4)	54 (80.6)	6 (24)	19 (76)	19 (20.7)	73 (79.3)	
Sedentary lifestyle	45 (67.2)	22 (32.8)	15 (60)	10 (40)	60 (65.2)	32 (34.8)	
Smoker	14 (20.9)	53 (79.1)	3 (12)	22 (88)	17 (18.5)	75 (81.5)	
Alcohol Consumer	17 (25.4)	50 (74.6)	7 (28)	18 (72)	24 (26.1)	68 (73.9)	

The correlation found between the possible diagnosis of metabolic syndrome and the presence of schizophrenia in personal history was significant in patients with hypertension, which increases in 4.8 times the risk of presenting metabolic syndrome (P-value = 0.044), as well schizophrenic patients with a history of obesity have 3.6 times more risk (P-value = 0.042). (Table 4)

Meanwhile, the results obtained for the case of bipolar disorder patients were less significant than the sociodemographic factors, only the age of the patient with this disorder was correlated with the presence of the syndrome, in at an older age, greater risk of this in 1.06 (P-value = 0.044). As for the habits related to health and the realization of physical activity, the act of dancing was significant, reducing the risk of metabolic syndrome in 0.125 (P-value = 0.049). (Table 5)

Table 4. Logistic regression between the presence of metabolic syndrome and risk factors present in patients with schizophrenia

Dimension	Variables	Schizophrenia	
Difficusion	variables	Odds Ratio	P-value
Dayson al History	Hypertension	4,889	0,044
Personal History	Obesity	3,679	0,042
	Sports	0,375	0,040
Habias and Dhasiash Assistan	Perform Exercises	0,267	0.019
Habits and Physical Activity	Walks	0,381	0,020
	Fleet	0,333	0,020
N. C.	Low salt	0,092	0,004
	Fat Consumption	0,423	0,017
Nutrition	Low in sugar	0,348	0,010
	Consumption of Fruits and Vegetables	0,407	0,012
	Glicemia (Mg/Dl)	1,053	0,009
	Hdl (Mg/Dl)	0.888	0,003
	Triglycerides (mg/dl)	1,009	0,018
Anthum amatria Danaslini sal Danarda	weight(Kg)	1,074	0,001
Anthropometric Paraclinical Records	$BMI(Kg/m^2)$	1,201	0,002
	Waist Perimeter	1,067	0,002
	Mean Systolic Pressure	1,097	0,001
	Mean Diastolic Pressure	1,106	0,003

Second generation Antipsychotics	Quetiapine	0,844	0,893
	Risperidone	0,711	0,591
	Clozapine	0,030	0,747
	Olanzapine	-	-

Table 5. Logistic regression between the presence of metabolic syndrome and risk factors in patients with Bipolar Disorder

Dimension	Variables	Bipolar Disorder		
		Odds	P-value	
		ratio		
Sociodemographic	Age	1,060	0,044	
Habits and Physical Activity	Dancing	0,125	0,049	
Anthropometric Paraclinical Records	HDL (mg/dl)	0.752	0,029	
	Weight(Kg)	1,121	0,038	
	Waist Perimeter	1,075	0,029	
Second generation Antipsychotics	Quetiapine	0,420	0,325	
	Risperidone	0,933	0,958	
	Clozapine	0,643	0,669	
	Olanzapine	-	-	

Finally, it was observed that none of the second generation antipsychotics used as treatment by schizophrenic and bipolar disorder patients affects the risk of presenting metabolic syndrome (P-value> 0.05).

#### 4. Discussion

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In the correlation analyzes, no statistical significance was found between the metabolic syndrome and the second generation antipsychotics, a similar outcome was presented by Estévez and McEvoy, in whose study in whose study throw non-significant values between the mentioned variables (Estévez et al., 2013; McEvoy et al., 2005). These authors argue that a possible cause for the lack of correlation could be the sample size, which in its case was 53, while in the present investigation it was also reduced, but with 92 patients.

Another possible cause for this lack of correlation may originate that metabolic syndrome is not necessarily arising from the effect of antipsychotics, at least in patients with bipolar affective disorder, which were considered in their study, but it is a multisystemic and multifactorial disease, clearly develops from other factors (Jaramillo, Mejía, Velásquez, Palacio, & Zuluaga, 2013). Another study in this regard is that of Almeida et al, cited by Jaramillo, who found that the onset of MS was greater among patients taking lithium than in those taking antipsychotics, which would be a clear indicator that the syndrome is not necessarily related to antipsychotics. At this point it is important to mention that lifestyle also triggers the onset of the syndrome in patients with mental disorders (Jaramillo et al., 2013).

Despite the above, there are studies that do demonstrate the relationship between antipsychotics and the syndrome, in which adverse effects were detected by the use of second generation antipsychotics in patients with chronic schizophrenia, such as weight gain due to the use of olanzapine and from here on with the metabolic syndrome (Aguilar, Coronas, & Caixàs, 2012; Cortés Morales, 2011; De Hert et al., 2009; Estévez et al., 2013; Jaramillo et al., 2013; McEvoy et al., 2005; Muñoz & Gallardo, 2004; Newcomer, 2007a, 2007b; Pato et al., 2017; Vancampfort et al., 2015).

Studies mention that there are high possibilities of presenting the syndrome in patients with physical inactivity and an excess of food intake, which promotes weight gain and obesity, in addition, smoking alters the function of insulin. In the study conducted, sedentary lifestyle was one of the most frequent habits, both in bipolar (60%) and schizophrenic (67.2%) (Jaramillo et al., 2013). Patients suffering from schizophrenia, especially those who have long duration of hospitalization have poor quality of life (Choo et al., 2017). Further research is required to assess the relationship between metabolic syndrome and quality of life in patients suffering from schizophrenia.

Within the personal health history it was found that obesity is present in 19.4% of schizophrenics and in 24% of bipolar patients, something similar happens with hypertension, these two conditions, at least in schizophrenic patients, kept relationship with the presence of the syndrome, and they may increase the risk of suffering from it.

From the above it could be thought that the effect of antipsychotics on the development of metabolic syndrome is indirect, because it affects the risk factors that trigger it, but not the syndrome itself. This statement could be supported by studies that recognize that weight gain is a well-documented side effect of antipsychotics during the acute and maintenance treatment of patients with schizophrenia, in this context, the weight gain is maximum with second-generation antipsychotics such as clozapine and olanzapine, in addition the weight gain becomes rapid during the first weeks, slows gradually and often reaches a plateau after one year of treatment (Correll, Detraux, Lepeleire, & De Hert, 2015; Martinez et al., 2017). The etiology of metabolic syndrome in patients suffering from schizophrenia include genetic factors and inflammation but this study did not measure these biological factors (Ho et al 2014). This is the main limitation of this study.

#### 5. Conclusion

Mental illnesses were differentiated according to gender, in male subjects predominated schizophrenia, while in female ones bipolar disorder. A possible low prevalence of metabolic syndrome was observed in both groups of patients. Of particular attention is that patients with risk factors such as weight gain that can lead to different cardiac pathologies that can be exacerbated with the consumption of antipsychotics, especially in the interaction of these.

It is necessary to promote healthy habits and the realization of physical activities at this population, since it was found a protective effect on the risk of suffering from the syndrome in those patients who perform blood pressure checks, carry out exercises, walks, as well as fleets, and dance sessions (especially bipolar subjects), it is recommended to institutionalize at the psychiatric center a program of physical exercise, aerobic by a person or a group of trained people, understanding that among the physiopathology of the SM and mental disorders such as bipolar there are common elements that can exacerbate any of the two pathologies or even both.

Obesity and hypertension were two of the most common conditions among psychiatric patients, and were discussed as elements that increase the risk of the metabolic syndrome.

It is recommended to design a sustainable and feasible diet, in addition to consider for future studies to include various psychiatric entities so that the study has a greater statistical significance.

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#### **Competing Interests Statement**

The authors declare that there are no competing or potential conflicts of interest.

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# Factors Affecting the Decision Making of HPV Vaccination Uptake Among Female Youth in Klang Valley (Influencing Factors): A Qualitative Study

Siti Nur Farhana Harun<sup>1</sup>, Mazrura Sahani<sup>2</sup> & Mohammad Zabri Johari<sup>1</sup>

Correspondence: Siti Nur Farhana Harun, Institute for Health Behavioural Research, Ministry of Health Malaysia, Jalan Rumah Sakit Bangsar, 59000 Kuala Lumpur, Malaysia. Tel: 60-3-2082-1400. E-mail: farhana@moh.gov.my

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#### **Abstract**

**Introduction:** Cervical cancer is estimated to affect 500 000 women each year globally, whereby 80% of the cases are in developing nations. Almost all cervical cancer cases were attributed to Human Papilloma Virus (HPV) infection.

**Aim:** To identify factors influencing the decision-making of HPV vaccination uptake as prevention for cervical cancer among female youth in the Klang Valley

**Methods:** This study used in-depth interview; purposive sampling and snowball sampling method. The questionnaire was based on the Health Belief Model, which consist of perceived susceptibility, severity, benefit, barrier and cues to action. NVivo 7 software was used to process, transcribe and analyse the data from interview sessions.

**Result:** This study found that the key driving factors that encouraged female youth to get vaccinated were due to the role of family members and friends, concerns on contracting HPV related illness, free/discounted priced vaccination, recommendation from health care personnel, government's policy, and benefit (believe in the effectiveness of vaccination). Meanwhile, deterring factors which prevented the uptake of HPV vaccination were lack of knowledge and awareness, costs, healthcare provider and services, time constraint and perceived not at risk.

**Conclusion:** Factors leading to the uptake of the HPV vaccine should be seen in a transparent manner to ensure the success of the HPV vaccination program in this country.

Keywords: HPV vaccine, cervical cancer, qualitative

# 1. Introduction

Cervical cancer is estimated to affect 500 000 women each year globally, whereby 80% of the cases are in developing nations (Cutts et al., 2007). Studies have shown that HPV 16 is the most oncogenic, accounting for almost half of all cervical cancers, and HPV 16 and 18 together account for approximately 70% of cervical cancers. HPV 6 and 11 are the most common strains associated with genital warts and are responsible for approximately 90% of these lesions (Braaten & Laufer, 2008). Genital HPV types are divided into high and low-risk types, according to the oncogenic potential. Molecular and epidemiologic studies have solidified the association between high-risk HPV types (especially HPV-16 and HPV-18) and cervical squamous cell carcinoma. HPV infection is often transient and self-limiting but uncommonly, the infection persists and progress to high grade lesions and cancer. In addition to persistent high-risk HPV infection, other viral factors such as high viral loads, HPV variants, infections with multiple high-risk HPV types and genetic predisposition contribute to the development of cervical cancer (Gomez & Santoz, 2007). In cervical cancer, conventional Papanicolaou smear (Pap smear) remains the main screening method, as it has been proven to reduce incidences by 43% and decreases its mortality by 46% (Cohn & Herzog, 2001). The sensitivity of Pap smear has a wide range from as low as 30% to as high as 87% indicating that many cases could be missed by this screening test. The specificity is 86-100% indicating that there are false positive diagnoses made (Hayati, 2003). Prevention via vaccination could be a more effective method

<sup>&</sup>lt;sup>1</sup> Institute for Health Behavioural Research, Ministry of Health Malaysia, Malaysia

<sup>&</sup>lt;sup>2</sup> Faculty of Health Sciences, Universiti Kebangsaan Malaysia, Malaysia

compared to just screening. Vaccination is more relevant in developing countries as a comprehensive screening program are not feasible due to limited resources (Ministry of Health Malaysia, 2011). This study was conducted to explore factors influencing the decision-making process of HPV vaccination uptake as prevention for cervical cancer amongst female youth in Klang Valley. Furthermore, this study also attempts to ascertain the level of knowledge, awareness and understanding perceptions of female youth regarding cervical cancer and HPV vaccination, factors influencing the uptake of HPV vaccine and the deterring factor for HPV vaccine uptake.

# 1.1 Prevention Strategies

The Malaysian government approved HPV vaccination program with three doses of HPV vaccine freely given to all 13- year-old girls from public or private schools on 21st February 2008; and the budget was approved on 19th August 2009. World Health Organization (WHO) recommended that routine HPV vaccination be included in National Immunization programs (Zaridah, 2014). According to the Annual Report of Malaysia Ministry of Health (2012), immunisation coverage achievement of a complete three dosage of HPV vaccine among 13-year-old girls in the year 2012 was 99.2%.

The Human Papilloma Virus (HPV) Quadrivalent Vaccine was approved by the Malaysian Drug Authority on 20th October 2006 while the Bivalent Vaccine was approved in 2007 (Rushdan, 2008). The vaccines are given in three doses and each injection are given within six months (month 0, 2, 6) (LPPKN, 2012). The optimal target age for prophylactic vaccination is pre-pubertal girls before coitarche (age 9–14 years). Catch-up vaccination involves slightly older women (15–18 years) (Kyrgiou & Shafi, 2008).

#### 2. Material and Methods

A qualitative study was conducted between 1st September till 30th January 2016 in Klang Valley, Kuala Lumpur. Randomization selection of study sites were carried out and three youth centers were selected. Participants were selected based on characteristics such as age group, gender, race, vaccinated and not vaccinated to ensure diversification of participants ranging through ethnicity, age, and personal background. Snowball sampling was used to ensure continuity of recruitment with suitable characteristics for this study. No sample size was determined since the study used a qualitative method whereby the important aspect in determining sample size for qualitative research is the saturation of information. The method of repetitions from the answers by the participants for all interview questions are the pre-determined criteria to stop data collection. This study used a sample selection and data analysis through an ongoing process until at a point where no new information or information obtained from the current interview was overlaid with information obtained earlier. Another method used by qualitative researchers to determine whether information collected has reached the saturation point is when researchers found that the participants began providing the same idea over and over again and no new information that can be shared.

Interview questions were developed from the specific objectives of the study; questions were derived from the Health Belief Model that consisted of five main constructs; perceived susceptibility (participants' susceptibility to HPV infection, risk to contract HPV infection, participants behavior to avoid the risk, participants' family health history), perceived severity (the severity expected if infected with HPV, participants' confidence in HPV vaccine to prevent cervical cancer), cues to action (motivation to find out the factors that encourage participants to take HPV vaccine), perceived benefit (benefits of getting HPV vaccine, the importance of HPV vaccine to the participants), and perceived barrier (emphasized to identify the obstacles faced by participants that prevented participants in getting the HPV vaccine) and perceived threat (to find out if threat is the driving factor to get HPV vaccine) (Rosenstock et al., 1994). For the first pre-test, a list of semi-structured interview questions was constructed and validated by feedback from two subject matter experts on HPV and health promotion and behavior. It was piloted to two participants selected randomly at a youth center in Klang Valley to ensure that the interview questions can be understood and to identify the gaps found in the interview questions.

#### 2.1 Data Collection, Management, and Analysis

Participants were interviewed by a trained interviewer. The interviews were carried out in either in Malay or English language depending on participants' preference, lasting approximately for 30 to 45 minutes every session. After the pilot study, improvisation were made and the researcher continued interviewing 15 other female participants in Klang Valley after reaching repetitions of answers for all questions. Data obtained from the interview sessions were transcribed verbatim and captured on the NVivo 7 software. Accuracy concerning the substance of the interview, the meanings and perceptions created and shared during a conversation was maintained through verbatim transcription. This was also done to not only capture the meaning and perception or the recorded interviews and focus group discussions, but also the context in which these were created. Discussion with the technical expert was carried out to avoid bias in this study through intercoder reliability when recognizing themes.

An Environmental Health expert was invited to give input on technical judgment on public health and a Senior Health Promotion Expert gave a technical opinion based on health promotion perspectives. Researcher organized key themes using deductive analysis guided by HBM framework (Rosenstock et al., 1994).

#### 2.2 Ethical Issues

Ethical approval was obtained from the Medical Research and Ethics Committee, Ministry of Health Malaysia.

#### 3. Results

### 3.1 Socio-Demographic

Basic ethnical data revealed that eight participants were Malays, two Chinese and five Indians. All participants were between 18 and 24 years old. Sociodemographic characteristic is depicted in Table 1.

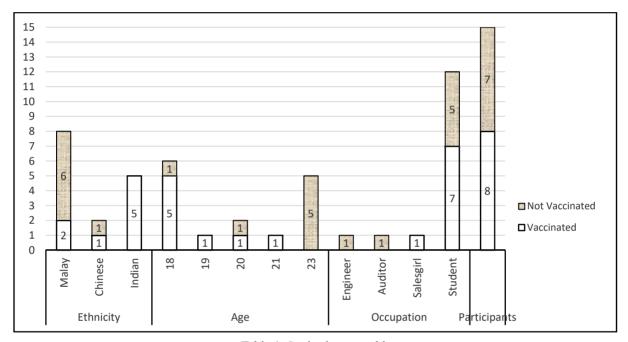


Table 1. Socio-demographic

# Code:

R= Participant's code number.

M, C, I= Malay, Chinese, Indian (ethnicity).

V= Vaccinated.

NV= Not vaccinated.

# 3.2 Level of Knowledge and Understanding

### 3.2.1 Understanding of Cervical Cancer (Causal Factors)

Understanding aspects of cervical cancer were evaluated from the participants' understanding of the occurrence cause of cervical cancer. The majority of participants were able to provide answers in fundamental factors causing cervical cancer. Amongst the answers that are often given by the participants to answer the question on factors that cause cervical cancer are sexually promiscuous, heredity or genetics and hygiene.

"Do you mind to explain what do you understand about cervical cancer?"

"Cervical cancer occurs near the cervix due to; one, genetics, two, sexual promiscuity and It may also be due to the environment. Environment factor such as cleanliness at female's private part was not kept clean can lead to cervical cancer "(R14, M, V).

# 3.2.2 Understanding of HPV Vaccine

Based on the interviews with participants, it was found that almost all participants have a low understanding on HPV vaccine. Very few participants knew that the HPV vaccine is to prevent cervical cancer while other participants admitted that they do not know and do not get enough information about the HPV vaccine.

"Can you explain what do you understand about HPV vaccination?"

"I think it is to prevent from getting cervical cancer." (R12,I,V)

"To be honest I do not know what HPV vaccine is. I have heard of it but I do not know what it does "(R1, M, NV).

#### 3.3 Awareness

### 3.3.1 Awareness on the Importance of HPV Vaccination

Through an analysis of in-depth interview, majority gave similar answers when asked about the importance of HPV vaccination. The most common answer is that HPV vaccination is known as a preventive measure for cervical cancer. Most participants also explained the important function of HPV vaccination is to reduce a woman's risk of contracting the human papilloma virus (HPV).

"In your opinion, what is the importance of HPV vaccination that you know?"

"The importance of the vaccine is to prevent us from getting infected by cervical cancer. Another thing is that we do not know what will happen and it is a benefit because we are still young. So better take it now as it won't be effective when we're old. Fear it would not be effective "(R14, M, V).

"The importance is a step taken to prevent and not regretting once you got cancer. (R11,I,V)

# 3.3.2 Awareness of the HPV Vaccination Regimen

A bigger number of participants knew the total number of dosages for HPV vaccination to be taken. However, a smaller number were unaware or unsure. Two participants did not answer the questions raised and only one gave an accurate answer about the HPV injection regime as stated below. Majority of the participants were able to state the number of injections needed which was three (3) times.

"Are you aware of HPV vaccine regimen? Do you realize how many doses do you need?"

"I have done it. The first one, and then you take the second one after two months, and then the third one after 6 months" (R10, C, V).

"I am not sure. But I think few doses." (R15,M,NV)

### 4. Factors Influencing the Uptake of HPV Vaccine

This study found the key driving factors for female youths to get HPV vaccination was due to the role of family members and friends, concerns on contracting HPV related illness, free/ discounted priced vaccination, recommendations from health care personnel, government's policy and benefit (believe in the effectiveness of the vaccine). Factors preventing female youth getting HPV vaccination were lack of knowledge and awareness, cost, health care provider and services, time constraint and perception of "not at risk".

# 4.1 Role of Family Members and Friends

Overall, the role of family members and friends were considered to be the biggest driving factor for HPV vaccine uptake, both to participants who had been vaccinated or unvaccinated. Almost all participants felt that parents and friends played a big role in influencing to get HPV vaccination. Five participants implied that parents were the strongest influencers to ensure their acceptance for HPV vaccination and seven participants stated that friends and the people around them influenced them the most in their decision to get HPV vaccination.

"What motivates you to get the vaccination?"

"My parents and also friends from my school. My friends, they said it is important to get the vaccination and also from the nurse who gave the briefing about the HPV." (R6, I, V).

"I don't want to take it at first, but my mom made me. She said "you have to take it, compulsory. It's good for health". (R12,I,V)

# 4.2 Concerns on Contracting HPV Related Illness

Concerns on contracting HPV related illness is the second important factor encouraging decision making of participants to opt for HPV vaccination in this study. During the in-depth interviews, more than half of the

participants mentioned they were concerned about the dangers of HPV related illness and the threat of it was a strong motivating factor for them to be vaccinated or to have an intention for opting to vaccinate. According to the participants, the threat of the deadly HPV related illness triggered their action in getting vaccinated.

"Do you think you have the risk of getting infected?

"Because all women are likely of contracting the illness. So I get frightened by it. We are also women, hence there's definitely a chance of contracting it". (R7, M, NV)

"For me, the threat is big enough for me to think to take the vaccine". (R14,M,NV)

#### 4.3 Free/Discounted Priced Vaccination

This study found that price reduction for vaccination through promotions was one of the driving factors for HPV vaccine uptake. About half of the participants mentioned by giving vaccination at a promotional price or free of charge will encourage female youths to opt for HPV vaccination. A total of six participants admitted opting for vaccination because it was free and one of the participants indicated that it is worthwhile to get vaccinated at a promotional price and the rest communally agreed if the vaccination was provided at a lower price.

"What do you think of the cost?"

"Maybe if you go to a private clinic, one injection cost you RM200 or RM100 plus. If it's not for the promotion, it's much more expensive, people will not go. I think it's worthy to get it when they do the promotion." (R10, C, V).

"If the vaccine is given for free, I can find time to go." (R7,M,NV)

"It's expensive. But then the government gave it for free." (R12,I,V)

# 4.4 Recommendation from Healthcare Personnel

The analysis also revealed recommendations from health personnel were seen to have an impact in influencing the decision to opt for HPV vaccination among female youths. Although only few of the participants gave such feedback, researchers felt this component to be vital. Participants explained, recommendations from doctors, advice from nurses and other health personnel such as Health Education Officers provided awareness so that they felt it was important to get HPV vaccination to prevent cervical cancer.

"What motivates you to get the vaccination?"

"The nurse once told this vaccine is to prevent cervical cancer, therefore she encouraged us to take." (R8,M,V)

"If it is suggested by the doctor to take the shot, I might". (R5,I,V)

# 4.5 Government's Policy

This study found that five participants who had been vaccinated while they were in school. Majority mentioned it was considered compulsory for all female students. Government policy mandated 13-year-old school girls to receive HPV vaccination was a stimulus for female youths to be vaccinated. However, there were also participants who went on their own initiative to get vaccinated as they were not eligible for the free vaccination at the school since it wasn't available during their time.

"I got it at school. Compulsory. If it is not compulsory, I won't go and get it (vaccine)" (R5,I,V)

"I just get it because it is compulsory". (R3,I,V)

### 4.6 Benefit (Believe in the Effectiveness of Vaccination)

Participants mentioned they believed in the effectiveness of vaccination and its benefit in terms of health. Participants explained they felt safe and worry-free after being vaccinated.

"It's like when you get yourself vaccinated indirectly you put yourself under control, you might not get the infection. When you do random sexual intercourse, it is like you are putting yourself in danger. So this vaccine can help." (R5,I,V)

"For me, it is to prevent us from cancer. So I do not have to worry about my future. HPV vaccine will protect me from cancer. That's good". (R8, M, V)

4.7 Factors Hindering the Uptake of HPV Vaccination

# 4.7.1 Lack of Knowledge and Awareness

The biggest contributor to the deterring factors of getting vaccinated was due to the lack of knowledge and

awareness on HPV vaccination. The majority acknowledged less exposure to HPV vaccination, lack of awareness on the importance of HPV vaccination and inadequate information resulting in participants feeling that HPV infection is less serious and not dangerous. Hence, the uptake of the HPV vaccine was not perceived as a priority by the participants.

"Because I'm not aware of its importance. It looks like it (HPV vaccine) is not important at all." (R13, M, NV)

"Perhaps my lack of knowledge regarding that matter, I don't think it is serious." (R15,M,NV)

#### 4.7.2 Costs

Cost was seen as a major deterrent in influencing the decision-making of getting HPV vaccination. Majority expressed cost as the biggest hurdle for them to get vaccinated. HPV vaccination costs RM180 for one dose and it is required to take three doses; this was considered too expensive, especially for students.

"For me, as I don't come from a well-off family. So if the HPV vaccine costs and money, may not opt for it." (R9, M, V)

"Because if three injections, I have to pay RM540, that is too much." (R10,C,V)

#### 4.7.3 Healthcare Provider and Services

Participants indicated that healthcare providers and timing of healthcare service contributed to the hindrance in getting vaccinated. Other than being afraid to see the doctor, they also felt that doctors' approach when interacting with patients on the topic of the reproductive system and other sensitive topics (sexual health topic) tend to be negative, hence they will try to avoid seeing the doctors. On top of this, being unaware of operating hours and places that offer vaccination were commonly mentioned as barriers.

"Mostly because they are feeling shy to open up about this topic and mostly in our country the specialist are male doctors so they do not get the exposure to go and talk about this kind of topic and the same goes to breast cancer." (R11, I, V)

"I don't know the place that provides HPV vaccine service." (R14, M, NV)

"It's how the doctor approach, or maybe I am afraid of doctors. So that might be a barrier for me." (R1,M,NV)

# 4.7.4 Time Constraint

Due to intense weekly working schedule, participants were reluctant to use their weekend time to get vaccinated but preferred to spend the available time with their family. Furthermore, the existing time limitation for obtaining vaccination (HPV vaccination in Malaysia has a certain/specific schedule time; not available daily) reduces the likelihood of participants getting the vaccination. If they felt they truly needed the vaccination, they must apply for annual leave; which they perceived as a waste.

"Time contributes to the hindering factors. Maybe we are students, we have class daily and other activities on the weekend." (R14,M,NV)

"Hectic working schedule and limited free time are indeed a barrier. Besides, long range of regimen (6 months) might result in participant to forget the schedule." (R8,M,V)

#### 4.7.5 Not at Risk

Another barrier commonly mentioned was participants were not interested in getting HPV vaccines due to the perception of "not being at risk". Participants explained they did not engage in sexual intercourse and always practiced a healthy lifestyle. Therefore, the risk for them being infected was perceived as low and felt it was pointless to take the vaccine if they were not at risk.

"If we don't have sexual intercourse means we have no possibility of being infected." (R13,M,NV)

"I think it is impossible to happen to me. If I did not do things that would put me at risk, it would be impossible to get the infection. Yes, that's what I mean." (R1,M,NV)

#### 5. Discussion

# 5.1 Family Members and Friends

Family members and friends serve as a catalyst for change in one's behavior. This study found that the majority of participants felt that parents and friends influence them to get vaccinated and give a large weight to the decision-making process. If parents and friends responded positively to the HPV vaccine, thus higher potential for female youth to get vaccinated. These findings support previous studies that showed the urge to act, for instance, the suggestions from friends, family or recommendations from doctors as a strong predictor for the uptake of HPV

vaccine (Bowyer et al. 2014).

# 5.2 Concerns of Contracting the Illness

Concerns of contracting the illness is one of the strong factors for behaviour change. Based on the findings, participants expressed their concerns on the dangers of illness and threats of it which; giving a strong motivating factor for them to take the vaccination. The threat of deadly illness triggered their behavior of getting vaccinated and expected high susceptibility in individuals who have health awareness can help them receive positive change when it comes to health. Individuals who have high awareness on health do not look at the obstacles as the problems, in fact, will try their best to see the positive side of it if it is beneficial to health. This finding is in congruence with other study conducted by Manhart et al. (2011) and Young et al. (2010) in which stated the assumption of getting cervical cancer is high may be the most important psychosocial factor that causes women intending to have such vaccine. The perception of the severity of the high cervical cancer increases the intention of participants to get the HPV vaccine. Women will take action to get vaccinated because they realized the severity of the illness that can cause death (Oscarrson et al., 2012).

### 5.3 Free/Discounted Priced Vaccination

HPV vaccination given at a discounted price or free could increase the expected benefits for young people to obtain HPV vaccination. Provision of subsidies can also be seen to overcome the barriers of getting vaccinated. One of the most powerful obstacles identified in the decision to opt for vaccination is the cost of the HPV vaccine (Conroy et al., 2009). This is because the regimen for the vaccine requires women to have 3 doses to complete and they are costly for them to take this vaccine. Each dose as indicated by the LPPKN could cost RM180 and 3 doses are approximately RM540 (Khor, 2018). With such cost, not all women can afford the vaccination especially for parents that have more than one daughter. The cost to vaccinate all their daughters would be greater. Therefore, the subsidies by concerned parties are needed to increase the uptake of the HPV vaccine.

# 5.4 Benefit (Believe in Effectiveness of HPV Vaccination)

The finding suggested perceived benefits and perceived effectiveness of HPV vaccination was associated with the acceptance of HPV vaccination. This finding has similarity with Chikandiwa (2013) which stated perceived vaccine effectiveness was associated with greater willingness to be vaccinated. Participants believed the benefit of getting themselves vaccinated, it will prevent them from contracting the illness.

### 5.5 Recommendation from Healthcare Personnel

In this study, participants stated the importance of recommendations from health personnel. According to them, it encourages their acceptance of HPV vaccination. This confirms the finding of the previous study by Chikandiwa (2013), which stated a doctor's recommendation for the vaccine, would result in a potential 84% vaccine uptake, while a recommendation from a spouse, friend or family member would lead to an approximate 60% uptake. A physician's recommendation of a vaccine has been identified as an important catalyst for vaccine acceptance. A number of studies have reported that higher acceptability of the vaccine was found in subjects who thought that their doctors would recommend it.

#### 5.6 Government's Policy

Policy-level interventions have been shown to be effective in increasing public health benefits. Government policies and mandates may result in improved HPV vaccination coverage and reduced disease burden, and alternative policies that improve unhindered access to HPV vaccination may allow success as well (Brandt 2016). Therefore, the Malaysian government took steps by approving HPV vaccination program with three doses of HPV vaccine freely given to all 13-year-old girls from public or private schools beginning 21st February 2008 (Zaridah 2014); Government policy mandated 13-year-old schoolgirls to receive HPV vaccines had become an enforcing factor for female youths to receive vaccines. By making it compulsory, this had strengthened HPV vaccination as the primary prevention of cervical cancer.

# 6. Barriers in the Uptake of HPV Vaccine

# 6.1 Lack of Knowledge and Awareness

The biggest contributor to the deterring factors of getting vaccinated is due to the lack of knowledge and awareness of the HPV vaccine. Majority of the participants stated that less exposure to HPV vaccine, lack of awareness about the importance of HPV vaccination and inadequate information resulting the negative perception from participants; HPV infection is less serious and not dangerous. Hence, the uptake of the HPV vaccine is not given a priority by the participants. In addition, from the analysis of the study found the main factor that prevented female youth who have not been vaccinated to get vaccinated are due to the lack of knowledge and awareness. The finding is in line

with research finding of Wong & Sam (2010) in which found a lack of knowledge and awareness regarding HPV vaccine could lead to a perception of less risk in contracting the illness and hence affect the decision-making in the uptake of HPV vaccine.

#### 6.2 Costs

Undeniably, cost is a vital factor that affects the decision-making in the uptake of the HPV vaccine. There are many studies that have been conducted to prove this statement. Results showed that the majority of participants stated that cost is the biggest hurdle for them to get vaccinated. HPV vaccination costs RM180 for one injection (Khor, 2018) and is considered too expensive, especially for the students. The studies in the Western countries show similarities whereby the high cost for the injection has been identified as a critical barrier in getting vaccinated. The fee of US\$360 is beyond the means of most women. Although many women show positive intention to get vaccinated, the high cost has become the main obstacle to behavioral prevention. Subsidies from the government is required to reduce the financial burden and indirectly to increase the uptake of the HPV vaccine in Asian countries (Hyunjin, 2011).

### 6.3 Healthcare Provider and Services

Results showed that participants felt that the service is deemed to be a barrier for them to get vaccinated. According to the participants, other than being afraid to see the doctor, they also felt the doctors' approach when interacting with patients on the topic of the reproductive system tend to be negative. In line with the findings of Rambout et al. (2014), social norms and values of a culture are important. As for Asia in particular, issues such as sex is considered a taboo and prohibited to be discussed in public. The findings of the qualitative study found that some health personnel try to avoid conversations and discussions about HPV vaccine for fear it was not appropriate to the culture.

### 6.4 Time Constraint

Time constraint is an important barrier that will affect the decision to take HPV vaccine as explained by the participants. The findings of this study is consistent with the findings from Hopkin (2013) which indicate that among the causes of negative acceptance of women is time constraints and they do not consider HPV vaccination as a priority. Support from employers is indispensable because the time of HPV vaccination services limited to working days requires the sacrifice of a female employee to seek leave from the employers if they wish to get HPV vaccination on working days. This inconvenience will lead to the refusal. This finding is in congruence with other studies that reveal busy schedules and other priorities such as family, work, and school were also barriers from getting HPV vaccine and completing the 3 doses (Mills, 2013).

However, a small number of participants in the study stated that time is not a barrier because health care to prevent cervical cancer is more important so they should be wise in managing their time to get the HPV vaccine. This opinion is parallel to Forster et al. (2012) where researchers found that the main factor of women aged 16 to 18 intending to get vaccination was because of the efficacy of the vaccine in protecting them from cervical cancer and HPV infection. This shows that young women who are aware of the benefits of taking HPV vaccine for good health are the main reason they get HPV vaccine.

#### 6.5 Not at Risk

Various misconceptions have arisen since HPV vaccine is introduced. The majority of participants have an understanding that the HPV vaccine is only for women who has engaged with multiple sexual partners. The analysis found that participants were not interested to get themselves vaccinated for the reason they did not perceive themselves to be at risk. Participants explained they have taken precautions to protect them by practicing safe sex or even some of them were never engaged in sexual intercourse, therefore, the risk for them being infected is low. This misrepresentation should be rectified so that the women out there will have the proper knowledge about this issue. Cancer is a disease that is difficult to anticipate and everyone is at risk for this lethal illness. Thus, cancer prevention should be addressed by all the same. Discoveries reported by Wong (2008) Many young women felt that they did not need the vaccine or would prefer to wait because they were not sexually active; this highlights the failure to educate women of the importance of vaccination before exposure to HPV. Young women must be made aware that the vaccine is most effective if administered before initiation of sexual activity (Goldie et al., 2004). Belief that only sexually active teenagers need to be vaccinated can cause parents to reject or delay HPV vaccination. Parents may underestimate their child's sexual experiences by saying they are unlikely to have such early sex and this has the potential for their children to miss the primary prevention opportunities.

#### 7. Conclusion

The results of this study can be used to change the community's perception towards HPV vaccination and place HPV vaccination as the primary prevention measure for cervical cancer. Most previous studies only looked at certain scopes; for instance the costs for HPV vaccination or factors hindering uptake of HPV vaccine. This study gives a significant value as it considers a wider scope in terms of knowledge, understanding, factors influencing uptake of HPV vaccination and the deterring factor for HPV vaccine uptake. The awareness on HPV vaccine is extremely important to ensure the increased uptake of HPV vaccine among female youth. Women should be made aware on the risks of HPV infection and its relation to cervical cancer. Many women are unaware that HPV infection is among the largest contributor to cervical cancer. Factors leading to the uptake of HPV vaccine should be seen in a transparent manner to ensure the success of HPV vaccination program in this country. On another note, the factors hindering the uptake of HPV vaccine should be studied in depth to find an effective solution in facilitating women for getting vaccinated.

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# **Competing Interests Statement**

The authors declare that there are no competing or potential conflicts of interest.

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# Oxidative Stress Biomarkers as Prognostic Indicators of Severity in Patients With Dengue

Raimundo Castro-Orozco<sup>1</sup>, Adolfo Marcelo<sup>2</sup>, María Paquita Garcia<sup>2</sup>, Nancy Merino<sup>2</sup>, Oscar Escalante-Maldonado<sup>2</sup>, Cinthya Mora<sup>3</sup>, Marlon Rodriguez<sup>1</sup> & Nelson Alvis-Guzman<sup>4</sup>

Correspondence: Raimundo Castro-Orozco, Universidad de San Buenaventura, Cartagena, Calle Real de Ternera No. 30-966 - PBX 653 5555, Cartagena, Colombia. E-mail: raimundo\_castro\_orozco@hotmail.com, rcastro@usbctg.edu.co

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#### **Abstract**

There is evidence for the role of oxidative stress in severe dengue pathogenesis. However, previous observational studies presents certain methodological limitations, which may affect its internal and external validity. This study was a case-control analysis of patients with severe dengue and dengue with warning signs, to evaluate the serum protein carbonyls-PCOs and lipid hydroperoxides-LOOHs levels and activities of superoxide dismutases-SODs (MnSOD, Cu/ZnSOD and total SOD), as potential prognosis indicators of severity in dengue patients, using binary logistic regression analysis and strategy of double cross-validation. Therefore, the study population was subdivided into a derivation group (pediatric patients, Barranquilla-Colombia) and an external validation group (children and adults patients, National Institute of Health of Peru). PCOs was the only oxidative stress markers that showed a strongest association with the severity of dengue, both in children and adults. In the derivation group, the optimal cut-off point was estimated at 5.29 nmol/mg of protein, and in the external validation group, it was 5.77 nmol/mg of protein. The prognostic models based on these two diagnostic thresholds showed a high discriminatory capacity of dengue severity, external reproducibility, geographic transportability, and typical characteristics of diagnostic validity and safety of screening tests.

**Keywords:** dengue, severe dengue, oxidative stress, protein carbonylation, superoxide dismutase, manganese, superoxide dismutase, Cu-Zn, lipid hydroperoxide, prognosis

# 1. Introduction

The World Health Organization-WHO considers dengue one of the 17 neglected tropical diseases (Molyneux, 2013), present in more than 100 countries, with reports of 50 to 100 million new cases and 20,000 deaths each year (Zapata, Cox, & Salvato, 2014).

Since 2009, WHO has implemented a new dengue classification scheme, reporting cases such as dengue without warning signs (DwoWS), dengue with warning signs (DwWS), and severe dengue (SD) (World Health Organization, 2009). These warning signs have been proposed as prognostic criteria for severe dengue (Leo et al., 2013; World Health Organization, 2009).

Although the current case classification system (WHO-2009) overcomes, in part, the conceptual and practical limitations identified in the previous scheme (WHO-1997) (Tsai et al., 2013), this could allow arbitrary interpretations of the severity of bleeding by medical personnel as consequence of the use of less rigorous definition criteria, due to the absence of quantitative parameters and because of their independence from laboratory tests in the identification of severe cases (Halstead, 2013).

The impact of these weaknesses could be limited in the case of being able to identify biomarkers that allow the early detection of those patients with greater risk of severity, independently of sociodemographic or virological

<sup>&</sup>lt;sup>1</sup> Group of Biomedical Research, Grupo de Investigaciones Biomédicas-GIB, Universidad de San Buenaventura, Cartagena, Colombia

<sup>&</sup>lt;sup>2</sup> National Institute of Public Health of Peru, Cartagena, Colombia

<sup>&</sup>lt;sup>3</sup> Universidad Simon Bolivar, Barranquilla, Colombia

<sup>&</sup>lt;sup>4</sup> Universidad de Cartagena, and Universidad de la Costa-CUC, Cartagena, Colombia

characteristics. Moreover, with the availability of this type of prognostic indicators, more specific and timely medical care could be provided, which is essential to improve patients' living conditions.

At this point, it is interesting to examine the conceptual relationships between dengue pathogenesis, endothelial dysfunction and oxidative stress. The most characteristic feature of cases of severe dengue and the best indicator of severity is plasma loss. This alteration of vascular permeability, which is present during the defervescence phase (4–6 days of illness), results more from endothelial dysfunction than from structural destruction of endothelial cells (Dalrymple & Mackow, 2012). Currently, a possible association between endothelial dysfunction and the severity of dengue disease in children and adults has been reported (Yacoub et al., 2015).

There are several references that explain the relationship between endothelial dysfunction and oxidative stress (Gori & Munzel, 2011; Pereira et al., 2008; Rodriguez-Manas et al., 2009; Silva, Pernomian, & Bendhack, 2012; Wadsworth, 2008) that show the participation of oxidative stress in the pathogenesis of various infectious diseases (Cunha et al., 2012; Fabbri et al., 2013; Hosakote, Liu, Castro, Garofalo, & Casola, 2009; Kalugalage et al., 2013; Levent et al., 2006; Macdonald, Galley, & Webster, 2003; Machado, Tanowitz, & Ribeiro, 2013; Valyi-Nagy & Dermody, 2005; Yang et al., 2010), including dengue (Gil et al., 2004). Soundravally, et al., propose that dengue infection-induced oxidative stress would have the ability to activate the release of pro-inflammatory cytokines, including TNF-α, participating in the pathogenesis of severe dengue, as a whole (Soundravally et al., 2014).

Despite considering lipid hydroperoxides-LOOHs and protein carbonyls-PCOs, as the most stable or specific markers to evaluate lipoperoxidation (Girotti, 1998) and oxidative protein modification (Dalle-Donne et al., 2003), respectively, there are few studies that report the behavior of these products of lipid oxidation (Gil et al., 2012; Gil et al., 2004) and of protein oxidation (Soundravally et al., 2008; Soundravally1 et al., 2008) in dengue patients.

Regarding superoxide dismutase-SOD, there are four studies that report their levels in cases of dengue (Gil et al., 2012; Gil et al., 2004; Ray, Kumar, Kapoor, Dutta, & Batra, 1999). Only one of these reported concentrations of this antioxidant enzyme in relation to the three clinical presentations of dengue indicated by the WHO-1997 classification system (Ray et al., 1999). Although the importance of TNF-α in the pathogenesis of dengue is recognized (Pawitan, 2011) and its ability to selectively induce MnSOD mRNA expression both in vivo and in vitro (Wong & Goeddel, 1988), there is no knowledge of the behavior of serum levels of this metalloenzyme in patients with dengue. Neither are known reports related to the cytosolic Cu/ZnSOD isoform.

The aim of the study was to evaluate the serum PCOs and LOOHs concentrations and activities of SODs (MnSOD, Cu/ZnSOD and total SOD), during the critical phase of dengue, as potential prognostic markers of severity in dengue patients.

#### 2. Materials and Methods

#### 2.1 Cases and Controls

A study was carried out with case and control design, in which cases were defined as patients who presented: (I) fever between the fourth and sixth day of evolution, accompanied by two or more of the following symptoms: headache, retro-ocular pain, myalgias, arthralgias, generalized pain, rash, anorexia, nausea, vomiting, petechiae, mucosal bleeding and leukopenia; (II) positive result for NS1-DENV or IgM anti-DENV and (III) requirement for specialized care in intensive care unit-ICU, due to the presence of severe manifestations of the disease, following the WHO-2009 classification scheme (World Health Organization, 2009).

The criteria for severe dengue were: (a) severe plasma leakage leading to shock or fluid accumulation with respiratory distress. (b) severe bleeding, and (c) severe organ involvement (myocarditis, encephalitis, hepatitis, acute cholecystitis, acute kidney failure, etc.) (World Health Organization, 2009).

For the selection of controls, the patients were considered: (I) with fever between the fourth and sixth day of evolution, accompanied by two or more of the following symptoms: headache, retro-ocular pain, myalgias, arthralgias, rash, anorexia, sickness, vomiting, petechiae, mucosal bleeding, and leukopenia; (II) with a positive result for NS1-DENV or anti-dengue IgM; (III) with the presence of one or more of the warning signs described in the current case classification system [5] and (IV) that did not require specialized attention in the ICU, because they do not develop severe manifestations of dengue.

Patients with comorbidities such as: severe cardiovascular disease, disorders of the haematopoeitic organs, metabolic, lung, hepatic or kidney disorders, autoimmune disease, malnutrition, pregnancy, malignancy, or comorbid infectious diseases were excluded.

# 2.2 Derivation Group: pediatric patients (Barranquilla-Colombia)

The evaluation of the prognostic capacity of the oxidative stress biomarkers was carried out in 60 serum samples

obtained from patients (20 cases and 40 controls), under 15 years of age, served in district hospitals of Barranquilla-Colombia, during the period comprised between January 2014 and January 2016.

# 2.3 External Validation Group: Pediatric and Adult Patients (Peru)

Similarly, for the external validation of the prognostic capacity of the biomarkers, 60 serum samples were used, obtained from patients (20 cases and 40 controls), of all ages, referred to the Laboratory of Viral Metaxenics of the National Institute of Health of Peru, during the period between January and February 2018. Serum samples of both cases and controls were stored at -80 °C until analysis.

#### 2.4 Data Collection

We reviewed the medical records of the 60 pediatric patients, identified as a derivation group, in order to record their sociodemographic information (age, sex, and geographic origin) clinical data (days of fever onset, length of hospital stay, length of ICU stay, and symptomatology) and laboratory of interest (haemoglobin levels, hematocrit values, platelet counts, neutropenia, leukopenia, lymphopenia, monocytosis, limphocytosis, basophilia, neutrophilia, altered transaminases, BUN and creatinine levels).

In contrast, for the case of the 60 patients from the external validation group, the epidemiological records were reviewed for the registration of the variables of interest, such as: age, sex, geographic origin, days of fever onset, symptomatology, qualitative detection of NS1-DENV in serum, thrombocytopenia, and hematocrit rise 20% or more.

# 2.5 DENV NS1 Antigen Capture Test (Derivation Group)

For the qualitative detection of NS1-DENV in the serum of the pediatric patients of the derivation group, a one-step immunochromatographic test (SD Bioline Dengue NS1 Ag, Kyong, South Korea®) was carried out, under the conditions recommended by the manufacturer.

# 2.6 Anti-DENV IgM and IgG ELISA (Derivation Group)

The detection of anti-DENV IgM and IgG in the serum of the pediatric patients of the derivation group was carried out by means of two enzyme-linked immunosorbent assays (ELISA, Vircell, Spain, References M1018 and G1018, respectively), under the conditions specified by the commercial house.

As serological evidence suggestive of secondary dengue infection, the IgM/IgG ratio <1.8 was used (Alera et al., 2016). Absorbance was measured at 450 nm (reference filter 620 nm) using a microplate reader (Stat Fax® 303 / PLUS, Awareness Technology, Inc. Florida, United States).

# 2.7 Anti-DENV IgM and IgG ELISA (External Validation Group)

The detection of anti-DENV IgM and IgG in the serum of the patients of the external validation group was carried out by means of two capture enzyme-linked immunosorbent assays (TARIKI-Dengue IgM, TARIKI-Dengue IgG, INS-Peru), under the conditions specified by the National Center of Biological Products of the National Institute of Health of Peru. Absorbance was measured at 450 nm (reference filter 620 nm) using a microplate reader (PHOmo, Autobio Co., LTD).

#### 2.8 Viral RNA Extraction (External Validation Group)

For the automatic and simultaneous extraction and purification of viral RNA, the magnetic particle technology of the QIAsymphony® Virus / Bacteria Mini Kit (Quiagen, Crawley, UK) was used from the serum samples of the patients from the external validation group in combination with the QIAsymphony® SP instrument, following the manufacturer's instructions, before real-time reverse transcription polymerase chain reaction (RT-PCR) analysis, since magnetic particle technology allows the purification of high quality nucleic acids that they lack proteins, nucleases and other impurities.

In each extraction and purification process, four positive controls were used (DENV-1 strain West Pac74, DENV-2 strain S16803, DENV-3 strain CH53489, DENV-4 strain TUP 360, working dilution 1/100) and a control negative (ultrapure water of PCR grade).

# 2.9 Reverse Transcription-PCR for Detection of DENV, ZIKV, CHIKV, and YFV (External Validation Group)

The simultaneous identification of DENV, zika-ZIKV virus and chikungunya-CHIKV virus, in serum samples of patients from the external validation group, was performed with a polymerase chain reaction protocol with reverse transcription in real time (Trioplex, CDC, Atlanta, USA) (Table S1). Three stages were used as amplification conditions: (I) 30 minutes at 50 °C, 1 rep; (II) 2 minutes at 95 °C, 1 rep; (IIIa) 15 seconds at 95 °C, 45 cycles and (IIIb) 1 minute at 60 °C [53].

For the molecular detection of yellow fever virus-YFV, 5.0 μL of extracted and purified viral RNA was taken to undergo RT-PCT in real time in the following conditions: 12.5 μL of RT-PCR master mix (1x), 0, 5 μL of oligonucleotides (10 μM) (Table S2), 5.0 μL of magnesium sulfate (5 mM), 0.5 μL of enzyme transcriptase/platinum Taq mix (Invitrogen, Carlsbad, CA, USA). The following amplification conditions were used: 30 minutes at 50 °C, 1 rep; 2 minutes at 94 °C, 1 rep; 15 seconds at 94 °C, 40 rep; 30 seconds at 55 °C, 40 rep; 2 minutes at 72 °C, 40 rep; 10 minutes at 72 °C, 1 rep.

# 2.10 Reverse Transcription-PCR for Serotyping of DENVs (External Validation Group)

Briefly, 10.0 μL of extracted viral RNA was used as template for the identification of DENV serotype, using the protocol described by Lanciotti, *et al.* (Lanciotti, Calisher, Gubler, Chang, & Vorndam, 1992), with the oligonucleotides described in Table S1. Reverse transcription of 10 min at 50 °C was followed by 45 cycles of amplification in a Rotor-Gene Q real time PCR cycler (Qiagen).

#### 2.11 Serum Protein Carbonyls Estimation

Materials and reagents of the Protein Carbonyl Colorimetric Assay Kit (catalog No. 10005020; Cayman Chemical Company, Ann Arbor, MI) were used for quantitative determination of PCOs in serum samples, using the alkaline method, which consists in a neutralization with 6 M NaOH subsequent to the step of derivatization with 2,4-DNPH to change the absorbance of carbonyl conjugated hydrazone at 450 nm (Mesquita et al., 2014).

Briefly, a mixture was made from equal volumes between 2,4-DNPH and serum sample (working dilution, 1:10). As a blank, an equal-volume mixture of 2,4-DNPH and phosphate buffered saline (pH = 7.2) was used. After 10 minutes of incubation at room temperature, in the dark, 200  $\mu$ L of 6 M NaOH was added. Then, it was incubated for 10 minutes at room temperature (Mesquita et al., 2014). Absorbance was measured at 450 nm (reference filter 620 nm) using a microplate reader (PHOmo, Autobio Co., LTD).

The amount of serum protein was calculated from a bovine serum albumin (BSA) standard curve (0.2-2.0 mg/mL) dissolved in guanidine hydrochloride and read at 280 nm.

2.12 Serum Manganese Superoxide Dismutase, Cu/Zn Superoxide Dismutase, and Total Superoxide Dismutase Estimations

Materials and reagents of the Superoxide Dismutase Assay Kit (catalog No. 706002, Cayman Chemical Company, Ann Arbor, MI) were used for determination of SODs activities. The addition of potassium cyanide-KCN (3 mM) to the assay allowed the inhibition of both Cu/ZnSOD and extracellular SOD, in order to detect only mitochondrial superoxide dismutase-MnSOD activity.

Briefly, in the preparation of the wells for the SOD standards, 200  $\mu$ L of the diluted radical detector and 10  $\mu$ L of one of the seven SOD standards available in the kit (0-0.25 U / mL) were added. For the preparation of the wells for the samples, 190  $\mu$ L of the diluted radical detector, 10  $\mu$ L of 3 mM KCN and 10  $\mu$ L of the patient's serum (working dilution 1: 5) were added. To determine the enzymatic activity of total SOD, 200  $\mu$ L of the diluted radical detector and 10  $\mu$ L of the patient's serum (working dilution, 1: 5) were added. The reaction was started with the addition of 20  $\mu$ L of diluted xanthine oxidase. To the blank, 20  $\mu$ L of the sample buffer available in the kit was added. After shaking for a few seconds, it was incubated for 20 minutes at room temperature.

The total enzymatic activity of SOD could be determined in absence of inhibitor and with the difference between activity values of total SOD and MnSOD, the enzymatic activity of the cytosolic Cu/ZnSOD isoform could be estimated. Absorbance was measured at 450 nm (reference filter 620 nm) using a microplate reader (PHOmo, Autobio Co., LTD). The interassay coefficient of variation was 4.6%, obtained with the calibrators available in the kit.

### 2.13 Serum Lipid Hydroperoxides Estimation

Serum LOOHs levels were measured by colorimetric assays using a commercially available kit according to manufacturer's instructions (Lipid Hydroperoxyde Assay Kit, catalog no.705003; Cayman Chemical Company, Ann Arbor, MI). Initially, the serum samples (working dilution, 1:20) were extracted with ethanol and chloroform. Then, 300  $\mu$ L of the sample extract, 300  $\mu$ L of the chromogen and 300  $\mu$ L of the ethanol-chloroform mixture were added. A calibration curve was made with the eight standards of LOOHs (13-hydroperoxyoctadecadienoic acid ethanolic solution, 13-HpODE, 0.0-5.0  $\mu$ M) available in the kit. Absorbance was measured at 492 nm (reference filter 620 nm) using a microplate reader (PHOmo, Autobio Co., LTD). The interassay coefficient of variation was 5.3%, obtained with the calibrators available in the kit.

# 2.14 Statistical Analysis

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Normality assessed with the Shapiro-Wilks test, one of the tests of goodness of fit with greater statistical power (Yap & Sim, 2011). Numerical variables are expressed as the mean and standard deviation, when it presented normal distribution and the median and lower and upper quartiles when presented non-normal distribution.

Statistical associations between research variables and the severity of dengue were identified with Fisher's exact test, accompanied by the respective effect size. Comparisons between two groups for serum biomarker concentrations were performed using Student's t-test of independent samples or the Mann-Whitney U test. Also, the respective effect size was estimated (Cohen'd or Rosenthal's correlation coefficient, respectively) (Gaskin & Happell, 2014).

Receiver curve (ROC) analysis was performed to find sensitivity and specificity for every potential cut-off values of each biomarker. To identify the optimum cut-off value, maximum value of the Youden Index (J) was used. Within the derivation group (20 cases: SD and 40 controls: DwWS), binary logistic regression was used to estimate the effect of prognostic variables or factors (dichotomised biomarker) on occurrence of severe dengue, with variable entered stepwise using the forward conditional likelihood ratio with p-in≤0.05 and p-out≥0.10.

We tested the goodness-of-fit for final models using Hosmer-Lemeshow test. A bootstrap method was used to internal validation of prognostic models. Each bootstrap sample was obtained by randomly sampling 10 000 times from the data sets. The prognostic model was refitted and tested on the original sample to obtain an estimate of predictive accuracy corrected for bias (overoptimism). Calibration and discrimination of the models were assessed with the ROA's efficient score statistic and with c-statistic, respectively (Nuñez, 2011). The criteria of Swets (Swets, 1988) were used to assess the accuracy of the sensitivity and specificity values. The AUCs of the different prognostic models were compared using the statistical test of Hanley and McNei (Hanley & McNeil, 1983).

All p-values estimated in the hypothesis tests were interpreted using the criteria of Sterne and Smith (Sterne & Davey Smith, 2001). However, to establish statistically significant differences between two independent groups, 95 percentage confidence intervals of the difference (CI95%<sub>diff</sub>) were interpreted between independent proportions, means or medians.

Final prognostic model was validated in two sets of serum samples obtained of dengue patients (20 cases: SD and 40 controls: DwWS) notified to the National Institute of Health of Peru (geographical external validation). Within the external validation group, calibration and discrimination measures of final prognostic model were estimated using the same methods of statistical inference. Finally, the double cross-validation strategy was also used (Osborne, 2000).

Data were analyzed using four statistical software: IBM® SPSS® Statistics version 23.0 (IBM Corp, Armonk, New York), GraphPad PRISM® version 6.01 (GraphPad software, San Diego, CA), EpiDat 3.1® (General Directorate of Innovation and Public Health Management, Xunta de Galicia, Spain, Pan American Health Organization and Higher Institute of Medical Sciences of Havana) and Stata® version 14.2 (Stata Corporation, College Station, TX, USA).

# 2.15 Ethical Statements

The present study was reviewed and approved by the IPS Universitaria Barranquilla-Colombia (Office of approval 10-02-2016-IPS Universitaria-Barranquilla) and by the National Institute of Health of Peru (Office of approval 535-2017-OGITT-OPE / INS).

### 3. Results

# 3.1 Clinical Characteristics of Derivation Group

All the pediatric patients belonging to this group came from the city of Barranquilla-Colombia and presented the same median for age (11 years; IQR: 10 to 13), both in the cases and in the controls. Despite a predominance of males (63.3%, CI95% 50.7% to 74.4%) among derivation group, we found no evidence of statistical association or significant difference between sex and the severity of dengue (p=0.573; CI95%<sub>diff</sub> -15.8% to 31.8%).

The median number of days after the onset of fever in cases was similar to that in controls (5 days vs. 4 days; p=0.192; CI95%<sub>diff</sub>-1.0 to 0.0). In contrast, the median length of hospital stay significantly differed between cases and controls (5 days vs. 3 days, respectively; CI95%<sub>diff</sub> 1.0 to 3.0). At the same time, we found a strong statistical association between the severity of dengue and the number of days of hospital stay (Rosenthal's correlation coefficient=0.6; p<0.0001).

Furthermore, there was no statistical association between clinical symptoms and severe dengue, except for

asthenia (p=0.036; OR=6.3; CI95% 1.1 to 36.3). Likewise, a strong statistical association was found between thrombocytopenia and severity of dengue (p=0.001; OR=12.0; CI95% 3.4 to 41.8). In relation to serum transaminases levels (glutamic-pyruvic transaminase-GPT and glutamic-oxaloacetic transaminase-GOT), elevated concentrations of these liver enzymes showed a strong statistical association to severe dengue in this group of pediatric patients (p=0.0007; OR=8.5; CI95% 2.5 to 28.9 and p=0.0001; OR=13.8; CI95% 3.8 to 49.6, respectively).

Approximately 50.0% (CI95%<sub>diff</sub> 29.9% to 70.1%) of the cases and 30.0% (CI95%<sub>diff</sub> 18.1% to 45.4%) of the controls presented serological evidence suggestive of DENV reinfection, but without showing statistically significant differences between them (p=0.161; CI95%<sub>diff</sub> -5.3% to 43.4%). The rest of the variables studied in derivation group are presented in Table 1.

### 3.2 Clinical Characteristics of External Validation Group

In this group, the median for the age of the cases was comparable to that in controls (20 years vs. 16 years, respectively; p=0.347; CI95%<sub>diff</sub>-10.0 to 4.0). Moreover, there was also no statistically significant difference in the distribution of age groups among cases and controls ( $\leq$ 15 years of age vs. >15 years of age: CI95%<sub>diff</sub> -6.4% to 41.4%; p=0.174). Likewise, we found no evidence of statistical association or significant difference between sex and the severity of dengue (p=0.176; CI95%<sub>diff</sub> -6.3% to 42.7%).

Although a moderate statistical association was observed between the presence of severe dengue and the number of days of illness (Rosenthal's correlation coefficient=0.3; p=0.031), a statistically significant difference could not be found when comparing the cases and controls (5 days vs. 4 days, respectively; C195%<sub>diff</sub> -1.0 to 0.0).

The only symptoms that showed a strong statistical association with the severity of dengue were: asthenia (p=0.004; OR=16.7; CI95% 2.3 to 113.1) and lethargy (p=0.0004; OR=15.6; CI95% 2.9 to 82.8), however, the presence of respiratory distress showed a moderate statistical association with severe dengue (p=0.042; OR=3.4; CI95% 1.1 to 10.7). The rest of the variables evaluated in the external validation group are presented in Table 2.

Approximately 55% (CI95% 34.2% to 74.2%) of the cases and 40% (CI95% 26.4% to 55.4%) of the controls presented serological evidence suggestive of DENV reinfection, but without show statistically significant differences between them (p=0.288; CI95%<sub>diff</sub>-10.9% to 38.5%). DENV-2 was the only DENV serotype identified (cases: 25.0%; CI95% 11.2% to 46.9%; controls: 30.0%; CI95% 18.1% to 45.4%). ZIKV RNA, CHIKV RNA and YFV RNA were not detected in any of the serum samples.

Table 1. Clinical and laboratory characteristics of pediatric patients with severe dengue and dengue with warning signs. Derivation group, Barranquilla-Colombia, 2014-2016

W. 2.11.	Severe Dengue	DwWS	1 4
Variables	n (%)	n (%)	p-value*
Fever	20 (100.0)	40 (100.0)	NE
Lumbar backache	10 (50.0)	24 (60.0)	0.582
Retro-orbital pain	15 (75.0)	28 (70.0)	0.769
Asthenia	5 (25.0)	2 (5.0)	0.036
Persistent vomiting	10 (50.0)	24 (60.0)	0.582
Lethargy	0 (0.0)	6 (15.0)	NE
Petechia	2 (10.0)	1 (2.5)	0.255
Rash	5 (25.0)	10 (25.0)	0.998
Swelling	1 (5.0)	3 (7.5)	0.998
Epistaxis	4 (20.0)	4 (10.0)	0.422
Hematemesis	2 (10.0)	0 (0.0)	NE
Abdominal pain	13 (65.0)	21 (52.5)	0.416
Pleural effusion	3 (15.0)	0 (0.0)	NE
Hemoglobin levels <12 g/dL	3 (15.0)	14 (35.0)	0.136

Variables	Severe Dengue	DwWS	l ÷
	n (%)	n (%)	p-value*
HCT rise 20% or more	9 (45.0)	11 (27.5)	0.246
DLC (to hospital admission)			
Thrombocytopenia	15 (75.0)	8 (20.0)	0.001
Neutropenia	4 (20.0)	13 (32.5)	0.375
Lymphopenia	4 (20.0)	13 (32.5)	0.375
Monocytosis	7 (35.0)	12 (30.0)	0.772
Lymphocytosis	5 (25.0)	18 (45.0)	0.166
Basophilia	3 (15.0)	6 (15.0)	0.998
Neutrophilia	6 (30.0)	12 (30.0)	0.998
Altered BUN levels	1 (5.0)	2 (5.0)	0.998
Altered Creatinine levels	4 (20.0)	3 (7.5)	0.208
Altered GPT levels	12 (60.0)	6 (15.0)	0.0007
Altered GOT levels	16 (80.0)	9 (22.5)	0.0001

<sup>\*</sup> estimated by Fisher's exact test; DwWS: Dengue with warning signs; NE: not estimated;

DLC: differential leukocytes counts; HCT: hematocrit; BUN: blood urea nitrogen;

GPT: glutamic-piruvic transaminase; GOT: glutamic-oxaloacetic transaminase

Table 2. Clinical and laboratory characteristics of pediatric patients with severe dengue and dengue with warning signs, external validation group, Peru, 2018

Variables	Severe Dengue	DwWS	1 .4
Variables	n (%)	n (%)	p-value*
Fever	20 (100.0)	40 (100.0)	NE
Asthenia	6 (30.0)	1 (2.5)	0.004
Epistaxis	2 (10.0)	2 (5.0)	0.595
Petechias	0 (0.0)	1 (2.5)	NE
Rash	5 (25.0)	15 (37.5)	0.395
Myalgias	17 (85.0)	29 (72.5)	0.347
Arthralgias	14 (70.0)	34 (85.0)	0.189
Lethargy	9 (45.0)	11 (27.5)	0.0004
Unconsciousness	3 (15.0)	1 (2.5)	0.103
Persistent vomiting	13 (65.0)	30 (75.0)	0.545
Hematemesis	1 (5.0)	4 (10.0)	0.656
Hematuria	2 (10.0)	1 (2.5)	0.255
Abdominal pain	13 (65.0)	30 (75.0)	0.545
Shock	3 (15.0)	0 (0.0)	NE
Hypothermia	4 (20.0)	0 (0.0)	NE
Decreased diuresis	3 (15.0)	2 (5.0)	0.322
Respiratory distress	10 (50.0)	9 (22.5)	0.042
Cold extremities	7 (35.0)	0 (0.0)	NE
SBP - DBP<20 mmHg	5 (25.0)	0 (0.0)	NE

Variables	Severe Dengue	DwWS	n volue*
	n (%)	n (%)	p-value*
Weak pulse	5 (25.0)	0 (0.0)	NE
Thrombocytopenia	2 (10.0)	11 (27.5)	0.186
HCT rise 20% or more	5 (25.0)	21 (52.5)	0.056

<sup>\*</sup> estimated by Fisher's exact test; DwWS: Dengue with warning signs; SBP: systolic blood pressure; DBP: diastolic blood pressure; HCT: hematocrit; NE: not estimated

# 3.3 Serum Protein Carbonyls Concentrations (Derivation Group)

In cases and controls, the medians serum concentration for PCOs were 23.49 nmol/mL (IQR: 21.53 to 26.91) and 16.26 nmol mL (IQR: 14.41 to 18.16), respectively. The concentration of protein-standardized PCOs in pediatric patients with severe dengue was 7.30 nmol/mg of protein (IQR: 6.75 to 8.60) and 4.82 nmol/mg of protein (IQR: 4.52 to 5.31) for patients with dengue with warning signs.

The analysis showed that serum PCOs concentrations of the cases were significantly higher than control group (non-standardized values: CI95%<sub>diff</sub> 4.03 to 9.08 nmol/mL; protein-standardized values: CI95%<sub>diff</sub> 1.45 to 2.95 nmol/mg of protein).

In line with the aforementioned, we found a strong statistical association between the occurrence of severe dengue and serum PCOs concentrations (non-standardized values: Rosenthal's correlation coefficient=0.5; p=0.0001; protein-standardized values: Rosenthal's correlation coefficient=0.5; p=0.0002) (Figures 1a and 1b).

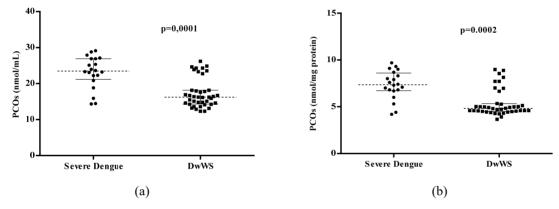


Figure 1. Serum protein carbonyls concentrations in pediatric patients with severe dengue and dengue with warning signs (DwWS). Derivation group, Barranquilla, 2014-2016. (a): non-standardized serum concentrations; (b): protein-standardized serum concentrations. Errors bars represent median and interquartile range

# 3.4 Serum Manganese Superoxide Dismutase, Cu/Zn Superoxide Dismutase, and Total Superoxide Dismutase Concentrations (Derivation Group)

The average MnSOD activity ( $\pm$ SD) in the sera of patients with severe dengue and patients with dengue with warning signs were 1.39  $\pm$  0.05 U/mL and 1.41  $\pm$  0.10 U/mL, respectively. No statistically significant difference could be demonstrated between these two values of enzymatic activity (CI95%<sub>diff</sub> -0.02 to 0.06, t=0.988, df=58; p=0.327) (See Supplementary Figure S1a). Studied cases had a mean concentrations of 3.21  $\pm$  0.05 U of total SOD/mL and 1.82  $\pm$  0.07 U of Cu/ZnSOD/mL. In the controls, serum levels of total SOD of 3.18  $\pm$  0.05 U/mL and 1.78  $\pm$  0.10 U of Cu/ZnSOD/mL were found.

We obtained evidence of a moderate to strong statistical association of occurrence of severe dengue with the enzyme activity of total SOD (t=1.989; df=39.83; p=0.054, Cohen's d=0.7) and evidence of a weak to moderate statistical association with the enzymatic activity of Cu/ZnSOD (t=1.996; df=52.96; p=0.051; Cohen's d=0.4), accompanied with scarce absence of statistically significant difference (total SOD-cases vs controls: CI95%<sub>diff</sub> -0.0004 to 0.05 U/mL; Cu/ZnSOD-cases vs. controls: CI95%<sub>diff</sub> -0.0002 to 0.09 U/mL) (See Supplementary Figures S1b and S1c).

# 3.5 Serum Lipid Hydroperoxides Concentrations (Derivation Group)

The mean concentrations of LOOHs of  $61.20 \pm 6.88~\mu M$  and  $59.79 \pm 7.08~\mu M$  were found in children with severe dengue and in children with dengue with warning signs, respectively. Neither, statistical association was found between serum LOOHs concentrations with the occurrence of severe dengue (t=-0.735; df=58; p=0.465) or statistically significant difference when comparing these serum values (cases vs. controls: CI95%<sub>diff</sub>-5.26 to 2.43  $\mu M$ ) (See Supplementary Figure S2).

### 3.6 Serum Protein Carbonyls Concentrations (External Validation Group)

In cases and controls, the medians serum concentration for PCOs were 20.02 nmol/mL (IQR: 18.34 to 21.59) and 13.62 nmol/mL (IQR: 12.11 to 16.26), respectively. The concentration of protein-standardized PCOs in patients with severe dengue was 6.95 nmol/mg of protein (IQR: 6.63 to 7.56) and 4.47 nmol/mg of protein (IQR: 4.00 to 5.19) for patients with dengue with warning signs.

The analysis showed that serum PCOs concentrations of the cases were significantly higher than control group (non-standardized values: CI95%<sub>diff</sub> 3.42 to 7.34 nmol/mL; protein-standardized values: CI95%<sub>diff</sub> 1.59 to 2.84 nmol/mg of protein). Again, we found a strong statistical association between the occurrence of severe dengue and serum PCOs concentrations (non-standardized values: Rosenthal's correlation coefficient=0.6; p<0.0001; protein-standardized values: Rosenthal's correlation coefficient=0.6; p<0.0001) (Figures 2a and 2b).

Something similar occurred when comparing medians for serum PCOs levels between pediatric cases and controls (non-standardized values: 20.13 nmol/mL vs. 12.11 nmol/mL, respectively; CI95%<sub>diff</sub> 5.33 to 9.42; Rosenthal's correlation coefficient=0.6; p=0.001; protein-standardized values: 8.40 nmol/mg of protein vs. 4.29 nmol/mg of protein, respectively; CI95%<sub>diff</sub> 2.27 to 4.82; Rosenthal's correlation coefficient=0.7; p<0.0001) and between adult cases and controls (non-standardized values: 19.74 nmol/mL vs. 15.00 nmol/mL, respectively; CI95%<sub>diff</sub> 0.62 to 6.17 nmol/mL; Rosenthal's correlation coefficient=0.5; p=0.007; protein-standardized values: 6.42 nmol/mg of protein vs. 4.63 nmol/mg of protein, respectively; CI95%<sub>diff</sub> 0.84 to 2.43; Rosenthal's correlation coefficient=0.5; p=0.001).

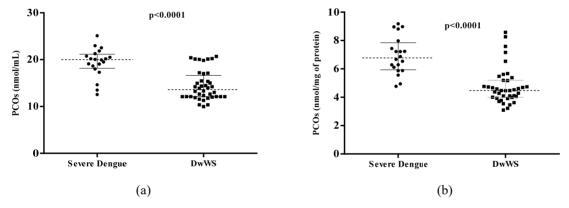


Figure 2. Serum protein carbonyls concentrations in patients with severe dengue and dengue with warning signs (DwWS). External validation group, Peru, 2018. (a): non-standardized serum concentrations; (b): protein-standardized serum concentrations. Errors bars represent median and interquartile range

# 3.7 Serum Manganese Superoxide Dismutase, Cu/Zn Superoxide Dismutase, and Total Superoxide Dismutase Concentrations (External Validation Group)

The average MnSOD activity ( $\pm$ SD) in the sera of patients with severe dengue and patients with dengue with warning signs were  $1.65 \pm 0.05$  U/mL and  $1.61 \pm 0.13$  U/mL, respectively. No statistically significant difference could be demonstrated between the severity of dengue and SODs activities (MnSOD: CI95%<sub>diff</sub> -0.08 to 0.01; t=-1.631; df=54.25; p=0.109; total SOD: CI95%<sub>diff</sub> -0.03 to 0.01; t=-1.365; df=28.56; p=0.183; Cu/ZnSOD: CI95%<sub>diff</sub> -0.02 to 0.07; t=0.973; df=56.71; p=0.335) (See Supplementary Figures S3a, S3b and S3c).

#### 3.8 Serum Lipid Hydroperoxides Concentrations (External Validation Group)

Neither, statistical association was found between serum LOOHs concentrations with the occurrence of severe dengue (t=-0.123; df=58; p=0.903) or statistically significant difference between the cases and controls (33.21  $\pm$  11.94  $\mu$ M vs 32.82  $\pm$  11.49  $\mu$ M, respectively, CI95%<sub>diff</sub> - 6.77 to 5.99  $\mu$ M) (See Supplementary Figure S4).

# 3.9 Optimal Cut-off Level and Area under the Curve of Protein Carbonyls (Derivation Group)

The optimum cut-off value of non-standardized PCOs concentrations for severe dengue was 18.50 nmol of PCOs/mL (J=0.63) (Figure 3) that carried sensitivity and specificity of 85.0% (CI95% 66.9% to 100.0%) and 72.5% (CI95% 57.4% to 87.6%), respectively with an AUC of 80.6% (CI95% 68.6% to 92.6%). For protein-standardized PCOs concentrations, the optimum cut-off value was 5.29 nmol/mg of protein (J=0.65) (Figure 4) with AUC of 80.2% (CI95% 67.2% to 93.2%) and sensitivity and specificity of 90.0% (CI95% 74.4% to 100.0%) and 75.0% (CI95% 60.3% to 89.7%), respectively.

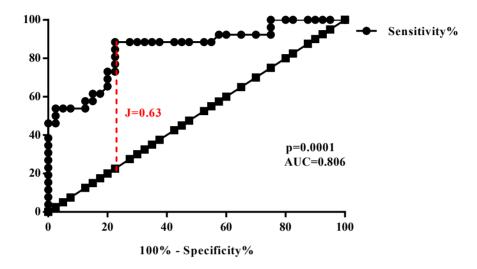


Figure 3. Receiver-operating characteristics (ROC) curve of non-standardized serum concentrations of protein carbonyls (PCOs) in pediatric patients with severe dengue and dengue patients with warning signs. Derivation group, Barranquilla-Colombia, 2014-2016

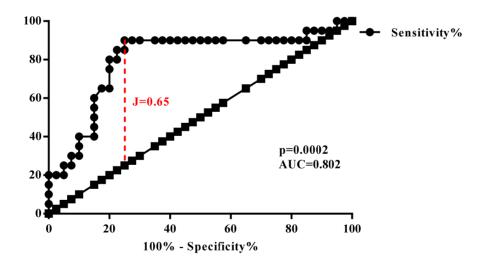


Figure 4. Receiver-operating characteristics (ROC) curve of protein-standardized serum concentrations of protein carbonyls (PCOs) in patients with severe dengue and dengue patients with warning signs. Derivation group, Barranquilla-Colombia, 2014-2016

#### 3.10 Logistic Regression Analysis of Oxidative Stress Biomarkers (Derivation Group)

PCOs was the only biomarker with prognostic capacity for severe dengue among pediatric patients. Table 3 shows the results of the binary logistic regression using the two optimal cut-off values estimated for serum PCOs concentrations, including bootstrapping results. By contrast, the remaining biomarkers did not meet inclusion

criteria of a variable in the prognostic model (MnSOD: p=0.216; total SOD: p=0.448; Cu/ZnSOD: p=0.188; LOOHs: p=0.643).

A cut-off value for protein-standardized serum PCOs concentrations of 5.29 nmol/mg of protein (PM-2: dichotomized predictor) was the best in identifying pediatric patients with severe dengue, in comparison with continuous predictor (90.0% vs. 55.0%, respectively; CI95%<sub>diff</sub> 7.2% a 57.0%).

Table 3. Binary logistic regression models to predict the probability of severe dengue in pediatric patients, using optimal cut-off points of serum concentrations of protein carbonyls. Derivation group, Barranquilla-Colombia, 2014-2016

First prognostic model (PM-1)					
Predictor (cut-off point)	В	Wald statistic (df)	p-value	Exp(B)	CI95%
PCOs (18.50 nmol/mL)	2.70	14.127 (1)	0.0002	14.94	3.65 - 61.20
Constant	-2.27	13.933 (1)	0.0002	0.103	
Regression equation-1: Ln(p/1-p)= -2.27	7 + 2.70 (serum	n PCOs levels of patient	≥18.50 nmol/m	ıL)	
Bootstrapping (10 000 samples)					
Predictor (cut-off point)	Bias	p-value			
PCOs (18.50 nmol/mL)	0.97	0.0001			
Constant	-0.95	0.0003			
Second prognostic model (PM-2)					
Predictor (cut-off point)	В	Wald statistic (df)	p-value	Exp(B)	CI95%
PCOs (5.29 nmol/mg of protein)	3.30	15.77 (1)	0.0001	27.00	5.31 - 137.36
Constant	-2.71	16.75 (1)	0.0002	0.07	
Regression equation-2: Ln(p/1-p)= -2.71	1 + 3.30 (serum	n PCOs levels of patient	≥5.29 nmol/mg	g of protein)	
Bootstrapping (10 000 samples)					
Predictor (cut-off point)	Bias	p-value			
PCOs (5.29 nmol/mg of protein)	0.45	0.0001			
Constant	-0.42	0.001			

PCOs: protein carbonyls; df: degree of freedom.

### 3.11 Calibration and Discrimination of Prognostic Model (Derivation Group)

Approximately, 47.2% of the variance of the criterion variable (severity of dengue) can be explained by PM-2 (Nagelkerke pseudo- $R^2$ =0.472) with a c-statistic of 0.825 (CI95% 0.729 to 0.921; p<0.0001).

The predicted probability of severe dengue in a pediatric patient ( $\leq$ 15 years) with serum PCOs concentrations greater than or equal to 5.29 nmol/mg of protein was 0.643 (CI95% 0.454 to 0.796), whereas the predicted probability of severe dengue in a pediatric patient with serum levels below the optimal threshold was estimated at 0.062 (CI95% 0.016 to 0.218; Chi-square test/omnibus test:  $X^2$ =24.92; df=1; p<0.0001).

# 3.12 Evaluation of Transportability of Prognostic Model (External Validation Group)

In applying of PM-2 in external validation group, an AUC of 83.8% (CI95% 74.4% to 93.2%; p<0.0001) was calculated. The predicted probability of severe dengue in a patient with serum PCOs concentrations greater than or equal to 5.29 nmol/mg of protein was 0.667 (CI95% 0.473 to 0.817), whereas the predicted probability of severe dengue in a patient with serum PCOs concentrations below the optimal threshold was estimated at 0.061 (CI95% 0.015 to 0.212; Chi-square test/omnibus test:  $X^2$ =26.92; df=1; p<0.0001).

Moreover, these probability values are similar to those estimated among pediatric patients (derivation group) (≥5.29 nmol of PCOs/mg of protein: CI95%<sub>diff</sub> -0.253 to 0.296; <5.29 nmol of PCOs/mg of protein: CI95%<sub>diff</sub> -0.126 to 0.128). No evidence of statistical association was found between the discriminative capacity of PM-2 with the two age groups evaluated in the external validation group (≤15 years of age vs. >15 years of age: 92.5% vs.

77.9%, respectively; Chi-square test:  $X^2=3.16$ ; df=1; p=0.076).

### 3.13 Double Cross-Validation

In line with this strategy, the optimum cut-off value was 5.77 nmol of PCOs/mg of protein (J=0.73) (Figure 5) with AUC of 90.0% (CI95% 81.8% to 98.2%) and sensitivity and specificity values of 90.0%, for each one (sensitivity: CI95% 74.4% to 100.0% and specificity: CI95% 79.5% to 100.0%).

Table 4 shows the results of the binary logistic regression using the estimated optimal diagnosis point (5.77 nmol of PCOs/mg of protein), including bootstrapping results. Approximately, 67.4% of the variance of the criterion variable (severity of dengue) can be explained by PM-3 (Nagelkerke pseudo-R<sup>2</sup>=0.674) with c-statistic=0.900 (CI95% 0.806 to 0.994; p<0.0001).

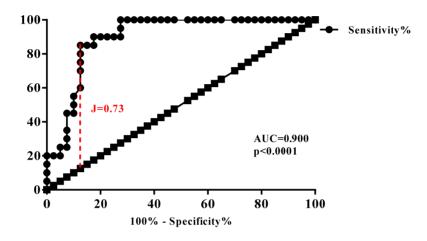


Figure 5. Receiver-operating characteristics (ROC) curve of serum concentrations of protein carbonyls (PCOs) in patients with severe dengue and dengue patients with warning signs. Retrospective validation. Derivation group, Peru, 2018

Table 4. Binary logistic regression models to predict the probability of severe dengue in patients, using optimal cut-off points of serum concentrations of protein carbonyls. External validation group, Peru, 2018

Third prognostic model (PM-3)					
Predictor (cut-off point)	В	Wald statistic (df)	p-value	Exp(B)	CI95%
PCOs (5.77 nmol/mg of protein)	4.39	23.17 (1)	< 0.0001	81.00	13.54 - 484.76
Constant	-2.89	15.83 (1)	0.0001	0.056	
Regression equation-3: $Ln(p/1-p)=-2$ .	89 + 4.39 (se	erum PCOs levels of patie	ent ≥5.77 nmol/	mg of protein	)
Bootstrapping (10 000 samples)					
Predictor (cut-off point)	Bias	p-value			
PCOs (5.77 nmol/mg of protein)	2.74	0.0001			
Constant	-2.37	0.0004			

PCOs: protein carbonyls; df: degree of freedom.

In applying of PM-3 among pediatric patients from Barranquilla-Colombia (external validation group), an AUC of 82.5% (CI95% 72.3% to 98.7%; p<0.0001) was calculated. The predicted probability of severe dengue in a patient with serum levels greater than or equal to 5.77 nmol/mg of protein was 0.680 (CI95% 0.478 to 0.831), whereas the predicted probability of severe dengue in a patient with lower serum levels to the optimum threshold was estimated at 0.086 (CI95% 0.028 to 0.234). These probability values are similar to those estimated in the derivation group (≥5.77 nmol of PCOs/mg of protein: CI95%<sub>diff</sub> -0.166 to 0.349; <5.77 nmol of PCOs/mg of protein: CI95%<sub>diff</sub> -0.100 to 0.154).

Table 5 shows the results obtained from the comparison of the discriminative capacity of the prognostic models,

based on the optimal diagnostic points, estimated in the derivation group and transported to the validation group, by the double cross-validation strategy (prospective and retrospective).

Table 5. Comparison of discriminatory capacity of binary logistic regression models to predict the probability of severe dengue in patients, using optimal cut-off points of adjusted serum concentrations of protein carbonyls. Prospective and retrospective validation

Validation strategy	Prospective	Retrospective
C( 1 1.4°	PM-2	PM-3
Study population	c-statistic (CI95%)	c-statistic (CI95%)
Derivation group	0.825 (0.729 to 0.921)	0.900 (0.818 to 0.982)
External validation group	0.838 (0.744 to 0.932)	0.825 (0.723 to 0.987)
p-value	0.855	0.262
$X^2$ (df)	0.03 (1)	1.26 (1)

PCOs: protein carbonyls; df: degree of freedom; X<sup>2</sup>: Chi-square statistic; AUC: area under the curve; PM: prognostic model.

#### 4. Discussion

This study continues our examination of biomarkers of oxidative stress as prognostic tool for dengue severity, using regression models for predicting medical outcomes.

Serum levels of PCOs were significantly higher in patients with severe dengue than in patients with dengue with warning signs, in both the derivation group and validation group. The above shows coherence with the evidence published in patients with DENV infection and healthy adults, during a DENV-3 outbreak (Rajendiran et al., 2008; Soundravally, Sankar, Hoti, et al., 2008). Although median serum PCOs concentrations estimated in this study cannot be compared with other reports (Rajendiran et al., 2008; Santhosh, 2016; Soundravally, Sankar, Hoti, et al., 2008), due to the different measures of central tendency and dispersion used, we suggest that the most severe cases of dengue present a higher concentration of irreversibly oxidized proteins in comparison to non-severe cases.

Recently, Cherupanakkal, *et al.* (Cherupanakkal et al., 2017), reported that MnSOD gene expression was not associated with severity of dengue disease in children and adults. In addition to the above, we have not found statistically significant differences in MnSOD activity between patients with severe dengue and those with dengue with warning signs, in both adults and children. All in all, the above evidences allow us to suggest that the antioxidant activity of MnSOD does not participate in the pathogenesis of severe dengue.

In addition to the explanations reported by Cherupanakkal, *et al.* (Cherupanakkal et al., 2017), it is necessary to consider the presence of IgM autoantibodies against MnSOD, which could inhibit the protective effects of MnSOD. These antibodies have been reported in patients with acute viral infections (Ritter et al., 1994; Semrau et al., 1998), and it has been shown that may contribute to the oxidative damage of endothelial cells (Dalpke et al., 2003). Likewise, no significant differences were found in total SOD and Cu/ZnSOD activities between cases and controls. In this regard, elevated levels of TNF-α and IFN-γ in dengue-infected patients could decrease the gene expression of antioxidant enzymes, including SOD (Ho et al., 2001).

As regards serum LOOHs levels, no statistically significant difference was found between cases and controls, in both the derivation and validation groups. It is not possible to compare our results with other studies (Gil et al., 2012; Gil et al., 2004), due some important methodological and analytical differences, such as WHO dengue case classification system, extraction procedure, and ferric ions indicator.

Here, we would like to point out that discordance has also been found in the correlation between LOOHs and PCOs concentrations in virus-infected insect cell culture (Wang, Oberley, & Murhammer, 2001) and in blood after exhaustive aerobic and nonaerobic isometric exercises (Alessio et al., 2000). This discrepancy can be explained by certain pre-analytical errors, effects of small size sample, and the differences between the reactions involved in formation of these oxidative stress biomarkers (Dotan, Lichtenberg, & Pinchuk, 2004).

Prognosis cut-off point of 5.29 nmol of PCOs/mg of protein showed high sensitivity and negative predictive value. For screening purposes, these characteristics are more important than a high specificity and positive predictive value, especially in the context of serious and treatable diseases (Bravo-Grau & Cruz Q, 2015).

In our study, severe dengue is 27 times more likely if the pediatric patient has a serum concentration of PCOs equal to or greater than 5.29 nmol/mg of protein, compared to a pediatric patient with serum values below this cut-off point. After resampling, this prognostic cut-off point maintains its discriminative capacity for dengue severity in the pediatric population.

External validity (transportability) proves to be a critical requirement of a prognostic model, since the transportability is taken to mean the ability of a prognostic model to maintain their accuracy when applied to patients and settings different from those on which the model was developed (Terrin, Schmid, Griffith, D'Agostino, & Selker, 2003).

Having a serum PCOs level of 5.29 nmol/mg of protein or more meant than 83-fold increased probability of having severe dengue, both derivation and external validation groups. According to Swets (Swets, 1988), serum concentrations of PCOs could be considered useful to distinguish early disease severity among pediatric patients with dengue.

With regard to the Peruvian population, approximately, 90.0% of the time a randomly selected patient who experienced severe dengue will have a serum PCOs level greater than or equal to 5.77 nmol/mg of protein, compared to a randomly selected patient who experienced dengue with warning signs. This was found to be true in pediatric patients population used as external validation group.

Leaving aside the differences between the 1997 and 2009 WHO dengue classification schemes, we emphasize that the estimated optimal cut-points (5.29 and 5.77 nmol of PCOs/mg of protein) are located between estimated cut-off points for predicting dengue hemorrhagic fever (5.22 nmol/mg of protein) and dengue shock syndrome (6.13 nmol/mg protein) among adult patients with dengue virus infection (Soundravally et al., 2008). It is worth pointing out here that most patients who meet the criteria for severe dengue can be categorized as dengue hemorrhagic fever patients (Tsai et al., 2013).

The four main limitations of our study are: (I) the heterogeneity between derivation and external validation groups in regard to age; (II) molecular detection of DENV and other arboviruses was not performed on serum samples obtained from 60 pediatric patients positive for NS1-DENV and/or anti-dengue IgM; (III) the level of completeness for the data set obtained through public surveillance system for dengue disease in Peru; and (IV) the use of hospital controls can lead to a problem of representativeness, that potentially affect external validity of the study (Gomez, 2003). Despite these limitations, our estimates do provide prognostic models based on two diagnostic thresholds showed a high discriminatory capacity of dengue severity, external reproducibility, geographic transportability, and typical characteristics of diagnostic validity and safety of screening tests.

Supplementary Materials, Figure S1: Comparison between serum enzymatic activities of dismutase superoxide (a: mitochondrial SOD; b: total SOD; c: cytosolic SOD) in pediatric patients with severe dengue and dengue patients with warning signs. Derivation group, Barranquilla-Colombia, 2014-2016; Figure S2: Comparison between serum concentrations of lipid hydroperoxides in pediatric patients with severe dengue and dengue patients with warning signs. Derivation group, Barranquilla-Colombia, 2014-2016; Figure S3: Comparison between serum enzymatic activities of dismutase superoxide (a: mitochondrial SOD; b: total SOD; c: cytosolic SOD) in patients with severe dengue and dengue patients with warning signs. External validation group, Peru, 2018; Figure S4: Comparison between serum concentrations of lipid hydroperoxides in patients with severe dengue and dengue patients with warning signs. External validation group, Peru, 2018.

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#### **Competing Interests Statement**

The authors declare no conflict of interest.

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# Body Composition in Iraqi Women With Systemic Lupus Erythematosus

Faiq I. Gorial<sup>1</sup>, Zainab A. Mahmood<sup>2</sup> & Sundus Al Obaidi<sup>3</sup>

Correspondence: Zainab A. Mahmood, F.I.B.M.S (Int. Med.), F.I.B.M.S (Rheuma. and Rehab.), College of Medicine, University of Basrah, Iraq. E-mail: zainab albahrani2000@yahoo.com

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#### Abstract

**Background and Objective:** SLE is one of systemic diseases, targeting young patients, so we try to study the one of factors that affected these patients.

The aim of our study is to describe the body composition in Iraqi lupus patients, and assess the effect of the disease activity, disease duration, treatment, and patients' social class in development of sarcopenia.

**Patients and Method:** Sixty women, age > 18 years with SLE and 56 matched controls were studied. Disease activity measured by systemic lupus erythematosus disease activity index, and functional status measured by systemic lupus erythematosus quality of life questionnaire. Body mass index, waist circumference measured for patients and controls. Body composition analyzed by dual energy absorptiometry x-ray.

**Results:** Mean age for patients was  $31.75\pm10.06$  years, and mean disease duration was  $19.62\pm10.76$  months. No differences in body mass index, central obesity, lean mass percentage, fat mass percentage, appendicular lean mass index, and bone mineral density between patients and controls. Z score was lower in lupus patients as compared with controls ( $-1.61\pm0.8$  for patients,  $-1.26\pm0.71$  for control, p= 0.013). Treatment with azathioprine found to decrease the risk of sarcopenia (p= 0.046). Medical social class and working social class show lower risk for sarcopenia compared to unemployed class (p= 0.003, 0.002 respectively). However disease duration, disease activity, using prednisolone, and functional status had no effect.

Conclusions: No significant differences in body mass index, fat mass percentage, lean mass percentage, and appendicular lean mass index in lupus patients and controls. Lupus patients have higher risk to loss their bone density.

**Keywords:** systemic lupus erythematosus, body composition, sarcopenia

#### 1. Introduction

Systemic lupus erythematosus (SLE) is an autoimmune disorder in which organs and cells suffered from damage mediated by tissue-binding autoantibodies and immune complexes. In these patients, autoantibodies are present for years prior to the first clinical symptom (Bevra, 2013). Early ischemic heart disease has appeared as a main cause of morbidity in SLE patients. Increased cardiovascular events can be explained by high prevalence of cardiovascular disease (CVD) risk factors such as metabolic syndrome (Rahman, 1999). In SLE, abdominal obesity as a key-feature of metabolic syndrome with pro-inflammatory and prothrombotic state contributes to atherosclerosis (Yang, 2016). Cytokines such as tumor necrosis factor alpha (TNF-a) are elevated in SLE and these have been linked to loss of fat-free mass (Roubenoff, 1992). Changes in body composition have been reported in SLE patients due to the systemic inflammatory nature of the disease and prolonged corticosteroid therapy. Abnormal body composition phenotypes may represent an additional risk for CVD in SLE patients (Mok, 2008).

# 2. Patients and Method

#### 2.1 Study Design

This is an analytical cross sectional study conducted at the Rheumatology Unit in Baghdad Teaching Hospital,

<sup>&</sup>lt;sup>1</sup> Rheumatology Unit, Department of Medicine, College of Medicine, University of Baghdad, Baghdad, Iraq

<sup>&</sup>lt;sup>2</sup> Department of Medicine, College of Medicine, University of Basrah, Basrah, Iraq

<sup>&</sup>lt;sup>3</sup> Baghdad Teaching Hospital, DXA Unit, Baghdad, Iraq

Medical City, (Baghdad) and Al Fayhaa General Hospital, (Basrah) from December 2016 till June 2017. Ethical approval was taken from Medical department, College of Medicine, University of Baghdad. Participants consent was taken for inclusion in the study.

# 2.2 Sample Selection

A total of 60 consecutive SLE patients were involved in the study. Eligible patients included in the study were: females >18 years diagnosed to have SLE according to SLICC classification criteria for SLE (Michelle, 2012). Exclusion criteria included: pregnancy, lactation, ischemic heart diseases, chronic kidney diseases, diabetes mellitus, overlapping inflammatory arthritis or other connective tissue disease. Another 56 —healthy volunteer women non relative to the patients who attended the hospital matched in age were participated in the study as a control group.

# 2.3 Clinical and Laboratory Assessment

Data collection was done using questionnaires and interview. Demographic and clinical features data included: age, sex, body mass index, smoking history, menstruation history, social class, disease duration, diseases activity, quality of life and medications used. SLE disease activity was evaluated using the SLEDAI. The disease activity scored as; no flare if <3, mild or moderate flare 3-12, and severe flare if >12 (Gladman, 2000). Functional status (disability) was evaluated using the SLE-QoL (Systemic Lupus Erythematosus, 2017) which contain 6 domains including physical functioning, activities, symptoms, treatment, mood and self-image. The response options/scale is 7-point response scale (subsections have different anchors, including "not difficult at all" to "extremely difficult", "not at all" to "extremely troubled", and "not at all" to "extremely often") and recall period for items is 1 week. Scores range from 26–182, with higher values corresponding to worse quality-of-life. Blood and urine samples (complete blood count, C3, C4, antidsDNA, urine for protein, RBC, WBC and cast) were collected and the required tests performed in order to calculate SLE disease activity. Social grade depended on the grading system used in National Readership Survey (NRS) (Social Grade, 2017).

#### 2.4 Anthropometric and Body Composition: Measurements and Definitions

Standing height (in cm), and body weight (in kg) were measured, and body mass index (BMI) (kg/m²) was calculated. Body weight classified according to BMI to; normal (BMI 18.5–24.9 kg/m²), underweight (BMI <18.5 kg/m²), overweight (BMI 25–29.9 kg/m²), obese (BMI 30–40 kg/m²), and morbidly obese (BMI >40 kg/m²). (CDC, 2013) Waist circumference was measured midway between the lower edge of the rib cage and the iliac crest. Abdominal obesity is defined according to International Diabetes Federation criteria for the Asian population 2009 as waist circumference ≥80 cm (Alberti, 2015). Body composition was measured by whole body (except head) DXA using Stratos densitometry and analyzed according to Turkish ethnicity. Fat mass index (FMI) was calculated by dividing body fat mass by the square of the height (kg/m²). Appendicular Lean Mass index (ALMI) was calculated by dividing lean mass of upper and lower limbs by the square of the height (kg/m²). Osteopenia is defined as total T score -1 to -2.5, while osteoporosis as total T score <-2.5 or Z score <-2 (Czerwinski, 2007). According to the criteria recommended by Janssen et al (Ian, 2004) low skeletal muscle mass (sarcopenia) was defined as a relative appendicular lean mass index of ≤5.75 kg/m² in women. Normal lean body mass is 60-90% of total body weight and usually <68% consider as unhealthy.

#### 2.5 Statistical Analysis

Normally distributed data presented using their mean and standard deviation, while non-normally distributed data presented as median and interquartile range. Binary logistic regression performed to calculate the odd ratio and it 95% confidence interval for predicting sarcopenia in SLE patients either in univariate analysis or multivariate analysis. All data analyzed using SPSS version 21, graph Pad Prism and mintab version 18. P value were considered significant if less than 0.05.

#### 3. Results

The mean age of SLE patients was  $31.75 \pm 10.06$  year and controls  $34.29 \pm 9.93$  year. The mean BMI of SLE patients was  $27.72 \pm 6.98$  kg/m<sup>2</sup> and controls  $28.62 \pm 5.92$  kg/m<sup>2</sup>. There was no statistical significant differences between SLE patients and controls regarding age and BMI (p>0.05). Other demographical features between controls and SLE patients were illustrated in Table 1.

Table 1. Demographic data of patients and controls

Variables	SLE patients	Controls	P value
Number	60	56	-
Age (year) mean±SD	$31.75 \pm 10.06$	$34.29 \pm 9.93$	0.175 <sup>a</sup>
BMI group no.(%)			$0.324^{b}$
Under weight	4 (6.7%)	1 (1.8%)	
Normal	21 (35.0%)	16 (28.6%)	
Over weight	15 (25.0%)	16 (28.6%)	
Obese	15 (25.0%)	21 (37.5%)	
Morbid obesity	5 (8.3%)	2 (3.6%)	
Smoking no.(%)			
Never	58 (96.7%)	52 (92.9%)	$0.427^{d}$
Current	2 (3.3%)	4 (7.1%)	
Marital status no.(%)			
Married	29 (48.3%)	34 (60.7%)	0.182 <sup>b</sup>
Divorced	7 (11.7%)	2 (3.6%)	0.182
Single	24 (40.0%)	20 (35.7%)	
Menstruation no.(%)			$0.526^{\mathrm{b}}$
Active	50 (83.3%)	49 (87.5%)	
Menopause	10 (16.7%)	7 (12.5%)	
YSM year (IQR)	1.5 (0.6 – 9.0)	2(0.5-5.0)	0.659 <sup>c</sup>
Social class no.(%)			
Middle class	3 (5.0%)	5 (8.9%)	
Lower middle class	4 (6.7%)	8 (14.3%)	$0.234^{b}$
Working class	1 (1.7%)	3 (5.4%)	
Unemployed	52 (86.7%)	40 (71.4%)	
Waist circumference (cm)mean±SD	$87.98 \pm 14.33$	$88.89 \pm 11.88$	0.712 a

a Independent t test, b chi square, c Mann Whitney U, and d Fisher exact

BMI, body mass index; IQR, interquartile ratio; SD, standard deviation; YSM, year since menopause.

The disease characteristics of SLE patients were presented in Table 2.

Table 2. Disease characteristics of the patients

Variables	Values
Number	60
SLEDAI mean± SD	$19.62 \pm 10.76$
QoL mean± SD	$48.20 \pm 16.72$
Prednisolone use, no. (%)	57 (95.0%)
Prednisolone dose(mg), mean $\pm$ SD	$15.17 \pm 10.73$
Prednisolone use duration(year), median (IQR)	1.0 (0.9 – 3.5)
HCQ use, no. (%)	23 (67.6%)
HCQ dose(mg), mean $\pm$ SD	$334.7 \pm 94.8$

HCQ use duration(year), median (IQR)	1.0 (1.0 – 3.0)
AZA use, no. (%)	27 (45%)
AZA dose(mg), mean $\pm$ SD	$98.1 \pm 25.9$
AZA use duration(year), median (IQR)	1.0(0.7-2.0)
MMF use, no. (%)	10 (16.7%)
MMF dose(g), mean $\pm$ SD	$1.6\pm0.5$
MMF use duration(year), median (IQR)	1.0(0.6-3.0)
MTX use, no. (%)	2 (3.3%)
MTX dose(mg), mean $\pm$ SD	$16.3 \pm 5.3$
Cyclophosphamide use, no. (%)	4 (6.7%)
Cyclophosphamide dose(mg), mean $\pm$ SD	$812.5 \pm 239.4$

AZA, azathioprine; HCQ, hydroxychloroquin; IQR, interquartile ratio; MMF, mycophenolate mofteil; MTX, methotrexate; QoL, quality of life; SD, standard deviation; SLEDAI, systemic lupus erythematosus disease activity index.

The Z score was statistically significantly lower in SLE patients compared to controls, the rest of the variables showed no significant difference between SLE patients and controls as illustrated on Table 3 and Figure 1.

Table 3. Anthropometric, body composition, and BMD characteristics of women with SLE and control subjects

Variables	SLE patients	Controls	P value
Number	60	56	-
BMI category no.(%)			0.324 <sup>a</sup>
Under weight	4 (6.7%)	1 (1.8%)	
Normal	21 (35.0%)	16 (28.6%)	
Over weight	15 (25.0%)	16 (28.6%)	
Obese	15 (25.0%)	21 (37.5%)	
Morbid obesity	5 (8.3%)	2 (3.6%)	
Central obesity no.(%)	41 (68.3%)	39 (69.6%)	0.879 a
Body composition			
LM% mean± SD	$51.17 \pm 7.16$	$52.04 \pm 6.16$	$0.484^{\rm b}$
LM group no.(%)			
Normal	1 (1.7%)	0 (0.0%)	1.0 c
Unhealthy	59 (98.3%)	56 (100.0%)	
ALMI (kg/m²)mean± SD	$6.35\pm1.24$	$6.51\pm1.00$	0.452 <sup>b</sup>
ALMI groups no.(%)			
Normal	39 (65.0%)	44 (78.6%)	0.105 a
Sarcopenia	21 (35.0%)	12 (21.4%)	
FM% mean± SD	$37.86 \pm 9.96$	$39.36\pm8.32$	$0.382^{b}$
FM group no.(%)			
Normal	16 (26.7%)	13 (23.2%)	
Overfat	17 (28.3%)	12 (21.4%)	0.610 <sup>a</sup>
Underfat	2 (3.3%)	1 (1.8%)	
Obese	25 (41.7%)	30 (53.6%)	

FMI (kg/m <sup>2</sup> )mean± SD	$10.99 \pm 5.20$	$11.57 \pm 4.33$	0.518 <sup>b</sup>
BMD (g/cm <sup>2</sup> )mean± SD	$0.84 \pm 0.13$	$0.85 \pm 0.08$	0.444 <sup>b</sup>
T score mean± SD	$-1.50 \pm 0.98$	$-1.23 \pm 0.86$	0.113 <sup>b</sup>
Z score mean± SD	$-1.61 \pm 0.80$	$\textbf{-}1.26 \pm 0.71$	0.013 <sup>b</sup>

<sup>&</sup>lt;sup>a</sup> Chi square, <sup>b</sup> independent t test, <sup>c</sup> Fisher exact test

ALMI, appendicular lean mass index; BMD, bone mineral density; BMI, body mass index; FM, fat mass; FMI, fat mass index. LM, lean mass; SD, standard deviation.

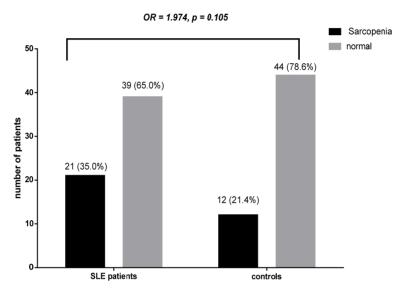


Figure 1. Bar shows abnormal muscle mass (sarcopenia) in SLE patients and controls with P values and OR (odd ratio)

In univariate analysis, patients with low BMI, lower middle class, not using AZA, low LM and high FM% were associated with sarcopenia. In multivariate analysis, only the use of AZA (reduces risk of sarcopenia) and middle class and working class (reduce the risk of sarcopenia compared to unemployed class) were independent predictors of sarcopenia, the rest of the variables were dependent predictors of sarcopenia, overall the multivariate module had R2 = 0.378 which indicate it has sufficient ability to explain sarcopenia, as shown in Table 4.

Table 4. Univariate and multivariate binary logistic regression analysis to predict sarcopenia in SLE

variables	univariate		multivarate	
	OR	P value	OR	P value
Age	0.976	0.392		
BMI	0.870	0.011	0.810	0.391
Smoking	1.900	0.656		
single	1.0			
Married	0.760	0.650		
Divorced	5000	0.088		
Menopause	0.773	0.717		
Social class				
Unemployed	Reference	-	Reference	-
Middle class	$1.2x10^{-9}$	0.002	$7.3 \times 10^{-10}$	0.003
Lower middle class	5.667	0.043	2.924	0.127
Working class	$1.2x10^{-9}$	0.002	$3.6 \times 10^{-10}$	0.002
Disease duration	1.027	0.702		
PND use	1.081	0.950		
PND dose	1.023	0.358		
PND duration	0.938	0.639		
AZA use	0.241	0.019	0.277	0.046
SLEDAI	0.993	0.781		
QoL	0.996	0.792		
WC	0.967	0.120		
BMD	0.278	0.571		
T score	0.855	0587		
Z score	0.581	0.156		
LM%	1.024	0.433		
FM	0.970	0.172		
FM%	0.951	0.031	1.122	0.140
FMI	0.912	0.119		

R2 (Cox & Snell) = 0.378 of the multivariate module.

AZA; azathioprine, BMD; bone mineral density, BMI; body mass index, FM; fat mass, FMI; fat mass index, LM; lean mass, PND; prednisolone, QoL; quality of life, SLEDAI; systemic lupus erythmatosus disease activity index, WC; waist circumference.

### 4. Discussion

The main finding of our study is that; central obesity, unhealthy lean mass, sarcopenia (low ALMI), and high fat mass were similar in both lupus patients and controls with no significant statistical difference (p value= 0.87, 1, 0.105, 0.61 respectively). We didn't evaluate the dietary intake, a known risk factor for altered body composition in the general population. These results are differ from study of Santos et al. (2011) which done in Caucasians population, when they found that patients with SLE and RA were likely to had abnormal body composition than noninflammatory controls. Also there is a study done by Lilleby et al. (2007) showed that body fat mass in childhood-onset SLE patients was higher and lean body mass was lower than in healthy controls. However our results are corresponding with results of Shamekhi et al. (2017) which done in Iranian population. Of course these difference reflect the social and dietary habits of different society. We found that the presence of sarcopenia in

lupus patients is not affected by the disease duration nor by the disease activity, also it not affected by corticosteroid treatment (neither the dose nor the duration), however we did not assess muscle performance in our study. These findings are consisting with all above three studies, but in contrast a significant negative effect of corticosteroids on FM and LM had been reported in Kipen et al. (1998) study. On the other hand we found that sarcopenia in lupus patients was significantly more in those who had lower BMI (p value= 0.011), however low BMI is found to be dependent risk factor that means BMI itself can't predict the presence the sacropenia (BMI does not discriminate between lean and fat mass), and the sacropenia was more in patients with higher FM% (p value= 0.031). Also sacropenia was significantly more in those not treated with azathioprine (p value=0.019). In our study, treatment with azathioprine was found to be independent protector against sarcopenia. To the best of our knowledge there is no other study showing the effect of azathioprine or other immunosuppressant on development of sarcopenia in lupus patients except for Santos et al. (2011) study who found that FM was not affected by any immunosuppressants. Lower social class across life was associated with higher fat mass in early old age and was also associated with lower lean mass in women after adjustment for fat mass as demonstrated by David Bann et al. (2014). In our study we found a similar results. The sarcopenia was significantly reduced among patients in middle class (p value 0.003, OR 7.3 x 10<sup>-10</sup>) and working class (p value 0.002, OR 3.6 x 10<sup>-10</sup>), while the reducing effect of lower middle class was dependent on the reduction of other risk factors. We did not study the effect of physical activity on body composition. In present study the bone density presented by total body BMD and T score was lower in lupus patients, however these lower values were insignificantly differ compared with healthy controls (p value= 0.444, 0.113 respectively). While Z score showed statistically significant lower value (p value= 0.013) among lupus patients. These results were differ from Abd El-Hady et al. (2017) study, Gilboe et al. (2000) study, and Gracanin et al. (2015) study who found that BMD, T score and Z score all were significantly lower in lupus patients. This difference also may be due to ethnic and society variations and because of bone loss in SLE is heterogeneous and likely a multifactorial process involving both traditional and lupus-related risk factors that may be due to the disease itself or due to its treatment.

In conclusion; there are no significant differences have been observed in patients' BMI, FM%, LM%, ALMI as compared with healthy individuals. Treatment with azathioprine may reduce the risk of sarcopenia and lupus patients have a high risk to loss their normal bone density.

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# **Competing Interests Statement**

The Author(s) declare(s) that there is no conflict of interest.

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# Participating in Organ Donation: Issues Among Black South Africans

Peter Masibinyane Dimo<sup>1</sup>

Correspondence: Peter Masibinyane Dimo, Department of Social Work, University of Zululand, Private Bag 1001, KwaDdlangezwa 3886, South Africa. Tel: 035-602-6664. E-mail: DimoP@unizulu.ac.za; charismadimo@gmail.com

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#### **Abstract**

The medical transplantation of human body organs remains the only efficacious therapy for patients who are confronted with the reality of death due to the breakdown of their vital body organs such as the heart, lungs, kidneys, pancreas, and liver. Nevertheless, their hopes of improving and prolonging their lives on earth are shattered by the consistent shortage and paucity of suitable organ donors. The scarcity of human organs is an issue of great concern in public health, both locally and internationally and the current outlook is bleak. This study seeks to explore factors that prevent black South Africans in Limpopo province from participating in organ donation. In a quest to explore factors that might impede black South Africans from participating in organ donation, a qualitative approach and explorative research design were used. Non-probability sampling was used to select 30 research participants. In-depths interviews were used to collect data and the data analysis method was a content analysis. The study was based on the theory of planned behaviour. The study established that the majority of black South Africans are not registered organ donors. A lack of awareness or educational, religious, and cultural backgrounds and myths regarding organ donation prevent black South Africans from registering and donating their organs. This study recommends further research into organ donation, and the development of a social work model to increase the awareness rate of organ donation in black communities. It calls for the evaluation of legislation that regulates organ donation and transplantation in South Africa.

Keywords: organ, organ donation, transplantation

# 1. Introduction and Study Background

The purpose of this study is to investigate factors that prevent black South Africans in Limpopo province in South Africa from registering as organ donors and donating their organs for transplantation. The medical transplantation of human body organs is the only efficacious medical intervention for patients who are confronted with the reality of death due to the breakdown of their vital body organs such as the heart, lungs, kidneys, pancreas, and thetg liver. Nevertheless, these patients' hopes of improving and prolonging the quality of their lives on earth are destroyed by the consistent shortage and paucity of suitable organ donors.

The scarcity of organs is an issue of great concern in public health and the current outlook is bleak. It is an indisputable fact that the success of any transplantation program is largely determined by the availability of committed and registered organ donors. There is no balance between the demand and the supply of human body organs. This view is supported by Merola, Pei, Rodriguez-Davalos, Deng, Mulligan, and Davis (2016), who report that more than 100 000 patients in the United States of America are added to the transplant waiting list in the hope of receiving an organ that could improve and prolong their lives. Furthermore, it is estimated that more than 7 000 patients die annually as a result of the shortage of organs. Australia has an organ donation rate of 15.1 per million populations, and this is the lowest and most unacceptable level or rate of donation (Hyde & Chambers, 2014). The imbalance between organ supply and the demand and the acute shortage of registered and committed organ donors are likely caused by the current system of organ donation in many countries, both locally and internationally. Organ donation is viewed as an altruistic act with most people feeling disinclined to participate. In South Africa, the Organ Donor Foundation (2016) reported that South Africa has over 4 300 patients who require an organ, and amongst these people who are waiting for life-saving organs are children who are forced to put their childhood interests and dreams on hold while they wait for a suitable organ. The reason for the current status quo regarding organ donation in South Africa is the opt-in system of organ donation, which does not bear positive results in terms of increasing the donor pool (Etheredge, Turner, & Kahn, 2013). According to previous organ donation studies,

<sup>&</sup>lt;sup>1</sup> Department of Social Work, University of Zululand, South Africa

insufficient human body organs and the unavailability of committed donors is occasioned by multidimensional aspects in various countries, and it would therefore be misleading to ascribe to global common reasons. Scientific investigations are the cornerstone of intervention programs in social work practice and medicine. Nevertheless, there is a chronic lack of scientific investigation in this area. Many studies have been done at a global level in countries such as the United States of America, Korea, New Zealand, and China. However, a few studies have been done in South Africa by researchers such as Muller (2013), Turner and Kahn (2014), Etheredge, Turner, and Kahn (2013), Venter and Slabbert (2013), and Slabbert and Venter who investigated organ procurement in Israel with the purpose of drawing lessons for South Africa. Scientific investigations on organ donation that have been conducted to date did not focus on the Limpopo province. Amongst the factors that prohibit people from participating in organ donation are: a lack of knowledge or awareness; socio-cultural factors such a culture and religion; negative attitudes and perceptions; and myths regarding organ donation. Moreover, demographic aspects, such as the age, sex, education, socio-economic status, knowledge, and personal experience of organ donation have been cited as factors that inhibit individuals from donating their organs. A lack of personal experience with organ donation is caused by the obvious absence of people who serve as role models in society, either as organ donors or as recipients of organs (Mithra et al., 2013; Philipson, Larsen-Truong, Pits, & Nonu, 2015).

The consequence of insufficient information on organ donation is the subject being shrouded in superstitious beliefs that generate fear in the minds of uninformed people (Mithra et al., 2013). Knowledge is a powerful weapon that can be used to dispel myths and inform black South Africans. The researcher maintains that the success of any transplant program or intervention is determined by knowledge; it is the pre-requisite. Knowledge shapes people's mind-sets, perceptions, and attitudes, whether positive or negative and determines the organ behaviour of communities; it helps people to make choices, and unfortunately these perceptions are transmitted from generation to generation. It is unwise to only blame lack of knowledge as a barrier to organ donation. It is imperative to investigate and assess the type of information that people have regarding organ donation and to establish the source of such information. The researcher believes that either people have incorrect information regarding the subject, or they have the positive information that is not translated into action.

The current organ donation system in South Africa makes it extremely difficult to obtain informed consent from family members. The opt-in system of organ donation requires an individual to express their consent to become a potential donor, while the opt-out system of organ donation presumes consent unless an individual expresses their refusal to become a potential donor. The opt-in system gives prospective organ donors the freedom to indicate that they wish to voluntarily donate their organs for transplantation upon their deaths. However, both systems should be examined. Firstly, the opt-in system that is currently in operation in South Africa protects people against policies that might seek to increase the donation rates, e.g. where benefits are hinted at, such as proposals to compensate donors. However, the amount of patients who are patiently waiting without hope in many countries for life-saving organs increases on a daily basis. Unfortunately, some patients die without ever receiving organs. Therefore, the researcher boldly maintains that the system is not bearing fruits, and it costs the state significant financial resources. It costs money to take care of patients who are suffering from end-stage diseases, not to mention patients that are financially unable to afford dialysis. The researcher further proposes that all government legislation should have at their centre the welfare of the population and the intention to meet their needs within the state's available resources. In support of this view, Dukelow and Considine (2017) assert that the primary purpose of social policy is to understand the social and economic structures that are central to people's lives, their life chances, and their quality of life. In addition to this view, social policy is about the study of how human needs are met and how people and their governments respond to these needs. This is the core business of governments' legislation and policies. The National Health Act No. 61 of 2003 attempted to regulate donation of organs, tissues, and blood, but its silence regarding the welfare of people who intend to save people's lives by donating their vital organs while they are still alive or after their death does not provide clarity. Although it is unethical to sell or compensate organ donors, several studies have discovered that a token of appreciation could increase the rate of organ donation.

For the purpose of this study it will be called 'a token of appreciation', even though the correct terminology that should be used is 'compensation'. Fisher, Butt, Friedewald, Fry-Revere, Hanneman, Henderson, Ladin, Mysel, Preczewski, Sherman, Thiessen, and Gordon (2015:1881), support this notion and state that financial rewards for a direct living kidney donor has the potential to increase the supply of kidneys, and this would reduce the cost of dialysis in the case of renal failure. This is a valid proposition, because the process of organ donation and the medical transplantation of human body organs are associated with financial costs, and emotional and psychological aspects, but in South Africa financial incentives for organ donation are forbidden, and it is also against the legislation that regulates 119 of organs used for donation.

Many researchers have identified socio-cultural factors such as religion and culture as impediments that prevent

black South Africans from making significant contributions in organ donation. Black South Africans are highly religious and cultural people. Religion and culture provide their sense of identity and unconsciously regulates their behaviour and their perspective of life events as well as their importance. Any behaviour that is regarded as contrary to the culture or the religion of a particular community is not tolerated, and is viewed negatively. While this study doesn't seek to enter into a definition of culture, it cannot be repudiated is that culture is a dynamic, controversial subject that is often misunderstood. The researcher is in agreement with Telleria's (2015) definition of culture as a set of values, principles, and standards that shape and condition a group's behaviour.

Furthermore, Simmers (2004: 216) describes culture as the beliefs, attitudes, languages, symbols, rituals, behaviours, and customs that are specifically unique to a particular group of people and which are transmitted from one generation to the next. The important message for organ donation coordinators and policy makers is that culture has the power to influence the behaviour of people. Culture also provides them with the lenses through which they view and interpret important life events, and prescribes how they should behave in certain circumstances. Chavis (2011: 472) states that human beings possess cultural experiences that affect their behaviour. The socio-cultural aspects of a particular group of people or a community also influence the decisions that they take regarding organ donation. This view is supported by Tarus and Gavrilovici (2015: 72) who also point out that culture is a strong barrier to organ donation. Another barrier to organ donation is religion. It is closely linked with culture, but it is addressed independently in this study. According Afifi, Morgan, Stephenson, Reichert, Harrison, and Long (2009), religion is described as associate-based beliefs and practices relating to God or a higher power commonly associated with a church or organised group. In addition to this view the researcher asserts both religious and spiritual beliefs determine how people perceive health, illnesses, pain, and suffering, including life and death. The limited space of this study does not allow the researcher to identify and discuss all South African religions, but the researcher will refer to the dominant religion, namely Christianity, as many of South Africa's religions are based on Christian principles. Christians believe in life after death, and they believe that they must appear whole before their Maker. Many black South Africans refuse to participate in organ donation due to their religious beliefs, which is a contradiction of their Christian principles because Christianity advocates sacrificial giving that is influenced by love. Religion shapes the people's attitudes towards organ donation and also engenders strong feelings about organ donation. Religion also taps into the political world, and it is politically correct to acknowledge that South Africans practice all the major religions, such as Christianity, Muslim, Judaism, Islam and Buddhism.

#### 2. Methods

Kara (2017) defines a methodology as a coherent and logical framework for research that is based on the views, beliefs, and values, and the purpose of this framework is to guide the researcher's choices. Furthermore, Thomas (2017) describes methodology as the general research strategy and the collection of research data, including the analytical techniques adopted in the research study. For the purpose of this study, the research methodology includes research approach and design, the type of research, population, sampling, data collection, analysis, theoretical framework, and ethical consideration.

# 2.1 Research Approach

In its quest to explore the socio-cultural factors that prohibit black South Africans from participating in organ donation, a qualitative approach was adopted. A qualitative approach is more appropriate, particularly when one is doing a ground-breaking study. There is a dearth of research on organ donation and transplantation, especially within the black community contexts. According to Brynard, Hanekom, and Brynard (2014), a qualitative approach allows the researcher to know research participants personally, to see them as they are within their natural settings, and lastly but crucially, to experience their daily struggles when they are confronted with real-life issues.

# 2.2 Research Design

The design of a study serves the purpose of explaining, in detail, the manner in which the researcher intends to conduct the research, namely, how questions will be asked in each research step (Sarantakos, 2013). Additionally, Gray (2014) defines a research design as an overarching plan for the gathering, measurement, and analysis of data. The nature and the purpose of this study called for an exploratory research design. The purpose of exploratory design is to gain an insight into a situation, person, or community. According to Bless, Higson-Smith, and Sithole (2013), exploratory research is preferred when limited knowledge or information exists about a particular subject. Babbie (2014) also proposes that this design is more suitable when the researcher examines a new subject or engages in a ground-breaking study. Research literature has proven that, many researchers are in agreement with the fact that, exploratory design is appropriate when there is a need used need to explore a subject under investigation using qualitative data before making an endeavour to measure or test it using quantifiable

approaches.

# 2.3 Type of Research

This study sought to find solutions that could remedy the acute shortage of organ donors for transplantation and the unacceptable imbalance between available life-giving organs and the actual demand for human body organs. This study can be classified as applied research, which is research that is implemented when there is a problem or a situation to be solved, however it serves two purposes, because it also generates new knowledge. According to Bless et al. (2013) and Brynard et al. (2014), the primary purpose of applied research is to assist in solving real problems that confront communities. Nevertheless, this is often achieved by applying basic research findings, as is argued in this study.

## 2.4 Population or Study Area

This study was conducted in Zebediela, which is in Limpopo province in the northern part of South Africa.

#### 2.5 Sampling

Sampling refers to the scientific technique that is used to select a small group with the view of determining the characteristics of a larger group (Brynard et al., 2014). In scientific investigations, the research approach and the population under investigation determine the type of sampling method used. This study adopted a qualitative approach and therefore non-probability sampling was relevant. Babbie (2014) postulates that non-probability sampling is suitable for studies that are conducted in situations that do not permit probability sampling. Non-probability sampling methods, purposive and snowball, were used to select a total number of 30 research participants. Kara (2017) states that purposive sampling is used when researchers use their own judgment to decide which participants will contribute in the study. However, snowballing was also used because participants also assisted in identifying other participants who had valuable information for the study. According to Babbie (2014) snowball sampling is a nonprobability-sampling method that is often used in field research. Each participant interviewed is asked to suggest additional research participants for interviewing. Participants were requested to sign confidentiality agreements in order to protect the privacy and the confidentiality of participants. The sample included five traditional leaders, five traditional healers, and twenty ministers from various religions.

# 2.6 Data Collection

Unstructured interviews or in-depth interviews were use used to collect data as these interviews are suitable for exploratory or qualitative investigations (Brink, Van der Walt, & Van Rensburg, 2012). This is a method that allows research participants to talk freely about events, behaviour, and beliefs in relation to the topic under investigation, and it has the potential to produce more in-depth information than any other data collection method (Mitchell, 2012; Brink et al., 2012). Field notes and audio-tapes were used to record data after obtaining permission from the research participants. The interviews were designed to elicit participants' views, perceptions, knowledge, and attitudes regarding organ donation. Data in this study was collected until saturation point was reached

#### 2.7 Data Analysis

For the purpose of this study, thematic content analysis was used to analyse data. Codes and themes were generated from the transcribed data according to Creswell (2014) and Bless et al.'s (2013) guidelines. Data analysis simply refers to the scientific process of bringing order and structure to the data. Babbie (2014) defines data in qualitative research as the non-numerical examination and interpretation of observation, with the intention of discovering underlying meanings of and patterns in relationships.

#### 2.8 Theoretical Framework

Teater (2010) states that theory is an important ingredient in social work practice since it guides the manner in which social workers view and approach individuals, communities, and the society. It is a tool that helps social workers to predict, explain, and assess situations and behaviours, and it also provides a rationale as to how social workers should react and intervene. The theory of planned behaviour (TPB) was used to explore factors that influence the organ donation behaviour of black South Africans. The TPB is an appropriate conceptual framework for understanding and predicting social, health-related behaviours (Ayodele, 2015). This view finds its support in Ayodele (2017) who further confirms that the TPB provides a conceptual framework for understanding and predicting social, health-related behaviour. The theory posits that behavioural intention is a function of attitude, subjective norms, and perceived behavioural control. This theory has three important constructs, which are presumed to be key in influencing the intentions of people to perform a certain behaviour. The first construct is the favourable or unfavourable assessment of a behaviour. Secondly, subjective norms are considered to be perceived

pressure to perform or not to perform certain behaviours. Lastly, behavioural control is perceived as how easy or difficult it is to perform certain behaviours. According to the TPB, registration of organ donors and organ donation discussions are determined by intention, which is mostly influenced by subjective norms and attitudes toward organ donation.

#### 2.9 Ethical Considerations

The basic purpose of research ethics in scientific investigations and social work practice is to protect research participants. Social work is arguably more ethics-based and directly concerned with values and priciples. De Vos, Strydom, Fouche, and Delport (2013) add that scientific investigations should be based on mutual trust, acceptance, cooperation, promises, and well-accepted conventions and expectations between all parties involved. The researcher was given permission by the Ethics committee to conduct the study. All research participants participated in this study voluntarily and signed an informed consent, which indicated the purpose of the study, and identified the researchers, their expertise, and qualifications. It also clearly highlighted the benefits and risks of study participation. All research participants signed confidentiality agreements to safeguard confidentiality. According to Sarantakos (2013), when confidentiality is ensured, the researcher may keep names linked to the data, however the information that is made available for public consumption cannot include the respondent's name. In adhering to these constraints, the researcher used symbols and numbers to identify the research respondents. All collected electronic data was stored on a password-protected device and the only person with access to data was the study leader who also signed informed consent. Acknowledging all information sources prevented the occurrence of plagiarism.

#### 3. Results

The results of this study are presented according to the themes that emerged during the interviews. Among the 30 research participants, only nine admitted that they had never heard of organ donation and/or transplantation. The study established that all participants are not registered as organ donors. It also emerged that they have neither the direction nor knowledge as to where and how they could register as organ donors. Their attitudes towards organ donation were positive, but six participants indicated that organ donation is unwarranted in back communities. The majority of participants, that is all of them, clearly declared that they would not give consent for the retrieval of body parts from their family members who are registered as organ donors. Although financial incentives did not form part of the study, it kept on emerging from the majority of participants, because the participants where given the opportunity to express themselves. There was a general view that hospitals might be selling their organs while participants themselves don't benefit from the process. Among the factors that prevented the participants from participating in organ donation was lack of awareness or education, even though it was only a small segment of the sample that mentioned a lack of knowledge. Culture and religion are still cited as deterrents to organ donation and registration. Organ donation is still shrouded in myth. Participants feared that if they registered as organ donors, they would be susceptible to poor health care and body mutilation.

#### 4. Discussion

The main themes that emerged during the interviews are lack of knowledge, attitides towards organ donation, consent in organ donation, financial incentives, culture and religion, fear of poor health and body mutilation. The findings of this study are discussed according to the themes that emerged.

# 4.1 Knowledge About Organ Donation

This study adopted the theory of planned behaviour as its theoretical framework. TPB is used to understand and predict health-related behaviour. It is believed that, all behaviour is learnt and people behave according to the information or knowledge they have. It was found that organ Organ donation was not an entirely foreign concept to the participants, as the majority of them admitted to knowing about it, albeit that their knowledge is limited. Historically, organ donation is not a foreign concept in South Africa, since Dr. Christiaan Barnard performed the first heart transplant in South Africa in 1967. Nonetheless, despite a sound history of organ transplantation, many researchers identify a lack of knowledge regarding organ donation as an impediment to the low rate of organ donation. Black South Africans have limited knowledge regarding organ donation therapy, and little insight into the plight of patients with end-stage organ failure (Paterson, 2013; Stein, 2011). These findings are supported by Perenc, Radochonski, and Radochonski (2012) who also identified a lack of knowledge regarding organ donation as a major barrier to people registering, donating, and discussing their intention to donate their organs. Conversely a small segment of the research sample reported that they had never encountered organ donation. Despite the scant insight that people have regarding organ donation, South Africa has the lowest donation rate. This finding is consistent with the findings of the study conducted by Organ Donor Foundation (2014). Indeed, a lack of

knowledge and the identification of donors are the thorny issues that have impacted on the success of organ transplantation.

# 4.2 Registration as Organ Donars

Knowledge precedes action in terms of organ donation however all research participants who took part in this study are are not registered as potential organ donars including those who have little insight about organ donation. Therefore, it can be hypothesised that being informed about organ donation does not guarantee registration. Of great importance was the participants' admission that the knowledge that they had was insufficient, and it also emerged that none of the participants were prepared to register as donors. This confirmed the basic philosophy of the theory underpinning this study, that is that people choose to behave how they behave, and they are influenced by their intentions (Ayodele, 2017). This was proved by the participants' reluctance to participate in organ donation due to the absence of financial incentives for donors. Three respondents declared that organ donation is unwarranted in black communities.

#### 4.3 Attitudes Towards Organ Donation

The majority of participants had positive attitudes towards organ donation, but their attitudes did not translate into positive actions of registering and declaring their intention publicly or to their families. The researcher maintains that there is a missing link between positive attitudes about organ donation and the actual registration. Although positive attitudes are vital in organ donation, they do not always lead to high volumes of donors.

#### 4.4 Socio-Cultural Aspects

The recruitment, registration, and donation of organs appear to be influenced by socio-cultural aspects such culture, religion, and demographic aspects such gender, level of education, and socio-economic status. Socio-cultural aspects have been found to be factors that are influencing the organ donation behaviour of black South Africans. Few participants reported that their religions do not allow them to partake in organ donation and transplantation. Bresnahan, Guan, Smith, Wang and Edmundson (2010) believe that solid reasons are available that can make one to believe that spiritual beliefs have an inhibitory impact on organ donation because many studies proved the existence of a close relationship between cultural values, spritritual beliefs and how these factors are manifested in organ donation behaviour.

#### 4.5 Informed Cosent

It also came to light that participants are neither psychologically nor mentally prepared to give consent for the retrieval of body organs from their family members. The current system of organ donation is altruistic in nature, however the possibility family members of not honouring the intentions of their deceased family member are significantly high because the remaining family members appear to have more legal powers than the deceased, even though they signed legal documents regarding the donation of their organs.

# 5. Conclusion

The lack of organ donors and organs are issues of great concern in South Africa as the majority of South Africans are not registered organ donors. Poor knowledge and lack of information, socio-cultural aspects, fear of body mutilation, and myths are barriers that prevent black South Africans from participating in organ donation. Organ donation is a highly misunderstood and significantly sensitive issue that is not encouraged in black families.

#### 5.1 Recommendations

This study recommends the evaluation of legislation responsible for the regulation of organ, tissue and blood donation. In the light of this study's findings, it is suggested that the presumed model of organ donation be accepted and implemented in South Africa, since the current opt-in system does not yield positive results. The study invites the Ministry of Basic Education to consider the inclusion of organ donation in its curriculum, as this will help children to become knowledgeable about organ donation during the early stages of their development. The study encourages different stakeholders, such as religious organisations, non-profit organisations, government departments, the private sector, and international organisations to join in regularly increasing public awareness of organ donation, including holding compulsory workshops in places of work. The study invites researchers to conduct more studies in this area, particularly in black communities. The Organ Donor Foundation is respectfully advised to open and activate satellite offices in all the nine South African provinces, as it is not currently visible in other provinces, particularly in Zebediela in the Limpopo province. The electronic method of registering organ donation is not accessible to all members of the population due to participants' financial inability to access the internet and information.

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# **Competing Interests Statement**

The researcher declares that he does not have competing interests for the publication of this study.

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# Learning Disabilities Teachers' Attitudes About Professional Development to Address the Needs of Students With Gifted and Learning Disabilities (SGLD): A Qualitative Study

Yasir A Alsamiri<sup>1</sup> & Salman A Aljohni<sup>2</sup>

Correspondence: Department of Special Education, Faculty of Education, University of Hail, Hail, Saudi Arabia. E-mail: yasser1352@hotmail.com

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#### **Abstract**

Learning disabilities teachers exercise a significant influence on the educational development of students with gifted and learning disabilities (SGLD). It is therefore important to understand their attitudes towards professional development in this area to effectively implement training and educational practices to address the needs of SGLD. The authors interviewed 8 learning disabilities teachers in Yanbu city in Saudi Arabia. The interviews were analysed using content analysis. Findings from the study suggest that further professional development in learning disabilities, giftedness and SGLD may assist in improving the educational outcomes of SGLD. The results of this study may assist teachers and educational personnel to seek the optimal methods to identify and assist SGLD.

Keywords: professional development, twice-exceptional, gifted students with learning disabilities, gifted, learning disabilitie

## 1. Introduction

This article explores the current intervention practices in primary schools in Saudi Arabia, on the importance of professional development for learning disabilities teachers in Students with Giftedness and Learning Disabilities (SGLD). The need for the professional development of learning disabilities primary school teachers is studied and presented in the relevant literature in several ways. However, at the core of such studies is the understanding that professional development is about the teachers' learning, in learning how to learn, and transforming their knowledge into practice for the benefit of the growth of SGLDs. A teacher's professional development is prevalent, with researchers considering it as central to the transformation of schools and crucial to school reform efforts (Garet, Porter, Desimone, Birman, & Yoon, 2001). A surprising gap in the literature revealed that little research has described the knowledge and training needs of learning disabilities teachers regarding students with giftedness, students with learning disabilities and SGLDs (Park Academy, 2010; Montgomery, 2007).

Many definitions for giftedness can be found in the research literature (Beckmann & Minnaert, 2018). The concept of giftedness has been much debated, depending on the scope of different research, the term is used in several ways (Mazzoli Smith & Campbell, 2016; Miller, 2009). Early key studies by Terman (1916) provided a basic framework that concentrated on the intelligence concept and applied the intelligence quotient (IQ) score to help identify giftedness. Gagné (2011) developed the Differentiated Model of Giftedness and Talent (DMGT). He defined giftedness as, "the possession and use of outstanding natural abilities, called aptitudes, in at least one ability domain, to a degree that places a person at least among the top 10% of age peers" (p.11).

The concept of learning disabilities was first developed by Kirk and Bateman (1962), and referred to children with average intellectual ability or overhead, who moreover, demonstrated learning problems (Beckmann & Minnaert, 2018). To date, the concept of learning disabilities continues to be hotly debated, particularly in how learning disabilities (LD) should be defined (Alqahtani, 2016; Alnaim, 2015). There is no consensus on the definition of LD, which may explain the elusiveness of LD terminology (Francis, Shywitz, Stuebing, Shywitz, Fletcher, 1996; Gilani, Roditi, & Bhattacharyya, 2017; Manthorpe & Martineau, 2013). The controversy around the definition of LD relates to the disabilities themselves. Because the term 'learning disabilities' refers to a variety of several types of learning difficulties, such as dyscalculia (impaired ability to learn age-appropriate

<sup>&</sup>lt;sup>1</sup> Faculty of Education, University of Hail, Hail, Saudi Arabia

<sup>&</sup>lt;sup>2</sup> Ministry of education, Yanb, Saudi Arabia

math), dyslexia (impaired ability to learn to read) and dysgraphia (impaired ability to learn to write), makes it a concept that is challenging to define.

Moreover, while learning disabilities vary from person to person, someone with LD may have multiple learning disabilities (Alqahtani, 2016; Alnaim, 2015; Fletcher, Morris, & Lyon, 2003 Firth, 2009). In Saudi Arabia, LD are defined as, "Disorders in one or more of the basic psychological processes involved in understanding or using spoken and written language which is manifested in disorders in listening, thinking, talking, reading, writing, spelling, or arithmetic and it is not due to factors related to mental retardation, visual or hearing impairments, or educational, social, and familial factors" (Ministry of Education of Saudi Arabia, 2002).

The concept of SGLD has been written about extensively, and while there have been few investigations, the concept has proven to be controversial (Lovett & Sparks, 2011; Chimhenga, 2016; Gari, Mylonas, & Portešová, 2015). Although there is a general understanding of what constitutes "giftedness" and "learning disability", there is little awareness that the two can sometimes be found in one student and can be considered mutually exclusive (Wormald, 2009; Mayes, 2016). These students are commonly referred to in the field as "twice-exceptional" (Foley-Nicpon, Allmon, Sieck, & Stinson, 2011). Twice-exceptional students, or as this paper refers to them as SGLD, are students who exhibit superior intellectual ability and demonstrate a significant discrepancy in their level of achievement in a particular area of academic study, such as mathematics, reading, written expression or spelling. Their performance shows lower levels of what would be expected based on their general intellectual ability (Alkhunaini, 2013; Barber & Mueller, 2011).

#### 2. Literature Review

#### 2.1 Professional Development in Gifted Education

Over the past few decades, research has identified the unique learning needs of gifted students (Henderson & Jarvis, 2016; Jarvis & Henderson, 2014). These needs can be met if appropriate programs are made available to students and if teachers are provided with opportunities for professional development (Benny & Blonder, 2016; Kraut, Chandler, & Hertenstein, 2016). According to several studies (e.g. Bangel, Moon, & Capobianco, 2010; Sears, 2016; Murin, 2016), professional development is an ongoing process that includes, knowledge; education; learning and support activities aimed to promote teachers; skills and values changes in teaching to more effective education of gifted students; and a balance between individual, school and national needs. However, studies indicate that teachers with little or no professional development in teaching gifted students experience difficulties in meeting their students' needs, which can lead to feelings of resentment and inadequacy (Siegle & Powell, 2004; Szymanski & Shaff, 2013).

Several researchers have concluded that there are differences between teachers who receive professional development to meet gifted students' needs and those who do not (Alkhunaini, 2013; Shaunessy, 2007). For example, a study conducted by Hansen and Feldhusen (1994), wherein student questionnaires and observations of teachers in the classroom were used to assess the teaching skills and classroom environment of 82 teachers of gifted students, showed that trained teachers have higher teaching skills and can establish classroom environments that are more positive, compared to teachers without professional development. Therefore, it appears that the impact of professional development in giftedness results in an improvement in teachers' abilities to meet these students' needs.

Evidence from several empirical studies shows that professional development in giftedness, while teachers are in-service or in postgraduate studies, results in a greater understanding of giftedness and gifted education, thus enabling them to constantly reassess their own knowledge (e.g., Cashion & Sullenger, 2000; Hansen & Feldhusen, 1994). However, teachers who possess negative attitudes towards students with giftedness are less likely to be able to assist such students. These teachers often reinforce misconceptions and myths about students with giftedness, such as the idea that these students do not require assistance. In addition, such teachers are unlikely to seek further understanding of giftedness (Bohner & Wänke, 2002). Moreover, they are unlikely to undertake professional development in giftedness. Teachers' attitudes have been proven to be important, as they often express a desire for professional development in giftedness with the aim to better understanding their students and providing appropriate support (Alsamiri, 2018).

#### 2.2 Professional Development in Learning Disabilities

Teachers' attitudes toward students with LD and special education are usually multidimensional and may vary according to the various types of learning disabilities, as well as according to the teachers' professional development on how to address these conditions (Chimhenga, 2016). Some teachers have noted that because teaching students with LD is a collaborative task, it is important for both head teachers as well as other teachers

to undertake professional development (Gari et al., 2015). Kamala and Ramganesh (2013) found that learning disabilities often go undetected in primary schools, and undiagnosed students do not receive the necessary assistance. This problem was considered a consequence of a lack of professional development with regards to learning disabilities. Alsamiri (2018) identified an interesting gap in the professional development of teachers. They examined the pedagogy and approaches for the inclusion of students with learning disabilities in Hong Kong and found that teachers who participated in the study, reported a need for professional development to help implement the curriculum to allow students with LD to participate within an inclusive environment, and learn with their peers in the mainstream classroom. Facilitating and implementing an inclusive environment requires knowledge about classroom management, differentiated instruction and balancing the behavioural needs of students with learning disabilities; all of which can be attained through professional development.

Professional development provides teachers with the necessary skills and strategies to assist all students. The literature shows that professional development can be long, intermittent, or as required (Karagiorgi & Symeou, 2007). In addition, the literature supports the idea that professional development can improve teachers' views on inclusion of LD (Avramidis & Kalyva, 2007). Carroll, Forlin, and Jobling (2003) report that when professional development is provided, teachers are more likely to help students acquire the necessary skills to help them cope.

#### 2.3 Professional Development in SGLD

The issue of the identification and support of SGLD is a complex one which requires input and cooperation from numerous stakeholders to consider a student's emotional and social, as well as physical and educational development; taking into account the students, their families, and the school communities. With recognition from the education systems of SGLD and their unique needs, the aid of professional development for teachers, and the support from senior educational staff, SGLD are more likely to be provided with opportunities to reach their academic potential (Bianco & Leech 2010; Wormald, 2009).

Bianco and Leech (2010) note that the research demonstrates that the lack of professional development in SGLD is the main obstacle to identifying and nominating SGLD for support programmes. Yet, these same teachers are expected to identify SGLD and make the necessary referrals through various screening methods (e.g., observation). This issue is only further aggravated by the general difficulty in identifying SGLD from the general population, especially if they were randomly included in standardised tests (Finger & Palmer, 2001). Furthermore, like learning disability teachers, mainstream classroom education teachers have not received adequate professional development in the attributes of SGLD (Shaunessy, 2007). This is a dire situation, as the number of classroom teachers who possess the skills in identifying the characteristics of gifted students – let alone SGLD is very small (Park Academy, 2010).

An issue that needs addressing is the dichotomy of SGLD, namely the strengths and weaknesses inherent in identifying and supporting SGLD, as well as the appropriate professional development required for teachers in helping them develop the necessary skills to assist such students. Therefore, professional development needs to facilitate the social and academic achievement of SGLD (Alsamiri, 2018). According to Wormald (2009), it is important that teachers of gifted students and students with LD unite to better identify SGLD and provide appropriate educational programming. However, Ferrara's study of first- and third-year pre-service teachers found little difference in their attitudes towards SGLD.

In Australia, Wormald (2011) conducted a mixed methods study to investigate teachers' knowledge of SGLD. Responses indicated that only one subject in gifted education had been studied at the undergraduate level by 9.2% of teachers. This is in direct contrast to an undergraduate study in LD, where 20.6% of teachers had studied one subject with learning disabilities. Two teachers had undertaken a course on gifted students, and one teacher a course on learning disabilities in their Master of Special Education degree. Most teachers, including those from selective high schools, had no formal training in either gifted education or learning disabilities. The literature on SGLD reveals that professional development in SGLD is necessary to meet the needs of these students. However, professional development in this area remains limited, with teachers demonstrating more understanding about learning disabilities, followed by limited understanding about giftedness, and very limited to no understanding of SGLD.

# 3. Research Design

The authors employed a qualitative research design to gain an in-depth understanding of teachers' attitudes about the importance of professional development to address the needs of SGLD. Fifteen participants were selected and all were interviewed. The interview questions were based on a critical review of literature focused on the teachers' attitudes about the importance of professional development. The interview questions were derived from

similar studies in the literature in this field. These questions were grouped into the following three categories and served to guide the interview process: the backgrounds of teachers, which included demographic questions; the importance of professional development in gifted as well as learning disabilities, which included eight questions; and the importance of professional development in SGLD, which included eight questions concerning teachers' perspectives on the support available for students with giftedness and learning disabilities, including their perspectives about the type of training or professional development necessary to help these students.

#### 3.1 Research Questions

This study aims to examine Saudi primary learning disabilities teachers' attitudes towards the importance of professional development to address the needs of Students with Giftedness and Learning Disabilities (SGLD). The following research questions inform this study:

- Why do teachers need professional development in giftedness to support students with gifted and learning disabilities?
- Why do teachers need professional development in learning disabilities to support students with gifted and learning disabilities?
- Why do teachers need professional development in SGLD to support students with gifted and learning disabilities?

#### 3.2 Procedure

Specify the research design in the Method section. Were subjects placed into conditions that were manipulated, or were they observed naturalistically? If multiple conditions were created, how were participants assigned to conditions, through random assignment or some other selection mechanism? Was the study conducted as a between-subjects or a within-subject design?

#### 3.3 Participants

The average age of the participating teachers was 27 years, ranging from 23 to 35. The participating teachers had an average of 8 years of teaching experience, and the majority held a Bachelor's degree (8), followed by a postgraduate diploma (1). None had received any training or professional development in SGLD.

#### 3.4 Data Analysis

An inductive content analysis (Elo & Kyng as, 2008) was conducted in this study and involved several steps. An inductive content analysis relies upon a coding unit consisting of words, sentences, or paragraphs that contain elements, 'related to each other through their content and context' (Graneheim & Lundman, 2004, p. 106). The authors listened to all audio-recorded interviews, reviewed them, transcribed them into Arabic to confirm the accuracy of the transcripts, and corrected a few inconsistencies. Following the data analysis, the interviews were translated into English.

To ensure validity, the author forwarded two interview transcripts for independent data coding to the second author, the co-coder. The first author independently coded one interview, and the co-coder coded the same interview transcript. The frsit author and the co-coder compared the results of their coding and discussed any differences. Once an agreement was reached, the authors conducted open coding of the remaining interviews, reading them line-by-line and identifying initial codes.

The authors then checked the results of the open coding for accuracy of coding, carefully reading the results. The authors then read the open coding several times, and as many headings as necessary were written in the margins to describe all aspects of the content (Hsieh & Shannon, 2005), Graneheim and Lundman (2004). The authors then refined and clustered the emerging codes and categories into themes (Hodgetts, Nicholas, & Zwaigenbaum, 2013, p.168). The evidence for an established theme was arrived at by the triangulation of codes, frequency of occurrences, and interview quotes (Hodgetts et al., 2013, p.168). The authors reviewed all themes for reliability; these were then reassessed and confirmed by the co-coder (Patel & Rose, 2014). The involvement of both authors and co-coder during each stage of the data analysis allowed for triangulation and peer checking (Brantlinger, Jimenez, Klinger, Pugach, & Richardson, 2005).

#### 4. Result

The following three key themes among the participants were identified by the authors: the need for professional development in giftedness, the need for professional development in learning disabilities, and the need for professional development in SGLD.

# 4.1 The Need for Professional Development in Giftedness

The main issue raised by participants was that they are not adequately equipped to identify SGLD because none have undertaken any professional development or training in giftedness. Referral to gifted programs is based on identifying a child as gifted in the first instance. However, this may not be possible if the teacher does not know what to look for, particularly if a student has learning disabilities. The urgency for training in giftedness is evident in the following response from one teacher:

I told the principal that I need some training in giftedness because some students who have a learning disability also present as very intelligent but they don't achieve academically. It is important to address the needs of all students so I asked the principal to request that the Ministry of Education provide us with some courses that will enable us to help these students (T3).

While participants indicated that identifying students as gifted is problematic without having had the training, they also noted the lack of opportunities for professional development in giftedness offered by their schools:

I believe that training in gifted education will help teachers identify and support SGLD but unfortunately, there is no professional development offered to teachers in giftedness (T1).

I had no training to rely on for referring or identifying gifted students so I hope to have some professional development in giftedness (T6).

Several participants suggested that as learning disabilities teachers, they were not trained on identifying giftedness, much less SGLD, which is a cohort with which some of the teachers in this study had little to no experience. Their pre-service training focused primarily on learning disabilities. Moreover, while all schools provide support for students with learning disabilities, few provide support for students with giftedness. Therefore, most teachers feel they would not be able to refer students, even if they could identify them. The following comment expresses some of the problems related to identifying giftedness and referring such students:

I am sure most learning disability teachers do not understand the process for referring students to the gifted program or how the identification process works for students who are gifted (T8).

As a learning disabilities teacher, professional development should be offered to teachers to assist them to identify gifted students because the undergraduate degree does not provide enough information about students who are gifted. So, I think that training in giftedness is very important for learning disability teachers (T7).

The urgency for training in giftedness for learning disability teachers is demonstrated in the responses above, which suggest that learning disability teachers are not very well equipped to meet the needs of gifted students or SGLD. What is necessary, as shown in the comments, is the urgent necessity of more resources allocated to schools such as teachers in giftedness or resources to meet the needs of these students as well as those with SGLD (T4).

# 4.2 The Need for Professional Development in Learning Disabilities

Another key theme that emerged is the need for continued professional development for learning disability teachers. Ongoing professional development can help teachers stay abreast of the latest developments in the field, including new and refined methods of identification, as well as improved support strategies. All teachers participating in this study expressed that professional development could enhance their ability to assist their students. For example, one teacher noted the importance of experience, but also emphasised the need for professional knowledge about identification and support for learning disabled students, which can only be attained through professional development:

Experience is very important for teachers to identify students with learning disabilities because I can help them, but I do not know the latest methods of identification or support. Are there new methods of identifying and supporting learning disabled students? Professional development in learning disabilities is very important for teachers to enable them to identify and support these students (T5).

This sentiment is echoed in other participants' responses, who indicate that specialization in the field of learning disabilities is not always sufficient without ongoing professional development. This is important because teachers may learn about SGLD during their professional development. At the very least, they may become aware of the existence of such students. The following comments indicate that pre-service training is inadequate if teachers and in-service training is required for Saudi teachers:

I completed an undergraduate degree in teaching specialising in learning disabilities. But that is not enough and I am not aware of any new developments in the field of learning disabilities (T1).

I've done an undergraduate degree in learning disabilities, and I am working with students with learning disabilities. However, I didn't know about SGLD because there is no professional development in learning disabilities. I'd never come across the term SGLD during pre-service training, so professional development would be useful to assist me to learn about these students (T4).

The need for professional development, undertaken both in Saudi Arabia and overseas, was cited by most learning disability teachers as important in continuing to provide their students with the highest quality assistance. However, opportunities for postgraduate study in learning disabilities are scarce and expensive, and therefore, out of reach for most teachers participating in this study. One teacher's view captures the general sentiment of most of the other participating teachers:

There are very few universities that provide postgraduate studies in learning disabilities. If I want to undertake such study, I have to pay for it myself, which is very expensive. In Saudi Arabia, only undergraduate degrees are free. I hope that the Ministry of Education will provide teachers with the opportunity to study about learning disabilities at a postgraduate level, both in Saudi Arabia and overseas (T8).

In summary, the need for professional development in giftedness and learning disabilities was noted by most teachers. Most expressed a desire for professional development to address the changing and varied needs of their students. Notwithstanding their desire to undertake further development, many teachers cannot afford the training; not to mention the limited opportunities for it within Saudi Arabia. Most claim that such opportunities should be made available by the Ministry of Education.

#### 4.3 The Need for Professional Development in SGLD

All teachers expressed a desire for professional development in SGLD. None of the teachers in this study had received any training in SGLD, as the comments below indicate:

There is no training for teachers to help SGLD because in my primary school we only provide training in support for students with learning disabilities (T3).

I was not given any training on SGLD. I hope to have training that helps me deal with gifted or SGLD. The Ministry of Education has never provided professional development or training for learning disabilities teachers either (T6).

Teachers cited professional development in SGLD as necessary to help them identify and support such students. Many teachers expressed the view that professional development in SGLD should be conducted overseas since none of them had heard about this cohort of students in either pre-service or in-service teaching:

I need training in identifying the characteristics of SGLD because there is no training for learning disability teachers to help SGLD. The Ministry of Education provides very few training opportunities for learning disability teachers to identify and support students. For example, the ministry provided a very short workshop, which did not even mention SGLD (T3).

When I was in pre-service, I did not receive training or sufficient information that would help me identify or support SGLD. I have only ever heard about or undertook learning disabilities training (T8).

I think in-service training, specifically in SGLD, is probably more important than pre-service training because then I would be more familiar with both the learning disabilities and giftedness of these students (T2).

I would like the Ministry of Education to provide opportunities for training and professional development in SGLD for teachers. This training and development should be in overseas universities because we need to know more about this area and we don't know very much at all about it in Saudi Arabia. (T7).

Teachers also claimed that teaching experience would not be enough to identify and support SGLD. They maintained that to identify and support these students, professional development, specifically in SGLD, is necessary. One teacher expressed this view for most:

I have been a learning disabilities teacher for five years, but during my teaching experience, I have not attended any workshops in learning disabilities. I do not know what is new in the field. In service training is not enough to identify and support SGLD and neither is experience as a learning disability teacher (T6).

To summarise, the data indicate that no teachers had undertaken any professional development in SGLD. The need for such training and professional development, both in Saudi Arabia and overseas, was cited as important to help identify and support this cohort of students. However, such professional development must be viewed as necessary by the Ministry of Education, according to teachers, who all claimed that opportunities for further study in training and development for learning disabilities, giftedness, and most importantly SGLD, is few and

costly.

#### 5. Discussion

This initial exploration of teachers' perspectives regarding the need for professional development in SGLD, suggests some possible solutions to the complex issue within schools in Saudi Arabia. A consistent factor which emerged in the three key themes is the need for professional development for teachers across the following areas of learning: giftedness, learning disabilities and SGLD. Notably, very few teachers had undertaken any professional development in giftedness and learning disability since becoming teachers. None had undertaken any professional development in SGLD, citing the lack of opportunity and cost as the primary reasons. This indicates that teachers are not necessarily aware of the latest developments in and strategies for teaching and learning students with learning disabilities or giftedness. Moreover, it is important to note that the lack of training in giftedness by learning disabilities teachers means they are unaware of the existence of SGLD and therefore, are unable to identify the characteristics of such students and make the appropriate referrals. The reason for this is because in eh literature, SGLD is usually discussed in terms of giftedness (Alkhunaini, 2013; Beckmann & Minnaert, 2018). Despite some teachers claiming to have observed students who exhibit both giftedness and learning disabilities within their classrooms, the emphasis in the Saudi education system is placed on a deficit model; as demonstrated in this study, teachers generally focus on learning disabilities and solely address these.

Additionally, the results indicate that despite the ability of teachers to observe both giftedness and learning disabilities in their students, none of them could attribute this phenomenon to SGLD because they were unaware of such a cohort of students. This is not an unusual, as other studies indicate similar results (Gari et al., 2015), wherein SGLD in Greece constitute a group that is entirely neglected and only identified as having learning disabilities. Like the participants in the study conducted by Gari et al. (2015), Saudi teachers are able to understand some of the characteristics of SGLD, but have difficulty comprehending where the balance lies between giftedness and learning disabilities.

These results seem to reflect other studies in the literature which demonstrate that training and professional development in giftedness, as well as SGLD, is limited (Henley, Milligan, McBride, Neal, Nichols, & Singleton, 2010). Troxclair (2013) argues that the ability of teachers in addressing SGLD needs will be detrimentally affected if they do not receive training or professional development in giftedness. According to Levi, Einav, Raskind, Ziv, and Margalit (2013), as well as Alsamiri. (2018), teachers who undertake professional development are more likely to understand students with giftedness and learning disabilities, and meet their needs. In this study, most teachers had received no professional development in either giftedness or SGLD.

The most important result which emerged from the themes in this study is the urgent need for professional development. If this study is representative of how little Saudi teachers know about SGLD, it suggests that there are many SGLD being neglected, or at the very least, underserved by the current education system and its focus on learning disabilities (Gari et al., 2015; Alkhunaini, 2013). The implications of the lack of professional development, particularly in giftedness and SGLD, are that learning disabilities teachers will be unable to address the unique and complex needs of these students. Consequently, SGLD are unlikely to achieve their full potential, especially in their area of giftedness, which remains unidentified.

According to the participants, results also indicate that responsibility for professional development should fall to the Saudi Ministry of Education. Moreover, if professional development is to be made available, it should come at no cost, or at the very least, be affordable. The results in this study indicate that despite the expressed desire of Saudi teachers to avail of professional development programs to better assist their students, the lack of available resources to them has proven frustrating. In relation to SGLD, a desire for professional development undertaken overseas was cited as important. This may be due to the scarcity of knowledge and possibilities for professional development in giftedness and SGLD in Saudi Arabia.

Additionally, the results indicate that the teachers' responses to the interview questions seem to be compatible with the educational needs of SGLD. For example, most teachers indicated that the educational needs of SGLD require the implementation of specifically tailored programs, including enrichment strategies and differentiated instruction for both learning disabilities and giftedness (Alsamiri, 2018). To provide this, a faculty who are aware of the needs of SGLD and the resources to effectively teach them, is required. The results in this study indicate that this is not currently the case in Saudi Arabia; however, teachers wish for such professional development (Alkhunaini, 2013; Alamer, 2017).

This study demonstrates the need for evidence-based practice when it comes to identifying and supporting SGLD.

This can only be made possible if teachers undertake professional development. For this type of professional development to be made available to learning disability teachers, the acknowledgement of SGLD as a unique and specific cohort of students is required by the Ministry of Education, followed by the necessary implementation of policy, programs and resources within all schools.

The limitations of this study include the type of teachers who participated; only learning disability teachers were interviewed. Results may have possibly differed if teachers of giftedness or mainstream teachers were included in the study. Another limitation is context, which was restricted to one area (Yanba) and may not be indicative of results in rural or regional areas. Gender is another limitation; as only male teachers were interviewed; thus a more gender-balanced sample may be necessary in future studies. A possible limitation is that this study only focused on public primary schools, omitting private schools. The inclusion of private primary school teachers in future studies may produce different results, as teachers in the private sector are provided with more opportunities for professional development. Moreover, the private sector has more resources to meet the needs of both learning disabilities students, as well as those with giftedness.

#### 6. Conclusion

In this paper, the results of the qualitative content analysis of eight primary learning disabilities teacher interviews are presented. The results demonstrate the urgent need for learning disabilities teachers to undertake professional development in SGLD. It is imperative for the Ministry of Education to formulate policies which acknowledge this cohort of students, and provide professional development opportunities for learning disabilities teachers in this area. In the absence or limited offering of professional development with regards to SGLD in Saudi Arabia, it is recommended that the Ministry of Education provides teachers with the opportunity to undertake professional development overseas, where much of the research in this field is conducted.

Without professional development, it is unlikely that learning disabilities teachers can meet the complex and unique requirements of this cohort of students. Consequently, SGLD will not achieve their full potential, and their giftedness will remain unidentified and thus, un-nurtured. As identifying learning disabilities in the gifted student population can be difficult, the role of learning disabilities teachers' knowledge and understanding is crucial in supporting and referring these students. Therefore, a recommendation is that learning disabilities teachers receive professional development, which will allow them to support SGLD and provide them with appropriately differentiated curricula or instruction, as well as other strategies and programs, specifically tailored for them.

#### **Competing Interests Statement**

The authors declare that there are no competing or potential conflicts of interest.

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# Health-Promoting Lifestyle Behaviours Among Primary Healthcare Professional Nurses in Eastern Cape Province, South Africa

Sizeka Monakali<sup>1</sup>, Daniel Ter Goon<sup>1</sup>, Eunice Seekoe<sup>1</sup> & Eyitayo Omolara Owolabi<sup>1</sup>

<sup>1</sup> Department of Nursing Science, Faculty of Health Sciences, University of Fort Hare, East London, South Africa Correspondence: Eyitayo Omolara Owolabi, Department of Nursing Science, Faculty of Health Sciences, University of Fort Hare, East London, 5200 South Africa. Tel: 277-30-719-622. E-mail: owolabiomolara101@gmail.com

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#### **Abstract**

Nurses play significant roles in health promotion and health education about healthy lifestyle practices and are considered role models of healthy lifestyle behaviours. It is unclear if their knowledge of healthy lifestyle choices translate to practice. This study assessed the lifestyle behaviours of primary healthcare professional nurses in the Eastern Cape Province, South Africa. This descriptive, cross-sectional study involved 203 purposively selected primary healthcare nurses in Eastern Cape Province, South Africa. We utilised the WHO STEPwise questionnaire to assess the lifestyle behaviour (smoking, alcohol use and physical activity) of the nurses. Descriptive and inferential statistics were carried out at a significance level of p<0.05. The participants' mean age was 45.17 (Standard Deviation±11.26) years. Of all the participants, 27% had ever taken alcohol, and 18% currently use alcohol. Only 8% had ever smoked and of these, 3% currently smoke. Of all the participants, 33% do not engage in physical activities, and only 29% of them met the WHO recommendation for being active. Most of them were aware of the benefits of physical activities. Majority of the participants cited lack of time (74%) and lack of commitment (63%) as barriers to physical activity and few of them cited health challenges (3.9%). Among the primary health care professional nurses in this setting, we found a high prevalence of alcohol use and low prevalence of smoking and physical activity among primary health care nurses in this setting. There is a need to implement effective workplace strategies and wellness programmes that will foster healthy lifestyle practices among the nurses.

Keywords: nurses, lifestyle behaviour, primary healthcare, Eastern Cape, South Africa

#### List of abbreviations

NCDS: Non-communicable diseases

PHC: Primary Health Care

WHO: World Health Organisation

SD: Standard Deviation

EC: Eastern Cape

BCMM: Buffalo City Metropolitan Municipality

#### 1. Introduction

Non-communicable diseases (NCDs) are significant public health, developmental, social and economic concerns, and are the foremost causes of morbidity and mortality worldwide (WHO, 2017). Various modifiable factors like smoking inadequate physical activity, poor dietary practices, harmful alcohol use, overweight and obesity are majorly responsible for the increase in the burden of NCDs\ (WHO, 2017). Irrespective of the gruesome burden associated with non-communicable diseases, they are largely preventable through the prevention of the associated risk factors.

While the focus of policy makers and researchers regarding the burden of non-communicable diseases has been on the general population, little attention is paid to the burden among health care workers. This might be as a result of the general belief that healthcare workers are more knowledgeable about NCDs and associated lifestyle behaviours (Blake & Harrison, 2013; Skaal & Pengpid, 2011). However, their knowledge might not necessarily translate to

practice as high prevalence of unhealthy behaviours, overweight and obesity has been reported among nurses (Blake, Mo, Lee, & Batt, 2012; Blake, Goon et al., 2013; Malik, Blake, & Batt, 2011; Mo, Blake, & Batt, 2011; Phiri, Draper, Lambert, & Kolbe-Alexander, 2014; Skaal & Pengpid, 2011; Stanulewicz, & Griffiths, 2017).

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Worryingly, this occupational group are at a very high risk as some of the non-communicable disease have been linked to working conditions such as long duration of work, high job expectations and rotational shifts which characterise the healthcare system (De Bacquer et al., 2009; LdCÃo, 2010; Morikawa et al., 2008; Zhao & Turner, 2008; Zhao et al., 2011). These factors put the nurses under stress and afford them little opportunities to engage in activities that promote health such as physical and recreational activities (Blake & Harrison, 2013; Blake et al., 2011; Melnyk, Hrabe, Szalacha, 2013; Naidoo & Coopoo, 2007). Nurses are reported to engage in ineffective coping mechanisms and unhealthy practices such as alcohol and substance abuse, smoking, and consumption of unhealthy diet which further increase their risk (Malik, Blake, Batt, 2011; Hensel, 2011).

Several studies conducted among nurses in various countries have highlighted a high burden of NCDs, overweight, obesity and unhealthy lifestyle behaviours such as alcohol use, smoking, physical inactivity and poor dietary practices among them (Blake & Harrison, 2013; Kurnat-Thoma, EL-Banna, Oakcrum, & Tyroler, 2017; Miller, Alpert & Cross, 2008; Naidoo & Coopoo, 2007; Phiri et al., 2014; Skaal & Pengpid, 2011). Generally, high burden of obesity, non-communicable diseases such as obesity (Adeniyi, Longo-Mbenza, & Goon, 2015; Owolabi, Goon, Adeniyi, Adedokun, & Seekoe, 2017a), diabetes (Adeniyi, Yogeswaren, Lonog-Mbenza, Goon, & Ajayi, 2016; Owolabi, Goon, Adeniyi, & Seekoe, 2016), hypertension (Day et al., 2015; Owolabi, Goon, Adeniyi, & Seekoe, 2016; Peer, Steyn, Lombard, Gwebushe, & Levitt, 2013) and their associated factors have been documented among South African adults, including nurses (Goon et al., 2013; Naidoo & Coopoo, 2007; Skaal & Pengpid, 2011; Van den Berg, Okeyo, Danhausser, & Mariette, 2012).

Health promotion and preventative measures, both formal and informal, are considered core components of nursing care (Blake, Malik, Mo, Pisano, 2011; Miller, Alpert, & Cross, 2008). Unhealthy lifestyle behaviours among nurses and other health workers have a two-fold impact; aside the detrimental effect on the health of the nurses, it could also impede the reception of lifestyle modification counsels given to the patients and the community by such nurses. Nurses' direct contact with patients, families and communities offer them the opportunity to influence changes in health behaviours among the general population (Blaber, 2005). These roles could be threatened by a high burden of NCDs among nurses (Blake et al., 2012; Bogossian et al., 2012). High burden of NCDs and unhealthy lifestyle practices among nurses could constitute significant threat to the individual and the healthcare system and adversely affect practice (Blake et al., 2012; Melynk, Hrabe, & Szalacha, 2013; South African Department of Health, 2012). Also, nurses with poor health behaviour may have a lesser likelihood of offering advice on the benefits of healthy lifestyle behaviours (Seir & Osler, 2002; South African Department of Health, 2012). Likewise, it may be unrealistic to expect patients and communities to be committed to plans on living a healthy lifestyle when the health educator advocating such behaviours does not model it (Miller, Alpert, & Cross, 2008). Finally, high burden of NCDs and unhealthy lifestyle practices among nurses and other health workers could impact on the healthcare workforce, in terms of reduced productivity and increased absenteeism at work (Bogossian et al., 2012; Skaal & Pengpid, 2011).

Although some studies have evaluated the burden of non-communicable disease, overweight and obesity among nurses and nurses in training in South Africa (Goon et al., 2013; Naidoo & Coopoo, 2007; Skaal & Pengpid, 2011; Van den Berg, Okeyo, Danhausser, & Mariette, 2012), only a few assessed their lifestyle behaviours such as tobacco use, alcohol use, dietary practices as well as engagement in physical activities, which are major contributors to the growing burden of NCDs. The few studies that assessed their lifestyle behaviours focused on their dietary and physical activity patterns (Phiri et al., 2014; Van den Berg et al., 2012), neglecting two other important factors; smoking and alcohol use. These previous studies have both documented poor dietary practices and physical inactivity among nurses in South Africa. Also, such previous studies considered only nurses in secondary and tertiary level of healthcare, neglecting nurses at the primary healthcare level who are mostly involved in primary healthcare which include health promotion and preventive activities. Therefore, the objective of this study is to assess the lifestyle behaviours (smoking, alcohol use, physical activities pattern) of primary health care professional nurses in an economically disadvantaged province of Eastern Cape, South Africa. In this setting, primary healthcare professional nurses are nurses who have undergone at least four years of formal training as a nurse, with an additional specialisation experience in primary health care/clinical health assessment and licensed to assess patients, diagnose and prescribe. The primary health health professional nurses are also the nurses who run the primary health care and community health care facilities. The findings of this study will help to determine how much the primary healthcare nurses in this setting model the lifestyle behaviours they advocate for. Also, such information is essential in designing appropriate workplace interventions targeted towards promotion of healthy lifestyle behaviour and reduction of the burden of NCDs among health workers.

## 2. Methodology

#### 2.1 Study Area and Design

A quantitative approach with a descriptive, cross-sectional research design was used to screen for the prevalence of overweight and obesity among professional primary health care nurses, working across 41 primary healthcare (PHC) facilities in Eastern Cape. The Eastern Cape forms part of the nine provinces of South Africa. Its capital is in Bisho. Eastern Cape Province was created in 1994 from the Xhosa homelands of Transkei and Ciskei along with the eastern segment of the Cape Province. It forms a base for the Xhosa people. The province has two metropolitan municipalities; Buffalo City Metropolitan Municipality (BCMM), Nelson Mandela Metropolitan Municipality and six districts; Amathole, Joe Gqabi, O.R Tambo, Sarah Bartman, Chris Hani and Alfred Ndzo.

#### 2.2 Sampling

A purposive sampling was used to select primary health care nurses from four randomly selected districts. First, four of the six districts and two metropoles of the Eastern Cape Province were randomly selected using simple randomization, namely, Buffalo City Metropolitan Municipality, O.R Tambo, Chris Hani, and Sarah Baartman Districts. The randomization was done by assigning numbers to the eight districts and these numbers were wrapped up by someone not involved in the study. After this, the researcher blindly selected four. From the four randomly selected districts/municipalities, 41 primary health care centres were then selected using convenience sampling.

There are approximately 880 nurses in the selected districts (OR Tambo = 250, Chris Hani = 230, Sarah Baartman = 100, and BCMM=300). At a confidence level of 95%, a sample size of 268 nurses would have been required. However, only 203 (76%) primary health professional nurses (PNs) were accessible and included in the study due to shortage of staff in PHC facilities, especially in rural districts like OR Tambo. The study was conducted between February and May, 2017.

# 2.3 Eligibility Criteria

Participants were included in the study if they were PHC professional nurses, aged 18 years and above, practicing in the PHC facilities, on duty and willing to participate in the study during the day of data collection. Exclusion criteria included pregnancy or any form of debilitation in such a manner that affects taking anthropometric measurement.

#### 2.4 Data Collection Instrument

The modified WHO STEPwise questionnaire with three major sections; demographic data, behavioral variables and anthropometric data was used for data collection. In order to determine suitability of the instrument, a pilot study was conducted among 20 PHC professional nurses at Mnquma sub district, under Amathole district.

#### 2.5 Data Collection

Face-to-face interview was used to obtain demographic and behavioural characteristics to ensure completeness of information. Sex, age, marital status, level of education, employment status, duration of practice and average monthly income were the demographic variables. Lifetime and current alcohol use was assessed by self-reporting of alcohol use using the questions; "have you ever taken any alcoholic drink?", "do you currently take alcohol?" "In the past 30 days, have you taken any alcoholic drink?", "In the past 30 days, how often did you take alcohol?", How many standard bottles of alcohol (containing 10g of ethanol) do you take at a sitting?".

Regarding tobacco use, lifetime and current tobacco use were also assessed. The questions asked were: "have you ever smoked or use any tobacco products?" "In the last 30 days, have you used any tobacco product?" "What type of tobacco product do you use?" and "how many sticks do you use on an average daily?".

Physical activity pattern was assessed with the following questions: Do you engage in any form of physical activity? How many days do you engage in moderate/vigorous activities? How many minutes do you spend on each day? The overall activity pattern was accessed using the WHO recommendation for physical activity; 150 minutes per week for moderate-intensity activities or 70 minutes per week of vigorous-intensity activity per week. Participants were categorised as either active or not active based on the Yes/No answer. Those who reported engaging in activities were then further categorised into those who met the recommended minutes and those who does not. The perceived benefits of physical activity and barriers were assessed. Data collection took place between February and May 2017.

#### 2.6 Ethical Consideration

The ethical clearance was obtained from the Research and Ethics Committee of the University of Hare (Reference number; EC-2015RP10-426) which followed the Helsinki Declaration. Permission to carry out the study was obtained from the Eastern Cape Department of Health (ECDoH), district managers, sub district managers and facility managers. We obtained written informed consent to participate in this study from all participants. We ensured anonymity and confidentiality throughout the study.

#### 2.7 Data Analysis

Data were analysed using SPSS version 23 for windows (SPSS Inc., Chicago, IL, USA). We expressed data as mean values  $\pm$  standard deviations (SD) for continuous variables. Counts (frequency = n) and proportions (%) were reported for categorical variables. Percentages were compared using chi-square test. Descriptive and inferential statistics were used for determining the prevalence and determinants of overweight and obesity among the study participants. All the variables which were significantly associated in the bivariate analysis were included in the logistic regression model analysis. An unadjusted regression analysis was done by computing models for each of the independent variables while the adjusted regression analysis included a model containing all the independent variables which was then adjusted for confounder, smoking. A p-value of < 0.05 was considered statistically significant.

#### 3. Results

The demographic characteristics of participants are shown in Table 1. The mean age of the study participants was 45.17 (SD±11.26) years. The average duration of practice was 15.98 (SD±11.07) years. Almost half of the participants were married (49.8%) and majority (65%) have a diploma certificate in nursing earning more than R15, 000 (60.6%).

Table 1. Socio-demographic characteristics of participants by gender

Variables	All	Female	Male
Age (years)			
21 to 30	26(12.8)	19(10.6)	7(29.2)
31 to 40	50(24.6)	41(22.9)	9(37.5)
41 to 50	42(20.7)	39(21.8)	3(12.5)
51 to 60	74(36.5)	69(38.5)	5(20.8)
61 to 70	11(5.4)	11(6.1)	0(0.0)
Marital Status			
Single	83(40.9)	71(39.7)	12(50.0)
Married	101(49.8)	90(50.3)	11(45.8)
Divorced	9(4.4)	9(5.0)	0(0.0)
Separated	1(0.5)	1(0.6)	0(0.0)
Widow/Widower	9(4.4)	8(4.5)	1(4.2)
Number of Children			
1	37(20.4)	33(20.4)	4(21.1)
2	61(33.7)	58(35.8)	3(15.8)
3	58(32.0)	49(30.2)	9(47.4)
4	18(9.9)	16(9.9)	2(10.5)
5	5(2.8)	5(3.1)	0(0.0)
6	1(0.6)	1(0.6)	0(0.0)
7	1(0.6)	0(0.0)	1(5.3)

Level of Education			
Diploma (Three-year nursing programme)	132(65.0)	117(65.4)	15(62.5)
Degree	67(33.0)	58(32.4)	9(37.5)
Post-graduate Diploma	3(1.5)	3(1.7)	0(0.0)
Masters	1(0.5)	1(0.6)	0(0.0)
Race			
Black	195(96.1)	171(95.5)	24(100.0)
Coloured	8(3.9)	8(4.5)	0(0.0)
Duration of Practice			
1 to 10 years	72(40.7)	59(38.1)	13(59.1)
11 to 20 years	41(23.2)	37(23.9)	4(18.2)
21 to 30 years	44(24.9)	41(26.5)	3(13.6)
31 and above	20(11.3)	18(11.6)	2(9.1)
Income			
10000 to 15000	65(39.4)	55(38.5)	10(45.5)
Above 15000	100(60.6)	88(61.5)	12(54.5)

Of all the participants, 27% had ever taken alcohol, while 67% of those who reported ever consuming alcohol (18 percent of the entire participants) still currently consume it.

# 3.1 Binge Drinking

The mean number of standard bottles of alcohol taken by the nurses was 4.31 bottles (SD $\pm 3.2$ ), with a higher mean among males (5.62) compared to females (3.55).

Of all the socio-demographic characteristics, only male sex, never married, younger age were significantly associated with ever using alcohol among the study participants.

Table 2. Association of lifetime alcohol consumption with socio-demographic characteristics

Variables	Consume Alcohol	Do Not Consume Alcohol	P-Value
Gender			
Male	18(75.0)	6(25.0)	< 0.001
Female	36(20.1)	143(79.9)	
Marital status			
Never married	29(34.9)	54(65.1)	0.019
Ever married	25(20.8)	95(63.8)	
Age (years)			
21 to 30	19(73.1)	7(26.9)	< 0.001
31 to 40	18(36.0)	32(64.0)	
41 to 50	10(23.8)	32(78.2)	
51 to 60	7(9.5)	67(90.5)	
61 to 70	0(0.0)	11(100.0)	
Income			
10000 to 15000	23(35.4)	42(64.6)	0.080
Above 15000	24(24.0)	76(76.0)	

# 3.2 Smoking Behaviour Among Nurses

Of the 203 participants, only 8% had ever smoked and of these, 47% (3 percent of the entire participants) currently smoke.

#### 3.3 Physical Activity Pattern

Of all the participants, 33% do not engage in physical activities, and of the remaining 67%, only 29% of them met the WHO recommendation for being active.

Of all the participants, 33% do not engage in physical activities, and of the remaining 67%, only 29% of them met the WHO recommendation for being active. Most of them were aware of the benefits of physical activities concerning weight loss (93.1%), better sleep and alertness (95.5%), and for better heart functions (96.5%). The majority of the participants cited lack of time (74.0%) and lack of commitment (63.3%) as barriers to physical activity and few of them cited health challenges (3.9%) (Figure 1).

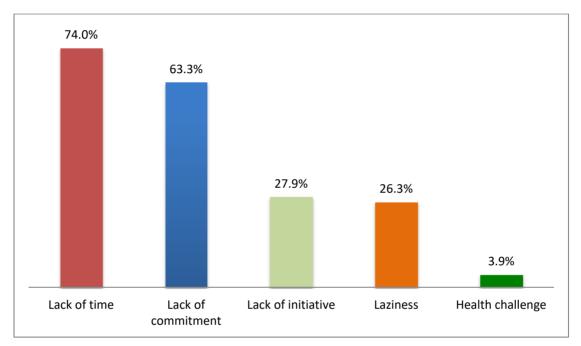


Figure 1. Barriers to physical activity participation

#### 4. Discussion

This present study examines the lifestyle behaviours (smoking, alcohol use, and physical activity) of primary healthcare professional nurses in Eastern Cape, South Africa. These factors among others have been identified as the underlying factors responsible for as much as 80% of the burden of non-communicable diseases (WHO, 2011). Of the 203 nurses involved in this study, only eight percent had ever smoked or used any tobacco product and only three percent of the nurses currently smoke. This proportion of nurses who had ever smoked and are current smokers is quite lower than the reported rate among nurses in Turkey (40%) (Adamek et al., 2012) and 45% (Sezer, Guler, & Sezer, 2007), Japan (18.6%) (Ohida, Osaki, Kobayashi, Sekiyama, & Minowa, 1999) and the United States (8%) (Sarna, Bialous, Sinha, Yang, & Wewers, 2010) When compared to the general population, the prevalence reported in this study is lower than the 15% reported among adults in the same setting (Owolabi et al., 2017c). This is commendable as this shows that the nurses in this setting detest smoking and this might have influence on the health education they offer to patients concerning smoking. Also, a decline in the rate of smoking among nurses has been shown to be accompanied by a fall in the prevalence of smoking in the general population (Sarna, Bialous, Sinha, Yang, & Wewers, 2010). Various workplace policies such as prohibition of smoking at workplace, especially at the healthcare settings might have contributed to this. However, there is still a need to further encourage the nurses and assist those who still smoke to quit smoking.

Primary healthcare professional (PHC) nurses play a significant role in health educating patients and communities on harmful alcohol use; however their disposition to alcohol use will significantly influence this role. Twenty

seven percent of the nurses in this study had ever consumed alcohol and only 18% currently consume alcohol. Comparison of alcohol consumption among nurses in South Africa is fraught with difficulty as scant data exist. The prevalence of ever consuming alcohol among these study participants is lower than the reported prevalence among Kenyan nurses (35.8%) (Mokaya et al., 2016). It is however higher than the prevalence reported among nurses in Norway, 0.3% (Edvardsen et al., 2014). The prevalence in this study is comparable to the reported prevalence (22%) among healthcare professionals, including nurses in another province of South Africa (Okeke, Ross, Esterhuizen, & Van Wyk, 2012). Also, it is comparable to the reported prevalence among doctors in Nigeria, 30.3% (Obadeji, Oluwole, Dada, Adegoke, 2015). This evidence further affirms the fact that health workers, including the nurses also participate in unhealthy lifestyle behaviours such as harmful alcohol use, and nurses in this settings are not exempted. Their rate of alcohol consumption is slightly lower than the reported prevalence (32%) among the general population in the same setting (Owolabi et al., 2017d). Considering the important role of nurses, particularly the primary healthcare professional nurses, in the advocacy for healthy lifestyle behaviors, alcohol use among them might impede this role. Alcohol use among nurses might affect the quality of care rendered or even their sense of clinical judgement, although this association was not established in this study. Alcohol use among nurses might constitute a major threat for the healthcare system and even further increase the challenges of high litigations faced by the South African healthcare system. In addition, given that harmful alcohol use predisposes to chronic illnesses, the health of these nurses might be compromised; and this might affect the healthcare workforce. In addition, the mean number of standard alcohol taken by the nurses in this study was 4.31 bottles with a higher mean among men compared to women. These recorded mean values are synonymous to the range for binge drinking (four or more standard drinks among women or five or more standard drinks among men at an occasion). This shows that those who consume alcohol among this cohort engage in binge drinking, a form of hazardous drinking. This will not only result in poor health outcomes such as chronic diseases and injuries but can also affect the quality of life of these nurses (CDC, 2017). This might also affect their work performance and the care rendered to the patients and the communities, which may see them as role models.

Male nurses had a higher prevalence of lifetime alcohol use. This is not surprising as similar findings have been documented among other populations (Owolabi et al., 2017d; Reddy et al., 2010). Alcohol use appears more socially acceptable among men compared to women (Bratberg, 2016). Also, as observed in this study, the use of alcohol decreases with advancing age. This is similar to other studies (Owolabi et al., 2017d; Reddy et al., 2010). As age advances, maturity and more responsibilities sets in. Even in the absence of those, disease conditions might also begin to develop. These could collectively contribute to older adults' decision to either reduce alcohol consumption or abstain from it. This might also be the underlying reason behind the higher prevalence found among the never married participants as they constitute those in the younger age groups. There was no significant difference between various income groups and alcohol. All the participants have a good purchasing power for alcohol as they all earn more than R15000 per month. Aside this, alcohol appears to be relatively cheap and easily accessible in this setting. Thus, irrespective of income, everyone have access to alcohol and can easily purchase it.

Considering the significant health implications of physical inactivity, this study assessed the physical activity pattern of the nurses in this setting. Of all the participants, 33% do not engage in physical activities, and of the remaining 67%, only 29% of them met the WHO recommendation for being active. Overall, as many as 71% were either not active or insufficiently active. When compared to studies outside South Africa, the observed prevalence of physical inactivity in this study is higher than the documented prevalence of physical inactivity among nurses in the United Kingdom (48%) (Blake, Stanulewics, McGill, 2017), United States (68%) (Fitzgerald, 2015) and among nurses in South Africa (Phiri et al., 2014), in which all the nurses were reported to have met the recommended physical activity level. This shows that the nurses in this setting are not modelling the healthy lifestyle in terms of physical activity they advocate for, and as a result of this, they might be at a risk of developing non-communicable diseases. Nurses constitute a larger percentage of the healthcare workforce; as such a high burden of non-communicable diseases among them might paralyse the healthcare system. Even though lack of physical activity might not physically be observable, however, one of its side effects of becoming obese is apparent. As a result of this, patients with similar lifestyle behaviour might find it difficult adhering to advice received from nurses who do not also comply.

When asked about the perceived benefits and barriers, majority of the nurses were aware of the benefits of physical activity. Some highlighted benefits include weight loss (93.1%), better sleep (95.5%) and alertness (96.5%). The listed benefits of physical activity is synonymous to the documented benefits; reduction of the risk of developing heart diseases, diabetes, cancer, injury, better mental health (CDC, 2017; NHLBI, 2016). However, this shows that the nurses' knowledge about the benefits of physical activity do not translate into practice. In spite of being knowledgeable about the various benefits of physical activity, they still do not feel obliged to engage in such

activities. This poor attitude towards physical activity among nurses in this setting warrants intervention. When asked about the perceived barriers to engaging in physical activities, the nurses highlighted lack of time (74.0%), lack of commitment (63.3%) as the major barriers. This is synonymous to the reported barriers among nurses in the UK (Blake, Stanulewicz, & McGill, 2017), and reported evidence in a review study (Trost, Owen, Bauman, Sallis, and Brown (2002). This is worrying as the nurses are knowledgeable and yet are not committed to participate in physical activity because of lack of sufficient time. There is a need to create a work environment which will facilitate exercise at work and implement physical activity promoting initiatives among the nurses. Also, more emphasis should be laid on observing the wellness days at work and physical activity participation should be incorporated in such days. This could motivate the nurses to be active and will promote their health and reduce their risk for developing NCDs, as shown in some interventional studies assessing the effect of physical activity on the health of nurses (Blaber, 2005; Gartshore & Blake, 2014).

#### 4.1 Limitations

The cross-sectional approach and self-reporting of the lifestyle behaviours are obvious limitations of this study. Also, the findings of this study might not be generalizable to the entire South African nurses. However, this study is the first to assess the lifestyle behaviours among nurses in the Eastern Cape Province, South Africa. The findings of this present study provides a snapshot of the healthy lifestyle behaviours of nurses in the study setting.

#### 5. Conclusion

The study documented high prevalence of alcohol consumption; commendably, low prevalence of smoking, but low physical activity among PHC professional nurses in Eastern Cape, South Africa. There is a need for the implementation of workplace wellness programmes that will foster healthy lifestyle behaviours among nurses in this setting.

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#### **Authors' Contributions**

SM, DTG and ES conceptualised and designed the study. EOO engaged in data collection, data analysis and drafting of the paper. All authors read and approved the final manuscript.

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# **Availability of Data**

Data from this study will be made available on request.

## **Competing Interests Statement**

The authors declare no conflict of interest.

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# Feasibility of Real-Time Mobile Phone Case Notification by Village Malaria Workers in Rural Myanmar: A Mixed Methods Study

Pyae Linn Aung<sup>1</sup>, Tepanata Pumpaibool<sup>1</sup>, Than Naing Soe<sup>2</sup> & Myat Phone Kyaw<sup>3</sup>

Correspondence: Tepanata Pumpaibool and Pyae Linn Aung, College of Public Health Science, Chulalongkorn University, Bangkok, 11330, Thailand. E-mail: Tepanata.P@chula.ac.th; pyaelinnag@gmail.com

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#### Abstract

Malaria burden has markedly decreased in Myanmar and is on course for elimination by 2030. Interrupting of local transmission is essential, and timely notification within 24 hours of disease occurrence by frontline village malaria workers (VMWs) is a crucial initial component of timely follow-up by response teams. Here we studied the feasibility of real-time case notification using mobile phones among VMWs in the remote Banmauk Township, Sagaing Region, Myanmar. A structured quantitative and qualitative questionnaire was used for data collection after implementing the intervention for six months between May and October 2018. Ten VMWs from the National Malaria Control Programme (NMCP) in ten scattered villages from the township were randomly recruited and given one day of on-site training on reporting methods and how to use their own mobile phone. VMWs received 5,000MMK (approximately 3USD) per month remuneration. The baseline demographics of VMWs were not significantly different. Twenty-four out of 25 (96%) malaria patients were notified within 24 hours by the ten VMWs during the study period. All submitted information were said to be complete and correct. VMWs suggested the system as simple and acceptable despite some challenges. In the qualitative study, almost all VMWs were satisfied with the system and willing to use it in the future. This mobile phone reporting system is more efficient and easier to use than other more complicated online mobile applications. However, only a few indicators can be submitted using this approach and the system cannot be used in areas without network coverage.

Keywords: real-time reporting, mobile Phone, case Notification, village malaria workers, Myanmar

# 1. Introduction

Despite markedly decreasing trends of both malaria morbidity and mortality, in 2016, around 43 millions of people are still living in 291 malaria endemic townships out of 330 in Myanmar. Among them, almost 105,000 cases have been confirmed malaria when 21 deaths were recorded (Department of Public Health [DOPH], 2016; World Health Organization [WHO], 2017). It drastically declined in compare with 1,707 deaths and 516,041 cases of malaria from 2010 (DOPH, 2016). Thus, Myanmar is now on course for elimination by 2030. In the elimination phase, the country should concentrate on detecting every symptomatic and asymptomatic infections and reacting to every confirmed case. Once a local case of malaria has been found and notified, a focus investigation is carried out by malaria staff within 72 hours (3 days) to describe the locality where malaria occurred for determining the underlying causes of ongoing transmission, and rapid measures (responses) should be applied in a given focus as early as possible but not later than 7 days to interrupt transmission and prevent its further spread (Cao et al., 2014; Feng et al., 2016; Wang et al., 2017). This particular can be handled by a township level malaria rapid response team (DOPH, 2016; WHO, 2012). Recording and reporting mechanisms and the systems within existing public, private and community-based health sectors should be established to address elimination challenges by timely detecting and immediately notifying the malaria programme of all confirmed cases by the fastest means possible. Although some kinds of smart phone based reporting system like DHIS-II and M-health have been introducing in Myanmar since 2017, overall coverage area is still low as in pilot stage and acceptability among providers is still trying to encourage (DOPH, 2016).

Again, the goal of eliminating malaria in Myanmar is more distant because the rapidity in achieving the declared

<sup>&</sup>lt;sup>1</sup> College of Public Health Science, Chulalongkorn University, Bangkok, Thailand

<sup>&</sup>lt;sup>2</sup> Disease Control, Department of Public Health, Naypyitaw, Myanmar

<sup>&</sup>lt;sup>3</sup> Department of Medical Research, Lower Myanmar

goal is influenced by the relatively high burden of malaria, the suboptimal development of national health systems and technical and operational constraints (resistance to antimalarial drugs, vector behaviours, accessibility of remote/border areas, uncontrolled migration etc.). In areas with poor public health infrastructure and services, the establishment of a network of Village Malaria Workers (VMWs) is the best and often only option to reach the total coverage of curative and preventive services, in order to detect, notify and treat every malaria infection in a proper and timely manner (Phommanivong et al., 2010). Currently in Myanmar, over 15,000 VMWs are scattering around the country and supported by 24 different implementing organizations including Vector Borne Disease Control (VBDC) team under National Malaria Control Programme (NMCP) (WHO, 2017; Myanmar Information Management Unit, 2018). Thus, while interrupting of local transmission is essential, timely notification within 24 hours of disease occurrence by frontline village malaria workers (VMWs) become a crucial initial component of timely follow-up by response teams. Globally, studies have found that mobile phone based malaria reporting system is an acceptable and feasible intervention for lay health workers and one that can significantly affect program operations and malaria transmission rates (Hamainza et al., 2014; Kukula et al., 2015; Meankaew et al., 2010; Kamanga et al., 2010). However, feasibility, acceptability and data quality should be assured while simple style of intervention is encouraged (Prue et al., 2013; Rassi et al., 2018).

In Myanmar, mobile SIM cards were not freely available and even cost more than hundreds of dollars until 2013. But since then, it has been transformed and become cheaper and cheaper as less than 2 USD in 2015 (LIRNE Asia, 2017). Nowadays, SIMs are freely available across the country and 90% of areas have network signal coverage. In 2015, 40% of total population owned a mobile phone (Galpaya, Zainudeen & Suthaharan, 2015). According to universal service strategy for Myanmar (2018-2022), most of the people (90%) will be covered by network and among them, around 85% will have internet access by 2022 (Post and Telecom Department, 2018). Particularly in Sagaing Region, only 4.2% of the area are uncovered by facility as of January 2018 (Zainudeen & Galpaya, 2015). To take advantage from this, in this study, a simple mobile phone reporting system was introduced among VMWs and evaluated from the aspects of timeliness of reporting, correctness and completeness of information, preference and challenges on using the system and acceptability for the future. Hence, this study will contribute evidence for the feasibility of real-time case notification using mobile phones among VMWs in the remote Banmauk Township, Sagaing Region, Myanmar, where real time reporting is rare but technology literacy is relatively high.

# 2. Methods

This study was conducted in ten villages of Banmauk Township, Sagaing Region, Myanmar. The township is located in the upper region of the country and consists of 223 villages. Four different organisations are performing intensive malaria control activities under the sponsorship of different donors. However, the Vector Borne Disease Control (VBDC) team of the National Malaria Control Programme (NMCP) under the supervision of the Township Medical Officer (TMO) plays an administrative and collaborative role and ensures that these activities do not overlap and that all villages are included. In general, the VMWs were residents of the various villages and were recruited on a voluntary basis after being nominated by the local authorities. After receiving five days of recruitment training, they were assigned to conduct malaria diagnosis and treatment and route data recording into carbonless paper report. They also participate in three days of annual refresher training. Malaria commodities, including rapid diagnostic tests (combo RDTs), artemisinin-based combination therapy (Artemeter plus Lumefantrine) tablets, disposable gloves, safety boxes, and behavioural change communication materials, such as pamphlets and posters, were distributed through a township-level supply chain. Monthly monitoring and supervision visits were also routinely conducted by the VBDC team, which relied on a standard checklist.



Figure 1. The ten study villages in Banmauk Township, Sagaing Region, Myanmar

As study participants, ten out of 50 VMWs trained and supported by VBDC team in ten scattered villages (Figure 1) from the township were randomly recruited and given one day of on-site training on reporting methods and how to use their own mobile phone along with the practical session. A hot-line number was provided and saved into their phone contact list. From each malaria patient, necessary information to be addressed for briefly case classification and also for routing surveillance purpose, date & time of diagnosis, age, sex, parasite species, travelling history and treatment given were collected and reported through a call. There was an assigned field supervisor at township level and responsible for receiving calls and recording of data from each VMW into a checklist paper. Then data were translated into English language, entry into computer and back up regularly into a password protected hard disk. (Figure 2) As a regular incentive, 5,000MMK (approximately 3USD) per month remuneration was provided. At the end of each month, the mobile bill has been directly filled with e-load system into registered number of each volunteer and ensured of receipt by a call. It is like a standard amount and regular top up regardless of number of patients found.

In addition to the data tracking checklist, a structured quantitative and qualitative questionnaire was used for data collection after implementing the intervention for six months between May and October 2018. It constructed with two parts; the quantitative part consisted of demographic characteristics of each VMW, simplicity of system, their acceptability, preferences and other challenges. The qualitative part explored for their overall comments as well as suggestions on this reporting system. At the end of October, data were collected at their village with the help of two graduated data collectors. In the meantime, the compiled data from checklist were cross-checked with their field carbonless data entry. Feedback on any discrepancies was provided and supported of solutions during monthly monitoring visit as well as at the end of project. Timeliness, correctness and overall completeness were also concluded. At the beginning of project, consent form was requested and signed by each VMW and for the ethical issue, this study was reviewed and approved by the Institutional Technical and Ethical Review Board, University of Public Health - Yangon, Ministry of Health & Sports (UPH-IRB 2018/Research/29). Data were encoded, entry and analysed by Microsoft excel 2015 for descriptive statistics.

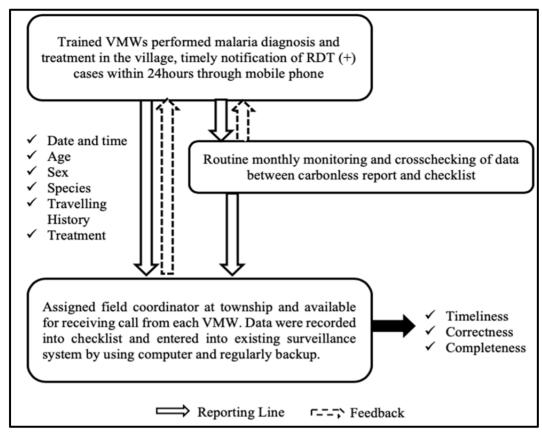


Figure 2. Mobile phone reporting system flow chart

## 3. Results

First, the baseline demographic characteristics of VMWs are reported in Table 1, revealing similar distribution of age, sex, and family income among study participants. Moreover, majority of the respondents are educated at the primary school level (70.0%), and while all the VMWs possess a mobile phone, 90% are using smart phone. During the study period, 24 of the 25 malaria patients (96%) were notified within 24 hours by the ten VMWs. Two (8.0%) of these cases were reported within 10–15 hours, while most of the remaining patients (88.0%) could be informed within 1 hour from the diagnosis. Unfortunately, there was a delayed case notification only after 24 hours. (Figure 3)

Table 1. Baseline demographic characteristics of VMWs (n=10)

Characteristics	Frequency	Percentage (%)
Age		
<30 Years	4	40.0
> 30 Years	6	60.0
Mean±SD	28.5±5.3	
Sex		
Male	4	40.0
Female	6	60.0
Family Income		
Enough	4	40.0
Not enough	6	60.0
Education		

Primary School	7	70.0	
Above primary school	3	30.0	
Ownership a mobile phone			
Yes	10	100	
No	0	0	
Types of mobile handset			
Smart Phone (Touch Screen)	9	90.0	
Key-pad	1	10.0	

<sup>\*</sup>SD=Standard deviation.

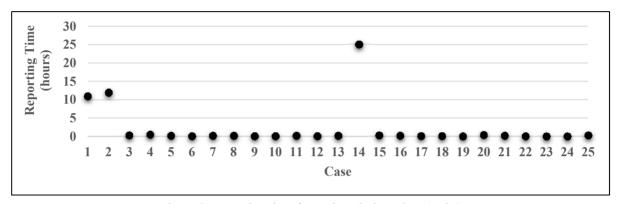


Figure 3. Reporting time for each malaria patient (n=25)

The findings pertaining to timeliness, correctness, and completeness of the information received from volunteers are summarized in Table 2. The median reporting time was 0.2 hours, and only one case (4.0%) was reported after the designated 24-hour period. On the other hand, all the variables were more than 95% correct when cross-checked between reports. Similarly, all questionnaire items were at least 95% complete, with the exception of age, which was provided by only 84% of the patients. Finally, timeliness analyses revealed that, in 96% of cases, patients could be notified within 24 hours, while full completeness and completeness were 92% and 80%, respectively (Figure 4).

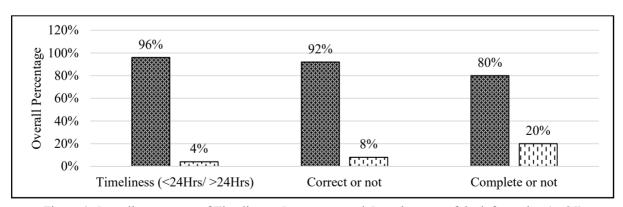


Figure 4. Overall percentage of Timeliness, Correctness and Completeness of the information (n=25)

Table 2. Timeliness, Correctness, Completeness of the information (n=25)

Descriptions	Frequency	Percentage (%)
Timeliness		
<24 Hours	24	96.0
Median	0.2 Hour	
>24 Hours	1	4.0
Correctness		
Date & time of diagnosis		
Correct	24	96.0
Incorrect	1	4.0
Age		
Correct	23	92.0
Incorrect	2	8.0
Sex		
Correct	25	100
Incorrect	0	0
Species		
Correct	24	96.0
Incorrect	1	4.0
Travelling History		
Correct	25	100
Incorrect	0	0
Treatment Given		
Correct	25	100
Incorrect	0	0
Completeness of Information		
Date & time of diagnosis		
Complete	24	96.0
Incomplete	1	4.0
Age		
Complete	21	84.0
Incomplete	4	16.0
Sex		
Complete	24	96.0
Incomplete	1	4.0
Species		
Complete	24	96.0
Incomplete	1	4.0
Travelling History		
Complete	25	100
Incomplete	0	0
Treatment Given		
Complete	24	96.0
Incomplete	1	4.0

When VMWs were asked to share their overall perceptions of this reporting system, 80% of the study sample suggested that it is simple and easy to utilize, while 90% of the respondents stated that they would accept implementation of this intervention. However, some individuals experienced difficulties using the application, such as poor signal (20%), time consuming (10%), and other challenges (10%), as shown in Table 3.

Table 3. Simplicity, acceptability, preferences and challenges among 10 VMWs regarding intervention

Descriptions	Frequency	Percentage (%)
Simplicity		
Yes	8	80.0
No	2	20.0
Acceptability		
Yes	9	90.0
No	1	10.0
Preferences		
Like	10	100
Unlike	0	0
Challenges		
Nil	6	60.0
Poor Signal	2	20.0
Time consuming	1	10.0
Others (Hearing Problem, etc.)	1	10.0

All the VMWs rated the system as reliable and felt that it was a viable reporting channel for timely notification of disease occurrence. Some of the reviews they provided following this qualitative study are summarized below:

It is particularly noteworthy that all participants were satisfied with the training provided, as well as the routine monitoring visits from the township level and the telephone bill remuneration. Moreover, despite some challenges noted above, most respondents would be willing to continue using this intervention.

## 4. Discussion

With the exception of education level and ownership of a mobile phone, the distribution of the baseline demographic characteristics of the VMWs was similar. In remote areas of Myanmar, a primary level education is most common because those seeking further study must travel to a middle or high school, most of which are located in central, downtown regions. However, according to the national criteria, being a VMW requires only the ability to read and write (Chongsuvivatwong, 2012). In addition, before the system was introduced, all VMWs owned at least a functioning mobile phone (mobile networks were expanded across the Sagaing Region in 2017) (LIRNE Asia, 2017). During the study period, a total of 25 malaria patients were identified by VMWs, of which 24 were reported through the mobile phone reporting system within 24 hours. In addition to early diagnosis and

<sup>&#</sup>x27;It was a great opportunity to learn such a new reporting system. As a result, I am more confident in treating my patients.'

<sup>&#</sup>x27;As network signal is sometimes terrible, I have to dial repeatedly and often have to call back three to four times.'

<sup>&#</sup>x27;To be honest, as malaria cases are becoming rarer, having one's mobile bill paid by the project is more than enough to promote the application use.'

<sup>&#</sup>x27;As not all people in this region know their exact age, we sometimes have to estimate.'

<sup>&#</sup>x27;Using the system is simple and a routine work, so I guess that we should continue using this reporting channel in the future.'

<sup>&#</sup>x27;I would say that I am overall satisfied with this kind of system, and have had no challenges using it.'

<sup>&#</sup>x27;We should call the hotline number as soon as we have found the patient, as we may otherwise forget.'

treatment, such real-time reporting is the essential step needed to carry out further case classification and foci investigations as well as to conduct management activities to fulfil the goal of malaria elimination, i.e., to interrupt the progress of locally acquired transmission of the disease (WHO, 2015; WHO, 2016). A study conducted in Tanzania (Francis et al., 2017) and Kenya (Soti et al., 2015) suggested that real-time notification through a mobile phone or mobile application was a feasible and practical approach. However, as discrepancies can occur between report and actual data, a regular, intensive monitoring system must be implemented (Githinji et al., 2014). Public health staff should manage the work of VMWs and other volunteers in collaboration with relevant malaria health personnel. A proper national guide should be developed to assist in implementation of VMW-related interventions, including regular supervision of their activities.

In this study, satisfactory levels of data accuracy and completeness were noted. By using a simple and user-friendly version of the intervention, the providers appeared to adhere closely to the guidelines and directions (Prue et al., 2013; Quan, Hulth, Kok & Blumberg, 2014). However, only (80%) accuracy was noted in terms of the reporting of patient ages. This was likely due to the typical practice of the local residents, who are either unaware of their correct age or who calculate it incorrectly due to the complicated Myanmar calendar year. It would provide a significant advantage if exact census information could be gathered on all residents. In addition, typing errors were observed in reports of patient data, such as age, date and time of diagnosis, and species classification. These errors likely occurred because of the difficulty of typing on a smartphone. Such errors were most often committed by female VMWs as, in Myanmar, men are generally more accustomed to working with technological devices, such as mobile phones, tablets, and computers (LIRNE Asia, 2017). To evaluate the implemented system, a follow-up study was organized to explore the overall perceptions of the VMWs. Most described the manner of reporting as easy, acceptable, and feasible to continue. One related study, conducted in Bangladesh (Prue et al., 2013) and South Africa (Quan, Hulth, Kok & Blumberg, 2014), also demonstrated the acceptability and ease of using a mobile phone reporting system. However, some challenges were reported, including concerns about network signals, prolonged reporting time, and other challenges, such as hearing difficulties. To overcome these issues, when the elimination continuum begins in this area, an alternative means of timely reporting, in addition to mobile phones and/or a traditional reporting system, should be secured. Moreover, other options for follow-up action should be made available to interrupt the transmission of malaria in the event of delayed notification. As it relates to network signals, these cannot be controlled, and it is hoped that signal strength will improve in the near future, as has been announced by the strategic plan (Post and Telecom Department, 2018).

During qualitative review, all of the VMWs described the system as reliable and useful, although they did mention some challenges. They also offered their preferences regarding an incentive scheme, monitoring visits, and training. To sustain both the intervention and VMW performance, there should be a regular incentive scheme, refresher trainings, regular monitoring, and a feedback system (Aung et al., 2018; Nyunt et al., 2016). Next, malaria and general health staff, with the support of VMWs, should develop materials and organize campaigns to inform communities about the availability of free malaria diagnosis and treatment at public health facilities as well as from VMWs to increase public usage of the service and avoid delayed reporting.

### 5. Conclusions

The results of this study demonstrate that the simple, efficient, and user-friendly mobile phone reporting system helps ensure timely and acceptable reporting of malaria cases by VMWs. For in-time disease notification purposes, this approach is better than more complicated, internet-based mobile applications. Regular monitoring should be implemented to address challenges with the completeness and accuracy of surveillance data. Some type of incentive scheme might be helpful in achieving better performance from the VMWs. The success of the reporting system notwithstanding, only a few indicators can be submitted using this mobile-based approach, and the system cannot be used in areas without adequate cellular network coverage. Future studies should expand the number of study participants and, if possible, compare them with the control villages. The sustainability issue should also be addressed by the consortium of health programmes, stakeholders, and local authorities as well as the donors. At the same time, it is important to exercise caution regarding overburdening the VMWs with the sudden introduction of new techniques and advanced tools.

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# **Competing Interests Statement**

The Author(s) declare(s) that they have no conflicts of interest.

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# Design and Validation of Questionnaires Investigating Access and Utilization of Cervical Cancer Treatment and Palliative Care

Oscar Tapera<sup>1</sup>, Greta Dreyer<sup>2</sup>, Babill Stray-Pedersen<sup>3</sup> & Stephen James Heinrich Hendricks<sup>1,4</sup>

Correspondence: Oscar Tapera, University of Pretoria, School of Health Systems and Public Health, 7-43 H.W. Snyman Building, Pretoria, South Africa. Tel: 26-377-254-9345. E-mail: oscar.tapera@gmail.com

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## **Abstract**

**Background:** Standardized tools to evaluate access and utilization of cervical cancer treatment and care remain scarce in developing countries. The objective of this study was to validate questionnaires to investigate access and uptake of cervical cancer treatment and palliative care.

Materials and Methods: We designed and validated two questionnaires for patient and community and health worker surveys to determine the main constructs of each of the draft questionnaires. Pilot data was collected randomly amongst 50 patient and community participants and 14 health workers respectively in Chitungwiza, Zimbabwe. Content and face validity were assessed qualitatively from expert evaluations. Construct validity, reliability and internal consistency testing were conducted using exploratory factor analysis and Cronbach's alpha correlation coefficient respectively.

Results: Twelve (12) experienced researchers, based on convenience, reviewed the questionnaires and validated their draft constructs based on experience and literature. Each of the questionnaires was sub-divided into 4 separate mini-questionnaires respectively. All the eight mini-questionnaires were analyzed independently and Kaiser-Meyer-Olkin coefficients ranged from 0.5-0.9 and Bartlett's sphericity tests were all significant, p<0.001, showing promising good constructs. Patient and community questionnaire had 15 meaningful constructs while the health worker questionnaire had 13. Cronbach's alpha ( $\alpha$ ) coefficients for internal consistency reliability testing of all the final constructs were greater than the minimum acceptable threshold of 0.70.

**Conclusion:** This analysis revealed the validity and reliability of questionnaires that could be used to evaluate access and utilization of cervical cancer treatment and palliative care in countries affected by the disease.

**Keywords:** cervical cancer, access, utilization, construct, questionnaire, validity, reliability, exploratory factor analysis, Cronbach's alpha

# 1. Background

Cervical cancer is the fourth most commonly diagnosed cancer amongst women worldwide and the most prevalent cancer in Zimbabwe's female population (Bruni et al., 2016). About five million (60%) of the 15–49 year-old Zimbabwean female population is at risk of cervical cancer. (Nyakabau, 2014). Despite the increasing availability of prevention and screening programmes, morbidity and mortality rates remain very high due to limited, centralized treatment services (Nyakabau, 2014; Kuguyo et al., 2017). While access and utilization of treatment and care for cervical cancer remains a huge challenge predominantly due to limited resources (Kuguyo et al., 2017), standardized tools to measure them remain limited in Africa. Understanding service access and utilization patterns is the first step towards evidence-based programme improvement and formulation of relevant national policies. Generally, access to healthcare is a complex and multidimensional concept which has three dimensions namely: affordability, physical accessibility and acceptability of services (Sundaresan et al., 2016). Margolis et al. (1995) defined access to health care as the timely use of personal health services to achieve the best health outcomes. The

<sup>&</sup>lt;sup>1</sup> School of Health Systems and Public Health, University of Pretoria, Pretoria, South Africa

<sup>&</sup>lt;sup>2</sup> Gynaecologic Oncology, Department of Obstetrics and Gynaecology, University of Pretoria, Pretoria, South Africa

<sup>&</sup>lt;sup>3</sup> Institute of Clinical Medicine, University in Oslo and Womens' Clinic, Oslo University Hospital, Norway

<sup>&</sup>lt;sup>4</sup> SefakoMakgatho Health Sciences University, Pretoria, South Africa

difficulties in measuring access and utilization of health services are largely due to complexity of the concepts, subjectivity and contextual differences in understanding (Sundaresan et al., 2016). Assessment of access and utilization of health care services are also further complicated by the need to integrate evidence from both the supply (health system) and demand sides (patients/community).

Some standardized tools have been developed to evaluate access and uptake of other health services such as malaria prevention interventions, HIV/AIDS, family planning and other sexual reproductive health services (ZDHS, 2015). These tools have been used to assess access and utilization of health services or interventions from the demand side with little attempt to integrate the supply side. Furthermore, these tools have failed to capture full breadth of the ideas enshrined in access and utilization concepts and their psychometric attributes remain unknown. Another weakness of the tools used in population-level surveys is that some proxies are used to measure access and utilization with no data on items and scorings available publicly. No studies have been conducted to test and validate tools that may be used to evaluate access and utilization of cervical cancer treatment and care in Zimbabwe.

We conducted this study to address the identified gaps by developing and validating some of the constructs that may be used to measure access and utilization of cervical cancer treatment and care in developing countries. Demographic and socioeconomic variables were adopted from Zimbabwe Demographic and Health Surveys (ZDHS) of 2015 for the patient and community survey questionnaire (ZDHS, 2015). This tool was validated and used for several rounds of the DHS surveys in the country. The ZDHS wealth quintile asset variables were simplified by adopting the approach from previous work by Chakraborty et al. (2016) to shorten the questionnaire for ease of administration. Variables to measure access and utilization of cervical cancer treatment and care were adopted from ZDHS and literature (Bruni et al., 2016; Nyakabau, 2014; Kuguyo et al., 2017; Sundaresan et al., 2016; Margolis et al., 1995; ZDHS, 2015; Andersen & Newman, 2005).

Several approaches have been developed and used to design and validate psychometrically sound questionnaires (Parsian & Dunning, 2009; Atkinson et al., 2011; Osborne et al., 2013; de JagerMeezenbroek et al., 2012; Yu & Richardson, 2015; Besnoy et al., 2016). In Australia, Parsian et al. (2009) reported the development and validation of a questionnaire to measure spirituality using content, face validity, construct validity using factor analysis, reliability and internal consistency testing using test-retest and Cronbach's alpha correlation coefficient. In another Australian study development of a tool to measure health literacy was done through consultative process involving workshops. The resultant tool was then validated using confirmatory factor analysis and item response theory (Osborne et al., 2013). In Netherlands, a questionnaire to measure spirituality was validated using Cronbach's alpha testing, factorial and convergent validity testing approaches (de JagerMeezenbroek et al., 2012). A four factor, 20 item questionnaire used to measure student online readiness in university freshmen was confirmed to be valid after exploratory factor analysis and Cronbach's alpha correlation coefficient approaches in USA (Yu & Richardson, 2015). A three factor brief pain assessment was validated to be superior to a one-factor model using confirmatory factor analysis by Atkinson et al. (2011) in New York, USA. A one factor model; traits, aptitudes, and behaviors score (TABS) tool was validated in southeastern USA for use by teachers to refer or nominate gifted students without bias using exploratory and confirmatory factor analyses (Besnoy et al., 2016).

This paper describes the conceptualization, psychometric development and validation of the new questionnaires based on approaches in literature. We endeavored to develop tools that could be used for the assessment of access and utilization of cervical cancer treatment and palliative care from population-level surveys through to programme improvement and policy formulation.

# 2. Methods

The methods used in the development and validation of the two study questionnaires included:

- Translational validity: content validity and face validity.
- Construct validity: exploratory factor analysis (EFA)
- Reliability test: internal consistency (Cronbach's alpha)

The process of validating the questionnaires is illustrated in Figure 1.The initial phase of the tool development involved extensive literature review of relevant publications to identify important domains related to the measurement of access and utilization of cervical cancer treatment and palliative care. A consultative process followed with cancer specialists, public health experts, policy makers and some patients to develop draft constructs. Validated tools used in recent surveys in Zimbabwe were also used to guide the development of draft constructs for both questionnaires (ZDHS, 2015). The ideas from literature, consultations and existing tools were used to develop the constructs and items for the drafts questionnaires. The draft tools were then tested after obtaining written

consent from patients, community members and health workers in Chitungwiza, Zimbabwe in cross sectional surveys to identify meaningful and psychometrically valid constructs. The draft patient and community survey questionnaire consisted of four mini-questionnaires, 13 constructs and a total of 140 items (excluding participant socioeconomic and demographic characteristics. Health worker survey questionnaire consisted of four mini-questionnaires, 6 constructs and 116 items (excluding health facility characteristics).

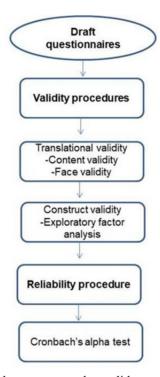


Figure 1. A flow chart depicting the process used to validate patient, community and health worker questionnnaires (Parsian & Dunning, 2009)

# 2.1 Translation Validity

# 2.1.1 Content Validity

Content validity was conducted to examine if the content of the two study questionnaires were appropriate and relevant to the study purpose. Content validity shows a complete range of attributes under study and it is usually carried out by at least seven (7) experts (Parsian & Dunning, 2009). To estimate the content validity of the two questionnaires, we defined the conceptual framework for access and utilization of cervical cancer treatment and palliative care using literature and seeking expert opinions. For this study the health utilization model (Andersen & Newman, 2005), was used as the conceptual framework. At least 12 purposively selected experts in the areas of research, public health, oncology, health policy, gynaecology and biostatistics were chosen to review the two questionnaires with 140 and 116 items, respectively. The experts reviewed the appropriateness and relevance of questions to answer the research questions for the study. The validity of each questionnaire was based on the qualitative comments or suggestions for improvements from the reviewers.

# 2.1.2 Face Validity

Face validity shows the appropriateness of a questionnaire to the purpose of the study and content area. Though this is the easiest validation process, it is the weakest as it measures the appearance of questionnaire in terms of feasibility, readability, consistency of style and formatting, and the clarity of the language used (Parsian and Dunning, 2009; DeVon et al.,2007). In order to assess the face validity of each of the two draft questionnaires in terms of readability, translations, contextual appropriateness of questions, length of questionnaire, formatting and flow of the tools, at least 12 purposively selected experts (oncologist, gynaecologist, public health specialists, social scientist and researchers) provided their evaluations through comments and suggestions for improvements. Secondly, a five member team of trained research assistants also reviewed and pre-tested the questionnaires through mock interviews and validity was determined by their qualitative evaluations.

# 2.1.3 Construct Validity

Construct validity refers to the degree to which an item on a questionnaire or data collection tool relates to the theoretical construct. It is used to determine how independent variable (construct) relates to the proxy dependent variable (indicator) (Parsian & Dunning, 2009). Cognitive interviewing, after obtaining consent, was conducted by administering questionnaires, eliciting responses to questions, and collecting additional information from respondents about how they understood the questions and how they selected their responses. The approach helps the researcher to be able to elicit the right data from the questions being asked (O'Sullivan & Rasmussen, 2017). This was done amongst 13 randomly selected participants in Harare until no more modification of the tools was required. When an indicator has multiple items, factor analysis is imperative (Parsian & Dunning, 2009) and for this study, exploratory factor analysis was applied to validate the draft constructs in the two questionnaires. The sample sizes for the exploratory analysis of n the patient and community questionnaire and the health worker tool were 50 and 12 respectively based on literature (Parsian & Dunning, 2009; DeVon et al., 2007).

Factor analysis is broadly used to summarize data so that relationships and patterns can be better understood (Yong & Pearce, 2013). It is a useful technique during questionnaire development and validation as it groups up items into common factors; interpret each factor on the basis of item loading and summarizing items into smaller items. Therefore, a factor is a list of items that can be clustered together (Bryman & Cramer, 1991). Loadings measure the relationship between an item and its factor and are used to identify items that could be lumped into a factor based on their magnitude. Unrelated items, those with low factor loadings, do not define a construct and should be deleted from the tool (Parsian & Dunning, 2009). Exploratory factor analysis (EFA) is applied to explore complex patterns within datasets and testing predictions. There are some conditions that need to be satisfied for EFA to be valid and these include:

- I. data must be normally distributed;
- II. no outliers;
- III. factor should have at least 3 items, though this depends on the design of the study;
- IV. variables under factor analysis should have at least 5-10 observations

In the analysis factors, we extracted factors based on two criteria; Kaiser's criteria and scree plots made in *STATA* version 14 (StataCorp LLC, Texas). Orthogonal varimax rotations were also conducted to produce factor structures that are uncorrelated to provide easier interpretation of results, and more parsimonious solutions (Brett et al., 2010). Factor analysis, like any other scientific method has its limitations which include: challenges in naming factors, some factors may be loaded onto others making interpretation difficulty, need for large sample sizes and using singular datasets collected at specific time points, and if collected at different points datasets cannot be combined for factor analysis (Yong & Pearce, 2013).

Sample size adequacy for the questionnaires for factor analysis was assessed using KMO statistic and the estimates ranged from 0.5-0.9 (see Tables 1-4). The KMO statistic values lie between 0 and 1, with values closer to 1 showing that factor analysis is appropriate. Zero value indicates that the sum of partial correlations is larger than the sum of the correlations, indicating dispersion in the pattern of correlations, thus rendering factor analysis inappropriate for analysis (Chakraborty et al., 2016). KMO estimates  $\geq$  0.5 are acceptable, 0.5-0.7 are mediocre, 0.8-0.9 are great and  $\geq$ 0.9 are superb (Kaiser, 1974). On running factor analysis, factor extraction was conducted based on Kaiser's criterion of eigenvalues  $\geq$ 1 and scree plots (see Figure 2) to determine the number of factors to be retained for each questionnaire. Items with communalities <0.5 were deleted from the factor solutions (Parsian & Dunning, 2009). Some researchers recommended that a factor is reliable if it has at least three items (Castello & Parsian, 2005).

We conducted EFA on data collected randomly during pilot testing using each of the two draft questionnaires based on the approaches above. Given the complexities of measuring access and utilization of health services in general and the several hypotheses under investigation in the study, the two draft questionnaires had many variables to fully understand demand (patients/communities) and supply side issues (health workers) based on literature and the theoretical framework (Andersen-Newman health model). This necessitated us to analyze the data in mini-questionnaire formats based on the draft constructs to avoid Heywood case in factor analysis (Castello & Parsian, 2005). Heywood case or negative variance estimates are common errors in factor analysis and given their impossibility their causes need to be understood. Some of the causes of Heywood case include outliers, non-convergence, empirical underidentification, structurally misspecified models or sampling fluctuations (Castello & Parsian, 2005; Kolenikov & Bollen, 2012). Furthermore, our approach made interpretation of outputs easier and resulted in meaningful factor models.

# 2.2 Reliability Testing

Upon completion of the validity procedures, internal consistency reliability testing was conducted on each of the meaningful constructs derived from the two questionnaires. Reliability is defined as the ability of a tool to measure an attribute and how well the items fit together conceptually (Parsian & Dunning, 2009). In tool design and validation, reliability is important but it is not sufficient to validate the tool and it is possible to have a reliable but invalid tool. Some researchers have recommended that reliability testing be conducted on validated tools. Two estimators are reported in literature to measure reliability: test-retest reliability and internal consistency reliability (Parsian & Dunning, 2009; DeVon et al., 2007). The most commonly used method is the internal consistency reliability and this was used to test the two questionnaires in this present study.

Internal consistency is a measure of inter-item correlation within a tool and how well the item fit together within that instrument. The total score of the items is also determined to measure the overall internal consistency of the questionnaire. Split-half reliability and Cronbach's alpha correlation are the two approaches that can be used in determining internal consistency. However, Cronbach's alpha correlation is the most commonly used method as it also averages all the possible split-half estimates (Parsian & Dunning, 2009; DeVon et al., 2007).

Cronbach's alpha was estimated for each of the meaningful constructs in the mini-questionnaires of both tools designed to measure access and utilization of cervical cancer treatment and palliative care. The total scores for each mini-questionnaire were also computed to obtain overall internal consistency alpha coefficient estimates (Parsian & Dunning, 2009; DeVon et al., 2007).

## 3. Results

## 3.1 Content Validity

Experts reviewed the two questionnaires and evaluated them as clear and appropriate to the subject under investigation. Based on their qualitative evaluations, the tools were determined validity in terms of their content.

# 3.2 Face Validity

Experts, research assistants and participants who evaluated the questionnaires reported that they were understandable and acceptable for the intended target audience.

## 3.3 Factor Analysis

After excluding binary and string variables and applying Kaiser's criterion, all the questionnaires were acceptable for factor analysis (Brett et al., 2010), see Tables 1–4. Using the guidance of Hair et al. (1998) who reported that factor loadings  $\geq$ 0.4 were important, we applied the same criteria to retain items in factor solutions. Meaningful factors were ultimately retained for each questionnaire based on literature and the subject under investigation.

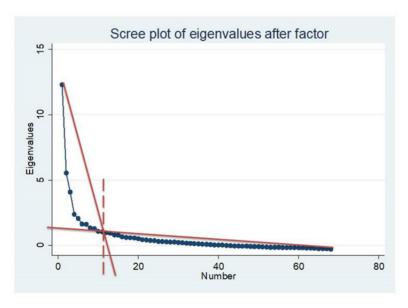


Figure 2. Scree plot retaining 11 factors in a questionnaire

Figure 2 shows a scree plot of questionnaire with 11 meaningful factors based on eigenvalues (Parsian& Dunning, 2009).

# 3.4 Internal Consistency Reliability Testing

Finally, once all the meaningful factors and items had been selected for each mini-questionnaire, we applied Cronbach's alpha correlation for internal consistency testing and all questionnaires had estimates  $\geq 0.7$ . The estimates showed that the questionnaires had high correlations amongst items and were consistently reliable. Some researchers have recommended alpha estimates  $\geq 0.9$ , though others suggested that alpha  $\geq 0.7$  is acceptable for new instruments (Parsian & Dunning, 2009; DeVon et al., 2007). We used 0.7 as our threshold in this study given that we were testing newly developed tools.

Table 1. Summary results from 15 factor solution of the final *Patient and Community* questionnaire from factor analysis and internal consistency testing for each factor

Ite	ms	КМО	Bartlett's test (p value)	Alpha (α)
1.	Knowledge of cervical cancer	0.7607	<0.001	0.75
a.	Knowledge about cervical cancer causes and treatment			0.80
b.	Sources of information			0.70
c.	Knowledge of palliative care			0.80
d.	Knowledge of cervical cancer treatment			0.70
2.	Access to cervical cancer treatment and palliative care	0.7150	<0.001	0.79
a.	Access to treatment and palliative care			0.94
b.	Health facilities that provide treatment and palliative care			0.70
c.	Health facilities that treat cervical cancer in Harare			0.73
3.	Utilization of cervical cancer treatment and palliative care	0.9016	<0.001	0.84
a.	Utilization of cervical cancer treatment and palliative care			0.89
b.	Challenges faced in accessing health services			0.75
c.	Access to cervical cancer screening			0.89
4.	Perceptions, attitudes and beliefs about cervical cancer treatment and palliative care	0.8132	<0.001	0.78
a.	Attitudes			0.88
b.	Availability of treatment and palliative care services			0.82
c.	Quality of care			0.70
d.	Perceptions about treatment services abroad			0.86
e.	Beliefs			0.70

The table above shows the questionnaire items from factor analysis and their KMO statistic and Cronbach's alpha coefficients which were acceptable based on literature- also see Table 3 (Appendix) (Parsian & Dunning, 2009; DeVon et al., 2007).

Table 2. Summary results from 13 factor solution of the final *Health Worker* questionnaire from factor analysis and internal consistency testing for each factor.

Ite	ns	KMO	Bartlett's test (p value)	Alpha (α)
1.	Health worker characteristics	0.532	<0.001	0.72
a.	Professional development			0.72
b.	Profession training			0.71
c.	Quality of care			0.70
d.	Working conditions			0.78
e.	Perception of cervical cancer strategies and policies			0.71
2.	Health facility characteristics	0.639	<0.001	0.79
a.	Characteristics of cervical cancer service providers			0.87
b.	Perceptions about provider quality of services			0.71
3.	Service characteristics	0.5	<0.001	0.70
a.	Cervical cancer services			0.70
b.	Cervical cancer service referrals			0.70
4.	Infrastructure, equipment and drugs capacity	0.538	<0.001	0.79
a.	Availability of basic services, equipment and drugs.			0.84
b.	Hygiene, sanitation and waste management capacity			0.70
c.	Supply of basic services, equipment and drugs.			0.70
d.	Availability drugs for treatment of cervical cancer.			0.91

Table 2 shows the questionnaire factor analysis items together with KMO statistic and Cronbach's alpha coefficient which were all within acceptable limits -also see Table 4 (Appendix) (Parsian& Dunning, 2009; DeVon et al.,2007).

# 4. Discussion

The integrity of any research data collection tool depends on accuracy of the measure being used particularly in the context of assessing complex phenomena such access and utilization of cervical cancer treatment and palliative care services. This study demonstrated the validity and reliability of the patient and community and health worker questionnaires to conduct both demand and supply side evaluations in the context of cervical cancer treatment and care services. The scientific approaches used in this study were rigorous and appropriate for the intended purposes. Face validity, while being the lowest form of validity was crucial in the administration of the tools amongst cervical cancer patients, healthy women in communities and health care workers. Content validity, which was measured qualitatively in this study, assisted in determining the relevance of content of both questionnaires to the concepts of access and utilization of cervical cancer treatment and palliative care. Exploratory factor analysis helped in assessing the theoretical constructs of the two questionnaires and meaningful factors were the ultimate outcomes of this analysis based on recommended best practices (Parsian and Dunning, 2009; Castello and Parsian, 2005). Cronbach's alpha (α) internal consistency reliability reached the acceptable threshold for both questionnaires. This demonstrates that the two questionnaires could be used confidently in clinical and public health practice to determine access and utilization of cervical cancer treatment and palliative care. These tools could also be used for programme improvement and policy formulation. The tools may be used to understand cervical cancer treatment and care gaps in order to design packages of interventions to address the limitations.

Understanding access and utilization of health care services is a fundamental public health priority though these concepts are difficult to measure given their complexities. However, this study provided psychometrically valid questionnaires to specifically measure access and utilization of cervical cancer treatment and palliative care. While it is plausible to extrapolate these tools to other cancers or disease areas, care must be taken to ensure their appropriateness given the differences in disease specific issues.

However, to strengthen scientific rigor, the researchers recommend further research using a bigger sample. Furthermore, the researchers endeavor to conduct extended analysis using structural equation modelling and

confirmatory factor analysis on a larger sample with diverse population that includes healthy women, cervical cancer patients and health care workers to support wider generalizability of the tools.

## 5. Conclusion

This study showed that patient and community and health worker survey questionnaires were valid and reliable and could be used to evaluate access and utilization of cervical cancer treatment and palliative care in countries affected by the disease. While a plethora of approaches have been developed and used in validating questionnaires in different fields of research, this present study presents a systematic and simplified approach that can be adopted by researchers investigating complex concepts.

5.1 Ethics Approval and Consent to Participate

This study was carried out as part of a PhD degree at the University of Pretoria and was approved by several ethics committees/bodies:

- 1) University of Pretoria, Faculty of Health Sciences Research Ethics Committee (REC 487/17)
- 2) Harare Hospital Ethics Committee (HCHEC 271017/77)
- 3) Joint Parirenyatwa and University of Zimbabwe Research Ethics committee (JREC 33A/18)
- 4) Medical Research Council of Zimbabwe (MRCZ/A/2271)

All participants in this study were consented in writing before interviews. Consent forms were administered by the researchers in the language of the participant's preference i.e English or Shona (local language spoken by majority of people in Zimbabwe).

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## **Competing Interests Statement**

The authors declare that there are no competing or potential conflicts of interest.

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# **Appendix**

Table 1. Full results from 15 factor solution of the final *Patient and Community* questionnaire from factor analysis and internal consistency testing for each factor

					Fact	or loa	ding	s										
Item	ıs	КМО	Bartlett's test (p value)	Alpha (α)	1	2	3	4	5	6	7	8 9	10	11	12	13	14	15
5.	Knowledge of cervical cancer	0.7607	<0.001	0.75														
e.	Knowledge about cervical cancer causes and treatment			0.80														
cerv	t are the causes of ical cancer that you wor have heard about?				0.64													
	is cervical cancer ented?				0.63													
	do you think cervical er may be treated?				0.51													
f.	Sources of information			0.70														
abou	nere did you hear/see at messages on ical cancer?					0.63												
	nere did you hear about ative care?					0.57												
g.	Knowledge of palliative care			0.80														
palli to ca inclu	e you ever heard about ative care that is given uncer patients uding those suffering a cervical cancer?						0.71											
	ere did you hear about ative care?						0.79	)										
	re are palliative care icesgiven in Harare?						0.70	)										
h.	Knowledge of cervical cancer treatment			0.70														
	ou think that cervical er can be treated?							0.55	5									
	w do you think it may eated?							0.54	ļ									

6.	Access to cervical cancer treatment				
	and palliative care	0.7150	< 0.001	0.79	
d.	Access to treatment			0.04	
	and palliative care			0.94	
If y	ou were to be				
	nosed of cervical				
	cer today do you think				
-	would have access to				0.91
	tment and palliative services in Harare?				
	ere would you go to c treatment?				
	ere would you go to				0.57
	for palliative care				
serv	rices?				0.85
	you currently				
	essing cervical cancer				
	tment or palliative				0.97
care	:?				
	at made you go for				0.96
	rical cancer screening				
just	before your diagnosis?				
Who	ere you were first				0.85
scre	ened and suspected of				
cerv	rical cancer?				
Do	you have access to				0.98
trea	tment for your				0.70
con	dition?				
Hov	v much have you paid				0.69
	re you paying on				
avei	rage for your treatment				
in o	ne month?				
e.	Health facilities				
	that provide				
	treatment and			0.70	
	palliative care				
Gen	erally, where would				0.54
	go or refer someone				
	cervical cancer				
pall	iative care services?				
Who	ere do you think people				
	be treated of cervical				0.50
can	er in Harare?				
Who	ere would you go to				0.50
seek	treatment?				
Who	ere would you go to				
	for palliative care				0.66
serv	rices?				
f.	Health facilities			0.73	
	that treat cervical			V.13	

cancer in Harare	
Where do you think people can be treated of cervical	
cancer in Harare?	0.64
	0.64
Where would you go to seek treatment?	
	0.49
Where were you referred	
for further investigations (histological tests) to	0.47
confirm your diagnosis?	
Where were you	0.45
commenced on treatment?	0.45
7. Utilization of	
cervical cancer 0.84	
treatment and $0.9016 < 0.001$	
palliative care	
d. Utilization of	
cervical cancer 0.89	
treatment and	
palliative care	
Do you have a regular	
doctor whom you see when you require health	0.92
services	
If you are not feeling well where would you go first?	0.64
If you were to be given	0.04
some medication or	
treatment for a disease	0.98
would adhere to it	
Have you ever been	
screened for cervical	0.91
cancer?	0.21
Who do you believe can	
manage cervical cancer	
better?	0.85
What challenges do you	
usually face in using	
health services?	0.65
How many times have you	0.05
visited your health facility	
or doctor for	
treatment/check up in the last 6 months?	0.51
Do you have a regular doctor whom you see	
when you require health	0.00
services?	0.98
What treatment are you on	
or have you received for	
your condition?	0.93
•	

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affo	e (Were) these fees ordable to you or your usehold?			
Wh	o do you believe can			0.98
bett	ter?			0.93
	at challenges do you ally face in using			0.72
e.	Challenges faced in accessing health services		0.75	
usu	hat challenges do you ally face in using lth services?			0.72
f.	Access to cervical cancer screening		0.89	
	ere were you screened?			0.78 0.79
scre	eening] affordable to or your household?			0.79
8.	Perceptions, attitudes and beliefs about cervical cancer	0.8132 < 0.001	0.79	
	treatment and palliative care	0.8132 < 0.001	0.78	
f.	Attitudes		0.88	
of c	an discuss experiences ervical cancer with my aily members.			0.59
of c	n discuss experiences ervical cancer with my nds.			0.51
can	areness of cervical cer is done in my nmunity			0.52
cerv	e local hospital offers vical cancer screening women.			0.54
cerv	e local hospital offers vical cancer cination to young girls.			0.50
[wo	partner/husband ould] supports me to go			0.64

0.58

for cervical

My partner/husband [would] support me to go

for cervical cancer treatment.		
My friends support me to go for cervical cancer treatment.		0.57
My family supports me to go forcervical cancer		0.59
treatment.		0.67
I encourage others to be screened and treated for cervical cancer		
I am too busy to go for cervical cancer treatment [R]		0.60
I do not have time to go for cervical cancer		0.57
treatment [R].  Cervical cancer treatment procedure is embarrassing [R].		0.51
Screening is important for early treatment of cervical cancer.		0.60
Cervical cancer treatment saves lives		0.64
Cervical cancer treatment gives a woman and their family peace of mind.		0.56
Cervical cancer treatment gives a woman control over her health.		0.52
HIV testing is optional when being screened for cervical cancer.		0.50
Cervical cancer treatment is for all women regardless of background		0.56
I am responsible for my health.		0.51
Test results for cervical cancer screening are immediate		0.53
Cervical cancer screening does not take too long.		0.52
g. Availability of treatment and palliative care services	0.82	
The local hospital offers treatment to women with		0.62

Health care workers who perform cervical cancer treatment are very helpful.						
i.	Perceptions about treatment services abroad	0.86				

perform cervical cancer treatment are well trained.

I get better value for money for cervical cancer	
treatment abroad than in	0.41
my local hospital/clinic.	
Cervical cancer treatment is best done abroad.	0.47
Health professionals	0.57
abroad provide better care for cervical cancer	
patients.	
Cervical cancer patients	0.53
treated abroad have better survival chances	
i Reliefs	
0.70	
	0.42
Cervical cancer patients	
should not be stigmatized.	
I encourage others to be	0.45
screened and treated for cervical cancer.	
I am afraid of cervical	
cancer treatment [R].	0.47
Getting results of cervical	
cancer screening is scary [R].	0.46
Women should go for	
cervical cancer screening only when they experience	
serious health problems	0.45
[R].	
Cervical cancer treatment is for people with money	0.47
[R].	0.47
Cervical cancer screening	
is for promiscuous people [R].	0.46
I am too busy to go for	
cervical cancer treatment	
[R].	
I do not have time to go for cervical cancer treatment	0.48
[R].	
Cervical cancer treatment	0.49
procedure is embarrassing	
[R].	
	0.43

Table 2. Full results from 13 factor solution of the final *Health Worker* questionnaire from factor analysis and internal consistency testing for each factor.

									Fac	ctor lo	ading	S				
Items	KMO	Bartlett's test (p value)	Alpha (α)	1	2	3	4	5	6	7	8	9	10	11	12	13
5. Health worker characteristics	0.532	<0.001	0.72													
d. Professional development			0.72													
Have you ever received any on-the job training on cervical cancer treatment and palliative care?				0.74												
Do you feel that you have received adequate training to provide cervical cancer treatment and palliative care services?				0.55												
Does your employer support your continuous professional development (CPD) in cervical cancer treatment and palliative care?				0.51												
Have you read or heard about the Zimbabwe Cervical Cancer Prevention and Control Strategy (2016-2020)?				0.65												
What are the general perceptions of cervical cancer patients and their families on the services you provide in this facility?																
e. Profession training			0.71													
What is your profession? Where did you receive your basic professional training?					0.49 0.66											
Where did you receive your specialist training?					0.40											
f. Quality of care			0.70													
Do most of your cervical cancer patients adhere to prescribed treatments?						0.53										
Are you motivated to provide your services to cervical cancer patients in this facility?						0.47	,									
d. Working conditions			0.78													
How many hours do you work in a week?							0.4	6								
Do you think the benefits (salaries and allowances) you are receiving are commensurate with the services you provide to cervical							0.4	9								

cancer patients?			
e. Perception of cervical cancer		0.71	
strategies and policies		0.71	
Does your facility have clinical guidelines for the treatment and palliation of cervical cancer patients?			0.44
Have you read or heard about The National Cancer Prevention and Control Strategy for Zimbabwe (2013-2017)?			
Have you read or heard about the Zimbabwe Cervical Cancer Prevention and Control Strategy (2016-2020)?			0.51
Do you think Zimbabwe has adequate policies and strategies for the treatment and management of cervical cancer?			0.46
Do you think that the cervical cancer surveillance system is adequate in the Zimbabwe to account for every case?			
6. Health facility characteristics	0.639 <0.001	0.79	
a. Characteristics of cervical			
cancer service providers		0.87	
Who owns this facility			0.92
Who mainly pays the salaries of staff at this facility?			0.96
Who mainly pays for running costs for this facility?			0.66
What is the type of the health facility?			0.90
b. Perceptions about provider quality of services		0.71	
			2.62
Besides health services where else are cervical cancer patients seeking help for their conditions?			0.60
Do you think cervical cancer patients are better off seeking treatment abroad than in Zimbabwe if they have the resources?			0.81
Would you recommend your cervical cancer patients to seek treatment abroad if they have the resources?			0.80
Are the available health professionals adequate to serve all			0.47

the patients (all disease areas) you				
receive?				
Do you have a specific number of beds reserved for cervical cancer patients in this health facility?				0.56
7. Service characteristics	0.5	<0.001	0.70	
c. Cervical cancer services			0.70	
Does this facility offer cervical cancer screening?				0.87
Does this facility offer treatment of pre-cervical cancer lesions?				0.67
What treatment options for pre-cervical cancer lesions are available in this facility?				0.71
What cervical cancer treatment services are available in your facility?				0.84
d. Cervical cancer service referrals			0.70	
Where do you refer patients for histological investigations?				0.61
Where do you usually transfer/refer cervical cancer patients for other services?				0.46
What services do you usually transfer/refer cervical cancer patients for?				0.78
8. Infrastructure, equipment and drugs capacity	0.538	<0.001	0.79	
a. Availability of basic services, equipment and drugs.			0.84	
What is the main source of water for this facility?				0.89
Over the last 3 months have you experienced water supply interruptions of this source of more than 2 hour?				0.54
Are there functional (soap and water) hand washing facilities for patients or in the toilets?				0.55
Does the facility have access to ambulance facility for emergency transport?				0.87
If the facility owns an ambulance is fuel available for use in cases of emergency?				0.75
Does the health facility have adequate basic equipment?				0.72
Is most equipment in this facility				0.66

for palliative care patients today?		
d. Availability drugs for treatment of cervical cancer.	0.91	
Does the facility have adequate stocks of drugs such as cisplastin for treatment of cervical cancer today?		0.70
Did the facility experience stock-outs of cisplastin in the last 3 months?		0.64

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# The Effect of Meditation on Concentration Level and Cognitive Performance

Runnan Zhang<sup>1</sup>

Correspondence: Runnan Zhang, Hyde Park High School, Austin, TX 78759, United States of America. E-mail: johnzrn007@gmail.com

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## **Abstract**

Many research studies have found that long-duration meditation sessions – ones that last at least 40 minutes a day – can contribute to individuals' concentration and cognitive performance. However, the effects of comparatively brief meditation sessions have not been widely studied. In this study, we tested whether a short meditation session affects cognitive performance and concentration when compared to a control group. Participants with no prior meditation experience underwent a short meditation session lasting 10 minutes, and then completed a section of either the reading or math portion of the SAT. We find no evidence that the short meditation session improves test performance, but subjective feedback from the participants suggests that meditation has a positive impact on their concentration level. The implications of this study and possibilities for future research on the topic will be discussed further.

Keywords: concentration level, cognitive performance, meditation

# 1. History of the Study of Meditation

Meditation can be practiced in different ways that vary considerably across cultures and religions, though it originated from Buddhist meditation traditions. Meditation in its various forms has been applied to support multiple mental and physical health conditions since the 1990s, and has also received much attention in psychological research. Currently, meditation is typically described as a practice of non-judgmental attention to the experience in the present moment. (Hart, 2012) This definition states that meditation requires both the regulation of attention (in order to maintain focus on immediate experiences, such as thoughts, emotions, body posture and sensations) and the ability to approach one's experience and environment with openness and acceptance. (Tang, Holzel, & Posner, 2015)

Meditation has also been the subject of neuroscientific research and healing practices. There are programs such as mindfulness-based stress reduction (MBSR) and integrative body—mind training (IBMT) that use mindfulness meditation as their basis. Evidence suggests that meditation can enhance individuals' self-regulation, which includes attention control, emotional regulation, and self-awareness. The attention network test (ANT) and other experimental paradigms have been used to investigate the effects of meditation on attention performance. (Chiesa, Calati, & Serretti, 2011)

# 2. Introduction

In "The Real Meaning of Meditation," Swami Rama writes: "Meditation is a precise technique for resting the mind and attaining a state of consciousness that is totally different from the normal waking state...In meditation, the mind is clear, relaxed, and inwardly focused." (Rama, 2013) Along with various other benefits, mindfulness meditation can improve individuals' error detection as well as their attention control. People who meditate are better able to sustain their attention during long tasks.(Tang et al., 2015) Research has shown that after three months of intensive meditation training ten to twelve hours a day, individuals are better able to sustain their attention during a dichotic listening test. (Brefczynski-Lewis, Lutz, Schaefer, Levinson, & Davidson, 2007) In addition, empirical evidence indicates that meditation training lasting only four days can enhance individuals' ability to sustain attention—benefits that are similar to those of long-term meditation training. (Zeidan, Johnson, Diamond, David, & Goolkasian, 2010)

Someone practicing mindfulness meditation focuses on the sensation of breath and body -- the air entering and

<sup>&</sup>lt;sup>1</sup> High School, Hyde Park High School, Austin, United States of America

leaving their nostrils and the environment around their body -- while maintaining a considerably relaxed state. During the practice of meditation, the meditator learns to acknowledge their thoughts and return his/her attention back to their breaths.

Besides enhancing individuals' attention during a task, meditation can also improve individuals' cognitive performance, as many studies have demonstrated. The N-back task, a task in which participants have to temporarily memorize information from the past then recall the information at the present, (Farnsworth, 2016) can determine individuals' cognitive performance. Through the multivariate analysis of variance (MANOVA) on the scores from the N-back task, a study showed significant improvements on scores and accuracy after meditation. The subjects who practiced meditation over four weeks out-performed a control group in multiple tests that measures cognitive abilities. In a verbal fluency test and the N-back task, (Farnsworth, 2016) the subjects prepared with long-term, long-duration meditation sessions were better able to perform better on cognitive tasks, increase attention, and relieve stress. It is possible that the calming effects of mindfulness meditation combined with the increased capacity to focus on the present improved cognitive performance after meditation training. Individuals who meditated were able to maintain focus and accurately retrieve information from working under conditions that require more rapid stimulus processing. (Tang et al., 2015) Many studies have shown that meditation improves conflict monitoring, the ability to detect errors, which contributes to individuals' cognitive performance. For example, a longitudinal study showed that only 5 days of integrative body-mind training (IBMT) 20 minutes per day led to improved conflict monitoring. (Tang et al., 2015)

Although research studies examining the effects of long- and short-term meditation interventions are growing, the effects of an extremely brief meditation session remain relatively unknown. In the present study, we examined whether a 10-minute meditation session can impact the subject's concentration level, to be measured through a task following their meditation. Specifically, we examined whether meditation can affect an individual's performance on the SAT math or reading test.

## 3. Muse Headband and EEG

The study required a standardized means of measuring the subjects' cognitive performance and concentration. For this we used a device adapted from the electroencephalogram (EEG), or the depiction of the electrical activity occurring at the surface of the brain; this activity appears on the screen of the EEG machine. Waveforms of varying frequency and amplitude measured in microvoltage EEG waveforms are generally classified according to their frequency, amplitude, and shape, as well as the sites on the scalp at which they are recorded (see Figure 1). The classifications of EEG frequencies usually include alpha, beta, theta, and delta.(Sucholeiki, 2017) The data is collected from the brain using electrode sensors on the scalp.

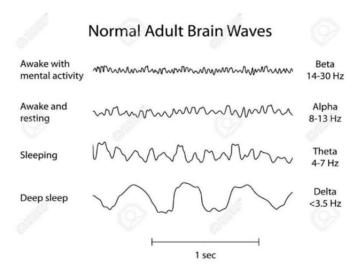


Figure 1. Image showing normal brain wave patterns

The electrical impulses collected from the brain are constant, and vary based on the subject's state of mind, as illustrated above. To describe brain waves, voltage and frequency need to be collected. The voltage of the neurons ranges from 0 to 200 microvolts; the frequency ranges from 1 to 50 times per second.

Wave	Frequency	Comments
Beta (β)	High	$\beta$ waves are typical of awake, mentally active individuals (with eyes open)
Alpha (α)	Low	α waves are seen in awake individuals (with eyes closed)
Theta (θ)	Low	θ waves are seen in drowsy or very relaxed states
Delta (δ)	Low	$\delta$ waves are seen in deep sleep when the cortex and thalamus are highly synchronized

Figure 2. Image showing brain wave frequencies and meanings

Beta waves dominate when people are hyper-alert or anxious. Alpha waves appear when people close their eyes and relax, and disappear when people open their eyes or become more alert in their thinking. Theta waves appear when people are drowsy or not fully paying attention. Delta waves appear when people are resting or sleeping (Figure 2). (Sivakumar, 2017)

The Muse headband is a device that has 7 sensors to detect brain waves. It transfers the data collected via Bluetooth to the "smart" device (see Figure 3). The Muse app offers meditation lessons that help users to meditate better, and it also features real-time feedback. When a person's mind is calm, the sound of the weather is nice; when they let their thoughts wander, the weather gets more intense. After each meditation session feedback is provided for the entire meditation session, which shows when the brain was in calm, neutral, and active states during the meditation. (Muse, 2018)



Figure 3. Muse Headband Sensors

## 4. Methods

# 4.1 Participants

The participants included six Chinese students studying in China and the US. The participants were four males and two females, all of whom were born in Qingdao, Shandong. With parental consent, we acquired participants whose ages ranging from 15 to 17, and all were enrolled in either a Chinese public high school or a private school in the United States. None of the participants had any prior meditation experience.

### 4.2 Materials

We used questions from the SAT Official Study Guide as a measure of cognitive performance, and the subjects could use a graphing calculator for the math portion. We also implemented the Muse headband to collect the raw EEG data. The participants listened first to the brief voice introduction to meditation with simple instructions from the Muse app on the iPhone.

## 4.3 Design

We conducted a 2 X 2 factorial designed experiment. This included two independent variables each with two levels (i.e. a temperature of 80 degrees versus a temperature of 40 degrees), with which we investigated the effects of

meditation (10-minutes meditation versus no meditation) and test categories (math or reading) on the subjects' cognitive performance and concentration level.

## 4.4 Procedures

The test category, math or reading, was chosen at random, and each participant takes two tests of the same category; between the two tests participants were given a 30-minute break. Participants completed a 10-minute meditation before either the first test or the second test, and the meditation was accompanied by a brief voice guide that explained the basics of how meditation works. Participants completed the test in a quiet environment. The questions were chosen from the *SAT Official Study Guide*, along with an answer sheet. After each test, the participants are asked how concentrated they felt on a scale from one to ten, and they provided comments about their testing experience.

## 5. Results

To analyze the collected data and examine the effect of a brief meditation training on participants' cognitive performance and concentration, we used an ANOVA (analysis of variance) on the data using SPSS Statistics (Statistical Package for the Social Sciences) by MIT. The accuracy of each test is recorded as a percentage, and the participants' self-rated concentration level is also recorded.

Table 1. ANOVA analysis using SPSS on scores

Descriptive statistics

Dependent variable: score percentage

Type	Meditation	Mean	Std. Deviation	N
	No meditation	69.6438	10.57780	8
Reading	Meditation	71.8025	8.93838	8
	Total	70.7231	9.52586	16
	No meditation	83.3350	23.03503	6
Math	Meditation	83.3350	23.03503	6
	Total	83.3350	21.96304	12
	No meditation	75.5114	17.71349	14
Total	Meditation	76.7450	16.79817	14
	Total	76.1282	16.95086	28

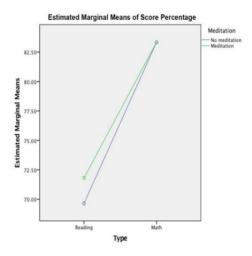
Test of Between-Subjects Effects

Dependent variable: score percentage

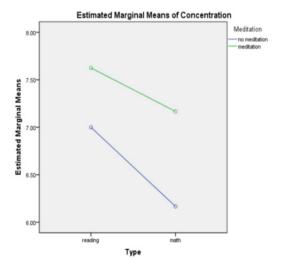
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	1109.334 <sup>a</sup>	3	369.778	1.335	.286
Intercept	162746.783	1	162746.783	587.479	.000
Туре	1090.693	1	1090.693	3.937	.059
Meditation	7.989	1	7.989	.029	.867
Type* Meditation	7.989	1	7.989	.029	.867
Error	6648.617	24	277.026	12	
Total	170032.091	28			
Corrected Total	7757.951	27			

Table 1 represents a 2 (types of test -- math and reading) x 2 (meditation/ no meditation) ANOVA analysis. The statistical result showed marginal effects for the type of test but no significant result over meditation. The result [Graph 1] shows that the math average (M (mean) = 83.34, SD (standard deviation) = 21.96) is 13.6% higher than

the reading average (M = 70.72, SD = 9.53). This difference was marginally significant: F-value (to reject the null-hypothesis, the f-value needs to be closer to 1.) (1,24) = 3.94, p (the statistical significance of the data) = 0.06. The statistical result is significant when p is less than 0.06. The test score average of participants who meditated before the test (math and reading) (M = 76.75, SD = 16.80) proved to be 1.23% more accurate than the control group (M = 75.51, SD = 17.71). This difference was not significant: F(1,24) = 0.03, F(



Graph 1. Score Average of Type of Test and Meditation



Graph 2. Estimated Marginal Means of Rated Concentration

We also did an ANOVA on the participants' self-scored concentration (Table 2). The rating of the tests after meditation (M = 7.4286, SD = 1.65084) is higher than the tests without meditation, but the result was not statistically significant: F(1,24) = 1.40, p = .25. As Graph 2 shows, the participants reported higher concentration during the reading test (M = 7.31, SD = 1.14) than the math test (M = 6.67, SD = 2.239), but the ANOVA analysis (Table 3) shows no significance in the results.

Table 2. Descriptive Statistics of Mean and Standard Deviation Dependent variable:Concentration

Type	Meditation	Mean	Std. Deviation	N	
	No meditation	7.000	1.30931	8	
Reading	Meditation	7.6250	.91613	8	
	Total	7.3125	1.13835	16	
	No meditation	6.1667	2.48328	6	
Math	Meditation	7.1667	2.40139	6	
	Total	6.6667	2.38683	12	
	No meditation	6.6429	1.86495	14	
Total	Meditation	7.4286	1.65084	14	
	Total	7.0357	1.77393	28	

Table 3. ANOVA analysis on Rated Concentration level

Dependent variable: Concentration

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	7.423 <sup>a</sup>	3	2.474	.766	.524
Intercept	1340.003	1	1340.003	414.746	.000
Type	2.860	1	2.860	.885	.356
Meditation	4.527	1	4.527	1.401	.248
Type* Meditation	.241	1	.241	.075	.787
Error	77.542	24	3.231		
Total	1471.000	28			
Corrected Total	84.964	27			

Participants left a simple comment about their experience with meditation after the test. Their responses (see Figure 4) demonstrated the positive impact on their test experience. Participant 2, for example, noted improvement in their concentration after meditation.

```
Participant 1:
    "Meditation helps me focus on the passage more."

Participant 2:
    "I felt really concentrated after the meditation."

Participant 3:
    "Just knowing I meditated made me more confident about taking the test."

Participant 4:
    "I consider it a normal performance.
    I really felt good after the meditation"

Participant 5:
    "I felt pretty refreshed after the meditation."
```

Figure 4. Participants' responses after the test with meditation

### 6. Discussion of Results

We found that the brief meditation session did not have a significant impact on participants' cognitive performance. However, the participants' survey demonstrated that meditation has a positive impact on their concentration from a subjective, though not empirical, standpoint. For example, one participant noted, "I felt pretty refreshed after the meditation." Others reported, "I think meditation helps me focus on the passage more." Another participant stated: "Just knowing I meditated made me more confident about taking the test." It is also important to reiterate that all of

the participants never had prior meditation experience. This implies that further study into a longitudinal research on effects of meditation may offer important insights.

# 7. Suggestions for Future Study

Future research should conduct similar studies with larger samples. Given that the sample size in this study was limited, its findings were also limited in respect to statistical accuracy. Future work should use tests that are adequately challenging to better examine how meditation can support students' performance in cognitive tasks. We could also conduct a more individually-designed study in which the tests are fit to each participants' aptitude in reading or math. Future studies may also include longer meditation sessions (i.e. 20-30 minutes) with more detailed instructions, because the introduction that the Muse app provided might be too concise to ensure participants had a comprehensive understanding of meditation. One participant even mentioned that longer instructions and more tips would help to improve his meditation experience.

If future studies were to prove that meditation helps people improve their cognitive abilities and concentration, the impact on the education community would be immense. Students could easily meditate before their tests and enjoy greater success. Meditation would be a tool employed by many students to facilitate their learning experience and allow them to work more efficiently. Moreover, imagine what an impact meditation would have on office workers with heavy cognitive tasks. They could perform better with meditation and be more focused during meetings to increase their productivity. It is clear that the successful application of meditation could bring many benefits to our world

## **Competing Interests Statement**

The authors declare that there are no competing or potential conflicts of interest.

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# Marriage, Pregnancy and Sexual Practices in University Female Students in Cartagena, Colombia

Esther P. Polo<sup>1</sup>, Ayda M. Cassas<sup>1</sup>, Natalia A. Senior<sup>1</sup> & Muna Hamdan<sup>1</sup>

Correspondence: Muna Hamdan R., University of Cartagena, Cartagena de Indias, Colombia. Tel: 57-301-347-0024. E-mail: mhamdanr@unicartagena.edu.co

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# Abstract

**Introduction:** Sexuality went from being a taboo to a matter of human rights regarding intimacy, sexual and reproductive disputes. Maternity in university students may produce a greater effort in the academic commitment, as well as limiting the time and quality of the academic activities. However, when pregnancy occurs, it is only the woman who carries its risk, "single mom" burden and child care in most cases.

**Objectives:** To determine the number of marital union and the factors of exposure to pregnancy risk in university students of exact sciences programs in a public university of Cartagena.

**Methods:** A quantitative research, of a descriptive type, with a population composed of students enrolled in 3 professional programs of Exact and Natural Sciences of a public university in Cartagena, Colombia, was carried out. A two-stage sampling was done. An Outline of the social and demographic profile of the participants for research purpose was prepared. Natality and exposure to pregnancy risk questions were applied. Data was processed using *Epi Info 7.0*, quantitative analysis was made using central tendency measures and qualitative variables and categories that applied to the study.

**Results:** 26% of the 89 participating students were women and were on average of 20 years old with a SD of 2.23. 63% belonged to the subsidized system of the Colombian Health System. 97% of the participants belonged to socioeconomic levels 1 and 2. 94% of the participants declared heterosexual behavior. Regarding the number of people with whom they have had sexual intercourse throughout their lives, the range of one to two people was 28%, while 18% answered that they have had coital encounters with three or more people. 16% of the participants said they felt pressured by some friends to start their sexual relations. 56% of the surveyed reported having vaginal sex, of which 47% have performed this practice without the use of a condom. In the same way, 19% practiced anal sex, where 9% of them did not use condoms.

**Conclusion:** It is necessary to develop initiatives in the academic context that embraces the guidelines developed by WHO and UNFPA regarding sexual life and sexuality.

**Keywords:** marital relationship, adolescent, youth, pregnancy (MeSH)

#### 1. Introduction

The contemporary world has experienced great transformations, within which those are referring to sexuality; it went from being a taboo in many parts of the world to a matter of human rights regarding intimacy, sexual and reproductive disputes. It represents a subject of interest in the agendas of international health agencies as well as economic and multilateral organizations, mainly due to the adverse effects in terms of sexually transmitted diseases, unplanned pregnancies, school dropout, female poverty, and maternal-perinatal mortality.

Although fertility rates have decreased worldwide due to the fact that higher rates of women are entering the workforce; however, the greatest challenges that we face today are, the decrease of early marriage in adolescents, the decrease of risk determinants such as unprotected sexual relations and the non-use of contraceptives, the lack of programs and initiatives that not only educate about physiological aspects, but cover social, gender and empowerment features, and emotional intelligence, considering that in 2015, approximately 14.5 million deliveries of adolescent mothers were registered in 156 countries (OMS, 2018). In developing countries, the unmet need for family planning services affects 12.8 million adolescents, (UNFPA, 2016), every year a total of 89 million unplanned pregnancies are registered in developing countries, 48 million abortions, 10 million spontaneous

<sup>&</sup>lt;sup>1</sup> University of Cartagena, Cartagena de Indias, Colombia

abortions, and 1 million cases of stillbirths (UNFPA, 2017).

Maternity in adolescents and university students is also a problem in developed countries. In the United States, a study shows that university students are increasingly involved in sexual relations at risk of conceiving. However, when pregnancy occurs, it is only the woman who carries its risk and "single mom" burden and child care (Brown & Amankwaa, 2007).

Maternity in university students may produce a greater effort in the academic commitment, as well as limiting the time and quality of the academic activities. Although, paradoxically Miller and Arvizu (2016) show that some young women report experiencing a new attitude towards life when becoming mothers, whether the pregnancy was planned or not, this new attitude generates in them a high degree of maturity and focus, to the point of considering their children as their only true argument to excel each day. Other studies, such as those of Caraballo Z (2007) show that "The experience of combining these two roles results in a hectic life where both roles come into conflict."

Moreover, in Colombia, it is important to highlight the increasing rate of pregnancies in students and adolescents, which is related to an extension of the reproductive period of women due to the early age of menarche, the elongated period of risk exposure to pregnancy with respect to the early start of sexual relations, the steadiness of their first couple relationship, and the increasing tendency to new couples and family re-conformation. National Survey of Demography and Health (ENDS, 2015).

# 1.1 Objective

To determine the number of marital union and the factors of exposure to pregnancy risk in university students of exact sciences programs in a public university of Cartagena.

#### 2. Methodology

A quantitative research, of a descriptive type, with a population composed of students enrolled in 3 professional programs of Exact and Natural Sciences (Mathematics, Chemistry and Biology) of a public university in Cartagena Colombia.

A two-stage sampling was carried out, where the initial groups were first year students (1st 2nd semester of each program), the number of students was established by proportional allocation and the established inclusion criteria were:

- Students over 18 years of age
- Students who are enrolled and active in their first year face-to-face programs
- Students who are willing to participate and sign the informed consent of the research

Out of the total number of students that were studied, 32 individuals met the criteria.

## 2.1 Instruments

Outline of the social and demographic profile of the participants for research purposes, was prepared by the study team

- Natality and exposure to pregnancy risk: Section 6 of the National Health Survey (ENDS 2015) questions from number 600 to 650. A survey with questions of multiple choice answers, providing information on relationship history, which accounts for the various ways in which pairs are set up, and reveals the plurality and diversity of the sexual and reproductive life of the Colombian population.

A data entry process was carried out by means of the surveys using the *Epi Info 7.0* program and the database was designed from which the expected statistics will be obtained, the quantitative analysis was made using central tendency measures and qualitative variables and categories that applied, the information obtained was presented in tables.

# 2.2 Ethical Considerations

This study followed all the procedures established in the resolution, No. 008430 OF 1993 of the Colombian Ministry of Health, Title II of the ethical aspects of research in human beings and the professional deontological code.

#### 3. Results and Discussion

# 3.1 Sociodemographic Profile of the Participants

26% of the 89 students enrolled in the first year in the programs of exact sciences were women. This low incidence

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of the female population enrolled in these programs can be explained by Herrera, I. et al. (2018) who describes that "in programs like these whose knowledge is ascribed to the hard sciences; the male student prevails. Other studies show that there is discrimination, exclusion and segregation of men and women who are inserted in professions considered as feminine and masculine whose spaces and activities are considered mostly generic attributes (Martinez & Mora, 2018).

The students who participated in the study were, on average, 20 years old with a SD = 2.23 age classified according to the World Health Organization as young adults (OMS), being at this stage where risk behaviors are most intense.

Regarding the academic program, 53% (17) of the women surveyed belonged to mathematics, the remaining percentage corresponded to the chemistry and biology programs, of I and II semester being 40% and 60% respectively.

Regarding religious belief, we observed a great proportion of Catholic students 44% (14). Religion, as a cultural component, modifies the attitudes of people generating transformations of sexual-social behaviors that provoke behavioral differences within the practitioners of each religion; however, in this study this variable had no important connection (Martinez, Parada & Duarte 2013; Kellogg, Rosenbaum, Dweck, & Millheiser, 2014).

Furthermore, 63% (20 students) belonged to the subsidized system of the Colombian health system, in addition, almost all of the participants (97%) belonged to socioeconomic levels 1 and 2, which are those with the least economic capacity (See Table 1).

Regarding sexual orientation, 94% declared heterosexual behavior. These results are similar to the one found by Zambrano, Tuscan & Gil (2015) in their study with university students, where the most predominant sexual orientation was heterosexual with 83%, and to a lesser extent, bisexual and homosexual orientation with 7%.

#### 3.2 Nuptiality and Risk to Pregnancy

In the study, 88% (28) of the university students surveyed are single, that is, they do not have a stable marital bond with a couple, and only 6% (2) have children, a result different to that found by Coschiza, Fernandez, Redcozub, Nievas and Ruiz (2016) where "87% of their university participants were single and one of four students had children".

The phenomenon of non-coexistence with the couple of the moment is linked to patterns of cultural change; Before, the parents supervised with great rigor their daughters whereabouts while growing up, since it implied matters of reputation and honor to guard the sexuality of their young girls, in such a way that the boys who befriended them had to have the permission of their parents, secret sexual or sentimental relationships were forbidden and punished with marriage; it could be thought that the way to maintain intimate relationships with their partners in the private sphere is not only a form of exercise of procreative sexual rights by young women, but a form of emancipation from parental supervision. Although, it is important to emphasize that gender inequality and the disparity in the enjoyment of sexual and reproductive health and rights are two fundamental aspects that do not receive enough attention. So that women and girls will remain trapped in a vicious circle of poverty, reduced capacities, and impossibility to exercise their human rights and develop their potential - especially in developing countries where the differences are most pronounced (UNFPA, 2017).

Regarding the question "With how many people have you had sex in the last 12 months?" 25% (8) of the participants answered only one person and in a smaller proportion 6% (2) were with two people. Likewise, they were asked; with how many people have had sexual intercourse throughout their lives, the range of one to two people corresponded to 28% (9), and 18% (6) answered that they have had coital encounters with three or more people (See Table 2). Hurtado et al. (2017) carried out a study about the link between multiple couples and early initiation of sexual relations, he found that there is statistically significant relationship, which makes young people vulnerable to acquire sexually transmitted infections, as well as unwanted pregnancy. In the same way Melo et al. (2016) in their research also found a relation with the number of sexual partners in university students with the frequency of HPV and *Chlamydia trachomatis*. The above clearly evidences the possible risks that university students may have.

#### 3.3 Conditioners of Risk

Group pressure: 16% of the participants said they felt pressured by some friends to start their sexual relations. This is related to what was found by Holguín et al. (2013) in his research; where they associated the influence of peers or friends in decision-making, with the early onset of sexual activity among adolescents. Similarly, the University of Utrecht in collaboration with the Psychiatric Institute of New York (year), through a meta-analysis, concluded that one of the main reasons why adolescents have an early start in their sexual relations is because their friends do

SO.

For this research, 58 studies from 15 countries were analyzed about the sexual behavior of almost 70,000 adolescents, mainly considering three variables: descriptive norms (How others act?; What they do?), norms of approval (What do group values have to do with?; Does my group support me doing this?). And the third variable: group pressure. All the variables had an extremely noticeable influence (Portalatin, 2015). In the same way, Martinez et al. (2013) found that "women are more prone to be influenced by their group". That is why; it is known that among young people, friendship relations may affect their adaptation to the social environment in which they live, copying their social attitudes and behaviors (Portalatin, 2015). What Navarrete, Castel, Romanos & Bruna (2017) imply to the lack of sexual health empowerment, and evidences the great susceptibility to peer pressure at this age.

Another risk factor in this study is the age of initiation of sexual intercourse, the average age was 16 years old SD = 1.58 years. Hurtado M. et al. (2017) found similar results, where the average age of the beginning of sexual intercourse for university females in Mexico was 17 years. Also, in Colombia, according to PROFAMILIA's report (2016), the percentage of women aged between 20 and 24 years who had their first sexual relationship, was before their 15 years of age. Thus, premature sex represents a public health problem due to the consequences that, in addition to unwanted pregnancies and STDs, brings with it family, economic and social problems (Mendoza, Claros, & Peñaranda, 2016) in addition, it is a "big risk factor in HPV infections" (Hurtado & Olvera, 2017).

The sexual curriculum of the couple with whom they initiate their sex life including their age can be considered another risk factor, where the average age of the person with whom they had their first sexual encounter was 20 years old and 60% of those were males. This is related to that reported by the II National Survey of Sexual and Reproductive Health of Costa Rica, (2016), which shows that the beginning of sexual life in both men and women is early and to a large extent occurs before adulthood. However, it can be clearly seen that, in the case of this study, the beginning of sexual life was established between minors and adults, which leads to disadvantaged and vulnerable conditions for the child in this case the females. Hence, usually before the age of 25, the proportion of men who have had sexual intercourse is always greater than that of women, this means that the men already have sexual curricula, the women or the girls, are just about to start.

Non use of condoms in the first sexual relationship: The use of condoms is a good practice, however, it was found that only 34% of couples used a condom in their first intercourse, this agrees with what was found by Martínez et al. (2013), where "the percentage of people who used condoms in their first sexual relationship was low". This may be due to the fact that negotiation in the use of condoms is more limited due to scarce information and the lack of development of sexual autonomy in adolescents (ENDS 2015). This is important because the use of the condom in the coital debut is a positive marker of sexual behavior; since it is expected that if a condom is used in the first encounter, there is a greater probability of continuing to use it in the next relationships, which leads to a reduction of STDs/STIs.

Likewise, 56% of the surveyed reported having vaginal sex, of which 47% have performed this practice without the use of a condom. In the same way, 19% practiced anal sex, where 9% of them did not use condoms. This is related to an investigation carried out in university students in Medellin, where 71% had vaginal sex in the last six months, and 12% said they had had anal sex, besides, they stated that they were performed without protection (Morales, Mesa, Arboleda, & Segura, 2014). This clearly reflects the risks to which newbie students are exposed to, in addition to, unwanted pregnancies, and in the worst cases to Sexually Transmitted Diseases.

The educational level attained by the young women in their beginning of active sexual life, is determinant in the possibility of increasing or decreasing the risks of motherhood, as it has been demonstrated that the educational level of women is inversely proportional to fertility (Meza & Junca, 2011). That is why access to higher education, as well as obtaining greater educational achievements makes marriage and conception a less attractive option. However, although women (and men) with higher education show later marital patterns, this relationship operates mainly as a function of the different periods of permanence within the education system (Miller & Arvizub, 2016).

Adolescent and university motherhood is a stressor, a reason for changes in the family and social dynamics of the youth, it is no secret that "unexpected" motherhood in the academic year often interferes with the studies, Miller and Arvizuc (2016) found in their research that women with children in college require more average time to complete upper secondary education. In this case, being single and not having children could favor the permanence and completion of the university studies in a timely and satisfactory manner. However, studies that deepen this affirmation would be required. It is important not to ignore that the adverse effects of adolescent motherhood also extend to the health of their infants. Perinatal deaths are 50% higher among babies born to mothers under the age of 20 years. Newborns of adolescent mothers are more likely to have low birth weight, with long-term risks (WHO,

2011).

#### 4. Conclusions

Natality is not experienced by young women with marriage or free union, but it is evident as active marital life with non-cohabiting couples.

Young women, although they are developing university studies, experience pressure from the group, they have an active sexual life with the non-use of contraceptives and condoms, which conditions the exposure to risk of pregnancy and other adverse results of unsafe sexual practices.

It is necessary to develop initiatives in the academic context that embraces the guidelines developed by WHO and UNFPA, such as limiting marriage before the age of 18, creating understanding and support to reduce pregnancies before the age of 20, increase the use of contraception, reduce sexual relations under coercion, and others, for the prevention of early pregnancy and adverse reproductive outcomes.

#### **Competing Interests Statement**

The authors declare that there are no competing or potential conflicts of interest.

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# **Appendix**

Table 1. Distribution according to sociodemographic characteristics of the students surveyed of exact and natural sciences. Cartagena 2018.

Academic Program	N	%
Biology	7	21.96%
Chemistry	8	25.00%
Mathematics	17	53.04%
Semester	N	0/0
I	13	40.62%
II	19	59.38%
Religion	N	0/0
Catholic	14	43.75%
Protestant	10	31.25%
Other	6	18.75%
Doesn't practice any	2	6.25%
Health System Regimen	N	0/0
Contributive	12	37.50%
Subsidized	20	62.50%
Socioeconomic Level	N	0/0
Level 1-2 = bellow US \$ 350.	16	50.00%
Level 3-4= between US\$ 350-700	15	46.88%
Level 5-6= a little over US \$ 800	1	3.13%

**Source: Study survey** 

# Nuptiality

Table 2. Distribution according to nuptiality of the students surveyed of exact and natural sciences. Cartagena 2018.

Marital Status	N	%
Single	28	87.50%
Free union	4	12.50%
Children	N	%
Yes	2	6.25%
No	30	93.75%

With how many different people have you had sex in the last 12 months?

No. of sex partners	N	<b>%</b>
1	8	25.00%
2	2	6.25%

With how many different people have you had sex throughout your life?

No. of sex partners	N	%
1-2	9	28.08%
3-4	3	9.36%
5-6	3	9.36%

# **Exposure to the Risk of Pregnancy**

Table 3. Distribution according to natality of the students surveyed of Exact and Natural Sciences. Cartagena 2018

Sexual orientation	Frequency	%
Heterosexual	30	93.75%
Bisexual	1	3.13%
Homosexual	1	3.13%
Total	32	100.00%

Ha	ve you had sex:	Yes	No	NA/NR
1.	Vaginal sex	56.25% (18)	37.50% (12)	6.25% (2)
2.	Have you had vaginal sex with no protection?	46.88% (15)	15.62% (5)	37.50% (12)
3.	Have you had anal sex?	18.76% (6)	68.75% (22)	12.49% (4)
4.	Have you had anal sex with no protection?	9.36% (3)	9.36% (3)	81.28% (26)

**Total:** 100.00%

1.	How old were you when you had your first sexual intercourse:	16.28 years DE= ±1,58 years
2.	Peer pressure to start sexual relations	15.60% (5)
3.	The first time you had sex, your partner used a condom	34.32% (11)
4	1 0 1 1 1 1 0 1	male: 59.28% (19)
4.	gender of the person with whom you had your first sexual relationship	female: 3.12 (1)
	oonuu retuvenemp	NA/NR: 37.60% (12)
5.	Age of the person with whom you had your first sexual relationship	19.85 years SD= ±3.83 years

With how many different people have you had sex in the last 12 months?

How many?	N	%
1	8	25.00%
2	2	6.25%

With how many different people have you had sex throughout your life?

How many?	N	%
1	5	15.60%
2	4	12.48%
3	2	6.25%
4	1	3.12%
5	1	3.12%
6	2	6.25%

How many?	N	%
1-2	9	28.08%
3-4	3	9.36%
5-6	3	9.36%

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# Elevated Blood Pressure of High Altitude Dwelling Andibila Adults in Oju, Nigeria

Daniel Ter Goon<sup>1</sup>, Charles Mpofu<sup>2</sup>, Vincent Oladele Adeniyi<sup>3</sup>, Uchenna Benedine Okafor<sup>1</sup>, Simon Wuhe Akusu<sup>4</sup>, Benjamin Ijuo Ejeh<sup>5</sup> & Unogwu O Unogwu<sup>5</sup>

Correspondence: Daniel Ter Goon, Faculty of Health Sciences, University of Fort Hare, East London, South Africa. E-mail: dgoon@ufh.ac.za

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#### Abstract

Objective: To examine the blood pressure of high altitude dwelling Andibila adults in Oju, Nigeria.

**Methods:** A cross-sectional survey of 121 Andibila adults living at a high altitude in Oju, Benue state, Nigeria. Body mass, stature, girths (waist and hip circumferences) were taken using standard procedures. Blood pressure (BP) measurement was assessed twice, and the average recorded. Participants with a systolic blood pressure (SBP) of  $\geq$  140 and diastolic blood pressure (DBP) of  $\geq$  90 were diagnosed as hypertensive.

**Results:** The participants mean age was 49.9 years (SD=16.5. The prevalence rate of elevated pressure was 55.9%. Traditional alcohol use was significantly common in males (49.1%; OR=31.8; 95% CI 7.1 –143.3; p<0.0001) than females (2.9%). Increase in SBP was significantly associated with increasing age (r=0.198; p=0.0301), WC (r=0.215; p=0.018) and BMI (r=0.242; p=0.008).

**Conclusion:** There is need for health education and awareness campaign concerning the risk of elevated blood pressure of lean Andibila adults living in a geographically secluded setting.

Keywords: elevated blood pressure, indigenous population, high altitude, Andibila, Nigeria

#### 1. Introduction

Indigenous people are behind everyone, everywhere, concerning their health (Stephens et al., 2005). They face great social disadvantages, poor health and neglect (Bourne, 2003) in national health screening programmes (Hirschler, 2015) compared with the general population (UNDESA, 2004). The lifestyles of traditional communities have generated research interest (Schofield et al., 2014) because it provides an insight into the possible benefits of living a traditional lifestyle dominated by physical activity and unprocessed foods. The Andibila people is one such tribal community that lives in an isolated mountain (350m above sea level) in Nigeria in Oju in the state of Benue. This tribal group, lives a traditional way of life and their day-to-day activities are free from interference from the contemporary Nigerian life with elements of Westernization (Goon, Amusa, Shaw, Shaw, & Akusu, 2013) Their life is therefore characterized by activities that involve a lot of physical strain fetching wood for energy, food and walking instead of any contemporary means of transport as there are no roads in this community. In addition, there is no modern health and social amenities as well as road networks. Interference from the contemporary Nigerian lifestyle is also limited by difficulty climbing the mountain (Goon, Amusa, Shaw, Shaw, & Akusu, 2013). The socioeconomic status of this population is lower than that of other Nigerians as measured by income and education level. Perhaps, due to their difficult-to-reach terrain, their health status is undocumented. Such information will provide insight about risk factors of living in highlands. Elevated blood pressure (BP) contributes significantly to global burden of disease and mortality, causing approximately 9.4 million deaths annually (Poulter, Prabhakaran, & Caulfield, 2015). Elevated BP, a precursor of hypertension is

<sup>&</sup>lt;sup>1</sup> Faculty of Health Sciences, University of Fort Hare, East London, South Africa

<sup>&</sup>lt;sup>2</sup> Faculty of Health and Environmental Sciences, Auckland University of Technology, New Zealand

<sup>&</sup>lt;sup>3</sup> Department of Family Medicine, Faculty of Health Sciences, Walter Sisulu University/Cecilia Makiwane Hospital, East London Hospital Complex, East London, South Africa

<sup>&</sup>lt;sup>4</sup> Department of Human Kinetics, Benue State University, Makurdi, Nigeria

<sup>&</sup>lt;sup>5</sup> Department of Physical and Health Education, College of Education, Oju, Nigeria

associated with the development of many chronic diseases (Khedr et al., 2013). It has been reported that the heart and pulmonary circulation of high altitude dwelling individuals are susceptible to some physiological and morphologic characteristics in relation to chronic hypoxia (Qi, Ma, Jiang, Li, Mai, Chen et al., 2015). The increase in systematic arterial pressure during acute exposure to high altitude, and the accompanying changes in blood pressure have been linked to increase in autonomic and sympathetic activity (Rhodes et al., 2011). The exposure of the lung at high altitude decreases inspired oxygen, thereby triggering hypoxic pulmonary vasoconstriction reflex (Fishman, 2004). Prolonged exposure hypoxia might result to sustain elevated arterial BP and diastolic BP (Hoit, Dalton, Gebremedin, Janocha, Zimmerman, & Zimmerman, 2011; Wolfel, Selland, Mazzeo, & Reeves, 1994). However, arterial BP remains normal by enhanced vascularization attributable to decreased total peripheral resistance in adults residing in mountainous regions (Fishman, 2004; Pocock & Richards, 1999). Again, other studies have reported that inhabitants of high altitude exhibits lower systolic and diastolic BP readings compared to low altitude population (Hoit, Dalton, Gebremedin, Janocha, Zimmerman, & Zimmerman, 2011; Hanna, 1999; Shrestha, Shrestha, Shrestha, & Bhattarai, 2012; Tripathy & Gupta, 2007). Whether this scenario would hold true for the Andibila population residing on a high altitude is speculative. Taken into account the complexity of indignity, risky lifestyles and known risk factors like high altitude living, this study examines the blood pressure of permanent residents of high altitude of rural Andibila, in Oju, Nigeria. Our confirmatory hypothesis would be that the high altitude Andibila population would exhibit 'relative' lower systolic and diastolic BP when compared to other high altitudes population elsewhere.

#### 2. Methods

The details regarding the setting, design, sample and sampling procedure of the study has been reported elsewhere (Goon, Adeniyi, Akusu, Ejeh, & Unogwu, 2017). Briefly, this was a cross-sectional survey of a conveniently sample of 121 Andibila adults residing at high altitude in Oju Local Government Area of Benue State, Nigeria. Ethical approval was sought and obtained from the community chief/elders of Andibila community. Prior to data collection, the aim and nature of the study was explained to the participants for the purpose of getting their verbal consent. Only participants who consented to participate in the study were included. A self-designed questionnaire included information on age, level of education, alcohol consumption, smoking and physical activity participation.

#### 2.1 Data Collection

#### 2.1.1 Anthropometric Measurements

Anthropometric measurements were measured following the International Society for the Advancement of Kinanthropometry (ISAK) recommendations (Marfell-Jones, Olds, Stew, & Carter, 2011). All measurements were taken on the right side of the participants. Stature was measured as the perpendicular distance between the vertex of the head and the feet. A calibrated vertical stadiometer (Seca Portable 217 Seca, UK) was used to measure stature to the nearest 0.1 centimetre. The participants were measured in a relaxed and upright position, without footwear or headgear. Body mass was measured in light clothing without shoes using a calibrated digital electronic weighing scale (Seca 813, Seca, UK) to the nearest 0.1 kilogramme. Body mass index was derived by dividing the body mass in kg by the stature in meter-square (m²).

Girths of the waist and hip was measured with a Lufkin non-extensible flexible anthropometric tape (W606PM, Rosscraft, Canada,) and recorded to the nearest 0.1 centimetre. Waist circumference (WC) was taken with the participant standing, by wrapping the tape at the level of the narrowest point between the lower costal (10th rib) border and the iliac crest. Hip circumference (HC) was measured at the widest diameter of the buttocks, at the level of the greater trochanter. Waist-to-hip ratio (WHR) was derived by dividing the WC by HC. Waist-to-stature ratio (WSR) was derived by dividing the WC by stature.

#### 2.1.2 Blood Pressure Measurement

Blood pressure was measured on the right arm, using an OMRON Professional Portable Blood Pressure Monitor (HBP-1300, OMRON, Kyoto, Japan). Measurements were taken after the participants have rested quietly for at least 5 minutes. Both systolic (SBP) and diastolic pressure (DBP) was consecutively measured twice, and the mean recorded. Participants who had a SBP of  $\geq$ 140 and DBP of  $\geq$  90 were classified hypertensive.

#### 2.2 Data Analysis

Data was analysed using both descriptive (frequency, percentage, means and standard deviations) and inferential statistics. The association between demographic, anthropometric and cardiovascular variables was investigated in unadjusted analysis and multivariate models. A p-value of 0.05 was set for statistical significant testing. All statistical analyses were carried out using the Statistical Package for Social Sciences (SPSS), version 22.0 for Windows (SPSS Inc., Chicago, IL, USA).

#### 3. Results

Table 1 displays the anthropometric and BP profiles of the participants. The overall prevalence of cigarette smoking, traditional alcohol use and elevated BP were 19.8% (n=24), 23.1% (n=28), and 55.9% (n=67), respectively (Figure 1). Traditional alcohol use was significantly common in males (49.1%, n=26/53; OR=31.8; 95% CI 7.1 –143.3; p<0.0001) than females (2.9% n=2/68). In bivariate correlation, predicted increase in SBP was significantly associated with increasing levels of age (r=0.198; p=0.0301), WC (r=0.215; p=0.018), and BMI (r=0.242; p=0.008). In univariate analysis, alcohol intake, cigarette smoking, and BMI were significant potential contributors of arterial hypertension (data not shown).

Variables	Male (n=53)	Female (n=68)	Female (n=68) Total (n=121)	
variables	Mean±SD	Mean±SD	Mean±SD	95% Confidence Interval
Age (years)	51.9±19.2	48.4±14.0	49.9±16.5	47.0-52.9
Weight (kg)	53.0±7.3	54.18±11.1	53.6±9.6	51.9-55.4
Height (cm)	161.6±16.0	156.6±7.0	158.8±12.0	156.6-161.0
BMI (kg.m <sup>-2</sup> )	22.1±17.0	22.0±14	22.1±11.6	17.8-24.6
WC (cm)	76.6±15.4	76.2±16.7	76.8±14.4	76.3-77.6
WHR	0.91±0.28	0.90±0.12	0.91±0.36	0.89-0.92
WSR	0.49±0.12	$0.48\pm0.14$	$0.49\pm0.09$	0.47-0.49
SBP (mmHg)	$141.5 \pm 22.1$	$148.3 \pm 26.0$	$145.3 \pm 24.5$	140.9-149.7
DBP (mmHg)	$78.7 \pm 14.2$	$81.4 \pm 15.2$	80.2 1±4.8	77.6-82.9

BMI: Body mass index, WC: Waist circumference, WHR: Waist-to-hip ratio, WSR: Waist-to-stature ratio, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, SD: Standard deviation.

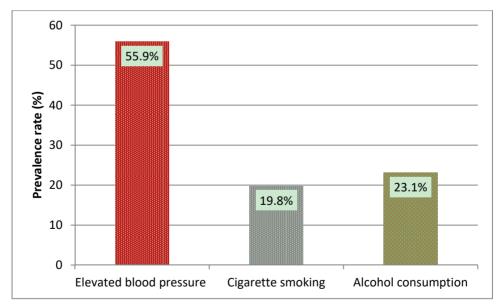


Figure 1. Elevated blood pressure, cigarette smoking and alcohol consumption

#### 4. Discussion

This is the first report on elevated BP of Andibila people residing on a high altitude in Oju, Nigeria. This study is important because it provides information on an important health indicator—blood pressure of a under researched and geographically isolated tribal group. There is no basic health and social facilities provided to the Andibila community by the government. From a public perspective, the health information of this tribal, high altitude

dwelling community, devoid of contemporary modern living is important for policy interventions. There is need to provide health care services and facilities to the Andibila community.

Intriguingly, the elevated BP of Andibila mountain dwellers is high (55.9%). Other researchers has reported high prevalence of hypertension among the lean Eritrean (Usman, Mebrahtu, Debru, Tesfazion, Gebresellasie, & Ghebrat, 2015) and Chinese (Nguyen, Adair, He, & Popkin, 2008) population. Arterial hypertension is known to be affected by heredity (age, race, gender), and lifestyle behaviour (smoking, obesity, alcohol consumption, physical inactivity, stress, and excessive salt intake). It is possible that the high elevated BP of among the Andibila people could be attributed to the type of community they live and perhaps affected by the unique mountainous (high altitude) challenges they encounter. Cultural beliefs and practices, as well as genetics could be possible risk factors for the elevated BP among the Andibila community. Norboo et al. (2015) study reported age, gender, socio-economic variables and changing lifestyle behaviours as correlates of hypertension among high altitude residents. It should be noted that at the time of conducting BP measurements among our sample, those with elevated BP were asked if they have ever being told about their BP levels; and whether they used too much salt for their food, most of the participants affirmed being diagnosed with high blood pressure and indicated taking some medications as well as adding too much salt to their food. Intuitively, the consumption of salt is high among the population. Besides, the consumption of alcohol and smoking of local tobacco among the Andibila people is a common traditional practice. These provide evidences for the elevated BP found our sample in this setting.

#### 5. Limitations

The small sample size of the participants limits generalisability, as well as age and sex statistical analyses. Second, a BP measurement at a single visit usually overestimates hypertension prevalence. Thus, in this paper, we use the term 'elevated BP' rather than 'hypertension. Third, information was not collected on other variables such as dietary habits, blood lipids and blood glucose, which are relevant to elevated blood pressure aetiology. Therefore, we cannot rule out the possibility that our findings might have been somewhat biased by the lack of these important confounders. Future studies should endeavour to assess these variables in order to clearly understand the complexity of the elevated BP levels of this high altitude population, and to enable proper intervention and treatment programmes. Despite these limitations, this study has made an inroad in documenting the nuance of health-elevated BP among a secluded and neglected indigenous Andibila people.

#### 6. Conclusion

Given the elevated BP found among the Andibila community living in an isolated, rural and mountainous setting, appropriate intervention strategies should be instituted by the Oju local government to prevent and control elevated BP among this tribal group by increasing awareness about regular check-up of BP, regular exercise, reduce salt intake, and abstinence from alcohol and smoking. The Andibila people, as part of the larger Oju community, deserve attention and care.

#### **Competing Interests Statement**

The authors declare that there are no competing or potential conflicts of interest.

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# Analysis of the Nutrients and Microbiological Characteristics of the Indonesian *Dadih* As a Food Supplementation

Helmizar<sup>1</sup>, Elya Yuswita<sup>1</sup> & Andani Eka Putra<sup>2</sup>

Correspondence: Helmizar, Department of Nutrition, Faculty of Public Health, Andalas University, Padang, Jalan Perintis Kemerdekaan Jati Padang, Padang 25144, Indonesia. E-mail: helmizar@ph.unand.ac.id

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#### **Abstract**

Dadih, an Indonesia traditional fermented buffalo milk produced and consumed by the *Minangkabau* ethnic group in the province of West Sumatra, Indonesia, is considered to be beneficial to human health. The objective of this study is to found out the nutrient compositions and bacteriological characteristics of dadih collected from *Tanah Datar* and *Agam* districs in West Sumatera province, Indonesia. This study was initiated with the analysis of biochemical protein, lipid, moisture value, pH, and titritable acidity contained in dadih. Bacteriological analysis has been conducted on total bacterial and total Acid Lactic Bacterial quantification. The study relveals that the total percentage of protein, lipid, moisture value, ash content, pH, and titritable acidity of dadih from Tanah Datar respectively is 12.41±1.30, 5.70±1.73, 66.09±6.00, 0.72±0.13, 4.55±0.21, 0.51±0.56. Total percentage of protein, lipid, moisture value, ash content, pH, and titritable acidity of dadih from Agam respectively is 10.89±2.55, 18.00±14.65, 61.94±20.18, 1.14±0.79, 4.33±0.46, 1.70±0.21. Dadih from Tanah Datar contains 1.9 x 10<sup>7</sup> CFU/g BAL and 2.3 x 10<sup>7</sup> CFU/g total bacteria. Ther study also shows that dadih from Agam contains 4.6 x 10<sup>6</sup> CFU/g BAL and 2.9 x 10<sup>8</sup> CFU/g total bacteria. The study concludes that there is not pathogenic bacteria in dadih from both Tanah Datar and Agam.

**Keywords:** nutrients, dadih, microbiological characteristics, food suplementation

#### 1. Introduction

Dadih is a traditionally fermented buffalo milk produced and consumed by several communities of Minangkabau ethnic group. Fermentation of dadih occurs spontaneously at room temperature (30 °C) for two days after the curd has been poured into a bamboo tube and closed with banana leaves (Surono et al., 2008). Dadih contains two types of probiotic strains of Lactic Acid Bacteria, including E. faecium IS-27526. Dadih is very popular in several districts/cities in West Sumatra Province such as Agam, Bukittinggi, Solok, Lima Puluh Kota and Tanah Datar. Various lactic acid bacteria contained in dadih can inhibit or remove certain pathogenic bacteria, and can be used for further assessment, product development, and clinical intervention in humans (Putra et al., 2011). Sadly however, the consumption of dadih by the people, especially the youths, has dropped in recent years. In fact, most of the Minangkabau youths are unaware of the benefits of functional food products that are rich in probiotics such as dadih. Therefore, dadih needs to be reintroduced to the community with its distinctive appearance using bamboo containers as packaging. In general, the dadih produced by the people of West Sumatra is unpasteurized and the bamboo tubes used are often uncleaned. This process has been carried out from generation to generation by the local community, making it difficult to change the habits of the farmers.

The development of technology and science has helped the local government and related parties such as researchers to contribute to the progress and development of dadih by West Sumatran farmers. The training on dadih processing from start to finish in accordance with food safety standards is very beneficial to the local communities as it allows them to produce quality dadih. Improving the quality of dadih through better processing will certainly attract consumers. Dadih can have an impact on health as it contains a number of living microbial cells ranging between 106–108 cfu/g (Tannock, 1999), or 107–108 cfu/g of product in its probiotic product (Charterist et al., 1998). The presence of Lactic Acid Bacteria in dadih acts as a probiotic that can regulate the digestive tract ecosystem. The metabolites produced by this Lactic Acid Bacteria can inhibit the growth of pathogenic bacteria, improve the immune system, prevent constipation, reduce cholesterol, antimutagenic,

<sup>&</sup>lt;sup>1</sup> Department of Nutrition, Faculty of Public Health, Andalas University, Padang, Indonesia

<sup>&</sup>lt;sup>2</sup> Department of Microbiology, Faculty of Medicine, Andalas University, Padang, Indonesia

anticarcinogenic, antivaginitis, and produce B vitamins and bacteriocin (Pato, 2003). These various benefits become the basis for using dadih as a supplement for the community members, especially pregnant women.

The consumption of dadih will be much efficient if it is accompanied by the consumption of zinc supplements to improve the nutritional status of mothers and babies. The supplementation of probiotic food sources with zinc to pregnant women can directly improve the nutritional status of infants, especially premature infants or low birth weight babies (Lutter & Chaparro, 2009). Some dairy products have been reported to contain probiotic bacteria, and if consumed in sufficient quantities, they can be very beneficial to body health. Up to the present, intervention studies based on local food products such as dadih with zinc supplementation during pregnancy have not been well elaborated. In addition, information about the effects of dadih and zinc supplementation to pregnant women regarding their body's humoral immune response and their infant birth weight in Indonesia is very limited. Because pregnancy outcomes are affected by nutritional intervention during pregnancy, it is necessary to conduct research on food-based nutrition interventions and zinc supplementation to optimize maternal and child health. Giving nutritional intervention during pregnancy is also in line with efforts to support a key government program i.e., the Efforts to Improve Nutrition National Movement in the First 1000 Days of Life (1000 HPK). This study aims to determine the nutritional value and characteristics of dadih bacteria in West Sumatra, especially in Agam and Tanah Datar regions.

#### 2. Research Method and Material

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The material used in this study is dadih, a traditional fermented buffalo milk obtained from Agam and Tanah Datar regencies in West Sumatra Province. This research was conducted from November 2016 to June 2017 at the Laboratory of Biochemical Analysis and Microbiology of the Agricultural Technology Faculty, the Faculty of Animal Husbandry Non Ruminants Nutrition Laboratory, the Laboratory of Biotechnology and Microbiology, and the Faculty of Medicine at Andalas University, Padang.

# 2.1 Making Buffalo Curd and Sensory Analysis

Buffalo milk was pasteurized at a temperature of 60–75 °C for 30 minutes, then cooled to room temperature (25) °C. The milk was then put into clean bamboo tubes. The bamboo tubes were closed and tied with plastic to allow the milk to ferment for 24–48 hours at 25 °C. Dadih was obtained when buffalo milk clumped to form a dense and white consistency. After consistency, organoleptic (hedonic) test was conducted by 30 semi-trained panelists from the community (pregnant women) in Bukittinggi and Agam on the nature of taste, color, aroma, texture, and general acceptance of dadih on a scale of 1 = dislike, 2 = rather like, 3 = ordinary/neutral, 4 = like, and 5 = highly like.

#### 2.2 Proximate Composition

The protein content of dadih samples was determined by using the kjeldhal method. The total lipid was extracted with hexane by using the soxhlet method. The moisture value was evaluated by using the oven drying method, the ash content was determined by using the furnace incineration method (AOAC, 2000). The difference method was used to calculate the carbohydrate by subtracting 100% crude protein, fat, moisture, and ash content. The first step for sample pH measurement i.e., three grams (3 g) of sample blended with 3 mL dH2O in a beaker was determined by using a pH meter (Jenway 3310, England). pH meter was calibrated with pH 4.0 and pH 7.0 buffer solution before the measurement. Titratable acidity began with the measurement of ten samples (10 mL) and three drops of 0.1 N phenolphthalein indicator added. The mixture was titrated against 0.1 N NaOH until the first permanent pink color appeared. The titrated acidity was then calculated and expressed as percent lactic acid.

### 2.3 Microbiological Analysis

The population of Lactic Acid, aerobic, and E. choli (cfu/mL) bacteria was determined by using MRS agar media (Oxoid, England), plate count agar (PCA) (Oxoid, England), and endo agar. (Oxoid, England). A total of 5 g of dadih samples from Agam and Tanah Datar was taken aseptically and put into a sterile tube containing 45 mL of buffered peptone water (Oxoid, England) 0.1% sterile. The samples were made into several serial dilutions, then planted on MRS media to allow the media, plate count agar (PCA), and endo to beububate by using an incubator (Memmert, Germany) at 37 °C for 24–48 h. The microbial colonies formed were calculated based on the Standard Plate Count (SPC) with the following formula:

Total Population (cfu/ml) = 
$$\frac{\text{N cawan}}{(\text{n1} + (0.1 \times \text{n2})) \times \text{d}}$$

Notes:

N = Number of different colonies in the count range (25–250 colonies).

n1 =The number of the first cup whose colonies can be counted.

n2 = Number of second cups whose colonies can be counted.

d = The first dilution calculated.

2.4 Selection of Respondents and Socialiszation

This research was conducted with the approval of Research Ethics Commission of the Faculty of Medicine Andalas University. Initial screening was conducted to find prospective respondents i.e., two trimesters gestational age pregnant women in Bukittinggi and Agam districts. The respondent criterion consists of volunteer women having a 12–16 weeks gestational age, Hb $\geq$ 10, and who were not suffering from anemia and chronic diseases. This study is aimed to identify changes as a result of the intervention with an  $\alpha$ =0,05, 1- $\beta$ =0,8, a difference in birth weight (0.3) of infants in accordance with the result of intervention studies in Indonesia (Dijkhuizen, 2001). The sample size is calculated by using sample size formula hypothesis testing between two means (Lemeshow, 1990).

$$n = \frac{2\sigma^2(z_{1-\alpha/2} + z_{1-\beta})^2}{(\mu_1 - \mu_2)^2}$$

Note:

n = number of sample size

 $Z_{1-\alpha/2} = Z$  score for significance level of  $\alpha$  in two sided hypothesis testing (5%)

 $Z_{1-\beta} = Z$  score for 1- $\beta$  power of statistical test (80%)

 $\sigma^2$  = Population Variance

 $\mu 1$  = Test value of population mean

μ2 = Anticipated population mean

# 2.6 Product Intervention

The intervention stage is the stage of giving dadih regularly to the respondent's house for  $\pm$  156 days (in the second trimester of pregnancy to delivery) except in the control group. Packed in bamboo tubes, the products were administered to each respondent every day except Sunday. The treatment was carried out on three groups, namely dadih, dadih + zinc, and control group. Every pregnant woman in the intervention group received 100 grams of dadih and 20 mg of sulfate zinc supplement every day for 6 months. Pregnant women in the control group did not receive treatment from researchers but their received intervention at Community Health Centers or *Pusat Kesehatan Masyarakat* (Puskesmas) through their routine programs. Fruit tastes or spicy sugar was added to dadih to make it more attractive. Monitoring of acceptance and consumption compliance were conducted every week. Nutrition education was given every month during the study. Health checks for pregnant women were carried out in accordance with ANC procedures by each Puskesmas.

#### 3. Results and Discussion

# 3.1 Characteristics of Dadih

The dadih used in this study originates from Agam and Tanah Datar regions. It is made by buffalo farmers in accordance with the standards set by the researchers. Until recently, farmers used to process dadih in a less hygienic way because of their limited knowledge. In this research, farmers were trained to make more hygienic dadih by paying attention to buffalos, equipment and workers sanitation. In addition, farmers were also taught how to pasteurize buffalo milk so as to kill pathogenic bacteria by heating milk at a temperature of 62–65 °C for 30 minutes. Dadih is fermented for ± 24–48 hours and takes the shape of a lump that condenses like tofu. It has a white color and smells like sour milk. According to Sirait (1993), a good dadih is white with a consistency resembling acidic milk. Sisriyenni and Zurriyati (2004) report that white dadih that has soft texture with a specific aroma is preferred by consumers. The consistency of dadih is influenced by its chemical components such as protein, fat, water, and lactic acid bacteria produced from the fermentation process of milk. The fermentation process involves Lactobacillus bacteria naturally found in milk. These bacteria produce β-galactosidase which will break down lactose into glucose and galactose. Glucose is changed to fructose 6-phosphate through the process of glycolysis. The end result of the glycolysis process is lactic acid formation (Horton et al., 2012).

#### 3.2 Sensory Evaluation

Sensory test results on the color, aroma, taste, texture, and general acceptance of buffalo dadih from Tanah Datar and Agam are presented in Figure 1. Based on the scores given by the panelists, Tanah Datar dadih sample was preferred by the panelists with a mean value of 4.53% common acceptance preference. The results of sensory value analysis showed that there was a significant difference between color, taste, texture and general acceptance between dadih from Tanah Datar and that of Agam with a value of p <0.05. However, in the panoramic assessment, there was no significant difference between both in terms of aroma (with p> 0.05 (Pv value 0.184).

A significant difference between Tanah Datar dadih and that of Agam, in terms of color, taste, texture and general acceptance indicates that Tanah Datar dadih is preferred by panelists to that of Agam. This is due to the fact that the former has a slightly whiter color, less acidic taste and a soft texture like a pudding. This is allegedly caused by the quality of milk used (Afdi, 2006). Milk quality is affected by animal feed. Tanah Datar buffalos are is fed with banto grass and additional supplements in the form of napal powder, while Agam buffaloes are fed with grass weeds. A buffalo can produce milk at 5 months of pregnancy, and at the time of birth of the cald (2 months old). The characteristics of superior dadih-producing buffaloes include large body, a large milk bag and fall, and upwards curved horns

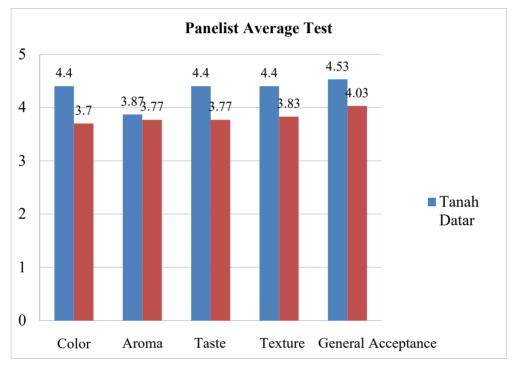


Figure 1. Panelist Average Test Value of dadih from Tanah Datar and Agam

The average buffalo can produce milk for  $\pm$  3 months. The average milk produced from 1 buffalo is 2–3 liters per day (in the productive period that is after the buffalo gives birth). Buffalo pregnancy period varies depending on the sex of the child being conceived. The age of buffalo pregnancy containing male buffalo is 11 months, while the age of the female buffalo is 10 months. Buffalo can be mated again after 1–2 months after giving birth. One way to allow buffaloes to reproduce is to feed them with additional food, namely palm sugar water.

# 3.3 Proximate Analysis

Proximate analysis carried out on dadih sample aims to determine the levels of protein, fat, water, ash, crude fiber, carbohydrate, pH, and acidity contained in the sample. Results of the observations of proximate analysis can be seen in Table 1.

Table 1. Results of West Sumatran Dadih Chemical Analysis

Characteristics	Source of Dadih		
Characteristics	Tanah Datar <sup>2</sup>	Agam <sup>1</sup>	
Protein (%)	$12.41 \pm 1.30$	$10.89 \pm 2.55$	,
Fat (%)	$5.70\pm1.73$	$18.00 \pm 14.65$	
Water content (%)	$66.09 \pm 6.00$	$61.94 \pm 20.18$	
Ash content (%)	$0.72 \pm 0.13$	$1.14 \pm 0.79$	
Carbohydrate (%)	$14.92 \pm 6.53$	$8.03 \pm 5.15$	
pН	$4.55\pm0.21$	$4.33 \pm 0.46$	
Acidity (%)	$0.51 \pm 0.56$	$1.70 \pm 0.21$	

Note. 1 Chemical characteristics of Agam dadih are the average of the results of test of Palupuah and Gaduik regions dadih.

The results showed that the pH value of dadih samples taken from Agam is lower than that of Tanah Datar. This is inversely proportional to the acidity level, where Agam dadih sample has a higher acidity value than Tanah Datar dadih. The lower the pH value produced shows the higher the acidity of the product. High acidity of Agam dadih samples illustrates that it has has a higher lactic acid content compared with Agam dadih samples (Table 1). The low pH value and the high level of acidity of Agam dadih are also thought to be caused by the type of buffalo food grass given. Agam dadih is produced from buffaloes fed with grass (Imperata cilindrica), while Tanah Datar dadih is produced from buffaloes fed banto grass and rice straws. It is known that weeds contain several acidic compounds namely malic acid and citric acid. It is suspected that these two compounds contribute to the flavor of Agam dadih's acid. The type of bamboo tube used as a container/packaging affects the chemical characteristics and water content of dadih. Agam dadih's water content (61.94%) is lower than that of Tanah Datar (66.09%). Agam dadih is packaged in Talang bamboo tube while Tanah Datar dadih is packed in Lapoh. Because Talang bamboo is bigger and thicker than Lapoh bamboo, its porosity is higher. Water or other liquid components can seep into it more easily. Nutrition given to buffalo also affects the chemical characteristics of dadih, including the levels of protein and calcium. Based on Table 1, it was found that the protein content of the analyzed samples is high at 10.89% in Agam dadih samples and 12.41% in Tanah Datar dadih samples. The protein content of Tanah Datar dadih is higher than that of Agam dadih. This is allegedly caused by the food supplements (Napal stones) given to buffaloes belonging to Tanah Datar farmers. Napal stone, usually called limestone, is calcium carbonate (CaCO<sub>3</sub>) rich in mud or mudstone containing a variable number of clay and aragonite.

The results of the study (Table 1) show that the protein content of both Tanah Datar and Agam dadih samples is higher (6.5%) than the protein content of dadih collected by Soenarto et al., (2013) from several locations of dadih production. Based on the results of the proximate analysis (Table 1), it was found that Tanah Datar and Agam dadih contain various nutrients needed by the human body. The weight of Tanah Datar and Agam dadih's macro nutrients can be calculated by using atwoter 4: 4: 9 conversion (carbohydrates: protein: fat). That is, every 1 gram of carbohydrate is equivalent to 4 kcal, protein equals 4 kcal, and the fat is equivalent to 9 kcal. The results of the calculation of dadih macro nutrition values are presented in Table 2.

Table 2. Dadih Nutritional Components per 100 grams

		Components			
No	Source Dadih	Calorie	Protein	Fat	Carbohydrate (g)
		(Kal)	(g)	(g)	
1	Tanah Datar	160.62	49.64	51.30	59.68
2	Agam	237.68	43.56	162.00	32.12

## 3.4 Microbiological Analysis

Microbiological analysis carried out on the sample is aimed to determine the content of lactic acid bacteria, total

<sup>&</sup>lt;sup>2</sup> Chemical characteristics of Tanah Datar dadih are the results of Padang Panjang dadih test.

plate count, and E. choli bacteria contained in the sample. The results of microbiological analysis observations can be seen in Table 3.

Table 3. Results of the Microbiological analysis of dadih from Tanah Datar and Agam

C1	Lactic Acid Bacteria	Total Plate Count	ount E. choli bactery
Samples	(cfu/g)	(cfu/g)	(cfu/g)
Tanah Datar dadih	$1.9 \times 10^7$	$2.3 \times 10^7$	-
Agam dadih	$4.6 \times 10^6$	$2.9 \times 10^8$	-

The results show that Tanah Datar dadih contains lactic acid bacteria estimated to 1.9 x 107 cfu/g, which is higher than the lactic acid bacteria in Agam dadih (4.6 x 106 cfu/g). The growth of bacteria in dadih is affected by nutrients, water, and temperature. The bamboo used as a dadih packaging is thought to contain a substrate that can supports the growth of lactic acid bacteria. Lactic acid bacteria are homofermentative bacteria belonging to mesophilic bacteria and have an optimum a temperature range for growth and development of 20-45 °C (Surono, 2016). Dadih, as a functional food, contains lactic acid bacteria that act as probiotics which is beneficial to human health (Hutami et al., 2013). The role of lactic acid bacteria is not only to regulate the digestive tract ecosystem, but it also contributes in the formation of texture of dadih. The lactic acid produced by bacteria can inhibit the growth of other harmful bacteria, such as bacterium E. choli, which causes diarrhea. Dadih mainly consists of buffalo milk by relying on microorganisms in nature as inoculants without using an additional starter. These microbes are thought to come from bamboo tubes used as containers (Zakaria et al., 2002), and from the banana leave tube covers or from the milk itself (Afdi, 2006). Probiotics are living microorganisms, which, when given in sufficient quantities provide health to their hosts (FAO and WHO, 2002). Probiotic bacteria are able to overcome saliva, stomach acid and bile obstacles during the journey to the digestive tract. These bacteria can survive in the digestive tract ecosystem, enabling them to reach a certain amount for a certain time. The amount/viability of probiotic microbes after going through the digestive tract ranges between 106-107 cfu/g mucosa (Bouhnik, 1993).

Probiotic bacteria can improve the health of the host's body through several ways, including by producing antimicrobial compounds such as lactic acid,  $H_2O_2$ , bacteriocin, renterin and compounds that inhibit the growth of pathogenic bacteria, stimulate the immune system and are able to change the activity of microbial metabolism in the digestive tract, and excel in competition to attach to fine epithelial cells and absorb nutrients needed by the body.

# 4. Conclusion

Dadih is a fermented buffalo milk that contains macro nutrients such as protein, fat, carbohydrates, and water. In addition, dadih also contain probiotics that are good for human health. This dairy product typical of West Sumatra can be found mostly in Tanah Datar and Agam regions. The dadih from Tanah Datar contains  $12.41 \pm 1.30\%$  protein,  $5.70 \pm 1.73\%$  fat,  $14.92 \pm 6.53\%$  carbohydrate, and  $66.09 \pm 6.00\%$  water. Meanwhile, dadih from Agam contains  $10.89 \pm 2.5\%$  protein, fat  $18.00 \pm 14.65\%$ , carbohydrate  $8.03 \pm 5.15\%$ , and water  $61.94 \pm 20.18\%$ . both dadih contain lactic acid bacteria with a number of  $1.9 \times 107$  cfu/g in dadih from Tanah Datar and  $4.6 \times 106$  cfu/g in dadih from Agam. Daih is very good for lactose intolerance sufferers. This is because lactic acid bacteria contained in dadih can inhibit the growth of E. choli bacteria which can cause diarrhea. Consumption of dadih can increase one's nutritional intake. Based on the research, it is known that dadih from Tanah Datar can provide 160.62 Kal, 49.64 g of protein, 51.30 g of fat, and 59.68 g carbohydrates. While Dadih from Agam can provide 237.68 Kal, protein 43.56 g protein, fat 162.00 g, and 32.12 g carbohydrates. Nutritious dadih along with its benefits is still less attractive to the public, especially among young people because of its taste and smell. Therefore, it is very necessary to process dadih technologically in order to turn it into an attractive dairy product for everyone.

## **Competing Interests Statement**

The authors declare that there are no competing or potential conflicts of interest.

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# HIV Voluntary Counselling and Testing in Namibia: Status, Successes, and Barriers

Daniel Opotamutale Ashipala<sup>1</sup>, Esther Kamenye<sup>1</sup>, Frans Muronga<sup>1</sup> & Len Tooley<sup>2</sup>

Correspondence: Mr Daniel Opotamutale Ashipala, School of Nursing, Faculty of Health Sciences, University of Namibia (UNAM), PO Box 88, Kaisosi Road, Rundu, Namibia. Tel: 66-268-6003. E-mail: dashipala@unam.na

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#### Abstract

Voluntary Counselling and Testing is one of the strategies to respond to the increasing number of Human Immunodeficiency Virus/Acquired immunodeficiency syndrome (HIV/AIDS) new infections. The purpose of this study was to assess the current status of HIV Voluntary Counselling and Testing (VCT) in Rundu urban and identify the barriers to fully effective service. The objectives of the study was to identify the barriers that prevents effective HIV Voluntary Counselling and testing services; asses its success and determine its status in urban, Namibia. A qualitative explorative and descriptive design was employed in this study where all health care and HIV/AIDS professionals including hospital nurses, employees and New Start VCT Centres, and representatives from relevant NGOs, Community-Based Organizations (CBOs), and the Ministry of Health and Social Services (MoHSS) providing Voluntary Counselling services in Rundu urban in Namibia were interviewed. In this study, in depth individual interview structured in accordance with interview guide was used. Content analysis method was employed to analyze the data. Themes that emerged from this study includes: Fear of a positive results (stigma that accompanies seropositivity) and lacks of perceived benefit to getting tested. In addition, financial barriers affecting the poorest populations in Rundu. To increase access and relevance of VCT services, it is recommended that the Ministry of Health and Social Services should develop more detailed counselling guidelines and increase the scope of counselling by addressing the inadequacies of current risk reduction. Despite these hopeful possibilities a number of barriers remains before VCT can be fully effective.

Keywords: HIV, counselling, voluntary counselling and testing, barrier, success, status

### 1. Introduction

HIV remains one of the biggest public health challenges globally and especially in Sub Saharan Africa and in Namibia. The UNAIDS (2014) fact sheet on Global Statistics indicate that to date 15 million people are accessing antiretroviral therapy (ART) by March 2015, 36.9 million people globally were living with HIV, 2 million people became newly infected with HIV and 1.2 million people died from AIDS related illness. Sub- Saharan Africa has 25.8 million people living with HIV, of which women account for more than half the total number of people living with HIV (UNAIDS, 2014). It is estimated that 1.4 million new infections in 2014 and these new infections account for 60% of the global total of new infections.

Namibia has achieved high treatment coverage of 86% using the CD4 count of 350 with 50% decreases in estimated new infections and number of AIDS related deaths (MoHSS, 2013). Following the first reported cases in 1986, data compiled by the Ministry of Health and Social Services (MoHSS) show that AIDS became the leading cause of death in Namibia in 1996. The 2008 MoHSS HIV projections show an estimated adult prevalence rate of 18%. Approximately 3,350 infants are infected with HIV per annum. The vast distances and low population density in Namibia make health care and HCT services inaccessible to many segments of the population who are at risk of HIV. Recent estimates indicate that 29% females and 18% males reported having gone for HIV testing within the past 12 months of the survey and knew their sero-status .Only 5% of those attending HIV Counselling and Testing (HCT) did so as couples (MoHSS, 2013).

There are three approaches to voluntary counselling and testing. Client-initiated HCT means that the client is the

<sup>&</sup>lt;sup>1</sup> Department of General Nursing Science, School of Nursing, Faculty of Health Sciences, University of Namibia (UNAM), Rundu, Namibia

<sup>&</sup>lt;sup>2</sup> Department of Anthropology, Faculty of Arts and Science, University of Toronto, Ontario, Canada

one that seeks out the services. The knowledge of status, and the counselling that accompanies it, can be a powerful catalyst for behaviour change. Provider-initiated means that health care workers recommend HIV testing to patients as part of routine health care services. The provision of provider-initiated HCT in health facilities and hospitals can improve diagnosis and save lives. Testing should be offered to patients in antenatal clinics, maternity wards, medical and surgical wards, outpatient departments, Sexual Transmitted Infections (STI) units, and Tuberculosis (TB) clinics. Finally a third approach, home-based HCT brings HCT services into the home (MoHSS, 2011).

The MoHSS (2014) Sentinel Surveillance among pregnant women estimates the second highest HIV Prevalence was Rundu (24.1%) after Katima mulilo (36%). Namibia has significantly expanded HCT services, through traditional VCT for people who seek to know their HIV status. It also has initiated Provider initiated Testing and Counselling (PITC) through HIV testing in antenatal clinics (ANC) through the prevention of mother to child transmission (PMTCT) programmes and through testing in TB and STI settings. Because of the critical shortage of qualified medical personnel in Namibia, the MoHSS trained and deployed lay HCT counsellors who are able to do both counselling and rapid HIV testing in public health facilities to complement the overburdened health care providers and provide both VCT and PITC services. The lay HCT counsellors, known as 'community counsellors', provide services such as HIV counselling, couples HCT, HIV rapid testing (if certified), male circumcision (MC) counselling and Anti-retroviral Therapy (ART)adherence counselling.

Voluntary Counselling and Testing is one of the strategies to respond to the increasing number of HIV/AIDS new infections, it provides the opportunity to know about ones status and acts as an entry point to access treatment, care and support services. Despite the efforts of the MoHSS to increase the number of health facilities providing VCT services and the increase of HIV Voluntary counselors in Namibia. It is not clear as to what causes the number of people who use VCT services to be low. Results indicated that 72% of all HIV tests reported to the Ministry of Health and Social Services (MoHSS) were conducted at Public Health Facilities (PHF). National Testing Day (NTD) and Standalone facilities conducted 15% and 12% of the tests respectively with workplaces recording the lowest proportion of 0.9%. The highest HIV positivity rate of 21% was identified at workplaces followed by PHF with 9% and 5% for NTD. Despite the increase of health facilities providing VCT services and the increase in Voluntary counsellors. There is a need for the increase of HIV Counselling and Testing service to be utilised to the maximum to know the HIV status timely to make crucial life decisions. The researcher is not aware of any study conducted in Namibia on this topic: HIV Counselling and testing at Rundu Intermediate Hospital in Kavango East Region: Status, Barriers and Success. The above phenomenon has led to the formulation of the research question: What is the status, barriers and success of HIV counselling and testing at Rundu Intermediate Hospital in Kavango East Region.

#### 2. Goals and Objectives

The goal of the study was to assess the current status of HIV Voluntary Counselling and Testing (VCT) in urban Namibia and identify the barriers to fully effective service. The objectives of the study was identify the barriers that prevents effective HIV Voluntary Counselling and testing services; asses its success and determine its status in urban Namibia.

# 3. Research Design and Methods

# 3.1 Design

A cross-sectional qualitative and explorative design.

### 3.2 Study Population

The study population included all health care and HIV/AIDS professionals including hospital nurses, employees and New Start VCT Centres, and representatives from relevant NGOs, Community-Based Organizations (CBOs), and the Ministry of Health and Social Services (MoHSS), Namibia.

#### 3.3 Inclusion and Exclusion Criteria

All health care and HIV/AIDS professionals including hospital nurses, employees and New Start VCT Centres, and representatives from relevant NGOs, Community-Based Organizations (CBOs), and the Ministry of Health and Social Services (MoHSS). In addition, health care and HIV/AIDS professionals including hospital nurses, employees and New Start VCT Centres, and representatives from relevant NGOs, Community-Based Organizations (CBOs), and the Ministry of Health and Social Services (MoHSS) who were not willing to participate were also excluded in the study.

### 3.4 Sampling and Sample Size

In qualitative studies the size of a sample is guided by the purpose of the inquiry. Therefore in this study there was no specification of the sample size but data saturation was determined by the sample size. Data saturation was reached with eleven (11) participants. Maree (2016), describe purposive sampling as a strategy that is used in qualitative studies whereby participants are grouped according to predetermined criteria that are relevant to a particular research question. Purposive sampling was used to select participants in this study.

#### 3.5 Data Collection Tool

In this study, in-depth interviews were used as the primary source of data collection. This data collection method was used for the study, as it is considered to be a relevant tool to use when the researcher seeks to learn about people's feelings, thoughts and experiences (Maree, 2016).

#### 3.6 Data Collection Methods

The researcher conducted face to face in-depth interviews with health care and HIV/AIDS professionals including hospital nurses, employees and New Start VCT Centres, and representatives from relevant NGOs, Community-Based Organizations (CBOs), and the Ministry of Health and Social Services (MoHSS).

#### 3.6 Data Analysis

In this study, in depth individual interview structured in accordance with interview guide was used. Content analysis method was employed to analyze the data.

#### 4. Ethical Considerations

HIV and AIDS are considered as sensitive issues due to the nature of the stigma and discrimination surrounding the disease. Participants in this study were assured confidentiality and anonymity. They were not obliged to divulge their names or personal particulars expect their gender, age and educational background. An informed consent form was considered prior participation. Participants were assured that research material and all documents with their response are going to be kept safe in an area only accessible to the researcher.

#### 5. Results

Table 1. Characteristic of Participants

Age	Total
27-30	5
31-40	4
41-50	1
51-60	-
Unknown	1
Marital Status	
Single	5
Married	3
Co-habitating	3
Widowed	-
<b>Educational Level</b>	
Grade 1-7	3
Grade 8-12	4
Tertiary Education	4
No education	0
Employment	
Employed	5
Unemployed	5

Professional rank	
Registered nurse	3
Enrolled Nurse	3
VCT counselors	4
NGO Representative (Social Marketing Association)	1

#### 5.1 Socio Demographic Description of Study Participants

Participants were health care and HIV/AIDS professionals including hospital nurses, employees and New Start VCT Centres, and representatives from relevant NGOs, Community-Based Organizations (CBOs), and the Ministry of Health and Social Services (MoHSS). All participants were under the age of 40 years old. Marital status of participants varied some were single, married and the others co-habiting. Educatinal level of participants also varied with less of them schooling till grade 7, most of the participants reached secondary school and some even went as far as tertiary education, only one participant had no schooling. It is evident from the table that participants were equally unemployed and employed, with the unemployed doing voluntary services at hospitals and mostly with the NGO's and Community-based Organizations.

Table 2. Themes and sub-themes of data analysis

Themes	sub-themes
5.1 Views of counselors regarding HIV counselling and testing of clients	5.1.1 Determining the risks of getting infected with HIV (Revealing of HIV status)
chents	5.1.2 Fear of infected due to unsafe sex practices
5.2 Participants different views regarding testing of partners	5.2.1 Involvement of partners in HIV testing
5.3 PMTCT	5.3.1 Difficulties in joining PMTCT programme
	5.4.1 New relationships and marriages
5.4 Clients rationales regarding HIV counselling and testing (difficulties and success of counselling)	5.4.2 Counselling and testing of a sick person
(announce and passess of volumes and	5.4.3 Other factors for counselling and testing
	5.5.1 Stigma
	5.5.2 Spatial and Financial Barriers to New Start HIV VCT Services
5.5 Barriers to HIV counselling and testing	5.5.3 Ideology and Services
	5.5.4 Ideology and Services
	5.5.5 Referrals between institutions
	5. 5.6 Gender, Income, and VCT

# 5.1 Views of Counselors Regarding HIV Testing

#### 5.1.1 Determining the Risks of Getting Infected With HIV (Revealing of HIV Status)

The counselors revealed that most clients are visiting the testing centers mainly to be tested and informed about their HIV status. To make the counselling and testing easier, it is always good to firstly find out from the clients the reasons why they are visiting the testing centers.

"Knowing clients' reasons for getting tested allows us to determine their risk of having been exposed to HIV, personalize the information given during the counselling".

The counselors further revealed that it is not always easy to get right answers from the clients

"...determining why clients had come to the clinic could be difficult: often they were ashamed or embarrassed about why they had come".

#### 5.1.2 Fear of Infected Due to Unsafe Sex Practices

The counsellors also revealed that people were most often getting tested for HIV because had practiced unsafe sex and were unsure of their sexual partner's HIV status or sometimes they were drunk

"Clients blamed their behaviors on being drunk at the time and thus "couldn't remember all of the details of what happened".

According to unpublished statistics given to the researchers by SMA, this accounted for approximately 44% of the visits to New Start Centres. Often people just wanted to know their status as they were worried they might have caught HIV. Counsellors said that they would respond to clients' anxieties by being "warm and open" and especially non-judgmental, repeatedly telling clients that they were not there to judge or criticize but educate and support. They often noted that as the counselling session progressed, clients would open up as they became more comfortable.

# 5.2 Participants Different Views Regarding Testing of Partners

# 5.2.1 Involvement of Partners in HIV Testing

The next most frequent reason cited was that of partner risk. This accounted for approximately 814% of visits to New Start Centres. Clients would tell the counsellor that although they had been faithful, they suspected their partner of "cheating" on them and were worried about HIV.

"I suspect my partner of "cheating" on me".

This problem proved to be very difficult for counsellors: while they could help clients learn their HIV status, it was often very difficult to help them find ways to change behaviours. Many clients said that their partner would leave them or be suspicious if they asked to use condoms, so this was not an option.

"I was frequently getting tested without my partner's knowledge".

This concern was most pressing for women, an issue that will be discussed in detail in the Gendered Experience of the HIV Test section on page 61.

#### **5.3 PMTCT**

#### 5.3.1 Difficulties in Joining PMTCT Programme

With regards to pregnant women, a major motivation to be tested, and thus a focus of the counselling, was the prevention of mother-to-child transmission (PMTCT) program now offered at hospitals. Pregnant women who go to the hospital are offered a chance to participate in the PMTCT program whereby they are tested for HIV and if HIV positive, given a large dose of Antiretroviral (ARVs, HIV-fighting drugs) prior to and during delivery. The baby is given also given a dose of ARVs soon after birth. This decreases the chances of mother-to-child transmission of HIV during the birthing process. Counsellors revealed also that it is not easy to make the mother understand the importance of joining PMTCT programme.

"Many mothers wanted to get tested for HIV at the center first before deciding whether they wanted to participate in the PMTCT program or not".

5.4 Clients Rationales Regarding HIV Counselling and Testing

#### 5.4.1 New Relationships and Marriages

Beginning a new relationship and marriage were two other relatively common reasons people were getting tested for HIV.

"We want HIV test before having sex so that we could know each other's status and thus prevent transmitting HIV".

Here the biggest issue that came up for counsellors was the possibility of discordant results, where one person is HIV positive and the other HIV negative. This situation incited a fair amount of discussion at the four day training conference, in which counsellors debated about whether they should counsel couples together or separately. Counselling couples together can be valuable because the counsellor can help them make decisions together and discuss condom negotiation. Counselling two people together, however, is often much more difficult than counselling them individually and some counsellors did not feel adequately trained for this type of situation. In the end it was left up to the individual counsellors whether they felt comfortable counselling couples together or separately.

#### 5.4.2 Counselling and Testing of a Sick Person

A final reason people were getting tested (often one of the more difficult ones for counsellors) was illness: a client would come in experiencing symptoms of an STD or opportunistic infection having decided to get an HIV test to see if this was the cause.

"I just want to be test, just to see whether this is the sign of HIV infection".

SMA noted in its New Start statistics that 7% of their clients cited illness as their reason for getting tested, and a further 3% were being tested because their partner or child were ill. This was another issue brought up during the role playing session at the central training. A counsellor from the Katima New Start Centre said that "most clients that come to the centre are already quite sick." Some were so sick that they couldn't sit upright during the counselling, had difficulty walking, and would even vomit or defecate on the floor. This proved to be highly problematic for counsellors in a number of ways. Many counsellors felt that they weren't trained to deal with a sick patient, and that it was difficult to give them the right kind of counselling as the patient often required more immediate medical attention. One counsellor said: "patients were sometimes so ill that they were hard to understand and could barely speak".

# 5.4.3 Other Factors for Counselling and Testing

These reasons were simply the most often mentioned while the researchers were doing the research, and certainly don't cover everyone's reasons for getting and HIV test. Some other motivations were: getting insurance, employment, school admission and scholarships, planned pregnancies, family planning, shared needles, blood transfusions and exposure in the workplace. Most counsellors indicated that their works are challenging, but very important.

"Knowing why people get tested for HIV is important – not only does it allow for more effective counselling, but it also gives us an opportunity to provide focused, targeted education and risk-reduction strategies".

With this background of reasons people do get tested, the researchers would now like to launch into a discussion as to why counsellors and other HIV/AIDS workers felt people are not getting tested for HIV. The researchers main conclusion was that stigma (leading to lack of awareness, education, and understanding) is one of the biggest factors preventing people from deciding to get tested.

# 5.5 Barriers to HIV Counselling and Testing

HIV VCT faces a number of barriers that affect its overall effectiveness. Some are simply the consequence of larger social issues (such as the stigmatization of HIV), while other problems are specific to VCT. Getting people to a testing center is not the only hurdle that must be overcome: for VCT to be considered fully effective, clients must also return to the centre for their results. According to New Start's statistics, at some centres as many as 25% of clients do not return for results, while at other centres the "no-return" rate is just above 0%.

## 5.5.1 Stigma

There is no doubt that HIV is a highly stigmatized disease. It is very common in Namibia to hear of people losing their partners, being shunned by their friends, family, and community, or losing their jobs – all because they were HIV positive.

"Even us who work in HIV/AIDS-related fields feel the strong effects of stigma: they often told us of people are speaking behind their back, saying that we were HIV positive and spreading nasty stories".

Stigma can be such a concern for some people that it makes anxious to even be seen in or around a New Start testing centre. Counsellors revealed also that clients were worried that someone in their community would see them entering or leaving the centre. One counsellor said that the client told her that "I am afraid to leave with any sort of papers or pamphlets, as people thought that I am HIV positive".

Not surprisingly, the most common reason many people do not want to get tested for HIV is fear of a positive result. Of course, fear of differential treatment by friends, family and community is the most recited story. Many people the researchers spoke to believed that this fear was exacerbated by the lack of attention paid to confidentiality in hospital settings prior to the availability of New Start centres. They said that fears of rejection by others could be reduced if people felt they could learn their status completely independently, without anyone else knowing. However, the legacy of broken confidentiality persists and makes a number of people wary of any HIV testing at all.

Counsellors also told the researchers that some patients were afraid of being tested for HIV because they believed that once they found out that they were HIV positive they would die soon. This was especially the case when people didn't feel that they had reliable access to ARVs, which slow down the progression of the HI virus in the

body. Therefore a sense of hopelessness (whether misplaced or not) was deterring people from getting tested for HIV.

#### 5.5.2 Spatial and Financial Barriers to New Start HIV VCT Services

The two principal factors restricting the accessibility of HIV testing are what the researchers have dubbed spatial and financial barriers. These barriers mostly affected the poorest populations in Windhoek, which should be of concern to both SM and PSI as their mandate is to reach the most 'at risk' populations.

While SMA highly subsidizes their VCT services, New Start Centres are still advertised as charging N\$10 per HIV test, which includes the pre- and post-test counselling as well as counselling for the following three months. This fee was not completely obligatory: SMA often promoted New Start centres in newspapers with a voucher for a free HIV test. Various centres would also sometimes waive fees if the client had been referred by a priest or if they could show that the services were too expensive for them to afford otherwise.

"For those who do not (or cannot) read the newspaper or come across a free voucher and do not know which centres will waive fees, however, even a subsidized fee of N\$10 can be too much".

When taxi fare to and from the centre, lost work time, and lost time spent with children or other family members are all factored in, the cost grows from a mere N\$10 to something much greater. If rapid testing is not available the results must be picked up on another day, which means twice the travelling and twice the time commitment.4

A second hurdle to accessing New Start centres is their physical location. New Start centres operate only in urban centres. "People living in more rural communities must travel a long distance to get tested".

Again, if the test results cannot be given on the same day, this means that the trip must be taken twice or that accommodations must be found for the waiting period. Another aspect of physical location that affects people's likelihood to attend a New Start testing Centre is its location and visibility within a community. If the centre is in a high-traffic area or located directly in the community it serves, people will be less likely to attend it as they will be seen coming and going: again, the fear of stigma rears its ugly head.

#### 5.6 Trustworthiness

Trustworthiness of this study was ensured by using the criteria of Lincoln and Guba namely: credibility, transferability, dependability, and conformability of the study (Guba & Lincon, 1985).

#### 6. Discussion

In discussing this findings, it has been established that clients' reasons for getting tested allows counsellors to determine their risk of having been exposed to HIV, personalize the information given during the counselling, and help them start thinking about ways they can reduce their future risk of contracting the diseases to reduce the risk of becoming infected or transmitting HIV. HIV testing empowers the uninfected person to protect himself or herself from becoming infected with HIV; assist infected persons to protect others and to live positively and offers the opportunity for treatment of HIV and associated infections. (NDHS, 2013) It empowers individuals and couples to adopt measures to prevent the transmission or acquisition of HIV infection. These study findings are similar with those of Velikoshi, Davis, and Ashipala (2018) where they found that in the case of correctional officers their main desire to seek HCT services was to simply know their status; while treating information as confidential had the biggest influence on respondents' decision to select a particular facility to utilize the said services.

This study finding revealed that HIV VCT faces a number of barriers that affect its overall effectiveness. Some are simply the consequence of larger social issues (such as the stigmatization of HIV), while other problems are specific to VCT. Getting people to a testing center is not the only hurdle that must be overcome. Barriers related to social and behavioral factors that were mentioned by the participants of this study-included fear of positive results, stigma, and risky sexual behavior. Societal factors that contribute to men not utilizing VCT services include stigma and men's gender socialization. Institutional factors include poor treatment by nurses and confidentiality concerns were raised by Shipanga, Nauiseb, Kloppers (2018).

This study results pointed out at Social stigmatization and lack of perceived benefits as not the only reasons some people don't get tested. The two principal factors restricting the accessibility of HIV testing are spatial and financial barriers. These barriers mostly affected the poorest populations in urban areas such as Windhoek, which should be of concern to both SM and PSI as their mandate is to reach the most 'at risk' populations. Notably, studies have demonstrated that health care workers often do not have adequate infrastructure or workforce to ensure completely confidential services, despite their willingness or desire to do so (Bott, Neuman, Helleringer, Desclaux, Asmar, & Obermeyer, 2015).

The challenge that comes along with this sort of organizational structure is ensuring consistency across New Start centres in terms of quality and breadth of the services provided. SMA has addressed these concerns by providing standardized guidelines, protocols, training, monitoring, and quality assurance. Despite this standardization, however, a number of inconsistencies remain. Institutional factors include poor treatment by nurses and confidentiality concerns came up in the study done Rouraa, Watson-Jonesa, Kahawitaa, Fergusond, and Rossa (2013).

It was found in this study that women are more like to attend a New Start VCT centre than men. It is interesting, then, that women also often have the most to lose by getting tested. Men seem to always be afraid of facing their HIV results and being seen visiting VCT centers. It was mentioned that knowing one's results would cause damage to an individual when he is confronted by bad results that might lead to depression. Fear of stigma was dominantly reported by men as the stumbling blocks to the uptake of HIV testing. It is therefore apparent that stigma and discrimination remain barriers to HIV testing as found in a study done by Shipanga, Nauiseb, and Kloppers (2018).

Financial barriers do not only affect whether a client will be able to afford getting to and from the centre to get tested and pick up the results. Similar findings were also found by Mwangi, Ngure, Thige, Ngure (2014) stated that income also influence how effective counselling can be in terms of future risk reduction, living healthily after discovery of a positive result, and accessing health services. A study conducted to determine the cost of VCT services in Kenya.

In addition, income levels can greatly affect the ability of some clients to reduce their risk of HIV in the future. This was also noted that lower income is associated with an increased likelihood of HIV infection among some groups, few studies have explored how structural factors such as poverty can influence an individual's ability to access services such as VTC services (Meyerson, Barnes, Emetu, Bailey, Ohmit, & Gillespie, 2014)

#### 7. Conclusions

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#### 7.1 Conclusions

Despite these hopeful possibilities a number of barriers remain before VCT can be fully effective.

The future of New Start VCT in Namibia looks quite promising: more and more centres are opening up and the number of clients being tested each month continues to increase. As time goes on the "word will get out" as to the quality of the service provided and New Start VCT will be given the opportunity to assist ever-growing numbers of Namibians in their attempts to deal with HIV. A number of the issues faced by centres and clients alike, such as stigma and lack of open discussion about HIV/AIDS are addressed simply by the existence of New Start centres. Each client that goes to a New Start centre is taught valuable details about HIV including how it is (and is not) transmitted, what it means to be HIV positive or live with someone who is, and the value to talking to partners and loved ones about the disease. The hope is that these clients will go out into their respective communities and talk about HIV with their peers, increasing general levels of awareness about HIV and decreasing the often intense stigma associated with the disease.

# 7.2 Recommendations

Based on the study findings, the following recommendations are made:

- Simplify and standardize fee deferral. Financial barriers can be a strong preventive factor for the poorest segments of the population.
- Establish more mobile VCT services. People who live far away from the centre, especially those living in rural communities, might find the trip to a New Start centre restrictive with regards to cost or time required
- Expand the availability of rapid testing. When test results are available to clients on the same day, issues such as the cost and time required to get to and from the clinic are greatly reduced
- Develop training for counselling couples and dealing with discordant results. Currently the option to counsel couples separately or together remains up to each individual counsellor and is based on their comfort level and training. Greater preparation to deal with these situations will increase the effectiveness of VCT for couples who come to the clinic to get tested as part of their relationship or marriage or if they want to have children.
- Address the inadequacies of current risk reduction strategies. The oft-heard mantra of Abstain, Be
  Faithful, and Condomize is simply not relevant to many clients, especially those of a lower
  socioeconomic status.

- Increase the scope of counselling to address larger socioeconomic and social concerns. Issues such as
  drug dependency and obtaining money, food and health care are of considerable concern to a number of
  clients
- Standardize condom distribution policy. Instructing clients how to use condoms and then opposing their distribution can often be confusing. Implement services appropriate to the population being served at locations where there are currently no services other than VCT offered.
- Integrate post-test counselling with other services such as employment finding or income generating programs, food programs, home-based care and assistance in seeking health care
- Formalize a third counselling session as part of the VCT procedure to take place sometime after the disclosure of results. A third counselling session would enable counsellors to follow up with clients, find out how they have been doing since they got their results, and ensure that their clients have been successful at accessing the services they were referred to.
- Improve communication with surrounding resources to inform them of the services provided at New Start Centres. By communicating more with other HIV/AIDS organizations, SMA could ensure that their clients were treated well at institutions to which they were referred, and those institutions could also refer people looking for testing back to a New Start centre.
- Intensify pressure on (especially male) political leaders to be vocal about VCT and issues related to HIV/AIDS in general.

#### 7.3 Study Delimitations and Limitation

The study was delimited to the health care and HIV/AIDS professionals including hospital nurses, employees and New Start VCT Centres, and representatives from relevant NGOs, Community-Based Organizations (CBOs), and the Ministry of Health and Social Services (MoHSS). The two greatest hindrances to this study were that of time and the (understandable) emphasis on confidentiality placed on VCT services by SMA.

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#### **Competing Interests Statement**

The authors declare that there are no competing or potential conflicts of interest.

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# The Readiness of Smokers to Quit Smoking

Septian Emma Dwi Jatmika<sup>1</sup>, Muchsin Maulana<sup>1</sup>, Kuntoro<sup>2</sup>, Santi Martini<sup>2</sup> & Beni Setya Anjani<sup>1</sup>

Correspondence: Septian Emma Dwi Jatmika, M.Kes, Faculty of Public Health, Universitas Ahmad Dahlan, Yogyakarta, Jl. Prof. Dr. Soepomo, S.H., Janturan, Warungboto, Umbulharjo, Yogyakarta 55164, Indonesia. E-mail: septianemma@ikm.uad.ac.id

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#### Abstract

**Introduction:** The aim of the study is to find out the archives of smokers' readiness to quit smoking after the application of the Smoke-free House (RBAR) program.

Material and Methods: This type of research is a descriptive analytic study by using cross sectional approach. The research was conducted in a hamlet neighborhood (RW) that had been implementing RBAR program, and were selected randomly. They are RW 8 Tegal Panggung, RW 5 Tegal Panggung, RW 11 Ngupasan, RW 12 Bumijeo, RW 11 Gowongan. The samples were taken by cluster random sampling technique and obtained 70 heads of families with criteria of willing to be respondents, family heads (male), active smokers and permanent residents who lives in the study site since the RBAR program was first set in 2010. Data analysis was done by *chi-square* test.

**Results:** The result shows that attitudes has significant relation to the readiness of smokers to quit smoking after the application of the RBAR program (p value = 0.030).

**Discussion and Conclusions:** The carried out interventions can be adjusted to the stages of the smokers' behavior change process.

Keywords: readiness, attitude, quit smoking, stop smoking, smoker, smoke free house, implementation

#### 1. Introduction

Smoking can murder up to half of consumers. Smoking murders nearly 6 millions people every year. More than 5 million of them are active smokers, while 600 thousand are passive smokers, this number exceeds the deaths caused by TBC, HIV/AIDS and malaria. Nearly 80% of the world's, 1 billion smokers live in low to middle income countries. About one person dies every 6 seconds because of smoking, accounting for 1 out of 10 deaths (World Health Organization, 2014).

Indonesia ranks the 3<sup>rd</sup> largest number of smokers in the world after China and India (World Health Organization, 2014). In 2007, Indonesia was ranked as the 5<sup>th</sup> largest cigarette consumer after China, the United States, Russia and Japan. In the same year, Basic Health Research stated that the population aged above 10 years who smoked was 29.2% and that number increased by 34.7% in 2010 for the age group above 15 years (Sjarif, 2011).

According to data (World Health Organization, 2011), Indonesia is one of the countries that has a higher smoking prevalence than the regional average and also higher than the world average. The increase in cigarette consumption has an impact to the higher burden of diseases caused by smoking and the rise of the death rate from smoking. In 2030 it is estimated that the death rate of smokers in the world will reach 10 millions and 70% of them come from developing countries.

The average number of cigarettes smoked per day for residents aged  $\geq 10$  years in Indonesia is 12.3 cigarettes (equivalent to one pack). The highest proportion of active smokers on daily basis at the age of 30-34 years is 33.4 percent, men got higher rate than female smokers (47.5% compared to 1.1%). Based on the type of work, farmers/fishermen/laborers are active smokers on daily basis who have the largest proportion (44.5%) compared to other occupational groups. The proportion of population aged  $\geq 15$  years who smoked and chewed tobacco tended to increase at Riskesdas (34.2%), Riskesdas 2010 (34.7%) and Riskesdas 2013 (36.3%). Based on Global Adult Tobacco Survey (GATS) study, in the population of the age group  $\geq 15$  years showed that the proportion of male

<sup>&</sup>lt;sup>1</sup> Public Health Faculty, Universitas Ahmad Dahlan, Indonesia

<sup>&</sup>lt;sup>2</sup> Public Health Faculty, Universitas Airlangga, Indonesia

smokers was 67.0 percent and in Riskesdas 2013 was 64.9 percent, while for women according to GATS, it was 2.7 percent and 2.1 percent according to the 2013 Riskesdas. The proportion of tobacco chewing according to GATS 2011 was 1.5 percent for men and 2.7 percent for women, while in the 2013 Riskesdas showed the proportion of men was 3.9 percent and 4.8 percent in women (Ministry of Health, 2014). The majority of cigarette factories develops their products without obeying the regulations set by the government such as not providing information to workers and consumers on the impact of the produced products (Etter, Zäther, & Svensson, 2013).

Second-hand smoke is a major health hazard, especially for infants and children. Center for Disease Control and Prevention (CDC) reports that every year, six million deaths worldwide are caused by the use of tobacco products. The rise of tobacco consumption is also responsible for the higher exposure to SHS where more than 50 carcinogens and 4,000 potentially dangerous chemicals and toxins are present. These compounds are involved in lung cancer, heart disease and other diseases among nonsmokers (World Health Organization, 2011).

Women and children are victims of disproportionate Second-hand smoke. About 30% of men smoke, compared to 13% of women and 12% of teens aged 13-15. It has been reported that as many as 40% of children and 35% of non-smoking women were affected by SHS in 2004. It is very likely that women and children, exposed to Second-hand smoke, have male family members who smoke at home or in personal vehicles. In low-income Southeast Asian countries, women are at least 50% more likely to be victims of Second-hand smoke exposure than men. Children with smoking parents are also significantly more likely to be affected by Second-hand smoke (Practices, 2016).

Passive smokers cause more than 600,000 premature deaths per year. Everyone must be able to breathe tobacco-free air. Non-smokers' have smoke-free health laws, very popular, however it cannot be used to stop smoking. More than 1 billion people, or 16% of the world's population, are protected by a comprehensive smoke-free law (World Health Organization, 2014).

According to the CDC, for about 50,000 Americans die each year from lung and heart cancer due to exposure of other people's smoke (CDC, 2011). Other people's smoke (AROL) is indoor pollution which is very dangerous because more than 90% of people spend time indoors. According to Research (Pradono, Kesehatan, 2003), more than two-thirds of Indonesia's population has been exposed to cigarette smoke since birth, both men and women. The highest prevalence of passive smoker is in children under five and women of reproductive age 15-49 years. Overall the prevalence of passive smoking in all ages in Indonesia is 48.9%. The prevalence of passive smoking in Yogyakarta especillay is between 53.4% -58.9%. The number of women at risk for respiratory tract cancer is 4,859.

Everyone has the right to get a high quality of health and free from tobacco-smoke environment. The Indonesian government has provided control of the cigarette issue, in the form of Government Regulation Number 109 of 2012 concerning Non-Smoking Areas (KTR). Non-Smoking Area (KTR) is a room or an which declared as prohibited area of smoking activities or activities in producing, selling, advertising, and/or promoting tobacco products. The arrangement of Non-Smoking Areas is a protection effort for the community against the risk of of health problems due to the polluted environment by cigarette smoke. The establishment of this Non-Smoking Area needs to be held in health care facilities, places of teaching and learning processes, places for children to play, places of worship, public transportation, workplaces, public places and other designated places (Ministry of Health, 2011).

KTR policies have developed in several regions. The results of the 2010 Riskesdas showed that Special Region of Yogyakarta (DIY) is one of the provinces with a high prevalence of smokers which, equal to 31.6%, and as many as 66.1% still smoke inside the house. Active household smokers are more husbands or household heads than wives or children (DINAS KESEHATAN KOTA YOGYAKARTA, 2013). The Special Region of Yogyakarta has a policy governed by the Governor of DIY Regulation Number 42 of 2009 concerning Non-Smoking Areas. This policy aims to protect vulnerable groups (infants, toddlers, pregnant women and the elderly) and the public from the threat of health problems caused by the exposure of cigarette smoke (Gubernur Daerah Istimewa Yogyakarta, 2009). The DIY community itself has not fully complied with the Governor Regulation, because it is not widely known yet what kind type of regulation it is (Nugroho & Istiyani, 2013).

In addition, the Mayor of the Special Region of Yogyakarta also gave a decision on Regional Regulation (Perda) Number 2 of 2017 concerning Non-Smoking Areas. The Non-Smoking Area, abbreviated as KTR, is a room or an area that allows smoking activities, selling and promoting tobacco products. The purpose of the regulations is to protect individuals health, families, communities and the environment from the risk of substances that can cause disease, death and degrade the quality of life (Pemerintah Kota Yogyakarta, 2017).

In line with the establishment of the Non - Smoking Area (KTR) around the city of Yogyakarta, Quit Tobacco Indonesia (QTI) in collaboration with the Yogyakarta City Health Office initiated a smoke-free house program (RBAR) in the hamlet neighborhood of Yogyakarta City Center which is based in the Faculty of Medicine, Gadjah Mada University. This program focuses on protecting families from the dangers of cigarette smoke inside the house. The percentage of smoke-free households in DIY in 2012 only reached 44.6% (Badan Penelitian dan Pengembangan Kesehatan Kementerian RI, 2010). This RBAR policy is very important, because this policy is one way to protect non-smokers from the dangers of cigarette smoke. One component is to eliminate smoking in the house (Ouit Tobacco Indonesia, 2013).

The RBAR program was first conducted in four pilot areas in 2010, they are RW 11 Mujamuju, RW 1 Gunung Ketur, RW 6 Suryowijayan, and RW 4 Pakuncen (Indonesia Conference on Tobacco or Health, 2015). Till March 2018, the number of hamlet that have declared themselves as smoke free houses hamlet (RW) is increasing, it hits 137 Hamlets (Primary data, 2018).

The program related to RBAR policy making has been carried out by (SHAFA & Murini, 2015) which is about the influence of RBAR on the smoking behavior of hamlet (RW) residents in Yogyakarta City. The results of the study showed that the number of mild smokers is decreasing from 32% to 6% as well as the number of heavy smokers from 34% to 6%. In another study conducted by (Herry, 2017) about the relation between knowledge and attitudes to taxes on adolescents in RBAR, Yogyakarta City. The results of the study showed that 42.86% of respondents had a good level of knowledge and 6.67% of respondents had insufficient knowledge. There were 35.29% of respondents were positive and happy, while 5.88% were negative respondents. In multivariate analysis compared to knowledge, attitudes have greater disruption (Herry, 2017). The results of the two programs show that the RBAR program over a period of 5-7 years can reduce environmental behavior in the hamlet (RW) as well as youth neighborhood of RBAR Yogyakarta.

According to Velicher in (DINAS KESEHATAN KOTA YOGYAKARTA, 2013) mentioning the process of a person's behavior transformation from the pre-reflection stage to the stage of contemplation which starts from increasing health awareness, dramatic flow/experience or experiencing disease risk, and reevaluating the environment, and realizing the negative impact of health problems. Then the process of behavior changing from the contemplation stage to the stage of readiness, namely self-evaluation. The change of behavior and smoking attitudes in the study above shows the rise of community awareness and environmental evaluation in RBAR hamlet neighborhood, thus, in this 8th year the community is already in the process of self-evaluation or being aware of behavioral changes to the stage of smoking cessation.

#### 2. Research Method

This type of research is an analytical study with a cross sectional design. The study was conducted in hamlet neighborhood which had implemented the RBAR program in Yogyakarta, they are Tegalpanggung RW 08, Tegalpanggung RW 05, Sorosutan RW 09, Bumijo RW 12 and Gowongan RW 11 starting from March until September 2018. The sample study was the head of the family which taken by cluster random sampling technique, with the following criteria: 1) willing to be a respondent, 2) family heads (male), 3) active smokers and 4) permanent residents who had stayed at the study site since the first time of the RBAR program was set in 2010. Thus the minimum number of samples in this study was 70 respondents. Primary data was taken using a questionnaire to find out the identity of the respondents, the attitude and readiness of the respondent to stop smoking after applying the RBAR program. The independent variable in this study is attitude while the dependent variable is readiness to quit smoking.

The attitude applied in this study relates to the response of respondents in the form of acceptance or refusal to stop smoking. The categorization of attitudes is divided into two, namely positive and negative. It is categorized negatively if the score < 45.22 and is positive if the score is  $\ge 45.22$ . This category is obtained from the calculation of the score which is the mean value of the respondents' total score. The attitude variable questionaire contains 20 statement items using a Likert scale

Smoking cessation readiness in this study relates to the stages that have been achieved by respondents in accordance with their goals and efforts to quit smoking. The categorization of smoking cessation readiness is divided into three, namely pre reflection, contemplation and preparation. Pre-contemplation is categorized if the respondent does not think of quitting smoking, contemplation is categorized if the respondent thinks he will stop smoking in the next 6 months, while preparation considered if the respondent thinks he will stop smoking in the next 30 days. Variable of smoking cessation readiness are 3 questions related to the effort of respondents to quit smoking after the implementation of smoke-free house program. The question form in the questionnaire is multiple choice and essay.

Data analysis in this study carried out by using Chi square test (M Sopiyudin Dahlan, 2011) The analysis was conducted to determine the relationship between attitude and smoking cessation readiness in smokers who live in the RBAR hamlet neighborhood, Yogyakarta City.

Then the results of the study were analyzed using Chi Square test. Ethical clearance for this research was obtained from the research ethics committee of Ahmad Dahlan University, Indonesia (Letter of Ethical Approval, Number 011807107). Appropriate ethical conduct was maintained throughout the study.

# 3. Results and Analysis

#### 3.1 Results

#### 3.1.1 Overview of Attitudes

The results showed that respondents who had a positive attitude to quit smoking had a greater percentage, which was 52.9% compared to respondents who had a negative attitude (47.1%). The description of the respondent's attitude based on the respondent characteristics is presented in Table 1 as follows:

Table 1. The overview of respondents' attitudes based on the characteristic (n=70)

ah ayaatayistia	Sikap				
characteristic	Negative n (%)	Positive n (%)			
Age					
17-25 years old	2 (6,1%)	0			
26-35 years old	3 (9,1%)	6 (6,2%)			
36-45 years old	8 (24,2%)	11 (29,7%)			
46-55years old	8 (24,2%)	16 (43,2%)			
56-65 years old	10 (30,3%)	4 (10,8%)			
>65 tahun	2 (6,1%)	0			
Latest education					
Elementary -Junior High School	16 (48,5%)	14 (37,8%)			
Senior High School	16 (48,5%)	17 (45,9%)			
Diploma	0	3 (8,1%)			
Bachelor	1 (3%)	3 (8,1%)			
Job					
Civil servants (PNS)	1 (3%)	2 (5,4%)			
Private employee	10 (30,3%)	14 (37,8%)			
Entrepreneur	10 (30,3%)	7 (18,9%)	<b>a</b> )		
Labor	12 (36,4%)	14 (37,8%)			
Tingkat ketergantungan nikotin					
Low	0	1 (2,7%)			
Average	12 (36,4%)	12 (32,4%)			
High	21 (63,6%)	24 (64,9%)			
Total	33 (100 %)	37 (100%)			

Source: Data Primer, 2018.

Based on Table 1, it can be seen that the largest percentage of respondents who have a positive attitude or support for quitting smoking are the respondents included in the age range of 46-55 years which is 43.2% (16 respondents), respondents with a history of education completed by diploma is equal to 45.9% (17 respondents), respondents who had private employment and laborers were 37.8% (14 respondents) and the respondents with low levels of

nicotine dependence were 64.9% (24 respondents).

# 3.1.2 Overview of Readiness

The description of respondent's readiness distribution is presented in Table 2, as follows:

Table 2. The distribution of respondents' readiness (n=70)

Readiness	Respondent number	Percentage (%)
Pre – reflection	12	17,1%
Reflection	22	31,4%
Preparation	36	51,4%
Total	70	100%

Source: Data Primer, 2018.

Based on Table 2, it can be seen that the results show the highest percentage of respondents is the respondents who are in the preparation stage for quitting smoking which is equal to 51.4% (36 respondents). This means that 36 respondents from the whole said they wanted to quit smoking in the next 30 days. The readiness portrayal based on the characteristics of the respondents is presented in Table 3 as follows:

Table 3. The overview of readiness based on the respondents' characteristics (n=70)

	Readiness			
Characteristics	Pre Reflection	Reflection	Readiness	
	n (%)	n (%)	n (%)	
Age				
17-25 years old	0	0	2 (5,6%)	
26-35 years old	1 (8,3%)	1 (4,5%)	7 (19,4%)	
36-45 years old	5 (41,7%)	10 (45,5%)	4 (11,1%)	
46-55 years old	4 (33,3%)	7 (31,8%)	13 (36,1%)	
56-65 t years old	1 (8,3%)	4 (18,2%)	9 (25%)	
>65 years old	1 (8,3%)	0	1 (2,8%)	
Latest Education				
Elementary -Junior High School	3 (25%)	6 (27,3%)	21 (58,3%)	
Senior High School	9 (75%)	13 (59,1%)	11 (30,6%)	
Diploma	0	2 (9,1%)	1 (2,8%)	
Bachelor	0	1 (4,5%)	3 (8,3%)	
Job				
Civil servants (PNS)	1 (8,3%)	1 (4,5%)	1 (2,8%)	
Private employee	4 (33,3%)	7 (31,8%)	13 (36,1%)	
Entrepreneur	3 (25%)	2 (9,1%)	12 (33,3%)	
Labor	4 (33,3%)	12 (54,5%)	10 (27,8%)	
The rates of nicotin dependence				
High	0	0	1 (2,8%)	
Average	2 (16,7%)	9 (40,9%)	13 (36,1%)	
Low	10 (83,3%)	13 (59,1%)	22 (61,1%)	
Total	12 (100%)	22 (100%)	36 (100%)	

Source: Data Primer, 2018.

Based on Table 3, it can be seen that the largest percentage of respondents who were in the pre-reflection stage or did not think about quitting smoking were the respondents in the age range of 36-45 years which was 41.7% (5 respondents), respondents with a history of completed education were 75% (9 respondents), respondents who have private jobs and entrepreneurs are 33.3% (4 respondents). Respectively, respondents with low levels of nicotine dependence are 83.3% (10 respondents).

The largest percentage of respondents who are in the stage of contemplation or intending to quit smoking in the next 6 months is the respondents in the age range of 46-55 years of 31.8% (7 respondents), respondents with high school education background were 59.1% (13 respondents), and respondents with low levels of nicotine dependence were 59.1% (13 respondents).

While in the preparation stage or intending to quit smoking within the next 30 days the largest percentage of respondents were the respondents in the age range of 46-55 years which was 36.1% (13 respondents), respondents with a history of elementary-junior high school education were 58.3 % (21 respondents), respondents who have private jobs amounted to 36.1% (13 respondents) and the respondents with low levels of nicotine dependence were 61.1% (22 respondents).

# 3.1.3 The Relation of Attitude and Readinesss

The researcher conducted a bivariate test for the smoking cessation attitude and readiness variables to find out the relationship between the two variables by using the *Chi Square* test. The results of the data show that the fulfillment of the *Chi-Square* test requirements is expected to be less than 5 by 0%, then using the output at *Pearson Chi-Square*. The results of the *Chi-Square* test are presented in table 4 as follows:

Table 4. The relation of respondents' attitude to the smoking cessation readiness

	The Si	moking Cess	ation Rea	diness			— Total		
Attitude	Pre Re	Pre Reflection		Reflection		Readiness		— Iotai	
	n	%	n	%	n	%	n	%	_
Negative	11	33,3%	8	24,2%	14	42,4%	33	100%	0.002
Positive	1	2,7%	14	37,8%	22	59,5%	37	100%	_ 0,003

Source: Data Primer, 2018.

In Table 4, it can be seen that the number of respondents who have either negative or positive attitudes, hold the same highest percentage in the preparation stage, which are 42.4% and 59.5%. The *chi square* test result value is 0.003 (p value <0.05) so it can be concluded that there is a significant relationship between attitudes and smoking cessation readiness.

#### 3.2 Analysis

#### 3.2.1 The Overview of Smoking Cessation Attitudes

The results show that more than half of the respondents had a positive attitude to quit smoking, namely as many as 37 respondents (52.9%). Most respondents agreed with the RBAR program and supported the program because it was often announced at community meetings about the rules in it. Factors that influence the formation of attitudes according to (Pradono et al., 2003) include personal experience, culture, others who are considered important, mass media, institutions, and individual emotions. Vulnerable time between the implementation of smoking bans and post-established rules is believed to be able to influence the increase in prevalence in the RBAR program (Mons et al., 2013, n.d.).

In this study, the characteristics of respondents who influence attitudes are the institutions or areas where the respondents live, who have implemented a smoke-free home program (RBAR). Based on the age characteristics, the highest number of respondents who have a positive attitude or support for quitting smoking is found in the group of respondents included in the age range of 46–55 years with a total of 16 respondents (43.2%) compared to the group of respondents in other age ranges. One of the factors that influence attitudes is emotional factors, this is occured especially as attitude is the expressions of individual emotions where one's emotions are influenced by age (Pradono et al., 2003).

In the characteristics of the educational background that was completed, respondents with the most recent education history of elementary and junior high schools had a negative attitude percentage or did not support

smoking cessation at most with a total of 16 respondents (48.5%). In the low education group, they tend to be weak to stop smoking, even though there has been a short intervention in the group (Mons et al., n.d.). This shows that all respondents with the most recent education history in junior high schools have a negative attitude to stop smoking. Educational and religious institutions, greatly determine individual beliefs so that it will affect the individual's attitude towards an object (Pradono et al., 2003). This explains the educational degree taken by respondents have an influence on the attitude of respondents regarding smoke-free homes where respondents who have a history of low recent education will be more -likely to have a negative attitude.

In the characteristics of job, respondents who have the most negative attitudes compared to other occupational categories are 12 respondents (36.4%) who work as laborers. Institutions or workplaces greatly determine individual trust so that it will affect the individual's attitude towards an object (Pradono et al., 2003). Research conducted (Ekpu & Brown, 2015) shows that the prohibition on smoking in the workplace has long-term benefits besides affecting smoking behavior as well as saving health costs and increasing worker productivity. This explains the institution or work places of the respondent has an influence on the respondent's attitude regarding to the smoke-free homes where respondents who work as laborers tend to have negative attitudes.

In the characteristics of the nicotine dependency level category, the respondents with the highest percentage of positive attitudes or supporting smoking cessation were 24 respondents (64.9%) with the lowest category of nicotine dependence. This explains the attitude factor are influenced by personal experience (Azwar Saifuddin, 2015). Respondents who had experienced smoking with the same level of nicotine dependence are tended to have a positive attitude to stop smoking.

#### 3.2.3 The Overview of Smoking Cessation Readiness

The results show that the number of respondents who were in the pre-reflection stage or did not think of quitting smoking were 12 respondents (17.1%). While respondents who are in the stage of contemplation or intend to quit smoking within the next 6 months are 22 (31.4%). At the preparation stage or intending to quit smoking in the next 30 days as many as 36 respondents (51.4%). The statistical results show that the data is not normally distributed with a value of sig 0,000 or less than 0.05.

Based on psychological assessments of the level of readiness to quit smoking, Tiara Rismala Sari from Gadjah Mada University used questions listed by The University of Rhode Island and developed from the TTM by Prochaska. There are 3 questions, two questions that can assess the level of one's readiness to quit smoking and one supporting question (SARI & Prabandari, 2016).

The first question is whether or not a smoker tried to stop smoking for at least 24 hours in the past year and the second question about whether or not there is a thought to stop smoking. Smokers who think of quitting smoking in the next 30 days with a history of never trying to quit smoking for at least 24 hours in the past year, he entered the stage of contemplation, while for smokers who have a history of trying to quit smoking for at least 24 hours in the past year, so he entered the preparation stage. Smokers think of quitting smoking in the next 6 months, entering the stage of contemplation. Smokers who do not think about quitting smoking at all enter the pre-contemplation stage.

Based on the explanation of the theory stated above, from this study it can be concluded that out of 70 respondents, 12 (17.1%) were in the pre-reflection stage, 22 (31.4%) were in the stage of reflection and 36 (51.4%) in the preparation stage. Most respondents are in the preparation stage. This is because 14 out of 36 respondents who were in the preparation stage had a history of smoking-related illnesses so they decided to stop smoking within the next 30 days. This is supported by the theory of Transtheoretical Model according to Velicher in (DINAS KESEHATAN KOTA YOGYAKARTA, 2013) mentions the process of changing a person's behavior from the pre-reflection stage to the stage of contemplation which starts from increasing health awareness, dramatic flow/experience or risk of disease, and environmental reevaluation, realizing a negative impact from health problems. Then in the contemplation stage to the preparation stage a person experiences self-reevaluation or realizes that behavior change is an important part of one's identity as a person. Then someone will experience self-liberation or make a commitment to change. Because 35.7% of respondents experienced health problems due to smoking, they made behavioral changes to the stage of preparation or stopping smoking within the next 30 days.

Based on the age characteristics of respondents who are in the preparation stage or intending to quit smoking in the next 30 days, most of them belong to the group of respondents in the age range of 46-55 years amounted to 13 respondents (36.1%). This is influenced by the self-reevaluation factor where one realizes that behavior change is an important part of one's identity as a person (Australia, 2012).

In the characteristics of the completed educational backgoround most of them were respondents with a history of elementary-junior high school education, namely 21 respondents (58.3%) who were in the preparation stage or

intended to stop smoking within the next 30 days. This is because 21.4% of respondents with a history of elementary school and junior high school have experienced health problems due to smoking. This is part of a behavior change process which is where a person experiences a Dramatic Relief of negative emotions (fear, anxiety, worry) that are in line with the risk of certain behaviors (Australia, 2012).

In job characteristics, the respondents who were labor are mostly at the stage of contemplation or intend to stop smoking within the next 6 months, as many as 12 respondents (54.5%). This is in line with the results above where the attitude of respondents who have labor jobs tends to be negative or not supportive of quitting smoking. According to (Wawan & Dewi, 2010) negative attitudes lead to a tendency to stay away from, avoid, hate, dislike certain objects. Then respondents who have a negative attitude tend to choose the stage of contemplation to stop smoking

In the independent level category, the majority of respondents in the category of low nicotine dependence were 22 respondents (61.1%) they were belong to the preparation stage or intended to quit within the next 30 days. According to (4) nicotine affects feelings, thoughts and functions at the cellular level. When someone sucks cigarette smoke, nicotine is extracted from tobacco, carried into the arterial circulation and reaches the brain. In this study, respondents had a low level of nicotine dependence, so it did not affect his mind to stop smoking too much.

#### 3.2.4 The Relation of Attitude and The Readiness to Quit Smoking

The results show that respondents who had a positive attitude or supported to quit smoking and the respondents who had a negative attitude or did not support quitting smoking were at the same stage at the preparation stage with 59.5% (22 respondents) and 42.4 % (14 respondents). This is supported by the results of statistical tests on the readiness data of respondents who are not normally distributed, thus it was resulted as above.

This is directly in line with *Prochaska's Transtheoretical Model* theory, which was developed by Velicher in (DINAS KESEHATAN KOTA YOGYAKARTA, 2013) in the contemplation stage to the preparation stage of someone experiencing self-reevaluation or realizing that behavior change is an important part of one's identity as a person. Then someone will experience self-liberation or make a commitment to change. A positive attitude is a form of self-reevaluation. The majority of respondents who have a positive attitude or support to stop smoking are in the preparation stage. In addition to the questionnaire question which points 35.7% (25 respondents) who have positive or negative attitudes claim to have experienced health problems due to smoking, this is what makes respondents who either have positive attitudes or negative attitudes or do not support quitting smoking dominate at the preparation stage or choose to stop smoking within the next 30 days.

As for other factors that influence smoking cessation readiness, that were not examined by researchers, were the length of smoking, knowledge of the hazards of smoking, advice on quitting smoking and health warnings on cigarette packs (Firzawati, 2015). In the study (Firzawati, 2015) said smokers who tried to quit smoking were smokers who had been smoking for less than 20 years, the longer smokers made their smoking habits would further reduce their chances of trying to quit smoking. Besides smoking behavior is related to knowledge and attitudes toward smoking, sufficient knowledge will motivate individuals to behave in a healthy manner. Firzawati also found that knowledge about the dangers of smoking is not wholly owned by smokers. Smokers who have knowledge of the dangers of smoking for their health will increase their desire to stop smoking (Firzawati, 2015). Research conducted (Layoun et al., n.d.) shows the intention to stop smoking in the first year, someone will try to reduce nicotine consumption, be negative about smoking and at a young age have a high awareness to regulate smoking cessation programs because they know the benefits of quitting smoking.

Based on the results of the study (Prayogi, Angraini, Majority, & 2017, n.d.) doctor's advice is more effective and needs to be done in order to help active smokers stop smoking and protect passive smokers. Health warnings call can help smokers stop smoking or reduce the number of consumed cigarettes (Prayogi et al., n.d.). Media campaigns are effectively used to help as if the messages are delivered well to the differentiated groups to support them qutting smoking (Levy, Nikolayev, & Mumford, 2005). According to the results of the study (Meko, 2016) the attitude of smokers who adequately support or apply warning images on cigarette packaging can make them have the motivation to stop smoking. Research conducted (Noar, Francis, Bridges, ..., & 2016, n.d.) in countries such as Thailand, Canada, Mexico, and the United Kingdom shows that to provide benefits for people, avoiding lung cancer, heart disease, and other organ damage. Pictures for smoking on cigarette packs present damage to internal organs that can be used for health (Meko, 2016).

The results of this study indicate that the test result value is 0.003. The p value is less than 0.05 so it can be concluded that there is a significant relationship between attitudes and smoking cessation readiness. This is

supported by the *Prochaska Transtheoretical Model* theory which developed by Velicher in (DINAS KESEHATAN KOTA YOGYAKARTA, 2013) that the process of changing one's behavior is one of their awareness. Since the rise of awareness caused by the experience of a health problem can change a person's behavior to quit smoking even though his attitude is negative.

#### 4. Conclusion

There is a significant relationship between attitude and readiness to quit smoking in the hamlet neighborhood (RW) of RBAR, Yogyakarta City. Thus, the results of this study can be used as material for evaluating the achievement of smoke-free home programs. It is better for the Yogyakarta City government to provide regular education about the purpose of a smoke-free home program so that smokers are aware and better understand the purpose of a smoke-free home program. For the development of further research, more in-depth research can be conducted on other factors that influence smoking cessation readiness, those are smoking time, knowledge of the dangers of smoking, smoking cessation advice and health warnings on cigarette packs. In addition, it can also be a more detailed research in the stage of quitting smoking so that it can be known not only in the stage of pre-reflection, contemplation and preparation but also other stages.

#### **Competing Interests Statement**

The authors declare that there are no competing or potential conflicts of interest.

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Address 1120 Finch Avenue West, Suite 701-309, Toronto, ON., M3J 3H7, Canada

Telephone 1-416-642-2606

Fax 1-416-642-2608 E-mail gjhs@ccsenet.org

Website gjhs.ccsenet.org