



# **EXPLORING COMMUNICATION STRATEGIES THAT PROMOTE SOUND INFORMED CONSENT FOR HIV VACCINE TRIALS**

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A dissertation submitted in partial fulfillment of the requirements for the degree of Master of Social Science (Health Research Ethics) in the School of Applied Human Sciences (Psychology) College of Humanities, University of KwaZulu-Natal, Pietermaritzburg.

10 March 2017

## DECLARATION

I, Limbanazo Matandika, declare that the thesis titled 'Exploring communication strategies that promote sound informed consent for HIV vaccine trial' which I hereby submit for the degree of Master of Social Sciences (Health Research Ethics) at the University of KwaZulu-Natal, Pietermaritzburg, is my original research except where otherwise indicated. I also declare that:

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2. This thesis does not contain another person's data, pictures, graphs or other information, unless specifically acknowledged as being sourced from another person.
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Name of Student: Limbanazo Matandika

Signature



Date 10 March, 2017

Name of Supervisor: Catherine Slack

Signature



Date: 10 March, 2017

# DEDICATION

I dedicate this work to my late father (the most amazing father he was), Clifford Mindiera, to my precious mother (motivator and friend) Lexa Mindiera, to my wonderful husband and precious father of our children, Pangani Matandika, to the one we share the same smile, my twin sister Mathero Mawaya, our precious gifts, Mphatso, Wanika and Jayden (my brave son, mum left you for studies when you were only 9 months old - God has been awesome); and to my brothers and sisters, Christopher, Patrick, Jean, Nellie, Failet, Kumbukani, Charles and Timeo.

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## ABSTRACT

The development of an HIV vaccine is a foremost universal health priority, necessitating research with human volunteers. It has been internationally accepted that informed consent is a fundamental ethical requirement for all clinical trials, including HIV vaccine trials (HVTs). However prospective trial participants often demonstrate a lack of understanding of information conveyed to them during the informed consent process. Ways of communicating complex concepts may need to be identified and developed to promote understanding. This study had the following aims: (a) To explore communication strategies reportedly implemented by key HIV vaccine trial stakeholders to communicate key concepts (Community Advisory Board or CAB members, Educators, Consent Counsellors) b) To explore correspondence between reported strategies and recommendations from the conceptual and empirical literature, and c) To explore the implications for strengthening informed consent for research in resource- constrained settings.

The study comprised an analysis of four Focus Group Discussions with key stakeholders at an HIV vaccine trial site in South Africa, that had been previously conducted by members of the HIV AIDS Vaccines Ethics Group from the University of KwaZulu-Natal (UKZN). These stakeholders included CAB members who interacted with participating-community members; Educators who interacted with interested community members at the site, and Consent Counsellors who interacted with persons interested in enrolment in actual HIV vaccine trials.

These transcripts were analysed using Thematic Analysis, informed by aspects of a popular framework for the informing process (the Meerwein model). This study adopted a qualitative approach which was broadly set in an *interpretive perspective* – focusing on practices, subjective meanings that stakeholders attached to their practices, and the context.

Study findings are presented under three main themes. The *informational* theme describes how site staff reportedly employed numerous strategies to ensure that *information* presented to potential participants was understandable, such as simplifying, using preferred language, using analogies, using culturally appropriate terms and promoting discussion. The *emotional* theme describes how site staff implemented several strategies to try respond to emotions of anxiety and to try address feelings of suspicion, such inquiring about and collating suspicions, using trustworthy sources (ex-participants or influential community members) and referring to safe, licensed vaccines. The *relational* theme describes how site-staff reportedly employed various practices to develop respectful relationships (by creating a friendly environment) that are responsive to cultural norms, such as requesting permission to break cultural norms, and using culturally acceptable terms.

The study concludes that strategies employed appear consistent with several key principles of adult learning, and communication, as well as with ethical guideline recommendations for HIV vaccine trials. These findings imply that the individual consent process is best understood as embedded in a larger process of engagement and that consent staff at sites need to have core communicative competencies, need to be sensitive to the emotional aspects of their engagements, and need to be culturally competent. Recommendations are made for key stakeholders such as Research Ethics Committees, CAB members, and ethical guideline developers. Recommendations are made to strengthen the informed consent process for research in resource-limited settings.

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# CHAPTER ONE

## INTRODUCTION

### 1.1 INTRODUCTION AND RATIONALE FOR THE STUDY

Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) is still a major health problem in the world. Since the beginning of the epidemic, almost 78 million people have been infected with HIV, and about 39 million people have died (World Health Organization (WHO), 2015). By the end of 2013, 35.0 million people globally were living with HIV (WHO, 2015). In 2012, HIV accounted for an estimated 1.6 million deaths (AVERT, 2015). However, the burden of the epidemic continues to vary considerably between countries and regions. Sub-Saharan Africa is the worst region affected by HIV/AIDS, and is home to nearly 25 million people living with the disease, representing 70 % of the global HIV burden (UNAIDS, 2013). South Africa (SA) has the highest and most high-profile HIV epidemic in the world, with an estimate of 6.1 million people living with HIV in a population of 48 million (AVERT, 2015). Even though a large Anti-Retroviral Therapy (ART) programme has been largely rolled out, HIV prevalence remains high at 17.9 % (AVERT, 2015). Even though ART has proven to reduce HIV mortality and has changed the face of HIV, several limitations of these regimens have emerged. These include poor daily adherence which may result in drug resistance (Siegel & El-Sadr, 2006), drug toxicities, and adverse drug reactions like inflammation (Lundgren, 2015).

The most promising way to impact the epidemic is to develop HIV prevention modalities, including effective HIV vaccines (Baeten & Celum, 2012; Myers & Mayer, 2011; Poynten, Zablotska & Grulich, 2012). The need for an HIV vaccine is paramount and remains a foremost universal public-health priority (Kim, Rerks-Ngarm & Excler, 2010). The successful development of effective HIV vaccines is expected to require that various candidate vaccines be investigated concurrently in diverse populations in many settings (UNAIDS, 2012). There are many ethical challenges which arise within the context of HIV vaccine trials (HVTs) (Lindegger et al., 2006; Macklin, 2009). These include that participating communities and participants may have certain vulnerabilities such as being drawn from settings with limited resources and power relative to sponsors (Slack et al, 2004), with inadequate healthcare systems (Glickman et al., 2009), with inadequate knowledge about research or low literacy levels (Glickman et al., 2009; Ndebele, Wassenaar, Munalula & Masiye, 2012). Participating

community members and potential participants may also be drawn from settings with cultural norms that are not shared by members of the sponsor or researcher team (Glickman et al., 2009).

It is internationally accepted that informed consent is a fundamental ethical requirement for all clinical trials, including HVTs. Consent to participation in HVTs requires that prospective participants are fully informed about key components of trial participation, and demonstrate comprehension of concepts and their implications (UNAIDS/AVAC, 2011; UNAIDS, 2012). Prospective participants often show a lack of understanding of key research concepts in clinical trials generally (Flory & Emanuel, 2004) including potential participants for HIV vaccine trials specifically (Koblin et al., 2010; Murphy et al., 2007). Poor comprehension of HIV vaccine trial concepts may result from numerous challenges including that medical terminology may not necessarily translate appropriately into the language used by potential participants, that potential participants may have low educational attainment or low scientific literacy and that concepts are complex (Lindegger, Quayle & Ndlovu, 2007; Stuurman, 2004; Watermeyer & Penn, 2008).

Accordingly, it has been argued that ways of communicating complex research concepts in various cultural and linguistic contexts may need to be identified and developed to promote understanding (Glickman et al., 2009; Rautenbach, Lindegger, Slack, Wallace & Newman, 2015), and other positive outcomes, in such trials. An emphasis on how complex concepts are communicated in interpersonal consent-related encounters is very important, alongside efforts to improve the length and readability of consent forms (Rautenbach et al., 2015). There has been little research exploring the communication practices implemented by key vaccine trial stakeholders to promote understanding in such trials (Penn & Evans, 2008; Rautenbach et al., 2015). This is despite the fact the key ethical guidelines recommend attention to such processes – for example to the communication of risks (Medical Research Council South Africa (MRC), 2003; Department of Health (DoH), 2004). One way to enhance the comprehension of prospective participants in HVTs might be to explore the practices of site-staff communicating such concepts to potential participants or participating community members. This might inform recommendations for stakeholders involved in such work currently, and inform recommendations for future empirical research.

## 1.2 AIMS OF THE STUDY

This study is an exploration of practices reportedly used to communicate complex concepts in HVTs. The key objectives are:

1. To explore strategies reportedly used by key site stakeholders in South African HVTs to communicate trial information
2. To explore the correspondence of reported strategies with recommended practices from the conceptual and empirical literature
3. To explore the implications for strengthening the informed consent process in resource-constrained settings.

## 1.3 OUTLINE OF THE DISSERTATION

This dissertation takes the following form:

**Chapter 2 - Literature review:** This chapter briefly reviews the HIV epidemic, and the need for HIV interventions, including HIV vaccines, necessitating the conduct of HVTs. It reviews the need for informed consent in such trials, and complexities with achieving understanding in consent. It reviews certain empirical studies in consent. It sets out the need for sound communication in consent. It briefly reviews theories of adult education and health communication and their usefulness in strengthening consent communication. It also reviews the issue of engaging with the participating community to try to strengthen consent processes.

**Chapter 3 - Aims and methods:** This chapter provides a description of how the research was conducted, including how the data was collected, and analysed, and measures which were implemented to ensure reliability, validity and rigour. It also describes the limitations of the study. It also provides a brief account of the researchers' consent experiences in Malawi, as a commitment to reflexivity.

**Chapter 4 - Research findings:** This chapter set outs the main findings of the study, including major themes and subthemes to shed light on the strategies used by key stakeholders to communicate concepts to participants and participating-community members.

**Chapter 5 - Discussion:** This chapter locates the main findings in relation to the existing literature.

**Chapter 6 - Conclusions and recommendations:** This chapter draws conclusions in relation to the main study aims, including the degree to which reported strategies correspond with recommendations from the literature. It sets out implications for strengthening informed consent for research in resource-constrained settings, and provides recommendations for key research stakeholders.

# **CHAPTER TWO**

## **LITERATURE REVIEW**

### **2.1 INTRODUCTION**

This chapter reviews the HIV epidemic and the need for HIV interventions. It describes the need for trials of experimental HIV prevention products, such as HIV vaccines. It further reviews the need for informed consent (IC) in such research, including strategies that promote sound consent communication and processes. It sets out empirical research on strategies that have been reported to enhance comprehension in both HIV vaccine trials and other studies. Ethical guidelines that govern the consent process in bio-medical research are discussed and benchmarks that govern the ethical conduct of research with human subjects. It reviews complexities regarding understanding in consent. Lastly, it provides the justification for conducting the research.

### **2.2 THE HIV EPIDEMIC**

HIV and AIDS continues to impact the public health of citizens globally, and AIDS is responsible for almost 40 million deaths in the world (WHO, 2015). By the end of 2013, 35.0 million people globally were living with HIV (WHO, 2015). In 2012 the epidemic accounted for an estimated 1.6 million deaths (AVERT, 2015). It is estimated that 2.3 million new HIV infections occurred globally in 2012, representing a 33 % decline from 2011 (UNAIDS, 2013). The burden of the epidemic remains to fluctuate significantly between countries and regions, with Sub-Saharan Africa home to nearly 25 million people living with the disease, representing 70% of the global HIV burden (UNAIDS, 2013).

South Africa has the largest HIV epidemic in Sub-Saharan Africa and worldwide (AVERT, 2015). In 2014, 6.4 million people were HIV-infected, representing 12.2 % of the South African population (UNAIDS, 2014).. Although the epidemic in South Africa is generalised, it has been reported that specific groups within the general population have HIV prevalence that is above the national average. These are classified as crucial populations with high risk of HIV exposure (UNAIDS, 2014). Examples of key populations and their prevalence rates include: adults aged 15-49 with estimated HIV prevalence at 18.9 % (UNAIDS, 2014) and Men who have Sex with Men (MSM) accounting for 9.2% of new infections (AVERT, 2015) and sex workers with 34-69

% HIV prevalence (AVERT, 2015). The HIV incidence rate in South Africa remains the worst in the world with over 400,000 new infections reportedly occurring in 2012 (Shisana et al., 2014). Other Sub Saharan countries are also affected. For example, Malawi is among the ten countries in the world with the highest HIV prevalence (UNAIDS, 2013). In 2014 an estimated 1,100, 000 people were living with HIV in a total population of 15.9 million (UNAIDS, 2014).

The expansion of HIV interventions globally has changed both the HIV epidemic and the broader public health landscape (UNAIDS, 2013). In 2012, the total number of people receiving Anti-Retroviral Therapy (ART) was reported at more than 9 million (UNAIDS, 2013). Vast advances in HIV/AIDS treatment regimens have essentially transformed the natural history of the disease and have sharply reduced the number of people who die from HIV-related diseases in countries where treatment is accessible (Bertozzi et al., 2006). South Africa has the largest ART programme globally (WHO, 2015). By 2012, South Africa provided ART to an estimated 2 million people, exceeding its national universal access target of 80% (AVERT, 2015). Other countries in Sub-Saharan African have also implemented responses. For example, Malawi is one of the few countries in Sub Saharan Africa with a successful ART service-delivery programme (Harries, Makombe, Libamba & Schouten, 2011). Malawi accelerated its ART national coverage in 2004 and ART coverage increased from 54 to 67 % between 2010 and 2011 (AVERT, 2015).

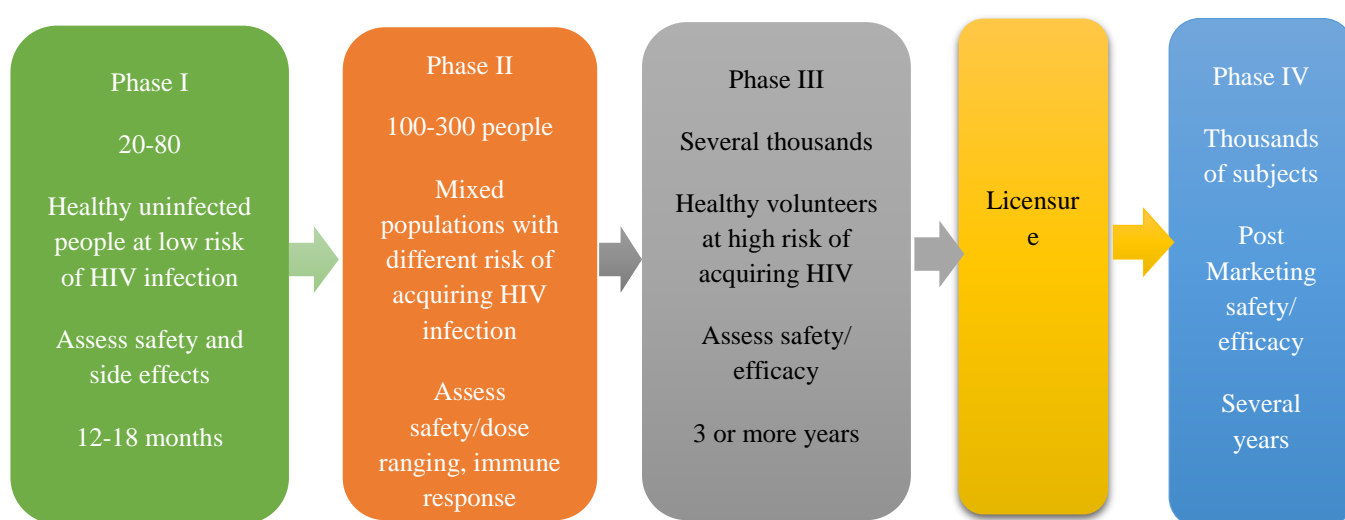
### **2.3 THE NEED FOR HIV RESEARCH, INCLUDING HIV VACCINE TRIALS**

Even though ART has been proven to reduce HIV mortality, methods to prevent HIV infection in the first place will likely have a major impact on the epidemic. Much effort has been channelled to reducing HIV transmission (Bunnell, Mermin & De Cock, 2006). South Africa has scaled up effort to reduce HIV infections by implementing the following HIV prevention strategies: PMTCT, PEP, social and behaviour-change campaigns, voluntary testing and counselling, integration of sexual and reproductive health services, condom use and distribution, and HIV awareness and education (*South Africa National Strategic Plan 2012-2016*, 2011). In many Sub-Saharan countries, there are several prevention modalities that are currently in use to prevent HIV (cf. National AIDS Commission, 2011).

Despite available prevention tools, it is also important to continue to research *new modalities* to prevent HIV acquisition (Essack, 2014). Current efforts include demonstration projects for Pre-Exposure Prophylaxis (PrEP) in gel or pill form which has been shown in clinical trials to



reduce the risk of acquiring HIV infection (Beyrer, Bekker, Pozniak & Barré-Sinoussi, 2015; McCormack et al., 2015; McGowan, 2014 ). It is recognized that the best way to eradicate a global viral epidemic is to systematically immunize target populations with an effective prophylactic vaccine (Baeten & Celum, 2012; Myers & Mayer, 2011; Poynten et al, 2012). Efforts are underway worldwide to develop and test HIV vaccines in human participants. The development process for vaccines is very rigorous, and demanding (Pharmaceutical Research and Manufacturers of America (PhRMA), 2013). Due to volatility of the biological micro-organisms required to produce vaccines, and due to ambiguity about how the human immune system will process and respond to the vaccine antigen, one of out ten candidate vaccines will achieve licensure (PhRMA, 2013). A candidate vaccine has to undergo clinical trials before licensure and trials take place in various phases. Figure 1 below outlines the vaccine development process and timelines required for each phase (Training and Resources in Research Ethics Evaluation (TRREE), 2014).



**Figure 1:** Vaccine development phases and time lines (TRREE Module, 2014)

The first HIV vaccine trial was conducted in 1987, since then more than 80 phase I/II trials of more than 30 candidate vaccines have been conducted (Esparza 2014). Several phase III trials have been concluded with some still ongoing (Esparza, 2014) and one due to be implemented in November 2016 (Cathy Slack, personal communication, 15 August 2016). The phase III trial of the RV144 vaccine candidate showed an estimated 31.2% efficacy of a vaccine regimen against HIV type 1 (HIV-1) and brought hope that vaccines can reduce the risk of HIV exposure (Nam-aidsmap, n.d.). The successful development of effective HIV vaccines will require that many candidates be studied at the same time in diverse populations around the world (Weidle, Mastro, Grant, Nkengasong & Macharia, 2002).

Even though Sub-Saharan Africa is the most hit region with HIV, there have been few phase I HIV vaccine trials (HVTs) (Nam-aidsmap, 2015). Several commentators have underscored the need for HIV vaccine development in Africa, and urged that HVTs are needed to assess the efficacy and safety of vaccines among its diverse populations (Weidle et al., 2002). South Africa continues to be a leading country in Africa in the conduct of preventive HVTs. The country has recently conducted a phase I study of the RV144 vaccine tested in Thailand to ensure it was safe and tolerable to South Africans (National Institutes of Health (NIH), 2015). Other Sub-Saharan countries have also been the focus of HIV vaccine trial activity. For example, Malawi was poised to test an HIV vaccine – a phase 1 trial with 20 participants (HIV vaccine tests in Malawi for UNC project, 2015), unfortunately the trial never received a favourable review from The National Health Sciences Research Ethics Committee in that country.

HVTs are ethically complex for a number of reasons. These include that they tend to involve communities and participants drawn from host countries with limited resources or power relative to partners in high-income countries (Slack et al., 2004). HVTs have invasive procedures with potential risks and burdens for enrolled participants. These include: repeated HIV testing and counselling, lengthy trial duration that may result in participation fatigue, vaccine administration which carries the risk of the preventive misconception (which may see participants engage in risky behaviour because they expect to be immune to HIV from the vaccine itself), and the risk of Vaccine Induced Seropositivity (VISP) whereby a person who has received a vaccine may test positive for HIV on routine tests, regardless of not actually being infected with the virus (which requires differential testing to be distinguished from a true HIV infection) (Milford, Barsdorf & Kafaar, 2007; Newman, Seiden, Roberts & Duan, 2009; Allen et al., 2001, as cited in Milford et al 2007; Jenkins et al., 2005, as cited in Milford et al., 2007). Trial procedures may be stressful (Slack et al., 2000; Tarimo et al., 2014) Social harms are possible, for example, stigma and discrimination against participants as well as negative reactions from friends, family and co-workers or disturbance of relationships (Milford, et al, 2007).

To address the ethical challenges, UNAIDS developed ethical guidelines for the conduct of HVTs in 2000 which were later updated in 2012 (UNAIDS, 2012). Also, much research has taken place to explore and respond to ethical-legal concerns in such trials. For example, in South Africa, the South African AIDS Vaccine Initiative (SAAVI) was established in 2000, which

included the HIV Vaccine Ethics Group (HAVEG) that conducts research to address ethical and legal complexities in HVTs.

#### 2.4 THE NEED FOR ETHICAL PROTECTIONS FOR PARTICIPANTS

It has long been recognized that collaborative research being conducted in low-resource-settings (LRS) is critical but requires careful attention to address ethical challenges (Butendeli, 2011). Challenges include: differences in the education, social and economic standing of the participants versus sponsor-investigators and inadequate health-care (Glickman et al., 2009). Participants may lack knowledge about research, and trial concepts are likely to be difficult to understand (Glickman et al., 2009; Ndebele et al., 2012). Scientific language may not be familiar to those with low literacy levels, e.g., double blinding, randomization and placebo (Ndebele et al., 2012). Some participants may be vulnerable – that is have some features that increase their risk of research-related harms, or features that compromise their ability to give consent which may require special steps to ensure that they make sound decisions about enrolment (Kruger, Ndebele & Horn, n.d.; MacQueen et al., 2015).

A number of guidelines have been written to ensure that research conducted in these setting has ethical merit, and promotes the safety and welfare of participants; these include the Belmont Report (Zucker, 2014). Key ethical principles to safeguard the rights and welfare of human volunteers in research include beneficence, justice and autonomy (Council for International Organizations for Medical Sciences (CIOMS), 2002; World Medical Association, 2013; Zucker, 2014). These principles attempt to safeguard the dignity, integrity, self-rule, privacy, and other rights of research participants, and set out the obligations and responsibilities of researchers. Principles include:

- **Respect for autonomy:** The principle asserts that research participants' "capacity for self-determination be treated with respect" (National Commission, 1979, p.19). Participants should be treated as autonomous agents and their choices be respected. By exercising their autonomy, persons may be protected from risks anticipated in research and are fully informed by being given significant information about the research.
- **Beneficence:** "Do good" and non-maleficence ("do no harm") underscore the obligations of researchers to ensure that anticipated benefits are realised and

anticipated risks are minimized (Beauchamp & Childress, 2012). These principles go beyond researcher respect for participants' choices to ensure that the research itself promotes 'good', and establishes strategies to offset risks (Helsinki, 2013).

- o **Justice:** This principle stipulates that there be fair distribution of benefits and risks in research and if there is unequal treatment it be justified. Researchers must ensure that research subjects have been selected equitably (Helsinki, 2013).

A popular framework has been developed to evaluate the ethical and scientific merit of research projects setting out key ethical standards for research (Emanuel, Wendler & Grady, 2000) and key benchmarks for research in LRS (Emanuel, Wendler, Killen & Grady, 2004). These standards are: collaborative partnership including that the research is responsive to local health needs, social value whereby the study should address a valuable question for the economic, socio-political and health context, scientific validity whereby the design is rigorous to realise results, fair selection of participants whereby participants are selected for sound scientific reasons and to reduce risks, favourable risk-benefit ratio including that anticipated risks are mitigated, on-going respect for recruited participants and study communities including feedback of research findings to all stakeholders, independent ethics review whereby an independent board reviews the initial application and regular study reports, and of most relevance to this study - informed consent – discussed in more detail below.

Key ethical bodies that are charged with reviewing the scientific and ethical merit of trials include Research Ethics Committees (RECs) (Kruger et al., 2014). RECs play a key role in safeguarding the ethical standards and scientific merit of research with human participants (Gelling, 1999) expected by society (CIOMS, 2002). RECs must ensure that the rights of research participants have been protected (Kruger et al., 2014). This includes ensuring that individuals are given adequate information, which can be easily understood (CIOMS, 2002). RECs should also attend to the interests of the community who will be affected by the research (Gelling, 1999).

Despite increasing attention to ethical standards and mechanisms in research, cases of unethical research are still recorded (Butendeli, 2011). For example, in Malawi a trial was conducted for which – reportedly - no ethical and regulatory approval for the study drug was obtained, several deaths were recorded, and consent was inadequate (Mkoka, 2008). It has been asserted that researchers capitalise on research participants' inadequate knowledge of

research and inadequate care in poor or low income countries (Macklin, 2009; Voo et al., 2008, as cited in Butendeli, 2011). Others assert that researchers fail to anticipate or merely observe associated harm that may occur to research participants and fail to do enough to prevent such harms (Benatar, 2004).

## **2.5 INFORMED CONSENT AS A KEY ETHICAL PROTECTION**

Informed consent is an ethical standard that ensures that participants only enrol in research that is consistent with their values and preferences (Emanuel et al., 2000). It requires that those who participate in research activities be fully informed about the research including its aims, procedures, risks, and benefits (UNAIDS, 2000; UNAIDS, 2012). Potential participants should have the freedom to agree or decline to take part (UNAIDS, 2000; UNAIDS, 2012). It is essential that prospective participants understand the research to which they are being invited to take part (Lindegger & Richter, 2000). The Declaration of Helsinki (World Medical Association, 2013) states that participants must demonstrate an understanding of research procedures, risks and benefits. Informed consent, as a major requirement for research with human subjects, is an expression of respect for autonomy, one of the major three ethical principles set out earlier (Beauchamp, & Childress, 2012). Informed consent allows participants to make an informed decision, hence exercising their autonomy. Sound informed consent helps safeguard the wellbeing of research participants by disclosing risk of harm and ensuring these are understood (Kruger et al., 2014).

The need for ethical standards in research came to light following a series of studies which were conducted during World War II (Nuremburg Code, 1949). This led to the establishment of the first international code of ethics in 1947, the Nuremburg Code, followed by the Declaration of Helsinki (most recently updated in 2013) that emphasized the importance of voluntary and informed consent in research with human volunteers. The main focus of informed consent has been to protect the autonomous choice and rights of research participants (Beauchamp & Childress, 2012) and requires efforts to achieve adequate understanding, and to avoid forms of manipulation (Beauchamp & Childress, 2012). In addition to international guidelines and standards, many countries have developed specific guidelines on research ethics tailored towards their own national ethics requirements.

## **2.6 SOUTH AFRICAN ETHICAL GUIDELINES ON INFORMED CONSENT**

South Africa has its own guidelines on informed consent stipulated in various documents. More specifically, the South African Department of Health ethics guidelines (second edition) published in 2015 (DOH, 2015) and the South African good clinical practice guidelines (second edition) published in 2006 (DOH, 2006), as well as the Medical Research Council South Africa (MRC) ethics policy: general principles (Book 1) published in 2001 (MRC, 2011), and finally the South African MRC guidelines for HIV preventive vaccine research ethics (Book 5) published in 2003 (MRC, 2003).

These guidelines underscore the need for respect for persons, and assert that participation in research must be affirmed by informed choices before the study begins and remain informed over the course of the study. Recommendations from these guidelines include: that potential participants should have time to consult others prior to deciding, and that RECs should assess 'the process' including training of consent staff and proposed measures to assess understanding (DOH, 2015, p. 26). Also there should be careful design of the IC document and the use of culturally-acceptable language of choice and consent procedures should be tailored to site characteristics (DOH, 2006). Also that participants should understand the risks and benefits of the study before decision-making and researchers should ensure information presented to participants is in line with their capabilities and will facilitate comprehension of study information and that the investigator and team should have skills on how to conduct the IC process (MRC, 2001).

Lastly MRC book 5 which governs all HIV vaccine trials conducted in South Africa, and was adapted from UNAIDS (2000), highlights the need for 'appropriately conveyed and understood information as well as its consequences' (MRC, 2003, p. 22), 'an optimal emotional context for the exploration of information' (MRC, 2003, p. 22), and sensitivity to the interpersonal interaction between consent staff and participants. Consent staff should 'facilitate' participants' understanding of 'technical concepts and their consequences, and the personal, psychosocial implications of trial participation' (MRC, 2003, p. 22). It calls on study staff to develop skills and knowledge on how to handle some of the factors which may hinder understanding of study information for example social desirability where participants pretend to understand to gain favour from the trial staff.

## **2.7 COMPONENTS OF INFORMED CONSENT**

It has been argued that informed consent incorporates several important components: i) disclosure of the relevant information about the study ii) understanding of this information to facilitate informed decision-making iii) freedom from undue influence as well as coercion (threat), meaning also that participants can withdraw their permission at any time (iv) explicit and formal permission typically in writing (Lindegger & Richter, 2000). Poor disclosure of all relevant study information raises concerns about interference with the ability of the participant to give an authentic consent. Understanding of the relevant study information with the absence of coercive influences enhances free participation (Beauchamp & Childress, 2012). Evidence that the participant agreed should be contained in documentation kept by the investigator or in a signed informed consent form (The National Commission, 1979).

## **2.8 COMPLEXITIES WITH INFORMED CONSENT**

Several challenges in securing informed consent for research participation have been noted (Kruger et al. 2014). Prospective participants often demonstrate a lack of understanding of concepts conveyed to them during the informed consent process. This may be because complex scientific terminology may not necessarily translate linguistically or conceptually into participants' preferred language (Lindegger, Quayle, & Ndlovu, 2007; Stuurman, 2004; Watermeyer & Penn, 2008) or linguistic background (Penn & Evans, 2009). The concepts themselves may be difficult to understand (Ndebele et al., 2012) such as "Vaccine Induced Sero-Positivity" or VISIP. There may be low education or low research literacy among potential participants (Marshall, 2007; Ndebele et al., 2012). The representation of research-related concepts held by potential participants may conflict with those offered by researchers (Newman et al., 2009; Rautenbach et al., 2015). Indigenous knowledge systems for disease and illness among cultural groups may differ from the explanations offered in the bio-medical model (Marshall, 2001, as cited in Woodsong & Karim 2005) and individual and community beliefs systems may serve important functions in cultural groups (Woodsong & Karim, 2005). Consent documents may be complex, lengthy documents at a high reading level with difficult terms that makes comprehension very challenging for the participants (Barata, Gucciardi, Ahmad & Stewart, 2006; Falagas et al., 2009, as cited in Afolabi et al, 2014; Jefford & Moore 2008; Priestley, Campbell, Valentine, Denison & Buller, 1992).

For a prospective participant to be able to provide consent in an informed way a good understanding of the key concepts is required but also of the *personal implications* of participation (Lindegger & Richter, 2000; Ndebele et al., 2012). Though the legal requirement of full disclosure of information may well be achieved by researchers, the ethical condition of ensuring that participants understand and make an informed decision may be more challenging (ibid). Lindegger and Richter (2000) have argued that what needs more recognition is how participants evaluate information for its personal implications. It is very challenging to measure the nature and the level of understanding that someone has of concept or its implications (Lindegger & Richter, 2000; Richter, Lindegger, Karim & Gasa, 1999; Watermeyer & Penn, 2008). Too much and too little information can undermine understanding – and not to exceed an individual's "absorptive capacity" is a recognized challenge (Lindegger & Richter, 2000, p. 315). Another complexity is the paternalistic attitude of some researchers which leads to one-way sharing of information, resulting in passive consenting, where researchers do not come to understand the values or concerns of study participants (Lindegger & Richter, 2000). It has been argued that providing participants with information must not comprise a ritualistic recital of the written document, but should be tailored to their level of understanding (Marshall, 2006).

## **2.9 THE NEED FOR COMMUNITY ENGAGEMENT TO STRENGTHEN CONSENT**

There is a greater appreciation that researchers should actively engage with communities to, amongst others, strengthen the consent process (UNAIDS/AVAC 2011). MacQueen et al. (2015, p. 1) defines the term community and engagement as "a group of people with some kind of shared social identity" and an "interactive relationship between a community and a research entity" respectively. It has been stipulated that a key aspect of informed consent entails the relationship between researcher and participant (Lindegger & Richter, 2000), and the consent process may be enhanced by developing a partnership between researchers and the community. Marsh, Kamuya, Mlamba, Williams & Molynux (2010) highlight that community engagement has delivered greater opportunities for researchers to address community concerns and comprehension of research in general. They assert that relationships with community members may improve levels of trust between researchers and community members.

A number of international and local guidelines have been developed specifically for HIV prevention trials which have recommended that researchers in HIV prevention trials engage



with participating communities to try to strengthen the consent process. WHO (2011) recognises the need to be sensitive to and to respect the communities' cultural and traditional practices, and to identify local cultural practices which may affect the informing process. UNAIDS/AVAC (2011) recommends the following: identification of working structures within communities, understanding literacy levels of communities, and identification of languages for obtaining informed consent. Further recommendations from these guidelines include how meetings with communities should be conducted, how community representatives should be identified and recruited, how local language that is well understood should be used, and how efforts should be made to understand communities concerns, needs, and experiences and how research literacy should be built (UNAIDS/AVAC, 2007; UNAIDS/ AVAC, 2011). From this standpoint, is it evident that community engagement is viewed as facilitating the informed consent process (UNAIDS/AVAC; 2011).

## **2.10 COMMUNICATING INFORMATION**

It has been argued that consent is best conceptualized as "a process, ideally a dialogue, that takes place over time and depends on interactions between human beings" (Flory & Emanuel, 2004). It has been argued that principles of adult learning, as well as communication may helpfully inform the issue of how to communicate complex information in the consent process (Flory & Emanuel, 2004; Meade, 1999). Both may inform the interpersonal processes or strategies employed when interacting with other people (Hargie, 2011) for informed consent. In the section below, some key principles from both fields relevant to consent are briefly reviewed.

### **2.10.1 ADULT LEARNING**

Research with learners has shown that adults learn in a specific way and have several characteristics (Ota, DiCarlo, Burts, Lairds & Gioe, 2006). Ota et al. (2006) have stipulated that adults have special needs which require careful consideration when one wants to impart knowledge to them. Adults acquire knowledge better if they associate new knowledge and information with formerly learned information, experiences and knowledge. A key principle of adult learning is that adult learners are *not blank slates* and bring a rich and extensive bank of experiences from which to draw when learning new material (Robin & Fogarty, 2007). That is, prior knowledge is considered critical when constructing new knowledge (Popkewitz et al., 2001, as cited in Martin, 2006) and where comprehension of key concepts is held to depend on

existing frames of reference (Martin, 2006). This suggests that researchers should make some effort to *assess prior knowledge* of potential participants bearing in mind that some people may overestimate what they know particularly in complex fields (cf. Dunning, 2014).

Also, learners are viewed as *active participants* in the learning process, and therefore it is recommended that learning encounters provide opportunities for adult learners to interact with each other and the educator (Dunning, 2014). This suggests that encounters where complex trial information is presented should be structured in a way that encourages participation. Furthermore, it is recognized that adult learners are most interested in information relevant to their needs; and that communication that emphasizes 'the facts' alone is inadequate because learner may not be sure what they are supposed to do with the facts (Meade, 1999, p. 125). This suggests that encounters where trial information is being disclosed should explore the needs of those 'learning', and try to balance the required elements of informed consent with the informational needs of subjects (Meade, 1999). This also suggests that implications of trial 'facts' should be explored with potential participants so they are able to appreciate the facts in terms of their daily personal lives (cf. Lindegger & Richter, 2000; Ndebele, 2010; Ndebele, Wassenaar, Masiye & Munalala-Nkandu, 2014). The above principles suggest that research staff should plan activities geared towards the acquisition of new concepts, skills, and attitudes (Popkewitz et al., 2001, as cited in Martin, 2006).

### **2.10.2 HEALTH COMMUNICATION**

Health communication is useful for facilitating health decision-making, and ensuring adherence to health interventions by patients (Ahmed, Hossain & Kabir, 2014). Health communication posits that there should be *active participation* by the patient in the exchange of information, rather than unilateral disclosure and passive reception of information by the patient. This suggests that encounters where key trial information is disclosed should ensure that potential participants are actively involved in the interaction, and that relevant information should be conveyed in focussed interactions that help participants to understand information and to choose an action corresponding with their health beliefs and desires (Meade, 1999).

It has been argued that key communication practices include both inquiring and informing - to assist patients to make decisions about treatment options that are shared between doctor and patient (White, Keller & Horrigan, 2003). *Inquiring* involves asking patients about their existing

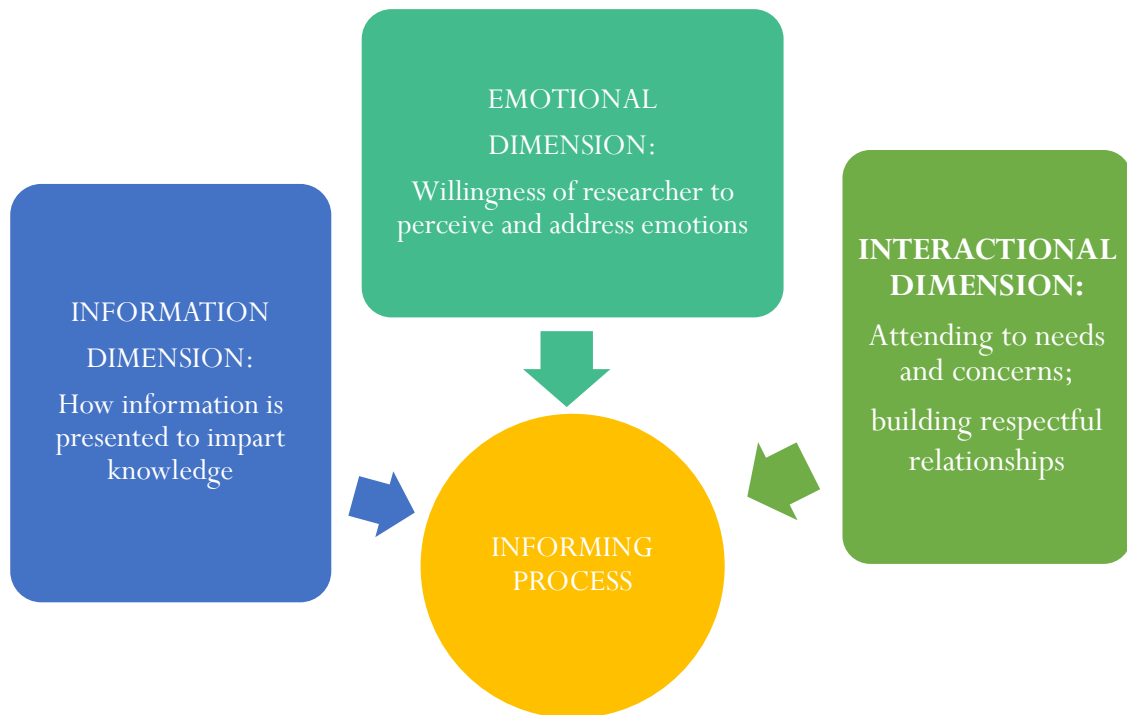
beliefs, preferences, understanding and values while *informing* involves providing the patient with information about the clinical evidence, options, risks and benefits (White et al., 2003). Inquiring is viewed as helpful for assessing the patient's knowledge, expectations, fears, and their beliefs that may have been derived from lay networks or other information sources (Charles, Gafni & Whelan, 1999; White et al., 2003). In this framework, a patients' comprehension is seen to depend mostly on the quality of communication from those providing consent (Albrecht, Franks & Ruckdeschel, 2005). This suggests that qualities of consent communicators are critically important (Cohn & Larson, 2007).

Many commentators have recommended good practices for communicating complex information for research including the following: establishing rapport with the participants (Penn & Evans, 2009), knowing more about the study participants (Penn & Evans, 2009), facilitating dialogue with the participant (Wade, Donovan, Lane, Neal & Hamdy, 2009), using language that is easy to understand and preferred by the participant (Watermeyer & Penn, 2008), encouraging participants to ask questions, creating an interaction during the process (White et al., 2003), verifying understanding and assessment through culturally-relevant methods, or asking the participants to explain in their own words (Ndebele et al., 2012; Ndebele et al., 2014), and ensuring opportunities to discuss the information with others (Wade et al., 2009). From this standpoint, informed consent should be viewed as a requiring an effective communication process that fulfils requirements for consent and allows potential participants to make informed decisions about research participation (Meade, 1999).

## **2.11 THE MEERWEIN MODEL OF THE INFORMING PROCESS**

Some commentators have identified various dimensions to be addressed during the informing process (Ndebele, 2010; Tomamichel et al., 1995). The Meerwein model (Meerwien, 1985, as cited in Tomamichel et al., 1995) asserts that there are three main dimensions of the informing process namely an *informational*, *emotional* and *relational* dimension (Tomamichel et al., 1995). In the model as adapted by Tomamichel et al. (1995) the *informational* aspect is concerned with the information itself and how it is explained, the *emotional* aspect is concerned with how emotions are addressed, and the *interactive* dimension is concerned with the capacity and willingness of the researcher to perceive and respond to needs and concerns of participants (Tomamichel et al., 1995). It is held to recognize important aspects of the investigator-participant relationship that impact on informed consent, namely, to

communicate complex information, to address emotions and to respond to concerns of participants (Tomamichel et al., 1995). The model has been mentioned as a valuable tool in teaching communication skills (Tomamichel et al., 1995). This model recognizes that “informing” is a process that comprises crucial features with regard to the manner in which information is provided and the relationship between the potential participants and the researcher (Ndebele et al., 2014).



**Figure 2:** Meerwein model of the informing process (Ndebele, 2010)

Furthermore, a commentator has used the Meerwein model to develop a framework comprising three stages (Ndebele, 2010). During the first stage, the investigator invites the potential participant to inform them about the study. The participant - upon acceptance of the invitation - is then provided with detailed information. The second stage involves the two parties having a discussion about fears, concerns, and questions. This stage involves provision of more focused and detailed information to ensure comprehension of study procedures and to build trust. The third stage is realised after utilisation of information where the potential participants decides whether to enrol into a study or not, after deliberating on the information which has been provided (Ndebele, 2010). The stages and key features are summarised in a table below taking into consideration expected key elements from both parties:

Dimension	Stage	Key elements(Participant)	Key elements(Researcher)
Informational	Informing	<ul style="list-style-type: none"> <li>• Processing information</li> <li>• Having adequate time to process information and consult</li> </ul>	<ul style="list-style-type: none"> <li>• Providing sufficient and clear information</li> </ul>
Emotional	Receiving information	<ul style="list-style-type: none"> <li>• Having opportunity to ask questions</li> <li>• Expressing fears and myths/ misconceptions.</li> </ul>	<ul style="list-style-type: none"> <li>• Responding to questions</li> <li>• Assessing understanding</li> <li>• Addressing fears, myths and misconceptions</li> <li>• Building trust</li> </ul>
Relational	Discussing/ Agreement to participate	<ul style="list-style-type: none"> <li>• Understanding responsibility</li> </ul>	<ul style="list-style-type: none"> <li>• Ensuring understanding of responsibility</li> </ul>

**Table 1:** Tabular representation of Meerwein stages and features as described in Ndebele (2010)

## 2.12 RELEVANT EMPIRICAL RESEARCH

CIOMS (2002, p. 33) guideline 4 states;

*...obtaining IC is a process that is begun when initial contact is made with prospective participants and continues throughout the course of the study - by informing the prospective subjects, by repeating and explanation, by answering their questions as they arise and by ensuring that each individual understands each procedure, investigators elicit their IC and in so doing respecting their dignity and autonomy. Each individual must be given as much time as is needed to reach a decision, including time for consultation with family members or others. Adequate time and resources should be set aside for informed-consent procedures.*

However several commentators have argued that there is still much to know about the quality of the verbal interaction during the consent process (Brown, Butow, Butt, Moore & Tattersall,

2004) and about the strategies being implemented to improve consent, so that comprehension of trial information is enhanced. Over the years, there has been some research exploring consent communication, for research generally and for HIV vaccine trials specifically, and a selection of key articles is briefly reviewed here.

#### **2.12.1 STUDIES ON NON-HIV PREVENTION CONSENT RESEARCH**

Flory and Emanuel (2004) conducted a systematic review of 42 trials that compared the understanding of research participants who had undergone a standard informed consent process to that of participants who had received an intervention to improve their understanding. Their findings concluded that “extended discussion” and holding one-on-one discussions with participants appears more effective in improving understanding than enhanced consent forms and multi-media interventions” (Flory and Emanuel, 2004, p. 1599). The authors hypothesized that “direct human contact” has more potential for *active engagement* and *responsiveness* to the individual needs (Flory and Emanuel, 2004, g. 1599). Also, Nishimura, Carey, Erwin, Tilburt, Murad, & McCormick (2013) conducted a review of 39 consent trials and concluded that enhanced consent forms and “extended discussion” are most effective in improving participants’ understanding (Nishimura et al, 2013) .

Ahmed et al. (2014) conducted a survey with 25 households selected at random from 30 Mauza villages in Bangladesh, India. The survey was conducted to explore the role of various communication media in enhancing understanding to facilitate informed decision-making for managing malaria-like illnesses. The findings indicated that interpersonal communication was viewed as more effective in improving knowledge than conventional print and audio-visual media. This author agreed with Flory and Emanuel (2004) that interpersonal processes are effective in improving understanding for research participation (Ahmed et al., 2014).

Saidu (2013) conducted a study with 200 mothers who provided informed consent for their children to take part in a Phase II randomized, controlled and observer-blind trial to evaluate the impact of a combined protein-polysaccharide vaccine on nasopharyngeal carriage of *Streptococcus pneumoniae* in Gambia. The findings showed that provision of trial-related information on separate (repeated) occasions enhanced the understanding of study information by study participants. Wade et al. (2009) conducted a study investigating what occurs during informed consent procedures in an ongoing multi- center randomised clinical trial in the UK. The study recruited 23 men aged 50–69 years old. The study showed that

eliciting views from participants enables participants to raise their concerns, as well as to state their beliefs which require clarification from research staff. They argued that eliciting and exploring beliefs is crucial for the consent discussion (Wade et al., 2009).

In an analysis of communication through translators (experts in local language) in health-care settings, Kaufert and Putsch (1997) explored concerns that arise from differences in culture and language. They conducted interviews (and gathered observational data) regarding the experience of 10 Canadian medical interpreters from a palliative care group. Their findings concluded that, in multicultural contexts, in order to develop a culturally-sensitive approach which may enhance health-care decisions, cultural competency is crucial. Carrese and Rhodes (1995) explored the use of language and its implications for disclosure of medical information amongst the Navaho nation in the USA and illustrated that language can exert powerful restrictions on medical communications.

Molyneux, Peshu & Marsh (2004) argued that a major tool in improving understanding includes pro- active (community based) information-giving, including holding workshops and open days at research centres and in communities where potential participants are encouraged to ask questions and start discussions. They asserted that having lengthy discussions in local language makes scientific terms more understandable to local individuals (ibid). Penn and Evans (2009) conducted a study in a large multi-site HIV treatment trial in South Africa. The study recruited 13 counsellors who had been trained to recruit patients with HIV or AIDS who were receiving ART. The first languages of the counsellors included Xhosa, Zulu and Sesotho. The study compared a standard protocol with a modified protocol matching the cultural and linguistic variables. In the latter protocol, the counsellors were encouraged to learn participant's language preference, deliver the message in several languages (code-switch) and explain simply. The authors recommended attention to language as a critical part of communication during consent, and attention to staff training as a key strategy to help participants comprehend study information. They recommended that consent staff should have the ability to display understanding of the content, should be able to explain clearly to study participants, should know their audience and should not merely read the written consent form.

### **2.12.2 STUDIES ON HIV PREVENTION CONSENT RESEARCH**

Ndebele et al. (2012) conducted a study in Malawi to assess HIV prevention trial participants' understanding of randomisation, double-blinding and placebo use, and found lower scores on certain complex concepts such as double-blind, and on the personal implications of participation. In a later paper, Ndebele et al. (2014) investigated the impact of an intervention on the understanding of low-scorers from the first study. The study intervention included: using laymen's language, using narratives of key concepts and their personal implications based on every-day examples from the Agricultural field (because Malawi has an agriculture-based economy), power-point presentations, and discussion of the concepts. The findings showed that low scorers assigned to the intervention had improved understanding compared to the control. Furthermore, information presented in the form of story "vignettes" was considered to be interesting and easy to follow. This represented the importance of encouraging participant's to understand research concepts by invoking real-life, every-day, meaningful, locally relevant examples or scenarios (Ndebele et al., 2014).

Fitzgerald, Marotte, Verdier, Johnson & Pape, (2002) in a study on HIV-1 transmission in Haiti enrolled 15 individuals who were given information during a single meeting with a physician and 30 volunteers who were given information by a counsellor during three meetings (with discussion), and the results indicated a 20% versus 80% pass score on oral examination respectively. They argued that holding multiple sessions of informed consent in communicating complex information increased the comprehension of members of a Vaccine Preparedness Group (Fitzgerald et al., 2002). Harrison, Vlahov, Jones, Charron, and Clements (1995) enrolled volunteers from the Injection Drug Use (IDU) population into a study exploring their levels of understanding – before their enrolment into a multicentre Phase II trial of two HIV recombinant GP 120 sub-unit vaccines. The study administered a forced choice checklist to assess understanding of study procedures prior to written informed consent. They found relatively high levels of knowledge, and concluded that this population could be assisted to comprehend the study, and identified foci for further education about the study protocol.

McGrath et al. (2001) conducted a study to find the best way to educate potential participants about phase III HIV vaccine trials and to evaluate their understanding of study information in Uganda. They enrolled 1,182 Ugandan military men who received education about vaccine trials and were interviewed 24 months later in follow up. The study intervention was vaccine trial education which provided detailed information about phase III vaccine trials, and an



interactive group format. The study team translated the information into local languages and employed the use of analogies for concepts like 'randomisation' and 'placebo'. It was reported that participant's levels of understanding in the enhanced educational programme was higher than in the control group. The findings underscored the need for *repeated* and ongoing trial education to impart knowledge about HIV vaccine trials concepts.

In summary, informed consent is critical for research because it acknowledges that individuals' need to be respected as worthy and capable of making individual choices given the right type of knowledge (Ng'ongo'la, 2016). Engagement of the participating community might help to make consent processes stronger (UNAIDS/AVAC, 2011). Efforts to communicate complex information in a way that optimizes understanding become very important. Current ethical guidelines for HIV vaccine trials (MRC, 2003) assert that interpersonal skills and processes to facilitate sound understanding are critical. However, there has been little research that explores the strategies being used by key HIV vaccine stakeholders to help communicate trial information (Penn & Evans, 2009; Slack et al., 2016). This study aims to fill that gap by exploring strategies reportedly being used by site-staff communicating trial information to potential participants and participating community members.

# **CHAPTER THREE**

## **STUDY AIMS AND METHODS**

### **3.1 INTRODUCTION**

This chapter will describe the study aims, the approach to the study, and the methods used to collect and analyse the data. It will motivate the methods employed, and describe measures implemented to ensure rigour of the study. Ethical considerations addressed during the conduct of the study will also be described.

### **3.2 STUDY AIMS**

This study aimed to explore practices reportedly used to communicate complex concepts in HVTs. More specifically it aimed:

- To explore strategies reportedly used by key site stakeholders in South African HVTs to communicate trial information
- To explore the correspondence of reported strategies with recommended practices from the conceptual and empirical literature
- To explore the implications for strengthening the informed consent process in resource-constrained settings.

### **3.3 STUDY APPROACH**

This study adopted a qualitative approach. This approach is useful for an in-depth or detailed exploration of a phenomenon in context (Mack, Woodsong, MacQueen, Guest, & Namey, 2005; Ulin, Robinson & Tolley, 2005). It strives to allow the researcher to understand a given research problem from the perspectives of the population participating in the research (Mack et al., 2005. Ulin et al. (2005) state that qualitative methods are naturalistic, insofar as they apply to real-world circumstances as they unfold naturally. Terre Blanche, Durrheim and Painter (2006) assert that this approach is useful for the study of unfolding processes in real situations. The approach is generally inductive, where findings materialize from themes inherent in the data, without the limitations imposed by organized methodologies (Strauss & Corbin, 1998) and is concerned with people's experience-near perspective - that allows the researcher not to start exclusively with prior concepts but to allow important concepts to

emerge from engagement with the data (Ulin et al., 2005). Qualitative research is oriented toward discovery and process (Mack et al., 2005). It is argued to be an ideal approach for the collection of information about the view-points and behaviours of those participating in the study (Mack et al., 2005). For the reasons above, a qualitative approach was considered appropriate for an exploration of the strategies used to communicate complex information in HIV vaccine trials to potential trial participants, and for addressing the aims in this thesis.

This qualitative study was broadly set in an *interpretive perspective* – focusing on practices, subjective meanings that stakeholders may attach to their practices, and the context (Ulin et al., 2005). This framework - which emphasizes people's perspectives linked to their practices – seemed to be a useful one in which to locate the study because the study was interested in the perspectives of site stakeholders linked to their practice reports of communicating complex information to potential participants (Ulin et al., 2005).

### **3.4 STUDY METHODS**

#### **3.4.1 BACKGROUND AND REFLEXIVITY**

The researcher has had several work-related experiences that led to her interest in informed consent. As a Quality Control/ Quality Assurance Officer at the University of North Carolina Research Project in Lilongwe, Malawi, she has reviewed informed consent forms for completeness. While doing this work, she experienced some concerns about the length of informed consent forms and scientific terminology used. The length of the consent form left her thinking about how potential participants affected by HIV might have to spend several hours working through the information, and wondering how their expectations, fears and concerns would be addressed. She also questioned how medical terms might be adequately translated in the local language (Chichewa) which is very limited in terms of scientific words/phrases. As a Co-Investigator on a study protocol exploring management of diabetes in patients living with HIV and AIDS, she was responsible for informed consent processes – more specifically her main role was to enrol potential participants into the study which included ensuring that they were given adequate information about the study and that they comprehended the information. Here she had personal experience of interacting with potential participants with little background in research, little formal education, and diverse cultural backgrounds. Here, she noticed efforts to try ensure understanding of the concept of 'efficacy' by referring to local cuts called "*kuwalitsa mphini*" (i.e. traditional marks put on parts of the body using a sharp object, where traditional concoctions are added to prevent different

diseases). The experience also allowed her to see the importance of regarding informed consent as a process where a researcher and a potential participant discuss the study, where participants can be active inquirers; but also allowed her first-hand experience of how challenging that can be.

Also, through her work at Malawi Liverpool Wellcome Trust, she became interested in the issue of communication because she was instrumental in providing training to study-staff on informed consent so the requirements stipulated in ethical guidelines (such as Declaration of Helsinki, 2013) could be met. Here she heard many challenges research staff encountered when conducting informed consent, e.g., how to ensure participants are fully engaged during the process, how to handle participants with myths and misconceptions; and how to address potential participants' cultural beliefs about traditional medicine. As a result of these experiences, she became motivated to explore empirically the issue of how to strengthen the communication of complex information for research participation. As part of her Master's degree in Social Science (Health Research Ethics) funded by the South African Research Ethics Training Initiative (SARETI) the researcher became aware of a research project exploring informed consent in HIV vaccine trials being conducted by the HIV AIDS Vaccines Ethics Group (HAVEG), and she approached HAVEG staff to explore becoming involved in the study for her dissertation requirement.

### **3.4.2 DESIGN**

This study comprised an analysis of existing data collected previously by members of HAVEG at the University of KwaZulu-Natal (UKZN). The broader HAVEG study, of which this analysis was a part, was reviewed and approved by several Research Ethics Committees, namely the Human and Social Sciences Research Ethics Committee at the University of KwaZulu-Natal (UKZN HSS REC 1332/012); University of Cape Town Human Research Ethics Committee (UCT HREC 213/2013; and the University of Toronto Institutional Review Board (UoT IRB 28859). The *analysis of existing data* for this thesis was approved under existing approvals. (see Appendix 1). This study was also approved by Higher Degrees Committee at the College of Applied Human Sciences UKZN, namely HSS/1236/015M. .

The broader HAVEG study aimed to explore representations of key trial-related concepts, as well as to explore interpersonal processes between key site-stakeholders and potential participants geared at enhancing comprehension of complex trial information or other

important outcomes. The broader HAVEG study therefore aimed to explore how complex information is communicated to participating-community members and potential participants during consent-related discussions at South African HIV vaccine trial sites - to inform sound decision-making for HVTs. The HAVEG team had already undertaken a separate analysis of the data to explore how key concepts were represented by various groups and identified various 'competing versions' or explanations of key consent concepts (Rautenbach et al, 2015). HAVEG was embarking on an additional analysis of how trial information was communicated to potential participants, and the researcher was invited to contribute to this analysis of collected data, as part of her Masters dissertation.

### **3.4.3 SAMPLE**

The HAVEG study had already recruited participants from key stakeholders at an HIV vaccine trial site with varying types of experience related to the issue under exploration, including *Community Advisory Board* members who interact with participating-community members; *Educators* who interact with interested community members at the site, and *Consent Counsellors* who interact with persons interested in enrolment in actual HIV vaccine trials. This reflected a form of purposive, non- probability sampling to include information-rich cases (Starks & Trinidad, 2007; Terre Blanche et al., 2006) and to identify specific groups of people who had knowledge relevant to the phenomenon being studied, and to enable exploration of strategies being used every day when communicating complex concepts in such trials. A range of informants was included to provide rich and possibly diverse sources of knowledge on the subject (May & Pope, 1995). HAVEG had already recruited an additional key informant, a *site-staff member* at the site knowledgeable about site processes.

### **3.4.4 DATA COLLECTION**

HAVEG staff members had conducted Focus Group Discussions ( $n = 4$ ) with representatives from three site-related constituencies, namely CAB members, Educators and Consent Counsellors. Two FGDs had been conducted with 10 CAB members each (i.e. 20 CAB-enrollees) late in 2013. One FGD with 8 Educators had taken place also late in 2013 (i.e. 8 educator-enrollees). One FGD with Consent Counsellors with 7 members had been conducted in early 2014. The FGDs were conducted in English, yet participants did speak in the language prevailing in the participating community as well. In the FGDs, several domains were explored, that is, HAVEG staff asked representatives to describe their role, to discuss trial information, how information is explained (including the use of analogies) and challenges they experienced.

Also, facilitators and FGD-participants engaged in role-playing – where explanation of concepts to ‘pretend’ participating-community members was role-played, in order to stimulate discussion about the information, how it is communicated, and challenges (cf. Rautenbach et al., 2015; Slack et al., 2016).

Sessions were audiotaped with permission and transcribed verbatim in English. (See also ‘ethical considerations’ section that follows later). The foremost advantage of FGDs is that they produce more information over a short period of time, and are effective in eliciting a comprehensive, diverse range of views on a specific topic (Mack et al., 2005). The semi-structured approach allows issues to be explored flexibly (Denscombe, 2003), and allows FGD-participants to communicate their experiences and describe their opinions in their own words, with no restrictions, and according to their knowledge and experiences (Terre Blanche & Durrheim, 1999).

### **3.4.5 DATA ANALYSIS**

The data set for this analysis comprised existing transcripts from 4 FGDs which constituted the “primary” data and 1 semi-structured interview as “secondary” data. After signing a Confidentiality Agreement, the transcripts were made available to the researcher. These transcripts were analysed using Thematic Analysis (Braun & Clarke, 2006). This was used because Thematic Analysis allows the identification, analysis and reporting of patterns or ‘patterned responses’ (themes) within a data set (Braun & Clarke, 2006, p.85). Another advantage of Thematic Analysis is that it is theoretically ‘flexible’ and is used across different qualitative frameworks (Braun & Clarke, 2006, p.28). For this study, it was suitable to answer questions related to people’s experiences about communication strategies used in communicating complex information, and was also able to capture experiences in the form of viewpoints and perceptions (Braun & Clarke, 2006). The researcher’s approach to analysis was informed by a step-by-step guide by Braun & Clarke (2006) with some variation. The following steps were taken:

*Step 1: Reading and becoming familiar with the data:* The researcher repeatedly read the data in an “active way” (Braun & Clarke, 2006, p. 16), searching for patterns. At this stage the researcher started taking notes, marking ideas for coding, and highlighting interesting quotes. This allowed the researcher to familiarize herself with the aspects of the data. The researcher read each transcript with the primary issue in mind – namely what are the strategies being used

to communicate complicated trial information? This helped to focus reading of the transcripts based on the main study question.

*Step 2: Coding:* Text was coded by giving portions of the text particular labels (Boyatzis, 1998, as cited in Braun & Clarke, 2006). Coding was guided by the central aims of the study. Text was labelled according to strategies or processes being used to communicate complicated information. The features of the data which appeared interesting to the researcher from the transcripts were extracted and placed into a coding table. Some codes were developed from reading the literature such as '*using analogies*' and these constituted deductive or top-down codes (Quinn-Patton, 2002). Others were developed from the reading of the transcripts such as '*referring to safe licensed vaccines*' and these constituted inductive or bottom up codes. Text was labelled in a semantic way, staying fairly close to the words used by study participants (Sandelowski, 2000).

*Step 3: Sorting codes into clusters:* At this time the researcher began to form ideas about how codes might relate to each other (Green et al., 2007). Codes were examined to see if they could be linked together to create coherent clusters (Green et al., 2007). For example the codes: '*referring to safe licensed vaccines*' and '*using trustworthy sources*' were clustered together because these appeared to be concerned with addressing suspicion or fear.

*Step 4: Sorting code-clusters (sub-themes) into master themes:* The data was examined to establish how sub-themes could be organized into higher-order master themes. Here the model advanced by Meerwein (1985, as cited in Tomamichel et al., 1995) was considered useful. As set out in the previous chapter, this model comprises of three dimensions namely: informational, emotional and interactive/ relational dimensions. The informational dimension covers how well a communicator explains important content or information; the emotional dimension addresses how well the communicator addresses feelings, and the interactive dimension addresses various relational elements such as how well a communicator responds to participants needs and concerns. This framework was not adopted in totality but rather it informed the development of the master themes. The list of codes, code-clusters and themes (and supporting quotes) was regularly discussed and reviewed with the supervisor (see section 3.5). The final code/theme list is set out in Chapter 4 (Results). Word processing software was used to capture themes, and no other software was used.

Step 5: *Writing themes into narratives*: A detailed description was written for each theme (Braun & Clarke, 2006). The narrative identified the “story” each theme was telling (Braun & Clarke, 2006, p. 90). These narratives identified the strategies being used to communicate trial information by key site stakeholders in important encounters at trial sites. Each theme was supported by the best data extracts. The narrative and selected quotes aimed to demonstrate the relevance of each theme and how it fits into the overall aim of this study.

### 3.5 STUDY QUALITY

The researcher set out her experiences and personal involvement in the subject matter (Malterud, 1993) in order to include a brief *reflexive account* that may show the influence of the researcher on the aims and the material considered relevant. The researcher reflected on her past experience in informed consent encounters as an educator and trainer (including challenges related to informed consent encounters) which informed her current research interests in strategies to enhance comprehension in HIV vaccine trials. She engaged with an interrelated body of empirical work which informed her research analysis. Also, the sampling method allowed the inclusion of multiple *different perspectives* from various stakeholders about the issue under investigation (Patton, 1999) to allow suitable diversity and scope.

Furthermore, a selection of transcripts were *co-coded* by the supervisor and discrepancies resolved by “reconciliation discussions” (Boyatzis, 1998, p. 152). To ensure development of comprehensive codes, and their consistent application, there was comparison of coding and discussion between student and supervisor which helped ensure that codes systematically accounted for all of the emerging data (Green et al., 2007). This process provided an important check on selective perception (Patton, 1999). In addition, the student and supervisor ensured that themes cohered around a central concept and were sufficiently distinct from each other (Braun & Clarke, 2006). Finally, in order to verify that all codes still applied or whether the older transcripts needed re-coding, previously coded transcripts were revisited (Green et al., 2007). *Saturation* was considered reached when new transcripts did not lead to further elaboration of codes and themes (Green et al., 2007). The researcher systematically made inquiries of the transcripts to ensure that the emerging analysis responded adequately to the research aims (Malterud, 1993).



### **3.6 ETHICAL CONSIDERATIONS OF THE STUDY**

#### **3.6.1 INDEPENDENT REVIEW**

As discussed earlier, this analysis of existing data obtained ethical approval.

#### **3.6.2 STAKEHOLDER ENGAGEMENT**

The HAVEG study ensured that stakeholder engagement at the relevant site was conducted to ensure buy-in and support. HAVEG members conducted presentations to describe the study, to hear concerns and to tailor the data collection accordingly. Permission to enter the site for the HAVEG study was obtained from relevant gate-keepers at the site, such as the site leadership and CAB leadership.

#### **3.6.3 INFORMED CONSENT**

The HAVEG study sought individual, written informed consent from each participant before data collection. Participants were informed about the study, and given the opportunity to discuss the study with the researchers. The research team ensured that all respondents signed the informed consent form and agreed voluntarily to participate in the study. The team also ensured that consent for recording of FGDs was obtained. Before the start of the FGDs, the research team described the aims of the study, and provided an opportunity for participants to ask questions and to present their concerns. Participants were assured of anonymization of the transcripts and secure storage of data.

#### **3.6.4 RESPECT FOR RECRUITED PARTICIPANTS**

The HAVEG study ensured that redaction of names and identifying details from study transcripts was implemented, to maintain anonymity of participants. In order to maximize protection of study records electronically, transcripts were password protected and, to ensure secure storage of study materials, study documents were locked in cabinets. To ensure sound data management, the audio-files were password protected. Data was stored in a secure environment including password-protected computers (for electronic files) and locked cabinets (for printed documents). The participating site was not named.

### 3.6.5 FEEDBACK TO PARTICIPATING SITE

The HAVEG team has provided feedback to the participating site about emerging results. Relevant findings from this analysis will be summarized as part of appropriate feedback for participants and stakeholders at the participating site.

### 3.7 STUDY LIMITATIONS

This study data comprised mainly of FGDs *at only one site*. This means that caution has to be exercised when generalizing the findings beyond the site, however, it is possible that other sites using the similar approaches and staffing might find the results useful (Slack et al., 2016). The study did not make use of any observational methods, but relied on *self-reported practices* (Slack et al., 2016). This means that some techniques which are not easily apparent to such staff might not be reported (for example, they may have forgotten about them). This also means that site stakeholders may report certain strategies but they do not actually implement them in practice, for example, site stakeholders may have experienced some 'social desirability' pressure to report communication practices because that was the focus of the study – even though they do not implement them. That is, they may have wished to please the investigators and to make a favorable impression (Lindegger & Richter, 2000). Observations would have allowed a richer understanding of the setting and the conduct of the members in that setting (Jorgensen, 1989).

The methods employed here cannot 'validate' the *actual* practices being used. Also the views of *potential participants* were not canvassed and the study did not identify different perspectives between stakeholder groups, which would have allowed the issue to be explored from a critical perspective. As set out in Slack et al. (2016) potential participants could have described their experiences of practices implemented to communicate with them, including what was useful or valuable to them – which would have increased the value of the data collected (Frechtling & Sharp, 1997). The FGDs were conducted by English facilitators, even though FGD participants spoke in both English and the local language during the FGDs. Because FGD participants may have experienced implicit pressure to communicate in English, this may have restricted their spontaneous communications, and impacted on the richness of data. The use of existing data imposed certain limitations because the analyst could not ask questions in subsequent focus groups based on analysis of earlier focus groups; rather the analyst had to accept the transcripts as they were.

# CHAPTER FOUR

## RESULTS

### 4.1 INTRODUCTION

This chapter sets out three master themes as developed by the analysis described in the former chapter. In the subsequent chapter, these strategies are located in the existing theoretical and empirical literature.

### 4.2 FOCUS GROUP DISCUSSION (FGD) PARTICIPANTS

The 35 FGD participants comprised a mix of men and women – 40% were male and 60% were female. They comprised participants with varying degrees of experience in their role. Most were fluent in the language prevailing in the participating community. One person involved in site management functions took part in an interview which comprised supplementary data.

### 4.3 THEMES

Theme 1 sets out findings related to strategies implemented by CABs, Educators and Consent Counsellors to communicate complex information (the *informational* theme); theme 2 sets out findings related to strategies implemented to address emotions (the *emotional* theme); and theme 3 sets out findings related to strategies implemented to develop respectful relationships with participating-community members and potential participants (the *relational* theme). The themes, sub-themes and codes have been summarised in the Table below:

Theme	Sub-themes	Codes
<b>1 Informational issues</b>	<ul style="list-style-type: none"> <li>Recognising challenges with information-provision</li> </ul>	<ul style="list-style-type: none"> <li>New information</li> <li>Complex/complicated information</li> <li>Too much information</li> <li>Participants with little educational background</li> <li>Participants with little background in research</li> <li>Participants use language with no research terms.</li> </ul>
	<ul style="list-style-type: none"> <li>Implementing strategies to communicate information</li> </ul>	<ul style="list-style-type: none"> <li>Simplifying</li> <li>Translating</li> <li>Ensuring language preference</li> <li>Code-switching</li> <li>Using supplementary aids</li> <li>Promoting discussions</li> <li>Rehearsing</li> <li>Repeating</li> </ul>

<b>2</b> <b>Emotional</b> <b>issues</b>	<ul style="list-style-type: none"> <li>• Recognizing negative emotions</li> </ul>	<ul style="list-style-type: none"> <li>• Fear of exploitation <ul style="list-style-type: none"> <li>- Site selection/ targeting black communities</li> <li>- Guinea pigs/using people as guinea pigs</li> <li>- Blood selling</li> </ul> </li> <li>• Fear of harm from vaccine research <ul style="list-style-type: none"> <li>- Side effects</li> <li>- Being infected with HIV</li> </ul> </li> <li>• Feeling of hopelessness <ul style="list-style-type: none"> <li>- Hope</li> </ul> </li> <li>• Feeling of mistrust/ suspicion <ul style="list-style-type: none"> <li>- Of site representatives</li> <li>- Of CABS</li> <li>- Of the site itself</li> <li>- Of researcher/medical researchers/white researcher</li> </ul> </li> </ul>
	<ul style="list-style-type: none"> <li>• Responding to negative emotions</li> </ul>	<ul style="list-style-type: none"> <li>• Inquiring about/ collating suspicions <ul style="list-style-type: none"> <li>- Asking about/ exploring</li> <li>- Keeping record</li> </ul> </li> <li>• Using trustworthy sources <ul style="list-style-type: none"> <li>- Ex-participants ('witnessing')</li> <li>- Community members/ influential community members</li> <li>- CAB</li> </ul> </li> <li>• Referring to safe, licensed vaccines <ul style="list-style-type: none"> <li>- Polio</li> <li>- Other childhood vaccines</li> <li>- Flu vaccine</li> </ul> </li> </ul>
<b>3</b> <b>Relational</b> <b>issues</b>	<ul style="list-style-type: none"> <li>• Recognizing cultural norms</li> </ul>	<ul style="list-style-type: none"> <li>• Cultural norms/ differing across sites</li> <li>• Trying to please persons in authority</li> <li>• Believing in traditional medicine</li> <li>• Talking about body parts or sex</li> </ul>
	<ul style="list-style-type: none"> <li>• Responding to cultural complexities</li> </ul>	<ul style="list-style-type: none"> <li>• Requesting permission to break cultural norms</li> <li>• Matching culture/races</li> <li>• Using culturally acceptable terms/words</li> <li>• Raising awareness about western medicine</li> </ul>
	<ul style="list-style-type: none"> <li>• Showing general respect</li> </ul>	<ul style="list-style-type: none"> <li>• Greeting</li> <li>• Making comfortable</li> <li>• Offering refreshments</li> <li>• Encouraging</li> <li>• Assuring about confidentiality</li> <li>• Giving time to decide</li> </ul>

**Table 2:** Themes, sub-themes and codes

#### 4.3.1 THEME 1 - INFORMATIONAL ISSUES

This theme describes how site stakeholders (CAB members, Educators and Consent Counsellors) faced challenges with providing information to participating community members and potential participants and describes how they attempted to address informational needs by using various strategies and approaches.

#### **4.3.1.1 Recognising challenges with information-provision**

CAB members, Educators and Consent Counsellors all acknowledged facing challenges with providing information to participating communities and potential participants. It was reported that a *lack of formal education* made it difficult for potential participants to understand complex concepts in HIV/AIDS vaccine research, for example, the concept of VISP or 'Vaccine Induced Seropositivity' where participants test HIV 'positive' but they are not infected with HIV. Site stakeholders recognised the need to take inadequate education into consideration, as well as little knowledge or experience with HIV vaccine trials, or research in general. Site stakeholders reportedly used various strategies to 'inform and educate' communities about research, vaccine trials and HIV/AIDS trials, and the following quote illustrates this point:

*I personally discovered that it's 95% of people, in, the areas we working to, they don't have much information, about vaccine which is now what our outreach worker/outreach workers it's our role (...) that we make sure that that 95% that doesn't have much information or, like, the basic information about vaccine and about what the trial .We make sure that we educated them. (FGD 3, Educators)*

CAB members and Consent Counsellors recognised the challenge of *language barriers* which existed between some members of the research team and participating communities/potential participants. It was reported that many scientific words/terms do not exist in the indigenous language prevailing in the community – which presented these stakeholders with a challenge - as one Consent Counsellor remarked:

*Most of the scientific terms do not exist at all, in the indigenous language, so we have to make a sentence in order to define that word. (FGD 4, Consent Counsellors)*

CAB members and Consent Counsellors also acknowledged how *complex HIV vaccines trials/terms* are – that is, the concepts that have to be transmitted are in and of themselves fairly complicated, but critical to understand because there may be consequences for participants. The concept of VISP or 'Vaccine Induced Seropositivity' was described as especially challenging. An Educator illustrates this point in the following quote:

*... another thing that needs to explain to the participant is this VISP thing is very crucial, very crucial, and I mean, they need also be explained that how long this VISP going to stay. You know because, I heard that it can be, stay it can stay in you about 15 years (...) You know, so that before he takes part, he understands... (FGD 3, Educators)*

Consent Counsellors admitted that they encounter challenges in communicating concepts at the beginning of any trial - illustrated in the following quote:

*Then we will start having a way of unpacking. Because, honestly for each and every new study, at first we struggle as counsellors. Cause one, you are trying, to get through this, to transfer that. (FGD 4, Consent Counsellors)*

Consent Counsellors also described that there was *so much information* to disclose. These reports appeared to be concerned with the volume of information that has to be disclosed and processed in the time-frame that is available. As one recounted:

*So for us we find it is very strenuous but there are these clauses that limit us that come from the sponsor that part of these visits these are the consents. Cause we feel it's too much, really, doing different consents in one time. (FGD 4, Consent Counsellors)*

#### **4.3.1.2 Implementing strategies to communicate information**

Representatives from all of these site constituencies described implementing certain practices to help communicate complicated information. CAB members and Educators reported implementing strategies to provide information to participating-community members and potential participants in a comprehensible manner. CAB members described *translating* terms in the informed consent using culturally-appropriate terms. Educators described that, by knowing terms commonly used in their respective communities, they were able to borrow these local, familiar phrases when explaining concepts (e.g. prevention or vaccine). For example, an Educator reportedly observed that in some communities people were not familiar with the word 'vaccine' but when the word vaccine has been phrased in their local language Xhosa ('*thintela gola*') people were able to understand the term. Educators reportedly made efforts to educate interested community members about key concepts by re-phrasing these in local familiar words - as exemplified in the following quote:

*There are people that they don't know, what is the word vaccine (...) when you come with the word vaccine, they will start to be shocked, but when it comes to, you take the word vaccine and say it in Xhosa, then they will know okay. (FGD 3, Educators)*

Consent Counsellors described the importance of *using simple (non-technical) language* that retains the same meaning in order to enhance understanding among potential participants. Consent Counsellors and CAB members recognised the importance of ensuring that participants are comfortable with the language to be used to facilitate their understanding of

the study information, and described providing information *using a preferred language*. This reportedly made it easier to understand scientific concepts and encouraged interaction with the study team. Consent Counsellors also described switching between indigenous language and English to explain and address questions from potential participants ('code-switching'). This reportedly made it easier for potential participants to understand more about research and procedures.

*Because as we can explain especially when it comes to Xhosa (...) you find that you get stuck, to explain in your own language. You know sometimes you would flip, you know, using English and then come back.* (FGD 4, Consent Counsellors)

It was stated that some concepts were best communicated *using visual aids* – or doing concrete tasks/ activities – Consent Counsellors reported that a number of topics which were difficult to comprehend were further explained in consent discussion groups through slide presentations, with pictures to reflect the concepts and procedures. It was reported that instruments (swabs, test tubes) were shown to increase understanding and trigger further discussion - illustrated in the following quote:

*... we again bridge that a little bit if we take the instruments, that we going to use. You bring it to them and we show them, pictures and this is what we going to do, this is how long it's going to take, this is the swab that we going to use, so you make it more personal and then- we find that they feel they can discuss it more. Give it to them so they can hold it and, look at it and, so it's not a faraway kind of procedure...* (IDI 1, Site Staff)

It was described that *promoting discussion* with participating community members and potential participants may help to promote understanding of difficult concepts. A number of strategies were reportedly used to promote interaction, such as conducting group-based educational events in the community and at the site, run by Educators, as well as conducting consent discussion groups at the site run by Consent Counsellors. It was reported that Educators would deliberately ask key questions in community locations to trigger debate and discussion between community members and site staff. It was also described that at these group events the asking of questions was expected, and encouraged and even modelled for attendees:

*...and also, and these you know we dealing with, nurses, we dealing with, teachers, people with, knowledge, you know they will want to know, if you know what you what*

*you are talking about. You know, by asking () a tricky question so, he or she want you to go deep, you know in whatever that you are, presenting. You know.* (FGD 3, Educators)

It seemed Consent Counsellors and Educators recognised the importance of *repeating* study information to participating community members and potential participants several times during the discussion or ongoing engagements. It was described that consideration was taken to ensure that difficult concepts have been revisited, for example 'VISP', to promote understanding. For example, IDI 1 Site Staff said: *We know we can touch just on those difficult topics again.*

Educators and Consent Counsellors described that communicating concepts by *using every-day examples* or common life experiences allow them to provide a clearer picture of HIV vaccine trials. It was reported that to ensure understanding of some concepts for example 'partial efficacy' site-staff made reference to every-day example of using 'Panadol' where it does not work 100% all of the time. It was further described that *analogies* were sometimes used (where one thing stands in for another) to describe difficult concepts for example '*the army*' to represent the immune system.

Consent Counsellors and Educators understood that they had a great impact on imparting knowledge to potential participants and participating communities therefore took into consideration that building their own capacity to do so was crucial to ensure they are able to communicate complex information. It was reported that rehearsing and practising the content helped them get familiar with the study information:

*... I mean at the end of the day they do understand. It depends on how to explain it. You need to understand it yourself, before you go I mean, tell somebody else...* (FGD 3, Educators)

#### **4.3.2 THEME 2 – EMOTIONAL ISSUES**

This theme sets out how CAB members, Educators and Consent Counsellors recognized the emotional concerns of participating-community members or potential participants, and how they attempted to 'intervene' on an emotional level.



#### 4.3.2.1 Recognizing emotional concerns

Educators described that many communities' members feel *hopeless* because they have witnessed the effects of HIV on their communities:

*... my role there is to help the community, in terms of first giving them the information, especially about the research the importance of doing the research because, I tell them that, if the, there is no research, happening, there will be no hope, at the end of the day that will get any, effective HIV vaccine that at the end of the day will help people who are HIV negative to be (.) protected against you know...* (FGD 3, Educators)

Educators and Consent Counsellors described concerns of potential participants and participating communities about perceived consequences of their involvement in HIV vaccine trials. *Fear of harm* from HIV research vaccine and experiencing side effects from receiving the vaccine was reportedly identified. Fears were aligned mainly to the side effects of the experimental vaccine; for example, in FGD 4, participants asked: *Am I gonna get sick?* Fear of being infected by researchers with HIV was also described as a key concern, as illustrated in the following quote:

*... sometimes when you speak about HIV vaccine, people they get scared you know, and then thinking that, 'oh, I, am I not gonna get, HIV?' You know 'are they gonna infect me with HIV.' Because you gonna get the HIV vaccine and then they think 'oh maybe I will, I might be infected they might inject you, inject me with HIV' ...* (FGD 3, Educators)

It was also described that complexities of HIV vaccine trial concepts may trigger some uncertainty or anxiety in potential participants, hence the need to try to address uncertainties and promote understanding of concepts:

*'It's not a virus, and then it looks like a virus then why are you giving it to me? If it's not a virus, am I gonna get sick? When will you give a participant a vaccine?'* (FGD 4, Consent Counsellors)

Also, CAB members, Educators and Consent Counsellors encountered many *suspensions* from community members and potential participants about key aspects of the research, such as why the studies are being conducted in Africa, why the studies are being conducted at this particular site, why blood is withdrawn from study participants and even why it is flown outside the country. Their concerns include that countries and sites are chosen because of poverty and that participants are likely to be "used" in an unfair way to test products and that in

international trials blood will be sold to other countries. These concerns suggest that participating community members suspect that participating communities and even participants will be treated badly or unfairly for the benefit of the researchers. The following quote illustrates this point:

*...they're very much aware of a guinea pig. (...) So now to them, that's what triggers them, that we making them guinea pigs. You see that's other thing that now we need to unpack that no, we are not making you guinea pigs. (FDG 4, Consent Counsellors)*

It was reported that participating community members experience much suspicion about the site, the site-staff, the researchers, and even medical research in general. Even the CAB was sometimes viewed as 'sell-outs' or 'brain-washed' - and not trusted to represent the views and needs of the community. With regard to the site, it was described that participating community members see it as a place where people are damaged ('we inject people, we kill people' (FDG1). With regard to researchers, it was described they are seen as taking advantage of black communities due to poverty, lack of experience with research and devastation from HIV, and cannot be trusted to advance the interests of the community. This is exemplified in the following quote:

*So these white people they come with their thing, they wanted to infect us because, they know that we are desperate for money we are hungry we are not working. (FDG 3, Educators)*

It was also described that the site (research center) has a bad reputation from some community members who hold misconceptions about the site, for example, seeing it as a place where people get HIV-'infected'.

#### **4.3.2.2 Addressing emotional concerns**

To respond to *hopelessness*, Educators reported providing information to participating communities and potential participant's on the importance of, and the potential of, HIV vaccine research. Educators underscored the need to instill hope in participating communities and potential participant's by describing responses to the epidemic, such as HIV treatment, and HIV prevention, and HIV prevention research. They described that education about HIV and HIV response efforts brought much renewed interest and inquiry about how people might become involved, and how their involvement may contribute to the common good. They reported community members asking the following:

*'Wow, this is amazing' and then 'when is it going to be, available.' I mean especially for, for HIV (...) 'where is for HIV? When is it going to be available?'* (FGD 3, Educators)

To address *suspensions*, it was reported that *inquiring about prior knowledge* about HIV vaccines and research in general helped to uncover suspicions (myths) prevailing in the community about vaccine studies, and messages could be tailored to this existing information. This enabled Educators to better impart knowledge of research and vaccine research at education sessions in the community, or at the site. A number of strategies were reportedly used to identify existing knowledge, such as inquiring about rumours, or allowing potential participants to ask questions regarding the concepts which revealed their concerns. Much discussion then is centered on the misconceptions/concerns to ensure that concerns have been addressed. Educators reported *recording suspensions* emanating from different communities.

To address *suspensions*, it also was reported that *utilizing past trial participants* to share their experiences with potential participants was a useful approach. It is likely that this approach builds trust in the communicated information, because ex-participants have had direct experience of the study procedures. Educators also reported that different teaching methods would be employed by different past trial participants (e.g. drawing on the board, taking time to explain a concept, revealing their own life experiences). It was reported that past trial participants are from within the same communities and are reportedly able to address communities concerns based on their knowledge and experience of the trials. Educators reported that 'bridging the gap' between communities and the research team by using ex-trial participants brings more understanding of what participants ought to expect, teaches communities more about research and brings complex concepts close to people through discussion and interaction. It was reported that this helps in addressing people's concerns, and addresses some of the misconceptions because some of 'their' members have lived through the experience of being part of the trial.

Furthermore, it was also mentioned that site-staff *utilize respected community sources* to provide information about trials, which helps in ensuring that there is enhanced discussion between the research team and the community. It may serve to build confidence and develop trust when their own community leaders are aware of trials, and able to answer questions that community members have. Clarification of issues coming from the community and provision of detailed information to community members forms part of these sensitization meetings.

Also, Educators and Consent Counsellors reportedly *referred to safe, effective vaccines* which are close to people's every-day experiences and which they may have encountered through the course of their lives - to address some of the concerns potential participants and community members have about vaccine trials. It was reported that some misconceptions about HIV vaccine trials (for example that people are deliberately harmed by injecting them with HIV) are well addressed if people are taught about the strict controls in vaccine research with humans. Educators and Consent counsellors promoted familiarization with new information about the trial vaccine by comparing it to proven vaccines already in existence, for example how vaccines protect from diseases e.g., polio vaccines which are used widely within the under-five population. This seemed to tap people's experience of benefitting from this technology, and using it to promote the health of vulnerable and deserving groups such as children. This approach seemed to not only to promote comprehension but also appeared to instil trust among potential participants about medical research, and its contribution to society. As one remarked:

*You have to start with what they know. You have to start with the flu vaccine, why did they get the flu vaccine. Something that is similar to that () you have to explain, scientifically but, be more clear, by using practical examples. Something that they do on a daily basis...*  
(FGD 4, Consent Counsellors)

#### **4.3.3 THEME 3 – RELATIONAL ISSUES**

This theme describes how key site stakeholders (CAB, Educators and Consent Counsellors) recognized cultural needs and preferences of community members and potential participants; and tried to interact with them in culturally respectful ways. Also, it describes how they tried to demonstrate respect more generally for participating-community members, and potential participants.

##### **4.3.3.1 Recognizing cultural norms**

It was reported that in the community, some people might act to *please persons in authority* and this meant that potential participants might report that they have comprehended information while they have not actually understood. Also, CAB members and Consent Counsellors recognized that there may be certain cultural beliefs and practices among potential participants and participating communities that may hinder discussion of key study information (both particular words and topics), and reported the need to ensure that - when

providing information – these factors are considered. They recognized the existence of cultural norms involved in *talking about sex or sexual body parts*. Consent counsellors reportedly observed that in the prevailing culture one should not discuss procedures involving sexual body parts (e.g. mucosal sampling, or circumcision of the male foreskin) with both women and men together. They reported that cultural norms also existed about what could be discussed between younger and older people. They noted that terms such as “anus”, “vagina” and “penis” when translated into local language are potentially disrespectful or offensive. CAB members and Consent Counsellors recognized the significance of cultural norms of participating-community members and potential participants.

*... some of the wording, when you have to translate them in to Xhosa, in our African people, like if you say, to talk about, rectal, (sampling),(....)when you have to explain to them, it seems as if you being rude, you know because, (...)even at home, so when you have to talk about anus, and, vaginas, and now when you have to explain it in Xhosa, it's becoming a big word and in her ears... (FGD, 4, Consent Counsellors)*

#### **4.3.3.2 Responding to cultural complexities**

It was reported that CAB Members, Educators and Consent Counsellors are *drawn from the same cultural backgrounds* – which served to facilitate understanding of study information by using appropriate language and examples, as well as ensure knowledge of prevailing cultural norms. As one Consent Counsellor remarked:

*... because we live in the same community, with them, we know the challenges that they go through. So each and everything that they know, we do know so by making practical example when you going through a consent form (...) so if you living in this community, you gonna make example that do exist in this community... (FGD 4, Consent Counsellors)*

In response to the sensitive nature of certain words and topics, various strategies were reported in response. For example, Consent Counsellors reportedly made efforts to ‘inform’ potential participants about such information without being rude and disrespectful by requesting advance “permission” from potential participants to discuss sensitive issues with them and preparing them in advance to discuss a sensitive topic, as exemplified in the following quote:

*...it's becoming a big word and in her ears. So you try to be like, even when you talk to her and say, "this is going to be sensitive. Now I'm going to explain what is going to happen to you. They are going to take this, and that, in this, and that" ( ....) so that she could*

*understand what is going to happen because they start to be shocked when you try to explain these words to them. So, at the same time, you as a counsellor you're trying to make it easier for them so that they will know the procedures... (FGD 4, Consent Counsellors)*

It was described that individual sessions (after group sessions) were sometimes used, where more sensitive information could be discussed. It was also reported that appropriate language was used in discussing sensitive words or topics (e.g. for body parts). It was also reported that some concepts can be discussed in general when in a mixed group, but when detail is required then it recommended that groups be separated into male and female groups.

*.... so if its men and women that you recruit for a study, and you have them in one discussion group, you can't really talk about circumcision. For example. Cos that, in the Xhosa culture is not something that gets discussed in front of women. So you have to be aware of that as well if there's something specific around circumcision that needs to be discussed, then you have to separate the two groups, to be able to do that... (IDI 1 Site-staff)*

Educators reported that, by knowing the cultural setting, they were able to provide messages to communities in a suitable and acceptable way. CAB members also reported the importance of making efforts to communicate with potential participants and participating communities using culturally-acceptable words. Also, to address the chance that people might respond to please persons in authority, Consent Counsellors reported asking potential participants to describe key concepts in their own words, rather than just rely on their self-reported understanding.

CAB members and Educators reported encountering beliefs about the value and use of traditional medicine when interacting with participating community members. They reported that the health-seeking behaviours of community members is influenced by traditional practices. They drew from that experience to try to raise awareness about the contribution of 'western medicine' to community health. They reportedly drew on their experience of common ailments, and commonly used medicines to clarify how research is conducted, and how medicines are developed. This is exemplified in the following quote:

*Make them understand that these doctors, you can never be able to get your own (high) blood treatment without it being researched. Somebody risked his or her life (...) and then people start to melt down and understand that... (FGD 2, CAB Members)*

In addition to trying to show respect for particular cultural norms and language, these respondents also reported the importance of showing general respect for people. Showing general respect was conducted in different ways and also mattered with different audiences, namely, participating community members invited to sites for general discussions with educators and potential participants interacting with consent counsellors. CAB members noted the significance of being accommodating, being friendly, and offering refreshments, as narrated by one CAB member:

*Another thing to come to a research site, it's most welcomed clinic, than in a public hospital. You will get, soft drink, and then you will be welcomed, and then you will be served, as early as, possible. (FGD 2, CAB Members)*

Educators identified that care should be taken to create an atmosphere for listening, learning and discussion of study information – where potential participants are put at ease – and this is achieved by treating people well. It was noted that potential participants bring misconceptions and fears but by allowing them to voice their concerns and listening them makes them feel respected. Educators recognized that the respect shown, and good hospitality provided, to potential participants might also encourage them to return to the site for more information.

Consent Counsellors also noted the importance of treating potential participants well (e.g. greeting, making them comfortable, taking time to discuss information). Consent Counsellors further reported that ensuring that participants are encouraged to speak and ask questions also shows respect and enhances understanding of study information. They reported assuring potential participants about confidentiality - to ensure that participants were respected by keeping their personal information secure and confidential.

*Because it's very important to understand the consent, so that they don't consent on something that they don't know. We give much detailed information on the nature of the study (...) And mostly, we include confidentiality because confidentiality is very most important, because, like for instance, like in (our files), we do have numbers instead of their names that includes confidentiality because when they take their bloods, no name is written on there. (FGD 4, Consent Counsellors).*

In summary, this chapter has discussed the key findings of this study. It described how site stakeholders reportedly implemented different strategies that addressed relational, emotional and informational needs of host community members and potential participants.



# CHAPTER FIVE

## DISCUSSION

### 5.1 INTRODUCTION

This chapter discusses the findings (3 major themes) set out in the previous chapter in terms of the existing literature relevant to informed consent, such as the literature related to community engagement, adult learning, health communication and empirical explorations of informed consent.

### 5.2 THEME 1 – INFORMATIONAL ISSUES

This section discusses the findings describing how site stakeholders (CAB members, Educators and Consent Counsellors) provided complex information to participating community members and potential participants by using various strategies.

The findings show that CAB members, Educators and Consent Counsellors reported facing challenges with providing complicated information to participating communities and potential participants. Complex and *complicated HIV vaccine trial terms* were reportedly difficult to understand by both the site-stakeholders themselves and participating communities/potential participants, such as Vaccine Induced Seropositivity'. The complexity of HIV vaccine concepts has long been noted as a key challenge (Lindegger et al., 2006; UNAIDS, 2000). These site stakeholders recognized that difficulty in comprehending research concepts was partly attributable to *little background or* knowledge about trials or research in general, and little formal education - factors which have been noted by several commentators (Glickman et al., 2009; Minnies et al., 2008; Ndebele et al., 2012). The findings also show that a lack of scientific terms in indigenous language ('language barriers') proved challenging to these stakeholders, which is in line with observations from several commentators (Kass & Hyder, 2001; Marshall, 2006; Ndebele et al., 2012; Penn & Evans, 2009).

Many of the practices reported here are consistent with recommendations from ethical guidelines to make efforts to disclose information in a way that is understandable (MRC, 2003; UNAIDS/AVAC GPP, 2011). For HIV prevention trials specifically guidelines (UNAIDS, 2012, UNAIDS/AVAC, 2011) recommend that researchers try to enhance comprehension of study

information using culturally acceptable strategies. Kass & Hyder (2001) have recommended that making use of indigenous-language speakers can ensure that the meanings of words are successfully conveyed to participating communities and potential research participants.

Many of the strategies reported here resonate well with empirical research underscoring the significance of *discussion* in promoting comprehension of research (Flory & Emanuel, 2004), for example, where Educators reportedly make use of group-based educational sessions and Consent Counsellors reportedly make use of group-based consent discussion groups, where asking questions is encouraged. Furthermore, Consent Counsellors reported using a kind of “teach back” (where they ask potential participants to describe concepts in their own words) which has been recommended as a good way to recognise gaps in understanding so they can be addressed (Lindegger et al., 2006; Penn & Evans, 2009; Wade et al., 2009). It also supports the findings by Ndebele et al. (2014) that explaining concepts to others (part of the effective intervention) can facilitate understanding. Researchers should make efforts to assess prior knowledge of potential participants (Dunning, 2014). Efforts to promote discussion resonate with adult learning principles, where it is recognized that adult learners are not blank slates but have a rich bank of experiences to draw from (Nishimura et al, 2013; Sharma , 2006).

Several commentators (Dickert & Sugarman, 2005; Fitzgerald et al., 2002; Rosenthal, 2006, as cited in Marshall, 2007; Preziosi et al., 1997; Wang et al., 2004; Woodsong & Karim, 2005) have also underscored the importance of discussion in enhancing comprehension – arguing that understanding is improved when research staff engage the potential participants/participating communities in “active discussions” of the study and study procedures (Woodsong & Karim, 2005, p. 414). Fitzgerald et al. (2002) reported that participants’ understanding of HIV vaccine concepts increased after discussions with a trained counsellor. Ndebele et al. (2012) found that an enriched consent process was associated with better understanding of HIV prevention trial concepts, and this included “asking participants to repeat in their own words or explain to others and inviting research participants to discuss with other potential or study participants” (p. 3). Promoting discussion of concepts may also help people make sense of ‘facts’ in a particular context – considered important in adult education (Meade, 1999). Promoting discussion might also help ensure that the implications of trial ‘facts’ are explored with potential participants so they are able to appreciate the ‘facts’ in terms of their daily lives (Lindegger & Richter, 2000).

In this study, Educators and Consent Counsellors reported *using 'aids'* to enhance understanding of research, particular studies and study procedures. Different strategies were reported (for example, making drawings on the board, using slides, showing blood tubes). Several of the techniques are in line with findings from other studies recommending aids, such as colourful pictures (Ndebele et al., 2012), and demonstrations of blood containers (Lally et al., 2014) to refute misunderstandings about “selling of the blood” (Stadler, 2010). To impart knowledge about new concepts, certain reported strategies resonated with principles of adult education and health communication (Knowles, 1980; Meade, 1999), for example, CAB members, Educators and Consent Counsellors all reported explaining research concepts by referring to common life experiences. This illustrates efforts to help potential participants and participating communities to understand novel research concepts by using familiar examples that clarify the research. This represented “efforts to help people understand new ideas by relating these to the rich reservoir of information and experience they already possess as adult learners” (Spezzini, 2010, as cited in Slack et al., 2016, p. 6) and helps make concepts meaningful (Ndebele et al., 2014). Educators reportedly used analogies to explain vaccines/ vaccine effects (e.g. the antibodies are like an ‘army’ that ‘fights’ intruders). Other commentators have pointed to the possible success of using of “analogies” in enhancing comprehension, noting that the strategy encourages the application of real life situations, or every-day scenarios to new ideas (Koblin et al., 2010).

### **5.3      THEME 2 - EMOTIONAL ISSUES**

This section discusses the findings describing how site stakeholders (CAB members, Educators, and Consent Counsellors) recognized and attempted to respond to the emotional concerns of participating community members and potential participants, such as anxiety and mistrust.

The findings show that potential participants and participating-community members reportedly experience some anxiety about the consequences of their involvement in HIV prevention research, namely being treated unfairly by the researchers or being harmed by the research. Complex HIV vaccine trial concept also reportedly triggered feelings of uncertainty in potential participants. Such feelings were reportedly recognized by both Educators and Consent Counsellors. Fears or concerns about harm were often aligned to the side effects of the experimental product (HIV vaccine). This suggests that helping people to understand research concepts should recognize fears and fearful beliefs that may have been derived from

lay information sources (Charles et al., 1999; White et al., 2003). Anxiety has been identified as an important emotion in decision-making because it may interfere with the processing of information (Lindegger & Richter, 2000).

The findings also show that participating community members experience considerable mistrust about the site itself, the site-staff, and the research procedures (such as blood draws). This mistrust was reportedly recognized by both Educators and Consent Counsellors. This is in line with previous studies, such as Stadler and Saithre (2010) who described much suspicion in participating communities/ potential participants about HIV prevention trials, including about blood being sold for profit. Andrasik et al. (2014) also found considerable suspicion about researchers, research procedures, and experimental HIV prevention products in participating community members, including that vaccines might cause HIV infection.

Barsdorf and Wassenaar (2005) investigated racial differences in perceived voluntariness of research participants in South Africa following Apartheid, characterised by systematic violation of the human rights of black South Africans. They highlighted how black South Africans may be apprehensive of scientific research in which black South Africans are perceived to be targeted for participation, irrespective of a sound purpose for involving them. They further stipulated that these potential abuses underpin and ground mistrust of medical research.

To respond to *mistrust or suspicion*, Educators and Consent Counsellors reportedly inquired about and collated information about participating communities' suspicions - representing efforts to identify existing knowledge and to uncover suspicions emanating from participating communities about vaccine studies. Kamuya, Theobald, Marsh and Parker (2015) reported exploring myths about involvement in vaccine studies in Kenya and noted this was helpful in provision of reassurance and clarifying misinformation. In this study, this practice of keeping records of rumours emanating from communities allowed educators to explicitly tailor their informational messages (cf. Woodsong & Karim, 2005). This practice resonates well with recommendations from Lally et al. (2014) to explicitly refer to and refute misconceptions in order to improve understanding but may go further insofar as this strategy might also decrease feelings of suspicion.

Also, the approach of utilizing ex-participants to provide educational information about study related activities, concepts and research in general was reportedly used. Furthermore, it was noted that influential figures in the community are commonly engaged by educational efforts. The importance of reaching out to recognized community leaders and representatives is underscored by several commentators (Kamuya, 2015; Ndebele et al., 2012; Rubincam, Lacombe-Duncan & Newman 2016; Woodsong & Karim, 2005) and making use of such 'trustworthy' sources may represent efforts to increase the credibility of information about the site and the research. Ethical guidelines also recommend that trials engage with respected community figures (UNAIDS/AVAC, 2011). The findings underscore the significance of researchers "creating the conditions for trust" in the communities where they are conducting research, making efforts to respect cultural or social needs of participants, building relationships, and "establishing rapport" (Guillemin et al., 2016, p. 5).

To respond to feelings of mistrust and even anxiety about research procedures and about vaccines, it was reported by both Educators and Consent Counsellors that they refer to safe, licenced vaccines. This served to highlight the rigor of the vaccine development process, and to invoke the contribution of vaccines to human health. This resonates with principles of adult learning and health communication which stipulate that prior knowledge is critical when constructing new knowledge (Popkewitz et al., 2001, as cited in Martin, 2006); that individual's previous experience help them establish a basis to advance their knowledge (Meade, 1999) and where comprehension of key concepts will depend on existing frames of reference (Martin, 2006). In addition, Consent Counsellors described several practices to try to set potential participants at ease (described in the results section under theme 3), namely to greet them, to use humour, to offer refreshments and other practices that might have the effect of lessening anxiety. Lindegger and Richter (2000, p. 3) asserted the following:

*... emotional factors are likely to impact substantially on the research participants' ability to evaluate the information given to them. Anxiety arising from an excess of information or apprehension of risk is an example of emotional factors likely to affect understanding.*

Overall, several of the practices described under this theme resonate with an important model recommended for use in consent-related interactions (the 'Meerwein model') – insofar as one aspect of the model is concerned with the capacity and willingness of research staff to perceive and discuss emotional needs, concerns and complaints of potential participants and to address these (Ndebele et al., 2012 ;Tomamichel et al.,1995). Several practices resonate with

recommendations in a key article arguing for sound consent communication, for example, Meade (1999) noted that addressing anxiety may help potential participants to engage in problem-solving and to make decisions in consent-related encounters.

#### **5.4     THEME 3 – RELATIONAL ISSUES**

Strategies to acknowledge the cultural norms of participating-community members and potential participants were reportedly engaged in by all constituencies (CAB Members, Educators and Consent Counsellors), such as *using culturally acceptable terms*. This reflects efforts to be sensitive to the language prevailing in the participating community and to use appropriate linguistic terms and match linguistic preferences (Lindegger & Richter, 2000).

In this study it was reported that CAB members, Educators and Consent Counsellors have many attributes that match those of the participating community (e.g. language, culture, traditions) and are familiar with terms and ideas commonly invoked in the participating community. For research generally, several commentators (Dickert & Sugarman, 2005, as cited in Marshall, 2007; Marshall & Rotimi, 2001; Strauss et al., 2001) reported that comprehension of study terms can be enhanced through making use of (or consulting) with “cultural experts” to ensure effective ways of communicating with potential research participants, and it is likely that the site-stakeholders in this study contribute their cultural expertise to the task of explaining difficult concepts (Sibbald et al., 2015, p. 2). ‘Matching’ cultural, racial and linguistic backgrounds might set the stage for improved understanding of information by using appropriate language and every-day examples, but might also ensure that interactions are sensitive to and respectful of cultural preferences.

It has been noted that being knowledgeable about culture can enhance effective communication (Buchwald et al., 1994; Campinha-Bacote, 1995). Chatalalsingh (2013) stated that “cultural competence” (p. 5) allows research teams to communicate respectfully across cultures and understand local perceptions of health, disease and illness. The stakeholders in this study reportedly recognised that health-seeking behaviours of community members are influenced by traditional practices and drew from that experience to try to raise awareness about the contribution of ‘western medicine’ to their every-day lives. They reportedly drew on community experience of common ailments, and common medicines to clarify how research is conducted to develop medical products that are popular, helpful and ingrained in community life. Lindegger and Richter (2000) also highlighted that research teams members with ‘cultural

competence' should give information to potential participants because they have a deeper understanding on how to frame the material.

Consent Counsellors recognized there may be certain cultural beliefs and practices among potential participants and participating communities that may hinder discussion of critical study information (such as mucosal sampling), and educators reported the same in discussions about safer sex practices and prevention modalities such as male circumcision. These stakeholders found ways to ensure that such information was in fact discussed which suggests they did not uncritically accept cultural norms about not discussing culturally 'taboo' topics (Bayer, 1994, as cited in Slack et al., 2016). For example, Consent counsellors reported that in order to inform potential participants about some of the trial procedures i.e mucosal sampling (which is a difficult topic to be discussed by female counsellors to male participants or vice versa) they reportedly 'prepared the ground' for exposure to sensitive information. This suggests that they did not necessarily view cultural norms as 'trumping' the critical importance of comprehending key study-related information (cf. Lindegger & Richter, 2000; Slack et al., 2016).

In addition to trying to show cultural respect, these constituencies described the importance of demonstrating general respect for persons. That is, Educators and Consent counsellors described the importance of being accommodating and being friendly to persons who visit the site expressing interest in the research (e.g. greeting, offering refreshments). Consent counsellors underscored the importance of showing general respect for each person over and above their value as a trial participant, and creating an environment conducive to building interpersonal rapport and to discussion of study information. Good participatory practice guidelines (UNAIDS/AVAC GPP, 2011) recommend that participating community members be respectfully engaged by site-staff to build the foundation necessary for these complex studies to be implemented. Eraut (2004) has highlighted the need to establish relationships before engagement in discussions of sensitive or personal material, to enable persons to disclose their concerns. Consent Counsellors also reported assuring potential participants about confidentiality which are consistent with ethical guideline recommendations to manage sensitive information appropriately (MRC, 2003; UNAIDS/AVAC 2011; UNAIDS 2012).

In summary, this chapter has examined the study's main findings in relation to the existing literature relevant to informed consent, such as the literature related to community

engagement, adult learning, health communication and empirical explorations of informed consent.



# **CHAPTER SIX**

## **CONCLUSION AND RECOMMENDATIONS**

### **6.1 INTRODUCTION**

This study aimed to explore practices reportedly used to communicate complex concepts in HVTs. The key objectives were firstly, to explore strategies reported by key stakeholders in South African HVTs to communicate trial information; secondly, to explore the correspondence of reported strategies with recommended practices from the conceptual and empirical literature; and thirdly, to explore the implications for strengthening the informed consent process in resource-constrained settings. This chapter sets out some concluding remarks in relation to these three aims. Recommendations are made for various stakeholder groups.

### **6.2 CONCLUSIONS**

#### **6.2.1 STRATEGIES TO COMMUNICATE TRIAL INFORMATION**

In terms of the first aim, this study concludes that site stakeholders (CABs, Educators and Consent Counsellors) reportedly employed various practices to explain complex trial information. These constituents reportedly employed numerous strategies to ensure that information presented to potential participants was clear, and linked to their day-to-day experiences. These included translating terms in the informed consent using local language, using simple (non-technical) language, and using preferred language familiar to participating communities and potential participants, to enable comprehension. Information was presented according to or tailored to literacy levels and other factors of groups. Teaching aids - which comprised presentations, pictorial representations, instruments and demonstrations - were reportedly used to try to address misunderstandings. Study constituents underscored the importance of creating interactive sessions, by encouraging and promoting discussion with different groups of potential participants, and with consideration of group dynamics, and linguistic needs (cf. Meade, 1999). The study further concludes that site-staff were instrumental in trying to provide consistent, relevant and correct information to potential participant's in order to enhance comprehension. Strategies to ensure that staff remain motivated and informed on how best to impart knowledge included 'rehearsals' with, and feed-

back from, site staff to build their skills in presentations, and to build their confidence to share information with a diverse population. However, further investigation is required to learn how practices of site staff actually impact these sessions, which is addressed in the final section of this chapter.

This study also concludes that – in addition to practices employed to improve understanding – these site stakeholders also appear committed to attending to the emotional aspects, and to interacting in a culturally respectful way. Some of the strategies reported here indicate the goals site staff had not only towards enhancing comprehension of complex concepts, but also towards respecting emotions and respecting culture of potential participants. That is, they reported strategies that show they are not just focussed on the information but try to respect feelings and to respond to cultural norms. That is they appear to have more than one goal in mind (cf. Slack et al., 2016).

#### **6.2.2 CORRESPONDENCE OF STRATEGIES WITH RECOMMENDED PRACTICES**

In terms of the second aim, this study concludes that many of the strategies reportedly implemented to enhance understanding expressed by the different constituents are consistent with recommendations from key literature and ethical guidelines. That is, the strategies reportedly employed to communicate complex information correspond with certain key principles of adult education and communication. More specifically, that prior knowledge or experience is critical when constructing new knowledge, which was realised in the study by exploring prior knowledge and experiences of potential participants. Also, that learning encounters for adult learners should employ interactive activities and processes which were reported as being achieved by engaging potential participants/ participating communities in educational encounters, where discussions, questions-and-answers sessions, and presentation of various aids took place. Also, that learning needs of adult learners should be explored which was realised by exploring the needs, and concerns of potential participants/ participating communities through inquiring, and compiling a list of rumours, myths and misconceptions to help site staff develop messages to refute them. Finally, by ensuring that existing frames of reference should be used to enhance understanding of new complex concepts which was realised by use of every-day life examples and familiar experiences in their daily lives (Charles et al., 1999; Flory & Emanuel, 2004; Meade, 1999; White et al., 2003).

The study concludes that site-staff appear committed to building trust and sound relationships between site staff and participating communities or study participants – which corresponds well with recommendations from ethical guidelines (UNAIDS/AVAC GPP, 2011). The strategies implemented to build confidence, and develop trust, included: utilising respected community sources to provide information about trials (engaging community members who hold various power structures within communities), use of community representatives familiar with the cultural, linguistic and social needs of potential participants as reported by the use of ex-trial participants as reported in the study and making reference to existing health programmes and already licensed vaccines widely used within communities locally. Ethical guidelines do not necessarily spell out the precise practices that sites should implement to build trust, but rather underscore the central importance of building trusting relationships with participating-community members.

The study concludes that several strategies are implemented to try respond to emotions of anxiety and to try to address feelings of suspicion, as well as to develop respectful relationships (by creating a friendly environment) that are responsive to cultural norms. The study concludes that efforts by the study constituents to address emotions are consistent with aspects of a useful model of the informing process - the Meerwein model – that is, to perceive and respond to emotions (cf. Ndebele et al., 2014; Tomamichel et al., 1995). The declared practices included exploring their existing knowledge, concerns and fears (with no reports of criticizing them about what they believe about vaccine trials and research in general although social desirability may have prevented such reports). Site stakeholders seemed committed to creating a conducive environment where participating community members and potential participants felt at ease, and were recognised and respected, and to conducting discussion sessions with consideration of cultural norms existing in the communities.

### **6.2.3 IMPLICATIONS FOR CONSENT PROCESSES IN RESOURCE LIMITED SETTINGS**

In terms of the third aim, the study findings have several implications for research conducted in low-resource settings. This site is implementing an approach where dedicated staff convey complicated information at various stages – by Educators out in the community, by Educators at the site, and by Consent Counsellors at the site holding group discussions. This approach is likely to be expensive (in terms of salaries and training for staff). This implies that researchers need to ensure such approaches are funded, and are included in line items of budgets, and it is not clear if such an approach would be feasible for all studies.

This approach also means that CAB members and site staff will be sharing information about the same key aspects of the trial, and that potential participants might hear information from more than one stakeholder. This implies that there could be the chance that the same information is explained differently by different stakeholders (even though this problem was not explicitly reported in this study) – which could lead to misunderstandings or suspicion or rumors where participants/ participating communities try to fill gaps in understanding (Marsh et al., 2010). This implies that all the groups involved in communicating key information may need some training on how to communicate ideas consistently and such training will also require resources. Training on communication aspects may require that researchers conducting research in low-resource settings partner with communication experts at local universities- to equip them with communication skills, which may be fairly inexpensive. This entails that funding for research in LRS take into consideration communication needs of research staff in order to build their communication competencies. .

This site is also implementing an approach where community representatives, ex-trial participants and CAB members are utilised to convey complicated information about study activities - to address misconceptions, fears, concerns and myths. This approach will require careful scrutiny and evaluation to ensure that the content being presented is relevant and consistent. Such evaluations will also take resources, and may have to be designed in a way that minimizes resource-use. To reduce costs of evaluations, site staff could develop standard materials to be used by community representatives when they are providing education to ensure consistency of messages. Site staff could hold educational inspections or observation where they can shadow community representative's education efforts to assess communication skills and information content. To help them to strengthen skills and assess how they present information site staff could conduct rehearsal sessions to help community representatives show- case their skills before they engage with fellow community members.

The study found that rumours, myths, misconceptions, fear and concerns are explored by site stakeholders – these 'myths' could inform how to develop recruitment and education tools (for example brochures), how to frame messages and how to engage communities. This might be an efficient way to design relevant materials and might not be that expensive.

These findings suggest that the individual consent process is best understood as preceded by a larger process of engagement (UNAIDS/AVAC GPP, 2011; Marsh et al., 2010; Strauss et al., 2001). That is, people presenting for consent for trial enrolment might well have been exposed to prior information in the community (Woodsong & Karim, 2005) so it would be best if that prior information in the community was accurate and consistent with information given in the individual informed consent. This implies that development of key messages for the individual consent needs to consider these lay understandings and beliefs. This implies that Educators interacting with participating community members should appraise Consent Counsellors interacting with potential participants – which could be done at little additional cost to the research team.

The approach of employing various stakeholders to help communicate complex concepts remains critical. However issues of power relations between site staff and potential participants, and social desirability concerns reported in guidelines (MRC, 2003) and empirical research (Lindegger et al., 2006) require further investigation in order to evaluate those strategies which actually enhance understanding of complex concepts 'on the ground' in real settings – which would offset a weakness of this study's reliance on reported strategies and their perceived impact on understanding.

This site is implementing an approach where site staff report the importance of 'cultural competence' - by using culturally acceptable terms, by coming from the same cultural, racial and linguistic backgrounds, by using appropriate language and every-day life experiences, by understanding local perspectives of health, disease and illness, and by respecting and recognizing cultural norms which may impact education and consent exchanges. This implies that site staff should have the ability to engage participants/ participating communities with diverse beliefs, norms, behaviours and values; and informing procedures should be tailored to suit cultural, racial, social and linguistic backgrounds. This implies that sensitivity is needed when recruiting and hiring such staff.

This approach means that site staff needs to be culturally competent by having the skills to manage their own preconceptions, to discuss study information respectfully and sensitively and to respect peoples own values and experiences. This means sites are responsible for having adequate understanding of relevant local communities (culturally and socially). However, Marshall et al. (2011) have noted the challenges in understanding cultural context as these are

not socially, geographically or historically static, and have articulated that culture is porous and dynamic and responsive to social and political realities.

Another implication lies in resource mobilization. To mobilise communities to engage in development of consent processes, and to work with communities to develop locally relevant research terms requires time, resources and the need to draw from expertise within communities from different areas. This may not be realised in resource-constrained settings due to lack of resources and capacity and commitment of staff, however, each site could develop good working practices and standard operating procedures, and could collect challenges over time – to inform new studies with best practices.

### **6.3 RECOMMENDATIONS**

In this section, recommendations are made for various groups, including researchers and research staff, ethics committee members, participating community members and finally for developers of ethical guidelines.

#### **6.3.1 FOR RESEARCHERS AND STAFF AT SITES**

There is a need to continue to equip those involved in informed consent and educational sessions with potential participants or participating community members with communication competencies to help them to convey trial information. This could be done by ongoing training for Consent Counsellors, Educators and site staff explicitly on good communication skills (especially those not reported here) such as gauging participants formal and informal verbal communication signs (cf. Meade, 1999).

However, in addition, there should be more explicit acknowledgement of how site constituencies try to handle different emotions expressed by participants or participating community members such as suspicion (this seems a somewhat under-recognized task) (Rautenbach et al., 2015), and they should be asked about the kind of support they need to manage this task. Also, it is essential that sites themselves try to evaluate how well site staff are 'educating' potential participants, including communication competencies and content delivery or development, including message consistency. There is need for ongoing development of consistent and relevant learning materials for potential and participating communities.

Because of the need for site staff to be 'culturally competent', decisions have to be made on a protocol basis about which site staff should engage with communities/ participants taking into consideration their cultural, linguistic and social expertise. Site staff views should be canvassed on how to develop cultural competencies to enable them engage with culturally diverse populations. There is a need for ongoing development of messages which will help refute misunderstandings, myths and misconceptions to ensure effective communication. Site staff need to develop and frame messages to address emotional aspects within their participating communities.

Site staff need to evaluate engagement strategies that are effective in offsetting myths, misconceptions. Site staff need to collect data on where rumours are coming from, why there are rumours, the patterns of rumours and what they signify – to help them plan their educational sessions and to develop message- content.

### **6.3.2 FOR RECS**

The review of informed consent by RECs should not only entail ensuring that researchers have stipulated important information in the consent forms but rather reflect on strategies and processes of how informed consent will be achieved (cf. Slack et al., 2016). This reflexive approach will help researchers reflect on good informed consent practices and remain accountable to achieving them during the conduct of the study. Also, RECs should employ mechanisms to collect feedback from researchers about challenges with informed consent in their studies. Getting feedback from researchers may help assess whether the team is conducting the process as stipulated in the protocol. Feedback may be a great chance for the REC to develop good practices and recommend their adoption in studies with similar context. Furthermore, continued monitoring of approved studies can be implemented by RECs to observe, inspect environments where informed consent procedures are conducted, and assess how site staff implement conduct informed consent procedures. Lastly, RECs should review planned practices for informing and educating the participating community – to assess if they are adequate.

### **6.3.3 FOR CAB MEMBERS**

The findings of the study indicate that CAB members encountered many suspicions from community members and potential participants about key aspects of the study. The findings highlighted by CAB member on the need to address participants' emotions of mistrust suggest CAB members may need ongoing support. The findings indicate some of the challenges experienced by CAB members in conveying complex concepts to participating-community are due to lack of formal education, lack of terms in local language and complex concepts. CAB members need to request materials to ensure consistency of terms. There is also a need to develop a curriculum for those who engage with communities informed by principles of communication and education, and key dimensions of the informing process. Also, there is need to scrutinize the selection process of CAB members, taking into consideration formal education level which may have an impact on understanding of research and complex concepts in general. It may also help to observe CAB members in the field as they educate the community, and evaluate their approach. Additional research is required on how CAB can enhance their relationship with community members and also act as independent entities.

### **6.3.4 FOR ETHICAL-GUIDELINE DEVELOPERS**

Developers of ethical guidelines should ensure that guidelines focus on process aspects of consent. For example, the Malawian national guidelines do not consider explicitly some of the challenges inherent in enrolling participants in complex trials - for example low literacy, complex medical terminologies, low research literacy (Lindegger et al., 2007; Stuurman, 2004; Watermeyer & Penn, 2008). Also, they do not focus much on the need for communication, and "cultural competence" of site staff (Buchwald et al., 1994; Chatalalsingh, 2013; Campinha-Bacote, 1995; Kaufert & Putsch, 1997).

### **6.3.5 FOR DEVELOPERS OF MODELS**

It is important for developers of conceptual models of the 'informing process' (such as the Meerwein model) to consider much more explicitly, and much fully, the role of trust and mistrust in this process. The findings here suggest that perceived credibility of information played a crucial role in how information was received, and also that strategies to ensure credibility were challenging. Mistrust was found to be a challenge between site staff and participating communities or study participants, yet there is not yet detailed consideration



in the Meerwein model about how trust might impacts comprehension of new information. Developers of conceptual models need to consider how issues of trust or mistrust could be more fully addressed.

### **6.3.6 FOR FUTURE RESEARCHERS**

It is crucial for future research to record, observe and analyse actual consent encounters and engagement encounters in HIV vaccine trials (*procedure of observation of sessions*), because this may help open an important “black box” of the actual practices implemented on the ground instead of relying on self-reported strategies for communicating complex information (Wade et al., 1999, as cited in Slack et al., 2016, p. 9). It may help to use the self-reported strategies in this study to develop an observational tool to evaluate how well concepts are communicated, how well negative feelings are addressed, and how well cultural aspects are addressed.

There is still a gap regarding the evaluation of how ethical guidelines for informed consent are actually implemented in resource-constrained settings. There is need for more empirical research to identify strategies that enhance comprehension especially in trials which has complex concepts. This may identify which interpersonal processes are effective in promoting understanding of complex HIV concepts, or even in increasing trust.

Participants enrolled in HIV vaccine trials need to be involved in future research in order to shed light how interactions with site staff are experienced, and what practices they find applicable to enhance their understanding of complex concepts. There is need to allow participants to report their preferred strategies which enhance comprehension, what kind of interpersonal interactions are believed to influence their understanding, to offset power relations between them and study staff, and to build trust.

Site staff and community representatives are engaged in “informing” potential participants however, little is known about how power relations between these entities impact on this process. Trust building has been one issue reported in the study, and there is need to further investigate how building trust might impact power relations, or how participants learn new information or how they make decisions to take part.

It was reported in the study that community representatives encountered many suspicions from their fellow community members. There is need to explore the roles of CAB and how they

can best maintain their trusted role of representing community members. Lastly, this study should be expanded to more than one site, and be implemented beyond the borders of South Africa.

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# APPENDIX



12 October 2015

Mrs Limbazono Matandika 215078232  
School of Applied Human Sciences  
Pietermaritzburg Campus

Dear Mrs Matandika

Protocol reference number: HSS/1236/015M

Project title: Exploring communication strategies that promote sound informed consent for HIV vaccine trials

**Full Approval – Expedited Application**

In response to your application received on 31 August 2015, the Humanities & Social Sciences Research Ethics Committee has considered the abovementioned application and the protocol have been granted **FULL APPROVAL**.

Any alteration/s to the approved research protocol i.e. Questionnaire/Interview Schedule, Informed Consent Form, Title of the Project, Location of the Study, Research Approach and Methods must be reviewed and approved through the amendment/modification prior to its implementation. In case you have further queries, please quote the above reference number.

**PLEASE NOTE:** Research data should be securely stored in the discipline/department for a period of 5 years.

The ethical clearance certificate is only valid for a period of 3 years from the date of issue. Thereafter Recertification must be applied for on an annual basis.

I take this opportunity of wishing you everything of the best with your study.

Yours faithfully

.....  
Dr Shenuka Singh (Chair)  
Humanities & Social Sciences Research Ethics Committee

/pm

cc Supervisor: Dr Catherine Slack  
cc. Academic Leader: Dr Jean Steyn  
cc. School Administrator: Ms Nondumiso Khanyile

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Humanities & Social Sciences Research Ethics Committee

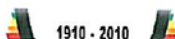
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