Black KwaZulu-Natal Students' Attitudes towards the Use of Medical Records for Research: A Qualitative study.

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ABSTRACT

Medical records are often used in research to provide evidence to help medical researchers improve their understanding of disease, develop potential treatments and improve patient care. However, patient medical information is confidential and sensitive, and this personal data must be safeguarded. There is considerable uncertainty about the process that should be taken when information from patient records may be accessed for research. Researchers and health practitioners are guided by different laws and ethical guidelines when accessing personal health information for research. Understanding the views of the public is essential if generally acceptable policies are to be developed that balance research access to general practice patient records with due protection of patients' privacy.

This study aimed to determine black students' attitudes towards the use of medical records for research purposes. To elicit these attitudes, one on one interviews and focus group discussions were conducted. The discussions were then transcribed, coded and analysed using thematic analysis. Findings from the study showed that people were generally ambivalent about the use of their medical records as there are many factors which contribute to the decision making process such as whether anonymity, confidentiality and privacy would be upheld.

The findings indicate that students had reservations about their records being used for research. However, it would be a mistake to conclude that students do not want their records to be used because they are aware of the benefits of such research.

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CHAPTER 1: INTRODUCTION

Recent years have been marked by a general rise in ethical awareness concerning the use of patients' medical records in research. As a result, emphasis is being placed on ethical regulations and laws on how these records should be used by researchers (Kass et al., 2003). In order for policies to be developed that strike a balance between the facilitation of important research that benefits society and the protection of individuals' rights to privacy and confidentiality, the views of patients are important and have to be understood (Campbell et al., 2007).

Increasingly, empirical efforts have turned towards investigating the attitudes of people towards researchers accessing and using their medical records. Such studies have highlighted that there is insufficient knowledge on what patients' attitudes are and factors that influence their attitudes. This information is considered critical to efforts aimed at assisting researchers when planning to access and research patients' medical records (Baker et al., 2014; Willison, 2003).

Unlike their international colleagues, South African researchers have not done any empirical studies on South Africans' attitudes to the use of their personal private information for research. This study explored attitudes among a sample of black South African students who use the camps clinic at the University of KwaZulu-Natal Pietermaritzburg campus, towards the use of their medical/clinic records for research.

1.2 Outline of the dissertation

This dissertation consists of six chapters, delineated as follows;

Chapter 1: Introduction. This provides a brief background on the use of medical records in research.

Chapter 2: Literature review. This chapter reviews relevant literature pertaining to the study and will start by giving an overview of why patients' attitudes are important by describing the ethical principles

Chapter 3: Rationale. The section outlines the rationale of the research and outlines the research objectives.

Chapter 4: Research methodology. This chapter begins with the aims of the study, followed by research design; sampling technique, instruments used to collect data, procedure taken to collect data, measures taken to ensure trustworthiness and concludes by outlining ethical considerations applicable to the study.

Chapter 5: Research findings and discussion. This presents the research findings after analysis of transcribed individual interviews and focus group discussions. The findings are categorised into themes and subthemes. The themes and subthemes are also discussed relating them to existing literature.

Chapter 6: Conclusion, recommendations and limitations: This part of the study sums up the study, provides key conclusions and recommendations emanating from the study findings.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This section reviews literature relevant to this study. Several electronic databases were searched. The inclusion criterion consisted of only those articles pertaining to the views of patients in different countries on the use of medical records for research purposes. Opinion pieces were also included, as a reflection of how individuals feel about the use of their medical records for research purposes. As an entry point, the researcher discusses what medical records are and how they are used in research, followed by a discussion on the different laws and ethical guidelines that govern the use of medical records in research. Lastly, there will be a review of empirical research which focused on public attitudes towards the use of medical records in research. The review includes articles from as far back as 1997 to show whether patients' attitudes have changed due to the different laws which have been passed and advancement of technology, and also to see how the issue has advanced with the development of knowledge systems and access to information that characterise modern life.

2.2 Medical records

Personal information in medical records has been found to be valuable for research. Medical records contain data spanning lifetimes which relate to morbidity and processes of care. The Data Protection Act 1998 of United the United Kingdom s68 (1) (a) defines a health record as any personal information recorded about a person for the purpose of managing their health care which can be recorded either electronically or on paper. Medical records include a variety of patients' records that are held within a hospital or practice (Tranberg & Rashbass, 2004). These include health visiting records, general practitioner's records, pathology reports, x-rays, pharmacy records, and outpatients' reports. All these form a record of the care and treatment a patient has received.

In primary care, traditionally, medical records were relatively brief documents used mainly to refresh doctors' memory (Tranberg & Rashbass, 2004). However, the nature of medical records has changed substantially. There is now an increase in the type and amount of information included in medical records. Doctors are now able to uncover more information about patients' health status because of advances in medical knowledge and diagnostic techniques. Practitioners now also record non-medical information about individuals such as family history and lifestyle choices, due to the increasing evidence of effects of such factors on health (Tranberg & Rashbass, 2004). Hence, all this information could be accessed when researchers use patients' medical records in research.

2.2.1 Medical records in research

Personal clinical records are a vital tool for much clinical and epidemiological research. Research studies that use medical records are mostly observational – which can be understood as;

> *"non-invasive, involving no risk and no interference with the mental or physical health of the human being, for example the unlinked and anonymous gathering of information about the person by means of a questionnaire or from clinical records" (Medical Research Council South Africa, 2002, p. 3).*

Nonetheless, when conducting these observational studies, great care must be exercised to protect privacy and maintain confidentiality, to avoid causing harm or distress to patients and/or their relatives (Black, 1996).

In the United Kingdom, USA and South Africa, retrospective record analyses may be done without patient consent provided they are done anonymously, but prospective record analyses require patient consent (Black, 1996). However, some argue that that consent should also be obtained, if possible, for retrospective analyses (Black, 1996). Retrospective enquiry into clinical data is often conducted by physician-scientists. In such research, the source of clinical data is the patient's medical record. However, medical records are primarily intended for patient

care and the data is not systematically recorded for research purposes (Black, 1996). Although medical records are mainly for patient care they are also important for research.

2.2.2 Importance of medical record research

Researchers who use medical records have linked certain lifestyle factors and medical conditions, for instance, linking smoking and lung cancer (Tranberg & Rashbass, 2004). Furthermore, by comparing demographic differences in disease incidence they identified sectors of the community that are at risk of contracting certain diseases, enabling preventative treatment programmes to be targeted appropriately. In order to achieve this, researchers need large, unbiased samples of accurate data. It is possible for researchers to obtain such data themselves by administering surveys and questionnaires; the information required often already exists in medical records (Tranberg & Rashbass, 2004). Researchers are, however, guided by laws and ethics when administering patients' records. Legal frames are discussed below as these are vital in understanding how researchers are regulated by law when using people's personal information in research.

2.3 Legislative frameworks

There is an overlap between what is legal and what is ethical. It is important to discuss what different legal systems say about the use of personal health information for research purposes. Since most of the studies reviewed in this literature review were conducted in the United Kingdom and United States of America, it is important to review their laws concerning the use of medical records as these influence how researchers conduct their research and how people want their records to be used. This section focuses on the different legal safeguards that have been put in place by different countries to protect the rights of patients and researchers.

2.3.1 South African legal system

The National Health Act (Act 61 of 2003)

This Act was set to regulate national health related activities by providing uniformity in health services across South Africa. The National Health Act 61 of 2003 makes it a legal requirement for researchers to get ethical approval from the patient, the head of the health establishment and the relevant registered Research Ethics Committee (REC) before they can use a patients' medical record for research. These RECs should also comply with the South African Department of Health Research Ethics guidelines (2015) which are discussed below (refer to section 2.5). However, section 15 of the National Health Act (Act 61 of 2003) allows use of medical records without REC approval on permissible exceptions which are when the court/law orders and requires disclosure, or in cases whereby disclosure would represent a serious threat to public health.

The National Health Act (2003) obliges healthcare personnel to respect patients' confidentiality and specifies the circumstances in which patients records can be accessed. Section 14 of the National Health Act (2003) states that information relating to health services, users' health status, treatment or stay in a health establishment may only be disclosed with users' written consent, or in compliance with a court order or if non-disclosure represents a serious threat to public health. Sections 15 and 16 point out that those health care workers who have access to medical records can disclose information for any legitimate purpose within the ordinary course and scope of their duties where such access is in the interest of the use. Furthermore, the act states that whoever needs to use medical records containing identifiable information for research, teaching and study have to get authorisation from the head of the establishment.

2.3.2 United Kingdom legal system

The Data Protection Act (1998)

This act seeks to establish equilibrium between individuals' rights concerning information held about them and those with legitimate explanations for processing and using their personal information (Data Protection Act, 1998). Those processing personal information must act in accordance with principles of good information handling, such as, data must be adequate, relevant and not excessive, processed for limited purposes, be accurate, up to date and not kept for longer than necessary (Data Protection Act, 1998). The Data Protection Act permits the use of sensitive personal information for medical research purposes without consent, provided the researcher is subject to the same duty of confidentiality as a healthcare professional.

In all its merits the Data Protection Act of 1998 has had negative effects on medical research. This act has made data custodians increasingly cautious for fear of litigation should they allow any access for research, even for audit, without each patient's informed consent (Peto, Olivia & Gilham, 2004).

The U.K Health and Social Act 2008

This act allows for the use of patients' medical information without their consent, to support essential medical purposes that are in the interests of the wider public, and where obtaining consent is impracticable (UK Health and Social Act, 2008). Furthermore, it allows for the use of data without patients' consent in instances where it can be proved that a low response rate would compromise the validity of the research. Disclosures of data to cancer registries and for the purpose of communicable disease surveillance have been approved.

This Act also prescribes for researchers who are not directly involved with the patients' clinical care to apply to the Patient Information Advisory Group after gaining ethics approval, in order

to use identifiable data without NHS patients' explicit consent (U.K Health and Social Act, 2008). Peto et al. (2004) argue against the terms of the Health and Social Care Act because they feel that it has usurped the authority of an effective national network of highly professional committees (which constitutes general practitioners, hospital specialists, ethicists, legal members, lay members and patients' representatives) by creating the Patient Information Advisory Group (PIAG). Junghans and Jones (2007) argue against application of the PIAG; they contend that it is a lengthy process and its conception of what constitutes research and disproportionate effort to obtain consent is open to interpretation.

2.3.3 United States of America legal system

US COMMON RULE 45 CFR46

The Common Rule is a US federal regulation governing human subjects' research. It defines a "human subject" as "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information" (Office for Human Research Protections, 2009, p. 4). The US Common Rule 45 CFR 46 applies to all research that involves human participants, which will be conducted or supported or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the policy applicable to such research. Subsection (b) of Section 46.101 states that research that involves the collection of existing data, records, documents, diagnostic specimens and pathological specimens, if they are publicly available or if the investigator records the information in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects are regarded as exempt and minimal risk.

The Common Rule also states that Institutional Review Boards (IRBs) (referred to as Research Ethics Committees (RECs) in South Africa) have the authority to approve, require modifications or disapprove all research activities that are covered by the policy (OHRP, 2009).

According to the Common Rule, IRBs can waive informed consent in instances whereby the research poses minimum harm or risk to the participants, if the only record linking the participants to the research is the consent document and the risk can lead to breaches of confidentiality. Participants can be asked if they want documentation which will link to the research and what the participants choose should direct the researchers on the course of action they should take(OHRP, 2009). The policy also states that in instances that consent is waived, researchers should provide participants with a written statement regarding the research (OHRP, 2009).

Although the policy has guidelines on what researchers should do when using personal health information, it does not take into consideration other instances that might apply for consent to be waived, such as when it is impractical to get consent. The Common Rule can also be used voluntarily by non-federally funded researchers it is non-obligatory, implying that oversight and regulation and ethics of non-federally funded research is inconsistent in the US (Cleaton-Jones & Wassenaar, 2010). The Common Rule is currently undergoing revision (Emanuel, 2015).

Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy rule
This US Privacy Rule focuses on the use and disclosure of individuals' health information. It directly regulates health care providers; it regulates their disclosure of health information to any researcher regardless of the funding source (HIPAA, 1996). According to the Privacy Rule, for providers to give protected information to any researcher, the researcher should have either written authorization from the patients or documentation that an IRB has granted a waiver, on condition that the research involves minimal risks, it will be impractical to conduct without waiver, and it would be impractical to get written authorisation (HIPAA, 1996). Furthermore,

if written authorization is given, it is only applicable to a specific research study. If health providers violate this rule they may be subjected to a civil or criminal penalty (HIPAA, 1996).

2.4 Guiding ethical principles

Just like any other professional endeavour, in conducting research, researchers have to abide by certain ethical principles and guidelines. These guiding principles apply mainly to primary research with human participants. These principles have been put in place as a safeguard against horrendous historical events that took advantage of people's integrity and lives, at the pretext of advancing knowledge (Amdur & Bankert, 2011). The principles, then, operate on the assumption that there is no justification for abuse of human beings in the name of advancing knowledge.

Prevention of harm and protection of human participants are the main reasons why researchers must adhere to these ethical principles. Therefore, researchers have a dual responsibility of observing the requirements of the ethical code and to keeping patients' best interest and well-being in mind (American Psychological Association, 2012). As an entry point, there is need to establish what is regarded as ethically correct when handling patients' medical records for research purposes, and the subsequent course of action researchers have to take to obtain information from these records. Major developments in research ethics are therefore outlined below.

2.4.1 Principles of the Belmont report
The Belmont report was issued by a National Commission in the United States of America (USA) in 1978, to set out fundamental ethical principles that should guide the conduct of research involving human subjects in any setting. This National Commission for Protection of

Human Subjects of Biomedical and Behavioural Research was established by the National Research Act of 1974. The report sets out the following principles:

Principle 1: Respect for persons

This principle states that individuals have the right to make their own decisions about their health and be free from interference in this regard (Amdur & Bankert, 2011). It also emphasises that individuals have an obligation to not constrain the autonomous actions of others unnecessarily, and to treat persons in such a way as to enable them to act autonomously (Amdur & Bankert, 2011). This principle protects the right to self-determination of persons, especially in the context of research. This principle includes issues related to access to personal information and the usage of such information. The implications of this principle are discussed below.

Informed consent

Informed consent is one of the four conditions that fall directly under the principle of respect for persons. Informed consent refers to participants' understanding of the important implications of their decisions to participate in the study. It is only after gaining such understanding that any participant can make a decision to actively participate in the study (Amdur & Bankert, 2011).

Informed consent is a core ethical dimension in healthcare and is a key concept in an individuals' freedom of choice (Tranberg & Rashbass, 2004). Patients have the right to make their own decisions regarding the treatment they receive, except in extraordinary and emergency situations. It is generally illegal to treat patients without their consent (Tranberg & Rashbass, 2004). As long as they are competent to make decisions, patients have the right to refuse treatment and go against medical advice. Consent is also at the heart of medical

negligence claims. In particular, whether enough information was given to the patient in order for the patient to provide valid consent and whether the procedure went beyond the scope of that consent is important (Tranberg & Rashbass, 2004). Since consent plays an important role in the delivery of healthcare, it is also important to review why it is favoured as a means to regulate the way in which medical records are used by both professional and patient groups.

The use of consent to regulate the use of medical records poses many benefits (Tranberg & Rashbass, 2004). For instance, it overcomes the problem that different people have very different attitudes to the use of their health information and gives credibility to the modern view of healthcare as being driven by patient needs. If the implementation of consent is done properly, consent will not only protect healthcare providers from legal liability but it will also increase patients' trust in health professionals (Tranberg & Rashbass, 2004). This will lead to more information-sharing and better treatment. In essence, consent is used in medical record management as a way to ensure that responsibility for maintaining dignity is placed in patients' hands.

As highlighted above, before giving consent patients have to be given full information on what they are consenting to (Amdur & Bankert, 2011). However, even where healthcare providers have been transparent about how they use medical records and patients have been given the opportunity to ask questions, they will often have little detailed understanding of the nature of these disclosures, the privacy and security policies that will be used to protect their information, or the extent to which these policies will be followed. Tranberg and Rashbass (2004) point out that patients may have difficulty understanding the information which they are given because they would have little or no experience and knowledge of research practices and hospital administration. As a result, some patients will be cautious and can even deny access to their

records. On the other hand, some will agree to disclosures in spite of their reservations and confusion.

Researchers have suggested that the emphasis on giving patients control of who views their medical records through supervising the consent process may be somewhat guarded (Tranberg & Rashbass, 2004). The real issue to be considered is maintaining patients' dignity and this can be achieved by protecting them from embarrassing and offensive disclosures (Kass et al., 2003). The implications of this principle on record review research are discussed below.

There are, however, different opinions about this principle. McSherry (2004) notes that an individual should have autonomy, liberty and free will to choose if he/she wants his/her medical records to be used in research, after obtaining adequate information about the study. In essence, it should be up to the patient to decide who should have access to personal health information (McSherry, 2004). Robling, Houston, Pill and Evans (2004) assert that public acceptability regarding use of medical records cannot simply be assumed and researchers should obtain informed consent from patients to use the information for research.

There are laws that allow for the use of anonymous data. Some USA laws permit identifiable data to be used without consent provided such use is necessary and any infringement of privacy is proportionate to the public interest and benefits of such use. Campbell et al. (2007) observe that tensions arise when there is use of identifiable data especially if the data is used by third parties. Patients accept that their data will be used by clinical teams responsible for patient care but not to be given to a third party for research without patients' consent (Campbell et al., 2007).

Karla, Gertz, Singleton and Inskip (2006) point out that when patients seek healthcare they are assumed to have given implied consent for their service providers to access their health records

for care-related purposes. Researchers often resort to honorary contracts in order to access patient records (Karla et al., 2006). Honorary contracts are described by the National Health Services (2010, p. 2) as "contracts used when individuals carry out duties within an organisation that is not their employing organisation". Thus the act of researchers acting as temporary members of health care teams gives them access to patients' records without patients' consent. Karla et al. (2006) argue that there should be strict legislation which guards against this kind of behaviour, because researchers are gaining confidential information under the pretext of being *de facto* clinical staff members.

According to Whitley (2009), giving consent for the processing of personal data, regardless of how effectively that consent was given, would seem rational if individuals were also able to annul that consent at a later stage to invalidate that any consent previously given. According to Kass et al. (2003) the use of blanket consent is more acceptable than just using people's medical records without asking them. Blanket consent is given in instances where patients come to the health care practitioners for care or when they join a medical aid scheme (Kass et al., 2003). However, Kass et al. (2003) argue that blanket consent should never substitute for individual informed consent and researchers should try by all means to get individuals' consent and should not use patient's records out of convenience.

Janosky, Laird, Robinson and South-Paul (2005) propose a solution on how researchers can obtain consent from patients. They suggest that through a registry - a file of documents containing uniform information about individuals, collected in a systematic and comprehensive way in order to serve a predetermined purpose – researchers can obtain individual consent. A patient will have to fill in a form if he/she wants to be contacted or if they want their medical record to be used in research. Hence, this registry will reflect people's preferences regarding their medical records being used for research.

Waiver

There are cases where consent can be waived. Willison et al. (2005) describe circumstances which might lead to the inability of researchers to get consent from patients. Firstly, if the size of the population is so large such that researchers would not have access to every individual, then the need for obtaining individual consent may be waived. Secondly, researchers might have difficulty contacting participants either directly or indirectly. Thirdly, a waiver avoids risk of breaching privacy, inflicting psychological, social or any other harm which they might cause to the patient if they contact him/her.

Willison et al. (2009) point out that in situations where researchers ask for consent when people come to a health centre, patients will at times be struggling to balance preferences for consent with pressure on time in the consultation. This implies that when people visit health practitioners, they will not have time to fill in the consent forms such that at times most people will end up not signing the consent forms. As a pragmatic necessity, it may, therefore, be warranted to waive this step.

Protection of privacy and confidentiality

The United States Office for Human Research Protections (OHRP, 2009) defines privacy as "having control over the extent, timing, and circumstances of sharing oneself (physically, behaviourally, or intellectually) with others". Confidentiality on the other hand refers to "the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission" (OHRP, 2009). These concepts allow research participants to control who has access to information that may harm them. McSherry (2004) asserts that the invasion of privacy or breach of confidentiality can cause social harm as it compromises an individual's reputation, employability, and insurability, and

might even lead to discrimination or stigmatisation. In instances where researchers have access to medical research (without consent), they usually go through a rigorous procedure to anonymise the data to protect patients' confidentiality. Hence, the intrusion on privacy is likely to be minimal, especially when balanced against the public interest in research the potential to promote public health and improve medical care.

Issues pertaining to control over access to private records are often regarded as a matter of ownership. Since medical records contain personal information which belongs to patients, it can be said that it is up to them to control who gets access to their information. As such, accessing people's medical records without their authorisation can be regarded as trespassing on a person's property. Miller (2008) cautions against such and gives an example of when the government taxes people and takes their money without their authorisation, and the taxed money will be used for the public's benefit. He argues that this is the same with the case of medical records, as such records can be accessed to help in guiding public policy, even without person authorisation of respective patients. Some research drawn from medical records can improve medical care, prevent disease and also prevent harm to patients.

Principle 2: Beneficence
This principle prescribes an obligation to secure the well-being of a research participant (Amdur & Bankert, 2011). Research should minimise potential risks and maximise potential benefits (Amdur & Bankert, 2011). Beneficence also encompasses a moral duty to the wider community.

The counter side of beneficence, non-maleficence prescribes that researchers have a moral duty to do no harm; they should therefore take steps to prevent harm to a participant by preventing breaches of confidentiality (McSherry, 2004). Non-maleficence requires safeguarding personal privacy as such breaches may not only affect an individual's dignity, but can cause harm. When

researchers use people's medical records, especially in observational studies, it is necessary to reduce any potential risks by de-identifying the records (Miller, 2008).

It is also important for researchers to prevent harm. The need to protect individuals from harm is one of the reasons why independent bodies such as Research Ethics Committees are in place. Research Ethics Committees are there to make sure that researchers take steps to minimise harm and increase benefit to the patients (Miller, 2008). RECs are also there to check that the privacy guidelines are adequate and that they are also followed. Patients whose medical records are used for research purposes are not direct beneficiaries of the research findings but other patients and future generations are more likely to benefit from such research. The findings can help change health and public policies, give information on morbidity and mortality, so such research promotes the common good.

Principle 3: Justice

The Belmont Report focuses on this principle as a response to studies that exploited vulnerable populations, such as the Tuskegee syphilis study (Amdur & Bankert, 2011). The principle of justice relates to the distribution of risks and benefits within society. It prescribes that research projects should not systematically target specific classes or individuals who are easily available or who are in a compromised position. They should only be selected for reasons which are directly related to the problem under study (Amdur & Bankert, 2011). The people who are likely to benefit from the study should bear equally the potential risks of the study. Traditionally, this principle focused on inclusion criteria (how people were selected to be part of the study), but now it also refers to exclusion criteria as some classes are being excluded when they are likely to equally benefit from the study. These principles are linked to moral principles which provide guidelines to research. The moral principles will be briefly discussed in the next section.

2.4.2 Moral principles governing research ethics

Ethics is a field of study which examines moral theories that help in the formulation and defence of moral principles and rules aiming at determining which actions are morally acceptable and which are not (McSherry, 2004). This specific field of study is known as normative ethics. This field is concerned with how decisions and judgements are made by individuals, on what they ought to do, and what actions are considered morally bad or good and which are supported by sound moral reasoning (McSherry, 2004). There are two main approaches to normative ethics: deontological and utilitarian. These will be outlined briefly below.

Deontological view

The deontological approach is a moral theory which was first articulated by Kant (McSherry, 2004). Deontological ethics is about moral duty. The assumption is that people act morally correctly if, and only if, their actions are in accordance with their moral duty, codified in objective rules and principles. There are different types of deontological perspectives, but only two are relevant to this study; patient-centred and contractarian deontological theories McSherry, 2004). Patient-centred deontological theories are rights-based and prescribe against an individual being used as a means for the production of good consequences without consent. Furthermore, it is against taking advantage of an individual for others' benefit. Therefore, patient-centred deontology would be against the use of patients' medical records without their consent even if the intention is good. Individuals should be able to make an informed decision on whether they want their records to be used.

Contractarian deontological theory, on the other hand, dictates that acts are morally wrong if they are forbidden by principles that people in a suitably described social contract would accept, or that would be forbidden only by principles that such people should not reasonably

reject. McSherry (2004) explains that the deontological view focuses on the correctness of an action, and this is determined by whether the research adheres to an appropriate moral rule regardless of the consequences. For example, there is a general moral duty to avoid passing on someone's remarks said in confidence, even if the information is going to help society (McSherry, 2004). Therefore, this ethical principle guides health professionals to keep patients' confidence; including their medical records.

Utilitarian perspective

The utilitarian approach is a moral theory which was first articulated by David Hume (1711-1776) and was fully developed later by Jeremy Bentham (1780-1832) and John Stuart Mill (1806-1873) (Beauchamp and Childress, 2008). The principle of utility dictates that what makes an action right are its consequences (Horn & Mwaluka, 2014). McSherry (2004) notes that a utilitarian perspective aims at identifying conduct that will result in the 'greatest good for the greatest number' in society. As such, utility theory is outcome focused. It is mainly used in health research and public health research whereby the aim is to maximise health benefits to as many people as possible. The focus is on improving health outcomes at a community level rather at an individual level. Therefore, everyone's interests are regarded as equal, regardless of where one stands in the social order. This could result from having access to health data, that is, health services planning and clinical research for the benefit of patients as well as access to quality of care audits, which in the end will benefit both patient and society.

Hence, according to this principle medical records can be used in research if they present greater good to a larger number of people, even if it side lines individual concerns. Although these principles are important in understanding the use of medical records for research, different health authorities do not necessarily follow these principle. However, they have their own ethical guidelines which govern researchers in their facilities which stem mainly from the

Belmont Report (Beauchamp & Childress, 2008). Some of these professional ethical guidelines are discussed in the next section.

2.4.3 South Africa Department of Health Research Ethics Guidelines (2015)

All health research in South Africa is subject to the South African Department of Health (SADoH) Research Ethics Guidelines (2015). These guidelines include steps which need to be taken when reviewing patients' medical records. According to the guidelines, researchers are not required to get participants' consent if it is impractical, too expensive, and if the process of getting the consent might cause undue concerns (SADoH, 2015). The guidelines state that in cases where the published work can have potential adverse consequences for participants and particular social groups, researchers should seek consent from the participants.

Registered Research Ethics Committees (RECs) should be consulted to advise whether record review requires individual consent (SADoH, 2015). REC's can approve retrospective and prospective review of clinical records for research. For retrospective studies of medical records, the REC should be satisfied with the scientific validity of the study on whether de-identifying the data would compromise the study; absence of an alternative study design which could use de-identified data, and also that confidentiality would be maintained in the study (SADoH, 2015). Furthermore, RECs can approve record reviews when they are satisfied that obtaining consent can cause unnecessarily anxiety to the patients, prejudice the scientific value of the study participants or their relatives or any collectivity will not have their rights or dignity compromised by the study, and; that it would be impracticably or impossible to obtain consent.

2.4.4 South African Medical Research Council's (SAMRC) ethics policy

The South African Medical Research Council is a statutory council which was established in terms of the South African Medical Research Council Act 19 of 1969. It functions, *inter alia,* 'to promote the improvement of the health and the quality of life of the population of the Republic' (SAMRC, 2002). The MRC has an ethics policy which guides researchers and institutions to practice responsible and ethical research. Furthermore, the MRC has five ethics booklets which are guidelines to   different aspect of research. These guidelines are on ethics for medical research general principles, reproductive biology and genetic research, use of animals in research, use of biohazards and radiation, and HIV preventive vaccine and research (SAMRC, 2002). The South African Department of Health has endorsed book 5 which focuses on ethical issues in HIV preventive vaccine research.

The SAMRC (2002) general guidelines state that research that involves access to personal health records must receive approval from a Research Ethics Committee. In general, the researcher should seek the consent of the clinician currently or most recently responsible for the care of the patient, before using the record for research purposes (SAMRC, 2002). In principle, it is also necessary to obtain the consent of the patient before the clinical record is used as a source of information for research purposes, especially if the patient's right to privacy might be infringed - by linking the research with the patient, for example (SAMRC, 2002). The point at which a record review is decided on has been seen in the past as decisive. Information derived from personal clinical records and stored in computers requires the same safeguards as conventional paper-based records (SAMRC, 2002). Particular care is required where information from clinical records is transferred to computers that can be accessed by many users.

2.4.5 Health Professions Council of South Africa (HPCSA) Guidelines (2004)

The HPCSA is a council which regulates and guides most health professions in South Africa, including professional conduct, ethical behaviour, education and training, registration and fostering compliance with healthcare standards. The Health Professions Act No 56 of 1974 obliges all individuals who practise any of the health care professions to register with the Council.

The HPCSA ethical guidelines were drawn from different sources, inclusive of the *South African Department of Health's Ethics Guidelines in Health Research: Principles, Structure and Processes (2004), South African Constitution, the South African Medical Research Council's Guidelines for Ethics in Medical Research (2002)* and *the Declaration of Helsinki (HPCSA, 2004)*. These guidelines serve as a reference for researchers registered with the HPCSA.

The HPCSA guidelines states that professionals must not pass on any patient's personal and confidential information acquired in the course of their duties, unless patients agree to disclosure, or there is a good and overriding reason whereby consent can be waived (HPCSA*, *2004). The South African regulation stipulates that consent might be waived in cases whereby the justification presented for seeking waiver of consent which should include the extent to which it is impossible to obtain consent. Professionals must not break confidentiality without a sound reason and without patients' knowledge.

2.8 Factors influencing public attitudes towards usage of medical records for research
purposes

People's attitudes are provoked by underlying factors that contribute to them feeling a particular way about their records being used for research purposes. Many studies claim to research public attitudes but focus more on contributing factors to particular attitudes. There is thus a need to address factors that influence their attitudes as there seems to be a blurred line between contributing factors and attitudes. This section will focus on some of the contributing factors that influence attitudes.

2.8.1 Confidentiality

Confidentiality is one of the major reasons why people have reservations about the use of their medical records for research purposes. According to Wylie and Mineau (2003) confidentiality is an obligation of a second party to not reveal private information about a person to a third party without the first party's permission to disclose such information. Wylie and Mineau (2003) further point out that public need for confidence in research activities and policies is essential not only to protect the individual but also to ensure advancement of science and research. McSherry (2004) points out that the well-being of people who are seeing a health professional is enhanced if they know that their confidence will be kept; that is, confidentiality promotes the disclosure only of information that allows the health professional to do good by facilitating treatment.

There are several steps which need to be taken to ensure that confidentiality is upheld when medical records are used for research. Doyal (1997) explains that for researchers to be able to conduct a study, they should inform their participants who will use the data, and why and how confidentiality will be maintained. Secondly, Doyal (1997) notes that for research to be

confidential, the researcher and clinic officials should make sure that they remove identifiers from medical records. Thirdly, researchers should also make sure that there is no link and contact between the researcher and the patient, so as to protect participants' identities. Doyal (1997) also notes that there should be restrictions on access to medical records and researchers should only have access to specific categories of information which have been approved by a REC. The researcher should also have been given permission by the relevant health practitioners or host institution to access confidential personal information.

Patients have varying perceptions on whether confidentiality is vital when accessing medical records for research. A UK MRC (2007) study showed that more women feel that it is important for their medical records to be kept confidential, as 81% of women responded in the affirmative to questions which emphasised the importance of confidentiality compared to 74% of men. The UK MRC study (2007) also showed that adults in the age group of 35-49 were of the view that medical records' confidentiality was the most important factor compared to the 18-34 age group. In the study, 78% of the participants felt that it was important that their medical records be kept confidential.

2.8.2 Anonymity

Anonymity, privacy and consent are vital influencing factors on how people feel about their medical records being used for research purposes. These aspects are important in building public trust.

Sugarman et al. (2003) in their USA study found that participants were only willing to participate on condition that their privacy would be protected. In the study, 28% indicated that they were concerned about privacy, and unlikely to allow personal health information to be used for research. Robling et al. (2004) showed that participants were supportive of research

on condition that the data would be anonymised. Campbell et al. (2007) stated that if medical records are used outside the clinical team, the general principle is 'consent and anonymisation'. They indicated that there is a need for researchers to clearly explain to study participants the difference between consent and anonymisation, as it has been shown that the public has a less nuanced understanding of some of these terms compared to the scientific community. To this end, Campbell et al. (2007) caution against the assumption that the public is well aware of the distinction between confidentiality and anonymity.

The UK Medical Research Council (2007) points out that the key tension within the public mind is between the greater good and the privacy of the individual, which anonymity and the issue of seeking consent are seen to protect. While most see the benefit of personal health information being used for medical research purposes, the very same people can hold reservations over the implications of such research for individual privacy.

The UK Medical Research Council (2007) suggests that there is a need for anonymity and consent to be explained to the public in simple language in order to gain their trust. In some instances the public may not understand the difference between anonymity and confidentiality. For example, data that is anonymised means that personal background details have been taken out and this has more limited value as compared to data that is confidential, which will still have personal information. The UK Medical Research Council (2007) explains that if the public conceives that they are in control of their medical records and its potential uses, they may be more inclined to allow their records to be used for research.

Barret et al. (2007), in their British survey, found that people were very supportive of the use of identifiable information without consent for public health surveillance and research. However, Buckley et al.'s (2011) findings show high level trust by participants for the clinical

teams with whom they share their medical information. The participants also indicated trust towards their general practitioners' ability to keep personal health information secure.

2.8.3 Consent

Patients have different views on whether researchers have to seek their consent before accessing medical records. In the UK MRC (2007) study, 67% of respondents opposed allowing researchers to see their medical records without their prior permission. About 95% of the respondents were also of the view that doctors should obtain consent first before they can release medical records for research, whereas 93% said that researchers should obtain consent before they can access people's medical records and genetic information. Willison et al. (2003) highlighted that people want to be asked for consent as a sign of respect. In Willison et al.'s (2003) study, participants wanted to be asked for consent so as to cause less confusion and uncertainty.

Patients have varying reasons justifying why they need to be asked for consent before their records can be accessed by researchers. Kass et al. (2003) also conducted a study investigating what patients think about the use of their medical records in research. Thirty-one percent (31%) of the participants agreed that researchers should have access to their medical records without the participants consenting to the research. The majority of participants wanted to be asked for permission for use of their records. Even though the participants did not want to know the specific research; they just wanted to be asked for permission. Participants in Robling et al.'s (2004) study indicated that they wanted to be asked for consent for courtesy's sake and to be able to opt out if they felt that they did not want their records to be used any more.

However, some patients are indifferent about whether they are asked for consent or not. A study conducted by Campbell et al. (2007) in the UK, which focused on what participants think about informed consent in research that uses medical records, found that the majority of participants preferred not to be asked for permission. The study showed that only a minority of the participants wanted to be asked before any material from their records could be used. The UK Medical Research Council (2007) states that, since there is more frequent contact between general practitioners and patients in surgeries, this should be used as a location for disseminating information about medical records being used for research.

In such cases, the general practitioner has to act as a buffer between researchers and the public, for the GP has to be independent of the researchers. Brown et al. (2008) point out that there is no single dominant position on the rights or wrongs of researchers gaining access to peoples' medical records. Miller (2008) noted that it is important for patients to be reassured and to discuss the issues around confidentiality and consent with a trusted neutral individual such as a health professional; either a general practitioner or a nurse.

Buckley et al. (2011) conducted a study whereby people were asked about circumstances under which they would prefer their medical records to be used. Buckley et al. (2011) coded the responses in terms of a traffic light system where red meant that patients did not want their medical records to be passed on to a researcher, amber meant that patients only agreed to their medical records which have identifiable data to be used for particular research, and green meant that patients allowed identifiable data to be passed on to a third party by only giving consent once. The findings showed that 67.5% of participants agreed with the amber option, 22.0% agreed with the green option. Hence, 89.5 % of the participants agreed with an ongoing consent arrangement that would allow for the sharing of anonymous data with researchers without the need to be asked for consent on a study to study basis (Buckley et al., 2011). On the other hand,

68.7% of participants felt that they would be happy for clinical teams to supply their names and addresses to researchers so that they could be sent research questionnaires based on the fact that they had a specific condition or for the researcher to use their medical records for the research. Therefore, the study conducted by Buckley et al. (2011) shows that the use of medical records to enable the researcher to identify and contact potential participants was acceptable.

In as much as obtaining consent from patients is important, there are also negative impacts on research when researchers only use those medical records to which the 'owners' have consented for research use. Buckley et al. (2011) note that there is a significant difference in outcomes of research which makes use of medical records between people who consent and those who do not consent. This implies that there is 'consent bias'; that is, if research is entirely reliant on consent, observational, epidemiological and health services research may become so seriously affected by selection bias such that the research will no longer be valid (Buckley et al. 2011). Buckley et al.'s (2011) study supported the use of anonymous data without consent and participants supported opt in on-going consent arrangements that would allow medical practitioners to pass anonymous data without the need to seek consent every time. Broad consent approaches are widely accepted.

However, there are different views about whether participants will be adequately informed for it to be valid and whether indefinite future research is respectful to participants (Bull et al., 2015). Furthermore, there is need for policies to be in place which monitor and determine course of action when there is a request to access data for different purposes. Therefore, broad consent is ethically acceptable on condition that it is accompanied by appropriate information in an accessible form at the time of consent. However, as seen above, with regard to consent, study findings are inconsistent, as some people prefer to be asked before their information is used and some do not mind. Hence, people have different preferences. For researchers just to assume that the patients do not mind their records being used seems unsatisfactory.

2.8.4 Lack of communication and awareness

Communication is also a vital aspect in research that uses such personal information. Sugarman et al. (1998) contend that how a researcher communicates with participants will affect their attitude towards the research. Kass et al. (2003) state that it is vital for researchers to adequately explain to patients why the research is important, why it is relevant to them and also why the researchers are interested in the medical records in question.

There is lack of knowledge and awareness about how medical records are used in research. Robling et al. (2004) illustrate that there is low awareness amongst the general public on the different safeguards for research and data security, such that some of the public's attitudes are prompted by this lack of awareness. There is low awareness amongst the general public on the secondary use of medical records (UK Medical Research Council, 2007). The qualitative phase of the UK Medical Research Council (2007) study showed that people did not really give much thought to the secondary use of their medical records. Many people did not have an understanding of what medical research entails, who conducts the research and why the research is being conducted. This is intriguing in that, as much as people know that they have medical records, they do not really give much thought to how these might be used for purposes other than that which they are prescribed for.

If people are well-informed and educated about medical research that uses medical records, they would have positive attitudes towards the research (UK MRC 2007). It would seem that communication is vital for people to understand what medical research is, such that when communicating about research that uses peoples' medical records, there is need to communicate in uncomplicated simple terms. Medical research is currently perceived by the general public as a 'closed shop'; there is need to change this if it has to reap its intended benefits. According to the UK MRC (2007), this has been caused by lack of public trust on the

conduct of medical research and its implications for public benefits. To change this image, might require effective communication between the research fraternity and the general public.

Buckley et al. (2011) cite previous studies that suggested that patients do not have adequate understanding of what kind of data is contained in medical records and how this information can be used in research. Others have approached the issue from a different angle, arguing against the use of medical records in research due to issues such as lack of communication of the results after the research (Williams et al., 2010). Due to poor communication, the public is not familiar with the terminology surrounding medical research, the secondary use of health information and the ethics governing such use. Hence, there is need to educate the public about the secondary use of their medical records and how this can help the individuals and the public at large.

2.8.5 Nature of information in the medical records

People are protective toward information that is sensitive, mainly relating to topics such as sexual health, abortion, mental health and substance abuse (Buckley et al., 2011). Kass et al. (2003) showed that when research is being done on a specific disease, participants who have the disease are more likely to engage in research because the research might seem to have more direct benefit for them. Robling et al. (2004) explain that sensitive information held in medical records may influence the public's attitudes. They also stress that if people have rare and stigmatizing conditions they are less likely to grant researchers access to their record. Hence, there is a need to collect more data on patients' viewpoints on the use of their medical records in research.

Patients' views are diverse and researchers must remain cautious in developing protocols for accessing patient data (Buckley et al., 2011). Kass et al. (2003) suggest that it is important for participants to be actively involved in research that uses their medical records because this would help all parties involved, by being able to share things like potential benefits and harms, which type of studies to engage in; that is acceptable versus unacceptable studies. Therefore, in the end, the interaction between researcher and participants will help both parties in enlightening each other about the research (Kass et al., 2003). According to Buckley et al. (2011), peoples' attitude to the use of personal information in research is determined by the nature of the information itself, what it will be used for, and who will have access to it.

2.8.6 Background

Since attitudes toward use of medical records for research purposes have been noted to vary between people, some of the differences in research findings could possibly be attributed to people's culture and past experiences. Sugarman et al. (1998) point out that past experiences can affect views of medical research and can determine whether or not a person agrees to participate in the research. Therefore, if a patient has had bad experiences in research that used medical records there will be greater probability of that person viewing research that use medical records in a negative way. Sugarman et al. (1998) found that African-American participants viewed research participation negatively because they associated it with harmful things that had been done to that minority group in the past. Barsdorf and Wassenaar's (2005) study in South Africa showed that there were racial differences in the perceived voluntariness of research participants, with black participants scoring significantly lower than Whites and Indians. Barsdorf and Wassenaar (2005) noted that this might be because of South Africa's history of apartheid, which resulted in pervasive mistrust by black South Africans of formal institutions. Hence, people might view research in a negative light because of past experiences.

2.8.7 Effects of medical research

Research which uses medical records can have both negative and positive consequences for the public, such that when people weigh the consequences they can either have positive or negative attitudes towards the research. Williams et al. (2010) point out that research findings obtained from a small, rural and ethnically identifiable community may cause stigmatisation, labelling and discrimination. For instance, if people know that the research was done in a particular area, that community can face potential adversities such as higher insurance rates, job loss and economic fallout. Some participants may be against the use of medical records in research, because they may feel that the results from the research might cause social and economic problems for local communities identified in studies.

2.8.8 How the study is conducted

Researchers have to be aware of how the conduct their research because this might have different effects on how the public views research that uses medical records. In research conducted by Sugarman et al. (1998), when the researchers used the term 'medical study' participants were willing to participate and did not associate the research with harm, but once the researchers referred to the study as a 'medical experiment' people associated it with harm. To this end, Kass et al. (2003) contend that how a study is conducted may also affect the patients' reaction to the study. For example, they state that who is asking the question in the research may affect the whole study; that is, when patients are asked for permission to use their records by an organisation or a person they receive care from, they are more likely to feel comfortable and confident that their records will be kept confidential.

This section has discussed several factors that determine publics' attitudes towards the use of medical records in research. The attitudes of patients will be discussed in the following section.

2.9 Attitudes towards use of medical records for research purposes

Studies examining public attitudes towards the use of medical records for research purposes have had inconsistent findings, such that there are contradictions amongst different studies from different cultures and time periods. The following section is mainly focused on studies reporting public attitudes towards use of medical records for research purposes.

2.9.1 Supportive

People are generally supportive of research provided that safeguards have been put in place to protect their privacy and security of their medical records (Kass et al., 2003; Medical Research Council, 2007; Robling et al., 2004; Willison et al., 2007). Sugarman et al. (1998) found that people had a favourable attitude to medical records being used for medical research, as indicated by 90% of participants in their study. Willison et al's. (2003) study in Canada reported that people had affirmative attitudes towards use of their medical records on condition that they would be consulted before the medical records can be used. As reported, 78% of the participants wanted to give verbal or written permission beforehand and 26% wanted to be notified passively about the records use in research. Peto et al. (2004) caution against believing widespread perceptions by politicians and civil servants, that the public does not tolerate access to their medical records. This might suggest the sensitive positions held by politicians and civil servants that make them at risk of influencing other people. In Peto et al.'s (2004) study 93% of their participants agreed to the use of their medical records as long as the project had been approved by an accredited research ethics committee.

In a UK Medical Research Council (2007) study, 69% of participants indicated that they were likely to allow personal health information to be used for medical research purposes. In Buckley's (2011) study the public perceived that advantages outweighed disadvantages when

their medical records were used for research, 70% of respondents felt that merits of research outweighed the disadvantages. Buckley et al's. (2012) findings are consistent with prior research, which focused on the use of medical records for research purposes; arguing that the majority of Irish participants wanted to be asked for consent before their identifiable information could be used for research purposes. Chareka's (2012) South African study also indicated that people were willing for their records to be used, on condition that some type of consent is given before researchers' access their records.

2.9.2 Helpful/Altruistic

Patients are generally altruistic in allowing researchers to use their medical records in research. Robling et al.'s (2004) findings showed that most participants would allow researchers to access their medical records for altruistic purposes, such as instances whereby the research could advance treatment to help others with the same disease. Campbell et al.'s (2007) findings were synonymous with Robling et al.'s (2004). They indicated that most participants agreed to their records being used if the study would help future patients with the same disease, would provide better information for the teaching of health professionals, would improve the national figures on the disease mortality rate, and if the information about the disease would be published in medical journals. Participants in Kass et al's (2003) study pointed out that they wanted their records to be used only if the research would help advance medical knowledge.

2.9.3 Cautiousness

Some people are very cautious about how their information will be used and whether the records will be de-identified before they are given to a research team (Buckley et al., 2011; Kass et al., 2003; Robling et al., 2004; Willison et al., 2007). Kass et al's. (2003) findings showed that 56% of their participants needed to know the risks and benefits of the research for

them to more certainly allow their information to be used. Robling et al. (2004) point out that respondents need a 'firewall' between their medical records and researchers. As indicated by 6 out of 10 of respondents; if independent ethics review boards approve the research to be conducted, they would be more predisposed to allowing their personal health information to be used. People felt that giving permission or denying consent could be a precautionary measure, as indicated by the majority of patients who felt that consent should always be sought before their medical records are used for research purposes.

2.10 Summary

Most of the reviewed studies indicate that the public is concerned about the privacy and security of personal health information. As such, legislation in different countries has been put in place to safeguard the use of personal health information in research. Nevertheless patients' attitudes towards the use of medical records for research can best be classified as supportive, altruistic and cautious. However, findings from developed countries cannot be generalised to developing countries. As indicated in *Table 1*, most studies were conducted in developed countries. Westin (2007) points out that opinion varies according to development, health care access, and with privacy trends.

Table 1: Summary

Author	Country	Study design	Sample	No. of participants	Scenarios/Hypothetical Measurements
Buckley et al. (2010)	United Kingdom	Focus groups and literature review	Public	1575	Assessed attitudes to research access to personal health information and factors that influence these.
Campbell et al. (2007)	United Kingdom	Questionnaires	Discharged patients	166	Information the participants would prefer giving permission for. Preferences on possible reasons why doctors might want to take information and what they might use it for. How participants would like to give their permission.
Chareka (2012)	South Africa	Questionnaires	Student patients	100	Students' perceptions on use of medical records
Damschroder (2007)	United States of America	Questionnaires and focus group discussion	Patients from Veteran Affairs facilities	217	Veterans' attitudes to researchers accessing their medical records
Robling et al. (2004)	South Wales UK	Focus groups	Public	49	Single GP reviewing own practice records
			Non-medical members of	4	Transfer of patient names and addresses to external research team

					Transfer of patient data to external disease register
Sugarman et al. (1998)	United States of America	Survey	Patients in hospitals	1882	Whether they had experience as a participant in medical research Reasons for enrollment in research The nature of experiences as a participant in research
Medical Research Council (2007)	London, Cardiff and Edinburgh (UK)	Workshops survey	Public	2106	Perceptions of personal information General attitudes towards personal health information Attitudes towards using health information for medical research; anonymity, consent and trust Risks and benefits of personal health information being used for medical research.

Willison et al., (2003)	Canada	Interviews	Public	17 (7 men, 11 women)	Preferences for being approached, the amount of detail to be provided about the research, the method of consent, conditions around consent for any future uses of the data, and the influence of different sources of funding on willingness to participate.
					Use of anonymised data
					Amount of detail the patients wanted to know about the research
					Preferred method of being informed
		survey		106	The length of time consent to be considered valid
					Impact of sponsorship and personal characteristics.

CHAPTER 3: RATIONALE

History has shown that it is the socially disadvantaged and powerless who have higher chances of being subjected to unethical research (McNeil, 1993). Due to violations of human rights during the apartheid era in South Africa (SA), health practice and research were also negatively impacted. Thus, research on the vulnerable might have created negative attitudes towards health research. Although health research using patients' medical records has become more popular, little is known on how the previously disadvantaged and vulnerable groups in South Africa feel about their records being used in research post-apartheid. African-American studies have demonstrated that there is mistrust among the black community and researchers because of past experiences (Sugarman et al., 1998). South African studies also found racial differences in voluntariness to participate in health research (Barsdorf & Wassenaar, 2005). Given these findings, it seemed worth exploring in some depth the perceptions of a black sample towards the use of medical records for research. Students are also readily available and might be easily influenced and taken advantage of by health researchers, and are frequent participants in research in the US (Wassenaar & Mamotte, 2012). Hence, this study investigated black students' attitudes towards research that uses information from their medical records.

As such, the rationale for conducting this research was to shed light on important ethical issues that researchers should address when using patients' medical records. Another reason for conducting the research was to gain an understanding and explain the dilemmas participants face when medical records are being used in research.

If knowledge can be attained about how people understand and conceptualise their medical information being used in research, this could serve to strengthen research practices and public belief in health research. This knowledge could also provide further informal guidelines for

RECs and researchers as how to better serve and relate to their research participants and find a balance between the rights of the individual and public benefit accruing from research.

The current study was influenced by several factors. Firstly, there is little knowledge on patients' attitude towards use of personal records in research and in S.A. Sankar, Moran, Merz and Jones (2005) point out that patients' perspectives are at the margins of scholarly attention even though they are the core of medical confidentiality policy. Sankar et al. (2005) searched Medline, bioethicsline and selected bibliographies, and found 5746 articles that focused on practitioner perspective on ethical considerations, against only 347 articles that focused on patient perspectives, and 230 opinion pieces. Of these, only 117 were from empirical studies. Hence, there is need for empirical research that focuses on patients' perspectives, since they are the ones who are personally affected by the use of their medical records.

Gaps in the existing literature provided a motivation for the present study which aimed at assessing black students' attitudes and perceptions of medical research that uses their medical records. We cannot assume that Africans have the same attitudes as Western participants, as they have different cultures and are affected by different diseases. Moreover, most of the studies were done with middle aged or elderly people, underrepresenting young adults. Issues of morbidity and process of care are different between developed countries and developing countries. Hence, there is need to conduct studies focusing on Africans' attitudes towards use of medical records for research purposes.

The fact that there is little related literature on patients' attitudes to use of medical records for research in the African context, other than a pilot study by Chareka (2012), gives more rationale for the current study. In a quantitative study on this topic, Chareka (2012) found that participants valued medial record research, and 91% of the participants would allow their

medical records to be used. In her study 89% of the participants agreed that 'Researchers should ask patients for permission every time they want to use their medical records'. However, when asked what was more important between consent and confidentiality 71% valued confidentiality more than consent. The present study anticipated expanding on Chareka's (2012) quantitative data, supplementing the findings with qualitative data.

3.2 Research problems and objectives

The current study addressed the following questions:

1. What do patients think about the use of medical records in research?

2. What, if anything, worries patients when their records are used in research?

3. Who do patients think should have access to medical records? For what purposes?

4. Who should give authority for use of patients' medical records?

5. Is anonymizing the data seen as sufficient protection?

6. Should researchers ask for consent when they want to access patients' medical records?

3.3 Objectives

The objectives of this study were to:

➢ Investigate what black students think about their medical records being used in research.

➢ Explore students' views on the most important ethical issues that researchers should address when using peoples' medical records.

Explore this data and discuss its relevance to current ethics guidance on use of medical records in South Africa.

3.4 Significance of the study

The findings from this research could hopefully be used to add new insights to the existing body of knowledge on patients' attitudes on the use of their personal health information for research. This study will hopefully provide preliminary data/findings that other future research can build on. This study is one of few such studies to be conducted in the African context. Furthermore, the findings could also potentially contribute to the development of new guidelines on the use of medical records in research.

CHAPTER 4: METHODOLOGY

4.1 Introduction

This chapter comprises a description of the aims of this study and the research methodology used in this study. The chapter also includes a rationale for using a qualitative method, followed by an overview of the research design, data collection techniques, method of analysis and ethical considerations for the study.

4.2 Aims and objectives

The objectives of this study were to:

➢ Determine students' attitudes on the use of personal medical records for research purposes, and;

➢ Establish students' views on the most important ethical issues that researchers should address when using peoples' medical records.

4.3 Research design

There are several approaches researchers use to carry out studies of this nature, namely qualitative, quantitative and mixed methods. The quantitative approach uses systematic empirical studies which involve quantifying through the use of mathematics and statistics (Bryman & Bell, 2007). Data is collected and transformed into numbers which are empirically tested to see if a relationship can be found in order to draw conclusions from the results gained. In other words, quantitative methods are associated with numerical interpretations. On the other hand, qualitative research does not rely on statistics or numbers, rather it relies on interpretation, understanding, observations in natural settings and closeness to data, with a sort of insider perspective (Creswell, 1997). Mixed methods, on the other hand, use both qualitative and quantitative approaches (Creswell, 1997).

4.3.1 Qualitative Research

In an attempt to understand and bring to the fore student perceptions on the use of medical records in research, an exploratory study with a qualitative approach was considered to be the most suitable research design. A qualitative approach allows researchers dealing with human participants to explore participant meaning in relation to a phenomenon (Creswell, 2009; Neuman, 1991; Starks & Trinidad, 2007), such as the one pursued in the current study. Creswell (2009) points out that the selection of a research design is mainly based on the research problem or issues being addressed; in this case, the personal experiences of the audience for the study and the researcher. The current study is a qualitative follow-up study on Chareka's (2012) quantitative study of students' attitudes towards the use of medical records for research. Chareka's (2012) study findings were consistent with other studies in developed countries. The researcher was interested in describing and understanding peoples' attitudes and how they are influenced by the students' contexts.

Furthermore, a qualitative research design was used because the study focused on generating a deeper understanding of participants' choices and views based on their history and beliefs. According to Neuman (1991), human behavior and issues are directly or indirectly linked to political, social, historical and, particularly, personal contexts and, therefore, cannot be separated from this broader milieu. Qualitative research demands that the world be approached with the assumption that nothing is trivial, that everything has the potential to be a clue to unlocking a more comprehensive understanding of what is being studied (Creswell, 2009). Neuman (1991) points out that qualitative research is mainly descriptive, such that the data collected will be in the form of words rather than numbers.

Limitations of qualitative research

Yin (2002) states that the limitations of qualitative research design are rooted in its nature. Qualitative research relies on a small sample, thus findings cannot be generalised to a broader population. However, Creswell (2009, p. 193) points out that "the value of qualitative research relies in the particular descriptions and themes developed in the context of the specific site".

South Africa is a hub of various epidemics such as HIV, rape and suicide, researchers have been drawn to undertake research in South Africa. Most of the avenues that researchers use to gain great access and acceptability is to collaborate with training institutions such as universities. Hence, one outlet that can be used is the university clinic and this is the reason why the researcher in this study used students using the University of KwaZulu-Natal (Pietermaritzburg) campus clinic.

4.4 Sampling technique

Purposive sampling was used in the selection of participants on the basis of their relevance to the research question (Silverman & Marvasti, 2008). This sampling method was most appropriate for this study because the aim was to select participants who could provide descriptions of their attitudes to the use of medical records in research, considering that this is an under-researched phenomenon as shown in the review of literature. Moreover, purposive sampling was used because the aim was to determine what students who use the campus clinic think about their medical records being used in research.

4.4.1 Inclusion Criteria

An inclusion criterion was used to determine whether a person could participate in the study, and to identify suitable participants. Eligibility criteria for inclusion were (1) University of KwaZulu-Natal students who had visited the campus clinic at least 3 times. This would be an indication that the students were regular users of the clinic such that they had an idea of what might be held in their medical records; (2) students between the age of 18 and 30; so as to allow the participants to feel free to discuss in the focus group with people of the same age group; (3) black students: since the study was focused on finding out how black students feel about their medical records being used for research purposes (in South Africa, Indians and Coloureds are also considered black, however this study focused on black African South Africans). This is because the study was aimed at finding out if black people in South Africa would differ from the other race groups reported in previous studies from other countries.

4.4.2 Recruitment

The researcher recruited students during their visit to the UKZN PMB campus clinic. The clinic opens daily from 0800-1200hrs and reopens from 1400-1600hrs. The researcher approached students waiting to be consulted by the nurse/doctor; and briefed them about the objectives of the study and asked them if they would be willing to participate in the study. The recruitment process took 3 days. The researcher first went on Monday in the morning session and met six people who were willing to participate. In the morning the campus clinic is usually busy, so the researcher did not have any problems getting people who were willing to participate. The researcher then went for a second recruitment on Tuesday for the afternoon session. The clinic was not as busy as the Monday session. The students on this day came in one by one. The first people who came just after lunch did not meet the inclusion criteria. The researcher only had four people who were willing to participate and who met the criteria. There were two other

students who were also included, but due to their ill-health they did not carry on with the study. The last recruitment took place on Wednesday morning. The researcher invited five people for one-on-one interviews. After interviewing four people, the researcher had reached data saturation – in that the participants were repeating what had been said in the focus groups and there were no new perspectives that were bring brought forward (Silverman & Marvasti, 2008).

4.4.3 Sample

The primary variable under investigation in this study was the attitudes of Black men and women towards use of medical records in health research. Thus the study sample comprised of twelve women and four men, drawn specifically from a student population at a tertiary education institution in KwaZulu-Natal. However, recommendations for further research included refining attempts to identify Black men and women's attitudes only, so as to narrow the focus of this race group to understand if underlying factors such as history, social group, and culture influence their attitudes. Hence, it was decided to include only black students in the current study to further explore their attitudes and what influences these attitudes.

The researcher initially intended to have an even distribution of men and women in the focus group discussions. However, due to the fact that fewer males reportedly visit the campus clinic, the final sample was made up of twelve females and four males, as shown in Table 2 below. Table 3 shows that there were four participants between the ages of 18-21, eight in the age group 22-25 and four in the age group of 26-30. Most of the participants were from the cultural group Zulu as there were eight Zulu participants, five were Xhosa and only three were from other cultural backgrounds as indicated in Table 4.

4.4.4 Demographics

Table 2: Gender

Gender	Males	4
	Females	12

Table 3: Age

Age	18-21	4
	22-25	8
	26-30	4

Table 4: Cultural groups

Cultural Group	Zulu	8
	Xhosa	5
	Other African	3

Table 5: Colleges

College	Humanities	7
	Agriculture, Engineering and Sciences	3
	Law and Management Studies	6

Table 5 indicates that there were seven students from the college of Humanities, three from the college of Agriculture, Engineering and Sciences and six from Law and Management Studies. Of these students two were first year, four were second year, three were third year, four were fourth year and three were postgraduate students, as indicated in table 6.

Table 6: Course levels

Course Level	1st year	2
	2nd year	4
	3rd year	3
	4th year	4
	Post graduates	3

4.5 Data collection techniques or tools.

4.5.1 Focus group

A focus group is a small group of 6 to 10 people led through an open discussion by a skilled moderator (Byers, 1991). Focus group discussions are a good way to gather people from different backgrounds or experiences to discuss a specific topic of interest (Neuman, 1991). Collection of data using focus group discussions is valuable when researchers are exploring aspects where little is known beforehand, or when they want to gain specific insight into existing beliefs, behaviors and attitudes (Byers, 1991; De Vos, Strydom, Fouche & Delport, 2002).

Two focus groups were used to discuss the use of medical records in this research, to explore similarities and differences in participants' opinions and experiences. Moreover, focus groups were used in this study because of their interactive nature and usefulness in exploring the knowledge and experiences of people. Focus groups were also used because, as Neuman (1991) points out, a focus group permits people to discuss and formulate meaning amongst them. Furthermore, they encourage a great variety of communication among group members. The researcher also used different techniques of communication such as jokes and arguments. For example, in one of the group discussions the researcher played 'devil's advocate' and argued that researchers are doing the research for the benefit of people so their research should not be placed under so much scrutiny if it was going to help the public at large. Such arguments prompted much responses from the participants. Much can be learned through this process, since not all knowledge and attitudes are embodied in reasoned responses to direct questions.

During the focus group discussions the researcher recorded the whole discussion session and wrote down what participants or group members said. The researcher also had a research assistant who helped with writing down some emerging topics on the board and also helped in the facilitation of the discussions.

Although focus group discussions yield detailed information on the topic of interest, they also had limitations. The main problem the researcher faced in the focus group discussions was that of people giving socially desirable answers (Neuman, 1991); evidenced by how participants gave answers that were always affirmative to what a previous participant would have said, but when they were probed to explain more they would then say what they thought about the specific issue. One participant even told the researcher after the first group discussion was over that she did not agree with what the other members were saying but she could not voice her opinion because she did not want to be opposed. This information helped the researcher in

conducting her second focus group discussion because she encouraged people to discuss freely their opinions, as there was no right or wrong answer.

4.5.2 Semi-structured interviews

While acknowledging that the interview has been the main data collection procedure in qualitative research, it is important to note that varying types of qualitative interview approaches exist. The four semi-structured interviews used provided basis for a loose structure form of data generation through which the researcher and the participants both pursued the recollection of participants' experiences in more detail. The researcher used clarifying questions such as; 'Can you tell me something more about…?' 'What do you mean when you say…?', 'Can you give me an example?' to probe participants further to obtain a rich description of their experiences. The interviews were conducted in English and tape-recorded with participants' consent and permission. They were conducted in English because it was the common language amongst the participants as participants spoke different languages.

Interviews were used because they allowed the researcher to explore individuals' opinions in-depth so that the researcher obtained rich detailed answers. Moreover, the researcher also gained a descriptive picture of participants' beliefs, views and perceptions on the use of medical records for research. Interviews are flexible, such that they allowed the researcher to ask follow-up questions on points of interest during the interview session. Participants were also able to give fuller descriptions of their expectations and attitudes towards the use of medical records in research.

4.6 Data collection instruments

4.6.1 Interview/ Focus group schedule

For the focus group discussions and one-on-one interviews the researcher was guided by a set of predetermined questions in a semi structured schedule, refer to appendix 2. Bell (1997) recommends the use of interview schedules because as much as participants should be allowed to talk freely about issues, there is need for some structure in the discussions to ensure that all relevant topics are covered. This also reduces problems of bias. The researcher developed the interview schedule after an extensive review of the literature and was also helped by her supervisor.

4.6.2 Open-ended questions

The researcher compiled a list of open-ended questions from different sources (see sections 2.8-2.9) which addressed patients' attitudes towards the use of medical records in research. Neuman (1991) explains that open-ended questions allow respondents to give any answer because they are not restricted to a narrow answer. Kanjee (2006) also notes that open-ended questions permit participants to communicate their opinions about a specific issue in their own words. Open-ended questions were used because they allowed participants to answer questions in detail. In cases where the researcher did not understand she asked for clarification from respondents. Neuman (1991) also points out that open-ended questions permit creativity, thick descriptions, and highlight individual understandings of different phenomena.

4.7 Data collection procedures

4.7.1 Focus Group Discussion Process

A semi-structured interview schedule was used to guide the focus group discussions (refer to appendix 2). The researcher followed De Vos et al's. (2002) suggestion of carefully planning who should participate in the discussions, questions to be asked and the setting in which the discussions would take place. The discussion took place at the campus clinic waiting area. Initially the researcher had planned to conduct the focus groups in the Honours room in the Psychology building. However, when she went for recruitment the first week to invite people for the focus group discussions, none of the 16 people who had signed up to come at the discussed time came. The researcher then decided to conduct the discussions in the clinic waiting room, because it was more convenient for the participants. They had no reservations about discussing it in such a relatively open place even after the researcher had explained there was no privacy. This setting was comfortable, however, it did not ensure privacy as people occasionally would walk in and out during the session and this distracted and disturbed the discussions, and some people who were not part of the focus group would pitch in and answer questions they found interesting. The topics did not cover any personally sensitive information and were thus of minimal risk.

The seating arrangements allowed the researcher to have eye contact with all the participants. The first 10 minutes constituted of introductions, brief background to the study, and formulation of ground rules of the focus group, how the discussion was going to unfold. The researcher then explained that the discussions would be recorded if they agreed. The participants were also told that participation in the study was voluntary and that they were free to withdraw their consent and participation at any time without them suffering any form of disadvantage. Before the discussion commenced, the participants were asked to sign consent

forms and confidentiality agreements (refer to Appendix 1). The focus group discussions took approximately 40-60 minutes. With the consent of the participants, the discussions were recorded. The researcher briefed the participants on what medical records are and how they are used in the research as a background on what the research was covering (refer to Appendix 1).

4.7.2 Semi-structured one-on-one interview process

The researcher conducted the one-on-one interviews with four (4) people. The interviews took place on an isolated bench outside the campus clinic. The bench is far from the clinic, such that people passing by could not hear the conversations. Hence, there was no threat to privacy and confidentiality. The interviews took approximately 10-15 minutes. The interviews were conducted in English, in instances where participants used their native language, a research assistant who was fluent in *isiZulu* translated.

4.8 Ethical considerations

Willing (2008) notes that in qualitative research ethical issues come into play from the beginning of the research, throughout interaction with the participants and continue until the dissemination of the findings. There are many ethical issues in qualitative research because "the human interaction in qualitative inquiries affects researcher and participants, and the knowledge produced through qualitative research affects our understanding of human condition" (Brinkmann & Kvale, 2005, p. 263). Permission to conduct the study was gained from the University of KwaZulu-Natal Registrar and the Humanities and Social Sciences Research Ethics Committee (approval number HSS/0730/013M) before data collection commenced (refer to Appendix 2 and 3).

4.8.1 Autonomy and Informed Consent

The principle of autonomy requires participants to have autonomy of thought, intention and action when making decisions regarding research. In the study the decision-making process was free from coercion. To ensure this, the researcher did not force or coerce anyone to be part of the study. As further protection, participants were asked to provide only minimal personal demographic information such as age, gender and year of study. All information collected will remain confidential and identification protected during and after the study.

Due to the fact that "researchers must provide potential participants with clear, detailed, and factual information about the study, its methods, its risks and benefits, along with assurance of the voluntary nature of participation, and the freedom to refuse or withdraw without penalties" (Wassenaar, 2006, p. 72), the participants were provided with an information sheet (refer to Appendix 1) explaining in detail the aims of the study. Furthermore, the researcher explained who she was, what the study focused on and what was expected of the participants. Participants were also informed that their participation was voluntary. They were thus free to leave if and when they felt uncomfortable. The participants were all young adults above the age of 18 and were not incapacitated so they could sign their consent forms without the assistance of a guardian. The participants signed a consent form before they could participate in the focus group discussions.

4.8.2. Justice

The principle of justice requires participants to be treated fairly and equally in all stages of the research. Fair selection was acquired through the use of asking people who met the inclusion criteria of the study. Since the study is mainly focused on the previously disadvantaged group,

that is black people. Black African students were selected to participate. During the course of the study participants were treated equally by getting equal chances of speaking and their views included in the analysis. The researcher did not use any deception in recruiting or during the course of the study.

4.8.3. Beneficence

While the participants in the study might have been unwell as they were visiting the clinic for consultation and to get treatment, every stage of the study aimed at minimising distress and risk. The researcher explained to the participants that the study would not have any direct benefit to them but the knowledge gained from the study might benefit society in the long run. To avoid breach of confidentiality which would have adverse effects on the participants, they were encouraged to sign confidentiality forms stating that they would not disclose the names of other participants in the study. In the semi-structured interviews the researcher assured the participants that no personal details would be collected ensuring anonymity.

4. 8. 4. Non-maleficence

The principle of non-maleficence ensures that no harm befalls participants as a result or consequence of the research. All stages of this study aimed to avoid and minimise harm and treat participants with respect at all times. Participants were also continuously informed that all data and personal information will be kept confidential.

4.9 Data Analysis

After the two focus group discussions and four interviews were conducted and recorded, the researcher transcribed the data. The data was coded to highlight the major themes. This approach to data analysis used in the study is termed thematic analysis, whereby patterns in data are noted, coded and sorted into themes which can be used to answer the research question (Braun & Clarke, 2006).

4.9.1 Thematic Analysis

Thematic analysis aims to "produce a detailed and systematic recording of themes and issues addressed in interviews in order to link the themes and interviews together under a reasonably exhaustive category system" (Burnard, 1991, p. 461). There are six steps to thematic analysis (Braun & Clarke, 2006). These are explained briefly below.

Step 1: Familiarizing the researcher with the data

The first step was to transcribe the data. At this first stage the researcher read and re-read the data and re-listened to the recordings so as to note down the important and prominent ideas which came up during the two focus group discussions. To achieve this, the researcher tried to immerse herself in the data and this helped in the identification of codes.

Step 2: Generating the initial codes

The second stage was to generate initial codes (Braun & Clarke, 2006). At this stage, the researcher organized the data into categories in a methodical way (Braun & Clarke, 2006). This was done by highlighting parts (colour-coding) of the transcripts that seemed important and labeled them with numbers grouping codes and assigning numbers to different codes. For example:

"If you just ask me and I say yes verbally its ok really, I don't really care to sign somewhere, because I will be aware, and trust me, I will be aware that I have consented for the records to be used."

Coded for: verbal consent -1

Step 3: Searching for themes

The third stage was to search for themes. After the data was coded and a list of different codes was identified, the researcher then sorted the different codes into themes (Braun & Clarke, 2006). Similar codes were grouped together to make up themes. For example

- Verbal consent
- Written consent

→ Consent preferences
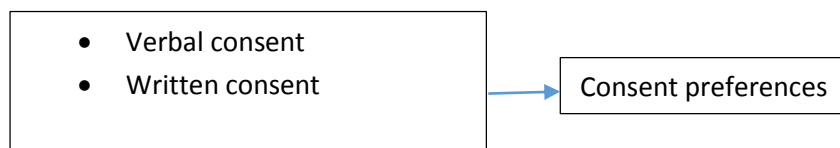
Step 4: Reviewing of themes

The next step was to review the themes. At this stage, the researcher looked at how themes matched the codes and if they answered and matched the research question (Braun & Clarke, 2006).

Step 5: Defining and naming themes

According to Braun and Clarke (2006) the fifth stage was to define and name the themes. The researched checked the consistency between the themes and the research questions. At this stage the researcher then defined and named the main themes and sub-themes (Braun & Clarke, 2006). The major themes were labelled with upper case letter, for example 'A', and subthemes were labelled in lower case 'a'. As illustrated below:

Consent preferences-*e* ← Informed Consent-B → Frequency of getting permission-*f*
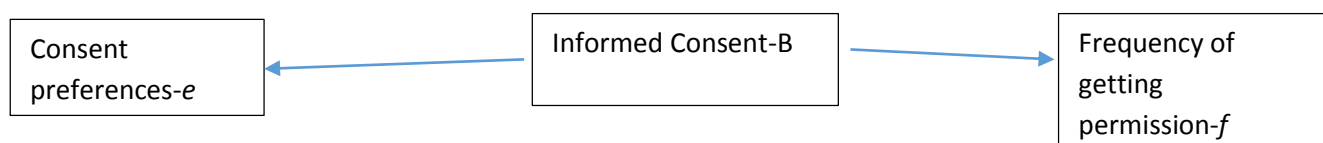
• Verbal Consent-*1* • Written consent-*2*	• Need to be asked every time *-1* • Once-*2* • No need to ask everytime-*3*

See Appendix 5 for the full thematic map

Step 6: Producing the report

The researcher used thematic analysis because it is flexible and also because she wanted to describe the issues that students regarded as important regarding the study questions. The researcher aimed for a detailed and systematic way of interpreting data. Qualitative analysis is cyclic in nature there was continuous review of themes and renaming of the themes where appropriate. Some themes were dropped because they were not consistent with the research questions.

4.9.2 Limitations of thematic analysis

The flexibility of thematic analysis allows a wide range of analytic options, thus a variety of things can be said about the data. This presented a challenge to the researcher in developing specific guidelines for analysis and for the researcher to decide what aspects of the data to focus on (Braun & Clarke, 2006).

4.10 Trustworthiness

The key value of qualitative research rests in the authenticity and trustworthiness of its findings (Babbie & Mouton, 2010). Trustworthiness depends on how a researcher is able to persuade him/herself and the readers the worthiness of his/her study findings. Several steps were taken

to ensure credibility, dependability, transferability and confirmability of the findings, to ensure neutrality of the study findings.

4.10.1 Credibility and Dependability

Credibility and dependability were sought by remaining in the field until data saturation was achieved (Babbie & Mouton, 2005). The researcher reached data saturation after conducting 2 focus groups which had 6 people in each group, and 4 individual interviews. Credibility questions if there is a link between constructed realities of the participants and those that are attributed to them (Creswell, 1997). Different techniques were used to be able to elaborate, justify and account for the conclusions in the study. Firstly, there was persistent observation, whereby the researcher constantly pursued interpretations in different ways such as "What do you mean when you say that?" "So are you in support or against…?". Credibility and dependability were also achieved by persistent observation of the data – that is, interpretation of the transcripts in different ways – and by confirming interpretation of responses given during the interviews (Babbie & Mouton, 2010). Secondly, by triangulation - this is when the researcher used different techniques to collect material from diverse sources, in the particular study the researcher used focus group discussions and one-on-one interviews. Data saturation was achieved when no new information on the students' attitudes were obtained. Lastly, by peer debriefing - whereby the researcher reviewed the data with a colleague - who was not involved in the study - perceptions, insights and analyses (Creswell, 1997).

4.10.2 Transferability

Transferability refers to the extent to which the study findings can be applicable to other contexts (Babbie & Mouton, 2010). Transferability was achieved by collection of detailed descriptions of perspectives by different participants. Transferability can be achieved through

thick descriptions whereby the researcher collects comprehensive descriptions of data in context and reports them with adequate detail and accuracy to permit judgments about transferability to be made by the reader (Babbie and Mouton, 2010; Silverman & Marvasti, 2008). Furthermore, transferability was achieved through purposive sampling (Babbie & Mouton, 2010), whereby data was collected from participants specifically relevant to the study, therefore enabling the collection of a maximum range of specific information.

4.10.3 Confirmability

Confirmability is the extent to which study findings are not a result of the researcher's biases (Babbie & Mouton, 2010). This was achieved by reviewing the recorded focus groups and interviews and the transcripts from the interviews and focus groups simultaneously. Furthermore, field notes and personal expectations were compared to the final themes and findings. Credibility was also achieved as a colleague reviewed the raw data in comparison to the final findings.

CHAPTER 5: FINDINGS AND DISCUSSION

5.1 Introduction

This chapter presents the research findings based on the central themes and sub-themes extracted from the focus group discussions and interview data after a thematic analysis was done. Extracts from these data sets will be used to support the themes. The identified themes will be compared and integrated with the relevant literature. In this section, all respondents will be referred to by pseudonyms. Table 7 illustrates the themes and subthemes which emerged in the study. These will be discussed in detail below.

Table 7: Themes and Subthemes

Themes	Subthemes
Anonymity	
Consent	The right to control
	Respect
	Lack of trust
	Communal and family privacy
Usefulness of research	Benefits of research
	Altruism
Reservations	Contents of the medical records
	Access of medical records by third parties
	Misinterpretations and misrepresentation of findings
	Social harms
	Coercion

5.2 Anonymity

Anonymity was one of the major themes which emerged in the study. Participants insisted that if their records are to be used, the most vital aspect which medical practitioners should ensure is that their personal identifiers are removed before a third-party could have access to their records. However, participants appeared to conflate anonymisation with protection. Protection entails either anonymization or de-identification. Moses* explicitly stated:

"Accessing my medical records as long as it doesn't identify me as the person, I really wouldn't have problems with it. As long as they don't know whose medical record it is, then there is really nothing that scares me."

These findings are consistent with other studies which found that participants were willing for their records to be used for research on condition that they are anonymized (Buckley et al., 2011; Campbell et al., 2007; Robling et al., 2004; Sugarman et al., 2003; UK Medical Research Council, 2011; Whiddet et al., 2006).

Participants also expressed concern about the potential of their anonymised records to be re-identified. Some participants wanted some sort of assurance that their personal information will not be included. Nox* explained:

"But it boils down to… there is no guarantee that they will remove personal information and that they will not be able to link it back to me. What guarantee do I have that my records will be anonymised when researchers access them? Unless I have proof that they are guaranteeing that the information is anonymised; at least someone has to be liable if this turns out nasty. So then how can I sue if there is no proof that they had promised me anonymity?"

This shows that there is a nuanced understanding by the participants of the complexities inherent in full anonymisation. It is also indicative of participants' concerns about trust in assurances of anonymity during research. As such, patients have to be informed about the different safeguards that have been put in place, so as to assure them that researchers abide by certain moral and ethical codes when they conduct such research with sensitive information. For instance, RECs have been established to review the scientific and ethical elements of studies (Kithinji & Ikingura, 2013). RECs exist to protect the rights and well-being of research participants and also assess the risk-benefit ratio of studies (Kithinji & Ikingura, 2013). However, some African REC's are challenged by a lack of resources and institutional capacity, so that even if they review a protocol thoroughly, sometimes they cannot do follow ups to investigate whether researchers are doing what they ought to be doing (Boateng, Ndebele & Mwesinga-Kayoyo, 2013).

Importance was placed on whether people would be able to identify individuals. If researchers could guarantee that no personal identifiers would be used, patients were very supportive of retrospective medical record studies. Participants argued that importance should be placed on anonymity rather than on whether medical records should be used because they are mainly worried about the public being able to identify them. Bukhosi* explained:

> *"Maybe the question should be after anonymity is guaranteed why should anyone care? What people fear is not that people out there will know that there is HIV. What people fear is that people out there will know that they in particular have it"*

This shows that people want their records to be used to further knowledge but do not want the world to know that they in particular suffer from a particular disease. In similar studies, the biggest predictor of peoples' willingness to allow researchers to access their medical records

was their trust that the information will be kept confidential and private (Damschroder et al., 2007).

On the other hand, some highlighted the importance of using identifiable records as they can be valuable for research. For instance, Sandra* illustrated this when she said:

"But sometimes names are necessary because they might need to do follow-ups. How are they going to do it if they do not know your name and where you stay? For me, if I'm eligible to be part of your study you can use my records but you need to ask me".

This is in contrast with Coleman et al.'s (2003) study, which had a high level of acceptance among UK participants in support of the use of personal identifying information without consent. However, this interpretation may be due to the questioning structure which was used by Coleman et al (2003). For this particular question, participants were asked if it was a breach of confidentiality if their information was used without consent. Furthermore, their study focused on a cancer registry, so participants may have seen it as a public health activity and not as some sort of research. Also, the disease which was being studied (cancer) might hold a special status in the publics' mind which is different from other health research. Cancer, while an infectious disease, is generally not stigmatizing.

It is a challenge for both researchers and participants because anonymity equates peoples' concerns over privacy. Anonymity is a safeguard to privacy, yet this also stands in the path of effective research. Anonymising the data can also hinder researchers from being able to directly help participating individuals, for example, if they find out that the individual has an increased predisposition to a particular disease (Willison et al., 2005). In this regard, some people may find it unethical because researchers also have an obligation to let people know if

there are at risk of getting a disease. Anonymising medical records is not easy if the records are paper based and not electronic. Although anonymising medical records has disadvantages, researchers have to abide by the principle of anonymising the data for people to be comfortable with their records to be used for research. As such, a balance has to be struck between credible data and protection of participants.

Willison et al. (2005) found that most patients were willing to allow anonymised material from records from primary care to be used for research purposes but most participants wanted to be asked for permission. In a study by Campbell et al. (2007) the majority of patients regarded the use of personal identifiable information by organizations such as the UK National Cancer Registry, for purposes of public health research and surveillance, not to be an invasion of privacy. Confidentiality involves the use of anonymous data and also permits identifiable data to be used without consent provided that such use is necessary (Coleman et al., 2003). Anonymisation of data strictly needs to be effected before researchers have access to the records but this can reduce the value of research if important data items be removed (Willison, 2005).

Rajeev, Kellner and Stahlberg (2007) suggest methods to secure data confidentiality. These include data exclusion, whereby certain information is not included in the records, data transformation, whereby some alterations are made to the data or some items might be removed, and data encryption, whereby data in the records is encrypted so that it cannot be recovered without specialized information external to encrypted data.

5.3 Informed Consent

The theme of informed consent also emerged. However, there were divergent opinions on whether researchers should have access to medical records with or without patients' informed

consent for retrospective medical chart reviews. Participants who wanted to be asked for consent explained that researchers should ask for consent so that they know that their records are being used for something else rather than the intended purpose. Participants who wanted to be asked for permission just wanted to be made aware of the kind of research that their records would be used for. Clara* illustrated this point:

"I think it's very important if they tell me first that they are going to be using my records for other purposes…And I should be able to give consent because I might have a disease that I don't want people to know about it. It would become a problem because they might be violating my rights."

Zodwa* added:

"Yeah some things are really traumatizing, because there might be studies out there, which have results on something you are going through….at a later stage you should have an option of pulling out but how can you pull out of something you did not know that you were involved in in the first place".

This is congruent with Willison et al.'s (2007) findings which indicated that most participants wanted to be asked before their anonymized data can be used for research. According to the UK MRC (2007), for people to accept the principle of their personal health information being used for medical research purposes, the public has to be fully informed about the research, that is, its objectives, risks and possible benefits. Westin (2010) explains that his study participants were not persuaded to let researchers access their records without giving consent, even after they were told that researchers had concerns about the heavy cost of getting advance notice and consent. The public can be enlightened about the research through various media, but then this

can also compromise anonymity because if researchers have to call or send messages to the participants it means that they would have access to personal information. The only alternate way is if the patients are made aware of the research when they initially visit their medical care center. At this point they can then be asked for permission to use their records for such research. This then leads to the risk of the research being based on a biased sample.

RECs also have an obligation to protect individuals, so how they look at the importance of consent in research that uses medical records is also important. Willison et al. (2007) showed that 47% of RECs required consent for a study to proceed, 10% highlighted that their response was dependent on whether potentially identifying variables would be managed, 38% did not require consent at all and only 7% suggested an opt-out and notification process. Tsoka-Gwegweni and Wassenaar (2014) point out that informed consent was the number one issue considered by an African REC. Their areas of concern with consent included patient protection, inconveniences, risks, discomforts and inadequate details to given to participants and risk minimization (Tsok-Gwegweni & Wassenaar, 2014). Therefore, there are procedural safeguards which ensure that researchers obtain consent before they can access private information.

However, some participants did not see the relevance of asking for consent for anonymised data. Bukhosi* illustrated this when he said:

> *"As far as I am concerned once my personal information has been removed the record is not mine…it is just a record of a patient who was once treated"*.

Thembani* also mentioned that:

"If the system guarantees anonymity, it is all fine by me. I don't have a problem with it. You don't even have to bother asking for my consent".

Bonginkosi* also elaborated that:

"I would go as far as saying that as long as the records are de-personalised as defined above, the institution should be given all the permission necessary to use the information."

Participants had different views on whether they should be asked for consent. There was no consensus on whether they wanted to be asked for consent or not. The different perspectives found in this African study are congruent with other studies, such as Buckley et al. (2011), Campbell (2007), Chareka (2012), Robling et al., (2004) and Willison et al. (2003). Campbell et al.'s (2007) study findings showed that the majority of participants had either no preference about having their permission sought, or preferred not to be asked. Westin's (2010) findings indicated that a small percentage of the participants showed that there was no need for researchers to ask for their consent, as long as the study concealed their personal identity and was supervised by an REC or IRB.

The need to be asked for consent can be attributed to participants' trust levels, the right to control how medical records are shared and as an indication that researchers respect them. These aspects will be discussed further below.

5.3.1 Trust

Trust was not mentioned explicitly and implicitly during the study. Trust can be cited as the major determinant in peoples' willingness to let researchers access their medical records. Gilson (2003) points out that trust strengthens the co-operation within health systems that is imperative to health production and it makes an essential contribution to building value in society. Participants who indicated that they did not mind their records being used without their consent, stressed that as long as their medical records were anonymised they had no problem. On the other hand, most of the participants who were not convinced that researchers would adequately anonymise the data, requested that they should be asked for consent. This echoes Damschroder et al.'s (2007) findings which highlighted that participants trusted the Veteran Affairs system so this determined the level of control participants wanted to have over how their medical records are used.

Willison et al. (2003) point out that a patient's trust in his/her doctor can confer benefits of trust to researchers in the process. In their study Willison et al. (2003) found that people showed high levels of trust in medical research. However, it was qualified trust, indicating that trust can erode in the event that there is a breach of confidentiality. When an individual trusts another person or organization it places him or her in a situation of risk by leaving them exposed to the actions of the other. Trust requires the participant to calculate and believe that the other will behave in ways that will not cause harm (Gilson, Palmer & Schneider, 2004). Westin (2010) emphasised the importance of trust, as anything that severely threatens the trust that patients' have in the healthcare system and health researchers can have a negative impact on health research. The UK MRC (2010) explains that in order to build trust the public has to feel informed. In this case, if patients are given more information on medical records research, they are more likely to trust researchers. Hence, it is important that patients are made more aware

of the greater good health research has for the society and that confidentiality will be honored. This seems equally relevant in SA where trust may be low because of past abuses (Barsdorf & Wassenaar, 2005).

Nass, Levit and Gostin (2009) suggest that effective communication has the potential to build public trust in the research community. Therefore, there is a need for greater community involvement. Researchers should also communicate research results to the communities they would have conducted their study in. According to Nass et al. (2009) researchers need to inform study participants about the results and the relevance and importance of the research findings. Williams et al. (2010) note that researchers need to communicate about the information being passed on, where it goes and how it is disseminated. According to Willison et al. (2003), 57% of their participants specified that they wanted specific information about any study such as the name of the study, the benefits of the study and funding source.

A study conducted in the UK (2006) reported the use of personal data in health research and concluded that public involvement in research is important for the success of information-based research. This is because a public which is well-informed about the value of research has greater enthusiasm and confidence in research and the research community at large. This can be regarded as a step in the right direction as researchers will be showing that they have the participants and their communities at heart. Hence, giving patients direct feedback could lead to improved health care for the individuals, if the results indicate that the study can alter course of care, is justified.

5.3.2 The right to control how medical records are shared and accessed

Participants explained that they should have some control to exercise their power over researchers having access to their records. Giving consent was cited as a display of power over third parties using their medical records for other purposes. Nox* explained that:

"In this way I feel like I have a bit of power to what happens with my records. Just like the HIV test, so if one doesn't want their records to be used that's the only time they can have to say no."

Furthermore, participants wanted control over their medical records because they wanted to be able to change their preferences. These findings extend to other studies which examined peoples' attitudes to the use of medical records, where it was noticed that patients needed control over access to their personal health information (Willison et al., 2009). In this instance, control can be viewed from two different perspectives. Firstly, control can occur at the start of a disclosure process. Secondly, it can be privacy control, which focuses on limiting what personal information is made available to other parties.

Different researchers have highlighted that patients can have varying levels of control and this can be influenced by different health conditions. However, this was not confirmed in Willison et al.'s (2009) study, which showed that there were no differences in the level of control between patients with different health conditions. Willison et al.'s (2009) study results have to be interpreted with caution, because they indicated that the results might have been affected by sampling bias.

Willison et al. (2009) point out that people were generally supportive of research but they do not want to completely relinquish control. Their study findings indicated that people wished

to have more control if there was a commercial element in the research. Willison et al. (2009) stress that people differ substantially in the amount of control they would like to exercise over research which uses their medical records. Whitley (2009) explains that the mishandling of personal information by government, companies and institutes, has resulted in a growing unease about modern society and the need for people to want more control over who accesses their records, such that individuals are looking for better ways to control the way in which their personal information is used by others. The Havasupai case is a good example of how people feel about misuse of their biological specimens and medical records, and how people prefer to have control of how their materials are used in research (Drabiek-Syed, 2010). The Havasupai case demonstrated the occurrence of dignitary harm when researchers insult domain of control by undermining the individual's right of control (Drabiek-Syed, 2010). Hence, the general public wants to retain to the power they have regarding who gets to see confidential information which is given to a medical professional with the intent of clinical diagnosis and treatment. Westin (2010) points out that there are models of voluntary patient control privacy policies, which are being offered by some new repositories of personal health record, for example, Microsoft's Health Vault.

5.3.3 Respect

Several participants indicated that when researchers ask for consent it is a form of courtesy which shows that the researchers respect the patients and their medical records. Tafadzwa* indicated this when he said:

> *"This thing of them just coming to get information is disrespectful…"*

Nkosi* also emphasised this point:

"Yes, I think we should be asked because sometimes we might have these genetic diseases that are supposed to be our own, so it should be kept within the family/ clan and we can be the only ones who have to know about it. So if they just take the records without our approval it means that they are exposing our secrets without us knowing about it."

Researchers have to respect participants during and after a study (Mamotte & Wassenaar, 2012). This echoes the findings of Willison et al. (2003) which showed that most participants wanted to be asked for permission every time researchers wanted to use their records, as this showed respect for participants. The Havasupai case also reinforces the importance of respect as the use of an individuals' biological specs outside the scope of consent is disrespectful (Drabiek-Syed, 2010). In African communities, the concept of ethics goes beyond confidentiality and consent. Hence, the aspect of respect is a very important issue in South African cultures, such that researchers should make sure that their actions show that they respect the community by enquiring about their cultures and values before they begin their studies.

5.3.4 Cultural Sensitivity

Participants also highlighted that they feared that medical records research could expose family diseases, such that it is important for researchers to consider how they conduct their studies in small communities, which are communally-oriented. Thembani* explained that*:*

"In my family when we have an illness, it must be kept amongst us until we are ready to talk about it. Such that when we go to the doctor, we want him to help us before our issues become public knowledge. That's why we need to be asked first, because that

disease might be peculiar to us only and people in the community might even know that they are talking about us in that research, because the whole family might have symptoms of the disease. That's why there is a need for them to get our consent first, because by that time we will be at peace knowing that people might even know that our clan was included in the research."

In contrast to other studies which showed that participants were more concerned with individual privacy, participants in this study were not only concerned about personal privacy but they were also concerned about family privacy. Ndebele, Mfutso-Bengo and Masiye (2008) argue that in African cultures individuals' interest are balanced with and at times they are even subordinated to those of the community. A person is guided and regulated by rules of interdependence which govern participation and identity. This could be because of the African cultural importance of *ubuntu* but this is not only peculiar to African cultures. The Havasupai case also demonstrates the importance of cultural sensitivity as researchers were unaware of how the tribe felt about them going through their medical records and biological samples in search of evidence of schizophrenia (Drabiek-Syed, 2010). Cultural sensitivity is also evident in the Havasupai case because research on individuals within Native American tribes impacts on all members because they form an identifiable group (Drabiek-Syed, 2010).

Emanuel, Wendler, Killen and Grady (2004) suggest that there is need for collaborative partnership in research, for it demonstrates awareness of and respect for cultural differences. If researchers and the community collaborate, researchers are more likely to be made aware of communal customs, needs and expectations. From this point, they can then best decide how to continue the study without the community feeling that there is a breach of communal and family privacy. This stage of collaborative partnership is vital because it helps researchers recognise and respect the host community's distinctive values, culture and social practices, which should be incorporated into the design and implementation of the study.

Emanuel et al. (2004) argue that there are different spheres of consent in developing countries. Depending on the community and type of research, access may require permission from village elders to leaders of the extended family or heads of household. In diverse cultural contexts people are defined in terms of membership of communities such that it might be viewed as inappropriate to see the individual as the locus of responsibility and decision making (Lindegger & Richter, 2000). It is important, therefore, for researchers to use access and consent procedures that are acceptable within the community they intend to research. Therefore, even though research that uses medical records has minimal risks, it is advisable that researchers go the extra mile to make people comfortable with their records being used. Researchers can do this by giving people information on the use of medical records in research and also cite the different steps taken when the records are used.

However, Horn and Mwaluka (2014) caution against the concept of community consent, and they argue that it is misleading and must be avoided. This is because community consent can only be obtained in communities that have recognisable political or tribal leadership. Horn and Mwaluka (2014) note that if community consent is used inappropriately, it can result in a false sense of security. Therefore, researchers should explicitly explain in their protocols, which they send to RECs, how they intend to engage with the community before, during and after the proposed study. Furthermore, household permission is also not very clear-cut, because it is hard to define a household and determine who is entitled to consent for the household (Horn & Mwaluka, 2014). Researchers should be cautious about community permission because it cannot replace individual informed consent (IJsselmuiden & Faden, 1992). Therefore, although getting permission from the community is important, researchers also have to get informed consent from participants.

5.3.5 Age

Most participants in this study were between the ages of 18-25. Participants in this age group indicated that they were inclined to allow their medical records to be used. This contrasts with the UK MRC (2010) study, which showed that young people between the ages of 16-24 were least likely to allow their medical to be used compared to older age groups. Buckley et al. (2011) highlighted that there were different perceptions between different age groups. However, in their study most respondents were between the ages of 66-85 years. Interpretation of these results in comparison to the current study should be managed cautiously since different age groups were assessed. Young adults are more skeptical about the use of medical records, probably because they are less informed than their older counterparts (UK MRC, 2010). The findings from this study are different from that of other studies, because the sample consisted of university students, who presumably have some education about research and what is important in conducting research. Education was listed as an influencing factor people's attitudes towards use of medical records (UK MRC, 2010). However, it is worth noting that other factors such as exposure to technology, insight into the information age, exposure to medical research and level of education may be confounding age as a variable.

5.3.5 Consent preferences

Participants in the study had varying positions on the type of consent they would like to give; varying between verbal or written consent. Nox* pointed out that:

"I will need to sign somewhere because when something goes wrong the researchers can also have proof that I agreed for my records to be used"

On the other hand Tafadzwa* stated that:

"If you just ask me and I say yes verbally its ok really, I don't really care to sign somewhere, because I will be aware, and trust me, I will be aware that I have consented for the records to be used."

In Willison et al.'s (2003) study, 78% of their participants indicated that they wanted to give either written or verbal consent, and the minority was satisfied with being notified passively about the use of their medical records for research. However, this patient-centred approach would inevitably introduce bias into the data used, because researchers would be only using medical records which the patients would have consented to for such use.

5.3.6 How frequently researchers need to obtain permission

 Since most participants indicated that they want to be asked for permission when their medical records are used for research, the issue of frequency was also discussed.

Nox* pointed out that:

"At least they should have some form of consent procedure like the moment you go to your doctor or hospital, they should have a section where they will be asking for your consent for the records to be used."

Sandra* also pointed out that:

"They should at least ask for consent once in a while…I don't want to be asked every time really, but at least I should consent to it. It would be unfair for them to use my records continuously for different studies. It should be periodic."

Clara* explained that:

"Every time a new research that wants to use my medical records, I should be asked for consent."

Participants had different perspectives on the frequency of giving consent. This is in line with Damaschroder et al.'s (2007) study, where 39% of participants felt that researchers should ask each time they want to use patients medical records for a study, 35% wanted blanket consent - whereby researchers ask once up-front for all future research studies, 26% rather wanted to opt-out of the studies - whereby they request their records to be excluded from a study. Willison et al.'s (2003) study indicated that 49% wanted consent to be valid only for the duration of the study, 31% required no time limit, 20% preferred an annual review. The majority of Willison et al.'s (2007) study participants highlighted that they wanted to be asked periodically for their consent choices, or consent to be sought each time. These findings indicate that there is no consensus on when, how and number of times participants want to be asked for consent, but what should be grasped from this is that most people want to be asked for consent. Researchers should be aware of this public perception and work towards meeting patients' needs when it comes to using their personal information.

Westin (2010) suggests that there should be introduction of user-friendly technologies for implementing notice and choice for patients. These technologies will register patients and collect their preferences, such that they will connect data seekers (health researchers) with data holders (service providers) and facilitate the exchange of that information without the data content ever being accessible to people who are not involved in the process (Westin, 2010). This approach can revolutionalise the ability of patients to make informed decisions about who uses their health information. Willison et al. (2003) also suggest that there is a need to develop information directives, whereby patients can identify in advance the purpose for which medical

records can be used, and have the opportunity to consent to use of data at different levels of detail depending on application.

5.4 Positive aspects of disseminating medical records for research

Participants had positive attitudes to the use of their medical records, as they understood the importance of such research and how it can better the health system of the country. These positive attitudes were attributed to how research can help individuals and the community at large. These attitudes will be discussed in detail in the following sections.

5.4.1 Research purposes

Participants had varying opinions on the type of research that the medical records would be used for. However, most participants were of the view that research which uses their medical records should be able to directly improve quality of health care in their communities and also to track different communicable diseases, such that data could be used to guide the Department of Health on what diseases it has to focus on and formulate campaigns to educate the public. Sandra* illustrated this when she explained:

> *"If we are to look at the current situation in South Africa, most research centres are focusing on issues surrounding HIV/AIDS, this can be attributed to studies like this which use people's medical records to see what is really going on in KZN. Such that when the research is out, the Department of Health has an obligation to devise a plan to counter attack this. We also have funders who are supporting this fight against AIDS because it has been made public that we are struggling with this disease."*

5.4.2 Importance of research

The pool of participants included students at different levels of study at a tertiary institution. As students, they had been taught about the importance of research and most of them had taken part in some sort of research. Bonginkosi* illustrated this when he said:

> *"It would not make sense for one to demand a public health care system that is functional and yet not allow researchers to use the stats (statistics) and records to better that system. Why can't the information actually be made public?"*

Nox* also indicated the importance of medical research:

> *"That would be very helpful because people will then know their chances of suffering from the disease, know the causes and prevention as well."*

Bonginkosi* also explained:

> *"Because, like I was saying that, this research will only find more relevance the more we computerise this part of the world and I want to get to why it would matter what the information would be used for. Why can't the information actually be made public information? If you think about it… health is a public good and knowing the stats about different places helps."*

Barret et al. (2006) argued that epidemiological studies of the changing incidence, prevalence, and outcome of disease is crucial for the delivery of effective health services and public health interventions. Health research is also important because it provides vital information about disease trends, outcomes of treatment, and public health interventions among many other reasons. Woolley and Propst (2005) found that the general public was very supportive of health research, because they were aware of the benefits. The participants indicated that heath research

is important for the economy, and some participants were even willing to fund health research. Furthermore, Woolley and Propst (2005) found that the majority of the general public in America believed that health research would maintain their lead in the world as the leaders of health research. The participants in Woolley and Propst's (2005) study pointed out that there is a need for more people to be educated and trained about conducting health research.

5.4.2.1 Need to educate the public about the importance of health research

Although participants indicated that they knew the importance of research, there is still a need to educate the public what medical research entails. Nass et al. (2009) point out that it is important to convey the importance of medical records research to patients. Patients also have to be educated about the negative impacts of incomplete datasets to research findings. Nass et al. (2009) note that an educated public reduces the potential for biased research findings. The public has to be made aware of the importance of health care improvements that have been brought about by medical records research, so that patients will become more willing to support information-based research that is conducted with REC oversight under a waiver of patient consent or authorization.

5.4.3 Altruism

The Oxford dictionary (2010, p. 19) defines altruism as "the principle or practice of unselfish concern or devotion to the welfare of others." Participants in the current study said that they would want their medical records used for research for altruistic reasons.
Sandra* pointed out that:

> *"I think if the research is going to help more people, greater good issue. We can even limit privacy if it's going to be helpful".*

Bonginkosi* also illustrated this when he said;

> *"It would not make sense for one to demand a public health care system that is functional and yet not allow researchers to use the stats and records to better that system.*

> ...

> *The clinic in question, pharmaceutical firms, anything from drug distribution planning to use on what awareness schemes are needed where really the debate of what the information is used for is obiter, if not useless, if we are to assume that it is just records that have been de-personalised."*

This corresponds with Sugarman et al. (1998) who indicated that 76% of participants enrolled in research because research was a way to help others, 69% showed that it was because research advances medical science, 69% enrolled because research gave them hope and 67% enrolled so as to get better treatment. Moreover, 68% of participants indicated that they were motivated by a combination of altruistic reasons such as to help others, advance science and self-interest, i.e for better treatment (Sugarman et al., 1998). Robling et al. (2004) showed that most participants would allow researchers to access their medical records if it was a form of goodwill; in instances whereby the records can be used to advance treatment to help others who are in the same medical situations as the patients. Damaschroder et al.'s (2007) findings also showed that veterans were supportive of research that would help them and the public at large. In Willison et al.'s (2007, p. 710) study 68% of participants were in strong agreement with the statement that "research that could be beneficial to people's health is more important than protecting people's privacy." Therefore, most people were of the view that medical research using people's medical records is important because it can help society at large. That is why they would agree to participate in the studies.

In the current study, 10 of 16 participants indicated that they would allow their medical records to be used for altruistic motives, regardless of gender. Buckley et al.'s (2011) study showed that most females chose to share their records for altruistic purposes. The sample size of the current study had more females than males. The researcher cannot conclude that the results would be the same if the same number of males were also enrolled in the study.

UK MRC (2007) participants were of the view that individual consent was more important than the greater good, irrespective of the research being important. According to the UK MRC (2007), there are debates over whether drug companies should be provided with personal health information, as they stand to gain financially from using and accessing such information. These concerns are balanced with the good that the drug companies serve as they develop new medicines. Respondents believed that there was a balance favoring health benefits.

UK MRC (2007) notes that the key tensions within patients' minds is finding a balance between the importance of confidentiality and being altruistic. The public is aware of the benefit of personal health information being used for medical purposes, but the very same public might have reservations over the implications for privacy on their personal records.

5.5 Reservations

Although participants had positive attitudes towards their records being used for research purposes, they also had reservations about how they are to be used because of what is contained in the medical records which could lead to stigma and stigmatization of the participants.

5.5.1 Contents of the medical record

According to Willison et al. (2007), people are generally protective of sensitive information. In this regard, participants' views from this study were no different from participants in previous studies. Several participants illustrated that they were very cautious of how the information is used because of the level of sensitivity.

> **Tafadzwa***: *"again it goes to the severity of the cases being studied, there are some diseases which are of sensitive nature like HIV and some epidemics. When you hear that 15 are quarantined, none would give the details because there are socio-economic factors that are at play in the identification of the groups."*

> **Clara****: "It depends hey… for me personally let's say I have HIV/AIDS, I don't want them to access my records without my knowledge. I don't even care if they put my name or not but the mere fact that they have maturity to ask me for my consent shows that they respect my information. I'm particular about HIV because I haven't come to peace with the virus. I still have issues with it, but any other disease which might be in my record I do not really care. Because I'm still freaked out by it.*

> **Nox*:** *"stigma of course, and there is also sensitive information in the records and probably when they know such about my community how are we going to be treated as a community, they should also look into that because it is not just about me that is being exposed, but that of UKZN students who use the clinic and even deter other people from coming here because they do not want to be a part of these studies."*

UK MRC (2007) notes that medical records are highly private and sensitive as they contain a person's personal medical information. UK MRC (2007) also points out that patients are

concerned about the misuse of sensitive information, especially if there is a central database which holds all health information about a person. Westin (2010) also found that people with stigmatizing health conditions such as HIV, sexually-transmitted infections and mental health conditions, were worried about health researchers accessing their medical records as this might expose them.

Findings from Westin (2010) indicated that the public did not believe that there was adequate protection of their health information by laws and organizational practice. Since this was an American study, it suggests that the HIPAA[1] has not created a sense of confidence and security in the public. This can be because of the high incidence of data breaches which are reported (Westin, 2010).

5.5.2 Access to medical records by third parties

Participants in this study indicated that they had reservations about some local researchers and medical aid companies having access to their medical records.

Nox* explained that*:*

> *"I think the people who do such research should be independent researchers from the society you are from, because people from your society can add 2 and 2 and find out that probably it is you who is suffering from such; which would be really bad. I think researchers from other communities should come and access them because then they won't add up any information and come up with accurate conclusion about the identity of the person.*

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[1] Health Insurance Portability and Accountability Act

Unlike other studies, participants in this study indicated that they had reservations about local researchers accessing their records because they were concerned that local researchers would be able to identify them and this could lead to risks to the participants. Even after being assured that the records will be anonymised before researchers can have access, participants were adamant that local researchers should not have access as they could link the information with a patient's medical history. **Sandra*** added:

> *"mmmm my medical aid should not have access to research because they can just add it up in their system that… oh probably it's this person, because she visited the clinic this many times… and they have information on their database on the time I visited the doctor and whether it is for consultation or treatment and they can then link it back and say so person A is (***name mentioned***).*

Participants in this study were more concerned with medical health insurers and researchers from their local communities accessing their medical records. This may be because the university setting is small, such that if people who know a particular individual accessed their information it can be easy to trace it back and even make it public knowledge that a particular individual suffers from a certain sexually-related disease or virus. Moore et al. (2013) pointed out that younger patients were very concerned with issues around sensitive information, especially if related to sexual behaviour. Moreover, when relating to their backgrounds and settings at home, it can also be a reason that they do not want the whole community to know that they might be linked to the disease under study by a local researcher. However, it has been suggested, and is even being implemented in Africa, that most studies should include local researchers as they are aware of the communities' language, culture and norms (Kithinji & Ikingura, 2013). This then begs the question of whether it is acceptable to use local researchers.

Previous studies indicated that participants had varying attitudes on who accesses their medical records as they are more comfortable with certain people accessing the records and reserved when others want to access them. Stone et al.'s (2005) study highlighted that participants were more concerned about employers and insurance companies accessing their records and viewed university researchers as the better option, but participants from the current study were not comfortable with fellow university researchers accessing their medical records. Participants in the UK MRC (2007) study indicated that there were not comfortable with commercial organisations accessing their medical records because they were of the viewpoint that the information will benefit the organisations rather the individual. Willison et al.'s (2007) participants indicated that they distrusted insurance companies, drug companies and the government. Other studies, on the other hand, indicated that participants were cautious about pharmaceutical companies using their medical records in research.

5.5.3 Social Harms

Participants indicated that they were afraid of social harms that could come about from research that uses their medical records. The harms identified were negative labelling, stigmatization and stereotyping of the community;

> **Bukhosi***: *As much as the research might have benefits, you should also consider the stereotypes around such studies when we then go out there people will mock us because we studied at UKZN where there is a high rate of HIV infection. At least they should ask me for permission first before I read about it in the newspaper or in a published article.*

Tafadzwa**: So with that kind of sensitivity, even anonymity is not enough such that in such studies there should be some level of consent because the immediate community might be able to identify who from the community participated such that consent guarantees that the participants are willing to risk being stereotyped and stigmatized by their own community. It will show maturity on the side of the researcher as well because this is a very sensitive issue and it shows how far they are willing to go.*

These harms are not unique to only black participants involved in this study; perhaps they were amplified by the ethnic backgrounds of the majority of the participants. There is a relative lack of published documentation of community harms resulting from research that uses patients' medical records, but this does not mean that these harms do not occur. Even if they have not occurred yet there is a need to protect individuals and communities before harms occur, rather than trying to find solutions after occurrence. HIV prevalence is very high in South Africa with 37.4% of the adult population in KwaZulu-Natal living with HIV compared with 0.8% worldwide (Eeanshaw et al., 2014). The stigma and discrimination associated with HIV can also be a major reason why communities perceive that medical record research can lead to social harm.

Sugarman et al. (1998) showed that 9% of their participants thought that research usually or always involves unreasonable risks to people. The predictors of these perceptions were being African-American, having fair or poor health, having no college degree, being under the age of 60 (Sugarman et al., 2003). Willison et al. (2007) suggest that people with stigmatizing conditions are more likely to have concerns over disclosure of their personal health information out of concern that it could lead to discrimination against them.

5.5.4 Misuse of personal health information

Participants also indicated that they had reservations about the use of their medical records because of fear that their records might be misused.

> **Mandy***: At the end of the day researchers are also humans, they are bound to have errors.

> **Zodwa***: With these social networks, your personal health information can be a topic of discussion on these social networks.

> **Zodwa*:** but you will find that even after the research is done then when the information is out there, the media can get hold of such information and write it in a negative light and your society can then be stigmatized against.

Some participants pointed out that they would participate only because of the assumed good that would come from the studies trumping the risks of taking part in the studies.

In Sugarman et al.'s (1998) study, 39% of participants indicated that they had little choice in deciding to participate in the studies they were enrolled in and 11% reported that they chose to participate in the studies because they were influenced by the view that research was the best way to pay their medical bills. Furthermore, 6% of participants in Sugarman et al.'s (1998) study thought that participants in research were usually or always pressured into participation.

5.5.5 Undue inducement
Participants also indicated that they are situations whereby they would agree for their medical records to be used for the perceived benefits of such use.

> **Nox***: But also guys there are situations like you are in a hospital and researchers come to ask for your permission to use your records. Just because you are sick and you need help you might be forced to say yes because you will be thinking that their research would help you as an individual. And some people might not even be comfortable with going to the hospital if they later find out that their information might be used for research without their knowledge.*

If participants agree for use only because of the perceived benefits and they would not do it under normal situations, would this potentially be a form of undue inducement? Undue inducements are defined by Dickert (2006, p. 47) as 'excessively attractive offers that lead people to do something to which they would normally have real objections based on risk or other fundamental values'. Emanuel (2006) points out that there are four aspects which should be encompassed for inducement to be labeled undue. The first aspect is when people are offered a good that is valuable or desirable in order for them to do something, the good can be in the form of financial payments, medical services etc. Secondly, the offer will be excessive such that it will be appealing and difficult to refuse for the individuals in that context. The offer will be unwarranted, improper or inappropriate. Thirdly, the good that is being offered elicits poor judgment on the individual's part, usually so that the individual takes a risk that they would otherwise not take. According to Emanuel, Currie and Herman (2005) when individuals make poor judgments they either overemphasize short-term benefits or underrate long-term costs. Lastly, due to the individual's poor judgment, there is a high risk of harm. Emanuel (2006) notes that when individuals are unduly induced they will be acting involuntarily. In this context, it is clear that the offered benefits and potential risks associated with research on medical records are not of such a magnitude that undue inducement is likely to apply, provided that anonymization and confidentiality are carefully attended to at all stages of the research.

5.6 Summary

The shared stories of participants produced an increased awareness of how black south Africans view the conduct of research and what matters most to them if their information would be included in any research endeavour. Participants seemed to be more concerned about anonymity, consent, and uses of research.

CHAPTER 6: CONCLUSION, LIMITATIONS AND RECOMMENDATIONS

6.1 Key Conclusions

The study was set out to explore students' attitudes towards the use of their personal medical records in research. It also sought to know whether an African sample has different attitudes compared to data reported on other nationalities. Despite having a relatively small sample, the researcher observed substantial individual variation in opinion. The general theoretical literature on this subject, specifically in the context of Africa, is inconclusive as there have been no available empirical studies that have been done in the context to assess public opinion in this regard except for Chareka's (2012) study. This section synthesises the empirical findings from the study.

The main conclusion that can be drawn from this study is that students support the use of medical records in research. However, they argued that researchers must be cautious when they use medical records by making sure that anonymity and privacy is guaranteed. Furthermore, the study also showed that participants were aware of the benefits of medical research and were willing to altruistically help advance medical knowledge through medical research. There are, however, a number of issues that need to be taken into consideration.

Consequently, the other key finding of this study was that consent is perceived to be a vital aspect in such studies because it gives the participants control over who accesses the records. Gaining informed consent from the participants was viewed as an indication that researchers respect the participants and willing to protect their personal, family and communal privacy.

Moreover, participants in the study indicated that they had some concerns about their records being used for research purposes. They were worried about how the records would be used, whether anonymity would be guaranteed, who would have access to their medical records, and the social harms that could result from the use of their records.

6.2 Proposed Implications

The results suggest that it would be a mistake to conclude that research that uses medical records is best avoided. The fact that most participants had reservations about such research can be seen as a call for a new model on how retrospective studies should be conducted. The following are some of the implications of the study:

Researchers who want to conduct retrospective studies should partner with communities. This partnership should include discussions on the need for such research, processes to protect individuals and the community from harm, whether consent is vital, if so, what type of consent, plans for dissemination of results and plans for how the participants and community at large will benefit from the research (Emanuel et al., 2008). Researchers should have plausible justifications for their topic of research and why they choose to access records of that particular community (Emanuel et al., 2008) so that they can justify the focus of their research so that it is acceptable to the host community/participants.

RECs, researchers and medical practitioners should ensure that adequate safeguards are in place to protect patients' privacy. RECs, health professionals and researchers should also remain cautious when designing and reviewing consent protocols for accessing patients' medical records because opinions vary widely and are influenced by various factors such that it may be difficult to identify consent protocols that are acceptable to all (Willison et al., 2009).

The uncertainties expressed by the current sample could decrease their willingness to participate in health research (Damschroder et al., 2007). Hence, there is need to educate the general public about the uses and benefits of research that uses their medical records. For example, the public should be educated on the difference between identifiable and anonymized data.

There is need for a system which documents individuals' consent choices for secondary use of their information and research (Nass et al., 2009). However, technical and legal challenges may be encountered when using such a system. Firstly, there is a need for legal authorisation of broad authorisation. Secondly, there should be an applicable repository to track consent choices. Thirdly, there will be need for structures which would function to ensure that patients' consent choices are honoured.

The current data suggests that researchers cannot just assume that people accept the use of their medical records with or without explicitly giving consent for a particular study (Willison et al., 2009). It is advisable to ask participants to state if they want their records to be used for research when they come into hospitals, clinics or healthcare service offices (Buckley et al., 2011). In this way at least researchers will know whether patients are willing for their records to be used. This method can be helpful in that it will at least cover some bases in that those who want to be asked for consent can see that researchers are taking the respectful initiative to ask for their permission while those who do not mind not being asked can also have an opportunity to say so, rather than just assuming (Buckley et al., 2011). However, this proposal can be problematic in that those who do not visit the health providers anymore won't have any control on how their records might be used.

6.3 Limitations

The results from this study must be interpreted with several limitations in mind. Firstly, the study was conducted in the waiting room of the University of KwaZulu-Natal Pietermaritzburg campus Clinic. The participants had to discuss their opinions in a fairly open environment, whereby other people who were not participating could possibly hear them, although efforts were made to maximise privacy. This could have affected their level of openness such that they might not have expressed what they really believed. Secondly, a significant number of the participants had never heard about research that uses medical records, such that the researcher

was exploring new territory with the participants and asking their opinions about something they were unfamiliar with. Therefore, some of their responses were spontaneous and possibly not something that they had really given much thought to.

The study was restricted to black students at UKZN who use the campus clinic. This attempt to understand people's attitudes is only through the reports of a few students. Such an approach does not account comprehensively for some of the attributes in which care and research are conducted. For the study findings to be transferable to all black patients; there is need, therefore, for further research in other settings. Students cannot be assumed to represent Black patients in general. Furthermore, the study only focused on their attitudes on one point in time, such that it only provides information on how they felt at that particular time. Opinions can change in time or even change when challenged. The study did not look at the factors that might affect their attitudes such as education. This student sample is relatively well educated and cannot be held to represent those unable to access tertiary education.

6.4 Recommendations

More research is needed in this particular area, as the range of dilemmas confronting the general public are likely to change and expand future research might sample a wider range of participants. There is need for studies to be conducted with different age, gender, sociodemographic and racial groups. Studying the public's attitudes towards the use of their medical records for research purposes is still in its infancy in Africa. Hence there is a need for more African research in this area, possibly applying indigenous value systems to the analysis.

REFERENCE LIST

American Psychological Association (2009). *Research ethics*. Retrieved from http://www.apa.org/about

Amdur, R. J., & Bankert, E. A. (2010). *Institutional review board: Member handbook* (3rd ed). London: Jones and Bartlett Publishers International.

Babbie, E., & Mouton, J. (2001). *The practice of social research*. Oxford: Oxford University Press.

Baker, L. C., Bundorf, K. & Kessler, D. (2014). Expanding patients' property rights in their medical records. National bureau of economic research 12 (1).

Barrett, G., Cassell, J. A., Peacock, J. L., & Coleman M. P. (2007). National survey of the British public's views on use of identifiable medical data by the National Cancer Registry. *British Medical Journal, 332*, 1068 –1072.

Barsdorf, N. W., & Wassenaar, D. R. (2005). Racial differences in public perceptions of voluntariness of medical research participants in South Africa. *Social Science and Medicine, 60* (5), 1087-1098.

Beauchamp, T. L., & Childress, J. F. (2008). *Principles of biomedical ethics* (6th ed). Oxford: Oxford University Press

Bell, J. (1997). *Doing your research project*. Buckingham: Open University Press.

Belmont Report. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research*. Retrieved from http://ohsr.od.nih.gov/guidelines/bemont.html

Black, N. (1996). Why we need observational studies to evaluate the effectiveness of health care. *British Medical Journal, 11* (312), 1215-1218.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology, 3*, 77-107.

Brown, L., Parker, M., & Dixon-Woods, M. (2008). Whose interest? British newspaper reporting on use of medical records for research. *Journal of Health Services Research and Policy*, *13* (3), 140-5.

Bryman, A., & Bell, E. (2007). *Planning a research project and formulating research questions in Business Research methods*. New York. Oxford University Press.

Buckley, B. S., Murphy, A. W., & MacFarlane, A. W. (2011). Public attitudes to the use in research of personal health from general practitioners' records: A survey of the Irish general public. *Journal of Medical Ethics, 37*, 50-55.

Bull, S., Cheah, P. Y., Denny, S., Jao, I., Morsh, V., Merson, L., More, N. S., Nhan, L. N. T., Osrin, D., Tangseefa, D., Wassenaar, D., & Parker, M. (2015). Best practices for ethical sharing of individual-level health research data from low- and middle-income settings. *Journal of Empirical Research on Human Research Ethics, 10*(3), 303-313.

Campbell, B., Thomson, H., Slater, J., Coward, C., Wyatt, K., & Sweeny, K. (2007). Extracting information from hospital records: What patients think about consent. *Quality Safety Health Care. 16*, 404-408.

Chareka, S. D. (2012). *Students' attitudes towards the use of medical records in research*. Unpublished honours dissertation. University of KwaZulu-Natal, Pietermaritzburg, South Africa.

Cleaton-Jones, P., & Wassenaar, D. (2010). Protection of human participants in health research-a comparison of some US federal regulations and South African research ethics guidelines. *South African Medical Journal, 100* (11), 710-716.

Coleman, M. P., Evans, B. G., & Barrett, G. (2003). Confidentiality and the public medical records-will we ever get it right? *Clinic Medicine, 3* (3), 219-228.

Corbie-Smith, G., Thomas, S. B., Marie, D., & George, M. M. (2002). Distrust, race and research. *Archives of Internal Medicine, 162* (21), 2458-2463.

Creswell, J. W. (2003). *Research design: Qualitative, quantitative, and mixed methods approaches*. Thousand Oaks, CA: Sage Publications, Inc.

Data Protection Act of 1998 United Kingdom. Retrieved from legislation.gov.uk.ukpga/1998

Damschroder, L. J., Pritts, J. L., Neblo, M. A., Kalarickal, R. J. Creswell, J. W., & Hayward, R. A. (2007). Patients, privacy and trust: patients' willingness to allow researchers to access their medical records. *Social Science & Medicine, 64*, 223-235

DeVellis, R. F. (2003). *Scale development theory and applications* (2nd ed). California: Sage publications.

De Vos, A. S., Strydom, H., Fouche, C. B., & Delport, C. S. L. (2002). Research at grassroots for the social sciences and human services professions (2nd ed.). Pretoria: Van Schaik.

Dickert, N. (2006). *Coercion and undue inducement in research: Money and other offers.* Baltimore: Johns Hopkins School of Medicine and Bloomberg School of Public Health. Retrieved June 27, 2013, from http://ocw.jhsph.edu/courses/EthicsHumanSubjectResearch/PDFs/Coercion.pdf

Doyal, L. (1997). Journals should not publish research to which patients have not fully given informed consent: With 3 exceptions. *British Medical Journal, 314* (7087), 1107-1111.

Eeanshaw, V. A., Smith, L. R., Shuper, P. A., Fisher, W. A., Cornman, D. H., & Fisher, J. D. (2014). HIV stigma and unprotected sex among PLWH in KwaZulu-Natal, South Africa: a longitudinal exploration of mediating mechanisms. *AIDS CARE, 26* (12), 1506-1513.

Egede, L. E. (2006). Race, ethnicity, culture and disparities in health care. *Journal of General Internal Medicine, 21* (6), 667-669.

Emanuel, E. J. (2006). Undue inducement: Nonsense on stilts? *American Journal of Bioethics, 5* (5), 9-13.

Emanuel, E.J. (2015). Reform of clinical research regulations, finally. *New England Journal of Medicine,* Nov 4th 20-15. Doi: 10.1056/NEJMp1512463

Emanuel, E. J., Currie, X. E., & Herman, A. (2005). Undue inducement in clinical research in developing countries: Is it a worry? *Lancet, 366*, 336-340.

Emanuel, J., Wendler, D., & Grady, C. (2000). What makes clinical research ethical? *Journal of the American Medical Association, 283* (20), 2701-2711.

Franfort-Nechmais, C., & Nachmais, D. (1996). *Research methods in the social sciences* (5th ed). New York: St Martin's Press.

Gallup Organisation. (2000). *Public attitudes toward medical privacy*. Retrieved from http://www.forhealthfreedom.org/Gallupsurvey/IHF-Gallup.pdf.

Gilson, L. (2003). Trust and the development of health care as a social institution. *Social Science & Medicine*, *56*, 1453-1468.

Gilson, L., Palmer, N., & Schneider, H. (2004). Trust and health worker performance: exploring a conceptual framework using South African evidence. *Social Science & Medicine*, *61* (7), 1418-1429.

Hair, J. F., Anderson, R. E., Tatham, R. C., & Black, W. C. (1998). *Multivariate data analysis* (5th ed). New Jersey: Prentice-Hall.

Health and Social Act 2012. (2012). Retrieved from http://www.legislation.gov.uk/ukpga/12/7

Health Insurance Portability and Accountability Act of 1996. (1996). Retrieved from http://privacyruleandresearch.nih.gov/healthservicesprivacy.asp

Horn, L. & Mwaluko, G. (2014). Public health research (including cluster randomised trials). In Kruger, M., Ndebele, P. & Horn, L. (Eds.), *Research ethics in Africa: a resource for research ethics* (pp. 99-108). Stellenbosch: SUN MeDIA.

IJsselmuiden, C. B., & Faden, R. R. (1992). Research and informed consent in Africa-another look. *New England Journal of Medicine, 326*, 830-834.

Janosky, J. E., Laird, S. B., & South-Paul, J. E. (2005). Development of research registry for primary care community based research. *Family Practice*, *22,* 358-60.

Junghans, C., & Jones, M. (2007). Consent bias in research: How to avoid it. *Heart, 93,* 1024-1025.

Karla, D., Gertz, R., Singleton, P., & Inskip, H.M. (2006). Confidentiality of personal health information used for research. *British Medical Journal, 333*, (7560), 196-198.

Kass, N. E., Natowicz, M. R., Hull, S. C., Faden, R. R., Plantinga, L., & Gostin, L. O. (2003). The use of medical records in research: What do patients want? *Journal of Law, Medicine & Ethics, 31*(3), 429–433.

Kho M. E., Duffett, M., Willison D. J., Cook, D. J., & Brouwers, M. C. (2009) Written informed consent and selection bias in observational studies using medical records: systematic review. *British Medical Journal, 338,* 866.

Kitzinger, J. (1994). The methodology of focus groups: the importance of interactions between research participants. *Sociology of Health and Illness, 16*, 103-121.

Kruger, R.A., & Casey, M. A. (1994). *Focus groups: A practical guide for applied research. (3rd ed*.). Thousand Oaks: Sage.

Kvale, S. (1996). *An introduction to qualitative research interviewing*. Thousand Oaks: Sage.

Lindegger, G., & Richter, L. M. (2000). HIV vaccine trials: Critical issues in informed consent. *South African Journal of Science, 96*, 313-317

Mamotte, N., & Wassenaar, D. (2012). Ethical issues and ethics reviews in Social Science research. In Leach M. M., Stevens M. J., Lindsay G., Ferrero A., Korkut Y. (Eds.), *The Oxford handbook of international psychological ethics* (pp. 268-282). Oxford, UK: Oxford University Press.

McSherry, B. (2004). Third party access to shared clinic mental records issues: Ethical issues. Retrieved from http://www.heinonline.org/HOL/Page?page=53andhandle=hein.journals%2Fpsylaw11andcollection=journals

Medical Research Council South Africa. (2002). *Guidelines on ethics for medical research: general principles*. Retrieved from http://www.saheathinfo.org/ethics/index.htm

Medical Research Council United Kingdom. (2007). *The use of personal health information in medical research general public consultation*. Retrieved from http://www.mrc.ac.uk/documents/pdf/the-use-of-personal-health-information-in-medical-research-june-2007/

Miller, F. G. (2008). Research on medical records without informed consent. *Journal of Law, Medicine and Ethics, 36* (3), 560-566.

Moore, M., & Chaudhary, R. (2013). Patients' attitudes towards privacy on a Nepalese public hospital: a cross-sectional survey. *BioMed Central Research Notes 6*(31), 1-5.

Nass, S.J., Levit, L.A., & Gostin, L.O. (Eds.) (2009). *Beyond the HIPAA privacy rule: Enhancing privacy, improving health through research*. Washington DC: National Academies Press.

National Health Act 61 of South Africa. (2003). Retrieved from http://www.chr.up.ac.za/unda/domestic/docs/legislation-55.pdf

National Health Services. (2010). Retrieved from http://www.nihr.ac.uk/document/policyand-standards/Faster-and-easier-clinical-research/Research-passport/Honorary-research-contracts-principles-and-legal-requirements

Ndebele, P., Mfutso-Bengo, J., & Masiye, F. (2008). HIV/AIDS reduces the relevance of the principle of individual medical confidentiality among the Bantu people of South Africa. *Theoretical Medicine and Bioethics, 29*(5), 331-340.

Neuman, W. L. (1991). *Social research methods qualitative and quantitative approaches.* Boston. Mass: Allyn and Bacon.

Office for Human Research Protections. (2009). http://hhs.gov.ohrp (accessed 8 August 2014)

Oxford Advanced learner's dictionary. (2010).http://oald8.oxfordlearnersdictionaries.com/ (Accessed 3 December 2013)

Peto, J., Olivia, F., & Gilham, C. (2004). Data protection, informed consent and research. *British Medical Journal, 328*, 1029-1030.

Regidor, E. (2004). The use of personal data from medical records and biological materials: ethical perspectives and the basis for legal restrictions in health research. *Social Science and Medicine, 59* (9), 1975-1984.

Robling, M. R., Houston, H., Pill, R., & Evans, H. M. (2004). Public attitude towards the use of primary care patient record data in medical research without consent: A qualitative study. *Journal of the Institute of Medical Ethics, 30* (1), 104-109.

Roter, C., & Hall, B. (1997). Gender differences in patient-physician communication. In Gallant, S. J., Keita, G. P., & Schater, R. R. (Eds.). *Health care for women: psychological, social and behavioral influences*. Washington DC: American Psychological Association.

Stone, M. A., Redsell, S. A., Ling, J. T., & Hay, A. D. (2005). Sharing patient data: Competing demands of privacy, trust and research in primary care. *British Journal of General Practice, 55*, 783-789.

Starks, H., & Trinidad, S. B. (2007). Choose your method: A comparison of phenomenology, discourse analysis, and grounded theory. *Qualitative Health Research, 17* (10), 1372-1380.

Tranberg, H., & Rashbass, J. (2004). *Medical record use and abuse*. Oxford, San Francisco: Raddcliffe Medical Press.

Terre Blanche, M., Durrheim, K., & Painter, D. (2006). *Research in practice*: *Applied methods for the social sciences*. (2nd ed.). Cape Town: UCT press.

Wassenaar, D.R**.,** & Mamotte, N. (2012). Use of students as participants in a study of eating disorders in a developing country. *Journal of Nervous & Mental Disease, 200,* 265-270.

Westin, A. (2010). *Healthcare data as a public good: privacy and security. Clinical Data as the Basic Staple of Health Learning: Creating and Protecting a Public Good: Workshop summary*. Retrieved from http://www.nap.edu/catalog/12212.html.

Whitley, E. (2009). Informational privacy, consent and the 'control' of personal data. *Information Security Technical Report, 14*, 154-159.

Whiddet, T. R., Hunter, I., Engelbrecht, J., & Hardy, J. (2007) Patients' attitudes towards sharing their health information. *International Journal of Medicine Informatics, 75* (7), 530-541.

Williams, R. L., Willging, C. E., Quintero, G., Kalishman, S., Sussman, A. L., & Freeman, W. L. (2010). Ethics of health research in communities: Perspectives from the Southwestern United States. *Annals of Family Medicine. 8* (5), 433-439.

Willig, C. (2008). *Introducing qualitative research in psychology, Adventures in theory and methods*. London: Open University Press.

Willison, D. J., Kesharjee, K., Nair, K., Goldsmith, C., & Holbrook, A. M. (2005). Patients' consent preferences for research uses of information in electronic medical records. *British Medical Journal, 326* (7385), 373-376.

Willison D. J., Schwartz, L., Abelson, J., Charles, C., Swinton, M., Northrup, D., & Thabane, L. (2007). Alternatives to project-specific consent for access to personal information for health research: what is the opinion of the Canadian public? *Journal of the American Medical Informatics Association 14* (6), 706-712.

Willison, D. J, Steeves, V., Charles, C., Schwarts, L., Ranford, J., Agarwal, G., Cheng, J., & Thabane, L. (2009). Consent for use of personal information for health research: Do people with potentially stigmatizing health conditions and the general public differ in their opinions? *BioMed Central Medical Ethics 10* (10), 1-12.

Wylie, J. E., & Mineau, G. P. (2003). Biomedical databases: Protecting privacy and promoting research. *Trends in Biotechnology, 21* (3), 113-116.

Yin, R. K. (2002). *Case study research, design and methods*. (3rd ed). Newbury Park: Sage Publications.

APPENDIX 1: INFORMED CONSENT FORM

UNIVERSITY OF KWAZULU-NATAL

INYUVESI YAKWAZULU-NATALI

Dear Student

Hello, my name is Samantha Chareka. I am a student at the University of KwaZulu-Natal Pietermaritzburg campus pursuing a Masters of Social Science in Health Research Ethics. I am doing a study on students' attitudes towards the use of medical records in research. The research is concerned with issues surrounding research ethics.

Participation is strictly on a voluntary basis so you are not obliged to take part. If you agree to participate, you will be placed in a discussion group to discuss the research topic, facilitated by the researcher. The discussions should last about an hour. No personal identifiers will be requested in the group discussions. Participants are encouraged to keep the participants' names and details disclosed in the discussion within the group itself. Although the researcher will treat all the information as confidential, she cannot guarantee that all other group members will do so. For this reason you are advised not to reveal any personally sensitive information in the focus group. If you agree, the focus group discussions will also be recorded to help the researcher to transcribe the data gained in the course of the discussion for analysis.

Feel free to ask questions or raise any concerns about the research procedure. Results and brief discussion of the study findings will be made available for interest early October 2013 these will be posted on the Psychology general notice board. There are no direct benefits to the participants, but hopefully the research will provide valuable information pertaining to students' attitudes towards the use of medical records for research.

If you have any other questions about the study, you may contact me at:

Email address: 209511072@stu.ukzn.ac.za

Cell phone number: 0847533099

You can also contact my supervisor Prof Doug Wassenaar:

Email address: wassenaar@ukzn.ac.za

If you have any ethical queries about the study you can contact Ms. Phume Ximba of the Human Social Science Research Ethics Committee at:

Email address: ximbap@ukzn.ca.za

Telephone number: 033 260 3587

Consent

I hereby agree to participate in research regarding students' attitudes in the use of medical records for research. I understand that the discussion will be recorded so that the researcher uses it for her data analysis, therefore I give the researcher permission to record the discussion. I understand that I am participating freely and I am not being forced in any way to participate. I also understand that I can stop participating in the focus groups should I choose to do so. This decision will not affect me negatively in any way.

The purpose of the study has been explained to me, and I understand what is expected of my participation. I understand that this study is not going to benefit me personally but it can be used to benefit the community at large. I understand that the findings from the study will be made available to students on completion of the study.

Confidentiality Agreement

All participants are urged to keep the names of participants and their personal details disclosed in the group confidential. You may discuss the contents of the focus group discussion but do not disclose any person's name. Although confidentiality will be encouraged, the researcher cannot guarantee that people will not make disclosures outside of the group. For this reason you are advised not to disclose personally sensitive information. The researcher will keep all information confidential and no identifiable details will appear in any published reports. All records will be anonymised and kept in password protected files and locked cabinets.

Signature of participant:... Date:……………………

If you have any other questions about the study, you may contact me at:

Email address: 209511072@stu.ukzn.ac.za

Cell phone number: 0847533099

You can also contact my supervisor Prof Doug Wassenaar:

Email address: wassenaar@ukzn.ac.za

If you have any other questions about the study, you may contact me at:

Email address: 209511072@stu.ukzn.ac.za

Cell phone number: 0847533099

You can also contact my supervisor Prof Doug Wassenaar:

Email address: wassenaar@ukzn.ac.za

APPENDIX 2: FOCUS GROUP SCHEDULE

Introduction

- Thank participants for agreeing to participants

- Introduce the researcher and the assistant

- Explain that the research has gained ethical approval from the Humanities Ethics Committee

- Express that there are no wrong or right answers, as the research is focused on getting peoples' views and opinions

- Make ground rules of the discussion

- Reassure participants about confidentiality and explain the confidentiality clause

- Ask permission to audio record the discussions

Personal Information

Purpose: to introduce participants to the topic of medical records in general

- What kinds of personal health information are there?

- As far as you know, who uses this health information?

- What do you think the information would be used for?

Note to facilitator: try to bring the focus more to medical records information in particular. Record what they say on a flipchart.

- Who should be able to see your personal information?

- For what purposes?

- What do you think about the principle of making personal health information available for medical research?

- Does it differ according to the type of information?

- Are there any drawbacks?

- Do your attitudes vary depending on:

1. The purpose of the research?

2. Who is doing the research?

3. Whether the information is anonymised?

4. Whether the information is linked to individuals?

5. The kind of information being sought?

- What concerns, if any, do you have about personal information being used for medical research were by medical researchers?

- Is consent necessary in such instances

- Which bits of information should be used in such research? Does anonymity make a difference?

- What are the risks and benefits of allowing medical records to be used?

Aim: establish how people think that their medical records are used, how they should be used and whether they are willing for it to be used in research under what circumstances. Probe to get their attitudes and views.

Closing

- **Sum up the research**

- **Inform the participants when the results will be available**

- **Vote of thanks**

APPENDIX 3: ETHICS APPROVAL

UNIVERSITY OF
KWAZULU-NATAL

INYUVESI
YAKWAZULU-NATALI

30 October 2013

Ms SD Chareka (209511072)
School of Applied Human Sciences - Psychology
Pietermaritzburg Campus

Protocol reference number: HSS/0730/013M
Project title: University of KwaZulu-Natal students' attitudes towards the use of medical records in research

Dear Ms Chareka,

Expedited Approval

I wish to inform you that your application has 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.

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

Yours faithfully

Dr Shenuka Singh (Acting Chair)

/ms

cc Supervisor: Professor D Wassenaar
cc Academic Leader Research: Professor D McCracken
cc School Administrator: Mr Sbonelo Duma

Humanities & Social Sciences Research Ethics Committee
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Website: www.ukzn.ac.za
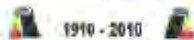
1910 - 2010
100 YEARS OF ACADEMIC EXCELLENCE

Founding Campuses: Edgewood   Howard College   Medical School   Pietermaritzburg   Westville

APPENDIX 4: GATEKEEPERS APPROVAL

UNIVERSITY OF KWAZULU-NATAL ™
INYUVESI
YAKWAZULU-NATALI

3 October 2013

Ms Samantha Chareka
School of Allied Human Sciences
College of Humanities
Pietermaritzburg Campus
UKZN
Email: 209511072@stu.ukzn.ac.za

Dear Ms Chareka

RE: PERMISSION TO CONDUCT RESEARCH
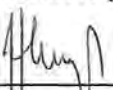
Gatekeeper's permission is hereby granted for you to conduct research at the University of KwaZulu-Natal towards your postgraduate studies, provided Ethical clearance has been obtained. We note the title of your research project is:

"University of KwaZulu-Natal students' attitudes towards the use of medical records in research".

It is noted that you will be constituting your sample by recruiting students from the University's Clinic waiting area to participate in the group discussions on the Pietermaritzburg Campus.

Data collected must be treated with due confidentiality and anonymity.

Yours sincerely

Professor J Meyerowitz
REGISTRAR

APPENDIX 5: THEMATIC MAP

Age-G

How frequently researchers need to obtain permission-F
- Need to be asked every time -1
- Once-2
- No need to ask everytime-3

Informed consent

Trust-A
- Depends on who will be accessing them -1

Consent Preferences-E
- Verbal consent 1
- Written consent 2
- Need to be asked -3

The right to control how medical records are shared and accessed-B
- Authority -1
- Autonomy -2
- Control-3

Cultural Sensitivity-D
- Family Privacy-1
- Clan information-2

Respect-C
- Consider how participants feel about researches accessing the information-1
- Respect family/clan-2

Anonymity

1

"Accessing my medical records as long as it doesn't identify me as the person, I really wouldn't have problems with it. As long as they don't know whose medical record it is, then there is really nothing that scares me."

"But it boils down to... there is no guarantee that they will remove personal information and that they will not be able to link it back to me. What guarantee do I have that my records will be anonymised when researchers access them? Unless I have proof that they are guaranteeing that the information is anonymised; at least someone has to be liable if this turns out nasty.

"Maybe the question should be after anonymity is guaranteed why should anyone care? What people fear is not that people out there will know that there is HIV. What people fear is that people out there will know that they in particular have it"

"But sometimes names are necessary because they might need to do follow-ups. How are they going to do it if they do not know your name and where you stay? For me, if I'm eligible to be part of your study you can use my records but you need to ask me".

"If the system guarantees anonymity, it is all fine by me. I don't have a problem with it."

The right to control

Informed Consent

How frequently researchers nee to obtain permission

Respect

Cultural sensitivity

Consent preferences

"In this way I feel like I have a bit of power to what happens with my records. Just like the HIV test, so if one doesn't want their records to be used that's the only time they can have to say no.

"This thing of them just coming to get information is disrespectful…" -1pg

"Yes, I think we should be asked because sometimes we might have these genetic diseases that are supposed to be our own, so it should be kept within the family/ clan and we can be the only ones who have to know about it. So if they just take the records without our approval it means that they are exposing our secrets without us knowing

"In my family when we have an illness, it must be kept amongst us until we are ready to talk about it. Such that when we go to the doctor, we want him to help us before our issues become public knowledge. That's why we need to be asked first, because that disease might be peculiar to us only and people in the community might even know that they are talking about us in that research, because the whole family might have symptoms of the disease. That's why there is a need for them to get our consent first, because by that time we will be at peace knowing that people might even know that our clan was included in the research."- 1pg, 2pg

"I will need to sign somewhere because when something goes wrong the researchers can also have proof that I agreed for my records to be used"2

"If you just ask me and I say yes verbally its ok really, I don't really care to sign somewhere, because I will be aware, and trust me, I will be aware that I have

"At least they should have some form of consent procedure like the moment you go to your doctor or hospital, they should have a section where they will be asking for your consent for the records to be used."-2

"They should at least ask for consent once in a while…I don't want to be asked every time really, but at least I should consent to it. It would be unfair for them to use my records continuously for different studies. It should be periodic."-3

"Every time a new research that wants to use my medical records, I should be asked for consent."-1

Positive aspects of disseminating medical records for research

Research purposes

- Need for such research-1

Importance of research

- Knowledge of research-1
- Impact of research-2
- Importance of knowledge-3
- Advancement of knowledge-

Altruism

- Help-1
- Do not need to benefit from it-2

Contents of medical records

- Sensitivity of information in records-1
- Identification-2
- Linking back to individual and community at large-3

Reservations

Misuse of personal health information

Social harms

- Stigmatisation-1
- Prejudice-2

Access to medical records by third parties

- Access by outsiders-1
- Confidentiality agreements-2

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                    Positive aspect of disseminating medical
                    records for research


    Research Purposes                Importance of research                          Altruism


"If we are to look at the current situation in    "It would not make sense for one to demand a    "I think if the research is going to help
South Africa, most research centres are           public health care system that is functional and    more people, greater good issue. We
focusing on issues surrounding HIV/AIDS, this     yet not allow researchers to use the stats      can even          limit privacy if it's going
can be attributed to studies like this which      (statistics) and records to better that system.    to be helpful".
use people's medical records to see what is       Why can't the information actually be made
really going on in KZN. Such that when the        public?"
research is out, the Department of Health has                                                      "It would not make sense for one to
an obligation to devise a plan to counter         "That would be very helpful because people will    demand a public health care system
attack this. We also have funders who are         then know their chances of suffering from the    that is functional and yet not allow
supporting this fight against AIDS because it     disease, know the causes and prevention as      researchers to use the stats and records
has been made public that we are struggling       well."                                          to better that system.
with this disease."
                                                  "Because, like I was saying that, this research will    …
                                                  only find more relevance the more we
                                                  computerise this part of the world and I want to    The clinic in question, pharmaceutical
                                                  get to why it would matter what the information    firms, anything from drug distribution
                                                  would be used for. Why can't the information    planning to use on what awareness
                                                  actually be made public information? If you think    schemes are needed where really the
                                                  about it… health is a public good and knowing    debate of what the information is used
                                                  the stats about different places helps."         for is obiter, if not useless, if we are to
                                                                                                   assume that it is just records that have
                                                                                                   been de-personalised."
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Reservations

Contents of the medical records

*: "again it goes to the severity of the cases being studied, there are some diseases which are of sensitive nature like HIV and some epidemics. When you hear that 15 are quarantined, none would give the details because there are socio-economic factors that are at play in the identification of the groups."

"It depends hey… for me personally let's say I have HIV/AIDS, I don't want them to access my records without my knowledge. I don't even care if they put my name or not but the mere fact that they have maturity to ask me for my consent shows that they respect my information. I'm particular about HIV because I haven't come to peace with the virus. I still have issues with it, but any other disease which might be in my record I do not really care. Because I'm still

Access to medical records by third parties

"I think the people who do such research should be independent researchers from the society you are from, because people from your society can add 2 and 2 and find out that probably it is you who is suffering from such; which would be really bad. I think researchers from other communities should come and access them because then they won't add up any information and come up with accurate conclusion about the identity of the person.

"mmmm my medical aid should not have access to research because they can just add it up in their system that… oh probably it's this person, because she visited the clinic this many times… and they have information on their database on the time I visited the doctor and whether it is for consultation or treatment and they can then link it back and say so person A is (name mentioned)

Social Harms

"As much as the research might have benefits, you should also consider the stereotypes around such studies when we then go out there people will mock us because we studied at UKZN where there is a high rate of HIV infection. At least they should ask me for permission first before I read about it in the newspaper or in a published article."

"So with that kind of sensitivity, even anonymity is not enough such that in such studies there should be some level of consent because the immediate community might be able to identify who from the community participated such that consent guarantees that the participants are willing to risk being stereotyped and stigmatized by their own community. It will show maturity on the side of the researcher as well because this is a very sensitive issue and it shows how far they are willing to go.

Misuse of personal health information

"At the end of the day researchers are also humans, they are bound to have errors." "With these social networks, your personal health information can be a topic of discussion on these social networks."

"but you will find that even after the research is done then when the information is out there, the media can get hold of such information and write it in a negative light and your society can then be stigmatized against.

But also guys there are situations like you are in a hospital and researchers come to ask for your permission to use your records. Just because you are sick and you need help you might be forced to say yes because you will be thinking that their research would help you as an individual. And some people might not even be comfortable with going to the hospital if they later find out that their information might be used