EXPLORING STAKEHOLDER PERCEPTIONS AND PRACTICES REGARDING RESEARCH IN PROVINCIAL HEALTH FACILITIES

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DECLARATION

I declare that this dissertation represents my own work, except for those where due acknowledgement is made, and that it has not been included in a thesis, dissertation or report submitted to this university or any other institution for a degree, diploma or other qualifications.

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ABSTRACT

This thesis aimed to explore the perceptions and practices of key stakeholders regarding research conducted in provincial public health facilities. Research plays a vital role in improving health and health care globally, as well as in KwaZulu-Natal (KZN), South Africa, where it has resulted in significant health gains particularly in the field of HIV/AIDS. However, in spite of a robust regulatory framework and guiding documents, health research may be fraught with challenges. In KZN, the Provincial Health Research and Ethics Committee (PHREC) is responsible for providing final permission for researchers to access public health facilities to conduct their research, or to recruit potential participants from these facilities. This permission is based on the support of health managers of public health facilities and programmes who provide the first level of permission in the PHREC approval process. This study explored the perceptions and practices of researchers and health managers regarding research conducted in provincial public health facilities, and regarding their inter-stakeholder relationships. A qualitative study design was adopted, using in-depth interviews as the means of data collection. Eighteen interviews were conducted – eight with health managers and ten with researchers. Interviews were analysed using Thematic Analysis. Three important themes were generated from the analysis: varying perceptions around the 'social value' of research, strained inter-stakeholder relations, and recommendations for strengthening research and relations. Although all participants agreed that health research was valuable, researchers tended to place more emphasis on its contribution to new knowledge and future beneficiaries, whilst health managers tended to emphasise its concrete and current contribution to the functioning of the healthcare system. Respondents perceived that their relationships were strained at all stages of the research process. Particular concerns included a lack of involvement of health managers in the conceptualization of research questions, frustration of researchers with a prolonged, onerous research application process, and poor feedback of research results to health managers. Important relationship issues included lack of trust, accountability, and transparency. Both stakeholder groups had a shared view regarding how to strengthen both the research process and inter-stakeholder relations. There was strong agreement on, amongst others, improving communication through more regular, formal and informal meetings, and entrenching a culture of research within the KZN Department of Health. The study concludes that researchers and health managers had subtly differing perceptions of what makes health research in provincial health facilities valuable, and that tensions between these groups were perceived across the life-cycle of the research process. The study makes various recommendations on how to build stronger relations between stakeholders, in order to facilitate the conduct of high quality research in such settings, that is valued by affected role-players.

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DEDICATION

For my darlings – Isabella, Christina and Georgina –

And for Damian

With love.

LIST OF ABREVIATIONS

AIDS: Acquired Immuno-deficiency Syndrome

DoH: Department of Health

HIV: Human Immunodeficiency Virus

KZN: KwaZulu-Natal

MCC: Medicines Control Council

MMC: Male Medical Circumcision

MMed: Master of Medicine

NDoH: National Department of Health

NHLS: National Health Laboratory Service

NHREC: National Health Research Ethics Council

PDoH: Provincial Department of Health

PHREC: Provincial Health Research and Ethics Committee

PMTCT: Prevention of Mother to Child Transmission (of HIV)

REC: Research Ethics Committee

TB: Tuberculosis

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CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

A critical and contemporary concern in the ethics of health research is how researchers can establish meaningful relationships with key stakeholders (MacQueen et al., 2015). Ethics scholars argue that researchers should strive to establish relationships with key stakeholders that represent "collaborative partnerships" (Emanuel, Wendler, Killen, & Grady, 2004, p. 932). Ethical guidelines posit that researchers should strive for relationships that are equitable and premised on the full engagement of all those interested in or affected by health research (UNAIDS/AVAC, 2011). It is argued that such relationships may have multiple benefits. Such relationships may ensure that the research questions are relevant for key stakeholders, including the communities in which the research is conducted. They may help to ensure that the research is valued by all those involved in or affected by it, and therefore facilitate the conduct of the research itself, as well as the utilisation of the research results. Finally, collaborative partnerships exemplify good practice in collaboration that may have an impact on broader society (Ross et al., 2010). Ideally, they should be based on mutual trust, respect and understanding, transparency, and accountability (UNAIDS/AVAC, 2011). Such relationships, however, may not be easy to achieve. They require a meeting of the minds of stakeholders with diverse interests and priorities. By definition, they require a level of equality between stakeholders that is rare in societies which are inequitable and hierarchical.

National ethics guidelines for health research conducted in South Africa assert that "researchers should engage key role players at various stages of planning and conducting research" (National Department of Health (NDoH), 2015, p. 16) underscoring the need for researchers to invest in collaborative relationships with key stakeholders. However, South African society is deeply inequitable (Leibbrandt, Woolard, Finn, & Argent, 2010). Poverty remains pervasive, is concentrated largely among black South Africans, and has a profound impact on population health (Coovadia et al., 2009). This, together with South Africa's history of colonisation and apartheid, has important implications for the development of collaborative partnerships in health research in the country (Barsdorf & Wassenaar 2006). Researchers and physicians are considered in most societies to be part of a social elite (Benatar 2002; Christakis 1992). In South Africa, this may be compounded by the "legacy of colonialism (which) evokes covert ethnic divisiveness between researchers and subjects"

(Benatar, 2002, p. 1134), as well as between researchers and those who control access to sites where data will be collected (so-called 'gatekeepers') (Broadhead & Rist, 1976; Campbell, Gray, Meletis, Abbott, & Silver, 2006; Singh & Wassenaar, 2016) and who may use the results of research.

However, it is crucial that health research in South Africa, and in particular in the province of KwaZulu-Natal (KZN), is fostered. KwaZulu-Natal carries a complex burden of disease. The province has the highest incidence of TB in the country (1,142 per 100 000) (Day et al., 2012: 89) as well as the highest HIV prevalence rate nationally (39.5%) (Day et al., 2012, p. 89). In addition, there are emerging epidemics of diseases of lifestyle, and trauma remains one of the most important causes of death among young men. Health research is vital to develop new modalities of prevention and treatment for this diverse range of health problems, and to support the health system to deliver these modalities effectively. Indeed, KwaZulu-Natal is a highly active region in terms of health research. It is home to several large and well-funded research organisations such as CAPRISA (Centre for the AIDS Programme of Research in South Africa), the Africa Health Research Institute (AHRI), units of the South African Medical Research Council (SA MRC), and BroadReach Healthcare, amongst others. Groundbreaking research with both local and global impact has been conducted in this province, particularly in the field of HIV/AIDS (Abdool Karim et al., 2010; Tanser et al., 2013). Research Ethics Committees (RECs) in this province process over 600 applications to conduct health research in the province annually, of which approximately 15% are clinical trials (D. Wassenaar, personal communication, September 22, 2015). Over and above the importance of health research in finding solutions to health problems, some have argued that it is important also because it is democratising – that is, the conduct of research (including health research) institutionalises scholarly debate that can only benefit society (Benatar, 2002).

South Africa has well-established national health research legislation, normative ethics guidance (Cleaton-Jones & Wassenaar, 2010; National Health Research Ethics Council (NHREC), (NDoH, 2015) and regulation and credentialing of all RECs by the National Health Research Ethics Council (NHREC). However, in spite of these structures and ethics guidelines, the conduct of health research may be undermined by the absence of collaborative partnerships between researchers and a key stakeholder group, namely the managers of health facilities and programmes, who control access to the health facilities hosting research (so-called 'gate-keepers') and who are potential users of research results when studies are completed.

Since 2012, I have been the Chair of the KwaZulu-Natal Provincial Health Research and Ethics Committee (KZN PHREC), which is responsible for reviewing and approving the conduct of research in public health facilities in the province. My experience in this position has demonstrated that there are tensions in the relationships between researchers and health managers in the province. These tensions have manifested themselves most visibly in the review of applications to the KZN PHREC to conduct clinical trials in provincial health facilities, where processing times have been protracted, leading some to argue that the conduct of clinical trials in the province is threatened (Singh & Mills 2005). 'Corridor conversations' to which I am party have revealed that both researchers and health managers within the Department of Health experience varying degrees of frustration towards one another. I have become increasingly of the view that it is important to understand perceptions around these relationships more fully, in order to better promote important health research in the province. I was of the view that tense relations may be manifestations of different beliefs about the ideal conduct of health research, but did not have a clear understanding of the perceptions of key stakeholders regarding research in public health facilities.

Such perceptions, and related practices, are arguably important subjects of research themselves. The 'moral map' of stakeholders in KwaZulu-Natal is diverse (Prozesky, 2009), and exploring the viewpoints of representatives of various groups may help to identify perceived difficulties in research in provincial health facilities, as well as contribute to a broader understanding of how stakeholders with diverse backgrounds, needs and priorities could work together to ensure excellent and useful research. It was in order to develop a better understanding of perceptions and practices of research in provincial health facilities, including researcher-health manager relations, and to recommend ways to strengthen such relations, that this research was conducted.

1.2 STUDY AIMS

This study had the following aims:

1. To explore the perceptions and practices of key stakeholders related to research conducted in provincial public health facilities, including processes around its planning, approval, conduct, dissemination and impact
2. To explore the perceptions and practices of key stakeholders regarding inter-stakeholder relations
3. To make recommendations to strengthen the ethical conduct of such research, including implementation and uptake of research results, and inter-stakeholder relations.

This study adopted a qualitative approach, using in-depth interviews (DiCicco-Bloom & Crabtree, 2006) to gain a deeper understanding of how stakeholders perceived such research in general, the research process and their relationships with other key stakeholders. It was important that the approach lend itself to the exploratory nature of this inquiry; where interviewees volunteer their own points of view, and are permitted to raise issues freely, and the investigator is allowed to probe their views during the data collection process (ibid).

1.3 DISSERTATION OUTLINE

In Chapter 1, the background to the study is presented, with references to important literature and including the investigator's personal experience and rationale for undertaking the study. In Chapter 2, a review of the literature relevant to the study is presented, which underscores the importance of health research, describes the various ethics guidelines available to facilitate the conduct of useful health research, and highlights the lack of empirical research into the relationship between the 'gatekeepers' of health facilities in which much health research takes place, and researchers themselves. In Chapter 3, the aims and methods of the study are set out; the qualitative approach used in the study is described and steps taken to enhance the quality of the study are outlined. In Chapter 4, the results of the study are described in terms of the themes that were generated in the data analysis. These themes were firstly, varying perceptions of the 'social value' of research; secondly, strained inter-stakeholder relations; and thirdly strengthening research and relations. In Chapter 5, these results are discussed with reference to the relevant literature, both local and international. The discussion is structured according to the three themes as presented in the results. In Chapter 6, the main conclusions of the study are described, and the implications of the study for research in provincial health facilities are considered. Recommendations are made for strengthening research in public health facilities in KZN, and improving relationships between key role-players in these facilities.

CHAPTER 2

LITERATURE REVIEW

This chapter sets out to describe the importance of health research. It sets out ethics recommendations (in frameworks and ethical guidelines) that researchers engage key stakeholders in an early and sustained manner in research, and selected other ethics recommendations. It describes the effect of inter-stakeholder relationships on health research. It highlights the gap in current knowledge around the role of health managers including as 'gatekeepers' of public health facilities in KZN, where much health research takes place, and the importance of addressing gaps in this knowledge, in order to make recommendations to strengthen research in provincial health facilities.

2.1 HEALTH RESEARCH

Research is defined in the Code of Federal Regulations 46.102(d) as "a systematic investigation … designed to develop or contribute to generalisable knowledge" (U.S. Department of Health and Human Services (USDHHS, 2009) and health research is essentially that which is undertaken to better understand human health (Harvard Medical School, 2017). It is a vast field, which includes, amongst others, clinical research (the study of disease mechanisms and therapeutic processes in the human body), basic (laboratory based) research, and health policy and health systems research (an interdisciplinary field that focuses on how societies develop and achieve health goals collectively) (WHO, 2017).

Health research involves multiple stakeholders (UNAIDS/AVAC, 2011). Besides researchers themselves, the stakeholders involved in health research projects may include the participants in the study, the communities from which those participants are drawn, funders, Research Ethics Committees (RECs) which review study protocols, research and academic institutions which conduct and support research, government departments which utilise research results, and 'gatekeepers' who control access to the communities or health facilities where the research will take place (Campbell et al., 2006). These actors are not passive in the research process, and have their own vested interests and expectations. Given the diversity of the field of health research, and the array of different actors involved, and their varying interests and priorities, it is not surprising that processes

of conceptualising, reviewing, approving, and conducting research, and utilising research results, are complex.

2.2 ETHICS GUIDANCE FOR HEALTH RESEARCH

Ethics scholars have developed popular and systematic ethics frameworks for health research. They have argued that health researchers should ensure that key stakeholders are engaged in a particular kind of relationship with them – a collaborative partnership that allows stakeholders to gain from the research, either through the process or the outcomes thereof (Emanuel et al., 2004). Collaborative partnerships should span the whole of the research process and involve "sharing responsibilities for determining the importance of [the] health problem, assessing the value of [the] research, planning, conducting, and overseeing research, and integrating research into the health-care system" (Emanuel et al., 2004, p. 931). Failure to establish these collaborative partnerships in the conduct of research can undermine the entire research process and its outcomes, as demonstrated in a number of early HIV prevention trials (Allman, Ditmor, & Kaplan, 2014; Ukpong & Peterson, 2009).

It is important that key stakeholders in health research work together in mutual collaboration, and useful ethics guidelines have been developed in order to facilitate this (MacQueen, 2012; HIV Prevention Trials Network (HPTN), 2009; UNAIDS/AVAC, 2011). The UNAIDS/AVAC Guidelines for Good Participatory Practice (2011) define stakeholders in research very broadly - as "individuals, groups, organisations, government bodies, or any other individuals or collections of individuals who can influence or are affected by the conduct or outcome" of a research study (p. 14). These ethics guidelines define stakeholder engagement as the process "through which …. funders, sponsors, and implementers build transparent, meaningful, collaborative, and mutually beneficial relationships with interested or affected individuals, groups of individuals, or organisations, with the ultimate goal of shaping research collectively" (UNAIDS/AVAC, 2011, p. 16). The ethics guidelines emphasise the importance of several 'principles' that underpin successful stakeholder relationships. These include: respect, mutual understanding, integrity, transparency, accountability, and respect for community stakeholder autonomy. These guidelines expressly list national and local healthcare authorities as key stakeholders.

The history of health research makes it clear that the relationships between researchers and other stakeholders have not always been characterised by such attributes (Annas & Grodin, 1998; Brandt

1978; Kim, 2012). Increasing realisation of and abhorrence for exploitative practices in health research have resulted in a proliferation of ethics guidelines to ensure the ethical conduct of health research over the past half century. These include the Nuremberg Code (1947), the various iterations of the Declaration of Helsinki (most recently in 2013), and the Council for International Organisations of Medical Sciences (CIOMS) Guidelines (most recently revised in 2016).

The CIOMS (2016) ethics guidelines for humans in health research call for 'community engagement' in health-related research. They state:

> Researchers, sponsors, health authorities and relevant institutions should engage potential participants and communities in a meaningful participatory process that involves them in an early and sustained manner in the design, development, implementation, design of the informed consent process and monitoring of research, and in the dissemination of its results. (CIOMS, 2016, p. 25)

'Community' is defined broadly by these guidelines, as various sectors of society that may have a stake in research. The CIOMS guidelines (2016) also advise that gatekeeper permission should be sought if considered necessary, prior to the conduct of a clinical trial. Such permission would be necessary if the trial "substantially affects …. organisational interests" and if there is an identifiable gatekeeper (who may be an individual or a committee or council of some kind) who has the "legitimate authority" to make decisions on behalf of the organisation or community (p. 80).

2.3 HEALTH RESEARCH IN SOUTH AFRICA

Health research is a vital component of health and health care in South Africa. The most outstanding example of how health research has benefitted South Africans is that of HIV research, where treatment modalities have been developed that have transformed a disease that was a death sentence two decades ago to a chronic disease that can be managed at a primary care level (Antiretroviral Therapy Cohort Collaboration, 2017). The centrality of health research to the field of health care is acknowledged by the current National Minister of Health, Dr Aaron Motsoaledi, in his foreword to the revised 'Ethics in Health Research: Principles, Processes and Structures' (NDoH, 2015).

South Africa is highly active in health research, both in the private and the public sector (Paruk, Blackburn, Friedman, & Mayosi, 2014). Between 1991/2 and 2009/10, government expenditure on

health research rose from 1.9% of GERD[1] to 3.5% (Paruk et al., 2014). Much of this health research takes place in public health facilities, especially research on diseases such as HIV and tuberculosis, which affect mainly the poorer parts of the population, who depend on the public sector for their health care (Keeton, 2010).

In South Africa, there are several factors that may undermine the establishment of equitable relations between health researchers and key stakeholders. These include its colonial and Apartheid history of racial exploitation including in research (Baldwin-Ragaven, London, & De Gruchy., 1999); therefore the potential for research to be, or at least to be perceived as, exploitative, is perhaps higher in South Africa than in many other countries. In addition, the profound income inequality in South Africa (Leibbrandt et al., 2010) may exacerbate the existing imbalances of power in research relationships, where researchers may already be perceived to be part of a social elite (Benatar 2002; Christakis, 1992). In post-Apartheid South Africa, many sectors of society continue to experience marginalisation and exclusion (Netshitenzhe, 2013). There is also the inherent imbalance of power between the researcher, who has by definition vast knowledge about his/her subject, and the research participant, who almost always has less (Benatar, 1998).

Thus in South Africa, this imbalance of power, real or perceived, may extend to the relationship between researchers, and the health managers (and staff) of government facilities where much health research takes place. These health managers arguably have crucial roles to play in the research process, from conception of study questions (where they might provide valuable insight into the most current and relevant issues facing health and health service delivery), to providing access to health facilities, patients and data (their 'gatekeeper' role), to the conduct of research (where they might facilitate the smooth implementation of research projects), to the utilisation of research results (where they might be instrumental in using results to inform health policies and protocols, and improve service delivery). The interaction between researchers and health managers therefore may have an impact on all of these stages in the research process.

2.4 ETHICAL-LEGAL FRAMEWORK FOR HEALTH RESEARCH IN SOUTH AFRICA

In South Africa, health research is governed by the *National Health Act* (no. 61 of 2003) (Republic of South Africa, 2004). This defines health research as any research:

[1] GERD is the "gross expenditure on research and development".

> which contributes to knowledge of (a) the biological, clinical, psychological or social processes in human beings; (b) improved methods for the provision of health services; (c) human pathology; (d) the causes of disease; (e) the effects of the environment on the human body; (f) the development or new application of pharmaceuticals, medicines, and (g) the development of new applications of health technology. (Republic of South Africa, 2004, p. 12).

According to the NHA (Republic of South Africa, 2004), all health research must be reviewed by a REC registered with the NHREC.

In KwaZulu-Natal, the province in which this study was conducted, health research is further governed by the *KwaZulu-Natal Health Act* (no. 1 of 2009). This Act provides for the establishment of the KwaZulu-Natal Provincial Health Research and Ethics Committee (KZN PHREC) and for the composition of the Committee, which must include representatives from the Department of Health as well as from research and academic organisations. The *KwaZulu-Natal Health Act* outlines the responsibilities of the Committee, which include setting health research priorities for KZN, reviewing and if appropriate approving proposals for research conducted in provincial health facilities (or with patients recruited from these facilities), reviewing research reports and ensuring that the research conducted "promotes health, contribute(s) to the prevention of communicable or non-communicable diseases or disability or result(s) in cures for communicable or non-communicable diseases" (p. 18). The regulations to the *KwaZulu-Natal Health Act* further provide, inter alia, for the review of applications to conduct clinical trials in provincial health facilities by the Pharmaceutical Services component of the KZN Department of Health (Section 12.4.(c)).

The KZN PHREC does not review each research application as a committee, but delegates the authority to approve observational research to the Chair of the committee, provided that applications have the support of the facility, district or programme manager concerned (the first level 'gatekeeper') as evidenced in a letter of support, as well as provisional REC approval. Once all these documents have been received in good order, the KZN PHREC issues a letter of permission to the researcher, thus acting as a second level 'gatekeeper' in the process. The researcher then sends this letter back to the REC concerned, upon receipt of which the REC issues the letter of final approval. The process for clinical trials is slightly different; due to their more complex nature, clinical trials are required to be approved by the Head of the KZN Department of Health and, in addition to the facility support letter, undergo review by relevant managers within the KZN Department of Health (KZN DoH, 2017). All research applications must be loaded onto the National Health Research

Database, which was established by the SA National Department of Health in 2014 and is managed on its behalf by the Health Systems Trust.

The conduct of all health research in South Africa is also governed by the National Department of Health's 'Ethics in research: principles, processes, structures' (NDoH, 2015). These ethics guidelines assert that "role player engagement" (NDoH, 2015, p. 16) is a key ethical norm and standard. These guidelines assert that:

> researchers should engage key role players at various stages of planning and conducting research to improve the quality and rigour of the research, to increase its acceptability to the key role players, to harness role player expertise where possible, and to offset power differentials where these exist. Engagement efforts may comprise of various activities, including awareness-raising initiatives for role players, including but not limited to participating communities. (NDoH, 2015, p. 16)

The main aim of these documents is the protection of participants in health research projects, and they outline key norms and standards in order to achieve this aim. However, despite recommendations in national ethics guidance, the research process is arguably also affected by the 'ethos' of health research, "that is, the visions and projects that orientate and direct the discourses and practices of different actors and groups, in different places, situations and periods" (Geissler 2011, p. 3). The ethos of health research is shaped by context, which in turn depends on historical, political, economic and sociological influences (Geissler 2011). Thus in spite of numerous international and local guidelines, and pieces of legislation governing the ethical conduct of research, the process of conducting research might be dependent at least in part on the perceptions and practices of stakeholders in the research process, and the relationships between them.

2.5 RELATIONSHIPS BETWEEN RESEARCHERS AND MANAGERS OF HEALTH FACILITIES OR PROGRAMMES

Researchers and managers of public health facilities make direct contact at several stages of the research process. At each stage, their attitudes or perceptions may affect the quality of the relationship between them, and thus may impact on the success or otherwise of the research itself. Frequently, the first of these contacts is at the time when researchers apply for permission to access a community or facility in order to conduct research (Campbell et al., 2006).

In KwaZulu-Natal, this permission is provided by the manager of the facility, district or programme in their capacity as 'gatekeeper'. 'Gatekeepers' in the context of research can be defined as "authorised signatories of the institution that hosts the intended research participants" (Singh & Wassenaar, 2016, p. 42). The right of gatekeepers to allow or refuse the conduct of research in their facilities is recognised by South African RECs (Singh & Wassenaar, 2016). For example, the Biomedical Research Ethics Committee of the University of KwaZulu-Natal (BREC) does not generally issue full ethics approval for research projects until permission has been received from the KZN PHREC (Singh & Wassenaar, 2016). Similarly, the KZN PHREC itself does not issue its letter of permission without the facility manager's letter of support (KZN DoH, 2017). The relationship between health managers and researchers may influence health managers' willingness to provide approval and subsequent access to the site, and such relationships are therefore likely to be vital for the conduct of research.

2.6 RELATIONSHIPS BETWEEN RESEARCHERS AND HEALTH MANAGERS AS 'GATEKEEPERS'

The relationship between health researchers and managers of health facilities as 'gatekeepers' has been somewhat neglected in the stakeholder engagement literature, both internationally and in South Africa. Much has been written about how participating communities, from which research participants are drawn, should be engaged by researchers, their capacity built, their concerns addressed and how they should negotiate research-related benefits with funders and researchers (Folayan et al., 2015; Kamuya et al., 2014; King, Kolopack, Merritt, & Lavery, 2014; Koen, Essack, Slack, Lindegger, & Newman, 2013; Musesengwa et al., 2017; Musesengwa & Chimbari, 2016; Tindana et al., 2007). There is also an increasing body of literature where researchers are publishing their approach to stakeholder engagement; notably, the engagement of community stakeholders around research projects is described as being more difficult and complex than is commonly depicted in the engagement literature (Kolopack, Parsons, & Lavery, 2015).

Similarly, guidance exists on the role of RECs in the research process, and how these can provide oversight of the research itself (Kruger, Ndebele, & Horn, 2014: UK Research Integrity Office, 2008) and how research teams should carefully engage RECs as a key stakeholder in their research (Wassenaar & Rattani, 2016). However, the relationship between (and respective perceptions of) researchers and health managers as 'gate-keepers' appears less frequently in the literature around health research. This is an important gap in efforts to achieve the collaborative partnerships in health research that are necessary to realise the full value of such research.

As stated above, the relationships between researchers and 'gatekeepers', and the relevant attitudes, have received some attention in the health research literature, but more in the areas of social work and education research. In several such papers, authors emphasise that negotiating access through 'gatekeepers' can be a complex and difficult process. One author even titled her research methods case study 'Gatekeepers: People who can (and do) stop your research in its tracks' (Ahern, 2014). Other authors describe their encounters with 'gatekeepers' as emotional and difficult (Peticca-Harris, de Gama, & Elias, 2016), and the researcher-gatekeeper relationship as unstable and inconsistent (Sanghera & Thapar-Bjorkert, 2008).

Several authors do suggest ways in which their relationships with 'gatekeepers' can become less fraught and their engagements more productive. For example, in the field of social work research, one study investigated researchers' perceptions of gatekeepers' motivations in the United Kingdom (Clark, 2011). Their study aimed to explore, through in-depth interviews, researchers' perceptions of the motivations of social workers, acting as 'gatekeepers', to engage with the research process. It found that 'gatekeepers' were more likely to engage with researchers if they felt that their views were appropriately represented, if they felt that they had a moral responsibility to engage, and if they felt that the research project itself would be useful to them. Another study explored the relationship between 'gatekeepers' and socially excluded communities, living in a low income housing estate in the north of England (Emmel, Hughes, Greenhalgh, & Sales, 2007). This study looked at ways in which 'gatekeepers' might facilitate or impede the access of researchers to socially excluded communities. It found that trust between 'gatekeepers' and the communities they 'protected' was a central issue in negotiating access by researchers to these communities.

A study in the field of health care (regarding obtaining access to staff and facilities for a primary study on safety in surgical operations) found that 'gatekeepers' (managers of the facility) may act as champions of the research project if they perceive that the research is important for the institution (Høyland, Hollund, & Olsen, 2015). In addition, there are several studies that comment on the 'gatekeeper' role, even though the stakeholders described are not explicitly labelled as such. For example, a paper describing the events around stoppage of the Tenofovir trial in Cambodia by the then Prime Minister Hun Sen, illustrated the importance of regular, effective and transparent communication with national government authorities around research projects (Upkong & Peterson, 2009). This paper illustrated that national government gatekeepers may find it necessary to block or stop research that they have concerns about, whether these concerns are justified or not.

In order to ensure that ethical and scientifically sound research takes place, healthcare authorities should be active and equal participants in the discussions around research, and its implementation and uptake (UNAIDS/AVAC, 2011). There is no empirical research investigating the relationships between researchers and health managers as 'gatekeepers' in public health facilities, in KwaZulu-Natal.

2.7 RELATIONSHIPS BETWEEN RESEARCHERS AND HEALTH MANAGERS AT LATER STAGES OF RESEARCH

Health managers do not only act as 'gatekeepers' by providing their approval for researchers to access sites for research participants. Once access to a health facility has been obtained, researchers and health managers may come into frequent, almost constant contact whilst the research is being conducted. Importantly, researchers and health managers also make contact at the stage of dissemination and utilisation of research results. Although authors acknowledge that, even in high-income countries, research results are often "imperfectly incorporated" into practice, they also emphasise the importance of this stage (Emanuel et al., 2004). Unless research results are made known to service providers and policy makers, creating opportunities to put the results into practice, the impact of research on health service delivery and on health itself may never be realised, rendering futile the investments that the research process entails. The importance of this stage in the research process is widely recognised and a myriad of tools have been developed to facilitate it (Wilson, Petticrew, Calnan, & Nazareth, 2010). Indeed, this stage of the research process has developed into a distinct entity ('knowledge translation') which has generated a vast body of literature and research (Armstrong, Waters, Roberts, Oliver, & Popay, 2006; Davis et al., 2003; Grimshaw, Eccles, Lavis, Hill, Squires, 2012; Oborn, Barrett, & Racko, 2010). However, in spite of this, commentators have argued that it remains poorly done in South Africa (Senkubuge & Mayosi 2013).

The relationship between researchers, managers and policy makers in the final stage of the research process (the knowledge translation stage) has been discussed by some authors, albeit seldom through empirical research. Armstrong et al. (2006) explored the theoretical foundations of how knowledge is translated into action, and proposed six models that describe varying degrees of involvement of policy makers and managers in knowledge production. They emphasised that knowledge is best used to inform policies and practice when policy makers and planners are directly involved in research, from the development of the research question, to the incorporation of results

into policy and practice. Ward et al. (2010) developed guidelines for stakeholders in the United Kingdom around the translation of knowledge into action, and emphasised the importance of context, and individual beliefs and attitudes, in the process.

A study conducted in Kenya, explored the views of health policy makers and implementers (several of whom would also meet the definition of 'gatekeepers') on what type of research should be conducted, and how the benefits of such research should be used by stakeholders (Lairumbi et al., 2008). In- depth interviews were conducted with stakeholders, using two case studies as the basis for discussions. The study found that government officials felt that they had little power in determining the research agenda, were often excluded from discussions around the research, including at the dissemination stage, and because of these factors, found it difficult to use the research results to influence policy and practice (Lairumbi et al., 2008). Aside from this study, there appears to be little empirical research on the relationship between public health facility stakeholders, and researchers themselves, and the perceptions and practices of these two groups, in low-resource settings. This lack of data may undermine efforts to improve relationships and to address the causes of negative perceptions where these exist.

2.8 SUMMARY

In summary, health research is necessary to make advances in understanding of disease aetiology and processes, the development of treatments and of ways to deliver these treatments. Health research is a complex field involving a wide range of actors with diverse interests and priorities (UNAIDS/AVAC, 2011). In order for the smooth conduct of research and for research results to be accepted and utilised, it is important that the relationships between research stakeholders are collaborative. Recent international ethical guidelines (CIOMS, 2016; UNAIDS/AVAC, 2011) and national ethical guidelines (NDoH, 2015) increasingly call for researchers to pro-actively engage key stakeholders in order to enhance the rigor of the research. There is an increasing amount of literature exploring how health researchers engage representatives of the participating-community (Kolopack et al., 2015). There has been less empirical research exploring the relationship between researchers and health managers who control access to potential health research participants, and who might use the results of health research. It is important that the perceptions and practices of researchers, and the managers of public health facilities and programmes in South Africa, be explored, in order to facilitate sound research in such settings. This study attempts to begin this

process by exploring perceptions and practices of these two stakeholders in public health facilities in the province of KwaZulu-Natal.

CHAPTER 3

STUDY AIMS AND METHODOLOGY

This chapter outlines the study aims, the methods used and the paradigm in which the study was located. Ethical considerations are also set out.

3.1 STUDY AIMS

The major objective of this study was to explore the perceptions of key stakeholders regarding health research conducted in in public health facilities in the province of KZN, in order to improve the conduct of research and utilisation of research results in KZN. Specific aims were:

1. To explore the perceptions and practices of key stakeholders related to research conducted in provincial public health facilities, including processes around its planning, approval, conduct, dissemination and impact
2. To explore the perceptions and practices of key stakeholders regarding inter-stakeholder relations
3. To make recommendations to strengthen the ethical conduct of such research, including implementation and uptake of research results, and inter-stakeholder relations

3.2 STUDY APPROACH

3.2.1 QUALITATIVE STUDY DESIGN

A qualitative approach was chosen for this study because qualitative methods enable the description, exploration and explanation of phenomena being studied (Ploeg 1999); this was therefore considered the most appropriate approach to obtain the in-depth data required to answer the study aims. This study was broadly located in an interpretivist perspective, which focuses on practices, subjective meanings that are attached to practices, and the context in which these practices take place (Fossey, Harvey, McDermott, & Davidson, 2002).

3.2.2 REFLEXIVITY

Qualitative researchers are encouraged, as part of a commitment to reflexivity, to describe their training (Malterud, 2004), their personal and professional experiences of the subject matter (Malterud, 1993), and any pre-conceptions or initial beliefs about the subject matter (Elliot, 1999). I joined the KwaZulu-Natal Department of Health in 2011 as Manager of the Epidemiology, Health Research and Knowledge Management Units, and was nominated by the then Head of Department to establish and chair the KwaZulu-Natal Health Research and Ethics Committee (KZN PHREC) (which is responsible for providing approval for the conduct of research in provincial public health facilities).

By virtue of these positions, I had encountered (anecdotally) competing views on ethics and research ethics, which I needed to understand and manage. There seemed to be significant tensions in the relationships between stakeholders of health research in the province, specifically between researchers, and the managers of public health facilities and health programmes. On the one hand, these managers had voiced their concerns that researchers seldom engage with them on the research they are conducting in 'their' health facilities, including in giving them feedback on research results. On the other hand, researchers had complained about the lengthy and onerous research application process, particularly the process of applying to conduct clinical trials. I was of the view that, while there was some understanding of the broad concerns, a much more detailed understanding was required of the perspectives of these two stakeholder groups, in order to facilitate a more productive research process for those concerned.

I have some experience with conducting research myself, namely through a Masters in Public Health (Lutge & Muirhead 2005), a Fellowship in Public Health and a PhD in Epidemiology (Lutge, Lewin, & Volmink, 2014; Lutge, Lewin, Volmink, Friedman, & Lombard, 2013). Whilst most of this research was quantitative, the PhD included some qualitative components that were central to the study (Lutge et al., 2014). My PhD examined the effect of a material incentive on the adherence of patients with TB to their treatment. The qualitative components explored the perceptions of facility managers, programme managers and patients regarding the incentive – the practicalities of how it was administered and utilised, and the more philosophical arguments around the merits of 'paying people' to behave in a healthy way. Incidentally, I followed the same application process to obtain permission to conduct this PhD study, as researchers do currently in KZN.

I also manage two Department of Health units (Research and Epidemiology). The Research unit acts as the secretariat for the Provincial Health Research and Ethics Committee, providing the final permission from the Department of Health for researchers to access health facilities to collect data. Therefore, I had some experiences that resonated with the views expressed anecdotally by both groups of stakeholders. However, I was concerned that neither of these groups seemed willing to spend the time or make the effort to understand the other party, and I was of the view that a detailed exploration might shed light on their perspectives. I was aware of my strongly held belief that research is crucially important for health and development in South Africa, and in the province. I also knew I would need to be cautious that I did not favour the viewpoints and imperatives of researchers over those of health managers. Whilst conducting this study I attempted to be open to all points of view, and explore concerns and perspectives even-handedly.

3.2.3 SAMPLING

Interviewees were selected purposively, that is, participants whom it was thought would provide rich and relevant information for the study, were approached preferentially to participate (Gentles, Charles, Ploeg, & McKibbon, 1999). Managers from health facilities where research was regularly and recently hosted were invited to participate. Also, currently active researchers, who were employees of the KZN Department of Health, as well as those who worked in organisations external to the Department, were invited to participate. Snowball sampling (defined as the identification of new participants through existing participants) (Atkinson & Flint 2001) was not used; and was not necessary to secure adequate enrolment.

Eighteen interviews in total were conducted – eight with health managers, and ten with researchers. There was only one refusal to participate; the person expressed concerns about time constraints.

3.2.4 DATA COLLECTION

Instrument: A semi-structured interview schedule was used for data collection. There were outlines of the major domains that should be covered in the interviews, but allowance was made for the interviewer to probe issues raised by respondents, and to explore issues considered to be important and relevant to the study (Britten, 1995). After conducting interviews with two interviewees (one health manager and one researcher), the interview schedule was very slightly modified (Tong et al. 2007). That is, more prompts were added on issues around the conceptualisation of the research

question, because this was identified by one interviewee (a health manager) as a significant deficit. Also more prompts were added on the accessibility of health managers to discuss issues around research, because this was identified by another interviewee (a researcher) as a major deficit. These minor modifications to the prompts did not alter the scope of the ethically approved study, and were in line with the iterative nature of qualitative research (DiCicco-Bloom & Crabtree, 2006).

The domains of the interview schedule included the following:

- Demographic and background information such as their role in organisation and their experience with research
- Views around the importance of research, both generally and for KZN in particular
- Perceptions around the benefits of research
- Perceptions on their relationships with researchers or health managers (depending on their own positions) at various stages in the research process
- Factors perceived to undermine research
- Factors perceived to facilitate research
- Factors perceived to affect the relationship between health managers and researchers.
- Recommendations for how research could be improved
- Recommendations for how relations could be strengthened.

Procedure: The principal investigator telephoned potential participants in order to explain the study and invite them to participate**.** If there was interest, the principal investigator emailed them the study informed consent form and information sheet (see Appendix 1), as well as a sample of the interview guide (see Appendix 2 and 3), and an offer to discuss any aspect of the study with them. After potential participants had emailed their interest in participating, a time and place for the interview was scheduled. Interviews usually took place in the participants' own offices. Upon meeting, the study was explained again to each participant, and an opportunity given to them to re-read the informed consent form and information sheet, to ask questions and to clarify areas that were not clear (Turner, 2010). This was considered important given empirical data that time in discussion is a useful method for enhancing participants' understanding of a study (Flory & Emanuel, 2004). Participants were also asked if they would give permission for the interview to be audio-recorded. On agreement, the informed consent form, giving consent for both the interview and the recording, was signed. Only one participant refused permission for the recording, and in this case detailed notes of the interview were taken (DiCicco-Bloom & Crabtree, 2006).

All interviews were face to face and conducted by the principal investigator. All interviews were transcribed verbatim by a study transcriber, assisted by the principal investigator. Transcripts of interviews were analysed on an ongoing basis, during data collection, so that points of importance that should be explored in further interviews, and the point of data saturation could be identified (Thorne, 2000). When no new themes were being identified (i.e. when data saturation had been reached) (Guest, Bunce, & Johnson, 2006) the researcher stopped approaching potential participants for interviews.

3.2.5 DATA ANALYSIS

Thematic analysis was undertaken in this study. Thematic analysis has been defined as a "method for identifying, analysing and reporting patterns within data" (Boyatzis, 1998, in Braun & Clarke, 2006, p. 79). It supported the interpretivist approach adopted (Braun & Clarke, 2006), and was feasible for the principal investigator who was relatively new to qualitative research and was able to build on the "core skills" of qualitative research through this methodology (Braun & Clarke, 2006, p. 4).

Thematic analysis involved the following steps:

Firstly, segments of text that encapsulated points or issues relevant to the study aims were coded, i.e. assigned a phrase that reflected their meaning and relevance to the study. Coding was both deductive, in that codes were developed 'a priori' based on the literature, such as the Good Participatory Practice Guidelines for Biomedical HIV prevention trials (UNAIDS/AVAC, 2011), and inductive, in that they emerged from engagement with the transcripts (Stuckey, 2015). For example, the phrase '*Unfortunately patients involved in clinical research get better care than patients [who] aren't*' was assigned the code 'Better care: superior to usual care'.

Secondly, codes, together with their illustrative fragments of text, were grouped together in code clusters or sub-themes (Green et al., 2007). Here, codes that shared a relationship were grouped into coherent clusters (Green et al., 2007). For example, the code '*Better care: superior to usual care*' was grouped with other similar codes into the sub-theme '*Value for enrolled participants*', which in turn was grouped into a main or master theme entitled '*Varying perceptions of 'social value*'.

Thirdly, theme tables were used to organise master themes, which contained various sub-themes, which in turn contained 'related' codes grouped into these sub-themes, as well as data extracts for

each code with interviewee identifiers. Fourthly, a narrative was drafted from each master theme table. These narratives formed the basis of the results reported in this study. The themes were described in the results, where more detail was given on the meaning of each theme, and illustrated by the text fragments (data) that supported the construction of the themes. Individual themes were described, using sub-themes to give explanatory detail, and the connections between themes were also described (Braun & Clarke, 2006).

The list of codes is attached as Appendix 4.

3.3 STUDY QUALITY

Due to the flexible nature of qualitative research, the application of a single set of criteria to ensure quality may be difficult (de la Cuesta Benjume, 2015). However, a stronger and more universally accepted set of criteria has been developing over the past few decade (Cameron, 2011). Whilst the term 'rigor' is often used to describe the quality of quantitative research, the term 'trustworthiness' is generally preferred when describing the quality of qualitative research (Cameron 2011). In order to ensure the trustworthiness of qualitative research, four criteria have been outlined (Cameron 2011; Shenton, 2004). These are: credibility (are the study findings a sound representation of participants' responses?); transferability (can the findings of the study be applied in other settings?); dependability (if the study were undertaken in the same context with the same participants, would similar results be obtained?) and confirmability (do the results of the study reflect the perspectives of the participants, as opposed to those of the researcher?) (Cameron 2011; Shenton 2004). Efforts to ensure a high quality of research in this study are described under each of these criteria below.

3.3.1 CREDIBILITY

Well established research methods were used in this study (Braun & Clarke 2006). In-depth interviews, analysed through Thematic Analysis, are well described methodologies in the field of qualitative research and there are many guiding documents which assist the researcher in applying these methods (Aronson, 1995; Boyatzis 1998; Braun & Clarke, 2006; Gentles et al., 2015; Green et al., 2007; Guest et al., 2006, Ploeg 1999; Shenton 2004). The researcher had some experience in conducting qualitative research as a sub-component of her PhD. Also, several transcripts were coded independently by both the principal investigator and the supervisor. Because inter-rater reliability checks are not considered appropriate for the interpretivist approach (Yardley, 2008), coding

differences were resolved by discussion (Boyatzis, 1998). The codes so developed were used as the basis for coding later transcripts.

Furthermore, it was in no way communicated to participants that they would be 'worse off' if they did not participate in this study (which would have been coercive) (Emanuel et al., 2004). Participants were assured of anonymity, to increase the likelihood they would be sincere and honest in their interviews, with less social desirability (Lindegger & Richter, 2000). Questions were re-phrased in the interviews, and clarity requested when necessary, in order to ensure that the information given by participants was correctly understood by the researcher.

In addition, the researcher (who also conducted the interviews) reflected on her own role in the study throughout, and the effect of her personal experience on the conduct of the interviews and the interpretation of the data, in an effort to improve the quality of the research (Palaganas, Sanchez, Molintas, & Caricativo., 2017). Also, views that were opposite to those generally expressed in the interviews were highlighted to ensure that they added depth and value to the analysis (Tong et al., 2007). For example, the following quote from a researcher was directly opposite to what most health managers felt, *'..so there is no way it (research) detracts (from service delivery). It… definitely makes health care better…'*

Lastly, the results of the other studies in the field were examined and it was found that the results of this study resonated with these (notwithstanding the fact that many of these were in fields other than health) (Campbell et al., 2006; Clark 2011; Høyland et al., 2015).

3.3.2 TRANSFERABILITY, DEPENDABILITY AND CONFIRMABILITY

Although transferability is not the main aim of qualitative research, it is useful to reflect on the extent to which the study findings might be applicable in other contexts (Shenton, 2004). The sample and methodology of the study have been described in sufficient detail (in Chapter 4) for others to judge their utility in other contexts (Green et al., 2007). It is possible that these findings might be useful in other settings that share similarities, such as in other provinces in South Africa. All other provinces have provincial health research committees, which provide final approval for researchers to conduct their research in public health facilities. Because the context of many of these provinces is similar to KZN, it is likely that some of the findings of this study will be useful in these provinces.

Also, interviewees were drawn from a variety of research organisations and public health facilities in the province, thus ensuring a range of perspectives and views were canvassed (Braun & Clarke, 2006). The data collection methods used were well known and well described, and responsibly applied in this study (Gill, Stewart, Treasure, & Chadwick, 2008). Data was collected over the period of a year, aiming for representivity over time as well as over a number of organisations (Shenton, 2004).

Efforts to ensure credibility also tend to support dependability in a study (Shenton, 2004), but in addition a clear description of the design and methods of the study, as well as a reflection on the researcher's own role in generating the results of the study, are presented in this chapter. In terms of confirmability, the researcher has made efforts to identify and articulate her own prior experiences, and pre-existing ideas, and the effect of this on the analysis and interpretation of the data, throughout this study (de la Cuesta Benjume, 2015).

3.4 ETHICAL CONSIDERATIONS

According to the *National Health Act* (Republic of South Africa, 2004), all health research in South Africa must be approved by an REC registered with the NHREC. This study was approved by the Biomedical Research Ethics Committee of the University of KwaZulu-Natal (reference: BE346/16). Permission to conduct the study was also given by the KwaZulu-Natal Department of Health (reference HRKM333/14) (see Appendices 5, and 6 respectively).

Anonymity: No names were recorded in this study, and no individuals nor individual research organisations, or health facilities were identifiable. In terms of storage of data, all data (hard copies of transcripts as well as electronic copies of transcripts and electronic recordings of interviews) were stored safely in locked drawers in the office of the principal investigator, and on the password-protected computer of the principal investigator.

A potential conflict of interest was managed in the following way: Because the principal investigator is involved in the approval of health research projects conducted in provincial health facilities or involving patients of the provincial Department of Health, this issue was discussed with potential interviewees, who were assured that their refusal to take part would not jeopardise the approval of their research proposals, and interviewees were assured that any views they expressed would not

affect their research proposals. The researcher was also alert to the potential for interviewees to express socially desirable views (Collins., Shattell & Thomas, 2005). In order to reduce social desirability bias, the principal investigator requested participants before the interviews to give honest answers; to enhance the likelihood that the results of this study might be used to improve the research process in KZN.

In terms of informed consent, the study was discussed with potential interviewees (who were given opportunity to ask questions and raise concerns) so that their understanding of the study could be ensured (CIOMS, 2016, Guideline 9; Declaration of Helsinki, 2013, articles 25 to 32). Once 'enrolled', interviewees were able to 'opt out' of answering questions if they so wished. In terms of payment, participants were not paid for their expenses because they did not incur any expenses. They were also not paid for their time, and this approach to payment was approved by the REC (National Health Research Ethics Council, 2012).

Feedback on preliminary results to stakeholders has already been given, through the Research Day held by the KZN Department of Health in 2016, which was attended by managers in the Department and researchers working in the province. Feedback to stakeholders in the future will also be given, by posting summaries of the study onto the web page of the Health Research and Knowledge Management Unit of the KZN Department of Health, and using them as a basis for discussion at the next provincial research prioritisation meetings (due to take place in 2018). Feedback to individual interviewees will be provided by emailing summaries of the study to them and discussing these in person if so desired.

3.5 STUDY LIMITATIONS

Participation of health managers in this study was confined to middle and lower managers within the KZN Department of Health. The highest rank of manager invited to participate was the Director level. That is, higher-level managers (e.g. Chief Directors, Deputy Directors General) were not invited to participate. This sample selection was intentional. Only managers who had direct involvement with researchers at their health facilities or in their programmes, and who played prominent 'gatekeeping' roles in the researcher-health manager relationship, were invited to participate. More senior managers who do not play the role of 'gatekeeper' were omitted from this study. However, because the latter do play an important role in translating research findings into policy and practice,

the omission of more senior managers may have diminished the richness of data on the latter phase of research, as well as the breadth and variety of views obtained for this study.

Similarly, health workers at operational level were not invited to participate. Although again this omission was intentional, it may have resulted in loss of detail around relations between researchers and health workers 'on the ground'.

Similarly, researchers who were active in conducting research at KZN Department of Health facilities were invited to participate. More senior members of research organisations (such as Directors and Chief Executive Officers) were not invited. Again, this may have resulted in the loss of important viewpoints which may either have reinforced the views of those selected, or added a variety of divergent views. In addition, members of the PHREC involved in the approval of research conducted in provincial health facilities were not sampled. As an important level of gatekeepers in KZN health research, this would be a useful addition to the sample in future research.

Although interviewees were asked to give honest views, and not to be constrained by the fact that the principal investigator was also the manager of the Research Unit at the KZN Department of Health, it is possible that they refrained from making critical comments that referred directly to the principal investigator herself, confining themselves to more general issues, or issues not relating directly to the principal investigator.

A further limitation is that document analysis (Bowen, 2009) was not conducted for the purposes of this study. Documents such as the operational guidelines of the KZN Provincial Health Research and Ethics Committee (KZN DoH, 2017), and even minutes of meetings of the KZN PHREC, may have yielded new codes not captured in the interviews, and generated new insights into the issues being explored.

Finally, respondents were not given the transcripts of their interviews for review, in order to confirm that the transcripts were a true reflection of their perceptions. This approach was not adopted and may have reduced the confirmability of this study.

CHAPTER 4

RESULTS

In this chapter, the sample is briefly described and the results of the study are reported. The results are structured according to the dominant or 'master' themes that emerged, informed by several minor or sub-ordinate themes.

4.1 SAMPLE CHARACTERISTICS

Eighteen (18) participants agreed to take part in this study. All but one respondent agreed to their interview being tape recorded and for the one respondent who refused, detailed notes were taken of the interview and used in the analysis. Eight (44%) of participants were managers of hospitals or health care programmes within the KwaZulu-Natal Provincial Department of Health. Seven (39%) were researchers employed by independent research organisations or by academic institutions. Three (17%) were physicians employed by the KwaZulu-Natal Provincial Department of Health who were active in the field of health research and had conducted research within the year prior to this study. Eight (44%) of the participants were female and all participants were between the ages of 40 and 67 years.

All researchers and physicians were currently active in research in KZN and had conducted research projects in public health facilities in the province within the year prior to the study. The institutions from which they were drawn varied from large ones, with strong national and global reputations, to small and lesser known organisations. All managers were drawn from research-active health facilities or programmes and had acted as 'gate-keepers' for researchers to access participants or their data in the year prior to the study. The 'gate-keeping' function entailed providing researchers with letters of support, confirming that they were willing to host the research in their institutions or programmes. This letter of support would be forwarded to the KZN PHREC, together with the research protocol and letter of provisional ethics approval. If all documents were in order, the study would then be given final permission by the PHREC.

Results are presented according to the three major themes which emerged from the analysis of interview data about research in public health facilities in KwaZulu-Natal. These are:

1. Varying perceptions of 'social value'

2. Strained inter-stakeholder relations
3. Strengthening research and relations.

Because this was an exploratory qualitative study, the exact number of interviewees holding a certain view was generally not reported (Marshall, 1996); instead, the reporting convention of 'some', 'many', 'most' or 'all' was generally used. Quotes from the interview transcripts are given verbatim. The notation ' …. ' has been used to show pauses in the interviewees' speech, and (…) has been used to show where words from the transcript were omitted. Where inserting a word helped to make sense of the quote, inserted words are given in square brackets [].

4.2 THEME 1: VARYING PERCEPTIONS OF SOCIAL VALUE

This major theme sets out how researchers and health managers perceived the value of research differently. This theme emerged as critically important during the analysis, not only as an 'independent' theme which conveys the varying perceptions of interviewees around the value of research in KZN, but also as one that had an important impact on the other major themes; that is, differing perceptions of the social value of research may have impacted on the perceived quality of inter-stakeholder relationships (Theme 2), and enhancing the perceived social value of the research for those involved was perceived as an important step towards improving stakeholder relations and enhancing the research process in KZN (Theme 3).

All interviewees perceived that health research in KZN did have social value – that is, that it was inherently important and had the potential to improve health and health care, as this researcher and health manager say:

> *[Health research is] extremely important. I think it makes [a] massive difference to public health.* (Interview 2; Physician researcher).

> *We have benefitted directly as a province. Clinical outcomes have improved as a result of research – these improvements we can prove are as a result of research.* (Interview 6; Health manager)

However, interviewees varied in their perceptions of what it was that made research valuable, and therefore for whom the research was valuable, and this variation tended to correspond with their roles in the research process. That is, the elements of research perceived as most valuable tended to

vary according to the role or stakeholder position of the interviewee. More specifically, most researchers tended to perceive the social value of research in provincial health facilities as residing in its contribution to knowledge, and in its value to future beneficiaries through its effect on policies, guidelines and clinical protocols, as exemplified in the following quotes:

> *I mean, we're in the business of providing evidence that will inform policies and decisions so it's critical.* (Interview 3; Researcher)

> *So there's multiple studies we've had … that have made not only local changes … but also changes to international guidelines.* (Interview 5; Researcher)

> *Ok we have had a number of standout things happen with research here. … We've have been involved in multi-national observational work … which basically has resulted in a new clinical entity being described … in periop[erative] medicine.* (Interview 2; Physician researcher)

> *Oh certainly it's very important. … and for many reasons … our province is … I think has one of the highest threats or prevalences of infection … So I think the population in this province need to improve on health aspects and this can only be achieved if we do research.* (Interview 4; Physician researcher)

> *And the only reason you can make decisions like that is by having your decisions being evidence based, not impartial [sic], totally above reproach - you can only do that when you have a good summary of evidence … to say well this is not my emotion, you know my whim, but this is best for the people.* (Interview 15; Researcher)

Some health managers also tended to value the contribution of research to improvement of clinical protocols and guidelines, but rooted this value in the beneficial impact on KZN specifically. They valued the contribution of research to their health systems issues, in helping the Department develop practical interventions for problems, and as the third quote in this paragraph shows, tended to emphasise this over the contribution of research to new knowledge.

> *Overall we need it and that is how we can go on as a health system… trying new things and seeing what can work better than what we have, it's a positive thing.* (Interview 1; Health manager)

Our service will get more quality so we need to know the gap because wherever we are we have a gap, we have a weakness. So we need to find our gap, our weakness so that, that is by the analyses of ... Doing more research so that we can get more implementation of research projects that is my belief. (Interview 8; Health manager)

… research should be used for action - some sort of action so I answer that with some reservation in the sense that if there is research being done there must be something that comes out of it apart from simply understanding something better … there must be a short term or long term impact for the Department of Health in general. (Interview 7; Health manager)

Some health managers perceived the value of research in provincial health facilities as located in the potential benefits to the healthcare system, i.e. they tended to value research that would lead to improved operations, improved functioning of the health care system or improved patient outcomes:

The positive one is where operational research is conducted, where it will make us re-think the way we do things (…) I love them because they are also simple and even simpler to implement the recommendations. (Interview 1; Health manager)

Research and practice and clinical outcomes go hand in glove – if you leave out one and think you can survive without it we will have problems. (Interview 6; Health manager)

For example, minimal invasive procedures which result in better management of patients and quicker responses to treatment, decreased average length of stay. (Interview 6; Health manager, page 1)

… one of the studies is the … in terms of HR "what is the impact of EPMDS in the workplace" so we need to know why we implementing the employment management to improve then we can see whether the EPMDS project or programme has affected to or changed the people behavior and attitude and the work ethic … (Interview 8; Health manager)

In valuing research conducted at public health facilities, health managers tended to assign weight to perceived 'concrete' benefits such as human resource development and capacity-building for health workers, as well as building infrastructure.

But for me it will even improve the health system more if the skills are also imparted on the people that do day to day work. (Interview 1; Health manager)

We have researchers that are very sensitive of what is happening, of the shortages of staff and the resources constrains that are there (….) Some even put in IT equipment in facilities, some assist with … with technical assistance, some clinical assistance, but others just come to gather information that you have, and take it and go and analyse … (Interview 18; Health manager, page 4)

Health managers perceived research as less valuable when it appeared to detract from the healthcare system by using resources meant for non-research patients. Whereas researchers seldom raised issues of concern about the conduct or effects of research in health facilities, health managers did so frequently and at length. One of their major concerns was the burden that research placed on health facilities and on the Department of Health, primarily in terms of the use of Departmental resources in research projects.

… they should not be using hospital resources for doing their study and that's where they assume that once the research is approved they can use resources of the hospital for the research. (Interview 7; Health manager)

… there are "whistle blowers"- people who complain that people are doing research and we are used in the process. So they complain that we do see things happening but we realize that this is not part of our work. It's part of someone's study. (Interview 10; Health manager)

The types of resources managers were particularly concerned about were hospital beds, diagnostic tests, and researchers' use of Departmental staff for data collection:

… we always have a problem with beds for patients but then I discovered there are a number of beds that are reserved for just clinical trials and I don't think that's fair. (Interview 1; Health manager)

I think the biggest problem …. [is] where they assume that once the research is approved they can use resources of the hospital for the research and the sponsorship doesn't get used up and I tend to wonder where that money then goes… (Interview 7; Health manager)

….Sometimes the staff has to collect the data (like give out file(s)). (Interview 8; Health manager)

Some of the researchers recognised concerns about resource-use and the importance of investing in health infrastructure and support for patients (such as computers for hospital wards, blankets for patients).

If we are running a research project in the facility we provide our own staff, we provide our own resources, and in fact almost on a compassionate basis - we provide additional resources to the facilities. (Interview 3; Researcher)

It's like my mantra for the past ten years you know we will not give you more work - we will take away you know work from you but sometimes inevitably .. it's like impossible not to …. (Interview 9; Researcher)

However, some researchers questioned the degree to which expectations of material investment were appropriate and questioned the limits of such investments:

I'm not a bank and I am unable to utilise the sponsor as a bank …. I completely understand that somebody is coming with fancy whatever it is - nice computers and we [the researchers] have an office and their [government] staff is crowded and so I do know that it's a fine balance to work. (Interview 10; Researcher)

In addition, one hospital manager appeared to question the value of too much research being conducted in one site. She perceived that certain hospitals were more utilised for research than others, for example, hospitals which cared for patients with conditions of interest to researchers. Her hospital was one such institution, and she said that at times as a manager she did feel 'overwhelmed' by the number of research proposals they received, asking *'Are we the only preferable site for research?'* (Interview 6; Health manager).

Almost half of the researchers perceived that some gatekeepers to health facilities did not value research in the same way, or according to the same criteria that they did (i.e., they did not attach as much importance to the knowledge-generation component). This in turn may have impacted on their perceived quality of relationships (discussed further under Theme 2). Researchers said:

Last thing that I find extremely frustrating is there's not a … a sense of importance associated with research… (Interview 2; Physician researcher)

One of the studies it was bought up you know what is my …. my responsibility as a Department of Health employee, … getting involved in research? ….. And … and I mean at that level for someone to ask you know why are you as a Department of Health employee getting involved in research … you know implies that that individual doesn't understand the importance of research … (Interview 5; Physician researcher)

Well I don't think the Department realises how important the evidence base is for what they do. I think that there is a responsibility for the Department to really look at their data and use it for their planning and their programmes. I don't think they do that. So if you don't do that then obviously research and evidence and data is not related to you, you're just going to continue doing whatever it is that you do. (Interview 16; Researcher)

…people are busy and they're being dragged in ten different directions; and they maybe don't have the time for research… (Interview 15; Researcher)

The different value assigned to research by some health managers was attributed to inadequate understanding of the research's scientific merits and purpose, as reported by one health manager and echoed by two researchers. This inadequate understanding reportedly impacted on health managers' ability to engage with researchers and to impact on the health research agenda, as shown in the quotes below:

…because for me it's one of those things where I'm like "why are we even doing this" but then again [it's] just me - as a programme person I have not much research experience. (Interview 1; Health manager)

They [health workers and managers]…they don't understand that [the study results] so we need to, as researchers, to come up with a better way of explaining things and I'm not sure if that's necessarily possible. (Interview 3; Researcher)

I think the main constraint is that people [DoH staff] don't see themselves as researchers and they don't think they can do that and therefore they don't want to get involved with research because of anxiety and fear... (Interview 16; Researcher)

In summary, the findings reported under Theme 1 indicate that, whilst most interviewees valued research in public health facilities, they differed on the aspects of research that made it valuable. Whilst researchers tended to value the contribution of research to knowledge and future hypothetical beneficiaries, and its future impacts on health and health care, health managers tended to value its benefits to the current health care system. Also, they perceived research as less valuable when it used system resources, and detracted from service delivery. Both groups reported some sense that the other group valued research differently.

4.3 THEME 2: STRAINED RELATIONS

This theme sets out the views of interviewees on the relationships between researchers and health managers in the KZN Department of Health, and their viewpoints on what factors impacted on these relationships. These perceptions are set out in the paragraphs below, categorised according to the 'chronology' or sequence of the research process where they emerge, namely conceptualisation, review, conduct and results dissemination. The perceived primary concern (such as communication, trust, respect, transparency, and accountability) at each stage is also set out.

Most interviewees perceived the relationship between researchers and provincial Department of Health staff as strained. Strained relationships were reported in all stages of the research process, from the first stage, that is, the conceptualisation of the research question, to the final stage, that is, the dissemination and utilisation of research results.

A few interviewees reported that relationships were generally poor. This is exemplified in the following quotes:

> *I think, my impression is that research in services there's not a lot of collaboration. Not everywhere but in general I don't think that there is marriage in the same way that I don't think that the Department works very well with the staff that are working in academic institutions.* (Interview 16; Researcher)

> *… you know I think it started with [names former SA Minister of Health] and it's a sort of antagonism towards researchers … and to some extent it's being carried on even by the present Minister … just a slight antagonism to the researchers instead of embracing them thinking that can actually help improve things.* (Interview 12; Researcher)

However, it is worth noting that a minority of researchers and health managers characterised their relationships as generally positive, as these quotations show.

> *… it's quite simple. I engage well with them; I get the responses that I need; we work very well together. I'm quite happy with the researchers …* (Interview 7; Health manager)

> *… and at their sites [provincial health facilities] there was always a sort of good relationship which was … which was key.* (Interview 15; Researcher)

4.3.1 CONCEPTUALISATION

A few researchers reported the view that it was important to engage Department of Health staff at the first stage of research, that is, the conceptualisation of the research question.

> *I think that [involving DoH at development of research question] is very important for various reasons. It improves the research and it also improves relations. Think about it - a person working in the job probably knows more about it than anyone else … so you really want to engage on the topic you're researching earlier on so that you can formulate research questions.* (Interview 16; Researcher)

However, this was experienced as challenging - as set out by these quotes:

> *… for research the first thing I think is identifying the problem… I think the difficulty is often what you see as a problem may not be seen as a general … so I think the one issue is … is determining the priorities of research … everyone has their own opinion you know of what's … what's important.* (Interview 5; Physician researcher)

> *What we found difficult was at that stage [conceptualisation of research question] was that we couldn't just easily communicate with the appropriate programme manager or general manager at province … To get a flat out opinion on what their feeling was. Um … We would pop in … or directly email proposals to the appropriate person … But even being able to set up a meeting at that point was … was often challenging.* (Interview 15; Researcher)

Three health managers expressed their views that the researcher-health manager relationship at this stage was characterised by inadequate engagement, ascribed to a lack of respect for managers as suggested by the third respondent, or a lack of communication, as suggested by the second and third respondents.

> *… in general I haven't come across anyone that approaches me for the conceptualisation of the question or anything like that…* (Interview 1; Health manager)

> *No, no … they only start involving the Department when they are seeking for approvals … and that's already at a stage where they already have funding for that research so they are bound to continue with that research …* (Interview 17; Health manager)

> *First you don't want to be funny but I like to be respected not as a person, I mean as an institution - and then it's really difficult when someone is pushing you to [sign support for research project] … first is there a need at [names provincial hospital] for this research, or is it your need because you need to have that research to graduate, but is it really interesting?* (Interview 13; Health manager)

A fourth manager complained that the hospital received "ready-made research proposals" and that inadequate consultation with facility managers early on in the development of a research project had an adverse impact on planning for the hospital (Interview 6, health manager).

Finally, some perceived that health managers were inadequately involved in this stage because health managers themselves were under-resourced (had inadequate time or training or knowledge) to engage:

> *I would love to be involved in the conceptualisation of research and planning and so on but it needs a little bit of resources in terms of getting a dedicated staff member even if it's not someone in research but someone to help with the paper work and that sort of thing as well …* (Interview 7; Health manager)

> *… but we look at research as something so specialised that it's something that you cannot do…* (Interview 1; Health manager)

At this early stage of the research process, representatives from both stakeholder groups reported that engagement was important, yet both groups reported frustrating experiences in the researcher-DoH relationship at this stage. Certain health managers reported experiencing inadequate communication about the research concept (late or not at all), while some questioned their own capacity to be meaningfully involved at this stage. Certain researchers experienced frustration with

managers' unavailability for early consultation meetings; and also perceived that health managers had different priorities to their own.

4.3.2 RESEARCH APPLICATION PROCESS

As outlined in the literature review, the research application process to conduct research in public health facilities in KZN involves obtaining a letter of support for the research from the facility or programme manager concerned, then submitting this together with the protocol and a letter of provisional ethics approval to the KZN PHREC for final permission. Researchers often did not distinguish between these two components, and at times conflated the application process of other regulatory bodies (such as the Medicines Control Council and RECs) with that of the Department of Health. However, only their perceptions related to the Department are reported here.

Researchers expressed frustration at the long duration of the application process, and described experiencing inefficiencies, inadequate accountability of staff engaged in the process, and a lack of transparent communication around the process of review

> *The second thing for also time constraints is the time it takes to get approval from all authorities - from ethics to Department of Health to even the site permission - it takes time …* (Interview 4; Physician researcher)

> *I think we should say … in so many weeks it will be reviewed and you will have your decision in so many weeks … It's unacceptable that you just have to wait and wait …* (Interview 2; Physician researcher)

One researcher perceived that the long period of review was due to inadequate capacity within the Department to comprehend, and make decisions about, research proposals.

> *... there needed to be some sort of capacity development there to … to enable them to at least read an abstract and understand what the major implications of the study are … because when they didn't they would sometimes sit on it for three months and only escalate to district after three months with back and back discussions … but you would never get to that point because the competency wasn't there.* (Interview 15; Researcher)

Related to this was the perception reported by one researcher that Departmental managers, who were supposed to give letters of support, were unwilling to take decisions around research projects related to lines of accountability.

> *… people don't dare to take ownership or take responsibility to make decisions … Right? So there is always a "yeah this is really interesting but you know it is not me, it is like the head of so and so …" and then the … the responsibility is deferred …* (Interview 10; Researcher)

One researcher questioned the added value of review by the Department of Health in addition to a number of regulatory and review bodies, and expressed frustration at the protracted period of review:

> *… so it's protocols that have gone through FDA etc. etc. … lots of other countries, then we go through our own ethics, then we go through the MCC, and then we go through the Department of Health, and I … I find it really frustrating to still have queries about the protocol when it's a protocol that has been seen literally hundreds of times around the world … and been approved.* (Interview 2; Physician researcher)

Several researchers perceived the provincial Department of Health as inefficient and unaccountable during the review process, which was an important cause of concern:

> *… [the review took] five or six months and I could not um understand the reason because they asked for re-submission of the same documents that were submitted at the beginning …* (Interview 4; Physician researcher)

> *… well we did an application, and then it was … a few months and then they came back to me saying I must redo the application because now there's a new form…* (Interview 2; Physician researcher)

Furthermore, the following researcher was of the view that adequate and efficient review depended on a personal relationship between the researcher and the gate-keeper involved in the review.

> *What makes a huge difference is um is knowing somebody. ….. Not just with research but especially with research… it makes a huge difference in terms of ah … if you know who you interacting with ….. In terms of that, that process is not transparent.* (Interview 3; Researcher)

Another researcher bemoaned the lack of clarity in criteria for obtaining permission from various levels of the health service; where one facility or manager may provide the letter of support to conduct research, another may not, without communicating an adequate reason for the refusal.

> *…that you know you go through like a year of approval processes and you talk to I don't know how many people, you know – Department of Health ethics, MCC you know whatever and municipalities and the clinic and hospitals and things - and then you finally start recruiting – you will always, always, always, always will there be a person who will say "I have never heard about this!" you know, and that has the potential of like really rocking the boat - "I'm gonna stop recruitment at this clinic, at this trial and this clinic! I have never heard about this!"* (Interview 10; Researcher)

A researcher described experiencing Department of Health staff as frequently changing, and where new staff might understand or interpret guidelines for supporting research differently from their predecessors.

> *…. because there were interim CEO's and interim you know medical managers you know and that was changing every six months. So whenever the previous one would put something in place the next one would change. And we'd need to re-engage…* (Interview 15; Researcher)

In the view of two researchers, the effect of the prolonged and challenging review process, which included the Department of Health process, was that they had lost or would lose funding and research opportunities.

> *We've lost … we and other research organisations have lost a lot of funding …. in big grants because of um delays in regulatory approvals. …….and there's actually there's been some networks that we've ah been excluded from and reason cited was delays in regulatory approval…* (Interview 3; Researcher)

> *…. we have to compete … for grants on a global scale, so if you have a study that's being sent out to multiple sites and they've … you know we take a year to get approval …. you're never going to be awarded those … those grants to run those … studies.* (Interview 5; Physician researcher)

Health managers on the other hand, perceived researchers as unrealistic in their demands for speedy response times, with one manager citing the necessity of consulting with the relevant clinical departments in the hospital, as well as managers for parking areas and security, before providing the

letter of support for the research (Interview 6; Health manager). Another facility manager perceived researchers to be unwilling to consider their points of view, even when it came to legal issues affecting the conduct of research.

> *So they would take tissue from that, so for them it is something that is discarded but they don't take into consideration the fact … of that guide on the use of human tissue; so then even the doctor(s) themselves just wrote we need this thing finalised quickly and unfortunately the provisional ethical approval did not even look into that. They needed to get approval from the institution so I had to indicate that please just look at the Tissue Act and understand how to take care of human tissue. You don't just take a piece and nobody knows what you are going to do with it. …. one had to make them aware of some of the processes that are in place but in most instances they just want to do research and they don't want to hear about other things.* (Interview 11; Health manager)

At this stage of the research process therefore, researchers perceived health managers involved in the review process to be inefficient, unaccountable and under-capacitated. They expressed concerns around the prolonged review process, which was difficult to understand and characterised by a lack of responsiveness and a lack of transparency on the part of the Department of Health. Health managers on the other hand experienced researchers as overly demanding, and unrealistic in their expectations regarding a speedy review process.

4.3.3 CONDUCT OF RESEARCH

At the third stage of research, that is the conduct of the study, tensions in the relationship were expressed primarily by health managers, who were reportedly mistrustful of researchers' actual adherence to their written research protocols and to sound ethical practices such as in securing informed consent and safeguarding data.

> *I always wonder what if [it] doesn't go as planned, are they promptly coming back to us to say "guys this is the problem", or do they try other things and then it becomes worse because we're also not there to actually follow up what they are doing …. I think my other concern is about getting an informed consent from patients. I feel as a Department once we see in their paperwork in their protocol what they would do but we don't know if they physically do that….* (Interview 1; Health manager)

…. that is something that I also have a concern about in terms of what they say and how they go about collecting the data and safeguarding the data and maintaining the security and so on we can only go by what they put on paper for us… (Interview 7; Health manager).

One manager was suspicious that researchers added research questions as the research proceeded, beyond those originally specified in the protocol

they start off researching on measles and then add sub-titles of addressing something else. (Interview 6; Health manager)

Furthermore, some health managers were mistrustful of researchers' motivations behind the conduct of research in public health facilities.

I think from all research that are coming probably about 25-30% truly have an intent of improving services or having some sort of benefit for the Department, whereas that remaining 75% or so is mainly to get the MMed or that primary degree … (Interview 7; Health manager)

Health managers questioned whether the conduct of the research might undermine or compete with service delivery in their facilities (as set out in Theme 1).

I'm not sure what is the problem for our institution whether it's big or not I don't know. But all the time our institution is a pilot for the pregnancy study, for the PMTCT and now I think it's the NHLS doing they project here - we are involved a lot. But usually there is no problem. The research has no problem; the problem is the participant and the staff. Sometimes the staff has to collect the data [like give out files]…. (Interview 8; Health manager)

… there's also a lot of tension between facilities in terms of service delivery …. and research staff. Um … there's often conflict between research staff and facility staff because it's seen as a … as an extraneous …. activity. (Interview 5; Physician researcher)

At this stage of the research process, relationships were characterised as strained largely due to health managers' mistrust of whether researchers would adhere to protocols, and to described procedures for securing consent, as well as honestly report problems arising during the conduct of the research. They did not always trust that the research would not undermine service delivery, especially where Departmental staff were asked to implement research procedures.

4.3.4 DISSEMINATION AND UTILISATION OF RESULTS

At the final stage of research, the strained relations were generally attributable to lack of commitment to the dissemination and utilisation of research results, by both sets of participants; health managers claimed that they seldom received any feedback on completed research, and researchers reported that there was no interest in research results when they did try to report them.

The following quotes from health managers illustrate their perspectives:

> *…. there is no feedback as it is supposed to be in the protocol. There is no feedback to us as to where we are. Not … [even] just to mention that the research is finished.* (Interview 13; Health manager)

> *Since I started [two years prior to this study] to collect the research proposals, not a single one of them has actually came back to us and said that this is what we have discovered and this is how it can benefit your hospital. ….. so I tend to doubt if people truly mean what they say in their protocols.* (Interview 7; Health manager)

> *The studies are done, people are presenting at international conferences and whatever the findings are we don't know how they can help the Department …* (Interview 11; Health manager)

One health manager said that her hospital had only received formal feedback on research once in the previous six years, and argued that researchers respected neither the terms of reference of their research permission, nor the right of the Department to get feedback (Interview 6, health manager).

One manager reported inadequate participation by researchers in a formal feedback session for all research conducted in the hospital:

> *We….we were thinking that you'll get people responding and we'll have to you know to … to … assess who can present, who can't present …. but we got so few responses that everybody who submitted will present anyway.* (Interview 11; Health manager)

However, certain researchers reported that research results were inadequately considered by Departmental staff even when these were communicated:

> *…. [names hospital] requires me to [send] my yearly progress report … but I've never received a query on that progress report … so you know no one's really interacting with that report …*

you know when [the research] gets published we send ah the publication to the facility but no one actually reads that …. (Interview 5; Physician researcher)

So I have said "Please, I want to come and talk and give this talk and I want to disseminate the information and I want to, want to, want to, want to …" … "Yes, we're going to invite you" …. Never happens! I have said this so many times and it just never happens. People are I don't know too busy, or too whatever … (Interview 10; Researcher)

I find that (laughs) in theory everybody's interested but … being in the health service, the day that you schedule to go and tell them about the research - you know something's happened …. and their minds are completely somewhere else …. (Interview 12; Researcher)

One health manager agreed that the Department did not engage sufficiently with research results when these were communicated and attributed this to inadequate ownership from the Department:

…. it's also very tiresome on their [researchers'] part to be able to get us as well to sit down and listen to their results [laughs] because mostly you find that it would take about three months for a partner to secure an appointment … with provincial staff ….to be able to give feedback. ….. So there is a lot of work that is going on but unfortunately even the results, some the Department would take and some the Department would not take because they are not fully involving internal people in that research …. there is no Departmental ownership (….) of those research studies because it is not conducted by the Department. (Interview 17; Health manager)

One researcher expressed mistrust that the Department of Health would implement research results timeously.

…the prevention of mother to child transmission …. I mean it took twelve years for that finding to be implemented - why? (Interview 3; Researcher)

However, another researcher applauded the rapid implementation of communicated research results in certain situations in South Africa.

… somebody in the Department of Health you know, National level, reads a … a research paper – "this is the new way, this is what we have to do, ooh ooh ooh [claps hands]! Change tomorrow!" It's fixed. Whereas you know anywhere else, well you know where we have to go through the WHO, and the USAID and all these things ….. So there are certain things that

happen immediately that I think are a huge advantage for this setting to be able to do that…. (Interview 10; Researcher)

One health manager felt that once communicated research results had been implemented, the evaluation of interventions was poor:

> *With other research we don't know what is going on - even we did a summary, we made a follow [sic] to see whether the implemented project is effective or not; for example now we are doing the MMC [male medical circumcision] because of the 60% of HIV prevention it could give, but we don't know after 10 years what it will be…* (Interview 8; Health manager)

At this stage of the research process, the relationships seemed to be characterised by mutual blaming. Health managers reported that researchers did not make the effort to give them feedback on research results, and researchers claimed that health managers did not make the effort to engage with them on research results. On both sides, a lack of accountability on the part of the other side seemed to be implied. Whilst managers claimed that they seldom, if ever, received feedback from researchers on completed studies, researchers were of the view that managers did not avail themselves for feedback meetings, nor did they engage with research results when researchers communicated them. Finally, even when research results were disseminated and implemented as policy, the evaluation of these interventions reportedly failed to happen.

In summary, the findings reported under Theme 2 indicate that both researchers and managers perceived that the relationships between them were strained, and such strains are evident over all stages of the research process. Strained relations appear underpinned by distinct concerns at different phases. Major concerns include trust, accountability, and transparency. Relationships were characterised by mistrust (for example, mistrust by managers that researchers would adhere to their protocols), perceived lack of accountability (for example, researchers' sense that managers did not respond to efforts to communicate results), perceived lack of transparency (for example, researchers' sense that the review process was arbitrary and its criteria obscure), and perceived lack of capacity (from both researchers and managers) on the part of Departmental managers to engage constructively with researchers.

4.4 THEME 3: STRENGTHENING PARTNERSHIPS

This theme reports on how interviewees could envisage stronger research and more robust stakeholder relations. Many ideas were shared across both managers and researchers, with many overlapping ideas from each group, and little direct conflict between these ideas. Respondents discussed ways to improve the process of conducting research in KZN provincial health facilities, which would in turn improve inter-stakeholder relations in the province, and indirectly, further the realisation of the social value of health research in KZN. These are outlined below in terms of the 'chronology' of the research process.

4.4.1 CONCEPTUALISATION

At the stage of setting the research agenda and conceptualising research questions, the importance of more discussion, in a formal regularly-scheduled forum, was underscored by both health managers and researchers.

> *We have … a technical advisory committee that sits on quarterly basis and we have the research that supports TB involved there. So one of the things that we do in that committee is to kind of guide the research agenda for the programme which really helps us ….* (Interview 1; Health manager)

> *…. to start with this like you know forums to bring people together ….. you know that would be …. I would love it if we could do that …. That doesn't come just from me it comes from other researchers as well and other clinical … staff …* (Interview 10; Researcher)

The following researcher felt that it was crucial to discuss the proposed research extensively with the Department prior to conducting the research, in order to gain support from the Department for the research, and in so doing, to pre-empt difficulties with the conduct of the research and to enhance the probability that the research results would be used.

> *I think … a lot of it is required as … before the study happens, you have to (…) ensure that you inform everyone what's happening …. and where where the study is placed, what the study can add to the system …. and also what the ultimate goal of the study is….. So sometimes the the study may not be adding to the service delivery of the site …. but making people understand that there's a … there is a bigger goal to the research …. so eventually people understand what the importance of research is….* (Interview 5; Physician researcher)

4.4.2 RESEARCH APPLICATION PROCESS

At the second stage of the research process, that is the application for permission to conduct research, researchers made recommendations for the Department of Health process (issuing of facility or programmatic letters of support followed by final approval by PHREC), as well as for other regulatory bodies. The latter are only included here when they relate to Departmental processes.

One researcher suggested that the different review bodies involved in the application process should work together so that reviews take place concurrently, thus reducing the period of review.

> *I still believe that the way we need to go is try and ensure that these processes run concurrently. …. I think um …it would really be good if the ethics committee and the provincial Department of Health …. sat on review boards together. So if a clinical trial goes to an ethics committee there should be a member of the Department of Health there ….so they can see the trial at that point …. not sequentially, not afterwards.* (Interview 2; Physician researcher)

Regarding granting support for researchers to enter the facility to collect data, one researcher said that managers at all levels of the health system needed to be better informed about Departmental processes and capacitated to take decisions, so that criteria for approval would be uniform across all levels of the health service, and decisions to support a study could be taken at the appropriate level.

> *[Departmental policy on research] has to be disseminated down. You know like …. people don't really understand what the systems are and they are afraid to take decisions and you know give approvals and things like that because they don't know what the systems are …* (Interview 10; Researcher)

One health manager suggested that each health facility should have a research committee to review and give support for research projects. Although in practice, such committees might slow down the review process, it is possible that increasing the capacity of a committee (as opposed to a single manager) would result in faster decision making.

> *I think there used to be research and ethics committees in the facilities - maybe if those can be revived. Make sure that each and every facility has those people, maybe get them trained …* (Interview 1' Health manager)

4.4.3 STUDY CONDUCT

In order to ensure adherence to research protocols, and to ensure patient safety, a few health managers suggested enhanced monitoring mechanisms for research conducted in public health facilities.

> *If somebody was looking at it from time to time reviewing, especially where we know that this is a bit dangerous and this is a bit gambling, so maybe those are the studies that we can monitor, organise clinicians within the Department that would spot check whether [things] are going as [they're] supposed to, are the patients not being compromised and what is happening with those patients ….* (Interview 1; Health manager)

> *I think the key (…) that is monitoring what goes on with the study; it could be a very difficult thing but if there could be some monitoring mechanisms especially with the prospective studies you know where people can monitor from time to time what is actually going on …* (Interview 7; Health manager)

Such monitoring should include ensuring informed consents are taken correctly from patients.

> *I feel we should as a Department maybe at a facility level where the study is conducted maybe just sit in when they're obtaining a consent from a patient so that we can really be sure that the right processes are being done there.* (Interview 1; Health manager)

During the conduct of the research, one researcher suggested that Department of Health staff collaborate as research partners, and this view was echoed by a health manager.

> *… I think it's really important that you even get a research collaborator from the province guiding and ensuring that that project is helping directly address the concerns or questions … they have ….* (Interview 15; Researcher)

> *… the research itself can be improved by … like I said earlier on, involving the Department employees as well in in the research …. so that at least in each research that any partner is conducting, there is somebody from the Department who is also an investigator in that research project…* (Interview 17; Health manager)

Another health manager emphasised the importance of transferring research skills to Departmental staff during the conduct of the research project.

So I think it can be made better, it's strengthening the health system in a way but if the people on the ground who are doing day to day service delivery can be empowered to look at things differently. Even with the routine information that they collect, just the analyses of that information doesn't happen and it's a big miss that could help the health system…. (Interview 1; Health manager)

The need to inculcate a culture of research within the Department of Health, and for research to be conducted routinely by Department of Health staff, was expressed by this researcher and these health managers.

I'm not going to be very pedantic about it … I think the Department has an obligation to do research, period. …. Everybody should be encouraged to do research all the time and I do think that routine collection of data and evidence by clinicians and other research people - that constitutes research - so it's a matter of encouraging people to look at their data, interpret and change … (Interview 16; Researcher)

… I feel that we … we do not stop to document what we do as a Department …. and that is very important and then we find people who are telling our story outside … without us (Interview 17; Health manager)

If there was a way of having workshops….. to make people aware that there is so much that can assist our output and our functioning if we were to do research not necessary aligned to a qualification but about what we do in our everyday work…. (Interview 11; Health manager)

We have I must say lot of research done here by people, some are being published but I think it's still minimum compared to the number of professions that we have … there is so much potential. (Interview 13; Health manager)

An important way to capacitate Departmental staff to conduct their own research was through mentorship, as this health manager described:

Mentorship can bring people closer together. (….) So if (…) the current researchers can provide mentorship to Departmental staff as well, it will help the Departmental staff as well and improve the relationships between the researcher and the Departmental staff as well. (Interview 17; Health manager)

One physician researcher said that the Department should make it easier for external organisations to support research within the Department.

> *…. also when it comes to external stakeholders …that they would like to donate and support …. We find very difficult um… that the ah Department of Health um will allow this donation before a very very long procedure to um follow regarding um well the clearing and the accepting these um items….* (Interview 4; Physician researcher)

Once the research project was completed, and as a way of minimising the perception that researchers "dump" patients back into public health facilities once the research is over, one researcher recommended:

> *What we do is we'll routinely get [patients] assessed via the Department of Health clinics so that they have a file, ah they have you know all the necessary documentation …. in the clinic already …. …. and then we take them into a research facility … so that when they need to go back … everything is done already … and it's not that they're starting all over again ….. what we have learnt was when you start referring them back and there's no cards, there's no files there, people say … feel that you're dumping the patient on them … so if there's a card and there's a file there … you know …. the perception is that these patients are already part of the system.* (Interview 5; Physician researcher)

A health manager further suggested that patients who are also research participants should be followed up for a longer duration, and that sufficient information on these patients should be given to the Department on completion of the research, in order to avoid such patients placing a burden on the Department after the research.

> *Maybe we need to make sure that somehow with clinical trials conducted maybe patients that have been exposed are followed for a longer period so that the unintended effects can be picked up a bit earlier and make sure that we have the patient within the finding of the study because then it becomes the DoH burden, because the patients are sick and sometimes it's really difficult to treat these people because you cannot really link to whatever research is being done.* (Interview 1; Health manager)

4.4.4 DISSEMINATION AND UTILISATION OF RESULTS

At the stage of feeding back research results, two health managers suggested that there should be negative consequences for researchers who do not provide their results to the Department of Health.

…. there is no negative consequences for not doing so [feeding back] I guess. Whereas if there was some stage in the process that maybe when they want to publish or to sign off the dissertation or something like that, at that point confirmation should be made whether whatever was written in the permission letter was done with evidence, before the next step. (Interview 7; Health manager)

A certain process must be there so that they need a letter before they graduate. Certain punishment, before they publish they need a letter from the institution where they conducted the research must give a proof letter that they receive the report no matter whether the institution use report or not… (Interview 8; Health manager)

However, researchers felt that, rather than being coercive, the submission, receipt and utilisation of research results should be done willingly by all stakeholders; they felt that researchers and health managers should take pride in the research conducted in public health facilities, and should even take joint responsibility for wider dissemination of the results.

I believe the Department of Health and the university are missing out here. They should be ensuring that these are um publicly reported. …. So I think there should be little snippets in newspapers …. about the research that has been conducted, ….what it means for people, so that the community start to understand the importance of the work and its implications. ….. We do important research …. we should be proud of it. People would engage more if they understood what we were trying to do. (Interview 2; Physician researcher)

A representative from both stakeholder groups perceived that disseminating results would be facilitated by regular formal feedback sessions between researchers and the Department of Health, and this view was echoed by the researcher below.

… if we can meet once or twice a year to get what has been done in that year…. (Interview 1; Health manager)

You know when [names provincial DOH manager] was the [manager] we used to have once a year a provincial TB research day ….. and it was lovely! (Interview 12; Researcher)

In summary, the findings reported under Theme 3 indicate that researchers and health managers shared several similar view-points regarding how to strengthen aspects of health research in provincial health facilities. However, the view of health managers that researchers who did not

submit feedback to managers should be penalised did not seem to be shared by researchers themselves. Interviewees made recommendations for each stage of the research process, and many of these related to more explicit and transparent communication, that is more regularly scheduled, and is more formalised. Others related to better monitoring of researchers, to assure Departmental managers of their adherence to their protocols, and the creation of a culture of research in the Department of Health, not least through capacitation and mentorship of Departmental staff by researchers, which might in turn engender shared pride in research projects in such facilities.

CHAPTER 5

DISCUSSION

This chapter considers the most important themes arising from this study, and, in the light of relevant literature, how these can be related to the local and global context of health research and stakeholder engagement. The three themes, although distinct, are strongly related. For example, disagreement over the social value of research may inform strained relations between researchers and health managers, which may limit the extent to which research results are disseminated, valued and utilised. It is important that the inter-relatedness of issues raised in this study is recognised and that interventions are developed with this in mind.

5.1 THEME 1: VARYING PERCEPTIONS OF SOCIAL VALUE

All interviewees in this study perceived that health research was generally valuable; however, there were subtle but important differences between the way researchers ascribed value to health research, and the way that health managers did. Researchers tended to emphasise the inherent value of new knowledge generated by research, as well as the benefit of research to future generations as a result of this new knowledge. Health managers on the other hand tended to perceive the 'incidental' aspects of research as being very valuable, such as the development of Department of Health staff, infrastructure and health systems that might occur during the research process.

This distinction reflects that drawn by King (2000), who differentiated between the benefits that accrue to future persons and society as a result of research (which she called 'aspirational' benefit) and the benefits that accrue to participants from the research (such as better clinical monitoring or more advanced diagnostic tests) (which she called 'collateral' benefits). King (2000) noted that participants' motivations for enrolling in research may be rooted in the desire for 'collateral benefits' (Lutge et al., 2017). This study's findings suggest that facility managers' motivations for supporting research may also be somewhat rooted in the hope of collateral benefits, not so much for themselves but rather for the healthcare system in which they work (Lutge et al., 2017). At least some researchers in this province also considered the need to ensure such benefits for the health facilities in which they conduct research.

It is clear that so-called 'collateral benefits' may be highly valued by stakeholders of health research, especially those in low income countries (Kamuya et al., 2014; Lairumbi, Parker, Fitzpatrick, & English, 2012). In these settings, research may be seen as a tool for the improvement of health services, and as such, a means of promoting social justice (Lairumbi et al., 2012). In a country with profound inequities like South Africa (Leibbrandt et al., 2010), the role of research in offsetting health injustices has been supported (Benatar & Singer 2010).

Also, leading ethics commentators (Emanuel et al., 2004; Emanuel, Wendler, & Grady, 2008) - in a popular framework for evaluating the ethics of health research - consider the benefits that research may confer to health systems to be an intrinsic part of its social value; and such benefits include capacity-building of staff and infrastructure-development. This stance, which is supported by some empirical studies (Kamuya et al., 2014; Lairumbi et al., 2012) confirms the idea that so-called 'collateral' benefits should be considered as part of assessments of value during the negotiations around research projects. The capacity building of staff would have an additional benefit in that it would enable health managers to engage with researchers on a more equal basis, thus achieving a true collaborative partnership (Emanuel et al., 2004). The findings of this study suggest that research in public health facilities in KwaZulu-Natal should do the same, because key stakeholders in the form of gatekeepers value such benefits highly.

This viewpoint is also consistent with the Fair Benefits approach (Participants 2004), which argues that stakeholders of research should negotiate the collateral benefits that will accrue as part of research, such as improved infrastructure and training of personnel. However, just as the Fair Benefits approach has excited some controversy (Lie, 2010; London & Zolman, 2010; Schüklenk 2010), so certain researchers in this study seemed to question to extent to which collateral benefits should be offered, perceiving the expectations of health managers as higher than they could reasonably meet. As seen in this study, health managers' perceptions of the ample resources of researchers may fuel expectations of collateral benefits that researchers feel unable to provide. Because these collateral benefits were considered an inherent part of the social value of research by gate-keepers in this study, and because they were a potential source of conflict, it is crucial that researchers and health managers communicate more openly about expectations, and which of these can be reasonably fulfilled.

Ensuring fair distribution of collateral benefits is important but conversely, it is also important that health managers do not feel that their institutions are being 'over-researched', as expressed by one

interviewee in this study. Although the term 'over-researched' is often undefined, with understanding of its meaning presumed rather than made explicit (Koen et al., 2017), the term is increasingly used in low and middle income countries (LMICs) (ibid). Importantly, for the concerns around strained relationships raised in this study, the term 'over-researched' seemed to be understood differently by researchers and research communities in a study which investigated stakeholders' understanding thereof. Whilst research communities tended to spontaneously define it as exploitation, researchers were less explicit (Koen et al., 2017). It is crucial therefore for researchers and health managers to engage on this issue, come to a common understanding of what it means, and ensure that steps are taken to mitigate against this perception.

This study found that researchers tended to value the knowledge-generation component of research highly. This perspective corresponds with the CIOMS Guidelines (CIOMS, 2016) which defines the social value of research primarily in terms of its scientific value. That is, '(s)ocial value refers to the importance of the information that a study is likely to produce' (p. 1). This view also corresponds with the first iteration of Emanuel's framework (Emanuel et al., 2004) where the social value of research was similarly defined as being the generation of 'knowledge that can lead to improvements in health' (p. 932).

This study found that gatekeepers perceived research in public health facilities to be less valuable when it undermined existing services in the facilities in which it was conducted. This was an important concern of health managers, but was not spontaneously raised by researchers in this study. The potential detrimental impact of research on service-delivery in health institutions is addressed in Emanuel's framework for ethical research (2004) where it is stated specifically that the socially valuable research should not detract from existing services and infrastructure (Lutge et al., 2017) and "conduct of the research should not undermine the community's existing health-care services" (Emanuel et al., 2004, p. 932). The use of Departmental resources for research without some appropriate compensatory benefit should no longer occur, and the provincial guidelines governing health research in the province have been amended to express this (KZN DoH, 2017).

The social value of research has been recognised as an important part of what makes research ethical (CIOMS 2016; Emanuel et al., 2004; Emanuel et al., 2008; Emanuel, Wendler, & Grady,, 2000) and Emanuel et al. (2004; 2008) importantly recognised that the value in research may be defined differently by different stakeholders. This study supports this view, finding that different role players may value research differently. The finding that researchers' and gatekeepers' conceptions of

'valuable' research have subtle yet important differences means that it will be important for these parties to discuss and come to a shared conception of what makes research valuable, particularly in this setting (Lutge et al., 2017).

Guidelines recommend that these differences should be approached with the relationship principles of respect and integrity (UNAIDS/AVAC, 2011). A clearer understanding of others' perspectives on what constitutes valuable research may improve relationships between these stakeholders, and as a result may improve the conduct of research projects and the utilisation of research results (see Theme two below for further discussion on this). In addition, recognising that the 'collateral' benefits of research are considered by some stakeholders to contribute as much to the value of research as the 'aspirational' benefits may result in a shift in thinking about research, from a perception that the role of research is to improve health in the long term, to a perception that research should also have an immediate benefit in the settings where it is conducted.

5.2 THEME 2: STRAINED RELATIONS

The importance of strong and positive relationships between stakeholders in health research has been emphasised by a number of authors as key to achieving the goals of research projects (Emanuel et al., 2004; UNAIDS/AVAC, 2011). However, only a minority of respondents in this study characterized the relationships between researchers and health managers as positive, with most experiencing strained relationships at various stages of the research. This has important implications for the outcomes of research projects undertaken in public health facilities in KZN. The strain in this relationship could be likened to the friction generated by the movement of tectonic plates past each other; such friction can generate "major tidal waves or volcanic eruptions" which may be disastrous for the conduct and outcomes of research" (Martens & Roos, 2005, p. 73). Major relationship failures were illustrated by the failed HIV prevention trials undertaken in Cambodia and Cameroon a decade ago (Mills et al., 2005).

In order to avoid such relationship breakdowns, it is important that stakeholders actively build positive relationships and maintain these over the duration of the research process. These relationships should not simply be based on contractual obligations, but should be personal (Martens & Roos, 2005) and reflect the following characteristics (UNAIDS/AVAC, 2011): respect; mutual understanding (which relies on socio-cultural and research competency); integrity (scientific and ethical); transparency (which is enabled by "open, honest, timely, and clear communication" -

UNAIDS/AVAC, 2011, p. 24); accountability; and respect for community stakeholder autonomy (which refers to the right of "community stakeholders … to support or refuse proposals to conduct research in a particular area" - UNAIDS/AVAC, 2011, p. 25).

The above characteristics are not only held to be important in and of themselves, but are key to fostering trust between stakeholders which in turn is foundational to positive and collaborative partnerships in research (Emanuel et al., 2004; UNAIDS/AVAC, 2011). Relationship-building should span the entire research process, from conceptualisation of the research question to dissemination and utilisation of the research results (fhi360, 2012; UNAIDS/AVAC, 2011). This section discusses the relationship tensions raised at various stages. At each stage in the research process, the key relationship issues that emerged most strongly from the data are discussed.

5.2.1 CONCEPTUALISATION

The importance of engaging DOH stakeholders on the development of the research question was recognized by both groups of interviewees in this study; however, respondents perceived that such engagement seldom if ever happened, with DoH interviewees questioning the adequacy of communication at this stage. Some health managers expressed concerns that engagement at this stage was not respectful.

It has been argued that the formation of collaborative partnerships in research requires commitment from all stakeholders (Emanuel et al., 2004); this commitment includes allocation of time for engagements over all stages of the research process, from all parties concerned, including managers in the Department of Health. This point notwithstanding, most ethical guidelines assign the core responsibility for engagement to researchers and sponsors (CIOMS, 2016; UNAIDS/AVAC, 2011) suggesting that these parties that must assume the 'lion's share' of responsibility for engagement practices at this stage.

Representatives from both stakeholder groups viewed communication as problematic at this stage of the research. It has been argued that communication is not simply the transfer of information; it is rather the process through which stakeholders "build transparent, meaningful, collaborative, and mutually beneficial relationships" (UNAIDS/AVAC, 2011, p. 16). Effective communication enables an understanding of the context in which research is conducted (Geissler, 2011).

The cited experiences of some health managers that engagement practices at this stages smacked of disrespect underscores the importance of the Good Participatory Practice Guidelines which list respect as one of the fundamental characteristics of a mutually beneficial research relationship (UNAIDS/AVAC, 2011). In order to show mutual respect, research stakeholders must act in ways that "that value and honour each other's perspectives and realities" (UNAIDS/AVAC, 2011, p. 22).

Both groups of stakeholders reported some concern about whether health managers can contribute meaningfully to this stage of the research process, based on their capacity. Ethical guidelines acknowledge that there may be significant disparities in "scientific knowledge and technical skills" between researchers and key stakeholders such as health facility managers (HPTN, 2009, p. 17). Increasing research 'literacy' is recognised as a key goal of researchers' stakeholder engagement, and arguably increases the likelihood of stakeholders making effective and informed contributions (UNAIDS/AVAC, 2011) and building research partnerships that are more equitable and therefore more truly collaborative (Emanuel et al., 2004).

The perspectives that health managers may give on research questions are different from those of researchers and may enhance the relevance of the research question to the health services. It is crucial that these perspectives are elicited early on in the research process. As stated strongly and frequently in the Good Participatory Practice Guidelines (UNAIDS/AVAC, 2011), if key stakeholders are engaged early in the research process, they are likely to support the research more strongly and, once it is completed, they are more likely to incorporate research results into practice.

5.2.2 RESEARCH APPLICATION PROCESS

In this study, the major issues relating to the review process were raised by researchers, and related primarily to the time the process took (sometimes perceived to be due to duplication of review by different regulatory bodies) and the lack of transparency and accountability in the process.

Researchers perceived that the review process took much too long, and that they were required to go through review processes with a number of different regulatory bodies which they felt duplicated reviews unnecessarily. These views resonate with views regarding the review process for TB vaccine trials in South Africa (Geldenhuys et al., 2012). Although review times for provincial health committees were not considered in this article, the median review time for the MCC was found to be 122 days, and that for Research Ethics Committees was found to be 60 days (Geldenhuys et al.,

2012). Review response times in Europe, the United Kingdom and the United States were noted to be much shorter than these.

Like respondents in this study, the authors found the review process to be perceived as excessively long, which had implications for the administration and funding of the trials, as well as the perceived suitability of South Africa as a setting for such trials (Geldenhuys et al., 2012). The authors noted that there was high variability in review times for different protocols, and these times did not seem to be related to the complexity of the trials themselves. The authors found this lack of predictability to be frustrating, and ascribed it to a lack of capacity within the regulatory authority to review such trials (Geldenhuys et al., 2012). Indeed, in a review of clinical trials for neglected diseases taking place globally, the lack of regulatory capacity in many settings was found to be an important stumbling block for such trials (Bollyky, Cockburn, & Berndt, 2010). Given the importance of rapid review in determining a country's competitiveness in clinical research (Lambers Heerspink, Dobre, Hillege, Grobbee, & de Zeeuw, 2008), the delays in review of research as reported by respondents in this study is a cause for concern.

It was not only the length of the period of review that researchers found frustrating in this study, but also the necessity for applying to a number of different regulatory bodies (ethics committees, the MCC in the case of clinical trials, and the provincial Department of Health), and the perceived lack of value added by the Departmental review to the rigour of the research. Although little research has been conducted into researchers' perspectives on the review process in South Africa, the frustration expressed by researchers in this study is echoed by that of researchers undergoing multi-centre ethics review in England, who faced challenges in terms of the high costs associated with applying to a number of different committees for the same application, and the lengthy review process which resulted in delaying the start of research projects (Tully, Ninis, Booy, & Viner, 2000). Similarly in Canada, different Research Ethics Committees have different applications forms and informed consent templates, which for researchers who are required to apply to a number of them, can be frustrating (Michael Smith Foundation for Health Research, 2007).

From the description that follows, it is clear that there is duplication in the review of health research applications in KZN, as well as potential for confusion regarding the different actors and their roles in the process. The review of health research applications in South Africa is governed primarily by the *National Health Act* (no. 61 of 2003), and by the Ethics Guidelines of the National Department of Health (NDoH, 2015). These stipulate that all health research proposals must be reviewed by a local

(South African) REC accredited with the National Health Research Ethics Council (NHREC). Whilst the first RECs were only established in South Africa in 1977, it has been argued that the ethics review process in this country is rigorous and of a high standard (Cleaton-Jones & Wassenaar, 2010). In addition, all research conducted in public health facilities in KZN (or recruiting patients from these facilities) must be granted permission by the KZN PHREC (KZN DoH, 2017), and clinical trials must also be approved by the MCC. In most parts of South Africa, these application processes are sequential.

In addition to the length of the application process, researchers in this study perceived there to be a lack of transparency about the status of their applications during the process of review. They perceived the criteria for Departmental approval of research to be opaque. Guidelines for Submitting Research Proposals to the KZN Department of Health are available on the Departmental website (KZN DoH, 2017) yet it is possible that as new managers enter their positions, they are not made aware of these.

It is important to note that gatekeepers have significant influence over whether research (and what research) is conducted in the facilities which they manage. This influence may be exerted in different ways: by "limiting conditions of entry, by defining the problem area of study, by limiting access to data and respondents, by restricting the scope of analysis, and by retaining prerogatives with respect to publication" (Broadhead & Rist, 1976, p. 325). This influence may be exerted purposefully, or by default, if managers are tardy or negligent in providing letters of permission. Given their influence on the conduct of research, it is important that gatekeepers are made aware of their responsibility, and that the Department of Health ensures that gatekeepers exercise this responsibility uniformly and transparently.

5.2.3 STUDY CONDUCT

Relationships at this stage of research were strained largely because managers of health facilities and health programmes were mistrustful that researchers would do what they say they would do, as specified in their protocols. Trust has been argued to be an important component of collaborative partnerships as described by Emanuel et al. (2008). Without it, research relationships can neither be true partnerships nor can they be collaborative (Emanuel et al., 2008). However, trust is not established quickly, can be easily broken and research stakeholders need to take note of the time and effort required to build trust within their relationships (Martens & Roos, 2005). Bennett and Gadlin (2012) have identified three different types of trust, all of which are relevant to inter-

stakeholder relationships in the conduct of health research. The first is identity-based trust, which is based on mutual understanding of each other's "wants, desires and values" (Bennett & Gadlin, 2012, p. 5). The second is calculus-based trust, which is developed when people consistently keep their word, that is, do what they say they will do. The third is competence-based trust, which depends on faith in the skills of the person concerned. Gatekeepers in this study were particularly concerned that researchers would not adhere to their protocols for research; in other words, they expressed 'calculus-based' mistrust in researchers. Specifically, they were concerned that researchers would not take proper informed consent from their study participants, and that they would not adequately safeguard the data they collected.

A systematic review, covering the period 1966 to 2004, shows that the process of securing informed consent may be challenging and that research participants may not fully understand the research in which they are engaged (Flory & Emanuel, 2004). Furthermore, potential research participants in developing countries may understand proposed research less well than their counterparts in developed countries, after participation in an identical informed consent process (Diemert et al., 2017). Ensuring participant understanding may require that the informed consent process continue over the duration of the research, in a way that responds dynamically to participant needs (Ssali, Poland, & Seeley, 2016). Although it is clear that some health researchers in KZN are aware of and try to overcome the challenges associated with the informed consent process (Lindegger & Richter, 2000; Rautenbach, Lindegger, Slack, Wallace, & Newman, 2015), it appears that important stakeholders perceive that more efforts need to be made in this regard. These suggested efforts are discussed further under the third theme of this discussion.

The protection of patient privacy and confidentiality is an ethical requirement of research (CIOMS 2016; Declaration of Helsinki, 2013, article 24) and RECs which review research proposals are required to confirm that this is provided for in the protocol (WHO, 2011, p. 16). However, breaches of patient privacy and confidentiality in research do happen (Helgesson, 2015), and the collection and storage of research data using electronic methods has made the leakage of patient data on a large scale easier (Myers, Frieden, Bherwanin, & Henning, 2008). Indeed, thousands of breaches of patient data security occur every year in the United States (Taitsman, Grimm, & Agrawal, 2013). Although no major breaches of patient confidentiality in research have been reported in South Africa in recent years, and no actual breaches were reported by interviewees in this study, gatekeepers perceived that researchers may not be trusted to secure their data as stipulated in their protocols. This concern is one that should be addressed, and is further discussed under the third theme below.

Relationship strain at this stage of the research was characterised by gatekeeper mistrust of researchers' motivations. There was concern that researchers are mainly conducting research to advance their own careers, and that their research, which may burden health facilities, does not benefit the facilities commensurately. Emanuel et al. (2004) stress the importance of sharing the fruits of collaborative research so that research is not perceived as exploitative and does not erode trust. Although there are examples of research projects not undermining, and indeed positively contributing towards, the health systems in which they are conducted (Angwenyi et al., 2015; Clark & Sinclair 2008), many health managers in this study expressed concerns about this. It has been noted that research which is conducted for individual ends and which does not result in some kind of change, at least in knowledge but preferably also in practice, may not be considered valuable, and such research may result in research fatigue in the facilities where it is conducted (Clark, 2008). Such research fatigue appeared to be an implicit concern for some health managers in this study, and it is important that the perceptions leading to this fatigue are addressed, to ensure that socially valuable research continues in KZN.

5.2.4 DISSEMINATION AND UTILISATION OF RESULTS

This stage of the research process, where the results of completed research projects are provided to research stakeholders, is crucial to realising the social value of research (Emanuel et al., 2004). If research results are not disseminated, so that knowledge is shared and the potential for action is created, then the research may just as well not have happened (Senkubuge & Mayosi, 2013). Furthermore, failure to disseminate research results may undermine future research efforts (UNAIDS/AVAC, 2011).

The poor communication that characterised the relationship between researchers and health managers was responsible for the general failure to disseminate and engage with research results as perceived by study participants. Poor communication was perceived on both sides of the relationship: on the side of health managers who failed to respond to research results when they were submitted to them, and on the side of researchers who did not provide reports consistently and did not provide results in formats or through media tailored for each specific audience (HPTN, 2009).

There is a vast literature on the dissemination of research findings, with one systematic review identifying 33 frameworks for research dissemination (Wilson et al., 2010). Formerly known as 'getting research into policy and practice (GRIPP)', and currently known as 'knowledge translation',

this subject has been the focus of intense scrutiny and publication activity over the last few decades (Oborn et al., 2010). However, in spite of the abundance of guidance (Wilson et al., 2010) on this subject, the dissemination of research findings or the translation of knowledge into practice in South Africa has been argued to be poor (Mekwa et al., 2016).

Such literature focuses more on the responsibility of the researcher to actively disseminate his/her research findings, and less on the obligation of research stakeholders to engage with these findings (Hamlyn, Shanahan, Lewis, O'Donoghue, & Hanson, 2015). However, in Emanuel's description of collaborative partnerships (one of the benchmarks of ethical research) (Emanuel et al., 2004), it is clear that such partnerships should be characterised by shared responsibility, including in the dissemination and utilisation of research results. The shared responsibility, and the equal ownership of the research project, is crucial for the uptake of research results by planners, managers and policy makers in the health services, where these results can have an impact on service delivery. Thus managers within the Department of Health should accommodate feedback meetings with researchers within their schedules, for the discussion of research findings and implications. Researchers on the other hand need to be cognisant of the demands on health managers' time, and tailor their feedback on completed projects to formats most accessible to the managers.

5.3 THEME 3: STRENGTHENED RESEARCH

Respondents from both stakeholder groups shared several similar views regarding ways in which research in public health facilities in KZN could be strengthened, at various stages of the research process. This theme is discussed in the same sequence, in the light of relevant literature.

5.3.1 CONCEPTUALISATION

In order to facilitate discussions, regularly-scheduled meetings between researchers and health managers were suggested by a number of respondents from both stakeholder groups. Such regular forums are already taking place within the TB Directorate of the KZN Department of Health, and these were cited by some of the respondents as an example of how such meetings should take place. Such forums could ensure that the communication essential to developing collaborative research partnerships takes place, but given health managers' perceived unavailability to engage with researchers as described above, it will be important to put mechanisms in place to ensure their full participation in these forums. Most guidelines on building inter-stakeholder relations in research emphasise the importance of frequent engagement and communication (HPTN 2009; MacQueen,

2012; UNAIDS/AVAC, 2011), and the formalisation of meetings may both institutionalise engagement between researchers and managers, and improve attendance by health managers.

5.3.2 REVIEW

A suggestion about which researchers felt strongly was that the different organisations involved in review of research proposals (such as ethics committees, the Medicines Control Council (MCC) and provincial health departments) should work together so that reviews take place concurrently instead of sequentially. This would save a considerable amount of time in the review process. This suggestion has already been implemented in the KZN Department of Health. Although final approval from the Department is only given once approval from the Research Ethics Committee and the MCC is received, clinical trials are reviewed by the Department at the same time as they undergo ethics and MCC review (KZN DoH, 2017).

The response to prolonged review, specifically for multi-centre studies, in the United Kingdom has been to centralise individual, local RECs into regional multicentre RECs and then to establish a Central Office for Research Ethics Committees to co-ordinate these (Mallick & O'Callaghan, 2009). In addition, in both the United Kingdom and the European Union, interventions to reduce the period of the application process for the conduct of clinical trials have included allowing parallel submissions to RECs and the national regulatory authority (Geldenhuys et al., 2012). This has resulted in shorter times to approval for clinical trials in these countries (Geldenhuys et al., 2012). However, in the United Kingdom at least, ethics and regulatory body review are still sought separately from site specific approval (which likely corresponds to the facility or programmatic approval in KZN). Ethics and regulatory body approval are sought first, followed by site approval, and this continues to cause delays in the process (Kearney et al., 2014). The parallel application process recommended by interviewees in this study and recently implemented in KZN (KZN DoH, 2017), may thus provide useful information in other research settings.

Another suggestion raised by researchers in this study was that all personnel in the Department of Health who are involved in the approvals process, should be better informed about the application process for research. Because there is a significant turnover of staff at the facility and district management levels, communication needs to take place regularly between provincial research head office and district and facility management, to ensure that all staff involved in providing support letters to researchers are aware of the procedures they should follow, and of the suggested criteria for giving their support to the research projects, and are able to voice their concerns regarding

specific research projects. This ongoing capacitation of the staff of regulatory or review bodies has been raised as a need by researchers who analysed the time to approval for clinical trials in South Africa (Geldenhuys et al., 2012). They argued that limited capacity within the national regulatory body was at least in part responsible for the delays and variability in approval times of that body. Thus, although RECs in South Africa are relatively well capacitated (Cleaton-Jones & Wassenaar, 2010), it seems that the other bodies involved in approving health research, including Department of Health managers and the national regulatory body, may be less so. Attention should be paid to building this capacity at the relevant levels within the Department of Health (and the national regulatory body) to avoid delays in approval jeopardising the conduct of useful research.

5.3.3 STUDY CONDUCT

Health service managers felt that it was important to improve the mechanisms for monitoring research conducted in public health facilities including ensuring that informed consents are taken correctly from patients, that protocols are implemented as written and no additional research questions are added, and that patients are followed up for the correct periods of time. Managers of the health services suggested that patients who are also research participants should be followed up for longer, to reassure the Department of Health that adverse events due to study participation have been ruled out, and will not therefore be the responsibility of the Department to treat. These concerns are not unique to KZN, nor to South Africa. In response to research misconduct in Canada, authors have suggested that the following should be monitored routinely in all health research: regular reviews of research as it takes place, monitoring of the informed consent process, monitoring of the adherence to the protocol, and monitoring of the collection and utilisation of the data (Weijer, Shapiro, Fuks, & Skrutskowska, 1995). Currently there is little to no monitoring of research taking place at public health facilities in KZN, and thus no evidence to reassure managers that researchers are adhering to their obligations. Assurance that such processes were occurring as they should might build up trust between Department of Health managers, and researchers.

Researchers also suggested that they themselves work on minimising the perception that researchers “dump” patients back into public health facilities. In order to rectify this perception, they should communicate with the Department of Health in good time, prior to ending a study; they should also ensure that prospective patients are registered as Department of Health patients before they are recruited into a study, so that when they return to the care of the Department after the study, they are not perceived as new patients.

Both researchers and health managers suggested that Department of Health staff should collaborate as research partners, in order to increase the sense of "ownership" of the research by DoH staff, and the likelihood that the research results will be utilised. Both groups of interviewees emphasised the benefits of involving Departmental staff in research, which included capacitation of these staff, increased interest in and attention to research from Departmental staff, and greater likelihood of the utilisation of research results. Indeed, it has been shown that "policy makers pay more attention to research findings if they have invested their own funds and time" in it (Martens & Roos, 2005, p. 74).

Health service managers considered that it was important to actively transfer skills to Departmental staff during the research process, to increase the value of the research from a Departmental perspective, but also to enhance the understanding of Departmental staff of the research process, so that a culture of research could be inculcated within the Department. This may enrich the research process, and establish greater equality in the relationship between researchers and health managers, thus bringing them closer to a truly collaborative partnership as described by Emanuel et al (2004).

5.3.4 DISSEMINATION AND UTILISATION OF RESULTS

Many respondents suggested the hosting of regular formal feedback sessions, in order to ensure the dissemination of research results to health managers. This dissemination should not take place using only conventional methods such as meetings and peer reviewed publications, but should include the use of different media such as newspapers and radio. Research results should not only be disseminated to health managers and policy makers but also to the general public (Medical Research Council (Great Britain); Opinion Leader Research Ltd.; Wellcome Trust (London, England), 2012). Research feedback should be packaged in ways appropriate for specific audiences, including the 'sound-bite' for quick and efficient dissemination such as that delivered on radio (ibid). Stakeholders should explore the art of "evidence-based story telling" (Martens & Roos, 2005, p. 78) to enhance the reach of their feedback of research results.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

This study aimed to explore the perceptions and practices of key stakeholders (researchers and health managers) regarding research conducted in provincial public health facilities in KZN, including regarding inter-stakeholder relationships. The study also aimed to make recommendations to strengthen the ethical conduct of research, including implementation and uptake of research results in public health facilities in KZN, and inter-stakeholder relations. This chapter sets out the conclusions of the study in relation to each of these aims, and makes recommendations for various stakeholder groups, which include recommendations made by study participants themselves, as well as those emerging from the research. Because many of the issues raised by the study were inter-related, it is likely that the recommendations if implemented will address more than one issue at a time.

In terms of the first aim (which was to explore the perceptions and practices of key stakeholders around research conducted in provincial public health facilities), this study concluded that, in general, both managers and researchers believed that research is important, and that it can have a significantly beneficial effect on health and health care. Beyond this level of consensus however, important areas of difference were described in two themes – that of the perceptions of these stakeholders around the social value of research, and that of perceptions of a strained relationship between researchers and health managers (gatekeepers) in KZN. This second theme corresponds well with the second aim of the study, which was to explore inter-stakeholder relationships. A third theme emerged as often-shared recommendations of the participants themselves, and this corresponds well to the third aim of the study, which was to make recommendations for improving research processes and inter-stakeholder relations around research in public health facilities in KZN. These themes were strongly inter-related. Some of the tensions that both groups of stakeholders (researchers and health managers) expressed around their relationships seemed to be rooted in their differing opinions of the inherent social value of research, and many of the recommendations suggested by both sides focused on communication to facilitate the understanding of these differences. Whilst acknowledging the strong inter-relatedness of these themes, the conclusions relating to each are presented separately below.

6.1 CONCLUSIONS

6.1.1 PERCEPTIONS AND PRACTICES OF RESEARCH

In terms of the first aim - to explore the perceptions and practices of stakeholders around research in public health facilities in KZN – this study concludes that stakeholders did not agree on the fundamental value of research in these facilities. This disagreement likely impacted how relationships between managers and researchers were perceived, at various stages of the research process (which is described in section 6.1.2 below).

Interviewees disagreed on why research in public health facilities was valuable. Health managers tended to emphasise the immediate benefits of research to health systems functioning, whilst researchers tended to emphasise the benefit of research for future patients through its contribution to new knowledge. Health managers valued the capacity and infrastructure benefits of health research, which corresponds with the so-called 'collateral' benefits described by King (2000) as distinct from the aspirational benefit to future persons and society arising from results. They perceived that research could also have a direct negative effect on the health facilities at which it is undertaken, and that there may be considerable burdens related to research in public health facilities, such as the use of hospital beds and other public health sector resources, to the detriment of public sector patients and staff. Therefore they viewed as less valuable research that undermined the facility and its functioning. Researchers on the other hand seemed to feel that any negative impact of research on health facilities would be more than compensated for by the general benefit of the research, both to the generation of new knowledge and to the facility in general, since some researchers did provide resources for the facilities in which they worked.

These conflicting views suggest important differences in how researchers and health managers value research. Health managers placed more value on immediate benefits of research to healthcare systems than on generation of new knowledge for future benefits. For example, they stressed the importance of building capacity of health care workers during research projects. In contrast, researchers placed greater value on the generation of knowledge for future long-term use than on immediate operational benefits.

Identifying these differences in perceptions regarding the value of research is an important first step in better understanding the quality of researcher-gatekeeper relations, for example, why researchers and health managers might experience conflict in their relationships. These differences

in perceived value might explain certain practices over the research process, and why these are perceived as frustrating and unreasonable, to the 'other side'. For example, researchers expressed frustration at the slow research review process – speedy review was reportedly important to researchers because research was valued; the speed of review was considered less important by health managers who questioned whether research would yield the kind of benefits they value. These issues are discussed further under Theme two below.

There has been limited investigation into stakeholder differences in the valuation of research. Social value has only recently been articulated as a dedicated ethical requirement for research in ethical guidelines (CIOMS, 2016) and ethical frameworks (Emanuel et al., 2000; Emanuel et al., 2004; Emanuel et al., 2008). Even in those documents where it is explicitly referred to, the notion that research may be valued differently by different stakeholders is seldom acknowledged (Emanuel et al., 2004; Emanuel et al., 2008). In the latest iteration of leading guidelines (CIOMS, 2016), social and scientific values are identified as two separate entities (CIOMS, 2016). However, social value is still defined in these Guidelines in ways that suggest scientific value alone; that is, social value is defined as "the prospect of generating the knowledge and the means necessary to protect and promote people's health" (CIOMS, 2016. p. 1) and as "the importance of the information that a study is likely to produce" (CIOMS, 2016, p. 1). The notion that some may perceive the most valuable aspect of research to be the strengthening of the health service as a by-product of capacity and infrastructure development, rather than the generation of new knowledge, is seldom recognised in ethical guidelines. However, it is likely that such differences of opinion do occur in other low-resource settings (Lairumbi et al., 2012), where the imperative of health managers is to improve their health services in resource-constrained environments, rather than to generate new knowledge. Therefore, this perception of value should be explicitly considered in early discussions around proposed research, so that the conduct of that research is valued by all stakeholders.

This study concludes that the 'traditional' definition of socially valuable research may not be shared by key stakeholders involved in research in provincial health facilities. Acknowledging that such stakeholders (especially in low and middle income countries) may value research differently, and identifying what they do value about research, may assist stakeholders to understand each other better. This may in turn lead to improved inter-stakeholder relationships, better quality of research and improved utilisation of research results.

6.1.2 PERCEPTIONS OF INTER-STAKEHOLDER RELATIONS

In terms of the second aim of this study, that is to explore the inter-stakeholder relationships around research in public health facilities in KZN, this study concludes that the relationships between health managers ('gatekeepers') and researchers appeared strained, and that perceived tensions in these relationships extended across the whole research process; however, tensions were characterised slightly differently at various phases (from conceptualisation of the research question, through the conduct of the research itself, to the feedback and utilisation of research results).

Health managers and researchers perceived a lack of mutual trust and respect, across the entire research process, as well as a failure to achieve a common understanding of the value of research over the research process. Reflecting their valuing of the knowledge-generation component of research, researchers suggested that research projects did not receive the respectful attention from health managers that they warranted. They reported that managers did not avail themselves for communication meetings to discuss proposed or ongoing research projects, and they perceived that the application process to conduct research at public health facilities was unnecessarily inefficient; and that 'gatekeepers' at facility level lacked transparency and accountability.

However, health managers (gatekeepers), reflecting their different estimation of valuable research, perceived researchers as demanding, inconsiderate of their needs; and centered on their own goals whilst disregarding those of the health services. Furthermore, health managers felt that they could not trust researchers' integrity in adhering to their research protocols. These tensions extended throughout the research process, including the final stage of dissemination and utilisation of research results, which both researchers and health managers agreed was poorly done, although both blamed the other for this.

It is recognised that strained inter-stakeholder relationships undermine the conduct of research and the utilisation of research results. In Cambodia, tenofovir trials were cancelled because of poor communication and misunderstandings between researchers, research participants and gatekeepers (Upkong & Peterson, 2009). In South Africa, the poor utilisation of research results is well recognised (Mayosi et al., 2012; Senkubuge & Mayosi, 2013). However, in the literature on South Africa, the issue of strained relations between researchers and gatekeepers is rarely raised (Singh & Wassenaar, 2016). Internationally, there is substantial ethical guidance on the development of good inter-stakeholder relationships in research (Critical Path to TB Drug Regimens Initiative (CPTDRI), 2012; UNAIDS/AVAC, 2011). All these ethical guidelines emphasise the importance of similar principles in

inter-stakeholder relationship building such as respect, fairness, integrity, transparency, accountability, and mutual understanding. However, the guidelines focus on *how* to ensure positive relationships; and the reasons *why* inter-stakeholder relationships may be poor are seldom discussed in such documents. Indeed, in the *Good Participatory Practice Guidelines for TB drug trials*, the lack of empirical evidence informing the development of the Guidelines is acknowledged (CPTDRI, 2012).

This study concludes that for these KZN stakeholders, strained relations exist between stakeholders over most of the research process. It concludes that different concerns may give rise to these strained relations at various stages of the research process. This may provide points at which interventions could occur, or at the very least, around which inter-stakeholder conversations could be started. This study has suggested reasons for the strained relationships that appear under-explored in much other literature. Some of these issues may be difficult to talk about, such as the lack of trust in the ethical behavior of researchers. However sensitive, it is important that these issues are acknowledged, so that they can be discussed and addressed by stakeholders in the future. Improving these relationships may assist stakeholders to articulate their view of valuable research and help realise the social value of research in KZN.

6.1.3 RECOMMENDATIONS FOR ENHANCED RESEARCH AND RELATIONS

In terms of the third aim – to make recommendations to strengthen ethical health research in KZN, and to improve inter-stakeholder relations – this study concludes that stakeholders from both groups share notions about how health research in KZN can be improved, at all its stages. In fact, except for the suggestion of punitive measures for researchers who fail to give feedback on their research results, there was remarkable similarity between the recommendations made by these two groups of interviewees. In this section, the focus is on the recommendations of study interviewees. In the recommendations section (6.2 below), both the recommendations of participants and recommendations of this investigation are outlined.

Health managers and researchers shared many views about the interventions that might improve research generally, as well as their relationships over the research process. Communication was key to most of the recommended interventions, such as a technical task team to discuss new research concepts, to regular meetings for dissemination and discussion of research results. Communication is also an important principle in the Good Participatory Practice Guidelines (UNAIDS/AVAC, 2011),

and this study reinforces the centrality of communication to good inter-stakeholder relationships in research.

Capacity building of Departmental staff was also considered important in order to facilitate their more equal engagement with researchers. This equality of engagement is arguably an important part of 'collaborative partnerships', held as the ideal inter-stakeholder relationships for the conduct of ethical research (Emanuel et al., 2000; Emanuel et al., 2004; Emanuel et al., 2008). Building capacity to facilitate such 'equal' engagement is one of the principles of recent ethics guidelines, such as the *Good participatory practice guidelines for TB drug trials* (CPTBDRI, 2012) and the *Good participatory practice guidelines for trials of emerging (and re-emerging) pathogens* (WHO, 2016). When the engagement between health managers and researchers is perceived as more equal, it may be easier for health managers to negotiate the benefits that they see as important components of valuable research.

Improved management of the review process with transparent review criteria and timeous responses was considered crucial by researchers whilst improved monitoring of research and negative consequences for unethical conduct on the part of researchers was considered important by health managers. Indeed, the process of review of research proposals should be held to similar ethical standards as the conduct of research (as outlined in research protocols). The principles of transparency, responsiveness and accountability should be applied in both. Researchers should expect certain standards of protocol review, just as health managers should expect ethical implementation of research by researchers. In building better relationships between researchers and health managers, standards for the conduct of both groups as outlined in this study could be incrementally improved.

This study concludes that the recommendations that interviewees made towards improving the research process and strengthening inter-stakeholder relations may be more shared than disparate. These recommendations may go a long way to enhancing communication, and building mutual understanding and respect between researchers and health managers in KZN. They are the basis of the recommendations described below.

6.2 RECOMMENDATIONS

A number of recommendations are made in this section for key stakeholders involved in research in provincial health facilities, which are not limited to the perceptions of the sample alone. These recommendations are linked to the relevant guiding principle in key ethics guidance (UNAIDS/AVAC, 2011).

6.2.1 RECOMMENDATIONS FOR BOTH GATEKEEPERS AND RESEARCHERS

A forum to discuss findings from this study related to different perceptions of social value would be important, so that a "shared vision" of socially valuable research could be negotiated (Lutge et al., 2017, p. 132) and "both aspirational and collateral benefits should be articulated and accommodated" (Lutge et al., 2017, p. 143)

In order to ensure collective development of regional research priorities and key research questions, workshops to build consensus regarding these should take place regularly, for example, every three to five years. From these workshops, priority health questions should be identified, which should be timeously distributed to core stakeholders (such as academic and research organisations within KZN) for uptake by researchers, academics and students. These workshops should be inclusive, so that not only researchers, academics and health managers are involved but also other key role-players (cf. UNAIDS/AVAC, 2011) such as community representatives, faith based and non-governmental organisations and traditional healers.

In order to ensure that the research priorities set are comprehensive and relevant, that the research process is acceptable, and the research itself is valued by all stakeholders, the discussions at the subsequent workshops should include the following points: gaps in current research (per programmatic area in the Department of Health); major emerging health or health systems issues (for the province as a whole as well as per district or sub-district); how Department of Health staff could be involved in answering these research questions (including issues of capacity building of staff, which would increase the social value of the research for managers of affected institutions or programmes); where the research could best be conducted (to avoid perceptions of 'over-research' in certain sites); how the health service could benefit from the research, such as through staff development (as above), or health system or infrastructure development (thus also increasing the social value of the research for health managers).

Once research priorities have been identified, researchers and the relevant managers should work together to frame the research questions. Regular research forums should be held to discuss ongoing research projects. These could be organised per health facility, per health programme (for example, TB, non-communicable diseases, etc.), or per geographic area (for example, district or sub-district), or both. At these meetings, the following should be discussed: concerns from either researchers or health managers regarding the conduct of the research (including issues such as use of Departmental resources by researchers, and adherence to research protocols; factors undermining (or facilitating) the research, and whether the timeframes of the research would be affected; interim results of the research; and plans for feedback of final research results).

In order to maintain open channels of communication, regular feedback meetings to present research findings to health managers should take place. These should take place in the facility where the research took place, as well as district and provincial programme offices. At these meetings, the following should be discussed: the implications of the research findings for policy and practice; practical ways of incorporating the research findings into Departmental policies and practice; the research questions remaining in the field; how these research questions should be prioritised; which research question should be addressed next; and how researchers and health managers could work together to address the next research question. In this way, meetings for the dissemination of research findings could also assist with research translation, and act as forums for research prioritisation in the field (also discussed below).

6.2.2 RECOMMENDATIONS FOR GATEKEEPERS

For health managers at facility or programme level: Health managers should ensure that they respond to communication from researchers timeously (where a reasonable limit should be negotiated). Where such communication revolves around new research projects, managers should ensure that they give input into new projects timeously, so that their valuable experience can be used to enhance the project, but also so that the project is not hampered by a delayed response. Health managers should within reason, attend all or most of the research meetings initiated by researchers. Health managers should be transparent about concerns they have about individual research protocols during the request for permission to enter sites and should discuss these with the relevant investigators timeously and in an honest manner. Where offers of research mentorship or capacity development are given, health managers should accept where possible or decline, acknowledging that the offer has been made.

For the PHREC: The KZN PHREC should make the criteria for approval of health research clear, should ensure that these are available in writing and accessible at all times (for example, on a website), and should ensure that these are understood by all managers involved in the process of review. When management staff change, new employees should be made aware of these criteria and the decisions required of them at their level of management. Health managers should take the decisions that are delegated to their level of appointment, and not refer such decisions to higher levels

The KZN PHREC should ensure that researchers can apply for Departmental permission for research in parallel with their applications to Research Ethics Committees and other regulatory bodies, instead of applying to these bodies sequentially, and thus reduce the total research application time. The KZN PHREC should establish a research monitoring team, to regularly visit research sites and ensure that research is being conducted according to protocol; and reports of these visits should be circulated to the relevant health managers. If budgetary constraints prohibit this, the KZN PHREC should consider training individuals at research active health facilities to implement this monitoring and report on it.

6.2.3 RECOMMENDATIONS FOR RESEARCHERS

Researchers seeking permission from facility managers to conduct research in their facilities should do so respectfully, acknowledging the other demands on managers' time. Researchers should submit their proposals for Department of Health review in good time, to allow gatekeepers sufficient time to review and consult on these. Researchers should commit to doing some capacity building of Departmental staff during the conduct of their studies; this should be commensurate with the duration and complexity of their studies. Capacity building may take a variety of forms, such as including a staff member to collaborate on the project, or delivering regular seminars at the institution etc. Researchers should follow up their patients for long enough to ensure that any sequelae of participation in research studies will be detected, and can be addressed by the researchers or organisations conducting the research. During the conduct of the study, researchers should refrain from deviating from their protocols, but if this is necessary, should ensure that any deviations are reported immediately to the manager of the health facility, district or programme concerned. Researchers should be open to monitoring visits from Department of Health officials, undertaken to ensure adherence to research protocols.

Also, researchers should be transparent about the Departmental resources that they require, or use, during the conduct of research and should be willing and able to reimburse the Department for the

use of these resources. Researchers should ensure that their research results are disseminated to the relevant managers within the Department of Health, and should avail themselves for meetings to discuss these results, or at least respond to electronic or telephonic questions about these results, after the study is concluded. Furthermore, researchers should use a variety of media to package their research results, so that they are easy to understand, presented in appropriate (non-academic) language, and are appropriate for the target audience. Researchers should meet their obligations (as outlined in their letters of permission from facility managers) of providing feedback to health managers on completion of their research

In summary, this study has concluded that, although researchers and managers agree that research in KZN health facilities is important, they disagree about what makes research valuable. Further, they report strained relationships across the whole of the research process due to a variety of factors, one of which is likely to be diverging perceptions of socially valuable research. The study makes a number of recommendations, both as suggested by participants themselves and those suggested by the investigator, to strengthen the conduct of research in KZN health facilities and to improve inter-stakeholder relationships. Although it is not expected that the process of conducting research in KZN, and the relationships between health managers and researchers would improve 'overnight' as a result of these recommendations, it is expected the recommendations may contribute towards enhancing trust and mutual respect between these stakeholders, which may in turn result in stronger relationships, an improved research process, and research which is highly valued by both health managers and researchers.

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APPENDIX 1: INFORMED CONSENT FORM

Dear colleague

I am Elizabeth Lutge from the KwaZulu-Natal Department of Health. I am conducting a study about health research in KZN public health facilities, specifically looking at how key stakeholders perceive such research and each other, the practices they engage in, and the impact of such views and practices on the entire research process.

What is the purpose of this study?

This study aims to explore the perceptions of key stakeholders regarding research in health facilities in KZN and the practices they implement, including engagement practices.

The study aims to make recommendations to improve or strengthen research and stakeholder-engagement practices for such research.

Why have you been chosen to participate?

You are invited to participate because you have experience in the conduct of research in health facilities in KZN and your contribution will enrich the results of this study.

This study will invite a variety of representatives from the health services, research and academic institutions in KZN, amongst other stakeholders.

What will the research involve?

You will be asked to take part in an interview. The interview is likely to take approximately one hour.

If you agree, it will be tape recorded. You will be asked questions about your experiences of the entire research process as it relates to studies conducted in health facilities in KZN, and your experiences of the relationships between various stakeholders in this research, and to identify areas that appear to work well, as well as areas that need strengthening.

Do you have to participate?

We hope that you will give your time and opinions to this interviewer, so that your views can contribute to this process.

However, you are free to decline. If you decline, this will not be held against you or your organisation/facility in any way.

You are also free to choose not to answer any questions in the interview if you so wish.

You may withdraw from the interview at any time.

If you do participate, are there any risks involved?

It is possible that you may feel some discomfort discussing your experiences. You are free to decline to any specific questions in the interview if you so wish.

What steps will be taken to ensure confidentiality?

Identifying details will be redacted from your transcribed interview.

Your interview will be assigned a unique number.

Your anonymized interview will be kept in a separate location from your signed consent form.

Your interviewer will not divulge your identify.

Your name will not appear in transcribed interviews, nor any reports, presentations or publications that emanate from this study

All data (such as transcripts) will be stored in a locked drawer at the KZN Department of Health for 5 years.

Electronic data (such as audio-files, electronic transcripts) will be stored password protected.

What are the benefits of this study?

Whilst you may not benefit directly from this study, it is hoped that the results will be used to improve the research process and stakeholder relationships for such research in KZN.

Will I be paid?

This study will only pay for out of pocket expenses incurred by participants and it is anticipated that participants will not incur such expenses during this study.

“Out of pocket” expenses include only reimbursement of mileage travelled in a personal motor vehicle, specifically to attend an interview for this study, calculated according to the rates determined by the KZN Department of Health.

What will happen to the results of this study?

Preliminary results will be presented at a stakeholder meeting.

Interviewees will be provided with feedback of the main results.

The results will also be written up in a report for the Head of the Department of Health, and the Provincial Health Research and Ethics Committee in the province.

They will be written up for a thesis as part of a degree at the University of KwaZulu-Natal.

They may be submitted for publication in a peer reviewed journal.

Who has approved this research?

This research has been approved by the Social Science Research Ethics Committee of the University of KwaZulu-Natal.

It has also been approved by the Health Research and Knowledge Management Unit of the KZN Department of Health.

Should you have questions about this research, please contact Elizabeth Lutge at 033 – 3952046 or elizabeth.lutge@kznhealth.gov.za

If you have any questions about ethical issues relating to this research, please contact the Social Science Research Ethics Committee of the University of KwaZulu-Natal: Prem Mohun at 031 260 4557 or mohunp@ukzn.ac.za

Declaration

I, _____ (full names of participant) confirm that I understand this consent form and the nature of the study and agree to participate

I understand that I can withdraw from the study at any time.

SIGNATURE OF PARTICIPANT DATE

_____ _____

Tape recording consent

I, _____ (full names of participant) consent to the tape-recording of the interview.

SIGNATURE OF PARTICIPANT DATE

_____ _____

APPENDIX 2: REC-APPROVED INTERVIEW SCHEDULE

INTERVIEW SCHEDULE

The following domains will be explored with all research participants, but depending on the participant, more depth will be sought for certain issues than for others.

- The participant's current role in the research process

- The participant's previous/ current experience with research

- The participant's view of the value/ worth of research, whether/ how it contributes to the improvement of health/health care in the province and whether the latter is a valuable goal

- The participant's perceptions and practices regarding various stages of research:
  - ✓ the conceptualization of the research question;
  - ✓ the development of the protocol;
  - ✓ the approval of the research proposal by the KZN Department of Health;
  - ✓ the conduct of the research;
  - ✓ the effects of the research on the health facility;
  - ✓ the effectiveness or otherwise of the resolution of problems that arise during the conduct of the research;
  - ✓ the dissemination of the research results;
  - ✓ the utilization of research results;
  - ✓ factors undermining or facilitating the research;
  - ✓ recommendations for improvement.

- The participants views and actions regarding stakeholder relationships including:
  - ✓ communication (transparency, frequency);
  - ✓ issues related to mutual understanding; trust and accountability;
  - ✓ factors enhancing or undermining engagement;
  - ✓ recommendations for improvement;
  - ✓ impact on research and stakeholder engagement;

- Specific incidents or experiences that might illustrate any of the above points.

APPENDIX 3: INTERVIEW GUIDE

PART 1

THE FIRST FEW QUESTIONS ARE ABOUT YOUR BACKGROUND AND EXPERIENCES OF RESEARCH

1. Where do you currently work?

2. What is your role in your institution?

3. What role do you play in any research that is conducted in your institution?

4. Please can you describe some of your experience with research projects in the last 2 years.

5. Please highlight experiences that stand out for you as being important or significant.
6. Please also highlight positive and negative experiences that stand out for you.

PART 2

THANK YOU FOR THOSE OBSERVATIONS…

THE NEXT QUESTIONS ARE ABOUT YOUR VIEWS OF RESEARCH IN KZN AND ITS VALUE

1. Do you think that health research is important for health in KZN? Why/why not?

2. Do you think health research improves or detracts from population health in KZN? Why/why not?

3. Do you think that health research improves or detracts from the delivery of health services in KZN? Why/why not?

PART 3

I'D ALSO LIKE TO FIND OUT ABOUT YOUR EXPERIENCES OF VARIOUS STAGES AND COMPONENTS OF RESEARCH IN KZN HEALTH FACILITIES

1. What has been your involvement in conceptualizing research question?

2. What have you experiences been like in developing protocols?

3. What have you experienced with regard to approval of the research proposal by the KZN Department of Health?

4. What has it been like for you conducting studies (in KZN facilities?)…?

5. What in your view have been the effects of the research on the health facility?;

6. What in your view are the problems that arise?

7. How are they resolved, if at all?

8. What has been your experience of results dissemination after research? ;

9. What ideas do you have about whether research results are used?

10. What undermines research in KZN facilities?

11. What might strengthen such research?

12. Any recommendations for improvement?.

PART 4

THE QUESTIONS THAT FOLLOW ARE ABOUT INTERACTION AND COLLABORATION BETWEEN RESEARCH STAKEHOLDERS INVOLVED IN RESEARCH IN KZN FACILITIES…

1. What has your experiences been like interacting with other research stakeholders?

2. Can you provide some comments on communication between SHs?

3. What in your view is the level of trust?

4. Any ideas or remarks about accountability?

5. What enhances engagement between key parties?

6. What undermines these relationships?

7. Recommendations for improving relationships?

PART 5

WE ARE NEARING THE END OF THE INTERVIEW, THANK YOU FOR YOUR HELP SO FAR.

1. **FINALLY, are there any specific incidents or experiences that might illustrate any of the above points?**
2. **If not yours, any you have heard? Incidents you have heard about?**

ADDITIONAL ISSUES

1. **IS THERE ANYTHING I HAVE NOT ASKED ABOUT? ANYTHING THAT IS IMPORTANT TO CAPTURE HERE?**

APPENDIX 4: CODE LIST

MASTER THEME 1: VARYING PERCEPTIONS OF SOCIAL VALUE

SUB-THEME: VALUE FOR FUTURE BENEFICIARIES

- Public/population health: global: generation of new internationally relevant knowledge
- Public/population health: KZN (local priorities different from global)
- Public/population health: global: millions of patients benefit
- Public/population health: KZN: unique problems addressed
- Public/population health: KZN: unique response to research

SUB-THEME: VALUE FOR KZN PROVINCIAL DEPARTMENT OF HEALTH

- Builds people (human capital): capacitates DOH staff
- Relevance of research: research for academic rather than practical purposes (problematic)
- Relevance of research: research to solve operational issues
- Impactful: health systems: help shape interventions
- Impactful: health systems: add improvements
- Impactful: clinical care: new drugs registered
- Impactful: clinical care: development of protocols based on research findings
- Impactful: exposes DOH staff to new treatments/modalities etc
- Impactful: health systems help shape improvements
- Impactful: health systems: research must result in improvements in order to be beneficial
- Impactful: increases DOH staff awareness of importance of data
- Material costs, burdens and benefits: research is expensive to conduct
- Material costs, burdens and benefits: research provides treatment for patients whom the DOH would otherwise have had to treat
- Material costs, burdens and benefits: PDOH does not support research
- Material costs, burdens and benefits: complex logistics of obtaining funding for research (researcher and DOH perspective)

- Value for PDOH as perceived by researchers: research is not valued
- Value for PDOH as perceived by researchers: research is not valued because it may be critical
- Lack of DOH encouragement/support of research
- Visible

SUB-THEME: BURDEN FOR PROVINCIAL DOH

- Material costs, burdens and benefits: post research burden on DOH when researchers run out of funding
- Material costs, burdens and benefits: post research burden on DOH when patients need drugs post trial
- Material costs, burdens and benefits: Using facility resources: general: researchers exploit
- Material costs, burdens and benefits: Using facility resources: general: researchers exploit and contribute
- Material costs, burdens and benefits: Using facility resources: general: researchers contribute
- Material costs, burdens and benefits: Using facility resources: general: researchers (should) contribute
- Material costs, burdens and benefits: Using facility resources: general: researchers contribute
- Material costs, burdens and benefits: Using facility resources: diagnostic tests: researchers exploit
- Material costs, burdens and benefits: Using Facility resources: hospital beds: researchers exploit
- Material costs, burdens and benefits: Using Facility resources: DoH staff time: researchers exploit
- Material costs, burdens and benefits: DoH perceptions of researcher wealth
- Material costs, burdens and benefits: DoH lack of support for research (researcher perspective)
- Material costs, burdens and benefits: DoH perceptions of researcher wealth (researchers refute)
- Causing harm: Unintended effects such as drug resistance not detected till years after research

- Causing harm: Undermining service delivery if DoH staff involved in research outside of routine work
- Excessive research in one facility
- Interfering with program
- Relevance of research: Not connecting with program
- Relevance of research: not implementable by Department
- Encouraging DoH staff to conduct research : constraints

SUB-THEME: VALUE FOR ENROLLED PARTICIPANTS

- Better care: superior to usual care
- Better care: access to current treatments
- Better care: improving access to new treatments
- Better care: more individual attention than usual care
- Material costs, burdens and benefits: incentive for trial participants but not for other patients

MASTER THEME 2: STRAINED RELATIONS

CONCEPTUALISATION

- Partnership: Importance of involving DoH at conceptualisation of research question
- Communication: Developing research question
- Communication: Obtaining support for grant applications
- Communication: Agenda setting
- Communication: relationship building
- Communication: lack of communication with researcher and hospital departments affects hospital planning
- Communication: lack of inclusiveness
- Material costs, burdens and benefits: complex logistics of obtaining funding for research (researcher perspective)

REVIEW

- Review: regulations from ethics committee
- Review: Danger of DoH as 'gatekeeper'
- Period for review: lengthy
- Period for review: lengthy: result of poor DoH research literacy
- Period for review: lengthy (outlying view)
- Period for review: justification for (DoH perspective)
- Period for review: lengthy, onerous
- Period for review: impact of for research grants
- Period for review: rapid or lengthy
- Duplication of review: lengthy because of sequential reviews by various bodies
- Duplication of review: lack of trust between regulatory bodies
- Transparency
- Transparency: failure to inform researchers of new application form
- Transparency: DoH decisions not transparent
- Transparency: failure to inform researchers of reasons for re-submission
- Accountability: failure of regulatory body to look after submissions
- Accountability: variability in quality depending on person involved
- Accountability: Failure of DOH staff to honour meeting appointments
- Communication: general
- Communication: lack of communication between regulatory bodies
- Communication: easy communication with regulatory bodies facilitates application process
- Communication: variability in quality depending on person involved
- Communication: within DoH re review process (poor)
- Communication: within DoH re review process (poor); responsibility in DOH for taking decisions (lack of)
- Communication: regarding review from DoH to researcher

- Trust: lack of trust between regulatory bodies
- Fairness: Faster process if personally acquainted with DoH representative
- Fairness: length of review process arbitrary, unpredictable
- Review at provincial level with NHRD

STUDY CONDUCT

- Power relations: DoH staff diffidence
- Power relations: superior researcher knowledge
- Power relations: superior researcher knowledge OR research literacy DoH staff
- Power relations: DoH staff inexperience OR research literacy DoH staff
- Power relations: only senior DoH staff conduct research
- Trust
- Trust: Long term unintended effects of research fall on DoH
- Trust: relationship built over long period of time
- Trust: Not trusting researchers to inform/ feedback to DoH
- Trust: Mistrustful of researchers motivation: money-making
- Trust: Mistrustful of researchers' motivation: getting degrees
- Trust: Not trusting researchers to report problems, adverse events
- Trust: Not trusting researchers' conduct research as per protocol
- Trust: Not trusting researchers' conduct research as per protocol: to do informed consent as stated
- Trust: Not trusting researchers conduct research as per protocol: safeguarding data
- Trust: Not trusting researchers conduct research as per protocol: anonymizing data
- Trust: takes time to build in relationship
- Communication: must be constant to avoid misunderstanding
- Communication: several lines of within DOH
- Facility resources: hospital beds: researchers exploit
- Facility resources: hospital beds; researchers exploit; also Trust: researchers conceal activities

- Material costs, burdens and benefits: use of facility resources: staff time: researchers exploit
- Value for PDoH as perceived by researchers: research is extraneous to/competing with service-delivery
- Value for PDoH: research perceived as criticism
- Value for PDoH: research is exposing problems within DoH therefore is not valued
- Builds people/capacity development
- Partnership between researcher and DoH staff

DISSEMINATION

- Transparency
- Implementation of results: effect in the real world
- Implementation of results: timeliness and effectiveness of implementation
- Feedback/dissemination of results:
- Feedback/dissemination of results: researchers do not feedback to DoH
- Feedback/dissemination of results: researchers feedback to DoH variably
- Feedback/dissemination of results: researchers do not feedback to DoH well
- Feedback/dissemination of results: DoH hears about research results elsewhere, not from researchers
- Feedback/dissemination of results: DoH does not engage with results
- Feedback/dissemination of results: DoH does not facilitate feedback
- Feedback/dissemination of results: DoH does not facilitate feedback; Accountability: Failure of DOH staff to honour appointments and to return calls
- Feedback/dissemination of results: making results accessible/understandable
- Feedback/dissemination of results: DoH is overlooked by researchers in favour of other forums
- Feedback/dissemination of results: DOH does not facilitate feedback; Accountability: Failure of DOH staff to honour meeting starting times
- Accountability: Failure of DOH staff to honour appointments and to return calls
- Even in feedback session organized by DOH facility, poor researcher participation
- Utilisation of research results: results are used to change protocols

SUB-THEME: RESEARCHER-RESEARCHER RELATIONS

- Trust: don't trust other researchers to behave ethically
- Competition between researchers
- Competition between researchers: Territorialism

MASTER THEME 3: STRENGTHENED RESEARCH AND RELATIONS

CONCEPTUALIZATION

- Agenda-setting
- Use of public health physicians
- Discussion group/forum

REVIEW

- Review: enhancing review process
- Review: enhancing review process: clarifying responsibilities at all 'gatekeeper' levels
- Review: Training/capacity development for facility gatekeepers
- Review: concurrent review processes

STUDY CONDUCT

- Improving process of conducting research
- Capacity development: encouraging DoH staff to conduct research
- Capacity development: encouraging DoH staff to conduct research: preference to people from middle and lower income countries
- Capacity development / research literacy for DoH staff
- Capacitation of researchers: ethics training to improve ethical behaviour
- Obligation for DoH staff to conduct research
- Material costs, burdens and benefits: Need for funding for DoH staff to conduct research
- Encouraging research in DoH: providing incentives
- Encouraging research in DoH: capacity building
- Encouraging research in DoH: providing incentives (academic)
- Encouraging research in DoH: capacity building received

- Encouraging research in DoH: need for DoH support
- Encouraging research in DoH: make research part of DoH staff performance agreement
- Impact on health services: need for researchers to dovetail with routine services
- Trust: Not trusting researchers to monitor themselves
- Monitoring and Evaluation: Need to improve monitoring of research by DoH:
- Monitoring and Evaluation: need to ensure proper informed processes are followed by researchers
- Monitoring and evaluation: spot checks to ensure researchers are conducting research as per protocol
- Monitoring and evaluation: ensure detection of adverse events or other problems during research
- Longer post-trial follow up of patients to ensure unintended effects of research are detected

DISSEMINATION AND UTILISATION

- Feedback/ dissemination of results: organize formal feedback sessions to DoH
- Feedback/ dissemination of results: Use newspapers and other media to disseminate research results
- Feedback/ dissemination of results: regular feedback to DoH regarding stages of ongoing research and results of completed research
- Feedback/dissemination of results: penalize researchers who do not feedback results to DoH
- Feedback/dissemination of results: enforce dissemination of research results
- Feedback/dissemination of results: committee to review research results and guide implementation
- Research literacy: broad social education around research
- Utilisation of research results: ensure research is relevant to maximize utilization of results
- Utilisation of research results: ensure DoH understands value of research to improve utilization of results
- Working together, relationships: ensure all stakeholders understand their roles in research
- Communication: ensure all stakeholders understand value of research and how it can benefit each

APPENDIX 5:
ETHICS APPROVAL (BIOMEDICAL RESEARCH ETHICS COMMITTEE)

UNIVERSITY OF
KWAZULU-NATAL
INYUVESI
YAKWAZULU-NATALI

RESEARCH OFFICE
BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Westville Campus
Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 260-4609
Email: BREC@ukzn.ac.za
Website: http://research.ukzn.ac.za/ResearchEthics/BiomedicalResearchEthics.aspx

21 June 2016

Dr E Lutge (973166877)
Discipline of Psychology
School of Applied Human Sciences
elizabeth.lutge@kznhealth.gov.za

Dear Dr Lutge

Protocol: Exploring stakeholder perceptions and practices regarding research in Provincial Health Facilities.
Degree: M Soc Sci
***BREC reference* number:** BE346/16 *(HSS/1570/014M)*

I wish to advise that your application dated 31 May 2016 has been noted by the Chair of the Biomedical Research Ethics Committee (BREC).

The chair has granted reciprocity to the approval letter from HSSREC dated 19 January 2016.

This approval will be noted at the next Biomedical Research Ethics Committee meeting to be held on 12 July 2016.

Yours sincerely

Ms Anusha Marimuthu
Senior Admin Officer: Biomedical Research Ethics Committee

cc postgraduate officer: Khanyilet@ukzn.ac.za
cc supervisor: Catherine Slack

APPENDIX 6: PERMISSION FROM THE KZN DEPARTMENT OF HEALTH

health

Department:
Health
PROVINCE OF KWAZULU-NATAL

Health Research & Knowledge Management sub-component
10 – 103 Natalia Building, 330 Langalibalele Street
Private Bag x9051
Pietermaritzburg
3200
Tel.: 033 – 3953189
Fax.: 033 – 394 3782
Email.: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

Reference : HRKM333/14
Enquiries : Mrs G Khumalo
Telephone : 033 – 395 3189

Dear Dr E Lutge

Subject: Approval of a Research Proposal

1. The research proposal titled **'Exploring stakeholder perceptions and practices regarding research in provincial health facilities'** was reviewed by the KwaZulu-Natal Department of Health (KZN-DoH).

The proposal is hereby **approved** for research to be undertaken at KZN-DoH.

2. You are requested to take note of the following:
   a. Make the necessary arrangement with the identified facility before commencing with your research project.
   b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.

3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Ms G Khumalo on 033-395 3189.

Yours Sincerely

Mr J Govender
General Manager: Health Service Delivery, Planning, Monitoring & Evaluation
Date: 22/12/14