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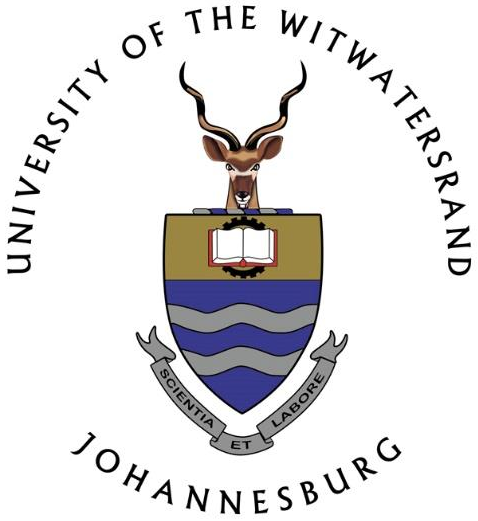
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How much community engagement of patient stakeholders has there been on the National Health Insurance?

A Bioethical Enquiry.



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Submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Medicine in the field of Bioethics and Health Law.

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(Director: Steve Biko Centre for Bioethics, University of Witwatersrand)

Declaration

I declare that this research report is my own unaided work. It is being submitted to the Degree of Master of Science in Medicine (Bioethics and Health Law) to the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination to any other University.


..... (Signature of candidate)

02 November 2018 at the University of Witwatersrand.

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"If I have seen further than others, it is by standing upon the shoulders of giants"

- *Sir Isaac Newtown*

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Dedication

I dedicate this Masters to my ancestors, the Matriarchs:

My Great Grandmother: Mrs Annie Tandwa

My Grandmothers: Mrs Nodathini Jiba & Mrs Nompumelelo Tandwa

My Mother: Mrs Nonzwakazi Tandwa

Thank you for being the pillars of my family. We shall realize your dreams and prayers.

"Many women do noble things, but you surpass them all." Proverbs 31:29

Abstract

Community engagement in health refers to the collaborative effort of citizens in a community to organize and participate in health promotion, research and policy development. Community engagement encompasses the participation of patients at micro, meso and macro levels. The National Health Insurance (NHI) is a South African health legislation that is under development which aims to ensure universal health coverage. Community involvement is a constitutional requirement and the policy makers of the NHI have a duty to involve the community and specifically; patients in the decision-making and implementation of the policy.

Mixed methods were employed in this research which include normative and empirical components. The normative component underscores that there ought to be meaningful and effective community engagement in the NHI policy process since this policy will directly affect health outcomes and people's lives. This component explores principles of autonomy in macro-engagement, procedural justice and the accountability for reasonableness ethical framework to highlight the importance of engagement and ways in which meaningful engagement can be achieved.

The empirical component was descriptive; cross-sectional and quantitative. 244 patients from the Internal Medicine Department at the Charlotte Maxeke Johannesburg Academic Hospital were interviewed to evaluate their awareness of the NHI and whether they had received an opportunity to participate in policy making process.

The majority of the participants (79.5%) were not aware of the NHI and 86% of the participants had not received an opportunity to be involved in the NHI policy development. The NHI policy makers have not met their ethical and legal obligations to involve patient stakeholders in the policy making process.

List of Acronyms

Accountability for Reasonableness: A4R

Choice on Termination of Pregnancy: CTOP

National Assembly: NA

National Council of Provinces: NCOP

National Health Act: NHA

National Health Insurance: NHI

International Covenant on Civil and Political Rights: ICCPR

International Covenant on Economic, Social and Cultural Rights: ICESCR

Traditional Health Practitioners: THP

Universal Declaration of Human Rights: UDHR

University of the Witwatersrand Human Research Ethics Committee (Medical): HREC

World Health Organization: WHO

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Chapter 1: Introduction and Overview of the Study

1.1. Background Literature

Health equity

Health equity is the "absence of systematic disparities in health between social groups who have different levels of social advantage/disadvantage – that is, different positions in a social hierarchy"[1]. Marmot, et al. describe health equity as inherently normative because it is value based and has ethical and human rights imperatives[2]. Health equity aims to achieve a just and fair health care system[1,2]. Universal Health Coverage (UHC) is defined as the "access to key promotive, preventive, curative and rehabilitative health interventions for all at an affordable cost, thereby achieving equity in access"[3]. Community engagement is the informed and active participation by members of communities in the issues of their health and the involvement in the law-making process and implementation of health policies[4].

Context of the study

The National Health Insurance (NHI) is health legislation that is under development. It aims to ensure health equity and universal health coverage in order to address the burden of diseases in South Africa. The history of the NHI in South Africa dates back to the Freedom Charter in 1955 and in 1994 preliminary discussions and investigations began on the possibility of a changing the health system of South Africa. These efforts informed the development of the NHI. The NHI hopes to achieve this through transforming the structure and the financing model of the South African healthcare system. The NHI is set to be rolled out over 14 years through three implementation phases namely; phase one: the transformation of the current system, phase two: registration and issuing of NHI cards and establishment of the NHI fund and phase

three will be dedicated to ensuring the fund and registered facilities are functional and successful[5,6].

The policy development of the NHI requires the involvement of key stakeholders to ensure that the NHI is consonant with the imperatives of health equity. The NHI Bill was gazetted in 2018 and is currently open for comments from the public[7]. Some of these stakeholders include; government, business and private sectors and community groups, civil society and patients[8]. Patients are not only users of health care system, they are also members of the community.

The Constitution of South Africa has identified the principle of participatory democracy which is achieved through public involvement as an imperative. Sections 59 (1)(a), 72 (1)(a) and 118(1)(a) clearly stipulate that the National Assembly, the National Council of Provinces and a Provincial legislature must "facilitate public involvement in the legislative and other processes" of the relevant legislative bodies and their committees accordingly [9]. Involvement in legislative processes is a constitutional requirement and an end that ought to be achieved. In South Africa the Constitution requires that our democracy has representative and participatory elements which ought to include community engagement. Community engagement enhances human and civic dignity and promotes a government that is based on the will of the people[4,10].

Community and Patient engagement

Community is the interrelation amongst people who may or may not have common cultural and value systems and who live in the same geographical area[11]. Community engagement is defined as "a process of working collaboratively with and for groups affiliated by geographical proximity, special interest or similar situation to address issues affecting the wellbeing of those people"[12].

Patient engagement is described in the literature as patient involvement, participation and even collaboration. These terms are used interchangeably, however engagement encompasses all the

properties of these terms[11,13]. Patient engagement is "to promote and support active patient and public involvement in health and healthcare and to strengthen their influence on healthcare decisions, at both the individual and collective levels"[14]. There are three levels at which patients can be involved in healthcare:

- Micro: refers to patients being involved at an individual level in clinical decision-making regarding their health, treatment and management.
- Meso: refers to the involvement of patients in decision-making at local or organizational level such as; hospital organization.
- Macro: the involvement of patients in policy decision-making at district, national and international levels[13–15].

Patients have been encouraged to be autonomous and active at the micro-level, as this promotes self-management of their health which directly affects health outcomes, safety and patient experience in the healthcare system. Shared decision-making between the practitioner who provides expertise and the patient who has preferences is important for treatment and management[15–17]. Patient involvement at the meso and macro-levels is uncommon, even when there are laws in place that encourage and necessitate the involvement of patients at these decision-making levels. At the macro-level priority setting, resource allocation and legislation affect the majority of the population. However, patients are not adequately represented. At this level the decisions will invariably affect all citizens[15]. Carman, et al. propose that a continuum of engagement at all levels would yield greater impact and change in the healthcare system to benefit the patient[14]. This continuum of engagement requires patients to have access to information and for there to be a bidirectional flow of information between policy developers and patients. Engagement allows for shared power and responsibility and public agency in health policy development, and for patients to be collaborators and partners in the process[13].

The Ottawa Charter (1986) identifies community engagement and action as the hallmark of health promotion and stipulates that: **"**Health promotion works through concrete and effective community action in setting priorities, making decisions, planning strategies and implementing them to achieve better health. At the heart of this process is the empowerment of communities, their ownership and control of their own endeavours and destinies."[18]. This underscores the importance of community and patient engagement in health. Engagement in health is not synonymous with compliance. The difference is that compliance means obeying directives from health providers and in the context of policy from policy makers. Engagement on the other hand initiates and ensures patient activation, which is the patient's ability to have an active role in their individual health and healthcare collectively[19,20]. Community engagement is an obligation and a duty that ought to be fulfilled in the policy development and implementation processes[4].

Raboshakga proposes a two-step approach in order to ensure that meaningful community engagement is achieved[4]. Policy makers need to equip the public with adequate information about the NHI that will enable and empower the public to be actively involved[4]. Policy makers also need to ensure that interested members of the community receive an opportunity for meaningful participation and for their views to be taken into consideration. Transparency is essential throughout the process of policy development and implementation with effective coordination mechanisms and appropriate accountability devices is necessary[4,21].

1.2. Rationale for the Study

It is stated in the NHI White Paper that there were 150 written submissions and more than 60 000 citizens were engaged through national and provincial roadshows during the development of the NHI Green Paper and White Paper[5]. In the NHI White Policy and the NHI Bill there is no mention as to whether the policy makers of the NHI have engaged with more

stakeholders. The number of people that were engaged in these workshops is a small percentage of the population of South Africa which is 57.73 million[6,7,22]. There is a legal obligation in the Constitution of South Africa to involve the community in policy development at multiple levels[9]. However, the ethical obligation from a normative perspective has not been explored sufficiently. Currently, to my knowledge, there is no normative study that explores the ethical obligation to involve the community and the relevance of community engagement in the NHI policy process. There is also a need to explore the awareness of patient stakeholders on the NHI and whether they have been involved in the policy making process.

1.3. Hypothesis

The policy makers have not met their ethical and legal obligations to involve the community, specifically, patient stakeholders in the development of the South African NHI.

1.4. Research Aim and Objectives

Aim:

To determine whether policy makers of the NHI have fulfilled their ethical and legal obligations and responsibilities to enable, promote and ensure community engagement in the policy development process.

Objectives:

1. To establish whether there is an ethical obligation to involve the community in the NHI policy decision-making.
2. To measure the percentage of patients in a community that have been provided with information on the NHI.
3. To measure the percentage of patients in a community who understand the NHI policy.

4. To establish whether patients are aware of their right to participate in the policy development process of the NHI.

5. To assess whether opportunities have been provided to the patients in the community to participate in discussions about the NHI.

2. Research Design

This study employs mixed methods which include both normative and descriptive components based on Kon's 'ideal versus reality' level of empirical research in bioethics[23]. Kon's 'ideal versus reality' is one of the four levels which includes both normative and empirical research. This type of bioethics research probes whether the NHI Policy development process (reality) reflects ethical ideals. The empirical component of research uses both quantitative and qualitative methodologies, and it is hypothesis driven[23]. The normative aspect of this study considers whether there ought to be community engagement in NHI Policy development process. The ethical obligation and the notion of 'meaningful' community engagement are also explored. The normative component analyses the ethics and laws relevant to community engagement, specifically for the NHI Policy. The empirical component of the study is descriptive and looks at what the reality is on the ground. The patients' awareness and knowledge of the NHI Policy is measured and whether patients have been involved in the policy making process is established. The empirical component is cross-sectional and quantitative.

3. Overview of Methodology

This is a prospective study that consists of mixed methods; normative and descriptive components. The normative component probes whether there ought to be community engagement in health care development? It sets out to answer the normative question in a systematic and critical fashion and to justify the answers. This component uses typical methods

applicable to philosophical research such as library-based and desktop searches to source literature in order to define, clarify and explore community engagement in the context of health policy development. This includes, but is not limited to textbooks, research articles and relevant government laws[24]. The normative component looks at patient autonomy, justice and the constitutional requirement to involve patients in health care development. The details of the normative methodology are further explained in the second chapter. The empirical component hinges on whether there has been public awareness on the NHI and investigates whether patients at 3 units at the Internal Medicine Department at Charlotte Maxeke Johannesburg Academic Hospital received an opportunity to be involved in the policy making process. An interview questionnaire was used to assess the awareness and involvement of participants. Prior to the data collection, a pilot study was conducted in order to evaluate whether the interview questionnaire was an appropriate tool for the study and to assess the feasibility of the study[25].

Main assumptions

1. There is an ethical obligation for meaningful community involvement in the policy development of NHI.
2. Patients, as members of communities do not sufficiently understand the basic tenets of NHI.
3. Patients, as members of communities are unaware of their right to participate in the policy development process.
4. The community has not been provided with opportunities to participate in the NHI policy discussions.

4. Reliability and Validity

The questionnaire used in this study to interview participants was adapted from a validated questionnaire developed by the South African Department of Health[26]. The adapted questionnaire was piloted in order to assess appropriateness of the questions and feasibility of the study[25]. The results of the study were validated by a statistician at the University of the Witwatersrand Health Sciences Research Office.

5. Ethics

Ethical clearance for this study was obtained from the Human Research Ethics Committee (Medical) at the University of the Witwatersrand in June 2017. The clearance number is: **M1704105** (annexure 1). Permission to conduct the study at Charlotte Maxeke Johannesburg Academic Hospital, Internal Medicine Department was obtained from the Hospital Clinical Director and Chief Executive Officer (annexure 2)**.** Prospective participants were provided with an information sheet that gave brief information about the study and what participating in the study would entail (annexure 3). Informed consent was obtained from all participants prior to enrolment in the study (annexure 4). All attempts were made to safe guard the anonymity of participants. All participants were numerically coded on the questionnaire to ensure that their details were anonymized (annexure 6).

6. Limitations

The main limitation of this study was language. Patients who could communicate in English, isiXhosa and isiZulu were included. However, due to the investigator being fluent in only these three languages, the patients who could not speak these languages could not participate in the study. Due to this research being a 50 % component of the degree, the participants were limited to patients from the chronic follow-up clinics at the Charlotte Maxeke Johannesburg Academic

Hospital Internal Medicine Department. However, since this research is a bioethical enquiry, the descriptive component is adequate to measure against the ideal[23].

7. Overview of Chapters

Chapter 1: Introduction and Overview of the Study

In this chapter the concept of community and patient engagement at the different levels in health and key elements to engagement were introduced and defined specifically in the context of the development of the NHI. The rationale, aim, objectives and hypothesis of the study were provided. An overview of the methodology, the reliability and validity, ethics and problems were also provided.

Chapter 2: Normative Ethics

In this chapter community engagement in health policy development is discussed and analysed. The methodology and the argumentative strategy of the normative component of the study is described. Autonomy and justice from Principlism[27] and the Accountability for Reasonableness Framework[28] are explored in order to consider the moral ought and the importance of community engagement in NHI. The legal obligation to involve citizens in health policy development in law is explored using national, regional and international law.

Chapter 3: Descriptive Ethics

This chapter describes the methodology of the empirical component. The research design, population sample, data collection and analysis methods are described. The description and results and the outcomes of the pilot study are also provided and discussed.

Chapter 4: Results

In this chapter the results of the empirical component of the study; descriptive statistics and analytical results are provided. These results address the empirical objectives of the study.

Chapter 5: Discussion

In this chapter the key findings and the meaning of the key findings are discussed. The 'moral ought' or ideal is compared to the reality, in that the elements of the normative chapter are juxtaposed with the key findings of the study.

Chapter 6: Conclusion and Recommendations

In this chapter the study is summarised and the key findings are highlighted. Recommendations for community engagement on the NHI are also presented.

Chapter 2: Normative Ethics

1. Introduction

The first chapter introduced community and patient engagement as a concept and practice. The importance of patient engagement specifically in health policy development was also introduced and underscored[15]. This chapter normatively explores the first objective of this research: to establish whether there is ethical obligation to involve the community in the NHI decision-making.

2.1. Methodology

Philosophical and bioethical research methods are used to define, posit and critically analyse the arguments in this component of the study. Some of the primary sources used include work by; John Rawls[29], Beauchamp and Childress[27] and Rachels and Rachels[30]. Research articles and relevant international, regional and domestic laws are used. The keywords used to conduct the searches include: National Health Insurance (NHI), public awareness, community engagement, patient participation and involvement, autonomy, justice, trust and trustworthiness, accountability for reasonableness, participatory democracy and legitimacy in health policy.

2.2. Argumentative Strategy

Both ethical and regulatory principles informed the argumentative strategy. The principles of autonomy and justice are explored to evaluate and justify the ethical obligation for community engagement in health policy development[27,29]. Models and frameworks, such as Accountability for Reasonableness, Ladder of Citizen Participation and the Wheel of Participation, which are tools used in community engagement are analysed in order to evaluate the levels at which community engagement in health policy development occurs[28,31,32]. Meaningful engagement is

constructive, effective and inclusive engagement[16]. This notion is explored in the context of an unequal and democratic society such as South Africa.

Relevant international, regional and domestic instruments are used to explore the legal obligation to involve community in government and social policy development. The instruments include: the Universal Declaration on Human Rights (1948)[33], International Covenant on Civil and Political Rights (1966)[34], International Covenant on Economic, Social and Cultural Rights (1978)[35], Declaration of Alma-Ata (1978)[36], African Charter on Human and Peoples Rights (Banjul Charter) (1986)[37], Constitution of the Republic of South Africa (1996)[9], National Health Act (2003)[38], Patients' Rights Charter (2007)[39] and case law.

3. Principlism

Principlism is an ethical framework that was developed by Beauchamp and Childress that focuses on ethical principles namely; respect for autonomy, beneficence, non-maleficence and justice. This section focuses on respect for autonomy and justice in community engagement as these are the most relevant principles for community engagement[27].

3.1 Respect for Autonomy

Autonomy is the capability of persons to self-govern. Autonomy can only be achieved when persons have the agency and liberty to make choices independently. Drawing from Kantian ethics the principle of autonomy recognizes that persons have intrinsic worth because they are rational agents. This means that persons ought to be free and have the capacity to make their own decisions and set their own goals[27,30,40]. Capacity includes the persons understanding, reasoning and ability to independently choose. Agency is the capacity to choose and be intentional, and liberty is the freedom to choose without interference and coercion [27].

Beauchamp and Childress claim that there are 3 conditions for autonomy which are: intentionality, understanding and non-control. Intentionality means the plans and desires of persons are reflected in their actions. Understanding means that a person's decision is based on their understanding. Without understanding persons would be limited from being fully autonomous. Non-control refers to persons making decisions without interference or coercion from internal or external parties, who could be sources of control or those with power [27]. These are the tenets of autonomy and without intentionality, understanding and non-control, persons would not have the capacity and liberty to self-govern. Autonomy is important in patient care from micro to macro levels as patients need to be actively involved in their health at all levels[16,19,27,40].

Respect for autonomy in micro-engagement

In the past the approach in health care was paternalist and practitioner-focused. Health practitioners were considered to be the informed agents and therefore possessed decision making power in the clinical settings. There has been a paradigm shift that has led to an increased focus in patient-centeredness in health care. There is recognition of patient's agency and the importance of respecting patient's autonomy in the consultation room [40]. This highlights the importance of patients being able to contribute to health care decision making that directly or indirectly affects their health [16,19]. Respect for patients' autonomy resulted in the promotion of the idea of shared decision-making and patient empowerment. This inclusive approach has resulted in the shift from patients' compliance to concordance in the consultation room[40]. The three conditions that Beauchamp and Childress posit need to be established in such an instance because the patient needs to understand the options available to them and have the freedom to choose in order to be fully autonomous and give informed consent without coercion from the practitioner[27].

Shared decision making in micro-engagement can be compared to shared decision making in macro-engagement, it is clear that these two levels of participation are equally needed to ensure that the principle for respect for autonomy is upheld. The dissimilarity however is that the decisions in micro-engagement and macro-engagement are individual and collective respectively. Nevertheless, the need to allow persons to self-govern and be active in their health is the same, especially since both micro and macro contexts affect the health outcomes of patients directly and indirectly[40].

Respect for autonomy in macro-engagement

Patients need to be empowered as citizens to be autonomous and active in health policy development[40]. Much like in micro-engagement, citizens' autonomy may diminish or they may not be fully autonomous when they do not understand the policy that is being developed. With limited capacity to be free and rational agents they could become vulnerable to coercion [27]. Without adequate understanding of the NHI by patients and citizens in general, there is the risk that their engagement will be impeded and their autonomy eroded the decision-making process. Lack of understanding limit autonomy and may discourage citizens from participating. This is important to consider since the NHI will be a legislation and therefore would affect all the citizens. Lack of understanding would result in superficial engagement, thereby compromising the legitimacy of the policy[27,40]. The agency of citizens as a collective is crucial because civic dignity ought to be respected. The collective intrinsic worth that citizens possess as reflected in a democratic society ought to be considered in the decision making of the NHI[27,30,41]. Another important element of respect for autonomy in both the individual and collective level in health care is trust which is pivotal in the consultation room and equally so in the policy making process[41].

Trust is an attitude that that we have towards people. In order for a trustor (the one who trusts) to have this attitude towards a trustee (the one who is to be trusted), the trustee needs to be trustworthy. Trustworthiness is a property that justifies the level of trust given to the trustee [42]. Trust can be established through one-to one relationships (micro) and at institutional level (macro)[43]. In this case the trustor would be patient stakeholders and the trustee is the NHI policy development and the public health system in general. Trust towards authorities and the government is known as vertical trust[44].

Trust in health is important because it enables compliance to treatment, promotes acceptance and enables cooperation[43,44]. Trust influences behaviour thereby influencing the compliance to treatment and hence health outcomes at the micro-level. The promotion of acceptance and cooperation at the macro-level is important because it encourages confidence, involvement and collective action in the community. Gilson posits that trust, fairness and legitimacy are linked. Civic trust is important because it influences social norms and social policies[43,45].

Trust is a relational notion that is voluntary and is based on expectations in a relationship and has a level of risk or uncertainty associated with it[44]. However, trust has intrinsic and instrumental worth and helps develop respect, communication and decision-making practices. Engagement is a way of establishing trust. Some key elements of trust are truth-telling, fairness, promise-keeping and solidarity. Moreover, procedural justice is grounded in trust[43].

It has been underscored above that shared decision-making in the consultation room or at the individual level is comparable to shared decision-making at the collective level and in particular in the development of the NHI. Patients and citizens ought to have active roles in their health and decisions made about their health to be fully autonomous. This allows for citizens to be free and rational agents who contribute to the development of policy decisions

on their health, and being involved in the setting of the goals as well the delivery of the NHI, while NHI policy makers foster trust and engagement with them[27].

3.2. Justice and Fairness in Health Policy

Justice is defined as "fair, equitable, and appropriate treatment" of all[27]. Justice as fairness by John Rawls refers to systems of cooperation and fairness and the role that citizens play in a democratic society. The foundational premise within such a society is that citizens are equal and free[29]. Citizens are allowed to utilize their liberties because they have the capacity of their conception of good, as reasonable and rational persons. They can identify, determine and pursue what they deem just for their society. Rational persons have moral identities and are able make claims on their duties and obligations and they can perceive what is to be in their best interest[29]. Citizens in a democratic society also have moral and political powers. Citizens' values and ideologies inform their political will and this ought to be reflected in their social policies.

Fair opportunities must be provided to reduce inequality. Therefore, justice as a moral imperative, will only be achieved through fair opportunity[27]. Fair opportunity means that no one should be advantaged or disadvantaged based on their social status from participating in policy development. There is no moral ground for selecting who ought to participate in social policies on properties such as those of social stratification. All citizens ought to have a fair chance to participate in the NHI because they are free and equal[27,29]. While the capability to be involved in policies is the potential that individuals in a society possess and which all citizens ought to possess, potential is not enough. In order to ensure that potential is realized and that it yields outcomes, opportunities are needed to actuate that potential. Fair opportunity is therefore absolutely essential in the process of policy development and in fulfilling the principle of justice as fairness.

Procedural justice focuses on the justness of procedures through which an outcome is achieved. These procedures are rules that ought to be observed and followed. There are three categories of procedural justice, namely: perfect, imperfect and pure procedural justice. All three consider the justness of both the procedures and outcomes. When procedures are followed the legitimacy of a policy is enhanced. However, while procedures do not automatically result in a just outcome, they play a pivotal role in the overall fairness of a decision and ought to be pursued[29,46].

Citizens are not only concerned with who leads the government and the outcomes of their work. They are concerned with the way the government operates as well; i.e., its procedures and how decisions are made. The means by which policy decisions are achieved are equally important as that of the policy ends. The perception of procedural fairness cannot be attributed to the outcome only, and therefore a just outcome does not equate to or result in procedural justice[4,47]. It is for this reason that procedural fairness needs to be realized in policy development.

In a democratic society such as South Africa procedural fairness ought to include the involvement of citizens in the policy making process[9]. Having established that citizens have the capability and liberties they ought to be actively involved in the conceptualization of a policy and this opportunity needs to be fair and equitably available for all. Empirical studies have shown that individuals are interested in policy making processes and want to be politically active. Citizens are capable of understanding the operational and technical issues[48]. There is an ethical obligation to ensure that citizen's autonomy is respected and that they are provided with fair opportunities to be involved in the NHI policy making process. Citizens have the capability to be agents in this process and the due procedures of this process need to be upheld to ensure the legitimacy of this policy.

4. Engagement

Consultation and deliberation are considered to be upstream engagement. Consultations are discussions wherein ideas and perspectives on what the issues are and how they should be addressed are considered. This process does not necessarily result in decision-making or lead to consensus-building. It is instead a platform where different ideas and perspectives are brought to the fore. Consultation ought to be representative whereby all the principles and perspectives of the participants are to be entertained equally[49,50].

Deliberation is an iterative process in which decisions are made. The dialogue must be open to new ideas from all parties. Deliberative democracy has a normative account of legitimacy and is also closely related to trust, civic autonomy and self-governance. The lack of deliberation weakens the legitimacy and therefore acceptance of the policy[49,51].

The deliberative theory is divided into micro and macro categories:

Micro: refers to deliberation at a small-scale which looks at the information, perspective and ideas comprehensively in order to make decisions. This is an impartial process with the aim of consensus-building. Some examples of micro-deliberations are citizen juries, citizen forums and conferences.

Macro: refers to big and broad scale political iterative processes in which decisions are made with the broader public. An example of macro-deliberation is a national debate[49,50].

Micro-deliberative process are usually accessible to the middle-class, i.e., those who have access to education and are from socially and economically privileged backgrounds. This deliberative process may struggle to involve ordinary voices and as a result there will be many citizens who get excluded from this process implicitly[49,50]. It is important that an engagement process includes consultation and both deliberative processes in order to engage as many

citizens as possible in order for this process to be representative, meaningful and effective. Trust and consent in these engagements are essential and promote social cohesion and reciprocity. In order for deliberations to be meaningful and effective there needs to be openness, accountability, respect and reciprocity[49,51].

Patient engagement has intrinsic good, in that it reflects the principles of the public and results in patient activation. Patient activation can result in meaningful engagement in health and improved health outcomes for the patients[13,16,19,52]. There are frameworks and models that can be used to facilitate and promote legitimacy of the decision making process of policies. These frameworks will be discussed in the section that follows.

5. Frameworks and Models of Community Engagement

In this section the frameworks and models that are used widely to categorize the levels of community involvement in policy development, will be considered. The frameworks are Accountability for Reasonableness, Ladder of citizen participation and Wheel of participation.

5.1. Accountability for Reasonableness

Accountability for Reasonableness (A4R) is an ethical framework that was developed by Norman Daniels and James Sabin (1997) (table 1). It serves as guide for the decision-making process when setting priorities and limits in policy development. They have identified and recommend four conditions that need to be met in order to achieve procedural fairness in the process of priority setting in policy development. Procedural fairness is comprised of legitimate and fair process in policy development and AR4 analyses how priorities are set instead of claiming legitimacy based on who sets the priorities[28,53]. The four conditions are:

1. Relevance: in this condition the rationales and justifications for each decision need to be clear and shared with the public. The relevance condition provides the

rationales for the decisions made in priority setting. These rationales should reflect the principles and values of the public. This condition is important in achieving acceptance and compliance of the decisions that are made.

2. Publicity: this condition is largely aimed at raising awareness on the direct and indirect decisions made during priority setting. Decision-makers should make the decisions and reasons behind these decision made available for public scrutiny. This allows the public to be aware of the values that inform the decisions and to scrutinize and evaluate the appropriateness of the procedures. Publicity facilitates the process of public acceptance. However, openness, transparency and accountability are required in order to fulfil this condition.
3. Appeals and Revisions: this is a deliberative process in which stakeholders are allowed to challenge the decisions that have been made once they are aware of the underlying reasons and arguments. Stakeholders can also be involved in revising the decisions made. Decision-making ought to be iterative to ensure that the process is fair.
4. Enforcement: This is a voluntary or public regulation established to ensure that the first three conditions for priority setting have been met[28,54,55].

Accountability for reasonableness ensures that decisions made in the priority setting of health policies are based on moral reasoning as opposed to majority vote only. Transparency is the hallmark of a fair process as it initiates trust and prompts legitimacy[53]. The A4R conditions are intended to address the problems of distrust, lack of accountability, legitimacy and fairness in policy development. Transparency is important in engagements in order for the deliberative process to be effective[53].

Maluka *et al*. conducted an empirical study to qualitatively test the effectiveness of implementing A4R in a district in Tanzania and to find out what contextual factors influence

the implementation of A4R conditions. A key finding from the study was that publicity increases the 'voice' of stakeholders because it is through awareness and access to information that stakeholders could have opinions and input. Even though efforts were made to raise awareness on the agenda setting in health care, the public did not participate because they were not aware that they had a right to be involved in priority setting[55].

The study also found that there are enabling and constraining factors in the Tanzanian context that influenced the implementation of A4R. Some of the major enabling factors that were identified include, perceiving the needs of stakeholders and involving researchers in the implementation of A4R. This increased the trust and acceptance of the adoption of the priorities that were set. A major constraining factor in the implementation of A4R was low levels of awareness of the public. This negatively affected each condition of A4R because the number of stakeholders who were actively were involved was inadequate and some of those that were involved were not clear on what their roles in the process were[55].

The study by Maluka *et al.* also identified that participatory initiatives should be decentralized and stakeholder engagement should be at district level. By decentralizing the stakeholder engagement, each district can be represented and the scope of issues would be discussed adequately. This would inform the priority setting process and ensure that the stakeholder's needs are addressed. This speaks directly to the relevance and publicity conditions, as each district has different health challenges and needs. Decentralization will allow for more awareness raising of the policy process and the decisions that were made in the process. This will ensure that stakeholders at all levels are informed, empowered and action is strengthened and this process will facilitate accountability and trust at multiple levels[15,55].

While A4R has been accepted and used widely in the health policy area, Friedman argues that this framework inadequate to ensure that health policy development is fair and legitimate.

When the relevance and publicity conditions are violated, the legitimacy and adequacy of the process is put to question in its entirety. Friedman claims that without publicity, the revisions and appeals condition is meaningless and therefore without publicity there is no accountability for reasonableness. Friedman advocates for more inclusivity and sensitivity to public input. The public is central to A4R and the public legitimizes the deliberative process hoped to be achieved[54]. In order to ensure that the revisions and appeals process is implemented properly, it is important that those involved in this iterative process are provided with the opportunity to express their views on the decisions and the process of priority setting and to make appeals. Even though there may be differing opinions and reasoning, people's inputs must be respected and the engagements must be facilitated in such a way that the process is optimal[55]. It is also very important that citizens are adequately represented and are enabled in this process to hold decision makers accountable, in order to fulfil the enforcement condition[48,54].

The A4R is a framework that can be implemented in the NHI policy making process to engage stakeholders effectively and ensure the legitimacy of the policy. There are other models that can be used to implement and assess community engagement in the health policy development process. It is important that these tools are considered in order to understand the levels at which community engagement can occur and what their effects in the policy making process will be.

5.2. Ladder of Citizen Participation

Sherry Arnstein (1969) proposed a ladder of citizen participation which is a prominent model for citizen participation that is used to describe institutions in private, public and non-government sectors (table 1)[31,56]. There are eight levels to this ladder. Manipulation, the first level and therapy, the second level are categorized as Nonparticipation. These are instances where citizens have no power and instead of participation being promoted, citizens are not enabled to be involved. The third level is informing, fourth level is consultation and the fifth

level is placation. They are categorized as Tokenism. Tokenism includes participatory levels with consultation being the first step towards effective participation. However, the levels of tokenism do not provide/promote representativeness and only 'hand-picked' citizens are involved for reasons that may not fair[57]. Degrees of citizen power includes the sixth level, partnerships; seventh level, delegated power; and eighth level, citizen control which shows redistribution of power between policy makers and citizens and this enables citizens to engage and have increased decision-making power[31,58].

Patient participation can occur at any of these levels and this range is indicative of the multiple ways in which participation has been approached by policy makers. Arnstein posits that participation needs redistribution of power in order for the process to be meaningful[31].

5.3. The Wheel of Participation

The wheel of participation is a non-linear model to community planning that was developed by the South Lanarkshire Council of Scotland and Scott Davidson in 1998 (table 1). The wheel provides categories of participation namely: informing, consulting, participation and empowerment. These categories are further classified into three types which describe the ways in which each of the five categories could be delivered[32,58]. Informing community members can be done through minimal communication, limited information and high-quality information. Minimal communication, limited or high-quality information are ways in which decision makers can choose to inform and communicate with the community, with high-quality information being optimal[59].

Consultation is classified as limited consultation, customer care and genuine consultation. Examples of limited consultation are the holding public meetings and customer care where members of the community complete comment or suggestion cards. Genuine consultation is having citizen panels and focus groups where the community is more active. Participation is

classified as effective advisory body, partnership and limited decentralized decision-making. The community could be involved in drawing up proposals as an effective advisory body. Partnerships refers to forming formal partnerships with the community and limited decentralized decision making includes allowing the community to make their own decisions. Empowerment of the community is classified as delegated control, independent control and entrusted control. The community has limited decision-making power in delegated control. In independent control the policy developers facilitate and enable the community to provide services. In entrusted control the community is given increased and substantial decision making power. The wheel of participation provides a spectrum for community participation[59].

Table 1: Framework and models that are used to categorize community participation.

Authors (year)	**Framework/Model**	**Summary**
Norman Daniels & James Sabin (1993)[28]	Accountability for Reasonableness	The conditions for A4R: 1. Relevance 2. Publicity 3. Appeals and Revisions 4. Enforcement
Sherry Arnstein (1969)[31]	Ladder of Citizen Participation	There are 8 levels of this ladder under three categories (from lowest to highest) namely: **Nonparticipation**: 1. Manipulation 2. Therapy **Tokenism**: 3. Informing 4. Consultation 5. Placation **Citizen Power**: 6. Partnership 7. Delegated Power 8. Citizen Control
South Lanarkshire Council (1998)[59]	The Wheel of Participation	The categories of participation: Information Consultation Participation Empowerment

The ladder of citizen participation was the first of its kind and over the years it has led to more research on community participation. The ladder has been used widely and some scholars have adapted the ladder over the years[56]. The wheel of participation draws from the ladder of citizen participation as well and introduces empowerment in the spectrum of participation[32].

Community engagement in the literature refers mainly to consultation and NHI White Paper referred to consultation and written submissions as the way in which key stakeholders were engaged[5]. The ladder of citizen participation categorizes consultation as tokenism because it tends to involve 'hand-picked' individuals and may not be representative. The ideal is to move from tokenism to empowerment as defined by the wheel of participation. Inequalities, discrimination, social exclusion and low levels of education are barriers to community engagement, therefore in order to empower patients and the community as a whole, these barriers need to be considered and accounted for. Irrespective of barriers, a chance to be involved in social policies needs to be available for all citizen[31,32,59,60].

The A4R framework and models of participation could assist policy developers in fulfilling their obligations to involve the community in decisions effectively when applied appropriately, considering the needs of the context. It is clear that meaningful engagement is important, however it is important to establish how it can be achieved considering the framework and models for community engagement that exist currently.

6. How can meaningful engagement be achieved?

Meaningful engagement is constructive, effective and inclusive engagement. Meaningful patient engagement is patient centred and prioritizes the needs of patients, their families and the community[16,58]. It is important to consider that when trying to achieve meaningful patient engagement in the context of a democratic society that comes from a history of inequality, ways to promote meaningful engagement need to be explored[14–16]. In order for community

engagement to be truly meaningful patients in a community which was previously disadvantaged and the community itself need to be empowered. Drawing from the literature, community and patient engagement in the South African context should focus on building capacity of the community, consultations and deliberations and building sustainable collaborative partnerships.

1. Capacity-building

It is correct to assume that by virtue of being born in a democratic state citizens have the capability and liberties to be involved in social policies[29]. However, in order for this involvement to be meaningful and effective there ought to be capacity building. Citizens need to be exposed to the issues around the priorities, technicalities and resource allocation, as well as the principles and rationales that inform these decisions prior to participating in discussions. Health literacy and awareness, considering all the levels in health, needs to be promoted[16,58]. There needs to be a bidirectional flow of information or information feedback between the citizen and the policy makers and this will ensure that citizens are engaged and understand the information provided to them[13,14]. The voices of the citizens are nurtured through the process of them being informed, and they will be equipped and empowered to engage in a meaningful way. Citizens need to be informed of their rights, duties and responsibilities regarding their involvement in the policy making process and the ways in which this involvement can be achieved. During capacity building awareness raising and galvanizing public interest on the policy is very important as without awareness it would not be possible to achieve meaningful engagement[4,54,56].

2. Consultations and Deliberations

This is an advisory and iterative process and requires prior capacity building is successful in order for negotiations to be effective [49,50]. Citizens need to involved in consultation and

the deliberation processes and receive feedback on the outcomes of these processes [61]. Transparency and respect are of paramount importance in achieving upstream engagement. Meaningful consultations and deliberations ought to be representative and inclusive. The public must be represented fairly using both micro and macro deliberative processes to ensure there is a fair opportunity to be involved in decision making of the policy. This is the precursor to shared power and meaningful engagement[49,50].

3. Collaborative Partnerships

Collaboration is defined as "a process that enables independent individuals and organizations to combine their human and material resources so they can accomplish objectives they are unable to bring about alone"[62]. Collaboration is 'what we do' and partnership is 'who we are'. Collaboration is central to partnerships[62]. Partnerships are formal, structured, constructive and joint working relationships in which there is shared interest, responsibility and power. This relationship is between policy developers and the community and is aimed at an integrated way of planning and making the decisions. Patients are supposed to be co-producers of the health system. Power sharing and negotiations ought to be fair and respect and trust are critical of this working relationship[14,16,63]. Collaborative partnerships ensure that the decisions that were made at the consultative and deliberative stage result in the desired outcomes through continued collective input and efforts. These collaborative partnerships also need to be multidisciplinary, engaging multiple sectors, in policy implementation and evaluation[63]. Having discussed meaningful engagement above, a table on benchmarks necessary for meaningful engagement is now offered in table 2 below.

Table 2: 3 C's Framework for meaningful engagement in health policy development.

Meaningful Engagement	Key Points
1. Capacity-building	• Information sharing • Health literary • Awareness of rights and duties • Empowerment
2. Consultations and Deliberations	• Transparency • Respect • Representativeness • Fair opportunity
3. Collaborative partnerships	• Joint working relationship • Power-sharing • Trust

7. Legal Framework

There are a number of international, regional and domestic instruments that are relevant to community or patient engagement which inform the law making process. The Constitution[9] of South Africa states in s (231)(5) that the Republic is bound by international agreements that are binding[9]. According to the Vienna Convention on the laws of treaties article (2)(1)(b)[64], international agreements include treaties that have been ratified, which means that the state has consented to them and is therefore bound by the agreement. South Africa is a signatory to several pertinent, for the purpose of this study, international and regional treaties:

- Universal Declaration of Human Rights (UDHR)[33]
- International Covenant on Economic, Social and Cultural Rights (ICESCR)[35]
- International Covenant on Civil and Political Rights (ICCPR)[34]
- Declaration of Alma-Ata (World Health Organization (WHO))[36]
- Ottawa Charter (WHO)[18]
- African Charter on Human and Peoples Rights (Banjul Charter)[37]

The UDHR, article (21)(1)[33]and ICESCR, article (1)[35] require that citizens have the ability to be involved *freely* in their government and to self-determine. The ICCPR, article (25)[34] states that citizens shall have a *right* and an *opportunity* to be involved in public affairs directly or indirectly without unreasonable restrictions. These international agreements highlight the importance of a public-centred government in which citizens are able to self-govern freely and without unreasonable restrictions (table 3).

The Declaration of Alma-Ata[36] and Ottawa Charter[18] are applicable to South Africa as a signatory to the World Health Organization (WHO). The Declaration of Alma-Ata enshrines the same principle, i.e., self-determination is important in primary health care and the Declaration necessitates full participation in the development of health decisions. It also states that people (individually and collectively) not only have right, but also have a duty to be involved in the planning and the implementation of health (table 3). Duty denotes obligation and responsibility to participate. Duty takes it a step further and necessitates participation in the policy development process[36].

The Ottawa Charter[18] states that access to resources that would enable the community is essential for effective participation (table 3). South Africa acceded to the African Charter on Human and Peoples Rights (Banjul Charter) (1986)[37] in 1996, which means that South Africa consents to be bound by this regional charter[37,64]. The Banjul Charter also promotes the importance of citizens having access to information (table 3)[37]. Active participation at all levels is an end, enabled by literacy to capacitate patients to participate in health policy making. Providing information encompasses health promotion and enhances health literacy[16]. This is pivotal to achieving effective community engagement, because without information the community is not adequately equipped to engage and will not have the capacity to participate in a meaningful way. Policy makers have an obligation to provide information about the NHI to the community while it is still in development and this is towards enabling, ensuring and

promoting patient engagement. Information would enable the right to an opportunity to participate in the development to be more effective[4,34]. Much like the international covenants, the Banjul charter also emphasizes the right to participate in the government *freely*[34,35,37].

The Constitution of South Africa (1996)[9] stipulates that national and provincial legislative bodies, which are the National Assembly, National Council of Provinces (NCOP) and provincial legislatures must involve the public in the policy making process (s 59(1)(a), s 72(1)(a), s 118(1)(a))[9] (table 3). This is consistent with regional and international laws. Public involvement will ensure that the public is represented in all decision-making processes and decision-making bodies ought to facilitate this process[9]. In the health sector there is a legal obligation for patients to be informed and involved in health policy decision-making. It is stated in the National Health Act (NHA) (2003) that health care users have a right to participate in decisions that affect their personal health (table 3). Although this right refers to the decision-making at the micro level, the law can be applied in decision-making at the macro-level as well[38].

The NHI emanates from the NHA and the NHI Bill states that the public is entitled to information about the fund, health service and benefits s (9)(b) and entitled to scrutinize details such as the funding of health services as seen in s (9)(n). The rights of patients and importance of access to information is recognized in the NHI Bill[7,38]. Patients have this right and it is important for the NHI policy makers to ensure that they enable the realization of this right. The Patients' Rights Charter (2007)[39] also expresses the right to be participate in health policies (table 3)[39]. Hence, domestic law relevant to community engagement related to policy development clearly articulates that patients have a right to access to information. Therefore, community engagement is a legal obligation that ought to be prioritized and fulfilled in order to achieve legitimacy. The NHI Bill s (27)[7] states that the Minister may establish a Stakeholder Advisory Committee and this committee will include health-related organizations and civil

society represented (table 3)[7]. Although the establishment of this committee may be a step towards community engagement, the NHI Bill states that the Minister may establish this committee and this means that this committee is not mandatory. This could result in stakeholder involvement at this level being not prioritized and procedural justice will not be fulfilled.

The importance and relevance of the domestic, regional and international laws aforementioned on public involvement is highlighted in a South African judgment, Doctors for Life *v* National Assembly (2006) by Judge Ngcobo[10]. Doctors for Life is an interest group that represents health professionals that challenged the South African Speaker of the National Assembly at the Constitutional Court. They challenged that parliament did not respect its constitutional obligation to involve the public in policy development in line with s 167(4)(e), and put to question the legitimacy of the Choice on Termination of Pregnancy Amendment Act 38 of 2004 (the CTOP Amendment Act)[65],the Sterilisation Amendment Act 3 of 2005[66], the Traditional Health Practitioners Act 35 of 2004 (the THP Act)[67] and the Dental Technicians Amendment Act 24 of 2004 [9,10,68].

Except for the CTOP Amendment Act, the other three health bills had already been promulgated[65–68]. These were challenged because there was no public involvement that was facilitated by the NCOP and provinces as required in the Constitution, s72 (1)(a) and 118(1)(a)[9]. The NCOP did not invite the public to make written or oral submissions on the development and amendments at the deliberative stages of the bills. This resulted in the THP Act and the CTOP Amendment Act bills being declared invalid as they did not fulfil the constitution obligation to facilitate public involvement in the law-making process. Parliament was given 18 months to effect the procedures and the bills had to be re-enacted. The challenge on the Sterilisation Amendment Act and Dental Technicians Amendment Act was dismissed[10,65–68].

A number of important factors emerged from this judgment that require consideration. The case illustrated that to facilitate means to 'promote' or to make public involvement easier. This means that the National Assembly, NCOP and provinces have a duty to make it easier and accessible for the public to be involved in the law making process. This is especially important given the history of inequality in South Africa. It is important to make it easier for the public to have access to information and be involved in the law-making process[9,10].

Public involvement and participation are symbolic in South Africa and go beyond the legal obligation. This is because public involvement is a traditional method that has been used in African communities to resolve and respond to issues and make decisions. 'Imbizo'/'Lekgotla'/ 'Bosberaad' are meetings held by the community to discuss issues and arrive at decisions that represent the community[10]. This symbolism also informs the democratic processes that this country employs when making decisions and developing laws. Law making processes must enhance democratic principles of, accountability, responsiveness and openness as established in s(1)(d), and self-governance and civic dignity[9,10].

Public involvement is described as "a continuum that ranges from providing information and building awareness, to partnering in decision-making." [10]. The law stipulates clearly that there is an obligation to inform patients about the financing models available to them and that they are allowed to challenge the decisions made about the policy that will directly affect their health. The NHI policy ought to engage the community in the policy making process as stipulated in national, regional and international instruments to avoid the legitimacy of the policy being questioned and risk of constitutional invalidity of the policy. If the legitimacy of the NHI, in terms of following the necessary procedures as required by the law, are put to question this will compromise the acceptance and therefore the success of this policy[9,10].

Table 3: Relevant international, regional and domestic instruments.

Law	Year	Section or Article
International		
Universal Declaration of Human Rights[33]	1948	Article (21)(1): "Everyone has the right to take part in the government of his country, directly or through freely chosen representatives."
International Covenant on Economic, Social and Cultural Rights (ICESCR)[35]	1976	Article (1): "All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development"
International Covenant on Civil and Political Rights (ICCPR)[34]	1966	Article (25): "Every citizen shall have the right and the opportunity, without any of the distinctions mentioned in article 2 and without unreasonable restrictions: (a) To take part in the conduct of public affairs, directly or through freely chosen representatives"
Alma Ata Declaration[36]	1978	Article 4: "The people have the right and duty to participate individually and collectively in the planning and implementation of their health care." Article 6: "Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of selfreliance and self-determination"
Ottawa Charter[18]	1986	Strengthen community action: "Community development draws on existing human and material resources in the community to enhance self-help and social support, and to develop flexible systems for strengthening public participation and direction of health matters. This requires full and continuous access to information, learning opportunities for health, as well as funding support."
Regional		
African Charter for Human and People's Rights (Banjul Charter)[37]	1986	Article (9)(1): "Every individual shall have the right to receive information." Article (13)(1): "Every citizen shall have the right to participate freely in the government of his country, either directly or through freely chosen representatives in accordance with the provisions of the law."
Domestic		
Constitution[9]	1996	s (59)(1)(a): "Public access to and involvement in National Assembly The National Assembly must - facilitate public involvement in the legislative and other processes of the Assembly and its committees"

		s (72)(1)(a): "Public access to and involvement in National Council (1) The National Council of Provinces must - (a) facilitate public involvement in the legislative and other processes of the Council and its committees" s (118)(1)(a): "Public access to and involvement in provincial legislatures A provincial legislature must - facilitate public involvement in the legislative and other processes of the legislature and its committees"
National Health Act[38*]	2003	s (8)(1) "A user has the right to participate in any decision affecting his or her personal health and treatment"
National Health Insurance Bill[7]	2018	S (9)(b) "a user is entitled to information relating to the Fund and health service benefits available to users" S(9)(n) "to scrutinise and have access to information on the funding of health service benefit" S27(1) "The Minister may appoint a Stakeholder Advisory Committee comprised of the following: e) two representatives from health-related non -governmental organisations; (f) two persons representing civil society or consumers in an official capacity"
Patients' Rights Charter[39]	2007	"Every citizen has the right to participate in the development of health policies and everyone has the right to participate in decision-making on matters affecting one's health"

*A narrow interpretation would confine this section to the micro-level. However, a broad interpretation of this section would infer application at the macro-level as well.

8. Conclusion

There are ethical obligations to enable, promote and ensure community engagement of patient stakeholders in the NHI policy development process. Community engagement has intrinsic and instrument value. Community engagement ought to be meaningful and effective in order to achieve health equity. Meaningful and effective engagement in the NHI requires that policy makers raise awareness on the policy, educate citizens about the content of the policy and its proposed outcomes. This will enhance the capacity of the citizens to be active role players in the policy making process. It is imperative that patients and the community at large are empowered. Consultative processes that are not representative undermine the purpose of consultations and deliberations. In these processes patients who have the capacity to self-

determine and contribute to health reform ought to be autonomous actors in the health system. The NHI policy makers need to promote consultation and deliberation, and make it easier for patients to be involved in these processes. Moreover, in order for the meaningful engagement with patients to be sustained, there ought to be collaborative partnerships that result in power-sharing which ensures that patients are co-producers of their health care.

The NHI policy makers also have legal obligations to facilitate public involvements in policy discussions on the NHI through providing information and opportunities for them to be involved. The domestic, regional and international laws stipulate this obligation. If the NHI does not involve the community in the policy-making process, this could result in the policy being declared invalid or illegitimate because it does not meet the constitutional obligations of the law-making process. The NHI will change the infrastructure and financing model of the health care system and this will directly affect the lives of all citizens. It is, therefore especially important for the policy developers to galvanize the citizens and involve them in the NHI development (NHI). The capacity and liberties of citizens need to be recognized by policy makers.

Chapter 3: Descriptive Ethics

1. Introduction

In order to achieve the ideal versus reality in research, an empirical component that is evident of the reality is needed[23]. The empirical component in this study set out to study four objectives: to measure the percentage of patients in a community that have been provided with information about the NHI, to measure the percentage of patients in a community who understand the NHI policy, to establish whether patients are aware of their right to participate in the policy development process of the NHI and to assess whether opportunities have been provided to patients in the community to participate in discussions about the NHI. This chapter describes the empirical methodology of the study which includes the information about the study population, inclusion and exclusion criteria and data analysis. A pilot study was also conducted and the results and outcomes of the pilot study will also be presented in this chapter.

2. Empirical Component Methodology

2.1. Research Design

The empirical component of the study was descriptive, quantitative and cross-sectional involving structured interviews. A cross-sectional study seeks to collect information from participants at a single point in time and in this study patients were interviewed once [69].

2.2. Population and Sample Size

The study participants were patients from the follow-up clinics at the Internal Medicine Department at Charlotte Maxeke Johannesburg Academic Hospital. Charlotte Maxeke Johannesburg Academic Hospital is a Central Hospital in the city of Johannesburg and receives referrals from regional and tertiary hospitals in the city. Data was collected from 244 participants who were randomly selected and allocated a number to ensure anonymity. The

sample size was determined using an 80% response based on a previous public awareness study on NHI in South Africa, a 5% margin of error, Confidence Interval of 95%, an estimated population size of 20 000 patients who use the Charlotte Maxeke Johannesburg Academic Hospital and a response distribution of 80%[26].

Inclusion criteria

Participants were enrolled into the study if they were:

- From the Rheumatology, Pulmonology and Renal follow-up clinics of the Internal Medicine Department at the Charlotte Maxeke Johannesburg Academic Hospital
- 18 years or older
- Both males and females
- Participants of all races
- Participants who could communicate in English, isiZulu and/or isiXhosa languages

Exclusion criteria

Participants were excluded from the study if they were who were

- Under 18 years old
- Could not communicate in English, isiZulu and/or isiXhosa

2.3. Data Collection and Analysis

The participants were interviewed using a questionnaire (annexure 6), and the data was collected between July – October 2017. The questionnaire comprised a demographic component and a component specific to the study objectives. Demographic data collected including: age, sex, race, employment status and education level. For the specific objectives of the study a Likert scale with three answer options for each question was used. Prior to the

collection of data a pilot study was conducted, where 10 participants at the same study sites were interviewed.

The data collected was analysed using descriptive statistics, frequencies, and univariate and multivariate analyses. STATA software version 14 was used to run the statistical analyses.

3. Reliability and Validity

The instrument used to investigate the objectives and hypotheses was a questionnaire that was adapted from a questionnaire that was designed and validated by the Department of Health[26]. This was done to ensure the appropriateness and reliability of the questions. The Internal Medicine Department provided diverse and representative participants because the patients are returning chronic patients from different units.

4. Ethics

Ethics approval to conduct this study was obtained from the Human Research Ethics Committee (Medical) (HREC) at the University of the Witwatersrand (annexure 1). In parallel with ethics approval from the HREC, permission to conduct the study was obtained from the hospital's Clinical Director and the Head of the Internal Medicine Department (annexure 2).

In order to respect the autonomy of the participants, they were provided with information about the study by the researcher, and they were allowed to ask questions about the study before participating (annexure 3). Once the participants were clear on what participating in this study entailed, informed consent was obtained from the participants and each participant signed an informed consent form prior to the interview (annexure 4). In order to safeguard the confidentiality of information obtained from the participants the data was coded to ensure anonymity. The researcher and supervisor were the only people who had access to data and a statistician from the Wits Health Sciences Research Office assisted the researcher with

statistics after the data was coded. The data will be stored under lock and key at the Steve Biko Centre for Bioethics for 2 years after publication or 6 years if there is no publication according to section 13.2 of the Health Professionals Council of South Africa's general guidelines for health researchers[70].

5. Limitations

Language barrier was a limitation of this study because the researcher is only fluent in English, isiXhosa and isiZulu. Only patients from three units in the Internal Medicine department participated in the study. Because this research is only 50% component of the degree the study was limited to the three units and did not enrol more broadly (see chapter 1 point 6).

6. Pilot Study

A pilot study is conducted prior to the data collection of a study wherein a small number of the study population is involved. The pilot study allows the researcher to trial-run the data collection phase from recruitment, obtaining consent, the procedure or process to the analysis of the study in the same study population. This process informs whether there are changes that need to be made to the tools, recruitment process and planned statistics tests. The study instruments that have been developed are tested in a pilot study to ensure that they are appropriate. The pilot study also tests the feasibility of the study and exposes the researcher to the realities of the study site in order to ensure that they are adequately prepared for the data collection phase[25].

The aim of this pilot study was to assess the appropriateness of the questions of the questionnaire and the feasibility of the study. The pilot study also sought to assess if the demographic options on the questionnaire provided a true indication of the sample population, (annexure 5).

6.1. Pilot Study Results

A total number of 10 participants from the Internal Medicine Department were in the pilot study. The age range of the pilot study participants was 50 – 73 years old. The mean age was 59.1 years and standard deviation was 7.56. 70% were male and 30% were females (table 4). 50% of the participants were Black, 40% were White and 10% were Coloured. 30% were employed and 70% were unemployed. 10% of the participants had received no education, 20% of the participants' highest education was at a primary level, 40% had received secondary schooling and 30% of the participants had received tertiary education. Most of the participants stated that they had not heard about the NHI prior to the interview, with only 40% responding that they had heard about the NHI (table 5).

Only 60% of the participants stated that they were aware that the NHI would change the South African healthcare sector and that it will pay for medical expenses and 70% of the participants knew that the funds for the medical expenses would be generated via the national budget. A total of 70% of the participants did not know who would be covered by the NHI and 70% did not know whether everyone would have the same access to medical service through the NHI. Most of the participants were not sure if the NHI has been under discussion for many years, with 70% responding that they did not know. 90% of the participants had not been provided with any information about the NHI and none of the participants had been involved in policy discussions on the NHI. 70% of the participants responded that they can participate in the NHI policy discussion and 90% of the participants knew that they had a right to be involved in policy making process such as the NHI. Even though all of the participants had not received an opportunity to be involved, 90% of the participants stated that they would be interested to be involved in the policy making process.

Table 4: Frequencies (n) (total n = 10) and the percentages of the participants' demographics.

Variables	Frequency (n)	Percentage (%)
Sex		
Male	7	70
Female	3	30
Race		
Black	5	50
White	4	40
Coloured	1	10
Indian	0	0
Other	0	0
Employment status		
Employed	3	30
Unemployed	7	70
Education level		
No education	1	10
Primary	2	20
Secondary	4	40
Tertiary	3	30

Table 5: Pilot study questionnaire. Total frequency (n =10).

Questions	Yes (%) (n)	No (%) (n)	I do not know (%) (n)
1. Have you heard about the South African National Health Insurance (NHI)?	40(4)	60 (6)	
2. Will the NHI change the South African Healthcare sector?	60 (6)	30 (3)	10 (1)
3. Will the NHI pay for medical expenses?	60 (6)	20 (2)	20 (2)
4. Will the NHI be paid for from South African national budget?	70 (7)	20 (2)	10 (1)
5. Will everyone have the same access to medical assistance through the NHI?	30 (3)	50 (5)	20 (2)
6. Will both the employed and unemployed access healthcare through NHI?	30 (3)	50 (50)	20 (2)
7. Has the NHI policy been under discussion for many years?	30 (3)		70 (7)
8. Have you been provided with information about NHI?	10 (1)	90 (9)	
9. Can you participate/ be involved in the NHI policy discussions?	70 (7)	30 (3)	
10. Do you have a right to participate/be involved in the policy making process?	90 (9)	10 (1)	
11. Have you received an opportunity to participate/ be involved in the NHI policy discussions?		100 (10)	
12. Would you be interested to participate/ be involved in the NHI policy discussions?	90 (9)	10 (1)	

6.2. Outcomes of pilot study

1. Upon interviewing the participants it became clear that the employment status options were limited with some participants stating that they were retired or semi-employed. These participants cannot be classified as unemployed and employed. Semi-employed participants are those that do not have formal employment such as piece jobs and those that work part-time.
2. Some of the participants responded ‘no’ to the first question: “Have you heard about the South African National Health Insurance (NHI)?”, however when the rest of the questions from the questionnaire were asked some participants would change the answer from no to yes. As a result the way in which the questionnaire was approached

needed to be changed to allow for both understanding and fairness. The amendment was that first a question would be asked, and after the participant responded a brief description of the NHI would be provided to all participants to allow them to confirm whether they have heard about the National Health Insurance or not.

The brief description given was: *"The National Health Insurance, which is also known as the NHI is a national health policy that is under development by the Department of Health of South Africa."*

As a result changes were required to the answering options for the first question; if participants responded 'Yes' before and after the description they would be classified as 'Yes (1)'. If the participant initially responds 'No' or 'I don't know' but after the brief description they changed their answer to 'Yes' they would be classified as 'Yes (2)'.

3. The way in which the interview would be conducted was changed in that the participants who replied that they had not heard about the NHI would not be asked the content questions about the NHI, therefore certain questions would be excluded. In the pilot study, 60% of the participants had not heard about the NHI and 90% had not been provided with any information about the NHI and therefore would not have been able to respond from their awareness and knowledge about the NHI. Therefore questions 2 - 9 and 11 needed to be excluded if the participant had not heard about the NHI before the interview (annexure 5).
4. The numbering of questions 10 – 12 was changed to allow good flow of the interview.

The final questionnaire was therefore a result of the need for amendments that became apparent during the pilot phase of the study (annexure 6). The amended questionnaire was submitted to the HREC for approval and clearance for its use was obtained.

5. All participants were given a National Health Insurance booklet that was developed by the National Department of Health after the interview was conducted to promote information sharing (annexure 7). This addition was also submitted to the HREC as an amendment to the protocol and clearance for it was obtained.

Chapter 4: Results

1. Introduction

The methodology for the empirical, descriptive component was detailed in the previous chapter. This chapter focuses on the results obtained from the interviews with the participants. The descriptive statistics of the questionnaire are presented. The univariate and multivariate statistics using STATA are also reported. This chapter seeks to address the following empirical objectives of the study: to measure the awareness on the NHI and whether patients have been provided with information and know about their right to be involved in the NHI policy making process? The final objective is to find out if the patients have been provided with an opportunity to participated in the policy making process.

2. Descriptive Statistics

Demographics

The age range of the participants was 18 - 82 years and the mean age was 41.49 years with the standard deviation being 15.2. A Shapiro-Wilk test for normality was run to test normality of the age. It revealed that the age is normally distributed. 39.75% of the participants were males and 60.25% were females (table 6). These percentages are marginally different to that of South Africa's sex demographics of 49% and 51% respectively[22]. Of all the participants 68.03% were Black, 14.75% were White, 7.38% were Coloured, 7.79% were Indian and 2.05% identified as 'Other'. 31.15% of the participants were employed, 4.92% were semi-employed, 50% were unemployed and 13.93% were retired. 0.41% of the participants had no education at all, 5.33% of the participant's highest education level was primary schooling, 56.15% had received secondary schooling and 38.11% of the participants had tertiary education. A minority of the participants knew about the NHI, with 20.49% (n=50) of the participants responding that they

had heard about the NHI. 19.67% participants replied that they had heard about the South African National Health Insurance (NHI) before a brief description of what the NHI was given and 0.82% of the participants replied that they had heard about the NHI following the brief description. 79.51% (n = 194) of the participants had not heard about the NHI before.

Awareness on the NHI

Table 7 depicts the results of the participants who said yes to question 1: "Have you heard about the South African National Health Insurance (NHI)?". 20.49% (n = 50) of the participants replied that they had heard about the NHI. Of the 20.49%, 68% of the participants knew that the NHI will change the South African Healthcare sector. The fact that medical expenses would be covered by the NHI was known by 58% and 62% of the participants knew that the expenses would be paid from the national budget. 64% of the participants were aware that all citizens would have the same access to medical assistance through the NHI, however 50% of the participants were not aware if both the employed and unemployed would receive the same access to medical services, with 36 % responding 'no' and 14% responding 'I do not know'. 76% of the participants were aware that the NHI has been under discussion for many years and 60% participants had been provided with information about the NHI.

Involvement in the NHI policy development

Participants were asked if they had received an opportunity to be involved in the NHI policy making process. Of the participants that had heard about the NHI, 62% of the participants knew that they could participate in NHI policy discussion, however 86% responded that they had not received an opportunity to participate in policy discussion about the NHI. All the participants (n= 244) were asked if they would be interested to participate in NHI policy discussions and 84.43% of the participants said that they would be interested in knowing more and being

involved in policy making process. The majority of participants (91.39%) knew that they had a right to be involved in policy making process.

Table 6: Frequencies (n) (total n = 244) and the percentages of the participants' demographics.

Variables	Frequency (n)	Percentage (%)
Sex		
Male	97	39.75
Female	147	60.25
Race		
Black	166	68.03
White	36	14.75
Coloured	18	7.38
Indian	19	7.79
Other	5	2.05
Employment status		
Employed	76	31.15
Semi-employed	12	4.92
Unemployed	122	50.00
Retired	34	13.93
Education level		
No education	1	0.41
Primary	13	5.33
Secondary	137	56.15
Tertiary	93	38.11

Table 7: Study questionnaire shows results from questions 2 – 9, which were applicable to those who had heard about the NHI. Total frequency (n) = 50.

Questions	Yes (%) (n)	No (%) (n)	I do not know (%) (n)
2. Will the NHI change the South African Healthcare sector?	68 (34)	18 (9)	14 (7)
3. Will the NHI pay for medical expenses?	58 (29)	18 (9)	24 (12)
4. Will the NHI be paid for from South African national budget?	62 (31)	14 (7)	24 (12)
5. Will everyone have the same access to medical assistance through the NHI?	64 (32)	28 (14)	8 (4)
6. Will both the employed and unemployed access healthcare through NHI?	50 (25)	36 (18)	14 (7)
7. Has the NHI policy been under discussion for many years?	76 (38)	4 (2)	20 (10)
8. Have you been provided with information about NHI?	60 (30)	40 (20)	
9. Can you participate/ be involved in the NHI policy discussions?	62 (31)	38 (19)	
10. Have you received an opportunity to participate/ be involved in the NHI policy discussions?	14 (7)	86 (43)	

3. Univariate Analysis

The older the participant, the more likely they were to know about the NHI and for every 1 year age increase the awareness of NHI increased by 4% (table 8). Males were 2.08 times more likely to have heard about the NHI compared to females and this was statistically significant. Compared to Black participants White and Indian participants were 2.36 and 2.76 times more likely to have heard about the NHI respectively and this was statistically significant. The Coloured participants were 72 % less likely to have heard about the NHI, and Other were 18% more likely to have heard about the NHI than black participants, however this was not statistically significant. Compared to the participants that were employed the semi-employed unemployed participants were 11% and 8% less likely to have heard about the NHI respectively, however these were not statistically significant. The participants who were retired

were 2.74 times more likely to have heard about the NHI than the employed participants and this was statistically significant. Compared to the participants who had tertiary education those who had primary and secondary education were 60% and 65% less likely to have heard about the NHI, the comparison for secondary education was statistically significant.

Table 8: Univariate Analysis between the each demographic category and the awareness of the NHI.

Variables	Odds Ratio	95% Confidence Interval (CI)	p-value
Age	1.041	1.02 - 1.06	0.000*
Sex			
Male	2.08	1.11 - 3.9	0.022*
Female (ref)	1	-	-
		-	
Race			
Black (ref)	1	-	-
White	2.36	1.06 - 5.26	0.035*
Coloured	0.28	0.036 - 2.17	0.222
Indians	2.76	0.10 - 7.60	0.050*
Other	1.18	0.13 - 10.96	0.884
Employment status			
Employed (ref)	1		
Semi-employed	0.89	0.174 - 4.50	0.884
Unemployed	0.92	0.44 - 1.94	0.828
Retired	2.74	1.11 - 6.76	0.029*
Education level			
No education	-	-	-
Primary	0.40	0.08 - 1.93	0.254
Secondary	0.35	0.18 - 0.68	0.002*
Tertiary (ref)	1	-	-

Ref: Reference variable

*: $p<0.05$ therefore significant

4. Multivariate Analysis

The multivariate analysis showed that when adjusting for sex, employment status and education level the race variable statistics did not change significantly from the univariate analysis. None

on the race variable results were statistically significant in this analysis. Compared to the Black participants the White participants were 2.04 times more likely to know about the NHI, the Coloured were 69% less likely to know about the NHI, Indians were 1.66 more likely to know about the NHI and Other were 1.38 more likely to know about the NHI than the Black participants. Since the statistics were not significantly different from the univariate analysis, the remainder of the multivariate analyses were run excluding race. The multivariate analysis for sex showed that when adjusting for education level and employment status, males were now 1.94 times more likely to have heard about the NHI and this was statistically significant (table 9). Adjusting for sex and education level; compared to those who were employed the semi-employed were 20% less likely to have heard about the NHI, the unemployed were 1.06 more likely to have heard about the NHI, however this was not statistically significant. The retired participants were 4.07 times more likely to have heard about the NHI than the employed participants and this was statistically significant. Adjusting for sex and employment status; compared to those with tertiary education, those with primary education were 77% less likely to have heard about the NHI, however this was not statistically significant and those with secondary education were 77% less likely have heard about the NHI and this was statistically significant.

Table 9: Multivariate analysis between multiple demographic variables and the awareness on the NHI.

Variables	Odds Ratio	95% Confidence Interval (CI)	p-value
Sex			
Males	1.94	1.00 - 3.79	0.051*
Females (ref)	1	-	-
Employment status			
Employed (ref)	1	-	-
Semi-employed	0.80	0.15 - 4.32	0.791
Unemployed	1.06	0.49 - 2.29	0.887
Retired	4.07	1.52 - 10.89	0.005*
Education level			
Primary	0.33	0.07 - 1.66	0.179
Secondary	0.33	0.164 - 0.66	0.002*
Tertiary (ref)	1	-	-

Ref: Reference variable

*: $p<0.05$ therefore significant

5. Conclusion

It is evident that most (80.5%) of the participants were not aware of the NHI. The univariate and multivariate analyses have shown how the demographic variables influence the awareness of participants. A minority of 12.29% had information on the NHI and 14% of the participants had received an opportunity to be involved in the policy making process of the NHI. The majority of the participants (91.39 %,) knew that they had a right to be involved in the policy making of the NHI, however the policy makers of the NHI have not fulfilled this legal obligation.

Chapter 5: Discussion

1. Introduction

The main questions of the empirical component of the present study were whether patient are aware of the NHI and whether they have received an opportunity to be involved in the policy making process. In the previous chapter the results of the study questionnaire which included the results for these main questions were reported. In this chapter, the realities of the public awareness and participation in the NHI policy development are compared to ideal, which is meaningful community engagement, wherein citizens are empowered as discussed in chapter 2. The comparison will assess whether the realities of engagement on the NHI thus far meet the standards of the ideal. This will establish whether the NHI policy makers have fulfilled their legal and ethical obligations to involve patients in the policy making process.

2. Overview and Interpretation of findings

The results show that the majority of the participants (79.5%) in the present study have not heard about the NHI. The interviews for this study were conducted after the release of the NHI Policy in June 2017, which is the phase that precedes the Bill of a policy[71]. At this point the knowledge levels on the policy may have been limited generally, however patients should at least be aware of the NHI.

A similar study that was conducted by Setswe, *et al*. in 2015 found that 80.3% of their participants were aware of the NHI[26]. This awareness percentage is the inverse of what the present study found. The study by Setswe, *et al* (2015) was conducted in 3 provinces in South Africa, with a combination of participants from rural, peri-urban and urban areas, and most of these areas were also pilot sites of the NHI. The high percentage of awareness reported in this study could be attributed to the study design being a 'pre-test and post-test quasi-experiment

community a based design'. This type of methodology measured the levels of awareness of the NHI before and after an intervention. The results of this study were the results of the post-test component of the experiment. The post-test awareness levels of the NHI may have been influenced by the awareness campaigns that the Monash-Oxfam NHI project ran in the same areas as the study was conducted. The data for this study was collected after the NHI pilot sites were launched and this could have introduced bias to that study[26,72]. Even though the awareness on the NHI was high at the pilot sites, it was found that majority of the participants did not understand or have adequate knowledge on the important concepts of health insurance. This means that even though there was increased awareness, which can be attributed to the awareness campaigns, there was limited knowledge on the NHI[26]. Unlike the study by Setswe, *et al*. the present study was conducted in an urban area which is a non-pilot site and there was no intervention prior to the data collection. This study sought to measure the levels of awareness at a single point in time and not before and after an intervention.

Of those participants who were aware of the NHI in the current study (20.5%), most of these participants were aware that this health policy would cover medical expenses for citizens and will be funded through the national budget. However, there was uncertainty as to whether the employment status would affect the access to services that patients had. The majority of those who were aware of the NHI knew that the policy has been under discussion for many years, with 60% of these participants responding that they had been provided with information on the NHI. Unfortunately the questionnaire did not include a follow-up question to better understand where the participants received information about the NHI. Information could have obtained via mass media including; news via television or radio and print media. The results show that most of the participants who were aware of the NHI knew the basics tenets of the NHI. These participants do not represent all participants because they were only 20.5 % of the total study population. Therefore, it cannot be claimed that patients at the Internal Medicine Department

are aware and have adequate knowledge on NHI. Most of the participants, both those who were aware of the NHI and those who were not, knew that they have a right to be involved in policy making of the NHI. Even though most of the participants were interested in being involved, they had not been provided with an opportunity to be involved in the policy making process. Unfortunately the questionnaire did not have a follow-up question to establish what the involvement of those who had received an opportunity to be involved entailed.

The results show that all the demographic variables have an association on the levels of awareness on the NHI. The older the participants were, the more likely they were to be aware of the NHI. This correlates with the results that show that the retired participants were 4 times more likely to be aware of the NHI than those from the working class. The retired participants had an increased likelihood of awareness of the NHI and this could be attributed to them not working, therefore possibly spending more time listening to or reading mass media. They may also be more concerned with changes in the health sector since they may be frequent users of the health system. Women are also considered more active users of the health system than men, however in this study it was found that men were more likely to be aware of the NHI than women[73].

Race was associated with the likelihood of awareness of the NHI, with White and Indian participants more aware of the NHI than Black participants, even though the majority of the users of the public health system and population are Black citizens[7,22].

Education is identified as a domain of public health action and promotes health equity[74]. Education plays an important role in the levels of awareness of the NHI, with those who had tertiary education being more likely to be aware of the NHI than those with primary and secondary school education only. There is a directly proportional relationship between education level and awareness. The higher the education level, the more likely citizens are to

have access to information and therefore have the ability to be involved in policy discussions[60,74,75]. A similar study on the awareness, knowledge and perceptions on the NHI found that the levels of support of the NHI were associated with the level of education, with higher education levels being associated with increased levels of awareness and support for the NHI[76]. This shows a causal relationship between the level of education and the level of awareness of the NHI, which is consistent with findings of the present study. Participants who had primary and secondary education only were up to 65 % less likely to have been aware of the NHI. Education is a confounding demographic variable. The greater the level of awareness the citizens have, the more likely they are to be aware of their social policies.

A study conducted in a Tanzanian district found that the community did not participate in the policy discussions because they were not aware that they had a right to be involved in policy decision-making[55]. This is contrary to the findings of the present study, as 91.39% of the participants knew that they have a right to be involved in the policy making process of the NHI. In order for this right to be realised, there ought to be a fair opportunity for patients to be involved in the policy making process, which the majority of the participants in this study weren't provided. Pateman (2012) found that even though citizens may not be au fait with the technicalities of health policies they are still interested in being involved[48]. The finding is consistent with the present study because of all the participants, 84.43% were interested in being involved in the policy making process. This is especially since health policies affect their lives directly[48].

3. Ideal versus Reality

In order to be able to be involved in the decision-making and implementation of the NHI in a meaningful and effective way patients need to be empowered such that their liberty and agency components of autonomy are supported, thereby enabling them to be aware of the NHI and

have sufficient knowledge and understanding of the policy[27]. Access to information on the NHI is essential in achieving meaningful engagement[16,58,74]. Based on the results patients do not have the knowledge and understanding to be involved in the NHI policy, because the majority of the patients are not aware of the NHI. Of the total participants only 12.3% (60% of 20.5%- those who were aware of the NHI) had information on the NHI. This means that the vast majority of the patients, including those who were aware of the NHI, have limited knowledge to participate in the policy making process. This weakens the voice of citizens and patients and hinders their self-determination[27]. Patients were therefore, not provided with the means to be autonomous and involved in the policy making process.

Transparency allows patients to have access to information on the NHI and it fosters vertical trust that ought to be established and maintained for community engagement[44]. Marais *et al*. believe that there is a correlation between transparency and trust. Therefore, lack of access to information is 'incompatible' with the notion of public participation[75]. Without transparency, the legitimacy of health policy is put to question and public trust is compromised. There has not been sufficient access to information on the NHI and since there has not been transparency, including providing the rationales behind the decisions made, trust is compromised[28,53,75]. When providing access to information, it is important to ensure that all citizens have access to information who are unequal in a social context[60].

All South African citizens are entitled to a fair opportunity to be involved in policy development. This fair opportunity means that for those who have been previously disadvantaged, it must be made easier for them to participate[9,10]. One away of promoting fair opportunity is access to information as already mentioned. Once citizens are adequately equipped to be involved, they must receive a fair opportunity to participate[4,27,29]. In this study the majority of patients have not received an opportunity to be involved in the policy development of the NHI. It cannot be assumed that patients were not interested in participating,

because the results show that the participants are interested in being involved in the NHI policy discussions. This opportunity ought to have been instituted by the policy developers since they have a constitutional obligation to ensure this is done[9]. Not providing citizens with an opportunity to be involved in the policy making process is against the principle of procedural justice and is unjustified.

The ultimate purpose of community engagement is to empower citizens and share power between authorities and the community. Patients and the community at large should be co-producers of the health policies because patients can be catalysts to the process of ensuring successful health policies. Patients play a pivotal role and are in fact assets and are capable of enhancing the policy process. Patients ought to be mobilized and feel a sense of ownership towards the policies that influence their lives directly and indirectly[31,59,60,77].

Trust fosters confidence and involvement fosters ownership towards a policy. Trust and ownership influence whether the NHI will be accepted by the public or not, and acceptance will influence the success of the implementation of the NHI. It is not only the outcomes, but also the means by which a policy is developed that result in trust, ownership and acceptance of a policy. Empowerment can be transformative and in a country such as South Africa that has a history of oppression, empowerment of citizens and acknowledging civic dignity is absolutely essential[43,45,77]. The international, regional and domestic instruments that enshrine the legal obligation to involve citizens in the policy making of the NHI have been infringed because the majority of the patients are not aware of the NHI and they have not received an opportunity to be involved in the NHI.

When comparing the different models and frameworks pertinent to community engagement, A4R is the framework that provides a comprehensive way to achieve meaningful engagement. The ladder of citizen participation and the wheel of participation provide important levels and

stages at which community engagement can occur. The difference between these two models and A4R is that the appeals and revisions and enforcement conditions in the A4R framework provide ways in which community engagement can be effective. Making appeals and revisions to a policy is a constructive way of engagement and this conditions highlights the important of active participation. Enforcement is the condition that ensures that relevance, publicity and appeals and revisions conditions are fulfilled. This condition is important because it ensures that conditions that promote effective and inclusive engagement are met and sustained[28,31,53,59]. Even though A4R would be the most appropriate framework to implement in the South African context, it is limited because the publicity and relevance conditions may not be enough in to ensure that all citizens have the capability to be involved. These two conditions need to be strengthened in the South African context through capacity-building in order to ensure that citizens can be involved in policy making in a meaningful way

4. Conclusion

The results show that patients are not aware of the NHI, nor do they have adequate knowledge to be involved in the policy making process. This would result in any engagement being of poor quality, however the patients were not even provided with an opportunity to be involved the policy making process. Constructive, effective and inclusive engagement has not been achieved in the development of the NHI, therefore the reality, when measured against the ideal, is unsatisfactory and unjustified. What could assist the NHI policy makers is a framework for community engagement. This is developed in the following chapter, which concludes the research report discussion and provides recommendations.

Chapter 6: Conclusion and Recommendations

1. Introduction

The previous chapter discussed the results of the current study and highlighted how the NHI policy makers did not meet their ethical and legal obligations to involve the community, specifically patients, in the NHI policy development. This chapter provides an overview of and concludes the current study. A recommended framework for community engagement in the South Africa context is also provided.

2. Overview of Study

Community engagement is a social process that has intrinsic and instrumental value. Community engagement becomes meaningful when patients are adequately equipped and empowered to be involved in the policy making process [4,77]. Capacity building is important and would equip patients to be involved in policy making. When patients have the capacity to be involved in policy making they need to be provided with an opportunity to be involved. This an important measure in South Africa given the history of inequality. The patients' voice needs be cultivated in order to enable patients to be autonomous and actively involved in policy making [4,10,27].

Once patients have a voice and capacity to be involved, they need to be provided with an opportunity to use their voice to advance equity in healthcare. An iterative process is essential rather than a didactic one and through this process patients need to be adequately represented and respected[29,77]. This iterative process can be achieved through consultations and deliberations. Patients ought to be empowered through collaborative partnerships. Collaborative partnership are way to ensure that community engagement is sustained. There are benefits to including the community in policy making such improved health seeking

behaviour and outcomes, acceptance of the policy and shared responsibility of the healthcare system.

Trust and transparency enable the process of community engagement to be meaningful and effective and must be fostered. In an ideal situation patients need to be mobilized, which is the genesis of patient empowerment in the policy making process. This highlights that there is, additional to the legal obligation, an ethical obligation to ensure that the community is involved in the policy making process[43,75,77].

Several local, regional and international laws applicable to the South African context stipulate that citizens should have access to information in order to exercise their rights to be actively involved in the policy making process. The Constitution states the public involvement should be promoted by national and provincial structures. The operative word is *promote*, which means to make it easier for the public to be involved[9,10]. It is for this reason that the policy makers of the NHI have a legal and an ethical obligation to ensure community engagement.

This research sought to determine whether policy makers of the NHI have honoured their ethical and legal obligations and responsibilities to enable, promote and ensure community engagement in the policy development process. Using normative and empirical components the ideals and realities of the NHI policy development process were explored. The results of this research show that the majority of patients are not aware of the NHI and have not been involved the policy making process. The results also show that the ideals have not been upheld in the policy making process of the NHI as patients have not been engaged.

A framework for meaningful community engagement in the South African context was developed and introduced in chapter 2 (table 2). Including the legal instruments also discussed in chapter 2 into this framework could assist the policy makers, and this is now offered in table 10. Capacity-building, consultations and deliberations and collaborative partnerships (3 C's)

are elements this framework that seeks to ensure constructive, effective and inclusive engagement in the South African context.

Capacity-building includes a bi-directional flow of information between citizens and policy makers in order to raise the awareness and knowledge of citizens. The voice of citizens needs to be nurtured and empowered in order to have the ability to realize their rights. Consultation and deliberations are an iterative processes where there is discourse and decisions are made. The decisions from this process need to be submitted to the policy makers and must inform revisions made to a policy. Finally, collaborative partnerships are joint working relationships that ought to be fair and foster power sharing in community engagement. These collaborative partnerships are there to ensure accountability and that the decisions that are made are implemented. Citizens ought to be involved in the implementation and evaluation phases of the policy processes as well and collaborative partnerships would help promote citizen's involvement at all policy process levels.

The 3 C's framework was developed during this research, taking into consideration the legal requirements of international, regional and domestic instruments for community engagement. This framework also encompasses ethical principles as well such as transparency, respect, fair opportunity and trust in community engagement to ensure that the ethical obligations for community engagement are upheld.

Table 10: The 3 C's framework for meaningful community in policy development.

Meaningful Engagement	Key Points	Relevant legal instruments
1. Capacity-building	• Information sharing • Health literary • Awareness of rights and duties • Empowerment	ICESR[35] Ottawa Charter[18] Banjul Charter[37] Constitution[9] NHI Bill[7]
2. Consultation and Deliberation	• Transparency • Respect • Representativeness • Fair opportunity	UNDHR[33] ICCPR[34] Alma Ata Declaration[36] Ottawa Charter[18] Banjul Charter[37] Constitution[9] NHA[38] Patients' Rights Charter [39] NHI Bill[7]
3. Collaborative partnerships	• Joint working relationship • Power-sharing • Trust	Alma Ata Declaration[36] Ottawa Charter[18] NHI Bill[7]

3. Recommendations

In order to achieve engagement in the NHI there needs to be awareness to prepare citizens for community engagement. The engagement needs to be decentralised to ensure that as many citizens as possible can be involved and the different provinces in the country are adequately represented[78].

- There needs to be a nation-wide campaign that raises awareness on the NHI. This can be achieved through mass media; television, radio, social media and print media. Information about the NHI should be readily available at all healthcare facilities and accessible to those that have low levels of education. Health professionals and community health workers need to be trained to share information on the NHI when they interact with patients.

- There needs to be consultations and deliberations at the community or district level that can be consolidated by provincial committees in order to represent the community at the national discussions on the NHI. The community also needs to be provided with feedback on new developments as they arise.

The above can be achieved in the framework developed in this research (table 10).

The NHI Bill states that a Stakeholder Advisory Committee, s (27) will be established which includes health NGOs and civil society[7]. Patient representatives committees need to be established to represent patients at the national level. The representatives need to be patient advocates from patient advocacy groups and must include representatives from rural and urban areas. The representatives need to serve as a channel for continuous community engagement and ensure that they reflect the needs of all patients equally. The presence of patients and civil society in such a committee can assist in determining the role patients can play in the health system that is context specific and advances the establishment of collaborative partnerships, therefore sustained community engagement.

4. Conclusion

Community engagement is an essential governance process and is very important in ensuring health policy success. The community should be more actively involved in the NHI development process because health policy affects their lives directly and indirectly. Without the considerations and involvement of relevant stakeholders in the NHI policy making process, the NHI would be constitutionally invalid and may experience implementation failure. This failure could compromise the quest to achieve universal health coverage and health equity in South Africa. The NHI policy makers should consider using frameworks such as A4R and the 3 C's to include ethical and legal principles to meet their obligations. Due to this research being 50% of the degree, this study was limited and could not implement the 3 C's framework. Future

research could be empirical studies that test the effectiveness of A4R and 3 C's in the South African context to establish how effective they would be in praxis.

Word count: 17 267

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Appendices

1. Plagiarism Declaration

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

FACULTY OF HEALTH SCIENCES

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I LIZEKA TANDWA (Student number: 552394) am a student registered for the degree of MSc (Med) Bioethics and Health Law in the academic year 2018.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature: LL Tandwa Date: 22/08/2018

2. Turnitin Report Summary

552394:Masters_Full_Report.docx

ORIGINALITY REPORT

7%	6%	5%	2%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	www.canberra.edu.au Internet Source	<1%
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3	Sally Wortley, Jackie Street, Wendy Lipworth, Kirsten Howard. "What factors determine the choice of public engagement undertaken by health technology assessment decision-making organizations?", Journal of Health Organization and Management, 2016 Publication	<1%
4	LexisNexis Publication	<1%
5	www.populationcouncil.com Internet Source	<1%
6	www.ajol.info Internet Source	<1%
7	Submitted to University of Cape Town Student Paper	<1%

Annexures

Annexure 1: Ethics Clearance Certificate

R14/49 Miss Lizeka Tandwa

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M1704105

NAME: (Principal Investigator)	Miss Lizeka Tandwa
DEPARTMENT:	Steve Biko Centre for Bioethics, School of Clinical Medicine Charlotte Maxeke Johannesburg Academic Hospital Internal Medicine Department
PROJECT TITLE:	How Much Community Engagement of Patient Stakeholders has there been on the National Health Insurance?: A Bioethical Enquiry
DATE CONSIDERED:	05/05/2017
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof Ames Dhai
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	09/06/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004,10th floor, Senate House/3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially review April and will therefore be due in the month of April each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature — Date: 12 JUNE 2017

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Annexure 2: Hospital Permission Letter



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Mr. J. Maepa
Office of the Clinical Director
Tell: (011): 488-3365
Email:Johannes.maepa@gauteng.gov.za
15 May 2017

Dear Miss Lizeka Tandwa

STUDY TITLE: How much community engagement has there been on the National Health Insurance?: A Bioethical Enquiry.

Permission is granted for you to conduct the above recruitment activities as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic Hospital will not anyway incur or inherit costs as result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the HOD and Unit Manager or sister in charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Supported / ~~not supported~~

Dr. M.L. Mofokeng
Clinical Director
DATE: 16/05/2017

Approved/not approved

Ms G. Bogoshi
Chief Executive Officer
Date: 18.05.2017

Annexure 3: Information Document

INFORMATION DOCUMENT

Study title: How much community engagement of patient stakeholders has there been on the National Health Insurance? A Bioethical Enquiry**.**

Dear Potential Participant

Introduction:

I, Lizeka Tandwa am doing research for my Masters degree requirements at the University of the Witwatersrand. Research is just the process to learn the answer to a question. In this study we want to learn how much patients as members of the community know about the National Health Insurance (NHI) and whether patients have participated in the policy development of the NHI.

Invitation to participate: We are inviting you to take part in a research study.

What is involved in the study: participants will be interviewed using a short questionnaire and this will take 10 minutes. I will be interviewing 243 patients from the Internal Medicine Department at Charlotte Maxeke Johannesburg Academic Hospital.

Risks: There are no risks to you participating in this study. You will not lose your place in the queue while you participate in the study.

Benefits: There are no direct benefits to you in this study, however I hope that the results of this study will inform policy developers and contribute towards the process of developing the NHI Bill.

Participation is voluntary: This study is entirely voluntary and choosing not to participate will not disadvantage you in any way.

Confidentiality: The information about the participants will be not be disclosed to other parties and will be kept confidential.

Contact details of researcher/s: Please feel free to ask any questions and I can be contacted at 011 717 2663, email: Lizeka.Tandwa@wits.ac.za

Contact details of REC administrator and chair: If you have any concerns with regards to this study you can call the Chair of University of the Witwatersrand Research Ethics Committee (Human Medical) at 011 717 2301, email: peter.cleaton-jones1@wits.ac.za.

Annexure 4: Written Consent Form

Written Consent Form

Title of the study: How much community engagement of patient stakeholders has there been on the National Health Insurance? A Bioethical Enquiry.

The nature and aims of the study have been explained to me by the investigator and I have had an opportunity to ask questions and seek clarity about this study.

I was informed by the investigator and understand that participation is voluntary and I may withdraw my consent at any time. If I choose not to consent my decision will not impact me negatively in any way.

I hereby feely give my informed consent to taking part in this study.

NAME: _____

DATE: _____

SIGNATURE: _____

Annexure 5: Pilot Study Questionnaire

Participant: ……..

Demographic information

Age: **……**

Sex: Male☐ Female☐

Race: Black ☐ White☐ Coloured ☐ Indian ☐ Other☐

Employment status: Employed☐ Unemployed☐

Education Level: No education ☐ Primary ☐ Secondary ☐ Tertiary ☐

Questionnaire

Questions	**Yes**	**No**	**I do not know**
1. Have you heard about the South African National Health Insurance (NHI)?			
2. The NHI will change the South African Healthcare sector?			
3. The NHI will pay for medical expenses?			
4. NHI will be funded from general tax?			
5. Everyone will have the same access to medical assistance?			
6. Both the employed and unemployed can access healthcare through NHI?			
7. The NHI policy has been under discussion for many years?			
8. Have you been provided with information about NHI?			
9. Can you participate in the NHI policy discussions?			
10. Do you have a right to participate in policy development?			
11. Have you received an opportunity to participate in the NHI policy discussions?			
12. Would you be interested to participate in the NHI policy discussions?			

Annexure 6: Study Questionnaire

Participant: …….

Demographic information

Age: **……**

Sex: Male☐ Female☐

Race: Black ☐ White☐ Coloured☐ Indian☐ Other☐

Employment status: Employed☐ Semi-employed ☐ Unemployed☐ Retired ☐

Education Level: No education ☐ Primary ☐ Secondary ☐ Tertiary ☐

Questionnaire

Questions	**Yes**		**No**	**I do not know**
1. Have you heard about the South African National Health Insurance (NHI)?	1	2		
2. Will the NHI change the South African Healthcare sector?				
3. Will the NHI pay for medical expenses?				
4. Will the NHI be paid for from South African national budget?				
5. Will everyone have the same access to medical assistance through the NHI?				
6. Will both the employed and unemployed access healthcare through NHI?				
7. Has the NHI policy been under discussion for many years?				
8. Have you been provided with information about NHI?				
9. Can you participate/ be involved in the NHI policy discussions?				
10. Have you received an opportunity to participate/ be involved in the NHI policy discussions?				
11. Would you be interested to participate/ be involved in the NHI policy discussions?				
12. Do you have a right to participate/be involved in the policy making process?				

1: Participant replied "Yes" without a description. **2** Participant replied "Yes" after a description.

Annexure 7: National Health Insurance Information Booklet

The National Health Insurance Information booklet is attached on the next page.