

“BARRIERS TO INITIATING INSULIN THERAPY FOR PATIENTS WITH POORLY CONTROLLED TYPE 2 DIABETES MELLITUS ON MAXIMUM DOSE OF ORAL AGENTS IN PUBLIC SECTOR PRIMARY HEALTH CARE CENTRES IN CAPE TOWN, SOUTH AFRICA”

BY

DR. Md. MONIRUL HAQUE

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Promotors: DR. D. MARYAM NAVSA

and

PROF. N. S. LEVITT

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ABSTRACT

Background: Most patients with type 2 diabetes in Cape Town are attending at primary care community health centers (CHCs) and have unsatisfactory glycaemic control. Insulin therapy is indicated in patients with type 2 diabetes, with inadequate metabolic control on maximum oral therapy. Insulin can be initiated in these CHCs.

Objectives: To examine the barriers to initiating insulin therapy with poorly controlled type 2 diabetes on maximum oral agents in the CHCs.

Design: A qualitative study

Setting: CHCs in Cape Town

Participants: Forty-six medical officers

Methods: Focus group discussions (n=5) and in-depth semi-structured individual interviews (n=10).

Results: Doctors', patients', and system barriers to initiating insulin therapy were identified.

Doctors' barriers were the following: fear of hypoglycaemia, lack of knowledge, training, and confidence; doctors' perceptions of patients' noncompliance, failure of use of the national guidelines and no clear protocol for insulin therapy, lack of support from nursing staff and other doctors, no trained diabetic sister and poor communication with the patients due to language barriers.

Patients' barriers, as perceived by the doctors also included, fear of needles, misconceptions, resistance and ignorance on the use of insulin.

System barriers were a lack of resources, including supplies of insulin, high patient-doctor ratios, lack of time, doctor turnover, lack of continuity of care and absence of a proper diabetic club.

Conclusion: Numerous barriers relating to doctors, patients and the health care system were identified. Overcoming these barriers will contribute to improved glycaemic control in patients attending at CHCs.

University of Cape Town

1. INTRODUCTION

I am a medical officer and have been working in the public sector's primary health care centres in the Western Cape Metropole for the past five years, although my total work experience in primary health care settings is ten years. The Western Cape Metropole has forty-four primary health care centres run by the Community Health Services Organisation (CHSO) of the Department of Health of the Provincial Administration of the Western Cape (PAWC). These primary care centres, called Community Health Centres (CHC), previously known as Day Hospitals, are the main providers of comprehensive primary care services for a population of three million in the Cape Metropole area.

Six CHCs also provide 24-hour emergency and trauma services. I have worked in a number of CHCs those being Crossroads, Langa, Nyanga, Guguletu, Khayelisha, Macassar and Mitchell's Plain. I have also worked at the 24-hours emergency and trauma units of the Elsies River, Retreat, Hanover Park, Khayelitsha and Mitchell's Plain CHCs. I have come across many patients with poorly controlled type 2 diabetes; the majority of whom receive maximum doses of oral anti diabetic agents. Many return with acute complications and need to be transferred to secondary facilities for treatment of severe metabolic abnormalities and complications. Others have never been put on insulin thereafter, despite having had persistent poorly controlled diabetes for prolonged periods of time, with or without complications.

These experiences have led me to pose the question:

Why has insulin treatment not been initiated for patients with poorly controlled type 2 diabetes on maximum oral dose?

There are many obstacles to initiating insulin in the primary health care setting in South Africa. Consequently the number of patients started on insulin treatment by my colleagues and myself are very few. I have always found that most patients with type 2 diabetes attending CHCs experience difficulties in achieving adequate glycaemic control. There is no end to the problems and complaints of these patients. However, I have come to realize that the problem lies not only with the patient, but also with the inadequate care provided at the CHCs. It is highly likely that some of the patients with poorly controlled diabetes would benefit from being given insulin.

Thus I began to look at the international literature on type 2 diabetes mellitus. The literature review will provide a detailed description of this.

2. LITERATURE REVIEW

2.1 BACKGROUND OF DIABETES CARE

Diabetes is a common disease in South Africa and its reported prevalence in Black communities is 4.8 to 8%,^{1,2,3} in the Asian communities, 11 to 13%^{4,5} and in the Coloured communities, 8-10.8%.^{6,7} In a single small study performed on the white community, the prevalence of diabetes in that white community was 3-5%.^{8,9,10} South African Indians have the fifth highest incidence of Type 2 diabetes in the world. The current estimate is that there are 1.4 million undiagnosed diabetics in this country.¹¹

The quality of primary level services for diabetes is poor and unsatisfactory glycaemic control is the rule.¹² Even though many diabetics are treated in the public sector primary care facilities (day hospitals), the implementation of policy with regard to diabetic patients along with the

decentralisation of diabetes care in these clinics is not far advanced.¹³ There are deficiencies in the public sector primary care for people with diabetes which include; poor assessment of complications, suboptimal glycaemic control and poor blood pressure control.¹⁴ There is an association between diabetes and premature death, especially in the poorest segment of the community, that is among black Africans and a significant proportion of the Coloured and Indian communities.¹⁵ Moreover, diabetic morbidity is measured, as the prevalence of severe retinopathy is also most frequent in these deprived populations.^{16,17} Discrepancy in the availability and quality of health services is likely to contribute to these apparent ethnic differences. For example, there is a lower rate of insulin treatment among some black adult onset diabetic patients than in their white counterparts, despite lower serum C-peptide levels in the former.¹⁷ The apparent reluctance to prescribe insulin for black diabetic may contribute significantly to a worse prognosis in this group.¹²

2.2 USE OF INSULIN IN PATIENTS WITH DIABETES:

In a recent study, where primary care sites were investigated the clinician relied on oral therapy and was reluctant to use insulin.¹² Those requiring insulin were generally referred to other providers, such as specialists or hospitals. This reluctance may have stemmed from inexperience with insulin and the perceived relevant cost to the sites or the patient. Patients in the “very poor” category, reflected the very limited value of oral hypoglycaemics and would likely be suitable candidates for insulin therapy.¹²

Furthermore there is evidence to suggest that although insulin is often required in African patients to achieve an acceptable outcome, it is frequently not prescribed.¹² In a comparative study of quality improvement in the care of diabetes in the Khayelitsha community health centre in Cape Town for the years of 1996 and 1997, results showed that glycaemic control remained poor.¹⁸ Despite this poor glycaemic control, the number of prescribed drugs was increased in only 10 out of 102 patients and only one patient was started on insulin. The lack of change in prescribed drugs reflects a lack of response to persistent poor control. This lack of flexibility with regard to prescribed drugs may also reflect a lack of understanding of the problem, particularly in the use of insulin as effective therapy for patients with poorly controlled type 2 diabetes on a maximum dose of oral agents.¹⁸

2.3 BARRIERS TO INITIATING INSULIN THERAPY:

There are no studies to determine and understand the barriers to initiating insulin therapy when appropriate, in public sector primary care facilities in Cape Town and other parts of South Africa. One study in Michigan U.S.A, in 1994 on "Barriers to care in non- insulin dependent diabetes mellitus" found that most community-based patients with NIDDM (type 2) are not aggressively managed because of attitudinal, educational and health system factors that act as barriers to optimal health care delivery.¹⁹ In the Michigan study, the problem was not in the initiation of insulin therapy, but rather in the delivery of the necessary intensive management of diabetes through education on diabetes, which included counseling on diet and examination by ophthalmologist.

In that study, community-based diabetes advisory councils determined that the main barriers to optimal care of community based patients with NIDDM (type 2 diabetes) were as follows:

- 1) NIDDM is not considered or managed as a serious problem by most physicians and their patients;
- 2) the genetic basis for and refractory nature of obesity are not generally appreciated;
- 3) as a complex, multi- systemic chronic illness, diabetes fits poorly into a health care delivery system designed to deal with acute and episodic illness.

In another study in the USA in 1998 on attitudes of primary care providers towards diabetes, “Diabetes was rated significantly more difficult to treat than hypertension, and they claimed that additional changes are needed in their health care system to shift from an acute to a chronic disease model. This would effectively support diabetes care efforts in addition to the CME, which addresses provider attitudes toward diabetes, as well as knowledge about diabetes”.²⁰

In South Africa few studies have reported on the barriers in diabetic care. Most of the studies utilised a record review or an audit and found that very few patients were put on insulin when indicated to prevent the early development of complications.¹² One study also found a high frequency of undocumented complications.²¹ Another study, entitled “Staff Knowledge, attitudes and practices in public sector primary care of diabetes in Cape Town” found that barriers in diabetes care were patient, organisation and staff related. Barriers to initiating insulin therapy were not an aspect of study.¹³

These studies highlight the need to examine the barriers to the initiation of insulin therapy in the public sector primary care centre.

2.4 DEFINITION, ETIOLOGY AND CLASSIFICATION OF DIABETES

Diabetes mellitus is a disorder of metabolism due to the defective production or action of insulin and is characterized by a number of clinical and biochemical abnormalities (primarily an abnormal increase of glucose in the blood) which, if untreated, may result in acute death or premature morbidity and mortality.²²

Type 2 diabetes results from the interaction of genetic and environmental factors. The occurrence of it within a population is also related to demographic and environmental characteristics such as age, the degree of obesity, physical activity and dietary habits. Even the intrauterine environment may alter the rate of development of NIDDM.²⁴ The nature of the inherited defect of type 2 diabetes has not yet been elucidated.²⁶

The National Diabetes Data Group (NDDG) (1979)/WHO (1980) classified diabetes into two types: Insulin-dependent diabetes mellitus and non-insulin dependent diabetes mellitus.²³ Their acronyms were IDDM and NIDDM. But the American Diabetes Association (ADA)/WHO proposed a new system of classification and diagnostic criteria for diabetes (1998). They eliminated the terms IDDM and NIDDM. This current ADA and WHO classification encompasses the clinical stages as well as the etiological types of diabetes and other categories of hyperglycaemia. The three clinical stages of glycaemia include normoglycaemia, IGT and or IFG (Impaired glucose homeostasis) and diabetes mellitus (not insulin requiring, insulin requiring for control, and insulin requiring for survival).

The current classification of diabetes is etiology based, and is as follows:

1. Type 1 diabetes (Beta cell destruction usually leading to absolute insulin deficiency)*
 - A. Immune mediated
 - B. Idiopathic

2. Type 2 diabetes (may range from predominantly insulin resistance with relative insulin deficiency to a predominantly secretory defect with insulin resistance)*

3. Other specific types:
 - A. Genetic defects of beta-cell function
 - B. Genetic defects in insulin action
 - C. Diseases of the exocrine pancreas
 - D. Endocrinopathies
 - E. Drug or chemical induced
 - F. Infections
 - G. Uncommon forms of immune mediated diabetes
 - H. Other genetic syndromes sometimes associated with diabetes.

4. Gestational diabetes mellitus (GDM).²³

*(Patients with any form of diabetes may require insulin treatment at some stage of their disease.

Such use of insulin does not, of itself classify, the patient)²³.

In fact any etiological type can pass through the phases of both normoglycaemia and hyperglycaemia. [Appendix -A].

2.5 RISK FACTORS OF TYPE 2 DIABETES

Obesity is the strongest independent risk factor for type 2 diabetes mellitus, and over 90% of newly diagnosed type 2 patients have a body mass index or BMI $\{Wt \text{ in Kg}/(ht \text{ in m})^2\}$ greater than 30.²⁵ In South Africa, well over 30% of women between the ages of 35 and 64 years have a BMI > 30 and one can't overlook the fact that obesity is associated with increasing urbanisation. In addition the prevalence of type 2 diabetes in South Africa has been linked to abdominal obesity.²⁵ Both obesity and type 2 diabetes are major risk factors for macrovascular disease, and they are independent risk factors for coronary heart disease. Moreover, the regional distribution of body fat, in particular body fat found in the truncal, abdominal or visceral region of the body, is associated with increased insulin resistance, hypertension, dyslipidaemia and type 2 diabetes.²⁵ Overeating, particularly of carbohydrate foods, leads to increased demands for insulin, and obesity itself causes resistance in the peripheral tissues to the action of insulin.²⁶

There is evidence that physical activity influences glucose metabolism and therefore important in the primary prevention of type 2 diabetes.^{27,28} Plasma glucose and insulin levels during glucose tolerance tests in marathon runners, are lower than those of untrained subjects of similar weight.²⁹ "This suggests that training or physical fitness increases sensitivity to insulin. Conversely, profound physical inactivity e.g. bedrest, is associated with the development of abnormal glucose tolerance and high insulin levels, suggesting that insulin resistance is promoted by inactivity."³⁰

2.6 COMPLICATION AND MORBIDITY OF DIABETES

Diabetes mellitus is the most common metabolic disease worldwide and, in terms of mortality and morbidity, ranks third after ischaemic heart disease and cancer. It is a disease that has significant implications for those affected by it, as well as for the broader society.³² Vascular disease is the most important cause of chronic complications in patients with diabetes. Vascular disease has been divided into two types, microvascular and macrovascular; microvascular disease includes retinopathy, nephropathy and neuropathy, while macrovascular disease includes coronary artery disease, cerebrovascular disease and peripheral vascular disease. Microvascular disease involves retinal capillaries, the renal glomerulus and vasa- nervorum which leads to substantial disability from blindness, retinopathy, renal failure and finally amputation of limbs. Macro-vascular endpoints are myocardial infarction, stroke, sudden death, ischaemic heart disease and heart failure. It is well recognised that diabetics have a three times greater mortality rate compared to non diabetics, with cardiovascular causes being four and half times greater in women and two and half times greater in men, as established in the Framingham study.³³

In type 2 diabetes, although microvascular complications do occur, it is cardiovascular complications which predominate. In contrast, microvascular complications are more common in type 1 diabetes. This chronic and debilitating disease, if detected early and adequately managed, may allow patients a normal life span and quality of life.²² Diabetes, however, often inflicts tremendous economic burdens on the patient, family, community and country.²²

The primary prevention of diabetes is a desirable goal, but the prevention of the disease's numerous complications remains the corner-stone of most diabetes prevention and control programmes.³⁴ Diabetes can also lead to acute metabolic complications like diabetic ketoacidosis. The main aim of the treatment of diabetes is to prevent premature morbidity, mortality and to optimise the quality of life.

2.7 PATHOPHYSIOLOGY OF TYPE 2 DIABETES

To understand the use of insulin in poorly controlled type 2 diabetes mellitus patients on maximum doses of oral therapy requires an understanding of the pathophysiology of hyperglycaemia and the complications of persistent hyperglycaemia. The genesis of hyperglycaemia in type 2 diabetes involves a triad of basic abnormalities that include excessive glucose production by the liver, impaired insulin secretion by the pancreas and peripheral resistance to insulin action occurring primarily in liver, adipose and muscle tissue.³⁵ For the most part, type 2 diabetics can be viewed as being insulin resistant. With insulin resistance, blood glucose levels tend to rise but, to compensate for this and to keep glucose levels normal, increased amounts of insulin are secreted, resulting in hyperinsulinaemia with normoglycaemia. As insulin resistance progresses, more insulin is secreted to maintain normoglycaemia. A point is reached where the body is no longer able to compensate. Thereafter insulin levels remain static and the glucose level starts to rise. This progresses through a phase of impaired glucose tolerance and eventually into frank diabetes, which can initially be treated with oral agents. There comes a point where the pancreas can no longer maintain the increased secretion of insulin and starts to decompensate with beta cell failure. At this stage exogenous insulin might be required to maintain normoglycaemia. Thus type 2 diabetes is but the end stage of a long process that has

been progressing for many years. Many patients have insulin resistance with hyperinsulinaemia and normoglycaemia. Many never develop diabetes but others, after exposure to dietary and other environmental factors, go on to develop diabetes.³⁵ Insulin resistance is only one component of insulin resistance syndrome (also referred to as syndrome X, the metabolic syndrome) comprising insulin resistance, central obesity, hypertension, dyslipaemia of a particular pattern, hyperuricaemia and increased PAI (Plasminogen Activator Inhibitor) levels. Patients with this syndrome have a propensity to develop atherosclerosis.³⁶ Even though hyperinsulinaemia has a very strong correlation with macrovascular disease and many of the other cardiovascular risk factors; there is much debate about whether it is truly a risk factor or merely a true marker. In support of this, the administration of insulin does not aggravate macrovascular disease. Current opinion supports hyperinsulinaemia as a true marker of macrovascular disease.³⁶

Theoretically, good glycaemic control should improve factors thought to have a role in the genesis of atherosclerosis such as advanced glycosylated end products, endothelial function and glycosylated enzymes, apoproteins and lipoproteins involved in lipoprotein metabolism. Diabetes is but the tip of the insulin resistance iceberg. Chronic hyperglycaemia in addition to being a marker of uncontrolled diabetes, is now recognised as having deleterious effects on insulin secretion and action and, as such, is a self-perpetuating abnormality (glucotoxicity).³⁷ Thus, in addition to the potential for reducing the long term complications of diabetes, reducing hyperglycaemia may also be expected to decrease the insulin resistance and the reduced insulin secretion underlying the disease.³⁷

Both obese and non-obese patients with type 2 diabetes have the same underlying pathophysiology, but their expression and contribution to the development of hyperglycaemia may differ. In obese patients with type 2 diabetes, severe insulin resistance in the liver and peripheral tissues predominates. Although the pancreas may produce a large quantity of insulin and insulin secretion is often excessive compared with the non-diabetic states and hyperinsulinaemia may be present, it is still insufficient to overcome the insulin resistance that is present and that hyperglycaemia causes.

In contrast, non-obese type 2 diabetic patients tend to have milder degrees of insulin resistance than the obese variety and hypoinsulinaemia caused by impaired or deficient insulin secretion is the pre-dominant abnormality.³⁸ It is important to understand and appreciate these fundamental differences when insulin therapy is considered for the patient with type 2 diabetes mellitus. Based on this knowledge, it can usually be predicted with considerable certainty that non obese type 2 diabetic subjects, in whom insulin resistance is mild or moderate in severity, will require considerably less insulin to control their hyperglycaemia than obese subjects. In contrast, large doses of exogenous insulin are the rule in the obese subject.³⁹ In the obese form of this disorder when euglycaemia is desired, it needs to overcome the severe insulin resistance.

Several other aspects of the patho-physiology of hyperglycaemia in type 2 diabetes, especially in obese form, deserve comment, when insulin therapy is used to achieve normalisation of glycaemia and glycosylated haemoglobin level.

The classic glycaemic profile of type 2 diabetes consists of elevated basal or fasting glucose levels upon which post prandial glycaemic excursions are super imposed.⁴⁰ Clearly the basal rate of hepatic glucose productions is the primary determinant of fasting plasma glucose level in type 2 diabetes. Postprandial hyperglycaemia is determined, in large part, by peripheral glucose utilisation and severity of insulin resistance.

However, in type 2 diabetes, hepatic glucose output is more sensitive to suppression by insulin stimulation of glucose uptake, which usually requires the presence of large pharmacological levels of circulating insulin.⁴¹ This is particularly important when one is striving to achieve normoglycemia in a patient with the obese form of type 2 diabetes, in whom exogenous insulin acts primarily to suppress excessive hepatic glucose output rather than to stimulate peripheral glucose uptake.⁴² Since the degree of peripheral insulinemia has been directly linked to the development of weight gain during tight metabolic control , one should consider using only that amount of exogenous insulin necessary to suppress hepatic glucose output and achieve normal fasting glucose levels.^{40, 42-45} Using more insulin to overcome peripheral insulin resistance may expose patients to excessive weight gain. The need for large amounts of exogenous insulin in obese type 2 diabetes also raises the issue about the most appropriate methods of insulin delivery.

2.8 GLYCAEMIC CONTROL AND GOALS OF TREATMENT OF TYPE 2 DIABETES

The goals for glycaemic control are a fasting (preprandial) glucose level of less than 6.7 mmol/L (<120 mg/dL) and a glycosylated haemoglobin level of less than 7% (normal range, 4% to 6%).³⁷

The ultimate goals of management of patients with type 2 diabetes are not different to those in patients with type 1 diabetes. Preventing the acute and chronic complications of diabetes is a primary concern. Normalising the glycosylated haemoglobin level while minimising hypoglycaemia and weight gain and maintaining an acceptable quality of life presents a major challenge to the health care provider.⁴⁶ Nevertheless the goals of therapy should be individually tailored for each patient.

Good diabetes control in type 2 diabetes include good glycaemic control with good control of associated cardiovascular risk factors including hypertension and dyslipaemia.⁴⁷

Table-1. Targets for glycaemic control in patients with diabetes (Type 1 and Type 2 are the same) ⁴⁷

Glycaemic parameter	Normal	Goal	Poor control and further Action suggested
HbA _{1c}	depends on lab technique	<1% above normal reference	>2% above normal
Finger-prick glucose (whole blood glucose)			
a)Fasting(mmols/l)	4.0-5.0	4.0-6.0	>8.0
b)Postprandial peak(mmols/l)	4.0-7.5	5.0-8.0	>10.0
Plasma glucose			
a)Fasting(mmols/l)	4.0-4.6	5.0-7.0	>8.5
b)Postprandial peak(mmols/l)	5.0-7.0	6.0- 8.5	>10.0

Control of diet, taking medication and doing regular physical activities are the three basics of glycaemic control in a patient with diabetes. But all of these need a catalyst like blood glucose monitoring to assess the level of control and to act on its results, it needs motivation and support from the doctors for augmentation of patient compliance on all of these.

An American study on patient and physicians perspectives regarding treatment of diabetes found that a reason for the lack of compliance with the practice guidelines may be the indication of physicians knowledge or problems in patient compliance. ⁴⁸

Patient compliance may include the ability of the patient to do the followings: ⁴⁹

- Taking medication as prescribed
- Attending clinic appointment regularly
- Making changes in lifestyle as recommended
- Completing necessary investigations.

Table 2 : Some factors with strategies to improve compliance ⁴⁹

Factors related to compliance	Strategies to improve compliance
Inconvenient facilities and difficulties in renewing prescription	Providing comfortable facilities and a appointment system allowing a patient sufficient time with doctors and nurses. Consider three months supply in selected cases.
Lack of knowledge and understanding in disease process with rejection of diagnosis and not accepting recommendations	Structured discussion with improving patient education opportunities and access to drug information services. Motivating by persuasion and practical help.
Complexities and side effects of treatment regimens	Using single rather than multiple dose regimens if available. Attention to side effects and explanation how best they can be taken.

The above list provides a brief incomplete compilation of factors related to compliance and strategies to improve this. A study among South African private general practitioner found patient centredness and in the consultation may increase patient satisfaction, compliance and improved long term control in the management of diabetes.⁵⁰

2.9 THE FEASIBILITY OF THE USE OF INSULIN FOR TYPE 2 DIABETES MELLITUS PATIENTS IN THE PRIMARY HEALTH CARE SETTING

For patients with type 2 diabetes who were cared for by generalist physicians, starting insulin therapy was found to be generally safe and effective in achieving moderate glycaemic control.⁵¹ However, insulin therapy was associated with increased resource use and was rarely effective in achieving tight glycaemic control even for those with moderate control.⁵¹ Another study⁵² in America found, that intensive conventional insulin therapy, when combined with capillary blood glucose measurements can be used to rapidly improve glycaemic control in type 2 diabetes without the development of unacceptable hypoglycaemia in out patient management.⁵²

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2.10 APPLICATION OF INSULIN THERAPY

Exogenous insulin therapy should be reserved for patients with type 2 diabetes in whom an adequate trial of other therapeutic measures such as dietary manipulation, exercise programs and maximum dose of oral anti-diabetic agents has failed to achieve appropriate control.⁵³ This step wise approach is currently advocated by both American and European diabetes association.⁵³ The goal of treatment in type 2 diabetes should be near normal glycaemia. Based on the natural history of type 2 diabetes, many patients with type 2 diabetes will eventually require therapy with insulin.⁴⁰ This period of time before insulin is necessary tends to be highly variable and based on a number of factors. The most important proposed explanation is B-cell exhaustion, resulting in endogenous insulinopenia.^{54,55,56}

Such factors often play an important role in determining when a patient's diabetes no longer responds adequately to diet, exercise, and oral antidiabetic agents. In addition to the natural history of type 2 diabetes, there is heterogeneity to the pathophysiology of type 2 diabetes, This may influence when patients are actually closer to having to insulin dependent or type 1 diabetes with severe insulinopenia. Many of those patients have been shown to have islet cell antibody positive or antibodies to glutamatic acid decarboxylase with a decrease in the C-peptide response to glucagon stimulation and a propensity for primary oral medication failure.⁵⁷ There are also wide geographical and racial differences that may influence when a patient with type 2 diabetes needs insulin therapy. For example, Asian patients with type 2 diabetes tend to be thinner, have their diabetes diagnosed at an earlier age, have oral hypoglycaemic agent treatment failure much sooner, and be more sensitive to insulin therapy than the classic centrally obese type 2 diabetic subjects usually seen in the U.S. and some parts of Europe.⁴⁶

Insulin therapy can improve or correct many of the metabolic abnormalities present in patients with type 2 diabetes. Exogenous insulin administration significantly reduces glucose levels by suppressing hepatic glucose production and increase post prandial glucose utilisation can improve the abnormal lipoprotein composition commonly seen in-patients with insulin resistance.^{40,45,58} Insulin therapy may also decrease or eliminate the effects of glucose toxicity by reducing hyperglycemia to improve insulin sensitivity and B-cell secretory function. Unfortunately, exogenous insulin therapy can also lead to hypoglycaemia, weight gain, and hyperinsulinemia.^{59, 60}

Table- 3 Metabolic benefits of insulin therapy⁴⁶

1. Reduces the fasting and post prandial glucose levels
2. Suppresses hepatic glucose production
3. Stimulates peripheral glucose utilisation
4. Increases glucose oxidation/ storage in skeletal muscle
5. Improves endogenous secretory availability.
6. Reduces glucose toxicity
7. Reduces glycosylated end products

There are five major arguments in favour of intensive insulin therapy:

- i) It may reduce the rate of progression of retinopathy, albuminuria and neuropathy.⁶⁰
- ii) There is increasing evidence from correlative studies that suggest HbA_{1c} is a predictor of macrovascular disease and events.
- iii) There are new methods of administering this therapy that make this approach more feasible than previously.
- iv) Lowering HbA_{1c} should have beneficial effects on other risk factors for macro-vascular disease.
- v) One intervention trial has shown that intensive insulin therapy after myocardial infarction in type 2 diabetes will significantly lower 1-year cardiovascular mortality.⁶¹

2.11 APPLICATION OF INTENSIVE INSULIN THERAPY

The term “intensive” refers to the extent to which all aspects of diabetes care are applied to achieve normal or near normal glycaemia³⁷. Candidates for intensive management need to be motivated, compliant, and educable and without other medical conditions and physical limitations that preclude accurate and reliable Home Glucose Monitoring (HGM) and insulin administration. In addition, caution is advised in older patients or those who are ignorant of the diagnosis and treatment of hypoglycaemia. Other limitations to achieving normo-glycaemia may include high titres of insulin antibodies, especially seen in patients with a prior history of intermittent use of insulin of animal origin. The site of insulin injection may also change the pharmaco-kinetics, and absorption can be highly variable, especially if lipo hypertrophy is present.

The peri-umbilical area has been shown to be one of the most desirable areas to inject insulin because of the rapid and consistent absorption kinetics observed at this location. Before insulin therapy is initiated, the patient should be well educated in HGM techniques, proper insulin administration, and self-adjustment of insulin dose when appropriate.

The problems associated with the HMBG are mostly related with patients.

These are shown at table -4

Table-4: Problems with Home Monitoring of Blood Glucose (HMBG)

<ol style="list-style-type: none">1. Patient can falsify the result1. Patient may not have money to buy the machine and strip to check the blood glucose level when necessary2. Patients need to have knowledge and training to use it properly. Technique needs to be reviewed regularly3. The older patient may need to get help from a second person and the second person needs to be educated and trained4. Patient can use it incorrectly5. Patient can use a poor quality machine6. The government cannot provide the machine to all patients
--

The patient should be knowledgeable about dietary and exercise strategies. The patient and family members also need to be informed about hypoglycaemia prevention, recognition, and treatment. Initial and on going education by the diabetes management team is crucial for long term success and safety.

2.12 RECENT DEVELOPMENTS ON INSULIN THERAPY

Middle aged and older diabetic adults are at high risk for microvascular and macrovascular complication, with mortality risks linked with increasing glucose level. More recently the largest clinical study in type 2 diabetes, the United Kingdom Prospective Diabetes Study (UKPDS) has confirmed that intensive blood glucose control with insulin or sulphonylureas reduces microvascular complication and does not increase macrovascular complication.⁶² A Comparison of insulin and sulphonylureas showed no significant differences in their effect on myocardial infarction incidence, and there was no significant increase in cardiovascular incidents, allaying fears that these agents may be harmful. So the administration of insulin for the control of diabetes does not appear to aggravate macrovascular disease. As reported in the UKPDS, the intensive policy seems to have affected diabetes-related events beneficially, but not diabetes related mortality. Analysis of the results showed that increases of HbA1c increase the risk of any diabetes-related endpoints. For a 1% change in the HbA1c concentration, there is a 21 % change in the risk. The benefits of intensive policy seems to be due mainly to improved microvascular outcomes, with only borderline support for a decrease in macro vascular disease, thus mirroring the results of the Diabetes Control and Complication trial (DCCT) in type 1 diabetes.⁶³ The main translatable finding is that intensive therapy of type 2 diabetes is beneficial, despite the associated weight gain (metformin is advantageous in not causing as much weight gain as insulin or sulphonylureas).

The absence of an obvious pernicious effect of either insulin or sulfonylureas on cardiovascular outcomes should be reassuring for sceptics who questioned whether the intensive therapy message of DCCT could be directly translated to type 2 diabetes. As the degree of glycaemia correlates with atherosclerosis, so improving glycaemic control may prevent macrovascular disease. With time, endogenous insulin secretion declines and most oral agents no longer suffice to maintain near normoglycaemia. At this point, combining oral agents or adding bedtime insulin may again bring glucose levels into the therapeutic range.

Combination treatment may be considered when oral hypoglycaemic agent failure occurs as a potential intermediate stage before insulin replacement. Over the course of 15 years, the proportion of patients using oral agents alone declines from about 65% to 25%, with a corresponding increase in those using insulin. About 36% of patients with type 2 diabetes in the USA use insulin and within 5 years of diagnosis, 50% or more of type 2 patients require insulin.^{21, 64} There can be little doubt that extension of better diabetes services beyond isolated academic hospitals, with emphasis on good glycaemic control and greater use of insulin, together with education for care, could substantially reduce the high rate of diabetes related mortality.¹²

Latest development in insulin is insulin lispro. Humalog (insulin lispro) is a rapid acting insulin analogue with an earlier and higher insulin peak and shorter duration of action compared with regular human insulin. This results in a more physiological blood glucose profile with lower post prandial blood glucose levels and a reduced level of hypoglycaemia in patients with type 1 and type 2 diabetes.⁶⁵

3. RESEARCH QUESTION

What are the barriers to the initiation of insulin therapy for patients with poorly controlled type 2 diabetes mellitus on maximum dose of oral agents in the public sector primary health care centres in CapeTown?

4. AIM OF THE STUDY

To improve glycaemic control and thereby prevent complications in patients with type 2 diabetes attending the public sector primary health care centres in Cape Town, by facilitating and promoting the use of insulin therapy where indicated.

5. OBJECTIVES OF THIS STUDY

- To determine and explore factors (Perceptions, attitudes, fears etc) acting as barriers to initiating insulin therapy where indicated, in patients with type 2 diabetes mellitus in primary health care centres in Cape Town.
- To present the findings and make recommendations to health care policy makers and all relevant health care providers.

6. RESEARCH METHODOLOGY

6.1 STUDY DESIGN

- A qualitative approach of research methodology was used to determine and explore factors acting as barriers to initiating insulin therapy in patients with poorly controlled type 2 diabetes mellitus.
- Focus group discussions and individual semi-structured interviews were conducted among the medical officers of the community health centres in the Western Cape Metropolitan region.

6.2 STUDY POPULATION

The research populations included all the medical officers working in the different community health centres of the Community Health Services Organisation (CHSO) of the Western Cape Metropolitan Region.

6.3 FOCUS GROUP DISCUSSION

A focus group is a group discussion, where the focus is on a particular topic of interest – usually a health problem or response to a situation or issue. A focus group gathers people from similar backgrounds or experiences to discuss the topic of interest to the researcher. The group participants are guided by a moderator (or group facilitator) who introduces topics for discussion and helps the group to participate in a lively and natural discussion among themselves.⁶⁶

This method provides insight into how a group thinks about an issue, about the range of options and ideas, and the inconsistencies and variations that exist in a particular community in terms of beliefs, experiences and practices.

The idea behind the focus group method is that group processes can help people to explore and clarify their views in ways that would be less easily accessible in a one to one interview. Although group discussions explore a predefined topic, they are open and flexible, thus allowing intensive exploration of opinions, feelings attitudes and behaviours which are not possible through quantitative methods.⁶⁷

Focus groups have been used successfully to assess need, to develop interventions, test new ideas or programmes, improve existing programmes and generate a range of ideas on a particular subject as background information for constructing more structured questionnaires.⁶⁸

The focus group is a special type of group in terms of its purpose, size, composition and procedures. The discussion is carefully planned, and is designed to obtain information on participants' beliefs and perceptions on a defined area of interest. A focus group interview enables one to gain a broad understanding of why participants think and act the way they do.

A focus group is usually composed of six to eight individuals but it can range from three to twelve people. "A focus group should usually be composed of homogeneous members of the target population. It is usually a good idea to form groups of respondents who are similar in terms of social class, age, level of knowledge, cultural - ethnic characteristics and sex."⁶⁸ This will help to create an environment where participants are comfortable with each other and feel free to express their opinions.⁶⁸ This also prevent the domination by one or two in the group.

The main strength of the focus group is the production of data through social interaction and group dynamics. The dynamic interaction stimulates the thought process of participants, reminds them of their own feelings about the research topic; informants build on the answers of others in the group in responding to each other's comments. "The stimulating nature of focus group discussion yields more and richer information than do the individual interviews with the same number of participants."⁶⁹

Group discussion is particularly appropriate when the interviewer has a series of open ended questions and wishes to encourage research participants to explore the issues of importance to them, in their own vocabulary, generating their own questions and pursuing their own priorities. When group dynamics work well, the participants work alongside the researcher, taking the research in new and often unexpected directions.⁷⁰ "During the interviews researchers can use prompts or probing questions. These help to reduce both researcher and research informant anxiety. The purpose of probes is a search for elaboration, meaning or reasons. Non-verbal prompts are perhaps even more useful. The stance of the researcher, eye contact and leaning forwards all encourage reflection."⁷⁰

6.4 SAMPLING OF THE FOCUS GROUP OF THIS STUDY

In focus group discussion, sample size is the number of groups, not the number of people. The number and composition of the groups depends on the research questions, the topic and also the purpose of conducting focus group discussion.

The CHSO has one hundred and forty doctors (medical officers) working in the forty four community health centres.(APPENDIX B -NAME OF THE CHC'S). These CHCs include seven that have 24 hours medical and surgical emergency and trauma units.

The duration of work experience for the medical officer in the CHC ranges from six months to twenty years. There are also sessional medical officers, who work part time in many of the CHCs.

Clinical:

The categories of medical officers in CHSO are as follows,

- 1) Community Services Medical Officer (COSMO)
- 2) Junior Medical Officers (JMO)
- 3) Senior Medical Officer (SMO)
- 4) Principal Medical Officers(PMO)
- 5) Medical Officers (Sessional)

Administrative:

- 6) Chief Medical Officers and Medical Co-ordinators and Superintendent.

Sampling was purposeful, with groups mostly homogenous in experience and staff categories, but heterogenous in terms of being representatives of the different community health centres from the total medical officers. In each group, medical officers, representing different ethnic areas of CHCs were invited, such as medical officers working in the traditionally black areas (serving the predominantly black community), in the white areas (community), in the coloured areas(serving predominantly in the coloured community), also areas such as Mitchell's Plain serving all population groups in the community.

The COSMO are first year post intern medical doctors. When the COSMO finishes a year of working and continues to work in the government services, he or she becomes a junior medical officer. The COSMO and junior medical officers constitute thirty percent of the total medical officer population, although their experience as medical practitioners range from six months to three years.

Five focus group discussions were conducted in addition to the pilot focus group discussion. The first focus group consisted of three COSMOs and two junior medical officers and only one senior medical officer. It helped to prevent the predominance of one participant by another participant. A second focus group consisted of three senior medical officers, two junior medical officers and one principal medical officer. The third focus group was heterogenous in terms of medical experiences and staff categories; consisting of four COSMOs, four junior medical officers, two senior medical officers and one principal medical officer.

The fourth focus group consisted of four principal medical officer and four senior medical officer and two junior medical officers (Table-5). The fifth focus group consisted of three COSMOs and two junior medical officers, one of the latter was a sessional doctor. Senior medical officer has between four to ten years of experiences. Principal medical officer has above 10 years of experiences.

When selecting the participants of the focus groups preference was given to reflective individuals, who enjoy contributing, but usually allow other participants to express their views and also to accept criticism. In some cases this ideal would be difficult to maintain, and the facilitator would control the situation if a problem arose. As I had worked in the CHSO for five years, I had present in many meetings and discussion of the principal medical officer. I was also doctor in-charge at Cross Road CHC and used to attend doctor in-charge meetings at head office of the CHSO. Based on the attendance of Dr in-charge meetings at the head office of the CHSO , I had the knowledge of the PMOs counteraction, responses and interaction during discussion and meetings. Those participants I had not met before, were chosen during my field visit to many community health centres to inform them about the research project.

Each group was supposed to include a sessional doctor, but due to their duty roster being from 08h00 to 13h00, they could not take part in the discussion at 14h00, except in the fifth focus group discussion which was done at 10h30. Besides that, in the third and fourth focus group discussion a few participants had been involved in private practice recently.

Fifteen medical officers were invited as participants in each focus group discussion, because of the possibility that some would attend.

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Fifteen medical officers were invited as participants in each focus group discussion, because of the possibility that some would attend.

The focus group would:

- Elicit a range of opinions.
- Identify inconsistencies and variations that exist in that group.

It would also elicit emotions in the group while discussing their perceptions, fears, feelings, and experiences related to initiating insulin therapy.

6.5 CONDUCTING THE FOCUS GROUP DISCUSSION IN THIS RESEARCH

Five focus group discussions, excluding one pilot focus group discussion, were conducted. Facilitators from outside the CHSO facilitated four of these discussions. A note taker observed and recorded the non-verbal reactions and interaction of the participants that might be of interest for the analysis. The note taker also ensured that the entire discussion was recorded with a tape recorder. I was the note taker in the first and second focus group discussions. I was co-facilitator and note taker in the second focus group discussion for the last few minutes when the facilitator asked me to mention or provide clarification on any thing else that needed to be explored. During my co-facilitation of the discussion, the facilitator was taking notes. In the third and fourth focus group discussion the facilitator and note-taker were outsiders and I was not present in the discussion room. I was busy seeing patients in the trauma and emergency unit till the discussion had finished.

The fifth focus group discussion I facilitated myself and this was audiotaped. All three facilitators who were qualitative researcher read my research proposal beforehand. The first and third focus group were done by Ms. Lauraine Vivian, Medical Anthropologist and qualitative researcher, Department of primary health care, University of Cape Town who read my research proposal. She also provided the technical advice in the pilot study. In qualitative research,

- The researcher adopts a person- centred and holistic perspective.
- This allows the researcher to understand the human experience.
- The researcher generates an in-depth account, which presents a lively picture of the participant's reality.

The researcher is an instrument in the research process.

I was neutral and non-judgemental during note taking or facilitating. I did not voice any opinions during the focus group discussion; I told them that I was there to take notes on their views and opinions, not to give my opinions. I was aware that a medical officer might not reveal the many facts on under-use of insulin in indicated patients with poorly controlled type 2 diabetic patients. However, my aim was not to get confessions on under use of insulin in primary health care centres. I was there to elicit their experiences on using insulin indicated patients with type 2 diabetes by using focus group discussion. Group dynamics did help to overcome the fear of relating their experience in front of other colleagues. But the group dynamics could not bring to light some of the issues on insulin such as guidelines and health system. For this reason semi-structured individual (one to one) interviews were also held.

My presence as a researcher and note taker/co-facilitator/facilitator in the focus group discussion did not prevent the participants interacting with each other. Two focus group discussions were done without my presence. It was hoped that any data which did not come to light in my presence in the focus group discussion, might come up in my absence. As I was the researcher, I needed to understand what was happening in the focus group discussion, although the audio-taping and note taking by note taker could help me to understand some of the issues. As some people would be afraid to talk in front of other colleagues, individual semi-structured interviews with some participants will help to get the enriched data, which was difficult to obtain during focus group discussion. Without being present, I could not detect and understand the real issue on barriers to initiating insulin. Not being present, as a note taker or facilitator, may be far more risky than my presence in this qualitative research for getting the data. I was aware that medical officers might feel too intimidated to explain their reasons for failure to initiate insulin therapy. They also may feel free and proud to tell how they can overcome the barriers to initiating it. If participants choose not to express their true feelings in the focus group in the presence of other colleagues, the chance of expressing it in my absence is very unlikely. The presence of this type of participant may not be totally avoided even in highly purposeful sampling.

The participants were sent a letter of invitation (Sample of invitation letter in Appendix C) well before the interviews, and they were reminded a few days before the discussion. The venues chosen were central to the CHCs. Ideally, a neutral venue was chosen, out of the hospital environment to keep the participants comfortable and free to talk. The first two were conducted at GF Jooste Hospital outside of the physical environment of the CHCs. As many participants were not keen to meet outside the CHCs, the next three focus group discussions each were held in a different CHCs.

A circular or semicircular seating arrangement was used and top quality recorders were used to record the discussion. The facilitator identified the agenda, managed the time effectively and ground rules were established. A non-directive approach was taken. The questionnaire was developed before starting the focus group discussion. However, after every focus group discussion, the note taker, facilitator and the researcher discussed the content and process of the focus group discussion and the pattern of the putting questions were changed in the next focus group discussion although the central question remained the same. The central question was, “What were the barriers to initiating insulin therapy in patients with poorly controlled type 2 diabetes mellitus on maximum oral dose in the public sector primary health care centres in Western Cape Metro-pole, South Africa.?”

The focus group discussion was exploratory and followed an interview guide with the some scopes of enquiry. In-depth individual interviews followed same interview guide.

(Interview guide and scope enquiry listed on appendix-D.)

There were some sample questions for focus group discussions. (Sample Question for focus group discussions are on appendix -E)

Appropriate probing was done during the focus group discussions. When to probe and how to probe was discussed with the facilitators, although it was difficult to predict how the discussion would proceed. Probing had also been discussed with the supervisors, before and after all focus group discussion. It helped to me appreciate the appropriate use of probing during focus group discussion.

Table 5: Description of the focus group discussion conducted

Focus group no	Focus group date	Total number of participants	Category of MO	Number of MO in each category	Site of the CHC, where the participant work	Venue	Duration
1.	21-12-2000	Six	COSMO JMO SMO	3 2 1	MP, K, HP, ER	G..F. Gooste Hospital, Board Room	70 Minutes
2.	12-02-2001	Seven	JMO SMO PMO	2 3 2	MP, G, HV and HP	G. F. Gooste Hospital Board room	70 minutes
3.	22-02-2001	Eleven	COSMO JMO SMO PMO	4 4 2 1	K,N, MP MM, G, HV	Seminar Room of MOU of MP-CHC	70 minutes
4.	27-03-2001	Ten	JMO SMO PMO	2 4 4	R,MP, HV, LR,	Seminar Room Retreat CHC	70 minutes
5.	09-04-2001	Five	COSMO JMO	3 2	MM	Staff Tea Room of MM-CHC	70 minutes

ABBREVIATIONS: CHC = Community Health Centre; MP= Mitchell's Plain; K= Khayelitsha; HV= Heideveld; ER= Elsies River; G= Guguletu; HP= Hanover Park; N= Nolongile; MM= Michael Mpongwana; RT= Retreat; LR= Lotus River. MOU= Midwifery and Obstetric Unit

6.6 SEMI-STRUCTURED INDIVIDUAL INDEPTH INTERVIEW

The researcher and facilitators had less control over the flow of discussion in the group as compared to individual interviews. Thus there were some unexplored themes on the initiation of insulin therapy in patients with poorly controlled type 2 diabetes in public sector primary health care centres in Cape Town. To uncover these themes and to strengthen the findings of the focus group discussion in this research, individual semi-structured interviews were conducted.

The focus group discussion identified relevant and appropriate questions for the semi-structured individual interviews. The key issues, such as issues on knowledge and experience of insulin therapy needed to be explored through semi-structured in-depth interviews, although the focus group discussion did deal with some aspects of the knowledge on insulin therapy. In the individual interviews, a series of open-ended questions would guide the interview and facilitation will occur to find answers. Participants who were not able to take part in the focus group discussion, but are able to take part in individual interview would be selected for semi-structured individual interviews. The participants were chosen by using purposeful sampling. To increase the validity of the data three different interviewees were used for the semi-structured interviews. I interviewed six participants on different days. The person who did the fourth focus group discussion also conducted two individual interviews; she had also read my research proposal and was an experienced researcher on diabetes. Of the ten in-depth interviews four were conducted by an independent person. Notes were kept during the interview. After every interview the researcher and interviewee discussed it. A pilot semi-structured interview was done before developing the final questionnaire for semi-structured individual interviews. (Appendix- F has the semistructured questionnaire).

Table -6 Description of semi-structured in-depth interviews

Serial No interview	Date of interview	Site of the CHC where the participant work	Position/ Category of the participant	Total year of experience of the participant	Duration of interview
1.	17-04-2001	LM -CHC (Plumstead)	PMO (Dr In charge)	18 years	19 minutes
2.	24-04-2001	LR CHC	PMO(Dr Incharge)	17 years	18 minutes
3.	24-04-2001	LR CHC	JMO (Worked at many CHC)	5 years	17 minutes
4.	03-05-2001	Dr AR CHC	PMO	20 years	14 minutes
5.	08-05 -2001	ER CHC	SMO	6 years	20 minutes
6.	15-05-01	KCHC	PMO(Dr In charge)	22 years	19 minutes
7.	24-05-2001	MP CHC	COSMO	2 years	19 minutes
8.	24-05-2001	MP CHC	PMO	12 years	16 minutes
9.	12-06-2001	N CHC	COSMO	2 Years	16 minutes
10.	30-06-2001	CR CHC	PMO	13 Years	15 minutes

Table -6: Details of the semi -structured individual interviewees with some demographics details.

ABBREVIATIONS: LM= Lady Michaelis; Dr AB = Dr Abdur Rahman, ER= Elsie's River; CR= Cross Road (Other has been given in table-5)

A brief background sketch of the participants, such as their years of experience was noted before starting the interview. (Sample form of collecting demographic details in appendix -G)

7. VALIDITY OF THIS STUDY:

The use of a combination of focus group discussions and in-depth individual interviews has increased the validity of this research. Conducting in-depth interviews after the focus group discussions permitted further explanation of the same issues and validated the findings of the focus group discussions.

The five focus group discussions were facilitated by three experienced researchers excluding myself. The ten individual interviews were also conducted by two experienced researchers, one of whom also facilitated a focus group discussion. All of the focus group discussions had a note taker. As I had completed the research method module in my course with the other Masters' students of the Faculty of Health sciences of the University of Cape Town, I was exposed to the theory of qualitative research. I also successfully completed a one-week winter course on qualitative research at the University of Western Cape in the Department of Public Health.

Two of the facilitators in the focus groups are sociologists, and Ms Lauraine Vivian (LV) is a medical anthropologist. Ms LV conducted an independent analysis of this work. Neither myself nor Ms Vivian had seen the analysis before completing our own analysis. My analysis reflected the same themes, as the independent analysis, although some sub-themes were different. However these sub-themes did not constitute any contradiction.

Two high quality cassettes were used to record the data, should one fail to record it. Although in the first focus group discussion the sound of a fan caused a disturbance, the presence of another cassette recorder in the same venue at a different position recording in the same time, helped to overcome this problem. The recorded data was transcribed and typed by an experienced transcriber at RC Parow, Tygervalley. All the transcriptions were checked by me, and any queries cleared with the help of field notes. Both my supervisor and I were astonished by the use of English of the participants, but in fact the focus group discussion process was so smooth, lively and emotional that some time even the participants forgot that they were participating in a discussion. However my supervisor has criticised the language usage repeatedly, as many participant used colloquial English. I have also mentioned that the data that my supervisor read, was the data provided by the participants. On one occasion I took all the recordings to her to listen to them, as a validity of the original recordings. All the recordings are available for inspection.

Both before and after the focus group discussions, I met with the external facilitator and note taker to provide feedback for better discussions in the next focus group discussion. All the focus groups were allowed to proceed according to their own flow, although some appropriate sensitive probing was done, without any intimidation or development of conflict. The total number of participants was forty eight, out of a total 130 to 140 doctors in the organisation. Although the total numbers of participants is not the issue in qualitative research, five focus group discussion and ten individual interviews nevertheless enriched the variety of data.

Thus, I would say my research data is validated by an independent analysis and through a process of triangulation. The components of this triangulation were:

- i) Focus group discussions;
- ii) Individual interviews; and
- iii) Field notes.

So, I have achieved the internal validity of this research by means of the following:

- i) Using the correct method of measurement to answer the question of the research
- ii) Sampling of the participants was purposeful, which helped me to obtain the richer data.
- iii) I closed the data collection based on the theory of saturation. (i.e. I stopped when the same kind information began to be collected from various participants.)
- iv) The process of the focus group discussion and individual interviews was open-ended and facilitatory. Trained facilitators and interviewers were used for this purpose.
- v) I used a stepwise procedure of the data analysis, such as open coding of the data, classifying the data into different categories and finally examining the interrelationship of the different categories of data. I used the codes, direct quotes from them and expression of the participants described. Grounded theory was used to code the data.
- vi) Triangulation of the data helped to increase the validity of the data.

The external validity or generalisability of this qualitative research is context and location specific. Western Cape primary health care services at CHCs have been seen as a model of community health care in South Africa. As 46 participants took part in this research and this research has internal validity, so the generalisability of the findings of this research to the public sector CHC may be relevant.

Although, this findings can't be generalise to all the CHCs in the Western Cape metropole region, but considering the wide representation of the CHC doctors, it is likely that this findings could be applied in the most CHC in South Africa and most certainly there is relevance to all doctors working in the primary health care setting.

Reliability and reproducibility refers to the extent to which similar information has been supplied when a measurement is performed more than once, i.e. the researcher will reach the same findings based on the same data. I have used a second person for analyzing the data, which revealed nearly same findings as the analysis conducted by myself.

In order to address the concern about multiple interviewers conducting the focus group discussion the following measures were taken:

- i) Each interviewer read the research proposal and I discussed the proposal with them
- ii) Each facilitator was provided with a single interview guide.
- iii) Experienced facilitators were used

8. LIMITATIONS OF THIS STUDY:

1. This study was limited to the doctors, thus excluding nurses and patients. It is possible that nurses' perception of the initiation of insulin therapy could be different. But as the decision to initiate insulin is taken by medical officer, it may not be a true limitation of the study.
2. An important limitation was that the patients were not included in the study. We had to rely on the doctors to provide their perceptions of the patients' barrier to this form of treatment.
3. Participants' limitations with regard to expressing their fears in front of other colleagues were noticed, but ultimately it did not prevent acquisition of the information required. Some semi-structured in-depth individual interviews by non-colleagues helped to provide some exploratory data.
4. My attendance at two focus group discussions as a note taker and at one of the focus groups as a facilitator, may have inhibited the discussion but I believe that my non judgemental and ready to listen approach over came these inhibition.
5. Failure of feedback of results to the participants may have reduced the validity of the data. But the barriers are such a sensitive issue, that feedback may be interpreted as a sensitive issue too.
6. Some of the recordings and thus the transcripts were unclear, but the note taker notes were adequate to fill in the gaps.

9. BIAS IN THIS STUDY

Sampling was purposeful in this qualitative study, which helped to prevent bias in the qualitative study. Nevertheless, some participants might not have expressed their opinion even with the highly purposeful sampling.

The facilitators and interviewers were neutral and non-judgmental. They were there to listen to opinions but not to give their opinions. This reduced the risk of including any facilitators' own agenda in the discussion and interview. I myself was immersed in the data without any personal preference of the data. Thus the bias was very limited.

10. ENTRY AND ETHICAL ISSUES IN THIS RESEARCH

A written application was made to the medical superintendent of the CHSO for the following:

- 1) Permission to conduct the study amongst the medical officers of this organisation
- 2) To issue a written letter with permission for the participants to take part in the research in the afternoon from 14h00 to 16h00.
- 3) To give the researcher an opportunity to attend a meeting of doctor in charge of CHC's at Woodstock to announce this research and to distribute the letters of permission to the participants to attend during their afternoon working hours. The doctors in charge were asked to relieve the doctors interested in participating in this research.

The participants were contacted by the CHSO internal post as well as telephonic contact. Personal contact was made with the participants as well, before the in-depth semi-structured interviews, and in some cases before the focus group discussion. Reassurance was given to each participant with regard to confidentiality and guarantees were given that the researcher and participants would not discuss the details of the interview with their colleagues individually. (Sample of consent form on Appendix-H). I would maintain strict confidentiality and confidentiality among the group members was assured and the research findings would be sent for publication without mentioning the names of the participants.

Participant were given a letter of introduction, mentioning the type of research and requesting written permission to audio tape the discussion in the group or in in-depth semi-structured interview. The principle of respect for the autonomy of the participants in this research was maintained by their free, independent and informed choice without any external influences. Participation was voluntary. Verbal and written consent were given by the participants.

Participants had the right to withdraw at any point in the research. The confidentiality of the recorded audio- tape and name of the participant was maintained.

The participants were informed that the time used would be the afternoon working hours. Thus for most of the participants, it would not be taking participants' personal time. Lunch was offered before the afternoon group discussion. During the semi-structured interview, the time and place of the interview was chosen according to participant's available time.

The place for the interviews was preferably out side the CHCs. The participants were informed that the outcome of the research would be used for service improvement and that the result would be relayed to the participants. It was hoped that the information obtained will lead them to clarify their duties, which could help to overcome the barriers to initiating insulin therapy for poorly controlled type 2 diabetic patients on maximum dose of oral hypoglycaemic agent.

The protocol was approved by the ethics committee of the University of Cape Town to conduct the study. (Letter included in Appendix- I)

This protocol also was submitted to the senior medical superintendent Dr E.W. Michael and medical co-ordinator Dr Cynthia le Grange and Chief Medical Officer DR. Rob Martell for their co-operation and permission to conduct the study. A pilot study was done with one group of medical officer comprising junior and senior medical officers.

Focus group discussions were conducted from the month of December 2000 to April 2001. In depth semi-structured interviews were conducted in the April 2001 to June 2001. Analysis of data was done immediately after each focus group discussion. The research was completed by August 2001.

11. ANALYSIS OF DATA

The central question was the same in both the focus group discussion and individual in-depth interviews, although these are different tools for gathering data in qualitative studies. As focus group discussions were conducted first, the individual interviews were used for confirmation of the focus group data and as well as searching for new findings, which were not able to be explored during focus group discussions. Some participants in the individual interviews were also chosen from the same CHCs as the participants in the focus group discussion. It validated the information that was given by the other participants in the focus group discussion of the same CHC. All audio taped material was transcribed by an experienced transcriber from the MRC (Cape Town) and rechecked by me. After final transcription, all the transcribed materials were given to one of my supervisors Dr Marayam Navsa, and some of them were given to my other supervisor, Prof N.S. Levitt to read. Lauraine Vivian who did the two focus group discussions was given all five focus group discussions and ten individual interviews to do a comparative analysis. A margin was kept on the transcript for coding and categorising. At first I used a coloured pen to highlight for common themes. Then I used the PC Microsoft word processor 'copy and paste' method to categorise the emerging data and identifying the common themes. Common themes were identified, first within the focus group discussion, and then separately for the individual interviews. This was followed by the next most common themes, which had emerged. While coding and analysing the data I tried to allocate every piece of information to a specific space if it was related to the barriers on initiation of insulin therapy using the rule of grounded theory. Extensive field notes were taken before, during and after the focus group discussion and in-depth individual interviews.

12. RESEARCH RESULTS:

12.1 Results of the focus group discussion:

The themes which emerged can be readily divided into doctors' barriers (most common), patients' barriers, system barriers in these primary health care centres and overcoming these barriers.

12.1.1. DOCTORS' BARRIERS (FACTORS RELATED TO DOCTORS):

In essence, many participants in the discussion expressed the views of other doctors rather than their own, although some participants expressed their own agenda directly. Many sub-themes emerged on doctors' barriers, namely:

A. Doctors' perceptions on initiation of insulin:

Different participants had different perceptions on the initiation of insulin for patients with poorly controlled type 2 diabetes. These perceptions acted as barriers to initiating insulin, for example;

i) Insulin is synonymous with life long imprisonment:

Insulin is seen as being restrictive of daily activities: As one participant said, *"it's no use to start...[with those]that kind of injections, you pretty much line[equate] patients with almost like imprisonment... because, you are putting patients onto lifelong injections"*.

ii) Injection is intolerable:

This participant made it clear by saying,

“The thought of having to inject my self twice a day would be horrendous.”

“I wouldn’t want to be injecting myself for insulin. Yeah, It will be awful.”

iii) Laziness of doctors:

Some doctors perceived others to be lazy. One participant felt that, *“To start insulin takes a lot of time, one has to counsel the patient and so on; may be [perhaps] the doctors are lazy as well. So doctors might leave the patient without insulin, instead of explaining the benefits of insulin to him or her. It is easier for the doctor to say that the patient refuses injection.”*

iv) Non-compliance with oral medication:

Many participants expressed the perception of patient’s non-compliance with oral medication in relation to potential treatment with insulin. Their concern was that if patients were not compliant with their diet and oral agent, they wouldn’t be compliant with insulin. Doctors felt that their (i.e. the doctors) awareness of the patient’s poor compliance to non-drug and drug treatment caused them not to initiate insulin. For example,

According to one participant, *“[A patient can be non-compliant], which means that you cannot change over to insulin, because you have not explored whether oral medication will work for this patient.... I’m quite right to say this because if a patient is not compliant on oral then he is going to be a mess on insulin.”*

So the participant felt non-compliant patients are not reliable. The implication of this would, arguably, results in patients’ possible non-compliance with insulin as well.

This view was supported by other participants,

“Until you know 100% that your compliance is 100% with your patient you cannot actually make a decision to switch over.”

“I don’t believe that my patients are compliant enough on their oral medication to start them on insulin.”

One participant told,

“They are not on diet and they’re not taking medication regularly and I’m not going to start them on insulin therapy.”

This also implies that when the doctor feels that the patients are not compliant with diet, the doctor is not willing to initiate insulin.

Yet another doctor confirmed this when he commented that he was, *“very resistant to starting patients who were not eating right diet”*

Another participant expressed the following concern, *“Well, the poorer your diet, the more insulin you’re going to need and it is just a continuous spiral upwards. It is well described.”*

v) Use of insulin in obese patient is not good:

It is not a good idea to initiate insulin in a severely obese patient. As one participant said,

“Initiating insulin in a patient, who is not compliant on a diabetic diet and who has morbid obesity is generally is not a very good idea.” This thinking has also worked as a barrier to initiating insulin.

vi) Initiation of insulin is a specialist treatment:

As one participant explained, *"I think there are too many factors involved in starting a patient on insulin. I will rather refer the patient first of all to a higher level hospital because that patient needs education about his disease at least [preferably] by a specialist"*.

Another participant expressed the view that he thought the following, *"It was my impression, when I was a medical student that diabetes was a tertiary health care problem and that only a professor should be involved in starting insulin or some thing like that. I believed that any body with diabetes had to be seen by him [a professor] at some point."*

Another participant was of the impression that monitoring of blood sugar was only satisfactory at tertiary level. He said, *"I am a bit worried about writing up the insulin for patients, because I know that those patients won't get the monitoring, they actually need. I would rather send them to a tertiary hospital or secondary hospital. There they will have their glucose tested on a regular basis, that being more than once a day."* (The obvious implication here being that the testing won't be a once of thing)

vii) Patients are too irresponsible to be treated with insulin:

The participant's perception was that patients are not responsible enough to be treated with insulin. One doctor felt that the public community health centre patients didn't take responsibility for themselves as in, *"We are talking about people not taking responsibility for their own health, their own lives and that's not only a big part of their disease and but also a big part of their attitude. This is a problem"*.

Another thing is that the patients default on their treatment, *"I think that the patients with diabetes often don't pitch and they miss their treatment and sometimes they haven't taken treatment for two or three months!"*

Thus doctors have labelled these patients as irresponsible people and defaulters. It was difficult for these doctors to believe that (some/many) patients may be taking their oral medication regularly and may be willing to comply with insulin therapy if prescribed. Participants gave this, (i.e. the perception of patients as irresponsible people), as a reason not to initiate insulin.

viii) Patients need to be familiar with insulin as a treatment:

Many participants felt that insulin treatment was not acceptable because it is not that familiar.

One participant said, *“When the community is more familiar with the kind of treatment they are more likely to accept it”*.

B. Doctors' attitude:

Many participants were reluctant to initiate insulin in public sector primary health care centres, which was evident from the following points:

i) Unwillingness to initiate insulin:

Many participants were very emphatic about not treating patients with insulin. This may be related to the level of education and lack of understanding of the diseases on the part of the patients as well as the lack of availability of facilities. For example:

“It's very third world, very rural, very uneducated, very like a poor segment type of society in which, they don't have any concept of disease most of the time, they don't understand our idea of it [diseases]”

“When the question of initiation of insulin therapy comes at any time, fully existing structures have to be present.... People could find it very difficult, they cannot attach importance to the disease unless, things [structures] are in place before- hand.”

Another participant's attitude was that if the patient didn't understand the disease, he/she should not be treated, as in, *“If they don't understand what sugar and salt in the blood means..., how can we even begin to try and treat the sugar issue?”*

ii) Shifting responsibility:

Many participants felt quite happy to shift responsibility to tertiary institutions. One of the perceptions was that secondary and tertiary hospitals may be well equipped to initiate insulin. As one participant said, *“At the tertiary hospitals they do have diabetic sisters. The advantage there is that the sister has time not only to educate the patient, but also to reinforcing it . Each time the patient comes back, factors such as diet, exercises and so on for sugar control can be dealt with.”* .

Another participant said in support of above, *“When they come back from tertiary institutions their blood sugar tends to be under control afterwards”*.

Another participant had already experienced shifting the responsibility to others and found it easier to transfer the responsibility to others during her private practice, *“When I used to do private practice and I decided to change the person from oral medicines to insulin, I didn't have to do anything, I would write a referral to a diabetic clinic, the medical aid would pay for it, there was nothing to it. In other words the doctor initially starts the dose, but further management of the patient is the other persons' responsibility....”*

iii) Treating patients with insulin is not seen as priority:

One participant didn't regard initiating insulin as a priority in his work place, *"Why should we be bothering about starting on insulin, that's a minor problem compared to all the other problems that you could have."*

C. Fear

Fear plays a major role in the reluctance of doctors to treat patients with insulin. As one participant said, *"I think the main barrier is the doctor barrier. I see this barrier as more important than the system barriers or patient barriers. When I look at my colleagues, I think most of them have the doctor barrier. Most of us are therefore reluctant or often scared to initiate insulin."*

They are psychologically hesitant because, they harbour so many fears such as:

i) Fear of hypoglycaemia:

Most participants expressed perceived danger on the usage of insulin and were therefore scared to initiate insulin in the primary care setting. Doctors were sending patients to secondary or tertiary hospitals for admission to initiate insulin saying that, *"We are worried about the risk of hypoglycaemia, which is quite serious for the patient? We don't want to put them at risk? But it should be a low risk if it is used correctly?"*

It has been exacerbated by the perception and experience of, *"I am starting a potentially hazardous drug on a patient in a situation where I am not sure it is going to be monitored properly."*

Fear of hypoglycaemia has been also exacerbated by fear of not having time to counsel patients as one participant said, *“I won’t start someone on insulin, if the system doesn’t give you a chance to counsel that someone, It is just going to be dangerous to start them on treatment”*

Another participant said, *“The risk of getting a hypoglycaemic attack from insulin is far greater than from oral medication”*

ii) Fear of blame due to patients misconceptions:

The patient blames doctors if they initiate insulin; as one participant said, *“They [the patients] know their family members, who have died on insulin and there is a very big misconception among the diabetes patients starting insulin, and they kind of feel that they will deteriorate; that means doctors fear being blamed and therefore don’t want to initiate insulin”*

iii) Doctors are coerced into complying with patients’ wishes:

Many participants acted according to the patients request or their reaction to the idea of insulin by giving them more chances to rectify their lifestyles. Doctors always complied with the patient request without making an effort to determine their concerns. As one participant mentioned,

“They will beg you! Please, I want anything but insulin, so you end up giving into them”

Another participant said, *“If they say their diet will be much stricter then you kind of feel that you should give them benefit of the doubt for that one month”*.

Yet another participant felt that patients were also impressionable and found that, *“they try harder, when they see another doctor, all is fine, normal, for a while, next month then their sugar level is back high again, they are desperate; then they amazingly rectify, they are just very impressionable”*.

D. Doctors’ Concerns:

Participants were concerned about the initiation of insulin in certain circumstances. Participants were also worried about the initiation of insulin in a patient from poor socio-economic conditions for a number of reasons:

i) Lack of regular meals:

Participants were worried about the initiation of insulin for patients in poor socio-economic circumstances, because such patients don’t have money to buy regular meals. As they said,

“It is difficult to start the patient on insulin if they are only going to have supper.”

“You know, [I don’t like] prescribing insulin to somebody whom I am not sure is going to have food the next day.”

ii) Lack of facilities to store insulin:

Participants were concerned that insulin was not going to be kept properly refrigerated, and this acted as a barrier to initiate insulin. As one participant said, *“They live in shacks, they don’t have electricity, don’t have fridges.... When I started a patient on insulin, I was wondering whether or not the patient would be able to keep this insulin cold.”*

E. Lack of knowledge, training and skill:

One participant felt that the benefits of use of insulin for patients, with poorly controlled type 2 diabetes, may not be known to the participants, as one participant said, *“In terms of doctors’ points of view, the doctors might or might not be aware that insulin should be used. So they [doctors] might not acknowledge it.”*

i) Gap between theory and practice of conventional teaching on diabetes:

The participants acknowledged that they have a gap in knowledge and training on initiation of insulin. It was evident by the following statements,

“You know when starting protophane...I am not sure what the maximum dose is before converting to actraphane...and how to convert it to other insulin...I mean, I have never practised the kind of things you learn at varsity. I just feel, you’re a very poor doctor with regards to insulin.”

ii) Inadequate training at undergraduate level:

Most of the participants felt their undergraduate training programme placed emphasis on treatment of acute and complicated conditions related to diabetes. As one participant expressed it, *“When I started training, undergraduate training was focused at serious conditions, like diabetic ketoacidosis, non-ketotic coma, and then you become an intern at the hospital, you treat the serious cases, those where that patients have a clear indication for insulin, so you were never taught that it is extremely simple to initiate insulin in a primary care setting.”*

Patients with diabetes at primary health care centres are seen in an entirely different context to those at secondary and tertiary institutions. The training acquired in a secondary and tertiary setting didn’t always translate practically in the primary care setting.

As one participant said,

“I think, we should say lack of experience, yeah, certainly and for most doctors, it started at tertiary settings or secondary care settings, in which they had done their house jobs. We didn’t really get much experience in seeing the primary care management of the diabetic person, which is always contextual.”

Most of the undergraduate training was in the in-patient environment. Another participant said that their training was not in a primary care setting, *“We have been trained in tertiary settings where we titrate. We have been trained in inpatients setting. I think it is definitely a different environment compared to a primary care setting.”*

Another participant, who had done his internship previous year, he said, *“When I was an intern last year, we only admitted patients for three days; all we had was one type of insulin so it made it simpler.”*

This that means the participant training on insulin was in an inpatient environment, which was never further updated.

iii) Not keeping up with changes and new developments:

Approaches to and treatment of diabetes keeps changing. One participant said, *“I think probably the switch to insulin is a relatively a new thing”*

As one participant said, *“Since I qualified in 1990 things have changed and are still changing. There have been many changes in this long time”.*

It was explained by another participant, who said, *“in the old days we were taught that you can’t use the two together, you can’t give some- one oral and insulin.”*

So not only is there lack of knowledge and training, but various inconsistencies exist on the use of maximum dose of oral agent before the initiation of insulin therapy. Such as

"We know that the maximum dose of oral agent varies between different doctors depending on the followings, different years in which they qualified, different training institutions, what constitutes maximum doses of oral medication? Some doctors were quite happy to go up to doses that exceeded our medicine formulary [SANF=South African National Formulary] recommended doses, and others could initiate insulin at doses below that."

iv) Doctors' are not aware as to what constitutes ideal control:

Not only are the different doctors using different doses of the drug, one principal medical officer mentioned, *"I think there are different levels of blood sugar as well, at which alarm bells start ringing. You see a patient's sugar level 14, 15 and 13 for a year. Nobody has spoken to them about this, which is clearly poor control. One feels one should do something, where as somebody who is just qualified might think that ideal control of sugar is seven and if it is more than that you need to do some thing."*

v) Lack of confidence:

One participant said there is lack of confidence as well; as he explained, *"I think one must bear in mind, a lot of doctors are junior doctors here and there are few doctors in our hospital who have initiated insulin and who are confident; so it really depend on the experience"*

Another participant said, *"You can see these guys are on maximum dosages of oral drugs and so on, and you probably need to go on the insulin, but you are not used to really starting insulin in that type of situation"*.

vi) Knowledge, training on guidelines, and conflict in between guidelines:

As different doctors are using different doses and levels of blood sugar to indicate poor glycaemic control, it meant that either the doctor did not know about the guidelines or that he did not practice the national guidelines for treatment of the patient with type 2 diabetes at a primary health care level. Most of the participants were not aware of any guidelines on type 2 diabetes. As one participant said, *"I don't think there is any guideline"*. One participant was aware of the guideline, but he could not make sense to use it in practically. He explained that the guideline is not clear on the amount of maximum doses of oral agents. As one participant said, *"I don't feel like when it comes to it, its actual maximum doses."*

Yet another participant found the guideline very complex to use, as he stated, *"Even it is at policy level or frame-work level, it seems be in a complex form."*

F. Difficulties in discussing concerns about practice pattern of seniors by Juniors':

Lack of organised mechanisms for communications in the system made it difficult for juniors to discuss treatment variation problems with seniors. One participant mentioned, *"The problem is that we have a doctor, who thinks that, he can go higher [oral dose]"*. This young generation doctor also expressed, *"I feel that being the youngest and most inexperienced today I have to go and knock on the door of my boss and say you shouldn't prescribe, but [I am scared to do so]."*

G. Language barriers:

Many participants found that the language of training and the language the patients speak, is different. As one participant said, *“I don’t speak any Xhosa, if you want to counsel a patient who only speaks Xhosa, you can’t communicate with them.”*

Many doctors don’t know Xhosa or other languages, which could be the patients’ preferred languages. The patient may misunderstand the instruction, i.e. if English is not their home language they may not understand the correct dosage and precautions. As one participant said *“Educating the patient is very difficult here, because language is the number one problem.”*

12.1.2. PATIENT BARRIERS AS PERCEIVED BY DOCTORS:

Most of the participants found that the patients’ factors as perceived by doctors acted as a barrier to initiate insulin in the public sectors primary health care centres.

A. Patient beliefs relating to insulin:

Patients have many beliefs about insulin which acted as barriers to initiate insulin, such as,

i) Insulin seen as a death sentence or cause of death:

A participant said that one of his patients was scared to take insulin because he thought that, *“Only when the sugar is very bad, will I go on to insulin, then I will die”*. Some believe insulin causes death, as one patient said to one of the participants, *“They know of family members, who have died on insulin”*

ii) Insulin seen as a cause of stroke:

As one of the participant said, *“I had a patient who was convinced that she got [had] a stroke because she was on insulin, two days after she was started on the insulin she had a stroke and after that she refused to take insulin and it was really difficult to convince her.”*

iii) You don't need insulin if you are stressed:

Patients believe that stress is the cause of high sugar and they believe as soon as the stress problem is addressed the sugar will return to normal. As one participant said, *“Their sugar goes up, when they are stressed, like when the children are giving them hard time, that makes that their sugar will go up, after that their is fine again and they think they don't need insulin.”*

iv) Insulin causes leg amputation:

As one participant said, *“Say no, they know some- body who takes insulin and has to have leg amputation, their perception is that the insulin is the cause of leg amputation, not diabetes.”*

v) Insulin makes you fat:

One participant said *“They have wrong ideas of what insulin is and they've been told by their friends that they must never start insulin, that they'll get fat and is all down hill from here.”*

vi) Insulin makes you sick:

The patient challenges the doctor that, *“It's only very sick people, they need insulin and [even that] going onto insulin therapy makes them sick.”*

B. Fears:

Most of the participants said their patients were very resistant and not willing to initiate insulin treatment. The reasons suggested include:

i) Fear of needles:

Many participants expressed their experiences of patients' fear of needles, such as:

"Maybe it is time to initiate injections and the patients' says doctor I don't like needles and that's where it stops."

"I had a couple around, I discussed it with them, what insulin is, why they need insulin and how it works, and they're afraid of pain from needles. This is a reason they give as an objection."

"Resistance of the people with regard to needles, because needles have equated with pain."

ii) Fear of getting pain:

Insulin injections are seen as a painful injection. As one participant said, *"They've [patients have] got the perception that you are going to have an injection that there is going to be pain."*

iii) Fear of injecting into the vein:

The reason for the fear of needles was related to previous experience of pain from an injection in the vein, as one participant explained, *"I had a lady the other day and I didn't check with her why she didn't want insulin. However I checked with her the next time and she said she thought that she would have to inject into a vein and she was terrified of doing that..., and when I discovered it was something as simple as that, I explained to her that you put it into your leg, after that she was fine and agreed that she'd take it."*

iv) Fear of damaging one's relationship:

A patient mentioned something, which is beyond bearing the pain of a needle, *“There is no way that I can go on to insulin because my husband will divorce me if I go onto insulin.”*

C. Lack of understanding of patients with diabetes:

Patients' lack of understanding is an obstacle to being treated with insulin. One participant was concerned that patients might not be able to understand many issues related to the use of insulin and said, *“The main concern is whether or not they understand that [taking] too much of the insulin is more of a risk than taking too little.”*

Participants suggested that lack of understanding of the disease was one of the reasons not to initiate insulin. Participants found that since diabetes is an asymptomatic disease patients didn't understand the long- term impact of poor control of sugar.

One participant felt that patients seek attention for an acute problem, and *“They don't have the ability to conceptualise the nature of a problem that might occur in five years time, or ten years time, because they live from day to day. Today, they come in because they are dizzy, that's what they come for, to get relief from an acute condition, [however] chronic care is a problem.”*

Other participants explained,

“You see they don't understand the seriousness of their disease so they don't control the disease seriously; the consequence of that is that they don't come to the realisation point that you expect them to.”

“Either they don't understand or they just have a perception that if something is wrong, you just go to the doctor and have it fixed.”

D. Poor economic circumstances of the patient:

i) Lack of money to buy food:

A participant felt that the poor patient may not like insulin because, *“Why is the patient so resistant? I used to say if they don't have money for food, if they don't eat every day, they might have more serious problems, [therefore] you might be doing them more harm by giving them insulin in that situation.”*

ii) Lack of home glucometer:

They can't afford to buy a glucometer for home monitoring, *“If a patient doesn't have a glucometer at home to monitor their own glucose, and you explain the symptom of hypoglycaemia to them, they can suddenly get hypoglycaemic not even feel, that is potentially hazardous because they can go into a coma.”*

E. Lack of family support for older patient:

Many participants felt patient family support is vital for initiating insulin in the case of an older patient for instance, *“I think the transitional stage is dangerous ...because the blood sugar levels has to be checked regularly. Most of the time it's old people who need somebody to have to be with them every time and they cannot afford a escort with every time, most of the time there is nobody looking after them and they have to give them the injection themselves that's a bit of a problem also.”*

F. Alternative medicine:

Taking traditional herbs and going to the traditional healer is a common practice in many communities. This type of practice was expressed as a concern by many participants and acted as barrier to initiate insulin, such as, one participant said, *“I started her on protophane, She did not take the protophane, she was taking traditional herbs, and she has been having sugar.”* It made the doctor reluctant and unhappy to start insulin on the next patient.

9.1.3. SYSTEM BARRIERS:

Most of the participants felt that an effective health system is necessary to initiate insulin in primary health care centres. For instance,

A. Lack of resources:

Most of the participants are compromising their work standard due to poor resources and an excessive workload in the public sector's primary health care centres.

i) Lack of human resources:

It is recognised that public sector primary health care centres in the Western Cape are overloaded with lot of responsibility but lacking in the proper resources. As it was expressed,

“We are so overburdened, we are so over stressed that it is totally chaotic to work here. I feel that due to chaos, we are definitely providing less than lots of true care and insulin is one of form providing true cares.”

“We all are overworked, we don't have a lot of time, because our patient loads are so high”

“The number of people in the area increases constantly, but the number of people who work at the day hospital stays the same...”

"I think what has been happening in our system here is that the community service has just replaced the medical officers. The actual numbers of medical officer hasn't increased."

The financial constraints are too much with the result, *" We have a ratio far too many patients to doctor in each area to be seen, we can't even give appointments to all the chronic disorders "* as one participant said.

The same participant said more about the impact of financial constraints on the public sector primary health care system, which also has a negative effect on the initiation of insulin.

ii) Lack of financial resources:

Lack of adequate finance has made it difficult to purchase the necessary resources. Lack of financial resources has led to an inadequate supply of insulin, too few available dieticians, not being able to order tests,

One participant said,

"We often turn people away because there are no doctors to follow them up, and there are not enough pharmacists to provide enough medication for all the people with chronic disorder, so we have financial constraints in terms of the fact even if you sometimes start, or you want to start somebody on insulin, you're thinking...em...are we going to be able to supply the insulin."

Another participant explained, *"if we hadn't had financial constraints, we would have a dietician everyday, you know, a dedicated diabetic sister, and more doctors who would be able to speak to the patients for longer, so yeah, I think financial constraints do affect the system, quite a bit"*.

Lack of all of the above resources made it difficult to take a decision to initiate insulin, One participant explained, *“They actually see a doctor once in three months, that means you are making decisions on their treatment only once in every three months, I mean that one single value of their blood glucose, for that one single day is not necessarily reflective of what’s been happening? ... It seems like there is a big gap in seeing patients, making decisions on this limited information.”*

The impact of inadequate financial resources has been expressed in many other ways, such as

a) Lack of Insulin:

One participant said, *“Certainly at our day hospital, they are out of stock [there is often a stock shortage]. This is a big problem. Whether it is lack of certain insulin or whether its needles it makes our job hard. You don’t know how you can give a person a vial of insulin without giving him the needles.”*

Running out of insulin stock is a common occurrence, as one participant said, *“The system barriers includes running out of insulin. We don’t have the insulin in stock when the patient needs the insulin. The patient gets a 5 day supply instead of a month supply, the patient’s gets 5 pens when they are on 100 units of insulin and they actually need 10 pens and so on.”*

A patient told one of the participants, *“They don’t give us enough needles. I used to use a penset now I must use a needle and I don’t know how the pharmacy runs out of stock.”*

b) Lack of Equipment:

Good quality of instruments were not available. As one participant said, *“Some of the machines they use, the gluco-stix machines don’t work well, sometimes they don’t use enough blood on the strip. You know there are all those types of problems, relating to general and diagnostic techniques.”*

Availability of quality glucometers, good calibration and accuracy in testing blood sugar level is of vital importance.

B. Lack of time:

Lack of time is closely linked to lack of resources. Limitation of time in primary health care centres has made it difficult to initiate insulin. This has been expressed by many participants. For example,

“I think historically the biggest obstacle has been the lack of time.”

It was felt that there was not enough time to educate patients on the disease and on use of insulin.

“Realistically speaking, the main issue is time. We don’t have the time to tell them [patients] all they need to know.”

“We are all seeing an excess of forty patients a day. I mean you just don’t have the time.”

Many participants felt they needed more individual (one on one) time to initiate insulin. As one participant said,

“You only have an average 6 minutes per patient. The time you’ve examined them and found out whether or not they’re diabetic or whatever their glucose level is, we cannot possibly educate in somebody in 3 minutes”

Another participant said, *"For people who are there to be put on insulin for the first time, there needs to be reinforcement of the education that has been given. In our kind of situation where we are at the moment, we don't have time to peacefully sit down and counsel each and every patient individually, about their respective insulin requirements and what it means to be on insulin and how to go educate them about changing things for themselves, changing their views about insulin itself"*

If a doctor wants to spend time with the patients, the consequence is having to cope with the backlog of other patients. As one participant said,

"Doctors don't have time to sit down and do check ups, how can you get patients learn in five minutes by the few minutes you spend with them and of that most of the time you are writing and although trying to listen to their troubles the result is you don't have a lot of time to teach them. We do try to make time for this but then you sit with a back log of patients."

C. Lack of proper nursing support:

Doctors are not supported with back up by the nurses in the CHCs. As one participant said, *"Everything, every single thing, even if the patient walks in with a bandage, it gets passed down to the doctor, there actually is really no support."*

Another participant said,

"There is no diabetic sister, [nor there is an] educator, there's a nutritionist but once again there is no educator".

D. Poorly managed appointment system:

There is no extra time allocated for the patient with poorly controlled diabetes who may need to start on insulin. If a doctor wants to initiate insulin, usually he has to follow up check for the next few days in his own time and his colleagues don't assist. The reason was explained by one of the participants as follows, *"You are booked months in advance. One disadvantage of these book appointments is that if you want to add that person, [the one you have just started on insulin] you have to add that patient at your own expense; you might have to stay afterwards to see that patient."*

E. Long waiting periods:

Due to the excessive patient load in the large CHCs, the patient needs to wait to get his/her folder at reception and this also discourages the patient from taking insulin, as one participant said, *"I find that when I suggest to a patient that he starts on insulin, he might be accept the notion originally, but as soon as I explain to them that they will have to come back in three days, or in be even two weeks and then he might have to go via another system without an appointment, that it will be a very long wait, this also becomes a serious barrier to him . Because he sees that now there's a lot of extra work that's cut them in the beginning..., and that this will be continue as long he has to use our place[facility]. This creates a real system barrier."*

F. Lack of emergency service support:

Participants felt that if the patient goes home to take insulin, the patient needs a proper emergency service back up in case of hypoglycaemic attack. *“Even our emergency service is wanting. If you tell a patient, to come in via ambulance if his blood sugar is low, you know our ambulance will take hours to get to the patients at his or her home to bring him or her into the hospital and it would be too late.”* said one respondent.

G. Literature not available in Xhosa:

Although the language barrier is evident, appropriate education material in the patient's preferred language is not available. As one participant said, *“I don't even have a diet sheet in Xhosa, it's written in English and they can't read it, and I've tried to get it in Xhosa but I had a big problem.”*

H. Lack of trained interpreters:

One participant was not happy with the method and quality of interpretation done for patients.

One participant felt that most of the available interpreters cuts down the instruction, as he said, *“As going through the interpreter all the time... Nurses shorten your statements, and I have noticed this, they shortened instruction drastically.”*

This drastic cutting down of the statements can lead to misunderstanding and misinterpreting of the instructions. It acted as a barrier to initiate insulin.

Other participant said,

“If I start a patient on insulin myself, I think if we can just go back to the problem of sisters interpreting the instructions and making them very simple, but the problem is that some of the sisters don't understand them themselves...”

I: Poorly functioning diabetic club:

The diabetic club is one of the ways to support patients and doctors for the patient with diabetes. But there were mixed feelings on the structure, staff and method of running the diabetic clubs. Some participants felt their diabetic clubs were functioning properly, while others disagreed.

a) Lack of interested personnel for running the diabetic club:

As one participant mentioned, *“One of the...em...weaknesses in our club is that the sisters who come into the club are only doing a three months stint. You get sisters in that club who are seriously interested in treating diabetics, they're absolutely dedicated to treating them well while for the other sisters its just a job, they're not really interested[they don't really care].”*

b) Lack of education in the diabetic club:

There are many concerns around the education of the patient with diabetes, as participants found, *“We have a diabetic bay, the nurses say they can't carry out the education because they are too busy doing everything else. They are short- staffed, so basically all the diabetics come on the same day and will get seen by us individually. However there is no group education happening which would be ideal”*

One participant mentioned about the diabetic club of a CHC, *“But all they do is check the sugar. If it’s okay then off they go and many a time there is absolutely no education which there should be. It’s just like a conveyor belt, the patients come inside, their sugar is okay and off they go, next and that’s it. I’ve seen it; patients have been diabetic for the last five years or even longer and there’s a big lack of education in our primary care system; education is not happening, they [the patients] don’t know anything about the disease or...and coming to using insulin..., which stops [us doctors], makes us think twice of starting insulin because of the total lack of patient education, which really needs.”*

J. Lack of continuity of care:

The same doctor seeing the same patient will improve the continuity of care. When someone sees a patient for some time, it is easy to develop a trusting relationship. But there is very little continuity of care in the CHCs.

There is a lack of opportunity to develop the doctor- patient trust and relationship, as one participant mentioned, *“there is a high turn over of doctors in the day hospital..., now Community doctor [spend] six months in the CHC. You can’t establish a continuity.”*

K. Lack of flow chart:

A participant who runs the diabetic clinic continually said, *“Another thing we need to have [in addition to] continuity of doctors, is to have records; a good record system and design, this should be considered because all the observations get lost in the massive folders. So it has to be called in each visit exact level of BP, any change of medication. When you see in our clinic we see 50 patients, you are not talking to your patients.”*

12.1.4 OVERCOMING THE BARRIERS:

In the discussion they expressed their frustrations, as well as their hopes. They shared their experiences and their suggestions on overcoming the barriers to initiate insulin in CHCs for patients with poorly controlled type 2 diabetes on a maximum oral dose. Thus the following sub themes on overcoming the barriers were identified:

A. Use of scare tactics to improve patient compliance:

Doctors have recommended the use of scare tactics for improving patients' compliance. Doctors usually scare patients into facing reality by using and presenting the complications of diabetes and even death as possible consequences of uncontrolled diabetes. Many participants want to use these techniques to convince patients to improve their compliance of the patients and to keep their diabetes under control.

One participant said, *"I think we are autocratic about being... on insulin; if you don't have insulin you're going to have your leg cut off, I mean, you have to get it straight, you sort of try and coerce patients about fear often and I think that has worked well"*.

Another participant explained, *"What is going to happen if they don't get insulin and you have to show them a kidney that is being affected, show them a right healthy kidney and make the comparison they have to be frightened?"*

Another participant said, *"We know that a lot of patients are coming in, every week and they don't listen..., I don't know what you have to do, bring them in and show them the amputation... and say, listen to this."*

Another participant, although unsure of whether it would work, wanted to try these techniques for a patient with poorly controlled diabetes. This participant explained, *“I mean it’s very difficult to actually convince them or scare them, sometimes you have to really scare them, like you are going to die in two months, something you know...I don’t know if it is something that will work”*

B. Providing patient centred care:

Some participants are aware that teaching the patient-centred approach with the principles of family medicine to doctors and practising it will help to overcome the frustration of patients' non-compliance and reluctance to use insulin. As one participant stated, *“There we are talking about the curriculum [of medical training] so the family medicine approach; patient centred care might help in this situation.”*

It was easier for patients to accept treatment with insulin when their doctors accepted and understood the patient circumstances. One participant said that he accepted and understood some of his patients' situations, *“Where people have got a poor and limited diet so that the only pleasure they have is putting a little bit of sugar in their tea and also I had people started on insulin.”*

Another participant became empathetic towards the patients and said, *“In fact sometimes over and over, reinforcing talking and something to action, patient wants because it is difficult to be diabetic, can’t even have sugar, can’t have any more chocolate, very difficult and I found that would be the biggest problem rather than some thing like initiating insulin therapy. A lot of the patients that are poorly controlled on oral hypoglycaemic maximum doses, I usually put them on insulin..., that works quicker, that should be.”*

According to one participant, if the doctor listens in a patient centred way, then, *“Both the patient and doctor are reaching a manageable plan and it is better for compliance as well. That’s what I am saying don’t just only say; not understanding the patient side of story*

Another participant said, *“Maybe if you had the continuity of care and unless, where you can develop a relationship with the patient, the interaction will be less doctor centered, but more patient centered..., and maybe that would help in terms of the patient understanding and accepting what you say”.*

C. Combining the treatment of insulin with oral medication:

Many participants may start with a small dose of protophane at night and oral medication once or twice a day. As one participant said, *“Often it helps some one when he needs to try to insulin to say, look why don’t we try. We continue taking the oral medicine; just you go another sort of insulin. Once you have over the needle hangout and what was; hardly feeling that overcome here”.*

Another participant explained, *“Protaphane nocte, add on to the orals. So, there isn't really a very big problem... you can see the patient a week later after initiating insulin at 0.2 units per kilogram, there is no big danger really. You explain to the patient the dangers of hypoglycemia..., counsel about most of these things, and we had overcome those problem here [in this CHC] and it works very well.”*

D. Training of undergraduates at community level:

Many participants felt that the development of undergraduate training on coping skills needs to start at undergraduate level. As one participant said, *"I think there is a bit of an imbalance and time being set in the medical student teaching and some-body is here before, I think really they can build confidence how to approach more common community related problem and how to deal with patient family is not much, you know recall. You get an out with the patient, who is not taking medication, not strict to the diet, you don't know. You get frustrated, too young, you just come out of medical school, I see the frustration and that I think that can be fixed."*

E. Continuing professional development with hands-on experience:

i) Need for support with professional development: At one stage a tertiary hospital Professor, a consultant and a diabetic sister came to a CHC to help some participants to overcome the barriers to initiate insulin therapy. As one participant explained, *"A Professor from endocrine and diabetic clinic of GSH coming to empower the doctor"*. They told them, *"It is right for diabetics, you know and you are saying it is safe to go up to that doses of oral medication and don't be scared of supplementing or replacing with insulin."*

Some one mentioned, *"Our confidence was brought up by our CME programme really..., diabetic sister came to our clinic..., they also taught them how to use insulin. How to demonstrate the pen etc."*

Another participant said, *"Prof K was also instrumental in bringing one of our tertiary level consultants to come to one of our day hospitals, teaching us a lot of things, including use of insulin, he was the first one who came sort of..."*

Another participant emphasised the need for practical training by saying, *“it was the only way, I think, that you are going to learn, a sort of a hands on experience”*.

ii) Scheduling continuing medical education at a more convenient time:

Recently the bulk of the Continuing Medical Education (CME) programme has taken place on a Friday afternoon for the CHSO. Participants felt that it was tiring to go on this programme after a hectic stressful working day in the CHC. As one participant said, *“You know on a Friday afternoon ... your mind does wander and you’re not really that interested, and you want to keep on sleeping, that is an honest thing. So, you know people create a course or going through the system... you can learn that way...”*

F. Adoption of the national guidelines:

One participant felt that the national guideline will help us to practice evidence-based medicine: *“Something to say, these are the national guide lines ... let’s stop little deviations... then adopt the national guideline and remind them it is working. Go through it again, because you see so much doctor to doctor variation in the way diabetes is treated.”*

G. Development of institutional protocol with adherence to the national guidelines:

Most of the participants felt that the national guidelines were not adequate on the use of insulin and there is a lack of standard protocol on use of insulin. They would like to have a protocol that clarifies the maximum time period to wait between introducing the maximum doses of oral agents to initiation of insulin use and the correct procedure for doing so. They made the following remarks,

“Protocols set up that if, say, after three months of being on this and this and the values are like this to initiate, things like that.”

“A protocol can actually be formed If you use it, for conversion onto insulin.”

“It would be nice in the beginning, to get a nice guideline especially when you start insulin, how to start it, how much to give, what to give, when to change, when do you add metformin ..., all these things that you pick up as you go around, but at the beginning you don't actually know, so some sort of guidelines would be quite efficient.”

H. Becoming culturally sensitive:

To succeed in the treatment of diabetes it is vitally important to patients' cultures and to have respect for that culture; as one participant explained, *“dietary is a very much a cultural issue,”*

I. Training and involving nursing staff:

As the doctor is busy, a diabetic club is necessary to provide the patient with education and continuing education on diabetes. As one participant said, *“Yes, the way it works, the sisters will take the sugars and the blood pressures and everything and while they waiting in the waiting room, they are supposed to be getting their education, while they are waiting for the doctor.”*

Another participant explained,

“If the doctor sees 50 patients a day, you can't spend that time educating the patient. You've got to get someone to educate the patient as to how to give the insulin, what are the side effects beginning the insulin, what they got to watch out for, and that sort of thing, so you really need, you need a...., you certainly need a nursing sister or a nurse. I think you need, probably need a, she can be the educator and the actual practical side on how to inject themselves and so on.”

J. Providing audio and video material on diabetes:

A small series of good video and audio material will help to educate the patient on diabetes and the use of insulin. As one participant said, *"I want to emphasise this with a slide show on diabetes for the patients waiting in the club, it will be just before those patients get in by the doctor, to actually show a slide show because... em.. .it's like speaking to my diabetic patients..., particularly having a language barrier."*

K. Patient involvement in the club:

Patients need to talk each other. As one participant said, *"If people talk, whatever might be, it is powerful."*

Another participant said, *"One way is to let somebody on insulin stand up in the club. That was so nice to have the patients to talk to each other.... They can educate each other, that will also break down some of the barriers."*

A further participant stated, *"In the club, people who have those diseases they demystify the disease amongst the people who, who got the same disease, their peers. I think if you can get people like that to come in, listen I'm a diabetic, but I'm on insulin, you know people going onto insulin and demystifying the injecting stuff."*

Yet another participant explained, *"There should be somebody educating a group of diabetics on the day; somebody gave them a talk on insulin, and everybody can sit there and discuss it amongst themselves maybe, they can get a patient who is there on insulin and tell everybody that it's not so bad, that's not happening for us."*

L. Establishing a diabetic clinic within the diabetic clubs for poorly controlled patients only:

As the patient numbers are huge, a large group of people attending in one club may not be as effective. As one participant indicated, *“In a huge group people don’t listen –if it is taken in a smaller group of 25, people seem to be more attentive.”*

Another participant said, *“I got there, there was a doctor who had a specific diabetic club, i.e not a club which is called diabetic clinic. Any patients poorly controlled, ah, because of the number of patients see every day, doctors don’t have lot of time for it and investigations. If the diabetes is poorly controlled it needs a lot of time and they used to send this patient to this diabetic clinic.”*

M. Creating a smart insulin sheet:

A separate single sheet, with the starting dose and date, space for follow up and adjustment of insulin dose has been introduced. As one participant who developed a smart insulin sheet with the collaboration of other colleagues said,

“For example, monitoring patients. We worked out a system that if we start a patient with insulin for example a sheet, giving all information they need to know it, How to take it? When to take it? I just show them how to use it? And then to showing them the danger of hypoglycaemia, explaining to them and giving them a sheet of paper telling them what to do? ... Then giving them like a kind of pass coming to hospital on a daily basis for few days, So insulin can be titrated. We start on a minimum dose, just considered safe, then bring them back in everyday. After then every two days.”

This procedure has helped to overcome many problems, including that of the patient waiting for his or her folder in the reception etc.

A sample of smart insulin sheet added in the appendix -J.

12.2 ANALYSIS OF THE TEN INDIVIDUAL INTERVIEWS:

Individual interviews were conducted after completion of data gathering from the five focus group discussions. All the participants were asked to describe the barriers to the initiation of insulin therapy in their CHC, followed by discussing barriers found in all the community health centres in the Western Cape Metropole, South Africa. Some of the issues, which arose in the focus group discussion, were not explicit enough to be understood or were not well enough supported to follow through the discussion. For example, the question “Would you comment on doctors’ knowledge, skill and training with regard to initiation of insulin therapy ?” arose, because it became evident in the focus group discussion that there was much variation in the both knowledge and training. Thus, further exploration of these topics was necessary.

The most commonly asked questions were followed by a semi-structured in-depth individual interview guide line. Which is included in the Appendix F.

All the participants, with the exception of one, experienced barriers in initiating insulin therapy. I will discuss one particular participant’s experiences and feelings in conjunction with an analysis of the individual interviews. The major themes identified were the same as in the focus group discussion, i.e. mainly doctors’ barriers, patients’ barriers as perceived by doctors, primary health care (so-called day hospital, now known named as a CHC) system barriers, and also overcoming these barriers. The sub-themes that emerged were attitudes, fears, awareness, knowledge, perceptions, support systems on the initiation of insulin use for patients with poorly controlled type 2 diabetes with a maximum dose oral therapy in public sector primary health care centres.

12.2.1: DOCTORS' BARRIERS:

A. Perceptions of doctors on initiation of insulin:

i) Insulin is not beneficial in obese patients with diabetes:

This was the major barrier to the initiation of insulin in such patients.

As one participant said, *"When they have too much fat in their body, they develop insulin resistance. Then you have a problem in treating the patient with insulin."* Another participant said, *"Very obese patient...,it usually dangerous and would not make a difference"*

ii) Patients are not compliant enough:

Many participants felt that lack of compliance with drug and non-drug management of diabetes is a common problem and that this makes them reluctant to initiate insulin therapy. This was suggested by one participant's view. *"I think there is not any point putting them on insulin if they're eating whatever they like or not having their pills"*

Another participant expressed his perception as follows, *"I think my number one barrier here is that we are very aware of non-compliance of our patients...to a certain extent that we're hesitant to starting insulin because...the frustration of knowing that the patients have not done any...have not done maximally, optimally, before we start insulin We have not done our jobs properly almost before that..."*

Yet another participant thinks that the initiation of insulin is a major decision.

"The glucose level is high, but she's on maximum oral therapy but... em... the diet might still make... so is not complying with her diet as she should be, switching somebody to insulin is a big step...em...because if she's not compliant on her oral medication, my feeling it is dangerous to give her now an injection, you know for her to now start using injections,"

iii) Insulin can kill the patient:

There appeared to be a perception that insulin could kill a patient, as one participant remarked, *“I used to be under the impression that one could kill patients by giving insulin.”*

iv) Difficulty in assessing patient compliance:

Many participants felt that it was difficult to assess patient compliance because patients might not tell the truth. One participant specifically had a problem in this regard,

“Been uncontrolled and she’s been on maximum therapy for a long time, it’s difficult to make an assessment, that’s my personal problem, whether this patient is 100% compliant or not, if there’s... em... you know, if she’s been taking her treatment like she should have, like if she’s compliant to her diet like she should have. I find that a very difficult thing, a lot of patients will tell you that they are eating right and you know...”

Another participant said, *“Compliance in our community is so poor. It is often hard to know if the patient is actually taking the medication, if the uncontrolled diabetes is due to incorrect medication or incorrect taking of medication by the patient.”*

One participant also found it very difficult to assess and then to decide to initiate insulin on the basis of the result of one blood test because, the participant perception is that, *“it’s not a simple question of the patient is on high, top dose of hypoglycaemics, the sugar’s not controlled because of one finger prick blood sugar, the whole process of going into why is it uncontrolled, is there any diet problems, is there compliance problems, is it only a once off thing, a week or two weeks, is there something going on or has it been going on for two three months that the blood sugar is high, high, high, high, and I think that makes it difficult, the record keeping..”*

v) Patients are unreliable:

Many participants felt that they can't rely on some patients to give insulin appropriately or correctly. One participant felt that *"the person is unreliable in regards to injections, injection technique, you can't send insulin home when you know he is not injecting it regularly"*

Other participant said, *"When you're sitting in consultation with a patient you often picked up the fact that the patient is not going to be reliable... a reliable type of patient to start on insulin, and that is also a factor when you're starting a patient."*

vi) Nothing works if patients are not educated:

Many participants think that education level can have an effect, as one participant said, *"In private practice..., those patients are educated and here our patients are not educated, even if the stuff is available, it doesn't make a difference."*

vii) The patient needs to understand the instructions given:

One participant was worried that *"Patient might not understand the instruction properly"*

viii) Patients need to be intelligent:

Many participants felt that to use insulin at home the patients' needed to be intelligent. As one participant said, *"Those patients can read in the first place and are intellectually advanced enough to follow the instructions."* and while another participant thinks that patients needed, *"Intelligence enough to adjust the dose [on their own]."*

ix) Insulin cannot reverse the complications:

A participant felt that insulin was not beneficial because, *“When they come here for treatment, they have already complications, so whether you are going to reverse... which is not obviously possible by starting insulin.”*

x) “Diabetes is an invisible disease”:

For this reason many doctors found it difficult to convince their patients that insulin was an important part of treatment for patients with poorly controlled type 2 diabetes.

xi) Possibility of losing patients’ trust:

One participant said, *“They don’t want the injection, let me see another month, they go to the another doctor.”*

xii) Patients must be kept overnight when initiated on insulin:

One participant still had a perception that patients needed to be admitted to hospital for initiation of insulin, as it had been done about 10 or more years ago. *“The day hospital, the kind of system, we don’t have the facilities to keep the patient overnight, you know we don’t have the facility to monitor them.”*

Others participant had the similar concern and said that,

“Setting is not good.”

“It’s too dangerous to do it, we won’t do it, in ...this setting, it won’t work.”

xiii) Patients might not cope:

One participant believed that *“the patient may not be able to cope on their own by giving themselves insulin.”*

xiv) Diabetes is a difficult disease:

Doctors think that diabetes is a difficult disease for patients to understand. *“Diabetes is a difficult disease to understand, it took me six months to understand at medical school...um... it takes a long time for the patients to know what it is all about, all they know is that their sugar must not be high.”*

B. Fears:

Doctors expressed many fears with regard to the initiation of insulin.

i) Fear related to lack of knowledge:

“Insulin to me appeared to be a no go way because it used to frighten me, because I had no idea on how to dose, to give the dosage for the patient”.

Another participant thought that fear of inexperience is another factor which acted as a barrier:

“Perhaps the doctor doesn’t feel comfortable about starting patients on insulin therapy, maybe the doctor’s cautious ...,someone who doesn’t know.”

ii) Fear of hypoglycaemia:

Participants are reluctant to initiate treatment with insulin fearing that they may induce hypoglycaemia in their patients. As one participant said, *“I mean, they may have hypo in the middle of the night, you cannot know of that...”*

C. Attitudes of the doctors:

i) Doctors not wanting to take responsibility:

One participant who didn't want to take responsibility said, *"I did in the hospital in the houseman ship. As houseman we would institute diabetic treatment with tablets and diet, then it would remain on the registrar, It was either him or the consultant that now decided this patient must go on insulin."*

ii) Shifting the responsibility:

One participant didn't have the confidence to initiate insulin in the primary care setting and explained, *" To me it means it's a confidence problem, not all doctors have the confidence to make the decision themselves and they want a specialist of somebody more senior to make that decision for them"*

iii) Accustomed to easier options:

To continue with oral medication is much easier than initiation of insulin, as one participant said, *"it is much easier to write up the orals... short-cut just to keep them on oral."*

iv) Using insulin as a threat:

Patients are scared of doctors because doctors use insulin as a threat. As one participant said, *"That's when they say, no doctor, let us see another month, so that's why some patients didn't come to me because I've already warned about the injections that is what... and then they're scared of the doctor."*

v) Doctors need a consultant to initiate insulin:

One participant felt that initiation of insulin in the absence of a consultant is not feasible. One participant who worked with many hospitals with the support of a consultant, said, *“Wherever we worked before the consultant know it, this is the only place we don’t know who our consultant are.”*

vi) Doctors disliking insulin:

As one participant said, *“Many doctors very freely say they don’t like insulin.”*

D. Lack of knowledge, training and skill:

Although most of them professed that they are knowledgeable on the initiation of insulin, half of the participants confessed that they needed knowledge on insulin and diabetes to use it in the primary care setting. Many participants, while acknowledging their own lack of knowledge, had a tendency to generalise this to refer to other colleagues as well. As one participant said, *“One needs knowledge to be able to make use of insulin. We can institute insulin treatment at primary health care level.”*

i) Lack of knowledge on use of insulin:

One participant claimed that he does have the necessary knowledge now, but added that, *“I had no idea how to dose, to give dosage for the patient. I never realised that insulin is a very useful drug when tablets are not helping..., as a result I used to refer them to hospital, until I spoke to professor.”*

The procedure for initiating insulin differs from one doctor to another. One participant said, *“How do you start insulin... em... I for instance am not sure of how to do it, and I’ve heard a lot of protocols, people say well you start them on something like 2 mg per kg, I’m not sure, 2 units per kilogram or whatever, at nighttime with the maximum dose, other people say you stop the maximum dose, you half the maximum dose, so that sort of thing differs a lot and it is difficult to get a clear cut opinion.”*

The same participant also mentioned, *“There’s no protocol for when to change people over, so the knowledge around this isn’t set somewhere on a piece of paper in the Elsies River Day Hospital that says: if you have got a diabetic that has sugars over this and this or long term sugar of this, then change him over to insulin.”*

ii) Not keeping up to date with changes and new developments:

Many participants admitted inconsistencies on numerous issues relating to initiation of insulin. When participants were asked about the use of the guidelines, it was found they were unfamiliar with the national guidelines.

“I don’t know if there are any?”

“I myself have not gone to search for those guidelines”

While another participant felt that, *“The problem with the guidelines is that people tend to interpret what is written and get a different understanding to what is said in the paper”*

One participant felt they needed support from the academics to update their skills and knowledge:

“The skills I think we also need to be updated on a regular basis, we’re not getting any support from different people like Groote Schuur or from the professors, educators, new ideas on diabetes, new ideas on control.”

E. Lack of experience:

Lack of experience with regard to the initiation of insulin in the primary care setting was a major concern. One participant said, *“I think we don’t have a lot of experiences on starting the insulin therapy, that is definitely a problem, gaining experience...”*

The same participant indirectly confessed that he lacked experience and manifested it by mentioning, *“I think they experience the same problems as I experienced... em... we found that the younger doctors tend not to initiate insulin, ... they have little experience of insulin, how it’s working and how to initiate it and how to calculate the imbalance and so on.”*

Other participants said,

“I think initially I was reluctant because I didn’t have the experience, and I asked around and we started doing it. Because you’re only, as you do it you get the experience and it becomes easier”.

“I think, lack of experience ..., You know, if you haven’t done it, you sort of worry about it.”

“I think we don’t have a lot of experiences starting off the insulin therapy, it is definitely a problem, gaining experience...”

F. Lack of confidence:

One participant who worked in both private and government hospitals didn’t initiate insulin and said, *“Well that was the main problem [confidence]. Also when I was in private practice I never even used to keep insulin in my office; I kept tablets for diabetes.”*

G. Lack of support and uniformity among doctors with regard to initiation of insulin:

All the CHCs are situated outside the university hospital campus. They have at least two doctors in the centres and several nurses to run the services. The participants expressed lack of team efforts, uniformity and support on the initiation of insulin.

"I think we are a team but not about insulin."

"I think there needs to be a little bit more uniformity amongst the doctors with regards to starting it[insulin]."

"Many doctors very freely say they don't like insulin."

One junior participant said, *"I haven't seen any juniors to initiate insulin here."*

Some doctors want to initiate insulin in the primary health care centre, but they don't have on-the-spot support to help with training and building confidence. A participant said, *"There's not always somebody to ask, there's no protocol, so the easiest thing is to just send them to hospital.... and let them make the decision for you."*

H. Language barrier:

Language also served as a deterrent to initiating insulin.

One participant said, *"Maybe even more so in your local., black communities where there is not., especially if there is no doctors that speak their language."*

Another participant agreed, *"Definitely, because it's a frustrating thing for the doctor who is not able to speak to his patient, in his preferred language, to try and say all the things that we say to a diabetic patient..."*

Apparently, even the pharmacist does not speak his patients' language and couldn't be relied on to educate the patient: *"The pharmacist is not the right person to explain to the patient, because the pharmacist doesn't speak the patient language."*

Even those who have a little understanding of the indigenous language, experienced problem and a participant, who has some knowledge of the local language said, *"I also struggle with the language barriers, so I don't understand my patients as well I might want to, or they might not understand me."*

Drs can also not rely on interpreters, as one participant said,

"With the little Xhosa I do understand, I often know that the interpreter is not telling me what the patient is saying and that lets me down and it is frustrating"

Participants expressed concern about the consequence of not communicating adequately with the patients. As one participant said, *"Medicine is a technical language, and one needs to explain to the patient in their own language the consequences of making mistakes in giving themselves doses of insulin."*

12.2.2 PATIENTS' BARRIERS AS PERCEIVED BY DOCTORS:

Most of the participants had experienced barriers from patient in initiating insulin therapy. Most participants found patients are not willing to initiate insulin and the following are the sub themes of the patients' barriers as perceived by doctors:

A. Patients' misconceptions and beliefs:

Insulin seen as a death sentence and one participant said, *"They had an uncle who went onto insulin and he died three months later, and so they didn't sort of think of that as part of their disease process that's what the insulin is part of..."*

B. Patient attitudes:

i) Resistance due to ignorance of benefit:

Participant expressed patient resistance to the use of insulin to be due to ignorance. As one participant said, *"They are resistant to insulin maybe because they are not aware of the benefits and also the thought of having to inject themselves"*

ii) Dishonesty about complying with diet:

Participants felt that patients were not honest enough in their efforts with diet control and maximum dose of oral agents. This lack of honesty makes doctors hesitant to initiate insulin.

As one participant said, *"It is a very complicated situation where you have some patients who are honest and some patients who are manipulative in line, and very often it's hard to tell the difference between them. And often I'm finding with my patients that my responses are often more guarded, because I'm not actually not sure who is being honest with me, and who is not."*

iii) Patients accustomed to tablets:

As one participant said, *"They used to be free of injection."* and *"They get used to the tablet so much."*

iv) Negligent about return visit:

Many patients do not come back after initiation of insulin. One participant said, *"But it obviously affect you in a way that you think, well if this one's not serious about it, the next one won't be either, so it makes you more reluctant to start it, it will make you more reluctant to start it in another patient"*. It makes it difficult for doctors to make future decisions.

C. Lack of knowledge in patients:

As participants perceived patients lack of knowledge to be an issue, *"I think patients are also afraid because of lack of knowledge, I would be and you would be if you didn't know what you were. And because we don't have the staff here to get them through a period where we teach them exactly why it is and why we're doing it and what its doing to their body, that lack of knowledge must be very confusing, .must be putting patients in a very doubt...creating doubt in their mind about what they've been using and why they use it, I think basically the feeling the frustration of not knowing"*.

D. Fear:

Patients fear, particularly fear of needles was perceived as a barrier. One participant said, *"Phobia to needles"*. Another participant said, *"I have had a patient who burst into tears a couple of times after I said that they should go onto insulin."*

E. Lack of education:

Most of the participants felt that the level of education of the patient has a role in the proper control of diabetes in poorly controlled type 2 diabetes mellitus with insulin.

“They can't read or write, and even when you show them the syringe[for the measurement of dose], they don't want to even look at that.”

One participant said, *“Most of them don't have post matric, further experience, never studied anything else... so, as far as education is concerned it's a bit low, lack there”*

F. Patients socioeconomic condition:

Many participants found that their patients' poor socio-economic conditions acted as a barrier to initiating insulin therapy, for example:

i) Lack of transport:

The affordability and availability of transport to patients is important, particularly when frequent monitoring of their blood sugar is required. Participants mentioned,

“You started to think I've started this person on insulin..., I want to see them, you know after a few days ..., quite more often, and it's a problem if they have a problem getting here.”

“They don't always have transport to get to the hospital if they should need to because of a hypo or complication of the therapy...they don't always have a telephone in the house so they can phone and get help....”

“I think it depends where you work, here we have people who got transport, if we put them onto insulin, we can get them back, you know to check. I would think that some of the township areas, that must be quite difficult”.

If the family of the patients are poorly motivated, they may not provide transport. Participants felt that the family needs to be motivated before initiating insulin therapy, so they can assist the patient by giving support, such as, providing transport to attend the CHC. Participants said,

"I think it is a problem if you got a fairly educated person in a poorly motivated family, who can't get easily to the hospital then you're going to have problems putting them on to insulin."

"You started to think I've started this person on insulin ..., I want to see them, you know after a few days..., quite more often, and it's a problem if they have a problem getting here."

ii) Lack of access to a telephone:

A telephone is necessary to contact the family or hospital for help or to get access to the available resources. One participant said, *"They don't always have a telephone in the house so they can phone and get help...."*

iii) Lack of money to buy a glucometer:

As one participant said, *"Then if you do start insulin, the follow-up...especially at home is the problem because patients can't afford a glucometer, so initially, they might not be able to get to the hospital immediately.... The monitoring of the patient is difficult."*

Another participant said, *"They don't have the machines where they can use to monitor themselves, you don't have a very good picture of what is really happening..."*

iv) Overcrowded conditions can cause needle stick injuries in children:

One participant felt there is a chance of accidental needle stick injury in children, because

"Often the patient lives in a household where there is overcrowding, they can't live in a household where kids....and sharing it with three or four other people, and there is needles lying around, there is just not that structure."

G. Problems associated with initiation of insulin in the elderly patients:

Elderly patients in themselves do not constitute barriers. But conditions unique to them were perceived as barriers by the doctors.

i) Poor visual acuity in elderly patients:

Poor vision is perceived as a barrier to initiation of insulin in the elderly. Participants said,

“The other thing about the barriers with the patient is they often don’t see well, so they can’t do it themselves...”

“And a lot of them are elderly as well, so they have to...they find it difficult to maneuver it and applying needles.”

“Some of them have poor eyesight as the reason not to use it, there is a question... they tend to be alone, so it is very difficult for them, and they also have to use insulin.”

ii) Elderly patients do not understand:

“I think don’t understand very well why they now should start to inject themselves, there’s usually no..., not somebody that can help them with it at home, so it is a problem. I am very reluctant to start insulin in an elderly patients because of those reason ...and what will happen when they do start using it.”

iii) The elderly patient needs an escort regularly:

It seems that older patients needed more support to initiate insulin therapy, As one participant said, *“first of all you need a family member if you do start insulin in the elderly patients they need to be educated about the risk of hypo... hypo.. .em... and then they...usually you have to bring them in regularly.”*

12.3 SYSTEM BARRIERS:

Numerous barriers with the CHC system were mentioned by the participants.

A. Lack of resources:

One participant said that there were so many patients with poorly controlled diabetes that it would be difficult for a system to run effectively without adequate resources. As one participant said, *“I promise you, out of 50 I saw yesterday at least 25 had a level over 12 and you can’t start [insulin] on all of them, all of them have maximum so far, brought to a point where they are on a higher dosage of oral medicine. There’s influx, where you cannot start everyone on insulin it just not going to work out for our pharmacy, it’s not going to work out sending all patients through to the injection room, to use the glucose services, lots of things...”*

i) Lack of human resources:

This affects every aspect of initiation of insulin for the patients with poorly controlled type 2 diabetes.

a) Low remuneration of doctors:

Doctors were under paid and therefore not motivated to spend time to educate patients. As one participant explained, *“Doctors and all the staff I would say are underpaid and overworked. The patient load is too high, there is little time to educate patients.”*

b) Doctor –patient ratio:

Another participant agreed adding, *“Yes you got to have that support. There are too many patients and too little doctors, too little medical and health care workers, to see to all the needs.”*

c) Patients are seen infrequently:

Failure to accommodate all patients leads to many being seen less frequently than necessary. As one participant said *“We see diabetics on a bi-monthly basis, sometimes it is only once in every 3 months. This is not good enough for a patient on insulin. I feel you need to see a patient on a monthly basis. In fact I think it is dangerous to send them home, when we can’t see them frequently enough, so a good support would be seeing them more frequently, but that’s not possible with diabetics, because there are simply too many patients.”*

Another participant said, *“You can’t accept patient for the next four month.... There are just too many of them .”*

ii) Lack of financial resources:

Lack of finance makes it difficult to obtain the necessary things, which would help in the process of initiation of insulin therapy.

a) Lack of enough blood glucose monitoring equipment:

There is no fund to buy home glucometers for patient or to do the home glucose monitoring. As one participant said, *“There’s not enough money to do regular blood tests or to give the patients home glucometers .”*

Failure to replace the faulty glucometers is a major problem. One participant said that when he and his colleagues checked the quality of instruments they found,

“The reading, one was 20 on the one and on another it was 13, this is a discrepancy of 7. So our immediate needs are[that instruments must be] to be calibrated, [The instruments] need to be replaced even. Let’s say on a yearly or bi-yearly basis or whatever the case may be, I don’t know how old those meters are.”

b) Restrictions on ordering important tests: Restrictions have been placed on ordering many important tests. Due to lack of funds the test to assess the long term sugar control as glycosylated haemoglobin can't be done. As one participant said,

"I mean you can do these other blood tests, you know these glycosylated haemoglobins, which we actually aren't allowed to do in a day hospital setting."

c) Erratic supply of insulin:

Pharmacies are under-stocked and frequently runs out of insulin. As one participants said,

"If there is stock at the pharmacy their adequate supply but sometimes the pharmacy is also under stocked"

"First of all I need to say that we once had three days at our day hospital where we didn't have insulin and though I prescribed it on that first day I think they only got it four days later..."

"The last time this happened we were without insulin for a week."

Some times various kinds of insulin are not available.

"We only have one type of insulin, we have the bi-daily diabetic insulin therapy, Actraphane? sometimes I give protophane but our pharmacy never stocks that ."

Pen sets which are more convenient for patients to use are not available, as one participant said,
"It would be easy if the pen sets are there but I don't have one here"

The lack of insulin supplies places added burden on the patients, who then prefers tablets, which are more readily available.

"It does affect the patients negatively, because, now it means that they have to come here again, go through the same circular system, waking up early morning, coming to wait here for one vial of insulin. It's quite frustrating, why would a patient continue with insulin if it's such a problem.

So then they switch over to the tablets [because] it is easier."

B. Lack of time:

Lack of time is directly related with lack of resources. Adequate time to educate patients on the use of insulin is necessary but not available. One participant said, *“There is a lack of time to start, you know, if you have got to initiate insulin you must have time to educate the patient and sometimes we are very short staffed, that’s one thing [problem].”*

Another participant explained *“I think there could be a problem in initiating insulin and then telling patients to go home and give themselves insulin. The patient actually need quite a lot of time to be shown [how to go about it] and to be made to understand the dangers. Because when you give a patient insulin you must also explain to them the danger of giving too much ..., you have to explain to them what symptoms and signs they will have when they are getting hypoglycaemic and what to do when they are having those signs and symptoms.”*

Only one participant, who works in a small CHC said, she didn’t experience any barriers and she felt that the doctors themselves are not making time to educate patients about insulin. She also felt that the time could be available to patients, but that as long as doctors perceived themselves not to have time, they wouldn’t prescribe insulin, *“you must make time to educate the patient.”* She had serious concerns about this *“I can’t see how they actually say that they don’t have time, that there is no time to educate the patient, because when you prescribe insulin you must be [through]. I see what you mean they [the doctors] are not even going to prescribe it because they feel there is not enough time?”*

C. Poor record keeping

Participants found that the records get lost and that this acts as a barrier to initiating insulin. As one participant said, *“A lot of time you don’t have a record of what the blood sugars have been like and what the compliance has been like and how they [the patients and doctors] are keeping this change and so on. A lot of times old records gets lost and, so you just get a snap picture of somebody with a once off high blood sugar.”*

Poor administration has been blamed for the loss of the records.

“The fact that there are administrative management problems and the records get lost.”

D. Lack of shared responsibility:

Many participants felt there is a need for shared responsibility to initiate insulin in public sector primary health care setting. For example,

i) Keeping patient for next doctor to initiate insulin:

Since the CHC is very busy and no shared support exists amongst doctors with the initiation of insulin, many times patients have been left repeatedly for insulin to be initiated at a subsequent visit because,

“again you have to think well, the patient needs to go onto insulin, I still need to get one of the sisters to talk to her, to show her how to do it, to educate her and so on, and on the days that I am very busy I think I’ll leave it till next time because here’s nobody to do that, which is not ideal but that’s what is happening in practice.”

ii) Predominance of individual responsibility:

The practice didn't recognise a group responsibility, as one participant said, *"It is very individual, every doctor does a bit of his own thing; his own way of initiating insulin, how he brings a patient back, the next day and then every two days after that; arriving at different times of the day to have their sugar tested and then discussing the problems that they have with giving themselves the injections, or the injections it self."*

E. Poorly functioning diabetic club:

i) Lack of education in the club:

"Well, you see our club doesn't really function as a sort of a club where they [the patients] get together. Our club basically just means that we see our diabetics on a certain day, that the doctors see, so many patients, they don't gather in a clubroom where they get education and things like that..."

ii) Lack of frequent club day:

Diabetic club don't operate frequent enough to provide adequate care. If a patient comes on the non-club day, it makes it difficult for the patient on insulin to follow up, because *"They [the doctors] may not have as much time, as they would if it were diabetic clinic day."*

iii) Insulin is not discussed in the club:

In the club they don't talk about insulin. As one participant said, *"At the diabetic club, once every three months where the sister generally tells them about diabetics...diabetes in general, not specifically insulin."*

F. Lack of information sheet on initiation of insulin:

“We’ve got little sheets which we give to those who have just started insulin, giving them a little bit of the symptomatology that they must watch out for, [but it is inadequate]. We don’t have a structured sheet that we give them and say this is what you should know, this what’s important We don’t have that at the moment”.

G. Lack of continuity:

Seeing the same doctor and having repeated consultations with the same doctor is known as continuity of care. Continuity of care helps in building the doctor- patients relationship and improves the relationship. A sound doctor patient relationship paves the way for better co-operation and compliance. It helps in establishing the patient’s belief in insulin and helps in resolving the patient fears. Many participants found problems in maintaining continuity during the treatment of patient and this acts as a barrier to initiate insulin, such as;

i)No doctor remains in the same Post works for long:

No doctors work permanently in theCHC. *“But the way health services are structured in a day hospital system there are a lot of doctors coming and going in all of the time, so there is a big turnover of doctors. There are also lot of junior doctors whot come in, as community service doctors[for a short while].”* explained one participant.

ii) “You don’t see your own patient”:

Lack of continuity, not only causes difficulties when initiating insulin, but it makes it difficult to do follow ups on the patients after the initiation of insulin.

“You don’t see your own patient in the day hospital, some time you’re not there the following day”. This makes it difficult for another doctor to initiate insulin due to all the factors which disrupt the programme, " You might change the treatment of them over today, but you’re not there the next day. So when the patient comes back says the doctor asked me to come back to check my sugar again, the next doctor says, the sugar is OK, go home, without going into what is actually happening and so on”

H. Lack of discipline:

Due to the heavy patients load, lack of resources and problems in the organisation it was difficult to enforce a particular procedure even when if it was necessary. As one participant said, *“We don’t have the resources and discipline and time to do it all, we have too many people on insulin, who come around on that particular day[club day]. It is very difficult because we have problems at the hospital.”*

I. Lack of sound clinical guidelines:

Many participants described a lack of clear and sound protocol on initiation of insulin in the public sector primary health care centres. *“We need to receive sound clinical guidelines and I think we really need to come to an understanding of these guidelines, if the glucose is so much in a patient of certain age, we need those type of guidelines...”*

12.4 PARTICIPANTS SUGGESTIONS FOR OVERCOMING THE BARRIERS:

A. Having one on one time:

One participant placed emphasis on educating patients on one on one basis. As he said, *“So if you’ve got like places[there are centers], we have a lot of patients with diabetes, then we have to try and find time. I suppose we could do it in groups. But, I still feel that if you’re putting somebody onto insulin they often need a little bit of one on one time, to make sure that they know how to use the injections and so on.”*

B. Providing good continuity of care:

One participant summed up the general feeling:

“If you see your patients regularly and you get to tell them about the benefits of having better sugar control then they begin to see that it’s needed. You help them to cope with this reaction to insulin and prepare them for family reaction on insulin, all those, all that as far as education you know, and then a lot of the barriers disappear.”

C. Overcoming fears with growing experience:

A participant said, *“ I think first of all you’ve got to decide, that if there is a patient who is not partially controlled, they need insulin and whatever fears , for the best interest of the patient they need to go onto insulin. And if you don’t know how to do it, you need to ask somebody else how to do it and get on with it. The more you do it the easier it will become because the more experiences you will have.”*

D. Developing a proper diabetic club:

i) Educating and preparing patient to initiate insulin therapy in the diabetic club:

One participant explained, *“The right moment to prepare the patient is when we send him to the injection room, and they [nurses] show the patients [he is shown how to inject himself]. We need somebody to explain to the patient what insulin is and its symptoms of having had too much insulin and what the patients should do afterwards and also often we would do ourselves. We take them through the symptoms that they will feel for example, if their sugar gets low as a result of insulin. We tell them that have something to eat sweet and then to go to the hospital.”*

ii) Offering group education on diabetes and the use of insulin in diabetes:

As one participant said, *“All the diabetics are there together, so the sisters and whom ever else can get information across in a better way must give health education each and every time they see the diabetic. That includes the compliance on diet as well as specifically with the insulin. Also we give instruction on how to give the injections. We tell them about the symptoms of hypoglycaemia, where to keep the insulin, etc.”*

iii) Involving the patient in the club:

“Ideally people who are on injections, should show the other patients how they do inject themselves here [in this CHC] so that the nurses can check if it’s done correctly.”

iv) Developing a diabetic clinic within the diabetic club:

As one participant said, *“We have thought of possibly bringing some of the poorly controlled diabetics back on some afternoons when we possibly have a bit more time, and speaking to them in groups and things, but we haven’t actually started that.”*

E. Involving, training and providing trained nursing staff:

Involvement of nurses and improving the collaboration with the sister is necessary: As one participant said, *"We also need to look into nurses collaboration with doctors, or perhaps they could be sitting together or discussing this that it needs to be, obviously updated one."*

One participant said they needed a trained sister knowledgeable about diabetes who could act as an interpreter: *"With an able diabetic sister or some such other person, one should be able to get across that barrier. At least an interpreter, who understands something about insulin and something about diabetes would be a help."*

F. Support from administrators to train and provide diabetic sisters:

"I personally think that the central agency, like Woodstock, or city of Tygerberg should be arranging diabetic- trained sisters who can go to the centre to retrain or perhaps be allocated on the specific days to the specific diabetic club"

G. Creating a smart insulin sheet:

A participant from the busiest and largest CHC providing with a 24 hours trauma and emergency service unit said, *"We have developed a spreadsheet for the patients which we issue to them and we sort of put them on a sliding scale, they just come here at 8 o'clock so they don't wait in queues and we adjust the random blood sugar test on them and adjust their insulin, that's it. And then of course we write them on the page itself, it's quite informative. It will tell a patient when not to take insulin, that he/she has to have a meal, what the danger sign and so on."*

She does the follow up herself, *"The way I do it is...to let them come back the next day and the day after, so two days afterwards."*

(A sample of insulin sheet has attached in the Appendix-J)

H. Overcoming the follow up problem:

i) Taking the responsibility in groups:

One participant in a small community health center said, *"We take responsibility for the Patients' that we start on insulin, and we might sometimes follow each others' Patients up."*

Another participant said, *"If I'm not here, they get seen by another doctor, so we do a basic check, we ask them if they are coping with it, check their blood sugar and ask them for symptoms, hypoglycemic symptoms mainly to see if there are any problems like that. Then we follow them up in two weeks, then monthly, and so on, once you know they managing on their own."*

Patients can also be followed up in triage, *"Follow-up is done by our triage doctor who sees the patient then on that morning that we ask the patient to come back for monitoring, he checks his glucose levels, and makes the dosage adjustment if it is required."*

I. Developing a self learning attitude:

Doctor should take the responsibility for their education. A self learning attitude explained by one participant, *"We have a physician who comes here once a month, and I ask him, and I ask other people, and then we've been working together to do it[Put into practice]."*

J. Developing of community awareness:

i) Involvement of the media consider with regard to insulin therapy and diabetes:

Development of awareness in the community is important as the community is also resistant to insulin as they are not familiar with insulin. Promoting awareness in the community would be beneficial,

“More information needs to be available to guardians, to family members and also the younger people, to be aware of insulin, someone to educate, for example, someone writing in the local newspaper what is insulin, why it is used, that would also be a benefit, I would like those things to be done.” explained a participant.

ii) Organising a community open program on diabetes:

The same participant also said, *“We can often have large groups of people getting together in our civic centers, in halls in Mitchell’s Plain for example; for people who are interested in diabetes, and or for people who have it.”*

K. Providing on the spot support:

Many participants felt that on site support is necessary to overcome the barriers to initiating insulin. *“I think they [patients] should have people available so that they can ask them questions if you are suddenly going to give them insulin, especially if they haven’t had insulin before,[they need a telephone number can of care workers] whom they actually possibly phone”*

L. Providing a proper support structure for the patient:

i) Good district nursing service:

For the elderly person the requirements are *“Better district nursing service, and home visits by the nurses and to see how people are managing with the injections at home...em...and then they can demonstrate where to inject themselves, how they inject themselves and so on..”* as one participant put it.

ii) Help from the Non governmental organisations:

Someone mentioned, *“The diabetic association, I don’t know how many of our patients actually belong to the association or actually contacted them...or had any contact with them, I’m not sure how much they support family members with information on the initiation of insulin.”*

iii) Special health card:

“It would help if the patient had a health card which they would carry around with them, you know or even their own booklet where they would note down what their sugars are and were. It will also help them to keep track of how well controlled they are, also if they would have machines...” as one participant put it.

M. Providing literature:

“If we had reading material for our patients, that would be nice.”

N: Supplying proper instruments:

As one participant said, *“We need better, more reliable monitoring of the glucose levels, at this moment right now. In my experience this is very important, having found out about discrepancies [in the past due to lack of such instrument].”*

O. Developing a uniform manual on the use of insulin:

Many participants felt that development of a manual on the use of insulin is necessary, as one participant said, *“I think that would be a way out, to develop some kind of manual, in which the management of insulin, the side effects, what you expect to do, what not to do, when you get*

hypoglycaemic episodes, things like that... in appropriate languages, and then you give it to the patient when you give the insulin, I think that would help. A patient can go with that administers the insulin and then monitor it him or herself, you know. .. at home , you know then come back, perhaps to see the doctor, to check the sugar again, and they can tritate the dose, you know."

P. Developing an institutional protocol:

Lack of resource- based institutional protocol was evident in the all CHCs. One participant summarised the whole issue of the development of protocol.

"The patients go from one doctor to the other and get different treatments. This is a big problem in day hospital settings. This problem can be addressed by getting an evidence based protocol, what are the prerequisites, and when a patient should be started over, how should start them over, and what kind of safety net can we [create] , what are the resources that will allow us ...um...to follow these patients up correctly? And once that's on a piece of paper I think it makes it a lot easier for people to do that"

So the protocol makes the decision easier. Participants felt protocol should address the important and specific issues, such as:

"We need to have a protocol where it says that once I've changed it over[to insulin] the next day the patient comes to the centre...it doesn't have to be the same doctor, he can come to the diabetic sister or whatever, whoever, he can get his blood sugar checked out, he is asked about problems with injections, asked about hypoglycaemic symptoms or whatever and once that's on paper, and every doctor has that...it doesn't really have to be the same doctor, but specific things need to be addressed when the patient comes back."

13. FIELD NOTES:

Some of the findings of the focus group discussion and in-depth interviews were supported by the comment and remarks I had received from the medical officers, who were not willing to come in focus group discussion or to take part in in-depth individual interviews. These discussions produced the following:

i) Denial:

One day I was visiting one of the CHCs to invite the doctors, but on the way I met the chief medical officer of that community health centre, When I explained to him about my research, he said, *“Who are you researching for? What are you researching for? We are fine, we don't have any problem.”* So this chief medical officer was not in favour of the research. He could see no need for this study, doctors working in the area he served, didn't have a problem initiating insulin therapy when necessary. So the senior are in denial in existence of the problems of initiation of insulin public sector CHC.

ii) Insulin can not reverse the complication:

One day, I was distributing the invitation letter amongst doctor to take part in this research, then one medical officer personally offered me the following comment, *“Dr, What ever you do for the patients with diabetes, they are going to get complications and insulin is not going to prevent it.”*

So this doctor is not aware of the benefit of use of insulin for good glycaemic control in a poorly controlled patients with type 2 diabetes.

iii) Lack of Time:

I made an appointment with a doctor in-charge of a CHC to invite him and his colleagues to take part in this research. But that doctor in-charge mentioned, *“You have time to do research on insulin, probably you have lot of doctors in your CHC, but we don’t even have time to see the all the patients comes here in our day hospital. We don’t have time to do the research.”* Here again time was a major factor.

iv) Fear of hypoglycaemia:

Fear inducing hypoglycaemia by treating patients with insulin was clearly expressed. As one medical officer commented during the visit of his CHCs,

“We need to start to use insulin in primary health care centre, main worry is hypoglycaemic attack, organising the medic alert forms to get the bracelet to have the information of the treatment of the hypoglycaemic attack, can help to prevent the death from hypoglycaemia.”

v) System barrier:

One medical officer told me, *“I am fade up of not having the previous information on the patient sugar control, as their folder get lost or the receptionist could not trace the folder. They [receptionist] give new folder, So I don’t get all the information I need to start insulin for that patient.”* So this lack of information due to folder lost is a system barrier to initiate insulin.

vi) Fear of patients has lack of education:

One medical officer told me, *“Patients are illiterate, they won’t be able to use the insulin.”*

He feels patients need to be educated to use insulin.

vii) Patients attitude and lack of understanding:

One of the medical officers didn't see any point in treating patients with insulin, because he perceived them to have minimal understanding of the disease and less concerned on control of diabetes.

"Patients here don't look after themselves, whatever you do they are not going to listen to you they won't take the insulin, they will eating all these chocolate, biscuits."

viii) Insulin used to be given in hospital:

One day I requested one of the retired doctors who works for a half day in a CHC for five years, he said, *"In my old age... I wouldn't be able to take part in your research on insulin, but we used give it in hospital, here we really don't give it."* But he sees patients with diabetes attending at that CHC.

ix) Patients are not compliant on oral medication:

One day I visited head office of this CHSO (Community Health Service Organisation). One of the senior doctors from the administration commented about the issue of use of insulin, *"Do you think? Our patients are not taking their medication, are they doing enough to control their sugar before you can initiate insulin, are they compliant enough."*

x) Doctors are not trying enough:

Same senior doctor who commented, patient's are not doing enough. She added, that doctors are not doing enough to help the patient, *"Doctors are not doing enough for the patients to control patients blood sugar."* Although this doctor doesn't see patients but they make policies on control of blood sugar of patients with diabetes in the CHCs.

14. SUMMARY OF THE ANALYSIS:

To summarise, I shall structure the sub themes of the focus group discussion and individual interviews in table format., where the most common sub-theme will appear in bold form.

Table –6 shows the sub theme of the doctors’ barriers which emerged from the both the focus group discussion and individual interviews.

Doctor’s Theme:

Table – 7: Sub themes of “Doctors Barriers”

From the focus group discussion	From the individual Interviews
<p>A) Doctors’ perceptions on initiation of Insulin:</p> <p>i)Synonymous with life long imprisonment</p> <p>ii)Using insulin in obese patients is not a good idea.</p> <p>iii)Patients are too irresponsible to be treated with insulin.</p> <p>iv)Patients lack of understanding</p> <p>v)Non compliance with oral medication</p> <p>vi)Laziness of doctors</p> <p>vii)Injection is intolerable</p> <p>viii)Patients need to be familiar with insulin to accept as a treatment.</p> <p>ix)Initiation of insulin is a specialist treatment.</p>	<p>A) Doctors' perception on initiation of Insulin:</p> <p>i)Insulin can kill patient</p> <p>ii)Insulin is not beneficial in obese patients with diabetes.</p> <p>iii)Patients are unreliable</p> <p>iv)Patients need to understand</p> <p>v)Patients are not compliant enough on oral medication</p> <p>vi)Difficulty in assessing patient compliance causing difficulties in assessment of initiation of insulin.</p> <p>vii)Nothing works if patients are not educated.</p> <p>viii)Patients needs to be intelligent</p> <p>ix)Insulin can't reverse complications.</p>

<p>B. Doctors Attitude:</p> <p>i)Unwillingness to initiate insulin</p> <p>ii)Shifting responsibility</p> <p>iii)Treating patients with insulin is not seen as priority</p> <p>iv)Doctors are coerced into complying with patient wishes.</p> <p>C. Fear</p> <p>i) Fear of hypoglycaemia</p> <p>ii)Fear of blame related to patients misconceptions</p> <p>D. Doctors' concern</p> <p>i)Lack of regular meals</p> <p>ii)Lack of facilities to store insulin.</p>	<p>x)Diabetes is an invisible disease</p> <p>xi) Chance of losing the patient trust.</p> <p>xii)Patient must be kept overnight when initiated on insulin</p> <p>xiii)Patients might not cope</p> <p>xiv)Diabetes is a difficult disease</p> <p>B. Doctors Attitude:</p> <p>i)Not wanting to take responsibility</p> <p>ii)Shifting the responsibility</p> <p>iii)Accustomed to easier Option</p> <p>iv)Using insulin as a threat</p> <p>v)Needs consultant to initiate insulin</p> <p>vi)Disliking Insulin</p> <p>C. Fear</p> <p>i)Fear of hypoglycaemia</p> <p>ii)Fear related to lack of knowledge</p> <p>iii)Fear that patients has lack knowledge</p> <p>iv)Inability to explain in an understandable language.</p> <p>D. Not applicable (N/A)</p>
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<p>E. Lack of knowledge, training and skill</p> <p>i)Gap between theory and practice of conventional teaching on diabetes.</p> <p>ii)Inadequate training at undergraduate level.</p> <p>iii)Not keeping up with changes and new development</p> <p>iv)Doctors are not aware as to what constitute ideal or accepted control</p>	<p>E. Lack of knowledge, training and skill</p> <p>i) Lack of knowledge on use of insulin</p> <p>ii)Not keeping up with changes and new development.</p> <p>iii) Lack of experience</p>
<p>F. Lack of confidence</p>	<p>F. Lack of confidence</p>
<p>G.Difficulties with regard to junior and senior medical staff.</p> <p>Difficulties in discussing concerns regarding practice pattern of seniors by juniors</p>	<p>G. Difficulties in regarding lack of support:</p> <p>Lack of support among doctors on initiation of insulin</p> <p>i)Lack of team effort</p> <p>ii)Lack of immediate support</p>
<p>H. Language barriers</p>	<p>H. Language barriers</p> <p>i) Doctors don't know patients language</p> <p>ii) No common language for communications.</p> <p>iii) Pharmacist does not speak patient language</p> <p>iv)Inability to explain in an understandable language.</p>

In summary the doctors' perceptions on the initiation of insulin therapy were that non-compliance with current therapy would translate into non-compliance with insulin therapy. Further barriers related to lack of knowledge, training and skills amongst the doctors and the problem with doctor- patient communication, due to language barriers.

Doctors fear of hypoglycaemia combined with lack of knowledge and confidence in the initiation of insulin made them inclined to shift the responsibility to tertiary hospitals. Exacerbating factors of the doctors around the perceived fear of hypoglycaemia to initiate insulin in the public sectors primary health care here shown in schematic way in appendix -L.

Table 8: Sub theme of “Patients Barriers Perceived by Doctors”

From the focus group discussion	From the individual interviews
<p>A. Patients beliefs and misconceptions relating to insulin</p> <p>i)Initiation of insulin seen as death sentence</p> <p>ii)Insulin seen as a cause of death</p> <p>iii)Insulin seen as a cause of stroke</p> <p>iv)You don't need insulin if you are stressed</p> <p>v)Insulin results in leg amputation</p> <p>vi) Insulin makes you fat.</p> <p>vii)Insulin makes you sick</p> <p>B. Patients attitudes</p> <p>i)Use of alternative medicine</p>	<p>A. Patients beliefs and misconceptions relating to insulin</p> <p>i)Insulin seen as a death sentence</p> <p>ii)Doctor can rectify patients health and day hospital is a repair shop</p> <p>B. Patients attitudes</p> <p>1)Resistance due to ignorance of benefits</p> <p>ii)Dishonesty about complying with diet</p> <p>iii)Patients used to the tablets</p>

<p>C. Fears</p> <p>i)Fear of needles</p> <p>ii)Fear of pain</p> <p>iii)Fear of injecting into veins</p> <p>iv)Fear of losing relationship with partner</p> <p>D. Lack of understanding of patients with diabetes.</p> <p>E. Poor socioeconomic condition of the patients</p> <p>i)Lack of money to buy food</p> <p>ii)Lack of home glucometer</p> <p>F. Lack of family support in older patients</p>	<p>iv)Negligent about return visit</p> <p>C. Not applicable</p> <p>D. Lack of education</p> <p>E. Patients socioeconomic conditions</p> <p>i)Lack of transport</p> <p>ii)Lack of telephone</p> <p>iii)Poorly motivated family don't provide transport.</p> <p>iv)Lack of money to buy glucometer</p> <p>v)Overcrowded condition can cause needle stick injury in children</p> <p>F. Problems associated with initiation of insulin in the elderly patients</p> <p>i)Less visual acuity in elderly patients</p> <p>ii)Elderly patients don't understand</p> <p>iii)Elderly patients need escorting to hospital</p>
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Doctors' awareness of the patients' beliefs that insulin makes one fat, sicker, causes stroke and even death acted as a barrier to initiating insulin. Patients' preference of using alternative medicine and their resistance to using insulin due to ignorance of the benefits of insulin acted as barriers as well. Patients' poor socio-economic conditions combined with lack of transport, telephones and access to the CHC for monitoring and initiation of insulin, made things difficult. Lack of money to afford a glucometer made it even more complicated. Elderly patients' isolation, poorer vision, lack of understanding, lack of family support and escorts to hospital were mentioned as difficulties to initiate insulin therapy.

In summary, doctors described patient misconceptions about insulin, lack of knowledge on values of insulin and good glycaemic control, home blood glucose monitoring and home support as being major patients' barriers to the initiation of insulin therapy.

Numerous system barriers to the initiation of insulin therapy were mentioned in the groups and interviews. Excessive workload, short consultation times, rapid staff turnover and lack of continuity of care by the same doctor was expressed by the all participants. Poor quality of glucometers in the CHC made it complicated for the medical officer to verify the blood glucose results obtained from them into the CHC. Lack of different kinds of insulin and erratic supplies of insulin made it very difficult to convince many patients to initiate insulin therapy. Doctors felt lack of team work on the issue of insulin was also a problem among doctors and nurses, as was poor support from the nurses.

Table 9: Sub themes on “System Barriers”

From the focus group discussion	From the individual interviews
A. LACK OF RESOURCES	A. LACK OF RESOURCES
i)Lack of human resources.	i)Lack of human resources
	a)Low remuneration of doctors
	b)Patients are seen infrequently
ii)Lack of financial resources.	i)Lack of financial resources
iii) Lack of insulin.	ii)Lack of insulin
iv)Lack of equipment	i) Lack of equipment
	ii) Restriction ordering important test
B. LACK OF TIME	B. LACK OF TIME.
	Not enough time available to initiate insulin.
C.LACK OF PROPER NURSING SUPPORT	C. N/A(Not available)
D.LONG WAITING PERIODS	D. N/A
E. POORLY MANAGED APPOINTMENT SYSTEM	E. N/A
F.LACK OF EMERGENCY SERVICE SUPPORT	F.N/A
G.LITERATURE NOT AVAILABLE IN XHOSA	G. N/A
H.LACK OF TRAINED INTERPRETER	H. LACK OF A PROPER INTERPRETATION SERVICE

<p>I. POORLY FUNCTIONING DIABETIC CLUB</p> <p>i) Lack of education in the diabetic club</p> <p>ii) Lack of interested personnel for running the diabetic club</p> <p>J. LACK OF CONTINUITY OF CARE</p> <p>K. LACK OF FLOW CHART</p>	<p>I. POORLY FUNCTIONING DIABETIC CLUB</p> <p>i) Lack of education in the club</p> <p>ii) Lack of club on a daily basis</p> <p>iii) Insulin is not one of the priority topics in the club.</p> <p>J. LACK OF CONTINUITY OF CARE</p> <p>i) No doctor remains in the same CHC for long time</p> <p>ii) Doctors don't see their own patients</p> <p>K. LACK OF FLOW SHEET ON INITIATION OF INSULIN</p> <p>L. LACK OF DISCIPLINE</p> <p>M. PHARMACIST DOES NOT SPEAK PATIENTS' LANGUAGE</p> <p>N. LACK OF SOUND CLINICAL GUIDELINES</p> <p>O. LACK OF SHARING OF RESPONSIBILITY</p> <p>i) Keeping the same patient for the next time to initiate insulin</p> <p>ii) Predominance of individual responsibility</p> <p>P. POOR RECORD KEEPING</p>
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Some of the system barriers are interrelated and this has been shown in the conceptual flow diagram in appendix in a figure format.

Participants' suggestions to overcome the barriers are as follows:

Table 10: Sub theme on “Overcoming the Barriers”

From Focus group discussion	From in depth individual interviews
<p>A. Continuing professional development with hands on experience.</p> <p>i) Support on professional development is needed</p> <p>ii) The scheduling of continuing more medical education should be at a more convenient time.</p> <p>B. Adoption of national guidelines</p> <p>C. Development of institutional protocol with the adherence to national guidelines.</p> <p>D. Training and involving nursing staff.</p> <p>E. Creating a smart insulin sheet</p> <p>F. Development of a diabetic club</p> <p>i) Patient involvement in the club</p>	<p>A. Overcoming fear and developing the experience to initiate insulin</p> <p>B. Developing a uniform manual on insulin use.</p> <p>C. Developing an institutional protocol</p> <p>a) Protocol makes decision making easier.</p> <p>b) Protocol should address the specific issue.</p> <p>D. More training is needed and trained nursing staff needs to be provided.</p> <p>E. Creating a smart insulin sheet</p> <p>F. Developing a proper diabetic club</p> <p>i) Offering group education on diabetes and use of insulin in diabetes.</p>

<p>ii) Establishing a diabetic clinic within the diabetic clubs for poorly controlled patients only.</p>	<p>ii)Preparing patients to initiate insulin therapy in the diabetic club.</p> <p>i) Involving patients in the club.</p> <p>ii) Developing a diabetic clinic within the diabetic club for the poorly controlled Type 2 patients.</p>
<p>G. Providing audio visual material on diabetes</p>	<p>G. Providing a proper support structure for the patient.</p> <p>i)Good district nursing service</p> <p>ii)Help from the non-governmental organisations(NGOs).</p> <p>iii)Special health card for patients.</p> <p>iv)Providing literature.</p> <p>v)Supplying proper instruments.</p>
<p>H. Not Applicable (N/A)</p>	<p>H. Having one on one time</p>
<p>I. N/A</p>	<p>I. Providing a good continuity of care</p>
<p>J. N/A</p>	<p>J. Overcoming the follow up problem</p> <p>Taking the responsibilities in group situation.</p>
<p>K.N/A</p>	<p>K. Developing a self learning approach</p>
<p>L. N/A</p>	<p>L. Developing community awareness</p> <p>i)Initiating newspaper involvement on insulin and diabetes</p>

	ii) Organising open programmes on diabetes within the community.
M. Use of scare tactics for improvement of compliance of the patient	M. N/A
N. Combining the treatment of insulin with oral medication.	N. N/A
O. Training of undergraduates at community level	O. N/ A
P. Becoming culturally sensitive	P. N/A
Q. Patient centred care.	Q. N/A
R. Use of scare tactics for improvement of compliance of the patient.	

To summarize, training of undergraduate and postgraduate student on insulin therapy and diabetes in the primary health care context is urgent. Reinforcement of doctors' and nurses' education on diabetes and insulin is important. Increasing the resources for the management of diabetes should be the first priority. Development of a manual on the use of insulin with adherence to national guidelines was mentioned. Collaboration with nurses for a proper diabetic clinic with the development of a mini diabetic club for the patients with persistently poorly controlled type 2 diabetes has been recommended. Permanent staff for running the dedicated diabetic club is vital.

15. DISCUSSION:

In the focus groups and interviews medical officers mentioned many barriers to the initiation of insulin therapy for patients with type 2 diabetes, on maximum oral agents in the public sector community/primary health care centres in Cape Town. The barriers most frequently mentioned by the doctors were patient related, but the most common issues which emerged and contributed to the barriers to the initiation of insulin were in fact related to the doctors themselves, such as their perceptions, attitudes, knowledge, training and experiences of initiation of insulin in public sector CHCs in Cape Town.

15.1 Doctors' perceptions on initiation of insulin:

15.1.1 Patients' compliance:

This was the most common sub theme; namely that the majority of patients are not compliant with pharmacotherapy and non-pharmacological modalities of treatment of diabetes and, as a consequence, initiation of insulin for these patients would not be appropriate. Indeed this perceived lack of patient compliance made doctors reluctant to initiate insulin in the primary care setting.

Doctors concern about non-compliance is clearly important as improved compliance with current treatment may obviate the need for insulin.

The traditional definition of compliance is following the doctors' orders or instructions and non-compliance means not following doctors' orders or instructions on the part of patients.⁷¹ Some of the commonly mentioned factors in non-compliance are described in table 11.⁷²

Table- 11 Factors in non- compliance

Factors in non- compliance:	Examples:
1.Patient factors	'Anti drug' attitude (synthetic versus natural/ alternative therapy), Fear of side and adverse effects, fear of getting addicted to prescribed medicine.
2. Disease factors	Loss of memory, difficulty in swallowing, diseases without symptoms.
3. Medication factors	Some medication regimens are complex, involving a change of lifestyle(no drinking of alcohol, no sweets, no salt in food)

In this study doctors' perception on patient non-compliance was largely based on patients use of alternative medicine, that the early stages of diabetes are often asymptomatic, that lifestyle changes as part of diabetes management are difficult to achieve and that some regimens are complex.

Regardless of the cause of the factors to non-compliance, doctors label the patient as a defaulter, difficult or simply a time waster. This one- sided and rigid perception of non compliance has led to the development of the concept of adherence to treatment. Literally, adherence means sticking to therapeutic regimes. Although the term 'adherence' has been used to circumvent the idea that the patient passively 'complies' with the orders of the doctors, low adherence to prescribed treatments is evident.

So the adherence to a management plan needs to be made through mutual decisions making as opposed to compliance, which implies obedience the doctors' order.

However a recent review suggested a few doctor/ pharmacist factors which influence adherence/ non-adherence.⁷³ Some of them are listed below,

- Doctor/ pharmacist commitment to and understanding of the challenge of adherence.
- Quality of doctor/pharmacist explanation of the importance of taking drugs, the risk of not taking drugs and regular face to face reinforcement of the importance of taking the drugs.
- Quality of doctor patient relationship (the doctor as a therapeutic tool/ agent).

All of the above factors depend on the quality of communication between doctor and patients. The failure in communication centres mainly around the beliefs of doctors and patients. Patients beliefs include misconception about disease and medication, questioning the necessity of continuing treatment, feeling well, physical and social vulnerability with lack of control over their lives and doubts about the accessibility and availability of the treatment. These all impact on adherence to treatment.⁷⁴ In this study patients are thought to have misconceptions about diabetes and insulin. In addition poor socioeconomic conditions and poor accessibility to and availability of insulin made it difficult for doctors to convince patients of the value of insulin.

However, the doctors' understanding and effective action to improve compliance needs to be revised. A recent study in a general practice setting in the UK, identified six major types of misunderstandings that have actual or potential adverse consequences for taking medicines.⁷⁵

- **Group one-Patients' information is unknown to the doctor:** Doctor is unaware of patient's views on medicine or anxieties about symptoms or treatment and patients' use of alternative or over the counter drugs.
- **Group Two- Doctor's information unknown to patients:** Patients want information and or he thinks that the patient will not understand the drug action.
- **Group Three- Conflicting information given:** Patient is confused by conflicting advice from the doctor and other sources of information (from another doctor? Or perhaps another hospital doctor?)
- **Group Four- Disagreement about attribution of side effects:** Misunderstandings or disagreements on the causes of side effects.
- **Group Five- Failure of communication about doctor's decisions:** Patient doesn't understand, remember or accept the diagnosis or treatment decision.
- **Group Six- Relationship factors:** One of the parties has a need to be liked or has a hidden agenda.

Failure to involve the patient in a shared decision- making process and the negotiation of a joint plan together often leads to non -adherence to therapy or management. In shared decision making the doctors listen to the patients and acknowledge the patients' preference. This movement from compliance to adherence to treatment was praised but was found to be inadequate and this led to the development of an approach to deal with it, namely the "Concordance initiative".

Concordance recognises the health belief of the patients, which could be different from those of the doctor, and tries to understand, determine, acknowledge and incorporate them into a negotiation between a patient and a health care professional. The aim of the concordance initiative is to help patients and prescribers to make a well-informed choice about diagnosis and treatment, about medications, benefits, and risks and to collaborate fully in a balanced therapeutic alliance. So this move from compliance via adherence, to concordance needs to be welcomed.⁷²

15.1.2 Insulin may not reverse the complications:

In my field notes I mentioned that many doctors have the perception that insulin is not beneficial for the patient with type 2 diabetes and further that insulin may not reverse complications. This indicates a clear lack of knowledge. In the first instance, Type 2 diabetes mellitus is a progressive disease. Residual beta –cell function decreases with time and if significant hyperglycaemia (Hb A1c > 8%) persists despite oral combination therapy, insulin therapy is warranted.⁷⁶ As progressive beta cell failure occurs in 30 –50% of the patients with type 2 diabetes, they will ultimately require insulin.⁷⁷ In the United Kingdom Prospective Diabetes Study (UKPDS) of patients with newly diagnosed type 2 diabetes, 40% of those patients who were taking sulphonylurea (randomised) and 22% of the patients who were taking metformin (randomised) were switched to insulin therapy after six years of study because of the failure of oral anti diabetic agents.

Based on the results of the landmark UKPDS study, the benefit of improved glycaemic control (HbA1C 7 vs 7.9) on microvascular complications was evident regardless of mode of therapy ie although oral hypoglycaemic agents or insulin, improved control may not prevent the macro vascular complication.

15.1.3 Obesity and Initiation of insulin:

Many participants have a perception that insulin is not beneficial in obese patients with diabetes and the insulin might increase the level of obesity.

It is recognised that the majority of patients with type 2 diabetes mellitus are obese. Many of these obese, type 2 diabetes patients will not achieve glycaemic control with maximum doses of oral hypoglycaemic agents. They will require exogenous insulin supplementation with a multidisciplinary approach in the management of obesity. The UKPDS study found that good glycaemic control with sulphonylurea or insulin is associated with weight gain. However, by using a combination of metformin and insulin compared to insulin alone or insulin/sulphonylureas, the degree of weight gain was minimized with at least good glycaemic control.⁷⁸ For the patient who is obese and who can not tolerate metformin, the use of 70/30 supper time insulin with glimepiride is a safe effective treatment when type 2 diabetes is not well controlled by sulphonylurea alone.⁷⁹ Unfortunately glimepiride is not available in the Western Cape CHC, however the other sulphonylureas which are available can be combined with 70/30 insulin for patients with poorly controlled type 2 diabetes.⁸⁰

Table 12: Benefits of combining of insulin and oral agent

1. Minimal education is required.
2. Patient does not need to learn how to mix different insulin preparations in the beginning.
3. Treatment is easily started in a community health centre setting.
4. Compliance may be better with one injection versus two or more
5. Patient has improved psychological acceptance of the needle, it helps to overcome the fear of needle.
6. It is effective in obese people and the chance of weight gain is minimal.

A recent article on how to use insulin therapy on type 2 diabetes cited that there is a lack of sufficient data as whether or not insulin mono-therapy or insulin combination therapy is ideal.⁸¹ Despite this, Yki-Jarvinen has suggested that combination therapy with insulin and oral agents has some advantage compared to insulin alone, especially those patients who have had treatment with insulin alone.⁷⁸

Rationalisation has been recommended in regard to insulin regimen.⁸¹ Patient factors to take into consideration when deciding on insulin regimen are: age and life expectancy, ability to perform self-- blood glucose monitoring, obesity, motivation, eating habit, flexibility of lifestyle and work environment. The same article has given the guide line on how to use insulin using the Yki-Jarven approach.⁸¹ This has been shown in the table- 13.

Table 13: Guideline how to initiate insulin ⁸¹

	Adding insulin to oral anti diabetic agent(OAD)	Switching from OAD therapy to insulin monotherapy.
Feasibility of the procedure	Safe to do it in outpatient setting	Best done in hospital setting.
Starting dose	0.2 to 0.35 unit/kg(initial dose should not exceed more than 0.35 unit/kg)	0.2 to 0.6 unit /kg.
Adjustment of the dose	Subsequent adjustment of the dose should be based on the result of blood glucose monitoring	This also depends on the result of Blood glucose monitoring. But i) for the twice daily regimen-2/3 of the total dose in the morning and one third in the evening. ii) for the basal regimen 1/3 of the total dose is basal dose and splitting the remaining two third to one third equally between the three meals.

With regard to combination method (i.e. combining insulin and oral agents treatment), I would recommend that when insulin therapy is commenced in combining with oral hypoglycaemic therapy; one of the oral agents preferably metformin should be maintained and that a low dose of insulin should be introduced slowly . The dose of insulin should be titrated according to the results of blood glucose monitoring.

It is important to mention however that in the study by Yki -Jarvinen patients were taught to adjust the insulin dose on the basis of fasting blood glucose measurement using a home blood glucose monitoring instrument.⁷⁸ In the Western Cape Metro-pole primary health care setting, neither the government nor the public can afford home glucose monitoring and there is a lack of any kind of education programme on diabetes and insulin. Despite this, it would be possible to initiate insulin treatment and ask the patient to return for a fasting blood glucose level after one week and thus revise the dose, but it would require improved infrastructure or a fast tracking system. So the fear of introducing hypoglycaemic episodes, considering the lack of proper education programmes in this setting may be valid, but this matter requires further research.

15.2 Fear:

15.2.1 Fear of hypoglycaemia:

Fear of hypoglycaemia was the greatest barrier to initiate insulin in the CHCs.

This concern of the participants is quite understandable, since:

- Hypoglycaemia is a well recognised side-effect in treatment with sulphonylureas or insulin.
- Hypoglycaemic unawareness coupled with excessive alcohol intake could be the cause of severe, frequent or unexplained episodes of hypoglycaemia.
- Hypoglycaemia could also be caused by excessive use of insulin, delayed or missed meals, low carbohydrate content of the meal or increased physical activities.⁸³

Thus, the participants concern about the shortage of food in some patients may be valid.⁸² In one study at Baragwanath Hospital, hypoglycemia was the most common cause for patients presenting with coma in that tertiary hospital setting. In that study hypoglycaemia had no mortality and no obvious long term effect.⁸³ The cause of hypoglycaemia was due to missed meals (36%), to alcohol excess (22%) (Which could be due to the fact of over representation of the males in the study) and use of sulphonylureas (32%).⁸³

Many countries have initiated insulin in the primary care setting or at outpatient clinic of secondary or tertiary hospitals; where there was a pre insulin education programme and a system of home monitoring of blood glucoses, particularly when conducting a study. In these, there was no patient loss solely due to hypoglycaemia.^{62, 84}

Very few patients needed hospital admission due to hypoglycaemia and although the frequency of hypoglycaemia with insulin therapy was not greater than that with sulphonylureas; the frequency does increase in the case of intensive control and particularly in elderly patients. However, serious and some- times fatal hypoglycaemia may occur in rural areas in Africa.⁸² Hypoglycaemia is preventable through patient education and cautious and sensible prescribing by the practitioner (starting with low dose insulin).^{83, 84}

Addressing the issues of hypoglycaemia, in a particular its causes, symptoms and management is essential in any patient being commenced on insulin. The fear of hypoglycaemia has been exacerbated by many factors as shown in Appendix -L.(FIG-1)

A relatively new insulin Humalog and Lispro, could help to overcome some of the fears of hypoglycaemia.⁶⁵ Owing to its rapid onset of action, insulin lispro can be injected immediately before and after a meal, thereby allowing the patient more life flexibility.⁶⁵ Unfortunately, Humalog insulin is not available in the Cape Town CHCs at present but may become available in the future.

15.3 Initiation of insulin in elderly patients:

Many participants were concerned about the initiation of insulin in older patients. The reasons given included: poor vision, living alone, lack of support, inadequate understanding and forgetfulness. Although many of these concerns may be valid, they can be addressed by the family orientated primary care approach using the maximum support available in the family, friends, neighbor and community. An essential component of treatment in patients' with diabetes mellitus is that treatment should be individualised and understanding that strict glycaemic-control may not be achievable or even desirable in many elderly patients.⁷⁶

In the elderly, relief of the osmotic diuresis associated with hyperglycaemia may be an achievable goal leading to improvement in quality of life. This issue was addressed in a recent SAMJ; CME where it was advised that tight glycaemic control should not be sought in the following:

- History of recurrent hypoglycaemia
- Inability to understand or carry out the stricter regimen
- The presence of advanced and severe complications of diabetes
- Presence of co-morbid disease that reduces the life expectancy.⁴⁷

A combination therapy of an evening dose of insulin with a long acting sulphonylureas is an effective treatment for improvement of hyperglycaemia in the elderly patient with type 2 diabetes in whom the maximum dose of oral agent is not successful.^{78, 80} This combination regimen is easier to follow for the patient who doesn't wish to or may not be able to adhere to a more complicated insulin regimen.⁸⁵

15.4 Patients socio-economical condition and initiation of insulin:

There were a number of socio economic factors or barriers mentioned by the participants; these included lack of refrigerators, poor financial conditions preventing patients from purchasing glucometers and transport for attendance at the CHC. The lack of a refrigerator in the patient's home for insulin storage is not a barrier to initiate insulin, but the lack of knowledge displayed by the doctors because it would appear that many doctors are not aware that insulin may merely be kept in a cool place. Slight loss in potency may occur after the bottle has been in use for over 30 days, especially if it was stored at room temperature.⁸⁶ Attention is being given to the development of more heat stable insulin by the pharmaceutical companies.

With regard to the concern expressed about unemployment and poor economical conditions acting as a barrier to initiate insulin in poorly controlled type 2 diabetes patients; in the UK, it was found that glycaemic control was not related to age, social class, lifestyle, attitudes, satisfaction, knowledge of the patient but rather to the better facilities, mini clinics and doctors with a special interest in diabetes.^{78, 87} That study did not address whether poor socio-economic conditions were a barrier to initiation of insulin. Unfortunately there is a paucity of data from South Africa, where high levels of unemployment prevail and CHCs provide care for the lower socio-economic group of people. Low socio-economic status may well be associated with lower levels of education and literacy. Nonetheless with adequate infrastructure, staff and education it is likely that insulin treatment could be satisfactorily introduced. A major deterrent would be the inability to monitor patients blood glucose level at home, which plays a role in self titration of insulin doses. Many patients can not afford to buy a glucometer and the CHCs don't provide glucometer. However patients could be instructed in the use of 'Haemoglucotest' which enables the visual reading of blood glucose levels by comparing colour on the strip with colours on the side of the bottle. Different blood glucose levels being indicated by the different colours. Once again it requires adequate staff education and time for patient education which will vary according to the patient level of literacy.

Alternatively patient could attend more frequently initially at once or twice per week after initiation of insulin and staff to measure the blood glucose level adjusting the dose of insulin and thus allaying the fear of hypoglycaemia. This could also lead to adequate control and increases patient satisfaction.

Former would be better option as the empowerment of patients is important. Transport costs and loss of earnings are important barriers to regular attendance at clinics for example in a study of non attendance at the diabetic clinic, the reason for the irregular attendance (25% of the original sample) in that study cited by patients, was the inability to afford the transport to the hospital and fear of losing their jobs because of lengthy dispensary attendance every four weeks.⁸⁸ The latter is a major problem in the CHCs where patients have to wait for up to six hours (including collecting folders in the morning to receiving medicine) to get the medication. A simple solution would be dispensing medicine for three months in those who are stable.

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15.5 Understanding, knowledge and education of the patient and initiation of insulin:

Many participants had a well founded perception that patients need to have a good understanding and knowledge of diabetes and insulin for initiation of insulin treatment.

Indeed it is recognised that candidates for intensive management by insulin therapy, should

- Be motivated, compliant and educable.
- Be knowledgeable and self disciplined.
- Be well educated in Home Blood Glucose Monitoring techniques, proper insulin administration and self adjustment of insulin dose if appropriate, before insulin therapy is initiated.
- Be knowledgeable on dietary and exercise strategies
- Be able to take control and responsibility for their health with the aid of their health professionals
- Be educated on hypoglycaemia prevention, recognition and treatment.⁴⁶ This applies to both the patient and family members as well.⁴⁶

This holds for any patients given insulin. Initial and ongoing education by a diabetes management team is necessary for long term success and safety.⁴⁶

Patients with diabetes should have a comprehensive knowledge of diabetes since it is unreasonable to expect a patient to take active steps to manage their condition without knowing what it is and its consequences. Without this we cannot expect people with diabetes to achieve or then maintain the behavioural changes needed to cope with the condition.⁷¹

Therefore a vigorous education programme should be an essential component of treatment of the treatment of type 2 diabetes with insulin, even if tight glycaemic control is not the therapeutic objective. Most of the studies on the initiation of insulin have been done in developed countries. Initiation of insulin in the primary health care centre setting is also more frequent in developed countries. In these countries they have tried to overcome the barriers in many ways by providing proper education, encouraging self blood glucose monitoring (SBGM), even developing programmes on blood glucose awareness training (BGAT-2).⁷⁸ However very little information is available to test the feasibility of initiating insulin in the poorer and often illiterate population of South Africa attending public sector primary health care centres of South Africa.

Nevertheless, it is a feasible idea that the initiation of insulin treatment can be achieved in deprived and impoverished Black African diabetic populations as opposed to their better educated and wealthier white and Indian counterparts. This was demonstrated in a study at the Johannesburg Hospital diabetic clinic.⁸⁸ In this study glycaemic control improved substantially in similar proportions of black, white and indian patients after attending a specialist diabetic clinic that provided education on self care and blood glucose monitoring. Interestingly fifty percent of the study population was illiterate. The improvement in control was generally associated with increased insulin and oral hypoglycaemic doses. Thus if education is provided, social class does not necessarily influence glycated haemoglobin and the potential barriers of poverty, lack of education and language can be overcome in some cases.

15.6 Doctors Attitudes and initiation of insulin:

The attitude of doctors on initiation of insulin was not always positive; the initiation of insulin was often not seen as a priority, Some of the doctors were unwilling to initiate insulin, don't like insulin in the primary care setting and don't continue to use it, even when a patient had already been started on insulin. There are number of reasons for adopting this negative attitude. Some of them are as follows:

- Many participants did not want to take the responsibility of initiating insulin in the primary care setting. Some even transfer the responsibility to the secondary or tertiary hospital.
- Many participants' use insulin as a threat. Consequently patients have the perception that insulin will be used as a punishment, if they don't take the tablets and maintain the diabetic diet. Patients need to be explained the merits of insulin from the very beginning in a patient centred way, so that they may explore their ideas on insulin and don't develop any negative attitudes towards insulin. Doctors in primary care setting need to be aware of this destructive technique and refrain from using it as a threat. The issues on insulin need to be discussed in a sensitive way with encouraging and supportive manner.
- Many participants felt that they don't have the knowledge and expertise to initiate insulin in primary health care setting. It was expressed as follows, "*It was a specialist job, you certainly have to have knowledge, confidence and the patient understanding*".

At the CHC, where I am working at present, the problem of diabetes is not even regarded as a priority; the major issue is reproductive health. Even the National government gives priority to HIV, TB and TOP in primary health care, diabetes does not feature.⁹⁰

I believe that primary care physicians are contextually well placed to initiate insulin treatment. This has been done in many countries at this level. If appropriate resources are available, it can be done in the South African context as well. But doctors also need training and skill.

In this study participants were not concerned with the cost. But there was a consensus that prescribing insulin to poorly controlled type 2 diabetic patient would increase utilization of facilities by patients. It would also mean extra work for the doctors in a setting with minimal resources, which could affect the decision not to initiate insulin therapy.

A qualitative study in the general practice setting in the UK found that prescribing any item in any condition is associated with discomfort.⁹¹ The main reasons for discomfort in prescribing decision experienced by studied doctors were

- Concern about drug toxicity, cost, work load, time management, ignorance and uncertainty about diagnosis and management, setting and breaking precedents, negative peer evaluation.
- Feeling being manipulated by patients, factors relating to the doctor-patient relationship, concern about negative patient evaluation, past events of special importance.⁹¹

Some of the above factors such as work load and time factors were mentioned in the present study as influencing decisions to initiate insulin, and some of the other related factors were also mentioned by participants, such as losing the trust of the patient and negative evaluation by the patient.

Access to guidelines is important, however many participants didn't consult or make an effort to find the guidelines for the management of type 2 diabetes at primary health care level in South Africa. They were not familiar with the guideline or didn't adhere to it. Some of them even found them too complex to apply. A few participants' had seen the guidelines, but didn't find clear and explanatory guidelines with regard to the maximum oral dose and use of insulin in patients with poorly controlled diabetes. There appears to be confusion about the issue of use guidelines the primary health care setting. This is a serious concern.

Another issue which is relevant to the initiation of insulin is what the accepted maximum dose of oral agents. Many participants found inconsistencies between the maximum recommended oral dose in South African National Formulary (SANF) and the dose mentioned in the guide -lines. Not unexpectedly, this results in confusion as to whether the insulin should be introduced or the dose of oral agents increased. A recent study in Cape Town found that the guidelines on diabetes and hypertension were not systemically implemented at local primary health care centres and that individual doctors consulted the guidelines infrequently.⁹⁰ The common barriers to the application of guidelines were time constraints, health system problems and patients' beliefs and conflicts with local practices.

There was also a lack of clarity as to whether the age or level of experience of the doctors involved had an impact on the initiation of insulin treatment. It is clear, however, that education is needed. Focus for the development of a special training programme on the basis of year of graduation is need not be mandatory, but a training programme focusing on the attitudes of doctors is necessary.

In this light, I refer to a study from the USA to the effect that an educational program on diabetes for the primary care physicians should focus on reported behaviors deviating from the recommended norm and that it possibly needed to target a subgroup of physicians to achieve more uniform level of care for all patients with diabetes.⁹²

Medical knowledge regarding diabetes and the use of insulin changes and increases every year. Thus many participants acknowledged that one needs both knowledge and training to initiate insulin therapy in the primary health care setting. One study found that the reluctance to use insulin was related to inexperience, it was also associated with lack of ongoing advice or support and cost to the site (primary health care centre).¹²

The participants' need for a consultant in the facility to initiate insulin treatment suggests both lack of confidence and abilities. Confidence may be developed by proper training, support and experience. Nevertheless it would be beneficial to have a consultant on family medicine, who could assist the doctors if they should have any query on the issue of initiation of insulin in the primary health care setting.

15.7 Patients' beliefs relating to the initiation of insulin (as perceived by doctors):

15.7.1 Patients' beliefs that initiation of insulin causes stroke and death:

There appear to be a number of myths and misconceptions held by patients about insulin and diabetes which need to be addressed. It is unclear why the initiation of insulin should be seen as a death sentence. Patients connect this belief with previous experiences of terminally ill friends or relatives who have died soon after initiation of insulin or amputation of their limbs. Educational sessions with patient, which incorporate presentation and discussion by a diabetic on insulin about their positive experiences may go a long way towards reversing these misconception.

These are however clear examples, where patients' impressions are well founded, such as that stress raises blood sugar levels. Research indicates that relaxation techniques are helpful but too simplistic to offer stress management for all patients with type 2 diabetes.⁹³ Reducing patients' levels of stress by identifying the sources of stress and working through these with the patients may alleviate this problem but it may be time consuming.

An additional problem for many patients may be their use of and belief in traditional healers and alternative medicine rather than conventional medicine as a part of their treatment of diabetes. The challenge for medical officers is to convince patients of the advantages of modern medicine. To convince the patient to use modern medicine, the doctor first needs to develop a relationship with the patient so that he or she will be encouraged to tell the doctors what herb they are taking or which alternative medicine they are using. The doctor should then inform them about the best available evidence. If necessary the use of alternative medicine, provided that the patient takes the modern medicine in addition to the herb, continues to inform to the doctor about their compliance with their medication and monitors their own progress of diabetes management, it should be accepted. Bridging the gap between traditional medicine and bio-medicine needs to improve in a patient centred way, and not in an authoritarian way.

Patients also express their concern that insulin makes people fat. Patients' belief that insulin causes weight gain is indeed valid, but working on their diet and encouraging exercise; coupled with the use of metformin, reduces the chance of weight gain. In the case of a patient who can't take metformin, they may expect a weight gain of 5 to 10 kg during the first year of therapy, but this should be discussed with the patient.

Many participants felt that patients were ignorant of the benefit of insulin and are negligent about return visits. This might however be due to inadequate explanations by the health care staff of the benefits of insulin, the pathogenesis of diabetes and the fact that they did not explore the issues on follow-up visits. Discussing the date of the return visit, or finding alternate ways to do follow up, should they have any problem on the appointment date and time of follow up, may prevent patients defaulting on their treatment.

15.8 Health system barriers to initiation of insulin therapy:

Health system barriers are so inter-related that they are difficult to discuss separately. The barriers were related to the centre itself and the primary health care system in these centres. The most common one was lack of time, followed by excessive workload and lack of resources. Due to an excessive patient load and pre-booking system, it was also difficult to follow up and set up an appointment for those patient who needed to be seen frequently i.e. before and after the initiation of insulin therapy. Doctors and patients rush through the appointment to finish by 2 pm. The rest of the afternoon could be used to educate patients or to book chronically poorly controlled patient for detailed consultations. Doctor don't see the same patient every time and therefore the trust and good relationship with the doctor doesn't develop. Lack of continuity not only causes difficulties in the decision to initiate insulin, but also makes it difficult to follow up on the patient progress after initiation of insulin. Even when starting insulin, patients need to see the doctor frequently, one week later and there-after; however due to the system and excessive patient load a doctor doesn't often see the same patient. So the use of an insulin sheet, which would help the patient to be seen by another doctor without an appointment or waiting for the folder in reception has been developed in some community health centre.

As mentioned earlier the inability to measure glycated haemoglobin in patients to provide an assessment of long term glycaemic control (Specifically, when patients can only be seen or come after three or four months) is a major problem. The current blood glucose level is related to the previous glycaemic status only in a very few cases of patients with type 2 diabetes.⁹⁴

Reliance on a single random blood glucose level test, which may be affected by so many factors such as the size of the last meal, time passed or the interval between last meal, stress etc, can be problematic when making a decision to initiate insulin therapy. Besides that the community health centre dextrostix measurements are problematic, as these glucometers are often faulty and poor technique is often encountered. The dextrostix measurement is not always available and only done once every three months.

16. CONCLUSION:

The barriers to initiating insulin therapy were related to doctor, patient and system barriers. Lack of resources together with heavy patient load, lack of time, high turnover, lack of continuity of care, lack of proper diabetic clubs and language barriers has resulted in a lack of education and counselling on the use of insulin and diabetes in the public sector primary health care centers. Fear of hypoglycaemia has also been a major barrier, due to a lack of knowledge, training, confidence and support amongst the doctors. Lack of support from the nursing staff and a lack of trained diabetic sisters has also acted as a barrier. Limitations on doing glycosylated haemoglobin together with lack of home blood glucose monitoring has made it difficult for doctors to decide and initiate insulin therapy in public sector primary health care centers.

Doctors' perception of patient compliance has also made doctors hesitant to initiate insulin treatment. Understanding the issue of noncompliance and addressing them within the patients' biosocial context is necessary.

A flow diagram on barriers to initiate insulin has attached in fig -2 in the last page of this thesis.

17. RECOMMENDATIONS:

A. Policy Related Recommendations:

1. As diabetes is one of the major causes of morbidity and mortality in South Africa a higher priority needs to be given to it by the national and regional Department of Health. This should take the form of setting specific objectives or targets to be achieved in patients with diabetes mellitus, such as achieving acceptable glycaemic control in 80% of patients in two years. This clearly would necessitate the appropriate use of insulin.
2. Development of a uniform manual and guidelines by experts in the field with the active participation of the primary health care professionals on the initiation of insulin use for the patient in primary health care settings
3. Incentives are needed to develop and stimulate the interest of the professional medical community on diabetes and the use of insulin. Efforts must be made to retain their services and to use them to train the future service providers.
4. Development of an effective district nursing service will help in the initiation of insulin and the follow up of old and disabled patients who can't attend the community health centre frequently.
5. The development of a diabetic disease based register in all the community health centres will provide the district health authorities with good statistics on diabetes, help to identify the different trends of diabetes in the different districts as well assist with the allocation of the resources according to the trends of the various centre.

B. Training

1. Regular continuing professional developments(CPDs) taking the form of interactive workshop discussing specific issues i.e. how to initiate insulin therapy, with follow up session to discuss the problem encountered.
2. Develop resources directed at changing doctors' attitude on diabetes and on the initiation of insulin.
3. Training on the use of patient centred approach to improve the compliance.
4. Training of nursing staff in the technique of insulin injections, monitoring, identifying and treatment of hypoglycaemia.

C. Organisational Development and Health System Related Recommendations:

1. Develop and utilize a booking system
2. Allocate enough time for a fifteen minutes consultation
3. Improving the continuity of care
4. Provide medication for 2-3 months period
5. Book patients throughout the day last appointment at 3-4 pm.
6. Create a fast tracking mechanism for patient started on insulin so they can briefly consult with the staff to adjust the dosages.
7. Develop an organized and dedicated club giving emphasis on systematic education and counselling.
8. Establishing a mini diabetic clinic within the diabetic club for the poorly controlled type 2 diabetic patient.
9. Ensure that the nursing staffs trained in diabetes remain as a resource for the diabetic

club.

10. Creation of a culture of learning in the CHC with the help of CHSO.

D. Further research:

1. Further research on doctors' knowledge about insulin and diabetes in the primary care setting is necessary.
2. In the context of private practice, barriers of initiation of insulin may be different, so this requires study.
3. Barriers to the implementation of recommendations contained in this report should be investigated.
4. Research on the cost of use of insulin in the primary health care setting and the medical costs incurred managing the complications of type 2 diabetes.
5. More research on incidence and prevalence of hypoglycaemia after initiation of insulin in primary care setting.
6. Research on doctors' behavior and patients' behavior on initiation of insulin in, patients with poorly controlled type 2 diabetes.
7. Investigation of the opportunity to negotiate with private general practitioners to initiate insulin for patients with poorly controlled type 2 diabetes on maximum oral dose attending public CHCs.
8. Patients' perception and feeling on initiation of insulin should be acknowledged and needs further study.
9. Feasibility study on the use of glucagon in primary care setting and in the patients to prevent hypoglycaemic attack.

18. BUDGET AND FUNDING:

A proposed budget for the study is included. (Appendix K)

Funding organisations, including the pharmaceutical companies, were asked for sponsorship.

The aim of my research was very different to promoting a product for a pharmaceutical industry and was not to promote any pharmaceutical product. None of the medical officers work for pharmaceutical company. No pharmaceutical was permitted to promote their product during or after the focus group discussions. Application for funding to the University of Cape Town was done as well. Thus the source of the funding did not influence the findings of my research.

Fortunately Eli Lilly Pharmaceutical industry donated fifteen thousand Rand (R 15000-00) to the University of Cape Town research Support Service as a research grant. I have used seventy percent of this fund for this research. University student support service has kept some of the remaining fund as an administrative fee.

19. EMERGING ISSUES, EXPERIENCES AND FEELING OF THE RESEARCHER OF THIS STUDY:

The issues that have arisen from this qualitative study with the doctors of primary health care centres in Western Cape Metro-pole are of paramount importance for further research.

The first issue was availability of the doctors. Getting doctors together from different CHCs to participate in focus group discussions, is difficult because of the following:

- Lack of staff and excessive patient loads making it difficult for the doctor in-charge to release doctors to join in the focus group discussion.
- Thursdays and Fridays are not suitable days for focus group discussion, because most of the time doctors take part in continuous medical education (CME), which involves earning of CPD point.
- Monday is always a busy day, because of weekends.
- On Wednesday many doctors attend the classes of their post graduate courses of the family Medicine Programme
- If the Tuesday, the only available day for the groups or interview, fell on a public holiday, no one was available to attend.
- In the morning it is difficult to get time off and some doctors are post night duty call.
- In the evening participants usually have some personal matters to attend to or will be doing night duty.

Deciding on the date for a focus group discussion was not an easy task and it was a vital task. Repeated re-assurance that, the discussion would start and end at the given time, and would not be more than one hour and fifteen minutes was necessary.

Getting time for individual interviews was also very difficult. Most of the participants preferred to be interviewed at their particular CHC, but CHCs are very noisy. Very few participants wanted to give of their own time, at home.

The second issue was that most of the staff were not aware of the process of this type of study, they are more used to dealing with questionnaire based research. Thus it was difficult to convince the doctor in-charge to release the doctors for the study.

The primary health care centre research has lots of obstacles because, the primary health care academics, administrators, grass root workers and the student researcher fall under different authorities, are not under a single authority. Obtaining support for this research was not easy. One authority may help to do the research, but other doesn't see the importance and benefit of it.

Finding my way around on qualitative research which is much more time consuming than a quantitative research, was no easy task. It was what I would imagine to be like climbing a steep rocky mountain. There was a need to proceed cautiously so as not to slip or fall also swiftly enough to make the progress. I needed resources within my self to meet the challenge.

I needed an office and part time research assistant for this research. As this involved detailed planning and preparation for all aspect of the focus group discussions. Faxing, telephoning, finding facilitators and note takers and following them up are very time consuming and expensive. I needed to use my accumulated leave and to take unpaid leave. Due to the extensive budget cut, my work place did not allow me to use the fax machine for faxing the invitation forms for doctors or reminder for doctors about the date for the focus group interview. I needed to use my personal fax machine.

Doing the research with doctors helped me to understand the complexity of CHC providers. I learned to respect the participants, who didn't want to participate in the qualitative research. One participant in the field note said, "*I am not expert on insulin, I wouldn't take part in this research*". I said, "*ok if you think you can contribute to this study please come*". As the topics were very sensitive, I needed to proceed sensitively.

The involvement in focus group discussions and individual interviews made me understand the technique of open-ended questions and proper probing at the right time. It will help me in my future research.

The tremendous task of organising, gathering and analysing data from five focus group discussions and ten individual interviews was very draining, mentally and physically. However, I found it very rewarding to finally watch the process take place.

It opened my mind to the use of patient centredness in the primary health care consultation, which is vital for overcoming barriers to any issues. I shall practice it more extensively to overcome some of the barriers to initiating insulin.

Doing the literature search, compiling it under appropriate heading, relation and places was a learning curve for me. I however needed to sacrifice many things in my life, including earnings, and time for my small son and daughter, in grade-1 and pre-school respectively.

My feeling is that this a complex topic in a complex environment, which encourages me to be simpler and more basic in doing future research. Although I believe, It would help me to do more multidisciplinary research at a later stage in my career.

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Appendix A

Classification and diagnosis of diabetes

Stage Aetiological process	Normoglycemia	Hyperglycemia			
	Normal glucose tolerance (achieved without pharmacological agents)	IGT and/or fasting hyperglycemia	Diabetes		
			Not insulin requiring	Insulin requiring for control	Insulin requiring for survival
Islet cell destruction ◆ Autoimmune ◆ Idiopathic	←		Type 1 diabetes		
◆ Predominantly insulin resistance ◆ Predominantly insulin secretory defects	←		Type 2 diabetes		
Other specific disorders (eg MODY, endocrinopathies)	←		Other specific types of diabetes		
Pregnancy related defects	←		Gestational diabetes		

Figure 1—Classification of diabetes. —→, In rare instances, patients in these categories may require insulin for survival.

Reproduced from the original article "Type 2 Diabetes Worldwide According to the new Classification and Criteria" of Diabetes Care 23(Suppl.2.): B5-B10, 200

COMMUNITY HEALTH SERVICES ORGANISATION

ADDRESS - TELEPHONE - FACSIMILE
(AS AT 19 JULY 1999)

SO: ADMIN OFFICE - Mountain Road, Woodstock, 7925 - Telephone: 4609100 / Facsimile: 4471959

Community Health Centres	Address	Telephone	Facsimile
Belhar	Chestnut Road, Belhar, 7490	9521010	9523306
Bellville	Kasselsvlei Road, Bellville South, 7530	9512326/7/8	9512998
Bishop Lavis	Lavis Drive, Bishop Lavis, 7490	9346050 BOARD - 9346161 MOU	9344143
Brown's Farm	Erf 2495, Msingezane Street, Philippi, 7785	346063	316398
Crossroads	Lansdowne Road, Crossroads, 7753	3861121 / 344156	3865689
Delft (Roosendaal)	1 Delft Main Road, Delft, 7100	9542237	9541207
Dr. Abdurahman	Ebbehout Street, Kewtown, Athlone, 7764	6379071/2/3	6375998
Elsies River	Cnr 29 th Avenue & Halt Road, Elsie's River, 7460	9310211/2/3-9310411 MOU	9318359
Good Hope	Justin Street, Ysterplaat, 7405	5118606	5113059
Goodwood	Dirkie Uys Plein, Goodwood, 7460	5925207/8	5925235
Grassy Park	Victoria Road, Grassy Park, 7945	7053814	7055712
Green Point	Portwood Road, Green Point	4210288	4210296
Guguletu	NY3, Guguletu, 7750	6371280/03 / 6371220/1	6375103
Hanover Park	Cnr Hanlyn & H/Park Ave, Hanover Park, 7764	6921240/1/2/3	6923921
Heideveld	Heideveld Road, Heideveld, Athlone, 7764	6378036/7/8	6376632
Hout Bay	CMC Building, Karbonkel Street, Hout Bay, 7800	7901050	7907520
Kensington	6 th Avenue, Kensington, 7405	5931150/1	5930933
Khayelitsha	Lwandle Road, Site B, Khayelitsha, 7784	3613470/1	3610259
Kleinvlei	Meteran Single, Denemere, 7581	9044416	9040955
Kraaifontein	303 - 6 th Avenue, Kraaifontein, 7570	9870080 / 9885900	9872310
Lady Michaelis	Burnham Road, Plumstead, 7800	7978171	7628020
Lotus River	Cnr Delia & Anita Roads, Lotus River, 7945	733131/2/3	735692
Macassar	Cnr. Hospital & Musica Streets, Macassar, 7130	8572330	8572251
Maitland	3 Norfolk Road, Maitland, 7405	5116272	5106473
Mamre	Cnr Adam & Liedeman Streets, Mamre, 7347	5761175	5761917
Mfuleni	Church Street, Mfuleni, Blackheath, 7581	9093138	9092942
Michael Mapongwana	Steve Biko Road, Harare, Khayelitsha, 7784	3613353	3632464
Mitchell's Plain	1 st Avenue, Eastridge, Mitchell's Plain, 7785	3925161	3912803
Durbanville	De Villiers Street, Durbanville, 7550	9703170	9703061
Nolungile	Site C, Khayelitsha, 7784	3871520	3875152
Nyanga	Cnr. New Eislieben Rd & Miller Str., Nyanga, 7755	3861280	3865691
Ocean View	CMC Building, Carcia Close, Ocean View, 7975	7831766	7831482
Parow	1 st Floor, Alcor Place, Voortrekker Rd, Parow, 7500	9304020	9305372
Ravensmead	Florida Street, Ravensmead, 7491	9326068 / 9313131	9317009
Reed Street	Reed Street, Bellville, 7530	9463790/1/2	9499115
Retreat	11 th Avenue, Retreat, 7945	7125105/55/92	721493
Robbie Nurock	89 Buitekant Street, Cape Town, 8001	4611124	4617962
Rusthof (Gustrow)	Hassen Khan Avenue, Rusthof, Strand, 7140	8458383/4	8458630
Ruyterwacht	Shopping Centre, Vereniging Rd, Ruyterwacht, 7490	544361/2/3	548789
Scottsdale	Roan Lane, Scottsdale, 7570	9870080	9872310
Strand	Boland Bank Acadia, Main Road, Strand, 7140	8533380	8547057
Vanguard	Candlewood Road, Bonteheuwel, 7764	6945540/1	6945584
Volkscentre	Kruskallaan, Bellville, 7530	9462306	9462021
Woodstock	Mountain Road, Woodstock, 7925	4609100	471959

APPENDIX -C

Community Health Services Organisation And University of Cape Town

Tel: (021) 3925161/730812; Cell: 0824080970; Fax: (021) 3912803

Email: monirulhaque@samedical.co.za

INVITATION TO PARTICIPATE IN A STUDY ON

“Barriers to initiating insulin therapy for patients, with poorly controlled type 2 Diabetes Mellitus on maximum dose of oral agents in the public sectors primary health care centres in Cape Town, South Africa”

Dear Medical Officer,

I have been working as a medical officer in the community health centre's of the CHSO for more than five years and I am currently studying family medicine at the University of Cape Town. As part of the course of M.FAM.MED, I am required to do a thesis. While working in the CHC's, I have come across many patients with type 2 diabetes mellitus on maximum oral therapy, who are poorly controlled, yet not been treated with insulin. This has been borne out by a study conducted in Cape Town. It is for this reason that I have chosen to conduct this study in order to better understand the “barriers to initiating insulin therapy ----- at CHC's”.

The aim of the study is “To improve the glycaemic control and there by prevent complications in patients suffering from type 2 diabetes in the public sectors primary health care centres in Cape Town, by facilitating and promoting the use of insulin therapy where indicated”.

The objectives of this qualitative study are:

- To conduct focus group discussions and in depth interviews, amongst the medical officers of the community health service organisations, to determine and explore factors (perceptions, attitudes and fears etc) acting as barriers to initiating insulin therapy where indicated in patients with type 2 diabetes.
- To present the findings and make recommendations to the health care policy makers and all relevant health care providers.

I am hereby inviting you to participate in the focus group discussion consisting of 5 to 15 medical officers from different CHC's. This will take place on a week day afternoon at a venue out side of your CHC. Discussion will be audio taped. Written consent will be required for participation and maintaining confidentiality. Confidentiality will also be assured by both the facilitator and the note taker.

You will be given a letter from the superintendent of CHSO giving you permission to have the afternoon made available by the doctor in-charge of the CHC. If you are unable to participate in the focus group discussion, I will still value your participation as an individual interviewee.

You will be informed of the time and venue for the focus group discussion. Lunch will be provided before the focus group discussion.

Should you require further information, please don't hesitate to contact me.

Yours sincerely

Dr. Monirul Haque

SUPERVISOR: DR. MARIAM NAVSA; CO-SUPERVISOR: PROF DINKY LEVIT

APPENDIX-D

FOCUS GROUP AND IN-DEPTH INDIVIDUAL INTERVIEW GUIDE

Central Question for Interview

What were the barriers to initiating insulin therapy in patients with poorly controlled type 2 diabetes mellitus on maximum oral dose in the public sector primary health care centres in Western Cape Metro-pole, South Africa?

SCOPE OF ENQUIRY:

The scope of enquiry included:

Experiences with initiating insulin therapy in patients with type 2 diabetes

Difficulties faced in initiating insulin therapy

Experiences with overcoming the obstacles to initiating insulin therapy at primary care level for poorly controlled type 2 diabetic patients

Patient attitudes to insulin therapy

Relation of knowledge, training and skill in initiation of insulin therapy

Attitudes of doctors, colleagues and multidisciplinary staff on insulin therapy with regard to insulin therapy at primary health care centre.

Cultural factors related to insulin therapy

Structured sheet for insulin therapy

Guidelines on initiation of insulin therapy

Support structure to initiate insulin therapy

Health system and insulin therapy

Suggestions of overcoming the barriers to the initiation of insulin therapy

APPENDIX- E

SOME SAMPLE QUESTIONS FOR FOCUS GROUP DISCUSSIONS

1. What are your feelings on initiation of insulin therapy in patients with poorly controlled type 2 diabetes on a maximum dose of oral agents in your primary health care centres?
2. Would you tell us about your feelings and experiences when you wanted to initiate insulin therapy in poorly controlled type 2 diabetic patients?
3. Have you experienced any problems during initiating insulin therapy?
4. What are factors preventing you from initiating insulin therapy?
5. Have you experienced any difficulties with patients in initiating insulin therapy?
6. What are the reactions patients have before and after initiation of insulin therapy?
7. How did you overcome the difficulties experienced during initiating insulin therapy in patients with poorly controlled type 2 diabetes?
8. Are there any special conditions of patient's that prevent you from initiating insulin therapy?
9. Is there any medication taken by the patients that prevent you from initiating insulin therapy?
10. What do you think the knowledge and training with regard to initiating insulin therapy in poorly controlled type 2 diabetic patients?
11. Are there any differences in the attitudes between recently graduated doctors and those who graduated ten years ago with regard to initiating insulin therapy for poorly controlled Type 2 diabetes mellitus?
12. I have heard from some doctors "old doctors are scared to prescribe insulin, while young doctors are usually feel more at ease when prescribing and initiating insulin"
13. What role do you think primary care centres should have with regard to initiating insulin therapy in patients with poorly controlled type 2 Diabetes?
14. How does the patient's socio-economic condition affects' patients on initiating insulin therapy?
15. Does patient education and training on glucose monitoring help the in initiation of insulin therapy?
16. What about the cost of insulin in the public sector?
17. What are the challenges that you face with regard to initiate insulin therapy?
18. Would you comment on the culture of the patient and its influence on initiation of insulin therapy?

APPENDIX-F

SEMI -STRUCTURED IN-DEPTH INDIVIDUAL INTERVIEW GUIDELINE:

(I am going to ask you some open questions on the barriers to initiating insulin in patients with poorly controlled type 2 diabetes mellitus in public sector primary health care centres in the Western Cape, and then I am going to ask you for some more information on the barriers that you will mention. Is that okay?)

- 1. Would you please explain what are the barriers you are experiencing with regard to initiating insulin therapy in patients with poorly controlled type 2 diabetes in your community health centre?**
- 2. What do you think could be the problems they are facing when initiating insulin therapy in other CHCs of the Community Health Services Organisation of the Western Cape Metro-pole?**
- 3. Would you take me through some of your other feelings and experiences on initiating insulin therapy in these CHC patient's?**
- 4. What criteria do you follow or use to initiate insulin therapy for patients with type 2 diabetes?**
- 5. From your experience, could you tell me what has helped you to overcome these barriers and how did you overcome these barriers to initiate insulin therapy?**
- 6. How did you overcome the fear of hypoglycaemia in type 2 diabetic patients?**
- 7. What are the important issues you experienced from the patient's point of view which prevents you from initiating insulin therapy?**
- 8. Would you tell me about support structures and initiation of insulin therapy in this CHC?**
- 9. What do you think about taking over a patient for insulin treatment with type 2 diabetes from another doctor in your community health centre?**
- 10. What about other colleagues and initiation of insulin therapy in poorly controlled type 2 diabetic patients?**

11. I have heard that “Some doctors are scared to initiate insulin therapy”; would you comment on this?
12. I have also heard that, “Young doctors feel more relaxed to prescribe insulin in primary health care centre” What is your comment on this?
13. What is your comment on the role, “Dedicated team effort and insulin therapy in primary health care centres?”
14. Is there any other special condition or medication of the patients which may prevent you to prescribe insulin?
15. Would you tell me about the health care system and the initiation of insulin therapy?
16. Would you comment on any issues relating to culture, language issues and the initiation of insulin therapy?
17. What do you think would make you more comfortable with initiating insulin therapy?
18. Would you comment on any issue relating to pharmacy and the initiation of insulin?
19. Tell me about any guidelines on diabetes and initiation of insulin therapy?
20. Would you comment on doctors’ knowledge, skill and training with regard to initiation insulin therapy?
21. Would you tell me about any other issue relating to the initiation of insulin on poorly controlled type 2 diabetic patient?
22. Would you comment on the diabetic club and the use of insulin?
23. Is there anything else you want to discuss about barriers to initiation of insulin in primary health care centre?
24. What would be your suggestions to overcoming the barriers to the initiation of insulin therapy?

APPENDIX –G

DEMOGRAPHIC DETAILS OF THE PARTICIPANTS

INTERVIEW DATE

1. NAME:
2. SEX:
3. NAME OF THE COMMUNITY HEALTH CENTRE IN WHICH YOU ARE WORKING NOW:
4. HOW MANY MEDICAL OFFICERS DO YOU HAVE IN YOUR CHC?
5. DO YOU HAVE DIABETIC CLUB OR CLINIC IN THIS CHC?
6. PERIOD OF WORKING EXPERIENCE IN THIS CHC:
FULL TIME:
PART TIME:
7. NAME OF ANY OTHER CHC WORKED IN WESTERN CAPE METROPOLE IN WHICH YOU HAVE WORKED
8. TOTAL EXPERIENCE OF WORKING IN A PRIMARY HEALTH CARE SETTING:
PUBLIC:
OR
PRIVATE:
Or both

**CONSENT FOR PARTICIPATION IN A RESEARCH STUDY
A QUALITATIVE STUDY
ON**

“BARRIERS TO INITIATING INSULIN THERAPY FOR PATIENTS, WITH POORLY CONTROLLED TYPE 2 DIABETES MELLITUS ON MAXIMUM DOSE ORAL AGENTS IN THE PUBLIC SECTORS PRIMARY HEALTH CARE CENTRES IN CAPE TOWN, SOUTH AFRICA”

**Researcher: Dr Monirul Haque; Supervisor : Dr Mariam Navsa;
Dept of Family Medicine and Primary Health Care; University of Cape Town (UCT)
Co-Supervisor: Prof Dinky Levit; Department of medicine and endocrinology ,UCT**

I have read and understood the explanation of the research project in which I have been invited to participate. I have also been informed that the group discussions or individual semi- structured interviews on this issue will be audio- taped and that the findings will only be used for medical research and publication without using the participant’s name. Group discussions will comprise of seven to fifteen people including a researcher and a note taker. I have been assured that the discussion will be kept confidential among the group. A written confirmation of keeping the discussion confidential among the group will be given by the facilitator, note taker and participants.

As a member of the focus group discussion, I agree to respect and maintain the confidentiality.

I hereby agree to participate in the above proposed researched project, with the understanding that I am free to withdraw at any stage.

Name: -

Signature: -

To my knowledge, consent was given willingly and with full understanding.

Witness:-

Signature:-

Date:-

UNIVERSITY OF CAPE TOWN



APPENDIX - I

Research Ethics Committee
Faculty of Health Science
Anzio Road, Observatory, 7925
Queries : Xolile Fula
Tel : (021) 406-6492 Fax: 406-6390
E-mail : Xfula@curie.uct.ac.za

2ND March 2001

REC REF: 036/2001

Dr. M. Haque
Family Medicine

Dear Dr. Haque

**BARRIERS TO INITIATING INSULIN THERAPY FOR PATIENTS WITH
POORLY CONTROLLED TYPE 2 DIABETES MELLITUS ON MAXIMUM
DOSE OF ORAL AGENTS IN THE PUBLIC SECTORS PRIMARY HEALTH
CARE CENTRES IN CAPE TOWN, SOUTH AFRICA**

Thank you very much for submitting your application to the Research Ethics Committee for reviewal.

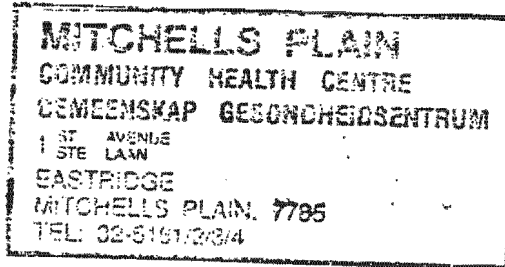
it is a pleasure to inform you that the committee has formally approved your study:

Please quote the above Reference number in all correspondence.

Yours sincerely

PROFESSOR CR SWANEPOEL
CHAIRPERSON

APPENDIX -J



DIABETICS ON INSULIN

Patient: _____

Date: _____

Insulin type: _____

Patient weight: _____

Starting dose: _____

Things to remember when taking insulin:

- Always take insulin 20-30 minutes before meals.
- Never take insulin without eating.
- Have regular meals and a snack at bedtime if possible.
- Always carry a sweet in your pocket in case your blood sugar drops too low.
- A low blood sugar is called "hypoglycemia" and the symptoms are one or more of the following:
 - ❖ Shakiness
 - ❖ Confusion
 - ❖ Mood change
 - ❖ Irritability
 - ❖ Weakness
 - tiredness
 - sweating
 - shivering
 - anxiousness
 - rapid pulse
 - pounding heart
 - blurred vision
 - dizziness
 - headache
 - difficulty concentrating

Your blood sugar may drop if:

- You take the wrong insulin dose ie. too much.
- You miss meals.
- You exercise excessively.
- You drink too much alcohol.

If you feel that your blood sugar is low you can do one of the following:

- Have 2 teaspoons of sugar.
- Drink a coldrink (not the diet one).
- Suck a sweet.

Always report episodes of hypoglycemia to your doctor.

DATE	Fasting B/Sugar	Random B/Sugar	INSULIN DOSE ADJUSTMENT		Comments
			AM	PM	

Onthou om u dokter vir űn Medic-Alert bracelet te vra.

- # Probeer om altyd gesond te eet en gereeld te oefen.
- # Goeie beheer van u suiker sal u oë en u niere beskerm.

U gesondheid is vir ons heel belangrik!



APPENDIX –K

BUDGET:

1. FACILITATORS FEE FOR CONDUCTION OF THE FOCUS GROUP DISCUSSION	R 2000-00
2. TRANSPORT CHARGES -	R 1000-00
3. INTERVIEWER FEE-----	R 1000-00
4. TRANSCRIPTION AND TRANSCRIBING OF THE FOCUS GROUP DISCUSSION----	R 1800-00
5. TRANSCRIPTION AND TRANSCRIBING OF THE INDEPTH INDIVIDUAL INTERVIEWS-	R 1000-00
6. LUNCH FOR THE PARTICIPANTS OF THE FIVE FOCUS GROUP DISCUSSION	R 2500-00
7. PRICE OF THE TAPE RECORDER FOR RECORDING AND LISTEN THE RECORDED INTERVIEWS:	R 1000-00
8. TELEPHONE AND FAX	R 500-00
9. PRINTER INK AND PAPER	R 700-00
10. MISCELLANEOUS	R500-00
TOTALS -----	R 12000-00

APPENDIX- L

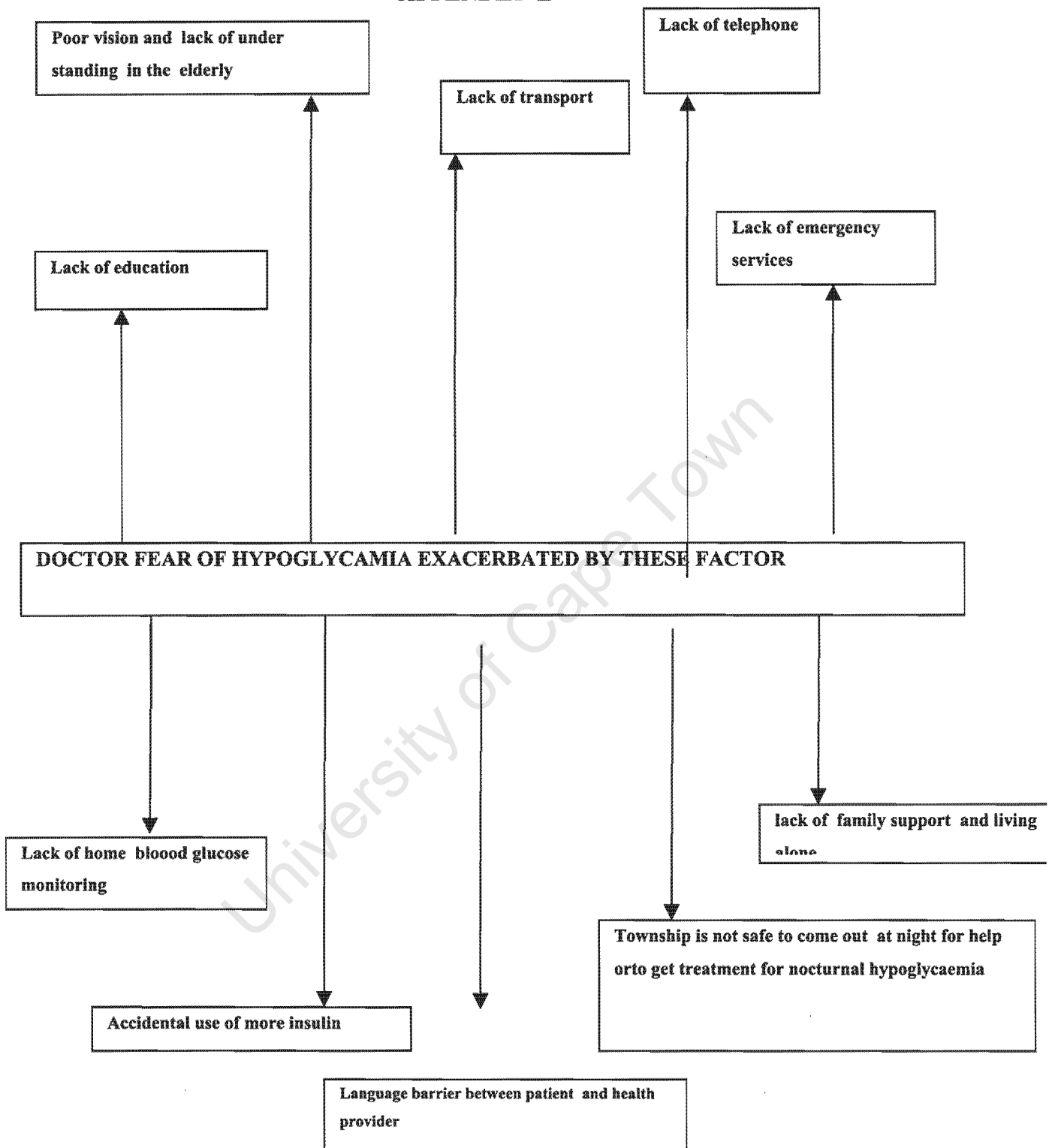


FIG1: FACTOR EXACERBATING THE FEAR OF INDUCING HYPOGLYCAEMIA

ENQUIRIES Dr E W MICHAELS

TELEPHONE (021) 4609116

FAX (021) 4476728

PROVINCIAL ADMINISTRATION: WESTERN CAPE
DEPARTMENT OF HEALTH

PROVINSIALE ADMINISTRASIE: WES-KAAP
DEPARTEMENT GESONDHEID

REFERENCE

ULAWULO, LWEPHONDO: INTSHONA KOLONI

DATE 6 December 2000

ISEBE LEZIMPILO

The Medical Officer
Doctor In Charge
Chief Medical Officer
Community Health Services Organisation

Dear Colleague,

RE: STUDY ON – “BARRIER TO INITIATING INSULIN THERAPY FOR PATIENTS WITH POORLY CONTROLLED TYPE 2 DIABETES MELLITUS ON MAXIMUM DOSE OF ORAL AGENTS IN THE PUBLIC SECTORS, OF PRIMARY HEALTH CARE CENTRES IN CAPE TOWN”.

Dr M Haque is a Medical Officer of C.H.S.O and postgraduate student of M.Fam.Med in the University of Cape Town will be conducting the above study. The participants of the qualitative study are Medical Officers of different CHC's.

I am giving permission to conduct their study and the Medical Officer will be allowed to attend in the focus-group discussion on a weekday afternoon (13h00 to 16h00) in a venue preferably outside CHC. Lunch will be served from 13h00 to 14h00.

Your co-operation by participating for this research in Primary Health Care level institution is important.

Any kind of support from any organisation for this research will be appreciated.

Yours faithfully

DR E W MICHAELS
SENIOR MEDICAL SUPERINTENDEN

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COMMUNITY HEALTH SERVICES ORGANISATION
GEMEENSKAPS GESONDHEIDSDIENSTE-ORGANISASIE
PRIVATE BAG 7 PRIVAAT SAK 7 WOODSTOCK CAPE TOWN 7915
TELEPHONE 021-4609100 TELEFOON 021-4609100 FAX 021- 471959

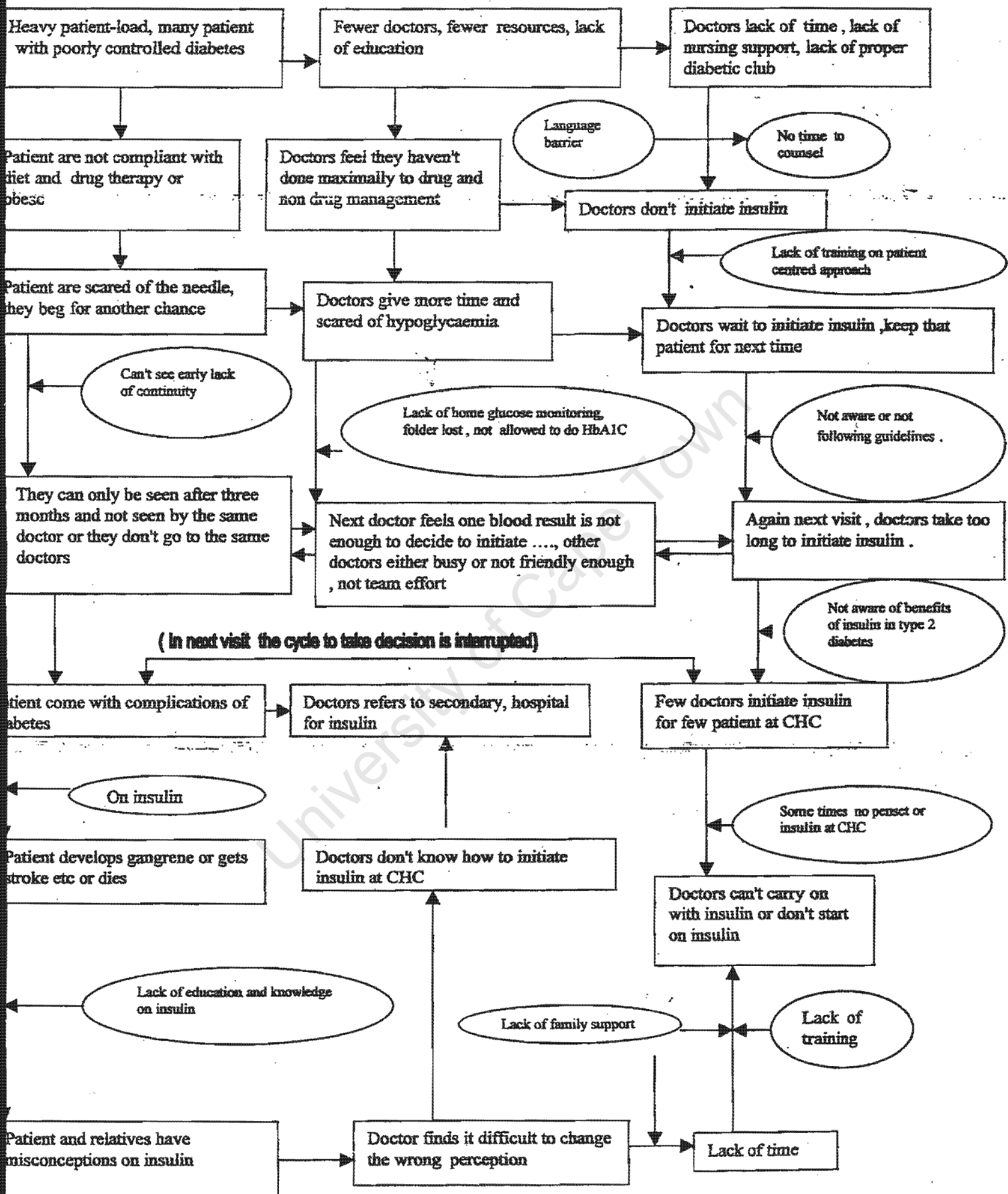


Fig: Flow diagram on barriers to initiate insulin at CHC