The Efficacy of an Intervention Program aimed at Diabetes Care Physicians regarding Quality of Diabetes Care at a Tertiary Care Hospital

by

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Authorship and Co - workers

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Declaration

I hereby declare that this dissertation presented to the University of Pretoria for the of Masters Science in Clinical Epidemiology degree is my own work and has not been presented previously to any other tertiary institution for any degree.

Abstract

The efficacy of an intervention program aimed at diabetes care physicians regarding quality of diabetes care at a tertiary care hospital

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Background: Diabetes mellitus is a common chronic disease which needs long-term glycaemic control to prevent complications. Guidelines are available to improve control, but these are seldom properly instituted.

Objectives: To determine if a physician education program and a structured consultation schedule would improve the quality of diabetes patient care in a diabetes clinic.

Setting: Two tertiary care diabetes clinics at Kalafong hospital.

Study design: Quasi-experimental controlled before and after study.

Methods: A baseline audit of the quality of care in two comparable diabetes clinics were performed. Thee hundred patients were randomly selected for audit of their hospital records. One hundred and forty one from the intervention clinic, and 159 from the control clinic. Thereafter a physician training program and a structured consultation schedule was introduced to one (intervention) clinic and maintained for a one-year period. The other (control) clinic continued with the usual care. Process and outcome measures were determined at a post-intervention audit and compared between the two groups. A score was derived for comparison of process measures. Consultation time was measured at four different stages during the intervention for both the intervention and control groups and compared with each other.

Results: At baseline the intervention and control groups were not statistically different with regards to process measure score ($p = 0.99$) and outcome measures (HbA1c and number of diabetes related hospital

admissions p = 0.31 and 0.38 respectively). Post-intervention the intervention group had significantly higher process measure scores than the control group ($p < 0.01$). Outcome measures did not significantly differ between the two groups; HbA1c ($p = 0.60$) and hospital admissions ($p = 0.38$). The average number of clinic visits reduced over time for the intervention group in comparison with the control group ($p < 0.01$), but the average consultation time was significantly longer ($p < 0.01$).

Conclusion: The introduction of a physicians education program and a structured consultation schedule improves the care of patients attending a tertiary care diabetes clinic. This however occurs at the expense of a prolonged consultation time.

Abstrak

Die effektiwiteit waarmee 'n intervensie program, gerig op geneeshere wat omsien na diabetes pasiente, die gehalte van pasient sorg verbeter in 'n tersiere hospital.

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Agtergrond: Diabetes mellitius is 'n algemene chroniese siekte wat langtermyn glikemiese kontrole vereis om komplikasies te voorkom. Riglyne vir die verkryging van goeie diabetes kontrole is beskikbaar maar, dit word selde behoorlik nagekom.

Doelwitte: Om te bepaal of 'n geneesheer opleidingsprogram asook 'n gestruktureerde kliniek konsultasie skedule, die gehalte van diabetes sorg kan verbeter.

Ligging: Twee tersiêre sorg diabetes klinieke by Kalafong hospital.

Sudie ontwerp: Quasi-eksperimentele gekontrolleerde voor en na studie.

Metode: 'n Basislyn oudit is gedoen in twee vergelykbare diabetes klinieke om die gehalte van sorg te bepaal. 'n Oudit is gedoen op die kliniese hospitaal rekords van 300 pasiente wat ewekansig geselekteer is, waarvan 141 uit die intervensie en 159 uit die kontrole kliniek kom. 'n Geneesheer opleidings program asook 'n gestruktureerde konsultasie skedule is in die intervensie kliniek geimplementeer vir 'n periode van een jaar. Die kontrole kliniek het voortgegaan met sorg soos gewoonlik. Proses en uitkomste is gemeet vir beide groepe tydens 'n post-intervensie oudit en met mekaar vergelyk. 'n Telling van proses meetings was bereken vir elke kliniek en met mekaar te vergelyk. Die tydsduur van konsultasies was gemeet voor en vier keer tydens die intervensie vir beide die intervensie en kontrole groepe vir vergelyking met mekaar.

Resultate: Met basislyn was daar nie 'n statisties beduidende verskil tussen die intervensie en kontrole groep ten opsigte van proses meeting tellings (p = 0.99) en uitkomsmetings (HbA1c en diabetes verwante hospital opnames p = 0.31 en 0.38 respektiewelik) nie. Post-intervensie toon die intervensie groep 'n beduidende hoër proses meting telling as die kontrole groep ($p < 0.01$). Die uitkoms meetings het nie betekenisvol tussen die twee groepe verskil nie: HbA1c ($p = 0.60$) en hospitaal opnames ($p = 0.38$). In die intervensie groep het die gemiddelde aantal kliniek besoeke oor tydperk verminder in vergelyking met die kontrole groep ($p = 0.01$), maar die gemiddelde konsultasie tyd het beduidend toegeneem ($p < 0.01$).

Gevolgtrekking: Die implementering van 'n geneesheer opleidings program en 'n gestruktureerde konsultasie skedule verbeter die gehalte van pasient sorg in 'n tersiere sorg diabetes kliniek. Dit gebeur ergter ten koste van 'n verlening in konsultasie tyd.

Contents

List of Tables

Chapter 1

Introduction and Literature Review

Introduction

Diabetes mellitus is a significant problem with an estimated 140 million sufferers worldwide, and an expected increase to 300 million by the year 2025. [1] South Africa is not spared from this chronic disease with an estimated 2.4 to 3.2 million patients of whom more than 1 million is still undiagnosed. [2] During the period 1990 to 2000 an increase of 30% in the prevalence of diabetes was reported in Africa, mostly due to a change to a more westernised lifestyle and an increase in obesity. [2]

According to the WHO [1]: Diabetes is the fourth largest underlying cause of death and is strongly associated with cardiovascular disease. Hypertension is a common co-morbidity to Diabetes in South Africa and contributes significantly to morbidity in diabetes. [3, 4, 5]
It is therefore very important to optimise the care of diabetic patients at primary, secondary and tertiary care level and to persist in the maintenance of care of the highest standard.
Multiple guidelines have been drawn up and circulated to health care workers but despite this, the level of diabetes care is still not optimal due to sub-optimal implementation strategies. Guideline implementation problems are a significant problem in South Africa as evidenced by the study of Levitt et al [6] who studied and attempted to improve the quality of diabetes care in primary care clinics in Cape town. This is however not only a local problem as evidenced by numerous international audits indicating sub-optimal and varied implementation of guidelines. [7]

This study attempts to describe and test a model to improve the quality of diabetes care in a tertiary care diabetes clinic, which includes a physician-training program as well as a structured consultation schedule based on the South African guidelines for diabetes care.[8]

Background (Literature Review)

Introduction

Diabetes mellitus is a common disease in black South Africans although limited data is available on the prevalence thereof. Three studies report the prevalence of diabetes in South Africa namely: Omar, Seedat and Motala [9] which estimates the prevalence of Diabetes amongst the black population of Kwa Zulu-Natal at: 4,2% (women 5,2% and men 2,3%). Overall age and sex adjusted prevalence was 5,3%. Impaired glucose tolerance was seen in 6,9% of the sample population (11,5% males and 5,5% females). Levitt, Katzenellenbogen, Bradshaw, Hofmann and Bonnici [10] reports the prevalence of Type 2 Diabetes in urban Africans in Cape Town to be 8.0% (CI 5.8% to 10.3%) and that of Impaired Glucose tolerance at 7.0% (CI 4.9% to 9.1%). Lastly the study by Mollentze, Moore, Steyn et.al. [11] reports the prevalence in two populations to be 4.8% (Rural population of QuaQua) and 6.0% (urban population of Mangaung).

The prevalence of diabetes in the rest of Africa is uncertain but studies done between 1958 and 1989 at various places in Africa reported figures between 0.1 and 3.8% of the population.[12] The most recent study (2000) on the prevalence of diabetes in Africa is that of Aspray et.al. [13] who reports the prevalence in rural and urban communities in Tanzania. The crude prevalence for the rural community was 1.5% (SD 0.6) and for the urban population 5.3% (SD 1.2) for men. Females had a slightly lower crude prevalence with 1.1% (SD 0.5) and 4.0% (SD 0.9) for the rural and urban populations respectively. The prevalence of diabetes is expected to rise in the order of 170% in developing countries of most of Africa forms part, mostly due to population ageing, unhealthy diets and obesity. [14]

Morbidity and Mortality of Diabetes in South Africa

Diabetes is not just common in SA but also contributes to extreme morbidity and carries a heavy mortality burden. Kalk, Pick and Sayed [15] estimated that diabetes in women accounted for 18,2% of deaths in Asians, 7,1% in coloured patients, 4,3% in blacks and 3,0% in whites.

Most of this mortality occurred in middle age. Amongst men mortality in black, coloured and white populations are 2,0 –2,5% but amongst Asians 4,9%.

In Africa, although information is limited, the prognosis for patients with diabetes seems grave. This was demonstrated in a large study done in Dar es Salaam [16] reported in 1990 where the five year survival rate of diabetic patients was only 71%. The author of this study concluded that diabetes in sub-Sahara Africa is, in many patients, a serious disease with a poor prognosis and that more effort is needed to increase public awareness, improve patient detection, management and follow-up.

Diabetes doesn't only contribute to mortality but also to morbidity, as demonstrated by a study done amongst black Africans attending public sector clinics in Cape Town. In this study retinopathy (any grade) was present in 55,4% of patients with 15,6% proliferative or pre-proliferative. Further more 7,9% of patients had cataracts, 27,6% had peripheral neuropathy, 8,2% had absent foot pulses, 1,4% had amputations, 5,3% had persistent proteinuria and 36,7% had an elevated albumin-creatinine ratio. [3]

The economic impact of Diabetes

The management of diabetes is primarily preventive. The aim of treatment is to prevent complications. Complications contribute to a significant proportion of hospitalisations and loss of man-hours. This also places a heavy burden on health and welfare services.

In a Tanzanian study by Chale et. Al. [17] they conclude, "Diabetes places a severe strain on the limited resources of developing countries. If African patients with diabetes have to pay for their treatment most will be unable to do so and will die."

If diabetes is treated, there are clear indications that proper management with an appropriate and effective program improve the quality of life and reduce the cost of healthcare needed by diabetic patients. [18]

In the South African government sponsored hospital sector the average cost of outpatient management of diabetes (excluding salaries of healthcare workers and clinic facilities), according to an unpublished audit done at Kalafong hospital during 2002, amounted to R 1050.00 per patient per year. [19]

Can the chronic complications of diabetes be prevented – Is it worth the effort?

Numerous studies indicate that good glycaemic and hypertension control in both types of diabetes leads to a decrease in microvascular and macrovascular complications. Thus good control can reduce the morbidity and mortality in diabetic patients. [20, 21, 22]

The current Quality of care

There is very little information available on quality of care in clinics and hospitals in South Africa, although the impression is that the care in general is poorer than advised in the current guidelines. According to an audit done in four community health centres in the Western Cape the guidelines for the management of diabetes and hypertension were not systematically implemented although it was available in these clinics. [20]

In a South African audit of primary diabetes care in the public sector of Cape Town a poor quality of care; together with a high prevalence of sub optimal glycaemic and blood pressure control was recorded. Diabetic complications remained largely unrecorded. [3]

Poor quality of care seems to be a worldwide problem, of which the following are examples:

Audit of care in a large urban hospital in the USA indicated that service rendered at different levels (within the same hospital) of care varies: HbA1c tests was done in 76% to 94% of patients annually with 31% to 43% of patients with HbA1c levels higher than 9.5% (highest risk category) and only 24% to 30% of patients with HbA1c of less than 7%. Process measures looked for, also have a large variation according to who delivers

the service: Endocrinologist supervised diabetes care in a well structured diabetes clinic seeing only diabetic patients consistently performed better than internal medicine clinics taking care not exclusively of diabetic patients. Ninety seven percent, 64% and 79% of patients seen in the dedicated diabetes clinic, supervised by endocrinologists, had a annual foot, dilated eye and nephropathy assessment compared to 55%, 50% and 67% respectively for the internal medicine clinic.[25]

Three studies illustrate the quality of diabetes care delivery to health care insured patients in the USA clearly, and is summarised in table 1.1. What is clearly to be noted is the number of annual visits to the health care provider, but in some instances still poor delivery of certain essential interventions or investigations.

Table 1.1: Comparison of three audits of insured healthcare delivery to diabetic patients in the USA. * Advised annually, reported of percentage of patients who received the intervention

Parameter of care	Srinivasan et. al. [25]	Arday et. al. [26]	Edelman et. al. [27]
Number of clinic visits	8 ± 5 (mean, SD)	15.7 (mean)	14 (median)
HbA1c (≥ 1x per year)*	70%	67.8%	98%
Urine test for microalbuminuria*	57%	-	34%
Lipid profile*	41%	56.8%	87%
Eye examination*	-	68.3%	74%
Foot examination*	37%	-	90%

Chin MH et. al. [28] assessed the quality of diabetes care in Midwestern community health centres (USA) and came to the conclusion that rates of adherence to process measures of quality were relatively low compared to targets established by the American Diabetes Association.

Among minority groups and lower socio-economic groups in the USA the quality of care are demonstrated in table1.2.

Table 1.2: ***Quality of care parameters in minority groups and low socio-economic groups in the USA. * Advised annually, reported as percentage of patients who received the intervention. ** Total cholesterol only.***

Parameter of care	American Indians [29]	Uninsured Rural patients [30]	Alaskan Natives [31]
HbA1c (≥ 1x per year)*	79.6%	88%	-
Urine test for microalbuminuria*	23%	62%	-
Lipid profile*	85%**	68.3%	
Eye examination*	55%	20.4%	56.5%
Foot examination*	61%	80.3%	62.8%

Models of Diabetes Care

Ovhed [32] described and compared two different team models of delivering diabetes care in the primary health care setting of suburban and rural Sweden. Care of each model was assessed by analysing patient records as well as conducting a structured telephone interview of all diabetic patients. The two models were compared with regards to the quality of care, frequency of diabetic patient consultations, patient knowledge of their disease and patient self-management. Care in the first model is scheduled to three nurse visits and one general practitioner visit per year. An agreed checklist was to be followed at each visit, which considered the different quality criteria. In this way the local guidelines were implemented.

The second model the care of diabetic patients were not formalised and checklists were not used. Diabetic patients were scheduled to see the general practitioner twice every year. Nurses acted as assistants to the doctors and only saw the patient if referred to them by the doctor for a patient specific need. A clear difference in the two models was observed when audited, glycaemic control was significantly better in the first model (HbA1c: 6.9 ± 1.6 and 7.7 ± 2.0 for model 1 and 2 respectively). Process measures for the two models clearly differ, with the more structured, guideline based consultation schedule, being clearly better (table 1.3).

Table1.3: ***Percentage of patients who received process measures annually***

Process Measure	Model 1	Model 2
HbA1c test	97%	36%
Total cholesterol	51%	11%
Serum triglyserides	49%	3%
Fundus photograph	73%	47%

A structured consultation schedule based on diabetes care guidelines can significantly improve the quality of care as well as improve glycaemic control in general practices and clinics rendering service to diabetic patients.

Measures of Ideal care

Diabetes associations worldwide publish guidelines and position statements in assisting physicians and other health care providers in rendering a minimum standard of diabetes care. Examples of such guidelines are:

- SEMDSA guidelines for management of type 2 diabetes. [33]
- American Diabetes Association Clinical practice recommendations (published annually). [34]

The ideal care would follow one of these guidelines; local guidelines are preferable since they are adjusted for local circumstances and health care policies.

Characteristics of good quality of diabetes care

Campbell et. al.[35] studied 60 general practices in England in an attempt to identify predictors of high quality of care of chronic diseases. High quality of care was strongly related to the duration of routine consultations, the size of the practice (larger practices tend to deliver better diabetes care), location of the practice (preventative care was worse in practices in low socio-economic areas) and lastly practices with a good team climate delivered a higher level of care.

Continuity and service provided to the patient by his or her usual provider at least once a year was associated with a better quality of care, as reported by patients with diabetes type 2, in a survey done in Texas. [36]

How to assess quality of care?

In assessing quality of care the first essential step is to set criteria against which the quality will be measured. [22, 23] In our hospital this measure is the SEMDSA clinical practice guidelines for type 2 diabetes. [33]
Two aspects could be measured: [37]

(a) Professional quality outcome: whether the service correctly meets the professionally assessed needs of its patients (outcome measures).

(b) Professional quality process: whether the service correctly selects and carries out the techniques and procedures which professionals believe will meet the needs of patients (process measures).

All the activities of assessment depend on the availability of appropriate and accurate information with regards to the outcome and process measures under investigation.

The most important source of information is the clinical records but these have obvious shortcomings, namely: They are frequently incomplete and the information frequently inaccurate with errors in diagnostic testing, clinical observation, clinical assessment, recording and coding. [38]
Luck et al. [39] did a prospective study, evaluating the validity of chart abstraction by directly comparing it to reports of patients, and concluded that chart abstraction underestimates the quality of care for common outpatient general medical conditions. Other ways to enhance the value of clinical record is to reassess laboratory results, X-rays etc. as well as by interviews with or questionnaires to practitioners and patients. [38]

Hospital admission and readmission rates might be a useful method to assess the quality of care and gives an indication of patient education, pre-discharge assessment and aftercare. Benbassat and Taragin [40] evaluated the validity of the above assumption and found that readmission rates are not a useful indicator of patient care and that most readmissions are due to patient factors and frailty.

Thus a few ways to assess the professional quality process is:

(a) Audit of Medical records. [41, 42, 43, 44, 45]

(b) Interviewing of patient. [46, 47, 42]

(c) Re-evaluation of laboratory results, X rays, ECG etc. [48]

(d) Evaluating patient admission and re-admission rates.[46]

Currently all the methods for assessment of professional quality are flawed in one way or another.

How to improve quality of professional care

Oxman and Thomson et al [49] conducted a systematic review of 102 trials of interventions with the aim of improving professional practice quality. The following types of interventions were assessed:

(a) Educational materials: Distribution of published or printed guidelines and recommendations for clinical care, audiovisual material and electronic publications.

(b) Conferences: Participation of health care providers in conferences, lectures, workshop etc. outside their practice settings.

(c) Outreach visits: Visit of a trained person to meet with health care providers in their practice settings to provide information and advice.

(d) Local opinion leaders: Use of provider's explicitly nominated by their colleagues to be educationally influential.

(e) Patient mediated interventions: Interventions aimed at patients e.g. Education, counselling and clinical information to make health care providers aware of expected care.

(f) Audit and feedback: Any summary of clinical performance of health care workers over a period of time, with or without recommendations for clinical action. This information may have been obtained from clinical records, databases, patients or observation.

(g) Reminders: Any intervention that prompts the health care worker to perform a clinical action.

(h) Marketing: Personal interviewing, group discussion or a survey of targeted providers to identify barriers to change.

(i) Multifaceted process: Inclusion of clinic doctors and other health care providers in discussions to ensure that consensus is reached on the appropriate management of a chosen clinical problem.

Of all these interventions none provides a magic cure for improving the quality of professional practice but all of them may, in the appropriate setting, be useful tools to improve professional practice and patient outcomes.

Motivation and Aim of the Study

Diabetes is a significant problem with a need for preventative measures to counteract and delay complications, which lead to enormous morbidity (with loss of quality of life) and mortality.

All strategies for prevention are labour intensive and should be maintained for life for each diabetic patient. Since diabetic complications develop insidiously health care providers tend to fail in their persistent vigilance for the development of complications as well as continuous patient assessment and education. It is therefore important to continually educate and motivate health care personnel in order to render a high level of health care.

The diabetic clinic should also be structured to optimally support health care, with a protocol for patient care and education.[42]

This study aims to measure the effect of a physician education program as well as a structured consultation schedule at a tertiary care diabetes clinic.

Chapter 2
Hypothesis and Methods

Summary of study methods

This is a Quasi-experimental study with a controlled before and after design, comparing two clinics with similar characteristics. Both clinics were initially audited in a cross sectional way to acquire baseline data on quality of patient care. The average consultation time was measured at the same time at baseline. A structured consultation schedule and a physician education program were introduced in one of the clinics. A second audit, at the end of the one-year intervention period was done to determine the efficacy of the intervention.

Aim of the study

To measure the efficacy of a physician education program and a structured consultation schedule to improve the quality of diabetes patient care at Kalafong hospital.

Study Question

Does the introduction of a structured consultation schedule and a physician education program improve the quality of diabetes care at Kalafong Diabetes clinic?

Hypothesis

1. A structured consultation schedule and a physician education program will improve the quality of diabetes care at Kalafong hospital diabetes clinics.

2. A structured consultation schedule does not significantly prolong consultation time.

Study design

This is a Quasi-experimental study with a controlled before and after design.

Setting

Two diabetes clinics at one tertiary care hospital.

Comparators

The quality of patient care delivered by physicians taking care of diabetic patients in two diabetic clinics was compared to each other. The clinics take place on Wednesdays and Fridays respectively and use the same premises and nursing staff. A consultant physician, one registrar and two medical officers run each of these clinics, and were not allowed to cross over to the other clinic during the study period. Each clinic deliver services to their own patients, and patients are not allowed to move to the other clinic unless on special request of the patient. The two clinics were very similar to each other with regards to patient characteristics and delivery of patient care at baseline, and can therefore be compared to each other.

Selection process

The Wednesday diabetes clinic was selected as intervention clinic and the Friday clinic as control clinic. From each clinic a sample of patients were selected randomly to evaluate the interventions on the intervention and control clinics.

Audit and Intervention

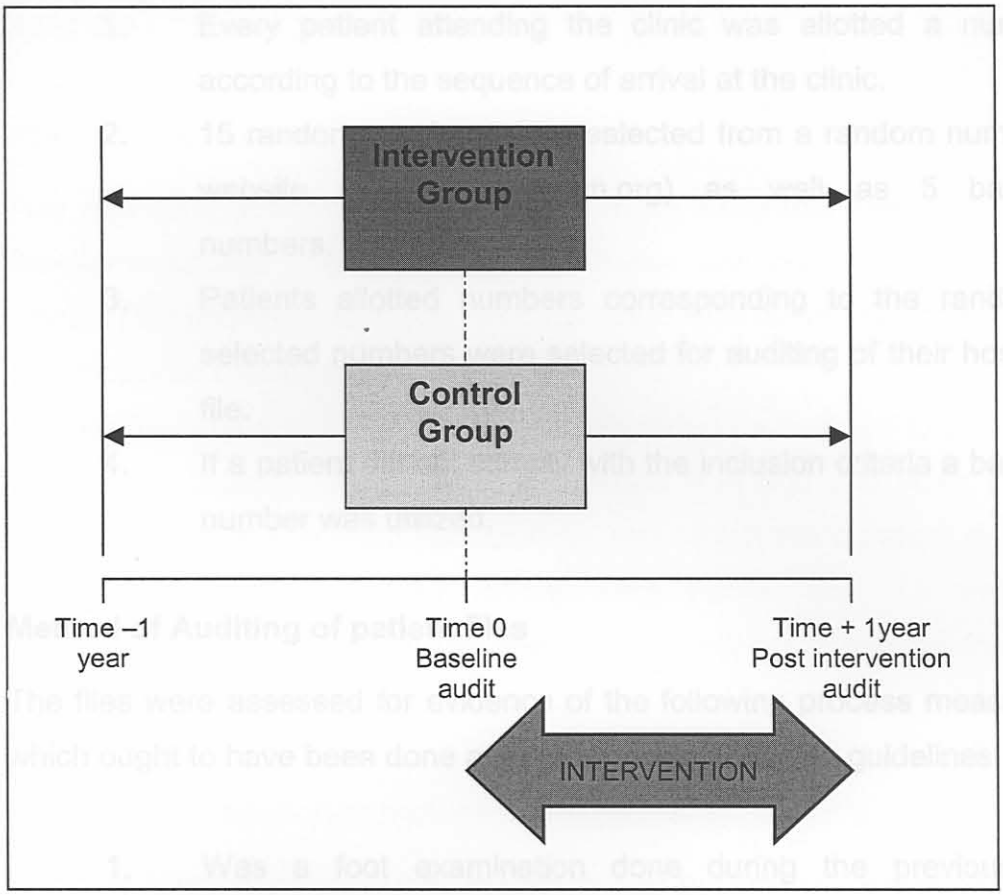
1. Audit of clinical records of diabetic patients attending the Kalafong diabetic clinics, the Wednesday (intervention) and the Friday (control) clinics, done at baseline before the introduction of the intervention. Notes made in every patient's record file during the 12 months before enrolment were audited at baseline.
2. Measuring consultation time per patient for both the intervention and control groups at baseline.
3. Introduction of the intervention, which included a structured consultation schedule as well as a training program for physicians attending to diabetic patients in the Wednesday (intervention) clinic. This was continued for a one-year period.
4. A second audit of clinical records of both Wednesday (intervention group) and Friday (control group) diabetic clinic patients, 12 months after the first audit, to assess the efficacy of the structured consultation changes and the education program.
5. During each 3 months of this study a measurement of the time spent per patient consultation was done for both the Wednesday and Friday clinics (intervention and control groups).

Audit of files

This was done on 2 occasions, at the beginning of the study (baseline audit) as well at the end of 1 year (post-intervention audit). This was done to compare and assess if patient care improved or not.

An independent physician with knowledge of diabetes audited 150 files of diabetic patients of both the Wednesday (intervention) and Friday (control) clinics. These files were randomly selected for audit.

Figure 2.1: *Schematic representation of the study design*



Selection of files for auditing

Inclusion criteria for patient files to be selected for audit was:

1. Duration of diabetes more than 1 year
2. Attending the Kalafong diabetes clinic for 1 year or longer or
3. 4 or more clinic visits at Kalafong diabetes clinic
4. Patients voluntary consent obtained that his or her hospital file data may be used anonymously

Exclusion criteria for selection of patient files for audit were:

1. Duration of diabetes less than 1 year
2. Less than 4 previous clinic visits at Kalafong diabetes clinic
3. New patients to a Kalafong diabetes clinic, or a patient of one of these clinics for less than 1 year
4. No consent given for audit of patient file

Randomisation was executed as follows:

1. Every patient attending the clinic was allotted a number according to the sequence of arrival at the clinic.
2. 15 random numbers were selected from a random numbers website (http//www.random.org) as well as 5 backup numbers.
3. Patients allotted numbers corresponding to the randomly selected numbers were selected for auditing of their hospital file.
4. If a patient did not comply with the inclusion criteria a backup number was utilized.

Method of Auditing of patient files

The files were assessed for evidence of the following process measures, which ought to have been done according to the SEMDSA guidelines:

1. Was a foot examination done during the previous 12 months?
2. Were the eyes examined, or was the patient sent for ophthalmologic assessment during the previous 12 months?
3. Was the patient's urine assessed for micro-albuminuria during the previous 12 months?
4. Was the patient sent for dietary counselling during the past 12 months?
5. Was an HbA1c done during the past 12 months?
6. Was a Lipid profile done during the past 12 months?

In addition the following were also noted from the files:

1. Admissions to hospital wards during the previous 12 months and the reasons therefore.
2. Number of clinic visits during the past 12 months.
3. The patient's current therapy: oral/ Insulin/ combination.

All this data were collected on a precompiled data collection form (see addendum 1)

Assessment of average consultation time

This was done at baseline and repeated every 3 months. Timing of these assessments was changed to include busier and quieter times of the month. This allowed evaluation of consultation time during each section of the structured consultation schedule.
An average time spent per patient was calculated for both the intervention and control groups. The physicians recorded start and end times at the beginning and end of each consultation from which the duration of each consultation were calculated. These were pooled and the average consultation time determined for the doctors working in the Wednesday (intervention) and Friday (control) clinics.

Structured consultation schedule and physician training program

Both the training program and the structured patient care schedule were based on the SEMDSA Guidelines for the management of type two Diabetes (the latest South African guidelines at the start of this study). [33]
All procedures and special investigations planned for this study were according to these clinical practice guidelines.

An interactive training program was introduced for all doctors working in the Intervention Diabetes clinic (Wednesday). This consisted of regular sessions for the mentioned doctors. None of these sessions were compulsory, but it was stated that doctors working in the intervention diabetes clinic would strongly benefit from these sessions.
These sessions included theoretical knowledge transfer as well as a practical approach towards diabetes care.

Topics included the following:

1. Glycaemic control in type 1 and type 2 diabetes.
2. Diabetic foot problems, prevention and diagnosis.

3. Diabetic eye problems, spectrum, diagnosis and prevention.
4. Macrovascular disease in diabetics, spectrum and how to reduce the risk
5. Dietary advice for diabetics.
6. Risk and management of micro-albuminuria.
7. Educating the diabetic

A change was instituted at the diabetic clinic, from the previously totally independent approach (where each doctor saw patients without constraint, and himself decided on examinations and special investigations) to a more structured approach.

This structured approach aimed to make the care more homogeneous.

Each patient was scheduled to attend the clinic quarterly. Every 3 months a different focus was set.

First quarterly visit
1. Proper foot examination
2. Education on foot care
3. HbA1c

Second quarterly visit:
1. Dietician consultation
2. Advice on medication use
3. BMI calculation
4. Evaluation of Cardiovascular risk factors and advice.

Third quarterly visit:
1. Urine Albumin: Creatinine ratio
2. Serum Urea, Creatinine and Electrolytes, Lipid profile and HbA1C

Fourth quarterly visit:
1. Eye assessment or referral to eye clinic
2. ECG

A new more user-friendly diabetes patient record form was introduced to structure the consultation. (See addendum 2)

Data management

All audit data was captured on a form designed on Microsoft Access; this program was also used to produce a data spreadsheet. All data cleaning and editing was done in Excel; thereafter data was transferred to SPSS statistical computer package, for analysis.

Statistical analysis

For comparison of the number of clinic visits and number of hospitalisations, between the study and control groups the Mann Whitney and Wilcoxon non-parametric test were used.

For comparison of variables with nominal frequencies Chi-square tests were done.

A score was compiled for each patient from the process measures the patient received. One point was awarded for each of the six process measures. The scores were analysed with the repeated measures ANOVA test.

The consultation times at different episodes were compared between the intervention and control groups as well as in relation to baseline for which an ANOVA test was used.

Continuous data done repeatedly on the same subjects was compared utilizing the repeated measures ANOVA test.

An α level of <0.05 was considered significant for all statistical interferences.

Time schedule

January 2002:	Baseline audit on hospital records of selected subjects from both the intervention and control groups.
	Initiation of the physician education program.
	Baseline assessment of time per consultation.

	Motivation and Information session for clinic staff and physicians.
February 2002:	Introduction of structured consultation schedule. Started with part 1 of the consultation schedule.
March 2002:	First assessment of time per consultation. Second part of physician education program.
May 2002:	Started with part 2 of structured consultation schedule.
June 2002:	Second assessment of time per consultation. Third part of physician education program
August 2002:	Started with part 3 of the structured consultation schedule.
September 2002:	Third assessment of time spent per consultation. Part 4 of physician education program.
November 2002:	Started with part 4 of the structured consultation schedule.
January 2003:	Fourth assessment of time spent per consultation.
February 2003:	Second audit of patient records.
April 2003:	Data analysis.
May 2003:	Preparation of dissertation.
June 2003:	Preparation of publication.
April 2004:	Presentation of results at SEMDSA congress

Ethical aspects

The protocol for this study was presented for assessment and approval to the Ethics committee of the Faculty of Human Health Sciences of the University of Pretoria. (Protocol number: 196/2001)

No Doctor's notes were audited prior to written informed consent was obtained from participating patients (See addendum 3) and doctors (See addendum 4).

All participating doctors and patients participated out of free will and without additional remuneration.

With regards to patients:

1. All patients received at least the same care than that provided before the start of the study.
2. All patients attending the Wednesday clinic (whether their hospital records were audited or not) was managed according to the structured consultation schedule.
3. Patient data utilized as process and outcome measures was and will remain to be treated anonymously.
4. If it becomes clear after the study that the care given to patients attending the Wednesday clinic is better than that in the Friday clinic, the structured consultation schedule and physician education program will be introduced in the Friday clinic and continued in the Wednesday clinic.

Chapter 3
Results of Study

Introduction

The results of this study will be reported in the following sequence. Firstly patient selection will be discussed; thereafter the demographic characteristics will be reported. Process measures will then be reported with comparison between the intervention and control clinics as well as comparison between baseline (audit 1) and post intervention (audit 2) data. Then reporting of outcome measures will follow; again the comparison between intervention and control clinics will be done first, with comparison between baseline audit and post intervention audit thereafter. Lastly issues with regards to changes in consultation time will be reported.

Patient selection for intervention and control clinics

305 patients were approached for inclusion to the study of which 150 were usually attending the Wednesday diabetes clinic (Intervention clinic) and 155 attending the Friday diabetes clinic (control clinic). Of these patients 5 were excluded from the study for not complying with the inclusion criteria, of which four attended the Wednesday, and one the Friday clinics respectively.

Patients enrolled in Wednesday clinic	
Patients randomly selected in the Wednesday clinic:	150
Wrongly classified as Wednesday clinic patient who were Friday clinic patients:	7**
Wrongly classified as Wednesday clinic patient who were following up for diabetes at another clinic:	2*
No consent (refused)	1*
No consent (mental retardation)	1*

** Excluded from study*

*** Evaluated in Friday clinic group*

Patients enrolled in the Friday clinic

Patients randomly selected in the Friday clinic:	155
Wrongly classified as Friday clinic patient who were Wednesday clinic patients:	2**
Patients not fulfilling inclusion criteria (diabetes for less than 1 year)	1*

* *Excluded from study*

** *Evaluated in Wednesday clinic group*

Five patients died during the study period, three from the intervention group and two from the control group (p = 0.44). These subjects remained included in the study for analysis.

Patient demographics

At baseline there were no statistically significant differences between the intervention and control clinics with regards to patient demographics. (Table 3.1)

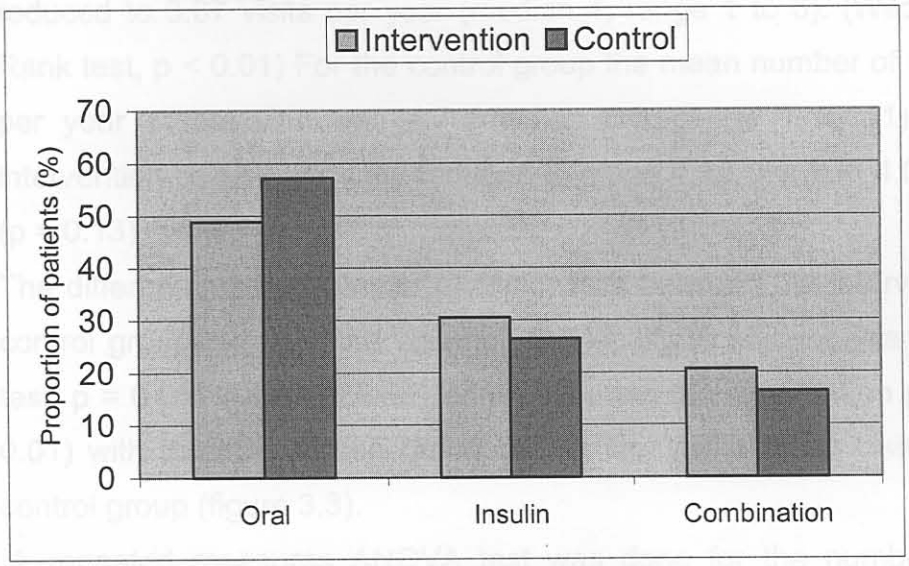
Table 3.1: ***Patient demographics for the intervention and control groups at baseline***

Variable	Intervention n (%)	Control n (%)	p
n	141 (47)	159 (53)	
Treatment: Oral	69 (48.9)	91 (57.2)	
Insulin	43 (30.5)	42 (26.4)	0.35
Combination	29 (20.6)	26 (16.4)	
Gender: Male	52 (36.8)	57 (35.8)	0.67
	Mean (SD)	Mean (SD)	
Age	56.38 (13.00)	54.72 (14.46)	0.30
Duration of Diabetes	10.36 (7.47)	9.82 (7.72)	0.54

Treatment: The majority of patients in both the intervention and control groups were on oral treatment although a significant proportion of patients were receiving Insulin. (Table 3.1, figure 3.1) Combination therapy refers

to patients receiving both oral therapy and Insulin injections. The proportions of patients receiving oral, insulin or combination therapy within the two groups did not differ significantly (p = 0.35).

Figure 3.1: ***Treatment distribution at baseline for the intervention and control groups***



Age: The age in the two groups were normally distributed, and the means did not differ significantly (table 3.1). (p = 0.30)

Gender: The majority of patients in both groups were female (table 3.1). The Chi^2 test confirms that the proportion Male to Female in the two groups does not differ significantly. (p = 0.67)

Duration of Diabetes: The mean duration of diabetes between the intervention and control groups did not differ significantly (table 3.1) (p = 0.54). Duration of diabetes approaches a normal distribution for both groups.

In conclusion: with regards to baseline demographics the intervention and control groups did not differ significantly. The two groups can therefore be compared.

Process measures

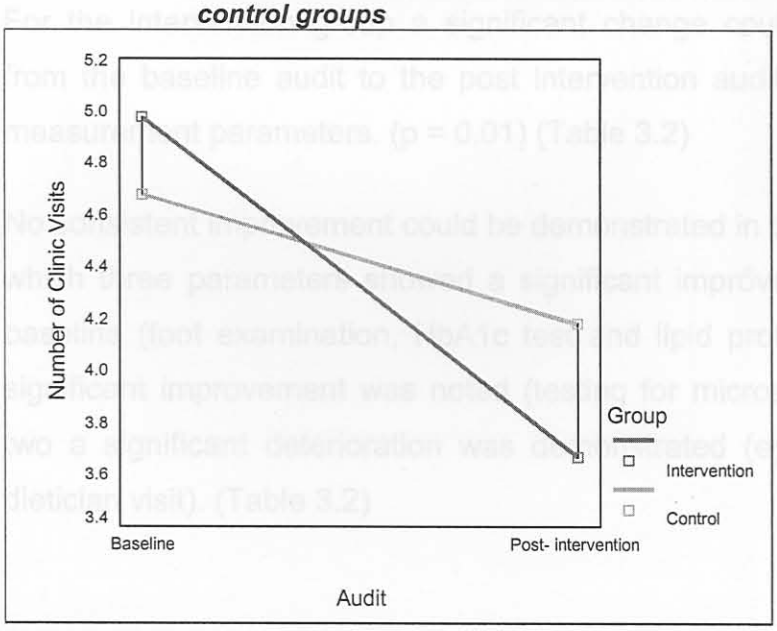
Clinic visits

The mean number of clinic visits for the intervention group at baseline was 4.97 per year (median 5.00, range 1 to 9), after the intervention it was reduced to 3.67 visits per year (median 4, range 1 to 6). (Wilcoxon Sign Rank test, $p < 0.01$) For the control group the mean number of clinic visits per year at baseline was 4.7 (median 5.0, range 1 to 11) and post intervention non-significantly reduced to mean 4.18 (median 4.00, 1 to 9). ($p = 0.13$)

The difference in the number of clinic visits between the intervention and control groups at baseline was not statistically significant (Mann-Whitney test, $p = 0.05$) but was clearly different during the intervention period ($p < 0.01$) with the intervention group having significant fewer visits than the control group (figure 3.3).

A repeated measures ANOVA test was done for the number of clinic visits, at baseline and post-intervention, between the intervention and control groups. This indicated a significant change in the number of clinic visits over time between the two groups ($p < 0.01$, with Huynh-Feldt correction) (figure 3.2).

Figure 3.2: ***Profile plot indicating the relationship of the number of clinic visits between baseline and post intervention audits for intervention and control groups***



Other process measures (Nominal)

With the pre-intervention audit a significant difference was noted in the proportion of patients who received foot examinations, HbA1c tests and dietician visits (p values respectively 0.01, <0.01 and 0.02). For all the parameters neither the intervention nor the control group were consistently better than the other at baseline (table 3.2).

Post intervention a clear difference could be demonstrated between the intervention and control groups with the intervention group consistently significantly better than the control group (Chi^2 test for all six process measures $p < 0.01$) (Table 3.2).

Table3.2: ***Comparison of process measures at baseline and post intervention for the intervention and control groups***

Parameter	Intervention N=141 (%)			Control N=159 (%)		
	Baseline	Post-intervention	p	Baseline	Post-intervention	p
Foot examination	33 (23.4)	126 (89.4)	<0.01	58 (36.5)	78 (49.1)	0.04
Eye examination	45 (31.9)	99 (70.2)	<0.01	63 (39.6)	32 (20.1)	<0.01
Test for microalbuminuria	20 (14.2)	103 (73)	<0.01	15 (9.4)	24 (15.1)	0.16
HbA1c test	91 (65.5)	133 (94.3)	<0.01	66 (41.5)	114 (71.7)	<0.01
Lipid profile	29 (20.6)	99 (70.2)	<0.01	24 (15.1)	54 (34)	<0.01
Dietician visit	28 (19.8)	89 (63.1)	<0.01	51 (32.1)	22 (13.8)	<0.01
	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	
Score	1.745 (1.533)	4.603 (1.478)	<0.01	1.742 (1.592)	2.038 (1.382)	0.08

For the intervention group a significant change could be demonstrated from the baseline audit to the post intervention audit for all the process measurement parameters. (p = 0.01) (Table 3.2)

No consistent improvement could be demonstrated in the control group, for which three parameters showed a significant improvement comparing to baseline (foot examination, HbA1c test and lipid profile), for one a non-significant improvement was noted (testing for microalbuminuria) and for two a significant deterioration was demonstrated (eye examination and dietician visit). (Table 3.2)

Score of process measures

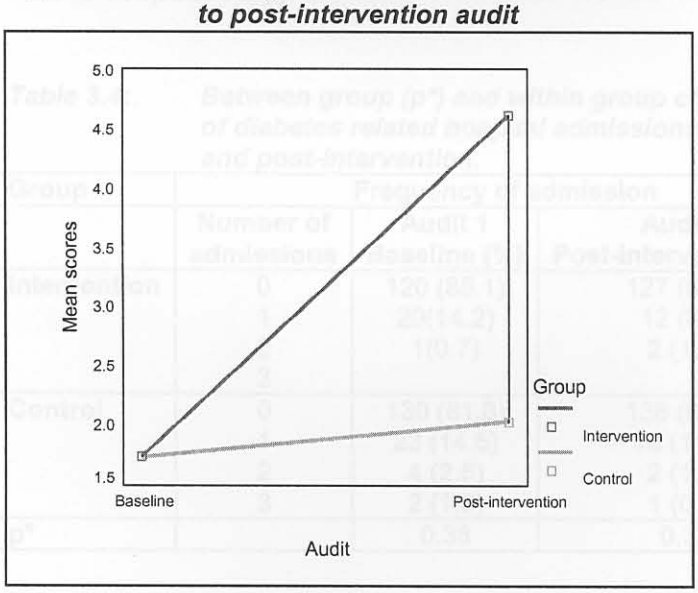
A score of the process measures was derived for each patient. One point was given to each of the process measures the patient received. (Six process measures, maximum score therefore six.)

At baseline no statistical difference could be demonstrated between the intervention and control groups ($p = 0.30$). After the intervention the intervention group scored clearly better than the control group. ($p < 0.01$) (Table 3.2)

Both the intervention and control groups showed an improvement from baseline at the post-intervention audit but only that of the intervention group was statistically significant (Intervention: $p < 0.01$, control: $p = 0.08$) (table 3.2).

A repeated measures ANOVA test indicated a significant change in scores between the two groups over time ($p = 0.000$, with Huynh-Feldt correction) (figure 3.3).

Figure 3.3: ***Change in mean scores from the baseline to post-intervention audit***



Hospital admissions

The total hospital admissions (diabetes related and not related to diabetes) (table 3.3) were not significantly different for the intervention group before and during the intervention. The control group on the contrary showed significantly less admissions during the intervention period (p = 0.02).

Table 3.3: ***Within group comparison of hospital admissions (All admissions, diabetes related and non-related) for the intervention and control groups***

Group	Frequency of admission			p
	Number of admissions	Audit 1 Baseline (%)	Audit 2 Post-intervention (%)	
Intervention	0	113 (80)	119 (84.4)	0.63
	1	21 (14.9)	14 (9.9)	
	2	6 (4.3)	5 (3.5)	
	3	1 (0.7)	0	
	4	0	1 (0.7)	
	5	0	1 (0.7)	
Control	0	113 (71.1)	130 (81.8)	0.02
	1	35 (22)	22 (13.8)	
	2	7 (4.4)	2 (1.25)	
	3	4 (2.5)	2 (1.25)	
	4	0	1 (0.6)	

For diabetes related admissions both the intervention and control groups showed a non-significant change from baseline (Table 3.4) (p = 0.35 and p = 0.18 respectively).

Table 3.4: ***Between group (p*) and within group comparison ($p^{\#}$) of diabetes related hospital admissions at baseline and post-intervention.***

Group	Frequency of admission			$P^{\#}$
	Number of admissions	Audit 1 Baseline (%)	Audit 2 Post-intervention (%)	
Intervention	0	120 (85.1)	127 (90.1)	0.330
	1	20(14.2)	12 (8.5)	
	2	1(0.7)	2 (1.4)	
	3			
Control	0	130 (81.8)	138 (86.8)	0.171
	1	23 (14.5)	18 (11.3)	
	2	4 (2.5)	2 (1.3)	
	3	2 (1.3)	1 (0.6)	
p*		0.38	0.38	

The amount of diabetes related hospital admissions between the intervention and control groups did not differ significantly at baseline nor at the post intervention audit (Table 3.4).

In the control group hyperglycaemia was the most common single cause of admission to hospital both at baseline and post-intervention, accounting for 11 (29.7%) and 10 (40%) respectively (p = 1.00). The number of admissions due to hyperglycaemia increased significantly from one to three for the intervention group (p = 0.95). At baseline hypoglycaemia were the most common cause of admission (36.4%) in the intervention group, but post-intervention only one admission were due to hypoglycaemia (p = 0.72) (table 3.5, figure 3.4 and 3.5). while that of the control group decreased non-significantly slightly from 11 to 10 (p = 1.00).

Table 3.5: ***Analysis of diabetes related hospital admissions between the intervention and control groups at baseline and post intervention.***

Reason for admission	**Intervention (% of admissions in group)**			**Control (% of admissions in group)**		
	Baseline	**Post-inter-vention**	**p**	**Baseline**	**Post-inter-vention**	**p**
Hyperglycaemia	1 (4.5)	3 (18.7)	0.95	11 (29.7)	10 (40)	1.00
Hypoglycaemia	8 (36.4)	1 (6.3)	0.72	6 (16.3)	2 (8)	0.86
Complications:						
Acute(hyperglycaemic)	5 (22.7)	2 (12.5)	0.90	9 (24.3)	2 (8)	0.73
Chronic	8 (36.4)	6 (37.5)	0.95	11 (29.7)	11 (44)	0.95

The number of admissions for acute hyperglycaemic complications (Diabetic keto-acidosis and hyperosmolar Non-ketotic diabetic states) declined for both the intervention (p = 0.90) and control groups (p = 0.73) although not significantly.

Of the chronic complications cataract surgery was the most common reason for admission at baseline and post intervention and for both the intervention and control groups.

Figure 3.4: ***Reasons for Diabetes related admissions for the intervention and control groups at Baseline audit***

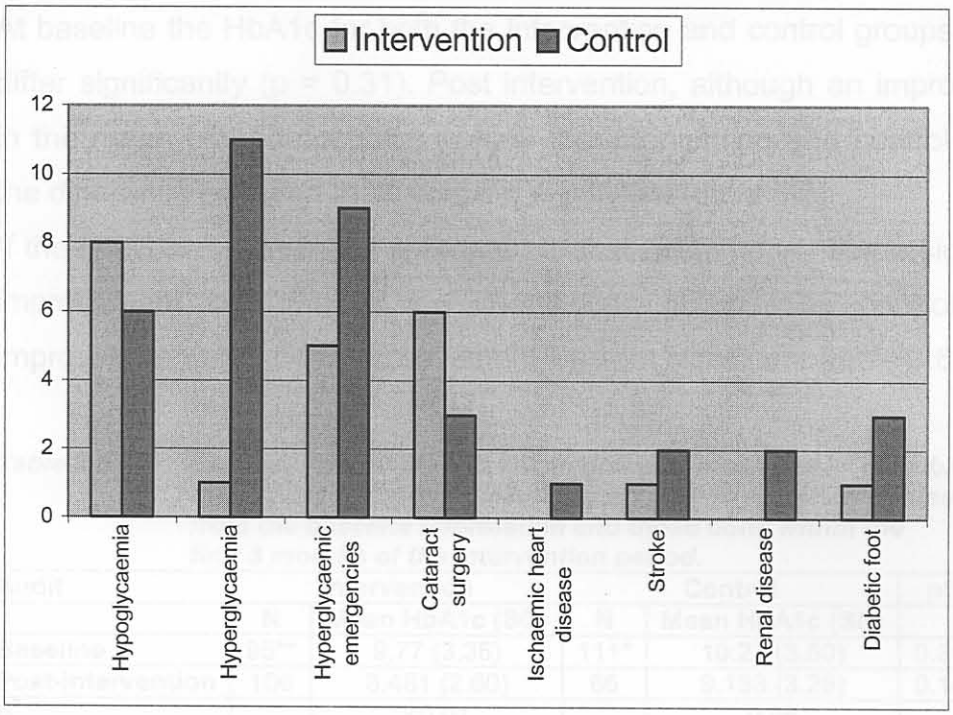
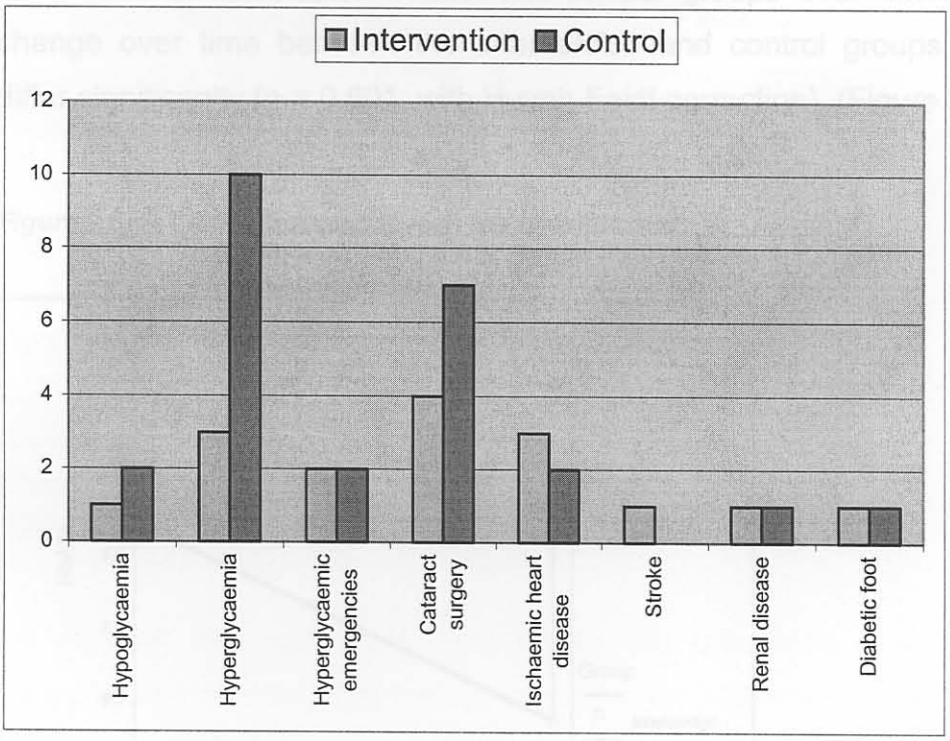


Figure 3.5: ***Reasons for Diabetes related admissions for the intervention and control groups at post-intervention audit***



HbA1c

At baseline the HbA1c for both the intervention and control groups did not differ significantly (p = 0.31). Post intervention, although an improvement in the mean HbA1c occurred in both the intervention and control groups the difference between them was not significant (table 3.6).

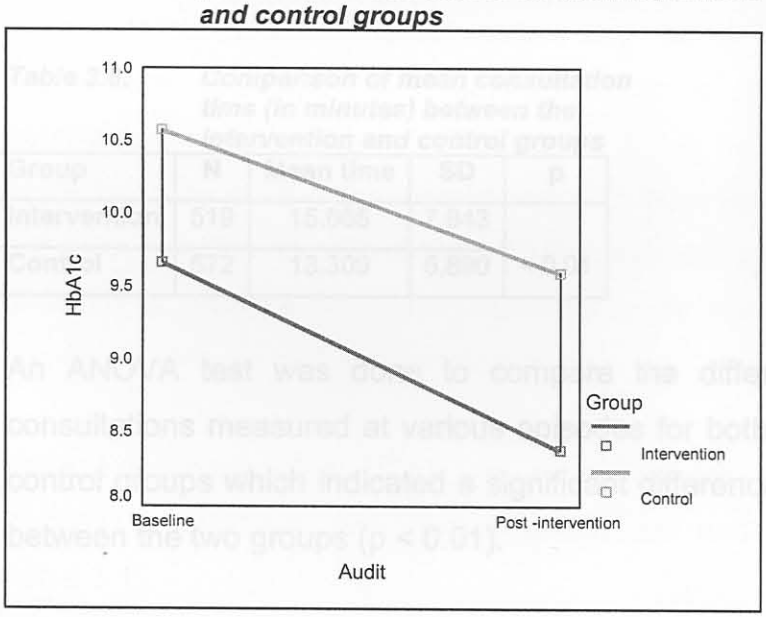
If the HbA1c at baseline is compared to that post-intervention a significant improvement occurred in the intervention group. The control group improved as well but the improvement was not significant (table 3.6).

Table 3.6: ***Between group (p*) and within group comparison (p#) of HbA1c at baseline and post-intervention. ** HbA1c results were used from the baseline information and those done within the first 3 months of the intervention period.***

Audit	Intervention		Control		p*
	N	Mean HbA1c (SD)	N	Mean HbA1c (SD)	
Baseline	95**	9.77 (3.36)	111*	10.27 (3.60)	0.31
Post-intervention	106	8.481 (2.60)	66	9.153 (3.29)	0.14
p#		<0.01		0.06	

A repeated measures ANOVA test was done to assess the change in HbA1c between the intervention and control groups over time. HbA1c change over time between the intervention and control groups did not differ significantly (p = 0.601, with Huynh-Feldt correction). (Figure 3.6)

Figure 3.6: ***Comparison between the baseline and post-intervention HbA1c for the intervention and control groups***



As seen in table 3.7 the proportion of patients with poor glycaemic control reduced in both the intervention and control groups and the proportion of patients with good glycaemic control increased although not statistically significant (p = 0.17 and p = 0.06 respectively). Between the two groups there were no statistically difference at baseline and post-intervention with regards to the proportion of patients with good, moderate and poor glycaemic control (p = 0.73 and p = 0.34 respectively).

Table 3.7: ***Percentage of patients in the intervention and control groups at baseline and post-intervention with poor, moderate and good glycaemic control***

Glycaemic control	HbA1c	Baseline		Post-intervention	
		Intervention	Control	Intervention	Control
Poor control	> 9.5%	47.4	54.1	36.8	39.4
Moderate control	7.5 to 9.49%	20.0	20.7	23.6	22.7
Good control	<7.5%	32.6	25.2	39.6	37.9

Consultation time

The duration of 1092 consultations were documented for the intervention and control clinics combined. This was periodically done at baseline and throughout the intervention period. Consultations were measured at baseline and 4 times during the intervention period for both the intervention and control groups.

The overall average time spent per consultation in the intervention group was significantly longer than that of the control group (table 3.8).

Table 3.8: ***Comparison of mean consultation time (in minutes) between the intervention and control groups***

Group	N	Mean time	SD	p
Intervention	519	15.665	7.943	
Control	572	13.309	5.890	< 0.01

An ANOVA test was done to compare the difference in duration of consultations measured at various episodes for both the intervention and control groups which indicated a significant difference in consultation time between the two groups (p < 0.01).

For the intervention group compared to the time spent per consultation at baseline, the time taken at various episodes throughout the intervention period was consistently longer per consultation ($p < 0.01$, < 0.01, < 0.01 and < 0.01 respectively.) The time spent with the second and third visits were the longest (mean difference of –6.03 and –8.16 minutes from the baseline time respectively).

For the control clinic the mean duration of consultations were also longer than that measured at baseline ($p = 1.00$, < 0.01, < 0.01 and 0.04)

Table 3.9: ***Comparison of the Median time per consultation between the Intervention and control groups at different measurements***

Measurement	Median time (range)		p
	Intervention	Control	
1 (Baseline)	10 (2 – 50)	10 (2 – 35)	0.91
2	17 (8 – 35)	12 (3 – 30)	< 0.01
3	13.5 (5 – 50)	13 (4 – 43)	0.91
4	20 (5 – 52)	15 (5 – 32)	< 0.01
5	14 (4 – 42)	11 (5 – 33)	0.06

Conclusion

Patients from the Wednesday diabetes clinic were selected as the intervention group and that of the Friday clinic as the control group. Doctors attending to the Intervention clinic underwent a diabetes-training program and a structured consultation schedule was introduced in the clinic. The control clinic did not receive any intervention although patients and doctors attending this clinic were informed and their consent was obtained.

At the baseline audit of both the intervention clinic and the control clinic did not differ significantly with regards to demographic parameters, number of clinic visits, process measures, outcome measures (HbA1c and hospital admission rate) as well as consultation time.

Patient demographics: The two groups did not differ significantly with regards to treatment, age, gender distribution and duration of diabetes (table 3.1).

Process measures included: Foot examination
Eye examination
Test for micro-albuminuria
HbA1c test performed
Lipid profile done
Dietician visited

A score derived from these process measures was calculated for each patient who's files were audited at baseline and post-intervention. At baseline the scores did not differ significantly between that of the intervention and control groups (table 3.2). A significant improvement in the score of the intervention group was seen after the mentioned interventions were implemented, compared to baseline and in comparison with the control clinic (table 3.2 and figure 3.3).

Outcome measures: Two parameters were used to measure the difference in outcome between the two groups namely the number of hospital admissions and HbA1c values.

Diabetes related hospital admissions did not differ significantly from baseline and between the groups (table 3.4). A shift in the reason for hospital admissions was seen from the baseline audit at the post-intervention audit. At baseline the most admissions were related to poor glycaemic control and hypoglycaemia while post-intervention most of the admissions were related to chronic diabetes complications (table 3.5).

HbA1c at baseline did not differ significantly between the intervention and control groups (table 3.6). Compared to the baseline HbA1c both the groups showed an improvement although this was not significant for the control group, but the intervention group did improve significantly. The change between the groups over time did not indicate significant improvement (figure 3.6).

Consultation time: Consultation time was measured on 5 occasions, at baseline and 4 times during the intervention period (every 3 months).

The overall consultation time was significantly longer for the intervention group than that of the control group during the intervention period (table 3.8). It seems that the improvement of process measures and the reduction in the number of patient visits accounts to a prolongation in consultation time.

This intervention resulted in a significant improvement of process measures in the patient care of diabetic patients with a reduction in the number of patient visits but at the expense of prolonged consultation time. Glycaemic control improved although not significantly over the duration of the intervention.

Summary of chapter

1. Baseline demographics between the intervention and the control groups did not differ significantly (table 3.1).
2. Clinic visits at baseline did not differ significantly, but a significant reduction in the number of clinic visits was shown in the intervention group comparing to baseline as well as in relation to the control group (figure 3.2).
3. A significant improvement in each of the process measures in relation to baseline and the control group was indicated (Table 3.2).
4. Overall the number of process measures each patient was expected to undergo or receive improved significantly in the intervention group when compared to baseline and to the control group (figure 3.3).
5. Diabetes related hospital admissions did not significantly changed from baseline nor did it differ between the intervention and control groups (tables 3.4).
6. Although the HbA1c improved in both the intervention and control groups, only that of the intervention group improved

significantly from baseline (table 3.6). The difference over time between the two groups was not significant (figure 3.6).

7. Consultation time in the intervention group was significantly longer than that of the control group as well as in comparison to baseline (table 3.7, 3.8).

Chapter 4
Discussion

This Study

This was a physician driven intervention study, investigating the quality of diabetes care at the diabetes clinics of a tertiary care hospital. Quality of care was assessed before and after the implementation of measures aimed at improving the quality of care rendered as well as in comparison with a control group without measures to improve the quality of care.

The care as indicated by certain process measures improved significantly from baseline as well as in comparison with the control group. It thus seems that the intervention, which included a physician-training program and the introduction of a structured consultation schedule, is effective in improving the quality of care delivered to diabetic patients.

This intervention also seems to improve the glycaemic control of patients over time although not statistically significant. Furthermore the proportion of patients with uncontrolled diabetes decreased and the proportion of patients with good glycaemic control increased.

The number of hospital admissions did not significantly reduce but the reasons for admissions did change from more glycaemic control related to more chronic complications related. The non-significant increase in hospital admissions due to hyperglycaemia in the intervention group should be interpreted in the light of the non-significant decrease in admissions due to acute hyperglycaemic complications. This as such is indicative of improved quality of care since better follow up improved the detection of complications and reduce the admission related to poor glycaemic control.

Problems encountered in the care of diabetic patients at Kalafong

Schooling and Literacy

More than one third of patients attending the clinics at Kalafong have schooling of less than four years and are therefore practically illiterate. About 13% of patients are educated to matric and higher. This state of affairs makes patient education more difficult and renders all written diabetes care information much less useful.

Language

Most of the patients attending the diabetes clinics are able to speak English although not their mother tongue. Most of the communication in the clinic is therefore done in English. A few patients are unable to communicate in the languages mastered by the attending doctors in which case the help of a nurse translator is used. The fact that service is not provided in the language patients primarily speak may also hamper the quality of patient education.

Socio-economic factors

Less than 50% of patients attending the clinics have a reliable source of income. More or less 50% of patients are unemployed, and a significant proportion of those who have a reliable income are state pensioners. All the patients come from a socio-economic disadvantaged population, which makes transport to and from the clinic costly and following a diabetic diet very difficult.

Glucometers

The hospital supplies patients with medication for diabetes and hypertension etc. but does not supply any patient with glucometers although test strips are supplied for the odd patient who is in possession of a glucometer. Glucometers are expensive and out of reach of the average

patient attending the clinics, this makes home glucose monitoring impossible with significant implications on glycaemic control.

Issues with regards to the study design

Quasi-experimental studies

Quasi-experimental studies are the most commonly used designs in guideline implementation studies where there are practical and ethical barriers in the conduction of randomised controlled trials. There are three types of quasi-experimental study designs namely: uncontrolled before and after studies, time series designs and controlled before and after studies.[50] Of these the best design is the controlled before and after study design. This study had a controlled before and after design and are therefore limited by the shortcomings of this type of design namely:

1. The study and control groups should have the same baseline characteristics and performance. For this study the intervention and control groups did not differ significantly with regards to baseline characteristics namely: demographical data, the number of clinic visits and consultation time. With regards to outcome and process measures the intervention and control groups did not differ significantly at baseline.
2. All other factors should be the same for both the intervention and control groups except for the intervention under investigation. During this study the nursing staff, and all other facilities remained the same for both the intervention and control groups.
3. Data should be collected at the same time for both groups before and after the intervention. All data was collected for both the intervention and control groups simultaneously at baseline and post-intervention. The same person collected the data at baseline for both groups and pos-intervention for both groups.

4. Between groups analysis should be done comparing the study and control groups following the intervention. This was done for this study and therefore the differences can be assumed to be due to the intervention.

Bias and Confounding

An attempt to reduce bias was made throughout the study.
Firstly the selection of patient files: both the intervention and control groups were randomly selected for record auditing. Thereby preventing the selection of patients with poorer care to be compared to patient with better care in the intervention or control groups. (Selection bias) This is evident in the absence of significant difference between the baseline parameters.

Secondly for the first (baseline) audit the same person audited the patient records for both the intervention and control clinics. The person performing the second audit (post-intervention) was also the same for both the intervention and control groups. Observer bias was therefore limited.

The two groups were kept separate as far as possible. A patient in the intervention clinic was not allowed to change to the control clinic and vice versa. A Few patients who were randomly selected for file audit at baseline came on the wrong clinic day and were therefore analysed in the group where they usually received their diabetes care.

All doctors attending to diabetes patients were blinded to which patients were selected for record auditing. No cross over of any physicians between the two clinics occurred during the study period.

Confounding by the Hawthorne effect (The non-specific beneficial effect of taking part in research) could not be prevented since all doctors taking care of diabetic clinic patients knew that they were studied and signed informed consent in that respect. This might explain why the control clinic,

although to a lesser degree, also showed improvement in the care and outcome measures.

Selection of the intervention and control clinic

The ideal would have been to randomise a number of comparable clinics to both the intervention and control arms of a study, but for this study this ideal was not feasible due to the fact that no comparable clinics could be found. The two Kalafong diabetic clinics compare the best with each other; the only difference between the two clinics was the difference in patient load. Due to the greater patient load in the Wednesday clinic, which made the intervention to improve the quality of care more difficult, the Wednesday clinic was selected to be the intervention clinic. If the proposed intervention were to be successful in the busier Wednesday clinic it would be more generalisable and valid. With regards to staff both the clinics have the same nursing staff. Two medical officers, one registrar and one consultant physician rendered medical care in each of the two clinics.

The Wednesday clinic was used as the intervention group and the Friday clinic as control group. The reason for this was as mentioned that the patient load is higher and an improvement in quality of care would therefore be more meaningful as it would occur despite this limitation (table 4.1).

Table 4.1: ***Number of patients seen at the diabetes (intervention and control) clinics of kalafong hospital during the first six months of the year 2001***

	Jan	Feb	March	April	May	June
Wednesday (intervention clinic)	161	111	124	126	195	121
Friday (control clinic)	124	143	123	155	128	115
Total	285	254	224	281	322	236

Study results in relation to other studies

Process measures

Data from the baseline audit of this study compare very poorly to that of audits related to quality of diabetes patient care elsewhere in the world. (Table 1.1, 1.2, 1.3) But the intervention group after the intervention compare very favourably to the quality of care delivered elsewhere in the world.

What is clearly different from these clinics is the average number of annual patient visits, which markedly exceed that of the two Kalafong diabetes clinics. (Table 1.1)

Outcome Measures

If the proportion of patients with poor glycaemic control in this study (table 3.7) is compared to that of clinics in a large urban hospital in the USA [25], the diabetes clinics of Kalafong at baseline compared poorly to them. After the intervention the local clinics compared much better to their American counterparts.

Shortcomings of this study

With regards to the study design a clustered randomised controlled trial with a number of clinics in each arm would have been better; although the cost, manpower and clinic cooperation would have been difficult to reach with the resources that were available for this study.

A limited number of measures were utilised to assess the quality of diabetes care in the two clinics studied but more outcome measures especially blood pressure and LDL cholesterol could have aided in a more comprehensive assessment of patient outcome.

Other than process measures and outcome measures, measures of patient education received in the diabetes clinics, with regards to diabetes,

would also have been useful in the assessment of comprehensive patient care. This however would be much more difficult to measure.

Questions arising from this study for further study

The first question arising is: How lasting will the effect of this intervention be on the improvement of diabetes care in the intervention group/ clinic?
Secondly, will this intervention improve the quality of care in the neighbouring primary health care clinics?
If the quality of outpatient care can improve, what will happen if a similar intervention is introduced to the management of inpatient diabetic patients?
Fourthly, how did this intervention change the total cost of diabetes care in the clinics?

Conclusion

In conclusion this study succeeded in providing evidence that a structured consultation schedule and a physicians education program improve the quality of diabetes care at a tertiary care diabetes clinic.

Chapter 5
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Addendum 1
Data collection form

DIABETES FILE AUDIT FORM

1. **Clinic Day** | Wednesday | Friday |

2. **Patient No** _____

3. **No of clinic visits during past 12 months.**

1	2	3	4	5	6	7	8	>8

4. **Gender** | Male | Female |

5. ..... Years **Age**

6. **Duration of Diabetes** ..... Years

7. **No admissions during past 12 months.**

0	1	2	3	4

Reasons? _____

_____

_____

8. **Is there any evidence in the patient file that during the past 12 months the patient had?**

(a) A foot examination.

(b) Eye examination (Fundoscopic) or sent to ophthalmology.

(c) A test for microalbuminuria.

(d) A dietitian consultation.

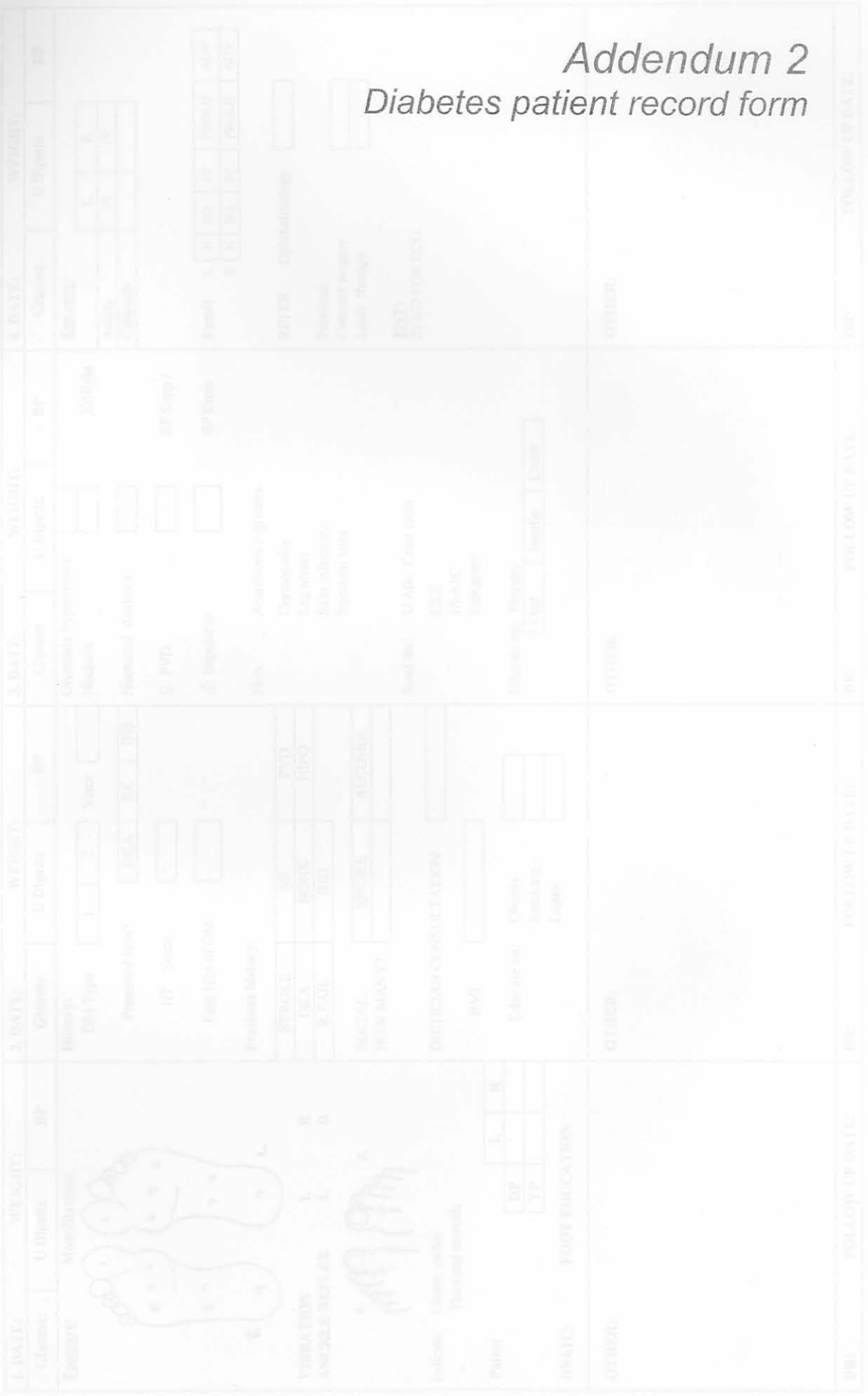
(e) An HbA_1C test.

(f) A fasting Lipogram

9. **Treatment:**

Oral	Insulin	Combination

Addendum 2
Diabetes patient record form



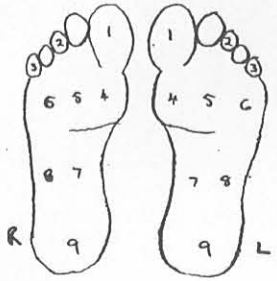
PATIENT: _____ PRESENT/YES = √ ABSENT/NO = X HEIGHT: _____

NO: _____ HOME LANGUAGE _____ AGE (DOB) _____

HIGHEST EDUCATION LEVEL _____

1. DATE:	WEIGHT:	
Glucose:	U Dipstix	BP

Footcare: Monofilament



	L	R
VIBRATION		
ANCKLE REFLEX		

Indicate: Ulcers, callus
Thickend toenails

Pulses	L	R
DP		
TP		

HbA1C: FOOT EDUCATION

OTHER:

DR: FOLLOW UP DATE:

2. DATE:	WEIGHT:	
Glucose	U Dipstix	BP

History:

DM Type: 1 | 2 Since: _____

Presented how? DKA | SX | INS

HT Since: _____

Fam Hist of DM: _____

Previous history:

STROKE	MI	PVD
DKA	HONK	HIPO
R FAIL	IHD	

SOCIAL:	SMOKE	ALCOHOL
HOW MANY?		

DIETICIAN CONSULTATION: _____

BMI: _____

Educate on: Obesity _____
Smoking _____
Liquor _____

OTHER:

DR: FOLLOW UP DATE:

3. DATE:	WEIGHT:	
Glucose	U Dipstix	BP

Ortostatic hypotention _____
Nocturia _____ X/Night
Nocturnal diarhoea _____
♀: PVD _____ BP Supp /
♂: Impotence _____ BP Erect

Skin: Acanthosis nigricans
Dermopathy
Leg ulcers
Skin infections
Injection sites

Send for: U Alb: Creat ratio
UKE
HbA1C
Lipogram

Educate on: Therapy

Oral	Insulin	Comb

OTHER:

DR: FOLLOW UP DATE:

4. DATE:	WEIGHT:	
Glucose	U Dipstix	BP

Eye care:

	L	R
Acuity	/9	/9
Cataracts		

Fundi

L	N	BG	PP	PROLIF	ADV
R	N	BG	PP	PROLIF	ADV

REFER Ophthalmology _____

Previous:
Cataract surgery _____
Laser therapy _____

ENT:
SEND FOR ECG:

OTHER:

DR: FOLLOW UP DATE:

Addendum 3

Patient informed consent form

PATIENT INFORMATION LEAFLET AND INFORMED CONSENT

TRIAL TITLE: The efficacy of an intervention program aimed at diabetes care physicians regarding quality of diabetes care at a tertiary care hospital.

INTRODUCTION: You are invited to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved. In the best interests of your health, it is strongly recommended that you discuss with or inform your personal doctor of your possible participation in this study, wherever possible.

WHAT IS THE PURPOSE OF THIS STUDY? You are suffering from Diabetes mellitus; this disease needs long term follow up and care. We, the investigators would like to assess the quality of care rendered by the physicians attending to you at the Diabetes clinics of Kalafong hospital.

WHAT IS THE DURATION OF THIS STUDY? If you decide to take part you will be one of approximately 300 patients. The study will last for 1 year. You are requested to continue with clinic visits as usual per appointment every 3 months.

WHAT ARE YOU SIGNING CONSENT FOR? If you sign consent you are giving the investigator permission to audit your patient record file, which include all clinical notes, results of laboratory tests and imaging investigations done on you. The investigator will use this data to assess the quality of care you received at the clinic. All data obtained from your file will be managed anonymously. In the reporting of the data no identifying data will be reported.

HAS THE STUDY RECEIVED ETHICAL APPROVAL? This study Protocol was submitted to the Research Ethics Committee of the Medical Faculty of the University of Pretoria and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2000), which deals with the recommendation guiding doctors in biomedical research involving human subjects. A copy of which may be obtained from the investigator should you wish to review it.

WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY? You participation in this study is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your access to other medical care. The investigator retains the right to withdraw you from the study if it is considered to be in your best interest.

MAY ANY OF THESE STUDY PROCEDURES RESULT IN DISCOMFORT OR INCONVENIENCE? You will not experience any additional discomfort above that usually experienced at the clinic. No additional blood or any other tests will be done in addition to those clinically indicated to manage your condition optimally.

WHAT ARE THE RISKS INVOLVED IN THIS TRIAL? No additional risk will be encountered above the usual risk of attending the clinic and taking your prescribed medication.

ARE THERE ANY WARNINGS OR RESTRICTIONS CONCERNING MY PARTICIPATION IN THIS STUDY? No

SOURCE OF ADDITIONAL INFORMATION: For the duration of the study, you will be under the care of your usual Doctor. If at any time between your visits you feel that any of your symptoms are causing you any problems, or you have any questions during the study, please do not hesitate to contact him/her. The telephone number is 373 8041, through which you can reach him/her or another authorised person.

CONFIDENTIALITY: All information obtained during the course of this trial is strictly confidential. Data that may be reported in scientific journals will not include any information, which identifies you as a patient in this study.

In connection with this trial, it might be important for domestic and foreign regulatory health authorities and the Research Ethics Committee of the South African Medical Association, the Medicines Control Council, as well as your personal doctor, to be able to review your medical records pertaining to this trial. Therefore, you hereby authorise your investigator to release your medical records to (The Company), its employees or agents, domestic and foreign regulatory health authorities, the Medicines Control Council and the Research Ethics Committee of the South African Medical Association. You understand that these records will be utilised by them only in connection with carrying out their obligations relating to this clinical trial.

Any information uncovered regarding your test results or state of health as a result of your participation in this trial will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this trial but this information will not be disclosed to any third party in addition to the ones mentioned above without your written permission. The only exception to this rule will be cases in which a law exists compelling us to report individuals infected with communicable diseases. In this case, you will be informed of our intent to disclose such information to the authorised state agency.

INFORMED CONSENT

I hereby confirm that I have been informed by, Dr .... about the nature, conduct, benefits and risks of this study. I have also received

and understood the above written information (Patient Information Leaflet and Informed Consent) regarding the study.

I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a trial report.

I may, at any stage, without prejudice, withdraw my consent and participation in the trial. I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the trial.

Patient's name _____ (Please print)

Patient's signature _____ Date _____

Investigator's name _____ (Pease print)

Investigator's signature _____ Date _____

I, Dr ..... herewith confirm that the above patient has been informed fully about the nature, conduct and risks of the above trial.

Witness's name _____ (Please print)

Witness's signature _____ Date _____

Addendum 4

Doctors informed consent form

INFORMATION LEAFLET AND INFORMED CONSENT

STUDY TITLE: Assessment of Quality of Diabetes Care at Kalafong hospital Diabetic clinic, before and after introduction of structural changes and a physician education program.

INTRODUCTION: You are invited to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved.

WHAT IS THE PURPOSE OF THIS STUDY? To measure the efficacy of a physician education program and a structured consultation schedule to improve the quality of diabetes care at Kalafong hospital.

WHAT IS THE DURATION OF THIS STUDY? This study will be executed over a one-year period, beginning in October 2001 and will continue until October 2002.

HAS THE TRIAL RECEIVED ETHICAL APPROVAL? This clinical trial Protocol was submitted to the Research Ethics Committee of the University of Pretoria Faculty of Medicine and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2000), which deals with the recommendation guiding doctors in biomedical research involving human subjects, a copy of which may be obtained from the investigator should you wish to review it.

WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY? You participation in this trial is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. If it is detected you did not follow the guidelines of the trial and the regulations of the trial facility, you may be withdrawn from the trial at any time.

WHAT ARE THE RISKS INVOLVED IN THIS STUDY? No increased risk above the risk of performing your normal clinic duties. There is a possibility that consultation time might increase for some doctors.

SOURCE OF ADDITIONAL INFORMATION: If any questions or Information is needed throughout the study period you can contact Dr DG van Zyl at 373 8041 or 0828232056

CONFIDENTIALITY: All information obtained during the course of this trial is strictly confidential. Data that may be reported in scientific journals will not include any information, which identifies you as a participant of this study. You will be acknowledged as co-worker in of any report or publication that may arise from the study.

In connection with this trial, it might be important for domestic regulatory health authorities and the Research Ethics Committee of the University of Pretoria Faculty of Medicine, to be able to review records pertaining to this Study. Therefore, you hereby authorize the investigator to release study records to Research Ethics Committee of the University of Pretoria. You understand that these records will be utilized by them only in connection with carrying out their obligations relating to this clinical study.

Any information uncovered regarding your clinical notes and practice as a result of your participation in this trial will be held in strict confidence

INFORMED CONSENT

I hereby confirm that the investigator, Dr DG van Zyl, about the nature, conduct, benefits and risks of study, has informed me. I have also received, read and understood the above written information and study protocol and Informed Consent regarding the study.

I am aware that the results of the trial, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.

I may, at any stage, without prejudice, withdraw my consent and participation in the trial. I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the trial.

Participating Physician's name _____ (Please print)

Participating Physician's signature _____ Date _____

Investigator's name _____ (Pease print)

Investigator's signature _____ Date _____

I, Dr. .....herewith confirm that the above physician has been informed fully about the nature, conduct and risks of the above study.

Witness's name _____ (Please print)

Witness's signature _____ Date _____

Witness's Signature _____ Date _____

Investigator's Name _____ (Please print)

Investigator's Signature _____ Date _____