

DIABETES FILE AUDIT FORM

Addendum 1
Data collection 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
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4. Gender Male Female

5. Years Age

6. Duration of Diabetes Years

7. No admissions during past 12 months.

0	1	2	3	4
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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 HbA1c test.
- (f) A fasting Lipogram

9. Treatment: Oral Insulin Combination

DIABETES FILE AUDIT FORM

1. **Clinic Day**

Wednesday	Friday
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2. **Patient No** _____

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

1	2	3	4	5	6	7	8	>8
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4. **Gender**

Male	Female
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5.

.....

Years **Age**

6. **Duration of Diabetes**

.....

Years

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

0	1	2	3	4
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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
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Addendum 2

Diabetes patient record form

1. DATE	2. DATE	3. DATE	4. DATE
<p>WEIGHTS</p> <p>U Dipets <input type="checkbox"/> BP</p> <p>MONITORING</p> <p>VEGETATION</p> <p>ANGLE REFLEX</p> <p>Indicate: Green: viable Thickened normally</p> <p>Prurin</p> <p>TP L R TP L R</p> <p>HEALTHY FOOT EDUCATION</p>	<p>GLYCEMIC</p> <p>U Dipets <input type="checkbox"/> BP</p> <p>HISTORY</p> <p>Diabetes Type <input type="checkbox"/> Since <input type="checkbox"/></p> <p>Presented with <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>HT <input type="checkbox"/> <input type="checkbox"/></p> <p>Foot Ulcer of DM <input type="checkbox"/></p> <p>Previous Malocclusion</p> <p>STROKE</p> <p>U Dipets <input type="checkbox"/> BP <input type="checkbox"/></p> <p>DM <input type="checkbox"/> <input type="checkbox"/></p> <p>HT <input type="checkbox"/> <input type="checkbox"/></p> <p>SOCIAL HISTORY</p> <p>SMOKES <input type="checkbox"/> ALCOHOL <input type="checkbox"/></p> <p>DIETETIC CONSULTATION</p> <p>DMI <input type="checkbox"/></p> <p>Educate on: Obesity <input type="checkbox"/> Smoking <input type="checkbox"/> Lipids <input type="checkbox"/></p>	<p>CLINICAL</p> <p>U Dipets <input type="checkbox"/> BP <input type="checkbox"/></p> <p>Diabetes symptoms <input type="checkbox"/></p> <p>Diabetes <input type="checkbox"/></p> <p>Neurological symptoms <input type="checkbox"/></p> <p>U Dipets <input type="checkbox"/> BP <input type="checkbox"/></p> <p>Diabetes <input type="checkbox"/></p> <p>Neurological symptoms <input type="checkbox"/></p> <p>Diabetes <input type="checkbox"/></p> <p>Neurological symptoms <input type="checkbox"/></p> <p>U Dipets <input type="checkbox"/> BP <input type="checkbox"/></p> <p>Diabetes <input type="checkbox"/></p> <p>Neurological symptoms <input type="checkbox"/></p> <p>Diabetes <input type="checkbox"/></p> <p>Neurological symptoms <input type="checkbox"/></p> <p>U Dipets <input type="checkbox"/> BP <input type="checkbox"/></p> <p>Diabetes <input type="checkbox"/></p> <p>Neurological symptoms <input type="checkbox"/></p> <p>Diabetes <input type="checkbox"/></p> <p>Neurological symptoms <input type="checkbox"/></p>	<p>CLINICAL</p> <p>U Dipets <input type="checkbox"/> BP <input type="checkbox"/></p> <p>Diabetes symptoms <input type="checkbox"/></p> <p>Diabetes <input type="checkbox"/></p> <p>Neurological symptoms <input type="checkbox"/></p> <p>U Dipets <input type="checkbox"/> BP <input type="checkbox"/></p> <p>Diabetes <input type="checkbox"/></p> <p>Neurological symptoms <input type="checkbox"/></p> <p>Diabetes <input type="checkbox"/></p> <p>Neurological symptoms <input type="checkbox"/></p> <p>U Dipets <input type="checkbox"/> BP <input type="checkbox"/></p> <p>Diabetes <input type="checkbox"/></p> <p>Neurological symptoms <input type="checkbox"/></p> <p>Diabetes <input type="checkbox"/></p> <p>Neurological symptoms <input type="checkbox"/></p>
<p>OTHER:</p>	<p>OTHER:</p>	<p>OTHER:</p>	<p>OTHER:</p>
DR. FOLLOW UP DATE:	DR. FOLLOW UP DATE:	DR. FOLLOW UP DATE:	DR. FOLLOW UP DATE:

PATIENT: _____

NO: _____

PRESENT/YES = √
ABSENT/NO = X

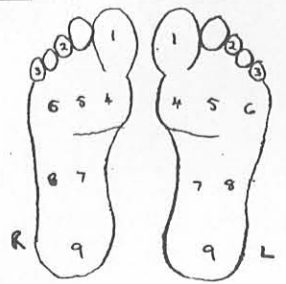
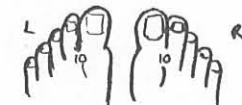


HEIGHT: _____

AGE (DOB) _____

HOME LANGUAGE _____

HIGHEST EDUCATION LEVEL _____

1. DATE:			2. DATE:			3. DATE:			4. DATE:																																												
WEIGHT:			WEIGHT:			WEIGHT:			WEIGHT:																																												
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Footcare: Monofilament  VIBRATION L R ANCKLE REFLEX L R  Indicate: Ulcers, callus Thickend toenails Pulses <table border="1"> <tr><td></td><td>L</td><td>R</td></tr> <tr><td>DP</td><td></td><td></td></tr> <tr><td>TP</td><td></td><td></td></tr> </table> HbA1C: FOOT EDUCATION				L	R	DP			TP			History: DM Type <input type="text"/> 1 <input type="text"/> 2 Since <input type="text"/> Presented how? <input type="text"/> DKA <input type="text"/> SX <input type="text"/> INS HT Since <input type="text"/> Fam Hist of DM <input type="text"/> Previous history: <table border="1"> <tr><td>STROKE</td><td>MI</td><td>PVD</td></tr> <tr><td>DKA</td><td>HONK</td><td>HIPO</td></tr> <tr><td>R FAIL</td><td>IHD</td><td></td></tr> </table> SOCIAL: HOW MANY? <input type="text"/> SMOKE <input type="text"/> ALCOHOL <input type="text"/> DIETICIAN CONSULTATION <input type="text"/> BMI <input type="text"/> Educate on: Obesity <input type="text"/> Smoking <input type="text"/> Liquor <input type="text"/>			STROKE	MI	PVD	DKA	HONK	HIPO	R FAIL	IHD		Ortostatic hypotention <input type="text"/> Nocturia <input type="text"/> X/Night Nocturnal diarrhoea <input type="text"/> ♀: PVD <input type="text"/> BP Supp / ♂: Impotence <input type="text"/> BP Erect Skin: Acanthosis nigricans Dermopathy Leg ulcers Skin infections Injection sites Send for: U Alb: Creat ratio UKE HbA1C Lipogram Educate on: Therapy <table border="1"> <tr><td>Oral</td><td>Insulin</td><td>Comb</td></tr> </table>			Oral	Insulin	Comb	Eye care: <table border="1"> <tr><td></td><td>L</td><td>R</td></tr> <tr><td>Acuity</td><td>/9</td><td>/9</td></tr> <tr><td>Cataracts</td><td></td><td></td></tr> </table> Fundi <table border="1"> <tr><td>L</td><td>N</td><td>BG</td><td>PP</td><td>PROLIF</td><td>ADV</td></tr> <tr><td>R</td><td>N</td><td>BG</td><td>PP</td><td>PROLIF</td><td>ADV</td></tr> </table> REFER Ophthalmology <input type="text"/> Previous: Cataract surgery <input type="text"/> Laser therapy <input type="text"/> ENT: SEND FOR ECG:				L	R	Acuity	/9	/9	Cataracts			L	N	BG	PP	PROLIF	ADV	R	N	BG	PP	PROLIF	ADV
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Addendum 3

Patient informed consent form

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 physician attending to you at the Diabetes clinics of Keatong 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 bio-medical 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.

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.

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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 _____ (Please 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 _____

INFORMATION LEAFLET AND INFORMED CONSENT

Addendum 4 *Doctors informed consent form*

STUDY TITLE: Assessment of Quality of Diabetes Care at Katalong 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 Katalong 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? Your 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 0628232056

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.

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.

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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

Investigator's Name _____ (Please print)

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 _____ (Please 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 _____