

STUDY SYNOPSIS

Title:

Community based multiple risk factors intervention strategy to prevent Cardiovascular and Chronic Kidney diseases Phase 2 [CORFIS2 Program]

Number of sites: 1000+

Number of subjects: 10,000-20,000

Anticipated dates:

First patient enrolled February 2009

Last patient enrolled 2014

Planned duration of study: 10 years

Introduction

The 3 most important chronic risk factors for cardiovascular (CVD) and chronic kidney diseases (CKD) are Hypertension (HT), Diabetes mellitus (DM), Hyperlipidaemias (HL). These risk factors are highly prevalent in our community; they are also poorly managed and controlled, resulting in costly and adverse health impact on our population. CVD for example is most likely the most common cause of death; while Malaysia ranks first in the world for the highest incidence of diabetic nephropathy leading to kidney failure.

We urgently need to improve the management of these chronic risk factors in our community. There have been considerable advances in our understanding of these risk factors and in our knowledge of the variety of approaches to achieving control of these risk factors. In the CORFIS program, we propose to implement the Chronic Care Model (CCM) in the primary care setting to address this problem of poor control of risk factors. The CORFIS intervention, based on the CCM, shall consist of a chronic disease management program employing multi-faceted interventions that is implemented in the primary care setting by a multidisciplinary healthcare team and supported by a purposively designed clinical information system

The first phase of the program was designed a randomized controlled trial to determine the efficacy of the CORFIS program for a treatment period of 6 months with respect to blood pressure, blood glucose and lipids treatment goals. While we await the results of the trial (anticipated in late February 2009), we are quietly confident of positive outcome to proceed with the Phase 2 of the program as described here.

Objectives:

The objectives are as follows:

1. To determine the extent that the blood pressure, blood glucose and lipids treatment goals can be sustainably achieved in the long term in the CORFIS program
2. To determine the factors which influence the achievement of treatment goals. Factors of interest shall include age, gender, educational attainment, socio-economic status, body size, physical activity, co-morbidities, and treatment adherence.
3. To establish the long-term effectiveness of CORFIS with respect to clinical endpoints. These are cardiovascular disease (IHD or cerebrovascular disease), doubling of baseline serum creatinine, ESRD and all cause mortality.
4. To determine the cost-effectiveness of CORFIS. This shall be quantified by the potential gain in quality adjusted life year saved (QALYs)

Program Design:

The program is designed as a longer term cohort study to establish the longer-term effectiveness of the CORFIS interventions with respect to clinical end-points. The program shall enrol 10,000 to 20,000 patients from about 500 to 1,000 private General Practices (GP) or Klinik Kesihatan (KK) in the Klang Valley.

However, the program is opened only to private GP or KK who are located in the neighbourhood of a CORFIS centre. The CORFIS centre is a physical outlet from where all the services in the CORFIS program are delivered to enrolled patients and their care are coordinated in collaboration with their primary care provider.

All patients who have given written informed consent, and on treatment for HT, DM or HL at a participating GP or KK may be enrolled.

Study population:

The study population consists of male or female patients on treatment for HT, DM or HL in participating GP or KK sites.

Inclusion criteria:

1. Patients diagnosed by participating GP to have Hypertension and/or Diabetes mellitus and/or Hyperlipidaemias, and currently on medical therapy for one or more of these conditions
2. Patients age 18 years and above.
3. Written informed consent obtained from patients.

Exclusion criteria:

1. History of unstable angina, acute myocardial infarction or coronary revascularisation procedure in the preceding 6 months.
2. Overt heart failure or history of heart failure in the preceding 6 months
3. Stroke in the preceding 6 months.
4. Serum creatinine more than 150umol/l in the preceding 6 months.

CORFIS intervention

The intervention comprises a multi-faceted **chronic disease management program** to be implemented in primary care (GP or KK) setting.

The program shall be delivered in collaboration with a **multi-disciplinary team** of healthcare professionals including:

- The GP or healthcare provider who enrol and manage patients with HT, DM and HL
- Clinical specialist advisors (general physician, endocrinologist, cardiologist & nephrologists) who provide feedback to participating GPs on therapy decision making or modification for individual patients
- Clinical sub-specialist advisors (ophthalmologist, cardiologist and nephrologists) who shall provide specialist opinion on screening tests for end-organ complications including retinopathy, cardiac diseases and nephropathy.
- Pharmacists who shall provide pharmaceutical care services to patients
- Dietician who shall provide medical nutrition therapy services
- Case managers (specialist nurse educator) who shall provide disease education, patient counselling services, patient follow up & coordinate care provided by the above multi-disciplinary team.
- Study monitor & other CRC project staff, who monitor study progress and manage the research project.

The program shall also extensively employ modern **information and communication technologies** (ICT) to enable efficient communication, including to:

- Organize and coordinate care among all the parties involved (patients, healthcare providers such as investigators, clinical specialist advisor, dietician, pharmacist, case managers, central lab, medical monitor and other CRC project staff)
- Provide reminders to prompt both providers and patients on specific required actions such as clinic visit appointment, blood taking for investigation, home monitoring, self-management educational activities...etc
- Communicate treatment target measures (central lab and home monitoring) to providers and specialist advisor
- Identify patients at risk because of failure to achieve treatment targets and hence requiring assessments and/or treatment modifications. Suggestions are also provided to care provider on specific therapeutic interventions to be considered for a particular patient at a particular point in time to achieve greater efficacy

- Provide urgent access to health-care advice for both anticipated and unforeseen problems
- Provide telephone and other contacts between clinic visits by case managers.
- Enable patients to input home monitoring data and access relevant information from his or her medical record
- Support web based patient education efforts
- Support activities of local patient association and support group
- Support continuous quality improvement combining cycles of analysis and intervention
- Support project management and quality control activities by study monitor & CRC project staff, who monitor study progress

The program also incorporates **specific interventions** to support physician's capacity to treat to target and patient's self-management capacity and adherence with life-long therapies:

1.	Protocol driven care and simplified drug regimen	<ul style="list-style-type: none"> ▪ Protocol driven simple stepped-care adapted from current guidelines that adopts a treat to target approach within agreed timeframe ▪ Single daily dosing; e.g. once daily tablet, long acting insulin
2.	Healthcare delivery that is patient centred	<ul style="list-style-type: none"> ▪ Convenient and patient friendly service ▪ Urgent access to health-care advice for both anticipated and unforeseen problems ▪ Regular face-to-face contact with healthcare team for education, counselling and self-care training, and to provide ongoing support to establish positive relationship with patients ▪ Engage patient between clinic visits through home call ▪ Assure continuity of care for patient receiving care from the same provider over time; thereby to improve relationship and communication with patient ▪ Healthcare delivery through variety of locations as appropriate to maximize contacts with patients such as at GP premise, specially established CORFIS centre and group session (so called CORFIS camp)
3.	Patient self management capacity	<ul style="list-style-type: none"> ▪ Patient counseling, provide disease education and self-care training; at usual face to face session and complemented by internet based audio-visual materials to support self-learning ▪ Home monitoring of BP, physical activity and glucose, where applicable ▪ Home call to engage patients in health care between visits; reinforce education and motivate adherence; address practical difficulties in adhering with treatment; early identification of

		<p>problems (home monitoring, side effects, poor motivation) and refer appropriately</p> <ul style="list-style-type: none"> ▪ Foster good doctor-patient relationship and communications through continuity of care and other patient-centered care ▪ Family and peer support (see #6)
4.	Integrated multi-disciplinary team	<p>An integrated team approach to provide care in collaboration with patient's care provider (GP). The team comprises physician qualified in Internal medicine acting as specialist advisor, case manager, dietician, and pharmacist. Coordination of shared care is achieved through web based technology as well as through call centre based nurses.</p> <p>The specific services provided by the various health professionals in the team are:</p>
4a	<i>Medical nutrition therapy (MNT)</i>	<p>This entails:</p> <ul style="list-style-type: none"> ▪ Assessment of patient needs ▪ Determination of Medical Nutrition Therapy objectives from needs based assessment ▪ Integration of MNT care plan with multidisciplinary approach ▪ Regular counselling and instruction on medical nutrition therapy by dietician ▪ Motivate patient for behaviour change [including exercise] to achieve adherence and achieve treatment goals ▪ Provision of patient support material ▪ Follow-up visits to determine achievement of MNT goals
4b	<i>Pharmaceutical care</i>	<p>This entails:</p> <ul style="list-style-type: none"> ▪ Participation of pharmacist in implementing and monitoring a therapeutic plan, including identifying & resolving potential and actual drug-related problems, and preventing future drug related problems. ▪ Regularly enquire about treatment efficacy and adverse drug reaction, providing medication-related advice and support as well as encourage adherence to therapy, and review home monitoring data
4c	<i>Patient education service</i>	<p>Disease education and patient counselling services, and training on self-care and home monitoring by case manager and other allied health professionals as appropriate. Coordinate shared care by all the healthcare professionals involved.</p>

<p>4d</p>	<p><i>Nurse advisory service</i></p>	<p>Regular home calls by case managers between clinic visits to reinforce patient self-care and motivate adherence.</p>
<p>4e</p>	<p><i>Medical advisory service</i></p>	<p>Clinical specialist advisors (physician, endocrinologist, cardiologist & nephrologists) who provide feedback to participating GPs on therapy decision making or modification for individual patients</p>
<p>4f</p>	<p><i>End-organ complication screening services</i></p>	<p>Screening tests for end-organ complications including retinopathy using digital fundus camera, cardiac diseases using digital ECG, nephropathy based on micro-albuminuria & diabetic foot screening. Clinical sub-specialist advisors (ophthalmologist, cardiologist, nephrologists & podiatrists) who shall provide specialist opinion on screening tests</p>
<p>5.</p>	<p>Efficient & effective communication & information sharing among health professionals & patient</p>	<ul style="list-style-type: none"> ▪ Availability of treatment target measures (BP, HbA1C and Lipid) at each clinical visit (point of care testing if feasible and necessary) to drive treatment decision making ▪ Sharing of patient information among all members of healthcare team ▪ Home monitoring measurements (BP, glucose, pedometer); data input by patient via the web and/or collected during home call by nurse advisor ▪ Patient access to own treatment record and target measurements ▪ Reminder to attend blood taking, clinic visit and group session ▪ Central medical advisory service by qualified medical specialist advisors to respond to GP's enquiries and to review patient's treatment plan & target achievement
<p>6.</p>	<p>Social support & connection with community resources</p>	<ul style="list-style-type: none"> ▪ Involve family members (clinic, group session, call at home) ▪ Group session among patients, organized as CORFIS camp ▪ Foster local patient association or support group for patient education, mutual support and motivation for self-care, and to create opportunities to ask questions and express concerns, and to support care delivery of local healthcare team ▪ Identify suitable patient to become "expert patients" to support activities of the local patient association or support group

7.	Incentives	Free lab tests, subsidized home monitoring devices, diabetic feet, diabetic retinopathy & nephropathy screening, ECG reading by cardiologist, free multi-disciplinary healthcare services
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Refer Appendices for detailed description of the following:

- Drug treatment protocol
- Medical nutrition therapy services
- Pharmaceutical care services
- Case management services
- Nurse advisory services
- Screening services
- Medical advisory services

Reference intervention (Non-intervention arm for 6 months)

None. This is a single arm study

Duration of intervention:

Long term cohort study for 5 years

Criteria for evaluation:

Efficacy parameter(s):

1. Proportion of patients who could maintain treatment goals defined as follows:

Target blood pressure	Target glycaemic control	Target cholesterol level
1. $\leq 140/90$ mmHg for patients without diabetes or chronic kidney disease 2. $\leq 130/80$ mmHg for patients with diabetes or chronic kidney disease	1. HbA1C $\leq 7\%$ 2. Fasting glucose 4.4-6.1 mmol/l 3. Non-fasting glucose 4.4-8.0 mmol/l	For patients with 1. 0-1 risk factor for CVD: serum LDL < 4.1 mmol/l 2. 2 or more risk factors for CVD: serum LDL < 3.4 mmol/l 3. Presence of coronary artery disease or diabetes: serum LDL < 2.6 mmol/l

2. Incidence of cardiovascular disease (IHD or cerebrovascular disease or both)
3. Incidence of composite renal endpoint of doubling of baseline serum creatinine or ESRD.
4. Incidence of all-cause mortality and cardiovascular mortality
5. Quality of life outcome as measured by Spitzer's QL index.

Study visits schedule and procedures flowchart

	Screen/ Baseline	Treatment Follow Up	Study end
Visit	1	2-20	5 yrs
Timeline for study visit (month)	0	Depending on diagnosis & disease control. Please refer to case manager manual	5 yrs
Procedures			
Check eligibility	X		
Written informed consent	X		
Medical History	X	X	X
Complete Physical Exam.	X		
Modified Physical Exam.		X	X
Vital sign	X	X	X
ECG	X	X	
Fundoscopy	X	X	
Urine dipstick	X		
Urine microalbumin	X		
Blood sample for lab investigations	X [§]	X [§]	X [§]
Report ADR		X	X
Prescribe drug treatment	X	X	-
Complete relevant section of CRF	X	X	X

§ Volume of blood sample and frequency of testing vary with type of lab investigation as follows:

- [#]Blood chemistry (5ml): 12 monthly except where there is any change in relevant medication (ACEI or ARB)
- FSL (3 ml): 3 monthly at each study visit
- Fasting glucose (2 ml): 3 monthly at each study visit (diabetic patients only)
- HbA1C (2 ml): 3 monthly at each study visit (diabetic patients only)
- Urine tests: 12 monthly (frequency is dependent on status of microalbuminuria)

Note:

[#] Blood chemistry: BUSE*, Creatinine*, LFT including liver enzymes, CPK, LDH (4ml)

*: Serum urea, electrolytes and creatinine should be checked within 1 month after commencing ACE inhibitors or ARB

All patients will be given a complete lab workout annually.