

# DHBRF Translational Research

## Final Report

### Krebs 09-586: Preventing diabetes in people with acute coronary syndrome and hyperglycaemia

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#### 1. Research Proposal

**Research Topic/Opportunity:** Abnormal glucose tolerance is a strong predictor of future cardiovascular events<sup>1</sup> as well as development of Type 2 diabetes mellitus (T2DM)<sup>2</sup>. The challenge is to identify these individuals and to effectively intervene<sup>1</sup>. This could be achieved by screening those people known to be at risk e.g. those people admitted to a Cardiac Care Unit (CCU) experiencing an acute cardiac event, and who do not have a known diagnosis of diabetes but have hyperglycaemia during admission. Identification of these at-risk individuals when in the secondary healthcare setting will enable a more proactive and strategic management in the primary healthcare setting.

Evidence already exists that intervention in individuals with impaired glucose tolerance prevents the evolution to type 2 diabetes<sup>3</sup>. Many resources to help these at-risk individuals are already present in the primary health care sector, but we have demonstrated that these are often not engaged once a person is discharged<sup>4,5</sup>. What is needed is better coordination of these services and improved communication between secondary care and primary care. The intervention plan will promote the need and tools for self care.

**Aim:** To reduce the incidence/development of Type 2 diabetes mellitus and further acute cardiac events for those admitted to Cardiac Care Unit with hyperglycaemia, by optimizing the primary and secondary healthcare resources in a more strategic focused plan.

**Background:** Diabetes mellitus is a known risk factor for cardiovascular disease and together increases mortality<sup>1,6</sup>. When people not known to have diabetes are admitted to a cardiac care unit with an acute coronary syndrome, many will present with a high blood glucose<sup>7</sup>, of which 20% may be diagnosed with diabetes on discharge. The GAMI (Glucose in Acute Myocardial Infarction)<sup>8,9</sup> and EURO Heart survey<sup>10</sup> studies both detected a high prevalence of impaired glucose metabolism in this population. Of the 181 patients examined in the GAMI study, the oral glucose tolerance test (OGTT) showed that 33% had a new diagnosis of diabetes, 34% impaired glucose tolerance and 33% had normal glucose metabolism. In New Zealand, we have also shown that a high percentage of those people admitted to hospital and have hyperglycaemia have developed diabetes 1 yr after discharge from hospital<sup>4</sup> or are at a higher risk for future cardiac events and other complications<sup>4,5</sup>.

In New Zealand, Maori and Pacific people have higher rates of type 2 diabetes and are at greater risk of cardiovascular disease. In a recent study, the prevalence of diabetes was 2.8 times greater for Maori and 4.1 times greater for Pacific people compared with Europeans<sup>11</sup>. However, detection rates for these ethnic groups is lower. Therefore using admission to

coronary care as a trigger for screening these ethnic groupings at high risk of developing type 2 diabetes is a good strategy<sup>1,5</sup>.

Detection of impaired glucose metabolism at early stages allows the delivery of strategies, such as the Diabetes Prevention Programme, for preventing the development of T2DM<sup>2-4</sup> and occurrence of cardiovascular complications<sup>1</sup>. This can be achieved by screening those people known to be at-risk. As has been demonstrated, those people admitted to a Cardiac Care Unit experiencing an acute cardiac event (e.g. unstable angina; ST elevation myocardial infarction (STEMI) and non-STEMI)<sup>12</sup> and who do not have a known diagnosis of diabetes but have hyperglycaemia on admission are an ideal target population<sup>1,7-9</sup>. Diabetes or impaired glucose metabolism can be identified by undertaking an oral glucose tolerance test (OGTT) within days of admission to a coronary care unit, or even before discharge<sup>8,10</sup>.

Often on leaving hospital after an acute coronary syndrome event, individuals are highly motivated to make changes to their lifestyle but have limited knowledge and support to foster this change. It is hypothesised that directed support and guidance in the primary healthcare setting in the first year of discharge from hospital, will provide the at-risk individuals with the tools to take charge of their life and ultimately reduce the risk of them suffering from further cardiac events or developing T2DM.

The aim of this study is to translate the evidence that co-ordinated diet and lifestyle modification can reduce the incidence of diabetes and further cardiac events by optimising and co-ordinating the resources that are already present in the healthcare sector to provide a more strategic focus on the at-risk groups.

**Design/Methods:** This is a prospective intervention study over nine months. This timeframe is to enable completion of the study within the timeframe of the grant requirements. However, additional funding will be sought to enable a longer-term follow up of these patients out to two years. People admitted to CCU with an acute coronary syndrome event and either a random plasma glucose  $\geq 7.8$  mmol/L, a fasting plasma glucose  $\geq 6.0$  mmol/L, or a 2 hour OGTT glucose  $\geq 7.8$  mmol/L will be included in this study. Subjects will have the biochemical and physiological measures normally taken while in CCU which will form the baseline data. In addition, they will be asked to fill in an SF36 questionnaire<sup>13,14</sup> to ascertain general health status. Glycated haemoglobin (HbA1c) will be determined and used as a measure for improvement in control of glucose metabolism over the 9 months of the study. The recruited CCU subjects will be randomised and go into either Group A, the control group, or Group B, the intervention group. Cluster randomisation will be used based on Primary Care practice to ensure no contamination occurs between the participants of the control group and intervention groups.

**For Group A:** Non-Intervention (Usual Care) group; n= 25

The patients General Practitioner will be notified of their inclusion in the study, but no other communication or intervention will be delivered. These subjects will have an examination of overall health status 9 months after discharge from the hospital. This will include the participant filling in an SF36 questionnaire, biochemical and physiological measures being taken and discussion about what healthcare services/management they have accessed after discharge from the hospital.

**For Group B:** Intervention group; n=25

This group will have a more proactive and structured programme once they have been discharged from the hospital. A focus will be to link secondary healthcare professionals with primary health care professionals and healthcare services to ensure the participants obtain the best optimized use of the current resources available in the primary health sector. Participants in the study will be enrolled in "Care Plus" (if not already) and asked to go to GPs for regular check-ups. At the first meeting they will have a composite package of information regarding, education, diet and exercise. This will utilise existing evidence based resources currently

provided by NGO's working in the sector e.g. Heart Foundation, Pacific Islands Heart beat, Te Hotu Manawa Maori, Diabetes New Zealand, Ministry of Health Education Resources, Quit group and other ethnic specific smoking cessation providers. Information about where people can get support with change management and managing with day to day life will also be provided on a local context, e.g. Counselling and Social support providers. A nurse researcher will be involved to follow-up organisations to ensure that dedicated care is occurring. Recommendations for management targets and cardiovascular risk factor reduction will be reinforced, and communication with secondary care teams in diabetes and cardiology will be facilitated. Participants will be invited to attend the 12-wk Phase 2 Cardiac Exercise Rehabilitation Programme, at Massey University, within the 9 months of the study. Biochemical and physiological measures will be taken at each of the 3, 6 and 9 month GP consults and the participants will complete a SF36 questionnaire at the end of the 9 months intervention. At the 9 months consult, examination of the healthcare services/management that the participants have accessed after discharge from the hospital will be determined.

**Biochemical measures:** include: FPG; HbA1c; OGTT; Full lipid profile for both groups. The physiological measures will include: weight; waist circumference, height and BP.

**Statistics:** This study is powered to detect a difference of 0.5% HbA1c between groups. Based on a previous study<sup>15</sup> and a two tailed test of significance, a total of 40 subjects are estimated to be required. Fifty (25 in each group) will be recruited to allow for dropouts. Group A (control) results will be compared to Group B (intervention study). All other biochemical and physiological measures of the intervention group will be compared to control group to determine if there is any improvement with structured care in the 9 months after discharge from the hospital. The SF36 questionnaire will help us to establish the general health and well being of the control group and intervention group at the end of the 9 months

**Qualitative Analysis:** The validated SF36 questionnaire<sup>13,14</sup> will be used for examining functional health and well-being. This questionnaire is a multi-purpose, health survey with 36 questions that will establish current physical and emotional health status. If emotional health status at the beginning of the study indicates more intense care is required then the participant will be directed to the correct healthcare facility for appropriate care. Participants from both groups will be interviewed at 9 months to ascertain their experiences of health services across the secondary and primary healthcare sectors. An interpretive descriptive approach will be used to analyse the data<sup>16</sup>.

**Main Outcome Measures:** Comparing control group to intervention group at 9 months: Group effect will be analysed by analysis of covariance (ANCOVA) using change scores (final - baseline) as the dependent variables, and baseline value of the dependent variable in the model as a covariate. A p value of < 0.05 and/or 95% CI not inclusive of 0 will be considered indicative of statistical significance.

- The primary outcome measure is HbA1c and the proportion of individuals with DM, IFG or IGT after 9 months.
- Secondary outcomes include: BP as a continuous variable and proportion with BP<130/80mm/Hg. Lipid profile and proportion taking statins.
- Qualitative analysis of general health and well being and utilization of primary and secondary healthcare resources.

**Translatability/Dissemination:** Evidence exists that individuals at high risk for developing diabetes can be identified during admission to CCU. Evidence also exists that structured diet and lifestyle programmes can prevent the progression to diabetes in these individuals. This project ensures coordination of existing primary and secondary healthcare services, communication between services and structured follow up of patients. If found to be effective in these goals, the programme will be directly translatable to other centres as it utilises existing resources.

This project has wide involvement and support from local PHOs. Results can therefore be directly communicated with the management teams and through them the clinical teams in primary care. Results will be disseminated more widely to primary and secondary healthcare professionals, providers, scientific and wider community. Academic findings will be published in national and international peer-reviewed scientific, medical and nursing journals and presented at national and international meetings.

**Potential to Improve Health Outcomes:** Diabetes is a major cardiovascular disease risk factor. Preventing or delaying the progression to diabetes in individuals at high risk will have a major impact on the health outcomes of those individuals. This study has significant potential to impact on this particularly as it focuses on improved co-ordination and communication between existing primary and secondary healthcare services, using evidence based interventions.

## **Research Significance**

### **Alignment to Organisational and/or Regional and/or National Health Priorities:**

This research responds to the priority goals and objectives recommended in the New Zealand Health Strategy<sup>20</sup>. Specifically; 1) reducing the incidence and impact of diabetes, 2) cardiovascular disease 3) reducing obesity, 4) improving nutrition, and 5) increasing the level of physical activity. This research project responds to Goal 3, Maori Development in Health, by collecting high-quality health information to better inform Maori policy and research. Though not limited to Maori, active recruitment and involvement with Maori is a focus. This project also focuses on the following NZ Health Strategy Goals<sup>20</sup>: Goal 5, Healthy communities, Goal 6 Healthy lifestyles, Goal 8 Better physical health and Goal 10, Accessible and Appropriate Health care services.

The research also address the goals of the primary healthcare strategy including, working with communities, removing inequalities, integration of primary and secondary services, long-term conditions, improving quality and developing the primary care workforce. These goals are echoed in the statement of intent from Capital and Coast Health, which goes further to identify key areas of focus for 2008/09 will be quality improvement, improving access for Māori and appropriate service options. “Early recognition of diabetes supports the opportunity for better self-management and reduced complications. Much of the morbidity and premature mortality from diabetes is linked to cardiovascular and renal complications of diabetes. Service coordination to optimise management of co-morbidity will improve the patient experience, provide safer and more efficient service, reduce avoidable admissions and improve health outcomes. Tailored approaches are needed to meet the information needs, lifestyle, family and cultural context of different population groups with high morbidity from diabetes.”

**Institutional, Organisational or Regional Support for Research:** As indicated above Capital and Coast Health are committed to the NZ health strategies and in line with this support this project both in philosophical and practical terms [Support Letter from CMO Geoff Robinson]. Primary care as represented by Capital PHO, Tumai mo te Iwi and Kapiti PHO’s and Compass Health Wellington in working with their primary care representative groups and Clinical Quality Board’s have identified the need for such co-ordinated approach and how this aligns with the chronic disease management goals for Primary Care [letters of support attached]. Massey University, IFNHH, has available in primary care sector a Phase 2 Cardiac rehabilitation exercise programme. This projects aligns with the research focus and vision of IFNHH Wellington [Letter of support attached].

**Relevance to Maori Health Outcome:** Previous studies have shown that there is a significantly higher incidence of diabetes and CVD in Maori communities in New Zealand<sup>11,12, 17-20</sup>. This project aims to bring a more structured coordination of all the available

healthcare services<sup>21,22</sup> that are available for promoting a healthy eating and healthy lifestyle intervention. Given the high incidence of diabetes in Maori there is an urgent need to consider using Maori worldviews and Maori research methodologies to determine appropriate self management and lifestyle support/coaching approaches for engaging Maori. Maori leadership and participation in this project will ensure that Maori participant views and whanau views are considered as influences of health behaviour. We cannot consider a Maori participant without considering their whanau, social and environmental lifestyle and identifying motivators for behavioural change which will ultimately provide the guidance to trial participant care pathways in this project. Having tikanga as part of the research process will demonstrate how the research team has a genuine desire to bring cultural sensitivity to participants and they will in turn feel that their contribution will add to the well being of Maori Health. Iwi Maori form an important part of the research team with Kaumatua guidance and support to the team.

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## 2. Challenges

There were several key requirements for this project to be successful. The first was engagement with primary care, to improve the communication between secondary care and primary care, to promote the concept of enhanced co-ordination of care using existing resources, and facilitate the delivery of these to the intervention group.

In order to engage primary care, early discussion was undertaken with the principal PHO in the Wellington region, and one of the management staff (BM) was included in the named investigators for this project. The research team also met with, and presented to, the combined PHO clinical governance committee, obtaining strong support for the study and understanding that the clinical measurements would be part of good clinical practice, and would be enabled through enrolment of patients in “care plus”. The investigators also included information about the study in local presentations to General Practitioner meetings. The research nurse for the study actively engaged with practice nurses and practice managers at local medical centres to inform them about the study. She also worked with the practices to compile comprehensive sets of resource material for patients.

As patients were enrolled in the study specific letters were sent to the General Practitioner, and these were followed up by telephone communication between the study nurse and the practice nurse. This was to ensure that the practice knew the patient was enrolled and the expectations for that patient. Patients were also given very clear written instructions outlining the expectations for their follow up, whether in the intervention or control group.

Despite the considerable effort put in to all of these aspects, engagement of primary care at individual general practitioner level was poor. There was a clear disconnect between the understanding of the PHO at management level and the willingness of many practices or General Practitioners to engage in the process. There was also very poor follow through by patients to engage in the level of follow up requested. This was despite the informed consent process, further verbal discussion and written material. This aspect of the study has limited the ability to answer the primary aim, but is a very important finding in itself. As a consequence the data for 3 and 6 months in the intervention group is very compromised. Once again this is an important finding in itself. To ensure that a better capture of data occurred at 9 months, where patients had not seen their GP, research staff independently facilitated the collection of data at this timepoint.

The second key element to the success of the project was achieving recruitment targets within the timeframe of the available funding. This also proved to be a great challenge and was identified in the interim reports. There were several challenges. Many patients were from outside the Wellington region. It was rapidly identified that including the Hutt hospital and Hutt Valley patients would enhance recruitment. Therefore consultation was undertaken with the Cardiology team at Hutt Hospital and with key PHO management in the Hutt Valley who were both supportive. However when attempts were made to engage at practice level, and to facilitate the necessary locality assessments in the hospital, it was clear that there were many barriers and this was not further pursued. The target enrolment was n=50 subjects. A flow

diagram of the recruitment path for the study is attached (appendix 1). In total 1998 admissions were reviewed by study staff between Sept 2009 and June 2010. Final recruitment was n=32.

### 3. Results to Date

The final patient was enrolled in June 2010, with final measurements being conducted in April 2011. Preliminary analysis of the data has been undertaken and these results have been presented at the New Zealand Society for the Study of Diabetes (NZSSD) annual meeting in May 2011 (see below).

A full analysis of the data is currently being undertaken. Table 1 below shows the key outcome variables. There is no difference between groups for any outcome.

**Table 1. Outcomes for control and intervention groups**

	<b>Control</b> n = 16		<b>Intervention</b> n = 16	
	Baseline	9 months	Baseline	9 Months
Weight (kg)	92.3 ± 17.0	94.7 ± 19.5	87.0 ± 12.6	89.2 ± 11.9
Waist circumference (cm)	104.7 ± 14.1	109.3 ± 12.0	102.4 ± 10.3	98.8 ± 12.3
BMI (kg/m <sup>2</sup> )	29.5 ± 6.1	30.3 ± 5.2	29.2 ± 3.9	29.7 ± 4.2
Fasting Glucose (mmol/L)	6.3 ± 0.9	5.6 ± 0.7	6.0 ± 0.6	5.5 ± 0.5*
HbA1c (%)	6.1 ± 0.9	6.1 ± 0.7	6.2 ± 0.5	6.0 ± 0.5
Total Cholesterol (mmol/L)	4.71 ± 0.9	3.99 ± 0.4	5.12 ± 1.2	4.43 ± 1.0
LDL cholesterol (mmol/L)	2.50 ± 0.6	1.98 ± 0.4	3.10 ± 1.2	2.18 ± 0.9*
HDL cholesterol (mmol/L)	1.13 ± 0.3	1.23 ± 0.3*	1.24 ± 0.4	1.55 ± 0.6*
Systolic BP (mmHg)	122.9 ± 16.9	126.6 ± 14.6	125.1 ± 18.2	131.2 ± 19.3
Diastolic BP (mmHg)	73.3 ± 8.2	81.4 ± 8.9	73.1 ± 12.4	76.0 ± 9.4

\* p<0.05 for within subject change from baseline

Analysis of the qualitative data is being done as part of a PhD thesis.

Initial results have also been presented at Wellington Health and Biomedical Research Society Scientific meeting, August 2010, and the NZSSD Annual Scientific Meeting in May 2011, Final quantitative results are being presented at the Australian Diabetes Society Annual Scientific Meeting being held in Perth, Western Australia in 31<sup>st</sup> Aug-2<sup>nd</sup> Sept 2011.

## 4. Dissemination Plan

### Presentations:

Results from the study have been presented or accepted for presentation at the following:

- Reducing further incidence of further cardiac events and type 2 diabetes. Wellington Health and Biomedical Research Society Scientific meeting, August 2010. Poster Presentation.



RICEWHBRSPoster2010.pdf

- Reducing further incidence of cardiac events (RICE) study. Oral presentation NZSSD, Nelson May 2011



Microsoft PowerPoint  
Presentation

- Quality of life: RICE study and Type 2 Diabetes Mellitus. Poster presentation NZSSD, Nelson May 2011



QoLRICEposterNZSSD2011.pdf

- RICE STUDY: Reducing Incidence of Further Cardiac Events and Type 2 Diabetes in At-Risk Individuals. Accepted for poster presentation Australian Diabetes Society Annual Scientific Meeting being held in Perth, Western Australia in 31<sup>st</sup> Aug-2<sup>nd</sup> Sept 2011.



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Findings will also be presented back to local PHOs, and to the PHO clinical governance committee.

### Publications:

Once the final analysis has been completed papers will be prepared for publication. It is proposed that there will 2 papers. The first will present the primary and secondary quantitative outcomes and will include a discussion on the challenges in conducting this research and the ability to translate evidence in to changes in process. The second paper will focus on the qualitative aspects.