Bringing Research In Diabetes to Global Environments and Systems

Application number:

Letter of intent, part 3

Project Title (if already available)

Improving Diabetes Care in Cap Haitien, Haiti

Total amount requested for the project (in US DOLLARS) if already available

1. Non-technical summary (max. 100 words)

Please summarize in non-technical terms the relevance of your project and how it will improve the quality of care of people with diabetes. Please ensure the summary is written in language easily understood by a non-medical audience. The summary may be used in a range of IDF publications to communicate the work of BRIDGES.

Haiti is the poorest country in the Western Hemisphere, with the lowest government expenditures on health care. Although prevalence data are few, hypertension is reported in greater than two-thirds of adults over age 40. Poverty, lack of education, political instability, and lack of resources all contribute to an excess burden of chronic illness.

We propose to develop a diabetes treatment program which will deliver the three most cost-effective interventions in developing countries: gylcemic control in poorly-controlled patients, blood pressure control, and foot care in high-risk individuals. Culturally appropriate educational materials will be developed and made widely available to the community.

2. Information on the project (maximum 3 pages)

Use the following subheadings to strengthen your application:

- Background information about the project including current evidence in the field and relevant literature
- Indicate how the project addresses the community's need for diabetes care and/or prevention.
- Aims/ Hypothesis/Research question
- Method(s): Briefly describe the study design, target population, sample size and sample selection process, inclusion and exclusion criteria data collection tools, data analysis procedures and outcome measures
- List the key indicators and milestones.
- Sustainability plan

Details of application

Purpose of proposed investigation with clearly specified objectives

Objectives:

1) Develop and disseminate educational materials and clinical protocols which are culturally-appropriate and evidence-based for resource-poor countries.

2) Implement interventions in high-risk individuals with diabetes and determine their impact on the three quality indicators (glycosylated hemoglobin [HbA1c], blood pressure, foot risk score).

3) Evaluate the effectiveness of implementation in achieving our process goals.

4) Evaluate the impact of the intervention on improving the three quality indicators.

Background

Haiti has the highest mortality rate in the Western Hemisphere. Extreme poverty, illiteracy, lack of material resources, and political instability all contribute to a high chronic disease burden. Although the IDF Diabetes Atlas[i] estimates the prevalence of diabetes and diabetic complications using data from Spanish Town, Jamaica,[ii] these may not be applicable to a much poorer country such as Haiti. One well-designed study of diabetes prevalence in Haiti, conducted in Port-au-Prince by our co-investigators at the Fondation Haïtienne de Diabète et de Maladies Cardio-vasculaires (FHADIMAC)[iii] reported a prevalence of diabetes of 7.4% in men and 11.1% in women. Hypertension was found in over 2/3 of men and women aged ≥ 40 years. In a recent report on diabetes practice in developing countries, only 7.5% of type 1, and 3.6% of type 2 diabetic patients met recommended targets for control.[iv]

The Justinien University Hospital is a 250-bed teaching hospital in Cap Haitien, Haiti's 2nd largest city. It is the largest health care provider in northern Haiti and serves as the reference hospital for an estimated 825,000 people. There is no clean, potable water in the hospital. Electrical supply is typically available for only a few hours each day. Doctors and nurses work long hours, and with few resources.

A Diabetes Clinic at JUH is staffed by a full-time registered nurse and Internal Medicine attending physicians and residents, and sees approximately 250 patients each month. Due to lack of electricity, serum glucose determinations cannot be made on the day of visit. Patients present to the clinic in late stages of disease, almost always having run out of their supply of medications long beforehand. Insulin supply is limited to NPH and Regular, is often unavailable and for most patients unaffordable even when available. Lack of electricity in the home presents a major problem for insulin storage in the tropical climate. The P.I. has made the following observations during several visits to the Diabetes Clinic:

- Due to staffing shortages, residents are often unsupervised, without the assistance of practice guidelines or standardized protocols. This leads to the prescription of "poly-pharmacy", without consideration of costs or complexity of regimen. Misinformation leads to avoidance of thiazide diuretics, and the use of medications that are outdated (alpha-methyldopa) or too expensive for most patients (e.g. statins). Patients invariably run out of them months before their return visit due to the inability to pay for them.
- High-risk feet are given little attention. Patients present with pre-ulcerative or ulcerative conditions, but there is little education in prevention, and no footwear to provide to patients. Amputation is performed at a rate of approximately one per week.
- Transportation barriers result in patients only coming to clinic for acute problems.
- Medical records are often unavailable or incomplete. There is no standardized Chronic Care Model[v] system in place for disease management, and delivery of preventive services (e.g. dilated eye exam) and education is not documented.

The proposed interventions will be designed to address each of these identified barriers. Although we will implement electronic data-tracking for study volunteers, it is beyond the scope of this feasibility study to implement electronic health records. The Canadian International Development Agency is working to improve medical records simultaneously, which should lead to better future data availability.

Our co-investigators at FHADIMAC have created a comprehensive clinic in Port-au-Prince for management of diabetes and hypertension, in operation since 1987. We will develop culturally appropriate educational materials using graphic displays, since the vast majority of patients is illiterate. Group educational sessions will be presented weekly which address topics covering nutrition, self-management, medications, and prevention of complications.

Detailed plan of investigation:

Design of the project: The proposed intervention will consist of **3 phases**, with an initial goal of implementing the interventions considered to be most cost-effective in a resource-poor environment, namely glycemic and blood pressure control, and preventive foot care.[vi] The scope of the interventions will be limited due to the numerous barriers to health care in Haiti, including poverty, lack of patient education, and limited resources in the clinic.

In **phase 1** of the project, we will collect data on all patients attending the JUH Diabetes Clinic, including serum glucose and other chemistries, urinalysis, blood pressure, and physical exam findings including assessment of the feet. Data will be entered into a database on a laptop computer modeled after an information system and medical record developed for use in rural Haiti.[vii] We will expand and refine culturally-appropriate educational materials developed at FHADIMAC, using pictorial messages to communicate health information. The content will include: nutrition, medications including insulin, preventive foot care, and local resources for information and support. We will develop clinical algorithms for cost-effective management of glycemia and blood pressure, emphasizing optimal dosing of generic medications in combination. We will recruit and train a nurse coordinator who will oversee data acquisition and entry. We will also recruit and train two community health workers (Agents de Sante) who will provide case management follow-up for high-risk patients targeted for the intervention. Working with Lucien des Augustes, Founder and President of the Association Diabète du Nord de Haïti (ADNH), we will identify potential Agents de Sante using the "positive deviance" model.[viii] Finally, we will develop a survey to be used by Agents de Sante on home visits to identify barriers to care.

In **phase 2**, we will implement the educational and clinical management protocols previously developed. We will initially work with resident and attending physicians, and clinic nurses, to assure familiarity with educational content and use of clinical protocols. Our nurse coordinator will work with Dr. Pierre to train Agents de Sante in the educational materials. Group educational sessions for patients will be conducted weekly in the afternoon on the same day as the Diabetes Clinic. Topics will vary from week to week, and patients seen at the Clinic will be encouraged to return for education on subsequent weeks. Individuals targeted for intervention (**INT**) will be identified by one or more of the following criteria: random blood glucose > 250 mg/dL with subsequent hemoglobin A1c (HbA1c) > 9%, blood pressure > 140/90, or evidence on foot exam of a high risk for future amputation. The latter will include plantar foot ulcer, or pre-ulcerative callus with one or more or the following: loss of protective sensation to Semmes-Weinstein 10 gm mono-filament, absent pedal pulses in either foot, or significant deformity (e.g. claw toes). Treatment regimens for **INT** subjects will be communicated by the nurse coordinator to the Agents de Sante. During monthly home visits, adherence to treatment regimens will be assessed, as well as measurement of blood pressure and findings on foot exam. Targeted educational sessions will be provided in the home setting for individuals who have difficulty attending the clinic due to distance or lack of transportation. Patients will be encouraged to keep scheduled follow-up appointments, with limited travel assistance provided.

In **phase 3**, we will assess the feasibility of implementation of the intervention. We will also assess in preliminary fashion its impact on clinical outcomes, including glycemic and blood pressure control, and assessment of foot exam scores. We will also be collecting data on the prevalence of high-risk characteristics in the overall JUH Diabetes Clinic population, to assess the impact of standardized educational and treatment protocols.

Target population: will consist of male and female patients, age 18 years and older, who attend the JUH Diabetes Clinic, within a 50-kilometer radius of Cap Haitien.

Community need for diabetes care is considered to be urgent. Diabetic control is judged to be very poor for most individuals, although prevalence data are lacking for Northern Haiti. Observations are that hypertension is very poorly controlled, medication adherence is poor, and rates of complications, including lower extremity amputations, are high. The proposed educational and clinical treatment tools should significantly improve the overall level of care, and reduce the risk for complications in diabetic individuals residing in the Cap Haitien area.

Data to be collected, data analysis, statistical support: We will collect demographic data for all patients attending the JUH Diabetes Center, including age, sex, place of residence, year of diagnosis, medication history, body mass index (BMI), blood pressure, findings on physical exam including the feet, and results of serum and urine chemistry testing.

We will assess the feasibility of implementation of the intervention by assessing the following process measures: number of patients attending classes (% of referred), keeping scheduled follow-up appointments (%), and adherence to medication and self-care regimen.

The patient population will be described using standard descriptive statistics. Clinical outcome measures (HbA1c, BP, foot risk score) will be measured as continuous variables. Our primary analysis will be a before-and-after comparison using paired Student's t test. We will enroll a random sample of 150 subjects into the INT group. Power calculations indicate that an N = 128 will detect an effect size as small as 25% of a standard deviation.

Statistical support will be provided by Dr. Philippe Larco, epidemiologist at FHADIMAC, and by Dr. Lee Lucas at Maine Medical Center's Center for Outcomes Research and Evaluation.

Milestones: are indicated in the Gantt chart included in the Appendix.

Measurable Outcomes:

For this two-year pilot project, we will measure the impact of our intervention on mean glycemia (HbA1c), blood pressure control, and progression of high-risk foot lesions to amputation in a cohort of high-risk individuals selected for intervention (INT). We will also examine process measures which assess the feasibility of this intervention in a resource-poor environment, including adherence by clinical providers and patients to treatment protocols, delivery of educational content in group and individual settings, and barriers to clinic attendance and self-management behaviors. We plan to analyze the cost-effectiveness of the intervention in order to inform its sustainability.

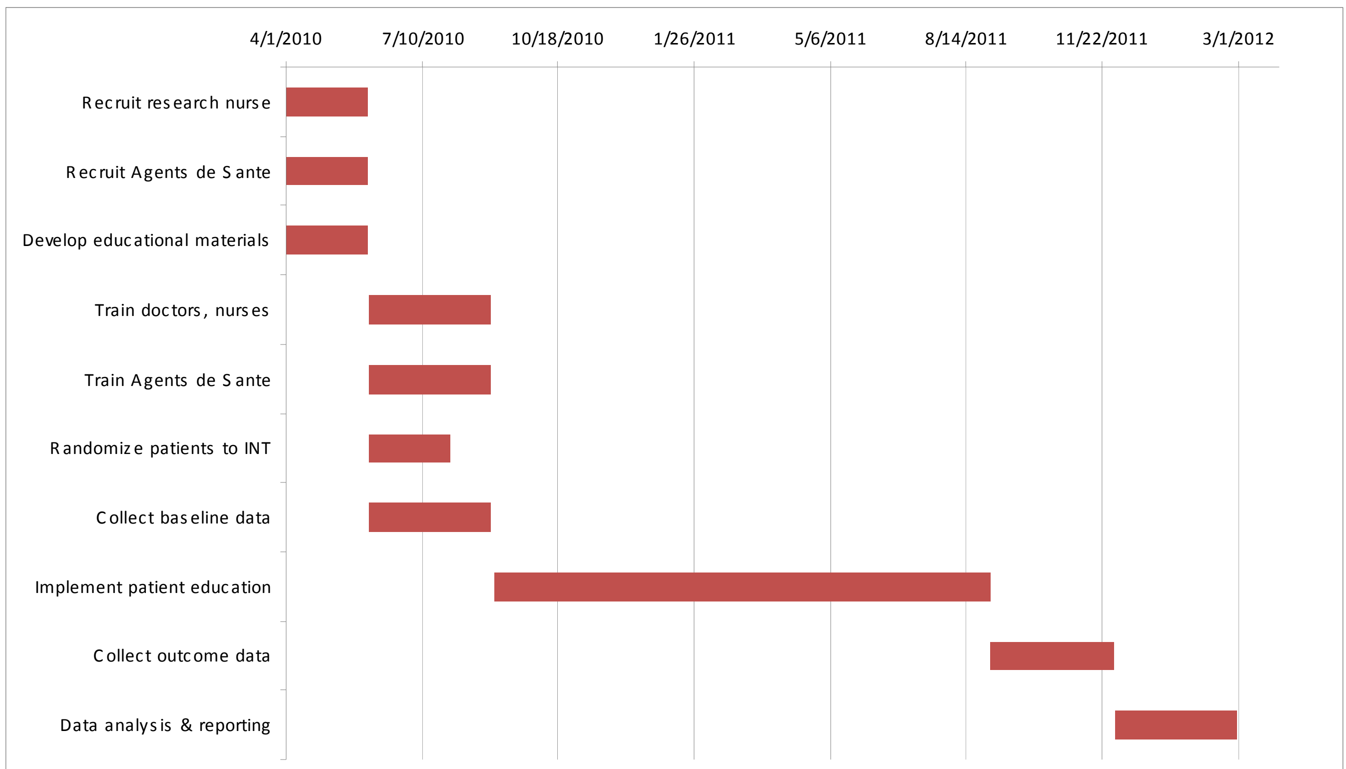
Sustainability and future impact of the project:

By focusing on patient and provider education, and use of low-cost clinical treatment algorithms, we will put in place a system that can be sustained at minimal cost in the future. We anticipate that trained Agents de Sante will be a cost-effective method of delivering case management in the home setting. Due to uncertainties in replacing grant support for salaries by support from the Haitian government, it is likely that the costs of employees proposed in the grant will need to be underwritten by future grants or non-governmental organizations.

APPENDIX

Diabetes Project	Start Date	Duration	End Date
Recruit research nurse	4/1/2010	60	5/31/2010
Recruit Agents de Sante	4/1/2010	60	5/31/2010

Develop educational materials	4/1/2010	60	5/31/2010
Train doctors, nurses	6/1/2010	90	8/30/2010
Train Agents de Sante	6/1/2010	90	8/30/2010
Randomize patients to INT	6/1/2010	60	7/31/2010
Collect baseline data	6/1/2010	90	8/30/2010
Implement patient education	9/1/2010	365	9/1/2011
Collect outcome data	9/1/2011	90	11/30/2011
Data analysis & reporting	12/1/2011	90	2/29/2012



References

[i] International Diabetes Foundation, *Diabetes Atlas*, 3rd edition. 2006.

[ii]Wilks R, Rotimi C, Bennett F, et al. Diabetes in the Caribbean: results from a population survey from Spanish Town, Jamaica. *Diabetic Medicine* 1999;16:875-883.

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[iv] Chan, JCN, Gagliardino JJ, Baik SH, et al. Multifaceted determinants for achieving glycemic control: The International Diabetes Management Practice Study (IDMPS). *Diabetes Care* 2009;32:227-233.

[v] Piatt GA, Orchard TJ, Emerson S, et al. Translating the Chronic Care Model into the community. *Diabetes Care* 200629:811-817.

[vi] Narayan KMV, Zhang P, Kanaya AM, et al. 2006. Diabetes: The pandemic and potential solutions. In *Disease Control Priorities in Developing Countries*, eds. Dean T. Jamison et al, 591-603. World Bank Publications.

[vii] Fraser HSF, Jazayeri D, Nevil P, et al. An information system and medical record to support HIV treatment in rural Haiti. BMJ 2004;329:1142-1146.

[viii] Marsh DR, Schroeder DG, Dearden KA, et al. The power of positive deviance. BMJ 2004;329:1177-1179.