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What works to reduce risk among Type 2 Diabetics?

I. Introduction

Type 2 Diabetes is a chronic disease that requires intense monitoring and personalized care over time. Currently, diabetes is managed in different forms from the single-intervention care models to multi-disciplinary interventions that involve enhancement of provider practices, improvement of patient self-management, community and technological approaches. Recognizing that some illnesses demand a comprehensive set of strategies, Disease Management has emerged as, "the concept of reducing health care costs and improving quality of life for individuals with chronic conditions by preventing or minimizing the effects of the disease through integrated care… It is a proactive, multidisciplinary, systematic approach to health care delivery" [1].

Despite a consensus on following a multidisciplinary approach to diabetes management, there is still limited clarity on which components are most effective at managing diabetes. Researchers have been looking for evidence on several of these elements, such as patient's education for self-management, use of monitoring technologies and enhancing the role of nurses in case management, among others. The goal of this report is to present evidence identifying what works to reduce the risk of complications among people with type 2 diabetes.

Identifying this information will aid in the design of a Social Impact Bond (SIB) on Diabetes Management Services in Mexico. This multi-stakeholder partnership seeks to finance cost-effective interventions to reduce complications and extend life among diabetic patients. This requires selecting those strategies that have the largest impact at the lowest cost. By examining the impact of each type of intervention, this review will inform the assessment of service providers and understand the suitability of the current landscape of interventions in Mexico.

This work focuses on the secondary prevention of diabetes—defined as the prevention of acute complications for patients who already have the disease—by looking into the effect of different interventions on glycated hemoglobin (HbA_{1c}). While primary prevention of high-risk populations can avoid the onset of diabetes, it is outside the scope of this report. First, primary prevention strategies are very distinct to strategies targeting already diagnosed diabetics—the former mainly focusing on lifestyle modification (i.e. diet and exercise) and not requiring specialist intervention. Second, primary prevention operates in a more diffuse population, meaning that only a small percentage of them in any given year go on to develop diabetes. Third, health outcomes associated with primary prevention typically take longer to observe than outcomes associated with secondary prevention. For these reasons the Social Impact Bond, and therefore this report, focus on secondary prevention of diabetes.

Moreover, the analysis presented here focuses on the effect on glycated hemoglobin (HbA_{1c}), which serves as a marker for the average blood glucose levels over the past three months. Due to its objectiveness and reliability, it is considered the 'gold standard' for monitoring long-term metabolic control among diabetics. Also, there is strong consensus about its close association with the risk for the development of long-term complications [3]. For these reasons, this research compares interventions treating type 2 diabetics focusing on their ability to reduce levels of HbA_{1c}.

This work begins in the next section by reviewing the methodology for assessing what works to reduce risk among diabetics. The third section presents the results, before finally, in the fourth section,

concluding with some final thoughts, considerations and next steps for how this work is informing the design of a Social Impact Bond to invest in diabetes management services in Mexico.

II. Methodology

A large set of literature looks at the effectiveness of diabetes interventions. The studies vary in the evaluation methodology and in the outcomes examined. For this reason, this work follows a strategy summarizing the most relevant findings of the most significant research of the last 30 years. In brief, this implied searching for systematic reviews that already synthesize evidence behind different interventions and then selecting one of these reviews for each intervention area addressed in this work. The following paragraphs describe in detail the five steps followed to accomplish this.

Our search strategy began by examining systematic reviews for the secondary prevention of type 2 diabetes. With this intention, we searched *The Cochrane Collaboration* and *Google Scholar* with the key words "diabetes systematic review". The exclusion criteria used was:

- Studies that look at primary prevention strategies.
- Studies in which type 2 diabetics do not make up the majority of the targeted population or in which the systematic review does not differentiate the effect for the group of type 2 patients.
- Systematic reviews that do not assess the effect of the intervention on health outcomes, such as glycated hemoglobin, blood pressure and HDL and LDL cholesterol levels.
- Systematic reviews in which the majority of studies reviewed are not randomized control trials (RCTs), which present the most rigorous evidence.
- Systematic reviews that only look at effectiveness of pharmacological interventions.

A total of 44 systematic reviews made it through the exclusion criteria and were collected for analysis.

Second, each systematic review was classified according to the intervention model assessed in each work. If a systematic review analyzed more than one intervention, it was added to multiple groups. From these 44 systematic review we identified 11 broad categories:

1. Lifestyle modification interventions
2. Computational tools for reminders, audit, advice, feedback and self-monitoring
3. Self-management training
4. Case management
5. Psychological treatment
6. Self-monitoring of blood glucose among non-insulin users
7. Social support
8. Integration of electronic medical records
9. Early screening
10. Professional training for physicians
11. Multidisciplinary teams

Third, criteria to prioritize the assessment of the 11 different interventions were applied. As a consequence, six groups were selected for analysis based on their relevance as potential interventions to be implemented within the context of a Social Impact Bond. These are categories 1-6 in the above list.

Fourth, the systematic review with the highest quality in each selected intervention category was chosen. Quality assessment followed the criteria below:

- Good fit - the set of interventions analyzed by the systematic review are a good fit of the intervention category that this work addresses.

- Quality of the source - the journal is well known and has a high impact factor.
- Methodology- the methodology used to synthesize the studies is of good quality, e.g. a Meta-Analysis of RCTs is better quality than a qualitative summary of studies.
- Recentness – the time frame criteria that delimited the search of the authors
- Number of studies included in the review
- Quality of studies - the review assesses the quality of the included studies in terms of design, biases and methodology.

Fifth, using the results of the selected systematic review, we identified three levels of evidence of the effectiveness of the respective intervention. Then, the six intervention categories were classified and organized according to these levels:

- **Strong positive evidence**: the systematic review found a statistically significant positive effect.
- **Mixed evidence**: the evidence is not strong enough to determine the sign of the effect. This assessment includes those Meta-Analysis yielding effects with no statistical significance.
- **Negative evidence**: the systematic review produced a statistically significant negative effect.

III. Results: Evidence of each intervention

This report describes the evidence of the following selected interventions: lifestyle modification interventions, computer-based tools for reminders, audit, advice, feedback and self-monitoring, self-management training, case management, psychological treatment, and self-monitoring of blood glucose. Table 1 presents a synthesis of the treatment effects analyzed by the systematic reviews used in this research.

Table 1: Summary of results

Intervention	Description	Percentage points (pp.) reduction on HbA_{1c} relative to control group	Evidence (systematic review & number of studies)
Strong positive evidence			
Lifestyle modification interventions	Strategies aiming at changing the daily habits of the patients, i.e. physical exercise and diet	0.67 pp. statistically significant reduction.	Umpierre et al. 2011, reviewing 47 RCTs in M.A.
Psychological treatment	Psychological therapies to generate change in emotional, cognitive, and behavioral functioning.	0.76 pp. statistically significant reduction.	Ismail et al. 2004, reviewing 12 RCTs in M.A.
Self-monitoring of blood glucose	Strategy to provide better understanding, motivation the adherence to treatment and lifestyle changes among non-insulin users.	For over 1 year diabetics compared to control: 0.3 pp. at 6 months follow-up and 0.1 pp. at 12 months follow-up. For newly diagnosed diabetics: 0.5 pp. at 12 months follow-up. Compared to SMU: 0.2 pp. at 6 months.	Malanda et al. 2012, reviewing 12 RCTs in a M.A.

Intervention	Description	Percentage points (pp.) reduction on HbA_{1c} relative to control group	Evidence (systematic review & number of studies)
Case management	Assigning a professional to be responsible for overseeing, coordinating and implementing long-term care plans, especially for high-risk patients. In order to prevent poor outcomes and excessive resources utilization.	0.4 pp. median statistically significant reduction.	Norris et al. 2002, reviewing 6 RCTs
Mixed evidence			
Self-management education	Interventions to help diabetics develop strong motivation, knowledge and compliance to the complex and demanding care regime.	Found effective only in the short term.	Norris et al. 2001 produced a systematic review of 72 RCTs.
Computer-based tools for management	Tools to deliver tailored contents, generate feedback and advice, deliver reinforcement and rewards, support patient's decision-making, send reminders and motive goal settings	0.2 pp., but deemed as not enough evidence	Pal et al. 2013, reviewing 16 RCTs and synthesizing 12 of them in a M.A.

A. Interventions with strong positive evidence

i. Lifestyle modification interventions

Lifestyle modification interventions refer to the strategies aimed at changing the daily habits of the patients, particularly regarding physical exercise and diet. It is indisputable that there is a relation between body weight, total calorie intake and glycemic control; thus dietary changes and physical activity are essential for diabetes management. However, it is not clear which interventions are more effective in improving glycemic indicators. Interventions range from limited recommendations of lifestyle modifications for patients to tailored prescriptions to adopt different types of exercises (e.g. aerobics, resistance) and/or diets (i.e. varying the proportion of carbohydrate, fat, and protein). Also, the frequency, intensity and progression required of the patient can vary widely.

In order to study the role of physical activity on diabetes control, Umpierre et al. 2011 conducted a systematic review to analyze how the effect of physical activity varied depending on the type of exercise, the rigor of the prescription and the combination with a dietary regime. Specifically, the authors compare structured exercise training—defined as planned, individualized and supervised programs—to physical activity advice, in which patients only receive instructions without adhering to a supervised program. To achieve this, they synthesized the effects found in 47 RCTs (covering 8,539 patients) through a meta-analysis using a random-effects model to calculate the pooled mean differences between the treatment and control groups. By pooling the effect of 23 studies, the authors found that any structured exercise training was associated with a reduction in HbA_{1c} 0.67 percentage points (pp.) larger than the effect on the control group. Specifically, structured aerobic exercise (18 studies) led to a decline of 0.73 pp., structured resistance training (4 studies) to a reduction of 0.57 pp. The combination of both (7 articles) led to 0.51 pp. drop in HbA_{1c} as compared with the control. Moreover, they found evidence that the effect was much larger when the structured physical activity extended over 150

minutes per week (0.89 pp. reduction compared to control group, in contrast to 0.36 pp. reduction for less lengthy exercises). Finally, interventions providing physical activity advice alone (24 studies) had no effect in improving glycaemia control; a reduction of 0.58 pp. was found only when combined with dietary advice. The authors found evidence that physical activity has a positive impact on hemoglobin and that the magnitude of the effect depends on the type of exercise, the rigor of the prescription, the duration and the combination with dietary advises.

ii. Psychological treatment

Diabetic people have to cope with various challenges related to treatment adherence and psychological problems derived from chronic disabilities. Frequently, people with diabetes develop depressive disorders and eating disorders, which tend to lead to suboptimal disease management and poor metabolic control. For this reason, it has been suggested that psychological and emotional factors deserve attention within the scope of diabetes management. In this regard, psychological therapies—opposed to educational interventions that only look to increase knowledge management methods—build, "an alliance between the patient and the therapist to generate change in emotional, cognitive, and behavioral functioning, including adherence" [2].

Using a meta-analysis of 12 RCTs, Ismail et al. 2004, compared the glycated hemoglobin between a group of people receiving psychological treatment and control groups. Most commonly, the treatments were cognitive behavior therapy and motivational interviewing or counseling. The control groups were composed of people receiving usual levels of care, education, waiting times and attention control; a few cases of patients received a less intensive type of therapy. They found that psychological therapies led to a decrease in HbA_{1c} that was on average lower by 0.76 pp. than the levels among non-treated people. Additionally, the review examined whether the effect varied according to the intensity of three treatment factors: type of therapy (most intensive was psychodynamic/interpersonal, followed by cognitive behavior therapy and then counseling), number of sessions, and duration of therapy. They found that the difference increased to 1.0 pp. when dropped from the control group studies that used a less intensive psychological therapy. However, they found no evidence that the number of sessions, the duration of the intervention and the duration of the follow-up are associated with glycated hemoglobin levels. Also, effects on blood glucose concentration and weight loss were not statistically significant. Nevertheless, the authors found evidence that psychological interventions are effective in improving HbA_{1c} among type 2 diabetics and these effects are large enough to lower the risk of the disease progressing into microvascular complications.

iii. Self-monitoring blood glucose among non-insulin users

Self-monitoring blood glucose (SMBG) among type 2 diabetics is recommended as a means to improve glycemic control. For those using insulin, self-monitoring is commonplace as it help patients adjust their insulin dosage. However, among non-insulin users, the strategy is much less commonly used. Self-monitoring of blood glucose among non-insulin users might be useful to identify their glucose levels at different times and after different behaviors (i.e. medication utilization, physical activity and food intake.) Consequently, it may lead to a better understanding of how their lifestyles are associated with risk factors, motivating an adherence to treatment and lifestyle changes. It also provides more independence to cope with their disease and may replace the usual three-monthly visits to the physician.

To test if type 2 non-insulin dependent diabetics benefit from SMBG, Malanda et al. 2012 synthesized the effects on glycemic control found in 12 RCTs. Through a meta-analysis, the authors compared HbA_{1c}

levels among patients performing SMBG to HbA_{1c} levels among patients undergoing usual care and/or self-monitoring of urine glucose. Specifically, the researchers distinguished the effect among four different subgroups according to both the diabetes duration (newly diagnosed or patients with diabetes for over one year) and to the duration of the intervention (follow-up period up to 6 months or between 6 and 12 months). The results showed that SMBG has a small and significant effect for short-term follow-up (2324 participants, 9 RCTs) of 0.3 pp. decrease in glycated hemoglobin compared to control group among the long-term diabetics. The effect fades off in the medium-term (6-12 months follow-up, 493 participants, 2 RCTs), shown by a statistically non-significant reduction of 0.1 pp. in HbA_{1c}. In the case of the newly diagnosed patients (345 participants, 2 RCTs), it was not possible to estimate a short-term pooled effect due to high heterogeneity. However, for the medium-term follow up, (6-12 months) the effect of SMBG on HbA_{1c} was a statistically significant reduction of 0.5 pp. In addition, the authors compared a SMBG group with a self-monitoring urine glucose (SMUG) group and found a statistical non-significant decrease in HbA_{1c} of 0.2 pp. (194 participants, 2 RCTs). Overall, the authors conclude that SMBG has a small short-term effect on type 2 diabetics whose disease duration is over one year and who are not using insulin, and this effect subsides after 12 months of initiation of the intervention.

iv. Case management

Case management consists of assigning, especially to high-risk patients, a professional who is not the direct health-care provider to be responsible for overseeing, coordinating and implementing long-term care plans. Case management has become relevant in the care of patients with chronic diseases. The particularities of these illnesses—such as the need to have highly monitored, patient-tailored and long-term care—have made it suitable to increase the role of nurses focusing on each patient's needs, preferences and goals. It aims at delivering effective care at optimal times, so that the presence of adverse outcomes and excessive health resource utilization is prevented. Most commonly, the case manager is a registered nurse but teams of specialists may also deliver it.

A systematic review of 15 studies conducted by Norris et al. 2002 synthesizes the evidence supporting case management. The authors followed the *Guide to Community Preventive Services* criteria in order to select the studies examining the impact of case management. Six of them were RCTs evaluating outcomes among type 2 diabetics. It was found that the median effect was a reduction of 0.4 pp. on glycated hemoglobin (interquartile range: 0.16 to 0.6.) In addition, the research examined the outcome when the intervention was combined with disease management, which in contrast with case management that only addresses the needs of patients at high risk, this is defined as a multicomponent approach that involves the whole population with a specific disease; it also incorporates interventions focused on the patient, on the provider and on the healthcare system. This assessment yielded a median effect that was not significantly different from a case management intervention alone: it reduced blood glycated hemoglobin by 0.53 pp. (interquartile range: 0.46 to 0.65.) Evidence was insufficient to support the value of this strategy in the reduction of lipid concentration, body mass index and blood pressure. The authors concluded that there is strong evidence of the effectiveness of case management in improving glycemic control, both when it is implemented on its own or alongside disease management.

B. Interventions with mixed evidence

i. Self-management education

Self-management education (SME) comprises a set of strategies that aim to empower patients and increase their participation in the treatment of the illness. Particularly for the case of diabetes, the level of involvement of the patient in managing his/her own disease is highly relevant. Hence, educational

programs for diabetes self-management have been structured to help diabetics develop strong motivation, knowledge and adherence to the complex and demanding care regimes that they need to follow throughout their lifetimes. These programs often differ in their specific objectives: they may seek to improve knowledge, lifestyle behaviors and/or teach disease management skills and coping skills. Also, they vary in their format as they may be provided by the physician, a nurse or another health facilitator. They may be individual or group-based and delivered through written material, videos, or face to face.

To assess the effects of SME, Norris et al. 2001 produced a systematic review of 72 RCTs. The diversity of the focus and format of interventions was reflected in the mix of results yielded by the research. For instance, studies with a follow-up shorter than six months showed great effectiveness in controlling glycated hemoglobin levels, whereas studies with follow-up periods longer than one year only had two reported positive results, including the caveats that they were either very intense treatments or they suffered from attrition bias. Likewise, prolonged interventions (i.e. those with follow-up longer than 12 months and regular contacts with the patient) generated inconclusive evidence since 10 studies showed no effect on glycemic control and two suggested some improvement but cannot be generalized. Moreover, collaborative interventions resulted in higher improvement compared to didactic individual education. Additionally, of 17 studies examining the association between increasing disease knowledge and glycemic control, only seven showed some association. There was also mix evidence about the effects on blood pressure: four studies reported a significant effect and the other four failed to do so. The authors conclude that their research supports the effectiveness of SME among type 2 diabetic patients in the short term; however, more research is needed to evaluate its long-term impact.

ii. Computer-based tools for reminders, audit, advice, feedback and self-monitoring

Computer-based interventions facilitate self-management activities and may support the persistent care that the patient needs. Computer-based tools provide processing power and the ability to allow remote access to information and algorithms, which can do the work of some components of the self-management education programs. These interventions vary widely according to technologies used and to the objective that is being pursued. The most common tools are desktop, laptop or handheld computers and mobile phones. Among the objectives, interventions seek to deliver tailored contents, generate feedback and advice, deliver reinforcement and rewards, support patient's decision-making, send reminders and motivate goal settings.

To study the effectiveness of the utilization of technological tools to improve metabolic control, Pal et al. 2013 synthesized the results of 16 RCTs, including 11 of them in a meta-analysis. These studies examined interventions with durations between 1 and 12 months. The intensity mostly varied according to how often the patient choose to use the tool, but some interventions were prescriptive and produced up to 2 interactions a day. There were 6 clinic-based (touch screen or other clinic computer), 5 home computer-based and 5 mobile phone-based interventions examined. The patients covered had an average age between 46 and 67 years and had a diabetes duration mean between 6-13 years. Overall, the review found that the effects on glycemic control are mixed: the pooled effect saw a reduction of 0.2 pp. in HbA_{1c} compared to the control group. However, only six studies found small and statistically significant effects. Three others reported higher improvements on the group but no statistical significance and the remaining six found no difference between diabetics using computational tools and those in non-computer-based programs. Additionally, it was found that this mean difference increased to 0.5 pp. among the subgroup using mobile phones for diabetes self-management purposes. The research by Pal et al. 2013 suggests that there is not enough evidence to support the use of computer-based interventions for diabetes management.

C. Interventions with negative evidence

None of the assessed interventions yielded negative effects in the level of glycated hemoglobin among type 2 diabetic people.

IV. Conclusions

This report examined the evidence of what works to reduce risk among type 2 diabetics. Based on the results of good quality systematic reviews, it was found that modifications of lifestyle habits, psychological treatments, self-monitoring blood glucose and implementing case management are four effective ways to reduce elevated HbA_{1c} levels and therefore reduce the risk of developing complications. There is less evidence to the support self-management trainings and the employment of technology for management of the disease.

It is worth underlining a few key ideas that came out of this research and are useful to complementing the analysis above. First, lifestyle modification programs are more effective when supervised, which may be an indication that it is essential to address the self-control problems associated with patient adherence to a treatment regime or lifestyle change. Second, the evidence here suggests that the psychological and mental health components of the disease are very important. Psychological interventions showed the largest impact on reducing glycated hemoglobin. One reason this may be so is due to their ability to also enhance the patient's motivation and capacity to maintain treatment adherence. Third, self-monitoring of blood glucose demonstrated an impact in the short-term, but failed to produce a long-lasting effect. Its effectiveness is strongly related to the patient's willingness and ability to make the corresponding lifestyle and medication adjustments according to daily blood glucose profiles, thus emphasizing again the importance of adherence. Fourth, case management, while expensive in the short-term, may for extremely high-risk patients avert future expenditure in treating complications. Fifth, besides improving adherence, patient's education for self-management can also reduce costs when it results in effective self-care replacing some components of otherwise *in situ* provision of health services. Finally, computer-based technologies are good at providing tailored information and reminders to the patient, but they are not sufficient in the absence of motivation to treatment adherence. The learning summarized in this work suggests that the impact of these strategies on the patient's health outcomes is highly associated to their ability to instill adherence in following treatment regimens and monitoring of health indicators. It is helpful to keep all the above considerations in mind when considering the most effective treatment.

In interpreting these results it is also important to keep in mind a number of potential limitations to the approach employed here. First, a finding of mixed evidence may potentially come from the high heterogeneity of the design of the studied interventions. For example, the systematic review of computer-based tools incudes strategies as varied as touch-screen computers in hospital clinics to apps on mobile phones. While the average effect may be mixed, some types of computer-based tools might be far more effective than others. It would therefore be imprudent to discredit all computer-based tools.

Second, this paper looked only at the effectiveness of interventions to improve health outcomes. It did not look at the cost to achieve that outcome. While two interventions may be equally effective, an intervention that costs $10 per patient treated would be preferable to another intervention that achieves the same outcome, but at a cost of $10,000.

Finally, it is important, to remember that no 'one-size-fits-all' solution exists in diabetes management. A multidisciplinary approach, as is common in chronic disease management, is better than individual strategies since the choice of interventions must be attuned to the particular biological, physiological, psychological and morbidity characteristics of the individual. Despite the ambiguity about the exact components that are the most effective combinations in disease management, this work found positive outcomes in four of the treatments reviewed. This merits future exploration for diabetes management services to improve health outcomes.

Next steps

This review will be used to map the current supply of services in Mexico to reduce the risk of complications among type 2 diabetics. A first step will be to draw the landscape of service providers. Next, we will link the programs being delivered by those service providers to this literature base in order to understand what types of organizations are currently providing interventions and where they fit into this evidence-base. Finally, the information will lead us to select qualified service providers and build out a cost-benefit model using as a starting point the individual studies found in the systematic reviews identified in this report.

V. Works cited

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Appendix: Quality assessment

Systematic reviews were assessed according to six criteria:

- Good fit: the set of interventions analyzed by the systematic review are a good fit of the intervention category that this work addresses.
- Quality of the source: the journal is well known and has a high impact factor.
- Methodology: the methodology used to synthesize the studies is of good quality, e.g. a Meta-Analysis (M.A.) of RCTs is better quality than a qualitative summary of studies.
- Recentness: the time frame criteria that delimited the search of the authors
- Number of studies included
- Quality of studies: the review assesses the quality of the included studies in terms of design, biases and methodology.

Of the 44 systematic reviews identified, we summarize the six we selected in each intervention area according to the criteria above.

Table 2a: Quality assessment of selected systematic reviews

Review	Umpierre et al. 2011	Ismail et al. 2004	Norris et al. 2001
Intervention	Lifestyle modification	Psychological treatment	Self-management education
Good fit	Yes. It studies the effect on glycemic control among type 2 diabetes patients of structured exercise training regimens and physical activity advice with or without dietary.	Yes. It assesses the effect glycemic control among type 2 diabetics of different the psychological therapies.	Yes. Analyzes effect of Self-Management Training among type 2 diabetics. Classifies intervention based into educational focus: knowledge or information; lifestyle behaviors, skill development and coping skills.
Journal	*American Medical Association*	*The Lancet*	*Diabetes care*
Method	Meta-Analysis of RCTs	Meta-Analysis of RCTs	Systematic review
Recentness	1980-2011	Up to January 2003	1980-1999
# Studies	47 RCTs	25 RCTs. Only 12 analyze effect on HbA_{1c}	72 RCTs. Only 64 analyze effect on HbA_{1c}
Quality of studies	Low. Of the 47 studies, 17 presented adequate sequence generation, 8 reported allocation concealment, 8 had blinded assessment, 45 described losses to follow-up, and 6 used the Intention-to-treat analysis. No publication bias was found.	Moderate to poor. The quality assessment looked for selection bias, attrition bias, and detection bias. 1 study met all criteria with low risk bias, 7 had at least one criterion only partly met with moderate risk of bias, and 17 had at least one criterion not met with high risk of bias.	Threats to internal validity were observed (performance, selection, attrition, and detection bias) in a number of studies reviewed, and external generalizability was often limited.

Table 2b: Quality assessment of selected systematic reviews (Continued)

Review	Pal et al. 2013	Malanda et al. 2012	Norris et al. 2002
Intervention	Computational tools for management	Self-monitoring of blood glucose among non-insulin users	Case management
Good fit	Yes. It studies the use of computer-based software applications to improve self-management domains through feedback, advice, reminders, goal setting, and patient's decision support, among type 2 diabetics.	Yes. It assesses the effects of SMBG among non-insulin users type 2 diabetics, compared with usual care and/or with self-monitoring of urine glucose.	Yes. It studies the impact of disease management and case management on several health outcomes, including glycated hemoglobin, among people with diabetes (mainly adults with type 2 diabetes).
Journal	Cochrane Database of Systematic Reviews	Cochrane Database of Systematic Reviews	American Journal of Preventive Medicine and published by Elsevier Science
Method	Meta-Analysis of RCTs	Meta-Analysis of RCTs	Systematic review following the Community Guide of the Community Preventive Services Task Force
Recentness	Up to November 2011	7 July 2011	1989-2000
# Studies	16 RCTs. Only 11 analyze effect on HbA1c	12 RCTs	15 studies. Only 6 are RCTs on type 2 diabetics.

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Social and Financial Returns to Investing in Diabetes Management Services in Mexico

I. Introduction

In recent decades, diabetes has become a significant public health issue in Mexico. In particular, diabetes has increased by more than 25% in the six year period between 2006 and 2012[1][13] with over 430,000 adults being diagnosed in just 2012 [5]. The National Health Survey (ENSANUT) reports that the quality of care for diabetics in the country is low: only 80% of those diagnosed with diabetes receive medical attention and, among those being treated, only 25% are under control, as measured by a percentage of glycated hemoglobin (HbA1c) lower than 7% [13]. In this regard, there are significant opportunities to improve service quality and the effectiveness of strategies in order to produce better health outcomes.

Investing in Diabetes Management Services (DMS) can yield high returns both for patient's themselves as well as for society and the state. The objective of this report is to identify and describe the potential financial and non-financial returns to investing in DMS in Mexico. Specifically, this report examines how DMS contributes to positive outcomes in individuals' financial, social and psychological wellbeing as well as improvements in society's welfare and the public finances.

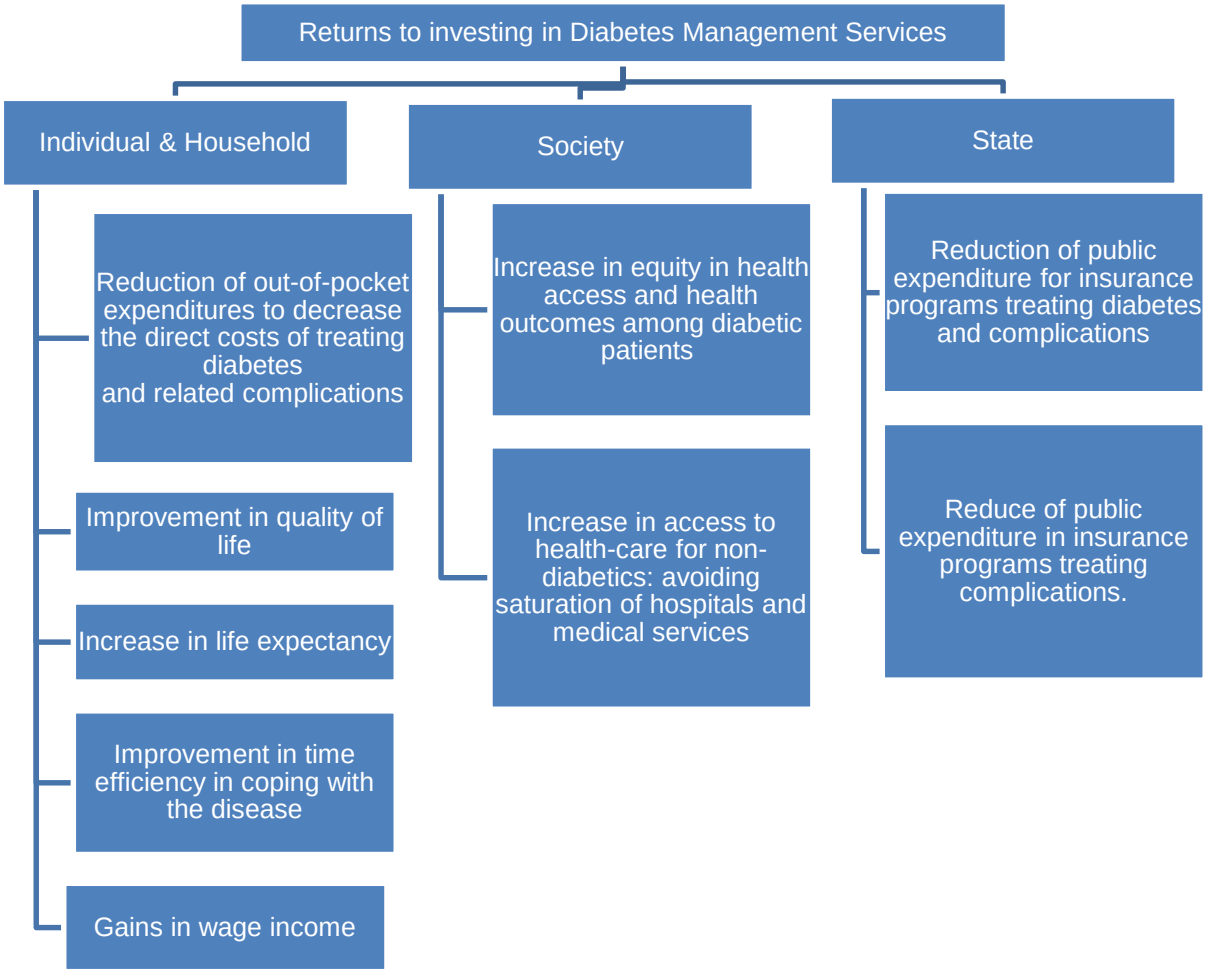
This paper identifies eight benefits associated with the delivery of effective DMS. Among them, two outcomes could be monetized: reduction of expenses for treating diabetes and related complications, both at the individual and the state level, and greater income from reducing workforce abandonment. Together, these expenditures amount to $ 7.7 billion USD per year [1]. If DMS can reduce the prevalence of poorly controlled diabetes and the associated chronic illnesses, then a large portion of this financial burden can be averted. Beyond the financial benefits, this report also finds that DMS's impact in saving lives and improving quality of life make it an important investment opportunity.

II. Potential returns to investing in diabetes management services: a framework.

Although Diabetes Management Services (DMS) is a strategy aiming to improve health outcomes among patients, effective control also produces a number of other positive externalities beyond the patient (Figure 1). This section examines eight financial and non-financial benefits generated at the level of the individual and household, the society and the state.

[1] As measured by the percentage of the adult population (20 years and older) that had already been diagnosed with diabetes prior to the survey.

Figure 1. Returns to investing in Diabetes Management Services



A. Individual and Household level

i. Reduction of out-of-pocket expenditures to decrease the direct costs of treating diabetes and related complications

Implementing care that effectively controls diabetes can decrease the economic burden on patients and their families. In Mexico, 75% of diabetics are at a high risk of developing complications and need to receive more intensive and ultimately more costly treatment [9]. The average diabetic patient in Mexico spends $2,066 USD each year to pay for consultations, diagnostics and drugs [1]. This represents 20% of the total expenditure of the average household [7]. In addition, diabetes creates long-term medical conditions that add to the lasting economic burden. One out of every two Mexican diabetics who visit the doctor for the first time has already developed complications [4], leading to hospitalization and other expensive interventions. In 2011, the average diabetic in Mexico incurred in an out-of-pocket

expenditure of $1,610 USD[2] to pay for hospitalization and for coping with diabetes-related illnesses. Among the many complications, nephropathy is the most costly: with a prevalence of 24% among Mexican diabetics and an average annual out-of-pocket expenditure of $3,696 USD [8]. This is followed by retinopathy ($305 USD), cardiovascular diseases ($221 USD), neuropathy ($126 USD) and peripheral vascular disease ($97 USD)[3]. When patients develop multiple complications, financial stress can be puts economic burden on the entire family unit. Thus, managing the disease early and proactively has a lifetime return on the household economic wellbeing.

ii. Improvement in quality of life

Providing effective DMS can improve quality of life by reducing disability and improving psychological wellbeing. Avoiding complications such as foot sores, amputations, loss of eye sight and dialysis gives patients greater freedom over their lives and their ability to contribute to everyday tasks. Patients who do complicate often put additional stress and responsibilities on friends and family. DMS help to preserve patient's belongingness and social by reducing the degenerative process of the dieases and giving the patient greater independence.

Avoiding these disabling complications can also improve mental health as well. Low self-esteem, anxiety or depression are often common among diabetics. Studies on type 2 diabetics [12] have found that mental health interventions, such as cognitive behavioral therapy and stress management, are associated with better self-care, a reduction in depression and anxiety and greater metabolic control. As a result, DMS that approach the psychological dimension can replace a negative perspective with a feeling of achievement and confidence that improves the patient's mental and physical perceptions of their quality of life.

iii. Increase in life expectancy

Treatment that is successful in improving health outcomes will also expand life expectancy. In 2012, the disease killed 84,797 Mexicans, accounting for more than 10% of deaths in the country and making diabetes the first cause of death at a national level [2]. Furthermore, it is estimated that 54% of the current diabetics will die in the next 20 years, having an average life expectancy of 10.9 years [2]. Research suggests that a reduction from 8% to 6% HbA1c results in a gain of 0.9 years of life, a reduction of total HDL cholesterol from 7 to 4 units can increase life expectancy in 1.5 years, and a decrease in Systolic Blood Pressure from 180 to 120 mmHg can produce a gain of 2.2 life years. More relevant, successfully addressing all risk factors together, is associated with an increase in life expectancy of 5.8 years [10]. Adding years to the patient's life is an invaluable outcome of investing in effective DMS.

[2] This number was calculated using the total diabetic population receiving some treatment, including those who did not develop complications; hence, the average could be even higher if the expenditure considers only those who actually spent on each complication or hospitalization service.

[3] The average quantities were calculated by dividing the total expenditure on each complication [1] by an estimated number of diabetics having the complication. The latter was calculated assuming that the incidence of every illness is the same for each group of diabetics attended by the different insurance programs. According to information referred by specialists and INEGI, it is considered that the illnesses have the following rates of incidence: retinopathy, 31%; cardiovascular disease, 75%; nephropathy, 24%; neuropathy, 15% and peripheral vascular disease 17%.

iv. Improvement in time efficiency in coping with the disease

Improving diabetes management also benefits patients by avoiding time-consuming care practices that are required once complications have appeared. Once complications are present, diabetics must engage in additional care practices, such as foot care, more frequent visits to the physician, more intense physical activity and monitoring of blood glucose, applying insulin and spending more time in special shopping and food preparation. To the extent that diabetes management avoids the worsening of conditions down the line, they will help patients decrease total care time over their lifespan.

v. Gains in wage income

Diabetes management can have a positive effect in the labor market by enabling diabetics to be more productive while they are on the job and to reduce the need to leave the labor market early due to disability or premature death. Patients with diabetes have a 30% higher workforce exit rate than those without the condition [14], showing that poor management of the disease may decrease household income. Improving health outcomes will have significant economic benefits in Mexico, where temporary disabilities resulting from diabetes totaled $16.22 million USD, permanent disabilities amounted to $4,092 million USD and lost wages related to early mortality reached $196.2 million USD in 2011 [1] (See Table 1). Delaying the deterioration and early loss of lives through diabetes care will keep diabetics in the labor market and help them maintain a higher level of earnings.

B. Society level

i. Increase in equity in health access and health outcomes among diabetic patients

Improving the provision and quality of DMS across insurance programs will overcome the asymmetries in access, resources allocation and quality of services that are currently intrinsic in the system. One of the primary problems in terms of equity is that not all the diabetics have access to care. In 2006, 26% of all diabetics lacked coverage; this sub-group was 73% female and had high concentrations of indigenous dialect speakers and rural inhabitants [2]. Secondly, health care accessibility is fragmented according to affiliation to a particular insurance program, which is associated with the employment status and capacity to contribute of the individual. Only 10% of the diabetic population in Mexico uses private care institutions, while 48% receives health care from social security institutions like IMSS and ISSSTE and 42% is taken care of by institutions that serve the uninsured like Seguro Popular and IMSS-Prospera [1]. However, the distribution of resources to serve diabetics is not commensurate to the distribution of patients across programs: for every $100 USD spent in diabetes care in Mexico, $51 are spent on private sector patients, $34 are spent on those insured by public institutions and only $15 are allocated on the uninsured. A third disparity issue is on the quality of care. Interestingly, according to a set of quality indicators measured by ENSANUT 2012, a patient attended by social security institutions receives attention that satisfies, on average, 36% of the indicators relevant to each patient. Second in order is Seguro Popular, providing services that on average accomplish 29% of them. Lastly, the service provision for diabetics taken care by private sector has an average rate of 25% fulfilled indicators [3]. Similarly, a study using data from ENSANUT 2006 found that those diabetics being treated by private facilities were more likely to present poorer indicators than those being taken care by IMSS [18]. However, the authors explain this as a possible reverse causality, meaning that patients with the worse health conditions are more prone to switch to private attention in order to deal with poor control. Investing in uniform DMS that are focused on improving the patient's health outcomes will ensure the provision of services in a more equitable manner. This means giving equal opportunity to all diabetics to receive good quality treatment and providing services according to the needs of each patient.

ii. Increase in access to health-care for non-diabetics: avoiding saturation of hospitals and medical services

Diabetic patients are overwhelming the Mexican health system. Reducing this burden can have benefits for the entire Mexican health system by opening up space for other patients lacking access to basic health care in otherwise saturated hospitals and clinics. In 2012, there were 153,142 diabetes related hospital releases and the total number of days spent in the hospital for diabetes was 842,915, the third largest total of any condition reported in Mexico [16]. Reducing the development of complications among diabetics can free hospitals capacity and reduce overcrowding in these
facilities. This is particularly relevant for a country like Mexico, where there are 1.6 hospital beds per 1000 people, one of the lowest rates among OECD countries [11]. What is more, a facility risks underperformance when it works at more than 85% of its capacity since it might respond poorly to high demand and it also puts the patient's health at risk. The current system runs this risk: in 2010 38 of IMSS's units, two ISSTE unit and 71 facilitates of the State Health services had average occupancy levels over 90% [17]. In a system with limited resources, decreasing hospital visits among diabetics can take stress and costs off a saturated system and improve quality of care for all patients.

C. State level

i. Reduction of public expenditure for insurance programs treating diabetes and complications

Effectively controlling diabetes care will reduce the financial burden on the public health system. In Mexico, there are two types of public institutions taking care of diabetics: those covering the insured population—mainly IMSS and ISSSTE—and those attending the uninsured—Ministry of Health's (SSA) program 'Seguro Popular' and IMSS-Prospera. In 2011 they spent a combined $1,538 million USD in treating diabetes and associated complications [1]. However, the financial burden is shared unequally among these institutions: IMSS spends more than double of what SSA spends and four times more than the expenses incurred by ISSSTE [1] (See Table 1). To further understand the burden bore by IMSS, this institution forecasted that in 2020 they would spend $3,553 million USD in consultations, medication, diagnosis and hospitalization for diabetics [6]; this implies that over the next five years, the accumulated expenditure would amount $19,031 million USD. With this same amount, the government can provide scholarships, food subsidies and health services during 3.5 years to the families that are beneficiaries of Prospera, the largest social development program in Mexico.

The potential reduction of diabetes-related public expenditure can be further analyzed if the total amount is broken down in two. On one hand, money is spent on usual treatment—consultations, diagnosis and drugs—to attend diabetics both with and without complications. This amounted to $868 million USD in 2011 [1]. On the other hand, money is being spent on hospitalization and other interventions to treat those who have developed acute conditions and chronic illnesses derived from diabetes, such as retinopathy, cardiovascular diseases, nephropathy, neuropathy and peripheral vascular diseases. This totaled $670.3 million USD [1].

Table 1: Direct and indirect costs of diabetes in Mexico, 2011 (million USD)

	SSA	IMSS	ISSSTE	Total Public sector	User	Private Health Insurance	Total
Consultations /diagnosis	71.0	160.3	37.5	268.8	310.6	17.9	597.3
Drugs	158.1	357.5	83.5	599.2	692.4	39.9	1331.4
Expenditure in usual treatment	**229.1**	**517.8**	**121.0**	**868.0**	**1003.0**	**57.9**	**1928.8**
Hospitalisation	47.5	107.2	25.1	179.7	207.7	12.0	399.4
Retinopathy	14.4	32.6	7.6	54.7	45.9	2.7	103.2
Cardiovascular disease	13.1	29.6	0.7	43.4	80.4	4.6	128.4
Nephropathy	95.8	216.3	50.6	362.7	430.6	24.8	818.2
Neuropathy	4.7	10.7	2.5	17.9	9.2	0.5	27.6
Peripheral vascular disease	3.2	7.1	1.7	11.9	8.0	0.5	20.4
Expenditure in treatment of complications	**178.7**	**403.4**	**88.1**	**670.3**	**781.8**	**45.1**	**1497.2**
Total direct costs	**407.9**	**921.2**	**209.1**	**1538.3**	**1784.8**	**103.0**	**3426.0**
Mortality	22.7	53.3	12.2	88.1	108.1	0.0	196.2
Permanent disability	471.9	1108.5	253.3	1833.6	2258.4	0.0	4092.1
Temporary disability	7.1	1.7	3.8	12.6	3.6	0.0	16.2
Total indirect costs	**501.7**	**1163.4**	**269.3**	**1934.4**	**2370.2**	**0.0**	**4304.5**
Total Expenditure	**909.6**	**2084.7**	**478.4**	**3472.6**	**4154.9**	**103.0**	**7730.5**

Source: Adapted from Arredondo & Reyes, 2013

III. Conclusions

Investing in Diabetes Management Services is critical both from a societal welfare and the financial perspective. With respect to the former, it is not possible to quantify the economic value of lives saved and improvement in quality of life for patients. Regarding the latter, the combined spending on treatment of diabetes and the associated illnesses expenditures and lost income from disabilities, absenteeism and premature death totals 7.7 billion USD annually for individuals, society and the state [1]. It is clear that investing in DMS is needed to shift from the current unbearable and ineffective expenditure to sustainable and impactful spending over time.

Future research will focused on developing a cost-benefit model which links the costs of implementing diabetes management services to the benefits it generates to households, society and the state. This work provides a framework for linking a DMS intervention to the benefits identified here.

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Short report of service providers of diabetes management services in Mexico

I. Introduction

The present work examines the supply of services for diabetes management in Mexico. In specific, it looks at private provision serving people at-risk and those living with diabetes. The goal of this report is to provide a selection of the methods and strategies currently in use to address diabetes, the leading cause of death in the country. Additionally, this summary provides information on how current operators are implementing evidence-based interventions and adapting them to the particular context and needs of the Mexican population.

II. The current landscape: selection of relevant providers

This section describes the intervention models and services of relevant operators in Mexico. Although this report includes a limited number of service providers, the referred cases provide enough information to understand the availability and quality of services for the diabetics. Below is the description of seven relevant operators.

Clínicas de Azúcar

Clínicas de Azúcar (Sugar clinics) is a for-profit enterprise that provides high-quality diabetes care to middle and low-income people at low cost. Their service delivery is innovative across three components: distribution, technology and financing. First, they integrate the whole value chain in "one-stop-shops" in which they offer six specialized consultations in the same visit, including nutritional and physical advice, and psychological support. Second, they use cutting-edge technology to make the costs of diagnosing diabetes-related complications, such as retinopathy, nephropathy and diabetic foot, affordable to the patient. They also developed a software program to monitor health indicators, educate the patient, and facilitate decisions with a patient-centered focus. Third, they provide a convenient payment method by charging an annual fixed-fee.

All these features of the business model lead to important benefits for the client. It saves 80% of the consulting time compared to a traditional care model; it reduces the probability of diabetes-related complications by 60%; it reduces the annual cost of care by 75% compared to the market average ($200 versus $1,000); and it increases access to private care from 10% to almost 80% of the target population. In sum, the model of care brings affordability and convenience to the patient, making it more likely that he receives attention in a consistent and effective way. Currently, Clínicas de Azúcar operates only in the city of Monterrey and its metropolitan area, but they plan to expand to other cities in Mexico and create 100 clinics in the next five years.

Asociación Mexicana de Diabetes

The Mexican Diabetes Association (AMD) is a not-for-profit organization that developed the Model of Attention and Education on Diabetes (MAD/AMD®). This model integrates interdisciplinary attention and therapeutic education with medical treatment. The main goal of the intervention is to develop patients' ability to self-manage through a program of self-care and emotional attention. They also offer

accessible services, including attention by physicians specialized in diabetes, pediatric endocrinology, nutrition, psychology, odontology, foot care, and blood glucose tests. It also provides direct support to the patients' families in the form of workshops, seminars, and certification courses that help them to take better care of the patient. Additionally, the AMD has a pharmacy with specialized products for diabetics.

CASALUD

CASALUD is a care model that uses cutting-edge technology from prevention to follow-up. The model is delivered by the Carlos Slim Health Institute (CSHI) and already operates in 21 out of 32 states in the country. It hinges upon four components that ensure effective access to continuous care. First, CASALUD implements proactive prevention strategies at the household and community level. They created MIDO®, the Integrated Measurement for Early Detection, a tool that determines risk profiles and delivers personalized recommendations. This cost-effective tool is available both in primary health-care settings and as a portable version administered in patient's homes. Second, CASALUD seeks to guarantee effectiveness using two technological innovations that support the patient self-care and adherence to treatment. They created ViveSano, an application that offers personalized education and helps the patient to self-monitor, interpret results, and adapt their lifestyle to prevent cardiovascular risk. They also developed Diabediario (diabetes diary), an application that helps people living with diabetes to improve compliance with treatment, through reminders, self-assessment tools and education. Third, CASALUD aims to strengthen human capital through an on-going professional education. They built up the Center for Education in Health, an online platform to inform and update in global best practices. Also they created the Digital Portfolio, a set of applications to help the health-care professionals (HCPs) measure indicators to prevent, diagnose and treat patients. Fourth, CASALUD seeks to assure availability of adequate supplies through a mobile phone application that allows HCPs to report stock levels and depletions.

Each of the components of this model has been evaluated providing positive proposition for scalability. Both ViveSano and Diabediario were tested in a controlled trial, but results are not yet available. The aim is that the Ministry of Health incorporates both tools in their National Strategy against Obesity and Diabetes so that they reach the whole target population. The Digital Portfolio and the Center for Education in Health have been qualitatively assessed and refined according to the feedback they received. The initial data has provided proof of concept of the model to be scaled to every state in the country by 2015 with a goal to achieve screening of the whole target population and to increase effective disease control for those living with diabetes by at least 50%.

Previta

Previta is a model for prevention and care that harnesses technology to increase access and integrate services for diabetics. The model uses telemedicine, health couches, and mobile clinic units to provide remote, continuous monitoring and disease control. Their multidisciplinary team consists of specialists in psychology, endocrinology, ophthalmology, cardiology, nutrition, and general practice. Moreover, an additional group of physicians conforms the Previta Prevention Coach®. They are the primary contact between Previta and the patients and are responsible for training the patient, designing a care protocol and providing general medical attention. They assist patients by telephone and by using the e-healthtracker®, software that contains medical information, protocols, monitoring alerts and risk indicators.

The element of mobile medicine units stands out in this model. The units travel to communities to deliver attention for prevention and control, including physical exams, education, personalized regimes, follow-up plans, and strategies to increase treatment adherence. Previta targets the low-income population by offering free services to those who are beneficiaries of "Seguro Popular", the public social security provider for the uninsured. They charge small fees to those that are not "Seguro Popular" beneficiaries. Because of their relevant work in preventing hospitalization and expensive health-care, Previta is setting out to work with the government under a pay-for-performance scheme.

Centro Especializado en el Manejo de la Diabetes del Distrito Federal

The Center Specialized on Diabetes Management (CEMD) is the first in Mexico City to specifically serve the diabetic population. Created by the local Ministry of Health, it follows the model of care developed by the Dasman Diabetes Institute in Kuwait. The center offers a multiplicity of services, including internal medicine, cardiology, psychology, nephrology, foot care, ophthalmology, orthopedics, education in diabetes and nutrition. Also, the same facility provides pharmaceutical products, laboratory tests, ultrasound scans and hyperbaric chamber. It provides access to a gymnasium and a kitchen, orienting their programs towards the promotion of healthy eating habits and daily physical exercise. Their services have met a high demand within the city. In 2013, the first year of operations, the center gave consultation to more than 15,000 people, 120 patients per day.

Centro Especializado en Diabetes

The Specialized Center in Diabetes (CED) provides integral attention to pre-diabetics and diabetics. Since its founding in 2010, the center has stood out for using cutting-edge technology for prevention and control of diabetes. Examples of these tools are 1) a specialized ambulatory glucose monitoring system, 2) biochemical and clinical diagnostic tests, used for developing risk profiles, 3) the tools to assess the metabolism profile of the patient, and 4) the Vacuum Assisted Closure treatment for diabetic foot that manages wounds and infections to avoid amputation. They also offer personalized dietary programs with intense follow-up and medical supervision.

Centro Multi-disciplinario de Diabetes

The Multi-disciplinary Center for Diabetes, established by the Medical Results, Research and Development (ReMeDi), delivers diabetes care using the Stage Diabetes Management® model. The aim of this model is to help the patient achieve control of the disease in the least amount of time possible. The interventions follow three principles: they are patient-centered, they are based in scientific evidence, and they are oriented to measurable outcomes. The centers also offer a unit for early detection of cardiovascular risk and micro-albuminuria, nutritional orientation, educational workshops, and specialists on diabetic foot control. The educational component is one of its core services. ReMeDi offers courses to increase the capacity of health-care professionals and to empower the patient with disease self-management abilities and tools. Some of these courses have been rolled for over 20 years. Currently ReMeDi operates three centers across the country: one in Mexico City, one in the northern border city of Reynosa Tamaulipas, and another in Veracruz.

III. Summary and conclusions

The above provides a landscape of services for the diabetic population in Mexico, highlighting two dimensions of the supply of diabetic services. It explains the intervention model and the exact type of services offered, providing insights about the extent to which evidence-based interventions are in place

in the country. It also describes the delivery, or provision, strategy, which is also relevant to understand how well supply is meeting the demand for these services. Both ideas are detailed below.

The effectiveness of the programs for diabetics in Mexico can be assessed based on the literature about evidence-based interventions. A previous report by Instiglio summarizing this literature found that modifications of lifestyle habits, psychological treatments, self-monitoring blood glucose and implementing case management are effective strategies to controlling diabetes. On the contrary, it found less evidence to support self-management trainings and the use of technology for management of the disease. Within the Mexican context, we observed that service providers are delivering integral attention to the patient through multi-disciplinary teams. This includes psychological assistance and, in some cases, giving patients access to gymnasiums and kitchens. As Instiglio reviewed before, these are effective components to keep the patient motivated and to promote a modification of their lifestyle. Second, most providers have a strong education component to help the patient develop self-care abilities. In particular, CASALUD provides mobile technologies as tools that empower the client to self-manage their own disease. The evidence has shown that the effectiveness of these tools highly depends on the motivation to treatment adherence, suggesting that strong accompaniment is important. In this line, case management has proved to be an effective strategy. Although most of the current service providers in Mexico use integrated electronic information systems to centralize information per patient, none of them explicitly work on a case management approach, though Previta's model of health coaches might somewhat get close to that.

The operative business model of each provider is also relevant to determine their capacity and effectiveness to reach the people in need. One important barrier that service providers are tackling is in identifying the diabetic population. In Mexico, it is estimated that only half of the people currently living with diabetes have been diagnosed. Local operators have incorporated outreach strategies to expand their diagnostic services in their models. For example, they partner with public health facilities to receive patient referrals and they work together with local governments to implement diagnostic and education campaigns in particular communities that lack access to high-quality services. Also, operators have focused on developing technological tools to provide more accurate diagnostics for pre-diabetics and diagnose diabetes-related complications early. Finally, the providers have not only developed models of care, but they are also integrating strategies to ensure access and continuation of the treatment. These strategies are focused on better distribution channels, such as remote assistance and mobile units, pricing and financing schemes that are affordable for the client, and using new technologies.

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INSTIGLIO
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MEMO

To: USAID Development Innovation Ventures
From: Instiglio, Inc. (Applicant 31452, APS-OAA-12-000004)
Subject: Update on Project Progress, Milestone 4
Date: April 10, 2015

This memo provides an update on project progress pursuant to milestone 4 of Instiglio's USAID DIV Award.

Based on the following project update, we conclude that USAID DIV's money is no longer most effectively spent in our project in Mexico on Diabetes. In a separate document we propose a modification of the award so as to use the remaining amount of the fixed obligation grant in another project.

Progress attracting outcome funders

From September 2014 until February 2015 we engaged our top-priority outcome funder (the *Institute Mexicano de Seguro Social*, IMSS) multiple times. In that period, two new pieces of information came to light that presented significant barriers to moving forward with a SIB in Diabetes in Mexico.

First, the work that we had done previously with IMSS on a performance-based contract for financing diabetes services took longer than expected.[1] We estimated that the start date for the implementation of the services under that tender would be May 2014, but by February 2015 that tender had not even been released for bidding. The reasons for the delay were principally bureaucratic: IMSS required market study of service providers and the uniqueness of this performance-based contract required more legal attention than was previously anticipated.

Second, due to the extra effort required to bring the performance-based contract to implementation, IMSS changed its stance with respect to our proposal for a Social Impact Bond in Diabetes. In October 2014, they expressed interest and requested more detailed information regarding the interventions and service providers under a SIB (precisely the work that USAID DIV would be funding under the award). But by February 2015 their perspective had changed as a consequence of the delay and effort expended in setting up the performance-based contract. IMSS anticipated that contracting a SIB would also take a long time and they preferred to wait until they saw the results of the performance-based contract before moving forward with a SIB.

Throughout this period, we also engaged other potential outcomes payers in the government of Mexico in addition to IMSS. These included the Ministry of Health, ISSTE, and Seguro Popular. Our assessment of the political and institutional environment of these other organizations suggested that the conditions were not ripe for the type of change that a SIB would require. In particular, we were unable to find the type of high-level political buy-in that we had found in IMSS.

[1] A performance-based contract differs from a Social Impact Bond in that: 1) no investor is involved; 2) only a small portion of the contract value is condition on results; 3) results tend to be outputs and shorter-term outcomes. In early 2014, Instiglio helped IMSS structure a performance-based contract to finance diabetes management services.

Faced with this challenge, we tried multiple strategies to increase buy in both in IMSS as well as in other agencies of the government. Specifically, we consulted with large national foundations (the Carlos Slim Institute for Health), multilateral institutions (Inter-American Development Bank) and Mexican public policy think tanks (*Fundación Idea*). None of these strategies were ultimately successful in increasing the buy-in of any potential future outcome payer.

Conclusion

Our initial assumption was that our previous work setting up a performance-based contract with the Government of Mexico would make it more likely that the Government of Mexico and that Service Providers would be interested in a Social Impact Bond. While we still believe that a SIB for Diabetes is an excellent value proposition for the government of Mexico, our assessment of the current situation suggests that it is best to propose a SIB for Diabetes *after* implementation of the performance based contract, rather than during its implementation. In 2017/2018, not only will we have an evaluation of the performance-based contract, we will also have at least three service providers who will have separately delivered and performed (or not) under a performance-based contract. Given that this will not occur within the time period under the USAID DIV award (December 2015), we recommend a modification of the award.

A description of the modification request is contained in a separate memo entitled, *Proposed modification of USAID's fixed obligation grant to Instiglio.*