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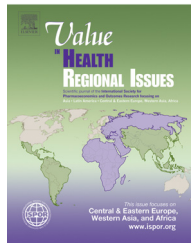

Project Baiterek: A Patient Access Program to Improve Clinical Outcomes and Quality of Life in Children with Type 1 Diabetes in Kazakhstan

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ABSTRACT

Diabetes is a key driver in the rise of noncommunicable diseases globally. It causes expensive and burdensome short- and long-term complications, with both an economic and social impact. In many countries, however, access to care and disease management in type 1 diabetes is suboptimal, increasing the risk for complications. In 2011, Project Baiterek was initiated as a collaborative effort between the Kazakhstan Ministry of Health, industry (Medtronic Plc), local physicians, and the Diabetes Association of the Republic of Kazakhstan to enhance patient access to continuous subcutaneous insulin infusion (CSII) therapy. It was the first countrywide project to provide equity and universal access to insulin pump therapy among children with type 1 diabetes, increasing pump use from zero to two-thirds of this population in less than 3 years. The project also involved instigating longitudinal data collection, and long-term clinical outcomes continue to be monitored. Here, we provide an overview of the clinical, quality-of-life, and economic outcomes to date associated with providing CSII therapy to children with type 1 diabetes in Kazakhstan. Initial clinical data show that CSII therapy improved clinical outcomes and quality of life for patients entered into the program and that CSII therapy was cost-effective relative to multiple daily injection therapy. The positive outcomes of Project Baiterek provide a template for similar patient access programs in other settings, and its framework could be adapted to initiatives to change health care infrastructures and standards of care for other noncommunicable diseases.

Keywords: continuous subcutaneous insulin infusion, cost-effectiveness, hypoglycemia, insulin pumps, Kazakhstan, patient access programs, pediatric, public private partnership, quality of life, type 1 diabetes.

Problem Statement: Care and Access to Care for Type 1 Diabetes is Suboptimal

Burden of Disease

Globally, there are approximately half a million children with type 1 diabetes [1], including a large number without access to high-quality pediatric diabetes care. The treatment of type 1 diabetes involves a complex regimen of exogenous insulin administration and the frequent measurement of blood glucose levels to attempt to improve overall glucose control. As a result, the long-term outlook for children with this disease varies substantially across settings because of the variability in resources, treatment options, and knowledge and experience of health care providers.

The World Health Organization has reported that diabetes (including both type 1 and type 2) is 1 of the 10 leading causes of death in middle- and upper-income countries [2]. Suboptimal blood glucose control in patients with diabetes results in life-threatening acute and long-term complications (e.g., renal failure requiring dialysis) that are devastating to the individual and costly to the health care system. Indeed, direct medical costs associated with diabetes and its complications exceeded €90 billion in 2012 in France, Italy, Germany, Spain, and the United Kingdom alone (2010 €) [3]. In contrast, optimal blood glucose management, such as that which can be achieved by continuous subcutaneous insulin infusion (CSII) therapy and that limits the amount of time spent in hypoglycemia and hyperglycemia, has been shown to reduce complication rates, improve patient

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outcomes, and reduce health care expenditures. Health ministries and health policy makers must allocate limited funds to maximize the public's health and often make decisions whose benefits may not be immediately appreciated, particularly if they involve changing health care infrastructure. Providing a strong evidence base for such initiatives can help minimize risk as projects unfold because interim outcomes and projected savings can be regularly monitored.

Barriers to Optimal Diabetes Care

In addition to clinical and economic implications, diabetes has a strong societal impact. It is well documented that diabetes has a negative impact on quality of life (QOL), especially in children. Indeed, in some countries, children with type 1 diabetes are automatically registered as handicapped and sometimes refused entry to mainstream schools [4,5], which can limit their full participation in society. Because type 1 diabetes is often a challenging disease to treat and requires specialized expertise, many countries do not have the infrastructure to optimize diabetes management. Barriers include a lack of specialists and localization of specialists in large urban areas, meaning that patients often have to travel long distances for treatment; for example, in Kazakhstan the number of endocrinologists per 100,000 population is approximately sixfold lower in rural areas than in urban areas [6,7]. Other barriers include a lack of disease knowledge among both patients and care providers as well as insufficient training on innovations and advanced technologies and treatments. For example, before the initiation of Project Baiterek, there were only four endocrinologists in Kazakhstan who had received training in the use of insulin pumps. Moreover, in some settings, epidemiologic data and long-term patient outcomes are often difficult to track owing to a lack of regionally or nationally organized patient registers. Changes in infrastructure, including the provision of specialist training and the dissemination of information to both physicians and patients, are necessary to improve the provision of care of type 1 diabetes, and these strategies may be applicable to other chronic noncommunicable diseases (NCDs).

Diabetes Therapy Solution: Optimizing Patient Outcomes Through Innovation and Technology

For survival, patients with type 1 diabetes are dependent on a lifetime of exogenous insulin administration, either in the form of multiple daily injection (MDI) therapy or with insulin pumps. Several previous studies have demonstrated that CSII therapy leads to improved glycemic control and fewer hypoglycemic events versus MDI therapy [8]. Good glycemic control, as indicated by hemoglobin A_{1c} (Hb A_{1c}) within the target range (<7.5% in children and <7.0% in adults [9]), is the single most effective way to prevent and delay costly long-term diabetes-related complications as well as acute complications, including hypoglycemic events and ketoacidosis [10–12]. CSII therapy represents a particularly useful treatment option for pediatric patients with type 1 diabetes, especially those with poor glycemic control or frequent or problematic hypoglycemic events. It offers more flexibility and freedom in terms of timing of meals and activity than does MDI therapy. In the United States, approximately 40% of patients with type 1 diabetes use CSII therapy [13]. In much geography around the world, however, the use of CSII therapy is very low due to cost and lack of trained health care providers. These barriers are present even in developed countries, such as the United Kingdom and France, where the use of CSII therapy in pediatric patients with type 1 diabetes is less than 20%, and even lower in adults [13,14]. Analyses from the payer perspective across multiple settings have shown that the initial cost is mitigated by the long-term reduction in cost relative to MDI therapy, due to the lower incidence of diabetes-related complications [15–18].

Project Baiterek: A Patient Access Scheme in Kazakhstan

In 2011 in Kazakhstan, a unique public private partnership (Project Baiterek) was initiated to improve the clinical outcomes and QOL in children with diabetes, while reducing the incidence of costly acute and long-term diabetes-related complications. In 2011, there were approximately 11,400 adults and 1500 children (aged 1–18 years) with type 1 diabetes [19], mainly treated with MDI regimens. In addition, in Kazakhstan, diabetes care was generally underfunded, there was a variable level of qualification of the country's endocrinologists, and there were significant differences in the quality of care between major cities and regional centers. Diabetes patients suffered from social stigma and poor QOL. They were considered "invalids," which limited their educational and professional opportunities.

Project Baiterek as a Collaborative Project

Project Baiterek was launched as a collaborative effort between the Kazakhstan Ministry of Health, the Diabetes Association of the Republic of Kazakhstan (DARK), Medtronic Plc, and local endocrinologists.

Ministry of Health Involvement

As part of the project, the Kazakhstan Ministry of Health secured funding to purchase 790 Paradigm Veo insulin pumps (Medtronic, Northridge, CA) for children aged 5 to 15 years, together with rapid-acting insulin analogues, consumables (insulin pump reservoirs and infusion sets), blood glucose meters, and 30 blood glucose test strips per patient per month.

Patient Recruitment

The project was conducted on a nationwide basis, with one to three local physicians identified from each of the 17 regions of Kazakhstan, and per-site enrollments ranged from 9 to 85 patients (Fig. 1). For initial inclusion, patients were required to be aged 5 to 15 years with a diagnosis of type 1 diabetes. All patients received intensive CSII therapy training with health care providers and Medtronic and a long-term treatment plan including frequent follow-up and adjustment of therapy when needed. All patients received follow-up appointments at 3-month intervals, and clinical data collection is ongoing, which will enable a longitudinal assessment of patient outcomes. A 24-hour patient support helpline was also established for the use of patients, parents, and care providers.

Care Provider Involvement

Between one and three physicians from each of the 17 regions of Kazakhstan participated in the project and in total 266 health care professionals received training on the use of CSII therapy (compared with 4 health care providers before the initiation of the project). Medtronic provided specialist training for physicians on pump therapy, created standardized patient training materials, established clinical monitoring procedures, and scaled patient support and operations. Advanced CSII therapy training was initially provided by leading pediatric endocrine experts at diabetes centers in Israel, Slovenia, Russia, and the United States, and followed by recurrent training sessions in Kazakhstan, Austria, and the United States. Medtronic also supported local endocrinologists with the collection of clinical (blood glucose levels, Hb A_{1c}, and rates of hypoglycemia and diabetic ketoacidosis), QOL, and health economic data to assess the long-term impact of Project Baiterek.

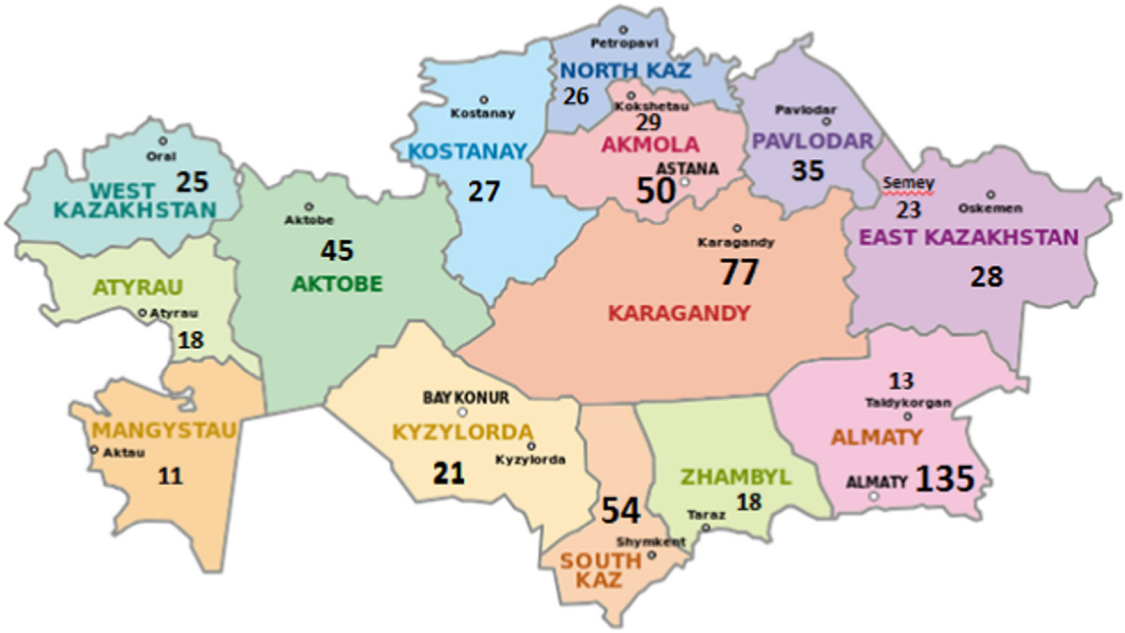

Fig. 1 – Number of insulin pumps in Project Baiterek according to region in 2013. From Toktarova et al. [20].

Diabetes Association of the Republic of Kazakhstan

DARK collaborated with the Ministry of Health and Medtronic to disseminate information related to the benefits associated with the use of insulin pump therapy and to raise awareness of the burden and the societal impact of type 1 diabetes. DARK was also involved in raising awareness of the successful collaboration between the Patient Advocacy Group, the Ministry of Health, health care professionals, and the insulin pump manufacturer (Medtronic).

Preliminary Findings from Project Baiterek

A total of 790 children, corresponding to more than two-third of pediatric patients aged 5 to 15 years with type 1 diabetes in Kazakhstan, have been enrolled in Project Baiterek (Fig. 1 [20]). Analysis of 6-month data showed that the initiation of CSII therapy resulted in improved glycemic control. Decreases in the frequency of severe hypoglycemic events and diabetic ketoacidosis, as well as improvements in all domains of health-related QOL, were also reported. More specifically, improvements of more than 100% from baseline in the QOL domains of social limitations, life interference, general satisfaction, flexibility, and convenience were reported at 6 months (Fig. 2). Twenty-four instances of severe hypoglycemic events were reported before switching to CSII therapy and three events after initiating CSII therapy; the corresponding numbers for ketoacidosis events were 175 and 65, respectively. In addition, for those patients with baseline Hb A_{1c} levels of 7.5% or more (mean Hb A_{1c} level of 10.5%) experienced a mean decrease of 0.9% at 6 months (Fig. 3) [21].

The clinical benefits in this cohort (patients with an Hb A_{1c} level of $\geq$7.5% at baseline) combined with the local (Kazakhstan-specific) costs of intervention and complications have been entered into the CORE Diabetes Model, a peer-reviewed, validated

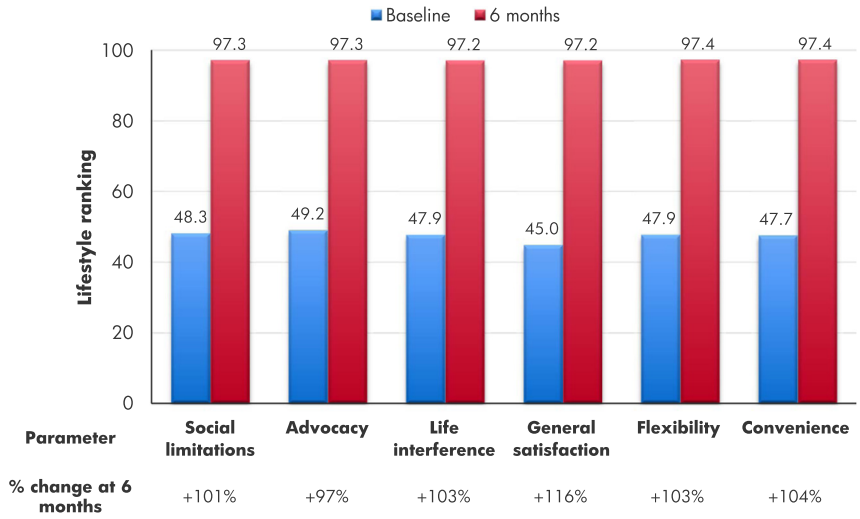

Fig. 2 – Change in six quality-of-life domains in pediatric patients with type 1 diabetes in Kazakhstan from baseline to 6 months on CSII.

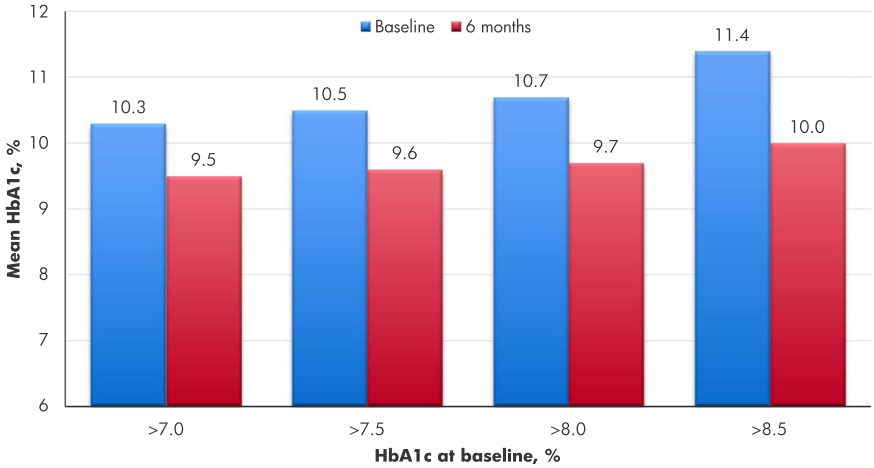

Fig. 3 – HbA1c at baseline and at 6 months. HemoglobinA1c, Hb A1c

model that uses standard Markov/Monte-Carlo simulation techniques to describe the long-term incidence and progression of diabetes-related complications [22]. Because the costs of physician training, patient training materials, marketing materials, and set-up of infrastructure changes required for longitudinal clinical data collection were borne by Medtronic, the cost-effectiveness analysis (in which cost inputs consisted of Kazakhstan-specific costs of CSII therapy together with costs of acute and long-term complications) represents the overall cost-effectiveness of Project Baiterek from the national payer perspective. The results of the cost-effectiveness analysis showed that over the lifetime of the cohort, the Hb A_{1c} reduction would be projected to lead to a reduction in the cumulative incidence of proliferative diabetic retinopathy, blindness, and end-stage renal disease by 25.3%, 5.6%, and 28.3%, respectively (Table 1) and an increase of 3.58 years in undiscounted life expectancy for CSII therapy versus MDI therapy [21]. Continued clinical data collection will allow for long-term longitudinal assessment of patient outcomes.

Short- and Long-Term Impact of Project Baiterek

Preliminary clinical results from Project Baiterek showed improved glycemic outcomes and QOL, as well as a reduced incidence of severe, costly, and potentially life-threatening hypoglycemic events and diabetic ketoacidosis.

The long-term cost-effectiveness analysis showed that in the context of the Kazakh health care system, CSII therapy was cost-effective relative to MDI therapy due to improved glycemic control [22], which itself is proven to reduce the incidence of costly diabetes-related complications including cardiovascular disease, renal disease, ophthalmic complications, and diabetic foot problems [10–12] (Table 1).

In addition to the direct clinical and QOL benefits, the long-term implications of the project include a successful change in the infrastructure of pediatric diabetes care, with the implementation of best management practices for patients. The collection of clinical data remains ongoing and will examine the long-term clinical and economic impact of improved Hb A_{1c} and reduced incidence of hypoglycemic events in this setting. Previous studies in other settings have shown that the clinical benefits associated with switching to CSII therapy are sustained for periods of up to 7 years [23,24].

The comprehensive nature of Project Baiterek has enabled the Kazakh pediatric endocrinologist community to meet international standards, such as the UK National Institute for Health and Care Excellence (NICE) guidelines. These guidelines state that insulin pump therapy should be initiated only in centers with sufficient infrastructure and specialist training [25]. In addition, Kazakh public health authorities have been able to advance competencies and knowledge in health economics and modeling, which can be applied to ongoing and future initiatives.

Project Baiterek as a Pioneering Patient Access Scheme

Over a 3-year time horizon, Project Baiterek has resulted in substantial clinical improvements for children with type 1

Table 1 – Summary of cost-effectiveness modeling findings.

Outcome	CSII	MDI	Difference
Quality-adjusted life expectancy (QALYs)	14.56	13.34	1.21
Direct costs (Kazakhstani Tenge)	9,225,694	4,459,297	4,766,396
Incremental cost-effectiveness ratio		3,935,375 KZT per QALY gained	
Reduction in cumulative incidence of complications with CSII (%)			
Proliferative diabetic retinopathy		25.3	
Blindness		5.6	
End-stage renal disease		28.3	
Gross proteinuria		17.7	

Data from Roze et al. [22].
CSII, continuous subcutaneous insulin infusion; MDI, multiple daily injection; QALY, quality-adjusted life-year.

diabetes. This likely will translate to long-term benefits in terms of reduced diabetes-related complications and reduction in direct medical costs. Before this project, insulin pumps were rarely, if ever, used in Kazakhstan. As of March 2014, more than two-thirds of the patients aged 5 to 15 years with type 1 diabetes (n = 790) in Kazakhstan were using CSII therapy, which now represents the standard of care in this setting. The uptake of insulin pump therapy in Kazakhstan exceeds that of many other countries. Indeed, in the United Kingdom, only 19% of pediatric and 6% of adult patients with type 1 diabetes currently use CSII therapy, which is below the expectations of NICE [26].

Moreover, this project has shown that through collaboration and successful partnerships between industry, payers, endocrinologists, and patient advocacy groups, nationwide changes in infrastructure and patient management practices can be established and serve as a framework for other NCDs. Two of the targets in the World Health Organization Global Action Plan for the Prevention and Control of NCDs and the Kazakhstan Alliance against NCDs include a 25% relative reduction in premature mortality from NCDs by 2025 and an 80% availability of basic and essential medicines [27,28]. The improved outcomes and care for type 1 diabetes in Kazakhstan are likely to contribute to meeting these goals, and, moreover, the project provides a roadmap that can be used to help achieve these goals for other NCDs.

Project Baiterek could be considered to be a world-leading example in terms of the swift and successful implementation of changes in health care infrastructure and standards of care, with successful clinical and economic outcomes. It is likely that the buy-in and close collaboration between the stakeholders was pivotal to the success of the project and that projects involving partnerships across governments, industry, patient advocacy groups, and local health care providers may be more likely than isolated initiatives to succeed. For example, in the United Kingdom, where insulin pump use falls below NICE target figures, funding alone does not ensure uptake of technology. The involvement of patient associations/advocacy groups to enhance patient access was also likely a key component of success in Project Baiterek. These groups play an important role in disseminating information to patients, and encouraging patient participation and compliance with new initiatives, and often represent a powerful voice in terms of lobbying policymakers for the introduction of new interventions.

There is little doubt that similar projects can be used in other regions around the world where there are barriers to insulin pumps and technology to promote patient access to CSII therapy. This project has provided policymakers with a model that they can use to justify investing limited funds in pediatric diabetes. Regions can follow the example of Kazakhstan, run a pilot scheme to determine feasibility, and then bring the project to scale if that is realistic and manageable based on local budget, needs, and limitations. By using a stepwise approach, policymakers can better manage priorities and planning. The initial cost associated with insulin pumps can be a significant barrier to uptake, particularly when there is patient participation in payment. The experience in Kazakhstan, however, suggests that the initial costs of insulin pumps can be mitigated by cost savings in the long-term associated with improved glycemic control and the resulting lower incidence of diabetes-related complications. Cost-effectiveness analyses conducted in several other settings have consistently shown that in the long-term, CSII therapy is cost-effective versus MDI therapy [15–18]. The consistency of findings of previous cost-effectiveness analysis and improved clinical outcomes present a robust and persuasive argument to payers to endorse the use of CSII therapy in pediatric patients with type 1 diabetes, particularly when combined with changes in infrastructure and training that are also likely to benefit adults with poorly managed type 1 diabetes.

Conclusions

Overall, Project Baiterek, which involved the widespread introduction of CSII therapy in pediatric patients with type 1 diabetes in Kazakhstan, was both effective and cost-effective and has improved the lives of more than two-thirds of pediatric patients with type 1 diabetes in the country. It advanced specialist training to health care providers, facilitated longitudinal data collection, and established long-term improvements in health care infrastructure. Presently, there are many settings in which standards of care for type 1 diabetes and other NCDs could be improved. The example set by Kazakhstan warrants a call to action for others to replicate the success of Project Baiterek for type 1 diabetes and other NCDs. The success of this project provides an example of a successful real-world patient access scheme that can be used in other regions around the world and for other NCDs.

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