DIABETER
VALUE-BASED HEALTHCARE DELIVERY IN DIABETES

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September 2016

SUBSTANTIAL VARIATIONS IN OUTCOMES OF TYPE 1 DIABETES CARE ARE A GLOBAL CHALLENGE

People with type 1 diabetes are at high risk for severe long-term microvascular and macrovascular complications, such as kidney disease, blindness, amputation myocardial infarction, and stroke. These complications have of course a huge impact on the patients and on the healthcare system and account for a large portion of the diabetes spent.

Over 30 years ago, the results of the Diabetes Control and Complications Trial (DCCT) showed the benefits of intensive diabetes management in delaying the onset and reducing the severity of the complications of type 1 diabetes.[1,2,3] After the DCCT, it became globally accepted to intensively manage and tightly control glycemia and to assess glycosylated hemoglobin (HbA1c) levels as a means to understand the short and long term risk of diabetes complications. National and international guidelines have recommended a target HbA1c level that is lower than 58 mmol/mol (7.5%) for children and Adolescents with type 1 diabetes. Average HbA1c levels that are higher than the target are strongly correlated with an increase in avoidable death, including that due to diabetic ketoacidosis, and a significant reduction in microvascular and macrovascular diabetes complications over the long-term. In addition, recent studies have shown the importance of glycemic control to preserve cognitive function of children with Diabetes. Finally, glycemic control has also an important impact on the mood and the therefore the burden of Diabetes management for the care givers and families.

A recent study compared HbA1c levels from national and regional registries of various European countries. Despite widely acknowledged treatment guidelines, it was shown that the majority of children (ages 1–15) and adolescents and young adults (ages 15–24) with type 1 diabetes had higher HbA1c levels than recommended putting them at increased risk for complications.[4] (See Exhibit 1 and 2.)

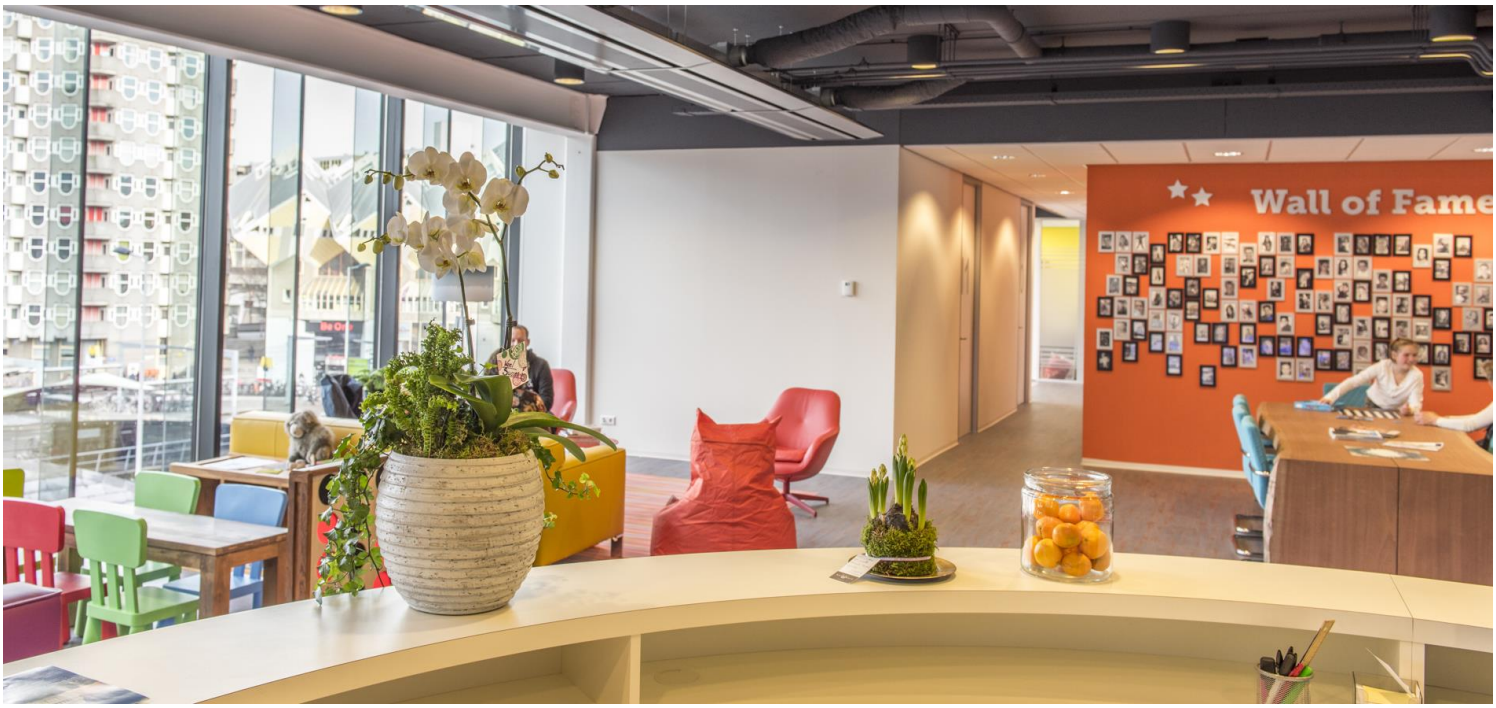
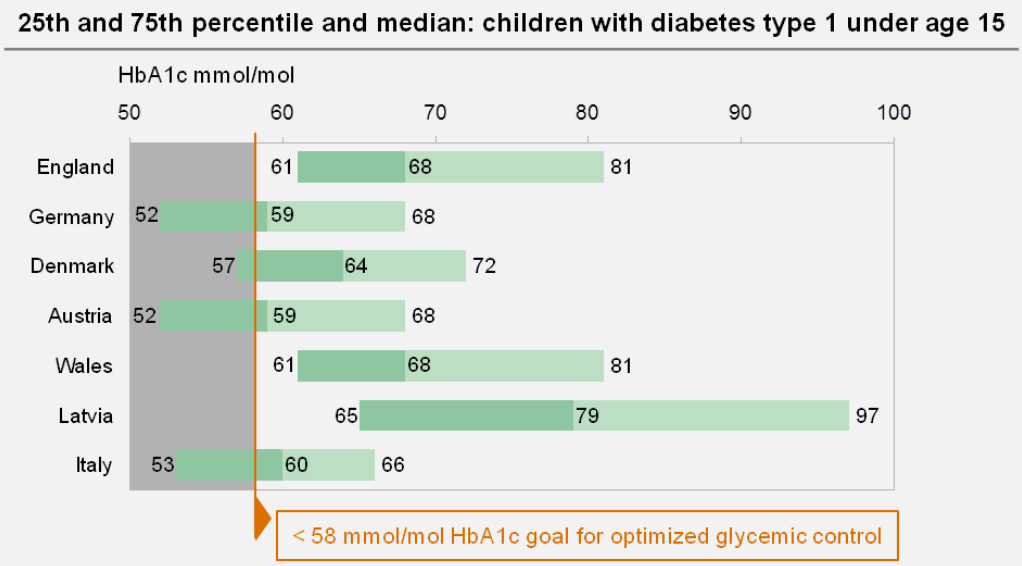
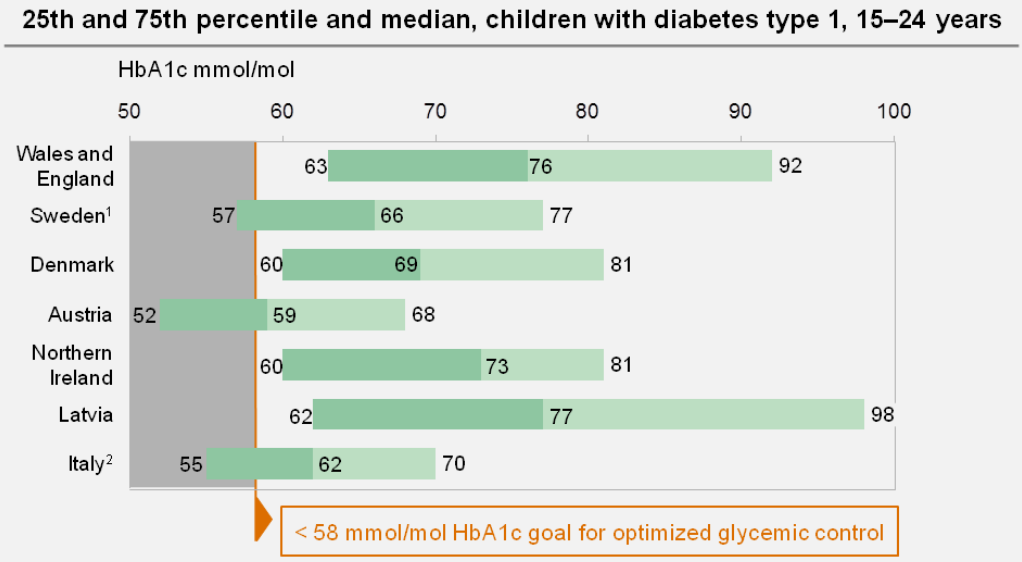


EXHIBIT 1 – Dramatic variation in glycemic control within and between industrialized nations; patients under age 15



The number of patients missing the target was highest among those 15 to 24 years of age because it is particularly challenging to manage glucose levels during adolescence as a result of the insulin resistance of puberty and because many young adults begin to live independently.

EXHIBIT 2 – Equal variation for patients 15-24 years



Diabetes care was transformed in the early 1980s when point-of-care glucose monitors and easy-to-use insulin injection devices enabled the majority of patients to better assess and manage their disease. With the advent of self-monitoring of blood glucose, the adoption of multiple insulin injection therapy, and the development of insulin analogues, support from health care professionals became increasingly important. Physicians, nurses, dieticians, social workers and exercise physiologists were required to adapt diabetes regimens and to teach insulin dosage adjustment, medical nutrition therapy, and the impact of physical activity and illness. Despite these advances, most children and teenagers still find it hard to manage their lifestyle, adhere to diet and take multiple insulin injections, and to adjust to having a chronic disease

The incidence of type 1 diabetes in the Netherlands is increasing. Comparing the incidence from 1978 through 1980 with the incidence from 2010 through 2011, it has almost doubled from 11.1 to 21.4 per 100,000 people.[5] Diabetes not only affects the well-being of patients and their families but also has substantial financial consequences for the overall health care system.

Type 1 diabetes patients in the Netherlands are treated according to international standards. However, looking at the performance of individual Dutch diabetes clinics, patient outcomes vary greatly. Less than 30% of the pediatric type 1 diabetes population manages to reach the HbA1c target of less than 7.5% (58 mmol/mol) set by the International Society for Pediatric and Adolescent Diabetes (ISPAD).[6] Thus, optimal short-term and long-term outcomes are not achieved by many patients.

THE DIABETER CLINIC MODEL

Diabeter is a Dutch-certified clinic network that specializes in providing comprehensive and individualized care for children and young adults with type 1 diabetes. Established in 2006, Diabeter's patient population has consistently grown, and today Diabeter has more than 1,800 patients in 5 different locations.

In the Netherlands, Diabeter has been a pioneer in value-based diabetes care. Diabeter offers a novel care model—one that is focused on diabetes patients, value-based e-health solutions, and a unique patient experience. The Diabeter patient population has exemplary clinical outcomes without increasing costs. (See Box 1.)

BOX 1 | DIABETER DELIVERS SUPERIOR RESULTS

The Dutch National Health Care Institute, Zorginstituut Nederland, publishes data on HbA1c levels among children at Dutch diabetes clinics. When comparing Diabeter to other clinics, it becomes clear that Diabeter is a top performer compared to those clinics with more than 100 patients. One dimension of the dataset describes the percentage of children reaching the HbA1c target of less than 7.5% (58 mmol/mol), as defined by the International Society for Pediatric and Adolescent Diabetes (ISPAD). At Diabeter, 55% of children under the age of 18 reach the target, which makes Diabeter the best performing clinic in the Netherlands. Another dimension of the data describes the share of patients that are outside the target. At Diabeter, only 6% of children have HbA1c levels that are higher than 58 mmol/mol. This means that Diabeter is among the top clinics in the Netherlands. (See Exhibit 3.) In addition, Diabeter's superior outcomes lead to less direct annual costs to type 1 diabetes patients. The savings are mainly driven by a lower patient hospitalization rate than that of other Dutch pediatric diabetes clinics. (See Exhibit 4.)

EXHIBIT 3 – Diabeter outperforming other Dutch diabetes clinics

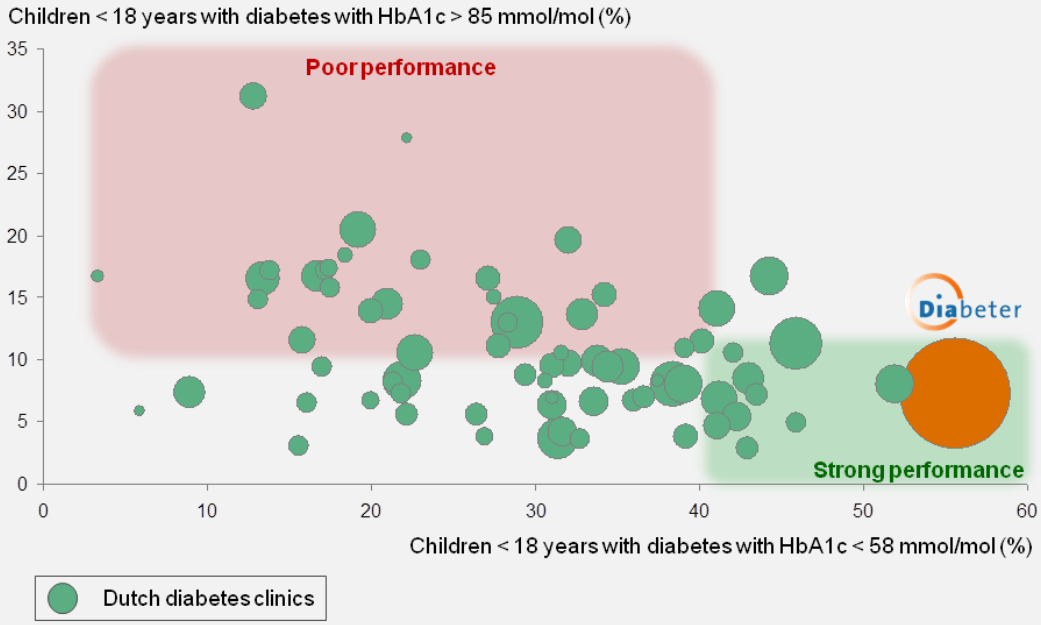
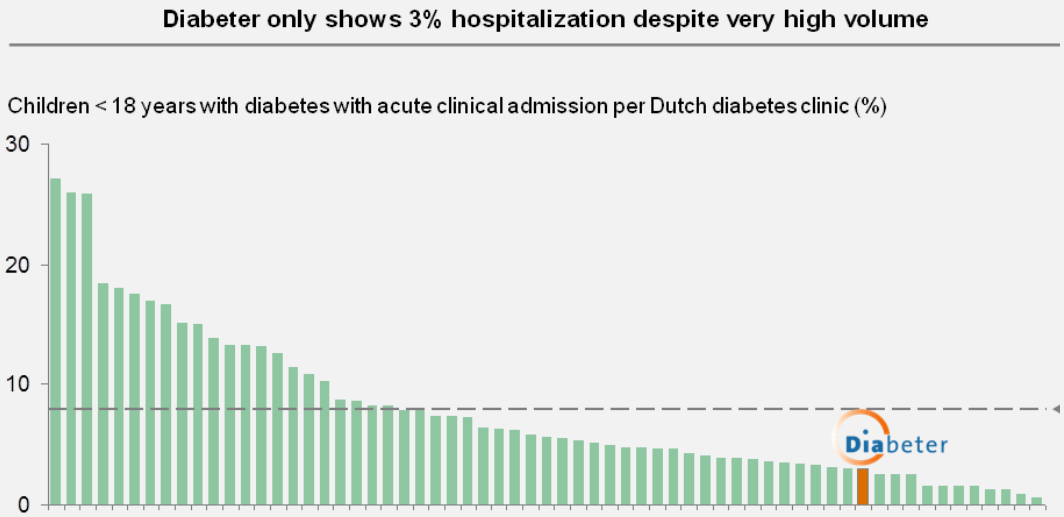


EXHIBIT 4 – 8% of children hospitalized in average Dutch Diabetes clinic



MEDTRONIC IS TRANSFORMING DIABETES CARE INTO VALUE-BASED CARE DELIVERY

For more than 30 years, Medtronic has been a leader in diabetes technology, continually innovating in areas such as insulin pump therapy and continuous glucose monitoring, as the disease represents one of the biggest challenges to the health care system given its exponential growth, the cost to the health care system, and the impact on people's lives. The vision of the Diabetes Group at Medtronic is to transform diabetes care so patients have greater freedom and better health.

However, health care systems today are challenged by quality issues, spiraling costs, and variations in outcomes at every level of care. Legacy payment systems that favor volume over value, as well as fragmented and disconnected care-delivery methods, are limiting patients' access to optimal care, particularly those with chronic medical conditions.

Medtronic believes that the combination of innovative technologies, patient-centric care delivery, and reimbursement on the basis of outcomes rather than volume will transform health care systems. Value-based health care, defined as achieving improved outcomes at lower costs, should allow the kind of health system transformation that will shift spending from acute interventions to improving and innovating around chronic disease management.[7] As the world's leading medical technology company, Medtronic is contributing to this transformation by broadening its traditional product-focused business model to a holistic solution model that systematically improves value.

MEDTRONIC AND DIABETER

As part of its vision to transform diabetes care, Medtronic will both focus on technology innovation and on developing and nurturing holistic solutions to enable and deliver better diabetes care.

By coupling technology innovation with big data and analytics that support an integrated, multi-disciplinary care delivery model, Medtronic will deliver comprehensive solutions to address the chronic nature of diabetes and to fill the gap between medical visits. The goal of such solutions will be to improve outcomes and reduce costs to the health care system.

Because Diabeter fits Medtronic's strategy of becoming a holistic diabetes management company, and because Medtronic believes Diabeter's value-based approach can be applied to patients across the globe, it acquired the Diabeter clinics in April 2015. This acquisition marked Medtronic's first entry into an integrated diabetes care model and is consistent with its desire to expand its role from selling medical devices to providing and enabling differentiated outcomes.

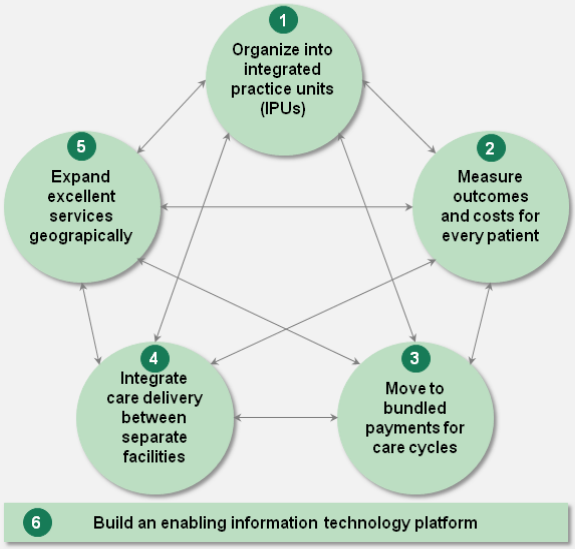
Jointly, Medtronic and Diabeter will be able to further advance integrated care models for patients with type 1 diabetes in the Netherlands and other countries around the world. Diabeter is maintaining its independence in clinical decision-making, therapy, and brand choice of medical technology, and it utilizes proven processes and principles to ensure these decisions remain at all times in the hands of physicians.

THE STRATEGIC AGENDA FOR MOVING TO A HIGH-VALUE HEALTH CARE DELIVERY SYSTEM

According to Michael E. Porter a professor of strategy at Harvard Business School, the overarching goal for providers, as well as for every other stakeholder, should be to improve the value of health care for patients. Porter defines value as the health outcomes achieved that matter to patients relative to the cost of achieving those outcomes. Improving value requires improving one or more outcomes without raising costs or, alternatively, lowering costs without compromising outcomes.[8]

The agenda for moving to a high-value health care delivery system has six components. (See Exhibit 5.) The first is to organize into integrated practice units (IPUs). Clinicians should be organized around the patient's medical condition.

EXHIBIT 5 – Six components of the value agenda



In primary care for chronic diseases, IPUs are multidisciplinary teams organized to support patients' various needs, such as routine checkups, lifestyle changes, and preventive care.

The second component is measuring outcomes and costs for every patient to track progress and improve results. Outcomes—such as the health status that is achieved or retained, the quality of life (QOL), and the complications or the long-term success or failure of treatment— really matter to patients. In addition to outcomes, cost must be measured for the entire care cycle for each patient. To increase value, providers must improve quality with justifiable cost increases or maintain quality while lowering cost.

Transforming care delivery also means transforming payment models. Therefore, the third component of the value agenda is to move to bundled payments for care cycles. Traditional fee-for-service and capitation models favor volume over quality; such models do not necessarily improve outcomes or value. Payments should be bundled for the entire care cycle and preferably be connected to outcomes.

The fourth component is to integrate care delivery. This component involves moving care out of existing locations to dedicated facilities that are better suited to deliver integrated care.

The fifth component is expansion across regions. Expansion is done either by opening satellite facilities or by partnering with excising facilities.

The sixth component in the journey is to build an enabling IT platform that is designed for data collection and decision support. To increase value, an IT platform should fulfill six criteria: be patient centered, use common data definitions, track all patient data, allow medical data to be accessible to all parties involved, include standardized templates and guidelines to facilitate IPU teams, and enable smooth data extraction.

To enhance value in health care in the most efficient way, the aforementioned six components should be advanced together.

DIABETER IS A PRIME EXAMPLE OF A VALUE-BASED HEALTH CARE DELIVERY ORGANIZATION

Diabeter's model for care delivery follows the strategic agenda as described by Porter. The following section will assess how Diabeter corresponds to each of the six components.

ORGANIZE INTO INTEGRATED PRACTICE UNITS

Diabeter clinics are each organized as an IPU: a multidisciplinary team of clinical and nonclinical personnel focusing solely on diabetes care for children and adolescents and taking joint responsibility for the full cycle of care. (See Exhibit 6.) The team, including medical doctors, nurses, dieticians, psychologists, and administrative staff, works toward the common goal of measuring and maximizing the patient's overall outcome as efficiently as possible. A care manager is assigned to each individual patient. This person coordinates treatment over the whole care cycle and serves as the contact person for a patient and the family. In IPUs, administrative work and scheduling are done for all patients by the administrative team in a single organizational structure. IPUs enable patients and their families to actively participate in the care by providing targeted education to advance self-management skills and informing them as to how they can contribute to successful outcomes.

Patients are normally referred to Diabeter when they are newly diagnosed or after they have been initially treated at a referring hospital or outpatient clinic. Usually patients and families request to become Diabeter patients. Newly diagnosed patients and their families are enrolled in a program that provides daily care for the first few weeks and then as needed. They are assessed by the multidisciplinary staff to devise an individualized medical therapy plan and to teach the required skills to use diabetes technology for effective self-management.

EXHIBIT 6 – An integrated practice unit enables value-based care delivery

Description of IPU by Porter	IPU implementation at Diabeter
An IPU is organized around the patient's medical condition	Diabeter is fully focused on type 1 diabetes care, treating all patients from children to adults
Involves a dedicated, multidisciplinary team that devotes a significant portion of time to the condition	Medical and non medical staff committ 100% of time to type 1 diabetes patient care and diabetes research
Providers are part of a common organizational unit	All Diabeter clinics under common organizational unit, following same care pathway and using same admin and IT infrastructure
Team takes responsibility for the full cycle of care	Diabeter covers all aspects of preventive and therapeutic diabetes care apart from emergency hospitalizations
Patient education, engagement and follow-up are integrated into care	Patients and families are trained in medical background, prevention, care, and using medical devices for type 1 diabetes
A single administrative and scheduling structure is used	Diabeter uses one scheduling unit for all patients a given clinic
Care is co-located in dedicated facilities	Diabeter clinics co-locate patients, clinicians, research, administration ,and supply shops on one floor
A physician team captain or a clinical care manager oversees each patient's care process	Patients each have a responsible nurse and medical doctor assigned to them that will not change during the care cycle
Team measures outcomes, costs, and processes for each patient using a common measurement platform	Proprietary digital solutions enable transparency on clinical indicators; activity-based costing has initially been done
Team meets formally and informally on a regular basis	Interdisciplinary team meetings are happening every week in order to discuss patients, care models and research findings
Team accepts joint accountability for outcomes and costs	All members of Diabeter's care team provide personalized care in order to keep patients within their HbA1c target and complications low

After the initial weeks, patients typically visit the clinic four times per year. Between visits, the Diabeter team supports the patients by e-mail, Skype, and phone to continuously adjust and maximize their treatment. Diabeter patients are offered an emergency hotline that gives them immediate access to a medical doctor at Diabeter 24 hours a day, 7 days a week. In order to simplify the distribution of medical consumables and medicines, Diabeter developed Diabstore, an independent but closely connected store that serves as a distribution channel for reimbursed items. Products are either picked up after a visit or ordered online by patients and delivered to them within a short time frame.

One of the key principles of value-based health care is to risk stratify patients by baseline characteristics. Diabeter stratifies its large patient cohort using metrics captured in their electronic database. While most pediatric patients follow a similar intensive treatment protocol from diagnosis, those with secondary diabetes follow alternate care pathways. For example, the 7% of Diabeter patients with diabetes due to cystic fibrosis, maturity onset diabetes of the young, monogenic diabetes, and secondary diabetes due to high-dose glucocorticoid treatment, have unique treatment protocols matched to the underlying etiology of their diabetes. The same occurs for the minority of patients with comorbidities or complications who are given individualized therapy to manage these additional conditions. In addition, as Diabeter has begun to follow more and more young adults, age- and lifestyle-specific care pathways have been developed.

To assess multiple diabetes outcomes, spanning physical and psychosocial metrics, quarterly follow up and annual comprehensive assessments are done. This allows for reassessment of regimens and intervention by the multidisciplinary team as required.

EXHIBIT 7 – Outcome measures for diabetes population

	Outcome measures	Type 1 diabetes in children and adolescents
Tier 1 Health status achieved or retained	Survival	• Mortality rate
	Degree of health or recovery	• Disease-specific quality of life of patients, such as the MY-Q measuring emotional well-being, social interaction (with parents, family, friends, at school), diabetes management (worries, treatment barriers, self-efficacy, self-esteem or problematic eating) • Parents' quality of life, such as the MY-Q
Tier 2 Process of recovery	Time to recovery and return to normal activities	• Time to diagnosis • Time to adequate care • Time to return to normal life
	Disutility of care or treatment process (e.g., complications)	• Type 1 diabetes-related hospital admissions for severe hypoglycemia or diabetic ketoacidosis (number of admissions and length of stay) • Severe hypoglycemia at home
Tier 3 Sustainability of health	Sustainability of health or recovery and nature of recurrences	• Angiopathy (acute myocardial infarction, stroke) • Nephropathy • Retinopathy • Neuropathy
	Long-term consequences of therapy[1]	• N/A

MEASURE OUTCOMES AND COSTS FOR EVERY PATIENT

In order to understand how care impacts outcomes, it is necessary to systematically collect data on patients' QOL in general as well as specifically—how QOL is impacted by the disease, by the disutility of care, and by the long-term complications of the medical condition.

Baseline data collection and outcomes measurement should be done in a standardized way regardless of how type 1 diabetes is treated—that is, regardless of whether patients are using multiple daily injections (MDIs), an insulin pump, or a sensor-augmented pump (SAP).

Outcomes that matter to patients fall into three tiers: Tier 1 involves the health status achieved. Tier 2 describes the care process and complications of treatment. And tier 3 relates to the sustainability of health. (See Exhibit 7.)[9]
For type 1 diabetes in children and adolescents, tier 1 outcomes should cover mortality rates (no diabetes-related deaths have occurred to date for Diabeter patients), QOL, and psychosocial parameters. Diabeter is also implementing systematic tracking and follow-up on QOL. (See Box 2.)

Tier 2 outcomes include the time it took to enroll a patient in an effective care program and the time it took for that patient to return to a normal life. Typical disutilities of care that need to be monitored include visits to the emergency room due to severe hypoglycemia or diabetic ketoacidosis. Diabeter receives information from inpatient and acute care hospitals about patients' hospitalizations and if they are related to diabetes. This information is, however, often already known from the Diabeter's medical hotline. Patients are also asked to provide information about severe hypoglycemia at home.

BOX 2 | CONTINUOUSLY IMPROVING THE QUALITY OF CARE: THE NEXT STEP OF THE VALUE JOURNEY

Diabeter strives to continuously evolve its care model in order to improve results. An example of this is the implementation of a QOL parameter in the systematic collection of data.

Studies undertaken by the Hvidøre Study Group showed that there is a strong relationship between patients' HbA1c levels and QOL. In addition, parents' QOL has also turned out to be related to patients' HbA1c levels. With these insights, Diabeter decided to systematically measure QOL for all patients. In order to do so, however, Diabeter had two challenges to solve. The first was designing a way of integrating the QOL protocol into existing data collection tools. This was done by co-developing the MIND Youth Questionnaire (MY-Q), which is a disease-specific validated instrument that assesses emotional well-being, social interaction (with family and friends at school and outside school), and diabetes management (such as worries, treatment barriers, self-efficacy, self-esteem, and problematic eating habits)[1)]. MY-Q will now be used for all patients at Diabeter and, when applicable, for their parents. The questionnaire will be digitally integrated in the automatically generated dashboard that is transparent to patients and caregivers.

The second challenge was to ensure that once the QOL was recorded and analyzed, Diabeter would be able to provide adequate support to manage patients and families with poor QOL. Diabeter invested in expanding its team of psychologists, all dedicated to support children with diabetes and their families.

[1)] *"Assessing diabetes-related quality of life of youth with type 1 diabetes in routine clinical care: the MIND Youth Questionnaire (MY-Q)."* M. de Wit, P. Winterdijk, H.-J. Aanstoot, B. Anderson, T. Danne, L. Deeb, K. Lange, A. Ø. Nielsen, S. Skovlund, M. Peyrot, F. Snoek. Pediatr Diabetes. 2012 Dec;13(8):638-46

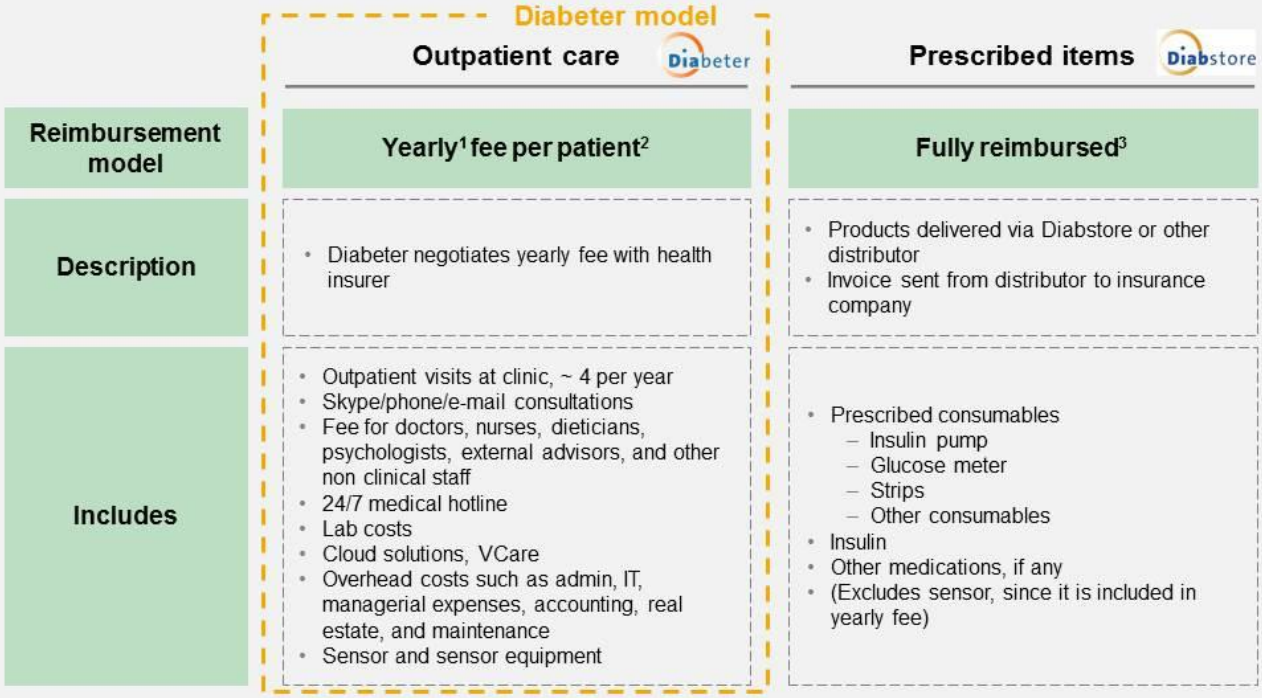
Tier 3 outcomes for pediatric type 1 diabetes include long-term parameters. Diabeter systematically tracks risks for complications in all patients. In annual comprehensive visits, data is collected on angiopathy (to track acute myocardial infarction and stroke), nephropathy, retinopathy, and neuropathy. Moreover, Diabeter collects data on family history to better understand future risk.
Summarizing Diabeter's outcomes collection, it is clear that the focus has been on tier 2 and tier 3. The future focus for Diabeter is to implement further tier 1 outcomes into the systematic collection of data. (See Box 2.)

Cost measurement started with an initial bottom-up cost data collection in the early days of Diabeter and has been maintained by regularly investigating the cost per patient. The cost per patient has turned out to be relatively stable over the years. In addition, Diabeter is planning to implement a rigorous cost per patient measurement system that will be able to track the cost impact for each patient.

MOVE TO BUNDLED PAYMENTS FOR THE ENTIRE DIABETES CARE CYCLE

Since the first Diabeter clinic opened in 2006, the Dutch funding model for diabetes care has changed. Each provider negotiates an annual bundled price with the Dutch health insurance companies. (See Exhibit 8.) The annual fee for patients at Diabeter is split into three payments and covers costs related to the care provided. Personnel costs make up 65% to 70% of the cost per patient, and the remainder is made up of laboratory costs and administrative expenses, such as IT, accounting, HR, marketing, and rent. The costs for prescribed items, such as medicines and consumables for monitoring glucose and administrating insulin, are in addition to the yearly fee and vary with treatment. The prescribed products are ordered by the patients and distributed through Diabstore or another distributor, depending on the patient's preference.

EXHIBIT 8 – Bundled payment negotiated between Diabeter and insurer



At present, there is the opportunity to refine current reimbursement models into value based models. This would allow for the integration of outcomes component to further incentivize patients and providers for superior clinical results. These discussions are currently ongoing with Dutch insurers to link a monetary incentive to clinical results in diabetes. Similar reimbursement models have already been introduced in the Netherlands, for example, for Longzorg Nijkerk treating COPD and asthma patients in primary care[10] and for Parkinson care provided by the ParkinsonNet coordination center at the Radboud University Nijmegen Medical Centre.[11] Both facilities have shown cost savings after the implementation of the new reimbursement models.

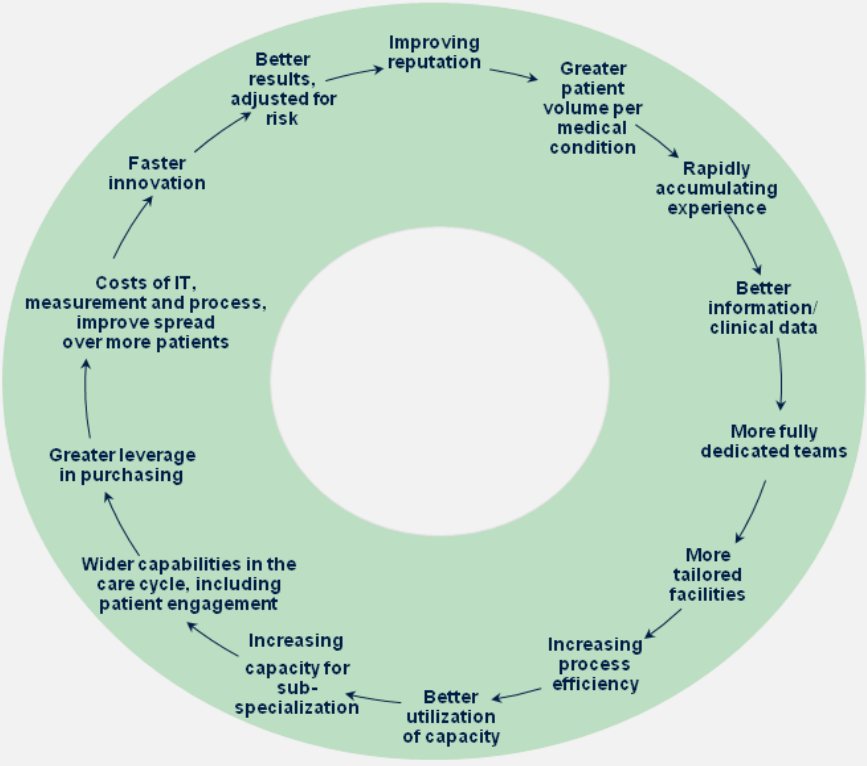
Another trend in Dutch health care financing is the expansion of care contracts from one year to multiple years. A recent example is the Isala hospital in Zwolle that agreed on a three-year payment cycle with Zilveren Kruis, which is part of the insurer Achmea. During the three years, Isala has committed to provide data, such as patient characteristics and frequency of care delivered, to ensure efficiency.

INTEGRATE CARE DELIVERY BETWEEN SEPARATE FACILITIES

Integrated care is provided most efficiently if single providers define a narrow scope of services, concentrate volume at a few locations, and integrate care for patients across locations. (See Exhibit 9.)

The Diabeter concept was developed in an academic research setting at a university hospital. However, with increasing patient volume and growing demand, it was determined that leaving the university hospital, where space and growth options were limited, would be required for Diabeter to grow. Diabeter was founded with the objectives of providing specialized care outside the traditional university hospitals to a well-defined patient population, namely children and adolescents with type 1 diabetes. Therefore, all Diabeter clinics are geographically separated from other care facilities. They also distinguish themselves from traditional hospital settings by their welcoming and modern interior design.

EXHIBIT 9 – Value of volume and experience in an IPU structure



Patients can easily move from one Diabeter clinic to another if needed. If complications occur or hospitalization is needed, Diabeter cooperates with nearby hospitals.

By moving to separate facilities and by providing specialized, patient-centric care, Diabeter has steadily increased patient volume. Patients are attracted to the specialized and dedicated team approach and to more tailored facilities. This has led to increasing desire of diabetes patients and their families to be part of the Diabeter care model. As a result, Diabeter is taking care of more pediatric patients with type 1 diabetes than any other clinic in the Netherlands.

Moreover, the large volume of patients also drives the efficiency of the organization and makes outstanding care available at reasonable and sustainable costs. Each full-time nurse and medical doctor at Diabeter can take care of a significantly higher number of patients with better outcomes. Thus, leveraging Diabeter's infrastructure and care model allows more patients access to highly dedicated clinicians than in conventional clinics.

EXPAND EXCELLENT SERVICES GEOGRAPHICALLY

Diabeter's first clinic opened in 2006 in Rotterdam in the southwestern area of the Netherlands. The second center, Diabeter East, opened in Deventer in 2008, followed by Diabeter South in Veldhoven in 2010 and Diabeter Schipol in 2015. In order to allow even more patients in the northern part of the country to access care at Diabeter, a fifth clinic is opening in Groningen in 2016. (See Exhibit 10.)

Diabeter has mainly applied the satellite strategy when expanding to new facilities. All Diabeter clinics apply the same care procedures, including using digital tools, and they share the administrative organization. In addition, some of the care staff is co-located between the clinics. The Diabeter concept is also planning to be applied outside the Netherlands and discussions are currently being held in the Middle East and the UK.

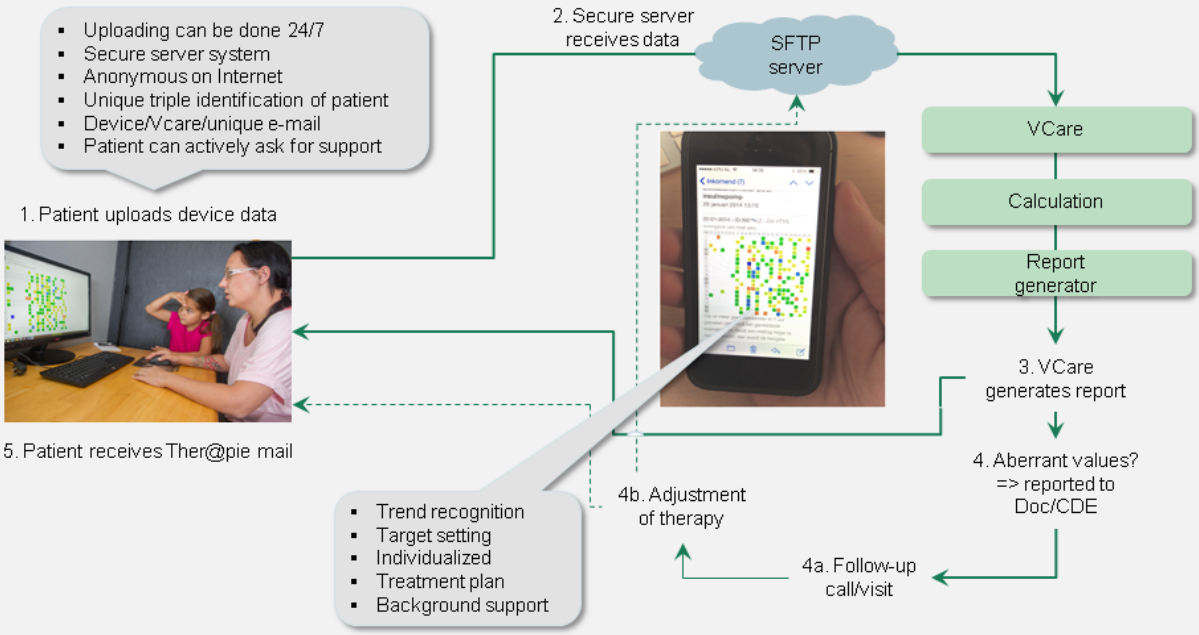
EXHIBIT 10 – Diabeter opening fifth clinic in Groningen

BUILD AN ENABLING IT PLATFORM

An integral part in Diabeter's care model is the collection of real-time patient data—a process that is transparent to the patient. Diabeter has developed the VCare system that electronically uploads data from a patient's insulin pump or glucose meter to a server that instantly displays the patient's real-time health status on a dashboard. (See Exhibit 11.) In addition, an extended report is sent to Diabeter, where the data is analyzed by a nurse. Patients then receive an e-mail called "Ther@pie mail" with information on trends, target settings, treatment plans, and next contacts with Diabeter. If there are large deviations in the data uploaded by the patient, an alert is automatically sent to one of the medical doctors for immediate action.

By continuously monitoring and analyzing health data from a patient with a chronic health condition, care providers and patients are able to immediately act to adjust therapy to optimize results. For example, on the basis of a patient's VCare data, Diabeter recommended that a male teenager rightly adjust his insulin dose because he was doing heavy physical exercise. While this was outside the usual recommendation, it had a positive effect on this patient. High patient volumes allow for opportunities to carry out clinical research. Diabeter can use VCare data, in addition to collecting research data within the scope of a clinical trial. To date, Diabeter and its founders have published 49 peer-reviewed papers since 2006.[12] In addition, one of the Diabeter founders chaired the International Diabetes Federation/ISPAD Charter, while the other founder became a charter member of the SWEET group.[13] The two founders are also engaging in a scientific collaboration with the university hospital Erasmus MC-Sophia to provide training to medical professionals.

EXHIBIT 11 – Digital tools enabling efficient data collection



DIABETER IS PROVIDING VALUE FOR ALL STAKEHOLDERS IN HEALTH CARE

The overarching goal in health care is value: the outcomes that matter to patients relative to the costs of achieving those outcomes over a patient's entire care cycle. Value can be delivered by improving outcomes without raising costs or by keeping outcomes at a high level while significantly reducing costs. Diabeter is actually doing both: improving outcomes in type 1 diabetes care to the highest available level in the Netherlands without increasing costs. (See Box 1.) At the same time, Diabeter is reducing costs for the health care system without compromising outcomes. Diabeter is a great example of what value-based health care is able to achieve for all stakeholders:

PATIENTS: benefiting from improved care results that really matter to them, in a setting centered on their needs; with reasonable health insurance premiums;

PROVIDERS: enjoying improved disease-specific knowledge and experience as well as growing patient numbers and revenues;

CLINIC MANAGERS: a working environment in which a fully dedicated, multidisciplinary team efficiently collaborates, allowing to attract, and retain the best clinicians, providing speciality care at scale with high-level of efficiencies;

PAYERS: a value-based health care system in which payers can offer their customers outstanding care at sustainable and fair prices; and an outcomes-based reimbursement model and risk-sharing contracts that enable providers to save money due to fewer complications and hospitalizations.

In addition, the entire health care system also wins: value-based health care means the right diagnosis and treatment at the right time by the right people as well as fewer complications and recurrences, slower disease progression, and lower costs. (See Exhibit 12.)

EXHIBIT 12 – Quality improvement is the most powerful driver of cost containment and value improvement

Prevention of illness	Fewer complications
Early detection	Fewer mistakes and repeats in treatment
Right diagnosis	Faster recovery
Right treatment for the right patient	More complete recovery
Rapid cycle time of diagnosis and treatment	Greater functionality and less need for long-term care
Treatment earlier in the causal chain of disease	Fewer recurrences, relapses, flare-ups, or acute episodes
Less invasive treatment methods	Reduced need for ER visits
	Slower disease progression
	Less care-induced illness

Better health is the goal, not more treatment

Better health is inherently less expensive than poor health

By systematically following the six steps of the value agenda, Diabeter was able to develop a group of value-based health care delivery centers for type 1 diabetes. In a recent analysis, Diabeter was able to demonstrate that its superior outcomes led to less direct annual costs to type 1 diabetes patients. These savings (8.6%) were mainly driven by a much lower patient hospitalization rate than that of other Dutch pediatric diabetes clinics. (See Exhibit 4.)

OPPORTUNITIES FOR FURTHER GROW THE DIABETER MODEL

The goal of Medtronic is to to further improve the Diabeter model by innovating and applying the latest medical technology and data collection and actively selling Diabeter's care bundles using outcomes-based reimbursement models. The next step in scaling the Diabeter model is to keep collaborating with leading Diabetes facilities in the Netherlands on VBHC. Leading Dutch payers are showing interest in enrolling more type 1 diabetes patients in Diabeter programs and agreeing on innovative reimbursement models.

However, other countries need to move away from their current, often flawed diabetes care models to a value-based approach. With Diabeter and Medtronic, leading health care providers and governments in Europe and the Gulf region are currently discussing how to bring this innovative and proven model to their countries.

Countries in the Middle East are particularly challenged not only by an exploding number of people with type 1 diabetes but also by a dramatic rise in the number of type 2 diabetes patients. The type 2 diabetes patient population worldwide is approximately ten times larger than the type 1 diabetes population. Although the underlying causes of type 1 and type 2 diabetes are different, the challenges of treatment options and disease-related complications are similar. Thus, it seems to be a natural next step for Medtronic and Diabeter to think about options for developing a similar care model for treating type 2 diabetes. Medtronic recently acquired the obesity clinic Nederlandse Obesitas Kliniek in order to tackle metabolic syndrome the main disease mechanism related to type 2 diabetes.

In summary, Medtronic is leading the way into Value Based Healthcare with acquisitions such as Diabeter. Outcomes driven care delivery could be a strong contributor towards the sustainability of healthcare systems around the world.

Diabeter as a pioneering integrated practice unit for the management of diabetes type 1 has already proven great success in the Netherlands. An international well driven expansion is needed to ensure that other patients and healthcare systems benefit from better outcomes at equal or better cost as a contributor to the transformation and viability of care.

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EXHIBIT SOURCES

1) Dramatic variation in glycemic control within and between industrialized nations: patients under age 15
   Source: "Glycaemic Control of Type 1 Diabetes in Clinical Practice Early in the 21st Century: An International Comparison." *DIABETIC Medicine*, 32 (8), pages 1036-50, Aug 2015. BCG analysis.
2) Equal variation for patients 15-24 years
   1. 18–24 years. 2. Regional population.
   Source: "Glycaemic Control of Type 1 Diabetes in Clinical Practice Early in the 21st Century: An International Comparison." *DIABETIC Medicine*, 32 (8), pages 1036-50, Aug 2015. BCG analysis.
3) Diabeter outperforming other Dutch diabetes clinics
   Source: Dutch National Health Care Institute.
4) 8% of children hospitalized in average Dutch Diabetes clinic
   Source: Dutch National Health Care Institute.
5) Six components of the value agenda
   Source: Michael E. Porter, Institute for Strategy and Competitiveness, Harvard Business School.
6) An integrated practice unit enables value-based care delivery
   Source: Michael E. Porter, Institute for Strategy and Competitiveness, Harvard Business School; Diabeter.
7) Outcome measures for diabetes population
   Source: Michael E. Porter, Institute for Strategy and Competitiveness, Harvard Business School; BCG analysis.
8) Bundled payment negotiated between Diabeter and insurer
   Note: Newly diagnosed patients are reimbursed separately for the first three months before the yearly fee commences. 1. The yearly fee is divided in three payments per year. 2. The fee is negotiated between Diabeter and insurers and differs among insurers. Moreover, the fee depends on the treatment method. 3. There are exceptions.
   Source: Diabeter.
9) Value of volume and experience in an IPU structure
   Source: Michael E. Porter, Institute for Strategy and Competitiveness, Harvard Business School.
10) Diabeter opening fifth clinic in Groningen
    Source: Diabeter.
11) Digital tools enabling efficient data collection
    Source: Diabeter.
12) Quality improvement is the most powerful driver of cost containment and value improvement
    Source: Michael E. Porter, Institute for Strategy and Competitiveness, Harvard Business School.