Case Study Innovation Management
Case Study Background

Le, V. / Mögerle, M. / Pfeiffer, D. / Pöhlchen, D. / Wühr, M. (2016):

Smart Tooth, in: Center for Digital Technology and Management (CDTM): Digital Innovation in Diabetes Care Trend Report 2016.

A revolutionary solution to automatically analyze carb intake while eating.

To keep blood-sugar levels within a healthy range, the body processes multiple, complex information from the brain, digestive system, and other sensory perception. Patients with T1DM, who suffer from a loss of their beta-cells due to an autoimmune reaction, are no longer able to produce insulin within their bodies. Patients with T2DM, in the early stages of the illness, suffer from an enhanced insulin-resistance, which can ultimately lead to a loss of their ability to produce insulin within their body. To bridge these shortcomings, the AP promises a great contribution to patients' perspective of leading a near-normal life again. These systems constantly measure the blood-glucose level and automatically inject insulin when needed.

Until now, the algorithms in the AP do not process information on the exact amount and composition of the food the patient is consuming. The Smart Tooth, adds this missing piece of information and closes the gap. Mounted to patients' teeth by a dentist, the Smart Tooth gives detailed information about the food intake. As it is extremely important for diabetics to eat healthily and measure their carbohydrate intake, this solves an essential problem for the patients. The Smart Tooth works based on a small spectroscope to analyse carbohydrates, as well as with a vibration sensor to track chewing and swallowing. Machine learning algorithms taking into account the patient's personal eating patterns are used to improve the calculation of the required insulin. The energy needed to power the Smart Tooth will be created by a piezoelectric element that simultaneously works as a pressure sensor. Through a small low energy Bluetooth sender, the data will be transmitted directly to the AP or another reception device, such as a bracelet. Finally, a mobile application visualizes the generated data.

The accompanying mobile application provides a secondary revenue stream, next to the Smart Tooth device itself, and will be offered in a freemium model. Every patient receives a basic version with limited insight to the data, whereas the optional premium subscription model is needed for access to the full holistic functionality of the health platform.

As long as there is no cure for diabetes, this combined system will enable the patients to take their minds off of the disease and increase

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their quality of life by removing the strenuous obligations to measure glucose, manually inject insulin, and adjust their insulin-dose after having consumed a heavy meal.

Key Partners

The most important key partners are the manufacturers of AP, who are customers, key partners, and a distribution channel at the same time. As the Smart Tooth is not a mere standalone system but rather a supporting device for the AP, a strong partnership with manufacturers of AP is of utmost importance. The focus lies in establishing a common ground for the technological exchange between the Smart Tooth and the AP. Furthermore, the algorithm and the API needs to be included in the AP, enabling the precise interpretation of the data coming from the Smart Tooth, and to implement machine learning algorithms. Due to cost considerations, both the manufacturing and assembly of components are outsourced to external suppliers, who consequently form the second group of highly important key partners.

Additionally, as the Smart Tooth is a medical product for diabetics, the expert knowledge and experience of physicians and diabetologists are very important for the success of the Smart Tooth. Particularly dentists and orthodontists, who will be installing the Smart Tooth, have to be trained on how to install and maintain the Smart Tooth components.

Insurances are involved as well, as their consent for reimbursement will have a huge impact on sales numbers and is closely related to the acceptance and success of the product.

The treatment of diabetes can be improved and costly follow-up diseases can be prevented with the Smart Tooth, which is an incentive for insurances to reimburse the installation and maintenance of the product.

Key Activities

A prerequisite for a successful medical product is the upholding of medical standards and approval as a medical device. This requires prototypes to be tested in clinical trials to conduct efficacy and effectiveness studies.

The key activity in business operations will be sales and marketing to doctors, hospitals, and insurances. The main goal is to achieve full reimbursement by insurances for most patients, to ensure a large market potential. Therefore, presenting the technologies at conferences, both in a medicinal as well as a business context, is of great importance. Training sessions for doctors on the benefits, as well as implementation and main- Key Activities tenance, are part of this important activity. Doctors have to be trained in the correct usage of the device and educated about the mechanism of the Smart Tooth.

Additionally, research and development (R&D) is key to continuously improve and adjust the product. This goes particularly for the required sensors and the algorithm-driven machine-learning aspects of the technology. The

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algorithm detecting the eating habits and predicting the insulin doses that are necessary must be developed along with the Smart Tooth API. The interface has to be designed in a way that it can interact with the algorithms of closed-loop-systems and other health applications. Finally, the visualization of the patient's data within the Smart Tooth App needs to be engineered.

Ensuring a consistently high quality of the device, and the analysis technique, has a big impact on patient satisfaction and subsequently, on business success. Closely related to this is the maintenance of the API to ensure an infallible interface between the Smart Tooth and the devices connected to it. Constant bug fixing, regular updates, and minor adjustments are part of the regular improvement activities. Alongside this, the purchase of the hardware parts has to be a focal point in operations due to the key relevance of price and quality for the business model. Consequently, maintaining good business relationships with trusted suppliers is necessary for inhibiting irregularities in quality.

Key Resources

The most important resource for the Smart Tooth is the intellectual property, as a result of R&D activities, and efforts to constantly improve the system. Protecting the Smart Tooth technology and brand is key for our commercial success. Through patents of multiple aspects of the carbohydrate-measuring technique, the business ensures long lasting profits from the technology developed. Another key aspect of intellectual property is that the advanced Smart Tooth

technology will attract business partners, investors, and shareholders.

Before a medicinal product can be used on patients, many clinical tests must be processed to prove clinical effectiveness and efficacy. Having demonstrated its efficacy and increased quality of treatment, the Smart Tooth will become state-of- the-art medical practice. Lastly, Smart Tooth relies on the knowledge and expertise of its employees. On the one hand, hardware developers are required for designing the Smart Tooth with its multiple sensors on a very small footprint. Their expert knowledge is also valuable to consult customers and partners and advise them on technical questions. On the other hand, software developers are needed to develop algorithms and interfaces for the communication with other medical devices and smartphones. They are also in charge of the user-friendliness of the smartphone application and the visualization of the Smart Tooth data. Furthermore, a committed sales force and marketing team are required to sell the product to doctors, hospitals, and insurances.

Value Proposition

Mounted invisibly to the rear teeth in a patient's mouth, the Smart Tooth offers an accurate, user-friendly and discreet way to count the carbohydrates eaten. This revolutionizes diabetes self-management and increases

patients' quality of life significantly.

Combined with an AP, the Smart Tooth builds a comprehensive closed-loop-system. While the tooth assesses the amount of carbohydrates eaten, the appropriate dose of ultra-fast-acting insulin is automatically released into the body by the AP. This system offers two major improvements to existing diabetes- management methods by extending the closed-loop: First, it measures the patient's actual food intake instead of only estimating it. Consequently, the accuracy of measurement increases significantly compared to current methods, such as patients manually assessing the amount of carbohydrates eaten or picture-driven mobile phone applications. Secondly, no human intervention is necessary, as the data is sent directly to the AP. Common AP systems still require patients to manually adjust the insulin release before eating, due to a measurement delay caused by measuring the blood glucose level in the abdominal interstitial fluid. The measurement of carbohydrates, simultaneous to their intake, saves valuable time and allows the AP to swiftly adjust the insulin release accordingly. A more accurate measurement of carbohydrate intake inhibits unnecessary insulin injection and thus, limits unnecessary feelings of hunger. This solves a widespread paradox: by dosing insulin incorrectly, patients tend to eat more, which often ultimately worsens their condition.

Patients' fear of hypoglycaemic events is a major issue in diabetes treatment. These can lead to dangerous, and even fatal situations. As a consequence, many patients risk a slight, constant hyperglycaemia to avoid those incidents. Since the longterm effects of too high blood glucose levels, such as blindness or acute microvascular diseases, can be severe and cost-intensive, avoiding these follow-up diseases increases patients' quality of life significantly. As a consequence of this perfected closed-loop-system, hypoglycaemia and hyperglycaemias can effectively be eliminated.

Customer Relationships

As the Smart Tooth shows the most potential when it is embedded into an AP' closed-loop-system, a close collaboration with the manufacturers of AP is necessary. This does not only matter greatly during the phase of development, but will also be highly relevant for sales and distribution later on. The goal is to have AP suppliers offer the Smart Tooth in their own product range. A permanent and personal relationship with our B2B partners fosters innovative cooperation and will help provide assistance in solving technical difficulties quickly.

Apart from keeping close contact with tech-companies, the ongoing exchange with physicians is central as well. As we are dealing with a highly specialized medical market, we plan to publish our results in medical journals, attend medical fairs, conferences, and diabetes conventions in order to raise awareness of the Smart Tooth.

We also want to make the patient, as our end-consumer, aware of the Smart Tooth. Additional to existing channels, an informative website and social media platform directly informs diabetics and health-conscious customers about our product. Patients have

the chance to co-create the future of Smart Tooth by giving feedback and suggestions to improve the measuring device and the application. Customers who actively use the Smart Tooth App receive regular updates and information on company news and developments.

Channels

There will be a twofold strategy for selling the Smart Tooth hardware to customers. As with most medical products, such as dental braces or sensory implants, patients do not buy the device directly from the supplier. Instead, physicians procure them from the manufacturers and are subsequently reimbursed by insurance companies. In that sense, a doctor prescribing the Smart Tooth follows the conventional sales approach of medical products. This represents the first sales channel of selling the Smart Tooth, directly via physicians. To a large extent, the Smart Tooth can be sold as an extension to complement AP closed-loop-systems. In these cases, the AP manufacturer would buy the Smart Tooth and sell it via his or her own channels to doctors and patients. This results in a large potential customer base acquired through companies that produce AP. By using the existing channels of these key partners, market entry is straightforward and costs can be saved. Support and service for the product are provided by dentists, who closely cooperate with the patients' diabetologists. The goal is to achieve a full recognition among experts and to be included in the medical guidelines for diabetes care. The goal of the sales channel is to convince diabetologists of

the benefits of the Smart Tooth and to encourage them to recommend it to their patient subsequently.

The smartphone application will be available in major app stores. The basic version of the Smart Tooth mobile phone application comes free of charge with the Smart Tooth package. It will be available for download in the Apple and Google Play Store and can then be upgraded by the patient with an in-app purchase. For this purpose, app store payment methods will be used.

Customer Segments

Due to the multitude of stakeholders involved in the market for medical devices, the definition of the customer segments is multi-layered. On the one hand, the end user of the Smart Tooth, namely users of a perfected closed-loop-system, is the diabetes patient who's quality of life and treatment is significantly improved.

Nevertheless, it is the physician who decides on the treatment method and thus needs to be convinced of the system's benefits and effectiveness. Ultimately, the health insurance provider pays for the product; therefore, it is necessary, and common practice, to approach physicians and insurances to promote the use of the Smart Tooth system. The main benefit is the possibility to provide improved treatments and lessen complications or follow-up diseases. Therefore, while the patient is the end user, he is not the targeted customer. Additionally, suppliers of AP systems can use the Smart Tooth and its API as a complementing extension of their closed-loop-system in order to improve their product. Since

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they already have developed sales channels, targeting them as customers and reaching their customer base as end users is very promising.

Patients are the direct customers for the premium subscription of the mobile phone application. As an optional extension of the Smart Tooth, the collected data is analysed to improve the patient's understanding of his or her own dietary patterns. Physicians are only involved in this aspect indirectly, if patients agree to share their data.
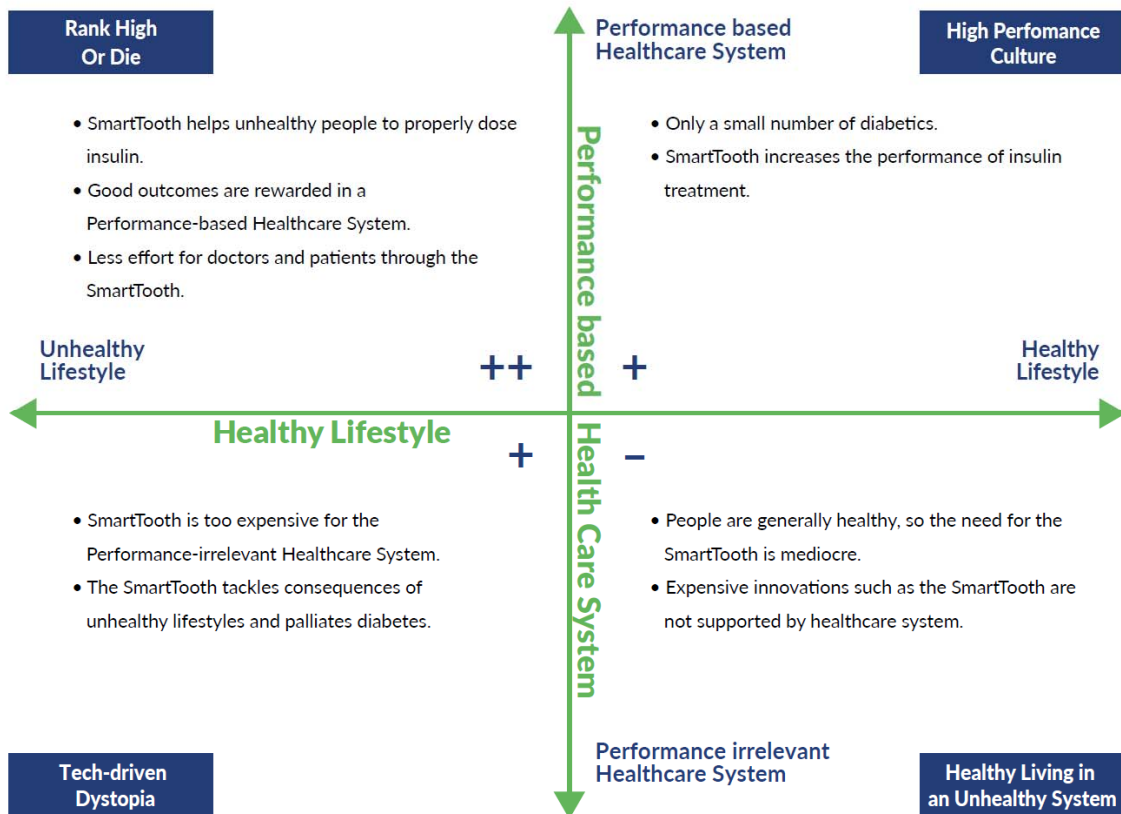
Cost Structure

The largest part of the fixed costs is the spending for R&D: for the hardware this includes the sensors, the energy generation, and the data transfer unit, as well as their mounting. Another important block of fixed costs is the development of the intelligent algorithm that interprets the data sent from the Smart Tooth and improves in accuracy using machine learning technology. Clinical efficacy studies as well as tests from the drug approval commissions are further fixed cost blocks. Since manufacturing is outsourced, there will be little or no fixed costs regarding the production of devices.

The variable costs consist mainly of contracts with manufacturing partners and hardware materials. The costs for purchasing sensors, energy elements, transmission units, and mounting materials are scalable and thus variable. Since a high and consistent quality of the product is essential, the purchase of these elements cannot be out sourced to the manufacturers. Human resources costs are also variable, and include costs for management and sales representatives.

Revenue Streams

The Smart Tooth offers three revenue streams: The first is the one-time payment for the purchase and installation of the Smart Tooth package, including the basic version of the app. Since it is planned to collaborate with business partners, e.g., manufacturers of AP, a second revenue stream comes from the fees received by providing the Smart Tooth API. To ensure a high-quality integration of the two systems, our services include the fine tuning of the interactions between algorithms. In addition, the App's API can be opened up to other stakeholders, who would have the possibility to integrate their content. This means, that third party developers, who are for example, working on fitness applications, can utilize the data from the Smart Tooth to enrich their user experience. Lastly, customers subscribing to the premium version of the app, which comes bundled with the Smart Tooth, will be paying a monthly subscription fee for receiving access to additional functions of the app and the patient platform.

Rank High Or Die

- SmartTooth helps unhealthy people to properly dose insulin.
- Good outcomes are rewarded in a Performance-based Healthcare System.
- Less effort for doctors and patients through the SmartTooth.

Performance based Healthcare System

High Perfomance Culture

- Only a small number of diabetics.
- SmartTooth increases the performance of insulin treatment.

Unhealthy Lifestyle ++ + **Healthy Lifestyle**

Healthy Lifestyle + −

Performance based Health Care System

Tech-driven Dystopia

- SmartTooth is too expensive for the Performance-irrelevant Healthcare System.
- The SmartTooth tackles consequences of unhealthy lifestyles and palliates diabetes.

Performance irrelevant Healthcare System

Healthy Living in an Unhealthy System

- People are generally healthy, so the need for the SmartTooth is mediocre.
- Expensive innovations such as the SmartTooth are not supported by healthcare system.

Rank High or Die

As the Smart Tooth drastically decreases the chance for costly follow-up diseases and fosters more efficient self-management of patients, insurances will generally be incentivised to reimburse the product. As people have an unhealthy lifestyle, the number of T2DM cases increases, resulting in a higher demand for the Smart Tooth. Additionally, due to the low health literacy, diabetes self-management will be poor. The healthcare system faces high costs because of an obese and ageing population. However, the Smart Tooth will be reimbursed for the patients who benefit most. For example, old patients who face the biggest obstacles tracking their food intake greatly benefit from the product. Patient groups with less obvious benefits might have to pay for the Smart Tooth themselves.

Very tech-affine patients may also be willing to pay for the Smart Tooth. The outlook in this scenario is particularly positive because the potential market size is significantly large due to the high number of diabetics. In addition, the targeting of self-paying customers is viable.

Tech-driven Dystopia

Because a non-performance-based healthcare system is designed to deliver symptom-driven, acute care, it is poorly configured to effectively treat chronic diseases, such as diabetes, that require the development of a collaborative daily self-management plan. Since people are not caring for a healthy lifestyle and governments have not yet introduced efficient regulations on nutrition, the number of T2DM cases in this scenario will be remarkably high. Consequently, there is a big market of patients whose management of T2DM could be

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improved with the Smart Tooth. Since insurances face high financial costs due to the large proportion of unhealthy people, only conservative, established treatments are covered. In very severe cases of diabetes, the Smart Tooth will be reimbursed. As the Smart Tooth generally increases the quality of life of obese people and offers convenient solutions to monitor the personal diet, there will be a market, independent of the healthcare system. Especially health illiterate patients will embrace the possibility of an easy carb counting tool. As a result, this scenario offers a fairly positive outlook for our business model.

High Performance Culture

The Smart Tooth will increase the performance of insulin treatment, consequently also patients' quality of life. Even though people know how to estimate their carbohydrates quite well, the Smart Tooth will nevertheless bring a significant increase for patient comfort, as they no longer have to think about what exactly they eat before a meal. Additionally, with the data from the Smart Tooth, the AP will be able to automatically adjust the insulin injections, making human intervention obsolete. However, in an environment with high health literacy, the number of people who suffer from T2DM is expected to be rather low, decreasing the potential market size. In this scenario, customers will mostly be young

T1DM patients, middle-aged adults suffering from T2DM despite a healthy lifestyle, and people with a general pancreas disorder who need to closely observe their carb intake and insulin therapy. An additional market will be very health-focused people, who wish to closely monitor their food intake.

Healthy Living in an Unhealthy System

People in a healthy living environment generally have a large interest in consuming wholesome food and are already highly educated on how to live healthily. Therefore, they are interested in constantly checking their food habits. However, there will not be an extreme need for the Smart Tooth as the prevalence of T2DM is low. As the structure of the non-performance- based healthcare system favours short-term fixes for acute symptoms, there is little inclination to pay for innovative and costly products. The Smart Tooth is neither a medical necessity nor covered by insurances, resulting in a rather low number of potentially interested customers. Beneficiaries will be limited to privately insured T1DM and T2DM patients and individuals willing to pay for the tooth themselves. In this scenario, we especially address customers who want to gain further insights into their lifestyle.