

A group of people are gathered around a rustic wooden table outdoors, enjoying a meal. The table is set with plates of food, including salads and pasta, and glasses of orange juice. The scene is brightly lit, suggesting a sunny day. A semi-transparent blue banner is overlaid on the image, containing the title text.

DIGITAL INNOVATION IN DIABETES CARE

TREND REPORT 2016



**Kindly supported by
the EIT Health**

EIT Health is one of the largest healthcare initiatives worldwide. Its goal is to sustainably advance the foundations of healthcare and thus promote the future conditions for healthier living and wellbeing of people across Europe. EIT Health is leveraging the expertise of more than 130 leading organisations spanning key areas of healthcare such as Pharma, MedTech, Payers, Research Institutions and Universities. Chosen by the European Institute of Innovation and Technology (EIT) to form EIT Health, the consortium offers best-in-class research capabilities, higher education and business expertise. With a budget of 2 billion EUR over the next decade, it will purposefully invest in Europe's best entrepreneurial talents and creative minds to foster the development and commercialisation of smart product and service solutions in the health sector, addressing the challenges imposed by demographic change and ageing societies.



**A project of the Center for Digital
Technology and Management (CDTM)**

The Center for Digital Technology and Management (CDTM) is a joint, interdisciplinary institution for education, research and entrepreneurship of the Ludwig-Maximilians-Universität (LMU) and the Technische Universität München (TUM).

It offers the add-on study program „Technology Management“ for students from various backgrounds, which provides students with tools and knowledge at the intersection of business and digital technologies.

The entire trend report was written by CDTM students under the close guidance of research assistants in 2016.

For more information about the CDTM and its related projects, please visit www.cdtm.de



Air Liquide Healthcare

AIR LIQUIDE is the European leader for cares of chronic diseases patients at home, with the ambition to expand its leadership in Europe and facilitate the access to new infusion therapies through innovative technologies and services. A successful integration of the Artificial Pancreas (AP) in AIR LIQUIDE French homecare operations service platform may be an excellent basis for outreaching and adapting its use to diabetes homecare in other European countries. The business model includes patients, payers, and prescribers management.

AIR LIQUIDE as a service provider is situated at the crossroads between physicians (prescribers), patients, and payers. Physicians forward prescriptions immediately to AIR LIQUIDE. AIR LIQUIDE's workforce includes pharmacists and nurses (but no physicians), who set up a safe and efficient treatment at the patients home by implementing and monitoring the use of the prescribed drugs, devices, and related consumables. Full compliance with the medical prescriptions is given by providing trainings to patients and nursing relatives in equipment and drug use, by supervising patient therapy adherence, reporting patient data to the physicians. In case of signals indicating

worsening of the patient health situation (telemedicine monitoring, telephone operators employed by AIR LIQUIDE) the service provider pro-actively reacts by coordinating services with healthcare professionals. Homecare services also facilitate re-implementation of homecare following discharge from the hospital.

Today's diabetes activities at AIR LIQUIDE are focused in France where AIR LIQUIDE is the leader (Vitalaire, Orkyn, Dinno Santé, LVL, Seprodom, Arair Tours) serving 25 000 pump patients at home for a total of 43 000 pump users; in Nordics (NordicInfu Care) and in Hong Kong (Celki). The objective of AIR LIQUIDE is to extend its leadership in the implementation of infusion therapies for the management of nutritional deficiencies and chronic diseases at the patient's home and extend the service value towards chronic care management (E-care, telehealth)

The key success factors of AIR LIQUIDE are a solid expertise, a dedicated team, the development of specific offers according to patients' profile, and providing innovation support. The AIR LI-

QUIDE value creation is managing a digital platform with associated programs (patient support, engagement and compliance, protocols, complication management)

By being part of the CLOSE EIT Health innovation-by-design project AIR LIQUIDE is going to innovate homecare by distributing a closed loop metabolic control system (Artificial pancreas) for severely ill patients with type 2 diabetes.



AG Diabetes & Technologie - AGDT

The ambition of the Working Group for Diabetes Technology (AGDT) is to provide constructive and critical support for the various technical options available for the diagnosis and treatment of diabetes. This ranges from the implementation of trainings up to the initiation of own studies. The AGDT also develops positions on technical developments that have not yet matured. In the field of tension between medical benefit and health economic considerations, the AGDT sees itself as a platform for the interests of patients and their therapists, but also stands for a responsible management of the resources of our health care system. A further pillar of activities is the education of physicians and patients to facilitate an optimal use of new technologies. The AGDT is allocated within the German Diabetes Association (DDG). Among the more than 200 members of the AGDT are many diabetologists, diabetes consultants, clinicians, scientists and employees of a number of companies active in this field.



German Center for Diabetes Research - DZD

The DZD is a national association aiming for the development of individualized strategies for the early detection and prevention of diabetes and its complications. The DZD also strives to devise personalized causal therapies to halt disease progression and improve patient care. An overarching objective is to rapidly incorporate research findings into medical practice, so that patients can benefit more quickly from the research.

The Helmholtz Zentrum München is one of the five partner of the DZD and its Institute of Health Economics and Health Care Management focusses on improving the effectiveness and efficiency of health care. Within the CDTM Trend Seminar the institute contributed a lecture on the economic burden of diabetes



Institute for Applied Quality Improvement and Research in Health Care GmbH – AQUA

The AQUA Institute for Applied Quality Improvement and Research in Health Care GmbH is an independent and impartial corporation that provides services for quality assurance. The Institute was founded in Göttingen, Germany in 1995 and has anchored itself in the field of science. It is one of the pioneers of medical quality circles (peer review groups), the evaluation of new treatment models, the development and implementation of quality indicators, patient surveys, and data driven quality management. It is one of the most experienced and successful providers of concepts and solutions in the field of healthcare quality improvement in Germany and can provide data analysis, counseling and strategies for quality improvement and quality assurance as well as the implementation of comprehensive projects. The Institute's extensive range of services also includes data management, healthcare reporting, automatically generated feedback reports, the implementation of guideline-based healthcare as well as the training and supervision for medical moderators. The AQUA Institute is an experienced partner also for qualitative and quantitative research, especially regarding healthcare claims data. The Institute is strongly involved in national and international quali-

ty research and quality assurance (e.g. projects in Algeria, Kenya and Tanzania). The AQUA Institute's qualified and interdisciplinary team consists of around 70 employees with long-standing experience in the fields of medicine, health and nursing sciences, pharmacy, information technology, statistics, economy, sociology and communication sciences.

Within the CLOSE partnership, AQUA contributes its expertise to the development of indicators for a comprehensive impact analysis, to healthcare research and assuring healthcare quality during the development and application of an artificial pancreas for patients with diabetes mellitus type 2 and the necessary services connected to this device.



IESE Business School of the Universidad de Navarra

IESE Business School of the Universidad de Navarra deploys a wide range of professional and training capacities in all managerial aspects, being at the vanguard of innovative management in business and public administration for more than 50 years. The health sector is one of the areas where IESE seeks to create a transformative impact through the development of management capacities and applied research.

To this end, the Centre for Research in Healthcare Innovation Management (CRHIM) was founded. The centre was built on more than 30 years of health sector activities, when in the 1980s, IESE helped develop managerial capabilities in regional hospitals in Spain. Since its creation, the Center has led and participated in a large number of training programs and research projects at national, European and international levels - including consultancy for public and private entities - in eHealth, Integrated Care, Chronic Disease Management, patient involvement and health policies. Here, CRHIM has positioned itself as a centre of excellence in investigating management of innovation within the health sector. The centre has supported leaders in healthcare, addresses their challenges and develops

opportunities to provide higher quality care that is more effective and affordable, while creating added value for patients and professionals.

The vision and mission of IESE-CRHIM naturally encompass the three components of the so-called „knowledge triangle“: education, research and innovation, and business. This forms the basis of EIT Health programs. Within EIT Health Project CLOSE, the IESE-CRHIM team has a role in developing the current knowledge on innovation in Type 2 Diabetes care and contributed in the CDTM Trend Seminar offering insights on healthcare business models, innovation in healthcare, and current trends. The team will lead business analysis and modelling of homecare solutions for Type 2 Diabetes management and will determine the potential for expansion and growth into new markets. The team will also produce a detailed analysis of the conditions in which cost-effectiveness will be delivered, entry barriers, key enablers for bringing this forwards and the value of an artificial pancreas and homecare services to all stakeholders. The impact of all this will have profound implications for European health and social care.



Medical University of Lodz - MUL

The MUL is one of the largest medical universities in Poland. Currently 8,500 students study in five faculties (Medicine with the Division of Dentistry, Pharmacy, Health Sciences with the Division of Nursing and Midwifery; Biomedical Sciences and Postgraduate Training, Military Medicine, with the Division of Studies in English) and 15 fields of study. The University also conducts studies in the English language and over 650 foreign students take part in medical and dentistry programmes, as well as doctoral studies. Its clinical facilities include four hospitals that score top positions in national rankings.

The MUL substantially contributes to the academic life of the city and country. The University educates future doctors and specialists in medical sciences and medicine-related fields. It carries out scientific research, developmental work and renders research services.

The range of educational services offered by MUL is continually changing and expanding. It considers above all the requirements of the labour market and the Bologna Process. Conditions for educating students and conducting research provided by the Medical University of Lodz are regularly being improved.

The modern Didactic Centre of the Medical University of Lodz houses unique scientific and research laboratories and a multi-media dental care centre.

MUL's activity covers all areas of medicine including clinical studies carried out in its own three teaching hospitals and numerous departments within other hospitals. MUL is the only university in Poland, which implements the concept of Business Process Management, using the BPMS platform for the daily management of the organization, not only in relation to the administration, but also for educational, research and clinical activities.

MUL participated in 5 projects under the 5. Framework Programme (including a coordination of a Centre of Excellence in Molecular Medicine), 10 projects under the 6.FP, and 18 projects within the 7.FP, including two coordinations (ABC – a small collaborative project, and Healthy Ageing Research Centre, which is a RegPot). MUL is also a member of EIT Health and part of the CLOSE EIT Health innovation-by-design project partnership.



Profil Institut für Stoffwechselforschung GmbH – Profil Germany

Profil Germany is a globally operating full service CRO founded in 1999 by Tim Heise and Lutz Heinemann as a spin-off of an academic study group at the department of metabolic diseases and nutrition at Heinrich-Heine-University of Düsseldorf. Profil Germany is uniquely positioned by its focus on clinical trials evaluating drugs and devices for people living with obesity, (pre) diabetes and diabetes complications. Profil has been involved in developing nearly all major anti-diabetic compounds and devices in the market today.

One of the core technologies used is the hyperinsulinemic euglycemic clamp for the evaluation of action profiles of insulin and insulin analogues, beta cell function and insulin sensitivity. The founders of Profil have worked for many years on refining the operation of the automated glucose clamp technique, seeking ways to improve the performance of the devices and make the experience easier for clinical trial subjects. Today Profil Germany uses ClampArt® - a fully automated modern glucose clamp device developed in-house that meets all EU regulatory standards and has awarded CE label in 2013. To address human metabolic pathways glucose clamp studies are combined with isotope dilution techniques and tissue biopsies.

Profil's in-house scientific expertise covers pharmacology,

obesity and prediabetes, nutritional sciences, cardiometabolic research, hepatology, endocrinology, the entire spectrum of diabetes complications, cell and molecular biology as well as metabolic monitoring and medical technology. By owning a continuously updated database with entries of more than 27.000 well characterised individuals (healthy, healthy "at-risk", type 1 and type 2 diabetes) the target groups benefitting from diabetes-related innovation can be addressed in clinical trials. Profil Germany has a fully GMP certified pharmacy, two large Clinical Research Units (Neuss and Mainz) and holds large expertise and capacities in Data Management & Statistics and Regulatory Affairs.

In order to be proactive in meeting the requirements of its clients, Profil Germany decided to become a core partner of EIT Health—one of the largest publicly funded initiatives for health worldwide. This opens up new avenues for extending Profil's service portfolio to accommodate paradigm shifts in the evaluation, licensing and reimbursement of drugs and devices. Profil Germany is coordinating the CLOSE EIT Health innovation-by-design project dedicated to bring an integrated solution package centered on closed loop metabolic control for severely ill patients with T2DM to the market.



KU Leuven – Clinical and Exp. Endocrinology (Prof. Chantal Mathieu, Prof. Pieter Gillard)

The group of Clinical and Experimental Endocrinology (Mathieu-Gillard) is one of the world leaders in Clinical and Experimental Diabetology. Beyond performing basic research in prevention and intervention in type 1 diabetes, obesity and type 2 diabetes the group is coordinating a large network of clinical research groups being part of very active pharmacological intervention programs, interacting with major pharma corporations and major initiatives in gestational diabetes (Bedip study on screening for gestational diabetes in Belgium) or diabetes care in nursing homes (InnovageD project).

There is also a strong engagement in translational research on islet transplantation and continuous glucose monitoring. Due to its involvement in the organization of diabetes care and the evaluation of clinical outcomes in diabetes, the group is very interested in the impact of the disease on the patients quality and quantity of life.

Since many years Prof. Mathieu and Prof. Gillard have been involved in EU research consortia (FP6 and FP7, recently coordinating NAIMIT (www.naimit.eu). At present they are coordinating a large IMI2 consortium (www.innodia.eu). They have published over 350 papers in high impact journals and are advising multiple research-driven pharmaceutical and medical device companies as well as national and international foundations (JDRF, Helmsley Trust, Diabetesliga).



European Research and Project Office GmbH - EURICE

The European Research and Project Office GmbH – Eurice offers comprehensive support services for the planning, initiation, and implementation of international collaborative research and innovation projects with competencies in project, communication and innovation management. Our multifaceted portfolio includes all aspects of project management: from strategic project planning and proposal writing to successful project implementation and exploitation of research results.

In addition to classical project management, Eurice offers strategic and operational support to maximise the value of project results through its extended network of internal and external Intellectual Property (IP) and innovation experts – fully in line with the priorities of Horizon 2020 to place more emphasis on systematic exploitation strategies and activities. Eurice partners benefit from many years of experiences in managing IP-related issues in European R&D and innovation projects and as a service partner of the European Commission for innovation support. As such, Eurice has developed a comprehensive EU-wide training and capacity building programme as well as corresponding guidelines for IP management within Horizon 2020.

Preface of the Editors

As Herman Kahn, one of the founding fathers of modern scenario planning, fittingly states, it is tremendously important for strategy and policy makers to get a deep understanding of possible future developments, in order to be prepared for them.

The Center for Digital Technology and Management (CDTM) aims to connect, educate, and empower the innovators of tomorrow. It is our mission to equip our students with the tools and knowledge they will need to become responsible leaders, who actively shape their future environment, rather than only reacting to changes.

This trend report is the result of the course Trend Seminar, which is part of the interdisciplinary add-on study program in Technology Management at CDTM. A class of 26 selected students of various disciplines – from Business Administration, to Economics, Psychology, Computer Science, Electrical Engineering, and more – work together on a relevant topic and relate it to ICT. Over a span of seven intense weeks of fulltime work,

the students dive deeply into the topic of the Trend Seminar. Working in several interdisciplinary sub-teams, students apply the knowledge from their main studies and gain new perspectives from their team members. They conduct trend research, develop scenarios of the future, generate ideas for innovative products or services, and detail them out into concrete business concepts.

In addition, we very much thank all of our lecturers, who shared their knowledge and largely contributed to this project's success:

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Prof. Freimut Schliess (Profil GmbH)

Andreas Schrems (Freelance Consultant)
Constanze Stegbauer (AQUA Institut)

Last but not least, we would like to thank the CDTM students of the class of fall 2016. They put great energy and enthusiasm into this project, which made it a pleasure for us to supervise the course and coach the individual teams.

Gesa Biermann and Florian Lachner
Center for Digital Technology and Management

“Everybody can learn from the past.
Today it is important to learn from the future.”

Herman Kahn



Preface by Sylvie Bove

I would like to congratulate the students of the Trend Seminar on “Digital Innovation in Diabetes Care” for their impressive efforts to tackle the challenges of this chronic disease. I would also like to thank the organisers of the seminar for supporting development of these new ideas, which are further detailed in the following pages.

The seminar was an excellent example of EIT Health pursuing its mission, to promote healthcare innovation, by fusing a promising pilot project with an advanced educational programme.

CLOSE, an EIT Health innovation-by-design project, is going to develop an artificial pancreas with the potential to revolutionise the lives of diabetes patients, making it possible for even the severely ill to stay at home. Using this idea as the inspiration for a Trend Seminar, CLOSE, and their educational partner CDTM, gave student teams an opportunity to address meaningful innovation challenges with real-life ramifications. The students developed new ideas that could eventually reach the market and make a difference for the more than 50 million diabetes patients in Europe – and the many others around the world.

The future impact for our health and our economy could be very powerful, but those potential gains were not the only benefits of this Trend Seminar. Regardless of how many of their ideas make it to market, the students learned about the elements that go into successful healthcare innovation. Meanwhile, this undertaking gave both EIT Health and CDTM a chance to test a useful model for cooperation to encourage the kind of healthcare innovation that can be commercialised.

It has been exciting to review the results produced by the students in this Trend Seminar. I am looking forward to watching the development of their ideas and start-ups, and I am certain that EIT Health will be working with some of them again, as they continue to undertake healthcare innovation.

Sylvie Bove
Chief Executive Officer EIT Health
eithealth.eu



Preface by Prof. Dr. Lutz Heinemann

The high number of people with type 2 diabetes (T2DM) worldwide represent not only a massive cost issue for health care systems but is also a massive burden for patients and their families. The demographic transition is a main driver of the diabetes pandemic which results in a high number of elderly patients with diabetes and comorbid conditions who are dependent on time- and cost-intensive care.

What is the therapeutic aim in such patients? It is clearly to prevent acute and often unrecognised metabolic deteriorations, frailty and disability, further disease aggravation, and to reduce avoidable hospitalisation. Modern diabetes technology enabling for a continuous monitoring of (blood) glucose concentrations can be of tremendous help to achieve this goal. For example, connecting a glucose sensor with an insulin pump by using smart algorithms enables an automatic adjustment of insulin administration according to current blood glucose concentrations. Such an Artificial Pancreas (AP) closes the loop between blood glucose profiles and insulin release into the circulation thereby mimicking healthy physiological conditions.

To date there are not too many approaches in AP systems targeting patients with T2DM. Most attempts focus on a technical cure of patients with T1DM. One reason for this might be the heterogeneity of T2DM which requires more personalised solutions. A big topic will be the costs associated with the implementation of AP systems in T2DM care. The AP needs to be designed for implementation in a care environment where it clearly improves risk- and cost-benefit balances. The approach of the CLOSE EIT Health innovation-by-design project is to focus on T2DM

patients treated under at-home conditions. CLOSE will embed the AP as part of an integrated solution package in a well-established homecare service provision portfolio.

In the following you will see what a group of 26 highly motivated students from different faculties have achieved in a relatively short period of time when developing business models about the future implementation of digital diabetes technologies. This report shows how thoughtful they have approached their task and the quite interesting scenarios and business ideas they have generated.

Let me congratulate and thank the students for having done an excellent job. It was a pleasure to work with these highly motivated and skilful people. Hopefully we can make use of their work in a manner that is of help for patients with T2DM in their daily struggle with this disease. Global societies have a high need for patient-centred innovations in diabetes care and this report clearly represents an excellent step forward in this direction.

Prof. Dr. Lutz Heinemann
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Preface by Prof. Dr. Freimut Schliess

In Europe 60 million people suffer from diabetes with a trend projected towards 70 million by 2030 – driven by obesogenic lifestyles and living environments and by the demographic transformation of European societies. Diabetes greatly increases the susceptibility to further health degeneration by precipitating frailty and disability as well as comorbid conditions. Accordingly many patients with diabetes depend on intensive nursing homecare and are highly susceptible for functional worsening, exacerbation of comorbidities and avoidable hospitalization.

CLOSE serves to innovate homecare for severely ill, insulin-treated patients with type 2 diabetes mellitus by offering an integrated product and service package (AP+). Blood glucose levels will be controlled by an Artificial Pancreas (AP) that will be installed at the patients' home, operated through trained caregivers, and remote controlled (telehealth).

CLOSE has four major ambitions: 1) improve homecare for patients, 2) alleviate strain on supporting relatives and caregivers, 3) prevent further health complications, and 4) reduce health care costs. CLOSE assembles a multi-national team of leading experts from nine partnering academic institutions and private partners from the health care industry.

Education of students, health care professionals and executives is integral to the innovation concept followed by CLOSE. The CLOSE partnership is proud of having been selected to provide the real world context for the CDTM Trend Seminar on "Digital Innovation in Diabetes Care". It was a pleasure for both industry and academic partners to contribute lectures and workshops and to enter into an inspiring discussion with this wonderful team of highly committed top-level stu-

dents. The outcome of their report is going to unfold a high impact on the implementation of digital diabetes technologies by and far beyond the CLOSE partnership.

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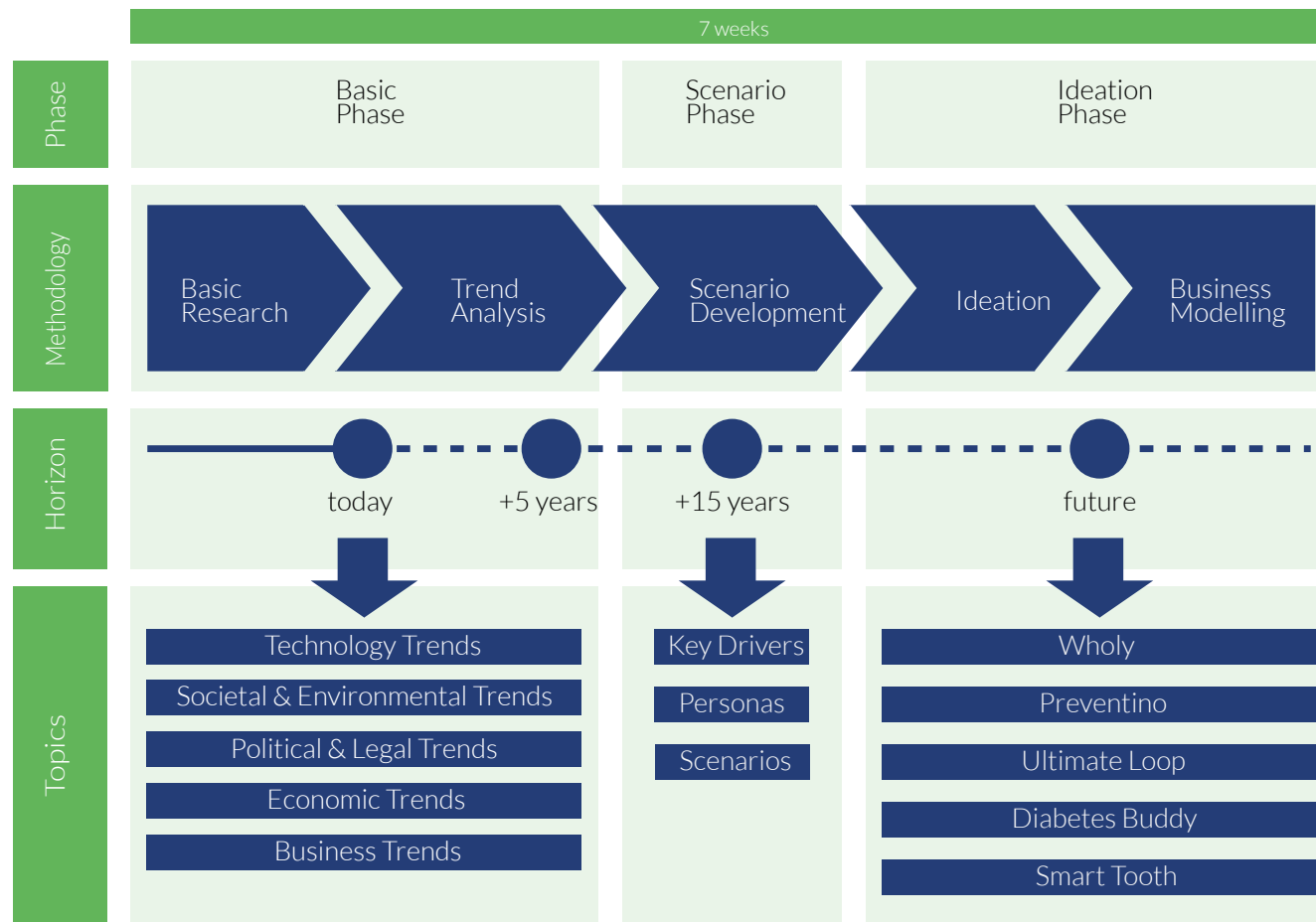
AP	artificial pancreas
BMI	body mass index
CAGR	Compound Annual Growth Rate
CGM	continuous glucose measurement
E-health	electronic health
EHR	electronic health record
EMR	electronic medical record
GP	general practitioners
GRI	glucose-responsive insulin
HFCS	high fructose corn syrup
IDF	International Diabetes Foundation
IMI	innovative medicine initiative
IoT	Internet of Things
mHealth	mobile health
MOOC	Massive Open Online Course
PGD	patient generated data
R&D	research & development
REM	rapid eye movement
SES	Socioeconomic Status
T1DM	Type 1 Diabetes
T2DM	Type 2 Diabetes
VBC	Value-based Healthcare
VR	virtual reality
WHO	World Health Organization

Methodology

For a given topic that is highly impacted by digital technologies, the Trend Seminar pursues three main goals:

- To analyze the status quo, recent developments and identify important trends
- To develop extreme scenarios of the future, in order to be prepared for upcoming challenges
- To develop future-proof product and service ideas and detail them out into business concepts.

These goals are represented by the three phases of the trend seminar, the Basic Phase, the Scenario Phase and the Ideation Phase. 26 students - supervised by two doctoral candidates - pursue the Trend Seminar in seven weeks of intensive full-time work. In each phase, interdisciplinary subteams are formed including students from technology and business backgrounds.



The **Basic Phase** yields a holistic overview on recent developments and trends in the environment of the overall topic. Based on the commonly used STEP approach, the status quo and trends in the fields society & environment, technology, economics, politics & legal, as well as emerging business models are analyzed. Knowledge is gathered by literature research, preceded by a series of input presentations by experts on the topic.

The class is split into five teams, each working on one of the thematic scopes. At the end of the Basic Phase, the teams present their key findings to each other in order for everyone to get a holistic view on the topic to build upon in the following phases.

The **Scenario Phase** builds upon the analyzed trends in order to create four extreme scenarios of different futures in twenty years ahead. Driving forces behind developments are identified and specified as drivers with bipolar extreme outcomes. Once specified, all drivers are ranked according to their respective impact on the overall topic and the perceived degree of uncertainty regarding their outcome. Two key drivers that are independent from one another and have both a high impact and a high degree of uncertainty are chosen and, with their bipolar outcomes, used to create a scenario matrix of four extreme scenarios. A timeline for each of the scenarios is created and the scenarios are sketched out using persona descriptions and visualizations.

The Scenario Phase starts with a two-day workshop followed by group work in four teams. Teams are newly formed in order to include experts from each subtopic of the Basic Phase in each new Scenario Team.

In the third phase, the **Ideation Phase**, the goal is to develop innovative business concepts, which are then tested against the previously developed scenarios. Within a two-day workshop on structured ideation following the SIT approach, a large number of business ideas are developed.

Out of these, the most promising five ideas are selected and further developed into detailed business concepts. The business model canvas by Alexander Osterwalder and Yves Pigneur serves as the base structure.

At the end of the seminar, the business model concepts are presented to the project partner and guests.

Trends

The following chapter lists current trends that have a strong impact on the future of diabetes. In accordance with the Basic Phase methodology, trends and related driving forces are structured in five areas: technological trends, societal and environmental trends, political and legal trends, economic trends and business model trends.

18 Technology Trends

44 Economic Trends

29 Societal & Environmental Trends

52 Business Model Trends

37 Political & Legal Trends

Technology Trends in Diabetes Care

Telehealth

Big Data and Machine Learning

Networked Care

Advancements in Glucose Sensor Technology

Non-Invasive Insulin Delivery Systems

Smart Devices

Closed-Loop Systems

Bioengineering and Gene Therapy

Food-Tech

Technology Trends in Diabetes Care

Diabetes is a chronic disease and can therefore be a constant source of stress for patients, due to its consistent presence in their everyday lives.

In order to mitigate the negative effects of diabetes, modern technologies play an increasingly important role by offering patients new tools to manage their disease effectively. Hereby, medical and technical progress is not just motivated by enhancing the actual treatment options, but also by the vision of improving the patients' overall quality of life. Specifically regarding Type 2 Diabetes (T2DM) patients, both a healthy lifestyle and patient self-management are essential for the treatment of the disease. Therefore, we identified eight diverse technological trends that range in impact; from helping patients to better self-manage their disease to completely curing the disease.

First, with the increasing digitization of communication, people have become more and more connected. The healthcare sector is influenced by this development as well, because connecting patients and physicians with telecommunication technologies, i.e. telehealth, overcomes formerly present geographical limitations. As a result, healthcare is no longer restricted to a physical presence at medical institutions, but allows patients to be consulted and treated by doctors remotely, which will be especially beneficial for people living in rural areas.

In addition, digitization increases the communication among patients in health-oriented social networks. These networks help patients to interact with each other and become more proactive towards self-managing their disease.

As a result of the digitized healthcare, big data technologies become more relevant in the healthcare sector. Progressing techniques in data analysis and machine learning algorithms offer new possibilities in diagnosis and monitoring, resulting in a more personalized and patient-centric treatment.

The massive adoption of smart devices, such as smartphones, is the primary reason for the accelerated transition to a digitized healthcare. Especially for diabetics, smart devices provide many useful apps, that make self-management of their disease more affordable and simple. In combination with newly developed sensors, which are capable of transmitting data to these smart devices, diabetics can continuously monitor their blood glucose levels on these smart devices. This benefits not only the patients, but also their families.

The use of invasive methods for monitoring the blood glucose level and insulin injection is very inconvenient, painful, and time-consuming. Currently, many less-invasive methods of blood glucose measurement and insulin delivery are under development. A significant step for glucose measurement

devices has been achieved with the ability to now continuously measure patients' glucose level throughout the day.

One ongoing development based on technical advancements in the different fields mentioned above, are closed-loop systems. These systems combine continuous glucose monitoring devices, a smart device calculating the required treatment dose, and the administration of that treatment dose in an automatic, holistic solution. The main idea of a closed-loop system is to imitate the function of a healthy pancreas. The primary example of such a system is the artificial pancreas (AP), where different medical devices are used to achieve this.

Further holistic solutions utilize bioengineering and gene therapy approaches with e.g., stem cell therapy having the potential to provide a complete cure for diabetes in the long run.

The last trend identified addresses the need for healthy eating habits of diabetic patients with T2DM. In the past years, the potential of functional food has attracted the interest of patients, healthcare systems, and food industry stakeholders. It is expected that functional and nano-foods will be available on the market in the future, thereby decreasing medical expenditures from diabetes-related complications and increasing patients' quality of life.

Telehealth

Enhanced homecare through remotely accessible health-related services and information

The healthcare industry is known for being a late adopter of new technologies [1]. However, there is currently a shift towards healthcare being delivered at home and through smartphones, instead of at medical institutions [2]. Telehealth is a form of remote treatment that can happen at any time from anywhere in the world. The triggers for this movement are upcoming telemedicine technologies, which enable the exchange of medical information between a patient and a physician. These act as a bridge between the two parties [3]. Primary use cases of telehealth include patient care via text, voice or video conferencing, medical education and mentoring, e-health patient portals, and remote patient monitoring [4]. Treatment plans can be adjusted remotely according to the patient's data, such as the blood glucose level, and patients can be automatically alerted based on this data [5].

Facts

- In rural areas in the US, there are on average only 40 medical specialists serving 100,000 patients (Iafolla, 2015).
- Almost 75% of all in-person doctor visits are unnecessary or could have been handled safely via phone or video [6].
- Telehealth supports the patient in blood glucose monitoring and dietary adherence [7].
- The global markets for telemedicine technologies is predicted to grow from 23.8 bn USD in 2016 to roughly 55.1 bn USD by 2021 [8].
- Major global players such as Apple (HealthKit, ResearchKit), Google (Google Fit), Samsung (Samsung Health) and Fitbit [1] are moving into the healthcare sector.

Key Drivers

- Telemedicine innovations which provide high-quality medical diagnostics, i.e. remote diabetic retinopathy evaluation through retinal imaging [9].
- Web and mobile applications that simplify virtual physician-doctor interactions such as *VSee Virtual Care App* for iPad
- Expanding coverage of broadband fiber and wireless networks [4].
- Shift to electronic medical records (EMRs) that save information about patients and can be connected to external systems [10].

Challenges

- Quality of service concerns since a remote-examination can be inferior to a physical examination [2].
- Remote care leads to a different physician-patient relationship which can result in trust issues [2].
- Risks involved when personal health data gets transmitted regarding security issues, question of ownership, and accuracy of generated data [4], [11].
- Legal issues and limited reimbursement by insurance companies [2].
- People older than 65 years still represent the group with the lowest internet usage percentage [2].

Impact on the Future of Diabetes Care

Telehealth changes the way the health industry and patients interact [4]. The care and consultation will move to the patient's home. The population in rural areas will benefit from an increase in accessible health related services [2]. Furthermore, there will be a positive impact on the availability of health data due to all the data produced by telehealth applications [12]. Moreover, platforms such as Apple Health, Google Fit or Samsung Simband, which are a central source of health related data and metrics, will have a positive impact on data analysis and research abilities. This can result in a better understanding of glucose level fluctuation and prediction [11].



Big Data & Machine Learning

Improving diabetes diagnosis, monitoring, and treatment by leveraging Artificial Intelligence technologies

Big data in healthcare includes structured and unstructured data such as patient-generated data, EHRs (electronic health records), and data from wearable technologies [13]. With cloud computing, healthcare providers can not only do patient-profiling and predictive analytics, but improve their operational efficiency as well [14].

Machine learning algorithms, such as logistic regression or support vector machine, learn and predict blood glucose patterns, thereby avoiding hypo- and hyperglycemic events [15]. In addition, deep learning techniques have been used for the diagnosis of retinopathy [16]. Cognitive computing allows patients to have a customized management of their illness by providing insights and coaching based on the combination of contextual information and real-time patient generated data (PGD) delivered by sensors [17]. Gene sequencing technologies allow for personalized disease prevention and treatment based on the patient's genotype. This leads to an earlier diagnosis of diabetes based on the genetic risk score [18]. In diabetes home-care, data-driven technologies allow for evidence-based self-management of the disease.

Facts

- The global healthcare system is digitizing with the healthcare analytics market reaching 18.7 bn USD by 2020 with a compound annual growth rate (CAGR) of 26.5% in the period between 2015 and 2020 [19].
- AI healthcare venture capital deals have grown from 10 deals in 2011 to 60 in 2015, resulting in 15% of total AI deals. Funding has increased by 460% from 64 m USD in 2013 to 358 m USD in 2014 [20].
- Roughly 70% of healthcare executives have invested in AI and machine learning technologies [21].

Key Drivers

- Decreasing prices in hardware and increasing processing power.
- Arising scalable cloud solutions such as Amazon Web Services or Hadoop [22],[23].
- Demand for real-time monitoring systems [22] leads to an increase in patient-related data coming from wearable technology or the Internet of Things (IoT).
- Growing interest of healthcare providers in machine learning technologies, such as deep learning.

Challenges

- Machine learning algorithms struggle to process medical data because it is unstructured, complex, and noisy [24].
- Poor regulatory framework regarding big data: data minimization, data encryption, data protection, privacy and security, and data ownership [1].
- Necessity to standardize IT systems and switch to data structures that are compatible among different organizations allowing interoperability [25].
- Lack of data expertise and poor infrastructure that support the shift from health analytics to the exploitation of the full potential of big data technologies [25].

Impact on the Future of Diabetes Care

Big data and machine learning technologies have revolutionized healthcare by shifting the current service-centered system to a more evidence-based and patient-centric one, thereby improving efficiency. An evidence-based healthcare system allows healthcare providers to evaluate the effectiveness of treatments based on facts. Moreover, knowledge systems based on big data support practitioners in decision-making, leveraging different data sources such as images, text, or historical medical data [13]. Furthermore, a data-driven healthcare system leads to a more personalized and patient-centric treatment by making monitoring devices smarter and supporting patients in self-managing their disease, which leads to a higher health literacy [26].

Networked Care

Enhancing knowledge exchange and improving the patient journey through data-driven medical crowdsourcing

Online data sharing platforms such as PatientsLikeMe and SERMO advance research and enhance medical knowledge with the data their users generate or exchange [27]. With the goal to improve the patient journey and accelerate research, patient related information such as biographic and genetic data, patient-reported data in the form of EHR, and data from wearables are processed and visualized. For instance, leveraging data science technologies, PatientsLikeMe contrasts companies' clinical trials' results, models diseases, evaluates quality metrics, and generates patient reported outcomes (PRO) [27]. Also, patient-related data is provided in aggregated form to healthcare stakeholders [27]. Platforms for physicians such as SERMO, advance medical knowledge by posting medical cases, creating polls and sharing medical data such as lab results, medical images or patient information [28]. Leveraging text mining, sentiment analysis and social media tools, SERMO Realtime offers real time and cost effective intelligence solutions, including quantitative market and social media research. Use cases include data-based tracking of market trends, evaluating brand sentiment, pre- and post-campaign sentiment analysis, or testing ideas for product development [28].

Facts

- As of 2012, 40% of patients in general had used social media to support health-related decisions and 20% had joined a health-related online community [29].
- PatientsLikeMe has more than 400,000 members, covers more than 2,500 diseases, has published more than 85 health-related research studies, and has 35 m data points about different diseases [27].
- Nearly 20,000 diabetic people use PatientsLikeMe to connect, track their biometric data, report symptoms, and to compare different treatments [30].

- SERMO's network has almost 600,000 global, verified physicians in 30 countries. As of 2015, 6,000 patient cases were posted and 626,000 comments were received [28].

Key Drivers

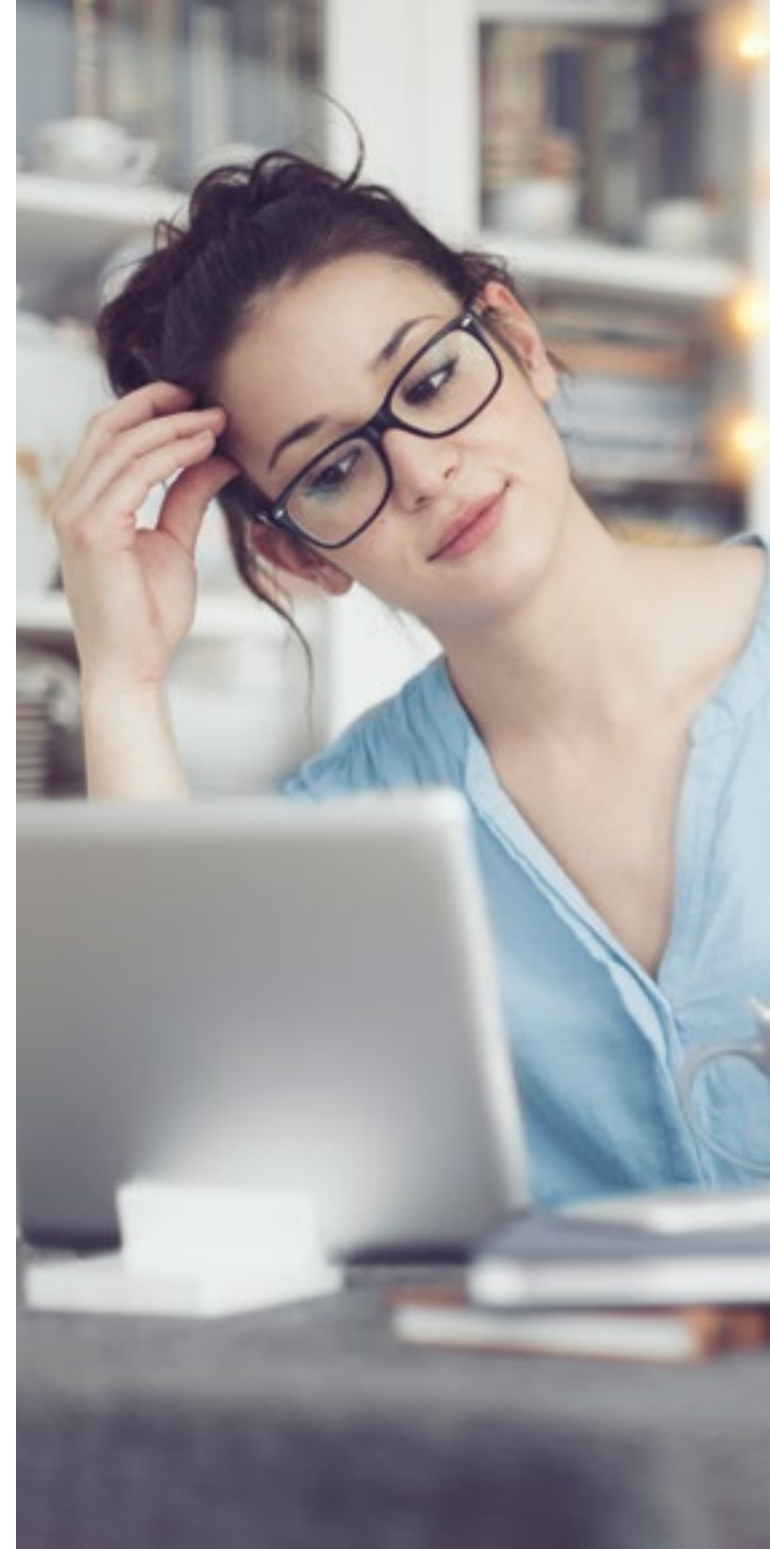
- Increasing digital literacy and adoption of social media technologies [31].
- More transparency in the business models of online platforms leads to an increase in trust in data related topics: data ownership and how personal data is handled [27].
- Increasing wearable technology device adoption, with a predicted CAGR of 50% by 2018 [32], thereby generating vast amounts of patient-data.

Challenges

- A more regulated and restrictive data policy in Europe compared to the US [33]. Concerns about data privacy, security, ownership, and general stigma of sharing disease related data.
- Poor data curation and validation leads to lack of accuracy and misinformation about diseases and treatments [34].

Impact on the Future of Diabetes Care

Online data sharing platforms empower patients in becoming more knowledgeable and proactive towards their disease and provide an intuitive interface for users to self-manage their diabetes, based on real-time data. Moreover, online platforms facilitate medical crowdsourcing, thereby allowing communities of patients to share knowledge and provide emotional support. The vast amount of patient-data online sharing platforms collect via medical crowdsourcing, advances medical progress and improves the supply-demand interaction, such as patient-pharma, patient-physician or physician-pharma communication channels. Thus, medical companies are closer to their customers, as they directly gather insights regarding their products, leading to a more patient-centric healthcare system. In a nutshell, online platforms increase patients' power in the healthcare domain since the data patients upload or generate drives medical progress and advances in medical products.



Advancements in Glucose Sensor Technology

More convenient glucose monitoring for diabetics

For diabetics, supervising their blood glucose level is essential for survival. It is essential to monitor the blood glucose level in order to prevent hypoglycemia and other diabetes complications [35].

Today, the majority of patients uses an invasive glucose measuring method. Consequently, they have to take a small blood sample by pricking their finger to check their glucose level. Both patients and parents of children with diabetes state that this method of blood glucose control is a psychological burden for them in their daily lives [36].

Different technical approaches and types of sensors are applied to facilitate the measuring of blood glucose level for diabetics. The application of continuous glucose measurement (CGM) systems reduces the manual measurement effort for diabetics. Moreover, those systems can warn the patient of incorrect glucose levels immediately.

Sensors for glucose measurement can be classified into invasive sensors, such as implantable sensors, and minimally invasive sensors, which try to estimate the current blood glucose level by measuring the glucose level in the tissue. Another category of sensors are non-invasive sensors, that are, e.g., based on the principle of spectroscopy [37].

Facts

- The application of CGM systems reduces the occurrence of severe hypoglycemic events [38].
- The market for CGM systems in Europe is expected to grow yearly by 38% from 2015 to 2021 and to be worth 351.7 m USD by 2021 [39].

Key Drivers

- Germany's compulsory health insurance will pay for the costs for CGM systems if the system can warn of upcoming hypoglycemia [40].
- Artificial pancreas systems depend on the availability of reliable and precise sensors for CGM [41].

Challenges

- CGM systems that estimate the blood sugar level by measuring the glucose level of other body fluids have accuracy and reliability issues (e.g., due to action delay and gradient), especially after meals or glycemic events [42].
- Single non-invasive blood glucose sensors are not accurate and reliable enough to be used as a stand-alone measurement device [37]. One approach to dealing with this issue is to combine several types of sensors in one device in order to increase the measurement's accuracy and reliability [43].
- In the case that non-invasive glucose sensors for wide-spread use are available, there would be a great financial challenge for health insurances to provide this technology for every patient.

Impact on the Future of Diabetes Care

The ongoing development in the glucose sensor technology field enables a more convenient and continuous monitoring of blood glucose levels. Consequently, a wide usage of CGM systems improves the health of patients and reduces the risk of long-term damages [45]. In addition, CGM systems can prevent patients from dangerous situations by warning of an upcoming hypoglycemia e.g., while driving a car.

Non-invasive Insulin Delivery Systems

Shifting away from subcutaneous injection enhances quality of diabetics' lives

Until recently, the conventional way of insulin administration was carried out through a rather inconvenient and painful intramuscular and subcutaneous injection. However, non-invasive administration methods have now shown to have a sufficient bioavailability for clinical applications. As a result, these alternative administration routes are currently being pursued [46]. Among these routes, the oral intake represents the most convenient administration method for diabetics. Hereby, insulin is being swallowed and delivered through the digestive tract. However, this type of administration is still being researched [47], whereas other routes such as the transdermal or the pulmonary intake are at a much more mature stage. In transdermal administration, microneedles embedded in a graphene based patch on the skin deliver the insulin. This administration route was already successfully tested on diabetic mice [48]. The pulmonary administration deals with finely-powdered insulin getting into the body through the lungs and is currently available on the market. Furthermore, researchers are exploring other routes, such as the inner cheek or the nose [46].

Facts

- The non-invasive device market is increasing at a CAGR of 10.5% in revenue between 2014 and 2021 [49].
- More than 1.5 m T2DM patients in Germany are treated with insulin, either as a combined therapy with pills and/or invasive insulin therapy (e.g. intensive insulinotherapy) [50].
- T1DM patients must currently still be treated via invasive insulin therapy for life [50].

Key Drivers

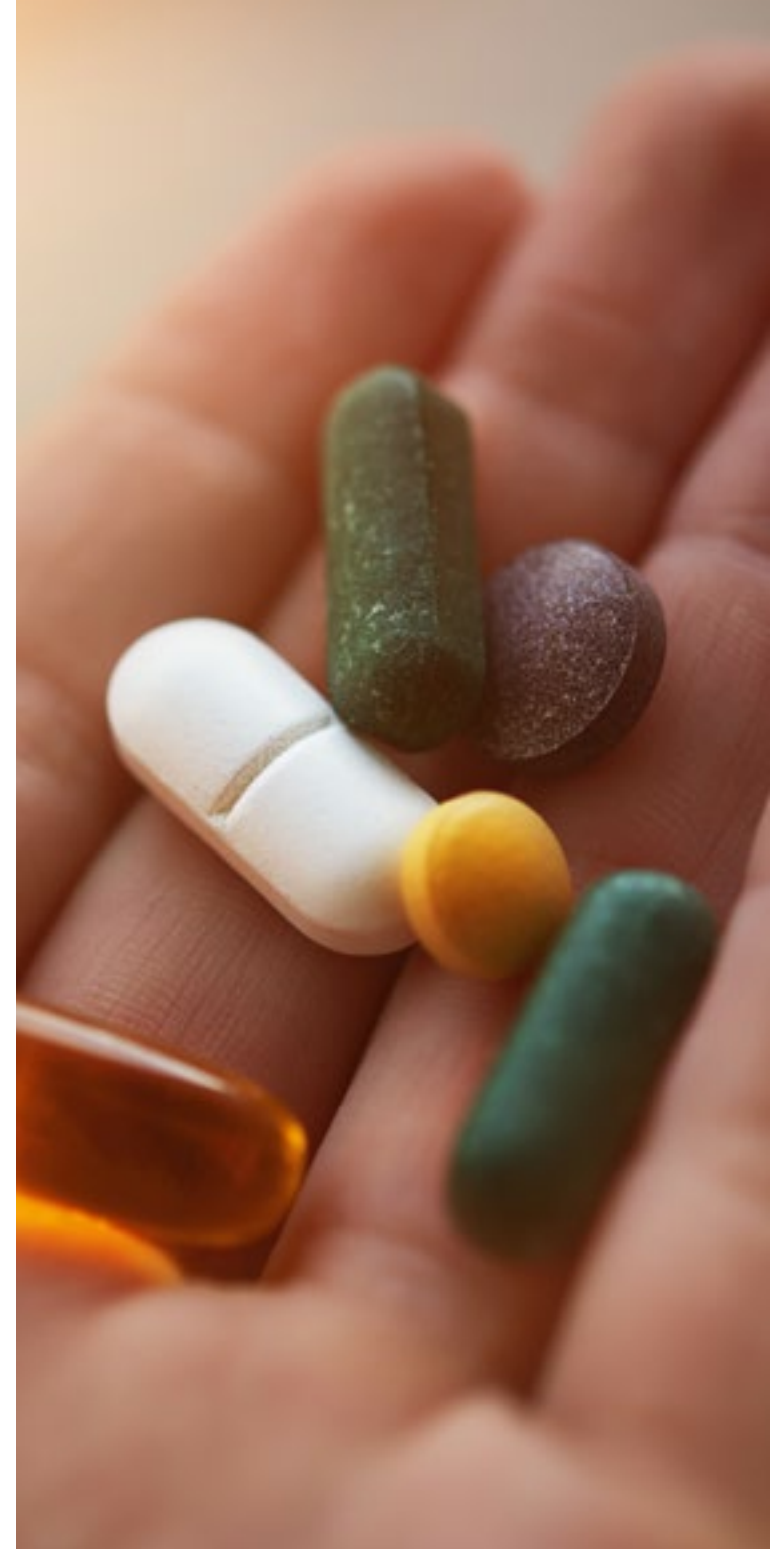
- Pain, physiological stress, inconvenience, cost, and risks caused by daily invasive injections [51].
- Emerging research and players in the development of non-invasive insulin delivery [51]: Oral (Emisphere Technology, Cortecs International, Provalis), Buccal (Genex Biotechnology), Nasal (Bentley Pharmaceutical, Vectura, MicroDose Technologies), Pulmonary (Nectar Therapeutics, Pfizer, Sanofi-Aventis, PDC, MannKind), Transdermal (Alza, Altea Therapeutics).

Challenges

- Oral: Sufficient blood insulin concentrations are yet to be reached [51] and the acidic environment of stomach degrades insulin [47].
- Transdermal: Patch must be large enough to release necessary dose of medication [48].
- Pulmonary: Not recommended for smokers, those with asthma or chronic obstructive pulmonary disease [47].
- Intranasal: Various factors, including dose, timing, and frequency of administrations, affect bioavailability of insulin [46].

Impact on the Future of Diabetes Care

Recently, advancements in the development of non-invasive insulin administration route such as oral, transdermal, pulmonary or intranasal were seen. With a mature alternative to invasive drug delivery systems, pain during subcutaneous injection, anxiety of needles, and potential infections can be avoided [47], which can lead to a much more regularly insulin intake. Some of the non-invasive delivery systems are expected to reach patients in the upcoming years, which would lead to an incisive shift in insulin delivery for billions of patients who are still dependent on the painful and inconvenient subcutaneous route [51].



Smart Devices

Improving patient's lifestyle and increasing patient self-management

Smart devices are mainly characterized by wearable technologies and smartphones apps. These new devices and software can help patients to continuously track their blood sugar level and monitor their body's condition [52]. Wearable devices capture the user's specific action or bodily measurement, generating data for further analysis [53]. While the smartphone becomes the central hub for different wearables, smartphone apps play an important role in integrating the collected data and displaying the analyzed results. Major use cases for diabetes related apps include insulin and medication recording, data exports, communication, and diet recordings [54]. Besides, existing smartphone apps already grant access to food databases, facilitate the scanning of food, or simply count calories. The apps assist patients in managing their nutritional intake according to the plan advised by a dietitian [55]. With the increasing growth of the mobile health (mHealth) and wearables markets, people can self-manage diabetes in multiple and more affordable ways.

Facts

- The total download of mHealth apps was 1.7 bn in 2013, 2.3 bn in 2014, and 3.0 bn in 2015 [1].
- Nowadays, more than 1,700 diabetes apps in total are available in app store marketplaces such as the Google Play or Apple App Store [56].
- 10 of the 13 studies in T2DM indicate that mHealth is beneficial for diabetics to manage their health while 4 of the 7 studies in T1DM report the same results [56].

Key Drivers

- The global number of smartphone users will reach 6.1 bn by 2020 and 90% of the world population aged over six will own a smartphone [57].
- The usage of diabetes apps by diabetics owning a smartphone was only 1.2% in 2014 and the number is expected to grow to 7.8% in 2018, which predicts about 24 m people in 2018 will actively manage their health with apps [58].
- The market for mHealth wearable devices is predicted to rise from 97 m USD in 2015 to 60 m USD by 2020 [11].
- Technology giants such as Apple and Google focus on how to create easy-to-use and accurate wearables for health management [11].

Challenges

- Adopting new technologies, such as smartphone apps or wearable devices, may be a challenge for the elderly, aged over 55, growing up without immersion in mobile technologies [55].
- Data privacy and security of wearable devices limit smart device adoption [53].
- Necessity of certification and approval on medical smartphone apps [12].
- Accountability is hard to clarify if the mHealth solutions, especially smartphone apps, fail and harm the interests of patients [1].

Impact on the Future of Diabetes Care

Once the data accuracy of wearable devices is precise enough for clinical use, it can replace expensive devices and make diabetes monitoring more affordable for patients [11]. In the future, healthcare professionals will play a significant role in suggesting appropriate and reliable apps for different needs [55]. Moreover, with the self-monitoring of blood glucose data logged on smartphones, giving recommendations about diet or medications will facilitate the healthcare professionals' job [59]. Smart devices will contribute to provide cheaper and easier ways for self-management.

Closed-Loop Systems

Increasing efforts to develop holistic solutions for diabetic treatment

Currently, diabetics have to manually perform a number of different tasks, such as monitoring their glucose level, determining the correct treatment, and its actual administration in order to keep their blood sugar levels in a safe range. Closed-loop systems automate such tasks in one complete treatment package, making life less cumbersome and reducing the possibility of error. Smart devices and big data analysis assist in finding and implementing efficient solutions. The current main technology trend in this area is the artificial pancreas (AP). Glucose responsive insulin (GRI) constitutes another potential closed-loop system in the long run.

In the case of the AP, a continuously monitoring glucose sensor first transmits real-time glucose measurements to an insulin administration device. The correct amount of insulin needed is calculated and the actual insulin administration is performed automatically, which completes the closed-loop control system [121].

GRI is a special chemical compound that works by automatically adjusting to the body's blood glucose levels by binding insulin during low glucose levels and unbinding from insulin when needed during high glucose levels [60].

Facts

- Increasing amount of publications regarding AP devices in the last 4 years [61] with numerous AP research initiatives existing around the globe [62].
- Successful results in current AP research, such as a lowered risk of nocturnal hypoglycemia, have been achieved in a clinical setting [63], [64].
- First market entries of hybrid closed loop AP is expected in 2017 [65]; of fully closed loop AP a few years later [66].
- Multiple smart insulin research activities are currently underway at both universities and private companies [67] with, for example, JDRF and Sanofi recently investing 4.6 m USD in GRI research [68].

Key Drivers

- Various technological advances related to healthcare have increased the feasibility of AP and smart insulin [69].
- Increased availability and processing power of smart devices, as well as big data methods, improve current treatment options [70].
- Advances in glucose sensor and insulin administration technologies [71], [72].
- Higher awareness of severity and increasing prevalence of diabetes leads to more funding for research activities and greater incentives for private companies to develop solutions [73].
- The current cumbersome and unsatisfying solutions create market demand for holistic solutions [74].

Challenges

- Accuracy of measurements in current subcutaneous CGM devices, especially after meals or glycemic events [42].
- Action delay of subcutaneous insulin delivery requires fast acting insulin to adjust glucose levels in time [67].
- Diabetes control algorithms have to cope with inaccuracies, action delays, and unexpected glycemic events [42].
- Legal issues in case of failures.
- Holistic solutions need to take patient expectations and satisfaction as well as multimorbidity issues into account [65],[75].
- Smart insulin research is only in its early stages and therefore still years away from a possible market entry [65].
- Current research focuses only on T1DM [60].

Impact on the Future of Diabetes Care

A closed-loop system can significantly increase a patient's life, especially for the elderly and very young, due to the automation of formerly manual processes. This results in a significantly reduced necessity for human interference and therefore fewer possibilities for human error. The continuous monitoring and quick reaction allows for the number of glycemic events to be reduced and an increased patient safety. From a doctor's or care provider's perspective, holistic devices provide a less time-consuming and more efficient treatment, especially in home care. Smart insulin would eventually allow minimal human intervention and an almost perfect imitation of beta cell function.



Bioengineering and Gene Therapy

Advancements in pancreas tissue transplant technology

In the past, pancreatic cell transplants suffered from poor availability of suitable donors, low success rates, and the lifelong necessity to take immunosuppressants. However, in recent years, multiple approaches have been developed that promise to mitigate or even solve these issues. One method involves the bioartificial pancreas equivalent transplant that uses microencapsulation with perm-selective coating of islets [76],[77]. A more advanced possible solution involves the usage of stem cells in gene therapy. Hereby, the final goal is to generate fully functioning, self-replenishing beta cells [78]. Current efforts allow for the creation of progenitor pancreas cells from embryonic stem cells that are inserted in vivo and then develop into other pancreatic cells, including the required beta cells, within the patient's body [79].

Facts

- Recent advances in pancreas transplants (pancreatic islet cell transplant) allow some patients to discontinue insulin therapy [80].
- General rise in survival rates of pancreas transplants in the last decades [81], with currently, a 91% survival rate five years after the transplant [82].
- Stem cells can successfully grow into induced pluripotent stem cells in vitro with ViaCyte having performed pancreatic progenitor transplantation with real patients [83].
- Allogeneic transplantation of cadaveric islets has already been performed on patients with positive clinical results [84].
- The technical failure rate of living donor pancreas transplants has decreased to almost zero [85].

Key Drivers

- Increasing prevalence of chronic diseases creates a stronger need for solutions [86].
- Increasing funding from governments into stem cell research [86].
- General technical and biological advances bring stem cell research closer to reality [87].

Challenges

- Bioartificial transplants require a suitable donor, the availability of which is limited [88], [89].
- The (current) lifelong need of chronic immunosuppressive medication [88].
- Generating mature pancreatic beta cells from stem cells is currently not feasible, requiring in vivo maturation [83].
- Transplants require major surgery, with the associated risks [77].
- Regulatory issues regarding stem cell research [90].

Impact on the Future of Diabetes Care

In general, the restoration of beta cell functionality increases the patient's quality of life. Due to the autonomous functioning of the transplanted beta cells, the necessity of human intervention through glucose measuring, insulin dose calculation, and administration is reduced to a minimum. This directly results in a lower possibility for human error. Also, treating physicians and healthcare providers face fewer and less frequent complications. Furthermore, both the society and economy profit from a healthier diabetic work population. Finally, a potentially successful stem cell therapy eliminates the need for human donors.

Food-Tech

Food industry shift towards nanofood and functional food to fight obesity

Diabetes is a metabolic disease affecting the carbohydrate, fat or protein metabolism. Diabetic foods, such as functional foods and nutraceutical products, improve one's health and reduce the risk of suffering from diabetes while preserving or even enhancing flavors and texture properties [91].

In general, functional foods enhance patients' health and decrease the likelihood of developing health problems by providing the necessary nutrition [92]. They include fortified foods, enriched foods, altered foods, and enhanced commodities, where components of high nutritional value are added or enhanced and unhealthy components are eliminated [91]. Thus, food technology controls obesity and diabetes by enabling the production of low-calorie and low-fat foods, such as the Nanoceutical Slim Shake Chocolate [93] and Fabules, the dietary product for appetite control [94], [95]. Nanotechnology manipulates food products at a molecular level and therefore has the potential to make the functional foods' encapsulation and delivery systems more effective. Delivery systems provide the functional component to the desired site of action and protect the component from any chemical or biological degradation. Nano-delivery systems for nutrients and compounds include association colloids, nano-emulsions, biopolymer matrices or nanolaminates [96].

Facts

- The functional food market, as of 2013, is worth about 168 bn USD and is growing roughly 9% per year [97].
- As of 2015, Europe is the major diabetic food consumer with 39% of worldwide market share [98].
- From 2016 to 2020, the expected CAGR for the global diabetic food market is equal to 11.97% [99].

- The 16 m EUR HEALTHGRAIN Integrated Project of the 6th EU Framework combined academia and industry with the goal to reduce metabolic diseases by researching technologies in order to optimize the nutritional value of whole grains [100].

Key Drivers

- Increasing prevalence of metabolic diseases such as obesity and diabetes [97].
- Rising number of people with T2DM due to an ageing society, a sedentary lifestyle, and multimorbidity [101].
- Growing consumer awareness and interest in diabetic food as well as the rising trend of living a healthy lifestyle [101].
- Rising interest from food industry players to offer products that fight food illnesses and improve the nutritional value, shelf-life, and traceability of foods [97].
- Increasing amount of scientific evidence showing the benefits of a healthy diet to prevent or treat diabetes [102].

Challenges

- Lack of regulatory framework: Current legislation does not differentiate between nanofoods and normal foods [97].
- Limited knowledge about adverse health effects: Risk assessment studies and tests evaluating the dosing impact, e.g., clinical deficiency and clinical toxicity are required [103].
- Low consumer awareness, acceptance, and misinformation, leading to rejection of processed food, e.g., nanofood [104].
- Lack of large-scale and cost-effective production methods prevents the production of nanofood [105].

Impact on the Future of Diabetes Care

The combination of healthy eating and physical exercise could prevent about 95% of T2DM cases [106]. With diabetes being one of the major causes for the development of blindness, kidney and cardiovascular disease, and amputation [102], a healthy lifestyle leads to fewer medical expenditures. This results in a more efficient and cost-effective healthcare system. Also, functional foods and nanofoods would increase the quality of life for patients, engineering the desired fat and calorie content of food while preserving its taste and texture properties.



Societal & Environmental Trends in Diabetes Care

Longevity

The Obesity Pandemic

The Digital Person

Democratization of Knowledge

Self-Optimization

Urbanization

Societal & Environmental Trends in Diabetes Care

Personal health and the health-orientation of one's lifestyle is mainly determined by societal standards, like socio-economic status (SES) and health literacy education. Alongside a nation's healthcare system architecture, the latter plays an important role for the prevalence and treatment of chronic diseases in a society, such as T2DM.

Taking a societal perspective means examining how social life impacts morbidity and mortality rates as well as investigating illness related stigmata. It also includes looking at societal risks and protective factors of chronic diseases and explaining why certain people seek particular types of care [107].

On the one hand, the widespread prevalence of diabetes is due to an increase in life expectancy and age-related diseases, as well as an obesogenic lifestyle. Ongoing urbanization, which facilitates diabetes-promoting behavior, and the SES have a huge impact on the T2DM development risk. On the other hand, current societal trends enable progress in diabetes treatment: Europeans assume an active role in their personal healthcare by constantly optimizing their dietary patterns and challenging their physical abilities. The increasing technology affinity enables new care concepts involving smart solutions in diabetes homecare. Lastly, ubiquitous access to the internet allows for new ways of educating people on prevention and treatment possibilities.

Generally speaking, a twofold development can be observed: Whereas the digital affine and health-conscious parts of the population profit from a self-determined and highly individualized lifestyle, there is a contradictory trend among the old, overweight, and less educated, who show rising incidence rates of T2DM. In the following sections, current societal trends that influence the incidence rates and treatment possibilities of T2DM will be discussed.

The first trend is longevity. The average life expectancy in Europe is continuously increasing and will continue to increase. This enhances the probability of developing a chronic disease such as T2DM, especially since older people are also more susceptible to the disease because of muscle loss, the tendency to reduce physical activity, and weight gain.

Obesity, the second trend, is one of the biggest T2DM risk factors and with an increasing amount of overweight or obese people, the number of T2DM patients is growing. The lack of exercise during childhood and child obesity increases the risk to develop T2DM later in life.

The next trend is the evolvement of the digital person. People are growing increasingly comfortable with digital networks and services, thereby developing an affinity for technology. Due to this development, even more complex and sensitive issues, such

as diabetes care, are entrusted to digital devices by patients.

With the arrival of the internet, information has become more easily accessible than ever. Being an almost endless and fast source of information, it revolutionized the way people inform themselves about their diseases. Research can also benefit from this trend, since patients become "partners in their own health" and increasingly collect and share their data. This is subsumed under democratization of knowledge.

Self-optimization is a trend where people are constantly trying to improve and quantify themselves. It is a result of an increasing urge for individualization in a digitized and connected world. Applications for smartphones, sports bracelets, and other tracking devices are released onto the market on a daily basis. The number of search queries like „best food for weight loss“ has increased ten fold in the last 10 years, which is evidence for an increasingly health-conscious society.

Finally, urbanization contributes to a deteriorating quality of life of diabetics living in rural areas due to the declining number of practitioners, increasing amount of people living in poverty, and a lack of opportunities for health education and exercise. In urban areas, however, this process leads to better medical care and access to prevention measures.

Longevity

Increased life expectancy is one of the main contributors to diabetes

The average life expectancy of a European is increasing [108]. This will result in a rise in age-related diseases - specifically in T2DM, since biological age and the risk for diabetes are closely correlated [109].

Firstly, people older than 45 have a high, age-induced risk to develop insulin resistance, which is “the most powerful predictor for future development of T2DM” [110]. Secondly, severe physical limitations among elderly people contribute to the development or deterioration of T2DM. Ageing also brings about difficulties in the health sector. A study in southern Germany revealed a high quota of undiagnosed individuals with T2DM or a disturbed glucose tolerance, an early indicator of T2DM [111]. Multimorbidities in older patients can cover symptoms of T2DM and thus complicate the diagnosis [112]. Furthermore, the patients’ restricted mobility can cause problems to access healthcare services [113] and consequently makes them dependent on home care [114]. Longevity will therefore influence the prevalence of diabetes in Europe.

Facts

- The European population over 65 will grow from 16 m in 2007 to 28 m in 2050 [115].
- 17% of men and 23% of women over 65 in Europe are not able to pursue their daily routine due to physical restrictions [114].
- Almost one in two people in southern Germany have disturbed glucose tolerance or diabetes, half of which are undiagnosed [111].
- In Europe, 35% of the male population over 60 have at least two chronic diseases, such as cardiovascular disease or high blood pressure [116].

Key Drivers

- Medical progress and better medical care lead to a higher life expectancy [117].
- Steady decline in mortality rate, even in the high age bracket, of 1-2% per year [108].
- Loss of muscle mass increases the T2DM risk for older people; due to a tendency to reduce exercise and to gain weight [118].

Challenges

- Achieve satisfactory T2DM diagnostic rates [112].
- Focus on diabetes prevention measures for older women as they have higher prevalence rates [113].
- Prevent budgetary problems resulting from excessive diabetic related medical costs for the elderly [119].

Impact on the Future of Diabetes Care

The cost of diabetes care in Europe will rise by over 11% in the next 25 years, partly due to an increase in life expectancy and a thus increasing number of diabetes patients [120]. To tackle the upcoming rising costs, it will be important to promote an active, healthy lifestyle for elderly people [112]. In order to improve the quality of life for the rising number of patients, entirely new care concepts will have to be developed. A lot of potential lies in the homecare sector, where individual nursing or at-home exercises can help prevent and treat T2DM while allowing the patients to stay in a familiar setting [121].





The Obesity Pandemic

Increasing rates in obesity lead to a rise in diabetes prevalence

Over the last decades the average Body Mass Index (BMI) has increased among adults as well as among children in Europe [122].

The most important reasons for this development are an increasing food intake, an unbalanced diet, and a decrease in physical activity [123]. Obesity particularly affects low income, less-educated people, hindering this group from improving its SES [124]. Obesity can lead to insulin resistance, which is one of the main causes for developing T2DM [125].

An increasingly overweight population therefore indicates a growing number of T2DM patients.

Facts

- Obesity currently affects up to 70% of adults in Europe, with an increasing trend [126].
- The number of overweight infants and children in Europe rose steadily from 1990 to 2008 [127].
- The rise in obesity affects all population groups, but obesity tends to be more common among disadvantaged socio-economic groups, less-educated people, and women [128].
- Maternal overweight is increasing and is associated with a higher risk of developing gestational diabetes [129].
- Maternal obesity increases the child's risk of obesity and related chronic diseases, such as T2DM [130].

Key Drivers

- Unhealthy diets: Europeans' consumption of processed and high-calorie food has grown [131].
- Lack of physical activity: Europeans spend less time on general physical activities and exercising [123].
- Sedentary behaviors: People spend more time in sedentary positions, resulting in a less-active lifestyle [132].
- Urbanization: Changes towards a more convenient, automated living environment and the range of food options available lead to an obesogenic lifestyle [133].

Challenges

- Educating children at an early stage to promote knowledge about nutrition and physical activity [134].
- Adjusting medical equipment to an increasing number of overweight patients.
- Reducing stigmatization of obesity and T2DM while promoting a healthy lifestyle [135].

Impact on the Future of Diabetes Care

The World Health Organization has named obesity as one of the greatest public health challenges of the 21st century. On the one hand, obesity will lower the general quality of life of the affected. On the other hand, a higher prevalence of obesity will trigger increasing T2DM incidence rates, especially among socially disadvantaged people. Rising childhood obesity is a matter of concern as it correlates with higher diabetes rates and an early onset of the disease. Therefore, a multi-step approach has to be taken: Caring institutions and home care settings will have to optimize their equipment and focus on dietary and physical action plans for this growing patient group. Most importantly, educational measures will be needed, to inform the population at a young age and throughout their lives in order to reduce the obesity pandemic.

The Digital Person

The rise in technology affinity offers opportunities in T2DM care

“As the world becomes increasingly interconnected, both economically and socially, technology adoption remains one of the defining factors in human progress.” [136]

Over the past two years, the amount of internet users and smartphone owners has risen noticeably [137]. This also includes people above 65 who increasingly use digital devices [138], but there is still an age-related digital divide [139]. Generally speaking, developments in mobile technology have the capability to advance healthcare drastically [140]. Electronic health (e-health) enables opportunities such as remote care and self-diagnosis [140]. Patients are increasingly willing to make use of e-health, agreeing to be monitored and wirelessly screened for their condition. Additionally, they welcome the flexibility that technology brings to their care [141]. The increase in technology affinity therefore offers ample opportunities for preventing and treating diabetes.

Facts

- The number of smartphone users will rise to 6.1 bn globally by 2020, and thus will be overtaking landline phone subscriptions [137].
- The average age of smartphone users is increasing [138].
- The digital divide between young and old is diminishing [142].
- The number of people who have at least one health related app on their smartphone has doubled from 2013 to 2015 [143].
- More than 70% of patients from all age groups want to use digital services for healthcare [144].

Key Drivers

- An increase in internet access [145].
- Digital technologies become more user-friendly.
- Forced transition towards digital technologies in various areas (e.g. transport system, banking system) forces older people to adapt [146].
- Educational programs on digitization for various target groups (immigrants, seniors).

Challenges

- Improve digital literacy among seniors.
- Design medical devices and manuals in a way that less tech affine people understand them [142].
- Encourage old people to use smartphones not only for calls and texting [147].
- Reduce concerns related to healthcare technologies [143].
- Regulate the use of digital technologies as medical equipment.

Impact on the Future of Diabetes Care

An increased media literacy and technology affinity bears many advantages concerning health and homecare settings: In terms of prevention, easily accessible health apps and websites can help reduce obesogenic behavior. In terms of treatment, the acceptance of e-health services has the potential to improve the speed of access to treatment, patient satisfaction, and the use of resources. The increasing acceptance and usage of the IoT, e.g., for ambient assisted living, paves the way for the rise in smart solutions in diabetes care, especially in the blood glucose monitoring field. Through smart home concepts, the patient's quality of life will notably improve.



Democratization of Knowledge

Easier access to knowledge empowers patients and questions the patient-doctor information asymmetry

The internet revolutionized access to information for the majority of people in Europe [145]. Know-how has become more accessible to a broad audience, leading to a democratization of knowledge [148], [149]. Consequently, the internet has become the primary source of information regarding health issues [150].

For centuries, medical care has been characterized by an asymmetrical patient-doctor relationship, with the physician being the sole source of information [148]. Through the possibility of acquiring additional information, patients can now influence the quality of their medical decisions. They increasingly perceive medical care as a service and develop a “consumerism” attitude towards it [151]. This is especially true for patients who suffer from chronic diseases who conduct online health research, as it significantly impacts their health choices [150]. Online forums and websites can help them to engage and interact, enhancing social support and providing health information [152]. Conversely, there is some concern about the quality of information provided, since content can be published without validation [153]. Uneducated people tend to approach this information uncritically, compared to highly educated people, who can profit from quality resources such as online tutorials or massive open online courses (MOOCs) [154]. However, broader access to information has the potential to alleviate the existing disparities in health literacy [149].

Facts

- The percentage of the European population who uses the internet for health purposes increased from 42.3% (2005) to 52.2% (2007) and will rise further [155].
- Online social support programs targeting chronic illnesses decrease symptoms, improve health behaviors, and reduce utilization of healthcare resources [156].

- Patients are becoming more health literate and take an active part in their healthiness [157].
- MOOCs and online tutorials provide schooling to the masses. Yet, people with low education levels do not profit from it [158].
- User-generated content, social media, and forums enable direct exchange between patients [159].

Key Drivers

- Computer literacy and tech affinity: growing use of the internet to search for health information [160], [161].
- High internet access availability: internet access for the majority of the population within the EU [148], [161].
- Medicalization of the world wide web: growing health related content on the web [162].

Challenges

- Increase the quality of information provided [151], [153].
- Counteract disparities in health literacy due to SES or age [154], [163].
- Encourage doctors and institutions to provide web-based information [148], [151].

Impact on the Future of Diabetes Care

The broad access to health information through the internet disrupts the traditional patient-physician relationship and empowers patients. They are enabled to gain control over their own healthcare and are thus less dependent on their physician [150]. Patients who are active and are involved in the self-management of their health are more likely to manage chronic conditions, like T2DM, effectively. The inclusion of T2DM patients in the development of a home care therapy is extremely beneficial, as patients’ daily decisions have the greatest impact on their condition [152].

Furthermore, patients and their relatives now have the opportunity to communicate online with people in similar situations. In online forums they can build communities to exchange experiences, recommend treatments or physicians, and support each other. Accordingly, better health choices and treatments can be achieved [150].



Self-Optimization

A new body cult leads to a rising health consciousness

In an individualized society, optimizing oneself increasingly turns into a lifestyle, where health and fitness emerge as new status symbols [164].

This development is mainly driven by the younger generation and Europeans with a high SES [165]. They equate personal success with constant improvements of their eating habits and physical activity. Health is therefore becoming the trademark of the performance-oriented societal elite, whereas being sick is often perceived as a personal failure [166]. Health-conscious people engage in activities, such as dietary monitoring or exercise tracking [167], and smoke less than previous generations [168]. Caring for their own body by applying detox-procedures and specialized fitness programs becomes an integral component of their healthy lifestyle [164]. Moreover, special diets, such as low-carb, and eco-friendly dietary patterns, such as veganism, are gaining popularity [169].

On the one hand, this lifestyle serves as a preventive measure for T2DM development in society by raising awareness for healthy diets and physical activity. On the other hand, this trend bears the risk of further stigmatizing people who differ from the norm.

Facts

- Searches for „best food for“ have grown 10 times since 2005, often followed by terms like “skin“, „energy“, „your brain“ and „gym workout“ [170].
- Exercise results and healthy meals are photographed and uploaded on social media platforms [171].
- Consumers are willing to pay more for products which claim to boost weight loss and increase one’s health [172].
- Digital applications for smartphones, sports bracelets or other portable devices are used to record physical performance, health markers, and vital signs [164].

- Popularity of self-tracking increases: In 2013, 60% of US adults tracked their weight, diet, and exercise routine. 33% monitored their blood sugar level, blood pressure, frequency and intensity of headaches, and sleep patterns [173].
- Worldwide shipments for healthcare wearables will increase annually from 2.5 m in 2016 to 97.6 m units by 2021 [174].

Key Drivers

- Urbanization: easier access to gyms, alternative restaurants or foods.
- Technological affinity: enables the quantified-self movement, where people extensively measure and track their health and fitness levels during their daily lives [175].
- Social Media: support and information by like-minded people is motivating [176].

Challenges

- Reducing the influence of socioeconomic advantage on people’s opportunities to engage in a healthy lifestyle [165].
- Enhancing self-discipline and motivation to overcome barriers which prevent people from starting a new fitness program or diet.
- Binding fitness app consumers to continuing use of the app over a long period of time [177].
- Developing digital education programs targeting the elderly, which promote a healthy lifestyle.
- Enforcing data privacy and media competence to counter security concerns about healthcare apps and wearables [177].

Impact on the Future of Diabetes Care

The movement towards self-optimization results in a more health-conscious society. Firstly, an active lifestyle increases one’s mental and physical well-being and thereby prevents diseases triggered by unhealthy lifestyle choices, such as T2DM [178]. Therefore, it is important to especially encourage T2DM risk groups to take responsibility for their own health as long-lasting changes are more likely when they are self-motivated [179]. Secondly, as healthy lifestyles become mainstream, the availability of medical wearables, access to fitness communities or nutrition blogs for risk groups of T2DM will increase. Summing up, an increased health-conscious society offers insights into how one should engage people to live a responsible and health-oriented lifestyle and this trend can counteract the European T2DM pandemic.



Urbanization

The impact of rural exodus and its consequences for T2DM

More and more Europeans leave rural areas to live in urban environments [180], which impacts patients left behind in those areas as well as those in the growing cities.

On the one hand, living in the city comes with high quality medical care and easy access to prevention measures [181]. On the other hand, an urban lifestyle increases the risk for T2DM due to high availability of processed foods [133]. Furthermore, people leaving rural areas leads to a decreasing number of doctors in the countryside [182]. Mainly affected by this development are old and immobile people, who stay behind in rural areas [183]. As they have a high prevalence for T2DM and often cannot be looked after by their children [360], innovative home care is needed.

Due to ongoing urbanization, a general increase in diabetes patients is expected, while people in rural areas face shortages in medical services.

Facts

- In 2015, around 75% of Europeans lived in urban areas compared to about 50% in 1950 [361].
- Deteriorated quality of life for diabetics in rural areas due to fewer exercise facilities, higher poverty, and fewer opportunities for health and diabetes education [184].
- Declining number of practitioners in rural areas [182].
- Increasing geographical distances and decreasing frequency of contact between parents and their adult children, with only 55% of adult children living within 1 hour of their mothers [185].
- Air pollution and sleep disturbance increase the risk for diabetes [186].
- Willingness to be treated at home is increasing [187].

Key Drivers

- Ongoing shift from the primary and secondary sector to the tertiary sector, which characterizes an urbanized service economy [188].
- Concentrated economic activities and professional opportunities make the urban environment popular [180].
- Environmental change drives people away from rural living because of changes in opportunities for farming [181].
- 67% of the European population already lives in urban areas, which leads to network effects [189].

Challenges

- Tackle the health challenges that come with an urban lifestyle in order to prevent diabetes.
- Educate people about the health challenges when transitioning to a more urban lifestyle.
- Bring home care to less mobile people who are left behind in rural areas.
- Teach less-educated and poor people in rural areas about diabetes.
- Counteract the increasing patients-per-doctor ratio in rural areas.

Impact on the Future of Diabetes Care

Due to the declining number of practitioners and experts, diabetics in rural areas face difficulties receiving treatment, care, and education [190]. Furthermore, the increasing geographic distance between parents and their adult children complicates family care.

The degree of urbanization strongly correlates with a loss of physical exercise in a person's daily life as well as a change of eating habits, due to the constant availability of fast food. People in countries with fast urbanization are therefore at a higher risk of degrading their general health condition and getting diabetes.



Political & Legal Trends in Diabetes Care

Health Literacy and Healthy Lifestyle

Internationalization of Standards

Increasing Collaboration

Data Aggregation, Processing, and Privacy Concerns

Audit and Control Processes

Political & Legal Trends in Diabetes Care

The rising number of people living with diabetes forces politicians to react. Diabetes prevention and the improvement of care and treatment are essential in relieving the increasing strain, diabetes is placing on the healthcare system. Continuous development in the health sector requires a legal framework to clarify the scope for all stakeholders to operate. Therefore, we identified five trends that shape the current political and legal debate around healthcare and diabetes care in Europe.

First, we discovered an increase in political involvement that encourages a healthy lifestyle and improves health literacy. Ten years ago a so-called “health in all policies” approach evolved. It urges legislators to consider a healthy lifestyle in all sectors that influence health. Furthermore, there is a focus on policies that improve health literacy by educating the population, as information about health-conscious behavior, nutrition, and diseases is essential for a healthy lifestyle.

Second, there is a stronger focus on unifying procedures in the health sector across the globe, through the internationalization of standards. Every government in the world tackles diabetes differently. Many diabetes associations or governments try

to consolidate efforts through international frameworks and guidelines. These common standards enable a homogeneous European market that can be addressed with digital innovations. The international market is addressed by experts from research, industry, and others branches. This leads to an increase in international collaboration. Stakeholders get more sensitive towards the complex problems of diabetes due to globalization and become more aware of the challenges it causes. A lot of different partnerships are established to share knowledge and progress on common goals. The government, industry, and research community demand joint projects as each project partner can build upon existing knowledge and they can together accelerate research and innovation. Successful cooperation in diabetes care is beneficial for both, project partners and society. Fourth, there is an increasing demand to clarify the legal situation of collecting patient data. Data aggregation, processing, and privacy concerns are topics that need to be tackled by governments all over the world. Governments and businesses have long collected, parsed, and used collective patient data to track the path of chronic conditions and contagious

diseases. This data is then used to evaluate the success rates of treatments, develop new cures, and improve the quality of providers’ services. Action needs to be taken to centralize databases, while ensuring their security and reliability. In the end, there is a compromise between increased research data sources and a loss of privacy and autonomy.

Lastly, there is a trend towards increasing the measuring and auditing processes in healthcare. Policies can enforce a high quality universal healthcare standard by forcing healthcare processes to be audited. Regulations are a government’s key tool to protect and accomplish their social, economic, and environmental goals. This influences the operability of companies and Non-Governmental Organizations (NGOs) as they have to abide by those regulations. Therefore, digital innovations in auditing are encouraged in order to improve healthcare.

This all shows a high political and legal impact in the field of diabetes care. Through regulations, funding, guidelines, and standards politicians have the power to steer the public debate and diabetes care trends. In the following sections, those trends will be explored further.

Health Literacy and Healthy Lifestyle

Increasing political involvement by encouraging a healthy lifestyle and improving health literacy

Over the last years, political involvement in the health sector increased [191]. A healthy lifestyle is encouraged by politics through the policies it introduces. In 2006 the term “health in all policies” was introduced that urges legislators to consider a healthy lifestyle in all sectors [192].

Furthermore, there is a focus in politics on improving health literacy through educating the population. Information about health-conscious behavior, nutrition, and about diseases is essential to live a healthy lifestyle. The lack of health literacy can be linked to a reduced therapeutic compliance. Groups with reduced health literacy are unhealthier and have a higher mortality risk. This leads to an overuse of emergency and hospital inpatient services, causing higher healthcare costs [193].

Politicians are able to set different points of focus within the healthcare sector through initiatives. The EU developed a healthcare program, which focuses on promoting health and preventing diseases with an overall budget of almost 500 m EUR [194]. This emphasizes the increasing political influence in the healthcare sector.

Facts

- In the comparative report of eight EU member states, only 4.8% of all participants have an adequate health literacy [195].
- IDF promotes healthy nutrition [196].
- IDF introduced an online information platform called „Diabetes Voice“ [197].
- Researchers and professionals interact through the Health Literacy Europe online platform [195].
- A European project called “Diabetes Literacy” specializes on diabetes patients and caregivers [193].
- 89% of all countries state that their national policies align with a healthy lifestyle including physical activity and nutrition [198].

Key Drivers

- Deficient number of health professionals with a solid understanding of diabetes care [199].
- Diabetes advocates, NGOs, and health organizations actively support policies that improve the lives of diabetes patients [200].
- Digitization enables a new distribution channel to educate more people [197].
- The focus of governmental spending shifts towards disease prevention [191].

Challenges

- Supranational policies need to be adopted on a national level [198].
- Sufficient funding, as well as personnel issues, avert the enforcement of healthcare policies [198].
- Diabetes education requires coping with the needs and habits of individuals, as everyone reacts differently to lifestyle intervention [201].
- Educate the elderly, racial and ethnic minorities, and patients with chronic diseases about health literacy [202].
- Design the educational system to address people of all levels of media literacy.

Impact on the Future of Diabetes Care

Due to political influences that aim to educate people in the health sector, the number of health conscious people increases. These people are able to clearly state their needs and expectations, which encourages product developers to create more patient-centered innovations [191]. This, in turn, leads to an increased demand for digital innovations. Furthermore, educated patients can utilize new technologies and innovation to improve their quality of life. Increasing political involvement raises trust, which reduces one’s hesitation to try out new technologies. This political support simplifies the commercialization of new technologies [203]. Finally, education raises peoples’ interests in a healthy lifestyle. This increases the use of digital innovations to overcome the challenge to live healthier.



Internationalization of Standards

Stronger focus on unifying procedures in the health sector across the world

Diabetes is a chronic disease with a worldwide impact and requires international standards. It is tackled differently by governments all over the world. To unify these differences, the WHO states that global commitments are required [204]. 15 member states of the EU came to an agreement about a policy framework and plans to fight diabetes [205].

To combine efforts and build standards, the IDF set up an approach for national governments to implement national diabetes programs. Their support program focuses on diabetes prevention and improvement of care. It provides a guideline for policies and action items [196]. To reach long-lasting benefits for both patients and the healthcare system, health promotion activities should be fostered by national and regional health policies. "Standards will facilitate both the implementation of health promotion and the assessment and continuous monitoring for quality improvement" [206].

Facts

- The IDF issued "The International Standards for Education of Diabetes Health Professionals" [207].
- Various international projects (e.g., the IMAGE project or the EUBIROP project) aim to improve the management of T2DM and reduce its impact across Europe [208].
- Standards for effective and immediate prevention are essential in lowering the burden of T2DM within the EU [203].
- In 2012, an EU patent law came into effect to simplify the process of bringing new innovations to the European market: One patent can be issued for many countries, instead of claiming one for each country [191].

Key Drivers

- The EU gave instructions concerning the standardization, quality, and safety in healthcare that all EU member states have to implement into their legislation and fulfill at a national level [209].
- Due to globalization as well as the increased worldwide collaboration of economies, common standards in healthcare are needed.
- By 2040, more than 640 million people worldwide will live with diabetes, which requires international standards to treat diabetes on an international level.

Challenges

- International guidelines may interfere with local restrictions as well as national goals.
- Standardization of various nutrition habits on a regional or even national level [203].
- Due to different socio-economic situations among all involved countries, there is not enough funding to implement international standards [203].
- Many interdisciplinary project partners with a willingness to contribute professional knowledge to the cooperation are required to successfully implement a standardized national prevention program [210].

Impact on the Future of Diabetes Care

Agreed standards within the European Parliament are easily applicable for EU member states. Digital innovations address a homogeneous European market with these common standards. It promotes the realization of collaborations to foster an interdisciplinary and innovative approach when designing new diabetes care solutions. The resulting products get more resilient through fulfilling international and diverse standards. On the one hand, this helps to accomplish a greater market and more patents. On the other hand, more diverse patients need to be considered regarding a bigger market [191]. Digital innovation is beneficial for collecting and exchanging data on an international basis and for data-driven improvement of treatment [203].

Increasing Collaboration

Experts from research, industry, and other areas start working together

The current trend is moving away from a noticeable separation between the different areas of development to an increased collaboration between stakeholders. In the past, communication between governments, research, patients, and SMEs was difficult, e.g., due to a regulation of ownership. These parties did not work together extensively to challenge tasks within diverse teams. Due to globalization and a rise in overall awareness, stakeholders are getting more sensitive towards the complex problems regarding diabetes [211]. A lot of different partnerships have been established amongst various stakeholders, such as research institutions and industry partners. Also, governments have joined collaborations and they are strongly pushing joint-operations by offering programs to support and fund such projects that meet a determined collaboration quota [191]. These collaborations provide an outstanding basis for sharing resources and meeting market needs in an innovative way, while all parties share potential risks and benefits. Furthermore, open science projects are sponsored by several initiatives that are supported by governments [196]. This trend towards collaboration is noticeable on all political levels – on the state, european and global level [212].

Facts

- Collaborative projects, like the school-food-approach, are globally connecting government and private initiatives [213].
- EIT Health is working together with 50 core partners and 90 associate partners from all areas (steadily increasing yearly) [203].
- The Innovative Medicines Initiative (IMI) works together with governmental support and partnerships on industry related open projects [214].
- The 'NRW Regional Innovation Network Diabetes' is a collaboration between governments, industry players, patients, and research institutions [215].

Key Drivers

- The EU is pushing for diabetes related projects by establishing a 20% collaboration quota, providing "Project Officers" who supervise and mentor projects, and by providing funding [191].
- The EU is encouraging partners to start projects in the diabetes field, thereby also raising awareness about the disease [216].
- Ongoing globalization and modern network technologies raise the awareness of diabetes issues to a higher global scope [217].
- Unsolved issues in diabetes care make it necessary for all stakeholders to join efforts and work together [203].

Challenges

- Bringing together the right people for a project in a way that fits their requirements and suits their individual capabilities [218].
- Aligning individual interests and goals of all project partners by agreeing on a comprehensive contract [191].
- Management and coordination of collaborative projects across different countries.
- Creating a common ground and establishing a collaborative working atmosphere from the beginning of a project [219].
- Projects with many partners need to clearly determine the owners of any results [220].
- Sustainable implementation and utilization of the joint-project results [191].

Impact on the Future of Diabetes Care

Funding and cooperation brings diverse people and experts from different fields together. This inspires them to generate new innovative ideas and solutions. In addition, comprehensive collaborations create synergy effects for the product, consortium, and all stakeholders. These collaborations consist of several project partners, which then serve as multipliers to reach a broader audience. Diabetes related collaborations foster innovative diabetes solutions, thereby potentially opening up new markets and providing new value to diabetics. For such products, all project partners can build upon each other's existing knowledge, thereby accelerating research and innovation. To summarize, successful cooperative work in diabetes care is beneficial for both: project partners and society.





Data Aggregation, Processing, and Privacy Concerns

Increasing demand to clarify the legal situation of collecting patient data

With increasing digitization, the possibilities for collecting and storing data are simpler and more precise than ever before. EMRs contain highly personal information, from illnesses over family generations to emotional statuses [221]. Furthermore, new channels (e.g., mobile apps) emerge to gather patient-driven data.

Governments and businesses have long collected, parsed, and used collected patient data to track the path of chronic conditions and contagious diseases. This data is used to follow the success rates of treatments, to develop new cures, and to improve the quality of providers' services. Today's EMRs are easily shareable – and hackable – and have different rules depending on state and organization. Some patients fear they have little to no control over the information being tracked by their personal health logs [221]. The increasing interest in privacy is based on experiences of stigma, fears of suffering disadvantages, and remaining anonymous in respect to one's sensitive data as well as the traceability back to a single patient [222]. Keeping the possibility to trace the data back to a single patient, in case indications for another disease are found during further analysis, are currently being discussed [203]. There is a need for clarifying the legal situation for data collection.

Facts

- The Linked2Safety project provides access to EHR across Europe for researchers and healthcare professionals [223].
- Only 5% of people with T1DM even attempt to access their data [224].
- Wider data analysis, more data re-use, and the combination of datasets from multiple sources are encouraged [225].
- Transparency is particularly improved by informing the public about agreements between public institutions and publishers for the supply of scientific information [226].

Political & Legal Trends

- The General Data Protection Regulation (GDPR) draft states that all data should be anonymized [227].
- The Future of Privacy Forum raises concerns about privacy policy in health and fitness apps; only 70% of top health apps had a privacy policy [228].

Key Drivers

- Moving from a “reporting approach (what has happened?) to a predictive approach (what will happen?)” [229].
- Researchers are increasingly turning to EMRs as a source of clinically relevant patient data to develop new products and/or optimize them [229].
- Health apps help to raise awareness of personal (medical) information [230].
- Scientists demand health data access to improve clinical trials and drug safety [223].

Challenges

- Tradeoff between protection of personal data and the benefits of mass information [227].
- Concept of data ownership is inadequate for health data; as researchers and organizations urgently need them for development purposes [231].
- Raising awareness among patients to take on “stewardship” of their own EMR (the patient is in charge of sharing his record) instead of concept of ownership [221].
- Building up a harmonized and centralized health database in countries where it is non-existent [219].
- Implementing a system ready for incorporating more patient-driven data changes [219].

Impact on the Future of Diabetes Care

On the one hand, gathered data accelerates research which leads to products and services that make treatment and diagnosis better, quicker, and cheaper [219]. This would be realized through a centralized database. This allows data to be compared, allowing the progress of a disease on a large scale to be analyzed and the development of more evidence-based and personalized therapies [203].

On the other hand, gathered data leads to concerns regarding technical challenges, unanticipated consequences, and a loss of privacy and autonomy [219].

Audit and Control Processes

Increasing interest to measure and audit processes in healthcare

Policies can enforce a high quality universal healthcare standard by forcing healthcare processes to be audited. The overall purpose of regulations, auditing, and compliance enforcement are used to control and increase workers' efficiency. Therefore, regulations are a government's key tool to protect and accomplish their social, economic, and environmental goals. Especially in the operability of companies and NGOs, these regulations have a high impact. To improve the safety and quality in hospitals, external pressure and top-down control are executed [232]. In hospitals and the overall health sector, the performance and auditing indicators are delivery, treatment, and patient safety [232]. Already, some hospitals are starting to record processes and evaluate the resulting audit reports. These records give a more detailed insight into the strengths and weaknesses in healthcare [232]. Political regulations are required as a framework to protect the patients as well as the healthcare environment [233].

Facts

- The EU is organized as a federal healthcare system; each member state provides its own healthcare [232].
- Governments within the EU differ in their auditing and clinical monitoring practices as well as how they provide feedback to workers [232].
- Early identification of a disease generally makes it easier to treat, but current processes often detect diseases very late [202].
- Clear recommendations and guidelines, used for early detection and screening, increase the discovery rate of diabetes [234].

Key Drivers

- Clinical guidelines are essential to stabilize and increase the overall population's health [200].
- To increase the overall health quality, the healthcare workers' performance is measured and recorded, allowing health institutions to improve their workers' performance [200].
- An improved internal quality control is required to enable Europeans to receive the same quality of care outside their home country [232].
- Increasing governmental involvement in recent research and innovation projects to streamline cooperation between different stakeholders [191].

Challenges

- Bad regulation design presents a risk of depressing economic growth [233].
- Diverse regulations within different countries make global product launches challenging.
- More precise separation of smart devices into "healthcare devices" and "lifestyle devices" for auditing purpose [202].
- Reimbursement restrictions are slowing down the development of solutions and lead to an increased time-to-market [202].
- More organization, and therefore work, is required for healthcare professional teams to successfully treat diabetes in a patient-centered way [200].
- Convincing physicians, nurses, etc. that auditing and controls are necessary to improve the system.

Impact on the Future of Diabetes Care

Digitization helps to ensure the quality in health facilities. Therefore, politicians aim to redesign the care processes by an increased usage of auditing processes [200]. These political efforts in digitization influence new digital innovations within diabetes care. Monitoring procedures and auditing will encourage digital innovations which aim to improve healthcare. It is important to divide this auditing into direct health-related monitoring of patients and general process monitoring, to apply the correct regulatory standards [202]. To conclude, digital innovations are able to aggregate data for auditing and monitoring processes within healthcare.



Economic Trends in Diabetes Care

Rising Cost of Diabetes Globally

Rising Inequality

Growing Diabetes Markets

Convergence of Global Healthcare Markets

Increasing Growth Opportunities for Corporations

Emergence of Preventive Care

Economic Trends in Diabetes Care

The increasing cost related to diabetes care threatens the sustainability of healthcare systems and economic prosperity.

The rising global prevalence of diabetes has severe economic implications for healthcare systems, healthcare providers, and society. This chapter deals with recent economic trends and developments as well as the status quo of multinational corporations in diabetes. While the geographical focus lies on Europe, facts and drivers on all continents were considered. With the goal of making healthcare better for diabetes patients in mind, the conducted research focuses mainly on cornerstones and limitations for the evolution of new innovations. Consequently, we identified six economic trends that will impact the development of diabetes care in the upcoming years.

Firstly, on a macro-level, we observed a rising prevalence of diabetes throughout all parts of the world, especially for T2DM. On the one hand, rising living standards lead to more obesity; On the other hand, a longer life expectancy leads to an aging society, with older individuals being at a higher risk of developing the disease. This has severe economic implications on healthcare systems, as the absolute costs of treatments are rising significantly. In some countries, diabetes already accounts for 20% of the total healthcare cost [235].

Staying on a macroeconomic-level, we can see an increase in income inequality. This development causes difficulties in financing a public healthcare system and threatens the prosperity of the economy as a whole. This situation is particularly challenging for low-income households, which struggle with the financial consequences of diabetes care. Homecare solutions could compensate the decreased accessibility induced by rising inequality. Since projections suggest a continuation of this development, the problem of rising healthcare costs is predestined to not only be a demanding question for economists, but one of the big societal challenges in the future.

On an industry level, we identified significant growth in the market for diabetes related goods and services. The global market sizes for products such as glucose monitoring systems increases steadily. Furthermore, the role of multinational corporations demonstrates how certain stakeholders can profit from the increased prevalence of diabetes. During the last years, large multinational companies were able to significantly increase their market shares, which accelerates the consolidation of the market. Despite the growing demand, margins of large pharma companies are decreasing due to intensified competition and a decreasing effectiveness of research activities.

Furthermore, we see companies finding new opportunities in regions such as the Middle East and Asia. As societal changes have a significantly stronger impact in emerging markets compared to the Western World, the growth potential there is even higher. In addition, prices increase and diabetes prevalence is growing rapidly as healthcare systems become more sophisticated. Consequently, large global players use their advantage of an international infrastructure and focus resources on these areas.

Finally, we assessed which emerging fields in the healthcare system might have an economic impact in the future. We identified the field of preventive care as one of the emerging areas that offers an answer to rising costs. Policy makers, insurance companies, and other stakeholders collaborate in the development of preventive care programs which target the overall health and fitness of the population. This is especially promising since approaches to tackle obesity not only reduce the risk of developing diabetes, but also many other chronic diseases. All trends taken together will profoundly influence the economic landscape of diabetes care in the upcoming years.

Rising Cost of Diabetes Globally

Total healthcare costs of diabetes increase significantly

A large fraction of the European healthcare expenses are spent on people diagnosed with diabetes [216]. The cost of diabetes can be divided into two types: direct and indirect costs. Direct costs consist of the healthcare costs due to diabetes treatment, e.g., insulin supply, and the costs caused by follow-up diseases, of which long-term vascular complications make up the majority [236], [237]. In contrast, indirect costs are mainly caused by the occurring productivity losses, e.g., workdays missed, or the reduced productivity while working due to health conditions [237].

The number of people diagnosed with diabetes in Europe is increasing; hence, the total healthcare costs are steadily increasing, even though recurrence of severe complications is decreasing. Furthermore, a large fraction of people with diabetes are unaware of their disease [216]. The increase of elderly people and the higher life expectancy amplify this trend [216].

Facts

- Today, roughly 156 bn USD of Europe's total health expenditure can be attributed to diabetes, growing to 174 bn USD by 2040 [216].
- The number of people diagnosed with diabetes in Europe will rise from about 9.1% to 10.7% of the adult population in 2040 [216].
- The increasing average life expectancy in Europe (today at birth: 81 years) causes individuals to be more exposed to risk factors of diabetes [238].

- 53% of the medical costs per diabetes patient in Germany (2001) were spent on the management of complications, mainly macro- and microvascular diseases [239].
- The costs of follow-up diseases of older patients due to diabetes are particularly high and account for the largest fraction of the costs induced by diabetes [240].

Key Drivers

- Significantly increasing fraction of the population affected by T2DM [216].
- Larger fractions of the population are at risk of developing T2DM due to an unhealthy lifestyle [241].
- Globally increasing life expectancy leads to greater exposure to chronic diseases [242].

Challenges

- The rise in total costs of diabetes care increases the pressure on healthcare systems, consequently requiring cost reductions to finance them sustainably.
- The demographic change leads to a greater demand for medical care. Together with upcoming changes in pension obligations, pressure on national budgets increases and will lead to financial distress for public healthcare systems.
- Higher cost of healthcare and the struggle to finance public healthcare systems can potentially lead to patients having to pay more themselves.

Impact on the Future of Diabetes Care

The higher costs of diabetes must be carried by the existing healthcare systems. Since the public sector is the main source of financing for healthcare systems in European countries, there is a strong need for new ways of funding the healthcare system. If governments do not implement substantial changes, the individual patient has to bear higher costs, while at the same time the quality of healthcare decreases [216]. Therefore, policy makers are encouraged to regulate healthcare through measures, such as preventive care or taxes on unhealthy food.

Rising Inequality

Rising inequality and divergence of individual economic situations

During the past couple of decades, rising income inequality was the result of the unequal income growth between the richest and poorest 10% of the population [243]. Consequently, more people live in poverty and are struggling financially. Moreover, both deprivation and poverty are negatively correlated with access to healthcare. In a less egalitarian society, more people are at risk of becoming diabetic, as diabetes prevalence is correlated with SES [239], [244], which results in substantial challenges for healthcare accessibility and financing, for low-income diabetes patients. Due to a higher relevance of transportation costs and less flexibility to miss work, accessibility is an even greater challenge for disadvantaged individuals. Consequently, it is harder for them to obtain treatment and homecare is poised to become more relevant as a treatment option in the future. A reliance on care from relatives can be a disadvantage to low-income families. Also, decreasing the productivity and income of caregivers can worsen their already difficult financial situation.

A clustering of low-income, high risk patients in public healthcare systems results in higher insurance costs and consequently crowding out healthy individuals due to an overconsumption of healthcare [245]. The higher expenses either result in a reduction of the coverage of high-quality healthcare, compared to private systems, or a rise in taxes and contributions, -presumably both [246]. With income growth driven mainly by the top 10% of society, private healthcare can afford high-end treatments and consequently becomes even more elite.

Facts

- The income share of the top 10% has risen from 29% to 35% in the last 30 years [247].
- Higher rates of both obesity and diabetes are found among the lower-income groups [239], [244].
- The risk of T2DM is 40% higher among people in the most deprived quintile of regions, compared with those in the least deprived quintile [248].
- In the UK, morbidity from diabetes complications is 3.5 times higher among the poorest individuals compared to the richest [249].

- Financial stress leads to a more difficult access to treatment, mainly due to increased relative costs of transportation [250].
- Blood glucose levels are elevated by financial stress [250].

Key Drivers

- Capital returns outpace economic growth in the 21st century, which benefits rich and high-income households, who can afford to save. This leads to a divergence of wealth [247].
- A continuing divergence of incomes, due to the prevalence of extremely high growth of incomes for top-earners and stagnating wages for the bottom 90%, increases wage-inequality [247], [251].
- Unequal access to education, attributed to economic disparities, reinforces a divergence of incomes and wealth, as both are highly correlated with education [252].

Challenges

- Deprivation of public goods (health infrastructure, education, and public transport) correlates with income and results in an even more unequal accessibility, making equal access to important infrastructures more necessary.
- To reduce inequality, social safety net improvements and more progressive taxation are needed in order to have a more uniform redistribution of wealth.
- Improving the financing of the healthcare system (disproportional contribution of high-income individuals).
- An accumulation of individuals more vulnerable to diabetes in public insurances results in a widened coverage gap of high-quality healthcare and/or a struggle to finance public insurances.

Impact on the Future of Diabetes Care

A larger fraction of the population faces the risk factors of diabetes because of their exposure to poverty and deprivation of important governmental infrastructures. Low-income patients cost the insurance more money and are more likely to get T2DM. This leads to a rise in costs and a struggle with accessibility in public healthcare systems, compared to private insurances. This results in a more unjust healthcare system. A segmented market also might restrict the treatment options for publicly insured patients and exclude them from access to high-end healthcare. With the decreased accessibility to healthcare, homecare is becoming a more important treatment category.



Growing Diabetes Markets

Growing global demand for diabetes related goods and services

An increasing number of people around the world suffer from diabetes. Especially in developing countries, the growth rate of new diabetes patients is high. This poses a serious challenge to existing healthcare systems, since diabetes related costs grow and the demand for more efficient and cost saving diabetes related goods increases [216]. This leads to a steadily growing market for insulin, anti-diabetic drugs, and diabetes related tools or devices, such as glucose meters, lancets, test strips, or insulin pumps [253]. Additionally, the global homecare market is growing due to the cost effectiveness and comfort of the offered services as well as the increasing number of elderly people with chronic diseases, such as T2DM [254]. In particular, continuous glucose monitoring devices have shown significant market growth and have gained popularity as a part of at-home diabetes care [253].

Facts

- The insulin market will reach 39.13 bn USD by 2020 with a CAGR of 8.1% from 2015 to 2020 [255].
- The market for T2DM will grow from 31.2 bn USD in 2015 to 58.7 bn USD in 2025 with a CAGR of 6.5% [256].
- The market for insulin pumps will grow at a CAGR of 8.05% from 2016 to 2020 [257].
- The continuous glucose monitoring market will reach 568.5 m USD by 2020 at a CAGR of 14.8% from 2013 to 2020 [258].
- The global home healthcare market will grow with a CAGR of 7.8% between 2014 and 2020 to a volume of 355.3 bn USD [254].

Key Drivers

- An increasing number of people around the world are being diagnosed with diabetes, especially in developing countries [216].
- Rapidly rising diabetes related costs and growing demand for more efficient products and services [216].
- Development of innovative diabetes healthcare goods and services [259].

Challenges

- Aligning incentives of pharma companies with healthcare systems and patients.
- Increasing competition for established pharmaceutical companies through innovative medtech startups.
- Price decrease through increased competition, disruptive business models, and a growing prevalence of generic drugs and biosimilars.

Impact on the Future of Diabetes Care

The growing diabetes market attracts innovative startups that introduce new diabetes related services and products. This might increase the pressure on established pharma companies and lead to a rising diversity and quality of diabetes related products in the market. Venture Capital firms anticipated this development and increased their activity in the biopharma industry [260]. For instance, the venture capital firm Andreessen Horowitz set up a 200 m USD fund for investments in new biotech startups [261].

Convergence of Global Healthcare Markets

Growth of emerging pharma markets drives adoption of western standards

Globalization and advances in communication technology enable the collaborative use of know-how, best practices, and new technologies [262]. Drug manufacturers face challenges producing drugs for the global market, since they have to meet diverse regulatory requirements in different regions. At the same time, new players in emerging markets and growing global competition put big pharmaceutical companies under pricing pressure [263]. In particular, the rising production and prescription of generic drugs and biosimilars, with significantly lower prices than the brand name drugs, accelerate this development [263]. This fosters the global accessibility of drugs and leads to a convergence of prices and quality of healthcare goods in developing and established markets [264]. Additionally, the healthcare spendings per GDP in developing and industrialized countries are converging [265].

Facts

- The growth rate of pharmaceutical exports between 1995 and 2014 has risen, with an average annual rate of 11% [266].
- The global generics sector reaches 518.5 bn USD in 2018, with a CAGR of 11.5% [8].
- Analysts expect the worldwide biosimilars market to increase from 25 bn USD to 35 bn USD by 2020 [267].
- Studies show that the healthcare spending per GDP converges between developing and OECD countries [265], [268].

Key Drivers

- Advances in Information and Communication Technology (ICT) leads to a spread of technologies and know-how [262].
- Increased production and global prescription of generic drugs and biosimilars [264].
- Globalization leads to an increasing pressure by NGOs and other countries on developing nations to invest in the quality of their healthcare systems [265].

Challenges

- Companies shift their focus away from Europe and towards developing countries with higher diabetes growth rates.
- Entering a global market, pharmaceutical companies face challenges to meet all regulatory requirements and practices in different regions [269].
- Big pharmaceutical companies face pressure on prices through increased global competition [263].

Impact on the Future of Diabetes Care

Diabetes companies shift their focus to more profitable markets, in particular to regions with higher diabetes growth rates, and therefore an increasing demand for medical supplies and treatment. Due to the harmonization of standards across borders, the development time and resources used for new global pharmaceutical products decline [269]. Finally, the global availability of drugs leads to easy accessibility to affordable diabetes care, resulting in good quality treatments for patients in developing countries [269].





Increasing Growth Opportunities for Corporations

Multinational corporations' success in diabetes continues despite decreasing margins

With the prevalence of diabetes growing rapidly worldwide, there is a significant growth opportunity for corporations but also substantial competition [270]. The Top 3 players are continuously increasing their market shares [238], [271]. The intensification of competition leads to a market consolidation, including mergers and acquisitions of major corporations [267]. Despite the growing market, margins of pharma companies are decreasing, mainly because of expiring patents and an increasing number of generics in the market. High discounts to retail and public sectors as well as the shift towards a VBC are additional factors that lead to decreasing margins [272]. Price increases highly depend on the development of new blockbuster drugs [273]. As a result, alternatives to traditional, high-margin blockbuster business models are becoming more relevant to position corporations for success in an outcome-based environment [267].

Facts

- The top 9 firms in the diabetes market increased sales in 2015 [271].
- Average unit costs for diabetes medications increased 7.4% from 2014 to 2015, reflecting the launch of new insulin pens and new therapies aiming to increase the quality of treatments [274].
- 52.5% of current diabetes drugs are generics, this number has risen due to the launch of the first insulin generic in December 2016 [275].

Key Drivers

- Strong global market growth drives sales, leading to increased competition and a need for differentiation in the market [267].
- Expiration of major patents (e.g., Sanofi Lantus) opens up the market for generics and new patents for drugs with higher effectiveness [271].
- The paradigm shift towards a more consolidated, connected, and convergent approach, leading to partnerships and acquisitions [267].
- Paradigm shift towards VBC, defined as patient outcomes divided by costs, is on the agenda of governments and regulators, consequently affecting pricing strategies and profitability of corporations [276].

Challenges

- Expiring patents affect the EBITDA of research-based pharma companies [267].
- Falling R&D productivity impacts long-term profitability; however, in the short term an increasing efficiency of R&D equalizes the lower productivity [267].
- The increasing market power of insulin producers – the market leader held 46% of the global insulin market in 2015 – raises the risk of long-term price increases, as seen in the US.
- In the US, insulin prices have risen 200% from 2002 to 2013 [277].

Impact on the Future of Diabetes Care

As healthcare providers, taxpayers, and governments strive to deliver effective, efficient and equitable care, pharma companies face a transition on two levels: business and operating models. In particular, the shift from volume-based to value-based care drives the development in both areas. First, business models will focus on the constant, long-term prevention and treatment of diseases instead of highly intensive, episodic care. Second, the operating model of pharma companies shifts from a provider-centered approach to a patient-centered approach. In summary, innovations around personalized, digital care enable pharma companies to utilize demographic and regulatory changes for further growth.

Emergence of Preventive Care

Preventive care as an answer to increasing health-care costs caused by T2DM

As stated before, the rising costs for treating diabetes and follow-up diseases, as well as indirect costs through loss of productivity and early retirement, pose a significant challenge to all parts of society. Some traditionally involved parties in the healthcare system are governments, pharma companies, healthcare providers, and insurances. In the case of T2DM, newly involved stakeholders, such as employers, are particularly affected by the loss of productivity [237]. Preventive care now emerges as one of the primary means to reduce the prevalence of T2DM [278]. Especially for newly involved stakeholders, population based prevention is a new chance to interact with the healthcare system and reduce the costs induced by T2DM. Many policy makers, insurance providers, and corporations have already implemented preventive care programs which have shown to reduce the overall healthcare costs. Preventive care in general is part of a larger trend towards personalized medicine. This includes treatments that can be aligned to the patient's genome as well as products for personal health management and fitness tracking.

Facts

- Allianz managed to cut costs by 210 m EUR a year by implementing a targeted secondary prevention program in primary care [279].
- Educational programs about preventive measures against diabetes have the potential to save 2.2 bn EUR of direct diabetes costs in the German healthcare system [280].
- The global market for preventive and personalized health products and services grew by 78% to 243 bn USD between 2010 and 2014 [281].
- The market size for preventive medicine was over 39 bn USD in 2015, and is projected to grow at 10.5% CAGR from 2016 to 2023 [282].

Key Drivers

- Rise in total healthcare costs linked to diabetes and rising prevalence of diabetes throughout the population.
- Limited possibilities to directly interact with the health of the population for key stakeholders, such as employers and insurance companies.
- Favorable government regulations, since preventive medicine or therapies are easier to get approved (compared to pharmaceutical drugs) or have no regulations at all.
- Trend towards fitness as a lifestyle, as for example seen in the rise of fitness trackers and smartwatches.

Challenges

- Preventive care is rarely subsidized by insurance companies. However, there is a trend towards more subsidization of prevention and personal health management (for example vouchers for fitness trackers).
- Goal of most preventive programs is to establish health improving habits, which implies inducing deep-rooted behavioral change in a large part of the population.
- There is a substantial lack of education about personal health as a preventive measure against diseases as well as a lack of knowledge about the benefits of a healthy lifestyle.

Impact on the Future of Diabetes Care

Preventive care and incentives for healthy living present an opportunity to avoid a collapse of the healthcare system. Furthermore, this allows corporations and insurance companies to implement diabetes prevention programs to lower long-term costs caused by an unhealthy population. Consequently, there is a scope of new and disruptive business models and startups to create innovative solutions. Another benefit are the low barriers of entry, due to preventive medicine being less regulated compared to the drug market and thus needing less upfront investment.



Business Model Trends in Diabetes Care

Internet of Things

Predictive Medicine

Online Job Platforms

Telemedicine

Changing Lifestyle

Emerging Business Models Utilizing Crowdsourcing

Value-Based Healthcare Model

Business Model Trends in Diabetes Care

A business model is the plan a company implements to generate revenue and profit. Contrary to common believe, new business models are not only beneficial for share- and stakeholders but also for the entire economy. When a new business model is established in the market, it usually has a competitive advantage through which it can offer an increased utility to its customers. Furthermore, other businesses can learn and improve upon these new concepts, thereby generating value to the entire market.

In this chapter, we present eight different business models which recently emerged due to new developments and trends. We discuss their facts, drivers, and challenges to assess their impact on diabetes care.

First, the Internet of Things (IoT) describes a web of connected devices which can be implemented into everyday life. The new data collected by sensors implanted in these devices present several possibilities for improvements in the healthcare sector, including: cost savings, risk reduction, and an enhanced patient care. These possibilities and the resulting monetization strategies provide new prospects for doctors, hospitals, insurance companies, and even the patients themselves.

Second, predictive analytics carry a high potential for cost savings. The new possibilities offered by this technology, such

as early detection mechanisms, present vast opportunities for disease prevention as well as for a better management of the treatment chain.

Third, online job platforms for professional healthcare personnel have the potential to cover shortages in the workforce and to achieve a better health worker - patient fit. These new matchmaking mechanisms could improve the lives of health workers as well as of patients, therefore improving the overall situation around diabetes homecare.

Fourth, telemedicine enables doctors as well as patients to partly free themselves from the spatial and temporal restrictions which were imposed by traditional visits to the doctor's office or through patient visits. The resulting improvements have the potential to increase the number of choices when selecting a doctor and to make finding appointments more effective and efficient.

Fifth, new business opportunities through consumer engagement and access, as well as creating incentives from the side of insurance companies, are evaluated. Insurance companies can use these new emerging possibilities to better assess risk and thereby save costs. These savings could spill-over to the consumer and make health plans more affordable.

Sixth, new lifestyle trends engage people to live a more active

and health conscious life. To manage all tasks connected with this lifestyle, such as a proper tracking of dietary habits, health apps are often used. Additionally, health apps can be helpful for chronically ill patients by supporting them when managing their condition. This offers opportunities for new business models, which impact diabetes care.

Seventh, crowdsourcing encompasses much more than only monetary contributions. The brainpower and knowledge of multiple individuals can easily be harnessed and used to come to more informed decisions. The fact that a group can now easily work towards a common goal also creates new opportunities for businesses.

Eighth, the idea that individuals only pay for the quality of service is also moving to the healthcare sector. Value-based healthcare (VBC) models are on the rise and offer new possibilities for businesses. Paying for a performance approach could increase a patient's treatment satisfaction while reducing costs, as only necessary tests and procedures are performed and the entire treatment process is considered by the physician.

In summary, these trends combined will shape the future of diabetes and healthcare for patients, doctors, and insurance companies.

Internet of Things

Emerging monetization strategies through connected devices and the IoT

The chronically ill, frail, and elderly currently rely at best on infrequent visits to their doctor to manage their conditions [283]. This issue could be mitigated via the IoT. The IoT enables patients to use devices equipped with sensors to gather acute or long term information. The patient generated data (PGD) collected by these sensors offers promising opportunities in chronic disease management and home care. Acute information, such as a sudden drop in glucose levels resulting in a diabetic shock, can be sent to doctors and emergency personnel to provide immediate help. Long term information about blood nutrient levels, or other indicators, can be used to adjust a patient's dietary habits or to check medication compliance [283]. This remote monitoring has vast potential to save costs and time as well as to improve patient care [284], [285].

Emerging business models in this area include generating revenue from fees for data analytics and cost reductions for insurance companies [286], [287] as well as hospitals, [288] due to an automated and more accurate data collection. The large amount of resulting data also carries a high predictive potential which could be used to reduce the risk for insurance companies.

Facts

- Remote patient monitoring is expected to save up to 36 bn USD globally over the next five years [289].
- Europe will likely become the largest mHealth region by 2017 [290]. The expected revenues are 6.9 bn USD, two thirds of which will be covered by remote monitoring [290], [291].
- Healthcare costs will be cut by 25%, because of savings generated by apps, sensors, implanted devices, and a web of wearables [292].
- The revenue of the Big Data Analytics Healthcare vertical segment will grow from 8.0 bn USD in 2015 to 17.0 bn USD in 2022 [293]. This sums up to a CAGR of 11% worldwide [293].

Key Drivers

- The world is experiencing a chronic shortage of approximately four million well-trained health workers [294].
- An ongoing decrease in sensor costs fuels the progressing developments in IoT technologies [295].
- Technology affinity and the demand for digital healthcare products are rising [144] (See: Society and Environment, Trend 4: Tech affinity).

Challenges

- Security and privacy concerns regarding the patient's sensitive data present obstacles that need to be eliminated [283], [291], [296], [297].
- Simultaneous and unsynchronized software developments pose hurdles for unified data standards, which would be useful for analytic purposes [283].
- Technology developments outpace legal requirements, which imposes regulatory barriers [283], [291].

Impact on the Future of Diabetes Care

There are three major areas of impact for emerging IoT businesses: An improved patient care, enhanced availability of medical staff, and a reduction of treatment costs [283].

Firstly, patient care will be improved by the increasing availability of accurate data. This data could be used to achieve better glycemic control [285]. Secondly, medical professionals daily administrative duties, such as filling in patient histories, can be reduced. This will free up their schedule and enable them to shift their focus towards more urgent activities.

Lastly, insurances could use the data generated by individuals to more accurately predict their chances of getting sick, thereby resulting in better risk assessment for the insurances and in fairer prices for individual health plans.



Predictive Medicine

Increasing cost-saving potential through predictive analytics

According to a new study, the global cost of diabetes reached 825 bn USD a year [298]. Predictive analytics reduces these costs by identifying patients at risk of developing a disease [299]. The resulting opportunities can be divided into two parts. Firstly, cost reduction because fewer people become ill: predictive analytics enables risk anticipation and thereby diseases can be avoided through preventive measures [300], [301]. Secondly, cost reduction along the complete treatment chain, which starts with the production of medicine and ends with the patient's last treatment [300]: at an early stage for instance, pharmaceutical companies are now able to approach hospitals with a risk-shared value proposition. By using predictive analysis, hospitals are capable of forecasting treatment options and possible responses. Pharmaceutical companies use this data to make medicine more effective, which is in the interest of both parties, pharmaceutical companies as well as hospitals. At a later stage, life science companies work together with providers on tailored plans for hospital patients to lower hospital admissions and readmissions. Tailored plans defined by predictive analyses motivate patients to stay on course with their treatment in order to tackle the problem of high costs of medication noncompliance [300].

Facts

- Carolinas HealthCare System, a network of 900 care locations, lowered readmission rates by a third by calculating the individual patient's risk of readmission to customize clinical interventions [300].
- Patients in the US that do not stay on course with their treatment (medication noncompliance) lead to annual costs around 289 bn USD [302].
- Preventively treated patients with diabetes have a life expectancy which is on average 3.7 years higher than non-preventively treated patients [303].

Key Drivers

- Advances in information technology, such as cloud-services, enable predictive tools to access and manipulate big data. Also, machine learning algorithms improve the accuracy rates of the predictive models over time [300].
- Predictive analytics is the essential enabler for the volume-to-value paradigm shift in healthcare [300]. (See: Business Models, Trend 8: Moving from fee-for-service to VBC model)
- Demographic ageing becomes a major burden on the healthcare system and through prevention measures, which are more precise because of predictive analysis, this burden can be relieved [303].

Challenges

- Privacy and security concerns regarding electronic health data, in particular the inappropriate release and resale of personal information [301].
- Acceptance of predictive medicine is slow on the uptake because there are potential public-relations disasters (e.g., using data to predict a woman's pregnancy without asking) [304].

Impact on the Future of Diabetes Care

Predictive analytics has an impact on diabetes care at different levels: from a macro-perspective, predictive analytics leads to a new diabetes ecosystem. Pharmaceutical companies, hospitals, and patients are increasingly working together instead of handing off information to the next entity in a linear process [300]. From a company perspective, a patient-centered business model is needed – one that realizes that diabetes care management needs to occur wherever the patient is, not just in a physician's office [300]. From a patient's perspective, predictive analytics leads to later first appearances of diabetes, lowers the risk of suffering from long-term consequences, and enables a more efficient care management [303], [305], [306].

Online Job Platforms

Reduction of labor-market dysfunctions through online job platforms

In 2035, the global health workforce shortage is predicted to be 12.9 million. Online job platforms are an efficient mechanism to bring employees and employers together in order to respond to this labor shortage challenge [307]. They connect job-seekers with work opportunities, thereby reducing labor-market dysfunctions [308]. Overall, the number of intermediary platforms for jobs has increased significantly in the last years [309]. Existing job platforms in the healthcare sector such as “ConvalentCareers” and “healthcare-jobs24.com” generate revenue by making connections instead of providing a tangible product or service, for instance by charging fees and selling advertisements [310].

Facts

- By 2025, online talent platforms are expected to increase global GDP by 2.7 trillion USD, while increasing employment by 72 m full-time-equivalent positions [308].
- Online job platforms are the most used recruiting channel in Germany, 92% of German companies use this channel to attract job candidates [311].
- A significant proportion of the existing health staff lack the overall knowledge on diabetes necessary to accurately treat diabetic patients [312].
- Due to the expected increase in older diabetics and the reduction of working-age people, a high number of specially trained caregivers is needed in order to take care of patients [112].

Key Drivers

- Increasing importance of network effects for online platforms, which can be seen from their long-term strategies, insures competitiveness in the online platform market [313].
- Information technology allows the analysis of large amounts of data, which can help increase the platform's value [314].
- Platform companies have fixed costs, the users are the ones who create content and value. That is why they are often “non-operators”, they charge fees for facilitating transactions [310].

Challenges

- To launch a job platform for healthcare professionals successfully, a sufficient critical mass of members (employees and employers) is needed [315].
- Job platforms risk a lack of acceptance in the population because of offloading responsibility for compliance with government regulations and payroll taxes [310].
- Job platforms may work well for ordinary professional positions, but it is hard to attract qualified trained employees and executives with simple job advertisements [316].
- To capture the job platform potential, labor-market regulations need to be updated and data-ownership and privacy rules need to be formulated more clearly [308].

Impact on the Future of Diabetes Care

Online job platforms have an impact on diabetes care in two ways: a better care management and an improved understanding of demanded skills. Firstly, a better care management will be achieved because of a larger diabetes workforce and a better allocation of diabetes personnel [317]. Secondly, the data which job platforms collect could be used to get insights into the demand for specific skills in the diabetes home care market [308]. Thus, the training and education of diabetes personnel could be adjusted to match the demands of the health industry.



Telemedicine

Spatially independent treatment options enabled by new developments in Telemedicine

“Telemedicine in its broadest definition is the assessment and review of patient information (history, examination, or investigations) by a health professional who is separated temporally and/or spatially from the patient” [318]. Telemedicine is already seen in emerging markets such as India, which have a need for cost and time effective diagnosis and treatment. There, they use a “hub-and-spoke” model where advanced hospitals in larger cities advise doctors in more rural areas using telehealth technology. In the developed world, this technology can help increase market efficiency and drive down costs [319]. In recent years, it has also been gradually expanding into the area of chronic diseases such as diabetes [2]. Telemedicine is reaching a point where it is not just used in experimental treatments, but becoming an industry standard. More and more people are focusing on “pragmatic applications” [2]. Telemedicine allows the health sector to use economies of scale to be increasingly more profitable while enabling new treatment options to be applied at a larger scale.

Facts

- In 2014, the Department of Veterans Affairs had more than two million telehealth visits [58].
- mHealth is already being used by 35% of patients in the developed world [320].
- Many people are homebound because of their age or their deteriorating health: about 2 million elderly people in the US are homebound [321].
- Medical diagnosis and therapy increasingly happens at the patient’s home, which is enabled by telemedicine technology [322].

Key Drivers

- The change in mobile behavior offers possibilities to improve healthcare systems and communication with healthcare providers [319] (see Tech, Trend 6: Smart Devices).

- Healthcare can be made easily accessible because of new technologies, such as the smartphone, and the increasing interconnectivity all over the world [2].
- Rising healthcare costs are motivating the use of telehealth to reduce costs [323] (see Economics, Trend 1: Rising cost of diabetes globally).
- Digital health mergers & acquisitions are increasing in volume: up to 10.4 bn USD in the first half of 2016 compared to just 6 bn USD in 2015 [324]
- In recent years, venture capital funding in this sector has been steadily increasing [325].

Challenges

- Due to the physical and emotional distance between physicians and patients, it is much harder to build trust and to engage in effective diagnosis and treatment [2].
- Experts are unsure whether telemedicine will be able to live up to the same standards as conventional medical treatment in a personal setting [2].
- Insurance companies are slow to adopt coverage for telemedicine methods and technologies [2].
- Data security and privacy is a major issue for telemedicine. Systems that can ensure protection of patient data while also offering all the possibilities for treatment are hard to implement [318].

Impact on the Future of Diabetes Care

Telemedicine can reduce short- and long-term costs associated with chronic diseases like diabetes [326]. Furthermore, everyone can have access to treatment for a disease such as diabetes from the comfort of their home. This is especially helpful since many patients are homebound because of side effects like obesity. Foot exams, for example, could be done virtually and a physician could consult the patient in the comfort of their own home. Finally, telemedicine can also help identify a disease, such as diabetes, more quickly since check-ups with physicians are possible on a more frequent basis and tests for the disease become more accessible through direct-to-consumer lab tests, where nurses travel to the patient’s home to draw blood to be sent to a lab for analysis [184].



Incentives in Medicine

New opportunities for insurers through consumer incentives, engagement, and direct consumer access

Increasing mobile device usage allows for new and unique business opportunities for insurers across Europe [327]. People are using mobile apps for every aspect of their lives. This behavioral change allows insurances to reward their clients for an active lifestyle since they can track their customers' activities. This includes, but is not limited to: "discounts, insurance premium reductions or other special offers." [328]. Therefore, patients are incentivized to be more active and to change their diet, guiding them to a healthier lifestyle and to save money. In turn, this will lead to an increased overall well-being of the general population [328]. Furthermore, the data collected can help with predictive analysis and allow insurers to expand their product portfolio. Insurers are in the position to bring digital innovation into healthcare as they can use their position to motivate their clients to live a healthier lifestyle [329].

Facts

- The Italian insurance company Generali has started a model for premium deductions based on a healthy lifestyle in Europe [330].
- In the United States, companies are already experimenting with new reward models. Instead of reducing premiums, the U.S. insurance start-up Oscar is giving away Amazon vouchers to their members for engaging in an active lifestyle [331].
- Having an economically profitable healthcare system is becoming increasingly difficult due to costs obstructing economic growth [329].
- Nearly 90% of healthcare organizations have started using mobile software to "engage patients within their organizations" [332].

Key Drivers

- Healthcare costs continue to rise in many countries. Even rather simple treatments are often not affordable for people without healthcare coverage. Coupled with the increasing demand for treatment availability, something needs to be done to address this problem [333].
- Healthcare systems are increasingly focusing on preventive care. Preventive care programs have been shown to reduce healthcare costs. A focus on preventive care drives the adoption of new consumer reward models (see Economics, Trend 4: Emergence of preventive care & see Business Models, Trend 1: IoT).

Challenges

- Quantifying patients has a social and psychologic impact on a person. The trust and in-person relationship with a physician are at risk if everyone is just seen as a combination of numbers and statistics [334].
- Ensuring the safety of patient data and achieving transparency of what is done with the data is essential for a functioning reward system [318].

Impact on the Future of Diabetes Care

Insurers can quickly bring digital innovation to patients across Europe. They can vastly drive the usage of health apps and the IoT. By working on one's health, people become more aware of their body while living with diabetes. Furthermore, it allows the insured to save money on their premiums and insurers to offer services based on the data they collect. This will in turn lead to better prepared, educated, and healthier individuals which should lead to a decrease in diabetes-related complications.



Changing Lifestyle

Increasing usage of health apps due to rising health consciousness

Society is tending towards a healthier lifestyle, which can be seen by the increasing demand for organic foods [335]. To facilitate this new trend, more consumers are using technologies to manage their lifestyle and to take care of their health [335] (see Society & Environment, Trend 5: Self-optimization). One important part of this trend is health apps, which focus on an active, health-conscious lifestyle [177]. For health app developers, the most important targets are chronically ill patients (31%) as well as health and fitness-interested people (28%) [58]. The main revenue sources of the health app providers are the following: 24% of the health app publishers state “pay per download” as the main origin of revenue followed by in-app advertising at 17% and in-app purchases at 5%. Half of the health app developer’s revenues are related to telemedicine (29%) as well as to the IoT (21%) [58] (see Business Models, Trend 1: IoT & 4: Telehealth). Therefore, health apps offer diverse business model opportunities for revenue generation.

Facts

- The total number of mHealth apps which have been released on iOS and Android from 2012 to 2014 has more than doubled, with more than 100,000 apps currently available [58].
- 60% of all downloaded health apps concern the topics diet, fitness, and movement [335].
- Revenue distribution in the market for health apps: 68% earn less than 10,000 USD, 17% earn between 50,000 USD and 1 m USD and 5% make more than 1 m USD [58].
- According to the research2guidance study (2014) [58] the market potential for health apps in developed countries is large and the app providers from developing countries estimate that the business potential in their countries might be equally large [58].

Key Drivers

- Increasing use of technologies for the management of health and well-being [335].
- Rising willingness to pay for technological health services or products [335].
- Digitization in society and diffusion of capable equipment: access to information and communication technologies not only for the generation of “digital natives” but also for the “generation X” [335].
- “Game-like elements” in health apps promote treatment compliance and motivation to improve performance [336].

Challenges

- Deficiency in data security as well as data standards [58].
- Need for a special health app store to simplify the search for the health app which offers the best individual fit [58].
- Wrong data collection either through errors in the app itself or through wrong usage of the app by the user [337].

Impact on the Future of Diabetes Care

Health apps have the potential to prevent the triggers of T2DM, such as obesity or a lack of movement, by supporting the user to live a more active and health-conscious lifestyle. Therefore, they help to avoid outbreaks of T2DM. In addition, health apps are useful “to support the self-management of chronically ill patients effectively and to increase adherence and compliance”. For example, health apps offer learning materials and patient diaries to help people manage their disease, including T2DM [338].

Emerging Business Models Utilizing Crowdsourcing

Increasing efficiency in business operations through knowledge crowdsourcing

When a group of people or “crowd” works towards a common goal, this is defined as crowdsourcing. Thanks to the growing worldwide connectivity, it is becoming easier for more people to collectively contribute to a cause [339]. The crowdsourcing market is rapidly increasing and is predicted to continue to expand over the next five years [340].

Problems are being efficiently solved through crowdsourcing by allowing many people to easily and effectively collaborate. GHDonline.org is using crowdsourcing by providing a platform which allows physicians all over the world to collectively collaborate on difficult medical cases. Since its launch, it has acquired almost 20,000 members belonging to 7,000 institutions in 185 countries and has helped to quickly solve many difficult cases [341]. Crowdsourcing can also be used to gather large amounts of data efficiently. Patientslikeme.com uses crowdsourcing to gather patients’ experiences and knowledge when receiving different forms of treatment. This knowledge is then shared on the website so that others can see how well the treatment works on other patients. Patientslikeme.com’s business model revolves around selling this data to companies in the Health Economics and Outcomes Research (HEOR) market or to companies doing market research [342].

Facts

- The Crowdsourcing market had a growth rate of 45% from 2011 to 2015 [340].
- Patientslikeme.com now has more than 200,000 patients on the platform and is tracking 1,800 diseases [343].

- Patientslikeme.com generates revenue by selling the data generated by the users to their partners.
- HEOR data is used by decision makers to decide whether a treatment is covered by health insurance, especially when there are many treatment options [344].

Key Drivers

- More people have access to the internet and social media [345] making it easier for people to share their experiences.
- Longer appointment waiting times from a shortage of doctors [346] causing patients to seek more convenient doctor visit alternatives.
- Decreasing patient satisfaction with their healthcare treatment [347].
- Increasing quantity and quality of free information on the internet.

Challenges

- Difficulties controlling the quality of the information shared which could result in inaccurate information [348].
- Privacy concerns when sharing health data online as there could be possible discrimination from employers, friends, and insurance companies towards the people sharing their information [348].
- When health data are shared, autonomy can be jeopardized [349].

Impact on the Future of Diabetes Care

Knowledge crowdsourcing platforms such as Patientslikeme.com allow for patients to see how other diabetics have responded to different treatments. This enables them to be proactive with their treatment instead of relying only on their doctor. It also allows them to better understand how the treatment can affect their daily lives, allowing them to make a more informed decision. This data can also be used by diabetes drug and device manufacturers to see how patients are responding to the treatment. Other crowdsourcing platforms such as GHDonline can be used to help diagnose diabetes through collectively collaborating on patient’s cases.



Value-based Healthcare Model

Moving from fee-for-service to value-based healthcare model: paying for quality not quantity

Healthcare systems around the world are struggling with the rising costs and uneven quality of healthcare services [350]. Patients who live in areas where Medicare spends more per capita are neither sicker than those who live in regions where Medicare spends less, nor do they prefer more care. They also show no evidence of better health outcomes [351]. With a VBC model, the care providers are paid based on the value of care they deliver and not by the number of visits and tests they order [352]. With this model, the physicians must consider the entire patient's experience, including the time spent at home and how the treatment fits best to their lifestyle. Managing the overall health and care delivery for a patient population requires an effective technology solution to efficiently collect, aggregate, and analyze patient data [351]. Some organizations have already undertaken large scale changes involving multiple components of the VBC agenda and have achieved striking improvements in outcomes, efficiency, and growth in market share [350].

Facts

- Health care systems worldwide are struggling with rising costs and uneven quality of treatment [350].
- An increase in healthcare costs is not strongly related to better healthcare quality, meaning healthcare efficiency improvements can be achieved [353].
- 51 m USD was saved at Sacramento ACO during the first 3 years they switched to a value-based model [352].
- There is a growing worldwide participation in the value-based payment model [352].

Key Drivers

- Rising costs and uneven quality of healthcare around the world are forcing healthcare providers to rethink the way they deal with patients [350].
- The widespread adoption of EHR has generated large amounts of data which can be used to assess the effectiveness of the treatments [354].

Challenges

- The change from FFS to VBC is financially risky and requires large capital investments, therefore healthcare providers are hesitant to change to a VBC healthcare system [352].
- VBC is a largely untested model and longterm impact on healthcare costs as well as patient satisfaction are still unknown [352].
- Patient data collection policies need to be changed as more data is needed to measure the treatment's effectiveness and cost for every patient.

Impact on the Future of Diabetes Care

With a VBC healthcare model, a patient with diabetes will only be prescribed drugs or tests which are necessary and improve the patient's life, reducing the overall treatment cost. It also results in a better lifestyle for diabetics as the physician will always provide the treatment which best fits towards the diabetic's lifestyle and provides the most value. This means the treatment will be adjusted towards a patient's lifestyle, and not the other way around, enabling them to live a more fulfilling life.

Scenarios

The following chapter describes four scenarios of different futures. The chosen scenarios are plausible, relevant, and of consequence for the user's decision, challenging, internally consistent, and recognizable from the signals of the present and near future. All four scenarios described below are equally plausible, extreme visions of how diabetes care might look like in the year 2035 with regards to two key drivers. Stories of personas experiencing a day in 2036 are used to envision the scenarios. Signposts (often described as weak signals) that indicate a development towards each scenario are identified in order to describe a possible path from the present to each of the four extreme futures.

63 Driver Matrix

64 Key Drivers

65 Other Drivers

66 Scenario Matrix

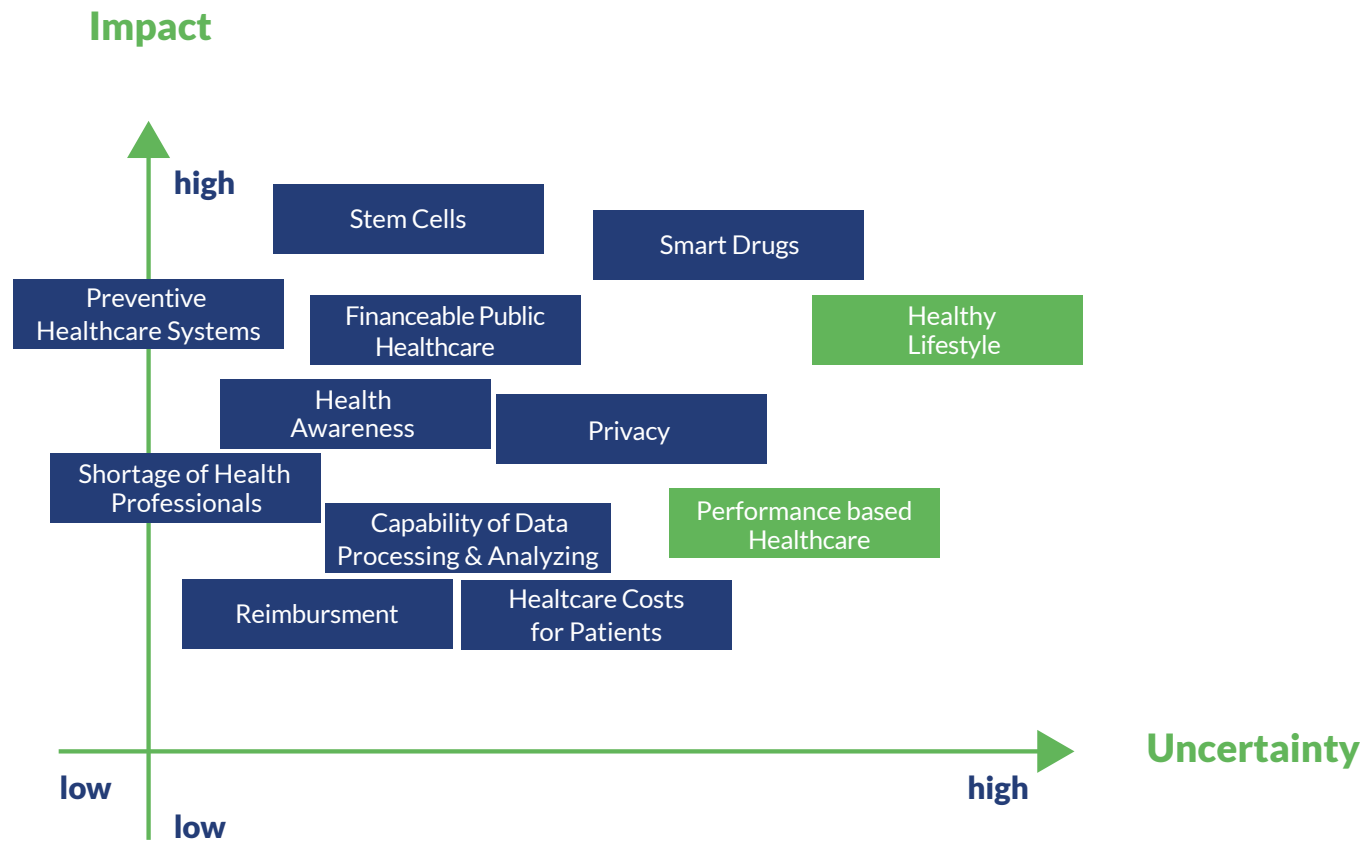
67 Scenario 1:
High Performance Culture

70 Scenario 2:
Healthy Living in an Unhealthy System

73 Scenario 3:
Tech-Driven Dystopia

76 Scenario 4:
Rank High or Die

Driver Matrix



The scenario building phase follows a structured approach. Based on the research from the basic phase of the Trend Seminar, current challenges and drivers for the future development of diabetes care are identified. Drivers are forces that shape the future of diabetes care and that are usually exogenous to an organization. All identified drivers are modeled with bipolar extreme outcomes. In order to create four equally plausible scenarios, two key drivers are combined in a scenario matrix (see page 66). The key drivers are characterized by a high impact on the future of diabetes care and a high degree of

uncertainty (i.e. it is impossible to assign probabilities to their respective outcomes). Furthermore, the key drivers are independent from each other and do not overlap.

In order to select the most suitable key drivers, all drivers are ranked in a matrix according to their respective impact and degree of uncertainty. Different combinations of potential key drivers are then compared and the best combination of key drivers is chosen.

Key Drivers

Extreme outcome: Nobody lives healthily

One extreme outcome is a completely unhealthy living society. There is no education about the right nutrition, leading to an obese and unhealthy population. In this case the government failed to enforce appropriate regulations concerning ingredients for food and education programs. The widespread acceptance of fast food and instant delivery services for processed food amplifies the problem of an unhealthy lifestyle. Due to new technology, people spend their free time at home. There are no sport facilities available as nobody is interested in engaging in physical activities. There are more people living with T2DM than ever before.

← Healthy Lifestyle →

The term “healthy lifestyle” takes into account all personal and social factors influencing the health of a single individual. A decisive element is the consciousness and awareness of a healthy lifestyle in society. This includes a comprehensive knowledge of healthy living. The involvement and efforts of individuals are essential for the implementation of a healthy lifestyle. Another aspect is the application of regular self-monitoring, the continuous alertness to early symptoms, and health changes in order to prevent diseases. Furthermore, the environment influences the health of every individual. The employment conditions factors, such as the working environment, occupational safety, and the average duration of work have an impact on a person’s physical and mental wellbeing. In addition, access to physical activity facilitations and healthy food can promote a healthy lifestyle.

Extreme outcome: Everybody lives healthily

In this extreme outcome the entire society is living a healthy life. Due to profound education, people have a precise understanding of healthy living and are living a health-seeking lifestyle. They value a balanced nutrition and force the food industry and gastronomy to adapt to these standards. People are interested in having accurate nutrition measures and use additional functional foods to optimize their health. Furthermore, staying active plays an important role, whether it is incorporated in the working day or during one’s spare time. Through self-management and by tracking one’s habits, everybody can control and improve their health.

Extreme outcome: Performance irrelevant Healthcare System

This extreme outcome describes a healthcare system where the prescription of the cheapest treatments is incentivized and not the quality. Insurances only reimburse the least expensive, conventional treatments. Therefore, GPs are incentivized not to prescribe expensive, high quality treatments which require self-payment. The smaller markets for innovative medical products result in severely slowed down research activities as less money is invested. Consequently, the healthcare system is inefficient as the cheapest treatments do not cure the illness best. GPs emphasize on treating symptoms instead of dealing with the causes of the disease. Since the effectiveness of a treatment with respect to the patient’s overall long term health is not evaluated, the lowest cost in the short term perspective acts as the most important decision criterion. Low-cost treatments with minor effects on patient’s health will also be prescribed, increasing the total amount of treatments in the long run.

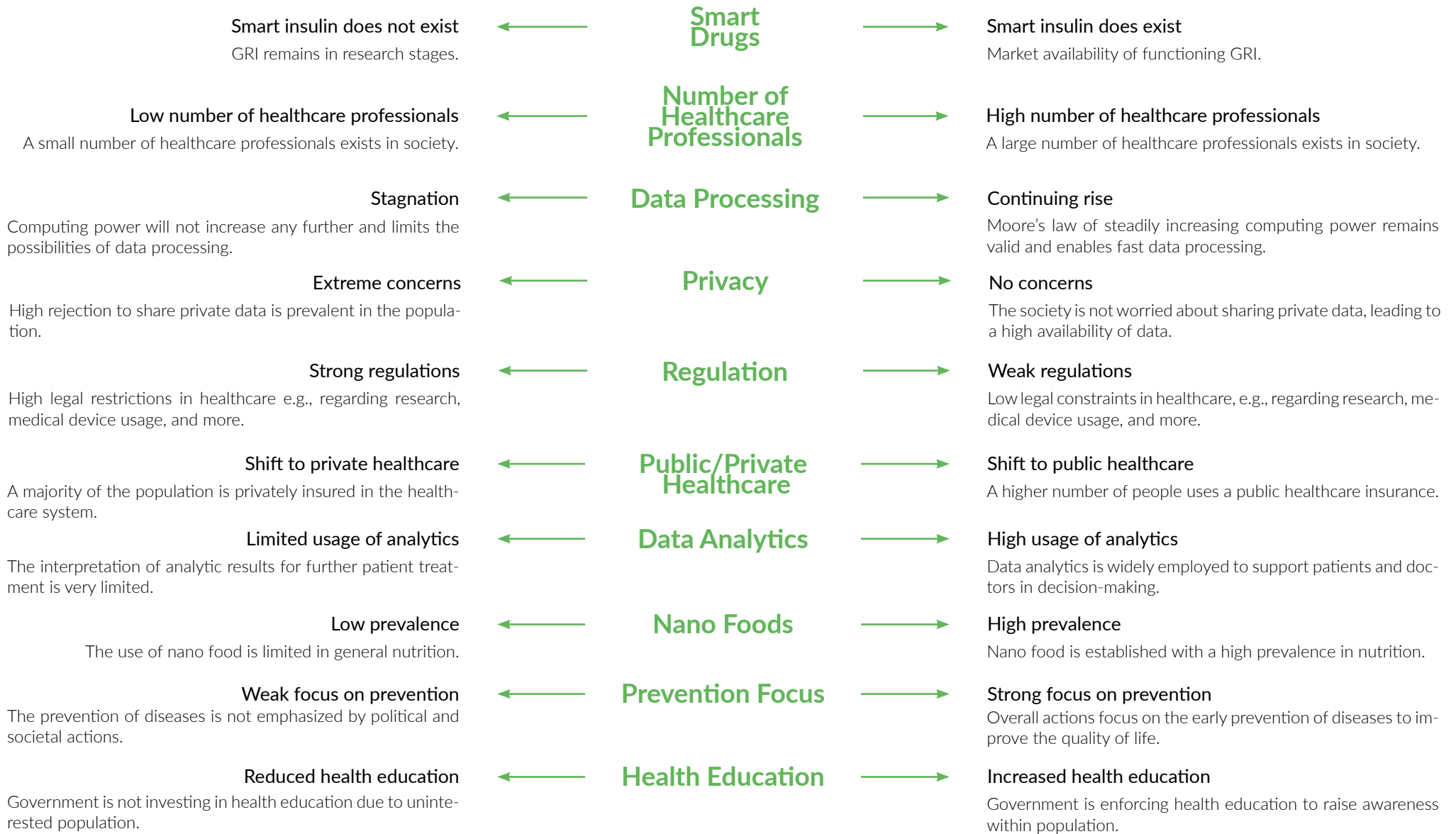
← Performance based Healthcare →

The healthcare system is currently under scrutiny since costs are rising (Porter & Lee, 2013) as well as patient satisfaction is decreasing (Raivio, Jääskeläinen, Holmberg-Marttila, & Mattila, 2014). A performance based healthcare model encourages general practitioners (GP) to focus on the patient’s overall wellbeing and treatment’s outcome. This is done by rewarding the GP’s performance, which is measured by various factors such as the recovery time and readmission rates. By rewarding the GP’s performance instead quantity and costs of treatments prescribed, the number of unnecessary tests or treatments is reduced and the patient’s treatment satisfaction is increased. To support a performance based healthcare system, patient data is needed in order to assess the treatment’s outcome and the patient’s response to a specific treatment.

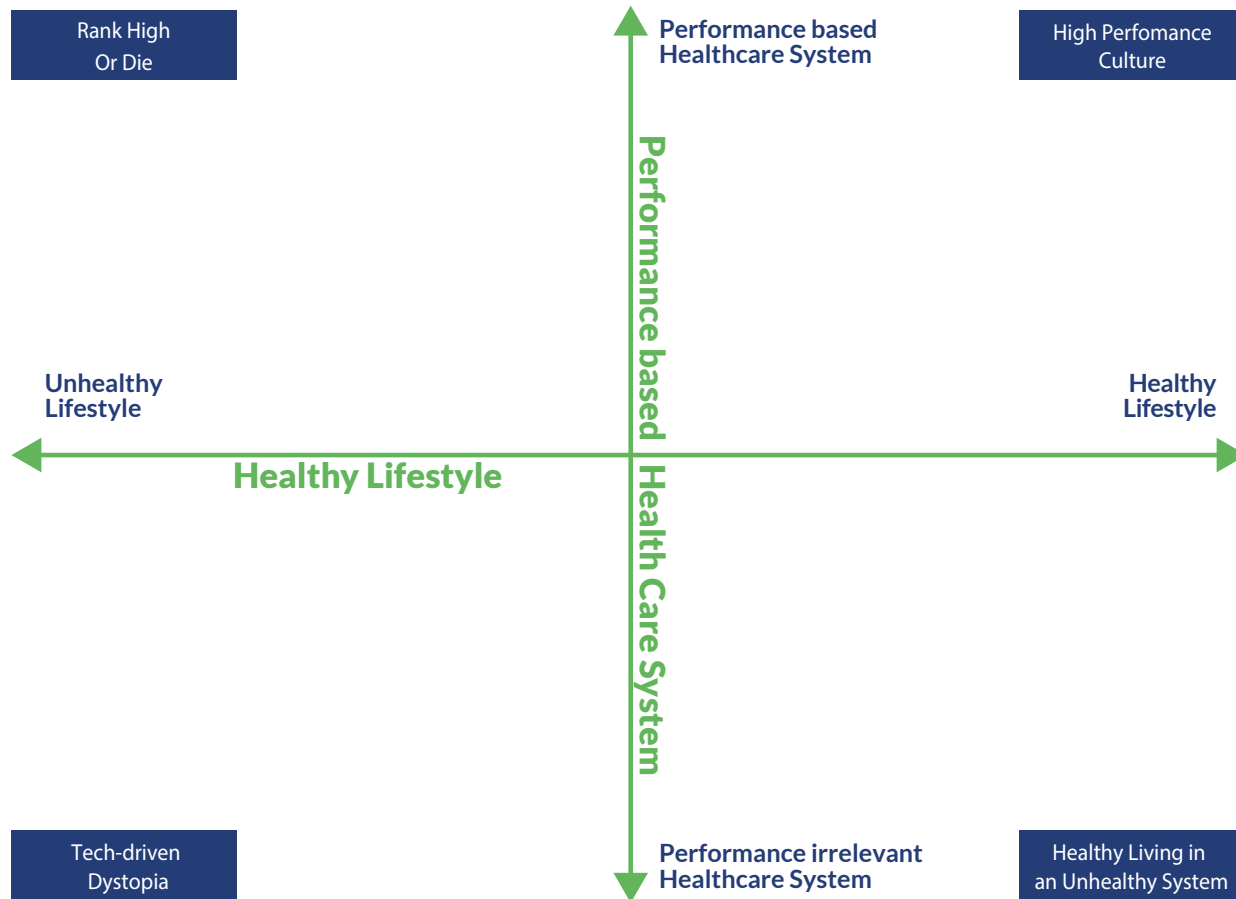
Extreme Outcome: Performance based Healthcare System

In a completely performance based healthcare system, the GP’s wage is dependent on the patient’s overall health. This increases the patient’s satisfaction, as treatments which provide the most benefit and fit best with patient’s lifestyle are prescribed. This also reduces the amount of treatments with minor beneficial health gains. This system is also very cost efficient, as only treatments which bring value to a patient will be prescribed and if started at an early stage of the illness, will lead to less follow up costs. Also, since the GP’s income is dependent on the patient’s response to a treatment, they might only see patients who can benefit from the current treatment options, possibly leading to severely ill patients being discriminated against.

Other drivers with high impact and a high degree of uncertainty



Scenario Matrix



The two key drivers and their outcomes create the scenario matrix. Each key driver represents one of the axes, with the bipolar outcomes on both ends. All four scenarios are based on extreme outcomes of both key drivers. Plausible and consistent outcomes of other important drivers are included in each of the scenarios, but not taken to an extreme.

„Rank High or Die“ describes a fully performance based healthcare system where an unhealthy lifestyle is highly common.

„Tech-driven Dystopia“ describes a world in which the spread of an unhealthy lifestyle is the same as in „Rank High or Die“, but the entire healthcare system is performance irrelevant. „Healthy Living in an Unhealthy System“ is a future with a purely performance irrelevant healthcare system without any unhealthy lifestyle. Accordingly, „High Performance Culture“ describes a future with a fully performance based healthcare system without any unhealthy lifestyle.

High Performance Culture

A day in 2036

In the city center of Berlin, Alex wakes up at 5 am. Without hesitation, his first move is to grab his smart wristband. He then smiles as puts the wristband back on the docking station next to him. He keeps forgetting that he no longer has to handle the device with his hands. "How is Lea?" he asks his wristband which has become a monitor for his daughter's health. "She is currently sleeping. Her blood sugar is 97 mg/dl and her HbA1c at 37 mmol/mol. Her eye movements suggests she will finish the current rapid eye movement (REM) sleep phase in about 1 hour and 45 minutes, which will be the best point to wake her up."

Alex sighs and gets up. His daughter is well. However, his own health values are not nearly as promising as his daughter's. Alex has T2DM and suffers from obesity due to bad eating habits he developed when his wife died in a car accident. While he is quickly changing into his gym clothes, his smart wristband informs him about his daily workout plan. He steps on the scales and Performance, the governmental personal fitness application, starts calculating his optimal workout plan. "Alex, congrats! You lost weight compared to last week! You are on a very good track. Since you have to be done 15 minutes earlier today to wake up Lea in time, I suggest the highly effective Zelos-training. It stimulates your cardiovascular system and supports your weight loss goal." Alex puts on his virtual reality (VR) glasses and starts the fitness program.



"Alex, it's 6:45 am, please wake up Lea". Alex looks at his smart wristband, swipes to stop the electronic voice and walks to Lea's room. "Good morning, sweetheart! Time to get up!", Alex calls out. "I'm awake, Dad", Lea answers. She talks fast. "Dad, are you joining me today to do Performance?" "I already did my training. Got a new personal best time!", Alex answers while he hands her a glass of water and adds: "Drink! You are dehydrated again, sweetheart."

While Lea is training and getting herself ready for school, Alex goes into the kitchen and uses his smart wristband to check the daily nutrition recommendation for him and Lea. In order to lose

weight, Alex drinks functional shakes instead of eating natural food. But he could never stand for Lea to get into his position, so he makes sure she eats healthy fresh food every morning. He tries to remember the last time he cooked for himself - it must have been 5 years since functional foods really started to break through. Since his and Lea's health status are analyzed in real time, and their unique genetic makeups are considered, the recommendations that he receives via his wristband are tailored perfectly to his body's needs. He touches his wristband to request the recommended shake that is created by a kitchen machine next to him. "Only 30 minutes until school starts", Alex notices with a look on his wristband. Shortly afterwards, Alex

High Performance Culture

slips into his e-car together with Lea. He knows he should take his bike. But Alex cannot face how strangers keep looking at his chubbiness, often muttering barely concealed insults. Going by car is the small bit of indulgence he allows Lea and himself.

In the car, Alex thinks: "Mornings are a lot easier, nowadays". For him, it had been such a relief when Lea received an AP two years ago. Before that, Lea had suffered from the dawn-phenomenon, repeatedly awaking in the morning with high blood glucose levels due to nightly hypoglycemia. This phenomenon is prominent among children and adolescent Type-1 diabetics. The new technology has resolved most of Lea's problems. It constantly measures and reacts to her blood glucose level in a closed-loop system. Lea can live an almost normal life now, and, apart from some check-up visits every six months, she does not have to see the doctor much nowadays. Despite its very high cost, the AP has been fully reimbursed because it prevents any kind of hypo- or hyperglycemia and consequently reduces the

risk of follow-up diseases. "The introduction of the performance based healthcare system really was a pivotal turn", Alex thinks. Doctors are nowadays encouraged to choose therapies based on their long-term efficiency, rather than on short-term costs. This has enabled children like Lea to get an AP – no matter their parents' budget.

Alex profits from the new healthcare system as well; his T2DM was diagnosed at an early stage and counter-action could be taken immediately. He was provided with workout plans and special nutrition. Because of this early intervention, he has a good chance of being cured from his diabetes in the long-term, yet he should have never let it come this far. He had always known his habits did not fit the society's idea of a healthy lifestyle. "But at least I will make sure that Lea will adopt a healthy lifestyle. She already gets taught at school about living healthily and I do my part by making sure she complies to a healthy diet", he thinks.



After dropping Lea off at school, he is parking his e-car at the office building when his smart wristband vibrates softly on his wristband. "Remember, you should take the stairs, Alex", flashes up on the display. Alex sighs, his smart wristband is right; those are the many small things that will help him to get back into shape. "Good morning, Alex! Congratulations on your new personal best time doing Zelos." Alex looks up and sees Miriam passing by the escalators. He sometimes forgets whom he has approved to see his personal health data. In the beginning he shared his medical records only with physicians but since he found it motivates him, he decided to share it with some friends and colleagues as well. "Thanks Miriam!", he answers hoping that she might go out with him once he is in better shape.

Slightly out of breath, Alex arrives at his desk. He sits down, puts on his VR glasses, and starts checking his messages on his virtual screen. Three hours later, his break starts and he walks up the

stairs to the company's gym. Alex takes part in the company fitness program. Today, the group of colleagues is doing an hour of a high intensity indoor cycling workout. It was introduced to reduce the employee's stress level and to promote a healthy lifestyle. After the training, Alex goes to the fridge to have his second functional food shake of the day. His smart wristband notifies him that his insurance premium has been reduced by five EUR this month for his efforts.

In the afternoon, Alex continues to work on his assignment before he leaves to pick up Lea in the late afternoon. While driving, he thinks back to 2030 when he had his crisis. He used to work too much and care too little for his own health, especially after the death of his wife. He became obese and as a consequence, developed T2DM. His rescue came with the roll out of the performance based healthcare system almost a decade ago. "Although it is tiresome having to drink shakes instead of eating real food and being constantly reminded to workout, the effects are nice", Alex thinks.

"Lea is waiting on the left side of the street", exclaimed the electronic voice of the car, pulling Alex out of his train of thought. Alex stops the car and Lea hops onto the passenger seat. "Hi Dad!" "Hi Lea, sweetheart, how was your day at school?" "Aw, it was boring. Ms. Meyer's health literacy lessons are always the same. But the physical education class was nice, I actually had one of the best swimming lap times!". Alex smiles to himself and answers: "Cool, well done!".

At dinner time, Alex checks for the recommendations from the nutritional advisory app on his smart wristband. He quickly agrees to the suggested shake for him, which comes out of the machine a moment later, ready to drink, and starts choosing Lea's food from an automated preparation system. When Lea enters the kitchen, she smiles. She sits down at the table where Alex has already put her food and his shake. "When are you gonna eat normal food again, Dad?", she asks a little worriedly. "Soon, sweetheart. I know it's weird for you, but it's really helping and I will be alright again if I strictly stick to it for a while." He takes a look at his wristband, his blood glucose level is 97 mg/dl. His medicine is already included in his shake. He is glad that he never has had to experience measuring blood sugar by pricking his finger and that he could take his insulin orally. "What a dreadful life diabetes must have meant 20 years ago", he mutters to himself.

After Lea has gone to bed, Alex gets a notification from his wristband: "You received a health status update, Alex." He is glad to see that his prevalence to blindness has decreased. "Good thing, Dr. Summers takes really good care of me", he thinks. He rarely sees his diabetologist in person, yet she receives and monitors all his health data. Most of their communication is done via telehealth systems, as she has many patients to monitor. Except for occasional scrutiny, he rarely has to go to the doctor's office for appointments. In Alex's opinion, this is a smooth way of dealing with the shortage of physicians.

His wristband vibrates softly to inform him that he needs to start getting ready for bed now. Before he falls asleep, he checks his wristband one last time: his blood glucose level is perfect.



Signposts

- Sugar tax is introduced
- A major European fitness company introduces VR to all of its studios and enables VR home training
- Smoking is ruled illegal
- EMRs are standardized
- The law enables citizens to choose who has access to their private health data
- Holistic tracking of personal health by smart devices becomes ubiquitous
- How to stay healthy in a modern world becomes a major part of the education system
- The performance based healthcare system is rolled out
- Strict regulations for food production (ban of fast food venues in its current form)
- Predictive analytics is routinely used to estimate chronic disease prevalence
- Healthcare costs decrease and diabetes related complications are at an all-time low
- Average life expectancy reaches 90 years

Healthy Living in an Unhealthy System

A day in 2036

7:15

The alarm starts to ring quietly while the sunlight, emitted by the lamp on his nightstands, gets brighter. Time to get up. Timothy opens his eyes and lifts his body into an upright position. He starts his morning routine with a look at the tracker on his wrist. The graph shows he slept well: Seven full REM-cycles. Nevertheless, he doesn't feel very well rested. The same recurring nightmare haunted his dreams again. In the dream, he successively becomes more overweight and the more he exercises the faster his health worsens. Trying to forget about it, he shakes his hand. After a quick shower he goes down to the kitchen, where his breakfast is already waiting for him: The delivery-drone has brought the customized mixture half an hour ago. It is the same arrangement as every day: A grey nano-pulp consisting of all nutrients his body needs and the white flavorless chewing brick which is used to exercise the jaw muscles and teeth. After saying goodbye to his mom and dad, Timothy grabs his bike and starts riding to school. The dim sky has a cloudy grey color. He takes a shortcut over a small green meadow to get to the bike-highway faster. It is rush hour, but ever since the bicycle-expansion-regulation of 2023, where all cars except the necessary heavy-transport vehicles were banned from the inner city, there have been no more major traffic jams. The way to school takes approximately 20 minutes, but his proud personal best is 11.5 minutes. After leaving the bicycle lane and arriving outside of the massive concrete school complex, he gets off his bike. As he walks towards the entrance, he takes a look at his vitals, which are displayed on the colorful screen of his wrist tracker. His heart rate is fine, his oxygen saturation is a bit low, and he burned almost 150 calories. Overall the stats are still within the normal limits. He is almost at the main gate when he hears a voice behind him: "Timothy! ...Tim! Wait!". It's

his friend Bryan. As Bryan catches up he gasps: "Hey!" between two deep breaths. They go through the gate together and hold their trackers against the scanner at the checkpoint. The scanner checks for changes in weight, nutritional levels, and exercise habits. Agreeing to the tracking of private health data is mandatory for attending high school. Whenever the scanner logs unhealthy changes in diet and exercise the principal is contacted. This year Bryan already had to go to the principal's office twice because his BMI rose above 22. Today though, the happy green face on the screen lights up, as both boys enter the school smiling.

09:00

Timothy is rather worried about the food history test he has to take in his next class. It covers the diabetes pandemic that started 50 years ago and could only be contained by high governmental efforts and the embrace of healthy living amongst the population. Timothy still can't believe how irresponsibly people treated their bodies back in those days - health is the most important thing in life, everybody knows that! During

his test, he also thinks about his grandpa who has to watch his nutritional intake even more than everybody else: He has got age related T2DM. Timothy takes a silent note to himself, reminding him to check his grandpa's blood glucose level on his remote tracker later.

The bell rings. Finally, the exam is over! It's time for the lunch break. All children rush outside to the schoolyard, which offers basketball courts, football fields, and even a swimming pool. He and his friends are highly competitive and they love to beat each other's high scores. After being exhausted from all the activities, the children gather together in the cafeteria. There are fruits, vegetables, fish, and all kinds of fresh, healthy foods. He remembers from kindergarten that it is best for his still developing body when he combines 50% vegetables with 25% healthy carbs and 25% good protein on his plate. There used to be soft-drink machines at his school but tap water fountains that offer fresh water and additional nutrients have replaced them. Having consumed such a well-balanced meal, Timothy feels energized again and leaves the cafeteria for the his next class.



13:00

In order to educate the children in a practical way, every week a different profession is presented to Timothy's class. This week, doctors from the neighboring hospital introduce the children to their everyday routine and the healthcare system. Trying to give them a historical perspective, they inform the children about the world 20 years ago: the unhealthy food, the lack of fitness, and increasing obesity, which lead to the T2DM pandemic. Tim cannot really imagine the world back then, as he rarely meets anyone obese and thinks only the uneducated people in society are overweight. The doctors continue to talk about how they handle patients: "It's really hard to be a doctor these days. Insurances only pay for the performance of treatments. Due to the general lack in physicians, there is a lot of pressure on the public insurances. Therefore", he continues, "doctors have to treat a large amount of patients in a very short time in order to make a decent living. People who can afford to get private insurance are certainly better off." I do not know whether I would recommend becoming a doctor." The doctors seem defensive as they try to justify the lack of innovation and quality in the healthcare sector. Bryan interrupts them with a question: "If I gave you my tracker data would you treat me better?" – "We only treat you, if you have symptoms of an illness. Otherwise we won't get any money. We can't treat the healthy people. It's important that we treat acute symptoms well, but it's your responsibility to avoid chronic ones by living healthily. You can be proactive about your health by using your tracker data." The class seems to agree, as they are used to checking their vitals continuously. After a few more questions the students leave school with a broader perspective on a doctor's daily life.

15:00

After school, Timothy decides to visit his grandpa Gregory, who has had Diabetes for almost 20 years. He wants to question him about his disease and discuss the general change of lifestyle with him. "Grandpa, how come so many people in your generation developed diabetes?". Gregory tells Timothy that there were unhealthy foods everywhere around them. So-called "fast food restaurants", which offered highly processed food containing too much salt, fat, and sugar were really popular and people had not yet grasped the importance of healthy nutrition. "On the other hand", Gregory continues, "people knew how to have fun

back then. You know, your mother and her friends used to go out at night and have a beer on the public places downtown! No one could imagine public drinking nowadays!" Timothy wonders why he has never discussed his grandfather's illness with him. "How is your diabetes treated?", he asks curiously. His grandpa lifts up his shirt a little bit so that Timothy can see the little box on his belly. "This is an AP", he explains. "Almost 20 years ago, this device was a real breakthrough in technology because it enables people to quit on manual blood glucose measuring.

Unfortunately, shortly after this, we had a change in insurance policy and innovative products did not get promoted anymore." Suddenly, Timothy's tracker starts to beep insistently. He remembers that he has not had enough exercise today. Even though Timothy still has a lot of questions on his mind, he says goodbye to his grandpa and puts on some extra speed on his bike.





18:00

Having arrived at home, his father is already waiting for him and wants to quickly check his tracker before dinner. As soon as he finds out that Timothy's vitamin measures are not optimal, he worriedly sends the tracker data to VitaBird, a company that delivers a personalized vitamin package within half an hour. Sometimes, Timothy gets annoyed by his father's constant health concerns and he often tells him to stop being a hypochondriac all the time. Luckily, his dad prepared his favorite dish for dinner: They are having 3-D printed meatballs with zucchini and tomatoes from the urban gardening community.

the lighting to help them sleep better. Their scent diffuser distributes etheric fragrances in the sleeping rooms that foster relaxation. She kisses her little boy and before he falls asleep, Timothy thinks to himself: "Hopefully, I will be spared from any bad dreams tonight".

20:00

Shortly after dinner, Timothy's mother takes the elevator up to the rooftop fitness studio in their apartment building. She had a rather stressful day at work and could not attend the daily workout session at the office. She loves the fact that a couple of years ago, the government introduced a law calling for at least one gym room in every ten-flat apartment building. When she returns from her workout, the family's intelligent housing system has already filtered all blue light waves from

Signposts

- Health and nutrition education becomes mandatory at all public primary schools
- Obligatory "traffic lights", indicating nutritional value, are introduced on all processed foods in Europe
- Fitness tracker usage exceeds 75% for people between the age of 16 and 65
- Introduction of health data-driven insurance: All insurances offer financial incentives for reaching activity and nutritional benchmarks
- Average life expectancy rises to 85, leading to an increase in healthcare costs and pressure on the healthcare system
- Switch to mass produced general medication instead of patient specific treatment due to austerity measures
- Time spent per patient decreases and patient satisfaction reaches all-time low.
- A refined sugar tax of 7% is introduced
- Strict regulations on advertisement for tobacco and alcoholic beverages is also applied to unhealthy food
- Clean tap water is available in every major European city
- Market share of functional foods exceeds processed foods
- Bike highways are completed in all major European cities
- A decreased demand in the health sector forces reductions in overall research and development (R&D) spending and the diabetes product market stagnates

Tech-driven Dystopia

A day in 2036

A day in the life of Jonas in 2036

Beep, Beep, Beep - the aggressive noise of his smartwatch jolts Jonas out of his dreams. After snoozing for as long as possible, he needs two attempts to lift his heavy body out of the bed. When he finally manages to get up, he starts to slowly make his way to the bathroom. Due to his obesity, he cannot reach most parts of his body himself and thus cleaning himself is extremely exhausting. But ever since he got his new extra wide fully automatic shower, he is starting to actually like it. He believes the shower is one of the more useful things he bought recently. Now at the age of 25, two years after he has been diagnosed with T2DM, he is still not used to the flashing light inside his contact lenses, reminding him to take his medicine. His doctor told him repeatedly to lose weight, but since the fat acceptance movement caught on and fashion models adapted in size, the social pressure of being slim vanished.

Afterwards, he starts his day with his usual breakfast, consisting of the XXL microwave bacon & eggs breakfast package, 1l of orange juice, and a bowl of sweetened cereals with milk. While eating, Jonas gets the latest news via his smartwatch. He quickly skims through the headlines - unemployment rate reaches 30% in Europe - suddenly a pop-up ad appears on the screen. Annoyed by the uselessness of his ad blocker, he listens to 30 seconds of advertisement for fat burning ice cream.



“What kind of people will eat this type of food?” he asks himself. Jonas tried functional food once during his last hospital stay, as part of a treatment for his kidney problems and hated it. He loathed the flavor, consistency, and the look as it reminded him of the so-called “natural food” of his childhood. Furthermore, the price of natural foods is skyrocketing and with his income, Jonas and everyone he knows is unable to afford it. Like most people, Jonas only eats artificial and processed food, which is delivered directly to his apartment.

After breakfast, his contact lenses automatically measure his blood sugar level and recommend him to take three pills. He forgets to brush his teeth and drops powerlessly into his orthopedic armchair, the only one that is reimbursed by the insurance, but so cheap that it is not helpful against his backache. “Time to start working”, he thinks, as he puts on his professional VR headset and grabs the two controllers. Jonas is working as a drone operator for Euro Logistics Company.

For lunch, he uses the McDonald’s home delivery app and orders the deal of the day. Five minutes later, the meal arrives and his home and his personal assistant robot brings it to his chair. After lunch, his smartwatch reminds him to go for a walk, but he decides to skip it. Three hours of repetitive and boring work later, a pop-up appears and a pleasant female voice starts talking:

“Dear Jonas, we regret to inform you that your employment is hereby immediately terminated. In these difficult economic times, we see ourselves forced to replace expensive human work by fully automated robots. We wish you a successful career.” Jonas drops the glass of lemonade, which he was holding in his hands. Shocked and upset, he removes his VR glasses and stares at the wall. He feels betrayed because the company just recently announced their plan to keep their workforce and even plans to increase it. Now he is part of the 30% unemployed. At least there is a basic income provided to everyone, which allows him to keep his living standard.

However, he does not have much time to pity himself because shortly after, his smartwatch starts to vibrate and the face of his doctor appears. After having a look at Jonas’s real time health data, the doctor informs him that he has to move more and to stop skipping the recommended exercises. Furthermore, the doctor reminds him of taking his medication and pushes him to continue with his MOOC based health education. Jonas feels that the doctor should not have such access to his health data, as he does not know what is being done with his data. “If you are unhappy with the medication and the recommended MOOC you can still get a sleeve gastrectomy, but you will have to pay for it yourself. The insurance only covers the cheapest treatments”, the doctor proposes. Now, since he is unemployed, Jonas could not even afford to have a surgery - even if he would have wanted it.

Tech-driven Dystopia

Frustrated by this stressful day, he orders his favorite food and decides to watch a movie. He barely makes it through half of it before falling asleep in his armchair.

A day in the life of Hannah in 2036

“Good Morning Hannah, hope you had nice dreams. It’s Tuesday, 13°C outside. Your blood glucose level is 120

mg/dl” After Hannah wakes up, the smart bed changes the sheets automatically and Hannah checks her health app. According to the app, her life expectancy has decreased by 1 month in the past weeks. “I really need a vacation”, Hannah thinks. The negotiations about replacing the drone-controllers in the logistic plant with robots have been very stressful, allowing Hannah to sleep only 4 hours a day over the past weeks. It rains outside. “Not again”, Hannah murmurs and asks her personal electronic assistant, “Javis, set up the VR jogging program, I’d

like to run in Manhattan.” “Of course”, Javis replies, “What would you like for breakfast? I suggest to eat 600 calories this morning, and Amazon Fresh food delivery just arrived. How about a cup of mixed juice with two Energy Eggs?” Hannah nods. In the past years, processed food replaced natural and organic food as the new commodity. Natural foods, functional foods, and nano foods have become luxury products that only the upper class of society can afford.

While commuting to work, the Euro Logistics Company, in her self-driving e-car, Hannah skims through the latest news: “First smart insulin provided by Smart Insulin GmbH, a small research institution financed by some of the richest Europeans, makes it to the market with a starting price that 99% of the population of Europe cannot afford”. “Finally the cure”, Hannah smiles as she has been looking forward to replacing her AP with non-invasive drugs. “Javis, what is my agenda for today?”, the car answers, “You have a VR visit at 10:00 am at the logistic plant in Tokyo and at 11:00 am the meeting regarding the automatization of the plant scheduled.”

After the VR visit of the logistics plant in Tokyo, Hannah is convinced about automating the drone operator’s jobs. Since they implemented the automated employee rating system, Hannah does not have to decide which person to fire anymore. The shift to the automated firing system has relieved Hannah from the burden of firing people herself, especially since the amount of fired people has increased considerably in the past years due to the artificial intelligence revolution that is transforming the industry.

For lunch Hannah eats at the best nano food restaurant in town and orders the nano-coated salmon, which enhances her kidney function and eyesight. Hannah’s colleague looks sad as he just received the blood diagnosis results from his doctor informing him that his child is at a Type-1 prediabetes stage. Hannah’s colleague asks, “I don’t know what treatment my child should receive if he has diabetes. The insurance reimburses only the cheapest treatments but which treatment is actually worth paying the extra money for?” “I personally would recommend the AP. Since I started wearing it, I don’t have to think about measuring anymore”, Hannah replies. “Oh, that sounds nice. By the way, have you received the last update from the government? They have increased taxes by 2% again”. “What? I don’t want to pay even more money for everyone else”, Hannah complains, “Those people spend their lives in a virtual world, eating junk



food and are burdening our healthcare system and now I have to pay even more? I wonder how much money the healthcare system would save if there was a higher health awareness and education. If I were a politician, I would ban all the processed food. They are the cause of obesity. I remember I used to sleep in a 90 cm bed when I was young. Now, the smallest bed one can find in stores is 120 cm wide.”

Hannah considers the current public education system as being very poor, since it is online and the children barely have any contact with their classmates. Therefore, she enrolled her children at an elite boarding school. After the exhausting workday, Hannah books the holiday for her and her children, whom she has not seen for a long time. While looking for holiday packages, she is surprised by how cheap the trips to Hawaii are. Unfortunately, those packages are VR holidays only. “Some people do not even move while going on holiday”, Hannah thinks. She has great expectations for the future holiday at the organic holiday resort. “Being in contact with nature again! It will be the perfect break from this world that is heading towards a collapse”, she thinks. With this thought and after drinking her multivitamin, one-meal, nano-fortified smoothie, she goes to bed while checking her health app again. The launch of the smart insulin and booking a holiday made her day, thereby increasing her life expectancy.



Signposts

- Artificial intelligence and robotics revolution cause a 30% unemployment rate
- Strong inequality gap due to artificial intelligence revolution leads to a concentration of wealth on the small elite part of society
- VR becomes affordable and mainstream, therefore people's lives shift from the physical world to VR in areas such as sports, work, entertainment, and holidays
- Food delivery services, especially for processed foods, become the most popular channel for buying food
- Guaranteed basic income for every adult
- Guaranteed health coverage through holistic public insurance
- Social safety net becomes biggest part of public budget, financed through high taxes
- Big advancements in medical research lead to population caring less about personal health
- Obesity rates and therefore T2DM rates have increased tremendously over the last 20 years to 20% of the European population
- Strong discrepancy in education between people relying on basic income and the elite
- Prices for organic food surge and functional food becomes mainstream for the elite

Rank High or Die

A day in 2036

Dr. Susan Green enters her office on the fourteenth floor in Medical Valley. The walls and ceiling of the bright room are as smooth as glass. The room is minimalistic in its furnishing with just a glass-topped table on an iron frame and a black leather chair. The big screen in the middle of the room automatically turns on as Dr. Green sits down. Today is teleconsultation day. Dr. Susan Green takes a deep breath. Consultation day means a tight schedule, many patients, and hard decisions that need to be made. A computer voice announces her schedule, "Good Morning Dr. Green. Today you have 47 appointments." She gasps, "It's hard to find help these days." Being a doctor is her dream job, but she also struggles with the current performance based healthcare system, which determines the patients that will be treated. On the one hand, she enjoys how effective her job has become and the improved quality of treatments. On the other hand, she sees downsides to the system, as some patients cannot be treated due to economic restrictions. Making life or death decisions on a regular basis has forced many physicians to quit due to severe depression and burnout which overall led to a reduced healthcare workforce.

A notification interrupts her thoughts. It's time for her first patient. "Give me some information about the next client." The digital medical assistant MEDecision v3.2 displays a picture



of a 12-year-old girl. Dr. Green looks at her health data. As always, she is impressed by the processing power of the computer, which is able to make better medical judgment than any human could ever do. This would have never been possible if the government had not diminished the strong regulations concerning data privacy. Also patients are now more willing to share their health data because it has a positive effect on their chances of treatment. She looks at the ranking calculated by the algorithm and quickly becomes aware that the girl's situation is

beyond remedy. She received a five, the lowest ranking possible, meaning a chance for curing the disease is very small and the insurance of the girl will not cover any therapy. Although Dr. Green has done this job for many years, it is still especially difficult for her to tell parents that she will not treat their children. The healthcare system only allows her to get paid in case of a beneficial outcome. Therefore, she exclusively treats patients with a high chance of treatment success.

Meanwhile, in the city center around 10 am: It is time for Max Smith to get up. Mornings aren't easy for him; he decides to push the snooze button for the fifth time. As he attempts to get up, his electric bed automatically adjusts itself, so that Max can get out of it with less effort. It has been hard for him recently, as his knee problems and obesity have become worse over the last weeks.

Slowly, he drags himself into the bathroom. He turns on the shower and his preferred water temperature is adjusted automatically. Starting to wake up, he hums the tune of his favorite song. In addition, the shower autonomously measures his weight. This data is immediately forwarded and stored in his digital patient file.

Back in his small living room, a big glass front offers a view of the city. Due to air pollution, Max can only see the next skyscraper twenty meters away. His living room consists of a big refrigerator, a comfortable seat, a surround sound system, and a microwave. He works as a software developer and has a decent salary. His biggest expenses are his rent and his private insurance. Max is not the only one who is privately insured, many people switched from public to private insurances in the last years to get a better MEDecision ranking.

Even after showering, Max feels a bit shaky. Additionally, every morning he feels lightheaded and very hungry. He opens the refrigerator; "Where are the chocolate donuts?" Realizing he had eaten the last one yesterday he heads to the door, opens it, and is relieved that the package is already there. In those moments Max is always overjoyed that he has acquired a smart refrigerator that immediately delivers his favorite foods when he runs out of something. He bends down to pick up the box, but he can't reach it because of his own weight. „Helpy!“ he shouts. From a corner of the living room, his small, ergonomically shaped service robot Helpy approaches. "Put the groceries into the fridge." The robot extends its tongs and heaves the shopping

bag effortlessly upwards, drives towards the refrigerator and quickly stows the groceries in it. Smiling, he reminisces how happy his mother was, when he gave her a service robot a year ago. Since then, she has already become completely immobile with multiple diseases and will not be treated anymore by physicians as she is ranked with a five. Therefore, she especially needs assistance. With a chocolate donut in the one hand and a big strawberry milkshake in the other, Max drops into his wing chair. Automatically, a hologram screen activates in front of his eyes and the surround sound system chimes an advertisement with a strong, convincing voice, "You need supernano food. Don't lose time eating out in restaurants. Have a meal in a cup, great taste combined with healthy nutrition!". "No, that's nothing for me. I enjoy natural food and the delivery service is already very convenient," Max thinks. Suddenly, a reminder pops up: Doctor's appointment in five minutes. "Shoot. I almost forgot about it." Quickly he gets his telehealth equipment, which autonomously measures his health data. Being able to do all that from home is extremely convenient for Max. His mother still tells him about times where patients had to go to a doctor's office and wait for a long time. Max also had to wait ten months for this appointment,



but since he changed his private insurance provider last month to a more expensive one, he got it faster.

A window on his hologram screen pops up, the connection between him and his physician Dr. Green is established. "Hello, Mr. Smith. How are you doing? I see your new health measurements are already in the system. Very good," she greets him. "Hello, Dr. Green. Good to see you. I wanted to speak to you as I have been feeling quite bad lately. I have to work a lot, so I can't afford to get sick. My boss really depends on me, as so many colleagues of mine are already on sick leave." Dr. Green nods, "Yes that's a common problem, Mr. Smith. In our fast-paced society, many can't cope with the stress anymore. Well, let's take a look at your health data. Ok, so our intelligent health system detected that you have dangerously high blood glucose levels. You have developed T2DM." "Oh. What's that?" Max worries. Dr. Green explains the disease to Max, who responds, "Never heard of it, it doesn't sound good. How did I get it and what can I do?" "Well, physical activity and a healthy lifestyle are the best preventive measures for T2DM. Although in our society this is very uncommon, as most patients don't have time for it. Engaging in a healthier lifestyle can also benefit the treatment process of diabetes," Dr. Green clarifies. "Uhh, well I don't know. I really need my chocolate donuts in the morning and my cigarettes. But I have been trying to play sports over a VR platform. It's fun, but in real life, I don't have the time for it. I heard that there are more

Rank High or Die

smart drugs on the market? Where you just take one and feel good again,” Max asks in a hopeful tone. “Hmm. Yes, that’s true Mr. Smith, unfortunately, those are barely tested on humans yet. But since T2DM incidents have risen dramatically over the last years, research in this area is flourishing. A possibility is, for example, an AP. It’s like your health belt, you just wear it and insulin is injected depending on your blood glucose level,” Dr. Green explains. “Yeah, that sounds like what I was looking for. But how are my chances of treatment?” Max asks. “Looking at your current health numbers, I can tell you that they are pretty good. I will send you a notification in a few hours when all patients are done for the day.” “Perfect, thanks. I hope it works out.” “Me, too,” Dr. Green thinks, “Mr. Smith seems like a nice guy and he is still very young.”

The telehealth-call is over. Dr. Green studies Max’s data again. No signs of any additional diseases. He has also continually

shared his health data, so the prediction of treatment success must be extremely accurate. Unlike the mentioned 12-year-old girl, she expects him to get a one or two as a ranking. Back in the city center around 7 pm: Max is increasingly nervous to know whether he will get a chance to be treated. In the afternoon he talked to his mother, who told him that he might not live very long if he does not get any treatment. The only other possibility remaining is to serve as a guinea pig for pharmaceutical companies, who try out their new medicine on patients who get refused by physicians.

A gong. He heads to his hologram screen and reads, “New notification from Dr. Green.” His heart races: Will he feel better soon? The message reads: “Congratulations. You have been ranked as one. Your appointment for treatment is scheduled. We’ll await you in six months on November 5th, 10 am in Medical Valley.” Relief.

Signposts

- Two-thirds of health professional’s payment is based on successful treatments instead of absolute number of treatments
- European Union enforces the use of EHRs in every European country
- 80% of German physicians make their diagnosis based on algorithms instead of human judgment
- For the first time more people in Europe are privately insured than publicly
- Half of the people in Europe use fast food delivery services, on average, more than three times a week
- The average BMI in European countries increases to 29
- Life expectancy of male Europeans drops to 70 years and birth rate drops to 1.2 children per European woman.
- European fitness studio market shrinks annually by 11%



Ideation

The following chapter describes five novel healthcare and corresponding business models. Each of the business models is described using the Osterwalder Business Model Canvas.

80 **Wholy**

101 **Diabetes Buddy**

87 **Preventino**

108 **Smart Tooth**

94 **Ultimate Loop**



Wholy

Wholy inspires people to achieve a balanced diet by providing a holistic platform which personalizes the user's nutrition.

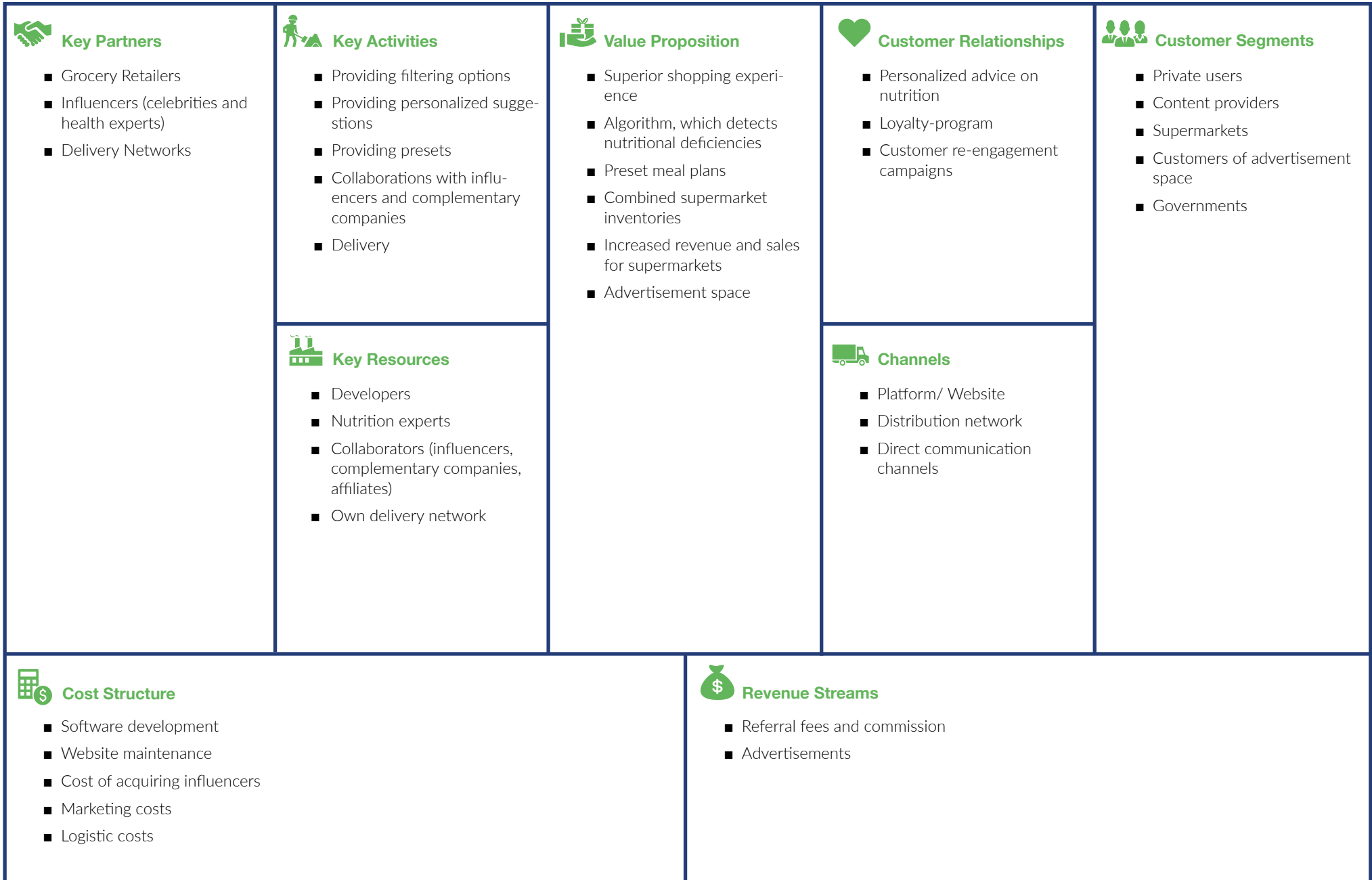
Wholy is a holistic solution to easily find the appropriate groceries for a user's diet. After entering the dietary restrictions and preferences, Wholy filters out every item which does not comply with the criteria. It relieves users of the overwhelming information overload they encounter by the infinite number of grocery choices, which are offered by traditional supermarkets, thereby eliminating the need to check every single item for its dietary compliance. After selecting the desired items, Wholy analyses the current and prior shopping carts and checks if any major nutritional deficiencies are present. If any shortcomings are detected Wholy suggests several product options to compensate for them. Wholy offers weekly shopping plans for an even more effortless shopping experience. These plans are either composed by dieticians or are following the eating habits of celebrities or fictional characters. When the user has completed his shopping, the groceries are delivered to his home. There are two steps by which Wholy wants to develop its business: Firstly, the users will have to choose an existing su-

WHOLY

permarket like REWE-online, Tengelmann, or Amazon Prime NOW and only the filtered inventory of the chosen market will be displayed. After the order is placed, Wholy sends it to the supermarkets existing delivery system and earns a referral fee as well as commission. Secondly, after a sufficient number of users is reached, Wholy plans to consolidate the different supermarkets' inventories by implementing its own delivery network. This will be achieved by offering time slots in which the groceries can be delivered. The dedicated delivery vans will do the collective grocery pick-ups and deliveries in alternating shifts, thereby ensuring that users do not get multiple deli-

veries from different supermarkets several times a day. Wholy attracts mainly two kinds of customer groups: Private and corporate customers. The former are users who want to live healthily or have some dietary restrictions like allergies. Most of the time these users need help with the whole process of eating healthy, which starts with the selection of the right groceries. The corporate customers are supermarkets which have an existing delivery system. This group would be interested in services Wholy offers, to further expand their customer base.

Business Model



 Key Partners

Retailers: The most important partners are the supermarkets, since Wholy does not provide its own inventory and, at the beginning, distribution. In order to fulfill the customer's purchases through the platform, close collaboration with retailers is required, especially since the commissions and referral fees make up the bulk of the revenue stream. Also, in order to fulfill these orders and deliver them to the customer's home, Wholy is dependent on their delivery services until it becomes profitable for Wholy to offer their own logistics solution (see above).

Influencers: A very important part of the platform is the collaboration with influencers such as fitness coaches, health experts or even celebrities such as Halle Berry, who has diabetes. The partnerships with these influencers can take on different forms depending on the specifics of the collaboration. While some are paid, to promote Wholy's platform, others have to pay to promote themselves. Both versions include uploading meal plans under their names as well as promoting these plans through their own channels. The basic difference is the degree of popularity and the benefits for the influencers: those who want to promote their non-competing, complementary products, for example as part of a meal plan, have to pay. Apart from typical celebrities, it is very important to collaborate with influencers for the younger generation since they are our target audience as well. This means bloggers, youtubers and other social media celebrities are potential partners for Wholy to collaborate with.



 Key Activities

The most important activity of this business is helping customers improve their diet. This is achieved through various proprietary pieces of software.

Providing filtering options: On the website and the app, filtering options are provided that take the customer's nutritional goals and restrictions (e.g., losing fat, veganism, low carb for diabetic people). Based on this information, Wholy suggests suitable food items to them. In this way, the user does not need to know what ingredients are contained in every item he or she buys - therefore eliminating a major pain point of our target group.

Providing personalized suggestions: The technology also provides customers with suggestions on how to improve their diet: If, for example, an iron deficiency is detected in the shopping behavior of a vegan person, Wholy suggests spinach or peas to counteract this deficiency.

Providing presets: Wholy provides presets from single recipes to weekly meal plans, which covers a collection of grocery items. These presets are provided by the platform and offer a more convenient way to shop for groceries. At the same time presets also lock in customers, as Wholy provides the option to put their grocery shopping in Wholy's hands.

Collaborations and community: The aforementioned presets can also be created in collaboration with celebrities and other influencers or alternatively, be submitted by the users themselves. This enables a feeling of community on the platform.

Delivery: For retailers that do not offer delivery themselves, Wholy will offer a pick-up and delivery service once Wholy's customer base is large enough to make this service profitable. With this service, customers will be able to select their groceries from retailers, and get everything in one delivery. Since this can only be profitable when enough orders come in for Wholy to combine them, this can only be implemented when Wholy achieves scale.

 Key Resources

Since the entire company is based on software and knowledge, the key resources required for this undertaking are knowledge, skills, existing software to build upon, and influencers.

Developers: In order to incorporate the expert's knowledge into algorithms and Wholy's products, developers are needed. Especially apps offer many opportunities for Wholy. More specifically, people with expert knowledge and experience in both web and app development are required.

Nutrition experts: The algorithms which help Wholy's customers improve their diet, require expertise in health and nutrition. It is therefore necessary to work in close collaboration with nutritionists and doctors. This means that those either need to be employed or they need to be brought on as contractors.

Existing technologies and distribution channels: For efficient development, Wholy's technologies build upon existing technologies in web and app development. This includes for example software development kits offered by Google and Apple to develop for their respective platforms. Also, to distribute the apps to customers, Wholy has to use their respective app stores.

Collaborators and affiliates: In order to gain traction and generate demand, it is important to emphasize the "trendiness" of healthy living. To reach Wholy's target group, collaborations with influencers and celebrities are required, where they, for example, provide a celebrity-branded meal plan on the platform and promote Wholy through their channels.

Own delivery network: The plan for the future is to build a delivery network that will enable customers to order from a much wider variety of retailers as well as order from multiple retailers at once, thus combining the strengths of each one and eliminating their restrictions.

Value Proposition

Superior shopping experience: By filtering out the products which do not fit the user's dietary restrictions, the shopping experience of Wholy's customers is improved. Wholy enables the users to shop more efficiently and ensures that the bought products are in line with their goals and preferences.

An algorithm detects nutritional deficiencies: Wholy's algorithm analyses the user's shopping cart and detects nutritional deficiencies. Based on the results complementary products are proposed to adjust for the shortcomings. This enables users to feel safe while shopping for groceries without having to know the exact contents of the selected foods, because Wholy ensures that their diet is balanced.

Preset meal plans: Preset meal plans contain the groceries for one whole week. Users can buy preset meal plans provided by other users, celebrities or physicians. Meal plans created by private users can go viral if many people follow them, thereby providing a feeling of appreciation. Celebrities get a chance to promote themselves or their diets to boost their public image and the respective users can easily feel connected to their idols. Physicians can create meal plans easier while providing a higher quality of life to their patients.

Combined supermarket inventories: The vision of Wholy is to combine the inventory of all major supermarkets by implementing its own logistics network. This service enables end users to receive one combined delivery, regardless of how many items from different markets they ordered.

An increase in revenue and sales for supermarkets: Revenue and sales are increased by attracting customers to the Wholy platform and afterwards forwarding their orders to the according store. Furthermore, an increase in cross selling is obtained by Wholy's algorithm, which suggests complementary products to a user's diet. This process results in an increased average size of the placed orders.

Advertisement space: The dedicated space for advertisements is especially attractive for food manufacturers, who are trying to gain attention for their products. With the advertisement space, a simple click refers the users to the promoted item.

Customer Relationships

In times of digitization, when it is easy to switch to a different online shop with just one click, customer relationship management is crucial. To ensure the success of Wholy, and to retain its customer base, personalized nutrition advice is provided, a bonus program is used to reward loyalty, and customer re-engagement campaigns are established.

Personalized nutrition advice: Customers are becoming more demanding due to the "internet of me", and therefore the need of personalization becomes increasingly crucial, to increase customer loyalty. It has been proven that personalized experiences increase loyalty [21]. Wholy implements this concept by analyzing past purchases, items placed in the shopping cart, and personalized presets. Based on this data, the Wholy algorithm recommends items and whole meal plans, which on the one hand fit the user's habits and on the other hand help the user to optimize his or her diet, by suggesting complementary items (e.g., detection of iron deficiencies for vegans). Customers can easily buy a suggested meal plan, which is in line with their goals and preferences, if they do not have the time or expertise to select the items themselves. Wholy makes sure that the customers can easily, effectively, and quickly get their grocery shopping done without any effort.

Loyalty-program: To maintain strong ties with customers, every customer of Wholy has a loyalty-points account, people automatically collect loyalty points if their purchase exceeds a certain threshold. Alternatively, every customer can also provide meal plans or recipes and they will get rewarded if it reaches a certain popularity. The collected loyalty points can be exchanged for special offers from Wholy's cooperation partners. These special offers include fee-reductions at fitness centers, online fitness coaching and vouchers for entertainment platforms, as well as physical goods.

Customer re-engagement campaigns: In case a customer did not order at Wholy for a certain time, he receives an automatic notification mail with personalized suggestions for food items, recipes and preselected meal plans. In some cases, vouchers are also included to build up incentives for shopping at Wholy.



Channels

Platform: The most important channel to Wholy is its platform - in the form of a website and an app - as it provides the interface for private users, the advertisement space for corporate customers and the option for people to create meal plans. The whole process of grocery shopping is digitized on the platform, to provide the most comfortable shopping experience possible. Personalized nutrition and shopping advice make the grocery selection more appealing on a personal level. This is the reason why users and content providers need to be able to create an account to easily save their preferences and settings. But it is not obligatory to have an account, as this might deter some users, who perceive this as inconvenience.

Distribution network: The second important channel, which is implemented after a critical mass of customers has been reached, is the distribution network, that will deliver the groceries to the customers. The delivery network aims at consolidating the inventory from all major supermarkets. The distribution network is necessary, especially for customers who wish to select items from different supermarkets. Without Wholy's own distribution network this would result in several deliveries at different points in time. This is why Wholy plans to use its own delivery vans, which will pick up the groceries at the supermarkets and afterwards deliver them as one delivery to the customer. The bundled orders will be delivered in shifts to provide selectable time slots for the customer and to make the logistics more scalable.

Direct communication channels: Wholy will need some dedicated personnel, which is solely responsible for handling inquiries by the cooperating supermarkets, as they represent Wholy's most important customers. This is a necessity since these key customers should be treated to the highest standard to ensure the stability of Wholy's core business.

 **Customer Segments**

Private users: Customers that use Wholy are people who need help adjusting their diet by simplifying the shopping experience, or who want to see the consolidated inventory of different shops. Wholy's customers are looking for a shopping experience which is quick, effortless and healthy at the same time. Wholy also attracts users who have severe dietary restrictions, such as allergies or celiac disease, and who want to make sure that all the products they see are in line with their needs. People who are at risk for T2DM benefit from Wholy as well, since it ensures a well-balanced diet which is optimized to their individual goals.

Content providers: People, who offer meal plans and recipes, are celebrities who want to promote their dietary plans, private persons, who want to share their eating habits, or physicians, who create mealplans for their patients. The primary intention of content providers is to gain popularity, or in the case of physicians, to improve the quality of life for their patients.

Supermarkets: Grocery stores and supermarkets are the most important corporate customers. Wholy provides supermarkets with an additional revenue stream by attracting new and broader customer segments. In exchange, the supermarkets pay a referral fee in addition to a commission, which depends on the value of each order placed.

Customers of advertisement space: Advertisement customers including the food industry, advertising agencies, or companies, whose product portfolio fits Wholy's target group. All these groups could place their advertisements on the dedicated space on the Wholy platform to promote their products and increase sales in an easy and effective way.

Governments: Governments could also be interested in Wholy's services to either promote healthy living amongst the population or to simplify nutritionally wholesome shopping for public entities, like schools.

 **Revenue Streams**

Revenue is primarily generated by fees for different services. Wholy has two main revenue streams which depend on the target groups: Supermarkets and Advertisers, where the latter are again divided into benefit provider and benefit receiver of Wholy's platform.

Referral fees and commission: Wholy attracts new customers with its attractive services, especially those customers who are looking for more convenient shopping routines. Thereby Wholy is able to reach a broad audience. This audience will be referred to the supermarkets, as Wholy provides products of supermarkets rather than its own products. Hence the grocery stores can increase online sales and have a huge benefit by cooperating with Wholy. For providing these key advantages, Wholy charges fees. On the one hand, Wholy is paid a referral fee every time a customer places an order at one of the supermarkets through the Wholy website. On the other hand, Wholy charges a commission fee, that is a percentage of the purchased value.

Advertisements: To attract customers Wholy works with influencers, such as celebrities and other thought leaders in the fitness and health industry. Wholy pays big influencers to promote the platform (see: costs structure). But Wholy also aims to collaborate with major influencers like celebrities or companies, who offer complementary products which do not cannibalize Wholy's current offers. Complementary products are for example fitness programs, fitness centers, cookbooks etc. These partners pay Wholy to promote their products to target customers based on shopping behavior, which means for example people who set their goal to building up muscles would get advertisements regarding work out programs.



 **Cost Structure**

Wholy is a sophisticated online platform, which is mainly based on the implementing new software, using existing software to build upon, knowledge, influencers (see: key resources) and operating cost.

Software development: The main cost factor is the software development, which includes the development of the website, app and the database. Since healthy living is especially important for elderly people, the site has to pay special attention to ease of use. But, as Wholy also provides comprehensive analyses, customer data needs to be stored efficiently and safely.

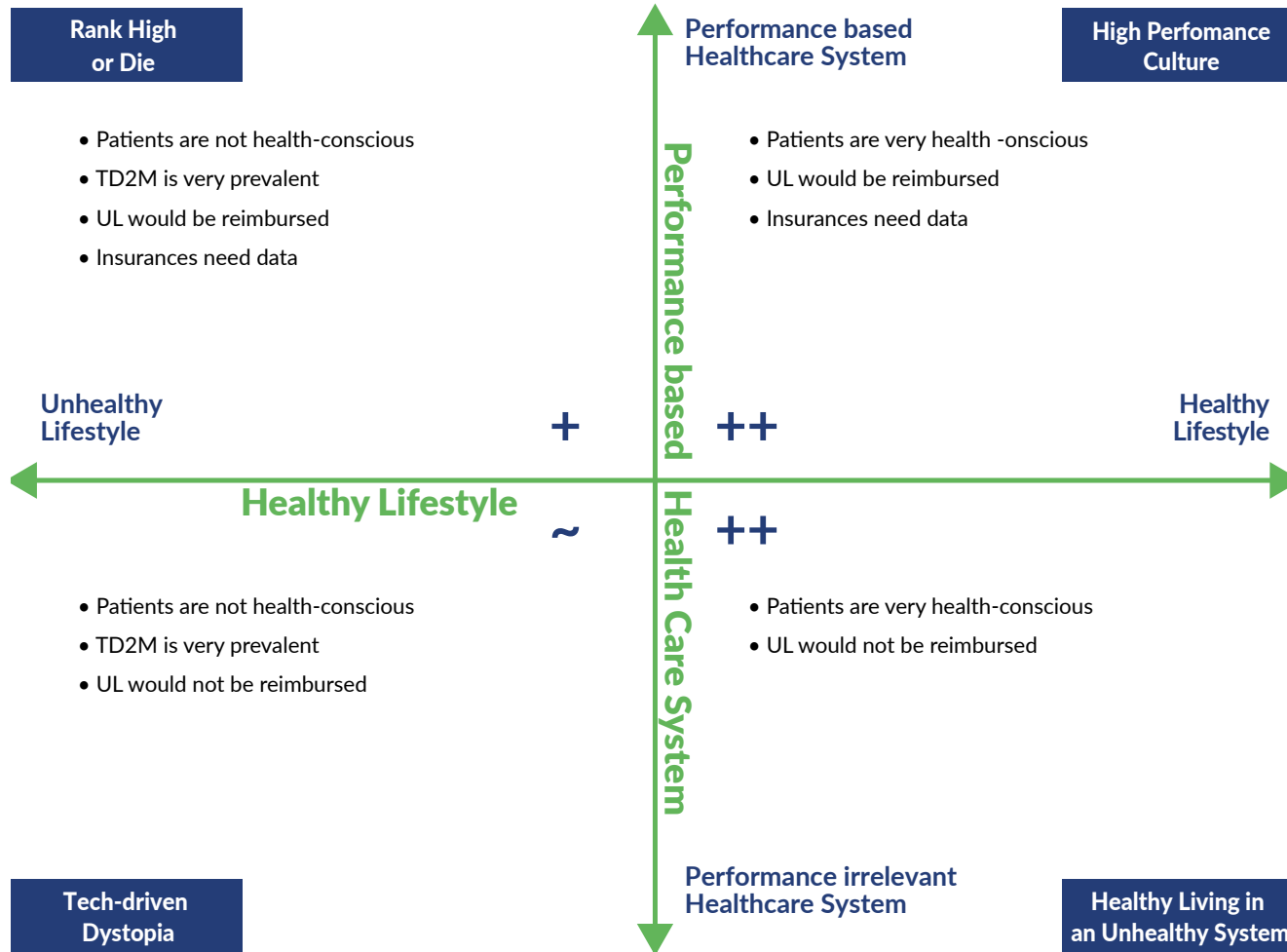
Website maintenance: Supermarkets change their offers daily, and a lot of work has to go into keeping our data up to date, which incurs costs. Constant changes in nutritional trends and new scientific findings have to be incorporated as well, for which expert knowledge is required.

Cost of acquiring influencers: To gain popularity Wholy works with celebrities, who have a big influence on society. Therefore, big influencers are paid to promote the platform. Wholy expects these partners to create meal plans, link and talk about the platform on their website, blog or further social media channels.

Marketing costs: Wholy aims to promote a convenient shopping experience and helps the customer to adjust their nutrition to their personal goals. To reach popularity this unique feature is to be promoted strongly on fitness and healthy living websites and social media. But costs also arise for advertising banners at hot spots such as fitness centers, universities, etc.

Logistics costs: As mentioned in the section channels, Wholy will implement its own pickup and delivery service, at a later stage. Hence costs regarding establishing and maintaining the logistics network will occur. This service enables customers to order products from different supermarkets and receive them in a single delivery. Moreover, Wholy benefits from providing this services, as it saves costs not paid for existing delivery networks, by using its own network.

Scenario Fit



Rank High or Die

In this scenario, nobody is living a healthy lifestyle. This leads to a high potential for a service that makes buying healthy groceries a convenient and fun experience. People do not know much about how to eat healthily and do not care about living a healthy lifestyle. Buying predefined meal plans from celebrities or other role models can help to adapt a healthy way of eating, even if there is a lack of health awareness in society. Governments may be interested in subsidizing Wholy, since it can counter the prevalence of obesity in society and thus tackle the rising number of obesity-related diseases, such as T2DM. In addition, physicians could use Wholy for prescribing predefined healthy meal plans to patients, thereby reducing the risk of disease onset. In a purely performance based healthcare system, such preventive measures are likely to be reimbursed.

Tech-driven Dystopia

The prevalent unhealthy lifestyle in this scenario's society causes many diseases, such as T2DM. In a performance-irrelevant healthcare system, physicians will rather focus on treating symptoms than causes of a disease. Therefore, they are unlikely to use Wholy for prescribing predefined healthy meal plans for patients to prevent diseases like T2DM.

However, governments and insurances may be interested in cooperating with a prevention and education platform like Wholy. This raises awareness and teaches consumers about healthy nutrition, as the number of treatments and healthcare costs is rising sharply. Wholy could tackle and prevent many obesity-related diseases which are difficult to cure with low-quality treatments.

In addition, people in this scenario may be willing to use a platform that allows you to follow the dietary habits of your role models and buy healthy and delicious food without any effort. Wholy's intelligent nutrition algorithm can help detect nutritional deficiencies for people who are not aware of healthy nutrition.

High Performance Culture

In this scenario, everybody is following a healthy lifestyle and there is a high potential for a service like Wholy - a tool for making shopping healthy groceries that fit your dietary restrictions extremely convenient. Preventing nutritional deficiencies is a big part of healthy living. Wholy's algorithm detects nutritional shortcomings and suggests products that you can add to your shopping card to counteract such problems.

Furthermore, predefined meal plans and recipes make preparing healthy meals or specific nutritional goals easy and comfortable. In a performance-based healthcare system, where effective treatments are likely to be reimbursed and incentivized, physicians could use Wholy to prescribe predefined healthy meal plans to patients, in order to reduce the risk of disease. Even though in this scenario most people are already trying to live healthily, Wholy can further support them in reaching their goals or following specific meal plans, recommended by their physicians.

Healthy Living in an Unhealthy System

In this scenario, the society is well educated about eating healthily and is open to a platform such as Wholy, which fosters the trend of living a healthy lifestyle. Wholy makes buying the right products even more convenient. The algorithm suggests products that fit your dietary goals, simplifies combining your favorite products from different shops into one order. In addition to that, following meal plans of fitness role models is very attractive in this scenario, since they have high popularity in the society and everybody strives to be as healthy as they are. In a performance-irrelevant healthcare system, physicians will rather focus on treating symptoms than the causes of a disease. Therefore, they are unlikely to use Wholy for prescribing predefined healthy meal plans for patients to prevent diseases like T2DM.

Challenges

- Tracking and analyzing additional nutrient intake, since people are not only shopping online, but also buying groceries in supermarkets or eating in restaurants
- Intelligent algorithm, which classifies grocery items and analyzes the shopping cart, requires skilled programmers and input from nutritional experts
- Persuasion of supermarkets to provide an API to their online delivery systems and to pay a referral fee on every order
- Differentiation from competing grocery delivery services based on Wholy's competitive advantages
- Building up an own delivery network in order to offer a wide range of products and in one order

Outlook

In the future, Wholy will become the leading platform for buying healthy groceries online, and connects all main grocery delivery services in one place. In a later stage, Wholy will provide the function to buy products from different shops in one single order, which will be delivered in one package. Therefore, it will become necessary to build up a proprietary delivery and logistics network, which is only possible after a critical mass of users and orders is reached.

Additionally, Wholy could evolve to an important educational platform, where people can get information on healthy nutrition and on the effects of certain dietary plans. Wholy's nutrition algorithm, which checks the shopping cart for nutritional deficiencies and predefined healthy meal plans, would help users to learn how healthy eating works.

Governments and insurances might be interested in cooperating with Wholy, which could become a central prevention platform that increases health awareness in society. This could have a significant impact on reducing long-term healthcare costs by preventing obesity-related diseases, such as T2DM.



PREVENTINO

Preventino

The Online Prevention Program against Diabetes.

Preventino is an intensive sixteen-week online prevention program, which aims to reduce diabetes risk factors in the long run. As Preventino focuses on medium-sized companies, Preventino is targeting apprentices roughly aged between 15 and 19. With the start of their career, a new period of life starts for them as they get more independent from their parents and start reflecting themselves. This major change creates openness for advice and the appropriate circumstance for sustainable prevention education.

Employers, who wish to implement a health-oriented company culture, in order to increase productivity, register their apprentices for the prevention program. They pay for the program in a subscription-based model. After registration, an entry-level test evaluates the current health status of the apprentice

and analyzes job conditions. The results are used to create the content of the four-steps program: In the first step, the apprentices receive educational lessons about the right nutrition as well as support to change their eating habits. In the following step, advice for more effective movement and workouts is given. The third and fourth steps focus on a change of the participant's habits and teaches them how to sustain the healthy lifestyle after the end of the program.

After successfully finishing the first phase, the participant gets a tracking device for the continuous recording of their heart rate and steps. The generated data is used by a personal health coach to adapt the program, give individual advice, and to further optimize the program. To minimize the dropout rate, age appropriate gamification aspects and an online commu-


nity are central parts of the product. The Preventino online community furthermore provides the possibility to exchange experiences.

The revenue generated through the monthly subscription fees cover the salary costs for the health coaches and the operational costs for the platform. Furthermore, an initial investment is needed to cover the developing costs for the technical implementation of Preventino.

Preventino's vision is to become the leading international diabetes prevention program in enterprises.

Business Model

 <p>Key Partners</p> <ul style="list-style-type: none"> ■ Experts as content providers ■ External health coaches as personal assistants ■ Employers as distribution channel ■ Vocational schools as marketing channel (participants) ■ Associations and scientific institutions as signal of trust ■ Wearables company as hardware supplier 	 <p>Key Activities</p> <ul style="list-style-type: none"> ■ Developing platform and content ■ Creating edutainment applications ■ Cooperating with employers ■ Organizing school events ■ Hiring skilled health coaches as freelancers 	 <p>Value Proposition</p> <ul style="list-style-type: none"> ■ Reduction of chronic diseases (especially diabetes) risk factors <p>Participants</p> <ul style="list-style-type: none"> ■ Personalized and contextualized interpretation of health status ■ Actionable advice via personal health coach ■ Health lectures ■ Edutainment features ■ Motivation via social interaction <p>Employers</p> <ul style="list-style-type: none"> ■ Prevention of productivity loss ■ Implementation of health-orientated company culture ■ Corporate Social Responsibility 	 <p>Customer Relationships</p> <ul style="list-style-type: none"> ■ Personal assistance via health coach ■ Communities ■ Online-trainings and customer support ■ Customer lock-in (fitness wristband, community) ■ Automated- and self-service (data transmission) 	 <p>Customer Segments</p> <ul style="list-style-type: none"> ■ Employers (and indirectly apprentices): subscription as scholarship for apprentices ■ Teenagers (age 15-19)
 <p>Cost Structure</p> <ul style="list-style-type: none"> ■ Initial costs: developing platform/algorithms; creating content and edutainment applications ■ Fixed operating costs: hosting services and maintaining platform ■ Variable operating costs: HR (especially health coaches); sales; marketing; continuous content research and development; hardware (wearables) 	 <p>Revenue Streams</p> <ul style="list-style-type: none"> ■ Sponsored monthly subscription fee from employers (who pay for their apprentices) ■ Monthly subscription fee from participants (teenagers) ■ Lowered subscription fee for follow-up program 			



Key Resources

- Content and advice provided by experts/coaches
- Generation and usage data of apprentices and algorithms for tailoring learning process
- Online community and network



Channels

- Distribution via employers and website
- Marketing (participants) via vocational schools and employers
- Marketing (employers) via direct initiatives and industrial fairs
- Software via mobile and web application

Key Partners

Preventino's key partners can be grouped into two sections. Those who are essential for creating and developing the actual program and those who are needed to reach the customer segments.

Healthcare professionals and educational experts are needed to create a youthful designed platform with appropriate content.

Preventino is also dependent on external health coaches serving as personal assistants, to guarantee individual guidance. The coaches need to have knowledge in several areas, especially healthy nutrition, fitness programs, and how to motivate and interact with the participants. To provide quality assurance, Preventino only employs certified experts. The last essential key partner to develop the online prevention program is the tracking device provider, who functions as a hardware supplier. To reach both, mainly the apprentices of employers and, in general, teens between the age of 15 and 19, the following key partners play a vital role: Firstly, the partnership with employers as a distribution channel has a multiplier effect, since most medium-sized companies employ several apprentices. To reach teens directly, a cooperation with vocational schools has to be established and information events have to be offered. Thereby, the program is promoted and the awareness for the risk of getting diabetes increases.

These marketing channels are essential because Preventino's website may not be enough in order to reach a critical mass of potential participants. Finally, collaboration with associations and scientific institutions is desirable. Proof of the effectiveness and the educational value of the program is important as integrity signals, since the B2B customer segment, i.e. the employers, will place great emphasis on whether the program is worth a long-term investment.

Key Activities

The technical system of the website and app needs to be set-up enabling it to capture and evaluate a lot of individual health data, which is generated by the users through tracking devices and manual input. As this data is highly sensitive, requiring technical experts, and an adequate infrastructure as a service (IaaS) solution needs to be rented.

The collected amount of health data will grow over time, making a continuous improvement and personalization of Preventino possible. Therefore, an adequate data managing system needs to be implemented. Additionally, algorithms for detailed data analysis need to be developed. Through the steady improvement of Preventino and the increasing network of apprentices and other teens, lock-in and network effects will facilitate Preventino's establishment in the market in the long run. Experienced health coaches have to be recruited because one of Preventino's most important value propositions is personal, individualized advice. In addition, the design of the educational lectures needs to be created in a way that is suitable for teens, thus a customer survey among young people must be conducted.

Furthermore, the cooperation of employers, who are willing to take part in the program, is crucial for successful implementation. Therefore, Preventino needs to convince them of the value prevention can offer for their apprentices and companies (see customer segments). The target companies are approached via employer fairs, direct mailing, and advertising in suitable magazines and newsletters. Another key activity is to reach out to vocational schools to promote the prevention program among apprentices. This partnership is needed to set up information events about obesity, unhealthy nutrition, and T2DM, in the extreme case (see key partners).



Key Resources

For the successful launch of Preventino three main resources are required: Technology and algorithms for data generation and evaluation, personalized program content, and a social network for participants.

Data generation and evaluation: Preventino uses various sources of data. From the very first day, participants are encouraged to upload pictures of their meals in order to evaluate their eating habits via image recognition. After the program's first phase, participants get a fitness wristband to track health data. It continuously records the participant's steps and heart rate. The data is then immediately transmitted to the health coaches who interpret them and give personalized advice. To visualize the data in an easily understandable way for health coaches and users, Preventino's technical experts need to develop appropriate algorithms and a mobile and web application, which should be capable of capturing, analyzing, and illustrating the user's data.

Creation of personalized program content: A key value for the participants is the personalized advice and content that is provided by qualified and experienced health experts. Therefore, experts in nutrition, sports, and medicine are required as they need to be able to design lectures and interpret data to provide the participants with helpful and high-quality recommendations. The content and the edutainment applications should be designed in a youthful style to address the target group's age. For this reason, Preventino needs to hire graphic designers and UX-experts as well.

Establishment of social network: To create lock-in and network effects, the establishment of a widespread social network is required. This gives the participants the opportunity to share information about their progress and to compete against each other. The program's value will increase with more users joining, thereby increasing switching costs for existing participants.

Value Proposition

Preventino is an online prevention program, which aims to reduce chronic disease risk factors, focusing on diabetes prevention. The value propositions can be broken down according to the customer segments.

Participants: At the beginning of Preventino's prevention program, every participant passes a personalized and contextualized entry-level test and is presented their health status results. Fitness activities, health parameters, and job conditions, such as the activity level of a specific profession, are considered. The results are used to adjust the program, which offers holistic step-by-step instructions to achieve a sustainable lifestyle. In the first step of the program, education about healthy nutrition and support for changing eating habits are provided. In the following step the participant is encouraged to exercise more often and concrete workout instructions are provided. Assistance in changing and sustaining lifestyle habits completes the program. During the term, Preventino refines the personalized content by using various sources of data, such as the activity data provided by the tracking device.

Personal health coaches give actionable advice based on the participant's current health status and the individual surroundings. Motivation to attend the program is fostered via an online community, where teens can communicate to peers and exchange their experiences, feelings, and achievements. To guarantee a high learning progress for teens, it combines evidence based health lectures with "edutainment applications" – content that is playfully brought across, such as an individual, modifiable virtual character that can be made to look similar to the participant and adapts to the teenager's health data (e.g., changing girth depending on the participant's behavior). The apprentice gains extra points to design the avatar by answering questions regarding diabetes prevention correctly.

Employers: The employers are incentivized to introduce the Preventino program in order to successfully implement a health-oriented company culture. As a long-term consequence, the number of sick days decreases and the employees' work performance increases. This results in an increase of overall productivity and significant savings potential. Additionally, the public perception of the company improves as the employer takes on corporate social responsibility by contributing to the apprentices' health.

Customer Relationships

Employers and teens consider Preventino's product a long-term investment since the positive impact of preventive measures are not immediately evident. Therefore, it is necessary for Preventino to establish a close relationship with their clients and offer professional customer service and personal assistance.

Furthermore, Preventino focuses on the exchange of experiences and best practices regarding the implementation of educational lessons within the prevention community. On the one hand, every user is individually assigned to a small group, going through the multi-staged program together and motivating each other. On the other hand, a global network of all participants is established, which focuses on the continuation of changed habits after the end of the sixteen-weeks program. The mentioned communities are also one of the reasons why the platform creates a customer lock-in effect.

Another instrument to improve customer retention and to increase the impact of Preventino is a wearable device that is provided to the users, without additional fees, after the successful completion of the program's first phase. This device is used to track activity data to be automatically processed and fed into the program. Because of the personal communication between participants and the supply of wearables, which are synchronized exclusively with the program, there will be high switching costs for participants.

Another goal within the context of customer relationship management is a balanced mixture of self-service and automated service elements. Self-service tools, such as the virtual personal fitness coach, allow the users to play an active role in shaping their program, which also leads to a higher commitment. Whereas automated service tools, like the seamless data transmission between wearables and the online prevention program, enable users to concentrate on their individual learning progress instead of administrative issues.

A strong tie is created by providing personal assistance through health coaches. Changing habits is a major challenge, making functional as well as psychological support fundamental in order to overcome obstacles. By providing coaching on a regular basis, Preventino is not only regarded as an online prevention program, but a real partner.

Channels

The marketing and sales channels are determined by the customer segments. As the offered program focuses on apprentices at the beginning of their work life, employers are the most crucial channel for reaching this particular peer group. Since the employer is going to pay for the participant's program, they need to be convinced of Preventino's value. The employers will be reached through direct marketing initiatives, such as direct mailing, in combination with visits on company fairs as well as advertising in suitable magazines and newsletters. As described previously, the focus will be on mid-sized companies. In the best case, participating employers directly advertise the program to their apprentices. Using employers as a multiplier would lead to significantly lower marketing and acquisition costs. This case is not unlikely since employers have a monetary incentive to promote the program, as already mentioned in the value proposition.

To approach teens, Preventino uses information events in vocational schools to increase health, and respectively, diabetes awareness among the students and further promote the program. Preventino's website also provides a signup form to address teens who want to subscribe by themselves. Search engine optimization (SEO) has to be done to assure appearance in the search results of this second peer group. Additionally, social media channels are used to address interested teens. As a later step, partnerships with healthcare insurances will be built to address more teens and further increase the user base as they can provide monetary incentives for their clients. The participants are able to access the prevention program day and night, via a mobile and web application. The personal assistance can be approached through the chat function, audio or video calls during certain consultation hours.



Customer Segments

Several studies, e.g. [355] have shown, that addressing the main triggers of diabetes at an early age is the most effective way to prevent the disease. Therefore, targeting very young children would be most efficient. Given the fact that young children are shaped by their parent's habits, and the difficulty of changing their behavior in the first place, this strategy is not very promising. For this reason, Preventino focuses on teens of ages 15 to 19. At this age, they start to make decisions independently from their parents, as they finish secondary school and start reflecting themselves, as a new period of their life is starting.

As integrating a fee-based prevention program in school curricula is difficult, Preventino focuses on apprentices and approaches the employers of those. This strategy seems most promising, as employers are able to offer Preventino's program directly to their apprentices. In this way, Preventino is even able to reach teens from families, who are living rather unhealthily. This solves the issue current digital health products like Freeletics have: They mostly reach people who are already interested in a healthy lifestyle.

At the same time, employers care for the long-term wellbeing of their apprentices, because this ultimately increases the productivity of their company. This mostly occurs because of increasing performance during working hours and decreasing number of days absent. Thus, employers are willing to subscribe to the program and provide a scholarship for their apprentices. Preventino places the focus on medium-sized companies, as they have the financial resources to sponsor such a scholarship, and heavily invest into loyalty of their employees.

Aside from apprentices, Preventino is also open for teens, who are motivated to take control of their own lifestyle. Usually they are already aware of the steps that need to be taken in order to live a healthier life but struggle with the execution. These teens have the opportunity to sign-up for the Preventino prevention program on their own, for a monthly fee.

Cost Structure

For the development of the platform and its courses and services, Preventino must front these initial costs. After setting up the online prevention program, fixed as well as variable operational costs will arise.

Initial costs: The development of the platform and algorithms as well as the creation of educational content requires a certain development budget. Besides that, edutainment applications, such as the adjustable virtual character, need to be developed and designed, which also up-front costs.

Fixed operating costs: To get the platform up and running, hosting services need to be paid. As Preventino's aim is to provide an excellent customer service, high maintenance costs need to be taken into account as the customer feedback needs to be implemented regularly.

Variable operating costs: This section makes up the majority of the expenses. Above all, Preventino needs competent staff, especially health coaches. Since the personal assistance is one of the main value propositions, both quality and quantity of health coaches are crucial and thereby costly. In order to be able to respond to fluctuations in demand quickly, Preventino will hire coaches as freelancers. Aside from human resources, some costs are also associated with sales and marketing. However, those items will not have a significant impact, since once a few medium-sized companies are acquired as customers, so does the number of apprentices due to the already mentioned multiplier effect. Furthermore, the continuous content research and development (R&D) as well as the purchase of wearables, are part of the variable operating costs.

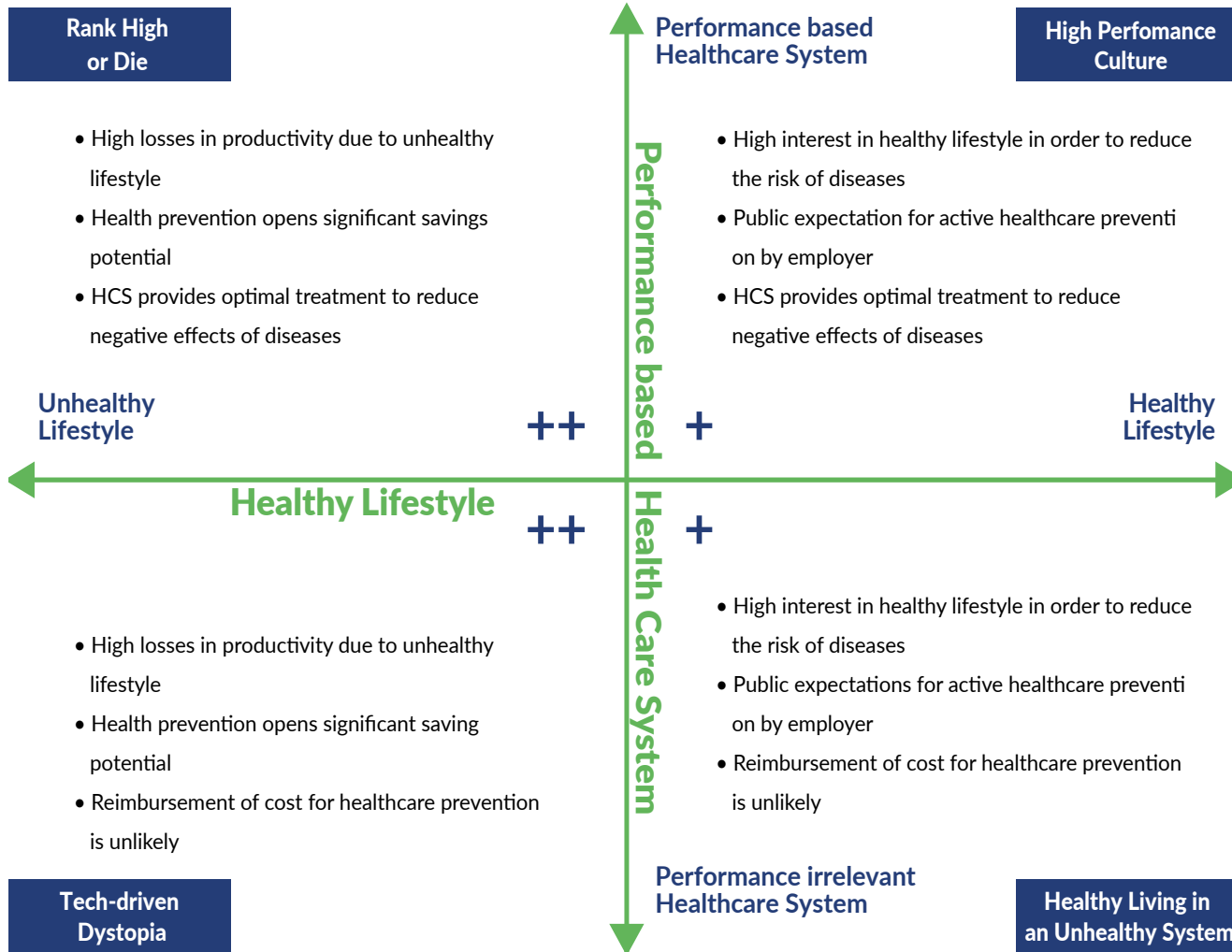
Once the software platform is developed and running, Preventino benefits from economies of scale, as new customers mostly lead to a higher demand in health coaches, whereas the infrastructure and other cost items will not be influenced.

Revenue Streams

Revenue is primarily generated through a monthly subscription fee paid by employers, who are offering the program to their apprentices. In addition, other apprentices and teens can also join proactively. The subscription-based model was chosen for three reasons: Firstly, the payment must be affordable for young people not getting a scholarship. A high one-time payment would have a sufficient deterring effect, whereas a subscription payment is more affordable for teens since they mostly have a monthly income. Secondly, a subscription, which can be cancelled at the end of each month, is more customer-friendly. Thereby the entry threshold is kept low so that teens can try out the prevention program. Thirdly, this business model creates a strong customer retention since users have to actively cancel the subscription. Therefore, with automatic renewals, more revenue can be generated from subscribers who forget about renewing. After the sixteen-week program, the subscription fee will be much lower (around 10% of the regular fee) to insure the participation in the follow-up program. The fitness wristband will be provided without an additional fee; the costs are already included in the price of the monthly subscription.



Scenario Fit



Rank High or Die

In a world where sedentary lifestyle and poor nutrition is widespread in society, the problem of diseases becomes a burden for the healthcare system as well as for the productivity of a whole economy. A performance based healthcare system uses the best available treatment methods and promotes promising prevention measures to counteract this problem. Employers can benefit from implementing a healthcare prevention program in their company since such programs improve the health awareness of their employees and therefore reduce productivity losses related to health problems. Once the positive impact and effectiveness of such a prevention program is proven, this scenario opens the opportunity for cross-financing the costs for the employers with payments from the insurance companies.

Thus, the business model of Preventino performs very well in this scenario as it provides value for employee, employer, and the involved health insurance companies.

High Performance Culture

In case of a society which lives completely health-oriented, the total number of cases of illness and the losses of productivity in the economy decreases. From a business point of view, incentives for the implementation of a prevention platform, such as Preventino, are decreasing due to the reduced overall saving potential.

In this scenario, a large target group of young people actually wants to use a prevention program as it satisfies their keen interest in how they can optimize their lifestyle from a health-care point of view. Since the basic knowledge about a healthy lifestyle is widespread in this case, the teaching content of the program focuses more on specialized advice, e.g., depending on the nature of an employee's activities in everyday working life. In an advanced stage, a collaboration with insurance companies is likely as Preventino represents an effective tool to reduce the risk of diseases. Then, the costs of the prevention program are reimbursed.

Tech-driven Dystopia

In this scenario a significant number of diseases are caused by the wide spread of an unhealthy lifestyle in society. The treatment of diseases offered for patients in a performance irrelevant healthcare system is not necessarily the most efficient and most promising approach to solve their health problems, since only the cheapest treatments are reimbursed.

Thus, the high losses in productivity and the days of absence of their employees forces the employers to intervene in this situation. In such a scenario the business model of Preventino perfectly satisfies the needs of a large number of employers. Since Preventino's program encourages new employees to follow healthy habits from the beginning of their working life, it represents a key factor for the successful implementation of a health-oriented working environment. By creating a fundamental understanding and awareness of a healthy lifestyle and by giving feasible advice for implementation, the program has a desirable impact on employees' lives.

Healthy Living in an Unhealthy System

In case of a society that lives completely health-focused, the prevention program of Preventino will meet the interest of many people and employees. As the majority of people already have basic knowledge, regarding their health, and the willingness to implement recommendations for a healthy lifestyle is given, Preventino focuses on further improvement of the participant's knowledge.

In this context, the total number of diseases and the productivity losses in the economy are decreasing. From a business point of view, the purely monetary incentives for implementing a prevention platform such as Preventino are decreasing, due to the reduced overall saving potential. Instead, the demand for a prevention platform is driven by the public expectation for an active healthcare prevention program to be provided by employers. This effect is intensified since it is unlikely that the performance irrelevant healthcare system covers the cost for a prevention program instead of just focusing on the treatment of symptoms. As a result, healthcare prevention is mostly managed by people on their own, e.g., by using Preventino.

Challenges

- Acquiring partners: vocational schools, companies interested in participating in the program
- Data privacy concerns and data security
- Missing acceptance of participants for intervention in their daily life habits (tracking of activities etc.)
- Establishing a critical mass and lock-in effects
- Decreasing number of apprentices in Germany (7% less apprenticeship contracts in 2015 than in 2010 in Germany)
- Continuously adapting the program to keep up with the interest and lifestyle trends of the young target group
- Ensuring sustainable behavior change of participants

Outlook

Preventino will be developed within the next six months, when the platform will be set up and the content created. At the same time, Preventino needs to search for partners, especially for participating companies and health coaches. Once the system is established, there will be a focus on the expansion of the community to achieve network and lock-in effects.

The trend of the insurance market towards rewarding their customers for sharing their health data will further strengthen [356], potentially leading to lower fees for people following a healthy lifestyle. Thus, the insurance's interest in prevention programs like Preventino will increase and a collaboration could become meaningful. Insurances could partly reimburse the costs for the prevention program to companies and participants as well as offer monetary incentives for users.

Once the program has a broad customer base, the target group will be expanded from apprentices to include all employees. Countries like Spain, Greece, and China aim to develop an apprenticeship system according to the German model, since the German system of apprenticeships helps to prevent youth unemployment [357]. Because of this, the potential market for Preventino will increase, which provides promising expansion opportunities in the future. Preventino's vision is to become the leading international diabetes prevention program for enterprises.



Ultimate Loop

A holistic concept for diabetes patients that prevents follow-up diseases and enables them to self-manage their illness.

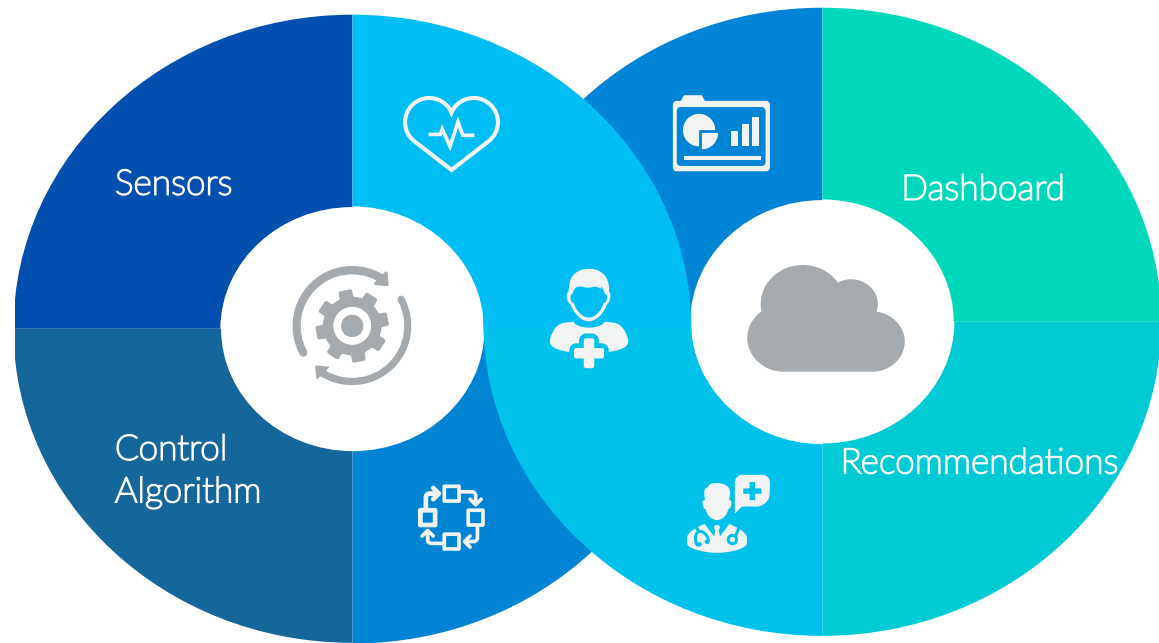
T1DM is characterized by deficient insulin production and requires constant monitoring and regular injection of insulin. The disease has a significant impact on a patient's life, who currently spend several hours a day measuring blood glucose levels, injecting insulin, and visiting physicians to regularly adapt their treatment. Emotional stress, in particular the fear of a hyper- or hypoglycemia, is a constant challenge. Hyperglycemia, or raised blood sugar, is a common effect of uncontrolled diabetes that, over time, can lead to blindness, kidney failure, and stroke [358]. Therefore, diabetes patients require a reliable and convenient solution that keeps blood glucose levels in the normal range while relieving them from the constant worrying of their disease. Ultimate Loop (UL) envisions to reduce diabetes-associated follow-up diseases by automating the monitoring and

adaption of glucose and insulin levels. It empowers the patient to self-manage the disease via a cloud-based platform.

UL combines hardware and software components. The hardware consists of a blood glucose measuring device and an insulin pump with several additional sensors. Both are connected via Bluetooth, and are controlled by a software algorithm. In contrast to other concepts in the market, UL contextualizes the glucose level with information about the patient's daily life, i.e. heart rate, steps taken, and GPS. The result is the most accurate algorithm on the market and the first one that allows the patient to do physical activities, without having to manually adjust the required amount of insulin.

Moreover, UL helps patients to self-manage their disease. Leveraging various data sources, our cloud-based platform offers patients the most complete overview of their health status, in form of a dashboard. And personalized recommendations. Add-on services for patients on the platform include a risk assessment of follow-up diseases from experts. Furthermore, the platform allows physicians to have access to their patients' data, enabling them to remotely adapt the treatment of a patient.

UL creates revenue in multiple ways. Patients can purchase the hardware at cost for a one-time fee, whereas the access to the cloud-platform is sold as a monthly subscription.



Business Model





Key Partners

Since UL focuses on software development, not sure if we partner with several manufacturers to develop the hardware components. The fabrication and assembly of the hardware products are outsourced, making suppliers our most important stakeholder. Strategic partnerships with research institutions and startups can accelerate further improvement of UL. Examples include inventing new sensors to measure food intake, stabilizing glucagon to design a dual hormone closed loop system, and finding new ways of insulin administration.

Partnerships with regulators in the healthcare industry are essential as well, as they have to approve the product before it can enter the market. In addition, health insurances are key partners of UL as their reimbursement policies affect the success of the products when expanding to the mass market. Policy makers can increase the attractiveness of our product by accelerating the transition to a value-based healthcare system, which would likely lead to full reimbursement and increased accessibility. For these reasons, the superior effectiveness of UL, in the reduction of hypo- and hyperglycemic events and follow-up diseases, has to be proven with extensive medical studies.

Patient and diabetes associations are key partners since they strongly influence the current discussion around diabetes technologies and solutions. Diabetic patients' choices for treatments are often influenced by key opinion leaders or news stories, blog posts, and interviews. Additionally, patient associations can provide access to participants for clinical trials.

The different features of the cloud platform benefit tremendously from additional data sources. The patient receives a more complete overview over his current health status as well as improved recommendations, when UL can utilize a greater variety of data. This makes third party applications in the health and fitness space important partners. They already have vast amounts of precise user data, which is integrated into UL's holistic cloud platform. In return UL's customers have a stronger incentive to sign up for the services of UL's partners. Examples include Runtastic, Freeletics and Apple Health.



Key Activities

Although UL also sells externally manufactured hardware, it is primarily a software company. The main activity is to design and develop both the software algorithm that controls the insulin pump and the cloud-based platform. While developing the software, collaboration with research institutions and patient associations, to constantly test prototypes, is essential. Building the cloud-based platform includes the web application for physicians and the mobile application for patients. Data processing is a key activity for UL's health analytics services, since the aim is to collect unstructured, noisy data from various sources, combine them to valuable insights and derive recommendations for the patient and the physician. Since technological progress, in particular machine learning, is accelerating, improving the software will be a constant activity.

Regarding the hardware, UL focuses its operations around the design of the hardware and the sensors. Additionally, UL's staff works on quality control and the approval processes of medical regulators, to ensure reliability of the product. The actual manufacturing of the hardware is outsourced, but managed by UL.

Finally, our hardware product and platform become even more valuable by integrating functionalities and data sources from partners. Therefore, partnerships with different sensor manufacturers, such as Smart Tooth, and third party applications, such as Apple Health, are established.




Key Resources



In order to execute the business model, the team is the most important asset. The development of the UL requires the collaboration of engineers, computer scientists, and physicians. Regarding the hardware, the insulin control algorithm acting upon multiple data sources is key for succeeding in the market and securing a leading position in hybrid closed-loop systems. Another central element of the business model is the personalized treatment, offered through the platform. One core asset is the algorithms which produce customized recommendations, based on the patient's medical needs and behavioral patterns. Since patients have the option to pay for more detailed reports about their health status, a team of medical experts will conduct the required research in order to provide high-quality personalized reports. In addition, the risk assessment algorithm, which uses health-related data to quantify the risk of developing additional diseases, is a further key resource.

Being a data-driven company, the patient database is a key resource in our business model as well. Data of diabetes patients is crucial to ensure the superiority and effectiveness of our medical device. Therefore, hosting the data and ensuring the safety of the platform is core to our business. As the topic of cybersecurity is extremely relevant when handling sensitive patient data, experts will secure the platform from privacy breaches.

In general, medical devices are a field where intellectual property plays an important role in the development of new solutions. For UL, it is essential to differentiate itself from competing patents as well as guarding the solution against imitations. Therefore, patents protecting the hardware, the cloud platform, and the integration of algorithms, are additional key resources.

Value Proposition

The UL empowers diabetes patients by making the disease more manageable. The advanced hybrid closed-loop system stabilizes the glucose level by injecting micro-boluses throughout the day, which enables the patient to fully focus on insulin management for meals. We increase the accuracy of the control algorithm through additional sensors in the hardware devices that provide context about the patient and his behavior beyond glucose levels. Additional data sources include the patient's heart rate, number of steps taken, and the GPS location. This lets the pump adjust the micro-boluses to the physical activity of the patient which can prevent hypoglycemia during or after sports. Through the increased predictive capabilities of our system, we are able to prevent more hyper- and hypoglycemic events, therefore reducing follow-up diseases. Additionally, heart rate measurements are a very accurate indicators of emergencies and would enable instant notifications in case of an emergency.

Aside from the hybrid closed-loop system, we offer a cloud platform, which provides patients, and their physicians, a broad overview and unique insights into their historical data. Many patients feel as if they are constantly chasing numbers and therefore do not have a real understanding of their disease and the implications of their daily habits. The combination of UL's hardware and software enables the patient to focus on the most critical parts of their disease management. The platform provides a holistic overview by utilizing as many data sources as possible, for instance nutritional diaries and data from third party applications such as Apple Health. Patients have access to a dashboard, which provides them with the most critical information at a glance. The combination of all data points is then used to provide the patient with actionable real-time recommendations, which encourage self-improvement and provides additional motivation. Finally, physicians benefit from the automatically collected data, which enables more accurate assessments of their patients' health.

Customer Relationships

The purchase of the UL is a life changing event for patients. It enables them to live a life with more flexibility and freedom. Although the UL is a substantial investment for patients and their insurance companies, it amortizes itself in the long run. In addition, the setup of the hardware is complex and requires professional instructions from physicians. For these reasons, establishing a close and trusted relationship, to both the patient and the physician, is crucial for the success of UL. Before market entry, partnerships with trustworthy institutions, such as the European Association for the Study of Diabetes (EASD), will be established. Actively integrating diabetes associations and key thought leaders in the development of the product increases credibility and general product awareness. Three additional measures establish a close connection to patients and physicians:

First, UL uses targeted marketing to create a pull-effect, which leads to patients actively asking their physician for the product and to physicians actively informing themselves about the new technology. Therefore, UL will initiate partnerships with celebrities who have T1DM (e.g., Halle Berry). In addition, UL uses targeted online advertising to convince patients and physicians of a purchase.

Second, since physicians are setting up the hardware with the patient, UL provides specialized online training and in-person workshops. Both focus on the question of how to use and calibrate the system according to the patient's needs. In contrast to the competition, UL provides online training for patients to continuously decrease their dependence on external help. Moreover, a virtual therapy assistant guides both the patient and the physicians through the first weeks of the treatment.

Lastly, UL offers 24/7 technical support for patients and physicians. Several channels such as a hotline, text messages, email, or social media are open for requests to ensure appropriate service for all age groups. The service is particularly focused on hardware issues, but is also open for requests regarding the cloud platform.

Customer Segments

UL aims to improve the glucose levels of patients to prevent diabetes related follow-up diseases and to empower patients, by helping them manage their disease. The developed hardware and software are applicable to different types of diabetes patients - in fact, every patient who receives insulin therapy is a potential customer. However, the product is particularly designed for T1DM and severe T2DM patients. The different technologies, uniquely combined in a holistic solution, ensure that patients in both groups value the solution. Within this customer segment, we identified sub-groups that have particular interest in a subset of the features offered.

Firstly, patients who frequently experience severe hypoglycemic events benefit from the accurate administration of the glucose and insulin levels. Data about physical activity, and therefore energy usage, improves the accuracy of the insulin administration. Secondly, parents of younger children strongly benefit from the emergency notifications feature that instantly informs them if the child shows critical vital signs. Moreover, patients who are particularly interested in a healthy lifestyle will value the in-depth health reports and real-time recommendations. Thirdly, athletes are especially keen on improving insulin management during intense physical activity. They will use the hybrid closed-loop-system to avoid hypoglycemic events during training and tournaments.

Our value proposition towards physicians is the simplified access to accurate patient data. With our holistic concept, we ensure complete and accurate data about the patient, which enables physicians to make better informed decisions about the patient's treatment.



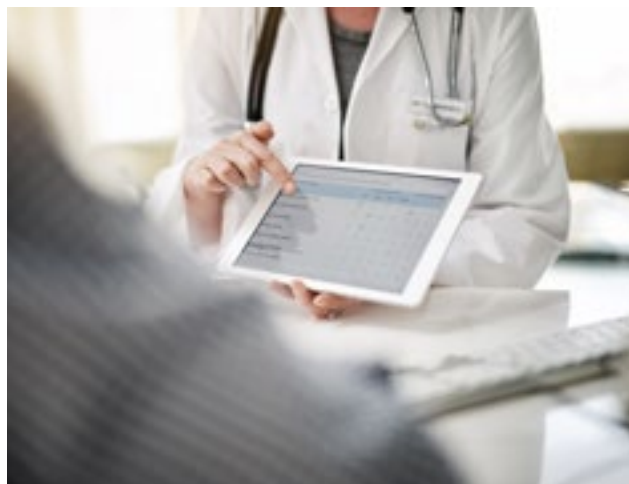
Channels

The way of distributing medicine and medical devices has not seen significant innovation in the last decade, mainly due to strong regulations. Until today, wholesale distributors buy products from manufacturing companies and resell it to physicians, pharmacies, and hospitals. For rare and expensive products, pharma companies send their own sales representatives to carefully explain the product as well as to convince the potential buyer of its value.

UL choses a different approach and uses three channels to distribute its hardware product. First, the increased digital literacy of patients and physicians is used to sell the hardware in a standalone online-shop. Physicians and patients can buy the medical device online and it will be shipped to the physician after he approved the purchase. This sales channel is strongly supported by the targeted marketing and communications measures, which help to identify T1DM patients. Targeted measures also help to identify physicians who treat diabetes patients regularly.

Secondly, UL's own sales representatives educate physicians, key opinion leaders, and strategically relevant hospitals of the product. They focus particularly on physician-leads that have been generated online through profiling and advertisement. Complementary to this, UL uses bulk sales to top tier distributors, ensuring broad availability in the market. The hardware product creates a lock-in effect, which leads the patient to the purchase of UL's software products. Additionally, the hardware will be sold at cost to increase accessibility.

All software products are distributed through the company's website. Here, the web application can be accessed and respective mobile applications can be downloaded, via Apple's App Store or the Google Play Store. This channel is strongly based on targeted advertising measures to existing users of the hardware and physicians who already had a first touchpoint with the product. In the long term, UL's platform will be the market leading distribution channel for third-party diabetes services.



Cost Structure

Fixed Costs: Since UL is building a complex software product combined with multiple hardware components from different suppliers, the major cost driver is highly qualified staff. Personnel costs are divided into three blocks: Firstly, personnel costs that are related to developing, building and maintaining the cloud-platform and the software algorithm. This includes not only the platform, but also mobile applications for physicians and patients. The second block consists of costs related to designing the hardware product and managing the manufacturing partners. This also encompasses quality assurance, clinical studies, and regulatory approval processes. The third block includes the 24/7 support team and an increasing number of people working in the sales department. The sales team is responsible for direct and indirect sales. Direct sales require a wide range of online-marketing activities to ensure patients discuss the UL with their physician and subscribe to the cloud platform. The indirect sales focus on building relationships with distributors, physicians and hospitals in order to push the UL into a broader market.

Variable costs: Production costs to build the UL are the main component of the variable costs. The three main hardware components are the glucose measuring device, the insulin pump, and the additional sensors. Moreover, costs for packaging, shipping, and the storage of hardware components need to be considered.

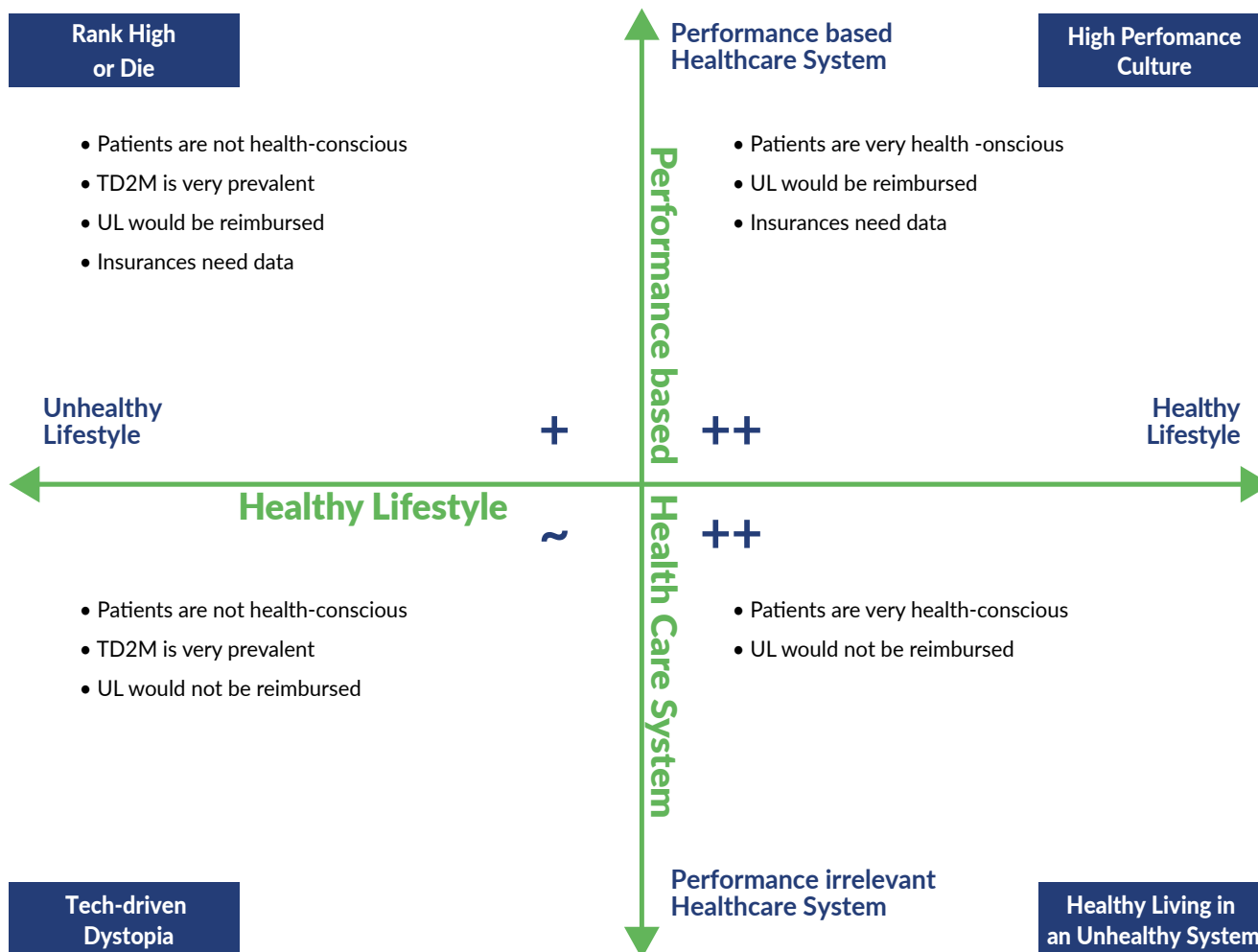
Revenue Streams

The business model consists of three major revenue streams: hardware, software and add-ons. At its core, UL sells the hardware at cost price to enable a wide range of patients to have access to the device. The continuous measurement sensors, which need to be replaced regularly, will be sold at a competitive market price. The second revenue stream consists of a subscription fee that patients pay for accessing the cloud-based platform. The third revenue stream is generated through cross- and upselling offerings for patients and physicians. Today, physicians only have access to self-reported data of the patient. With our platform solution, they can now access detailed reports on the health status of their patient. Patients can also request personal in-depth reports and risk assessments. For each in-depth analysis, a transaction fee is charged.

As UL offers an expensive medical product, we are dependent on reimbursement of insurance companies; otherwise a wide range of patients would not be able to afford the product and the potential market size would be smaller. Since follow-up diseases comprise the largest part of the diabetes-related economic burden, the long-term costs for society would decrease substantially through the use of UL. A Health Technology Assessment (HTA) will be carried out to demonstrate that reimbursement is essential for patients, physicians and society. This will make UL available to the mass market.



Scenario Fit



Rank High or Die

In a performance based healthcare system, UL's products, both hardware and software, are reimbursed because of the improved quality of life for patients. Therefore, the entrance to the mass market is accelerated and UL's customer segments are not limited to wealthy patients. Furthermore, physicians prescribe and use UL's platform themselves because it increases their efficiency and thus, their economic outcome. Moreover, the data platform is valuable to insurances to help them identify the best performing therapies, due to the patient-related insights they obtain.

Additionally, in case of an unhealthy population, there is a high prevalence of T2DM. However, patients are less health aware and have lower interest in analytical products. Thus, patients are not motivated to improve their health and reluctant to pay for the analytical products of the cloud platform.

High Performance Culture

UL's value proposition fits best to a scenario with a performance based healthcare system and a healthy population, maximizing the market size for all products. Reimbursement policies in a performance based healthcare system are beneficial for UL, since all the products are paid for by the insurances because of their increased performance. Moreover, for UL a healthy population does not necessarily imply a decreased market size, since a healthy lifestyle does not affect the prevalence of T1DM.

Furthermore, the health-consciousness of the population increases longevity, which again leads to a higher prevalence of T2DM, since it is related to old age. Greater health awareness leads to a higher interest in health-analytics products and therefore UL's cloud platform. Patients are willing to improve themselves and follow the actionable recommendations suggested. Additionally, there is an increase in revenues because more in-depth health reports are requested.

Tech-driven Dystopia

In case of a performance irrelevant healthcare system and an unhealthy population, UL faces major challenges and the strategy may need to be adapted.

A performance irrelevant healthcare system leads to a decrease in market size, since the products are not reimbursed and are therefore limited to a premium market. Self-paying patients are the only customers that can afford UL's products. However, in case of an unhealthy population, patients are not interested in using all UL products, particularly the analytical features of the cloud platform. This scenario poses challenges to UL's strategy because of the smaller market size for the hardware and reduced interests in the platform. Therefore, UL could modify the products to the mass market's needs by offering a cheaper hybrid closed-loop system.

Healthy Living in an Unhealthy System

In this scenario UL can thrive as the leading premium medical device provider in the diabetes market. In a performance irrelevant healthcare system, self-paying patients are the only ones that have access to UL's products, since insurances reimburse only the cheapest treatments.

However, a healthy population has a high interest in health analytics services. UL's cloud-based platform includes data sources not only from the hybrid closed-loop system but also from third-party data providers. Therefore, even though UL's hardware product is adopted by a reduced percentage of the population, the software product would be successful because of its affordability and the high interest of the population in analytics products. Consequently, the best strategy would be to focus on the cloud platform until decreasing manufacturing costs make a hybrid closed-loop system more affordable for the mass market.

Challenges

- Medical devices entering the market are subject to a rigorous review process (clinical trials and HTA required), which makes the development process very capital intensive
- The expansion of UL's products to the mass market highly depends on the reimbursement policies of the insurances
- Competition is high, as competitors will launch a similar product in the next years
- A fully autonomous closed loop system would require the development of new sensors to measure food intake
- In Europe, compliance and data regulation is fragmented, therefore the product needs to be adapted for every country

Outlook

UL's mission is to help diabetes patients forget about their disease. Therefore, the goal is to offer a fully autonomous system that completely mimics the human pancreas. Thus, UL aims to include two additional functionalities in the long run: the administration of glucagon and the automatic estimation of ingested carbohydrates. First, the integration of the administration of glucagon treats severe hypoglycemic events. Second, data sources related to food intake relieve the patient from the tedious task of computing the amount of needed insulin to be injected. In the future, UL has the ambition to integrate revolutionary sensors such as the "Smart Tooth" or sensors measuring incretins - hormones released in the gut that induce insulin secretion - for the estimation of food intake.

Moreover, UL aims to open up the platform to third-party providers that offer additional services to diabetes patients. One example of such a service is a retinopathy test to detect signs of deteriorating eyesight as early as possible. The goal is to facilitate the integration of patient data, that makes partner's products smarter by providing APIs to food producers, grocery stores, and gyms. Regarding the platforms' analytics services, UL's ambition is to become the leading health analytics provider, offering customized recommendations and diagnostics services by integrating patient's genetic data.



Diabetes Buddy

An online matching platform connecting recently diagnosed diabetics with more experienced mentors.

The main goal of Diabetes Buddy is to provide emotional support, a sense of belonging, and guidance, but also factual knowledge for newly diagnosed diabetics, especially in the difficult early stages of the disease. Such an offer is especially relevant for diabetic children and their parents, since current possibilities of receiving help are limited to short doctor visits and impersonal internet forums, leaving them insecure about many day-to-day activities and in an often fragile emotional state.

Diabetes Buddy remedies this problem by providing an online platform where diabetics can participate either as a mentee, in case of little experience with the disease, or as a mentor, in case of greater familiarity with diabetes. A cutting-edge matching algorithm then finds a perfectly fitting mentor-men-

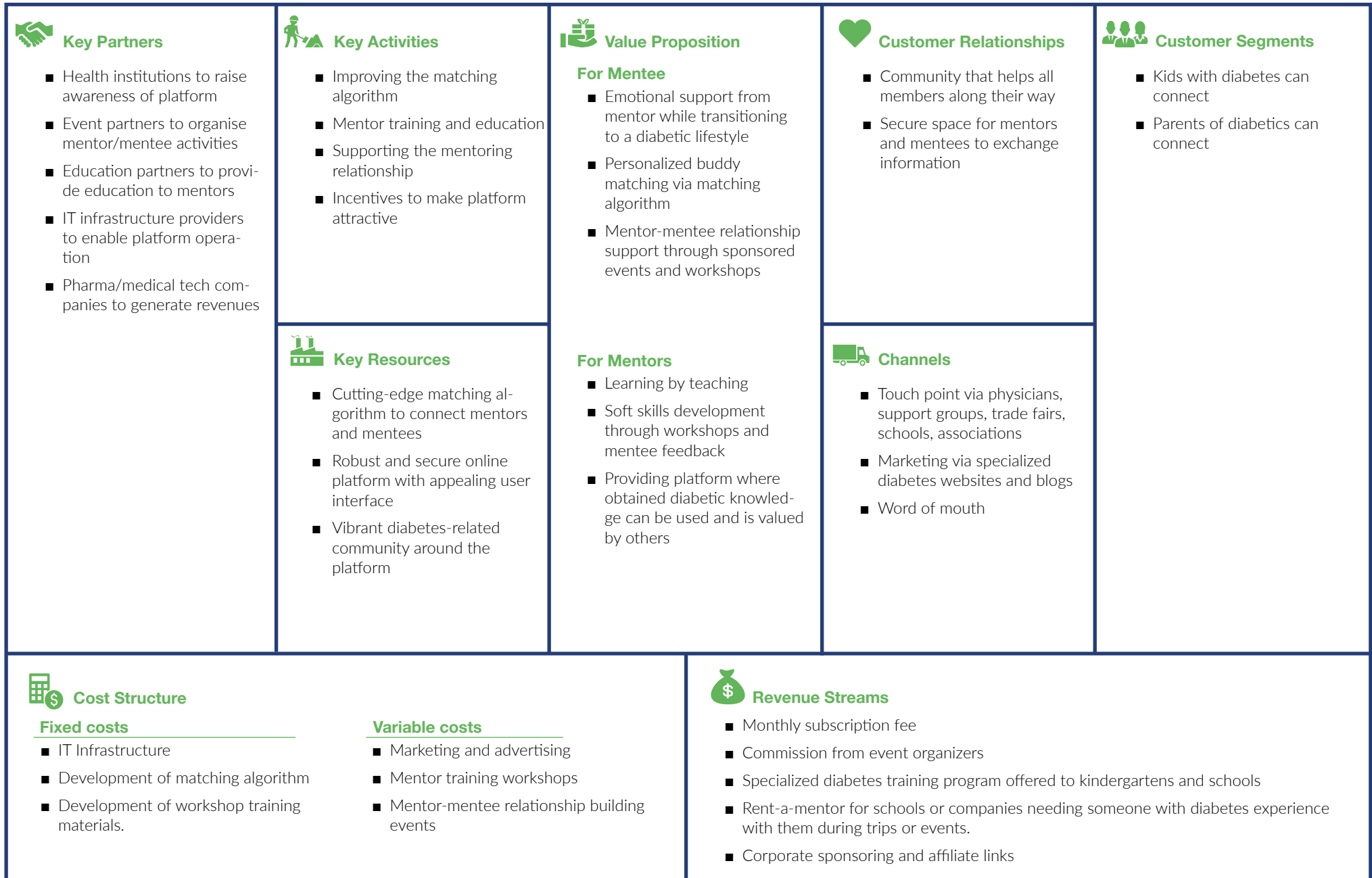


DIABETES BUDDY

tee pair using both personal and medical information about the diabetics. Afterwards, the platform supports the creation of a vivid and long-lasting relationship between each pair, by suggesting various events especially suitable for fostering diabetes-related discussions, but also taking the individuals' backgrounds into account. In addition, the mentors receive specifically targeted education, teaching them how to guide their mentees and interact with them both on an emotional as well as a factual level. Apart from the core one-on-one interaction, Diabetes Buddy also provides an online diabetes community with topic-related product information.

In its initial phase, Diabetes Buddy aims to cooperate with health institutions, to awareness of the platform, but also in order to receive funding and access to experts necessary to educate the mentors. As a next step, a network of event partners to provide the mentor-mentee pairs with fitting activities will be developed. New revenue streams will be opened up via commissions from event partners and affiliate link integration of Pharma-/Medical Tech company partners in the platform. Also, steady improvements of the matching algorithm using aggregated data, continuous modernization of the user-interface, and better integration of third party content, will be carried out, to maintain a robust, secure and user-friendly platform.

Business Model



Key Partners

Diabetes Buddy requires several key partners who assist in creating and fostering mentor relationships as well as generating revenue to finance the platform. In its initial phase, the key partners for Diabetes Buddy are in the health sector as such as insurances and governmental entities. Due to the shared goal of improving the quality of life of diabetes patients, they provide financial and educational resources as well as marketing channels directly, via their website, flyers etc. and indirectly, via physicians and care providers.

Collaboration with pharma and medical tech companies is important to generate revenue in the long run. Their products could be integrated into the platform, via affiliate links, and the aggregated user data of Diabetes Buddy could be sold to them. In order to keep mentors and mentees interested in the platform after the initial matching as well as to assist them in forming long lasting relationships, and create a lively community, a significant number of event partners for leisure activities is needed. These activities are specifically selected by the event partners and are suggested to the members on the platform. Due to the importance of well-trained mentors for the platform, Diabetes Buddy needs education partners, who provide the necessary knowledge via workshops and seminars. This includes both factual information, such as recommendation on the usage of diabetes devices or determining the bolus intake, as well as training in handling the emotional and societal aspects of diabetes.

Especially in the beginning, the platform requires external partners to provide the underlying infrastructure. In order to maintain a secure and robust platform, a working IT infrastructure is a crucial necessity. In addition to that, offices for administrative purposes and seminar rooms to host the educational workshops are needed to enable Diabetes Buddy to offer the complete range of its services.

Key Activities

There are three main key activities for Diabetes Buddy: Improving the matching algorithm, mentor training and education, as well as supporting the mentoring relationship. Diabetes Buddy's main function is to provide an optimal mentor-mentee match through the matching algorithm. As more users from different locations sign up, and once many mentors

have been reviewed by their mentees and diabetes buddy's local support staff, the matching algorithm will be adapted to use this new data to provide better mentor-mentee matches in the future. To further increase the quality of new matches, and data-sets, such as new treatment options, will be evaluated to see if it can further increase the pairing quality.

Once the partners have met through Diabetes Buddy, the focus switches to the mentor-mentee relationship. To support this, we will provide guidance seminars for the mentors, giving them the most important soft skills to foster the relationship and to show them how to take advantage of the buddy program. In addition to these soft skill seminars, the participants will also partake in workshops where they will be taught facts regarding the issue of diabetes. This combination of imparting detailed knowledge about the illness, and guidance on how to interact, creates a fruitful environment for the participants. Beyond training and matching, Diabetes Buddy offers suggestions to the mentors and mentees on how they could spend their time together. This enables them to foster their relationship on their own. This is accomplished by working together with several partners to offer a variety of ideas and possible activities that can be done together. To further increase the quality of suggestions, Diabetes Buddy will use data from previously attended events, as well as the user's interests, to suggest more appropriate activities to them.

Key Resources

The potential success of Diabetes Buddy depends on the availability of the following key resources. The matching algorithm lies at the core of the business model, since it is used to find the optimal pairing of mentor and mentee. The algorithm uses both personal (age, school, interests, etc.) as well as illness related information (time of diagnosis, current experience with the disease, etc.) to first establish a ranking of available mentors for each mentee and vice versa. In a second step, members of each group are paired up to achieve the overall most beneficial outcome for the community. In order to guide and assist newly diagnosed patients in their life with diabetes, a significant number of experienced mentors, with both the factual knowledge as well as the necessary empathy and emotional intelligence, are needed. Only then can a successful and beneficial experience for the mentees be

provided. Also, a team responsible for managing the platform is indispensable.

Furthermore, Diabetes Buddy needs an IT infrastructure on which the matching platform itself is built and on which supporting tasks can be performed upon. It consists of both hardware (servers, administrative computers) and software (matching algorithm, web frontend and backend) to allow platform access via browser, mobile or desktop app, data handling and storage, platform testing, improvement and maintenance, as well as proving robustness, error handling, and scalability possibilities.

In order to preserve its usefulness after the initial matching process, and to increase its overall attractiveness, a vivid online community regarding diabetes related topics has to be created around the platform. This includes not only actively participating mentees but also a considerable number of lecturers, educators, event organizers, and other external partners remaining involved with the platform in the long term.



Value Proposition

Diabetes Buddy's core mission is to connect people who have been living with diabetes with people who have been newly diagnosed with diabetes. This includes the parents of newly diagnosed diabetics. As a new diabetic, or parent of a diabetic, there is a steep learning curve, which can be overwhelming. Receiving support, both emotionally and educationally, from someone who has been living with diabetes for a long time, is a precious valuable asset, for both the mentor and mentee.

Mentee: Through the personalized matching algorithm, Diabetes Buddy can match mentors and mentees based on their geographical location, type of diabetes treatment, age, and overall lifestyle, to ensure the best match. This is valuable to the mentee, as they get a mentor who has had a very similar experience and can therefore give very relevant and helpful advice. The platform also offers a mentor evaluation feature, which allows the mentee to rate the mentors they've been in contact with to ensure a high quality of mentors. To further enhance the mentee's user experience after a match has been established, the platform is also a place where people can organize fun events, workshops and exchange information. This helps to establish a community and provides the mentees with a sense of belonging. These exciting and fun events will also be recommended to the mentees, based on previous events attended and lifestyle.

Mentor: As a mentor, there is always something to be new in diabetes treatment to be learned and this is where the value of learning by teaching comes into play. By providing support to a mentee, the mentors will also learn new things that the mentee might suggest or has discovered. Valuable social skills can be acquired by showing empathy and providing emotional support. Diabetes Buddy also offers workshops to the mentors to help them develop their soft skills, so they can get better in mentoring. Through the mentor-mentee feedback system, the mentor can also improve through direct feedback from the mentee's as well as the mentor-mentee pairing can be changed early in the relationship if the match did not fit. Finally, the platform provides a communication channel, where the mentor can use the obtained diabetes experience and knowledge to bring value to other people, providing a sense of purpose and belonging in the diabetes community.

Customer Relationships



Once Diabetes Buddy has acquired customers, we want to make their experience in our buddy program as secure and valuable as possible in order to make it the best place to talk and share knowledge about diabetes. We will organize events where mentors and mentees can meet up with their mentor, but also other buddy pairs. We want to establish a community, which both mentors and mentees can always turn to.

Before entering the buddy program, mentors will be trained in a workshop to prepare them for their upcoming tasks. In these workshops, they will also get to know other mentors. Diabetes Buddy's platform will be a secure space for mentors and mentees to exchange their experiences as well as share activities that can be suitable for future meetings. Thereby they will get to know a whole community of people to share their experience with the disease.

Through our social media presence, we also want to inform and be a source of information for diabetes. There will be events for our diabetes buddies to socialize. We want to especially focus on the mentors and show them appreciation for their actions.

In general, it is possible for customers to evaluate their buddies and share their experience. After a successful mentoring relationship, the mentee is encouraged to become a mentor for a newly diagnosed diabetic. This process allows us to create a full customer lifecycle and profit from mentors who previously had the experience of being a mentee. This helps Diabetes Buddy build a strong community.

Channels

Diabetes Buddy raises awareness about the buddy program through doctors and diabetic care centers. Newly diagnosed patients will get introduced to the program by their doctor or caretaker, who will provide them with a pamphlet containing information about the program and how to join. After this first touchpoint, patients who are interested can go to the website or speak to a mentor or mentee who already joined the program to get more information. Doctors and caretakers are also valuable resources to suggest mentors for the program, as people with more experience with diabetes still require periodic check-ups. People who could be a potential mentor will be contacted by Diabetes Buddy directly with an invitation to take a look at the program, if a doctor has recommended them with their consent. Furthermore, Diabetes Buddy will offer informational events at diabetes centers as well as at meeting and fairs of local diabetes support groups. With this offline approach, Diabetes Buddy focuses on connecting with the customers from an early stage on and shows them how the platform can help them deal with the disease.

To reach out to even more people, Diabetes Buddy's platform and social media presence will offer a lot of information about the program. Diabetes Buddy will publish a recap of events that have been organized on social media to show the mentor-mentee relationship in order to attract attention and explain the program. Diabetes Buddy also collaborates with diabetes bloggers, telling them about the program and getting them involved as either mentors or supporters of the buddy platform. Thereby, Diabetes Buddy can reach the target audience and people who want to learn more about diabetes care in an efficient way.





Customer Segments

The initial strategy of Diabetes Buddy is to focus on children who have diabetes and their parents, and use an advanced matching algorithm to find suitable mentor-mentee relationships, thus enhancing the quality of life for all parties. Hence, the customer segment consists of two major groups: Parents of children with diabetes, where the parents want to participate in a parent-to-parent mentoring relationship, and children who have diabetes and want a mentor-mentee relationship.

Parents: Parents want to provide their children with the best care available. More than one third of all parents experience high stress when their child is diagnosed with diabetes [359]. Diabetes Buddy can provide a mentor for them, who experienced a similar situation and can thus provide support. This support ranges from tips regarding doctors to mental welfare. Furthermore, knowing that their child has a personal and similarly aged mentor, parents can be reassured that it has a go-to-person who shares the same problems.

Furthermore, Diabetes Buddy's goal is to enable a transition from a mentee role towards a mentor role for the parents, meaning that parents who gained experience in dealing with their child's illness can contribute and share their experience with parents of newly diagnosed children.

Children: Diabetes Buddy's main target group are young children who have been recently diagnosed with diabetes. Especially when starting school, the necessity to explain their illness to others in combination with the need of consistent glucose measuring and wearing a pump can overwhelm a child. Diabetes Buddy believes that with the right mentor - in form of an older or more experienced pupil, who assists the child by giving advice and helping out - the transition to a diabetic lifestyle becomes much easier.

Furthermore, the child can mature from a mentee position to a mentor position and thus support others. Diabetes Buddy will not only assist in this journey by finding the right mentor-mentee matching but also by organizing events for the buddies and workshops for the mentors.



Cost Structure

The cost of Diabetes Buddy can be divided into variable and fixed costs.

The variable costs consist of the workshop costs, in which the mentors learn to guide and support their mentees. These workshops require the booking of a trained expert as well as suitable facilities. In addition to the educational and emotional training that is taught in the workshops, events for mentors and mentees for leisure activities also need to be planned. If these events are realized in cooperation with a partner, the location and staff need to be paid. In order to raise awareness for Diabetes Buddy and thus have a sufficient user base with enough mentors and mentees, investments into marketing are necessary. Marketing activities will be focused on being present at diabetes fairs and medical congresses. These offer great possibilities to show the product to doctors and other stakeholders. Direct marketing is focused on online marketing through Facebook and Google ads.

Beyond the variable costs, the fixed costs consist mainly of personnel costs, IT administration costs and workshop training material development costs. Diabetes Buddy needs staff for administration, for organizing the events and workshops, as well as to support the users. Furthermore, the matching algorithm development needs specialists in the field of computer science or mathematics, who will optimize the matching process. The IT administration costs consist of maintenance of the current IT infrastructure as well as improvements. Furthermore, support staff is needed to help users who experience technology related problems. Finally, to consistently and properly train the mentors during the workshops, the training material needs to be developed.



Revenue Streams

Revenue is generated through five different sources: mentee subscription fees, commission from events organized by the event partners, through corporate sponsoring and affiliate links, through specialized diabetes training programs offered to kindergartens and schools, and through the rent-a-mentor program.

Subscription fee for mentee: As the platform brings the most benefits to the mentees, only the mentees will be charged a monthly subscription fee. This fee can potentially be covered by their health insurance, as many people with diabetes have a high risk to develop depression. The Diabetes Buddy mentoring program is a prevention and treatment method for depression as it is focused on providing emotional support and the subscription fee program would be significantly cheaper than seeing a therapist.

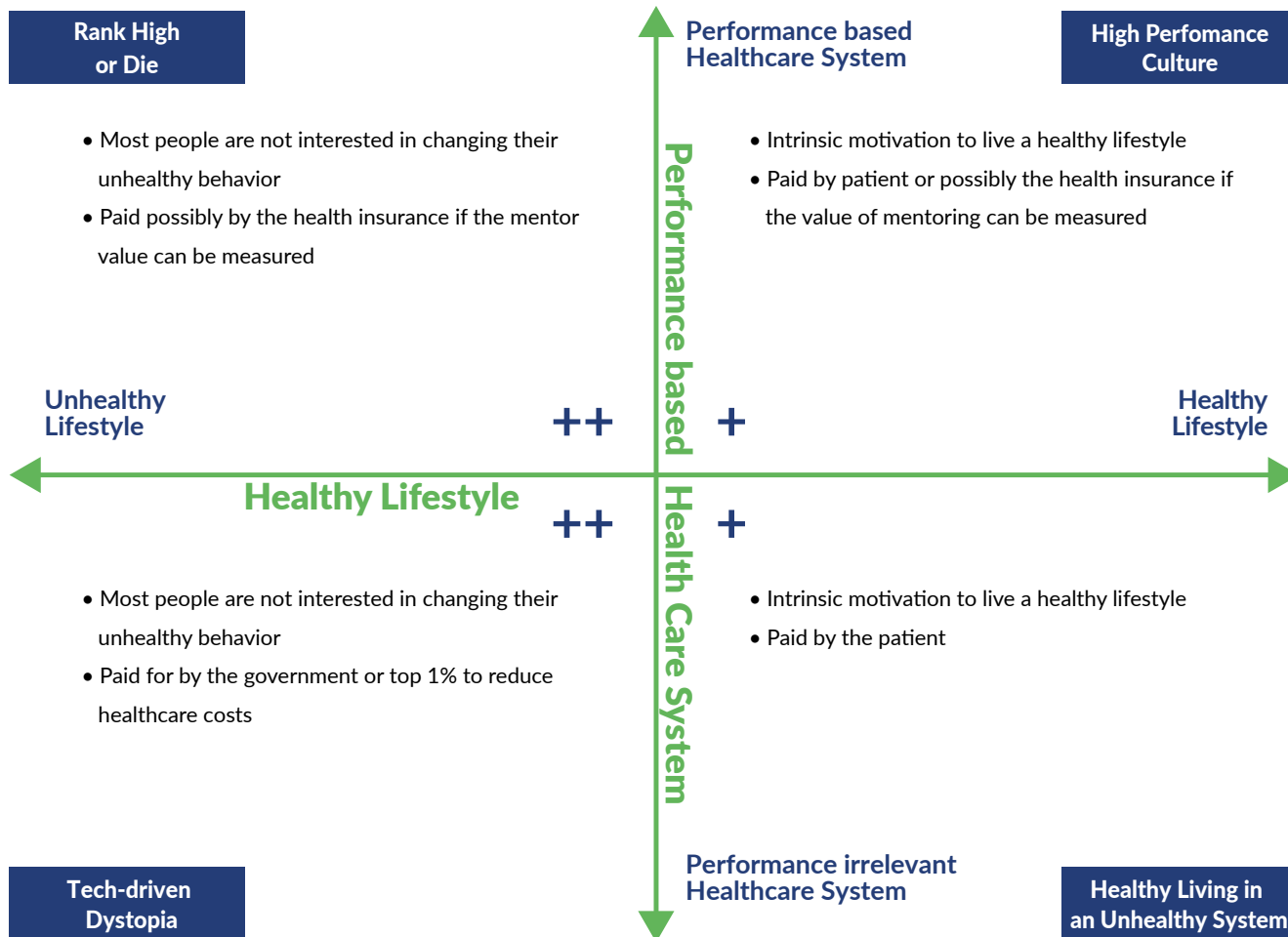
Event Commission: Events which help foster the mentor-mentee relationship will be organized by Diabetes Buddy but will be hosted by local businesses. Since Diabetes Buddy helps local business generate revenue and acquire new customers, Diabetes Buddy will receive a referral fee, based on the number of people attending these events. As the number of Diabetes Buddy members increases, so does the commission negotiation power. This leads to an increase in revenue as the company expands.

Corporate Sponsors: Since many different diabetes treatments are available on the market, there are opportunities for companies to offer their services to diabetics as well as generate awareness for their products. Companies can sponsor Diabetes Buddy, giving them a new way to reach customers. Diabetes Buddy would also receive a commission fee through any products bought via these affiliate links.

Specialized Diabetes Training: Once a large trusted mentor program has been established, the experienced mentors, specifically parents of diabetics, will be used to train kindergartens and schools on how to handle children with diabetes. These courses will be offered to various institutions needing diabetes training, especially when dealing with children and parents.

Rent-a-Mentor: When schools or companies with diabetics take trips or attend events, having someone who is experienced working with diabetes can be extremely helpful. Experienced adult mentors, with the appropriate training, will be paid to accompany the school class or during company events, to take care of any diabetes related issues. Part of this fee will go back to Diabetes Buddy.

Scenario Fit



Rank High or Die

In this scenario it is hard for sick people to receive treatment if they have little chances of a successful treatment. As T1DM diabetes is a chronic disease, some might not get the treatment and information that they need, especially if they are very unhealthy and the available treatment will not significantly improve their health. For those who can see a doctor, Diabetes Buddy can provide a lot of value to the overall lifestyle of the patient and will be recommended. If this value can be measured, then the health insurance providers will reimburse the monthly subscription costs. If it cannot be measured, then the patient will have to pay for the service themselves. Only patients who see the benefit in getting emotional support, for example people who have depression problems, will see the benefits and will be willing to pay.

Tech-Driven Dystopia

In the tech-driven dystopia, most people are not interested in living a healthy lifestyle and this behavior is accepted as being normal. Only the cheapest treatments, which treat the symptoms will be reimbursed, which could result in the root cause being neglected. People need education and help in how they can change their behavior, thus Diabetes Buddy is a great solution. Diabetes Buddy helps people to get more education about the disease and healthy living. Diabetes Buddy is not enforcing their help but they offer the opportunity to get a mentor who deals with the same problems to talk to. Diabetes Buddy will not get funding from insurances, but rather the government, as the high healthcare costs are putting a burden on the system.

High-Performance Culture

In this scenario people live healthily and actually want to improve their health in every way possible. Thus they will likely take the opportunity to get into a mentoring relationship regarding their health, once they are diagnosed with diabetes. This will help them to tackle their disease and give them the right information on how to handle it.

Insurances will pay for the patient's Diabetes Buddy monthly subscription fee as they see the long-term benefits from people helping each other. Modern technology is present to achieve a better health status and advice to improve personal health and is valued by everyone. With Diabetes Buddy's focus on educating children about their disease from early on, this service offers a great solution in this scenario. Since Diabetes Buddy is also a community, people will be curious how other people in the community are living with their disease and is another main reason for people to join and engage with Diabetes Buddy.

Healthy Living in an Unhealthy System

In this scenario people have an intrinsic motivation to live a healthy lifestyle. People who are sick want to improve their health and do everything to stay as healthy as possible. Therefore, Diabetes Buddy brings value as it offers a solution, apart from doctors and caretakers. Physicians do not really have time to explain diseases and properly care for their patients, as they do not get paid for taking good care, but only for prescribing medication and returning patients. As only the cheapest solution, which treats symptoms, will be reimbursed, Diabetes Buddy may not be paid for by health insurances, as it does not directly treat diabetes symptoms. In this scenario, parents might be willing to pay for such a service because they strive for their children to live a healthy life with diabetes and Diabetes Buddy helps to provide this.

Challenges

- To grow quickly and reach critical mass, so that the growth becomes self-sustaining
- Establish a high retention rate on the platform and Diabetes Buddy communities
- Create a community, in which members actively want to participate and help other diabetics
- Generate a stable revenue stream, by getting Diabetes Buddy reimbursed by insurance companies

Outlook

Diabetes Buddy has a very bright future. Regarding the service of Diabetes Buddy, the next step will be to implement a doodle-like scheduling service that allows an easy scheduling of meetings. This helps customers with the management of their mentor-mentee relationship and Diabetes Buddy by generating an incentive for customers to use the service.

In a further step, Diabetes Buddy will expand geographically and open up to new markets in other countries, as especially Asia and America will become diabetes hot spots. An even further step regarding the customer base is the approach to extend the Diabetes Buddy mentor-mentee relationship to other diseases, like depression, and use the gained experience to provide a support network. On the financial side, a next step is to strengthen the partner network and then use diabetes medical device manufacturers communication channels for advertisement. By cooperating with device manufacturers, both parties benefit, as customers get a supporting mentor to help them with their transition toward, for example, a diabetes pump. In a long-term perspective, after successfully implementing the mentor-mentee-community for children and parents, the next step will be the transfer to the adult customer segment. This transition allows Diabetes Buddy to first get insights into the market with a manageable niche group and then target a broader customer segment. In the end, Diabetes Buddy will not only support children with diabetes, but enable them to become mentors themselves and help others to live a happy life despite diabetes.



Smart Tooth

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 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.

Business Model

 <p>Key Partners</p> <ul style="list-style-type: none"> Artificial pancreas manufacturers for development and sales Assembly of components is outsourced to external manufacturers Diabetologists and dentists For joint development and installation of the device Insurances to reimburse the Smart Tooth 	 <p>Key Activities</p> <ul style="list-style-type: none"> Research and Development Getting medical approval Sales, marketing and education of doctors, hospitals, insurances Quality management to ensure standards 	 <p>Value Proposition</p> <ul style="list-style-type: none"> Avoid patient's constant thinking of diabetes Improve calculations for insulin injections Enable better diabetes treatment Measure amount and composition of food intake Detect eating habits and eaten carbohydrates Provide a user friendly smartphone app 	 <p>Customer Relationships</p> <ul style="list-style-type: none"> Dedicated personal assistance with artificial pancreas suppliers Ongoing exchange with physicians Responsive, informative and supportive social media interaction with end-customers 	 <p>Customer Segments</p> <ul style="list-style-type: none"> Artificial pancreas suppliers Patients Dentists 		
 <p>Key Resources</p> <ul style="list-style-type: none"> Intellectual property Clinical effectiveness and efficacy Experts in fields of medicine and technologies 	 <p>Channels</p> <ul style="list-style-type: none"> Direct sales via physicians Using distribution channels of key partners App-stores for the Smart Tooth freemium application 					
 <p>Cost Structure</p> <table border="0"> <tr> <td data-bbox="168 1236 548 1340"> <p><u>Fixed costs</u></p> <ul style="list-style-type: none"> Research and Development Medical Approval </td> <td data-bbox="660 1236 952 1380"> <p><u>Variable costs</u></p> <ul style="list-style-type: none"> Material Manufacturing Services </td> </tr> </table>		<p><u>Fixed costs</u></p> <ul style="list-style-type: none"> Research and Development Medical Approval 	<p><u>Variable costs</u></p> <ul style="list-style-type: none"> Material Manufacturing Services 	 <p>Revenue Streams</p> <ul style="list-style-type: none"> One-time payment for device Smart Tooth app in freemium model Fees of partners to access API 		
<p><u>Fixed costs</u></p> <ul style="list-style-type: none"> Research and Development Medical Approval 	<p><u>Variable costs</u></p> <ul style="list-style-type: none"> Material Manufacturing Services 					

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-

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 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 long-term 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 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.

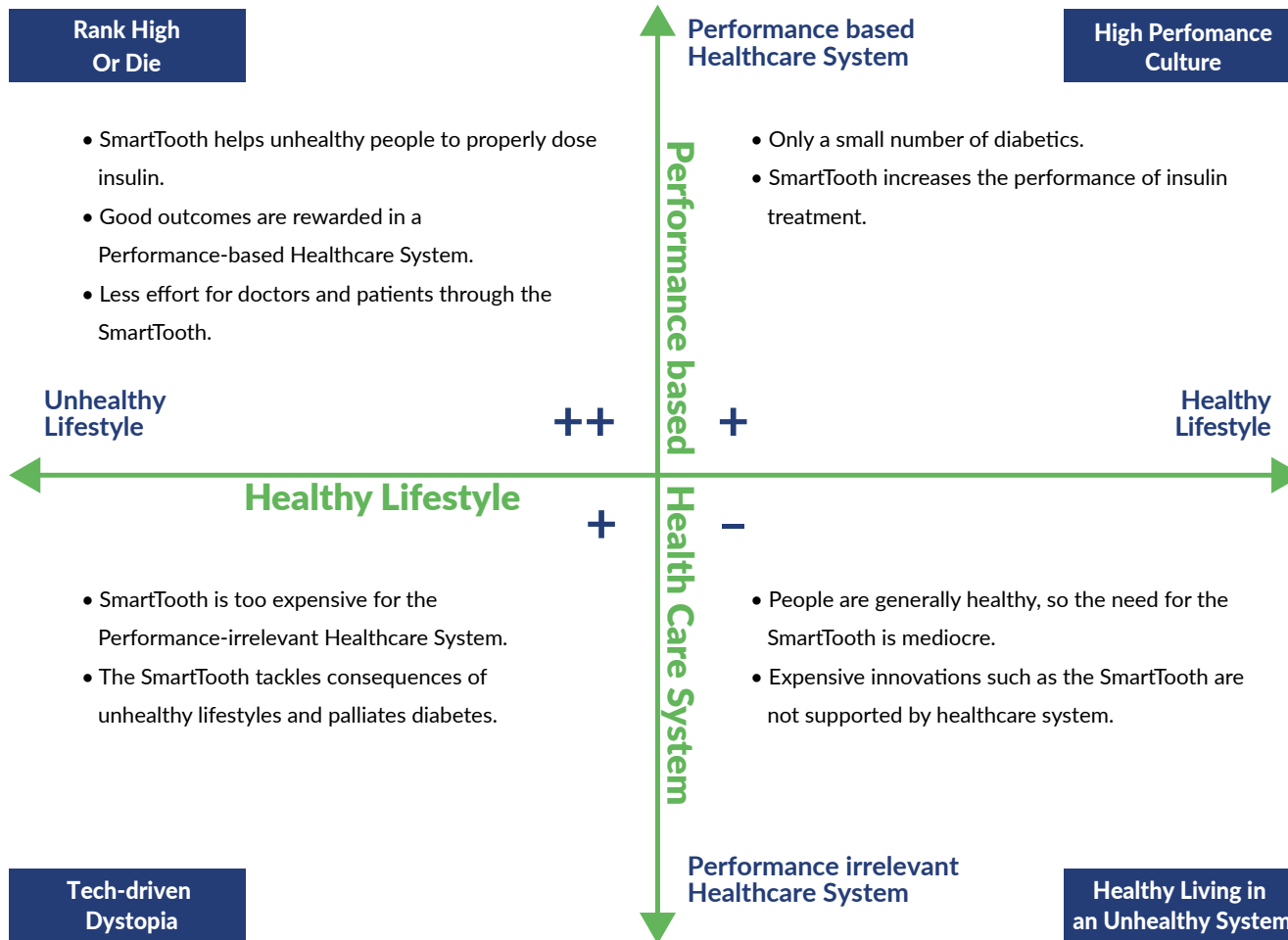
The variable costs consist mainly of contracts with manufacturing partners and hardware materials. The costs for purchasing sensors, energy elements, transmission units, and mounting materials are scalable and thus variable. Since a high and consistent quality of the product is essential, the purchase 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.



Scenario Fit



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 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.

Challenges

- Designing, manufacturing, and commercializing such a product carries high costs, which in turn affects the end-customer
- Fitting all components, such as sensors, integrated circuit, and antenna, in a tiny, non-obstructive device is a major obstacle. Yet, we expect technical components to get smaller in size with time
- Especially spectrometers need to be manufactured in smaller dimensions and require a light source in order to receive a spectrum. Patients might be concerned having an infrared light source in their mouth
- Highly advanced algorithms, which detect patients' eating habits, have to be developed
- Besides providing more data about the food intake, another goal of the Smart Tooth is to eliminate the pre-meal bolus. Thus, ultra-fast-acting insulin is needed, which is currently still in development
- The systems must be constructed as self-sustaining as possible to reduce check-ups to maintain the Smart Tooth

Outlook

Advances in the performance and accuracy of continuous glucose monitoring systems lead to reliable input data for closed-loop algorithms. Within the next years, different types of AP devices will be on the market. Furthermore, several companies are working on ultra-fast acting insulins that decrease the time lag between the injection and the blood-glucose lowering effect. This might even enable injection simultaneously to eating a meal. Both developments serve as preconditions to the Smart Tooth. Our product enables the closed-loop system to function without any major manual intervention. In the long term, we also want to target new customers, such as health-conscious persons or athletes, who will have the Smart Tooth installed as a standalone tool, because they want to keep track of their carb intake. Moreover, we want to develop a comprehensive health platform for premium subscribers that integrates health data from various sources and provides customers with additional advice on physical activity and food intake.



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Digital Innovation in Diabetes Care

Diabetes is a set of chronic metabolic diseases, in which the body can either not produce enough insulin or not process insulin correctly, resulting in raised levels of blood glucose. Diabetes not only has a high prevalence – currently affecting one out of eleven adults worldwide – but is also a very serious condition: In 2015, diabetes caused more adult deaths globally than HIV/AIDS, tuberculosis, and malaria combined according to the International Diabetes Federation. Current trends, such as the obesity pandemic, increasing life expectancy, and urbanization lead to a growing prevalence of the disease and the need for innovation in diabetes care.

Technological development is opening up remotely accessible treatment options through telemedicine, the Internet of Things can potentially increase patient's quality of life, and preventive care is becoming more feasible through, e.g., machine learning. However, growing processing power, combined with the in-

creasing collection of health-related data, also leads to legal challenges in handling patient data. Furthermore, the growing number of diabetes patients worldwide is putting economic pressure on healthcare systems.

This report consists of three parts: First, the authors analyze trends in the field of diabetes care. From these findings, four scenarios are derived that vividly depict possible futures. In the final part, five business ideas are elaborated and validated in each of the four scenarios.

The concepts ideated range from an online prevention program for teens, a platform that makes shopping under dietary restrictions easy, a mentoring program to support newly diagnosed diabetics, an artificial pancreas matched with a platform to holistically manage disease-related data, to a smart device that makes manual interference in diabetes treatment a thing of the past.



The Center for Digital Technology and Management (CDTM) is a joint interdisciplinary institution of education, research, and entrepreneurship of the Ludwig-Maximilians-Universität München (LMU) and the Technische Universität München (TUM).

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