RRI Case Study

Telemedicine for diabetes care – the case of GlucoTel™

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Executive Summary

This case study takes a look at telemedical applications in the area of diabetes care through the case of GlucoTel™, a telemonitoring system developed by BodyTel™. It links the company's activities to aspects of Responsible Research and Innovation (RRI) such as addressing societal challenges, stakeholder engagement, legal requirements and open access. In addition to describing the relationship between the telemedical diabetes monitoring system from BodyTel™ and RRI activities of the company, this case study also takes a global perspective into account.

The number of people with diabetes worldwide is projected to increase from 171 million in 2000 to 366 million by 2030. Diabetes is not only a challenge for Europe or the USA but also for low and middle income countries. It is a global societal challenge which is connected with health complications, secondary diseases and skyrocketing costs for health care services as well as absenteeism from the workplace.

Telemedicine provides an integrated approach for patients and caregivers with efficient tools to support their daily tasks in diabetes care. As part of the BodyTel™ system, GlucoTel™ is such an approach. It is a sensor for telemedical blood glucose monitoring and diabetes management and is used for automatic, continuous documentation of all blood glucose levels. It is part of the three-stage BodyTel™ system which consists of a measuring device with Bluetooth technology, an app for mobile phones and tablets, and an online diary which is connected to the secure Medical Data Cloud where all data is stored.

BodyTel™ and its devices and services are certified regarding EN ISO 13485:2012 and ISO 15197:2015 to meet legal requirements for medical devices. In 2012 the company became part of the Continua Health Alliance to follow an open access approach which allows a standardized interface for higher compatibility with other products and services. Furthermore, BodyTel™ engages stakeholders such as patients and caregivers during its development processes to improve the treatment of chronic diseases and contribute to higher quality of life for patients. It also contributes to building an overall standardized telemedical system which allows a better and more efficient treatment of chronic diseases such as diabetes.

All these activities are closely connected to the RRI approach and not only benefit patients and caregivers but also the company itself. The feedback gathered throughout engagement activities allows BodyTel™ to improve the usability of their devices which is key for the success of such solutions. Furthermore, contributing to the development of an overall standardized telemedical system allows BodyTel™ to set parts of this standard, and could guarantee great competitive advantage through lock-in effects. Also, the open access approach with the Continua certification benefits the company, leading to better cooperation and the establishment of new partnerships as well as cost savings.

Overall the case study shows that integrating RRI principles into company processes not only benefits users – in this case patients and caregivers - but can also have great benefits for the company, e.g. by guaranteeing competitive advantage.

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Field of Industry or Service

Diabetes as a global societal challenge

Diabetes mellitus, commonly referred to as diabetes, is a group of metabolic chronic diseases characterized by a sustained elevated blood glucose level, which is caused by a reduction in the action of insulin secretion where related metabolic disturbances generate severe, acute and long-term complications and secondary disease that are responsible for premature death and disability.[1]

In Western societies, diabetes and its complications are causing a great amount of suffering and continue to be a major health problem which leads to as much as 8% of national spending in health care.[2] It is rapidly emerging as a global health care problem that threatens to reach pandemic levels by 2030.[3] The number of people with diabetes worldwide is projected to increase from 171 million in 2000 to 366 million by 2030.[4] The increase can be observed in high income settings such as Europe or the USA but will mainly occur in low or middle income countries (LMICs). This shows that diabetes, which is often caused by being overweight or obesity, is not only a challenge for Europe or the USA but can be seen as a global challenge (see figure 1[3]). Also the incidence and prevalence of diabetes among children are increasing at an alarming rate, with potentially devastating consequences. This increasing number of diabetes patients is a huge challenge when it comes to being a healthier society and is connected with skyrocketing costs for health care services.

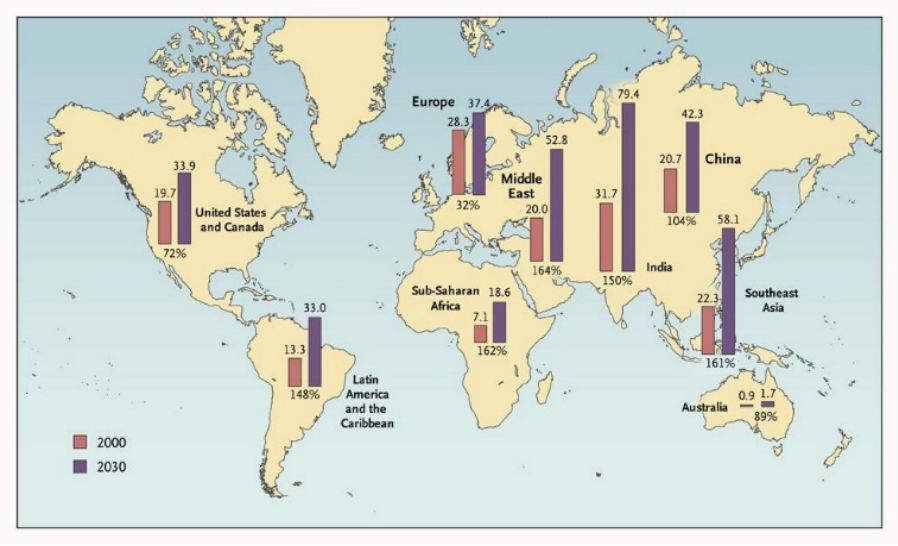

Figure 1: Millions of cases of diabetes in 2000 and projections for 2030, with projected percent changes (Source: see reference 3)

Nowadays, a well-treated insulin-dependent diabetic patient can expect to have an almost normal life span due to the benefits of intensive management reducing long-term complications.[5] Nevertheless, the achievement of the therapeutic goals implies a significant increase in the amount of patient data to be monitored.[2] The basis of diabetes therapy and the therapy approach itself are diaries, written by patients or their nurses: a regular obligation with many potential sources of error. The consequences can include dosing errors, bad metabolism, as well as deviations from treatment recommendations, all of which can result in avoidable secondary complications. These errors often lead to in-patient stays connected with high costs such as hospital costs but also absenteeism from work.

For the last two decades, diabetes has been a major clinical focus for advances in information technology[6] such as telemedical applications. Telemedicine provides an integrated approach for patients and caregivers to support their daily tasks in diabetes care. This is a fundamentally different healthcare model, particularly in the way healthcare is delivered.[7] A main goal of

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telemedical diabetes care is to minimize potential sources of error and optimize treatment to reduce the risk of secondary disease and other complications. From an economic point of view such solutions could help ensure savings in care and nursing services.

The GlucoTel™ system

GlucoTel™[a] is a sensor for telemedical blood glucose monitoring and diabetes management. It is used for automatic, continuous documentation of all blood glucose levels and is part of the three-stage BodyTel™ system, consisting of a measuring device with Bluetooth technology, an app for mobile phones and tablets, and an online diary (see figure 2).

Figure 2: The GlucoTel™ System (Source: BodyTel™ GmbH)

BodyTel™ is a German telemedicine company which has developed a comprehensive monitoring and management system for chronic illnesses. The aim is to provide patients and persons authorized by patients (e.g. medical professionals or family members) with the most up-to-date and precise information that is possible about the patient. Decisions about changes of treatment can thus be made more quickly, secondary illnesses can be minimized, and quality of life can be improved.

GlucoTel™ addresses a variety of users. For example **parents of affected children** who want to know if the child performed the necessary blood glucose measurements and about the measurement's value. Through the GlucoTel™ system, they can be informed about any measured value automatically. But **people of all ages** can benefit from the GlucoTel™ system by not having to manually document their measured values anymore. An online diary stores all values and can be printed out before seeing the doctor, or more generally shared with the caregiver. Additionally, **people who worry about elderly dependents** can also take advantage of the system. The GlucoTel™ system can help older generations with diabetes to live an independent life for longer. Also **medical caregivers** such as physicians or diabetes advisors benefit from the GlucoTel™ system. The automatic and complete data storage provides seamless documentation. With the authorization of the user, caregivers can access the diary and provide direct feedback. This may reduce unnecessary doctor visits, and questions can be clarified on the phone.

[a] All information about the product and the company is taken from the company website: http://bodytel.com/?lang=en.

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All values measured with BodyTel™ devices are sent wirelessly via Bluetooth through a cell phone or home gateway into the patient's online record. All patient records are located in BodyTel™'s secure Medical Data Cloud, which is part of the medically approved overall system. All patient data remains the exclusive property of the patient, who has access to these values in their personal online record. With the optional monitoring function the patient alone may permit third parties (e.g. doctors or family members) to view the record. Caregivers can independently decide whether they want to receive real-time alerts via text message, e-mail or fax for every incoming measurement value, only for unusual ones, or none at all. These authorized monitoring rights can be withdrawn any time by the patient. The online diary provides comprehensive displays and summary functions. It enables doctors or medical caregivers to monitor and control the measurement behavior of a large number of patients.

Event or Activity

The BodyTel™ ecosystem & stakeholder engagement

During the development of products and services the BodyTel™ team addresses a wide variety of stakeholders to develop tailored solutions. The BodyTel™ ecosystem includes five major groups:

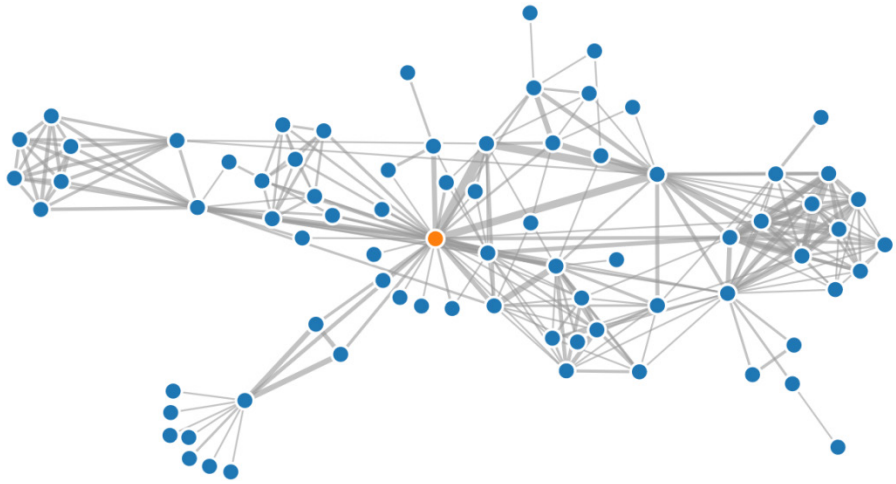

Figure 3: Business ecosystem (exemplary – source: own illustration)

- *Patients & family*

  The main stakeholders of BodyTel™ are patients and their families, as its solutions address people suffering from diabetes who want to better document their health data and control their chronic disease. Furthermore BodyTel™ provides solutions for people who want to care for their family and friends who suffer from chronic diseases such as diabetes. This might happen in the case of school children, grandparents, or friends living far away.

- *Caregivers & medical advisers*

  Another key stakeholder group is made up of caregivers and medical advisers, who can use the BodyTel™ system to obtain complete documentation and, if authorized, observe the parameters of their patients. This way, physician visits can be reduced,

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and smaller problems cleared up on the phone, without the necessity for the patient to visit the doctor's office personally.

- *Health insurance companies*

  As a large share of the costs of the health system is caused by the treatment of patients with chronic diseases such as diabetes, insurance companies are another important stakeholder. The use of telemedicine can improve the treatment of patients and reduce costs, as problematic values can be detected faster, avoiding costs for regular doctors' visits. Thus, telemedical care programs can offer competitive advantages for health insurance companies.

- *Medical technology & pharmaceutical companies*

  For medical technology or pharmaceutical companies telemedicine has the potential to open up new market opportunities. They can position themselves with innovative products and use telemedicine and telemonitoring to become full-service companies.

- *Integrators of sensors and services*

  By providing an interface description of the telemedical blood glucose meter, as well as offering partners the ability to connect their solutions with our Medical Data Cloud BodyTel™, GlucoTel™ creates the opportunity to easily integrate new products or services which benefit customers and patients.

During the development of products and services BodyTel™ interacts with different groups of stakeholders. As BodyTel™'s focus is on the development of medical devices and services, patients and caregivers are of crucial relevance. According to Michaela Klinger, Head of Marketing & Business Development Manager of BodyTel™ GmbH, patients and caregivers often provide usability improvement hints during the project phase in which devices are tested on a smaller scale. The feedback is collected and handed over to the development department for implementation to improve the devices and services.[8] In the case of GlucoTel™ this happened during an 'Einsteigerprogramm'[b] in which BodyTel™ gave away compatible mobile phones including BodyTel™ SIM cards to patients who agreed to answer a product questionnaire every 3 months. In this way BodyTel™ has collected a lot of feedback over the years.[9]

Besides engagement during the development phase of products and services, BodyTel™ also collaborates closely with other actors in the field when it comes to the secure Medical Data Cloud and mobile App. At MEDICA 2015 BodyTel™ presented an overall solution for a standardized electronic health data infrastructure in cooperation with Cisco Systems, Parsek and Tiani Spirit. This makes the health data measured with the GlucoTel™ system available for the German telematic infrastructure. This enables the first European IT-system which meets the criteria for standardized electronic patient data and enables the transfer of blood glucose values or other health data measured at home via the mobile app and the Medical Data Cloud to established IT-systems in hospitals and doctors' offices.[10]

Overall, one could state that the engagement activities of BodyTel™ have two major goals: First, to improve their products and services, which guarantees BodyTel™ a competitive advantage, and second, better usability for patients, caregivers and other users, which

[b] Einsteigerprogramm (German) means program for novices.

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improves the treatment of chronic disease, improves the acceptance of new tools and helps to save health care costs.

Regulators also play a role as medical products are required to meet specific criteria to be sold on certain markets. BodyTel™ addresses this demand by certifying its processes and products according to industry standards as outlined below.

Certifications

BodyTel™ GmbH is certified regarding EN ISO 13485:2012 in the areas of the design, development, production and running of medical software (mobile Apps and online portals) for the management of health data, as well as services and trade of medical devices. EN ISO 13485 represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices, and is tailored to the industry's quality system expectations and regulatory requirements. In addition to this general certification of the company, the GlucoTel™ system is certified regarding ISO 15197:2015 which specifies requirements for in vitro glucose monitoring systems that measure glucose concentrations in capillary blood samples, for specific design verification procedures, and for the validation of performance by the intended users. These systems are intended for self-measurement by lay persons for management of diabetes mellitus. ISO 15197:2015 ensures certified systems meet specific criteria when it comes to performance.

Besides these two ISO certifications which can be seen as a first step in achieving compliance with regulatory requirements, BodyTel™ joined the Continua Health Alliance[c] in 2012,[11] which is dedicated to:

> [p]romote the adoption, standardization and appropriate regulation of personal connected health devices and systems in order to empower individuals to better manage their health and wellness from anywhere, at any time, with stronger links between consumers, their social networks and providers.[12]

Continua promotes its own standard for the transmission of medical data based on the Bluetooth health device profile (HDP) which allows the compatibility of Continua certified devices and systems. The goal is to benefit customers and patients through a greater variety of products and services compatible with each other, and allow the integration of a wide variety of sensors into the BodyTel™ Medical Data Cloud.

Why does this fall under Responsible Research and Innovation?

Health, demographic change and wellbeing is one of the societal challenges defined by the European Commission in the ‘Horizon 2020’ program which reflects the policy priorities of the Europe 2020 strategy.[13] Addressing societal challenges through innovation is part of Responsible Research and Innovation (RRI), as defined, for instance, by Rene von Schomberg. Von Schomberg emphasizes the societal desirability element of RRI, when he

[c] The Continua Health Alliance is part of the Personal Connected Health Alliance (PCHA): http://www.pchalliance.org/continua.

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argues that research and innovation have to bring “the right impacts and outcomes”[14]. This also becomes evident by taking a look at the definition of RRI given by the European Commission:

> RRI is an inclusive approach to research and innovation (R&I), to ensure that societal actors work together during the whole research and innovation process. It aims to better align both the process and outcomes of R&I, with the values, needs and expectations of European society.[15]

Inclusion is one of the most important dimensions addressed by RRI. In an industry setting this means companies should engage stakeholders throughout their innovation process and collaborate closely with them. By engaging a diversity of stakeholders during the innovation process aspects of sustainability, acceptability and desirability of products and services should be taken into account. But RRI is not exclusively about coping with societal challenges and collaboration; it also takes other aspects like legal requirements or open access into account.[16]

As described above, diabetes is a threat not only in Europe or the USA. It can be seen as a global societal challenge which need to be addressed through innovative solutions. Hence telemedical programs can be found both in Western countries as well as in LMICs. Especially in rural areas telemedicine can help to improve the treatment of diabetes. The Chunampet Rural Diabetes Prevention Project is an example of such a program. It was conceived with the aim of implementing comprehensive diabetes screening, prevention, and treatment using a combination of telemedicine and personalized care in rural India.[17] Although the project uses a combination of telemedicine and personalized care, it emphasizes the potential of telemedical applications in rural areas. In general, LMICs have good preconditions for implementing telemedical diabetes care programs as there is an increasing number of people with access to mobile internet and mobile phones. Figure 4 shows this rapid development for countries in which 2015 GNI per capita was $12,475 or less, including countries like China and India, which are assumed to be highly affected by the increase of diabetes (as figure 1 shows).

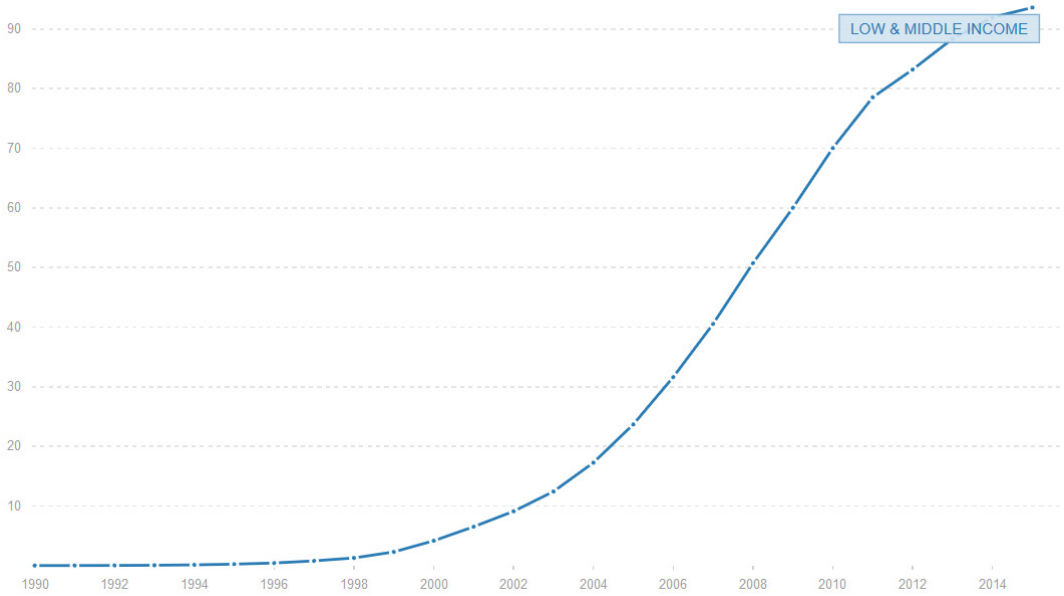

Figure 4: Mobile cellular subscriptions per 100 people from 1990-2015 for low & middle income (Source: Worldbank)

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The potential for telemedical applications is high as it allows more efficient care due to a better patient–medical advisor ratio, and lower complications and secondary disease rates. This allows a better quality of life as well as cost savings for health care and nursing. From an economic point of view this is an important factor, especially for LMICs which face great challenges in providing health care services. When telemedical applications can be made accessible and affordable to the countries most affected, then telemedicine has great potential help in solving the global societal challenge of diabetes care.

From this macro scale of RRI to the micro level, BodyTel™ follows several aspects of RRI in its activities. First, the company engages stakeholders such as patients and caregivers during the development processes to improve the treatment of diabetes, which contributes to higher quality of life for patients. Second, it complies with legal requirements through ISO certifications. And third, BodyTel™ follows an (partly) open access approach when it comes to its interface technology through the Continua certification. Besides the fact that BodyTel™ engages with stakeholders, complies with legal requirements and follows an open access approach, most importantly BodyTel™ contributes to building an overall standardized telemedical system which allows better and more efficient treatment of chronic disease such as diabetes, which are global societal challenges.

What are the benefits for industry?

The main benefits for BodyTel™ of the activities outlined above can be described as follows. Overall, the integration of different stakeholders during the development of products and services improves the usability of their devices which is key for the success of such solutions. In this context, Michaela Klinger stated that through the feedback provided, BodyTel™ is able to make the tools both more usable and smarter which encourages doctors and nurses to monitor patients more closely. In addition, she added that the improvements that can be implemented in the project phase are often beneficial for everybody; for BodyTel™ to improve the product, for caregivers to effectively monitor patients, and for the patients who feel they are in good hands.[8] The feedback gathered throughout engagement activities allows BodyTel™ to further develop their products, and thus is able to improve the monitoring process which benefits patients and caregivers as well as the company itself.

> User feedback is most valuable. They are the ones working with the stuff we develop on a daily basis and they face problems much faster and in a higher intensity than we could ever imagine. This feedback was the most important one. If you are not listening to what they have to say you are developing stuff for yourself but not for the people.[9]

Another benefit resulting from the close collaboration with stakeholders can be seen in the contribution to the development of an overall standardized telemedical system, which allows BodyTel™ to set parts of this standard, and could guarantee great competitive advantage through lock-in effects. Furthermore, the open access approach through the Continua certification not only benefits customers and patients through a greater variety of products and services compatible with each other, it also helps BodyTel™ to further promote their products and services, as Stefan Schraps, CEO of BodyTel™ stated:

> The Continua certification will make GlucoTel™ compatible with a large number of telehealth systems from leading manufacturers. This especially benefits companies

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> that are setting up a telehealth solution together with BodyTel™ – they rely on a safe standard and save both development effort and cost. In addition, our work in the consortium will help create future standards and lets us establish close relationships with industry peers.[11]

Thus, opening up parts of the technology, namely the interface to the company's ecosystem, allows better cooperation and the establishment of new partnerships, as well as cost savings, while simultaneously benefiting customers and patients.

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