
Tackling global health challenges with telemedicine

The development of a telemedical diabetes monitoring system as a learning case for Responsible Research and Innovation in ICT

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Abstract: This case study showcases the development of the telemedical diabetes monitoring system GlucoTel™ as a learning case for RRI in ICT. It therefore links the activities along the development process with RRI aspects, such as stakeholder engagement or open access. By taking a business perspective, the study shows that the integration of RRI principles into company processes not only benefits patients, caregivers and other users but can also have benefits for the company, such as competitive advantage. In addition, the case study takes a global perspective and outlines the potential of telemedicine for coping with the global societal challenge of diabetes and secondary diseases which are a major health care problem worldwide.

Keywords: Societal Challenges, Stakeholder Engagement, Responsible Research and Innovation, Telemedicine, Diabetes, Health, ICT, Case Study.

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Introduction

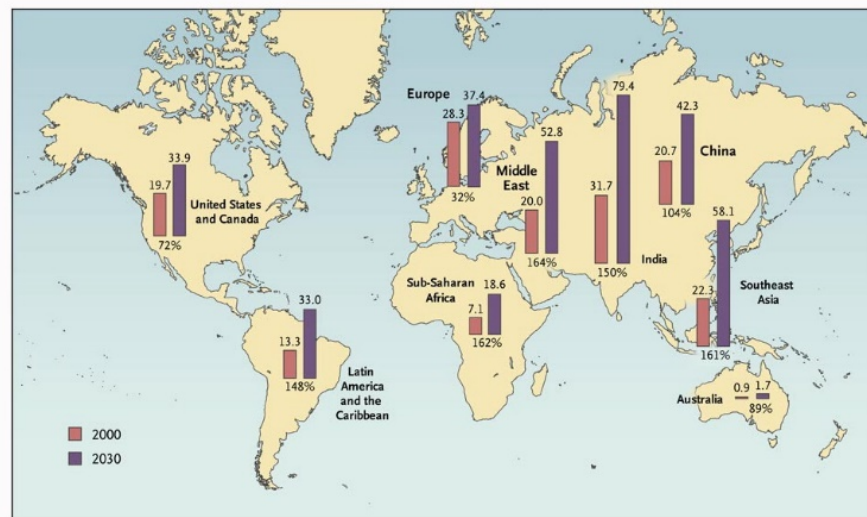
This case study takes a look at telemedical applications in the area of diabetes care through the case of GlucoTel™, a telemonitoring system developed by BodyTel™. It links the company's activities to aspects of Responsible Research and Innovation (RRI)

such as addressing societal challenges, stakeholder engagement 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. Therefore, it starts with describing the societal challenge of diabetes, which global relevance becomes evident by looking at the numbers and their distribution. People with diabetes worldwide are projected to increase from 171 million in 2000 to 366 million by 2030; not only in Europe and the USA but also in low and middle income countries, which is connected with health complications, secondary diseases and skyrocketing costs for health care services as well as absenteeism from the workplace. In the second chapter telemedicine is described as an integrated approach for patients and caregivers with efficient tools to support their daily tasks in diabetes care and GlucoTel™ as part of the BodyTel™ system is described in detail. It is a sensor for telemedical blood glucose monitoring and diabetes management and is used for automatic, continuous documentation of all blood glucose levels as part of the three-stage BodyTel™ system. In the following chapters the BodyTel™ ecosystem, stakeholder engagement activities and certifications are illustrated. BodyTel™ and its devices and services are as medical devices and is 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. 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. Based on this illustration of stakeholder engagement and certification activities the next chapter discusses telemedical applications and the development of GlucoTel™ in particular in the context of RRI to learn from already existing practice how aspects of RRI could be implemented. The outlined activities can be understood as a learning base for the RRI approach. They not only benefit patients and caregivers but also the company itself. These particular benefits for industry by integrating RRI aspects into business activities are described in the last chapter before the conclusion summarizes the insights and contributions, illustrates the limitations and gives some outlook for future research.

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 has benefits for the company, e.g. by guaranteeing competitive advantage. In general, this work should be understood as a learning case. RRI is a contestable concept and its implementation – especially in industry – is still unclear. This learning case takes a look on business activities of BodyTel™ and examines its relations to RRI to learn how RRI might be implemented. Scholars in the field should orientate on aspects that are already implemented within organizations and use such as a springboard to enrich the RRI debate. Therefore, this learning case illustrates various aspects of diabetes, the development of telemedical applications for diabetes care, their relation to RRI and possible benefits for integrating RRI aspects during the development of such applications.

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 (Leiva et al. 1995).



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 (Gómez et al. 2002). It is rapidly emerging as a global health care problem that threatens to reach pandemic levels by 2030 (Hossain et al. 2007). The number of people with diabetes worldwide is projected to increase from 171 million in 2000 to 366 million by 2030 (Wild et al. 2004). 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). 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.

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 (The Diabetes Control and Complications Trial Research Group 1993). Nevertheless, the achievement of the therapeutic goals implies a significant increase in the amount of patient data to be monitored (Gómez et al. 2002). 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 (Carson et al. 2000) 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 (Gomez et al. 1999). A main goal of 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™¹ 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).

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.

¹ All information about the product and the company is taken from the company website: <http://bodytel.com/?lang=en>.

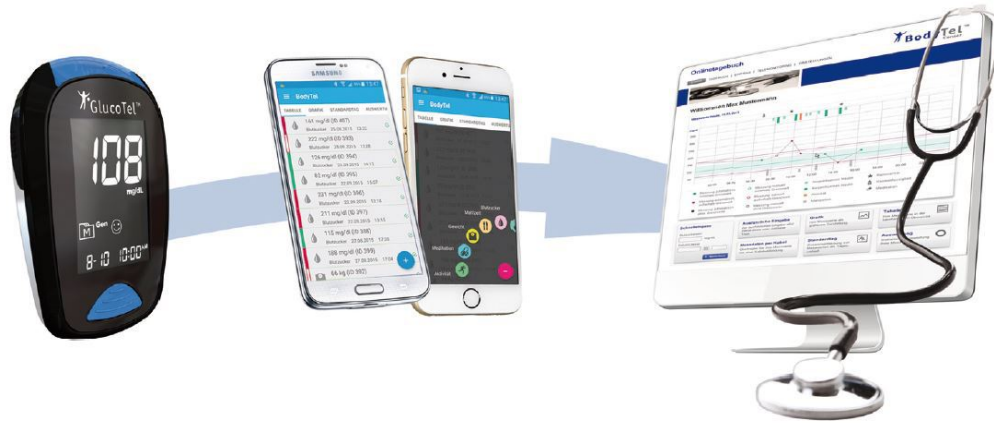


Figure 2: The GlucoTel™ System (Source: BodyTel™)

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.

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.

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:

- *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, 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 the 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 (Klinger 10/15/2014). In the case of GlucoTel™ this happened during an 'Einsteigerprogramm' (Einsteigerprogramm is German and means program for novices) 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 feedback over the years (Klinger 1/26/2017).

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 (Lifespot Capital 11/12/2015).

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 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 Alliance² in 2012 (BodyTel 6/25/2012), 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” (*Personal Connected Health Alliance 4/22/2014*).

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.

Telehealth for diabetes care and RRI

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 (European Commission 2014c). Addressing societal challenges through innovation is part of RRI, as defined, for instance, by Rene von Schomberg. Von Schomberg emphasizes the societal desirability element of RRI, when he argues that research and innovation have to bring “the right impacts and outcomes” (Schomberg 2013, p. 56). 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

² The Continua Health Alliance is part of the Personal Connected Health Alliance (PCHA): <http://www.pchalliance.org/continua>.

innovation process. It aims to better align both the process and outcomes of R&I, with the values, needs and expectations of European society” (*European Commission 2014b*).

Collaboration is one of the most important dimensions addressed by RRI (Stilgoe et al. 2013; Bolz 2017). In an business setting this means companies should engage stakeholders throughout their innovation process and collaborate closely with them (Bolz, König forthcoming). 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 open access into account (European Commission 2014a).

As described above, diabetes is a threat not only in Europe or the USA. It can be seen as a global societal challenge which needs 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 (Mohan et al. 2012). 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 3 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).

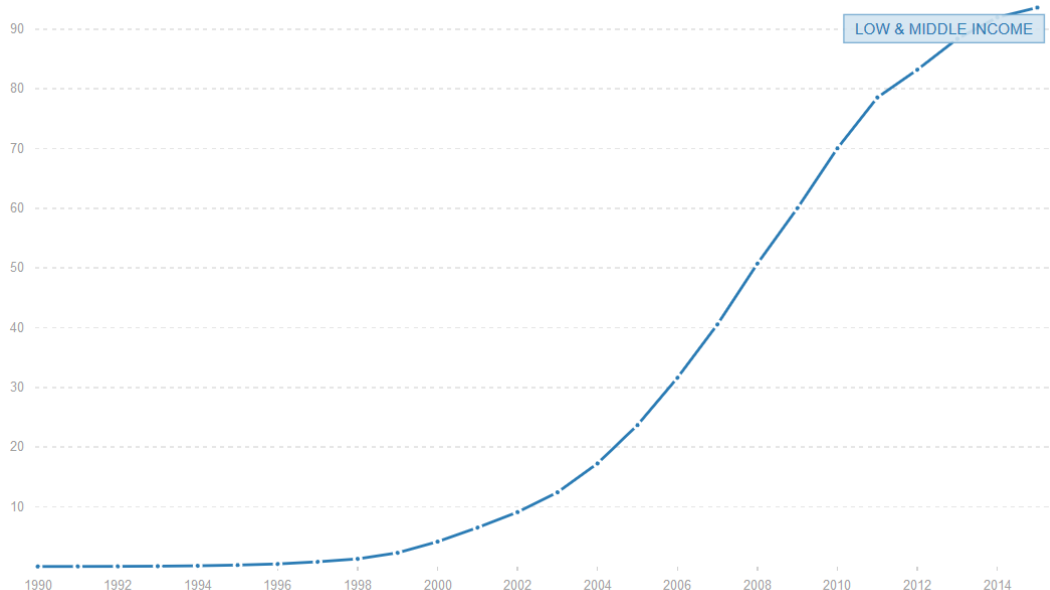


Figure 3: **Mobile cellular subscriptions per 100 people from 1990-2015 for low & middle income (Source: Worldbank 2017)**

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.

Besides this global level of RRI this learning case also focuses on 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 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 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.

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 (Klinger 10/15/2014). 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” (Klinger 1/26/2017).

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 (such as MP3 for the Fraunhofer Society or VHS for JVC). 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 Schrap, 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 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” (BodyTel 6/25/2012).

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.

Conclusion

Overall this learning case shows that there are already concepts applied in practice which are at the heart of RRI, such as stakeholder engagement and open access. The case of GlucoTel™ shows the potential of such approaches for industry. They help benefit patients, caregivers as well as the company. As outlined in the introduction this study should be understood as a learning case that explores the connection of applied concepts and RRI. This scope of the study also comes with limitations. It is an ex-post analysis which foremost relies on secondary data gained from the company website and press releases as well as on two questionnaires answered by Michaela Klinger from BodyTel™. This narrows the perspective of the study towards a company perspective with limited critical reflections. However, I argue that this perspective is sufficient for the scope of the study as a learning case which aims to inform the debate on RRI in industry. The global perspective of RRI is addressed to strengthen the relevance, need and potential for the implementation of the concept regarding the global challenge of diabetes. In general, the study offers entry points for RRI in industry and thus contributes to the debate on the implementation of RRI.

Instead of looking at industry from a ‘faultfinder’ perspective, we – as the RRI community – should acknowledge efforts from industry and search for entry points that allow us to start a conversation on RRI with business leaders. Future research could focus on the search for such entry points and actively engage with industry to find ways how to implement RRI in business practice.

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