Digital Health

Digital Solutions for Today’s Health Care Challenges

The German E-Health Act became effective in January 2016. It promotes the use of information and communication technology within the German healthcare system. It defines the uniform framework for future cross-sectoral networking and cooperation between healthcare providers and the parties paying for healthcare services. The German Federal Ministry of Health is responsible for the design of the legal framework of the telematics infrastructure. The German Society for Telematics (gematik) is responsible for the introduction of the telematics infrastructure and the Electronic Health Card. The Electronic Health Card allows digital storage and retrieval of patient data. Its applications will be introduced gradually.

Video: Smart Hospitals in Germany

With aging populations and increasing demand for medical services, AI and other digital innovations are going to become a crucial part of the healthcare of the future.
A thriving healthcare start-up scene, growing insurance provider partnership opportunities and a changing legal framework provide ideal conditions in Germany’s mobile health market set to grow to EUR 3 billion in 2017.

Digital Health Market

According to Arthur D. Little, the global market for digital health will grow to more than USD 200 billion through 2020. The use of information and communications technology (ICT) in healthcare allows new business models to be established to enhance efficiency and, at the same time, maintain high quality in healthcare provision. The significant potential of digitization to reduce healthcare costs has been proven by a number of studies. The Fraunhofer Institute for Systems and Innovation Research estimates that integrated digitization of data and processes could achieve annual savings of EUR 9.6 billion in the German healthcare system alone.

Telemedicine

Telemedicine combines telecommunication and information technologies to provide remote health care and other health-related services. A number of telemedicine initiatives have sprung up in recent years, with about 200 telemedicine projects currently active in Germany. Detailed information about ongoing and implemented projects is provided by Deutsche Telemedizinportal, part of the eHealth Initiative founded by the Federal Ministry of Health. The aim of the initiative is to pave the way for meaningful applications past the project phase into standard care.

“Time is Brain” - Telemedicine Closes Gaps in Health Care Provision

One example that vividly illustrates how digital health is not just about saving money but also lives is the use of telemedicine solutions for the treatment of strokes. Germany has a dense network of stroke units and tele-stroke units. There are more than 300 hospitals with certified stroke units in Germany. Tele-stroke units complement the high quality and comprehensive medical care of strokes in areas where the admission to a hospital with a stroke unit would take too long. Since 2011, tele-stroke units are also certified to ensure the high quality of these telemedicine networks.
Smart Solutions for Heart Failure Management

The German market for heart failure solutions will grow by 16% through 2022

Revenue forecast for digital heart failure solutions 2016 – 2022 (in EUR million)

Source: Statista Digital Market Outlook 2017
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Smart Solutions for Diabetes Management
As defined by the World Health Organization, "mobile health" (also mHealth), covers medical and public health practice supported by mobile devices. This includes medical applications (also apps) which connect to medical devices or sensors, such as bracelets or watches or act as personal guidance systems, health information and medication reminders.

Mobile health solutions are the main driver of the significant growth recorded in the digital health market. The GSM Association estimates that total mobile health market revenue will reach EUR 18.8 billion by the end of 2017.

**German mHealth Market Outlook**

The key and most attractive segment of mHealth in Germany is monitoring. According to a study conducted by Price-waterhouseCoopers, monitoring will generate 72 percent of mHealth revenue in 2017. Thanks to the dynamic advances being made in wearable devices, the monitoring of vital signs is expected to receive a further boost in the coming years. The most popular medical apps in Germany are those related to nutrition (e.g. calorie and step counters).

mHealth is therefore seen as having a significant role to play in supporting the shift towards preventative measures. mHealth solutions in Germany enjoy widespread consumer acceptance, with fitness trackers, smartwatches and health and fitness apps growing in popularity. According to BITKOM, 31 percent of the German population uses fitness track-
ers to monitor their vital signs. Thirty percent of Germany’s smartphone users install health apps that monitor vital signs, search for physicians and pharmacies, promote weight loss or help improve sleep patterns.

**Fitness Trackers**

**Fitness Tracker Revenue in Germany in EUR million**

The German market for fitness trackers has grown significantly during the past two years: Revenue went from EUR 39 million in 2014 to EUR 107 million in 2016. At present, fitness trackers are typically used as lifestyle products. However, the great potential of such wearables and other mHealth solutions goes way beyond prevention and lies in patient medical care. The increased use of mHealth in the professional health sector will improve prevention and therapy adherence rates and, accordingly, help reduce hospital admission/readmission levels and doctor’s visits. Adjustments to today’s technological possibilities within the legal framework and the remuneration system will most likely result in a dramatic uptake in the professional mHealth market.
Caterna Vision Therapy
Caterna, the first reimbursable medical app to be prescribed by physicians in Germany, is provided by Caterna Vision GmbH. The Caterna Vision Therapy is an on-screen application that can be used as an adjunct to occlusion treatment of childhood amblyopia. With the Caterna Vision app, patients can use the extended functions of Caterna Vision Therapy on their mobile devices. Caterna Vision Therapy is a medical product and meets all provisions of the Directive 93/42/EEC and is approved for the European market (CE-marked).

Apps as Medical Devices
Medical apps can be classified as medical devices. In Germany this classification is determined by the German Medical Devices Act and European guidelines (more specifically, the Medical Device Directive 93/42/EEC). Apps which enable medical findings (e.g. heart rate monitoring via smartphone) are considered medical devices and have to be verified in accordance with EU guidelines and CE-marked. In Germany this classification is determined by the German Medical Devices Act (MPG) and European guidelines (more specifically, the Medical Device Directive 93/42/EEC).

App Categorization
The German approval body, the Federal Institute for Drugs and Medical Devices (BfArM), provides guidance on differentiation between fitness or wellness apps and medical apps (i.e. apps that are considered to be medical devices). When distinguishing between medical devices and health or fitness products, the decisive issue is whether they are intended for medical or non-medical use. This is defined by the product manufacturer. Decisions regarding the differentiation and the classification of an app are to be based on the intended purpose of the embedded software are the responsibility of the manufacturer in agreement with a notified body.

For more information, please see Fact Sheet "The Mobile Health Market in Germany"

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Submit your question