

**SPOTLIGHT HEALTHCARE** No. 2 | 2016

Data, analysis, perspectives

# Health apps

A powerful – but underutilized – patient empowerment tool



- Digital health applications for citizens have the potential to make the vision of patient empowerment a reality and to improve healthcare
- Offerings in this area are growing rapidly – in the »out-of-pocket« market for those goods and services not covered by traditional insurance providers
- Primarily supply-driven, the market for such apps has focused less on the actual needs of prevention and healthcare
- The market is largely opaque and effective procedures for identifying and evaluating innovations have yet to be established
- Pro-active government and industry measures are needed to help innovations in this area gain traction in a rapidly changing market

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**M**edia coverage of health apps is growing day by day. Reports characterize these new digital opportunities for patients as a transformation or, in some cases, a revolution in medicine. Two developments are usually cited as evidence of this: the rapid growth in sheer numbers of apps available in stores (more than 100,000 should it be) and the success – or anticipated success – of several apps in particular. In Germany, some apps – available on »prescription« and as such financed by individual healthcare insurance providers – are drawing attention.

But what lies behind the large number of health apps? Which types of offers are dominating the market? How are they changing the landscape of healthcare provision? What is the relevance of these »digital helpers« for epidemiological concerns and the health economy? In the search for answers to these questions, the Bertelsmann Stiftung teamed up with experts Karsten Knöppler and Tobias Neisecke to conduct a systemic analysis of the digital health app market. In the »Digital Health Applications for Citizens« (Digital-Health-Anwendungen für Bürger) baseline study, the authors surveyed the current literature on the subject and developed a comprehensive classification scheme for digital health apps. Applying their scheme to a sample of 106 applications, the authors then identified seven application types. These were then evaluated in terms of their relevance for nationally defined health targets.

Drawing on this study and on a systematic analysis of the subject, this edition of Spotlight Healthcare proposes eight theses regarding the current state of public digital health app offerings. The key message is that these apps bear substantial potential in strengthening patients' role and thus improving healthcare services. This potential, however, is vastly underutilized as only a few relevant apps are widely used. In order to render these apps useful, healthcare policymakers and providers must be more pro-active in developing strategies and mechanisms for the use of such apps.

»It's a very fast-moving market and, so far, not fully transparent for all actors. Transparency, however, is necessary if health apps are to realize their full impact in terms of advancing medicine.«

Dr. med. Urs-Vito Albrecht, Head of MedAppLab,  
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## Digital health offerings are undergoing dynamic growth – beyond the classical healthcare system

Digitization is a megatrend which is rapidly expanding throughout healthcare. From cloud computing to the Internet of Things to big data or wearables: the sheer presence of new technologies and opportunities is advancing several developments in the healthcare sector. These changes are driven by the growing use of smartphones in particular. Carried in close proximity to one's body, they can provide assistance in several areas of health-related issues anywhere and everywhere.

A second driver of digital health offerings beyond technological advances is the much noted »cultural shift« underway in health care. In terms of their health-related behavior, people are increasingly more confident about making their own decisions. The well-informed patient has become a role model in society, politics and science. Parallel to this, the demand for information, participation and interactive exchange has grown.

It is important to note, however, that dynamic growth is observed primarily in the out-of-pocket market, that is, products and services offered in the German healthcare system that are not paid for by statutory or private health insurance. The traditional, so-called first health system has been slow to respond to this trend. Aside from a few

### Digital health applications for citizens: classification dimensions

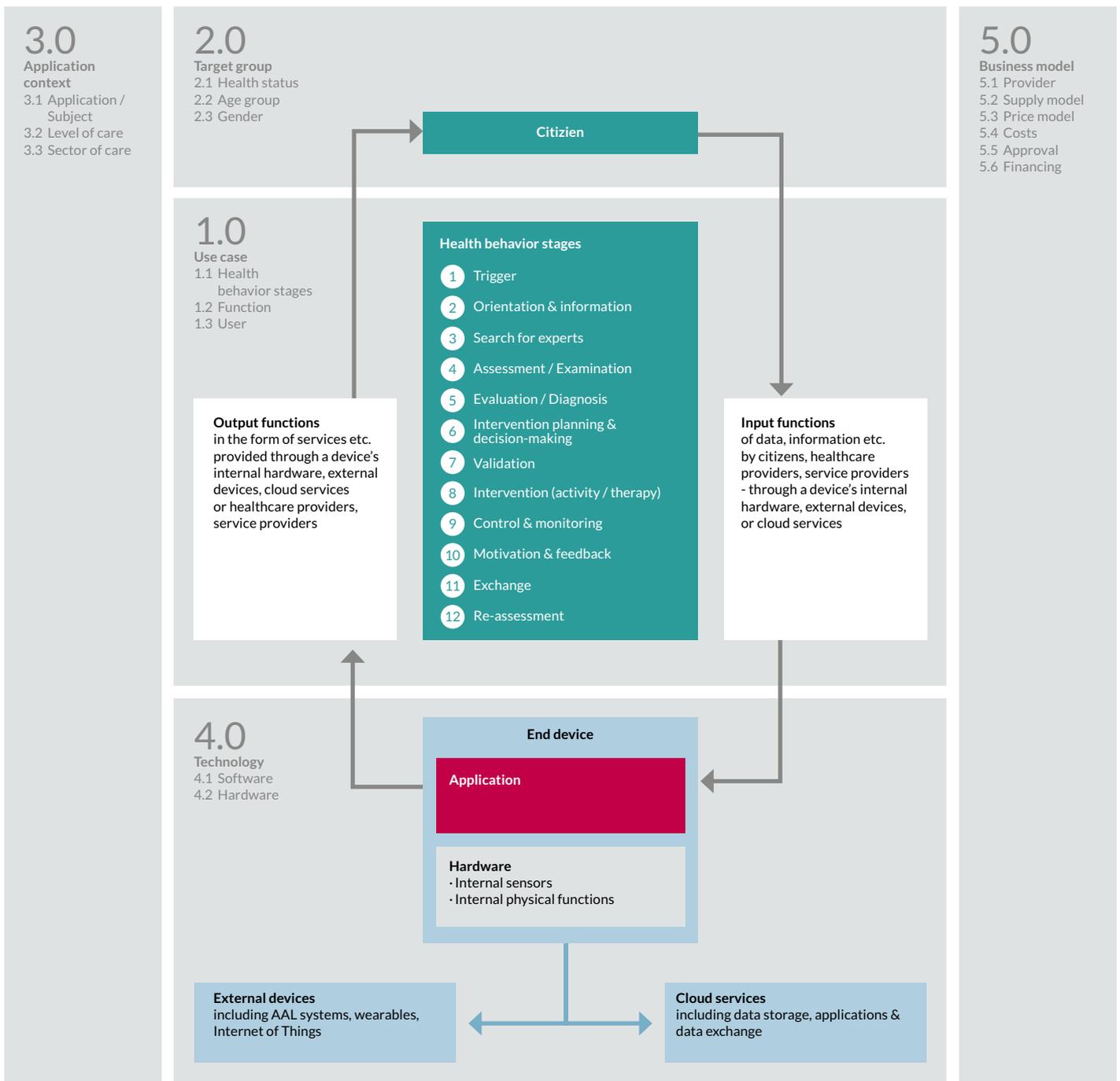


Figure 1 | Source: Authors' own

## Digital health applications for citizens: seven types



pioneers in the field, most doctors, insurance providers and other stakeholders in Germany's healthcare system are either skeptical of these developments or overwhelmed by the changes underway. There is little in the way of exchange or innovation transfer in care between the two »worlds.«

### A classification process and typology for a transparent market

Analogous to the aforementioned cultural shift, a procedure for classifying digital health applications focused on citizens' health behavior was developed for the Bertelsmann Stiftung study. Determining what use the applications have for citizens is at the heart of this classification. It is based on a new model describing health behavior in terms of an ideal process. Further dimensions of the classification include target groups, the application context (e.g., sector of care), the technology involved and the business model (Figure 1). The process, comprised of 17 sub-dimensions and their features, allows for a systematic classification and description of all digital health applications.

A sample of 106 applications was used to test the procedure. Each app was comprehensively and systematically assessed in order to classify and evaluate their features. Seven application types were established (Figure 2). This allows for a typology of an otherwise vast and complex market of digital offerings that can help focus future discussions regarding market developments more effectively.

### Digital health applications for citizens: eight theses on the status quo

In addition to facilitating a structured classification of the market for citizen-centric digital health apps, the »Digital Health Applications for Citizens« (Digital-Health-Anwendungen für Bürger) study revealed several major trends underway in the field. This led to the following eight theses:

**1 Digital health offerings bear the potential to strengthen citizens and patients in their respective roles and make patient empowerment a reality, which can improve the quality of care.**

Patient empowerment is not only a driver of the development of digital health apps. The apps themselves can also significantly enhance empowerment by providing patients the opportunity to self-manage their health more knowledgeably. Smartphones in particular can become powerful tools in the hands of patients by providing information, fostering the exchange of experience and knowledge or enabling self-directed interventions. The evidence shows that improved literacy levels and self-management or greater adherence among patients leads to improved healthcare outcomes.

**2 The market for digital health apps is largely non-transparent. The logic of rankings in app stores and search engines influences consumer access and selection. It is practically impossible for consumers to independently assess the quality of individual apps.**

Users access digital health apps primarily through app stores or online search engines, which use their own algorithms to sort rankings. The criteria used to establish relevance are not objective with regard to quality criteria. For consumers – but also for scholars, scientists, payers and healthcare providers – it is virtually impossible to gain a compre-



## Approval process for digital health applications

A manufacturer's defined purpose of a medical product is central to its respective classification. The product must fulfill its intended purpose in the diagnosis, prevention, monitoring, treatment or alleviation of illness, injury or disability and have a primarily physical effect.

The functional spectrum of an application is also relevant in determining whether a digital health app is a medical product. For example, digital health applications designed simply to store, archive, reproduce or transfer medical data are not classified as medical products in the EU when they do not process or, for example, prepare data through graphics.

In both the EU and the United States, medical products are classified according to risk. Most requirements for the approval of a digital health application are determined by the risk category to which the application is assigned.

Approval processes in the United States and the EU include testing product safety and performance. In the United States, proof of effectiveness is currently required only for medical products of certain risk classes. So far, no proof of effectiveness is required for approval in the EU.

hensive and unbiased understanding of current offerings, let alone to assess the quality of individual applications.

**3** The current digital health discussion focuses too narrowly on mobile applications. It makes more sense to differentiate according to function and to consider web and system applications.

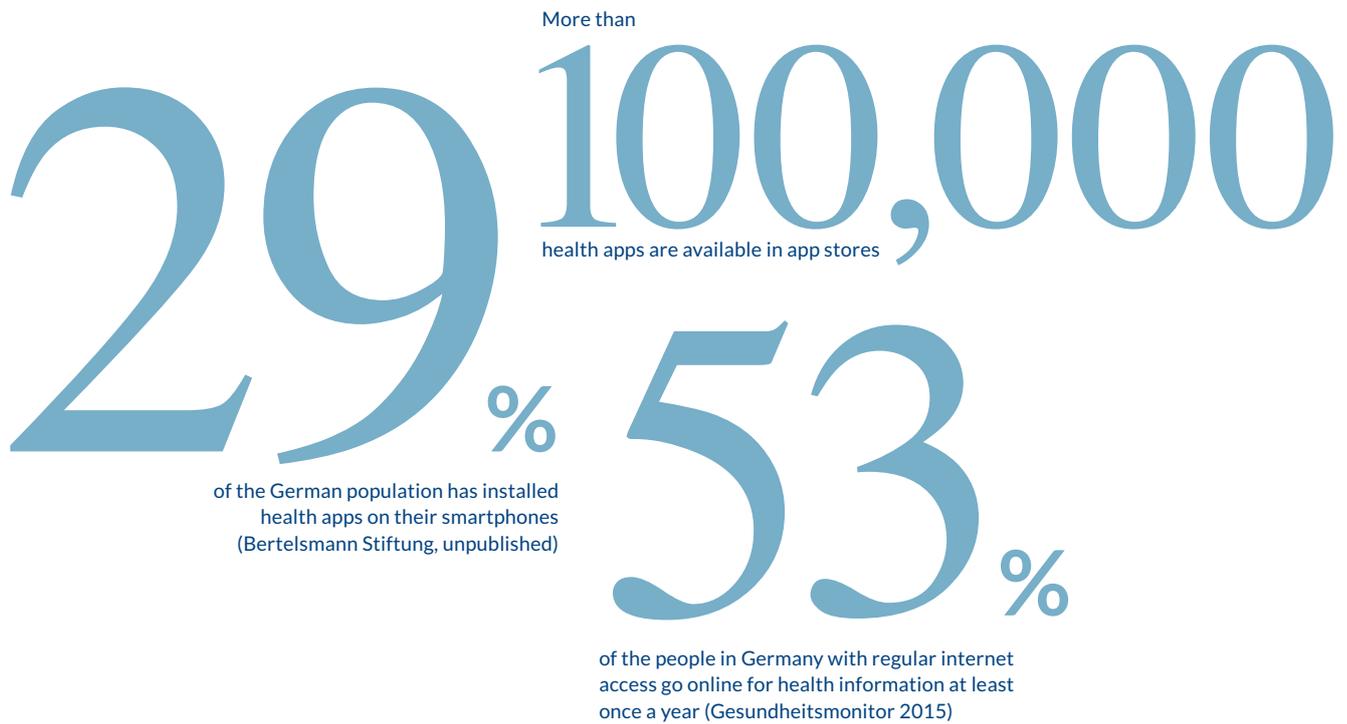
Access to digital health takes place primarily through applications on mobile operating systems. Yet public discussion focuses too narrowly on mobile apps (mHealth). In addition to these, however, there are vast numbers of web and system applications (i.e., applications that are part of an operating system). Considering a broader range of applications helps put function before technology, especially in a context of dynamic growth.

**4** The development of applications today is driven primarily by supply and is (supposedly) market-oriented. Actual healthcare needs play a secondary role.

In applying the classification scheme, the study confirmed that the majority of mobile digital health applications target healthy individuals (e.g., lifestyle and fitness apps). Vendors' economic interests and sales opportunities appear to play a much greater role in developing new applications than do epidemiological or economic challenges in preventive medicine and healthcare services. This state of affairs can be attributed to the clear division between the traditional and out-of-pocket health markets.

**5** The technological potential of digital health applications has been underutilized. Several applications simply transfer analog offers to the digital context.

Applications designed to »improve health literacy« in particular often underutilize the potential of the technology. The personalization of information and



interactive options are two key areas that could be optimized.

**6** Current approval processes for medical products are not yet designed to address all issues relevant to digital health applications. In addition, they remain intransparent for consumers.

Digital health applications categorized as medical products must meet specific regulatory requirements (see box on page 6). There are strong parallels between the relevant procedures followed in the United States and those in the EU. Yet they are not fully appropriate to the needs of the product class – for example with respect to the duration of the process. Furthermore, consumers cannot identify which criteria are relevant in determining approval and what significance the approval has.

**7** To date, there is little evidence of and no appropriate procedure for assessing digital health application effectiveness. Unsurprisingly, there is no appropriate procedure for the transfer of innovations to standard health care.

There are only a few studies on the effectiveness of digital health applications. This is in part due to the fact that such applications are relatively

new but also to the limited (financial) opportunities available to vendors, many of which are small startups unable to afford protracted clinical studies. As a result, there is scant opportunity to identify genuine innovations and to transfer these to standard care.

**8** From a public health perspective, most digital health applications are not relevant for healthcare services.

In most cases, digital health applications are not relevant from a public health perspective. Directly relevant to health care are applications of the »analysis and awareness«, »indirect intervention« and »direct intervention« types. When it comes to promoting health knowledge among citizens, »improving health literacy« applications can play a key role.

#### Imprint

Publisher:  
Bertelsmann Stiftung  
Carl-Bertelsmann-Str. 256  
33311 Gütersloh  
www.bertelsmann-  
stiftung.de

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Photos:  
Kai Uwe Oesterhelweg,  
Shutterstock / Dean Drobot,  
Shutterstock / nulinukas  
Design: Dietlind Ehlers  
Editor: Sophia Gottschall,  
Burkhard Rixin  
Translation: Barbara Serfozo  
Printed by: Druckhaus Rihn

ISSN (Print): 2364-6101  
ISSN (Online): 2364-611X  
Publication date:  
April 2016

## Recommended actions

### Digital health applications should serve medicine

To date, the market for digital health applications targeting citizens has been primarily driven by supply instead of proven healthcare needs. Classical healthcare stakeholders, physicians and insurance providers, in particular, must show initiative in tapping health apps' potential to empower patients and healthcare in general and integrate these apps into the market in ways that deliver real benefits to patients.

#### Focus on relevant applications

- › More time and attention should be spent focusing on specific types of applications – particularly on those that are potentially relevant to healthcare policies.
- › Broad-based implementation will require concrete application scenarios. The needs of the healthcare system, of medical guidelines and of patients with high-risk factors or chronic illnesses must be taken into consideration here. Good practices must also be made well known.

#### Expand healthcare research

- › The practical use of digital health applications must draw on evidence-based research. Healthcare research should consider potential negatives (e.g., self-tracking can lead to overdiagnoses) and differing levels of media literacy among patients.

#### Promote exchange between healthcare markets

- › Developing healthcare-relevant applications demands more dialogue and cooperation among stakeholders in the traditional and out-of-pocket healthcare markets.
- › A technological interface between applications for citizens and for service providers is needed. A telematic infrastructure with a secure interface should be provided for citizens to upload and access healthcare-relevant data used in a variety of health-related services.

- › New technologies and their effect on the physician-patient relationship should be integrated into physicians' (continuing) education and training.

#### Set quality standards

- › In order to improve market transparency for citizens and healthcare stakeholders alike, new processes for identifying application types need to be developed and effectively communicated. Simply awarding certificates or labels without the context of a typology is not enough.
- › There is a need for a fact-driven debate on data protection and its requirements that focuses on healthcare needs. Citizens must maintain control over their data.
- › Applications intended to be used as a medical product will require new approval procedures.

#### Develop opportunities for innovation transfers

- › In the short term, insurance providers (through optional benefits) can act as key drivers in establishing digital health. Whether or not an application is reimbursed should be based on its potential use and on the extent to which it fulfills healthcare needs. Shared standards could be developed to foster the identification of innovations.
- › Self-government should be included in determining app effectiveness or innovations reflective of the dynamics of the digital market.

SPOTLIGHT HEALTHCARE is an initiative of the »Improving Healthcare – Informing Patients« program at the Bertelsmann Stiftung. Published several times a year, SPOTLIGHT HEALTHCARE addresses topical issues in healthcare. The Bertelsmann Stiftung is committed to promoting a healthcare system relevant to public needs. Through its projects, the Stiftung aims to ensure the provision of needs-based and sustainable high-quality healthcare in which patients are empowered by access to readily understandable information.

This edition of SPOTLIGHT emerged from the Bertelsmann Stiftung's »Digital Patient« project which explores the opportunities and risks of digitization in healthcare. Through analysis and debate, the Digital Patient project promotes the effective use of technology in healthcare and targets greater social inclusion for patients through digital media developments.

Further information: [www.bertelsmann-stiftung.de](http://www.bertelsmann-stiftung.de),  
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