

Smart point-of-care testing – Today's key challenges

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A starting point that can address current challenges of the pharmaceutical and healthcare industry is to reduce complexity in medical testing by administering tests directly at the point of care which facilitates immediate diagnosis. Up to now these point-of-care tests have a limited range of application areas. New standards in data transmissions, however, will enable tests to be more connected and can add a number of "smart" features to the tests. In this article we will discuss today's trends in point-of-care testing and will point out necessary requirements that need to be met in order to make smart point-of-care a key success factor for pharmaceutical and healthcare companies.

Point-of-care testing – Today's key challenges

The healthcare industry, among other industries, is currently exposed to several challenges and market developments that call for the need to reshape the future focus of the industry. The greatest challenges are related to demographic transitions that many societies around the world are facing today. These transitions will bring with them important changes in medical product requirements and the way medical care is provided. Partly resulting from digitalization, another development is the growing awareness of patients regarding their healthcare data and status as well as a desire for self-diagnostics. Economic per-

formance of companies in the healthcare industry will be determined by the extent those companies successfully address these challenges and market developments. One promising solution that gained importance during recent years that may approach the described challenges and market developments is point-of-care testing (POCT).

Point-of-care testing

Medical testing is quite often a time-consuming process. The classical process of diagnosing begins with taking samples of e. g. blood or urine that are sent to a laboratory. The laboratory then analyses



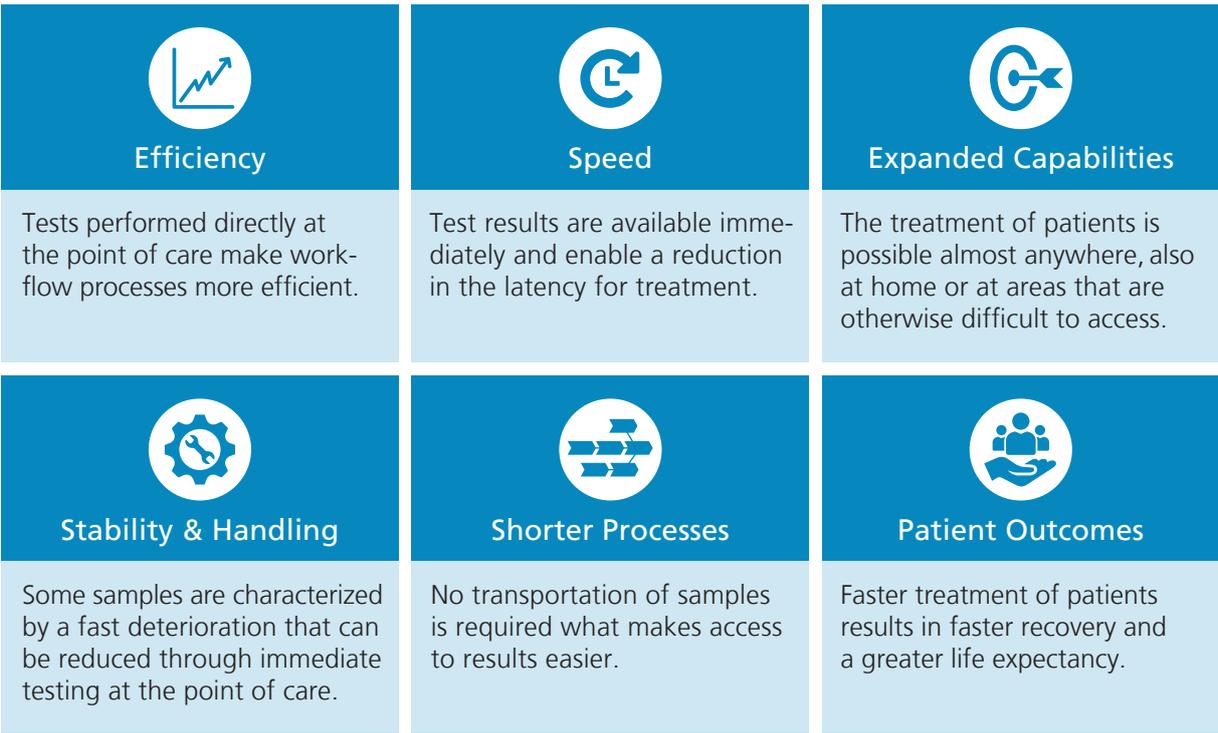


Fig. 1: Benefits of POCT

the samples and sends the results back. Overall, this process might last up to a week, sometimes even longer. In case the test results do not shed light on patient’s symptoms further tests need to be carried out that delay the course of treatment. In comparison to this traditional example of medical testing POCT is characterized as a procedure at or near the point of care – that means, at the place and time of where care to the patient is provided, with the assumption that test results will be available ad hoc or in a very short period of time to assist physicians and caregivers with immediate diagnosis. As such, the rapid diagnostics in point-of-care testing facilitates better disease diagnosis, monitoring, and management. It enables quick medical decisions, as diseases can be diagnosed at a very early stage, leading to improved health outcomes for patients by enabling the early start of treatment. As a result, point-of-care reduces costs of treatment and enables medical care to be made available to a larger number of patients. See Figure 1 for an overview of further benefits of POCT.

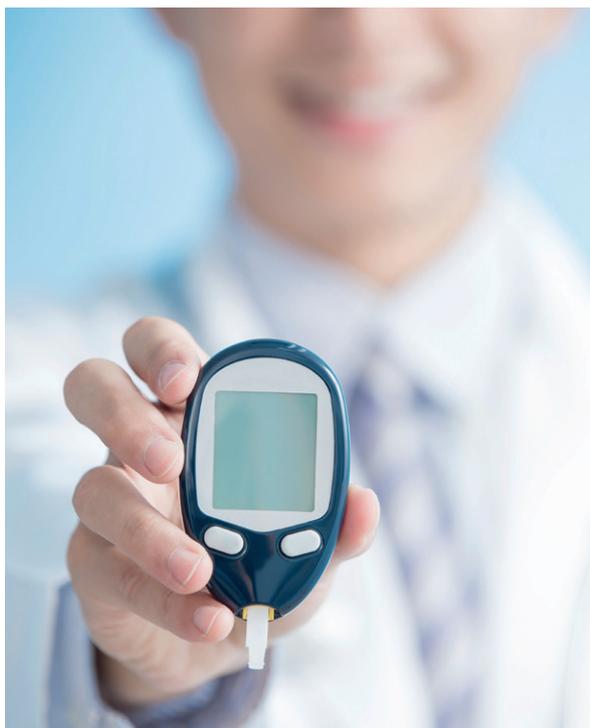
Current trends in POCT

There are many different POC tests on the market. Common examples of POC test tools include blood glucose monitors, thermometers, home pregnancy tests and rapid strep tests. Some tests provide the opportunity to measure various analytes simultaneously with the same sample, allowing a rapid and reliable quantification. An analysis of POC tests that are currently on the market shows that there are advances to make point of care tests “smart”, which means that devices are increasingly connected, wireless, mobile and equipped with various sensors that are able to track parameters such as temperature and geo-information.

Future scenarios in POCT are inclined strongly towards smart devices equipped with mobile health-care, which could be a true revolution to healthcare industry, thereby paving the way for the next generation of POC tests.

Combining POCT with the functionalities of mobile devices therefore seems very promising as these devices complement each other well regarding their fields of application which will bring important benefits. The diffusion of mobile devices such as smartphone and tablet PC has dramatically increased and even got ahead of desktop PCs in recent years. Several applications for mobile devices have been commercialized for the diagnosis, monitoring and management of basic health parameters, such as pulse rate, blood pressure, physical activity, weight, and blood glucose levels. In the near future, mobile devices will become more popular, powerful, and inexpensive, all of which are providing a promising forthcoming for smartphone-based POCT.

Next to the these advantages of smartphones and tablet PCs another benefit is the fact that these devices have a rich set of built-in sensors (e. g. camera, microphone, flashlight) that can be used for the diagnosis of physical symptoms, have powerful processors for the analysis of results and the storage of data, and a screen with a high resolution in order to display results. To transmit test results, technologies such as Wireless Fidelity (Wi-Fi), Bluetooth, and Universal Serial Bus (USB) can be used, allowing short-distance and long-distance communication



Smart point-of-care scenario



You are not feeling well? Then take a drop of your blood, fill it into the opening of a palm-sized cartridge and place it in a compact device about the size of a small purse. Close the flap and press the button. Wait a little – and test results showing the medical reasons for your discomfort will be available on your mobile phone.

between the test device and for example a physician in a hospital. Using smartphone-based POC diagnostics enables the application of in vivo tests by the smartphone's external sensors as well as in vitro tests that are combined with biochemical reactions.

Necessary requirements for "smart" POCT

Combining POCT with mobile technologies is able to create a paradigm shift using portable, easy-to-use devices that may foster improved outcomes for patients, thereby addressing the current challenges of healthcare industry. However, there are several necessary requirements that need to be met before creating "smart" POCT.

One of those requirements is connectivity. The devices need to be connected with each other and external devices like mobile phones, while assuring that devices are not interrupted by each other and there should be no interference with transmissions from other devices. First efforts to meet connectivity are made by the introduction of the ISO/IEEE 11073 family of standards for POC medical device communication, an architecture for service-oriented



Finally, developing a strong collaboration between industry, clinicians, laboratorians, caregivers and patients is of utmost importance. Only proper collaboration can optimize the flow of information among various stakeholders and enhances communication, thereby laying the foundation for the digital patient file.

In summary, POCT can be part of the solution to the rising healthcare and welfare costs without any loss of healthcare quality. A key success factor seems to be the implementation of mobile devices to make them “smart” POCT, thereby providing a promising future for POCT.

distributed POC medical devices and medical IT systems. Along with the connectivity of devices, it needs to be guaranteed that the devices offer privacy of personal data and are immune against cyber-attacks and viruses.

Another requirement that has an influence on the acceptance of devices is related to the ease of use. Product developers should take usability into account as it is a critical factor for success, especially in emerging markets like POCT. In order to develop highly usable POC products the following recommendations are given:

- Minimize the number of steps that are needed to obtain a result.
- Make results easily interpretable.
- Develop products that are easy to clean and sanitize.
- Develop products that are operable even with sterile gloves.

Sources

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