Opinion Paper

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What is happening to laboratory medicine in Denmark?

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Abstract: A number of current trends will affect and probably change laboratory medicine, as we know it. Scientific and technological developments, digital health with big data and artificial intelligence, and centralization will change the interfaces among the specialties of laboratory medicine. They might even challenge the identity of some specialties. Other trends such as demographic changes, increased complexity of health care, digital health with electronic health records, and more demanding and well-informed patients will change the way laboratory medicine specialties deliver their services. This paper discusses the possible changes of laboratory medicine in Denmark – a Scandinavian country where almost all hospitals are public. If Danish laboratories grasp the new possibilities instead of trying to avoid them, laboratory medicine is likely to prosper. Such a positive development will call upon good leadership and a genuine willingness among laboratory specialist to adapt to a future where their own specialty might be very different from today.

Keywords: artificial intelligence; big data; digital health; disruption; laboratory medicine.

Introduction

According to the *Cambridge Business English Dictionary*, disruption means an interruption in the usual way a system, process, or event works. However, disruption is often used in a meaning inspired by Professor Clayton M. Christensen from the Harvard Business School. He introduced the concepts of disruptive technology and disruptive innovation [1, 2]. These concepts try to explain why

leading companies often fail to stay on top when new technologies emerge and change the market. Leading companies are in close contact with their incumbent customers when they consider if they should invest in new technologies. However, focusing on the present need of their incumbent customers involves a risk of overlooking how new technologies can change the market and call for new business models. When small, entrepreneurial companies grasp such opportunities they might take over big parts of the market by using cheaper, better and more effective solutions – and thereby start the decline of established companies. In this case, the decline of the classical specialties of laboratory medicine as we know them.

The second EFLM strategic conference focuses on digital health. This makes sense because digital technologies, big data, bioinformatics, and artificial intelligence are especially important in the disruptive innovation due to the fierce development in this area. However, a number of additional trends are also likely to play a significant role. In the present paper, Denmark is used as an example in the attempt to predict the future for laboratory medicine.

Discussion

“It is difficult to make predictions, especially about the future”. Even though it is difficult, this paper will try to predict how the enormous development in digital health technologies together with other important current trends might affect and disrupt laboratory medicine in Denmark. Local conditions and the organization of the health care system are likely to affect the results of a disruption, even though similar developments are likely to happen in all countries. It is, therefore, relevant to start by describing the present situation for laboratory medicine in Denmark – as well as the trends considered.

Laboratory medicine in Denmark and important trends

Denmark is a small Scandinavian country covering 43,094 km² (1/8 of the area of Germany) and with a

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population of 5.8 million inhabitants (1/14 of the German population). The private hospital sector is very small, around 2%, and almost all laboratories are located in public hospitals. The organization of laboratory medicine is generally one specialty – one department with its own leadership and budget. Almost all hospitals have their own department of clinical biochemistry including common hematological analyses. The other specialties, i.e. clinical microbiology, clinical immunology, anatomical pathology, and clinical genetics are located at the bigger hospitals, sometimes with satellites at smaller hospitals.

The included trends are scientific and technological developments, digital health and big data, centralization, demographic changes, increased complexity of health care, well-informed and more demanding patients, and digital health and electronic health records. The discussion falls into two parts. The first covering trends challenging the identity of the laboratory specialties, as we know them today. The second covering trends changing the way laboratory medicine deliver their services and the way we communicate with patients.

Trends, which might challenge the identity of the laboratory specialties

Scientific developments such as molecular genetics have increased the possibilities of laboratory medicine tremendously and all specialties have implemented the new techniques. This has started a debate in Denmark about which is the specialty that “owns” the right to perform the different tests as well as the right to advise the clinician about the results. Technological developments have, at the same time, given us bigger, faster and more reliable and expensive analytical machines. Some of these machines are disruptive meaning that they are able to perform laboratory tests that previously belonged to a number of different specialties of laboratory medicine. Both the scientific and the technological developments affect the interfaces among the classical specialties. For instance, clinical biochemistry will probably have to perform an increasing amount of tests “belonging” to other specialties in order to deliver results quickly at hospitals where clinical biochemistry is the only laboratory specialty present. In hospitals with more laboratory specialties, it will be difficult to provide each specialty with its own, optimal assembly of analytical machinery due to the high costs. Consequently, there needs to be more collaboration and sharing of analytical machines at the bigger Danish hospitals.

The revolution of computer science in digital health is perhaps the most important trend. This revolution makes

it possible to work with big data and bioinformatics so that personalized medicine comes within reach. However, there is still a long way to go. Laboratory medicine produces large amounts of data and is likely to become a key player in the process towards personalized medicine. In order to fulfill the potential of personalized medicine, it is necessary to use bioinformatics and data from many different sources in order to characterize the deep phenotype of the individual patient. In this process, it is meaningless to focus on the data from only one specialty of laboratory medicine. Laboratory data from all specialties have to be included together with clinical data from the electronic health record (EHR) as well as with register data in order to obtain the optimal basis for the process of bioinformatics. Good bioinformaticians are in short supply and it will be expensive and difficult to build competent units of bioinformatics in the hospitals. It is, therefore, unlikely that each laboratory specialty will get access to their own unit of bioinformatics. They will have to share, and this will weaken the boundaries among the classical specialties of laboratory medicine.

We are only at the very beginning of using artificial intelligence in clinical medicine, but its potential is enormous. So are the possible effects on both clinical and laboratory medicine [3, 4]. So far, some of the best results of artificial intelligence are within image analysis, where the accuracy of artificial intelligence in some cases has demonstrated a greater accuracy than that obtained by the physician [3]. Within the near future, the use of artificial intelligence might replace the laboratory specialists in the examination of microscopic slides in anatomical pathology. In the long perspective, artificial intelligence might make the counseling from specialists in laboratory medicine redundant in the diagnostic process, unless they adapt and learn to contribute to the development of artificial intelligence in laboratory medicine. So far, artificial intelligence has been developed and used in a black box concept. This causes severe ethical challenges [5]. It is of paramount importance that the health care providers understand and contribute to the design of the artificial intelligence systems. If not, there is a great risk that unwanted biases are built into systems that will affect decision-making in an inappropriate way.

Denmark completed a reform that centralized the hospital sector in 2007, so that the number of hospitals was reduced by more than 50%. In addition, the National Board of Health got the power to decide which hospitals can perform a certain specialized function. The number of hospitals that can perform a certain highly specialized function is now restricted to only one to three hospitals. This process was difficult for laboratory medicine due

to disagreements among the different specialties about the “ownership” to different analyses, especially within molecular genetics. The disagreements are ‘territorial’ and miss the greater opportunity and flexibility from a more integrated process that is beneficial to patients and the organizations.

Trends, which might change the way laboratories deliver their services

A demographic change is happening in Europe. Its populations are either growing very slowly or stagnating while the proportion of elderly people is growing. Even though the health of elderly Europeans has improved their mobility is relatively low in the later part of their life, and many live outside the bigger cities. At the same time, the departments of laboratory medicine are restricted to hospitals in the bigger cities. It is important to overcome this mismatch and perhaps to strengthen the collaboration between the laboratories and the primary sector. Should it for instance be easier to take laboratory samples in the homes of the elderly? Should we increase the use of POCT at the offices of GPs and at nursing homes? Will the scientific and the digital revolution provide solutions we can hardly dream of today? Small portable monitoring devices combined with smartphones and telemedicine might for instance be able to replace many of the present direct physical contacts between the patient and the laboratory.

The complexity of health care is growing rapidly. New, advanced diagnostics and treatments are constantly becoming available. The number of occupational professional groups is growing and the same happens to the number of specialties with further sub specialization. At the same time, the patient’s length of stay in the hospital decreases and the mean value in Denmark is now around 4 days. Finally, new and demanding tasks move from the hospitals to the GPs and the municipalities in the primary sector. Many Danish patients experience communication gaps and poor clinical pathways in this complex system. Consequently, one of the most urgent questions in the Danish health care system is how to ensure coherent clinical pathways. This includes good collaboration among the health care providers and a real involvement of the patients and the relatives. Relational coordination and interprofessional collaboration and learning might be useful tools in achieving this [6, 7]. Laboratory medicine can contribute significantly in several ways:

- By making laboratory test results easily available across hospitals and the primary sector. The biggest obstacle here is the strict regulation of data security.

- By making it easier for the clinicians to order the right panel of tests and to interpret complex results. This is important both in the hospitals and in the primary sector.
- By ensuring a close collaboration among the different specialties of laboratory medicine both when receiving clinical requests and when delivering results.
- By communicating directly with the patient when relevant.

The last point is controversial and it requires a close collaboration with the other clinicians. However, right now laboratory medicine has an excellent opportunity to consider a more direct interaction with the patients.

The role and the attitude of the patients have changed. The patients of today are often well informed, and they demand to be involved in the diagnostic process and their following treatment. Several years ago, EFLM realized that this might affect laboratory medicine. EFLM therefore formed a working group on patient focused laboratory medicine in 2013. The work of this working group demonstrates clearly, that patients want access to their own results and that they want help to interpret their results [8]. The patients believe that specialists in laboratory medicine could help in this respect [8]. Interestingly, specialists in laboratory medicine might not yet be ready to take on this task. A third of the specialists participating in a survey performed by the working group showed a negative attitude towards delivering laboratory results to the patients [9]. However, digital health with modern electronic healthcare records are likely to result in a closer and more direct contact between the patients and the specialists in laboratory medicine. This does not necessarily have to be a bilateral communication between the specialist of laboratory medicine and the patient. It could be a triangular communication involving both GPs and other hospital doctors also.

EHRs have divided Denmark into two, a western part using the Systematic EHR [10] and an eastern part using the Epic EHR [11]. On top of this, there is a national EHR called Sundhed.dk (meaning Health.dk) where medical doctors can access and read patient data from all Danish public health care systems [12]. One of the big strengths of Sundhed.dk is that the patient’s data are available all over the country. If the patient becomes acutely ill in another part of the country, doctors at the local hospital have immediate access to the patient’s medication, laboratory results and other clinical data via Sundhed.dk. The patients can access their own data from their home in all three EHRs. It means that they have access to the results of their laboratory tests shortly after the release from the laboratory. This might raise questions about the implications of the results,

which the patient wants to discuss with the hospital. Both the Systematic EHR and the Epic EHR have a module with which the patients in their homes can communicate directly with nurses and specialists at the hospital. These lines of communication are of course also available to laboratory medicine if specialists want a more direct interaction with their patients. The patients are ready [9].

Summary

It is difficult to make predictions, but “laboratory medicine as we know it” will change. The changes are likely to follow two main currents. One challenging the present identity of the classical laboratory specialties – and one offering laboratory medicine a more active and direct role in the clinical process. If laboratory medicine meets the challenges with good leadership, willingness to adapt, and a genuine wish to serve the patient and the other parts of the health care sector [13], then laboratory medicine is likely to prosper. On the other hand, specialties and departments are likely to lose if they fight the disruption by trying to preserve status quo.

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