Editorial

Michael Neumaier and Ian D. Watson

The end of Laboratory Medicine as we know it?

This special issue of *Clinical Chemistry and Laboratory Medicine* is dedicated to the 2nd Strategic Conference of the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) that was held from 18th to 19th June 2018 in Mannheim, Germany. The congress was entitled "The End of Laboratory Medicine as we know it? Handling disruption of Laboratory Medicine in digital health". The meeting considered the disruptive impact that on-going digitalisation of technologies and a digitalised society may have on the medical laboratory's place in future healthcare.

Over the last 50 years, Clinical Chemistry/Laboratory Medicine has been a particularly successful field in diagnostic medicine. It has brought major advances for health care through the adoption of new analytical technologies, fitting them to the purpose of answering diagnostic questions and then implementing them into the medical laboratory for patient care. Up till now the major achievements of Laboratory Medicine include the standardisation of key parameters to allow for commutability and metrological traceability of analytical results, the reference method concept, the definition of reference ranges and the concept of biological variation, etc., all aiming at improving patient safety and health. Currently, Laboratory Medicine keeps hundreds of diagnostic tests available for diagnosis, monitoring and prognosis of disease conditions in the routine health care setting and is developing and introducing newer, better tests through collaborative clinical research. Laboratory Medicine has also fostered important research into pre-analytical and post-analytical influences on test results. Finally, it continues to provide clinical and methodological guidelines and regulations for international network structures and to allow for comprehensive external quality assurance programmes in medical laboratory testing.

With the advent of the digital revolution in medicine described as "disruptive" and the "creative destruction of medicine", diagnostic medicine will enter a new arena, and the weights between technical and analytical face of the profession and the new opportunities for compiling, integrating and visualising increasingly complex diagnostic data are very likely to shift. The conference discussed some key aspects that will impact medical laboratory diagnostics in future health care as a result of disruptive developments in the on-going digitalisation of technologies and a digitalised society. Specifically, the sessions were dedicated to disruptive technologies in analytics, biomedical informatics and the role of the laboratory in communicating results to the "empowered patient". Video recordings of the majority of the presentations are available on the EFLM home page (https://elearning.eflm.eu/course/view.php?id=38).

In the opening session, the first keynote presentation on the disruptive technologies in laboratory analytics, Larry Kricka gave a comprehensive and critical account on the history of disruptive technologies and their power to predict the future of laboratory medicine [1]. The question of how technological quantum leaps in analytical technologies are being identified and developed into products by the IVD industry, was the topic of a presentation given jointly by the very senior science officers from Roche Diagnostics, Siemens Healthineers and Sysmex. The impact of microfluidics and nanotechnology on laboratory test systems was discussed in the context of applicability for routine testing outside classical laboratory settings. Klaus Pantel gave a comprehensive overview on the potential of circulating cell-free nucleic acids in bodily fluids, a new universe in the field of Laboratory Medicine [2]. It became very clear that this field is revolutionising diagnostic laboratory testing particularly in oncology by allowing "liquid profiling" of molecular tumour defects that represent actionable health information for therapeutic decision-making.

Session 2 entitled "disruption through biomedical information technologies" addressed a major challenge in the "horizontal integration" of laboratory data to increase efficiency and the "vertical integration" of clinical context data and databases. A specific account was given by Josep Roca, who presented the use of big data for diagnostic prediction systematic data mining and machine-learning [3]. The IT company SAP presented innovative concepts for cloud technologies to manage and store medical data [4]. Thomas Ganslandt explored the role of consortia in biomedical informatics to establish infrastructures for a sustainable use of structured clinical data together with laboratory data in an interdisciplinary fashion [5].

Relevant obstacles exist, e.g. at the judicial, semantic and the laboratory levels and represent important challenges for future comprehensive medical data integration and usage. Michael Neumaier's presentation entitled "Diagnostics 4.0" tried to extrapolate developments for Laboratory Medicine from recent years' digital revolution in "Industry 4.0" [6].

In session 3, recent advances of the integration of laboratory and clinical data systems to maximise information value were addressed in a keynote by Jonathan Kay, such as hyperlinking LabTestsOnline into primary care physicians' databases or effective workload management through order communication systems. The effectiveness of the use of a national database approach was illustrated by Per Jorgensen's consideration of the Danish experience [7], the big data aspect of this was further explored by Ferrucio Cerrotti [8] tying this into the Diagnostics 4.0 concept; there are issues of clarity reflecting data standardisation and harmonisation when considering sharing or accessing data across borders, but also a need to be cognisant of the ethical and legal issues as addressed by Petra Wilson.

Session 4 recognised that laboratory data has a number of stakeholders: the requestor, the provider and, not least, the patient. Holly Wittman shared her experience of providing numerical data in readily comprehended human centred design that enables insight by patients and professionals [9]. This is particularly relevant in the era of patient focussed laboratory medicine with direct provision of results to patients with comments; the difficulties and ultimate satisfaction of both patients and primary care physicians with such an approach was confirmed by Wytze Oosterhuis [10]. Patricia Wilkie is an influential advocate for the patient's perspective, which is paramount in their healthcare engagement and they expect that they can, and will, be treated as an equal partner [11]. A view reinforced by general practitioner Richard Fitton who describes how, in his large primary care practice, he had implemented patient focussed approaches that had empowered his patients [12].

Session 5 was the final session entitled: Patient empowerment and the laboratory. Ian Watson [13] argued that direct communication of laboratory results to patients through Specialists in Laboratory Medicine in an agreed context was a feasible and necessary approach benefitting all stakeholders; such activity is dependent on utilising the technology of the information revolution, and now we all use smartphone apps Snezana Jovicic presented an assessment of the effectiveness and reliability of phone apps that utilise laboratory medicine data [14]. Direct patient involvement in their healthcare

through monitoring their biochemistry in a structured system utilising point-of-care devices provided a very effective way of delivering necessary acute interventions as described by Paul van der Boog. Finally Gilbert Wieringa addressed the issue of the necessary competencies and training Specialists in Laboratory Medicine will need if they are to develop an integrative patient-focused role [15].

With the digital revolution spreading into every realm of modern medicine, we will experience a democratisation of health care, i.e. a comprehensive data usage not just being in the hands of health care professionals, but also in the patients. Indeed, a central concept of digital health medicine is patient empowerment as demonstrated by key words like "electronic health record", "patient access", "health apps", "wearable health tech", etc. In this rapidly changing health care environment, Laboratory Medicine must redefine its positions, not only acting in its classical role as the provider of laboratory results, but also adopting new roles and responsibilities in the clinical dialogue with both patients and physicians.

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Corresponding author: Michael Neumaier, President of the European Federation for Clinical Chemistry and Laboratory Medicine, Institute for Clinical Chemistry, Medical Faculty Mannheim of Heidelberg University, Theodor-Kutzer Ufer 1-3, D-68167 Mannheim, Germany,
E-mail: Michael.Neumaier@medma.uni-heidelberg.de
Ian D. Watson: Former President of the European Federation for Clinical Chemistry and Laboratory Medicine, Department Laboratory Medicine, University Hospital Aintree, Liverpool, UK