Direct-to-Consumer Testing: The Business with Lifestyle Tests

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IFCC Committee on Clinical Laboratory Management
http://www.ifcc.org/ifcc-education-division/emd-committees/c-clm/

Symposium on Improvement in Clinical Laboratory Services: Approaches to Adding Value

IFCC WorldLab Durban
Durban International Convention Centre
Durban, South Africa - October 25, 2017

Objectives

- detail many forms of DTCT and how these tests should be considered within the realm of what we traditionally consider POCT
- experiences with DTCT in Germany and the US
- describe differences between clinical pathology labs (healthcare) and non-healthcare lab testing services
- challenges of DTCT in genetics testing (inaccurate promises, discrimination, data protection)
"The best way to find out if you can trust somebody is to trust them."
Ernest Hemingway

Humatrix has set standards: highest level of automation, first in selling in pharmacies, its unique safekit and a year-long partner of major TV stations. Therefore, you can rely on us in quality and safety.

Real Medical Labs (Rilibäk)

5.2 Personnel

Medical laboratory examinations must only be performed by personnel who are professionally qualified corresponding to legal regulations, and who are authorised by management.

The number of personnel must be sufficient with regard to the amount of work.

6.2 Procedures for conducting medical laboratory examinations

6.2.1 The medical laboratory may only use examinations procedures that meet medical requirements.
6.2.2 The medical laboratory may only use validated examinations procedures. It has to document the procedure used for validation and the results obtained.

The Directive on Consumer Rights aims at achieving a real business-to-consumer (B2C) internal market, striking the right balance between a high level of consumer protection and the competitiveness of enterprises.
Challenges by DTC/DAT

no quality criteria at all have to be followed if laboratory tests are performed by non-health care professionals allowing a free movement of services under the consumer rights directive 2011/83/EU

laboratory = a facility that performs certain testing on human specimens in order to obtain information that can be used for the diagnosis, prevention, or treatment of any disease or impairment of a human being

CLIA regulations and standards do not differentiate between facilities performing DAT and facilities performing provider ordered testing. All facilities must obtain CLIA certificate prior to conducting patient testing, including DTC/DAT. FTC regulates advertisements.

Orth: Direct to Consumer Testing

Evidence based medicine

Healthcare

Lab Tests

POCT

Animal testing, food testing

DTCT

Commercial lab testing

Lifestyle

Orth M. Point of Care 2017;16(3):124-27 doi: 10.1097/poc.0000000000000144
Healthcare -- „Medical Act“

- Restriction of healthcare (=diagnosing illnesses, prescribing diagnostic examinations, using invasive/risky diagnostic techniques, determining medical treatment, prescribing medications, clinical monitoring of patients with problematic health, pregnancy care and deliveries, isolation measures) to physicians

- Healthcare = principle of solidarity and principle of demand

- Healthcare NOT principle of market economy

- Physician may not extend services by hiring employees unlike a commercial firm

- Prohibition of (exclusive) telemedicine

- Critical: (external) IT service provider essential in medical process

  *primum non nocere, secundum cavere, tertium sanare*
Examples of laboratory testing requiring supervision by a physician in Laboratory Medicine

- INR self-testing
- Reporting of complex laboratory tests
- Blood Coagulation testing
- Assessing medical necessity
- Establishing clinically relevant cut-offs
- Verification of methods: a medical evaluation
- Evaluation of the laboratory errors: a medical act
- Setting up and updating rules auto-validation rules

Value-based care
Rockwell KL JAMA 2017 (317), 2485-6

An Unwelcome Side Effect of Direct-to-Consumer Personal Genome Testing
Raiding the Medical Commons

Amy L. McGuire, JD, PhD
Wylie Burke, MD, PhD

It is now possible for individuals to learn about their genetic susceptibility to dozens of common and complex disorders, such as coronary artery disease, diabetes, obesity, prostate cancer, and Alzheimer disease, without ever seeing a physician. Direct-to-consumer personal genome testing companies hope to empower consumers to take control of their health by providing tailored assessments of genetic risk based on reported associations between genomic variation and susceptibility to disease.

Several states limit or forbid this practice as a violation of state law that requires the appropriate involvement of a licensed physician when providing medical diagnostic information. Personal genome testing companies claim that their services are for informational and educational purposes only. They warn consumers that the information should not be used for diagnostic, treatment, or health assessment purposes and direct them to physicians if they have questions or concerns about their health status.1

- Follow up costs

Yet social media and online comments also offer an easy way to inject biased, incorrect or misleading information. And because engagement with critics is a core element of scientific practice, researchers may feel obliged to respond even to 'trolls' (online harassers).
Agony, Alarm and Anger for People Hurt by Theranos’s Botched Blood Tests

By Christopher Weaver

The Wall Street Journal Updated Oct. 20, 2016 9:52 p.m. ET

Douglas Simon

Gee do you think there's a reason that medical training requires a minimum of seven years post graduate education and training? Oh no a Stanford drop out can bypass all this because she’s a “genius” with “vision”. All of her financial backers and co-conspirators should bear responsibility for this mess. They illegally practiced medicine without licenses and training. Where were the regulatory authorities while this mess was being perpetrated? People should be in jail for this for a very long time.

I and my former medical colleagues worked hard for many years to be qualified to take care of people. These are extremely bright and intellectually curious people who sacrificed years of family time and earnings power to be able to administer blood tests and interpret the results. It’s delusional to think that a lone person with minimal education, no matter how innately intelligent, could replace this system with their superior vision and intellect. Where’s Elizabeth Warren when people’s lives are at stake?

6 days ago
The Lykon platform can support professional medical advice or treatment by a licensed physician or a professional nutritional counselor, but in no case replace it. On the platform, Lykon clearly points out that the services are merely a supplement.

**Intended use / Disclaimer**

Lykon/Vimeda.de

The platform is an online-based medical application that allows the customer to evaluate self-collected blood tests using medical algorithms and to generate feedback on different biomarkers. In addition to the visualization of his lab biomarkers, the customer receives medical recommendations for treatment based on the evaluation of the individual laboratory values.

The medical evaluations and recommendations for action are also prepared in such a way that they can be made available to a doctor as a medical basis for further diagnostics and therapies.

**Much lower cost?**

Point-of-care (POC) devices used by Theranos phlebotomists – technicians licensed to take blood – draw blood virtually painlessly through a trigger tap on the subject’s finger. …. The more sophisticated tests require at the very most no more than a drop of blood (around 100 µl). But new technologies developed by the company are pushing this down to the 1 to 3 µl level …

The technology can work on tiny samples due to the application of two methods: dilution and detectors. When a sample is diluted, it is possible to detect signals from multiple substances present in the sample in widely varying concentrations. This enables a more complex analysis …

Offering greater accessibility to blood tests, virtual painless testing, and a much lower cost, Holmes’ invention helps patients get tested earlier and more frequently. In one example, a women with diabetes reduced the costs … of tests she required from € 711 using traditional blood analysis methods down to € 28 using Holmes’s technology
### Testing fees THERANOS - DE (private) - DE (public)

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<th>Test</th>
<th>EBM</th>
<th>GOÄ</th>
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<td>Aspartate Aminotransferase (AST)</td>
<td>$0.22</td>
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<tr>
<td>Calcium</td>
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<td>C-Reactive Protein (CRP)</td>
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<td>Prolactin</td>
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**Orth: Direct to Consumer Testing**

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**Quadruple times more outliers in DTCT than in real lab tests**

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*J Clin Invest.* 2016;126:1734–44
doi:10.1172/JCI86318
Genetic exceptionalism

- laws for protection and anti-discrimination
- Protection of individuals (and their relatives) from their own curiosity
- Challenging definition of purpose of genetic testing (diagnosing, risk assessment, forensic, lifestyle)
- Post hoc analysis of genetic data is frequent
- BUT: All medical information is precious, private and deserves vigorous protection
- patient/consumers are both capable and better informed about most pros and cons of genetic testing for certain inherited diseases than most physicians

23andMe's co-founder and CEO Anne Wojcicki (was) married to Google co-founder Sergey Brin

HEALTH

23ANDME GETS FDA APPROVAL FOR DIRECT-TO-CONSUMER GENETIC TESTS
IT'S NOW THE FIRST COMPANY OF ITS KIND TO GET THE FEDS' GO-AHEAD

By Alexandra Ossola  Posted October 21, 2015

What is in the kit?
FDA ORDERS PERSONAL GENOMICS COMPANY 23ANDME TO STOP MARKETING DNA TEST

"FDA IS CONCERNED ABOUT THE PUBLIC HEALTH CONSEQUENCES OF INACCURATE RESULTS."

By Paul Adams  Posted November 25, 2013

According to the letter, the FDA has been seeking information needed to approve the test for a while, "including more than 14 face-to-face and teleconference meetings, hundreds of email exchanges, and dozens of written communications":

...months after you submitted your 510(k); and more than 5 years after you began marketing, you still had not completed some of the studies and had not even started other studies necessary to support a marketing submission for the PGS. It is now nine months later, and you have yet to provide FDA with any new information about these tests. You have not worked with us toward de novo classification, did not provide the additional information we requested necessary to complete review of your 510(k)s, and FDA has not received any communication from 23andMe since May. Instead, we have become aware that you have initiated new marketing campaigns, including television commercials that, together with an increasing list of indications, show that you plan to expand the PGS’s uses and consumer base without obtaining marketing authorization from FDA.

23andMe has not yet responded publicly.

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23andMe

Bring your ancestry to life through your DNA.

Discover your ancestral origins and trace your lineage with a personalized analysis of your DNA.

- Ancestry composition
- DNA relatives
- Neanderthal percentage
- Family tree tool
- Maternal and paternal lineages

order now
FDA Letters to Genetic Testing Companies

"FDA appreciates that many consumers would like to be informed about their genomes, and their genetic risk for development of future disease. We agree that access to tests through a DTC model can allow consumers to take responsibility for certain aspects of their health, and to learn more about genetics and its contributions to risk, among other probable benefits. **We believe that certain types of tests are being appropriately offered through the DTC model**, but others may need to demonstrate that they are safe and effective and that appropriate controls are in place to mitigate risks"

**Effects of a Frequent Apolipoprotein E Isoform, ApoE4\textsuperscript{rotenberg} (Leu28→Pro), on Lipoproteins and the Prevalence of Coronary Artery Disease in Whites**

Mathias Orth, Wei Wang, Harald Funke, Aminis Simikrate, Gerd Asmann, Matthias Nauck, Jutta Dieckes, Andrew Ambrose, Karl H. Wiegrothe, Robert W. Matvey, Henrik Westland, Claus Luby

*Arterioscler Thromb Vasc Biol.* 1999;19:1306-15
Conclusions of Lifestyle DTCT

- DTCT bears severe risks to its patients/customers
- Lacking claims of usefulness and lack of harm
- Bogus evidence
- Negative impact on medical commons (psychic harm, follow up testing)
- Exclusive situation of healthcare as well as of EBM is jeopardized by DTCT
- Particular risks of healthcare professionals using DTCT data!
- Essential and medically sound regulations for genetic tests are leveraged by DTCT

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