The Challenges for European Laboratory Medicine

Dr Ian D Watson
Past President
European Federation of Clinical Chemistry and Laboratory Medicine
Via Carlo Farini 81
20159 Milano
ITALY
- EFLM
- Europe
- Languages
- EFTA
- EU
- Directives
- Reimbursement
- Consolidation
- Innovation
European Federation of Clinical Chemistry and Laboratory Medicine: EFLM

- Federation of societies of laboratory medicine in Europe
- Regional organisation for Europe of IFCC (International Federation of Clinical Chemistry and Laboratory Medicine)

Activities
- Science
- Education & Training
- Quality & Regulation
- Lobbying within Europe
39 member countries

- Albania
- Austria
- Belgium
- Bosnia-Herzegovina
- Bulgaria
- Croatia
- Czech Republic
- Cyprus
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Israel
- Italy
- Kosovo (provisional member)
- Latvia
- Lithuania
- Luxembourg
- Montenegro
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Russia
- Serbia
- Slovak Republic
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- Ukraine (+Affiliate)
- United Kingdom
European Languages
European Union

Trade

The EU is the world’s biggest trader, accounting for 20% of the world’s imports and exports. Free trade among its members was one of the EU's founding principles, and it is committed to liberalising world trade as well.

EU institutions and bodies

- European Parliament
  - Committee on International trade
- Council of the European Union
  - External relations
- European Commission
  - Trade
Directives and Regulations (D&R) in the EU are subject to agreement by:

- The European Parliament: Directly elected
- The European Council of Ministers: Minister representing of each member country
- The European Commission: Administration responsible for delivering and monitoring D&R
EU: Health

- EU for freedom of trade and workforce across national boundaries
- Health is an issue of subsidiarity i.e. responsibility of Nations
- Trade is subject to EU D&R
- Are clinical laboratories Health or Trade?
EU: Directives affecting Laboratories

- Revision of IVD Directive to a Regulation
- Revision of Professional Qualifications Directive
- Directive on Cross-Border Health
Labs: National Laws/Regulations

- Entitlement to Reimbursement from Public Funds
- Entitlement to Private Practice
- Requirement for ISO 15189
- General Laws on employment rights; health and safety etc
Revised Directive on *in vitro* Diagnostic Medical Devices 98/79/EC

- Extensive consultation on Directive revision: Governments, Industry, professions

- Subject to common requirements as agreed by the EU ENVI (Environmental, Public Health & Food Safety) Committee through the National Notified Body who are representative on the ENVI Committee

- European Databank on Medical Devices: EUDAMED
  - Covers all medical devices including IVDs
  - CE Marking
Revised Directive on *in vitro* Diagnostic Medical Devices 98/79/EC

- IVD Directive to become IVD Regulation
  - In-house devices requirement to regulate (e.g. 3D printer)
  - In-house assays
  - POCT health professional use
  - -omics: consent, application, companion diagnostics (EMA oversight: European Medicines Agency)
  - HTA and market surveillance: cross-border impacts
- Reference Laboratories
- Classification (aligned with GHTF)
Revised Directive on Professional Qualifications 2005/36/EC

- Recognition of qualifications across Member States enables Freedom of Movement

- Automatic for Medical Graduates if graduating from an recognized EU training program ((one of 7 sectoral professions)i.e. Freedom of Movement

- Non-medical clinical staff either pharmacist (as a laboratory professional) or scientist NOT recognized automatically i.e. INABILITY to move freely within EU
Revised Directive on Professional Qualifications 2005/36/EC

- Liberal Professions i.e. graduates that in the practice of their profession use their professional judgment to make decisions on behalf of others e.g. Engineers

- Cross-border recognition to allow Freedom of Movement
  - Equivalence of training
  - Language skills
  - Enable skill deficits in one country to be addressed by movement from another country

- European Professional card
  - Electronic certificate

- Alert mechanism for suspended/de-registered individuals
  - Not all Nations recognize professions through a competent authority
Consequences of the Directives

- Regulatory impact of IVD Directive on manufacturers and on externalised laboratory services

- National Budget restrictions resulting in inadequate staff pool cannot be recruited from countries with a surplus as Freedom of Movement inhibited by the lack of cross-border recognition of qualifications and training; the Directive will address this.
Research & Innovation

- Horizon 2020: Research & Innovation Project

The SME Instrument
Seamless Business Innovation Support from Idea to Market...

Phase I:
Grant of €50,000 (lump sum) + coaching support

Phase II:
Grant of €1 Million to €3 Million (70% of funding)* + coaching support
*as a general rule

Phase III:
Risk Finance (Private/Public)

Concept & Feasibility Assessment
Idea to Concept

Demonstration Market Replication
R&D
Concept to Market-Maturity

Commercialisation
Market-Maturity to Market Launch

Idea > Business Plan
Elaborated Business Plan
Commercialisable Output
Market Success

...Your Highway to Deliver Innovation on the Market!

Apply at any time!
6 months
12-24 months
ABOUT SPIDIA

SPIDIA is a 4.5-year project, funded by the European Union FP7 programme to the value of 9 million Euros, which brings together a consortium of 16 leading academic institutions, international organisations and life sciences companies.

The project is coordinated by QIAGEN GmbH and aims to tackle the standardisation and improvement of pre-analytical procedures for in-vitro diagnostics. The proposed research and standardisation activities cover all steps from creation of evidence-based guidelines to creation of tools for the pre-analytical phase to testing and optimisation of these tools through the development of novel assays and biomarkers.

+++ LATEST NEWS +++ LATEST NEWS +++ LATEST NEWS +++ LATEST NEWS +++ LATEST NEWS +++

SPIDIA was invited by the "Ministry for Innovation, Science and Research" of North Rhine-Westphalia as one of the Best Practice Examples of European Funded Research to present their results at the opening event of "HORIZONT 2020.NRW"

read more here.

+++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++++

The SPIDIA cooperation partner OBBR (Office of Biorepository and Biospecimen Research, NCI) has released Standard Operating Procedures (SOPs) for the collection of normal human biospecimens. Please read more here.

+++ LATEST NEWS +++ LATEST NEWS +++ LATEST NEWS +++ LATEST NEWS +++ LATEST NEWS +++
EU Entrepreneurship 2020

- EU support for entrepreneurs
- Labs can be SMEs or large organisation
- Risk for professionals as entrepreneurs:
  - Civil
  - Penal
  - Deontological i.e. Breach of Professional Code of Conduct
Cross-Border Health
Cross-Border Health

- With significant cross-border movements for employment, residence and leisure there is a need to access home country health records; this includes lab results.

- Differences in Lab reference ranges, quality standards.

- Confusion of units of concentration:
  - Molar SI
  - Mass SI
  - traditional units
Addressing the Challenges

- Lobbying of National Government Competent Bodies (feed through EC)
  - Regulation of POCT in IVD Directive
- Lobbying of EU/EP/EC (trialogues)
  - Professional Qualifications Directive
- Collaboration with like-minded organizations e.g. EDMA (European Diagnostic Manufacturers Association)
  - ‘banning’ of Triton X
  - IVD Directive
Organization of Health Services

- Private Insurance Group
- Insurance re-imbursement e.g. Belgium
- National provision e.g. Norway
- Regional provision within a Nation e.g. Spain
- County Council e.g. Sweden
- Regional commissioning e.g. England
Who runs labs

- **Medical Staff**
  - Some countries mandate by law medical staff as head of lab (Norway, Germany, Austria)

- **Scientists**
  - Suitably post-graduate qualified scientific staff equivalent to Medical staff and can head labs (Netherlands, UK, Ireland)

- **Reimbursement issues**
  - May need to be through Medical staff for private work or public reimbursement schemes
Non-medical Staff Skills

- Increasing automation and regulation means less technical skill sets for most staff
- Development/specialist work: high skill set
- Added value issues require better skills
  - POCT training/quality
  - Knowledge management
- EU: polyvalent skill set
- UK: Modernising Scientific Careers
## How is the Reimbursement Situation in Europe?

<table>
<thead>
<tr>
<th>Country</th>
<th>Private Labs</th>
<th>Basis for Reimb.</th>
<th>Hospital Labs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norway</td>
<td>Reimbursed by the government</td>
<td>Cost per test basis (regulated)</td>
<td>Fixed basic budget plus price per test</td>
</tr>
<tr>
<td>England</td>
<td>1. Payment by Ins. Comp. 2. Directly by patient</td>
<td>Cost per test basis (regulated)</td>
<td>DRG based annual budget through commissioning</td>
</tr>
<tr>
<td>France</td>
<td>Directly by patient (who is reimbursed by his Ins. Comp.)</td>
<td>Regulated prices per test (some test are not reimbursed)</td>
<td>Annual budget, not regulated</td>
</tr>
<tr>
<td>Netherlands</td>
<td>1. Reimbursement per test if ordered by GP or other Spec. 2. if not, pat. pay themselves</td>
<td>Reimbursement per test (regulated)</td>
<td>Reimbursement per test (Ins. Comp. carry the risk)</td>
</tr>
<tr>
<td>Czech Rep.</td>
<td>1. If ordered by GP reimbursement by Ins. Comp. 2. if not, pat. pay themselves</td>
<td>Reimbursement per test (regulated) New tests are calculated extra</td>
<td>Historically calculated budget, annual cutting by 5% ; 25 basic tests are paid per day</td>
</tr>
<tr>
<td>Croatia</td>
<td>1. Re-imb. by Ins. Comp or 2. the pat. himself</td>
<td>Reimbursement per test (regulated)</td>
<td>Annual budget decided by the hospital management</td>
</tr>
</tbody>
</table>
Different reimbursement (€) for a lipid profile in Europe

<table>
<thead>
<tr>
<th></th>
<th>Germany</th>
<th>Croatia</th>
<th>Netherlands</th>
<th>France</th>
</tr>
</thead>
<tbody>
<tr>
<td>T-chol</td>
<td>0,25 - 2,68</td>
<td>1,10</td>
<td>1,70</td>
<td>7,74</td>
</tr>
<tr>
<td>LDL</td>
<td>0,25 - 2,68</td>
<td>17,20</td>
<td>(Friedewald calculation)</td>
<td>7,74</td>
</tr>
<tr>
<td>HDL</td>
<td>0,25 - 2,68</td>
<td>7,00</td>
<td>3,35</td>
<td>7,74</td>
</tr>
<tr>
<td>TG</td>
<td>0,25 - 2,68</td>
<td>1,70</td>
<td>2,28</td>
<td>7,74</td>
</tr>
<tr>
<td>Lp(a)</td>
<td>12,80 - 20,11</td>
<td>12,00</td>
<td>10,05</td>
<td>(18,0) not reimbursed</td>
</tr>
</tbody>
</table>
International comparison of costs for laboratory tests
What are the activities of profit oriented laboratory companies?

<table>
<thead>
<tr>
<th>Country</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>Increasing „consolidation“ activities by private companies or <em>Laborverbünde</em></td>
</tr>
<tr>
<td>Norway</td>
<td>Only one big private national laboratory</td>
</tr>
<tr>
<td>England</td>
<td>Increasing examples of privatisation or ppp activities</td>
</tr>
<tr>
<td>France</td>
<td>Centralisation and concentration of analyses in an accredited laboratory; some financial comps are buying labs but they have to follow the same rules</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Profit oriented companies would like to start taking over public services; some private labs</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Synlab and some other nat. private labs are already on the market</td>
</tr>
<tr>
<td>Croatia</td>
<td>One big private national lab</td>
</tr>
</tbody>
</table>
consolidation

- Cost variations indicate amalgamation will reduce costs
- Area lab networks
- Challenges:
  - LIMS
  - Harmonization of ranges/reertoire
  - Staff terms and conditions
Service Redesign

- Pressure to form consolidated labs
- Network for specialist tests
- Hierarchy of referral
- Contractual flexibility/inflexibility
- Compatibilities
- Organizational redesign
  - Time
  - Personnel
  - Enabling costs
Service Redesign

- Commoditization of analysis and processes
- Adding Value
- Knowledge management
  - Investigation
  - Interpretation
  - Diagnosis
  - Optimal Service Use
- Innovation in Service Models
Types of service amalgamation

- Publicly directed merger
  - Budget led (UK)
  - Reimbursement led (France)
- Public-private partnership
  - Create an entity e.g. Limited Liability Partnership
- Private led with public contribution
  - Medical staff contracted in
- Private
  - Private service
  - Public service
## Actual Examples for Consolidation of the Market in Germany

<table>
<thead>
<tr>
<th>Year</th>
<th>Buyer</th>
<th>Acquired</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>synlab</td>
<td>MVZ LEYERBÜREN</td>
<td>70 m €</td>
</tr>
<tr>
<td>2010</td>
<td>SONIC HEALTHCARE</td>
<td>Labor Lademannbogen</td>
<td>n.a.</td>
</tr>
<tr>
<td>2009</td>
<td>BC Partners</td>
<td>future SYNLAB</td>
<td>300 m €</td>
</tr>
<tr>
<td>2009</td>
<td>Labco</td>
<td>ASSICLAR</td>
<td>n.a.</td>
</tr>
<tr>
<td>2008</td>
<td>Institut für Hämatopathologie Hamburg</td>
<td></td>
<td>n.a.</td>
</tr>
<tr>
<td>2008</td>
<td>SONIC HEALTHCARE</td>
<td>GIP medical Group</td>
<td>31 m €</td>
</tr>
<tr>
<td>2008</td>
<td>SONIC HEALTHCARE</td>
<td>Labor 28</td>
<td>74 m €</td>
</tr>
<tr>
<td>2007</td>
<td>General Atlantic</td>
<td>wagnerstibbe</td>
<td>n.a.</td>
</tr>
<tr>
<td>2007</td>
<td>SONIC HEALTHCARE</td>
<td>bioscientiantia</td>
<td>190 m €</td>
</tr>
<tr>
<td>2004</td>
<td>SONIC HEALTHCARE</td>
<td>Dr. Med Bernd Schottdorf</td>
<td>29 m €</td>
</tr>
</tbody>
</table>
Using private providers

- Provide investment in weakened public service
- Perceived more efficient in business terms
  - Tackle staffing costs
  - Better business development
- More amenable to service change
- Concern over loss of transparency
- Diminution of clinical orientation
Importance of Private Patients for Laboratory Sales

Ten percent of the privately insured patients cause 15% of the test volume but approximately 35% of the sales of a medical laboratory.
Legal Issues

- EU Tender
- Principle of provided service
- Value Added Tax exemptions (~20%)
- Recent decisions
More for Less

- 20/20 “Vision” [20% ‘more’ for 20% less]
- Reimbursement reductions e.g. Cours des Comptes [France]: Impact on private sector
- Budget reductions: Impact on public sector
Our decision produces unsatisfactory consequences: our conclusion that the appellant’s supplies are to a large extent exempt from VAT means that it is to that extent unable to recover input tax, of which it incurs a substantial amount; whilst treatment of the supplies in issue as taxable would require output tax to be charged, the supplies are principally made to entities in the healthcare sector that can recover VAT paid out by them pursuant to s 41 of the Value Added Tax Act 1994. The effect of our decision will be to make the supplies more costly to the recipients, as the charges will have to incorporate irrecoverable input VAT.
Maintaining and Improving Standards

- Accreditation to ISO 15189
  - Mandatory for reimbursement (France)
  - Expected (UK)
  - Competitive advantage in private sector

- Legislation
  - France for ISO 15189
  - Head of Laboratory e.g. Germany

- Laissez-Faire
Disseminated labs

- Inclusion of Laboratory Medicine as part of healthcare service mandates

- Satellite labs
  - High cost to lab, but economic benefit
  - Reimbursement may not recognize this

- POCT
  - Quality standards
  - Training overhead

- Patients
  - Self-monitoring
  - Direct access
The Professionals view:
POCT is a mini-laboratory!
Self-Monitoring Blood Glucose Errors

Long-term self-monitoring Diabetic patients had a 1 in 10 sampling error rate on 1\textsuperscript{st} stab and 1 in 20 on up to the 4\textsuperscript{th} attempt.

Of the failures:

- Insufficient sample 33%
- On-screen error 32%
- Unable to apply sample 19%
- Result not trusted 15%
Age is a factor in self-testing
Mayhorn & Carpenter *Work* 2012; 41: 370-3

The elderly more prone to SMBG errors

The type of meter matters

Changing meters causes an increase in errors

Diabetics at higher risk of cognitive impairment
Patient response to self POCT

Patients self POCT for cholesterol

Errors of

Commission

Omission

Timing

Self determined diet response RATHER than refer to doctor:

Missed opportunity to intervene appropriately and to confirm
Adding Value

- Recognition that if ~40% of all tests are unnecessary, then there is an educational need for service users:
  - Advice on best testing
  - Agree investigation protocols
  - Interpretation of results
  - Innovation of service/clinical pathway
Error Rates

- **Laboratory**
  - Pre-analytical: ~60%
  - Analytical: ~15%
  - Post-analytical: ~25%

- **POCT**
  - Pre-analytical: ~33% Smith et al Point of Care Testing 2011; 10; 189-192
  - Analytical: ~67% O’Kane et al Clin Chem 2011; 57: 1267-1271
  - Post-analytical: ~3-95% Tighe Accred Qual Assus 2001; 6: 402-4
Pre-Analytics Cost

- Aintree Hospitals Liverpool UK identified 46,000 pre-analytical errors per annum
- If it cost £5/phlebotomy then to repeat these tests error-free would be ~ £230,000 pa
- Lack of whole organisation quality system
Patient engagement

- Direct Patient access to labs
  - Direct pay prior to medical consultation e.g. Greece
  - Direct access through primary care physician for reimbursable payment e.g. Belgium

- Indirect access to labs
  - Through healthcare provider e.g. UK

- Opportunities to educate patients
Laboratory Professionals Advocacy

- Three recent meetings advocate laboratory professional engagement with patients:
    - Cancer & pathology
  - Co-Diagnostics Forum Curran & Platero Pharmacogenomics 2011: 12; 465-470
    - World Companion Diagnostics Summit
    - Main concern to have ownership of genomic results
Diabetic Patient Understanding of CHD Risk Modified by Education
Siklosi et al Diabetic Medicine, 2008; Vol. 25: 811-817

**Figure 4:** Actual, perceived, understood and recalled risk of coronary
I understand what the result means:

55% did not (Falcon et al Patient Ed Couns 2010; 78: 134-7) This is associated with poor education and immigrants.

The comprehension of HbA1c improves with better understanding. (Beard et al Patient Ed Couns 2010; 80:227-232)


Type 1 Diabetics had a good comprehension of their HbA1c values.

(Skeie et al Clin Chem 2001; 47: 1212-1217)
What do Test Results mean?

- **Reassurance:** Systematic review found no evidence for this (van Ravesteijn et al. Patient Ed Couns 2012; 86: 3-8)

- Mailed Written reports to patients:
  - Took 6 - 33 days to arrive
  - 50% did not understand
  - Unmet expectations
  - Negative emotional responses evoked
  - Need to empower through use of simple explanation
Pathology Expert System Report

<table>
<thead>
<tr>
<th>Clinical Parameter</th>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC_Cut_Off_5</td>
<td>True</td>
<td>True</td>
</tr>
<tr>
<td>HDL_chol</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>LDL_chol</td>
<td>3.2</td>
<td>3.9</td>
</tr>
<tr>
<td>LDL_Cut_Off_1</td>
<td>True</td>
<td>True</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>0.3</td>
<td>1.9</td>
</tr>
<tr>
<td>TG_Cut_Off_1</td>
<td>True</td>
<td>True</td>
</tr>
<tr>
<td>TC_HDL_ratio</td>
<td>5.1</td>
<td>5.5</td>
</tr>
<tr>
<td>Marked_Elev_LFT</td>
<td>False</td>
<td>False</td>
</tr>
<tr>
<td>ALP</td>
<td>30–34</td>
<td>45</td>
</tr>
<tr>
<td>ALP_Marked_Elev</td>
<td>False</td>
<td>False</td>
</tr>
<tr>
<td>ALT</td>
<td>0–55</td>
<td>37</td>
</tr>
<tr>
<td>ALT_Marked_Elev</td>
<td>False</td>
<td>False</td>
</tr>
<tr>
<td>ALT</td>
<td>0–45</td>
<td>35</td>
</tr>
</tbody>
</table>

Current Episode
This pattern is commonly seen in oestrogen use (HRT) and in non-fasting specimens. Other conditions where it may be seen are bile-acid sequesterant usage and in association with high alcohol intake.
Patient-Focussed Laboratory Medicine?

- Educate patients so they understand
  - Why they need tests
  - Which tests and when
  - What the results mean

- Engage clinicians in the concept
  - An adjunct to clinical engagement, not a usurpation of their role
  - Interpretation by lab clinicians [within limits]
Final Thoughts

• Within a Nation lab provision is clear and varies considerably in organisation and standards between Nations

• European legislation will impact on competition and quality

• European workforce will become more flexible; experience with medical staff is that this will be at the expense of the poorer countries

• Lack of comparability will be exposed as HER projects across-borders mature.