Lab Medicine: Economics, Financing and organization in the new French / EU environment

Bernard GOUGET
SFBC-EFLM representative
Public Health and Medical Biology department FHF
Vice-Président Comité section Santé Humaine COFRAC
b.gouget@fhf.fr
French Health care system
general population 66,03 million

Based on fundamental principles:

- Solidarity between all citizens
- Universal health coverage
- Diversity in the delivery of healthcare (hospital, outpatient care services)
- Patient’s freedom of choice

Built on the dichotomy between:

- Public and private sectors
- Hospital and ambulatory care
<table>
<thead>
<tr>
<th><strong>Public hospitals</strong></th>
<th><strong>Not-for-profit hospitals</strong></th>
<th><strong>For-profits hospitals</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 1000</td>
<td>1444</td>
<td>1408</td>
</tr>
<tr>
<td>- 32 UHC</td>
<td>1,3 M hospitalisations</td>
<td>3,3 M hospitalisations</td>
</tr>
<tr>
<td>- 519 CH</td>
<td>4,5 M outpatient care</td>
<td>1,1 M outpatient care</td>
</tr>
<tr>
<td>- 89 SHC</td>
<td>830 000 visits to ER</td>
<td>1,8 M visits to ER</td>
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<tr>
<td>- 324 LH</td>
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<tr>
<td>8,5 M hospitalisations</td>
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<tr>
<td>3,8 M outpatient care</td>
<td></td>
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<tr>
<td>13 M visits to ER</td>
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Legal persons governed by public law with administrative and financial autonomy

Almost the same rules as those applied for public hospitals

Lots of small structures where the main activity is scheduled surgery
Human ressources and ambulatory care:

- **Practising doctors**: 217,000 (3.3 for every 1000 inhabitants), which include over 50% GPs.
  - 75% of GPs and 68% of specialists are in private practice
- **Dentists**: 40,599 / **Pharmacists**: 73,127
- **Midwives**: 18,800, which 16% are private midwives
- **Nurses**: 520,000, which 14% are in private practice

Hospital care:

- **1 hospital for 20,000 people** versus **1 for 40,000** in Europe
- 6.2 hospital beds for every 1000 inhabitants (average OECD 34: 4.4 beds)
- 44% of the consumption of care and medical goods / 4% of GDP

Patients are free to choose the public or the private sector, hospital or outpatient care.
Total Health Budget 2014: 179.1 billion €
- Ambulatory care: 81.1 billion €
- Public and private institutions: 75.5 billion € (41.8% of CCMG)
- Medico-social: 17.6 billion €
- Others: 1.7 billion €

11.6% of GDP
3275 € per capita
99.9% of the population covered, thanks to the creation of:

- Universal Healthcare coverage (CMU) in 1999
- Assistance with Purchasing Top-Up Health Insurance (ACS) in 2004

77.4% of health expenditures covered by the statutory health insurance

- GP’s consultation: 23 €
- Specialist’s consultation: 25 €

13.8% covered by private insurers

8.8% of rest supported by patients
A major player in economy:

- 4.6% of GDP
- 2 million direct and indirect jobs
- 16 billion euros of purchases per year

Threefold mission:

- Care: 2/3 of birth, 75% of oncology, 90% of emergencies
- Education: Initial formation: 60,000 medical students, 100,000 paramedical students
- Research: 2 billion euros per year for research, education, and innovation
Public hospital: a dynamic activity

- The hospital activity has increased by 8% on the whole activities of the medical-surgery-obstetrics sphere in a 5 years period

- Large reorganization movement implemented:
  - Optimisation of the care pathway, ambulatory development, pooled purchasing, various externalizations
  - Cooperations with public, private and outpatients care services

- Hospital park modernisation has improved patients reception and working conditions of hospital civil servants
For 30 years, healthcare reforms are responding to the same movement:

- Redefine public hospital’s position in the healthcare system
- Rationalize resources to lower health insurance expenditures for public hospitals
- Find the ideal management and organization
Main last reforms

- Transition from global budget to activity based payment

- Medical pole’s setting up in order to decentralize management issues

- Regional Health Agencies’ setting up
  - Renew hospital governance and strengthen the hospital director
  - Facilitate cooperations
Flow chart of health system

State which fixes each year the health policy guidelines and determines the growth rate of health insurance expenditure

Regional Health Agencies
(responsible for planning and allocations of resources)

Contracts of objectives and means

Public hospitals

Contracts of management

Poles Poles Poles
Tomorrow’s challenges

- Restoring the link between local communities and hospitals

- Creating a real territorial public service by reinforcing cooperation between hospitals (hospital group territory)

- Refocusing supervisory agencies on their strategical steering mission: RHA should propose a global viewpoint, support local actors and promote decompartmentalisation

- Encouraging in this new context the local hospitals, which ensure coordination with doctors from the liberal sector, medico-social structures
Tomorrow’s challenges

- **Develop alternatives to full hospitalisation**: hospital at home, hospital hotel, ambulatory medicine

- **Build a new human resources management policy** more adapted to care network

- **Improve public hospital funding** through defining a fixed part, which would correspond to public service missions, and a variable part, whose purpose is to valorize the relevant activities and cooperation actions

- **Enhance the information system** to become more efficient

- **Improve health democracy**: build a common culture between patients and professionals through the creation of the Patient Institute
La carte des régions de France au 1er janvier 2016.
périmètres de coopération territoriale
laboratoires hospitaliers franciliens

+ 6 coopérations en petite couronne

+ 4 coopérations à Paris

Légende
En vert : coopérations abouties ou
Commencement de mise en œuvre
En bleu : projet

Source : ARS Ile-de-France
Quality Management and patient safety:

• A French procedure, compulsory, managed by the « High Health Authority » « Certification HAS »

• Accreditation of the Medical labs, histo-pathology, imagery......
Certification according to the High Health Authority (V2014)

- Procedure driven by experts (who do not belong to the hospital which asks for procedure)

- Who measure gaps between observed practices in the hospitals and practices which have been defined as optimal

- The aim is to write a public report on the level of quality in the different fields of the hospital
The French Lab Med context

• **10 000** medical biologists
• 16,5/100 000 inhabitants vs 5,8 in UE
• **7000** private sector / **3000** hospital

• ¾ pharmaceutical ; ¼ medical background
• Medical Lab demography is decreasing

• **41 000** people are working the private sector
• Before 2010
  – 3800 private labs
  – 1200 Hospital labs
• Today
  – In total **1081 medical labs** ( 3600 sites) / **359** Hospital Labs ( 32 UH)
• There is a movement for concentrating laboratories, increasingly pursued by investment funds.
European IVD Market 2013 (million €)

- Germany: 2,159
- France: 1,786
- Italy: 1,660
- Spain: 971
- UK: 784
- Turkey: 367
- Belgium: 353
- Switzerland: 345
- Netherlands: 309
- Poland: 281
- Austria: 249
- Greece: 220
- Portugal: 216
- Sweden: 185
- Norway: 168
- Denmark: 144
- Czech Republic: 143
- Ireland: 131
- Finland: 105
- Romania: 93
- Hungary: 61
- Slovakia: 44
- Slovenia: 33
- Bulgaria: 32
- Lithuania: 27
- Latvia: 23
- Estonia: 14
- Iceland: 11
- Cyprus: 2
- Malta: 2

**TOTAL IVD Market 2013:**
- EU-27 + EFTA + Turkey (except LU): €10,918 Mio.
Medical Biology in France: Economic aspects

FR Gross Domestic Product (GDP): 2113 BM€
Total Health Budget 2014: 179,1 billion €
- Health 11,6%
- Hospital (86,7 BM €)

Medical Biology
- 1,8% routine health care expenses
- 3-5% of the Hospital Budget
- 2,4% Consumption of care and medical goods
- (Total: 7,23 Md€ (60,5% private Labs, 6,4% clinic, 33,1% Hospital)
- 2,4 Md€ hospital, 4,83 Md€ private sector refundable by the National Health Insurance
- 9,7% Consumption of ambulatory health care
History of the French reform of the medical labs

- **2009:** HPST: Art 69 de la loi n° 2009-879 du 21 juillet 2009 portant réforme de l'hôpital et relative aux patients, à la santé et aux territoires

- **2010:** Ordonnance Janvier 13 2010 (REGULATION)

- **2011:** Proposition de loi de M. Jean-Pierre Fourcade modifiant certaines dispositions de la loi n° 2009-879 du 21 juillet 2009 portant réforme de l'hôpital et relative aux patients, à la santé et aux territoires (n° 65, 2010-2011), censurées par le Conseil constitutionnel.

- **2012:** l'Assemblée nationale le 26 janvier 2012, Une proposition de loi de Mme Valérie Boyer, M. Jean-Luc Préel et plusieurs de leurs collègues portant réforme de la biologie médicale (n° 3989, AN XIIIème législature), reprenant le même texte, a été adoptée

- **2012:** Sénat fev 2012, sans toutefois être inscrite à l'ordre du jour avant la fin de la législature.

- **2013:** LOI n 2013-442 du 30 mai 2013 portant réforme sur la biologie médicale
Four major objectives of the new law on Medical Biology (2013)

• to ratify the 2010 ordinance regarding laboratory medicine

• to enhance the medicalization of the profession.

• to harmonize the public and private sectors

• to define the organization of laboratory medicine

• to ensure the quality of medical biology tests.
The Cofrac

Board of Administrators

Internal Audit Commission

General Director

Quality & international affairs Manager

Services: finances, human resources, communication, IT, assessors

Laboratories Section

Inspection Section

Healthcare Section

Certifications Section

Lead assessors and technical assessors
Survey regarding accreditation of medical Labs within EA

( sent to 30 ABs received from 26 ABs)

H Mehay Cofrac (FR)

Standard used for accreditation for medical laboratories

- 50% ISO 15189 only
- 31% ISO/IEC 17025 only
- 15% Both standards but with preference of ISO 15189
- 4% Both standards but with preference of ISO/IEC 17025
- 0% Both standards (ISO 15189 and ISO/IEC 17025) without any preference

Germany (Dakks) : ISO/IEC 17020 for pathology
Turkey (Turkak) : ISO/IEC 17020 and ISO 15189 for pathology
Is accreditation of medical laboratories mandatory?

- No: 63% (15 AB)
- Yes: 37% (9 AB)
Technical fields in the medical area covered by accreditation

- Cytology: 77%
- Histopathology: 77%
- Clinical chemistry: 92%
- Clinical toxicology: 65%
- Pharmacology: 58%
- Bacteriology: 88%
- Mycology: 85%
- Virology: 85%
- Serology: 85%
- Parasitology: 92%
- Haematology: 88%
- Immunohaematology: 92%
- Histocompatibility: 50%
- Cytogenetics: 69%
- Molecular genetics: 96%
- Immunology: 92%

Other: Research and imaging services (biometrics), clinical neurophysiology, isotope medicine, clinical physiology, Radiology; Neurophysiology, Nuclear Medicine, Doping, IVF, molecular pathology, in-situ techniques in pathology
The Netherlands: 260 accredited and 17 in a process of accreditation by CCKL
UK: 1000 in a process of transfer from CPA-UK
Law No. 2013-442 of 30 May 2013 which amended Ordinance No. 2010- 49 of 13 January 2010 :

• Accreditation of all Medical Labs
  - 100 % of their tests to 1 November 2020;
• Two steps to organize the scalability of accreditation:
  – On October 31, 2016 : all LBM are accredited on 50 % and at least one test by « family »
  – On October 31, 2018 : all LBM are accredited on 70%.

• All labs have crossed the entry into the accreditation process in 2013 :

• On 31 October 2013: 1380, private and public ( 359) LBM referenced in the BIOMED information system
Les laboratoires de biologie médicale (LBM) poursuivent leur démarche d'accréditation !

<table>
<thead>
<tr>
<th></th>
<th>Accréditations effectives au 01/09/15</th>
<th>Processus d'accréditation en cours (évaluation initiale réalisée) au 31/08/15</th>
<th>Demande initiale d'accréditation reçue au 31/08/15*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nombre de LBM</td>
<td>573</td>
<td>64</td>
<td>431</td>
<td>1 068</td>
</tr>
<tr>
<td>Dont LBM «hospitaliers»</td>
<td>173</td>
<td>26</td>
<td>123</td>
<td>322</td>
</tr>
<tr>
<td>(CHU, CH, GCS, CLCC, HIA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dont LBM «privés» et «autres publics»</td>
<td>400</td>
<td>38</td>
<td>308</td>
<td>746</td>
</tr>
</tbody>
</table>

* Après recoupement avec les informations détenues par les ARS, notamment en lien avec les restructurations en cours, le nombre de dossiers déposés en application du décret du 23/02/15 a été réévalué.
RÉPARTITION RÉGIONALE DES LABORATOIRES DE BIOLOGIE MÉDICALE (LBM) ENGAGÉS DANS LE PROCESSUS D’ACCRÉDITATION AU 1ER SEPTEMBRE 2015

Focus sur les LBM :
- Nombre de LBM accrédités
- Nombre de LBM dans le processus d’accréditation (évaluation initiale réalisée)
- Nombre de LBM ayant déposé une demande initiale d’accréditation

Focus sur les LBM hospitaliers (CHU, CH, GCS, CLCC, HIA) :
- Nombre de LBM hospitaliers accrédités
- Nombre de LBM hospitaliers dans le processus d’accréditation (évaluation initiale réalisée)
- Nombre de LBM hospitaliers ayant déposé une demande initiale d’accréditation
Challenges of Accreditation of medical labs according to NF EN ISO 15189 ( DGS: Sept 4, 2015)

- To ensure a level of proved quality for the patient and clinician for public health reasons,

- To accelerate the Consolidation of Med Labs to increase their expertise and skills and to reduce the operating costs,

- To Contribute to the control of volumes and prices in the context of a medical accreditation: lower costs for health insurance to support sustainability;

- To facilitate participation in international biomedical research

- To Encourage the international competitiveness of French medical services. All obligations of means (provided by LABM Act 1975) were replaced by the mandatory accreditation
Lessons to be learned..

• 60% of LBM are already accredited or in the process of being:
  • it is a remarkable result achieved through the efforts and the mobilization of all parties
  • A development of accreditation of LBM consistent and slightly ahead of the international development of accreditation in medical biology in the world: an asset for France;
  • A drive-related effect "to pass a course in 2016"

• Positive feedback on the added value of accreditation in efficiency and safety, and the continuous improvement process that it implies,

• Mutual understanding between the COFRAC and the professional still need to be corrected,

• But a slow and gradual entry into the process leading to:
  - Less than 10% of accredited LBM meet at this stage, the two criteria to achieve 31 October 2016 with 50% of the tests, one test by a family
  - less than half accredited LBM meet at this stage the sole criteria of 50%
With very important consequences.....

• A considerable effort remains to be done in 1 year, to carry out initial assessments and extension (one thousand evaluations), which implies strong resources available evaluators, including medical biologists

• Available resources remain worrying despite better mobilization in recent months, particularly in hospital;
  - Quality assessors 91 (70 external)
  - 231 medical biologists Technical Assessors (45 are from Hospital, 19%) - - - 79 candidates of Assessors under examination techniques (of which 27 are from hospital medical biologists, 34%)

• Still clearly insufficient number of technical evaluators to pass the "cap" end October 2016
Actions Ministry of Health and COFRAC: 4 priorities

• To achieve and to implement, by the end of 2015, the optimization measures of the accreditation process to provide flexibility and to save time for technical evaluators

• To optimize the process and reduce the time for qualification of candidates technical assessors

• To redefine prioritization assessments by adapting the scope of initial accreditation if needed and to maintain a dynamic extension of the scope of accreditation

• To continue actions to increase the number of technical assessors in a collaborative approach with all stakeholders
New proposals from the COFRAC under discussion...

- Prioritize assessment of the **431 unaccredited LBM without an initial assessment**. The extension visits will wait...

- **Setting a more limited scope to achieve the objective of accreditation**:
  - Suppression the condition of **50%** and one test per family (1 November 2016);
  - Suppression the condition of **70%** Accreditation (1 November 2018);
  - Accreditation 100% of all LBM (1st November 2020);

- Referal to
  - Legal affairs at the Ministry level
  - the Constitutional Council
  - In order to declassify a part of the Law 2013 > decree of The French Conseil d’état
In summary

• The Law 2013 is far too detailed > any change is difficult., but...

• The concept of accreditation is accepted by all the Health professionals (+ 60% of accredited labs) > patient safety and wellness

• But still Complex relationships between:
  Ministry, Syndicates, Cofrac

• Med Lab reform, restructuring and geographical reorganisation, medical demography and evolution of the profession encourage stereotypes

• Future >Precision medicine: a challenge for the Lab medicine