14.30 - 15.30 Sala Tiziano 2

Simposio Educazionale

Automazione: azioni concrete per il cambiamento strategico della medicina di laboratorio

15 anni tra integrazione e consolidamento

Davide Giavarina (Vicenza)
<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Area</td>
<td>737 Km²</td>
</tr>
<tr>
<td>Population</td>
<td>321,559</td>
</tr>
<tr>
<td>Public hospitals</td>
<td>2</td>
</tr>
<tr>
<td>Beds</td>
<td>816</td>
</tr>
<tr>
<td>critical care</td>
<td>43</td>
</tr>
<tr>
<td>long-term care</td>
<td>30</td>
</tr>
<tr>
<td>medical</td>
<td>376</td>
</tr>
<tr>
<td>surgical</td>
<td>248</td>
</tr>
<tr>
<td>maternity and paediatrics</td>
<td>119</td>
</tr>
<tr>
<td>critical care</td>
<td>43</td>
</tr>
<tr>
<td>long-term care</td>
<td>30</td>
</tr>
<tr>
<td>Employees</td>
<td>3,478</td>
</tr>
<tr>
<td>Districts</td>
<td>4</td>
</tr>
</tbody>
</table>
### Lab numbers

<table>
<thead>
<tr>
<th></th>
<th>Year 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test /y</strong></td>
<td></td>
</tr>
<tr>
<td>inpatients</td>
<td>2.104.320</td>
</tr>
<tr>
<td>outpatients</td>
<td>2.428.890</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>4.533.210</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reports /y</th>
<th>Year 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>inpatients</td>
<td>148.977</td>
</tr>
<tr>
<td>outpatients</td>
<td>317.764</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Role</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Director, MD</td>
<td></td>
</tr>
<tr>
<td>7 MDs</td>
<td>(waiting for 2 units more)</td>
</tr>
<tr>
<td>2 Biologists</td>
<td></td>
</tr>
<tr>
<td>35 Biomedical scientists</td>
<td>(2 pt) (w. for 4 more)</td>
</tr>
<tr>
<td>2 Head Biomedical scientists</td>
<td></td>
</tr>
<tr>
<td>5 Auxiliary operators</td>
<td></td>
</tr>
<tr>
<td>8 Clerical staff</td>
<td></td>
</tr>
<tr>
<td>19 Nurses</td>
<td>(18 pt)</td>
</tr>
</tbody>
</table>
Core-Lab:
Chemistry and Immunochemistry (cardiac marchers, oncologic markers, thyroid, fertility, anemia,)
- Chemistry
- Haematology
- Haemostasis and thrombosis
- Point of care testing network
  (20 emogas-analysiers, 90 glucometers)

Quality system management

Immunometry and hormoners

Allergology & autoimmunity

Protidolology

TDM & Tossicology, screening and confirm (to law..)

Laboratory information system
- in & out patients, 16 front-offices, 34 wards, 4 districts, more than 100 family physicians, 4 rest homes, other public and private hospitals; more than 250 connections all over.

Outpatient medical offices
(blood and biological fluids collection)

Satellite LAB
(Spoke Hospital of Noventa Vicentina)
Compartmentalized Laboratory

- TAT
- Loss of Efficiency
- Lack of Space
- Fewer Personnel
- Maintain/increase QUALITY

AUTOMATION

SCHEMATIC REPRESENTATION OF OPTIMAL SPECIMEN FLOW-SPECIMEN PROCESSING SCHEME FOR LABORATORY AUTOMATION PLATFORM
Why automation as a driver for lab organization

*Technological tools have meaning only as a means to allow active relationships between human beings and environmental elements, these elements are objects and other human beings*

" (Akrich 1993: Les formes de mèditations techniques)"
What automation could change

- Solve flow problems (TAT, productivity)
- Improve efficiency
- Maintain the previous logical processes
- Provide for expansion
- Maximize profits
- Optimize space
- Improve the quality of work
- Improve quality, overall
What automation can change: Standardizing is like improving quality
Choosing a solution..

• What are the problems, the bottlenecks, the really major practical issues in the laboratory?

• To make this assessment is essential.

• Then you can start to look at the fit between the problem and the kind of solution you need.

Jacques Baudin
Specialised area for routine tests

- Closed areas
- TAT depending on the organization and on LIS
- High numbers of tests
- Restricted range of tests for each workplace
- High trueness

STAT Laboratory

- Closed area
- Short TAT
- Low number of tests
- Wide range of tests
- Less trueness
Goals

• One staff (same skills)

• Closing STAT test lab (all tests are STAT)

• **Consolidating** Chemistry and Immunochemistry

• Improving **preanalytical** processes
  - avoid manual decapping
  - automating centrifugation

• **Changing role for biomedical scientist**, from test maker to process manager
The first tender (2000): the main drivers

- One staff (same competences)
- Consolidating Chemistry and Immunochemistry
- Closing STAT test (all test are STAT)
- Improving preanalytical processes
  - avoid manual decapping
  - automating centrifugation
- Changing role for biomedical scientist, from test maker to process manager
Conveyor & Middleware

Turn Around Time

Prenalitical processes

Middleware
TAT simulation

<table>
<thead>
<tr>
<th>Avg Test TAT</th>
<th>Solution A</th>
<th>Solution B</th>
<th>Solution C</th>
<th>Solution D</th>
</tr>
</thead>
<tbody>
<tr>
<td>1650_1</td>
<td>59</td>
<td>64</td>
<td>53</td>
<td>38</td>
</tr>
<tr>
<td>1650_2</td>
<td>68</td>
<td>71</td>
<td>55</td>
<td>39</td>
</tr>
<tr>
<td>1650_3</td>
<td></td>
<td></td>
<td>53</td>
<td>39</td>
</tr>
<tr>
<td>Centaur_1</td>
<td>61</td>
<td>43</td>
<td>65</td>
<td>42</td>
</tr>
<tr>
<td>Centaur_2</td>
<td>62</td>
<td>44</td>
<td>63</td>
<td>45</td>
</tr>
</tbody>
</table>

ASAP (STAT) tests inside the routine

Turn Around Time

Prenalitical processes

Conveyor & Middleware

Middleware
Turn Around Time

Prenalitical processes

Middleware

Centrifuge in year 2000

Centrifuge in year 2008
Middleware

Process Control

Rules
  Filter

Instrument
  Console
    Autoverification
    QC
    Specimen Management
    Other

Technical
  Support
    Reagent Management
    Testing Parameters
    Workload Optimization
    Other

Remote Diagnostics
  Technical Alerts
  Peer Calibration
  Other
consolidation of different activities
Quality control linked to single results
What automation has changed

• We have saved five FTEs that have been relocated in the 24H shift, permitting us to close the STAT Lab.
• We standardized the TAT, both for STAT and for Routine tests.
• We reorganized the staff activity, with a wider skills.
• In the last 10 years, activity has increased over 5% per year (50% at total), without any increase of required personnel; cost per test do not increase, notwithstanding 2.4% per y of inflation (actually it decreased by 24% over ten years).
Pros and cons during the experience

**PROS**
- Solve flow problems (TAT, productivity)
- Improve efficiency
- Maintain the previous logical processes
- Provide for expansion
- Maximize profits
- Optimize space
- Improve the quality of work
- Improve quality

**CONS**
- High volume of activity to maintain skill levels and (Training)
- High volume of activity in the communication between operators
- Preanalytical problem in the first five years (CENTRIFUGES!)
The new project: second tender
what to improve?

• More automatic control and management
• Further reduction of personnel
• Further improving of TAT
• Maintaining all the functionality of the middleware
• Manage the shift from LabCell towards the new automation solution
The new tender (2012)

CORELAB — CHEMISTRY AND IMMUNOCHEMISTRY

Test/year

- **2,900,000** CHEMISTRY TESTS
- **530,000** IMMUNOCHEMISTRY TESTS
- **52,000** URINE CHEMISTRY TESTS
- **460,000** TESTS for the SATELLITE LAB
Minimum Requirements

- Use of primary tubes (13 x 100 mm and 13 x 75 mm) and tubes for urine (16 x 100 mm);
- Allowing for loading of samples and reagents continuously, without instrument interruption;
- Point-in-space and front-end loading and unloading samples;
- to have selective random access;
- to be fully automated;
- **to have at least 95% of the tests integrated or consolidated in one instrument.**
- to be able to handle requests for the same patient on different biological specimens;
- To use standardized methods and reagents according to the recommendation of the major scientific societies and / or international organizations;
- to be complete with all components and accessories for the connection Bi-directional middleware and software management (LAS) proposed in the offer;
- to use positive identification of samples via barcode (interleaved 2 of 5) with digital recognition of the sample type;
- Performing quantitative measurement of serum indices (hemolysis, lipemia, jaundice).
Automation shift
working in a construction site

- Economic resources
- Respect of Time
- Accuracy of work
- Cooperation between laboratory personnel and all other workers

Plant, electrical, network, data, plumbing, masonry
working in a construction site

one tube, one man (woman), one instrument

Same middleware
Same rules
Same organization
RFID (Radio Frequency IDentification) and Point in space sampling
Centrifuge in year 2000
New Centrifuge (2008)
Centrifuge
Decapper

LABCELL

APTIO
Automation 2.0

First pros and cons and what we are waiting for...

Track and preanalytical

• Easier
• Faster
• Robust
• Secure
• Accessible
• Less noise
• Nothing to declare

Analysers

• Reliable
• Easier
• Much more automatic (reagents, calibration, controls, calls, etc.)
• Robust
• Secure
• High traceability
• Remote control
• More noise
• Less flexibility in sample dilution
Centralink

Application Databases System Libraries

Name: CentraLink
Version: 14.0.4 (Distribution version)
Progress product: Run-Time 10.2B
Terminal type: WIN3
Current directory: D:\Centralink
Temporary directory: D:\Centralink\tmp\nServer identifier: PHCCYJBZTFI2IVV

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CentraLink®
Data Management System

Developed by MIPS (Medical Information for Professional Systems) for Siemens Healthcare Diagnostics.
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Siemens Healthcare Diagnostics Inc.
Tarrytown, NY 10591 USA
Centralink and APTIO

• There is a complete integration between LAS and Centralink.

• Personnel did not perceive any difference during the shift from LABCELL to APTIO

• Processing samples and validation of the results did not change during and after the new installation

• Centralink remain the powerful tool to control all the technical processes during the analytical phase
Conclusion
On the road to automation, proceed with caution

Automating a laboratory without first streamlining its processes is like paving a cowpath

- Anne Ford, 2004 (CAPTODAY senior editor)
2000, the beginning

from test makers to processes managers

2014, today