Why Traceability is important for the Public?

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Euromedlab, Athens, 2017
Why Traceability is important for you?

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Big Themes in (laboratory) Medicine

- Evidence-based medicine
- Electronic Medical Record
- Patient Movement
- Data analysis (data mining / big data)
- Cost savings
- Patient Safety

These all require traceable results
Contents

• What is traceability
• History (and philosophy)
• Why is it important
• What we need to do
What is traceability?
• Traceability is how we get the right answer

What is the right answer?
• An accurate answer
• The answer we would get with the best method

How do we know if our result is traceable?
• The method has been compared with a better method (and adjusted to give the same result)
“The Kilo”
BIPM, Paris

Traceable results are comparable
"The Kilo"
BIPM, Paris

Traceable results are comparable
“The Kilo”
BIPM, Paris

Traceable results are comparable
Traceable Measurements

• Weight (mass)
• Length
• Time
• Temperature

........
Metrology - BIPM

Bureau International de Poids et Mesures (International Bureau of Weights and Measures)

(Pont de Sevres, Paris)
<table>
<thead>
<tr>
<th>Base quantity</th>
<th>SI base unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Name</td>
</tr>
<tr>
<td>length</td>
<td>metre</td>
</tr>
<tr>
<td>mass</td>
<td>kilogram</td>
</tr>
<tr>
<td>time, duration</td>
<td>second</td>
</tr>
<tr>
<td>electric current</td>
<td>ampere</td>
</tr>
<tr>
<td>thermodynamic temperat</td>
<td>kelvin</td>
</tr>
<tr>
<td>amount of substance</td>
<td>mole</td>
</tr>
<tr>
<td>luminous intensity</td>
<td>candela</td>
</tr>
</tbody>
</table>
• **Measurement** Traceability
• Trueness
• Bias
• “Getting the right answer”

• Traceability makes results the same: anywhere, any time
Our current scientific, manufacturing, technological civilization is built on traceable measurements – The Systeme Internationale (SI)
History and Philosophy
Black figure amphora. Men weighing merchandise, Taleides 560 - 530 BC
Mass – Ancient Greece

• Set of official weights, about 500 B.C.
• Found near the Tholos
• Inscribed with the name of the weight and a symbol.
• Also inscribed with the phrase *demosion Athenaion*, "public (property) of the Athenians."
Fourteen cubit rods range from 523.5 to 529.2 mm and are divided into seven palms, each palm is divided into four finger and the fingers are further subdivided.
• Clay public measure
• 4th century B.C.
• Inscribed *demosion*, indicating that it is official.
• Validating stamps are included.
By about 500 BC, Athens had a central depository of official weights and measures, the Tholos, where merchants were required to test their measuring devices against official standards.

By about 1875 AD, The modern world had a central depository of official weights and measures, the BIPM, where measurement services were required to test their measuring devices against official standards.
What do you want?

An accurate Lab!
(producing a traceable result)
**Example:**

Mr Bill Bloggs (DoB 1 Jul 1950)
Sample Collected: 21 Aug 2012, 10:00 am

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum creatinine:</td>
<td>125</td>
<td>umol/L</td>
</tr>
</tbody>
</table>
Interpreting laboratory results

Φ+θ/μ-βχπ or λ ??
Interpreting laboratory results

Your results are interpreted by comparison with:

• A clinical decision point

• A reference interval (normal range)

• Your previous result

Creatinine: 110 125 umol/L

Professor Per-Hyltoft Peteresen, Sydney 2005
Interpreting laboratory results

Your results are *correctly interpreted* when your lab is comparable to:

- A clinical decision point
  - *The method used in the paper*
- A reference interval (normal range)
  - *The method used in the study*
- Your previous result
  - *The method used before*

**Professor Per-Hyltoft Peteresen, Sydney 2005**
Does it matter if results are different?
Applying Evidence

When comparing with a clinical decision point derived from the medical literature

• You want the best evidence
• Medical evidence comes from everywhere in the world
• (Freely available: INTERNET!)

• Labs around the world must be traceable to allow “Evidence based medicine”
E-Health

- The Future is an **Electronic Medical Record**
- Patients want “all pathology results available”
- Different labs need to be comparable (or display and interpretation difficult)
- The public expects this!

➔ Labs must be traceable to be IT Ready
When patients travel...

- From GP to hospital
- From GP to specialist
- Use a different laboratory
- To a different city
- To a different country (holiday, work, migration)

- To manage your health, you need your pathology
- Results from different labs need to be the same

*Labs must be traceable to allow you to move*
Financial effects?

- When results are not comparable
- Patients need to be tested again when:
  - Admitted to hospital
  - Visiting specialist
  - Changing location or laboratory

→ Traceable results avoid Waste
Public expectations

• “you are scientists aren’t you”
• “why are the results different in different labs”

• Because commutable, historical, new method, blah, blah blah ....

Traceable results are what the public expects
Big Data / Data Mining

- Involves combining data from many sources
- Used to see patterns, plan services
- Requires comparable results

*Traceable results are needed for combining databases*
If the laboratories are different:

Results not comparable with other lab: (biased) →

• Wrong diagnosis
• Wrong management
• Incorrect monitoring

→ Traceable results can avoid some patient harm
Laboratory Medicine is:

Not evidence-based

Not IT Ready

Not safe

Wasteful

Doesn’t serve patients needs

You need traceable results!
Laboratory Measurements
Laboratory Measurements

- All numerical laboratory measurements are made by comparison.
- Analyte concentration in the sample is compared with concentration in the assay calibrators.
- Calibrator values are assigned by traceability.
Calibration Hierarchy or Traceability chain
The top of the traceability chain

- All assays are “anchored” in one of the following
  - A Material
  - A Method (eg Enzymes)
Joint Committee for Traceability in Laboratory Medicine (JCTLM)

- JCTLM - Joining of:
  - Metrology Community (BIPM)
  - Laboratory Medicine Community (IFCC)
  - Accreditation Community (ILAC)

- Aim to bring rigour and processes of metrology to laboratory medicine
The temple of lab standardization – Pillars

1. Reference methods
2. Reference materials
3. Reference labs
4. Quality manufacturers
5. Quality Laboratories
6. Common Units
7. Common Reference Intervals
8. External Quality Assurance
How are we going?

- Some tests fully traceable
- Some tests reasonable
- Some tests poor

“I give us a B”
What is needed?

- More reference materials/methods
- Assay improvement by companies
- Laboratories selecting good assays
- Regulatory support
- Units, reference intervals etc

“lets get an A+”
Measurement Traceability

• Every civilisation and every craft has its tools for spreading measurement standards
• Traceability is the modern version
• It is vital we apply this to Laboratory Medicine