Post-analytical factors and their influence on analytical quality specifications

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Post-analytical factors and their influence on analytical quality specifications

Post-(post-)analytical factors:
1. Reporting
2. Interpretation
3. Overall error management
4. Throughput times
5. Context fit
6. Critical difference (1/4 BV_{ii}, zero error)
7. Follow up

Their influence on analytical quality specifications:
1. Define graphics
2. Clinical outcome indicators
3. Define redundancy
4. Define logistical checks
5. Check and double check
6. Define patients context
7. Provide consultation routinely
• It started with time dependencies (first within the lab, than outside, att.f.)
• Lundberg: loop PA-A-PA
• Goldschmidt and Lent:
  Data + Context → Information (CFV)
• Goldschmidt: loop PPA-PA-A-PA-PPA
• Weggeman: \( K = I \times E \cdot S \cdot A \)
• Error budget calculation
• NEXUS model
The brain-to-brain information loop

- Patient medical history
- Physician’s brain
- Action
- Ordering
- Interpretation

75%
- Test request
- Collection
- Identification
- Transport
- Preparation

15%
- Analysis

10%
- Report


relative error rate
- types of errors: sporadic, systematic and analytical
The brain-to-brain information loop

Introduction

Post(-post)-analytical

Error management NEXUS

Post(-post)-analytical recommendations

Conclusions


relative error rate

Types of errors: sporadic, systematic and analytical
The brain-to-brain information loop

1. Patient medical history
2. Ordering
3. Collection
4. Identification
5. Transport
6. Preparation
7. Analysis
8. Test results
9. Action

Types of errors: sporadic, systematic and analytical

Relative error rate:
- Test request: 75%
- Test results: 10%
- Action: 15%

Complete Diagnostic / Therapeutic Loop

PRE PRE Analytical Phase

PRE Analytical Phase

POST Analytical Phase

POST POST Analytical Phase

DOCTOR

EPR

Laboratory Box

Introduction

Summary

Medical loops

Error management NEXUS

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Conclusions

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Quality of the product (medical treatment not the isolated lab test)

The medical laboratory in the medical process

K(knowledge) = I(information) * E(experiences) * S.skills) * A(attitudes)

Goldschmidt HMJ
Postanalytical factors and their influence on analytical quality specifications.
Linking the concepts of biological variation and medical allowable error

Table: Calculated and studied error rates

<table>
<thead>
<tr>
<th>Phase</th>
<th>frequency of occurrence</th>
<th>justification source</th>
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<tbody>
<tr>
<td>Pre-pre-analytical phase</td>
<td>1:8</td>
<td>12.0 % own enquiry(^1)</td>
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<tr>
<td>Pre-analytical phase</td>
<td>1:49</td>
<td>2.0 % literature</td>
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<td>Analytical phase</td>
<td>1:625</td>
<td>0.2 % results lab author (^2)</td>
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<td>2.2 % literature</td>
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<tr>
<td>Post-post-analytical phase</td>
<td>1:19</td>
<td>5.0 % own enquiry(^3)</td>
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Overall error rate           | 20.0 %                  | see paper for calculation     |
Error budget that can be afforded | 26.9 %              | see paper for estimation     |

1 Interviewing clinicians,  
   checking for errors in e.g. thinking wrong hypothesis  
2 Internal, not external, quality control figure  
3 Interviewing clinicians, checking for e.g. misinterpretation of results
NEXUS approach: linking all concepts

Goldschmidt HMJ Clin Chem Lab Med 2004 42(7) 868-873

1 Patient’s request based upon an event

2 Physician's request

3 data generation and registration

Pre-pre analytical (feed forward)

Pre analytical

Analytical

Post analytical

Post-post analytical (feed backward)

4 Physician's answer

5 context check, information generation and check on general medical knowledge

6 decision (action)

7 Patient’s answer

Error Budget spent

Error Budget allowed

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In a way the two approaches are: what is right now practically achievable and what is, from a theoretical point of view, possible.

So the potential of laboratory medicine is given by the biological variance concept.
Post and post-post analytical steps possible errors linked to potential solutions

**Step 7 reporting**
- Transcription errors
- Computer errors
- Delayed reporting
- No delta check done
- Conflicting rules
- Wrong validation

**Step 8 interpretation**
- Interpretation errors
- No, wrong reflex test
- Consultation error
- Delayed consult
- Erroneous reference values
- Missed interaction test medication
- Computer errors
- Diagnostic uncertainty

**Step 9 action**
- Erroneous action
- No action taken while was required
- Wrong medication
- Missed interaction medication
- Medical action outside protocol
- Computer errors

- ICT check and double check
- Second opinion, interactive software
- Second opinion, interactive software, protocol monitoring software
- ICT
- ICT check and double check
- Reduction measurement variability, other test
- Second opinion
- Second opinion protocollairy approach
- ICT
- ICT check and double check

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DCT

Diagnostisch Centrum Tilburg
Quality of laboratory information

The Stockholm statements:
1999 quality of laboratory results
The Antwerp statements:
2003 quality of laboratory information

Jean-Claude Libeer formulated the following questions:

*Is our information useful for patient care?*

*Do we know what clinicians want?*

*Do clinicians know what we can offer?*
The patient in the lead: all involved
The patient in the lead: all involved

- Introduction
- Summary
- Medical loops
- Error management NEXUS
- Post(-post)-analytical recommendations
- Conclusions

- Consulates by hospitals or specialized care
- Home doctor
- Health care inspection
- Family friends
- Government politics
- Health care insurance

Health care insurance

Patient
RECOMMANDATIONS

1. Use graphics to report
2. Use clinical outcome indicators
3. Use redundancy
4. Use logistical checks
5. Check and double check
6. Define the patients context
7. Provide consultation routinely
1. Use graphics to report
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The guessing experiment

Histogram of 611 Z-scores of clinical test results of 3 outpatient clinics and 4 physicians. The Z-scores are the context fits a particular clinical chemical test result.

In:
Chemistry / Hematology

Exemple 1 (Biochimie)

http://www.ifrance.com/valab/

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# Coagulation

<table>
<thead>
<tr>
<th>Date</th>
<th>Accn#</th>
<th>Analyte/Flag being tested</th>
<th>Results</th>
<th>Problems identified</th>
<th>Changes made</th>
<th>Test performed by</th>
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<td></td>
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<td>Normal patient should autoverify</td>
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<td>&gt; 4 hours from collection</td>
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<td>HPTTT &lt; 22.3</td>
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<td>&gt; 4 hours from collection</td>
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- **Diagram:**
  - Graph showing test result in arbitrary units over time.
  - Observed and expected mean indicated.

**Diagnostisch Centrum Tilburg**
Context geared

Goldschmidt, H.M.J. and Lent R.W.,
Chemometrics and Intelligent Laboratory Systems 28 (1995) 181 - 192
Define *personalized* analytical specifications

- It’s time to recognize the physician as well as the patient
- Use comprehensive models
- Use time dependencies
- Use autovalidation and autoverification
- Bring the quality up to the new level:
  - systematic errors: zero
  - random errors: $\frac{1}{4} \text{BV}_{ii}$
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