Non-Compliance with Guidelines: Motivations and Consequences in a case study

The ischemic stroke management

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Most of the GLs are evidence-based

**Level I** - Evidence is obtained from meta-analysis of multiple, well designed, controlled studies. Randomised trials with low false-positive and low false-negative errors (high power).

**Level II** - Evidence is obtained from at least one well-designed experimental study. Randomised trials with high false-positive and/or negative errors (low power).

**Level III** - Evidence is obtained from well-designed, quasi-experimental studies such as non-randomised, controlled single-group, pre-post, cohort, time, or matched case-control series

**Level IV** - Evidence is from well-designed, nonexperimental studies such as comparative and correlational descriptive and case studies

**Level V** - Evidence from case reports and clinical examples
"Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients… Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients”

(David Sackett)
Motivations for non compliance

- Inter-patients variability
- Low evidence level
- Recommendations derived from multiple studies
- Trials are performed in “optimal” conditions
- Unclear or ambiguous purpose
GL evaluation is necessary

For these reasons, even if they are "evidence-based", guidelines should be evaluated "on the field" to assess both their applicability and the effectiveness of their implementation.

Analysing non-compliance may lead to:

• site-specification of the guideline,
• users education,
• healthcare administrators involvement,
• organisation re-engineering, including resource re-assignment.
The AHA Guidelines for Ischemic stroke: a full evaluation study

- effectiveness
- cost
- compliance analysis
What is stroke?

Stroke is a type of brain injury. Most strokes are ischemic, i.e. caused by reduced blood flow to the brain when a vessel is blocked by a clot.

Other strokes are haemorrhagic.

People who survive a stroke often have weakness on one side of the body or trouble with moving, talking and thinking.
GL and EPR
When detecting non-compliance

- It’s a very GL-tailored choice
  - time-intensity of the user-computer interaction
  - time-specificity of the GL recommendations
- In our case
  - after the acute phase (6 hours from the symptoms onset)
  - after the sub-acute phase
  - at the discharge
  - at the user request
Detecting non-compliance

SELECT DISTINCT a.codpaz,"no brain MRI for POCI"
from admission a, history h, acutephase ap
where
a.codpaz=ap.codpaz and
a.codpaz=h.codpaz and
h.tempo_esordio_sintomi<=6 and
a.stroke_ischemico=4 and
ap.rmnencefalo = 0 and ap.tcencefalo>0

the query looks for patients that, while having a suspect of posterior ischemia, underwent a Computer Tomography scan but not an early Magnetic Resonance
Detecting non-compliance

SELECT DISTINCT a.codpaz, "no anti-platelet treatment"
FROM admission a, subacutephase sf, history h
WHERE a.codpaz=sf.codpaz and a.codpaz=h.codpaz and
(a.discharge_status="alive" or # temporal condition
 a.discharge_status="dead" and a.discharge_date-h.symptoms_date>6
 or a.discharge date is null and date()-h.symptoms_date>6)
 and
 atrial_fibrillation="absent" and sf.stenosis="absent" and
 transthorax_echocardio="normal" and
 not exists
 (select codpaz from
  medical_therapies_subacute_phase
  where codpaz=a.codpaz and terapy_type in ("ASA", "ticlopidine"))

the query checks for the existence of anti-platelet pharmacological treatment as the secondary prevention therapy in patients with no specific cardiac problems
At discharge

- 368 patients
- NCR computed for each patient
  - (NCR=non compliance rating, i.e. the number of tasks recommended by the guideline, but that were not executed)
- NCR range: 0 – 47

Diagram:

- Non-compliance
  - Outcomes: effectiveness
    - Cost
  - Motivations
Analysis of the effectiveness

Micieli, Cavallini, Quaglini et al., Stroke 2002
Kaplan-Meier survival estimate

Survival

Time (Days)

<= 5 non-compliances

> 5 non-compliances

p<0.005

n=183

n=175
### Survival analysis (Cox proportional hazards model)

#### Univariate analysis

Significant prognostic factors: age, type of stroke, number of non-compliance, atrial fibrillation, cardiac insufficiency and Barthel index at the admittance

#### Multivariate analysis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.03 (1.01-1.06) , p&lt;0.03</td>
</tr>
<tr>
<td>Number of non-compliances</td>
<td>1.07 (1.01-1.15) , p&lt;0.03</td>
</tr>
<tr>
<td>Barthel score at admission</td>
<td>1.10 (1.05-1.16) , p&lt;0.001</td>
</tr>
</tbody>
</table>
Barthel index (disability measure) improvement from admission to discharge

\[
\frac{(\text{Barthel}_{\text{final}} - \text{Barthel}_{\text{initial}})}{(20 - \text{Barthel}_{\text{initial}})}
\]
Analysis of the costs

S. Quaglini, A. Cavallini, G. Micieli, Health Policy 2004
Compliance/Cost evaluation

We used a micro-costing approach, because we wanted to compare the different resources consumed by different categories of patients, characterized by the degree of guideline compliance.

In particular, we wanted to discover which cost components were mostly affected by guideline compliance.
A causal model for cost evaluation

Rehabilitation ward

home assistance

Discharge possibility

GL compliance

complications

stroke evolution

diagnostic procedure

length of hospital stay

drug treatment

HC-operators' assistance

COST

major cost component
## Attention to possible biases

<table>
<thead>
<tr>
<th>Destination at discharge</th>
<th>Real length of hospitalisation (biased) (days)</th>
<th>Theoretical length due to stroke (days)</th>
<th>Barthel Index at discharge</th>
<th>% of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>At home, with assistance</td>
<td>12.3</td>
<td>10.3</td>
<td>15.27</td>
<td>27%</td>
</tr>
<tr>
<td>At home, alone</td>
<td>11.9</td>
<td>10.3</td>
<td>19.17</td>
<td>37%</td>
</tr>
<tr>
<td>Other hospital ward</td>
<td>13.3</td>
<td>12.8</td>
<td>5.33</td>
<td>3%</td>
</tr>
<tr>
<td>Rehabilitation ward</td>
<td><strong>18.3</strong></td>
<td><strong>14.1</strong></td>
<td>7.38</td>
<td><strong>28%</strong></td>
</tr>
<tr>
<td>Long-stay ward</td>
<td><strong>30.2</strong></td>
<td><strong>16.3</strong></td>
<td>4.56</td>
<td><strong>5%</strong></td>
</tr>
</tbody>
</table>

Patients stay 4-15 days more than necessary!!
## Cost components (Euro)

<table>
<thead>
<tr>
<th>Component</th>
<th>Overall</th>
<th>NC&lt;5</th>
<th>NC=5</th>
<th>p-value$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs</td>
<td>128 ± 122</td>
<td>100±75</td>
<td>175±163</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diagnostic Tests</td>
<td>1095±339</td>
<td>1061±345</td>
<td>1151±394</td>
<td>ns</td>
</tr>
<tr>
<td>Specialist Visits</td>
<td>25±24</td>
<td>23±23</td>
<td>29±26</td>
<td>ns</td>
</tr>
<tr>
<td>Nurses</td>
<td>443±393</td>
<td>345±265</td>
<td>604±502</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Accommodation Costs</td>
<td>1019±442</td>
<td>951±317</td>
<td>1131±575</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Physicians</td>
<td>508±312</td>
<td>449±232</td>
<td>604±393</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>TOTAL</td>
<td>3218±1946</td>
<td>2929±992</td>
<td>3694±1814</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

GL compliance does not increase the cost of diagnostic procedures.
### Multivariate regression

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>Std. Error</th>
<th>t value</th>
<th>p</th>
<th>$e^b$</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Intercept)</td>
<td>8.007</td>
<td>0.0593</td>
<td>135.1</td>
<td>0.0000</td>
<td>3001.89</td>
</tr>
<tr>
<td>NIH</td>
<td>0.0131</td>
<td>0.0046</td>
<td>2.88</td>
<td>0.0042</td>
<td>1.0132</td>
</tr>
<tr>
<td>Barthel index (square)</td>
<td>-0.0009</td>
<td>0.0001</td>
<td>-6.28</td>
<td>&lt;0.0001</td>
<td>0.9991</td>
</tr>
<tr>
<td>number of non compliances</td>
<td>0.0137</td>
<td>0.0061</td>
<td>2.23</td>
<td>0.0264</td>
<td>1.0138</td>
</tr>
</tbody>
</table>

A unitary increase in the number of non-compliances leads to a **1.38%** increase in cost.

**Example:** Considering a patient with a Barthel = 10 and an NIH Stroke Scale = 5

- treated according to all the guideline suggestions, the cost will be (on average) **2929 EUR**.
- violating 10 guideline suggestions, the cost will increase to **3359 EUR**.
Analysis of the non-compliances
Non-Compliance distribution

ACUTE PHASE
Median: 3 (range: 1-15)

SUB-ACUTE PHASE
Median: 5 (range: 3-13)

Cultural bias: stroke is too invalidating to take any aggressive action

Cultural bias: stroke is not considered an emergency, and Stroke Units are rare
The portion of the organisation ontology used for the analysis of non compliance

- Organisation
  - agent
    - role
      - has_member
      - consumes
        - available_in
          - organisation unit
            - has_member
            - performed by
              - organisation unit
            - collaborates with
              - rehabilitation ward
            - available_in
              - stroke unit
            - consumes
              - resource
                - technology
                - drug
        - temporal constraint
        - location constraint
          - constraint
            - constrained_by
              - activity

Analysing specific non-compliances

- **Vital signs** (BP, SO₂, ...) are NOT monitored in 80% of patients

- **Cause**: mainly “Lack of technology”, i.e. monitored beds.

- **Adverse effects**: we demonstrated a good outcome at discharge in monitored patients vs non-monitored (OR: 2.63, 95% CI: 1.4-4.8, p<0.02).

  causal mechanism: if patients are not monitored, adverse changes in vital signs remain undiscovered, complications are not early detected, and this leads to more complex treatment and slower recovery, with bad impact on both health and costs.

- **Feedback to**: hospital administrators, that should equip Stroke Units and neurological departments with monitoring devices.
Analysing specific non-compliances

• Delay in diagnostic procedures:
  
  • General and neurological examinations (the guideline recommends performing them within the first 15 minutes, non-compliance rate 53%)  
  
  • Chest X-ray should be performed on every patient with a suspect of stroke within 2 hours (non-compliance rate 38%).

• Cause: Lack of intra-hospital coordination

• Adverse effect: cumulated delays impede thrombolisis (effective treatment window: 3 hours)

• Feedback to: HIS responsible, a workflow management system could improve this aspect
Analysing specific non-compliances

- antibiotics and drugs for secondary prevention are rarely administered (non-compliance rate 57%)

- **cause**: physicians’ reluctance to change their behaviour (the motivation provided was their “personal opinion about risk and benefit of the therapy”)

- **adverse effect**: increased number of complications and relapses

- **feedback to**: physicians themselves and control audit (if any)
Conclusion

- **too many non-compliances are still related to physicians’ resistance**
  - a better education is needed to remove some behavioural and cultural biases

- **how to improve compliance:**
  - demonstrating that compliance improves health outcomes and/or cost effectiveness ratio
  - illustrating the adverse effect of non-compliance on the outcomes.

- **analysing non-compliances and their motivations should**
  - foster healthcare administrator to adopt adequate technological solutions (for example workflow management systems, if non-compliances are related to organisational pitfalls).
  - help designers of decision support systems to improve their tools with specific and more impressive reminds about particularly critical recommendations.

- **the role of the information technology is fundamental**
  - without an efficient information system, it is impossible to perform a detailed analysis on the non-compliances.
THE END
## Results (threshold 30%)

### Acute phase

<table>
<thead>
<tr>
<th>activity</th>
<th>times to do</th>
<th>times not done</th>
<th>%</th>
<th>Possible motivation (in addition to disagreement)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early physiotherapy</td>
<td>110</td>
<td>100</td>
<td>90</td>
<td>lack of internal co-ordination</td>
</tr>
</tbody>
</table>
| MRI for POCS                    | 19          | 17             | 89 | Instrumentation out of order  
Lack of internal co-ordination |
| Protocol enrolment              | 110         | 97             | 88 | lack of resource (drug)                                                   |
| Vital signs monitor             | 109         | 88             | 80 | lack of resource (instrumentation)                                        |
| Physiatrist visit               | 109         | 67             | 61 | failed communication among organisations                                   |
| Preliminary assessment time <=15 minutes | 110     | 58             | 52 | bad co-ordination or bad  
human resource allocation or scarcity of human resources |
| Chest RX                        | 109         | 42             | 38 | Instrumentation out of order  
Lack of internal co-ordination |

The American Heart Association Guidelines
Queries to detect non compliance

**Diagnostic tests**

SELECT distinct a.patient,"glycemia" ,-1 from fase_subacuta f,anamnesi an where f.patient=an.patient and an.onset_time > 6 and f.glycemia is null

**Therapies**

SELECT distinct a.patient,"terap_protocol",-1 from anamnesi a where a.onset_time<=6 and not exists (select ap.patient from acute_phase ap where ap.patient=a.patient and (ap.therapy in (6,7)))

SELECT distinct a.codpaz,"therapies_to_avoid", -1 from anamnesi a, acute_phase ap where a.patient=ap. patient and a.onset_time <=6 and ap.therapy in (9,10,11,12)