Human Factors Methods to Support the Experts’ Review of Automatically Detected Adverse Drug Events

Nicolas LEROY  Brian BJØRN , Adrian BACEANU,
Marie-Catherine BEUSCART-ZEPHIR
PSIP: a research project (7th FP – ICT)

Consortium: 13 partners

1/ Hospitals
France, Denmark
With / without CPOE

2/ Industry:
Oracle, IBM, Medasys
(CPOE editors)
Vidal (pharmaceutical Kbase)

3/ Academic teams
Data & Semantic mining,
Decision Support Systems,
Human Factors Engineering

Duration: 40 months
(Jan 08 → April 2011)
Validation of rules in PSIP

PSIP

Rule generation

Data mining
Validation of rules in PSIP

PSIP

Validation of the rule

Knowledge based

- Literature review
- Knowledge about drugs

chart review

Validation in the clinical context

Rule generation

Data mining
Validation of rules in PSIP

**Rule generation**
- Data mining

**Validation of the rule**
- Knowledge based
  - Literature review
  - Knowledge about drugs
- Chart review
  - Validation in the clinical context

**Integration in a CDSS Module**
- Detection of dangerous situation
- Feed back to clinician

**PSIP**
Validation of rules in PSIP

PSIP

Rule generation

Data mining

Validation of the rule

Knowledge-based

• Literature review
• Knowledge about drugs

Validation in the clinical context

Integration in a CDSS Module

Detection of dangerous situation

Feed back to clinician

Expected benefit:
Help clinicians to improve the patient safety

Potential Risk:
Over alerting

Help clinicians to improve the patient safety

Over alerting
Validation of rules in PSIP

**PSIP**

- Rule creation
- Data mining

**Validation of the rule**

- Knowledge based
  - Literature review
  - Knowledge about drugs
- Chart review

**Integration in a CDSS Module**

- Detection of dangerous situation
- Feed back to clinician

**MIE 2009 – Sarajevo, August 31 2009**
Validation of rules in PSIP

**Rule creation**
- Data mining
- Semantic mining

**Validation of the rule**
- Chart review
  - Validation in the clinical context

**Integration in a CDSS Module**
- Detection of dangerous situation
- Feed back to clinician

*The Expert review requires:*
- Human experts review medical records
- Decide whether the rules properly explained the observed abnormality
Validation of rules in PSIP

Our objective:
• Develop a methodology supporting the evaluation and the improvement of the PSIP rules
• Involve the end users in this evaluation process

chart review
Validation in the clinical context
Chart review - Method

The chart review is performed in two different hospitals:

- The Region H hospital (Copenhagen – Denmark)
  - Two physicians of the patient safety unit
  - Work in progress

- The hospital of Denain (France)
  - The Head Pharmacist
  - The head clinician of the internal medicine department
  - Review completed

Data: 80 hospital stays, 40 “abnormal” (detected by a PSIP rule) vs. 40 “control”
Chart review - Method

Chart review

Consultation
of the files
Chart review - Method

Consultation of the files
Chart review - Method

Chart review
Consultation of the files

Rule evaluation in the clinical context
Analysis of the rule
Evaluation of the relevance
Chart review - Method

Chart review

Consultation of the files

Rule evaluation in the clinical context

Analysis of the rule

Evaluation of the relevance

Agree with the rule?
Chart review - Method

Chart review
- Consultation of the files

Rule evaluation in the clinical context
- Analysis of the rule
- Evaluation of the relevance

Agree with the rule?
- Yes
- validated
Chart review - Method

Chart review

Consultation of the files

Rule evaluation in the clinical context

Analysis of the rule

Evaluation of the relevance

Agree with the rule?

Yes

validated

No

Not validated

(this rule could not explain the case under review)
Chart review - Method

Chart review
Consultation of the files

Rule evaluation in the clinical context
Analysis of the rule
Evaluation of the relevance

Agree with the rule?
Yes
validated
No
Not validated
do not know
Uncertain
Chart review - Method

Chart review
- Consultation of the files

Rule evaluation in the clinical context
- Analysis of the rule
- Evaluation of the relevance

Agree with the rule?
- Yes
- No
  - do not know
    - validated
    - Not validated
    - Uncertain

Think aloud methodology
Think aloud - Method

• **Objective**: track the user mental and behavioral action with a system

• **Instructions**: The experts were asked to “think-aloud”.

• **Technical device**: A recording system allows to track all the experts’ actions with the Expert Explorer application

• **Transcription**: All the experts’ verbalizations are typewritten and coded.
Coding of the verbal protocols

Creation of the coding scheme
• Two ergonomists read the comments of the experts
• They listed all the categories of explanation of rule rejection
• 11 categories were identified and organized in a two dimensional coding framework.

Coding of the verbalizations
1. Each ergonomist coded independently all the verbalizations
2. A debriefing session allowed to clear the rare disagreements
Results

The hospital of Denain (France)
Results – Evaluation of the rules
Results – Evaluation of the rules

Independently of the clinical context, Do you agree with the rule?
Results – Evaluation of the rules

Independently of the clinical context, Do you agree with the rule?

Expert 1
- Yes 86%
- Do not know 12%
- No 2%

Expert 2
- Yes 81%
- Do not know 19%
Results – Evaluation of the rules

Do you think that the rule applies to the case under review?
Results – Evaluation of the rules

Do you think that the rule applies to the case under review?

Expert 1
- No: 48%
- Do not know: 12%
- Yes: 40%

Expert 2
- No: 51%
- Do not know: 33%
- Yes: 16%
Results – Evaluation of the rules

Do you think that the rule applies to the case under review?

Expert 1
- No: 48%
- Do not know: 12%
- Yes: 40%

Expert 2
- No: 51%
- Do not know: 33%
- Yes: 16%

Jha 2008
- Yes: 94%

Hwang 2008
- Yes: 79%
Results – Evaluation of the rules

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Jha 2008: 94%
Hwang 2008: 79%
## Results: Coding scheme

### Categorization of comments

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Problems with Data
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- Problems with Data

- Depending of the clinical context

- Independent of the clinical context
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Examples of verbalizations
## Categorization of comments

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**Effect**: Effect is not « important » enough to be significant

- Effect explained by patient characteristics
- Normal reaction of the patient

- About the lab results of a patient detected as abnormal « Yes, but it is a very very tiny effect, it’s just over the superior bound »
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*About the lab results of a patient detected as abnormal « *Yes, but it is a very very tiny effect, it’s just over the superior bound* »*
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*(about a thrombopenia effect)*

« No, it’s the Innohep that would cause the thrombopenia. It’s a much better candidate than the beta-lactams »
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« The thrombocytosis appears on day 12 while the metronidazole treatment is given on days 1, 2 and 3, so the delay is too important. »
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« We don’t have the home treatment »
## Results Think Aloud

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Discussion

- Acceptance of the future CDSS:
  - Experts = future users of the system
  - Expert review of past hospitalization allows:
    - To anticipate the acceptability of the system
    - To incorporate their knowledge in order to refine the rules and better contextualize them

- Review Process:
  - Based on common chart review methods used in other similar project
  - Addition of the think aloud method
    - Allows to identify problems weakening the clinical relevance of the rules
    - Support a continuous improvement of the PSIP rules
  - The flexibility of statistical procedures used to generate the rules allows to fix most of the problems detected by the think aloud protocol
## Discussion

### Parameters used in the rule

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### Judgment in the clinical context

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Conclusion - Discussion

Next step
- The think aloud methodology were useful but time consuming
- We built a questionnaire based on the coding scheme.

Continuous improvement:
- The questionnaire has been successfully tested on a sample of stays and will be integrated in the Expert Explorer
- It will support the continuous evaluation and improvement of the rules by the end users
  - Increase the number of relevant feedback for the improvement of the rules
  - Good way to support the implication and motivation of the end users
- This questionnaire may also be generalized to projects using similar evaluation methodology
Conclusion - Discussion

Thank you for your attention