PSIP

A European project

www.psip-project.eu
Agenda

• General Presentation of the European Project: R. BEUSCART

• Patient safety: The example of incident reporting in DK. J. EGBEBART

• Rationale: M.C. BEUSCART-ZEPHIR
  – Presentation
  – Questions from the audience

• Identification of ADE: R. BEUSCART, E. CHAZARD, and S. DARMONI
  – Presentation
  – Questions from the audience

• Knowledge elicitation: M.C. BEUSCART
  – Presentation

• Questions and discussion with the audience
PSIP General presentation

Régis Beuscart
PROJECT PARTNERS

1. University Hospital of Lille and University of Lille2 (F)
2. University of Rouen (F)
3. Denain General Hospital (F)
4. 10 hospitals from the « Capital Region of Copenhagen » (DK)
5. Oracle (Europe)
6. IBM Danmark – division ACURE (DK)
7. Medasys (F)
8. Vidal SA (F)
9. KITE solutions (I)
10. Idea Advertising (Romania)
11. Aristotle Thessaloniki University (Greece)
12. Aalborg University (DK)
13. UMIT –Innsbruck University (A)
The Project: A Research Project
(7th PCRDT – IST)

• Context:
  – Adverse Drugs Events are too frequent and often severe
  – CPOE are developing and they are more and more coupled with Decision Support Systems

• Objectives:
  – A better identification of ADE in Hospitals through the mining of Patients Records
  – A better contextualisation of the Prescription-Dispensation-Administration Process
Agenda of the Project

- Duration: 40 months
- 13 partners – 13 workpackages
- Signature: 19 December 2007
- Kick off: January 2008
- Experimentations: 1st quarter 2010
- End of the project: April 2011

- May 08 = 4 months of work
Patient safety
The example of incident reporting in DK

Jonas Egebart, MD
Patient Safety Manager

Capital Region of Denmark
Unit for Patient Safety
Capital Region of Denmark

- 1.6 million inhabitants
- 14 hospitals
- 10,000 hospital beds
- 31,000 staff
Incident reporting in Denmark

• First country to make incident reporting mandatory
  – 1 January 2004

• Currently only hospital-based healthcare
  – Planned extension to cover primary care
  – Planned extension to let patients report

• A huge success!
  – More reports than expected
  – Reporting from doctors at a level corresponding to their proportion of total staff
Annual number of reports

![Annual number of reports chart](image)
Principles for reporting

• Mandatory
  – All licensed healthcare personnel working at hospitals must report

• Confidential
  – Reports excluded from freedom of information regulations

• Non-punitive
  – No action can be taken by employer, licensing authorities (National Board of Health), or courts of law
What is reported?

• All incidents, excluding
  – Known complications
  – Events that were prevented due to an effective safety culture
Reports – Q3 2007 (Capital Region)

Total: 1792

- Medication: 578 (32%)
- Other: 1214 (68%)

Total: 1792
Stage in medication process involved

- Prescribing: 33%
- Documenting: 11%
- Dispensing: 37%
- Administering: 19%
CPOE errors
fraction of medication errors

5%
### Incident reports inspires CDSS cases

**Scenario 3: Non-Steroidal Anti-Inflammatory Drugs (NSAID)**

<table>
<thead>
<tr>
<th>Incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admitted from home after falling on the stairs. Is diagnosed with a hip fracture needing surgery. After the surgery the patient is placed on the standard analgesics plan, including an NSAID. The patient develops a bleeding gastric ulcer and undergoes gastroscopic treatment. The bleeding cannot be stopped and the patient dies.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age and sex</td>
<td>58, female</td>
</tr>
<tr>
<td>Weight and height</td>
<td>48 kg, 163 cm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medical history</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Medications</td>
<td></td>
</tr>
<tr>
<td>Alendronate 70 mg once a week, <em>anti-osteoporosis</em> drug</td>
<td></td>
</tr>
<tr>
<td>Paracetamol 500 mg x 3-4 as needed, <em>analgesic</em></td>
<td></td>
</tr>
<tr>
<td>Codeine 25 mg x 1-4 as needed, <em>weak opiate</em></td>
<td></td>
</tr>
<tr>
<td>Bendroflumethiazide 5 mg x 1, <em>diuretic</em></td>
<td></td>
</tr>
<tr>
<td>Zolpidem 7.5 mg at bedtime, <em>hypnotic</em></td>
<td></td>
</tr>
<tr>
<td>Omeprazole 20 mg when needed, <em>antacid</em></td>
<td></td>
</tr>
<tr>
<td>Prior diagnoses</td>
<td></td>
</tr>
<tr>
<td>M81.9 Osteoporosis</td>
<td></td>
</tr>
<tr>
<td>I10.9 Hypertension</td>
<td></td>
</tr>
<tr>
<td>K25.0 Gastric ulcer, bleeding</td>
<td></td>
</tr>
<tr>
<td>Allergies</td>
<td>None</td>
</tr>
</tbody>
</table>
Scientific Background

Marie-Catherine Beuscart-Zéphir
Lille, F
The scientific questions addressed

- « To get a better knowledge of the prevalence of Adverse Drug Events (ADE) and of their characteristics per hospital, per Region, per Country »
  - **Identification** of ADE

- « To develop concepts and methods to achieve the contextualization of CDSS (alerting) functions »
  - **Prevention** of ADE
• A drug given to a patient had a negative consequence on his health.
Medication errors?

• In the context of the medication use process: a gap between what has been done and what should have been done

  Failure of a planned action to be completed as intended (i.e., error of execution), or the use of a wrong plan to achieve an aim (i.e., error of planning).
  An error may be an act of commission or an act of omission.
  *Preventing Medication Errors, IOM, Quality Chasm Series, 2007*

  - WRONG (drug, dose, route, etc.) at any stage (prescription, dispensing, administration)

• A medication error may result or not in patient harm
Identifying ADE: reporting systems

• Prevailing method

• Reporting systems focused on ADE:
  – Pharmaco surveillance (ex: MedDRA)
  – Difficult to tell adverse DRUG events from « normal » negative outcomes due to patients’ illness (old people, multiple pathologies, complex treatments)
    → Underreporting

• Reporting systems for medication errors
  – Similar to error reporting systems in other domains (aviation)
  – Identify and fix causes of errors and accidents
  – Difficulties: fear of blame
    → Underreporting
Identifying ADE: other methods

• Medical records review and analysis
  – Focused on medication errors
  – Time consuming
  – Easier with computerized records and CPOE
  – Extrapolation to larger populations:
    • \( \rightarrow \text{risk of overestimation} \)

• Direct observations of work procedures
  – Focused on medication errors
  – Extremely time consuming
  – Extrapolation to larger populations:
    • \( \rightarrow \text{risk of overestimation} \)
Identifying ADE: heterogeneous results

• ADE: probably a major public health problem

• Most of the cited numbers are estimates (France 10,000 up to 25,000 deaths)

• Lack of epidemiological results at each level:
  – Europe
  – Countries
  – Regions
  – Hospitals
Identifying ADE: the PSIP approach

- To track back ADE from their outcomes

- Data and semantic mining of large healthcare repositories
  - To identify atypical hospital stays potentially due to ADE
  - To characterize these atypical stays along a number of dimensions to support the interpretation

- To provide epidemiological results at each level:
  - Europe
  - Countries
  - Regions
  - Hospitals
Preventing ADE: the « quality » approach

• Example: HFMEA (Healthcare Failure Mode and Effect Analysis)

• A systematic approach to identify and prevent product and process problems before they occur

• Efficient but:
  – Highly time consuming
  – Requires a strong commitment from institutions and HC professionals
Preventing ADE: CPOE

• Electronic prescribing and CPOE systems are efficient

• But most of the systems (++ commercial ones) suffer from inexistent and inefficient alerting and decision support systems (Alert fatigue)

• Less than 10% of hospitals are equipped with a complete CPOE system

• HC professionals need contextualized and task-oriented decision support functions
Preventing ADE: the PSIP approach

- The data and semantic mining procedures should provide us with the context of occurring ADE:
  - Characteristics of <patient> and <disease> and <drugs> and <medical department> and ...

- The question of the content of the alert is a difficult one:
  - Adopt a user-centred approach
  - Use the knowledge issued from the reporting system
  - Other…
Data Models

Régis BEUSCART
Lille, F
• Data are imported from 4 groups of Hospitals (Fr, Dk), with different medical records, different CPOEs, different Lab Medical Systems.

• But the items on which the mining will be performed must be identical

• Types of data:
  – Computerised medical records, including DRG systems
  – Biological results
  – Drugs (commercial name + ATC code)
  – Anonymised reports and letters
Data Models

ITEMS

RELATIONSHIPS

1. Stays
   - 1-1-keys
   - 1-2-patient
   - 1-3-resuscitation
   - 1-4-medical units
   - 1-5-dates, duration
   - 1-6-misc

2. Steps of the stay
   - 2-1-keys
   - 2-2-medical unit
   - 2-3-misc

3. Diagnosis
   - 3-1-keys
   - 3-2-diagnosis

4. Acts
   - 4-1-keys
   - 4-2-acts

5. Drug prescriptions
   - 5-1-keys
   - 5-2-drug

6. Biology
   - 6-1-keys
   - 6-2-biology

7. Reports
   - 7-1-keys
   - 7-2-reports

Physical files

PSIP – MIE Workshop - Goteborg – may 2008
Data Model agreed upon and used by all the partners

General Presentation

Complete documentation on the data fields
Main Problems

- Technical problems in the hospitals to extract data from their Hospital Information System -> delays in the delivery of the anonymised files
- Some data are only exported. Some have to be calculated by scripts. The management of the quality of data is a high level challenge

Solved problems

- Complete agreement on the coding systems and catalogs to be used
- After 2 months of work, all the hospitals have agreed on the data model, which is now stable
- It is an iterative process
Data Quality Analysis and Controls

files

SFTP

Hospital

Quality analysis

Validation and corrections

Errors report

Automatic report on the quality of the data

Hospital files

SFTP

Validation and corrections

Errors report

Automatic report on the quality of the data
Generalisation:
- This model was approved by 4 hospitals
- Applied in 2 hospitals with CPOEs, 2 hospitals without CPOEs (but reports, letters)
- Same data should be available from every European hospital (to be validated)

Other data bases to be explored:
- Vigilance databases
- Data from information providers (Vidal)
Data Mining

Emmanuel CHAZARD
Lille (F)
Methods

• Methods to be used: statistical methods
  – Decision Trees
  – Association Rules
  – Logistic Regression Analysis
  – Multi-factorial Analysis: Principal Component Analysis, Multiple Component Analysis

• It is currently a preliminary phase:
  – On currently available databases and items
Assumptions

• Coding Systems:
  – ICD 10: 18 000 possible Diagnosis codes
  – Drugs data bases: 9 000 possible drugs

• Information has to be aggregated to allow statistical analyses
  – Objective: to reduce the number of variables; to increase the number of patients
  – Examples concerning AVK
    • 9 ICD -> 1 ATC category
    • Gastric Ulcer -> possible bleeding lesion
    • Hemarthrosis -> hemorrhages
    • Too high INR -> coagulation disorders

• All kinds of data have to be filtered :
  – Possible effect of an ADE
  – Possible context or cause of an ADE
Available data have to be classified:
- cause or context of an ADE
- possible ADE manifestation !!!

Examples on diagnoses:
- chronic diseases
- Acute events

Examples on biology:
- Existing abnormality at the entry of the patient
- Biological abnormality occurring during the hospitalisation

Examples on drugs:
- Prescription
- Antidotes
1- identification of atypical stays (0/1 or “how much”)

2- Identification of a link (predictors)

3- Knowledge production

4- Rules production

5- Alert output
Examples of methods: decision trees
First results obtained from logistic regression analysis

• Example 1
  – Circumstances: Heparin, liver insufficiency, existing thrombopenia
  – Effect: ICU transfer after some days of hospitalisation

• Example 2
  – Circumstances: heparin, renal insufficiency, normal coagulation when admitted
  – Effect: thrombopenia

• Example 3
  – Circumstances: elderly patient, no renal insufficiency, too low INR, AVK prescription, diuretics, enzyme inhibitor, high number of associated diagnosis
  – Effect: renal insufficiency occurring during the stay
• Example 4
  – Effect: too low INR during the stay
  – Circumstances: renal insufficiency, too high INR, AVK, anti-thrombinic agent

• Example 5
  – Effect: rapid re-hospitalization
  – Circumstances: heparin or anti-thrombinic agent

• Example 6
  – Effect: ADE declaration
  – Circumstances: high INR at the entry
Perspectives

• To complete the work and obtain new results
  – Identification of atypical hospitalizations that could be linked with ADE
  – Identification of the drugs associated with these hospitalizations

• Provide understandable Results
  – Worksheets
  – Medical Records susceptible to be associated with an ADE

• Validate this research
  – Probabilities of abnormal events
  – Rules weight
  – Queries in the databases
Semantic mining

Stefan Darmoni
Rouen Fr
Why Semantic mining in PSIP

• Extract from discharge summaries
  – Medical terms in various health terminologies
  – Drugs (commercial or international names)

• Completion to data mining, useful when no CPOE in HIS
Modeling the medical terminologies in PSIP

- SNOMED CT & SNOMED Int.
- ICD10
- MeSH
- CCAM (French equivalent to US CPT; )
- MEDDRA, WHO ART (for adverse effects) (not yet)
- ATC classification
- CAS number
- Commercial names, ATC codes, specific codes in France (CIP, CIS, UCD) provided by Vidal
- Generic model to allow interoperability between terminologies
- Draft deliverable on the PSIP Web site
How semantic mining is generic

• Semantic mining is closely related to languages => difficulty in Europe with so many different languages

• Modelling of the terminologies is not language-dependant

• Need to translate main terminologies in the various languages in Europe

• Need to develop semantic mining tools in each language
| Title | Cancer de l'enfant: particularités épidémiologiques diagnostiques et thérapeutiques  
(Cancer in children: epidemiologic, diagnostic and therapeutic specificities) |
|-------|-------------------------------------------------------------------------------------------------------------------------------------|
| F-MTI mono-terminology (Title) | Neoplasms/epidemiology  
Child |
| F-MTI multi-terminology (Title) | Neoplasms/epidemiology  
Neoplasms/therapy  
Child |
| Manual indexing (Full Text) | *Neoplasms/diagnosis  
*Neoplasms/epidemiology  
*Neoplasms/therapy  
Child  
Continuity of Patient Care  
Pediatrics/education |
Knowledge Elicitation

Marie-Catherine Beuscarts-Zéphir
Lille, Fr
Knowledge elicitation: objectives

• Select the most relevant abnormal stays
  – Validate the list of variables describing the abnormal outcomes
  – [Provide additional outcomes variables]
  – Confirm that these abnormal stays are probable ADE

• Characterize the abnormal stays on a number of dimensions (medical, pharmaceutical, biochemical and human factors expertise)
  – → predictors of ADE

• Validate association rules between predictors and outcomes
Knowledge elicitation: methods

- Involve different categories of experts (pharmacists and pharmacologists, physicians, nurses, patient safety and HF experts)

- 1st step: individual review of the atypical cases
- 2nd step: debriefing session
  - Harmonisation of results
  - Editing of association rules
Knowledge elicitation: expert review

• Each expert is presented with:
  – A set of abnormal stays characterized along all the dimensions of the data model
  – The association rules statistically characterizing these stays
    <age over 70> AND <severe renal insufficiency> AND <anticoagulant>

• For each case, the expert answers the following questions
  • Abnormal stay?
  • ADE?
  • Drug(s) involved?
  • [interpretation]
  • Consistent with association rule?
  • Other information required?

• Experts reasoning is monitored
Knowledge elicitation: experts debriefing

• Clear potential inconsistencies between experts’ conclusions

• Edit the knowledge rule for input in CDSS rule
  – Ex: expert validation of the rule

IF <age over 70> AND <severe renal insufficiency> AND <anticoagulant> THEN [ADE] send an alert
The content of the alert: a difficult question

- The alert must incorporate professional knowledge and be contextualized

- Data mining will provide information about the context

- Professional knowledge will be incorporated by adopting a cooperative user-centred approach for the design of the alerts
• PSIP Four Phases:
  • Knowledge Elicitation
  • Knowledge implementation
  • Contextualisation
  • Implementation and validation

• From the identification of ADE to their prevention