Single source information systems can improve data completeness in clinical studies: an example from nuclear medicine

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Agenda

- Introduction
  - HIS data completeness
  - Single source information systems

- Methods
  - CRFs within HIS
  - Workflow and system architecture
    - Follow-up system
    - Reminder system

- Results
INTRODUCTION
HIS data is commonly incomplete

Review on EHR data quality (35 studies):

- "data completeness varied substantially across studies, ranging between 0.1% and 51% for blood pressure and 10% and 38% for smoking status assessment"
- "In the ambulatory setting, the omission rate for medication data was substantial across different clinical populations, from 27% of medications for ambulatory oncology patients to 53% for primary care patients"

[Chan et al., Med Care Res Rev. 2010;67(5):503-27]
Dual source information systems

clinical data input

clinical documentation

CIS

LIMS

communication server

RIS/PACS
departmental systems

HIS

research data input

(e)CRF

research data
Disadvantages of dual source approach

- Multiple documentation: delays, increasing efforts and costs
- Delayed documentation in the study database
- Transcription errors
- Transformation of free text into structured data is error-prone
Single source information systems
Advantages of single source systems

- Redundant data entry is avoided

- Optimized quality control (both clinical QC and study QC): Monitoring can be supported by HIS tools

- Patient recruitment for clinical studies is facilitated
A typical clinical study

Several visits:
- Initial assessment
- Several follow-up visits need to be organized and documented
- Follow-up data needs to be collected at certain time points

Data completeness in studies is a critical and widely unsolved problem:
- Organizational issues, for instance regarding scheduling, can cause loss to follow-up
OBJECTIVES

Implementation of two workflows in the HIS and comparison of data completeness before and after this intervention:

- HIS-based follow-up system to support study documentation by automatic creation of follow-up forms according to study protocols

- A generic reminder system to monitor completeness
METHODS
Design of the single source information system in nuclear medicine

- Electronic CRFs within the local HIS
- Structured data entry: checkboxes, radiobuttons, lists, number fields
- Plausibility checks
- Work list of incomplete forms
- HIS report generator for data export
Medical history form within HIS

Indication/question

Suspicion of CHD:
○ yes ○ no

Suspicion of toxic cardiomyopathy:
○ yes ○ no

St. p. heart transplantation:
○ yes ○ no
Heart transplantation date: 01.06.2006

Known CHD:
○ yes ○ no
○ 1 vessel CHD
○ 2 vessel CHD
○ 3 vessel CHD

Last cardiac catheter examination:
○ < 1 month ○ 1 - 3 months ○ 3 - 6 months
○ 6 - 12 months ○ > 12 months ○ unknown

St. p. infarction:
○ yes ○ no

St. p. stent implantation:
○ yes ○ no

St. p. bypass surgery:
○ yes ○ no

Vessel status:

☐ RCA
☐ unknown
☒ proximal RCA
☐ medial RCA
☐ distal RCA
☐ posterior descending artery

Degree of stenosis:
☐ unknown 70% yes PTCA, Stent

Therapy:

☐ LCA
☐ LAD
☐ RCX

Cardiomyopathy:
○ yes ○ no
Workflow reminder system

start

Form incomplete? no

Grace period expired? no

notification of study physician

Form still incomplete? no

Second grace period expired? no

notification of principal investigator

end
Workflow follow-up system

START

identification of case ids required by a specific study n

resulting case id

Is a follow-up event due?

no

generation of a follow-up event

yes

Is another case id available?

no

yes

END
RESULTS
Setting

- Nuclear Medicine, University Hospital of Münster
- 1308 outpatients
- 301 attributes on 3 forms per patient
- 8 physicians, 8 radiographers
- 3 months without versus 3 months with reminder system
- grace period reminder system: 1 day, escalation after 1 week
Significant increase of completeness

- Rest injection protocol: 31% versus 100%
- Stress injection protocol: 90% versus 100%
- Medical history form: 93% versus 100%
Summary & discussion

- Single source information systems are technically feasible in commercial HIS environments
  - Scalability
  - Limitations of commercial systems

- Completeness in HIS data is heterogeneous

- HIS-based reminders can improve data completeness
Questions?

Thank you for your attention.

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System architecture follow-up system

1. execution of queries
2. resulting case ids
3. follow-up event in a proprietary form
4. translation into an HL7 message
5. import

CIS / departmental systems
database package
communication server
RESULTS reminder system details

- Grace period 1: 1 day, recipient: responsible study physician
- Grace period 2: 1 week, recipient: principal investigator
- Completeness increased highly significantly ($p < 0.0001$) for each form type after implementation of the reminder system:
  - Medical history form: 93% versus 100%
  - Stress injection protocol: 90% versus 100%
  - Rest injection protocol: 31% versus 100%
- 46 reminder e-mails to the responsible study physician
- 53 reminder e-mails to the principal investigator
- Incomplete forms: 2 medical history forms, 8 stress and 20 rest injection protocols
RESULTS reminder system details

- The 2 medical history forms were completed after 1 and 56 days.
- Median processing time of stress injection protocols: 18 days (range from 1 to 60 days)
- Median processing time of rest injection protocols: 26 days (range from 5 to 37 days)
RESULTS:
Completeness of documentation
Follow-up system

- A HIS-based follow-up system to automatically generator follow-up forms was implemented for the study in nuclear medicine.
- 196 follow-up forms were automatically generated within 13 weeks of operation