Single Source Information Systems to Connect Patient Care and Clinical Research

Martin Dugas
WHAT MEANS "SINGLE SOURCE"?
single source

patient records

routine healthcare clinical research
single source versus dual source
WHY IS "SINGLE SOURCE" RELEVANT?
documentation workload of physicians

Guess:

What proportion of daily physician work is related to documentation?

- <5%
- 5-10%
- 10-20%
- 20-30%

- ~ 25% of daily clinical work related to documentation, in particular junior doctors

=> redundant documentation is very expensive & prone to error

=> need for efficient documentation processes

Example:

- JAMA paper coronary stenting (2008)
- routine data from 38917 patients
- observational study
- access to procedure and diagnosis codes from hospital claims

single source: methodological challenges

- mapping of HIS to study data
- HIS interfaces to clinical research database
- data quality
- monitoring
- validation
- ...
SINGLE SOURCE AND MULTICENTRIC STUDIES
single source in multicentric studies

research data input
clinical data input

(e)OF
clinical documentation

HIS 1

data input

data input

monitoring

monitoring

monitoring

export

export

export

departmental systems

communication server

RIS / PACS

CIS

LIMS

RIS / PACS

HIS 1

multicentric study

research data

HIS 2

HIS 3

data input

communication server

departmental systems

RIS / PACS

CIS

LIMS

RIS / PACS

HIS 1

HIS 2

HIS 3
A SINGLE SOURCE SYSTEM FOR A MONOCENTRIC PROSTATE CANCER STUDY
A single source system for a monocentric prostate cancer study

- prostate biopsy workflow
- pre-post-study
- 87 paper-based versus 86 electronic cases
- time span from biopsy to final report was decreased by more than one day per patient ($p < 0.0001$)
- data export for clinical research

time from biopsy to final report

association of prostate volume and proportion of malign biopsies
SINGLE SOURCE:
HIS-BASED PATIENT RECRUITMENT
Lasagna's law (1979)

- In clinical research the prevalence of any disease falls to about 10% of what you thought it was the day you start to look for cases for your study.
- Single-dose, postsurgical trial: 8000 patients were screened, but only 100 suitable consenting volunteers.

Recruitment to randomised trials: strategies for trial enrolment and participation study. The STEPS study

MK Campbell, C Snowdon, D Francis, D Elbourne, AM McDonald, R Knight, V Entwistle, J Garcia, I Roberts and A Grant (the STEPS group)

Data sources: Part A: database of trials started in or after 1994 and were due to end before 2003 held by the Medical Research Council and Health Technology Assessment Programmes.

Results: In the 114 trials found in Part A, less than one-third recruited their original target within the time originally specified, and around one-third had extensions.

=> efficient patient recruitment is a challenge for clinical trials!
HIS

eligibility verification

automated report

E-mail

[Dugas M, Lange M, Berdel WE, Müller-Tidow C. Trials. 2008;9:2]
HIS-based patient recruitment in Münster, Germany

- active in 32 clinical studies (status July 2009)
- approval by data protection officer
- implementation for different study types
  - observational studies
  - Phase I/II-studies
  - Phase III-studies
- positive feedback from study personnel

=> We are searching for partners to implement and evaluate HIS-based patient recruitment on the EU level
Acknowledgements

- Prof. Dr. Axel Semjonow, Department of Urology, Universitätsklinikum Münster
- Prof. Dr. Carsten Müller-Tidow, Department of Medicine A, Hematology and Oncology, Universitätsklinikum Münster
- Bernhard Breil, Department of Medical Informatics and Biomathematics, University of Münster
- Dr. Matthias Lange, Markus Eckholt, IT Centre, Universitätsklinikum Münster