AMIS
Acute Myocardial
Infarction
in Switzerland

Audit Visits In AMIS Plus Hospitals

Performed by the Clinical Trial Unit, Basel

Results

2011 – 2016

DR/August 2016

Objective

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- The objective of the audit visit was to review selected data items per source data verification SDV (check of source data versus database entries) to ensure compliance with the protocol/AMIS Plus guidelines.
- Random selection of participating hospitals (3 regional/smaller hospitals and 2 large centres)
- Random selection of 5-10/12 patients pro hospital to be audited per year.
- The investigational site was checked with regard to the completeness and correctness of the selected data items.

Grading of findings (EMEA INS/GCP/4)

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- Critical findings:
  - Findings that affect the quality and integrity of data. Observations classified as critical may include a pattern of deviations classified as major, poor quality of the data and/or absence of source documentation (e.g. date of birth, gender, PCI performed, outcome)
- Major findings:
  - Findings that may adversely affect the quality and integrity of data. Observation classified as major may include a pattern of deviations and/or numerous minor observations (e.g. prescript drugs, history of hypertension)
- Minor findings:
  - Findings that would not be expected to adversely affect the quality and integrity of data (e.g. time variable, time of symptoms, admission, biomarker)

Overview

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- Audit Sites Visited: 20
  - 12 smaller hospitals
  - 8 large hospitals
- Total Source Data Verification
  - 126 CRF with 2235 data items
- Total Findings
  - Critical 3 (0.13%)
  - Major 5 (0.22%)
  - Minor 50 (2.2%)

Findings

- No findings in 6 hospitals
- Findings
  - Critical
    - Date of birth *21*.10.1951 instead of 29.10.1951
    - PCI performed *no* instead of yes
    - Outcome in-hospital
  - Major
    - Beta blocker at discharge *yes* instead of no – 3x
    - Killip class *1* instead of 2
    - History of hypertension *unknown* instead of yes
  - Minor
    - 25 x - admission time entered incorrectly in CRF (rounded)
    - 19 x - PCI start time (11 entered incorrectly (rounded), 2 estimated, 6 missing)
    - 2 x - pain at admission incorrect
    - 4 x - biomarker at admission incorrect 2, not communicated 1

First Round of Audits

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November 2011 – January 2012

Selected data items	A1	A2	B1	B2	B3
Critical findings	0	1	0	0	0
Major findings	0	1	0	0	0
Minor findings	9	0	3	0	1
Total findings	9/150	2/180	3/75	0/75	1/75

Critical findings (n=1): Date of birth *21*.10.1951 instead of 29.10.1951
Major findings (n=1): Beta blocker at discharge *yes* instead of no
Minor findings (n=13):

1. PCI time
   - PCI time differed from source (door-to-balloon time difference +/-10min): 3
   - PCI time estimated (not available in B hospitals): 2
   - PCI time missing: 4
2. Pain (not exactly documented): 2
3. Biomarker missing: 2

To improve:

- PCI time recording in A hospitals and its capture in B hospitals

Second Round of Audits

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November 2012 – March 2013

Selected data items	A1	A2	B1	B2	B3
Critical findings	0	0	0	0	0
Major findings	0	0	0	0	0
Minor findings	1	0	4	6	0
Total findings	1/150	0/180	4/75	6/75	0

Minor findings (n=11):

1. Admission time entered incorrectly: 11
   - Hospitals usually record several different admission times. The admission time data were not always uniformly used in hospitals where various people entered data.
   - Most of the incorrect entries of admission time were due to rounding the time.

To improve

Admission time should precisely correspond to the time available in source data (not rounded)

Third Round of Audits
May – October 2014

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Selected data items	A1	A2	B1	B2	B3
Critical findings	0	0	0	0	0
Major findings	0	0	0	0	0
Minor findings	2	8	3	2	0
Total findings	2/180	8/180	3/80	2/80	0/80

Minor findings (n=15):

1. PCI time
   - PCI time differed from source (door-to-balloon time difference +/-10min): 8
   - PCI time missing (not available in B hospitals): 2
2. Admission time entered incorrectly: 4
3. Biomarker not entered: 1

To improve

1. PCI start time must be provided and precisely entered
2. Admission time should precisely correspond to the time recorded in source data (not rounded) and hospitals need to use unique source data for admission time

Fourth Round of Audits
December 2015 – April 2016

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Selected data items	A1	A2	B1	B2	B3
Critical findings	0	0	1	0	1
Major findings	0	0	0	0	2
Minor findings	0	0	2	4	3
Total findings	0/150	0/150	3/75	4/75	6/75

Critical findings (n=2):

- Death after re-admission not during initial hospitalisation
- PCI performed but not entered

Major findings (n=4):

- Beta blocker at discharge *yes* instead of no: 2x
- Killip class *1* instead of 2
- History of hypertension *unknown* instead of yes

Minor findings (n=7):

- Admission time entered incorrectly: 6 (rounded)
- Biomarker not entered: 1