

Electronic health records

Annual Pharmacovigilance course 2013
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Definitions

- Electronic medical record (EMR)
 - An electronic medical record (EMR) is a digital version of the traditional paper-based medical record for an individual. The EMR represents a medical record within a single facility, such as a doctor's office or a clinic.
- Electronic health record (EHR)
 - An electronic health record is an official health record for an individual that is shared among multiple facilities and agencies.



What is an Electronic Health Record (EHR)?

- Can include information about:
 - Patient demographics (Age, Gender etc.)
 - Drug prescriptions
 - Medical diagnoses (Myocardial infarction, fever etc.)
 - Lab tests and results
 - Images (X-rays etc.)



What are EHRs good for?

- Increase quality of care
- Information sharing
 - between health professionals
 - with the patient
- May reduce costs
- Secondary use of the data
 - signal detection
 - epidemiological studies
 - etc.



Secondary use initiatives

- OMOP (<http://omop.fnih.org>)
- FDA's Sentinel initiative (<http://mini-sentinel.org>)
- PROTECT (<http://www.imi-protect.eu>)
- SALUS (<http://www.salusproject.eu>)
- EU-ADR (<http://www.eu-adr-project.com>)
- epSOS (<http://www.epsos.eu>)

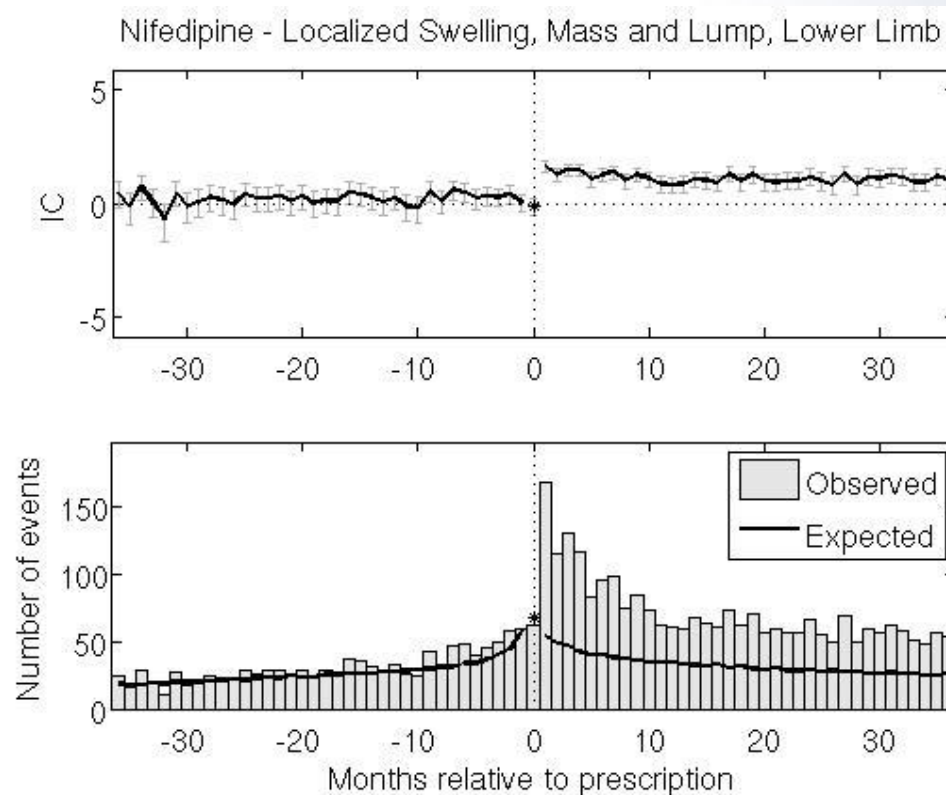
Secondary use of EHRs at UMC

- Finding needles in the haystack
 - First pass screening using statistical method (IC_{Δ})
- Adding meat to the bones through
 - Visualization of the temporal pattern
 - Summation of the case-patient information and contrasting that to a control-patient group



Analysing EHRs at UMC

- $IC_{\Delta} = 2.05 \Rightarrow$ signal ???
- Temporal pattern \Rightarrow more confidence



Cohort characterization

⚠ Risk factors

Event	Proportion
🚭 Smoking	37% (45)
🩺 Diabetes	30% (37)
👤 Obesity	25% (30)
🍷 Alcohol	18% (22)

Top 5 therapies on day of prescription ⓘ

Therapy	Proportion
🩹 Acetylsalicylic acid	2% (2)
🩹 Bendroflumethiazide	2% (2)
🩹 Lactulose	2% (2)
🩹 Fusidic acid	1% (1)
🩹 Labetalol	1% (1)

Top 5 therapies 1 week prior ⓘ

Therapy	Proportion
🩹 ATENOLOL tabs 100mg	2% (2)
🩹 GLYCERYL TRINITRATE spray 400micrograms/dose	2% (2)
🩹 RAMIPRIL caps 5mg	2% (2)
🩹 ATENOLOL tabs 50mg	1% (1)
🩹 ASPIRIN ec tab 75mg	1% (1)

Top 5 events on day of prescription ⓘ

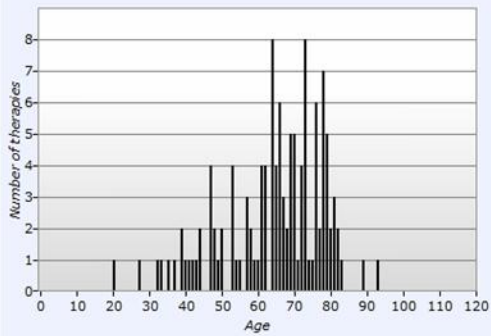
Event	Proportion
⚡ Essential hypertension (G20..)	20% (24)
⚡ Hypertensive disease (G2...)	9% (11)
⚡ Cardiac disease monitoring (662..)	8% (10)
⚡ Angina pectoris (G33..)	7% (9)
⚡ Raynaud's syndrome (G730.)	5% (6)

Top 5 coreported medical events ⓘ

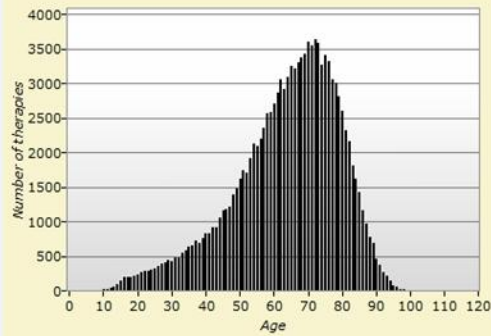
Medical event	Proportion
⚡ Drugs and other substances-adverse effects in thera	4% (5)
⚡ O/E - blood pressure reading (246..)	2% (3)
⚡ Essential hypertension (G20..)	2% (3)
⚡ Chest pain (182..)	2% (2)
⚡ O/E - BP reading raised (2466.)	2% (2)

Cohort characterization

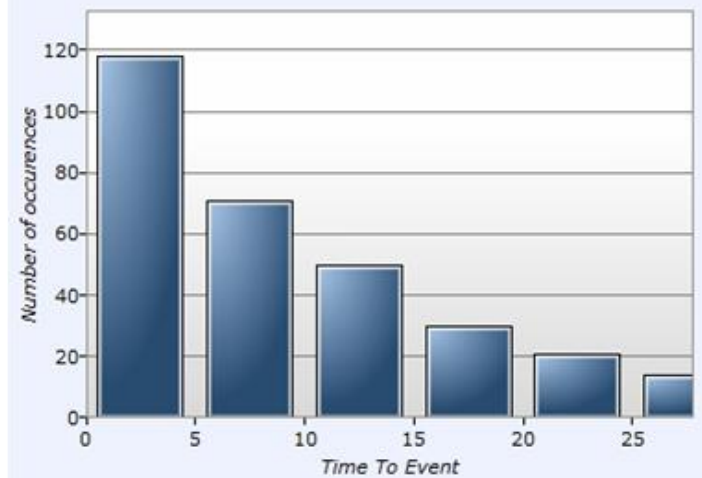
Observed cases
Age distribution



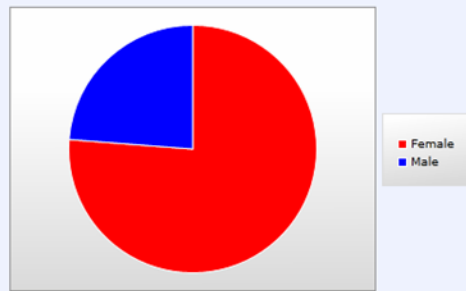
Current therapy
Age distribution (Drug)



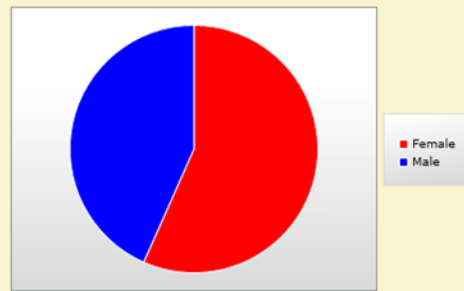
Time to Event: 1 Month



Gender distribution



Gender distribution (Drug)



ICSRs vs EHRs

Crime scene



Surveillance



Signal detection (+ and -)

ICSR

- Patient snapshot
- No comparator
- Reporting biases

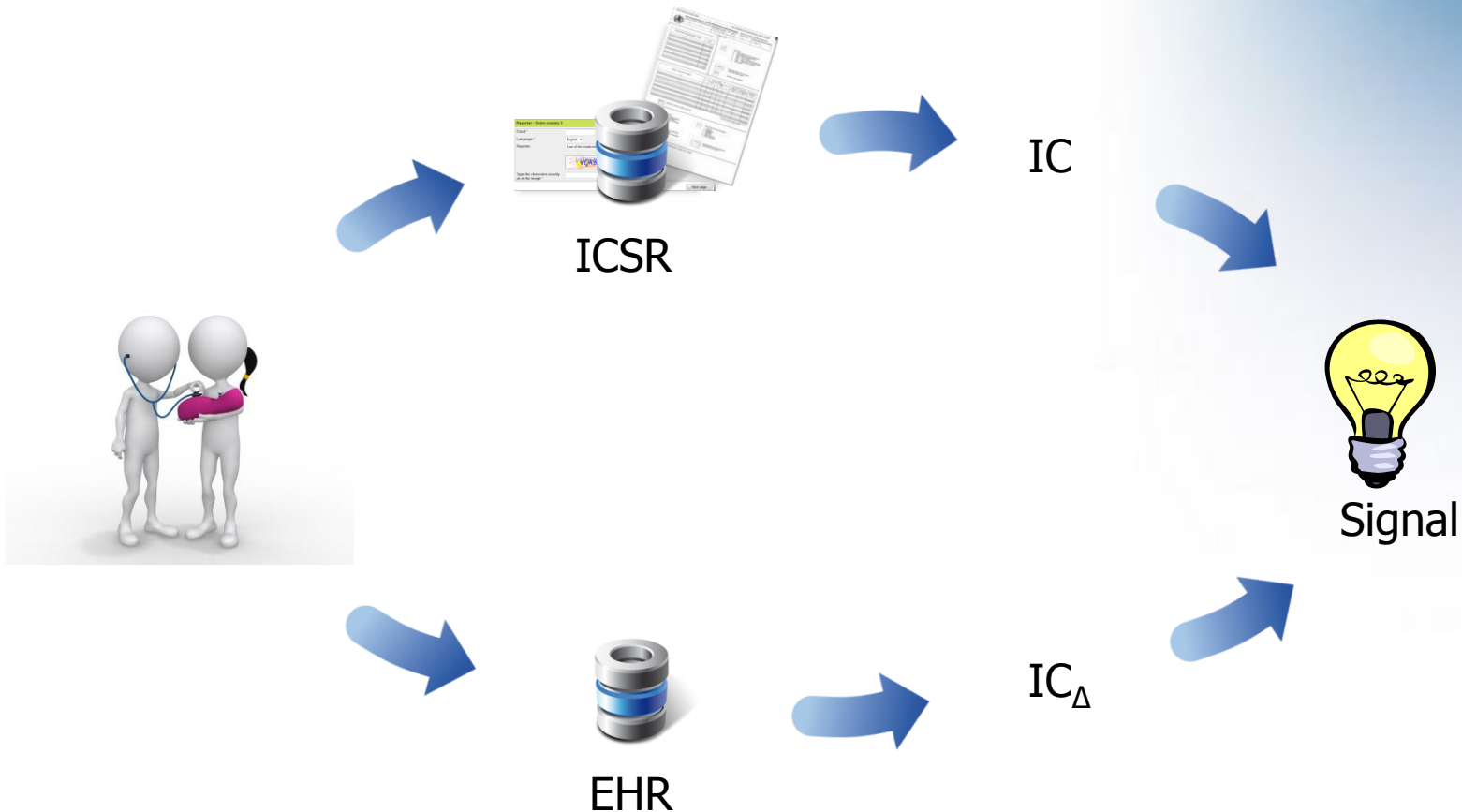
- + Huge coverage
- + Clinical suspicion
- + Common format (E2b)

EHR

- + Patient history
- + Known comparator

- Small coverage
- No clinical suspicion
- No common format

Signal detection current situation



Integrating ICSRs and EHRs

- SALUS project (<http://www.salusproject.eu>)
 - Semi-automatic ADE detection
 - Semi-automatic ICSR (E2b) creation using EHR data
 - Capture clinical suspicion of ICSR in EHR data
 - Enable secondary use of different data sources through a common architecture
 - even though the sources uses different databases, terminologies and communication platforms
 - Security and privacy mechanisms

Future pharmacovigilance

Today



ICSR

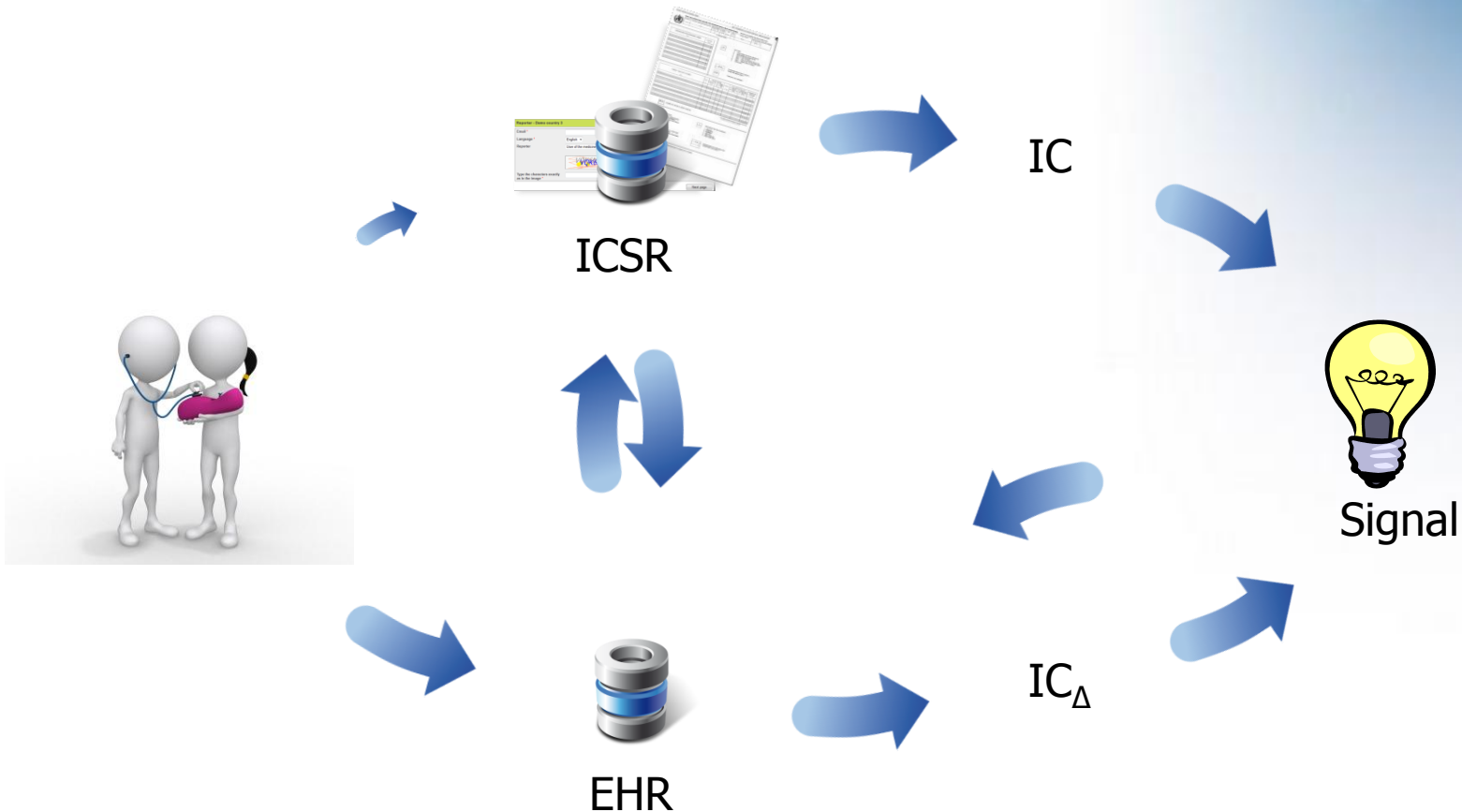
EHR

Tomorrow



Together we can reach higher

Signal detection in the future



Thank you!

