Medication errors detected among spontaneously reported ADRs to HALMED

Viola Macolić Šarinić

Prague , 28.10.2015.

For public health

Aim of the study

The objective of the study was to:

- ✓ identify,
- ✓ evaluate and
- ✓ describe medication errors (MEs)

among the spontaneously reported ADRs to the Croatian Agency for Medicinal Products and Medical Devices (HALMED).

Method

- A retrospective observational study was performed on the first 200 spontaneously reported ADRs in 2013
- The previously validated “P-method” [1] was employed to systematically detect MEs in individual case safety reports (ICSR) sent to the Croatian Pharmacovigilance Centre (PVC) at HALMED
- ME that lead to ADR identified by reporter as well as ME suspected by assessor are described

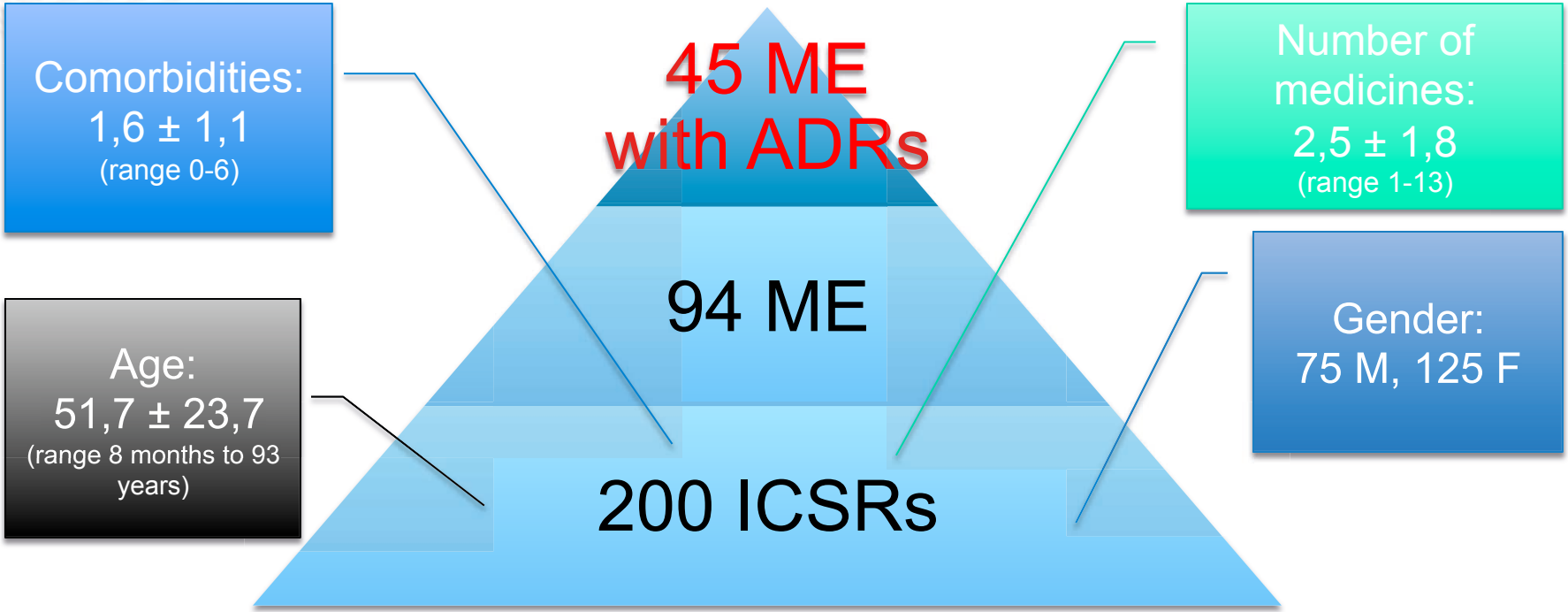
[1] Soulaymani-Bencheikh R, Khattabi A, Benabdallah G, Alj L, Sefiani H, Hedna K, Ouammi L, Olsson S, Pal SN. **Assessment of a new instrument for detecting preventable adverse drug reactions.** Drug Saf. 2015 Apr;38(4):383-93

Method (cont.)

- Additionally, ME were categorized according to „Good practice guide on recording, coding, reporting and assessment of medication errors”:

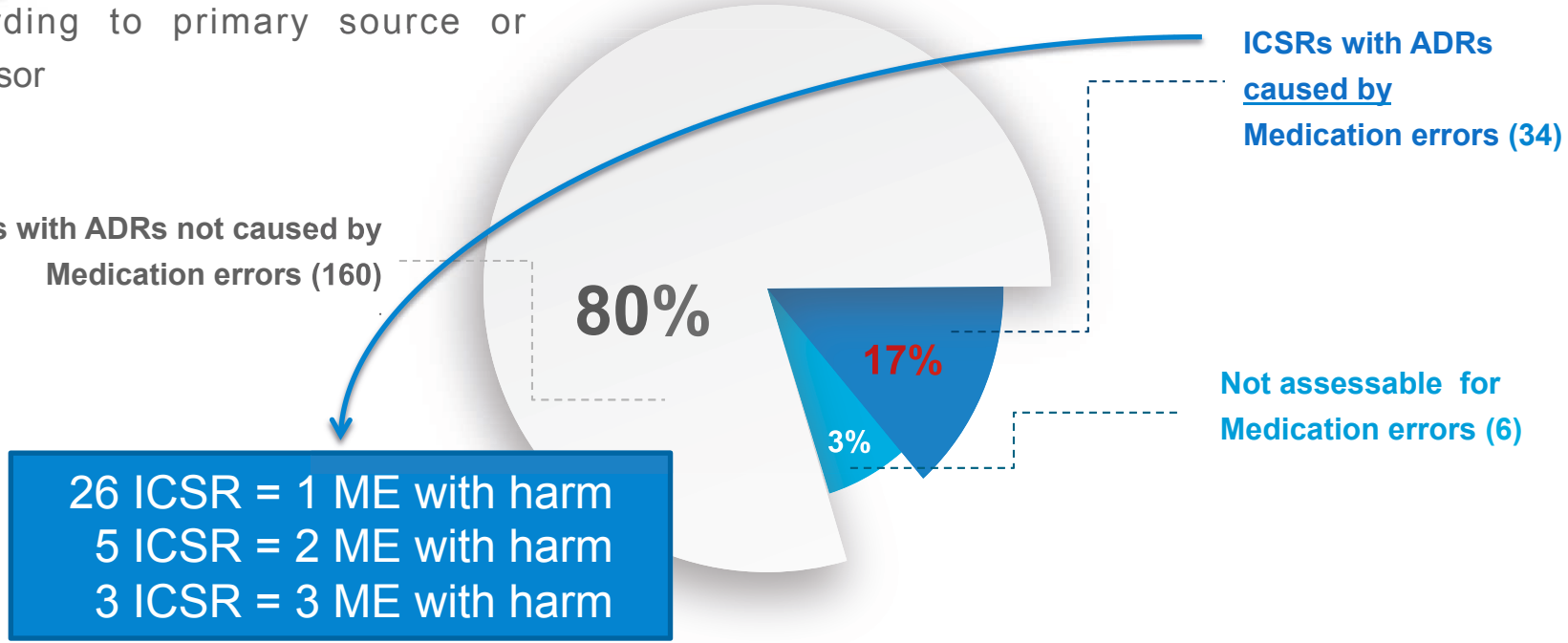
  - ✓ medication errors associated with adverse reaction(s),
  - ✓ medication errors without harm,
  - ✓ intercepted medication errors and
  - ✓ potential medication errors

Results


Comorbidities:
1,6 ± 1,1
(range 0-6)
Age:
51,7 ± 23,7
(range 8 months to 93 years)
45 ME with ADRs
94 ME
200 ICSRs
Number of medicines:
2,5 ± 1,8
(range 1-13)
Gender:
75 M, 125 F

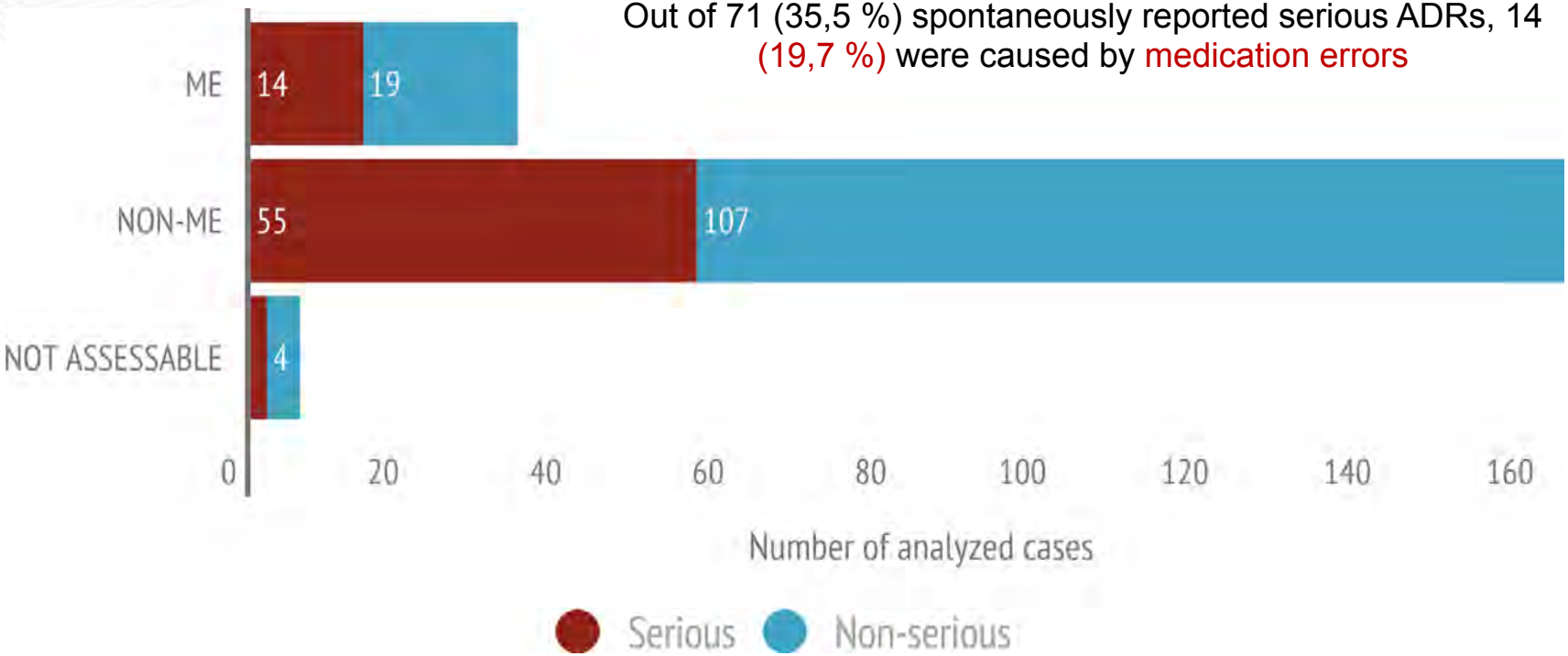
Medication errors

- Number of ICSR with medication errors associated with adverse reaction according to primary source or assessor

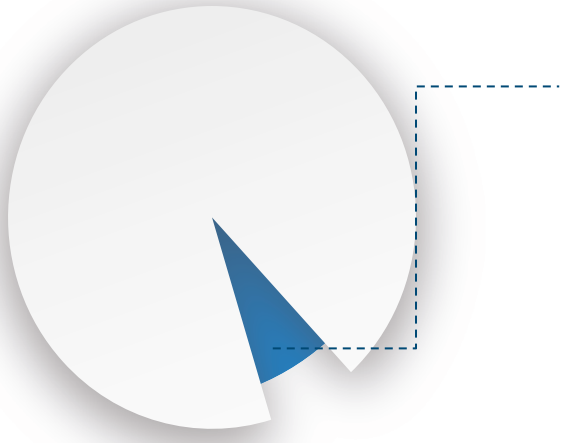


NUMBER OF ICSRs REPORTED AS SERIOUS vs. NON-SERIOUS ADRs

Out of 71 (35,5 %) spontaneously reported serious ADRs, 14 (19,7 %) were caused by medication errors



Number of ICSRs with medication errors associated with ADRs according to primary source



In Only 3 ICSR out of 34 (9 %) with ADR/ ADRs suspected to be caused by Medication Errors the primary source has clearly stated that a medication error has occurred

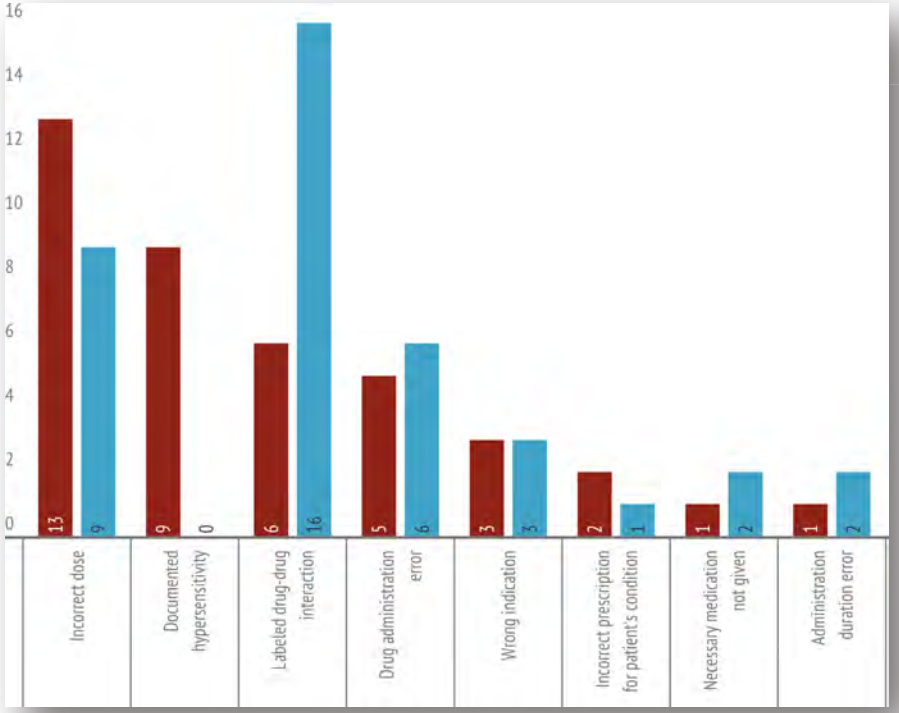
THE MOST COMMONLY IDENTIFIED MEDICATION ERRORS

The two most commonly identified preventability criteria for ADR occurrence were:

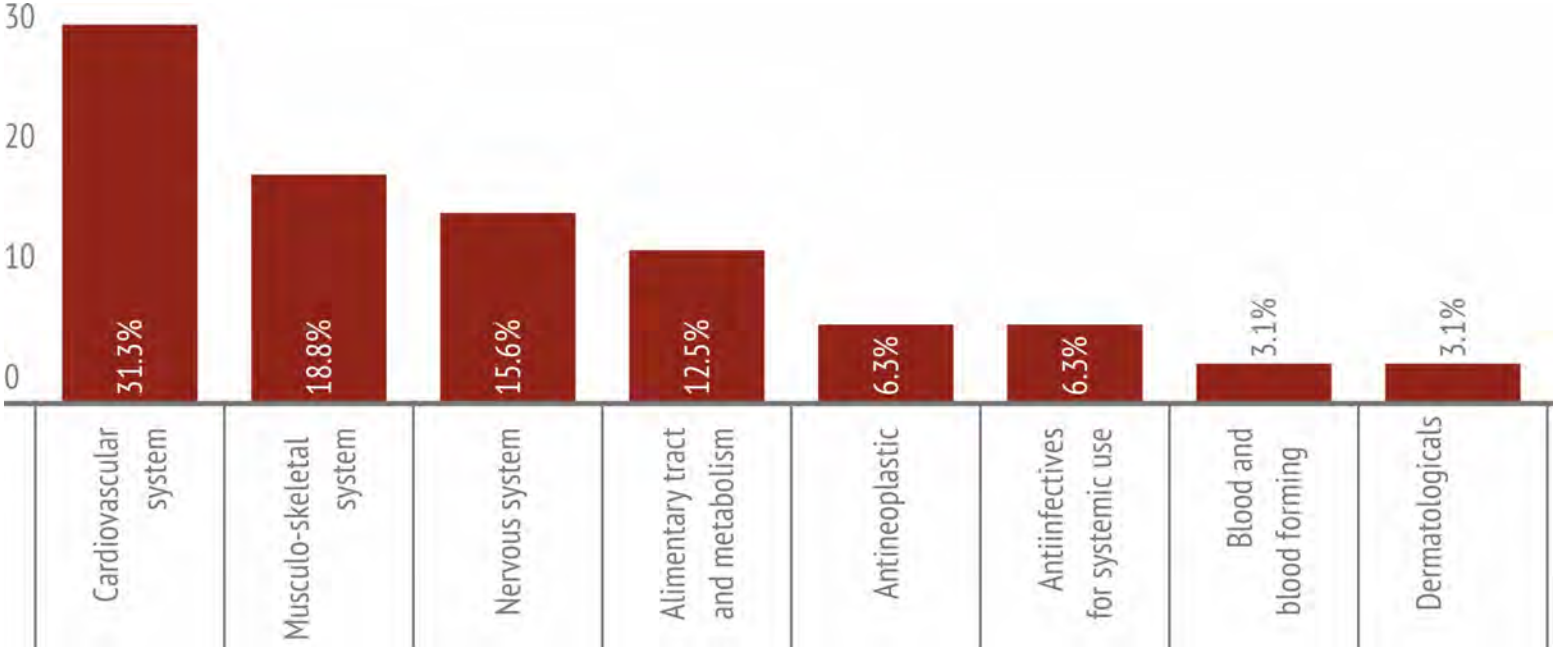
- “Incorrect dose” 28,3 %;
- “Documented hypersensitivity to administered drug” reported in 17,4 % of MEs associated with ADRs .

Among MEs without harm:

- “Labelled drug-drug interaction” (32.7%) was the most commonly identified type of ME.



THE PERCENTAGE OF MEDICATION ERRORS AMONG THE DIFFERENT MEDICINES



Discussion and Conclusion

Good practice guide on recording, coding, reporting and assessment of medication errors

Annex 4 - Business process proposal for using ICH E2B (R3) for recording medication errors in ICSRs

This draft proposal for recording medication errors in ICSRs using ICH E2B (R3) was finalised by the EudraVigilance Expert Working Group (EWG) in March 2015 and should be read in connection with chapter 5.5.2. of this guidance.

Once implemented after a successful EudraVigilance audit, the ICH E2B (R3) data element G.k.10.r 'Additional information on drug (coded)' should always be populated with the respective code for medication error at drug level (i.e. code 7) if the primary source has indicated that any type of medication error may have occurred. As this is a repeatable field, other codes may be used as appropriate.

If there is no explicit indication of a medication error by the primary source which would clearly transpose into a MedDRA term in the reaction section but there is a *hint that there may have occurred* an error in the context of the clinical course description, the sender may choose to populate data element G.k.10.r at their discretion to 'flag' a medication error. *The case should be followed up to* confirm if there was actually a medication error. The use of G.k.10.r also refers to intercepted errors where the cases are recorded as ICSRs in the database for PSURs.

Discussion and Conclusion (cont.)

Good practice guide on recording, coding, reporting and assessment of medication errors

Scenario	Flag G.k.10.r	Reaction E.i.2.1b	Sender's comment H.4	Sender's diagnosis H.3.r.1.b
Reported as medication error, sender agrees	✓	✓	As applicable	
Reported as medication error, sender assessment provides alternative 'diagnosis'	✓	✓	✓	✓
Not explicitly reported as medication error but information and assessment of case leads to suspicion that a medication error was involved	At discretion	MedDRA PTC: Do not infer	Disclaimer* may be used as an option	✓

*Disclaimer as referred to in chapter 5.7.1.

Discussion and Conclusion (cont.)

- High number of additional cases should be followed up
- Additional burden to NCAs, MAHs, HCPs…
- Process of identifying ME is **very sensitive** and relationship between reporter and national pharmacovigilance center should be taken into account
- Not all follow up are sucesfull[1]

[1] Anton C, Cox AR, Ferner RE. **Improving follow-up rates in spontaneous adverse drug reaction reporting: effectiveness of a targeted letter used by a regional centre in the UK.** Drug Saf. 2009;32(12):1135-40.

Discussion and Conclusion (cont.)

Improving number of cases with medication errors associated with adverse reaction reported by primary source:

- Education of reporters
- Improving reporting forms (decision tree)
- Liability for Medication errors by HCPs

For safe and effective medicines.

www.halmed.hr