Universität Zürich[UZH]

Institut für Hausarztmedizin

# CIRS

SGAIM-Herbstkongress
20. September 2018

Markus Gnädinger,
www.forum-hausarztmedizin.ch

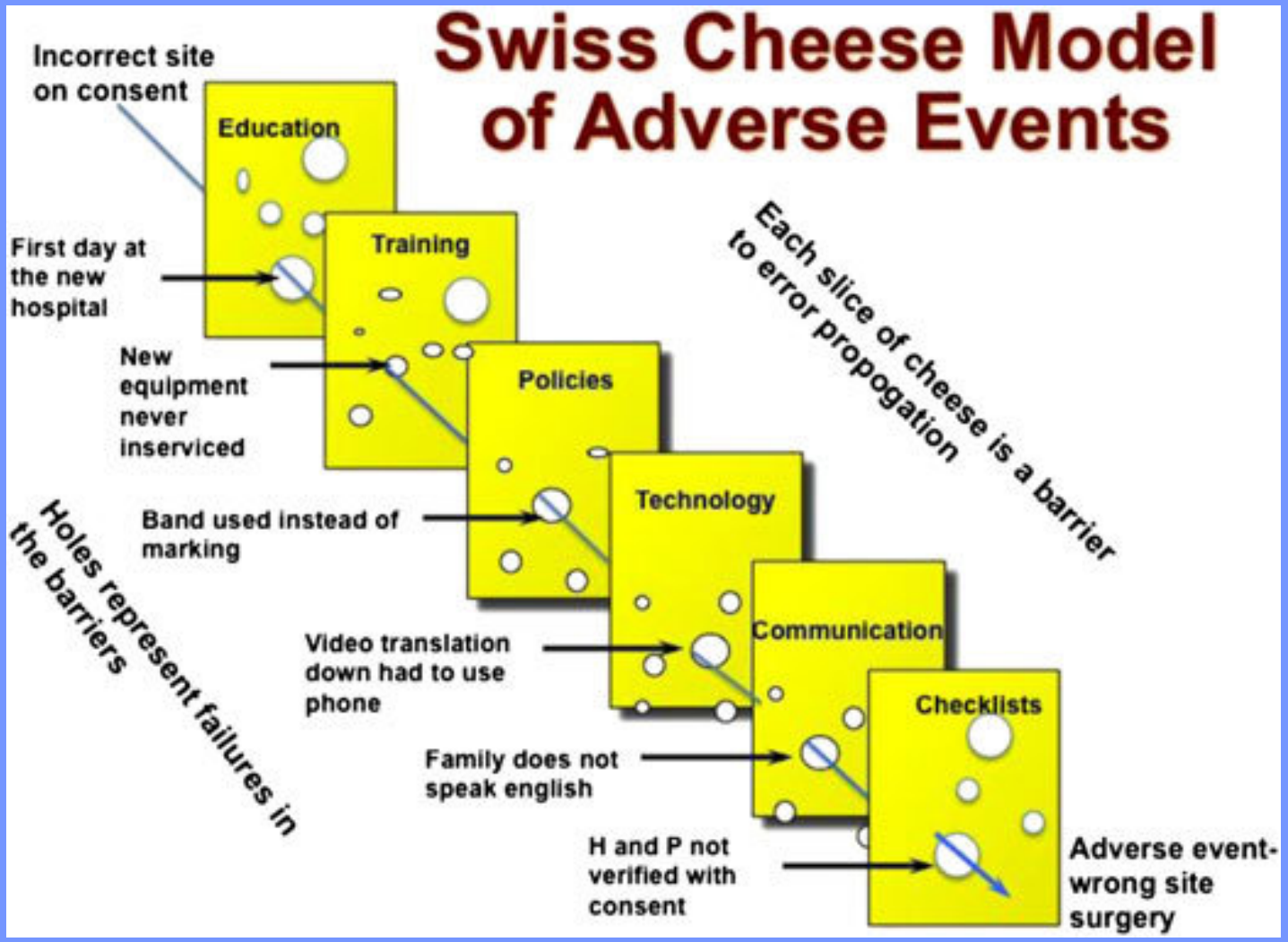
Nicolas Perone

L’enfer, c’est les autres…  J.P.Sartre

# Errare humanum est…

Errare humanum est, **sed in errore perseverare diabolicum.**
(Variante: stultum est in errore manere)


seen on
Kekskopf.de
biologisch abbaubar: LACHSCHON.DE


Swiss Cheese Model of Adverse Events
Incorrect site on consent
Education
First day at the new hospital
Training
New equipment never inserviced
Policies
Band used instead of marking
Technology
Video translation down had to use phone
Communication
Family does not speak english
Checklists
H and P not verified with consent
Adverse event- wrong site surgery
Each slice of cheese is a barrier to error propogation
Holes represent failures in the barriers

# Vaccine expired

Definition of a medical error:

**"That was a threat to patient wellbeing and should not happen. I don't want it to happen again".**

Makeham MA 2002

Definition of a critical incident:

**“An incident is an event or a circumstance that could have resulted, or did result, in unnecessary harm to a patient.”**

WHO 2018

# Harm classification

- **Delayed diagnosis**
- **Inconvenience**
- **Unnecessary interventions**
- **Distrust, deception**
- **Cost**

WHO 2018

*Potential* harm / endangerment

- minimal, no measures needed
- little, minimal harm / disappointment of patient
- medium, surveillance / therapeutic intervention is due
- severe, life threat, hospitalization or permanent damage

(does not apply)
(unknown)

# *Real* harm

- None
- Little
- Medium
- Severe

(Can not be judged yet)
(Does not apply)
(Unknown)

Does *not* meet definition

- Adverse drug reaction
- Bad evolution of case in spite of usual care and precautions
- Rare disease diagnosed after time delay
- Everything that could have performed better without explicit erroneous incident

*Obligatory notification to Swissmedic:*

**Serious adverse drug reactions (ADR)**

- death,
- life-threatening,
- hospitalization or hospitalization prolonged,
- persistent or significant disability / incapacity,
- congenital anomaly / birth defect,
- medically important (MI) event or reaction.

# Legal definition of an error

➔ Performance of average physician
➔ Information of the patient

Universität Zürich[UZH]

Institut für Hausarztmedizin

# Medication incidents in primary care medicine: a prospective study in the Swiss Sentinel Surveillance Network

*BMJ Open* 2017;7:e013658

# Aim

To describe the type, frequency, seasonal and regional distribution of medication incidents in primary care in Switzerland and to elucidate possible risk factors such as age, gender, poly-medication, morbidity, and previous hospitalization.

# Inclusion criterion:

Any *erroneous* event (as defined by the physician) related to the medication process and interfering with normal treatment course.

# Exclusion criterion:

Lacking treatment effect, adverse drug reactions or drug-drug or drug-disease interactions *without* detectable treatment error.

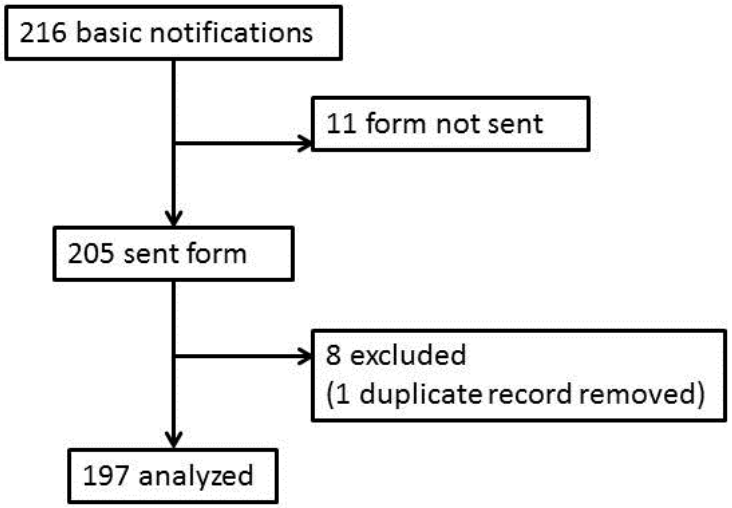
# Data sources

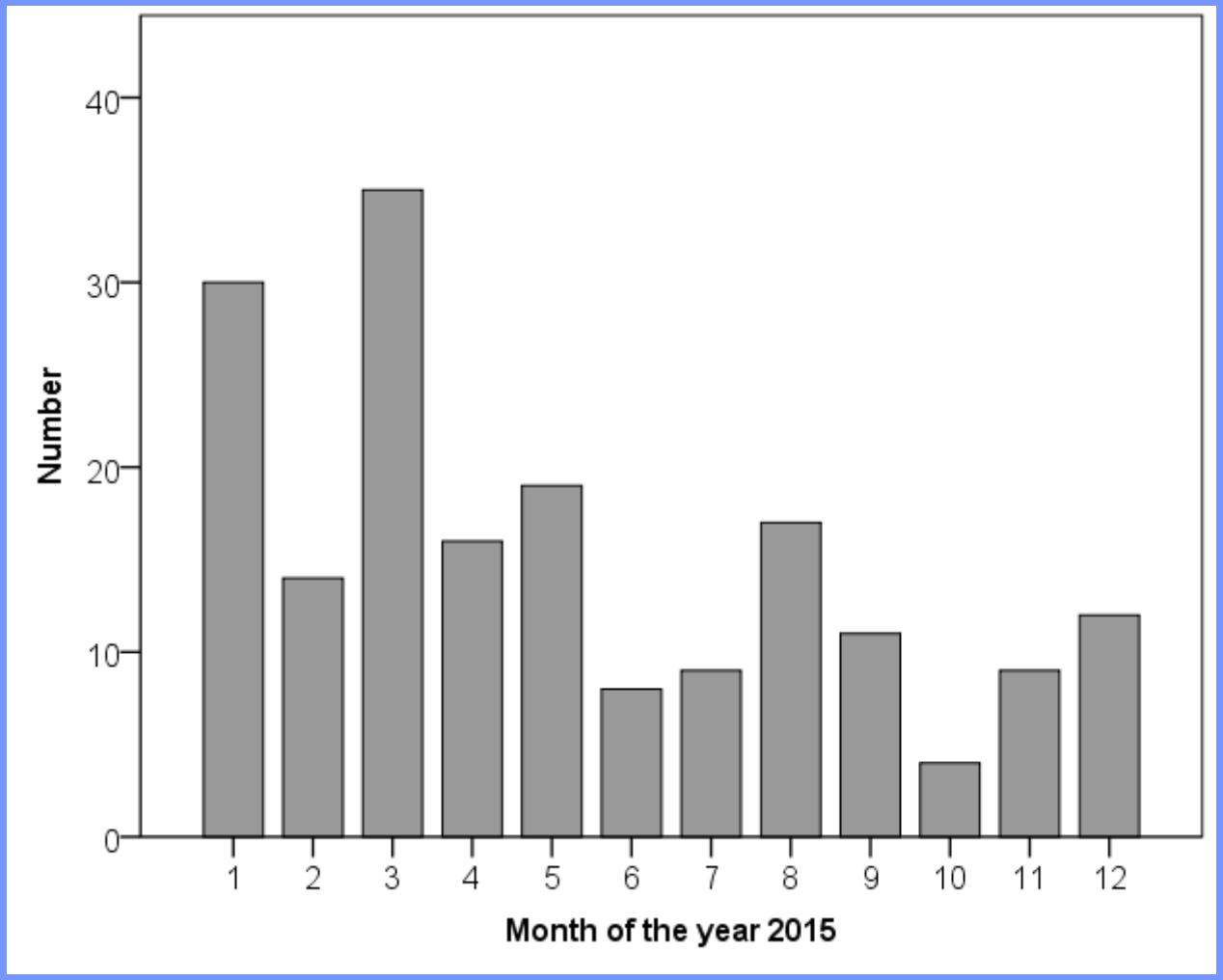
Sentinella physician list and yearly physician to patient contacts

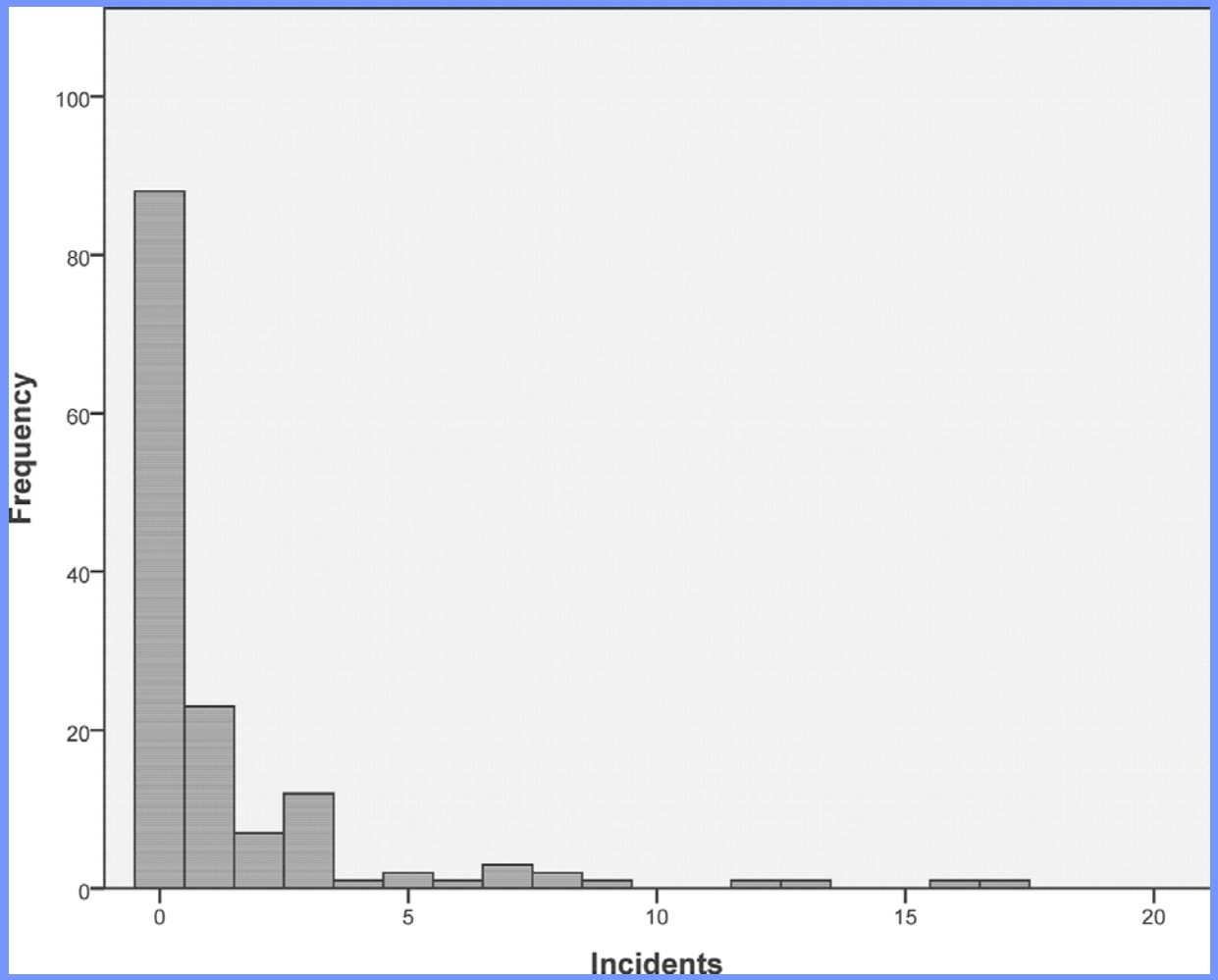
Physician initial questionnaire
Physician final questionnaire
Incident questionnaires
Denominator data (“age and gender”)
Queries
*Coding of open answering items*

Data from Interpharma (indication groups, ATC-code)
Data from Blue-Care (“patient’s age tree”)
Data from Swiss Medical Association (physician data)

# Results


216 basic notifications
11 form not sent
205 sent form
8 excluded
(1 duplicate record removed)
197 analyzed


Number
40
30
20
10
0
1
2
3
4
5
6
7
8
9
10
11
12
Month of the year 2015


Frequency
100
80
60
40
20
0
0
5
10
15
20
Incidents

| | |
|---|---|
| Number of cases | 197 |
| Patients age | 69.3 ± 20.8 |
| Patients gender, % males | 37.6 |
| Physicians specialty, % pediatricians | 1.5 |
| Linguistic region, % | |
| - German | 72.6 |
| - French | 22.3 |
| - Italian | 5.1 |
| Physician-to-patient relationship, % | |
| - own family physician | 83.2 |
| - urgency / holiday replacing | 2.0 |
| - institution physician | 13.7 |
| - other | 1.0 |

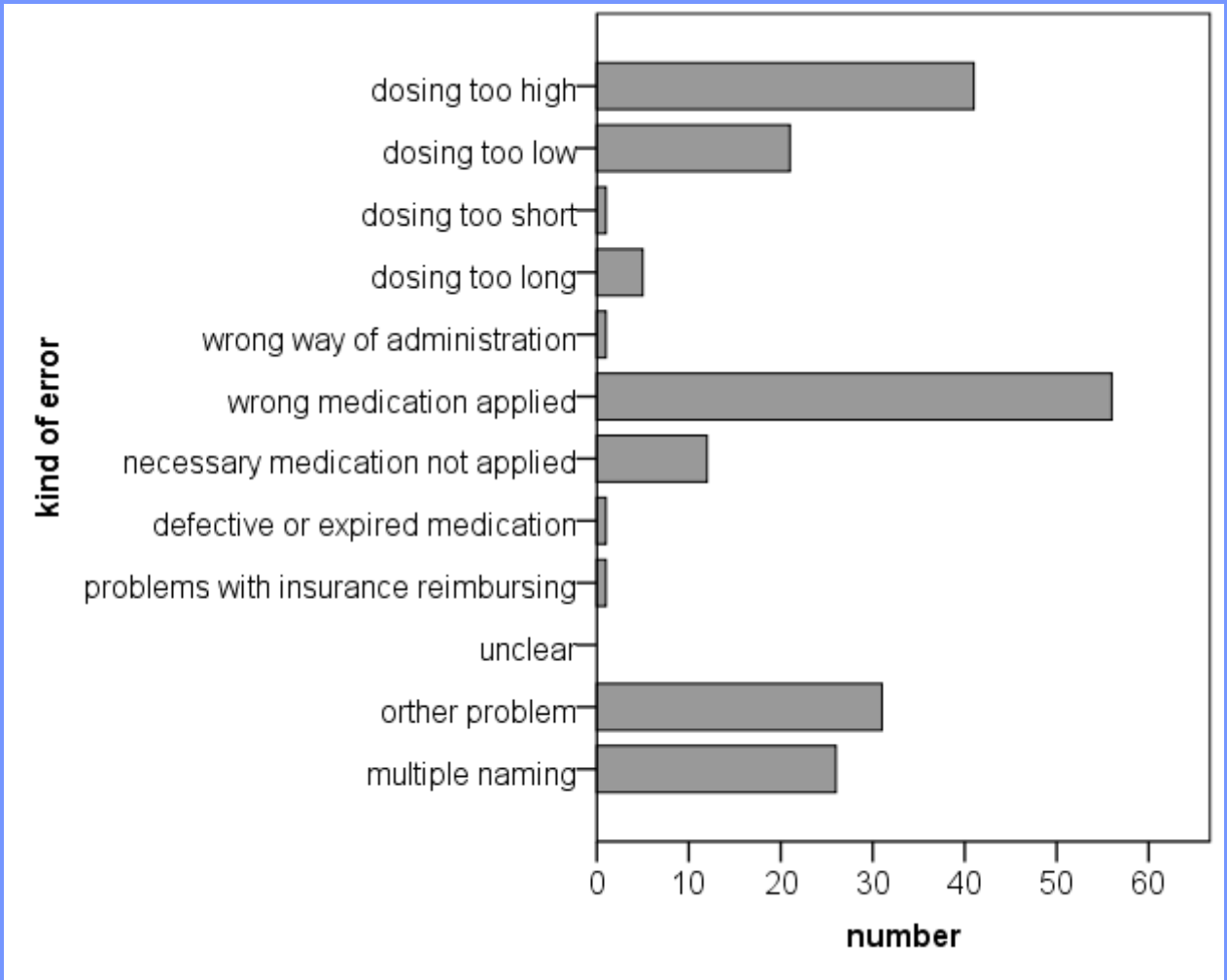
| Observer of the incident: | % |
|---|---|
| - physician / practice staff | 50.3 |
| - patient / proxies | 22.3 |
| - community nurse | 2.5 |
| - institution (where patient lives) | 15.7 |
| - hospital | 1.0 |
| - other physicians | 1.5 |
| - pharmacist | 6.1 |
| - other | 0.5 |

*GP*

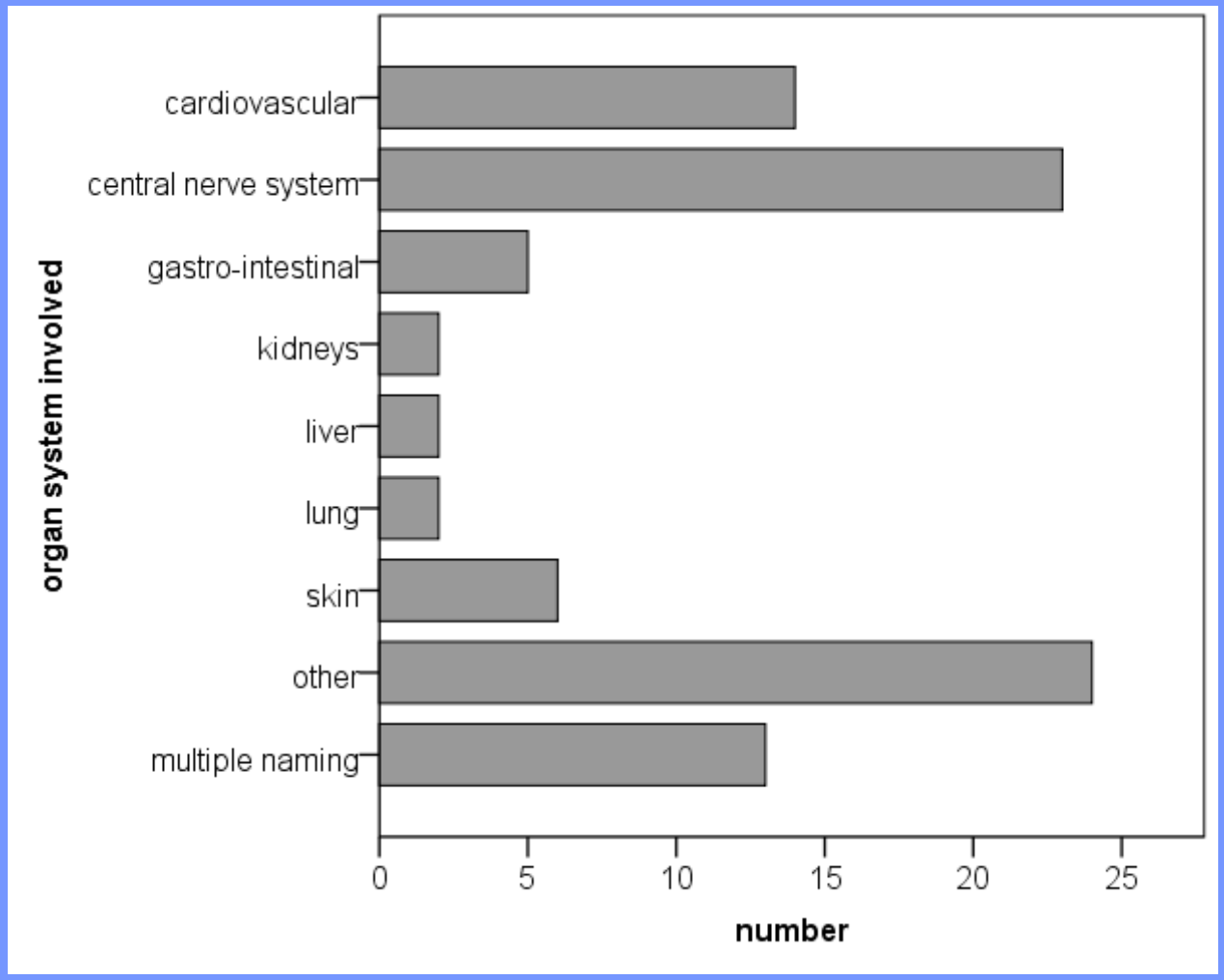
| | |
|---|---|
| - incidents | 194 |
| - reporting physicians | 148 |
| - physician-to-patient contacts | 4’456 |

Incidents

| | |
|---|---|
| - per physician and year | 1.31 |
| - per 100’000 physician-to-patient contacts | 29.4 |


kind of error
dosing too high
dosing too low
dosing too short
dosing too long
wrong way of administration
wrong medication applied
necessary medication not applied
defective or expired medication
problems with insurance reimbursing
unclear
orther problem
multiple naming
0
10
20
30
40
50
60
number

| **Severity of disturbance** | n | % |
|---|---|---|
| - no symptoms but pathological laboratory tests | 15 | 8.0 |
| - light | 44 | 23.4 |
| - moderate | 22 | 11.7 |
| - severe | 10 | 5.3 |
| - fatality | 0 | 0.0 |
| ***Subtotal*** *(this is the base of the next rows)* | ***91*** | *48.4* |
| - no symptoms, normal (or no) laboratory tests | 97 | 51.6 |
| Total | 188 | 100.0 |
| Missing data | 9 | n.a. |
| All patients | 197 | n.a. |


organ system involved
cardiovascular
central nerve system
gastro-intestinal
kidneys
liver
lung
skin
other
multiple naming
0
5
10
15
20
25
number

| **Recovering** | n | % |
|---|---|---|
| - without sequels | 78 | 85.8 |
| - with light to moderate sequels | 2 | 2.2 |
| - with severe sequels or fatality* | 5 | 5.4 |
| - not yet known or missing information | 6 | 6.6 |
| *All patients with disturbances* | *91* | 100.0 |

| **Time** until recovery | n | % |
|---|---|---|
| - hours | 26 | 28.5 |
| - days | 41 | 45.1 |
| - weeks | 15 | 16.5 |
| - not yet known or missing information | 9 | 9.9 |
| *All patients with disturbances* | *91* | 100.0 |

| **Treatment / surveillance** | n | % |
|---|---|---|
| - not needed | 48 | 52.7 |
| - ambulatory care | 33 | 36.3 |
| - hospital care** | 7 | 7.7 |
| - missing information | 3 | 3.3 |
| *All patients with disturbances* | *91* | 100.0 |

** incl. surveillance room

| *Causes of the incident* | N | % |
|---|---|---|
| Out of hours | 2 (3) | 1.0 |
| **Communication problems within staff** | **10 (11)** | **5.1** |
| Generic substitution of original trade medication by pharmacist | 3 (3) | 1.5 |
| Difficulties when reading hand-written prescription | 1 (1) | 0.5 |
| Multiple conflicting prescriptions | 5 (8) | 2.5 |
| **Lacking alertness of physician or practice staff** | **50 (17)** | **25.4** |
| Insufficient documentation | 3 (11) | 1.5 |
| Insufficient patient instruction | 7 (17) | 3.6 |
| Lacking cooperation of patient / proxies | 6 (17) | 3.0 |
| Confusion by reading package leaflet | 1 (0) | 0.5 |
| Confusion after “Googleing” | 1 (0) | 0.5 |
| Administrative problems | 2 (3) | 1.0 |
| Defective medication as caused by manufacturer | 3 (0) | 1.5 |
| Lacking maintenance (e.g. emergency case) | 1 (0) | 0.5 |
| Lacking use of treatment aids (e.g. Dosett) | 0 (6) | 0.0 |
| Other source of trouble | 54 (18) | 27.2 |
| Unknown | 3 (0) | 1.5 |
| Multiple naming | 45 (n.a.) | 23.1 |
| Total | 197 (115) | 100.0 |

| *Reactions to the incident* | N | % |
|---|---|---|
| Changing standard operating procedures of the practice | 14 (3) | 7.2 |
| Better instruction of patients | 23 (4) | 11.7 |
| Communication with other institutions | 31 (3) | 15.7 |
| Notifying manufacturer | 1 (2) | 0.5 |
| Reporting the incident to the critical incident reporting system | 10 (6) | 5.1 |
| No reaction at all | 55 (n.a.) | 27.9 |
| Other type of reactions to the incident | 49 (9) | 24.9 |
| Missing information | 1 (0) | 0.5 |
| Multiple naming | 13 (n.a.) | 6.6 |
| Total | 197 (27) | 100.0 |

| *Proposals* | N | % |
|---|---|---|
| Cross-check of medication lists | 6 (14) | 4.8 |
| Patient instructions | 2 (3) | 1.6 |
| Reduction of time pressure / stress | 3 (6) | 2.4 |
| To observe adverse drug reactions also with “nature products” | 1 (0) | 0.8 |
| Four eyes check when dispensing medication | 2 (4) | 1.6 |
| No medication without prescription | 3 (6) | 2.4 |
| To critically audit polymedication | 3 (2) | 2.4 |
| To avoid similarly looking or named medication in drug master | 2 (3) | 1.6 |
| To demand medication plans to be brought to the consultation | 0 (4) | 0.0 |
| To provide medication plans routinely | 2 (8) | 1.6 |
| In-deep checking before delivering “new” medication to the patient | 4 (1) | 3.2 |
| To provide patients with allergy / intolerance cards | 2 (1) | 1.6 |
| To let patients themselves write their medication card (and controlling afterwards) | 0 (3) | 0.0 |
| To instruct patients to come into the practice immediately after hospitalization | 3 (0) | 2.4 |
| To broach regularly “medication safety” on staff meetings | 5 (6) | 4.0 |
| To provide information in patients’ native language | 0 (2) | 0.0 |
| To share important information about patients with practice nurse | 0 (2) | 0.0 |
| To improve information flow | 11 (16) | 8.8 |
| To organize follow-up controls | 10 (28) | 8.0 |
| To wait for laboratory results before prescribing | 1 (0) | 0.8 |
| Other | 12 (9) | 9.6 |
| Multiple answering | 53 (n.a.) | 42.4 |
| Total | 125 (118) | 100.0 |
| None | 72 (n.a.) | (n.a.) |

42.4%

36.5%

| *Item* | Patient group | | OR (95% CI) (crude) | OR (95% CI) (adjusted) |
|---|---|---|---|---|
| | Denominator | Incidents | | |
| n | 26’852 | 197 | / | / |
| Age (mean±SD), years | 46.7 ± 27.5 | 69.3 ± 20.8 | 1.004* (1.001;1.006)[a] | 1.001 (0.996;1.005) |
| Gender, | | | | |
| ● male | 47.0 | 37.6 | 1 | 1 |
| ● female | 53.0 | 62.4 | 1.048 (0.916;1.197) | 1.055 (0.878;1.196) |

[a] p<0.05, * per year

Universität Zürich[UZH]

**Institut für Hausarztmedizin**

| *Item* | Patient group | | OR (95% CI) (crude) | OR (95% CI) (adjusted) |
|---|---|---|---|---|
| | Denominator | Incidents | | |
| n | 26’852 | 197 | / | / |
| Care-dependency*, | | | | |
| ● none | 16’335 (85.5%) | 96 (51.6%) | 1 | 1 |
| ● yes, by proxies | 954 (5.0%) | 12 (6.5%) | 1.121 (0.789;1.594) | 0.979 (0.674;1.423) |
| ● yes, by community nurse | 723 (3.8%) | 22 (11.8%) | 1.458 (1.025;2.073)[a] | 1.201 (0.821;1.758) |
| ● yes, by institution | 1’099 (5.8%) | 56 (30.1%) | 1.802 (1.399;2.323)[c] | 1.528 (1.141;2.046)[a] |

* adult patients only, [a] p<0.05, [c] p<0.001

| *Item* | Patient group | | OR (95% CI) (crude) | OR (95% CI) (adjusted) |
|---|---|---|---|---|
| | Denominator | Incidents | | |
| n | 26’852 | 197 | / | / |
| Number of diagnoses (median, IQR) | 2 (0;4) | 5 (3;7) | 1.052* (1.029;1.075)[c] | 1.030* (0.994;1.067) |
| Number of chronic active treatments (median, IQR) | 1 (0;4) | 6 (3;9) | 1.052* (1.030;1.074)[c] | 1.030* (0.995;1.067) |

[c] p<0.001, * per diagnosis or medication

Universität Zürich[UZH]

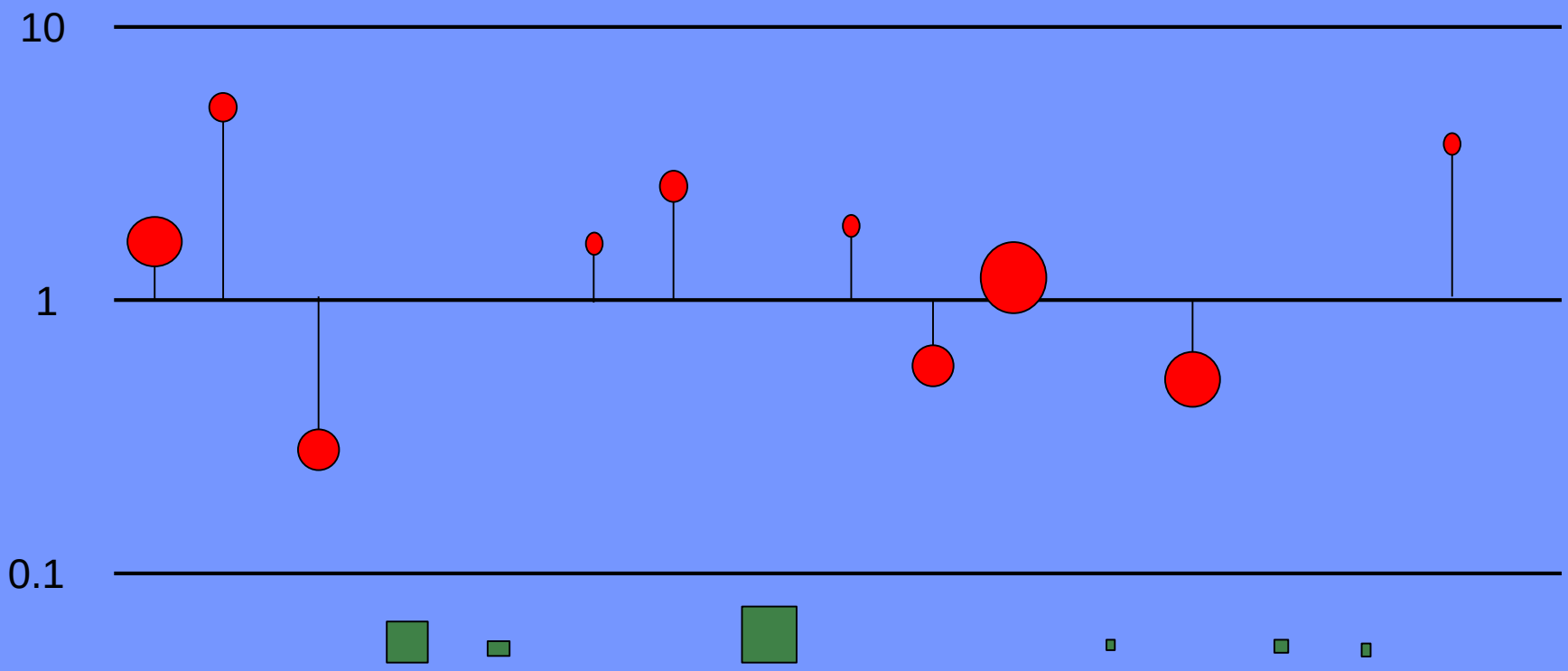
**Institut für Hausarztmedizin**

| *Item* | Patient group | | OR (95% CI) | OR (95% CI) |
|---|---|---|---|---|
| | Denominator | Incidents | (crude) | (adjusted) |
| n | 26’852 | 197 | / | / |
| | | | | |
| TMI value (n, %) | | | | |
| ● 0 | 8’463 (31.5%) | 24 (12.2%) | 1 | 1 |
| ● 1 | 3’611 (13.4%) | 8 (4.1%) | 0.989 (0.787;1.242) | 0.908 (0.694;1.190) |
| ● 2 | 4’102 (15.3%) | 23 (11.7%) | 1.049 (0.847;1.300) | 0.898 (0.685;1.169) |
| ● 3 | 3’877 (14.4%) | 39 (19.8%) | 1.131 (0.914;1.399) | 0.830 (0.611;1.127) |
| ● 4 | 2’119 (7.9%) | 39 (19.8%) | 1.292 (1.004;1.662)[a] | 0.901 (0.643;1.265) |
| ● 5 | 1’539 (5.7%) | 38 (19.3%) | 1.420 (1.078;1.868)[b] | 0.823 (0.547;1.239) |
| ● 6 | 709 (2.6%) | 26 (13.2%) | 1.680 (1.178;2.396)[c] | 0.866 (0.523;1.436) |
| missing values | 18 | 0 | | |

[a] $p<0.05$, [b] $p<0.01$, [c] $p<0.05$.

Universität Zürich[UZH]

## Institut für Hausarztmedizin




| A | B | C | D | G | H | J | K | L | M | N | P | R | S | T | V |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Alimentary tract and metabolism | Blood and blood forming organs | Cardiovascular system | Dermatologics | Genito-urinary system and sex hormones | Systemic hormonal preparations (excluding sex hormones and insulins) | Anti-infectives for systemic use | Infusion liquids | Antineoplastic and immune-modulating agents | Musculoskeletal system | Nervous system | Anti-parasitic products, insecticides and repellents | Respiratory system | Sensory organs | Diagnostic use | Various |

## Strength and limitations

This is the first Swiss prospective and systematic collection of incident data in primary care. It covers three linguistic regions and two distribution systems. It was done by experienced physicians and with high response rates.

There was – as expected – bias from selective and underreporting or non-detection. The broad range of incident descriptions, circumstances and causes delivered more qualitative than quantitative information.

## Conclusion

Medication incidents are common in general medicine, whereas they rarely occur in pediatrics, in which polypharmacy is less prevalent. Reasons for medication incidents are diverse but often seem to be linked to communication problems. Older and multimorbid patients are at a particularly high risk for medication incidents. Anticoagulants are specifically prone to generate incidents.

Universität Zürich[UZH]

Institut für Hausarztmedizin

Universität Zürich[UZH]

www.forum-hausarztmedizin.ch