

# BMJ Open Medication incidents in primary care medicine: protocol of a study by the Swiss Federal Sentinel Reporting System

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**To cite:** Gnädinger M, Ceschi A, Conen D, *et al*. Medication incidents in primary care medicine: protocol of a study by the Swiss Federal Sentinel Reporting System. *BMJ Open* 2015;**5**:e007773. doi:10.1136/bmjopen-2015-007773

► Prepublication history and additional material is available. To view please visit the journal (<http://dx.doi.org/10.1136/bmjopen-2015-007773>).

Received 26 January 2015  
Revised 13 March 2015  
Accepted 18 March 2015



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## ABSTRACT

**Background/rationale:** Patient safety is a major concern in healthcare systems worldwide. Although most safety research has been conducted in the inpatient setting, evidence indicates that medical errors and adverse events are a threat to patients in the primary care setting as well. Since information about the frequency and outcomes of safety incidents in primary care is required, the goals of this study are to describe the type, frequency, seasonal and regional distribution of medication incidents in primary care in Switzerland and to elucidate possible risk factors for medication incidents.

**Methods and analysis:** Study design and setting: We will conduct a prospective surveillance study to identify cases of medication incidents among primary care patients in Switzerland over the course of the year 2015. *Participants:* Patients undergoing drug treatment by 167 general practitioners or paediatricians reporting to the Swiss Federal Sentinel Reporting System.

*Inclusion criteria:* Any *erroneous* event, as defined by the physician, related to the medication process and interfering with normal treatment course. *Exclusion criteria:* Lack of treatment effect, adverse drug reactions or drug–drug or drug–disease interactions without detectable treatment error. *Primary outcome:* Medication incidents. *Risk factors:* Age, gender, polymedication, morbidity, care dependency, hospitalisation. *Statistical Analysis:* Descriptive statistics to assess type, frequency, seasonal and regional distribution of medication incidents and logistic regression to assess their association with potential risk factors. *Estimated sample size:* 500 medication incidents. *Limitations:* We will take into account under-reporting and selective reporting among others as potential sources of bias or imprecision when interpreting the results.

**Ethics and dissemination:** No formal request was necessary because of fully anonymised data. The results will be published in a peer-reviewed journal.

**Trial registration number:** NCT0229537.

## INTRODUCTION

Patient safety is a major concern in healthcare systems worldwide. Although most safety research has been conducted in the inpatient

## Strengths and limitations of this study

- First Swiss prospective and systematic collection of incident data in primary care.
- Covering three linguistic regions and two distribution systems.
- Bias from selective and under-reporting or non-detection.

setting,<sup>1</sup> evidence indicates that medical errors and adverse events pose a serious threat for patients in the primary care setting as well, since most patients receive ambulatory care.<sup>2–4</sup> Gandhi and Lee<sup>5</sup> noted that safety concerns in the outpatient setting differ from those in the hospital setting in obvious and non-obvious ways. Medication-related incidents are also important in primary care, but are perhaps not as well documented as in secondary care. A study by Gandhi and Lee<sup>6</sup> in primary care showed that 25% of 661 ambulatory care patients with at least one prescription had such an incident, of which 13% were classified as serious and 39% as preventable or ameliorable. In a study by Pirmohamed *et al* in the UK, medication-related incidents caused about 6.8% of all hospitalisations<sup>7</sup> and in Switzerland, these incidents are responsible for about 7.2% of hospitalisations.<sup>8</sup> Diagnostic errors<sup>9</sup> and adverse drug events have been identified as frequent safety concerns; furthermore, there is a body of literature about the safety of outpatient procedures and the consequences of coordination as well as continuity-of-care failures.<sup>10</sup> Hospital and outpatient care also differ in their infrastructure and in many processes, as well as in their ability to detect, monitor and address safety issues. Information about the frequency and outcomes of safety incidents in primary care is required to identify risks or ‘hot spots’, to prioritise them and to take action as needed.

## Definition of terms

For the purpose of our study, we use the terminology of the International Classification for Patient Safety (WHO).<sup>11</sup> Here, a *patient safety incident* is defined as an event or a circumstance which could have resulted or did result in unnecessary harm to a patient. There are several possible causes. (1) An *error*, defined as: failure to carry out a planned action as intended or an application of an incorrect rule; (2) A *violation*, defined as: deliberate deviation from an operating procedure, standard or rule; (3) An (external) *circumstance*, defined as: a situation or factor that may influence an event, agent or person. We want to distinguish incidents from *adverse drug reactions* (ADR) which are defined as: unexpected harm resulting from a justified action where the correct medication process was followed for the context in which the event occurred. The same applies to *drug–drug* or *drug–disease interactions* (DDI). *Critical Incident Reporting System* (CIRS) refers to a voluntary anonymous database system to which Swiss family physicians or paediatricians may report incidents as those occurred in their practices.

We will restrict the topic of our study to medication-related incidents. *Medication* or medicine refers to a pharmaceutical drug, officially called a medicinal product, which can be loosely defined as any chemical substance—or product comprising such—intended for use in the medical diagnosis, cure, symptomatic treatment, or prevention of disease (Wikipedia).

## Information retrieval

Methods to collect information about adverse incidents are manifold.<sup>2 11–14</sup> In the literature, different ways to collect adverse incident information are described: voluntary versus mandatory reporting systems, patient questionnaires, or pharmacists reporting to registries. Interviews can be held with physicians or questionnaires can be filled out by them. Charts of deceased patients can be audited meticulously or medicolegal cases may be analysed. Information may be derived prospectively in an actual case by case manner or retrospectively along case vignettes. The two methods most commonly used are incident reporting and chart review. Both methods have the potential to systematically cover information on the entire range of safety events in medical offices in common.

*Incident reporting* has a long tradition in clinical risk management and is increasingly used in outpatient care.<sup>15–18</sup> Indeed, incident reporting has been the dominant method for the study of safety incidents in primary care.<sup>19</sup> It is based on voluntary and usually anonymous reports of physicians and nurses, and is used to describe the types and characteristics of patient safety incidents. These reports may vary considerably with respect to the information which is included and the likelihood of ‘true’ incidents being reported is unclear. Studies based on this method describe large variations in the number of reports submitted.<sup>20</sup> Moreover, professional groups differ in their frequency of reporting; in-hospital care physicians reported preferentially severe incidents, while nurses cover

the whole spectrum of impact levels.<sup>20</sup> Selective reporting by physicians may have multifactorial causes such as lack of time, thinking that an ADR which is already known is not worth mentioning, or concerns about data confidentiality. Non-reporting may be as frequent as 94%.<sup>21 22</sup> O’Beirne *et al* concluded from a very low report rate (<1 report per person per year) that incident reporting may be “a costly but not very effective way to study safety problems in primary care”.<sup>23</sup> A recent Swiss study analysed safety issues in primary care.<sup>12</sup> This was a semiquantitative, retrospective investigation involving over 300 nurses and physicians. Seven of 23 issues were related to drug treatment. Frequently named issues were insufficient monitoring of potential side effects, missing prescriptions of required treatment, and errant medication relating to the route of administration, dosage or timing. The low and perhaps, selective reporting of incidents in any system makes it difficult or virtually impossible to collect valuable quantitative information from CIRS.<sup>24</sup>

In *chart review*, medical records are analysed by independent experts in order to identify adverse events, and to assess potential harm and preventability in each case.<sup>25</sup> Such analysis requires complete and correct patient documentation to provide valid results. In many cases relevant information may be unavailable.<sup>25</sup> As chart review is a time-consuming approach, many resources are needed to analyse a large number of patient records at different primary care offices; furthermore, this kind of analysis is usually retrospective.

Sandars and Esmail<sup>2</sup> described a frequency of 5–80 medical errors per 100 000 consultations in primary care patients. Incidents, as defined above, may also result from circumstantial factors (without any errors) and therefore, occur somewhat more frequently. In order to not overburden the participating physicians with our study, we decided to limit our focus to medication incidents. These make up between 9% and 42% of all registered incidents<sup>2 9 26–28</sup> and of these, approximately 70% may be prescription errors.<sup>29</sup> In contrast to the study by Sandars and Esmail, our pilot study found a rate of approximately one medication incident per 2 months and per physician (see online supplementary appendix 1), while the former reported a rate of about one in 2 years.

Concerning predisposing factors, Avery *et al*<sup>30</sup> found a propensity for becoming a victim of medication errors with the young (<15 years) or elderly (>64 years) ages. The latter was confirmed by Salanitro *et al*.<sup>31</sup> Two studies by Field *et al*<sup>32 33</sup> reported morbidity as promoting errors. All studies listed polymedication as a key factor.<sup>30–34</sup> Better knowledge of factors associated with medication errors would be helpful to implement preventive measures and therefore, reduce the frequency of avoidable incidents in the future.

## The Swiss National Sentinel Reporting Network (<http://www.sentinella.ch>)

To apply a supplementary method to gaining insight into safety hot spots in primary care, we aim to assess

medication errors by using the Swiss National *Sentinel Reporting Network*. Founded in 1986, it was mainly designed to survey transmissible diseases. Later, it also assessed other health problems of public interest. In 2015, besides our project, the areas covered are: surveillance of mumps, whooping cough, flu or *Borrelia*, pneumonia and middle ear infections, tick bites, vaccinations against measles or whooping cough, and alcohol use among adolescents. One hundred and forty general internal medicines and 27 paediatric practices report to the system, 109 of them in the German, 44 in the French, and 14 in the Italian part of Switzerland. It generates daily to weekly current data and covers the entire geographic and linguistic regions of our country.

## METHOD

### Aims of the project

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, polymedication, morbidity, and previous hospitalisation.

### Study design

We will conduct a prospective surveillance study to identify cases of medication incidents among primary care patients over the course of 1 year.

### Population

Any person undergoing drug treatment in general internal or paediatric practices participating in the Sentinella network. The latter covers a representative sample of patients in primary care for Switzerland (see above). These patients include children, individuals with mental retardation or the elderly—all of whom might be at increased risk for medication errors.

### Inclusion criteria

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

### Exclusion criteria

- ▶ Lacking treatment effect, ADR, or drug–drug interaction or DDI *without* detectable treatment error.
- ▶ Refusal of patients to refer data to the Sentinel system.

### Questionnaire development

As we could not identify questionnaires suitable for continuous reporting and adaptable to our local conditions, we had to develop new ones. We tested these in an 8-week pilot study (see online supplementary appendix 1).

In the Sentinella study, the Italian speaking physicians had to decide whether to report in German or French. For the main study, we developed only two language sets of questionnaires, since these had to be filled in only by physicians, not

by patients. We deemed assessment of construct validity of the questionnaires not imperative, since we did not measure hidden constructs (like ‘depression’) by our questions and information was mainly needed about influencing our target variable, that is, the type and frequency of incidents.

### Data to be collected

The data to be collected in our study are summarised in **boxes 1** (physician related) and **2** (patient related/incident related); for the latter, only pre-existing data from medical records will be collected. Furthermore, we collected denominator data as depicted in **box 3**.

### Time schedule

The pilot study took place from July until September 2013. The final questionnaires in both languages and their English translation are available at <http://www.medication-incidents.ch>. The main study takes place from January until December 2015. Evaluation of the study data and writing of the publication will be performed in 2016.

### Statistics

#### Expected number of cases

On the basis of our pilot trial (see online supplementary appendix), we expect at least one drug-related incident to be reported every 2 months per physician. In the Sentinella system, there are currently 167 physicians actively reporting, among them are 27 paediatricians.

#### Box 1 Physician-related data

##### Initial questionnaire

Sentinella identification number  
 Gender\*  
 Age\*  
 Specialisation (general practitioner or paediatrician)\*  
 Number of physicians in practice, and among them those reporting to Sentinella\*  
 Working hours per week\*  
 Drug distribution system (by pharmacist or by physician)  
 Drug prescription system (electronic, machine written, hand-written)  
 Electronic drug–drug interaction (DDI) system  
 Availability of X-ray, ECG, ultrasound  
 Medical history (electronic or paper based)  
 Quality certificate  
 Team sessions  
 Physician’s participation in quality circle  
 Localisation (urbanity, language region)\*  
 Special education/interests  
 Caring for institutions  
 Final questionnaire  
 Proportion of non-reporting incidents during the study

The data are collected from each physician reporting to the Sentinella system. The questionnaire and the coding plan are available at <http://www.medication-incidents.ch>.

\*These data is delivered by Sentinella administration. All other data will be collected by use of questionnaires.

**Box 2** Patient-related data*Patient-related/incident-related items*

Week of reporting  
 Year of birth  
 Gender  
 Physician-to-patient relationship  
 Dwelling situation  
 Social problems  
 Dementia or learning disabilities  
 Psychiatric problems  
 Use of psychotropic drugs  
 Linguistic problems  
 Smoking or substance abuse  
 Visual blurring or hearing loss  
 Gait disturbance  
 Renal insufficiency  
 Liver cirrhosis/insufficiency  
 Previous hospitalisation (12 months)  
 Care dependency  
 Number of chronically administered active drugs\*  
 Number of diagnoses for chronic disease  
 Scale value of 'Thurgau Morbidity Index' (TMI)<sup>35</sup>  
 Description of incident  
 Who noticed the incident  
 What went wrong  
 Name of drug  
 Other drugs used possibly related to the incident  
 Endangering of patient  
 Amount of damage  
 Organ system involved  
 Duration  
 Recovery  
 Treatment/surveillance  
 Causal triggers  
 Interface problems  
 Information to the patient about the incident and his reaction  
 Consequences of the incident  
 Responsibility  
 Possibility to anticipate the incident  
 Whether a similar incident was previously notified within the study  
 General proposals  
*Physician-related items*  
 Sentinella identification number

The data are collected for each incident. The *basic reporting* of a medication incident is collected weekly. It includes the Sentinella identification number, the gender of the patients and their year of birth. The questionnaire and the coding plan are available at <http://www.medication-incidents.ch>.

\*Each regularly prescribed or administered pharmacological specialty counts per active substance contained, according to the latest available medication list. All therapies regularly taken during at least 1 month are considered. Drugs that are prescribed for shorter periods (eg, antibiotics for a week) are not included. Regularly administered eye drops, inhalations, nasal sprays count if a general systemic effect is intentional (eg, calcitonin nasal spray) or must be taken into account (eg, timolol eye drops). Also transcutaneous, subcutaneous or vaginal hormone-releasing systems, and preparations administered by the specialist (eg, gynecologist: birth control pills) should be recorded. Herbal drugs count—regardless of the number of plants—as one medication. Homeopathic drugs, cell salts, etc, are not counted. Multivitamins count if they are taken due to a medical indication (eg, short bowel syndrome), but not when the administration was adopted as 'roborant'; multivitamins are considered *one* drug. Also therapies at the hospital administered such as oncology are counted. Whether the patient also applies the drug (compliance) is irrelevant to the study, the important thing is that it is so prescribed. Prescribed medications to relieve on requirement which do not need to be taken daily, or self-medication is not recorded.

When assuming that they work 10 months per year, this would result in 660 reported incidents. We, hence, have to decrease this number to some extent because not all

physicians work 100%, there will be some non-reporting or non-detection of incidents, and paediatricians report lower rate of incidents (according to the results of our

**Box 3** Denominator data

*Fortnight analysis (only once in study, from 7 to 20 March 2015)*

Previous hospitalisation (during the preceding year)

Care dependency

Number of active drugs chronically administered

Number of chronic diagnoses

Scale value of 'Thurgau Morbidity Index' (TMI)<sup>35</sup>

Year of birth\*

Gender\*

Multiple consultation (within the 14-day period)

Sentinella identification number

*Daily analysis*

Physician-to-patient contacts

Sentinella identification number

The data are collected from each patient consulting the practice during the year 2015, irrespective of the presence of an incident.

\*Year of birth and gender will be collected during another 14-day period in fall but without the other items. The questionnaire and the coding plan are available at <http://www.medication-incidents.ch>. Definition of medication count: see [box 2](#).

pilot study). So we expect approximately 500 incidents in our study.

**Statistical methods**

For the analysis of our data, we will use descriptive statistics in order to describe the type, frequency, seasonal and regional distribution of medication incidents. We will use logistic regression to assess the association of medication incidents with potential risk factors. We will use SPSS.

**Independent ethical committee**

The ethical committee of Canton Zurich decided that our study did not need formal approval, because the data are completely anonymous (KEK-ZH 2014-0400). The study was recorded in <http://www.ClinicalTrials.gov>: NCT02295371, as well as in our national study registry (<http://www.kofam.ch>; SNCTP000001207).

STROBE statement: Where applicable, our publication will follow the general STROBE guidelines (<http://www.equator-network.org/>).

**RESULTS FROM A PILOT STUDY**

From the existing literature,<sup>12</sup> we included questions on the social and clinical state of the patients, on the type of incident, and on possible causative factors, and tested these in a pilot study, from July until September 2013, with a sample of general physicians or paediatricians; these were in two language sets (German and French) for the three different language regions of Switzerland (German 11, French 7, Italian 3) for 8 weeks. Fifty-one cases were recorded, leading to an incident rate of 0.4 (median, IQR 0.4) per family physician, and week or 4 (5) per family physician and 1000 patient contacts. Virtually no incidents were observed by paediatricians (details of this study are presented in online supplementary appendix 1).

**DISCUSSION****Strength and limitations**

Our study is the first prospective and systematic collection of incident data in Swiss primary care. The well-motivated reporting physicians, the duration of 12 months and the coverage of the three main linguistic regions as well as of two drug distribution systems will deliver new and relevant insights.

Not all cases may be reported; there may be some selective reporting of cases of higher clinical importance, and some cases may not be reported due to lack of time or legal considerations. Some cases may not be detected by the physicians. Some non-prescription treatments may be missed if they are not causally linked to the incident. The sample size may be too small for inferential statistics. The 14-day denominator period may not be representative for the patient collective over the whole year. The definition of inclusion criteria may be interpreted varyingly by the physicians. Qualitative information may be missed in this study and has perhaps to be further addressed in qualitative research. The low and perhaps selective reporting of incidents in any system makes it difficult or virtually impossible to collect valuable quantitative information from CIRS.<sup>24</sup>

**CONCLUSION**

Data on safety issues in ambulatory primary care patients is scarce and this is also true for Switzerland. The retrospective qualitative study by Gehring *et al*<sup>12</sup> and the study by Livio *et al*<sup>8</sup> on hospitalisations makes it reasonably clear that things are in no way better than that in UK<sup>7</sup> or USA,<sup>6</sup> where 6.5% of all hospitalisations and 4.0% of all hospital care days as well as 1 in 667 hospital deaths are caused by medication incidents. Since up to 72% of these appear to be preventable or ameliorable, it seems worthwhile to focus on these so as to further elucidate risk factors.

The data of our study should allow for describing the type, frequency, seasonal and regional distribution of medication incidents in Swiss primary care practices and for helping to identify risk factors. The definition of 'hot spots' could sensitise the physicians to focus on dangerous situations and help them to redefine their standing operational procedures (SOPs).

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**Acknowledgements** The authors are grateful to Lee Wennerberg for English language corrections, the Federal Health Agency for the translation of their

pilot study questionnaires into French, Dr Sven Staender, Männedorf, for the helpful comments. They thank all colleagues participating in the pilot study (Banderet HR, Bigler M, Dafflon M, Ebnöther S, Ferrazzini G, Frey J, Fröhlich F, Haftgoli N, Köhler B, Marty F, Mühlmann N, Merz A, Oppliger S, Pasche O, Pilet F, Quack C, Sébo P, Schwarzenbach HR, Spirig M, Valentin J).

**Contributors** MG lead the study, did the pilot study (questionnaire development, data entering and processing), wrote all documents, made all the contacts with the Sentinella administration, ethics committee and others, programmed the electronic questionnaires, will enter the hand-written questionnaires into the database, will do the data processing and will write the publication after data collection. LH is French speaking and will help others to understand the French-printed questionnaires. MP was responsible for sound methodology. AS conceived the idea for the study. All the authors have seen all the study documents and contributed intellectually to this publication. All the authors have contributed to the revision of the draft of this publication, and approved the submitted version of this publication.

**Funding** The study was funded by Bangeter-Rhyner Foundation, Basel (grant number 8472/HEG-DSV).

**Competing interests** None declared.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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