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Patient safety in ambulatory care from the patient's perspective - A retrospective, representative telephone survey

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Patient safety in ambulatory care from the patient's perspective - A retrospective, representative telephone survey

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ABSTRACT

Objectives: Data on patient safety incidents (PSIs) in ambulatory care are scarce. The aim of the study was to record the frequency, type, severity and point of origin of PSIs in ambulatory care in Germany.

Design: Retrospective cross-sectional study.

Setting: Computer-assisted telephone interviews (CATI) with randomly recruited citizens aged ≥ 40 years in Germany who were asked about their experiences with PSIs in ambulatory care.

Participants: 10.037 citizens ≥ 40 years.

Measures: A new questionnaire was developed to record patient experiences with PSIs in ambulatory care. The study reported here targets patient experiences in the last 12 months. The questionnaire focuses PSIs in 7 areas of medical treatment: anamnesis/physical examination; medication; vaccination, injection, infusion; aftercare; outpatient surgery; office administration; other areas. For each PSI reported, detailed questions were asked about the specialist group concerned and on the most serious harm, the severity of the harm and its consequences. The target parameters are presented as proportions with 95% confidence intervals and extrapolated to the population of all ≥ 40 -year-olds in Germany.

Results: 1,422 of the respondents (14%) reported 2,589 PSIs. The areas most frequently affected by PSIs were anamnesis/physical examination (61%) and medication (15%). General practitioners accounted for 44% of PSIs, orthopaedists for 15% and internists for 10%. 75% of PSIs were associated with harm, especially unnecessarily long pain or deterioration of health; 35% of PSIs led to permanent damage. 804 PSIs (32%) prompted patients to see another doctor for additional treatment; 255 PSIs (10%) required inpatient treatment.

Conclusion: PSIs experienced by patients are common in ambulatory care in Germany. Extrapolated to the population of all ≥ 40 -year-olds in Germany (47.2 million) an annual 12.2 million PSIs must be expected affecting 6.7 million ≥ 40 -year-olds in Germany. PSIs often lead to harm to health and additional ambulatory and inpatient treatments. Measures to prevent PSIs in ambulatory care are necessary.

Strengths and limitations of this study

- For the very first time, data were collected on the frequency, type, severity and consequences of patient safety incidents (PSIs) in ambulatory care in Germany.
- The sample of 10.037 citizens ≥ 40 years was randomly selected and represents the population ≥ 40 -year-olds in Germany (47.2 million).

- Since the research method only considers the patient's perspective, a medical objectification of the reported PSIs and reliable statements about their preventability is not possible. Nevertheless, the analysis of patient reported PSIs can help to develop starting points for their prevention and improve patient safety.

INTRODUCTION

Patient safety, as a key feature of quality healthcare,[1] is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.[2] Health care's growing complexity and an increasing number of multimorbid patients lead to an increasing risk of patient safety incidents (PSIs) in both inpatient and ambulatory care. A PSI is defined as an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.[2]

Both internationally and in Germany, knowledge about the frequency of PSIs is limited. Regarding only inpatient care and based on a literature review by the German Coalition for Patient Safety, the German Advisory Council on the Assessment of Developments in the Health Care Sector estimated in 2007 that 5-10% of all hospital patients experience an adverse event (AE), 2-4% a preventable AE, 1% experience treatment errors and 0.1% die from preventable AEs.[3] For the German ambulatory care sector, there is hardly any data on the frequency of PSIs. But even the few international studies allow only rough estimates. From the Netherlands, Gaal *et al*[4] report a PSI rate of 21.1% based on a retrospective analysis of medical records kept by primary care physicians; 5.8% of the PSIs resulted in harm and 0.7% led to hospital stays. Stocks *et al*[5] collected PSIs through personal interviews of a representative sample of ≥15-year-olds in Great Britain; the PSI rate within the last 12 months was 7.9%. Michel *et al*[6] encouraged GPs in France to record all PSIs occurring within one week, and concluded that the PSI rate was 2.6% of all consultations. In a first review, Sandars & Esmail[7] estimated the PSI rate in primary care at 5-80 PSIs per 100,000 consultations. In a recent literature review, Panesar *et al*[8] concluded that 1-24 PSIs occur per 100 consultations, of which 4% (range 1-44%) are associated with severe harm.

One reason for this inconclusive evidence could be the process of recording PSIs in ambulatory care, because the methods tested in inpatient care, such as the analysis of medical records, routine and/or harm data, CIRS and direct observation reach their limits. First, patients leave the practice immediately after ambulatory treatment, leaving only a short time window for PSI capture, and second, routine ambulatory care data contain too little information for PSI discovery. The website "Every error counts", which collects PSIs in the German GP sector, illustrates the dilemma of spontaneous PSI reporting in ambulatory care: By mid-2019, i.e. during 15 years since the existence of the register, the approximately 55,000 German GPs

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3 106 had reported a total of 948 PSIs.[9] For this reason, it is internationally recommended to include
4 107 patients themselves as sources of information for PSI recording.[10-13] Only patients are able
5 108 to report on the effects of treatments across sectors and over long periods of time; their
6 109 information on incidents is usually more accurate than those of physicians,[14] who also show
7 110 more resentment towards PSI reporting.[15]
8 111 Against this background, our study aims to report on the frequency, type, severity and point of
9 112 origin of PSIs in the ambulatory healthcare sector in Germany based on a population survey.
10 113

11 114 **METHOD**

12 115 **Study design**

13 116 This retrospective cross-sectional study is based on original telephone survey data on
14 117 experiences with PSIs within the last 12 months from the patient's perspective.
15 118

16 119 **Participants**

17 120 For economic reasons, the survey is limited to the population aged ≥ 40 years in Germany
18 121 (2017: 22.5 million men and 24.7 million women; 57% of the total population), since more
19 122 physician visits and thus potentially more PSIs are expected for ≥ 40 -year-olds than in the total
20 123 population. The number of physician visits in this population can only be estimated. According
21 124 to the National Association of Statutory Health Insurance Physicians survey of insured
22 125 persons, every citizen visited a doctor about 6 times in 2017.[16] However, following the figures
23 126 of the 2007 expert report of the German Advisory Council on the Assessment of Developments
24 127 in the Health Care Sector, every citizen has 17 doctor visits per year.[3] Taking these diverging
25 128 data into account, the study expects an average of 10-20 visits to the doctor per citizen ≥ 40
26 129 years per year.

27 130 From the population aged ≥ 40 years, a sample of 10,037 citizens was interviewed via
28 131 computer-assisted telephone interviews (CATI). This number was based on a sample size
29 132 calculation of 10,000 interviews, with which a two-sided 95% confidence interval of one
30 133 percentage point can be secured with an estimated incidence of 7.5%. The realized sample
31 134 was based on a random sample of nationwide listed and permuted landline and mobile phone
32 135 numbers (70:30 distribution). The target person in multi-person households was the adult with
33 136 the last birthday. About 81,000 of the almost 700,000 telephone numbers generated were
34 137 identified as belonging to the target group; of these, about 65,000 were interviewed during field
35 138 time. 84.4% refused to participate. Only a few interviews were discontinued (150) or not
36 139 evaluable (5), thus a participation rate of 12.4% was achieved (10,037/81,108). The
37 140 participants in the sample corresponded largely to the population as a whole. In order to be
38 141 able to make reliable representative statements, the sample results were also extrapolated to
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the total population using the weighting variables gender, age group, household size, school education, employment status, nationality, federal state and municipal size classes.

Patient and Public Involvement

Due to the absence of a validated CATI survey instrument, a new questionnaire was developed for the study by means of a literature review on types of errors in ambulatory care and qualitative interviews with physicians (N=10) and patients (N=20) on their experiences with PSIs.

Survey instrument and implementation

The survey instrument captures PSI experiences within the last 12 months, PSIs; since the 40th birthday, and severe PSIs of relatives through proxy-interviews. The study reported here targets patients' PSI experiences in the last 12 months. The CATI-instrument consists of three modules (see box): a) introductory questions on the current state of health and the last GP and specialist visit in the last 12 months. If a physician visit had taken place a short information text briefly explained the type of errors the survey was about. In module b) individual PSI types were queried in seven medical treatment areas, whereby multiple answers were possible for each case: each person was allowed to report several PSI types if one or several physician visits had taken place in several treatment areas. For each PSI reported, detailed questions were asked about the specialist group concerned and on the most serious harm, the severity of the harm and its consequences. In order to minimise cognitive stress and to avoid memory bias, complex filters were used in such a way that the interviewees were just asked the questions relevant to them in a targeted manner. In module c) socio-demographic data were also collected.

Box Categories and items of the survey instrument

(a) Introductory questions

- Current health status
- Chronic illnesses
- Last general practitioner/specialist visit

Short Information text

Where people work, errors occur. Errors can also occur in medical offices. This can happen during treatment, but also during laboratory tests or when writing prescriptions. In the following, we introduce you to specific errors that can occur in the practices of general practitioners and specialists in Germany. So it is not about errors that occur in the hospital. In each case, In any case, I will ask you whether, according to your knowledge or assessment, you have found such an error in your general practitioner or specialist. Please also think of errors that you learned about later.

(b) 12-month incidence of PSIs in 7 areas of medical treatment

- Anamnesis/physical examination
- Medication
- Vaccination, injection, infusion
- Aftercare
- Outpatient surgery
- Office administration
- Other areas

Detailed questions per reported PSI:

- Treatment area (just anamnesis/physical examination and outpatient surgery)
- Frequency
- Presumed causes
- Specialist group concerned
- Type of harm
- Severity (of the most severe harm)
- Recovery time (of the most severe harm)
- Additional treatments
- Hospital nights
- Dealing/response behaviour

(c) Socio-demographic Data

- Sex
- Citizenship
- Highest school-leaving qualification
- Current main occupation
- Self-reported social status
- Household size
- Monthly net income

The questionnaire was checked by means of cognitive pre-tests on 20 patients with regard to the comprehensibility of the questionnaire items, completeness of the response categories and memorability of the events experienced. Methodically, think-aloud and interview techniques were combined (17). Necessary changes were implemented and subsequently tested using standardized pre-tests (N = 110) under field conditions. Misleading question formulations, optimization possibilities in the filtering or the question blocks were discovered, modified in the electronic questionnaire and released for the main field after final testing. The survey took place from May to October 2018.

Analysis

12-month PSI incidences including 95% confidence intervals (CI) are reported in terms of frequencies and distributions of ambulatory PSI types. The data refer either to the weighted participants or to their reported PSIs. In addition, the incidences are extrapolated to the population of all persons ≥40 years in Germany, with each participant representing an average

of 4,700 citizens. The analyses were carried out with SPSS version 25 and cross-checked with the statistics package R version 3.5.2 (Base Package).

RESULTS

Participants

The survey participants (N=10,037; 12.4% participation rate) were 61 years old on average, and 52% were women. 73% assessed their current state of health as (very) good to mediocre; 47% stated that they had at least one long-lasting chronic disease at the time of the survey. 8841 of the 10,037 participants (88%) experienced at least one ambulatory GP or specialist visit within the past 12 months.

Incidence and medical treatment areas affected by PSIs

The weighted sample comprises 8,776 patients with an ambulatory GP or specialist visit, of whom 1,422 (16%) experienced at least one PSI in the last 12 months. They reported a total of 2,589 PSIs, i.e. an average of 1.8 PSIs per participant. In relation to the total sample, 14.2% experienced at least one PSI (1,422/10,037). The most common areas affected by PSI were anamnesis/clinical examination (66% of patients, 61% of PSIs) and medication (22% of patients, 15% of PSIs). Table 1 shows the distribution of PSIs in all treatment areas including 95% CIs.

Table 1 Patients affected by PSI and distribution of PSI by treatment areas and extrapolation to the total population ≥40 years.

Treatment areas	Patients			PSI			PSI in population ≥40 years***
	n*	%	95%-CI	n	%	95%-CI	N
Anamnesis/physical examination	938	66.0	63.5 to 68.4	1,583	61.1	59.3 to 63	7,441,971
Medication	316	22.3	20.1 to 24.4	398	15.4	14 to 16.8	1,869,245
Vaccination, injection, infusion	100	7.0	5.8 to 8.4	112	4.3	3.6 to 5.2	527,089
Aftercare	53	3.7	2.8 to 4.8	65	2.5	2 to 3.2	304,567
Outpatient surgery	41	2.9	2.1 to 3.9	61	2.4	1.8 to 3	287,828
Office administration	208	14.6	12.9 to 16.5	254	9.8	8.7 to 11	1,196,407
Other areas	116	8.1	6.8 to 9.7	116	4.5	3.7 to 5.3	545,177
Sum	(1,422**)			2,589	100.0%		12,172,286

*Multiple answers possible; sample: 8.776 weighted patients ≥40 years with a doctor's visit within the last 12 months.

**Individual patients, some affected by several PSIs.

***PSI number projected to the population of ≥40-year-olds in Germany in 2017 (47.2 million).

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204 Extrapolated to the total population of all patients ≥40 years in Germany, an estimated 6.7
205 million patients (14.2% of 47.2 million) per year experience a total of 12.2 million PSIs (**table**
206 **1**). Based on an average of 10-20 ambulatory doctor visits per year per patient aged ≥40 years,
207 1.3-2.6% of these visits are associated with a PSI.

208
209 **PSI types**

210 **Table 2** shows the distribution of the specifically surveyed PSI types per treatment area. In the
211 two areas most frequently affected by PSIs (anamnesis/physical examination and medication),
212 the most frequent PSI types are distributed as follows: 35% of all PSIs or 57% of PSIs in the
213 field of anamnesis/physical examination (N=1,583) are attributable to "important questions
214 about complaints not asked" as well as "insufficient physical examination". In the area of
215 medication (N=398, 6.2% of all PSIs), 20.8% of medication-related PSIs were due to "wrongly
216 prescribed drugs" and "prescribed without considering the interaction with another drug"
217 (19.7%).

218
219 **Distribution of PSIs between specialist groups**

220 Of 2,521 reported, clearly assignable PSIs, about 44% occurred among general practitioners,
221 15% among orthopaedists and 10% among internists. The other specialist groups received up
222 to 5% of the PSI entries (supplementary **table 1**).

223
224 **Types of harm, severity and time to recover**

225 1,935 (74.7%) of 2,589 PSIs were associated with harm to the patient (**table 3**). A total of 5,656
226 harms were reported, i.e. an average of 3 harms per PSI. Two thirds were described as harm
227 to health, one third as financial/temporal/other harm. Due to the possibility of giving multiple
228 answers, about 82% of PSIs were associated with at least one harm to health, 71% had at
229 least one financial, temporal or other harm. Among the harms to health, "unnecessarily
230 prolonged pain" was most frequently mentioned in 16.5% of all PSI harms and "deterioration
231 of the state of health" in 16.1% of all PSI harms.
232 Of the 1,935 PSIs with at least one harm, 55.8% were rated as (very) severe. 35.3% of PSIs
233 led to "permanent harm" or required "more than one month" of recovery (24.1%). 804 PSIs
234 (31.5%) prompted patients to see another doctor for additional treatment; 255 PSIs (10%)
235 required inpatient treatment overnight, with 2.4% requiring an inpatient stay of more than 2
236 weeks (**table 4**). The extrapolation of hospital stays to the total population of ≥40-year-olds
237 shows 1.2 million inpatient stays per year.

Table 2 Distribution of PSIs (N = 2,589) among specific PSI types in ambulatory care

PSI types per treatment area		PSI (n)	PSI (%)	95%-CI
Anamnesis/physical examination	Important questions about complaints not asked	515	19.9	18.4 to 21.5
	Insufficient physical examination	381	14.7	13.4 to 16.1
	Medically necessary examination not made	157	6.1	5.2 to 7.0
	Results communicated too late / not at all	136	5.3	4.4 to 6.2
	Wrong diagnosis	128	4.9	4.2 to 5.8
	Serious illness not recognized or recognized too late	97	3.8	3.1 to 4.5
	Faulty examination	69	2.7	2.1 to 3.3
	Incorrect test result communicated	54	2.1	1.6 to 2.7
	Wrong examination	46	1.8	1.3 to 2.3
Medication	Wrongly prescribed drugs	83	3.2	2.6 to 3.9
	Prescribed without considering the interaction with another drug	78	3.0	2.4 to 3.7
	Necessary drugs not prescribed	72	2.8	2.2 to 3.5
	Prescribed in the wrong dose / form	65	2.5	2.0 to 3.2
	Prescribed, although the doctor knew of an intolerance	54	2.1	1.6 to 2.7
	Discontinued too early / too late / not at all	46	1.8	1.3 to 2.3
Vaccination, injection, infusion	Administered without noticing the interaction with another medication	42	1.6	1.2 to 2.2
	Administered in the wrong place	23	0.9	0.6 to 1.3
	Not administered, although necessary	20	0.8	0.5 to 1.2
	Administered with a wrong active substance	19	0.7	0.5 to 1.1
	Administered, even though the doctor knew of an intolerance	8	0.3	0.1 to 0.6
Aftercare	Not at all	34	1.3	0.9 to 1.8
	Belated	28	1.1	0.7 to 1.5
	Wrong	4	0.1	0.1 to 0.4
Outpatient surgery	Not done properly	44	1.7	1.3 to 2.3
	Performed too late	9	0.4	0.2 to 0.7
	Result of surgery not communicated / communicated too late	4	0.2	0.1 to 0.4
	Result of surgery communicated incorrectly	2	0.1	0.0 to 0.3
	Wrong surgery	1	0.0	0.0 to 0.2
Office administration	Examination results not / not completely available	152	5.9	5.0 to 6.8
	Confused with another patient	73	2.8	2.2 to 3.5
	Home visit not performed	29	1.1	0.8 to 1.6
Other areas	Other PSI	116	4.5	3.7 to 5.3

Table 3 Distribution of PSI with harm and harm types

PSI with harmful consequences		PSI (n)	PSI (%)	95%-CI
Harm / no harm	PSI without harm	621	24.0	22.4 to 25.7
	PSI with at least one harm	1,935	74.7	73 to 76.4
	Refused to answer	18	0.7	0.4 to 1.1
	Don't know	15	0.6	0.3 to 0.9
Types of harm	Unnecessarily prolonged pain	934	16.5	15.6 to 17.5
	Deterioration of the health status	909	16.1	15.1 to 17.1
	Mental / social harm	619	10.9	9.2 to 11.8
	Serious illness not recognized / recognized too late	306	5.4	4.9 to 5.7
	Other part of the body injured	228	4.0	3.4 to 4.6
	Wound infection / inflammation	223	3.9	3.3 to 4.5
	Mild allergic reaction	218	3.9	3.4 to 4.4
	Other side effects	139	2.5	2.1 to 2.9
	Bleeding	117	2.1	1.7 to 2.5
	Severe allergic reaction	65	1.1	0.9 to 1.5
	Total reported harms to health	3,758	66.4	65.2 to 67.7
	PSI with ≥1 harm to health	1,584	81.9	80.1 to 83.5
	Temporal harm	1,164	20.6	16.2 to 21.7
	Financial harm	393	6.9	6.3 to 7.1
	Other harm	341	6.0	5.4 to 6.7
	Total reported financial, temporal and other harms	1,898	33.6	32.3 to 34.8
	PSI with ≥1 financial, temporal, other harm	1,378	71.2	69.2 to 73.2

Among the 2,589 PSIs recorded, the PSI type "important questions not asked about complaints" (a) was the most frequent with 515 (19.9%) responses, followed by "inadequate physical examination" (b) with 381 responses (14.7%) (table 2). A sub analysis revealed 136 (a) and 107 (b) cases, in which participants had only experienced this one PSI type once in the last 12 months. 100 (a) and 70 (b) of these patients reported harmful consequences. These resulted in a deterioration of health status or persistent pain in 90 (a) / 72 (b) cases, were (very) severe in 55 (a) / 23 (b) cases, permanent in 34 (a) / 24 (b) cases, and resulted in 12 (a) / 11 (b) hospital stays (supplementary tables 2 and 3).

Table 4 Differentiation of severity, recovery time and additional treatments of the severest harm per patient with at least one PSI

Differentiation of the 'severest' harm (N = 1,935)		n	%	95%-CI
Severity	Very light	139	7.2	6.1 to 8.4
	Light	689	35.6	33.5 to 37.8
	Severe	794	41.0	38.9 to 43.2
	Very severe	287	14.8	13.3 to 16.5
	Don't know	25	1.3	0.9 to 1.9
	Refused to answer	1	0.1	0.0 to 0.2
Recovery period	Less than a week	294	16.9	15.2 to 18.7
	More than a week, but less than a month	347	19.9	18.1 to 21.9
	More than a month	419	24.1	22.1 to 26.1
	Permanent harm	615	35.3	33.1 to 37.6
	Don't know	37	2.1	1.5 to 2.9
	Not applicable	28	1.6	1.1 to 2.3
Additional treatment*	Went to see another doctor	804	31.5	29.7 to 33.3
	Medical on-call service / emergency service	126	4.9	4.2 to 5.8
	Emergency room	227	8.9	7.9 to 10.1
	Inpatient treatment (overnight)	255	10.0	7.8 to 10.0
	<i>Up to one week</i>	98	3.8	3.2 to 4.7
	<i>Between one and two weeks</i>	96	3.8	3.1 to 4.6
	<i>Two week and more</i>	60	2.4	1.8 to 3.0
	<i>Don't know</i>	1	0.0	0.0 to 0.2
	Rehabilitation	206	8.1	7.1 to 9.2
	None of it	927	36.3	34.5 to 38.2
	Don't know	4	0.2	0.1 to 0.4
	Refused to answer	2	0.1	0.0 to 0.3

*Multiple answers possible for additional treatments.

DISCUSSION

Please also think of mistakes that you learned about later, for example from another doctor. For the very first time, our study reports the frequency, types and consequences of patient safety incidents (PSIs) in the ambulatory care sector in Germany, as measured by a representative sample of ≥40-year-olds. It thus provides an important starting point for PSI prevention measures and improving patient safety. Within the last 12 months, 1,422 out of 10,037 respondents (14% of the population and 16% of those with a doctor's visit, respectively) had experienced a total of 2,589 PSIs. Extrapolated to the total population at risk in Germany (47.2 million ≥40 years), 12.2 million PSIs must be expected for 6.7 million patients ≥40 years per year. Based on an average of 10-20 ambulatory doctor visits per year in this age group,

1.3-2.6% of these visits are associated with a PSI. According to patient reports, around 1.2 of the current 19.4 million inpatient cases (6.2%) per year in Germany are due to PSIs in ambulatory care, which is experienced by patients ≥ 40 years alone. With an average case value of 3,457 € in 2018, these hospital stays cost around 4.15 billion €/year. As a matter of priority, the harm to patients resulting from PSIs must be avoided; additionally, the prevention of PSIs in ambulatory care would also be of huge economic importance.

According to our study, the PSI rate in Germany is in the lower range of the range of 1-24 PSIs per 100 consultations reported by Panesar *et al.*[8] undercuts the PSI rate of 21%[4] from the Netherlands, which was collected in a review of medical records, but is higher than the PSI rate of 7.9%[5] for ≥ 15 -year-olds in Great Britain. Different recording methods, age groups and health care systems (e.g. primary care systems without specialised physicians in private practices as is the case with Germany) must be considered, which makes international comparison difficult.

Considering only those PSIs associated with harm to health, the proportion of people who have experienced at least one harm to health in the past year due to a PSI in ambulatory care is 10% (889 out of 8,776 participants visiting a doctor, data not reported here) and thus comparable to the upper estimate range of the inpatient sector, in which 5-10% of cases experience an adverse event.[3]

With regard to the medical treatment areas most frequently affected by PSIs, it can be stated that the most frequent ambulatory diagnostic and therapeutic activities (anamnesis/physical examination, medication) are associated with most PSIs. Particularly medication is also repeatedly highlighted internationally as a frequent source of PSIs with harmful consequences in ambulatory care.[8] Similarly, more PSIs occur in specialties with a higher number of visits (general practitioners and internists), with the exception of orthopaedists, who account for 14.5% of all PSIs, although they account for only 5% of all physicians in the ambulatory care sector in Germany. This phenomenon is also known from inpatient and ambulatory malpractice statistics.[18] An astonishing result of our study is that patients most frequently name PSI types that doctors think are hardly likely to cause harm and sometimes doubt that patients are able to assess them correctly. This applies in particular to the most common PSI types from the area of anamnesis/physical examination, namely, "important questions not asked about the complaints" and "insufficient physical examination", which together make up 35% of all PSI types. A possible explanation for this finding could be that many patients claim to have visited another doctor (31.5%) or even a hospital (10.0%) later and that during this visits it was explained that a certain question should have been asked or an examination carried out at the first contact. In addition, the sub-analyses prove that even these supposedly harmless PSIs were the cause of permanent harm in about one third of the cases from the perspective of

those patients who had only reported this type of PSI, and projectedly led to 113,000 hospital stays.

Strengths and limitations of the study

The main strength of the study is the first-time survey of PSI frequencies and distribution on a representative, extensive population sample, so that a high degree of certainty in PSI incidence estimates is achieved. A further strength relies in the structure of the instrument to minimize both, the burden for the interviewee as well as the risk of memory bias, as PSIs of the last 12 months should be reported, a period that is also used in the PREOS-PC survey [19]. The short introductory information text points out that the interview focusses on “errors” that the participants themselves have experienced and perceived in the last 12 months as well as on those “errors” they learned about later. Furthermore, complex filter guides were used in such a way that the target person was only asked the questions relevant to them. By this, both, the increased burden as well as the risk of memory bias were systematically reduced - however, as in other studies,[20] they cannot be avoided completely.

Limitations exist with regard to the interview participation rate of 12.4%, which is in the lower range of the rates in telephone surveys in Germany. However, decisive aspects suggest that there is no significant selection bias and that the results can be generalized to the population of ≥40-year-olds: The sample was randomly selected in the field and selectivity analyses show, this alone achieved a good overall representation of the population with only minor deviations. The survey participants represent the target population in all major variables, thus a selection bias towards persons with potentially higher PSI risk (e.g. high utilizers, multimorbidity) is unlikely. The proportion of women in the study corresponds to the population statistics; as in the study, 51.2% of ≥40-year-olds in Germany describe themselves as chronically ill[21] and, as in the study, 88% of the total population had at least one ambulatory doctor visit in the last 12 months.[22] In addition, the results were weighted and extrapolated.

A main limitation may be seen in the research method used to generate data on PSI frequency and distribution in ambulatory care. Critics may question whether asking patients is suitable for generating valid statements about PSI frequency and distribution at all. The method deliberately considers only the patient’s perspective. We did not intend a medical objectification of the reported PSIs.

This objection can be counted as follows. First, there is an international demand to follow exactly this path, since patients are considered to be a valuable and often the only source for PSI data collection.[10-14] Weingart et al impressively showed in their study that only about half of the PSI reported by inpatients and validated by physicians were documented in the medical records. None of them were documented in the error reporting system.[23] Additionally, physicians often have resentments towards PSI reporting.[15] Second, the PSI

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types most frequently reported by patients in our study are consistent with studies that have recorded the occurrence of these types in both outpatient physicians and patients[22, 24-26]. Thirdly, the increasing number of written safety instructions for patients strengthens the perception and expectations of patients by providing information and guidelines for a good and safe visit to hospitals or outpatient physicians. Fourthly, the Thomas theorem known from sociology should be taken into account, which states that subjective situation determinations, regardless of whether they stand up to an objective investigation, have real consequences.[29] Kenneth Poole, Head of the Patient Experience Department at the Mayo Clinic in Phoenix, Arizona, recently put it this way: "Keep in mind these data are reflective of patients' perception of their care; whether or not we, as medical providers, agree, that perception is legitimate."[30] In view of the well-known lack of PSI reporting methods, the increasing demand for patient empowerment and the consideration of patients' subjective perceptions and evaluations, patient reports on PSI they have experienced must be taken seriously as a valuable source for analysing PSI epidemiology and as a basis for constructive discussion on improving patient safety in ambulatory health care.

Conclusions

In the ambulatory care sector in Germany, patient reported patient safety incidents (PSI) experienced occur frequently. In many cases, these lead to harm to health and additional ambulatory and inpatient treatments. The analysis of PSIs can help to develop starting points for their prevention and to improve patient safety. There is an urgent need to raise awareness of the issue of patient safety and participation in reporting and learning systems (CIRS) in ambulatory care.

Contributors All authors had full access to all of the data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study guarantor: MG, dC. Study concept and design: MG, SK, JL, dC. Analysis and interpretation of data: MG, SK, MS, AO, JL, dC. Drafting of the manuscript: MG, SK. Critical revision of the manuscript for important intellectual content: all authors. Statistical analysis: SK, MS. Study supervision: MG.

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Competing Interests

The authors declare that there is no conflict of interest.

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supplementaryTable 1 Distribution of PSI by specialist group

Medical specialist group	PSI (n)*	PSI (%)	95%-CI
Family physicians	1,101	43.7	41.8 to 45.6
Orthopaedists	367	14.5	13.2 to 16.0
Internist	259	10.3	9.1 to 11.5
Neurologists	129	5.1	4.3 to 6.0
Surgeons	95	3.8	3.1 to 4.6
Gynaecologists	76	3.0	2.4 to 3.7
Urologists	71	2.8	2.2 to 3.5
Radiologists	60	2.4	1.8 to 3.0
ENT specialists	50	2.0	1.5 to 2.6
Dermatologists	42	1.7	1.2 to 2.2
Ophthalmologists	35	1.4	1.0 to 1.9
Other specialists	236	9.4	8.2 to 10.5

*A total of 2,589 PSIs was reported. 2,521 PSIs were clearly assignable to specialist groups.

supplementaryTable 2 Sub-analysis of the PSI 'important questions not asked about complaints': Proportion of PSI with harm, distribution of harm types, and differentiation of severity, recovery time and additional treatments

PSI 'important questions not asked about complaints'		n	%	95%-CI
Persons with this PSI type exclusively *		136	1.5	1.3 to 1.8
Harm and its consequences		n	%	95%-CI
Harm / no harm	PSI without harm	36	26.5	19.8 to 34.5
	PSI with at least one harm	100	73.5	65.5 to 80.2
Types of harm	Unnecessarily prolonged pain	49	26.8	20.9 to 33.6
	Deterioration of health status	41	22.4	17.0 to 29.0
	Mental / social harm	32	17.5	12.7 to 23.6
	Serious illness not recognized / recognized too late	19	10.4	6.7 to 15.6
	Other part of the body injured	8	4.4	2.2 to 8.4
	Other side effects	8	4.4	2.2 to 8.4
	Mild allergic reaction	6	3.3	1.5 to 7.0
	Severe allergic reaction	3	1.6	0.6 to 4.7
	Bleeding	2	1.1	0.3 to 3.9
	<i>Total reported harm to health</i>	180	98.4	95.3 to 99.4
	Temporal harm	60	32.8	26.4 to 39.9
	Other harm	25	13.7	9.4 to 19.4
	Financial harm	18	9.8	6.3 to 15.0
	<i>Total reported financial, temporal and other harm</i>	103	56.3	49.0 to 63.3
Severity	Very light	6	6.0	2.8 to 12.5
	Light	38	38.0	29.1 to 47.8
	Severe	36	36.0	27.3 to 45.8
	Very severe	19	19.0	12.5 to 27.8
Recovery period	Less than a week	12	14.1	8.3 to 23.1
	More than a week, but less than a month	22	25.9	17.8 to 36.1
	More than a month	14	16.5	10.1 to 25.8
	Permanent harm	34	40.0	30.2 to 50.6
	Don't know	3	3.5	1.2 to 9.9
Additional treatment	None of this	46	46.0	36.6 to 55.7
	Went to see another doctor	44	44.0	34.7 to 53.8
	Medical on-call service / emergency service	7	7.0	3.4 to 13.7
	Emergency room	13	13.0	7.8 to 21.0
	Inpatient treatment (overnight)	12	12.0	7.0 to 19.8
	<i>Up to one week</i>	5	5.0	2.2 to 11.2
	<i>Between one and two weeks</i>	1	1.0	0.2 to 5.4
	<i>Two weeks and more</i>	6	6.0	2.8 to 12.5
	Rehabilitation	7	7.0	3.4 to 13.7

supplementaryTable 3 Sub-analysis of the PSI 'inadequate physical examination': Proportion of PSI with harm, distribution of harm types and differentiation of severity, recovery time and additional treatments

PSI 'inadequate physical examination'		n	%	95%-CI
Persons with this PSI-type exclusively *		107	1.2	1.0 to 1.5
Harm and its consequences		n	%	95%-CI
Harm / no harm	PSI without harm	37	34.6	26.2 to 44.0
	PSI with at least one harm	70	65.4	56.0 to 73.8
Types of harm	Unnecessarily prolonged pain	38	21.8	16.3 to 28.6
	Deterioration of health status	23	13.2	9.0 to 19.1
	Mental / social harm	15	8.6	5.3 to 13.7
	Serious illness not recognized / recognized too late	14	8	4.9 to 13.1
	Mild allergic reaction	12	6.9	4.0 to 11.7
	Other part of the body injured	7	4	2.0 to 8.1
	Wound infection / inflammation	6	3.4	1.6 to 7.3
	<i>Total reported harm to health</i>	115	66.1	58.8 to 72.7
	Temporal harm	37	21.3	15.8 to 27.9
	Financial harm	12	6.9	4.0 to 11.7
	Other harm	10	5.7	3.2 to 10.3
	<i>Total reported financial. temporal and other harm</i>	59	33.9	27.3 to 41.2
Severity	Very light	7	10	4.9 to 19.2
	Light	40	57.1	45.5 to 68.1
	Severe	16	22.9	14.6 to 34.0
	Very severe	7	10	4.9 to 19.2
Recovery period	Less than a week	15	23.4	14.7 to 35.1
	More than a week, but less than a month	13	20.3	12.3 to 31.7
	More than a month	10	15.6	8.7 to 26.4
	Permanent harm	24	37.5	26.7 to 49.7
	Not applicable	3	4.7	1.6 to 12.9
	Don't know	1	1.6	0.3 to 8.3
Additional treatment	None of this	34	48.6	37.2 to 60.0
	Went to see another doctor	30	42.9	31.9 to 54.5
	Medical on-call service / emergency service	3	4.3	1.5 to 11.9
	Emergency room	10	14.3	7.9 to 24.3
	Inpatient treatment (overnight)	11	15.7	9.0 to 26.0
	<i>Up to one week</i>	3	4.3	1.5 to 11.9
	<i>Between one and two weeks</i>	8	11.4	5.9 to 21.0
	Rehabilitation	2	2.9	0.8 to 9.8

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Patient safety in ambulatory care from the patient's perspective - A retrospective, representative telephone survey

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Patient safety in ambulatory care from the patient's perspective - A retrospective, representative telephone survey

ABSTRACT

Objectives: Data on patient safety problems (PSPs) in ambulatory care are scarce. The aim of the study was to record the frequency, type, severity and point of origin of PSPs in ambulatory care in Germany.

Design: Retrospective cross-sectional study.

Setting: Computer-assisted telephone interviews (CATI) with randomly recruited citizens aged ≥ 40 years in Germany who were asked about their experiences with PSPs in ambulatory care.

Participants: 10.037 citizens ≥ 40 years.

Measures: A new questionnaire was developed to record patient experiences with PSPs in ambulatory care. The study reported here targets patient experiences in the last 12 months. The questionnaire focuses PSPs in 7 areas of medical treatment: anamnesis/physical examination; medication; vaccination, injection, infusion; aftercare; outpatient surgery; office administration; other areas. For each PSP reported, detailed questions were asked about the specialist group concerned and on the most serious harm, the severity of the harm and its consequences. The target parameters are presented as proportions with 95% confidence intervals.

Results: 1,422 of the respondents (14%) reported 2,589 PSPs. The areas most frequently affected by PSPs were anamnesis/physical examination (61%) and medication (15%). General practitioners accounted for 44% of PSPs, orthopaedists for 15% and internists for 10%. 75% of PSPs were associated with harm, especially unnecessarily long pain or deterioration of health; 35% of PSPs led to permanent damage. 804 PSPs (32%) prompted patients to see another doctor for additional treatment; 255 PSPs (10%) required inpatient treatment.

Conclusion: PSPs experienced by patients are common in ambulatory care in Germany. The study reveals in which areas of medical treatment efforts to prevent PSPs could make the greatest contribution to improving patient safety. It also demonstrates the valuable contribution of patient reports to the analysis of PSPs.

Strengths and limitations of this study

- For the very first time, data were collected on the frequency, type, severity and consequences of patient safety problems (PSPs) in ambulatory care in Germany.
- The randomly selected, extensive population sample of 10.037 citizens ≥ 40 years guarantees a high degree of certainty in the PSP incidence estimates.
- The study provides insights into which PSPs are most likely to cause harm, thus providing a good indication of where the focus of efforts to improve patient safety should be.

- Patient reports as a research method for generating data on PSPs without cross-checking with comparative data (e.g. medical records) do not allow medical objectification of the reported PSPs.

INTRODUCTION

Patient safety, as a key feature of quality healthcare,[1] is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.[2] Healthcare's growing complexity and an increasing number of multimorbid patients lead to an increasing risk of patient safety problems (PSPs) in both inpatient and ambulatory care. Below we use the term PSP to capture both errors, i. e. failures to carry out a planned action as intended or application of an incorrect plan, and patient safety incidents (PSIs), i. e. events or circumstances that could have resulted, or did result, in unnecessary harm to a patient.[2] PSIs, on the other hand, also include adverse events (AEs), i.e. incidents which resulted in harm to a patient.[2]

Both internationally and in Germany, knowledge about the frequency of PSPs is limited. Regarding only inpatient care and based on a literature review by the German Coalition for Patient Safety, the German Advisory Council on the Assessment of Developments in the Health Care Sector estimated in 2007 that 5-10% of all hospital patients experience an adverse event (AE), 2-4% a preventable AE, 1% experience treatment errors and 0.1% die from preventable AEs.[3] For the German ambulatory care sector, there is hardly any data on the frequency of PSPs. But even the few international studies allow only rough estimates. From the Netherlands, Gaal *et al*[4] report a PSI rate of 21.1% based on a retrospective analysis of medical records kept by primary care physicians; 5.8% of the PSIs resulted in harm and 0.7% led to hospital stays. Stocks *et al*[5] collected potentially harmful preventable problems through personal interviews of a representative sample of ≥15-year-olds in Great Britain; the problem rate within the last 12 months was 7.9%. Michel *et al*[6] encouraged GPs in France to record all PSIs occurring within one week, and concluded that the PSI rate was 2.6% of all consultations. In a first review, Sandars & Esmail[7] estimated the medical error rate in primary care at 5-80 errors per 100,000 consultations. In a recent literature review, Panesar *et al*[8] concluded that 1-24 PSIs occur per 100 consultations, of which 4% (range 1-44%) are associated with severe harm.

One reason for this inconclusive evidence could be the process of recording PSPs in ambulatory care, because the methods tested in inpatient care, such as the analysis of medical records, routine and/or harm data, CIRS and direct observation reach their limits. First, patients leave the practice immediately after ambulatory treatment, leaving only a short time window for PSP capture, and second, routine ambulatory care data contain too little information for PSP discovery. The website "Every error counts", which collects errors in the German GP sector, illustrates the dilemma of spontaneous PSP reporting in ambulatory care: By mid-2019,

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i.e. during 15 years since the existence of the register, the approximately 55,000 German GPs had reported a total of 948 errors.[9] For this reason, it is internationally recommended to include patients themselves as sources of information for PSP recording.[10-13] Only patients are able to report on the effects of treatments across sectors and over long periods of time; their information on incidents is usually more accurate than those of physicians,[14] who also show more resentment towards PSP reporting.[15] Against this background, our study aims to report on the frequency, type, severity and point of origin of PSPs in the ambulatory healthcare sector in Germany based on a population survey.

METHODS

Study design

This retrospective cross-sectional study is based on original telephone survey data on experiences with PSPs within the last 12 months from the patient’s perspective. We followed the STROBE checklist for reporting observational studies (see online supplementary file 1).[16]

Participants

For economic reasons, the survey was limited to the population aged ≥40 years in Germany (2017: 22.5 million men and 24.7 million women; 57% of the total population), since more physician visits and thus potentially more PSPs are expected for ≥40-year-olds than in the total population. From the population aged ≥40 years, a sample of 10,037 citizens was interviewed via computer-assisted telephone interviews (CATI). This number was based on a sample size calculation of 10,000 interviews, with which a two-sided 95% confidence interval of one percentage point can be secured with an estimated incidence of 7.5%. The realized sample was based on a random sample of nationwide listed and permuted landline and mobile phone numbers (70:30 distribution). The target person in multi-person households was the adult with the last birthday. About 81,000 of the almost 700,000 telephone numbers generated were identified as belonging to the target group; of these, about 65,000 were interviewed during field time. 84.4% refused to participate. Only a few interviews were discontinued (150) or not evaluable (5), thus a participation rate of 12.4% was achieved (10,037/81,108). The participants in the sample corresponded largely to the population as a whole. In order to be able to make reliable representative statements, the sample results were weighted using the variables gender, age group, household size, school education, employment status, nationality, federal state and municipal size classes.

Survey instrument and implementation

Due to the absence of a validated CATI survey instrument, a new questionnaire was developed for the study by means of a literature review on types of PSPs in ambulatory care and qualitative interviews with physicians (N=10) and patients (N=20) on their experiences with PSPs. The survey instrument captures PSP experiences within the last 12 months, PSPs since the 40th birthday, and severe PSPs of relatives through proxy-interviews using closed questions and dichotomous answers. The study reported here targets patients' PSP experiences in the last 12 months. The CATI-instrument consists of three modules relating to the last 12 months (see [box](#) and [supplementary file 1](#)): (A) introductory questions on the current state of health and whether the last visit to a GP or specialist took place within the last 12 months. If a physician visit had taken place a short information text briefly explained the type of PSPs the survey was about. In module (B) individual PSP types were queried in 7 medical treatment areas, whereby multiple answers were possible for each case: each person was allowed to report several PSP types if one or several physician visits had taken place in several treatment areas. For each PSP reported, detailed questions were asked about the specialist group concerned and on the most serious harm, the severity of the harm and its consequences. In order to minimise both, cognitive stress and memory bias, complex filters were used in such a way that the interviewees were just asked the questions relevant to them in a targeted manner. Module (C) collected socio-demographic and socio-economic data.

The questionnaire was checked by means of cognitive pre-tests on 20 patients with regard to the comprehensibility of the questionnaire items, completeness of the response categories and memorability of the events experienced. Methodically, think-aloud and interview techniques were combined.[17] Necessary changes were implemented and subsequently tested using standardized pre-tests (N = 110) under field conditions. Misleading question formulations, optimization possibilities in the filtering or the question blocks were discovered, modified in the electronic questionnaire and released for the main field after final testing. The survey took place from May to October 2018.

Box Categories and items of the survey instrument

(A) Introductory questions

- Current health status
- Chronic illnesses
- Last general practitioner/specialist visit

Short Information text

Where people work, errors occur. Errors can also occur in medical offices. This can happen during treatment, but also during laboratory tests or when writing prescriptions. In the following, we introduce you to specific errors that can occur in the practices of general practitioners and specialists in Germany. So it is not about errors that occur in the hospital. In each case, In any case, I will ask you whether, according to your knowledge or assessment, you have found such an error in your general practitioner or specialist. Please also think of errors that you learned about later.

(B) 12-month incidence of PSPs in 7 areas of medical treatment

- Anamnesis/physical examination
- Medication
- Vaccination, injection, infusion
- Aftercare
- Outpatient surgery
- Office administration
- Other areas

Detailed questions per reported PSP:

- Treatment area (just anamnesis/physical examination and outpatient surgery)
- Frequency
- Presumed causes
- Specialist group concerned
- Type of harm
- Severity (of the most severe harm)
- Recovery time (of the most severe harm)
- Additional treatments
- Hospital nights
- Dealing/response behaviour

(C) Socio-demographic Data

- Sex
- Citizenship
- Highest school-leaving qualification
- Current main occupation
- Self-reported social status
- Household size
- Monthly net income

Analysis

12-month PSP incidences including 95% confidence intervals (CI) are reported in terms of frequencies and distributions of ambulatory PSP types. The data refer either to the weighted

participants or to their reported PSPs. The analyses were carried out with SPSS version 25 and cross-checked with the statistics package R version 3.5.2 (Base Package).

Patient and Public Involvement

Patients were not actively involved in the development of the research question but participated in guided interviews that were conducted to generate items for the survey instrument. Patients were also involved in the study to pretest the survey instrument and finally participated as interviewees. We presented the study results at the German Coalition for Patient Safety conference 2019 where we explicitly invited patient representative as discussants.

RESULTS

Participants

The survey participants (N=10,037; 12.4% participation rate) were 61 years old on average, and 52% were women. 73% assessed their current state of health as (very) good to mediocre; 47% stated that they had at least one long-lasting chronic disease at the time of the survey. 8841 of the 10,037 participants (88%) experienced at least one ambulatory GP or specialist visit within the past 12 months. **Supplementary table 1** compares the socio-demographic and socio-economic parameters of the weighted study population with a population survey conducted as part of Germany's health monitoring 2014. The study population largely corresponds to the participants in the population survey.

Incidence and medical treatment areas affected by PSPs

The weighted sample comprises 8,776 patients with an ambulatory GP or specialist visit, of whom 1,422 (16%) experienced at least one PSP in the last 12 months. They reported a total of 2,589 PSPs, i.e. an average of 1.8 PSPs per participant. In relation to the total sample, 14.2% experienced at least one PSP (1,422/10,037). The most common areas affected by PSP were anamnesis/clinical examination (66% of patients, 61% of PSPs) and medication (22% of patients, 15% of PSPs). **Table 1** shows the distribution of PSPs in all treatment areas including 95% CIs.

Table 1 Patients affected by PSP and distribution of PSP by treatment areas.

Treatment areas	Patients			PSP		
	n*	%	95%-CI	n	%	95%-CI
Anamnesis/physical examination	938	66.0	63.5 to 68.4	1,583	61.1	59.3 to 63
Medication	316	22.3	20.1 to 24.4	398	15.4	14 to 16.8
Vaccination, injection, infusion	100	7.0	5.8 to 8.4	112	4.3	3.6 to 5.2
Aftercare	53	3.7	2.8 to 4.8	65	2.5	2 to 3.2
Outpatient surgery	41	2.9	2.1 to 3.9	61	2.4	1.8 to 3
Office administration	208	14.6	12.9 to 16.5	254	9.8	8.7 to 11
Other areas	116	8.1	6.8 to 9.7	116	4.5	3.7 to 5.3
Sum	(1,422**)			2,589	100.0	

PSP types

Table 2 shows the distribution of the specifically surveyed PSP types per treatment area. In the two areas most frequently affected by PSPs (anamnesis/physical examination and medication), the most frequent PSP types are distributed as follows: 35% of all PSPs or 57% of PSPs in the field of anamnesis/physical examination (N=1,583) are attributable to "important questions about complaints not asked" as well as "insufficient physical examination". In the area of medication (N=398, 6.2% of all PSPs), 20.8% of medication-related PSPs were due to "wrongly prescribed drugs" and "prescribed without considering the interaction with another drug" (19.7%).

Table 2 Distribution of PSPs (N = 2,589) among specific PSP types in ambulatory care

PSP types per treatment area		PSP (n)	PSP (%)	95%-CI
Anamnesis/physical examination	Important questions about complaints not asked	515	19.9	18.4 to 21.5
	Insufficient physical examination	381	14.7	13.4 to 16.1
	Medically necessary examination not made	157	6.1	5.2 to 7.0
	Results communicated too late / not at all	136	5.3	4.4 to 6.2
	Wrong diagnosis	128	4.9	4.2 to 5.8
	Serious illness not recognized or recognized too late	97	3.8	3.1 to 4.5
	Faulty examination	69	2.7	2.1 to 3.3
	Incorrect test result communicated	54	2.1	1.6 to 2.7
	Wrong examination	46	1.8	1.3 to 2.3
Medication	Wrongly prescribed drugs	83	3.2	2.6 to 3.9
	Prescribed without considering the interaction with another drug	78	3.0	2.4 to 3.7
	Necessary drugs not prescribed	72	2.8	2.2 to 3.5
	Prescribed in the wrong dose / form	65	2.5	2.0 to 3.2
	Prescribed, although the doctor knew of an intolerance	54	2.1	1.6 to 2.7
	Discontinued too early / too late / not at all	46	1.8	1.3 to 2.3
Vaccination, injection, infusion	Administered without noticing the interaction with another medication	42	1.6	1.2 to 2.2
	Administered in the wrong place	23	0.9	0.6 to 1.3
	Not administered, although necessary	20	0.8	0.5 to 1.2
	Administered with a wrong active substance	19	0.7	0.5 to 1.1
	Administered, even though the doctor knew of an intolerance	8	0.3	0.1 to 0.6
Aftercare	Not at all	34	1.3	0.9 to 1.8
	Belated	28	1.1	0.7 to 1.5
	Wrong	4	0.1	0.1 to 0.4
Outpatient surgery	Not done properly	44	1.7	1.3 to 2.3
	Performed too late	9	0.4	0.2 to 0.7
	Result of surgery not communicated / communicated too late	4	0.2	0.1 to 0.4
	Result of surgery communicated incorrectly	2	0.1	0.0 to 0.3
	Wrong surgery	1	0.0	0.0 to 0.2
Office administration	Examination results not / not completely available	152	5.9	5.0 to 6.8
	Confused with another patient	73	2.8	2.2 to 3.5
	Home visit not performed	29	1.1	0.8 to 1.6
Other areas	Other PSP	116	4.5	3.7 to 5.3

Distribution of PSPs between specialist groups

Of 2,521 reported, clearly assignable PSPs, about 44% occurred among general practitioners, 15% among orthopaedists and 10% among internists. The other specialist groups received up to 5% of the PSP entries ([supplementary table 2](#)).

Types of harm, severity and time to recover

1,935 (74.7%) of 2,589 PSPs were associated with harm to the patient ([table 3](#)). A total of 5,656 harms were reported, i.e. an average of 3 harms per PSP. Two thirds were described as harm to health, one third as financial/temporal/other harm. Due to the possibility of giving multiple answers, about 82% of PSPs were associated with at least one harm to health, 71% had at least one financial, temporal or other harm. Among the harms to health, "unnecessarily prolonged pain" was most frequently mentioned in 16.5% of all PSP harms and "deterioration of the state of health" in 16.1% of all PSP harms.

Table 3 Distribution of PSP with harm and harm types

PSP with harmful consequences		PSP (n)	PSP (%)	95%-CI
Harm / no harm	PSP without harm	621	24.0	22.4 to 25.7
	PSP with at least one harm	1,935	74.7	73 to 76.4
	Refused to answer	18	0.7	0.4 to 1.1
	Don't know	15	0.6	0.3 to 0.9
Types of harm	Unnecessarily prolonged pain	934	16.5	15.6 to 17.5
	Deterioration of the health status	909	16.1	15.1 to 17.1
	Mental / social harm	619	10.9	9.2 to 11.8
	Serious illness not recognized / recognized too late	306	5.4	4.9 to 5.7
	Other part of the body injured (e.g. an internal organ or nerve)	228	4.0	3.4 to 4.6
	Wound infection / inflammation	223	3.9	3.3 to 4.5
	Mild allergic reaction (e.g. skin rash, itching)	218	3.9	3.4 to 4.4
	Other side effects (e.g. stomach bleeding)	139	2.5	2.1 to 2.9
	Bleeding	117	2.1	1.7 to 2.5
	Severe allergic reaction	65	1.1	0.9 to 1.5
	Total reported harms to health	3,758	66.4	65.2 to 67.7
	PSP with ≥1 harm to health	1,584	81.9	80.1 to 83.5
	Temporal harm (e.g. extra waiting time, additional doctor visits)	1,164	20.6	16.2 to 21.7
	Financial harm (e.g. additional treatment costs)	393	6.9	6.3 to 7.1
	Other harm	341	6.0	5.4 to 6.7
	Total reported financial, temporal and other harms	1,898	33.6	32.3 to 34.8
	PSP with ≥1 financial, temporal, other harm	1,378	71.2	69.2 to 73.2

Of the 1,935 PSPs with at least one harm, 55.8% were rated as (very) severe. 35.3% of PSPs led to "permanent harm" or required "more than one month" of recovery (24.1%). 804 PSPs (31.5%) prompted patients to see another doctor for additional treatment; 255 PSPs (10%) required inpatient treatment overnight, with 2.4% requiring an inpatient stay of more than 2 weeks (table 4).

Table 4 Differentiation of severity, recovery time and additional treatments of the severest harm per patient with at least one PSP

Differentiation of the 'severest' harm (N = 1,935)		n	%	95%-CI
Severity	Very light	139	7.2	6.1 to 8.4
	Light	689	35.6	33.5 to 37.8
	Severe	794	41.0	38.9 to 43.2
	Very severe	287	14.8	13.3 to 16.5
	Don't know	25	1.3	0.9 to 1.9
	Refused to answer	1	0.1	0.0 to 0.2
Recovery period	Less than a week	294	16.9	15.2 to 18.7
	More than a week, but less than a month	347	19.9	18.1 to 21.9
	More than a month	419	24.1	22.1 to 26.1
	Permanent harm	615	35.3	33.1 to 37.6
	Don't know	37	2.1	1.5 to 2.9
	Not applicable	28	1.6	1.1 to 2.3
Additional treatment*	Went to see another doctor	804	31.5	29.7 to 33.3
	Medical on-call service / emergency service	126	4.9	4.2 to 5.8
	Emergency room	227	8.9	7.9 to 10.1
	Inpatient treatment (overnight)	255	10.0	7.8 to 10.0
	Up to one week	98	3.8	3.2 to 4.7
	Between one and two weeks	96	3.8	3.1 to 4.6
	Two week and more	60	2.4	1.8 to 3.0
	Don't know	1	0.0	0.0 to 0.2
	Rehabilitation	206	8.1	7.1 to 9.2
	None of it	927	36.3	34.5 to 38.2
	Don't know	4	0.2	0.1 to 0.4
	Refused to answer	2	0.1	0.0 to 0.3

*Multiple answers possible for additional treatments.

Sub analysis of the most frequent reported PSP

Among the 2,589 PSPs recorded, the PSP type "important questions not asked about complaints" (a) was the most frequent with 515 (19.9%) responses, followed by "inadequate physical examination" (b) with 381 responses (14.7%) (table 2). A sub analysis revealed 136 (a) and 107 (b) cases, in which participants had only experienced this one PSP type once in

the last 12 months. 100 (a) and 70 (b) of these patients reported harmful consequences. These resulted in a deterioration of health status or persistent pain in 90 (a) / 72 (b) cases, were (very) severe in 55 (a) / 23 (b) cases, permanent in 34 (a) / 24 (b) cases, and resulted in 12 (a) / 11 (b) hospital stays ([supplementary tables 3 and 4](#)).

DISCUSSION

For the very first time, our study reports the frequency, types and consequences of patient safety problems (PSPs) in the ambulatory care sector in Germany, as measured by a representative sample of ≥40-year-olds. It thus provides an important starting point for PSP prevention measures and improving patient safety. Within the last 12 months, 1,422 out of 10,037 respondents (14% of the population and 16% of those with a doctor's visit, respectively) had experienced a total of 2,589 PSPs. Extrapolated to the total population at risk in Germany (47.2 million ≥40 years), 12.2 million PSPs could be expected for 6.7 million patients ≥40 years per year. Based on an average of 10-20 ambulatory doctor visits per year in this age group, 1.3-2.6% of these visits might be associated with a PSP. According to the patients' reports, around 1.2 of the current 19.4 million inpatient cases (6.2%) per year in Germany might be due to PSPs in ambulatory care, which are experienced by patients ≥40 years alone.[18] With an average case value of 3,457 € in 2018, these hospital stays cost around 4.15 billion €/year. As a matter of priority, the harm to patients resulting from PSPs must be avoided; additionally, the prevention of PSPs in ambulatory care would also be of huge economic importance. According to our study, the PSP rate in Germany is in the lower range of the range of 1-24 PSIs per 100 consultations reported by Panesar *et al*,[8] undercuts the PSI rate of 21%[4] from the Netherlands, which was collected in a review of medical records, but is higher than the potentially harmful preventable problems rate of 7.9%[5] for ≥15-year-olds in Great Britain. Different recording methods, age groups and health care systems (e.g. primary care systems without specialised physicians in private practices as is the case with Germany) must be considered, which makes international comparison difficult. Considering only those PSPs associated with harm to health, the proportion of people who have experienced at least one harm to health in the past year due to a PSP in ambulatory care is 10% (889 out of 8,776 participants visiting a doctor, data not reported here) and thus comparable to the upper estimate range of the inpatient sector, in which 5-10% of cases experience an adverse event.[3] With regard to the medical treatment areas most frequently affected by PSPs, it can be stated that the most frequent ambulatory diagnostic and therapeutic activities (anamnesis/physical examination, medication) are associated with most PSPs. Particularly medication is also repeatedly highlighted internationally as a frequent source of PSIs with harmful consequences

in ambulatory care.[8] Similarly, more PSPs occur in specialties with a higher number of visits (general practitioners and internists), with the exception of orthopaedists, who account for 14.5% of all PSPs, although they account for only 5% of all physicians in the ambulatory care sector in Germany. This phenomenon is also known from inpatient and ambulatory malpractice statistics.[19] An astonishing result of our study is that patients most frequently name PSP types that doctors think are hardly likely to cause harm and sometimes doubt that patients are able to assess them correctly. This applies in particular to the most common PSP types from the area of anamnesis/physical examination, namely, "important questions not asked about the complaints" and "insufficient physical examination", which together make up 35% of all PSP types. A possible explanation for this finding could be that many patients claim to have visited another doctor (31.5%) or even a hospital (10.0%) later and that during this visit it was explained that a certain question should have been asked or an examination carried out at the first contact. In addition, the sub-analyses prove that even these supposedly harmless PSPs were the cause of permanent harm in about one third and led to inpatient treatment in 13.6% of the cases from the perspective of those patients who had only reported this type of PSP. With regard to the survey instrument, PSPs of the last 12 months should be reported, a period that is also used in the PREOS-PC survey.[20] The short introductory text informs the patients that the interview focusses on PSPs that the participants themselves have experienced and perceived in the last 12 months as well as on those PSPs they learned about later. Furthermore, complex filter guides were used in such a way that the target person was only asked the questions relevant to their specific situation. By this, both, the increased burden as well as the risk of memory bias were systematically reduced - however, as in other studies,[21] they cannot be avoided completely.

Strengths and limitations of the study

The main strength of the study lies in the fact that, for the first-time, PSP frequencies and distribution in the ambulatory care sector were collected in a representative, extensive population sample, so that a high degree of certainty is achieved in the PSP incidence estimates. Our study identifies that three-quarters of all PSPs reported by patients occur in the areas of anamnesis, clinical examination and medication. It also provides insights into which PSPs are most likely to cause harm. Thus, the study provides a good indication of where the focus of efforts to improve patient safety should be. Our study also reveals that the majority of reported ambulatory PSPs leads to an additional use of the health care system, thus demonstrating that PSPs reported by patients are of great importance for the ambulatory health care system.

A limitation exists with regard to the interview participation rate of 12.4%, which is in the lower range of the rates in telephone surveys in Germany. Nevertheless, the random selection of

participants resulted in a sample that allows to generalise the results to the population of ≥ 40 -year-olds. Our selectivity analyses show that random selection alone achieved a good overall population representation with only minor deviations and that the survey participants represent the target population in all important variables. For example, the proportion of women in the study corresponds exactly to the population statistics. In addition, the comparison with the last population survey of the Robert Koch Institute, which is responsible for health monitoring in Germany, shows that – almost exactly as in our sample - 51.2% of ≥ 40 -year-olds in Germany describe themselves as chronically ill[22] and 88% of the total population had at least one outpatient visit to the doctor in the last 12 months.[23] A selection bias towards persons with a potentially higher PSP risk (e.g. High recyclers, multimorbidity) cannot, however, be excluded with absolute certainty.

Another limitation may be seen in the research method used to generate data on PSP frequency and distribution in ambulatory care. Critics may question whether asking patients is suitable for generating valid statements about PSP frequency and distribution at all. This method deliberately considers only the patient's subjective perspective and does not use comparative data (e.g. medical records of the participants) to objectify the reported PSPs medically. However, studies that did not use patient reports but other methods to measure the type and frequency of PSP and harm also have to deal with weaknesses. Studies using e.g. voluntary reports from physicians[24-27] have been criticised as an unreliable source, as physicians report PSP and harm less often than they actually do occur.[15] Even the analysis of medical records and error reporting systems cannot be regarded as the best solution. As impressively shown in the study by Weingart *et al* only about half of the adverse events validated by inpatient physicians were documented in the medical records. None of these were documented in the error reporting systems.[28]

Recommendations for research and practice

Despite these limitations, our study provides important insights into both the risk of PSPs and the importance of the patient as an actor in the identification and reporting of PSPs in ambulatory care.[29, 30] Based on our own findings as well as those of Sharma *et al*,[31] who show in their review that patients and their relatives could report more frequently on patient safety issues such as chemotherapy toxicity and events such as suboptimal service quality and communication problems that have not been perceived or identified by service providers, we believe that patient reports should play a more important role in improving patient safety. To this end, it will first of all be necessary to raise awareness of the existence of patient safety problems in ambulatory care, both among physicians and other medical professionals, but also among patients and policymakers. The publication and discussion of our study results can contribute to this. In the medical profession, patient safety in ambulatory care should be

addressed more frequently within the framework of the quality circles already introduced for doctors in private practice. Quality circles are also suitable for analysing patient safety problems in open discussions and developing ways of preventing PSPs. They are also useful for reducing the previously widespread reluctance to recognise patient reports as a valid source for recording patient safety problems. In addition, critical incident reporting systems (CIRS) for the ambulatory care sector could be supplemented by those items that have proven to be particularly significant in our study. In Germany, all medical institutions are obliged to participate in error reporting systems, but the participation rate has so far been extremely low.[9] It is questionable to what extent mandatory active participation is conducive or rather leads to harming the intrinsic motivation of medical professionals. At the very least, one could consider to follow the English example and, within the framework of the review of internal quality management, checking whether an institution actually reports patient safety problems in CIRS. Considering the importance of anamnesis and clinical examination for the occurrence of patient safety problems, it would be appropriate to increase the appreciation of these basic activities in patient care. So far, technical examinations and procedures in the German health care system are much better remunerated than anamnesis and clinical examination. For this reason, typically only little time is spent, a cause for complain for many patients. In Germany, a change in the remuneration of ambulatory physicians is therefore recommended in order to take advantage of this approach to improve patient safety.

Conclusions

Our results show that PSPs in the ambulatory care sector in Germany, patient safety problems (PSP) are frequently reported by patients and often lead to harm to health and additional ambulatory or inpatient treatment. Our findings can help to identify critical medical care situations and to develop targeted measures to avoid PSPs. Furthermore, our study indicates, that patient reports are a valuable and complementary source to identify PSPs and to improve patient safety and the quality of ambulatory care.

Contributors All authors had full access to all of the data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study guarantor: MG, WdC. Study concept and design: MG, SK, JL, WdC. Analysis and interpretation of data: MG, SK, MS, AO, JL, WdC. Drafting of the manuscript: MG, SK. Critical revision of the manuscript for important intellectual content: all authors. Statistical analysis: SK, MS. Study supervision: MG.

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Competing Interests
The authors declare that there is no conflict of interest.

Patient consent for publication Not required.

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Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Deidentified data will be made available after all ongoing analyses are completed. Requesters will be required to sign a Letter of Agreement detailing the mechanisms by which the data will be kept secure and access restricted to their study team. The agreements will also state the recipient will not share the data with anyone outside of their research team.

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supplementary file 1 CATI survey instrument related to the last 12 months

(A) Introductory questions		
I.	How would you describe your current state of health? a) very good b) good c) mediocre d) bad e) very bad	7: refused to answer 8: don't know
II.	Do you have one or more long-lasting chronic diseases?	1: yes 2: no 7: refused to answer 8: don't know
III.	When was the last time you saw your GP or a specialist? a) during the last 3 months b) 4 up to 12 months ago c) more than a year ago	7: refused to answer 8: don't know
<p><i>Where people work, errors occur. Errors can also occur in physicians' offices. This can happen during treatment, but also during laboratory tests or when writing prescriptions. In the following, we will present concrete errors that can occur in offices of general practitioners and specialists in Germany. So, we are not concerned with errors in the hospital. I will ask you in each case whether, according to your knowledge or assessment, you have experienced such an error with your GP or specialist in the last 12 months. Please also think of errors that you only learned about later.</i></p>		information text: <i>if the last GP / specialist visit was during the last 12 months</i>
(B) 12-month incidence of PSPs in 7 areas of medical treatment		
1. Anamnesis / physical examination		
	Let's get to medical examinations first. Have you had a physical examination, a laboratory examination, a gastrointestinal or colonoscopy or ultrasound, X-ray or other examinations in the last 12 months?	1: yes 2: no 7: refused to answer 8: don't know
**	If, as far as you can tell, one of the following errors has occurred: Did (not) your physician ... a) ... ask important questions about your complaints? b) ... perform an insufficient physical examination? c) ... make a medical necessary examination? d) ... recognize a serious illness or recognized it too late? e) ... make a faulty examination f) ... make a wrong examination? g) ... make a wrong diagnosis? h) ... communicate incorrect test results? i) ... communicate the results too late or not at all?	1: yes 2: no 6: does not apply 7: refused to answer 8: don't know
**	Where did this error occur? During a ... a) ... physical examination, including examination talk? b) ... laboratory examination, e.g. blood, urine, stool? c) ... imaging examination, e.g. X-ray, ultrasound or examination in the tube such as CT or MRT? d) ... examination with a catheter, e.g. on the heart, vessels or urethra? e) ... endoscopic examination, e.g. examination of the stomach, intestines or lungs? f) ... puncture, e.g. of organs or joints? g) ... or any other examination?	1: yes 2: no

supplementary file 1 continued CATI survey instrument related to the last 12 months

2.		
**	Did you need drugs from your GP or specialist in the last 12 months? Please remember all drugs prescribed by your physician, e.g. tablets, ointments, creams and sprays, pain patches and suppositories.	1: yes 2: no 7: refused to answer 8: don't know
	If, as far as you can tell, one of the following errors has occurred: Did (not) your physician ...	1: yes 2: no
	a) ... <i>prescribe wrong drugs?</i>	6: does not apply 7: refused to answer 8: don't know
	b) ... <i>prescribe necessary drugs?</i>	
	c) ... <i>prescribe drugs in the wrong dose or form, e.g. solution instead of tablet?</i>	
	d) ... <i>prescribe drugs, although your physician knew of an intolerance?</i>	
**	e) ... <i>prescribe drugs without considering the interaction with another drug?</i>	
	f) ... <i>discontinue drugs too early, too late or not at all?</i>	
3. Vaccination, injection, infusion		
**	Have you received a vaccination, injection or infusion from your GP or specialist in the last 12 months?	1: yes 2: no 7: refused to answer 8: don't know
	If, as far as you can tell, one of the following errors has occurred? Did (not) you get a vaccination, injection or infusion administered...	1: yes 2: no
	a) ... <i>although it was necessary?</i>	6: does not apply 7: refused to answer 8: don't know
	b) ... <i>with a wrong active substance?</i>	
	c) ... <i>in the wrong place, e.g. in muscle instead of blood vessel?</i>	
	d) ... <i>even though the physician knew of an intolerance?</i>	
**	e) ... <i>without noticing the interaction with another medication?</i>	
4. Aftercare		
**	Now we're talking about aftercare. This can be a wound follow-up, a cancer follow-up, or a follow-up after an operation. Did your physician carry out a necessary aftercare treatment incorrectly, belated or not at all within the last 12 months to your knowledge?	6: does not apply 7: refused to answer 8: don't know
	a) <i>yes, wrong</i>	
	b) <i>yes, belated</i>	
	c) <i>yes, not at all</i>	

supplementary file 1 continued CATI survey instrument related to the last 12 months

5. Outpatient surgery		
	Have you been operated in the last 12 months by your GP or specialist in the office or in an outpatient clinic?	1: yes
		2: no
		7: refused to answer
		8: don't know
**	If, as far as you can tell, one of the following errors has occurred: Did (not) your physician ... <i>a) ... perform a surgery too late?</i> <i>b) ... perform a surgery not properly?</i> <i>c) ... perform a wrong surgery?</i> <i>d) ... communicate the results of surgery incorrectly?</i> <i>e) ... communicate the results of surgery or communicated it too late?</i>	1: yes
		2: no
		6: does not apply
		7: refused to answer
		8: don't know
**	Did this error occur during a surgery on/in ... <i>a) ... the eye?</i> <i>b) ... the nose, ears or sinuses?</i> <i>c) ... a joint?</i> <i>d) ... the heart vessels?</i> <i>e) ... the abdomen or internal organs?</i> <i>f) ... the urinary tract or sexual organs?</i> <i>g) ... the skin?</i> <i>h) ... the muscles?</i> only for women: <i>i) ... the uterus?</i> <i>j) ... the ovaries?</i> <i>k) ... the context of an abortion?</i>	1: yes
		2: no
		7: refused to answer
		8: don't know
6. Office administration		
**	According to your knowledge, we would like to know if it has happened to you during the last 12 months, that ... <i>a) ... you have been confused with another patient?</i> <i>b) ... your examination results were not or not completely available?</i> <i>c) ... your attending physician did not perform a necessary home visit?</i>	6: does not apply
		7: refused to answer
		8: don't know
7. Other areas		
**	In the last 12 months, as far as you can tell, have you experienced another error that we have not yet asked you about?	1: yes
		2: no
		7: refused to answer
		8: don't know

** multiple answers possible.

supplementary file 1 continued CATI survey instrument related to the last 12 months

Detailed questions per reported PSP		
1.	How often has this error happened in the last 12 months?	____ times 7: refused to answer 8: don't know
2.	Did this error happen with a GP or a specialist? a) GP b) specialist c) both, GP and specialist d) GP or specialist, don't know which one e) error occurred during an outpatient treatment f) error occurred during an inpatient treatment	7: refused to answer 8: don't know
3.	To which group of physicians did the specialist belong who made the error? a) internists b) gynaecologist c) ophthalmologist d) orthopaedists e) ear, nose and throat specialist f) neurologist, psychiatrist, neurologist g) surgeons h) dermatologist i) radiologist, radiologist j) urologists k) another medical specialist	7: refused to answer 8: don't know
4. **	What do you think caused this error? That ... a) ... the physician is not technically competent? b) ... the physician suffers from stress and lack of time? c) ... the physician does not listen; does not take you seriously or only uses incomprehensible technical terms? d) ... the patient records are poorly kept? e) ... the practice is badly organized? f) ... other causes?	1: yes 2: no 7: refused to answer 8: don't know
5. **	What harmful consequences have you experienced as a result of this error? a) mild allergic reaction, e.g. skin rash, itching b) severe allergic reaction, e.g. anaphylactic shock c) other side effects, e.g. stomach bleeding d) deterioration of the health status e) unnecessarily prolonged pain f) wound infection / inflammation g) bleeding h) other part of the body has been injured, e.g. an internal organ or nerve i) a serious illness has not been recognized or has been recognized too late j) financial harm, e.g. additional therapy and treatment costs k) temporal harm, e.g. you had to go to the practice again l) mental or social harm m) other harmful consequences	6: no harm occurred 7: refused to answer 8: don't know

supplementary file 1 continued CATI survey instrument related to the last 12 months

6.	Please tell us how heavy or light was (the most serious) harm for you? a) <i>very light</i> b) <i>light</i> c) <i>severe</i> d) <i>very severe</i>	7: refused to answer 8: don't know
7.	How long did it take to recover from (the most serious) harm? a) <i>less than a week</i> b) <i>more than a week but less than a month</i> c) <i>more than a month to recovery</i> d) <i>or has the harm remained permanent?</i>	6: does not apply 7: refused to answer 8: don't know
8. **	Due to this (severest) harm, did you ... a) <i>... go to see another physician?</i> b) <i>... call the medical on-call service / emergency service?</i> c) <i>... go to the emergency room?</i> d) <i>... go to the hospital overnight for treatment?</i> e) <i>... need rehabilitation?</i>	6: none of it 7: refused to answer 8: don't know
9.	How long have you been in the hospital overnight? a) <i>up to one week</i> b) <i>between one and two weeks</i> c) <i>two weeks or more</i>	7: refused to answer 8: don't know
10. **	We would like to know how you did you deal with this error/harm. Did you or a relative tell the error/harm to someone, for example ... a) <i>... the physician with whom the error occurred?</i> b) <i>... another general practitioner or specialist?</i> c) <i>... your health insurance fund or health insurance coverage?</i> d) <i>... the medical association?</i> e) <i>... an independent patient advisory centre?</i> f) <i>... a lawyer?</i> g) <i>... another person or entity?</i>	6: no one 7: refused to answer 8: don't know
11. **	How did you react to this error/harm? Did you ... a) <i>... complain to the attending physician?</i> b) <i>... lost your confidence in the physician?</i> c) <i>... change physicians?</i> d) <i>...give a negative rating on the Internet?</i> e) <i>... sue the physician?</i> f) <i>... react in another way?</i>	6: didn't respond any further 7: refused to answer 8: don't know

** multiple answers possible.

(C) Socio-demographic Data		
1.	Which sex do you have? a) <i>male</i> b) <i>female</i> c) <i>diverse</i>	7: refused to answer 8: don't know
2.	Do you have the German citizenship?	1: yes 2: no 7: refused to answer 8: don't know

supplementary file 1 continued CATI survey instrument related to the last 12 months

3.	Have you had the German citizenship at birth?	1: yes 2: no 7: refused to answer 8: don't know
4.	Did your mother and father both have that German citizenship at birth? (Those born in the former German eastern territories up to and including 1955 had the German nationality at birth)	1: yes 2: no 7: refused to answer 8: don't know
5.	What is your highest general school leaving certificate? a) School ends without graduation b) Primary or lower secondary school leaving certificate c) Secondary school leaving certificate d) Polytechnic secondary school (POS) with an 8th grade diploma e) Polytechnic secondary school (POS) with 10th grade diploma f) Specialized secondary school diploma g) University entrance qualification or Extended Secondary School (EOS) with 12th grade degree or vocational training with Abitur (university entrance qualification) h) another school leaving certificate i) still a pupil	7: refused to answer 8: don't know
6.	Which main occupation do you have: are you currently... a) full-time employed (35 hours or more) b) part-time gainfully employed (15 to less than 35 hours) c) partial retirement, irrespective of the stage at which it takes place d) minor gainfully employed (less than 15 hours) e) occasionally or irregularly engaged in gainful activity f) in in-company vocational training / Apprenticeship g) in retraining h) in military service / Federal voluntary service / Social year i) on maternity leave, parental leave, parental leave or other leave j) not gainfully employed (including students not working for money, unemployed, early retirees, pensioners) k) In school education l) employed in a one-euro job	7: refused to answer 8: don't know
7.	To which group does your current or last occupation belong? a) self-employed farmer b) cooperative farmer (formerly LPG) c) academics in the liberal profession (physician, lawyer, tax consultant, etc.) d) self-employed in trade, commerce, crafts, industry, services, also in a "Me PLC". e) civil servant / judge / professional soldier f) employee g) worker h) vocational training/apprenticeship i) assisting family members j) never been in employment	7: refused to answer 8: don't know

supplementary file 1 continued CATI survey instrument related to the last 12 months

8.	Are you or were you a civil servant / judge / professional soldier ... a) <i>in the lower or middle grade of the civil service</i> b) <i>in the upper grade of the civil service</i> c) <i>in the higher grade of the civil service</i>	7: refused to answer 8: don't know
9.	Are you or were you an employee ... a) <i>with an activity which is carried out in accordance with instructions</i> b) <i>with independent performance in responsible activity</i> c) <i>with comprehensive management tasks</i>	7: refused to answer 8: don't know
10.	Are you or were you a worker and namely ... a) <i>unskilled / semi-skilled</i> b) <i>skilled worker</i> c) <i>foreman, column leader / master, foreman, brigadier</i>	7: refused to answer 8: don't know
11.	In our society, there are population groups that tend to be at the top and those that tend to be at the bottom. Where would you place yourself on a scale from 1 to 10? 1 means that you are at the bottom, 10 means that you are at the top. With the numbers in between, you can gradate your position. 1: at the bottom ... 10: at the top	7: refused to answer 8: don't know
12.	Please tell me briefly: How many people are currently living in your household, including children and yourself? Number: _____	7: refused to answer 8: don't know
13.	How high is the monthly net income of your household as a whole, i.e. of all those who receive an income? (This refers to the sum of wages, salaries, income from self-employment, pension or annuity, in each case after deduction of taxes and social security contributions. Please also add income from public subsidies, income from renting, leasing, housing benefit, child benefit and other income.) I'll read you some income categories now and please say 'Stop' if it applies. a) <i>less than 500 Euros</i> b) <i>500 to less than 1,000 Euro</i> c) <i>1,000 to less than 1,500 Euro</i> d) <i>1,500 to less than 2,000 Euro</i> e) <i>2,000 to less than 2,500 Euro</i> f) <i>2,500 to less than 3,000 Euro</i> g) <i>3,000 to less than 4,000 Euro</i> h) <i>4,000 to less than 5,000 Euro</i> i) <i>5,000 Euro and more</i>	7: refused to answer 8: don't know
14.	For this scientific study, it is important to know which treatment errors occur particularly rarely or frequently in which population groups. This also includes the question of whether those affected are more likely to receive a lower or higher income. Can you therefore at least tell us roughly whether your monthly net household income is less or more than 1,500 euros? a) <i>less than 1,500 Euros</i> b) <i>more than 1,500 Euros</i>	7: refused to answer 8: don't know

supplementary table 1 Socio-demographic and socio-economic data

		PAV* (%)	95%-CI	GEDA-14** (%)	95%-CI
Gender	Male	47.6	46.7-48.6	47.9	47.1-48.7
	Female	52.3	51.4-53.3	52.1	51.3-52.9
Age groups	40-59 years old	51.1	50.1-52.1	53.3	52.6-54.1
	60-79 years old	38.0	37.0-38.9	39.4	38.7-40.2
	80+ years old	10.3	9.8-11.0	7.2	6.8-7.6
Current state of health	Very good	15.9	15.2-16.6	9.9	9.5-10.4
	Good	45.3	44.3-46.3	50.9	50.1-51.6
	Mediocre	27.8	27.0-28.7	31.4	30.7-32.2
	Bad	8.0	7.5-8.6	6.2	5.8-6.6
	Very bad	2.8	2.5-3.1	1.0	0.9-1.2
Chronic diseases	Yes	46.6	45.7-47.6	53.7	53.0-54.5
	No	53.0	52.0-53.9	45.3	44.5-46.0
Last GP or specialist visit	During the past 12 months	87.5	85.8-89.1	89.0	88.5-89.4
	More than 12 months ago	12.4	11.8-13.1	10.2	9.7-10.7
Inpatient treatment in the past 12 months	Yes	23.5	22.6-24.3	18.3	17.7-18.9
	No	76.2	75.4-77.1	81.1	80.5-81.7
Citizenship	German	81.9	81.1-82.6	96.2	95.9-96.5
	Non-German	17.0	16.2-17.7	2.6	2.4-2.9
Household size	1-4 persons	95.1	92.1-98.3	95.3	94.9-95.6
	≥5 persons	4.1	3.5-5.1	3.8	3.5-4.1
Monthly net income	Up to less than 1,000 Euro	7.4	6.8-8.2	18.3	17.5-19.1
	1, 000 to less than 5,000 Euro	62.6	59.1-66.2	79.4	76.4-82.5
	5,000 Euro and more	9.7	9.1-10.2	2.4	2.1-2.6
SSS / SES***	Low	11.7	11.1-12.3	21.3	20.7-22.0
	Medium	50.3	49.3-51.3	58.6	57.9-59.4
	High	33.9	33.0-34.8	19.7	19.1-20.4

*PAV, study population of ≥40-year-olds: 10,037 participants

**GEDA-14, study population of ≥40-year-olds: 16,452 participants

***PAV-Study: SSS=subjective social status; GEDA-14: SES=socio-economic status (objective)

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supplementary table 2 Distribution of PSP by specialist group

Medical specialist group	PSP (n)*	PSP (%)	95%-CI
Family physicians	1,101	43.7	41.8 to 45.6
Orthopaedists	367	14.5	13.2 to 16.0
Internist	259	10.3	9.1 to 11.5
Neurologists	129	5.1	4.3 to 6.0
Surgeons	95	3.8	3.1 to 4.6
Gynaecologists	76	3.0	2.4 to 3.7
Urologists	71	2.8	2.2 to 3.5
Radiologists	60	2.4	1.8 to 3.0
ENT specialists	50	2.0	1.5 to 2.6
Dermatologists	42	1.7	1.2 to 2.2
Ophthalmologists	35	1.4	1.0 to 1.9
Other specialists	236	9.4	8.2 to 10.5

*A total of 2,589 PSPs was reported. 2,521 PSPs were clearly assignable to specialist groups.

supplementary table 3 Sub-analysis of the PSP 'important questions not asked about complaints': Proportion of PSP with harm, distribution of harm types, and differentiation of severity, recovery time and additional treatments

PSP 'important questions not asked about complaints'		n	%	95%-CI
Persons with this PSP type exclusively *		136	1.5	1.3 to 1.8
Harm and its consequences		n	%	95%-CI
Harm / no harm	PSP without harm	36	26.5	19.8 to 34.5
	PSP with at least one harm	100	73.5	65.5 to 80.2
Types of harm	Unnecessarily prolonged pain	49	26.8	20.9 to 33.6
	Deterioration of health status	41	22.4	17.0 to 29.0
	Mental / social harm	32	17.5	12.7 to 23.6
	Serious illness not recognized / recognized too late	19	10.4	6.7 to 15.6
	Other part of the body injured	8	4.4	2.2 to 8.4
	Other side effects	8	4.4	2.2 to 8.4
	Mild allergic reaction	6	3.3	1.5 to 7.0
	Severe allergic reaction	3	1.6	0.6 to 4.7
	Bleeding	2	1.1	0.3 to 3.9
	<i>Total reported harm to health</i>	<i>180</i>	<i>98.4</i>	<i>95.3 to 99.4</i>
	Temporal harm	60	32.8	26.4 to 39.9
	Other harm	25	13.7	9.4 to 19.4
	Financial harm	18	9.8	6.3 to 15.0
	<i>Total reported financial, temporal and other harm</i>	<i>103</i>	<i>56.3</i>	<i>49.0 to 63.3</i>
Severity	Very light	6	6.0	2.8 to 12.5
	Light	38	38.0	29.1 to 47.8
	Severe	36	36.0	27.3 to 45.8
	Very severe	19	19.0	12.5 to 27.8
Recovery period	Less than a week	12	14.1	8.3 to 23.1
	More than a week, but less than a month	22	25.9	17.8 to 36.1
	More than a month	14	16.5	10.1 to 25.8
	Permanent harm	34	40.0	30.2 to 50.6
	Don't know	3	3.5	1.2 to 9.9
Additional treatment	None of this	46	46.0	36.6 to 55.7
	Went to see another doctor	44	44.0	34.7 to 53.8
	Medical on-call service / emergency service	7	7.0	3.4 to 13.7
	Emergency room	13	13.0	7.8 to 21.0
	Inpatient treatment (overnight)	12	12.0	7.0 to 19.8
	<i>Up to one week</i>	<i>5</i>	<i>5.0</i>	<i>2.2 to 11.2</i>
	<i>Between one and two weeks</i>	<i>1</i>	<i>1.0</i>	<i>0.2 to 5.4</i>
	<i>Two weeks and more</i>	<i>6</i>	<i>6.0</i>	<i>2.8 to 12.5</i>
	Rehabilitation	7	7.0	3.4 to 13.7

supplementary table 4 Sub-analysis of the PSP 'inadequate physical examination':
Proportion of PSP with harm, distribution of harm types and differentiation of severity,
recovery time and additional treatments

PSP 'inadequate physical examination'		n	%	95%-CI
Persons with this PSP-type exclusively *		107	1.2	1.0 to 1.5
Harm and its consequences		n	%	95%-CI
Harm / no harm	PSP without harm	37	34.6	26.2 to 44.0
	PSP with at least one harm	70	65.4	56.0 to 73.8
Types of harm	Unnecessarily prolonged pain	38	21.8	16.3 to 28.6
	Deterioration of health status	23	13.2	9.0 to 19.1
	Mental / social harm	15	8.6	5.3 to 13.7
	Serious illness not recognized / recognized too late	14	8	4.9 to 13.1
	Mild allergic reaction	12	6.9	4.0 to 11.7
	Other part of the body injured	7	4	2.0 to 8.1
	Wound infection / inflammation	6	3.4	1.6 to 7.3
	<i>Total reported harm to health</i>	<i>115</i>	<i>66.1</i>	<i>58.8 to 72.7</i>
	Temporal harm	37	21.3	15.8 to 27.9
	Financial harm	12	6.9	4.0 to 11.7
	Other harm	10	5.7	3.2 to 10.3
	<i>Total reported financial. temporal and other harm</i>	<i>59</i>	<i>33.9</i>	<i>27.3 to 41.2</i>
Severity	Very light	7	10	4.9 to 19.2
	Light	40	57.1	45.5 to 68.1
	Severe	16	22.9	14.6 to 34.0
	Very severe	7	10	4.9 to 19.2
Recovery period	Less than a week	15	23.4	14.7 to 35.1
	More than a week, but less than a month	13	20.3	12.3 to 31.7
	More than a month	10	15.6	8.7 to 26.4
	Permanent harm	24	37.5	26.7 to 49.7
	Not applicable	3	4.7	1.6 to 12.9
	Don't know	1	1.6	0.3 to 8.3
Additional treatment	None of this	34	48.6	37.2 to 60.0
	Went to see another doctor	30	42.9	31.9 to 54.5
	Medical on-call service / emergency service	3	4.3	1.5 to 11.9
	Emergency room	10	14.3	7.9 to 24.3
	Inpatient treatment (overnight)	11	15.7	9.0 to 26.0
	<i>Up to one week</i>	<i>3</i>	<i>4.3</i>	<i>1.5 to 11.9</i>
	<i>Between one and two weeks</i>	<i>8</i>	<i>11.4</i>	<i>5.9 to 21.0</i>
	Rehabilitation	2	2.9	0.8 to 9.8

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

For manuscript: “Patient safety in ambulatory care from the patient's perspective - A retrospective, representative telephone survey”

submitted by Geraedts et al, 161219

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-6 (plus supplementary file 1)
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	N/A

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		(d) If applicable, describe analytical methods taking account of sampling strategy	6
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7 (plus supplementary table 1)
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	N/A
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7-11 (plus tables 1-4 and supplementary tables 2-4)
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	7-11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	13-14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Patient safety in ambulatory care from the patient's perspective - A retrospective, representative telephone survey

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Patient safety in ambulatory care from the patient's perspective - A retrospective, representative telephone survey

ABSTRACT

Objectives: Data on patient safety problems (PSPs) in ambulatory care are scarce. The aim of the study was to record the frequency, type, severity and point of origin of PSPs in ambulatory care in Germany.

Design: Retrospective cross-sectional study.

Setting: Computer-assisted telephone interviews (CATI) with randomly recruited citizens aged ≥ 40 years in Germany who were asked about their experiences with PSPs in ambulatory care.

Participants: 10,037 citizens ≥ 40 years.

Measures: A new questionnaire was developed to record patient experiences with PSPs in ambulatory care. The study reported here targets patient experiences in the last 12 months. The questionnaire focuses on PSPs in 7 areas of medical treatment: anamnesis/diagnostic procedures; medication; vaccination, injection, infusion; aftercare; outpatient surgery; office administration; other areas. For each PSP reported, detailed questions were asked about the specialist group concerned, and, on the most serious harm, the severity of the harm and its consequences. The target parameters are presented as proportions with 95% confidence intervals.

Results: 1,422 of the respondents (14%) reported 2,589 PSPs. The areas most frequently affected by PSPs were anamnesis/diagnostic procedures (61%) and medication (15%). General practitioners accounted for 44% of PSPs, orthopaedists for 15% and internists for 10%. 75% of PSPs were associated with harm, especially unnecessarily prolonged pain or deterioration of health; 35% of PSPs led to permanent damage. 804 PSPs (32%) prompted patients to see another doctor for additional treatment; 255 PSPs (10%) required inpatient treatment.

Conclusion: PSPs experienced by patients are widespread in ambulatory care in Germany. The study reveals in which areas of medical treatment efforts to prevent PSPs could make the greatest contribution to improving patient safety. It also demonstrates the valuable contribution of patient reports to the analysis of PSPs.

Strengths and limitations of this study

- For the very first time, data were collected on the frequency, type, severity and consequences of patient safety problems (PSPs) in ambulatory care in Germany.
- The randomly selected, extensive population sample of 10,037 citizens ≥ 40 years guarantees a high degree of certainty in the PSP incidence estimates.

- The study provides insights into which PSPs are most likely to cause harm, thus providing a good indication of effective fields of action to improve patient safety.
- Patient reports as a research method for generating data on PSPs without cross-checking against comparative data (e.g. medical records) do not allow medical objectification of the reported PSPs.

INTRODUCTION

Patient safety, as a key feature of quality healthcare,[1] is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.[2] Healthcare's growing complexity and an increasing number of multimorbid patients lead to an increasing risk of patient safety problems (PSPs) in both inpatient and ambulatory care. Below we use the term PSP to capture two types of error, i.e. failures to carry out a planned action as intended or application of an incorrect plan, and patient safety incidents (PSIs), i.e. events or circumstances that could have resulted, or did result, in unnecessary harm to a patient.[2] PSIs also include adverse events (AEs), i.e. incidents which resulted in harm to a patient.[2]

Both internationally and in Germany, knowledge about the frequency of PSPs is limited. Regarding only inpatient care and based on a literature review by the German Coalition for Patient Safety, the German Advisory Council on the Assessment of Developments in the Health Care Sector estimated in 2007 that 5-10% of all hospital patients experience an AE, 2-4% a preventable AE, 1% experience treatment errors and 0.1% die from preventable AEs.[3] For the German ambulatory care sector, there is hardly any data on the frequency of PSPs. But even the few international studies allow only rough estimates. From the Netherlands, Gaal *et al* [4] report a PSI rate of 21.1% based on a retrospective analysis of medical records kept by primary care physicians; 5.8% of the PSIs resulted in harm and 0.7% led to hospital stays. Stocks *et al* [5] collected potentially harmful preventable problems through personal interviews of a representative sample of ≥15-year-olds in Great Britain; the problem rate within the last 12 months was 7.9%. Michel *et al* [6] encouraged GPs in France to record all PSIs occurring within one week, and concluded that the PSI rate was 2.6% of all consultations. In a first review, Sandars & Esmail [7] estimated the medical error rate in primary care at 5-80 errors per 100,000 consultations. In a recent literature review, Panesar *et al* [8] concluded that 1-24 PSIs occur per 100 consultations, of which 4% (range 1-44%) are associated with severe harm.

One reason for this inconclusive evidence could be the process of recording PSPs in ambulatory care, because the methods tested in inpatient care, such as the analysis of medical records, routine and/or harm data, CIRS, and direct observation, reach their limits. First, patients leave the doctor's surgery immediately after ambulatory treatment, leaving only a short time window for PSP capture, and second, routine data in ambulatory care contain too little information for PSP discovery. The website "Every error counts", which collects errors in the

German GP sector, illustrates the dilemma of spontaneous PSP reporting in ambulatory care: By mid-2019, i.e. during 15 years since the existence of the register, the approximately 55,000 German GPs had reported a total of 948 errors.[9] For this reason, it is internationally recommended to include patients themselves as sources of information for PSP recording.[10-13] Only patients are able to report on the effects of treatments across sectors and over long periods of time; their information on incidents is usually more accurate than those of physicians,[14] who also show more resentment towards PSP reporting.[15] Against this background, our study aims to report on the frequency, type, severity and point of origin of PSPs in the ambulatory healthcare sector in Germany based on a population survey.

METHODS

Study design

This retrospective cross-sectional study is based on original telephone survey data on experiences with PSPs within the last 12 months from the patient’s perspective. We followed the STROBE checklist for reporting observational studies (see online supplementary file 1).[16]

Participants

For economic reasons, the survey was limited to the population aged ≥40 years in Germany (2017: 22.5 million men and 24.7 million women; 57% of the total population), since more physician visits and thus potentially more PSPs are expected for ≥40-year-olds than in the total population.

From the population aged ≥40 years, a sample of 10,037 citizens was interviewed via computer-assisted telephone interviews (CATI). This number was based on a sample size calculation of 10,000 interviews, with which a two-sided 95% confidence interval of one percentage point can be secured with an estimated incidence of 7.5%. The realized sample was based on a random sample of nationwide listed and permuted landline and mobile phone numbers (70:30 distribution). The target person in multi-person households was the adult with the last birthday. About 81,000 of the almost 700,000 telephone numbers generated were identified as belonging to the target group; of these, about 65,000 were interviewed during field time. 84.4% refused to participate. Only a few interviews were discontinued (150) or not evaluable (5), thus a participation rate of 12.4% was achieved (10,037/81,108). The participants in the sample corresponded largely to the population as a whole. In order to be able to make reliable representative statements, the sample results were weighted using the variables gender, age group, household size, school education, employment status, nationality, federal state and municipal size classes.

143 Survey instrument and implementation

144 Due to the absence of a validated CATI survey instrument, a new questionnaire was developed
145 for the study by means of a literature review on types of PSPs in ambulatory care and
146 qualitative interviews with physicians (N=10) and patients (N=20) on their experiences with
147 PSPs. The survey instrument captures PSP experiences within the last 12 months, PSPs since
148 the 40th birthday, and severe PSPs of relatives through proxy-interviews using closed
149 questions and dichotomous answers. The study reported here targets patients' PSP
150 experiences in the last 12 months. The CATI-instrument consists of three modules relating to
151 the last 12 months (see [box 1](#) and [supplementary file 1](#)): (A) introductory questions on the
152 current state of health, and whether the last visit to a GP or specialist took place within the last
153 12 months. If a physician visit had taken place, a short information text briefly explained the
154 types of PSP collected in the survey. In module (B), individual PSP types were queried in 7
155 medical treatment areas, with multiple answers possible in each case: each person was
156 allowed to report several PSP types if one or several physician visits had taken place in several
157 treatment areas. For each PSP reported, detailed questions were asked about the specialist
158 group concerned and on the most serious harm, the severity of the harm, and its
159 consequences. In order to minimise both, cognitive stress and memory bias, complex filters
160 ensured that the interviewees were just asked the questions relevant to them. Module (C)
161 collected socio-demographic and socio-economic data.

162
163 The questionnaire was checked by means of cognitive pretests on 20 patients with regard to
164 the comprehensibility of the questionnaire items, completeness of the response categories and
165 memorability of the events experienced. Methodically, think-aloud and interview techniques
166 were combined.[17] Necessary changes were implemented and subsequently tested using
167 standardized pretests (N=110) under field conditions. Misleading formulations of questions and
168 optimization possibilities regarding filtering or question blocks were discovered, modified in the
169 electronic questionnaire, and released for the main field after final testing. The survey took
170 place from May to October 2018.

171

Box 1 Categories and items of the survey instrument

(A) Introductory questions

- Current health status
- Chronic illnesses
- Last general practitioner/specialist visit

Short Information text

Where people work, errors occur. Errors can also occur in medical offices. This can happen during treatment, but also during laboratory tests or when writing prescriptions. In the following, we introduce you to specific errors that can occur in the surgeries of general practitioners and specialists in Germany. So, it is not about errors that occur in hospital. In each case, I will ask you, whether, according to your knowledge or assessment, you have experienced such an error while treated by your general practitioner or specialist. Please also think of errors that you learned about later.

(B) 12-month incidence of PSPs in 7 areas of medical treatment

- Anamnesis/diagnostic procedures
- Medication
- Vaccination, injection, infusion
- Aftercare
- Outpatient surgery
- Office administration
- Other areas

Detailed questions per reported PSP:

- Treatment area (just anamnesis/diagnostic procedures and outpatient surgery)
- Frequency
- Presumed causes
- Specialist group concerned
- Type of harm
- Severity (of the severest harm)
- Recovery time (of the severest harm)
- Additional treatments
- Hospital nights
- Dealing/response behaviour

(C) Socio-demographic Data

- Sex
- Citizenship
- Highest school-leaving qualification
- Current main occupation
- Self-reported social status
- Household size
- Monthly net income

Analysis

12-month PSP incidences including 95% confidence intervals (CI) are reported in terms of frequencies and distributions of ambulatory PSP types. The data refer either to the weighted

participants or to their reported PSPs. The analyses were carried out with SPSS version 25 and cross-checked with the statistics package R version 3.5.2 (Base Package).

Patient and Public Involvement

Patients were not actively involved in the development of the research question but participated in guided interviews that were conducted to generate items for the survey instrument. Patients were also involved in the study to pretest the survey instrument and finally participated as interviewees. We presented the study results at the German Coalition for Patient Safety conference 2019 where we explicitly invited patient representatives as discussants.

RESULTS

Participants

The survey participants (N=10,037; 12.4% participation rate) were 61 years old on average, and 52% were women. 73% assessed their current state of health as (very) good to mediocre; 47% stated that they had at least one long-lasting chronic disease at the time of the survey. 8,841 of the 10,037 participants (88%) experienced at least one ambulatory GP or specialist visit within the past 12 months. **Supplementary table 1** compares the socio-demographic and socio-economic parameters of the weighted study population with a population survey conducted as part of Germany's health monitoring 2014. The study population largely corresponds to the participants in the population survey.

Incidence and medical treatment areas affected by PSPs

The weighted sample comprises 8,776 patients with an ambulatory GP or specialist visit, of whom 1,422 (16%) experienced at least one PSP in the last 12 months. They reported a total of 2,589 PSPs, i.e. an average of 1.8 PSPs per participant. In relation to the total sample, 14.2% experienced at least one PSP (1,422/10,037). The most common areas affected by PSP were anamnesis/clinical examination (66% of patients, 61% of PSPs) and medication (22% of patients, 15% of PSPs). **Table 1** shows the distribution of PSPs in all treatment areas including 95% CIs.

Table 1 Patients affected by PSP and distribution of PSPs by treatment areas.

Treatment areas	Patients			PSPs		
	n*	%	95% CI	n	%	95% CI
Anamnesis/diagnostic procedures	938	66.0	63.5 to 68.4	1,583	61.1	59.3 to 63
Medication	316	22.3	20.1 to 24.4	398	15.4	14 to 16.8
Vaccination, injection, infusion	100	7.0	5.8 to 8.4	112	4.3	3.6 to 5.2
Aftercare	53	3.7	2.8 to 4.8	65	2.5	2 to 3.2
Outpatient surgery	41	2.9	2.1 to 3.9	61	2.4	1.8 to 3
Office administration	208	14.6	12.9 to 16.5	254	9.8	8.7 to 11
Other areas	116	8.1	6.8 to 9.7	116	4.5	3.7 to 5.3
Sum	(1,422**)			2,589	100.0	

*Multiple answers possible; sample: 8,776 weighted patients ≥40 years with a doctor's visit within the last 12 months.

**Individual patients, some affected by several PSPs.

PSP types

Table 2 shows the distribution of the specifically surveyed PSP types per treatment area. In the two areas most frequently affected by PSPs (anamnesis/diagnostic procedures and medication), the most frequent PSP types are distributed as follows: 35% of all PSPs or 57% of PSPs in the field of anamnesis/diagnostic procedures (N=1,583) are attributable to "important questions about complaints not asked" as well as "insufficient physical examination". In the area of medication (N=398, 6.2% of all PSPs), 20.8% of medication-related PSPs were due to "wrongly prescribed drugs" and "prescribed without considering the interaction with another drug" (19.7%).

Table 2 Distribution of PSPs (N=2,589) among specific PSP types in ambulatory care

PSP types per treatment area		PSP (n)	PSP (%)	95% CI
Anamnesis/diagnostic procedures	Important questions about complaints not asked	515	19.9	18.4 to 21.5
	Insufficient physical examination	381	14.7	13.4 to 16.1
	Medically necessary examination not made	157	6.1	5.2 to 7.0
	Results communicated too late / not at all	136	5.3	4.4 to 6.2
	Wrong diagnosis	128	4.9	4.2 to 5.8
	Serious illness not recognized or recognized too late	97	3.8	3.1 to 4.5
	Faulty examination	69	2.7	2.1 to 3.3
	Incorrect test result communicated	54	2.1	1.6 to 2.7
	Wrong examination	46	1.8	1.3 to 2.3
Medication	Wrongly prescribed drugs	83	3.2	2.6 to 3.9
	Prescribed without considering the interaction with another drug	78	3.0	2.4 to 3.7
	Necessary drugs not prescribed	72	2.8	2.2 to 3.5
	Prescribed in the wrong dose / form	65	2.5	2.0 to 3.2
	Prescribed, although the doctor knew of an intolerance	54	2.1	1.6 to 2.7
	Discontinued too early / too late / not at all	46	1.8	1.3 to 2.3
Vaccination, injection, infusion	Administered without noticing the interaction with another medication	42	1.6	1.2 to 2.2
	Administered in the wrong place	23	0.9	0.6 to 1.3
	Not administered, although necessary	20	0.8	0.5 to 1.2
	Administered with a wrong active substance	19	0.7	0.5 to 1.1
	Administered, even though the doctor knew of an intolerance	8	0.3	0.1 to 0.6
Aftercare	Not at all	34	1.3	0.9 to 1.8
	Belated	28	1.1	0.7 to 1.5
	Wrong	4	0.1	0.1 to 0.4
Outpatient surgery	Not done properly	44	1.7	1.3 to 2.3
	Performed too late	9	0.4	0.2 to 0.7
	Result of surgery not communicated / communicated too late	4	0.2	0.1 to 0.4
	Result of surgery communicated incorrectly	2	0.1	0.0 to 0.3
	Wrong surgery	1	0.0	0.0 to 0.2
Office administration	Examination results not / not completely available	152	5.9	5.0 to 6.8
	Confused with another patient	73	2.8	2.2 to 3.5
	Home visit not performed	29	1.1	0.8 to 1.6
Other areas	Other PSP	116	4.5	3.7 to 5.3

Distribution of PSPs between specialist groups

Of 2,521 reported, clearly assignable PSPs, about 44% occurred among general practitioners, 15% among orthopaedists and 10% among internists. The other specialist groups received up to 5% of the PSP entries ([supplementary table 2](#)).

Types of harm, severity and time to recover

1,935 (74.7%) of 2,589 PSPs were associated with harm to the patient ([table 3](#)). A total of 5,656 harms were reported, i.e. an average of 3 harms per PSP. Two thirds were described as harm to health, one third as financial/temporal/other harm. Due to the possibility of giving multiple answers, about 82% of PSPs were associated with at least one harm to health, 71% had at least one financial, temporal or other harm. Among the harms to health, "unnecessarily prolonged pain" was most frequently mentioned in 16.5% of all PSP harms and "deterioration of the state of health" in 16.1% of all PSP harms.

Table 3 Distribution of PSPs with harm and harm types

PSP with harmful consequences		PSP (n)	PSP (%)	95% CI
Harm / no harm	PSP without harm	621	24.0	22.4 to 25.7
	PSP with at least one harm	1,935	74.7	73 to 76.4
	Refused to answer	18	0.7	0.4 to 1.1
	Don't know	15	0.6	0.3 to 0.9
Types of harm	Unnecessarily prolonged pain	934	16.5	15.6 to 17.5
	Deterioration of the health status	909	16.1	15.1 to 17.1
	Mental / social harm	619	10.9	9.2 to 11.8
	Serious illness not recognized / recognized too late	306	5.4	4.9 to 5.7
	Other part of the body injured (e.g. an internal organ or nerve)	228	4.0	3.4 to 4.6
	Wound infection / inflammation	223	3.9	3.3 to 4.5
	Mild allergic reaction (e.g. skin rash, itching)	218	3.9	3.4 to 4.4
	Other side effects (e.g. stomach bleeding)	139	2.5	2.1 to 2.9
	Bleeding	117	2.1	1.7 to 2.5
	Severe allergic reaction	65	1.1	0.9 to 1.5
	Total reported harms to health	3,758	66.4	65.2 to 67.7
	PSP with ≥1 harm to health	1,584	81.9	80.1 to 83.5
	Temporal harm (e.g. extra waiting time, additional doctor visits)	1,164	20.6	16.2 to 21.7
	Financial harm (e.g. additional treatment costs)	393	6.9	6.3 to 7.1
	Other harm	341	6.0	5.4 to 6.7
	Total reported financial, temporal and other harms	1,898	33.6	32.3 to 34.8
	PSP with ≥1 financial, temporal, other harm	1,378	71.2	69.2 to 73.2

Of the 1,935 PSPs with at least one harm, 55.8% were rated as (very) severe. 35.3% of PSPs led to "permanent harm" or required "more than one month" of recovery (24.1%). 804 PSPs (31.5%) prompted patients to see another doctor for additional treatment; 255 PSPs (10%) required inpatient treatment overnight, with 2.4% requiring an inpatient stay of more than 2 weeks (table 4).

Table 4 Differentiation of severity, recovery time and additional treatments of the severest harm per patient with at least one PSP

Differentiation of the 'severest' harm (N=1,935)		n	%	95% CI
Severity	Very mild	139	7.2	6.1 to 8.4
	Mild	689	35.6	33.5 to 37.8
	Severe	794	41.0	38.9 to 43.2
	Very severe	287	14.8	13.3 to 16.5
	Don't know	25	1.3	0.9 to 1.9
	Refused to answer	1	0.1	0.0 to 0.2
Recovery period	Less than a week	294	16.9	15.2 to 18.7
	More than a week, but less than a month	347	19.9	18.1 to 21.9
	More than a month	419	24.1	22.1 to 26.1
	Permanent harm	615	35.3	33.1 to 37.6
	Don't know	37	2.1	1.5 to 2.9
	Not applicable	28	1.6	1.1 to 2.3
Additional treatment*	Went to see another doctor	804	31.5	29.7 to 33.3
	Medical on-call service / emergency service	126	4.9	4.2 to 5.8
	Emergency room	227	8.9	7.9 to 10.1
	Inpatient treatment (overnight)	255	10.0	7.8 to 10.0
	Up to one week	98	3.8	3.2 to 4.7
	Between one and two weeks	96	3.8	3.1 to 4.6
	Two weeks and more	60	2.4	1.8 to 3.0
	Don't know	1	0.0	0.0 to 0.2
	Rehabilitation	206	8.1	7.1 to 9.2
	None of it	927	36.3	34.5 to 38.2
	Don't know	4	0.2	0.1 to 0.4
	Refused to answer	2	0.1	0.0 to 0.3

*Multiple answers possible for additional treatments.

Subanalysis of the most frequently reported PSP types

Among the 2,589 PSPs recorded, the PSP type "important questions not asked about complaints" (a) was the most frequent with 515 (19.9%) responses, followed by "inadequate physical examination" (b) with 381 responses (14.7%) (table 2). A subanalysis revealed 136 (a) and 107 (b) cases, in which participants had only experienced this one PSP type once in

the last 12 months. 100 (a) and 70 (b) of these patients reported harmful consequences. These resulted in a deterioration of health status or persistent pain in 90 (a) / 72 (b) cases, were (very) severe in 55 (a) / 23 (b) cases, permanent in 34 (a) / 24 (b) cases, and resulted in 12 (a) / 11 (b) hospital stays ([supplementary tables 3 and 4](#)).

DISCUSSION

For the very first time, our study reports the frequency, types and consequences of PSPs in the ambulatory care sector in Germany, as measured by a representative sample of ≥40-year-olds. It thus provides an important starting point for PSP prevention measures and improving patient safety. Within the last 12 months, 1,422 out of 10,037 respondents (14% of the population and 16% of those with a doctor's visit, respectively) had experienced a total of 2,589 PSPs. Extrapolated to the total population at risk in Germany (47.2 million ≥40 years), 12.2 million PSPs could be expected for 6.7 million patients ≥40 years per year. Based on an average of 10-20 ambulatory doctor visits per year in this age group, 1.3-2.6% of these visits might be associated with a PSP. According to the patients' reports, around 1.2 of the current 19.4 million inpatient cases (6.2%) per year in Germany might be due to PSPs in ambulatory care, which are experienced by patients ≥40 years alone.[18] With an average case value of 3,457 € in 2018, these hospital stays cost around 4.15 billion €/year. As a matter of priority, the harm to patients resulting from PSPs must be avoided; additionally, the prevention of PSPs in ambulatory care would also be of huge economic importance.

According to our study, the PSP rate in Germany is in the lower range of the range of 1-24 PSIs per 100 consultations as reported by Panesar *et al*,[8] undercuts the PSI rate of 21%[4] from the Netherlands, which was collected in a review of medical records, but is higher than the potentially harmful preventable problems rate of 7.9%[5] for ≥15-year-olds in Great Britain. Different recording methods, age groups and health care systems (e.g. primary care systems without specialised physicians in private practices as is the case with Germany) must be considered, which makes international comparison difficult.

Considering only those PSPs associated with harm to health, the proportion of people who have experienced at least one harm to health in the past year due to a PSP in ambulatory care is 10% (889 out of 8,776 participants visiting a doctor, data not reported here) and thus comparable to the upper estimate range of the inpatient sector, in which 5-10% of cases experience an adverse event.[3]

With regard to the medical treatment areas most frequently affected by PSPs, it can be stated that the most frequent ambulatory diagnostic and therapeutic activities (anamnesis/diagnostic procedures, medication) are associated with most PSPs. Particularly medication is also repeatedly highlighted internationally as a frequent source of PSIs with harmful consequences

in ambulatory care.[8] Similarly, more PSPs occur in specialties with a higher number of visits (general practitioners and internists), with the exception of orthopaedists, who account for 14.5% of all PSPs, although they account for only 5% of all physicians in the ambulatory care sector in Germany. This phenomenon is also known from inpatient and ambulatory malpractice statistics.[19] An astonishing result of our study is that patients most frequently name PSP types that doctors think are hardly likely to cause harm and sometimes doubt that patients are able to assess them correctly. This applies in particular to the most common PSP types from the area of anamnesis/diagnostic procedures, namely "important questions not asked about the complaints" and "insufficient physical examination", which together make up 35% of all PSP types. A possible explanation for this finding could be that many patients claim to have visited another doctor (31.5%) or even a hospital (10.0%) later and that during this visit it was explained that a certain question should have been asked or an examination carried out at the first contact. In addition, the subanalyses prove that even these supposedly harmless PSPs were the cause of permanent harm in about one third and led to inpatient treatment in 13.6% of the cases from the perspective of those patients who had only reported this type of PSP. With regard to the survey instrument, PSPs of the last 12 months should be reported, a period that is also used in the PREOS-PC survey.[20] The short introductory text informs the patients that the interview focusses on PSPs that the participants themselves have experienced and perceived in the last 12 months as well as on those PSPs they learned about later. Furthermore, complex filter guides were used in such a way that the target person was only asked the questions relevant to their specific situation. By this, both, the increased burden as well as the risk of memory bias were systematically reduced - however, as in other studies,[21] they cannot be avoided completely.

Strengths and limitations of the study

The main strength of the study lies in the fact that, for the first-time, PSP frequencies and distribution in the ambulatory care sector were collected in a representative, extensive population sample, so that a high degree of certainty is achieved in the PSP incidence estimates. Our study identifies that three-quarters of all PSPs reported by patients occur in the areas of anamnesis, clinical examination and medication. It also provides insights into which PSPs are most likely to cause harm. Thus, the study provides a good indication of effective fields of action to improve patient safety. Our study also reveals that the majority of reported ambulatory PSPs leads to an additional use of the health care system, thus demonstrating that PSPs reported by patients are of great importance for the ambulatory health care system. A limitation exists with regard to the interview participation rate of 12.4%, which is in the lower range of the rates in telephone surveys in Germany. Nevertheless, the random selection of participants resulted in a sample that allows to generalise the results to the population of ≥40-

year-olds. Our selectivity analyses show that random selection alone achieved a good overall population representation with only minor deviations and that the survey participants represent the target population in all important variables. For example, the proportion of women in the study corresponds exactly to the population statistics. In addition, the comparison with the last population survey of the Robert Koch Institute, which is responsible for health monitoring in Germany, shows that – almost exactly as in our sample - 51.2% of ≥40-year-olds in Germany describe themselves as chronically ill[22] and 88% of the total population had at least one outpatient visit to the doctor in the last 12 months.[23] A selection bias towards persons with a potentially higher PSP risk (e.g. high utilisers, multimorbidity) cannot, however, be excluded with absolute certainty.

Another limitation may be seen in the research method used to generate data on PSP frequency and distribution in ambulatory care. Critics may question whether asking patients is suitable for generating valid statements about PSP frequency and distribution at all. This method deliberately considers only the patient's subjective perspective and does not use comparative data (e.g. medical records of the participants) to objectify the reported PSPs medically. However, studies that did not use patient reports but other methods to measure the type and frequency of PSP and harm also have to deal with weaknesses. Studies using e.g. voluntary reports from physicians[24-27] have been criticised as an unreliable source, as physicians report PSP and harm less often than they actually do occur.[15] Even the analysis of medical records and error reporting systems cannot be regarded as the best solution. As impressively shown in the study by Weingart *et al*, only about half of the adverse events validated by inpatient physicians were documented in the medical records. None of these were documented in the error reporting systems.[28]

Recommendations for research and practice

Despite these limitations, our study provides important insights into both the risk of PSPs and the importance of the patient as an actor in the identification and reporting of PSPs in ambulatory care.[29, 30] Based on our own findings as well as those of Sharma *et al*,[31] who show in their review that patients and their relatives could report more frequently on patient safety issues such as chemotherapy toxicity and events such as suboptimal service quality and communication problems that have not been perceived or identified by service providers, we believe that patient reports should play a more important role in improving patient safety. To this end, it will first of all be necessary to raise awareness of the existence of patient safety problems in ambulatory care, both among physicians and other medical professionals, but also among patients and policymakers. The publication and discussion of our study results can contribute to this. In the medical profession, patient safety in ambulatory care should be addressed more frequently within the framework of the quality circles already introduced for

doctors in private practice. Quality circles are also suitable for analysing patient safety problems in open discussions and developing ways of preventing PSPs. They are also useful for reducing the previously widespread reluctance to recognise patient reports as a valid source for recording patient safety problems. In addition, critical incident reporting systems (CIRS) for the ambulatory care sector could be supplemented by those items that have proven to be particularly significant in our study. In Germany, all medical institutions are obliged to participate in error reporting systems, but the participation rate has so far been extremely low.[9] It is questionable to what extent mandatory active participation is conducive or rather leads to harming the intrinsic motivation of medical professionals. At the very least, one could consider to follow the English example, and, within the framework of the review of internal quality management, check whether an institution actually reports patient safety problems in CIRS. Considering the importance of anamnesis and clinical examination for the occurrence of patient safety problems, it would be appropriate to increase the appreciation of these basic activities in patient care. So far, technical examinations and procedures in the German health care system are much better remunerated than anamnesis and clinical examination. For this reason, typically only little time is spent, a cause for complain for many patients. In Germany, a change in the remuneration of ambulatory physicians is therefore recommended in order to take advantage of this approach to improve patient safety.

Conclusions

Our results show that in the ambulatory care sector in Germany, PSPs are frequently reported by patients and often lead to harm to health and additional ambulatory or inpatient treatment. The findings can help to identify critical medical care situations and to develop targeted measures to avoid PSPs. Furthermore, our study indicates that patient reports are a valuable and complementary source to identify PSPs and to improve patient safety as well as the quality of ambulatory care.

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Contributors All authors had full access to all of the data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study guarantor: MG, WdC. Study concept and design: MG, SK, JL, WdC. Analysis and interpretation of data: MG, SK, MS, AO, JL, WdC. Drafting of the manuscript: MG, SK. Critical revision of the manuscript for important intellectual content: all authors. Statistical analysis: SK, MS. Study supervision: MG.

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Competing Interests

The authors declare that there is no conflict of interest.

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supplementary file 1 CATI survey instrument related to the last 12 months

(A) Introductory questions		
I.	How would you describe your current health status? a) <i>very good</i> b) <i>good</i> c) <i>mediocre</i> d) <i>bad</i> e) <i>very bad</i>	7: refused to answer 8: don't know
II.	Do you have one or more long-lasting chronic diseases?	1: yes 2: no 7: refused to answer 8: don't know
III.	When was the last time you saw your GP or a specialist? a) <i>during the last 3 months</i> b) <i>4 up to 12 months ago</i> c) <i>more than one year ago</i>	7: refused to answer 8: don't know
<p><i>Where people work, errors occur. Errors can also occur in medical offices. This can happen during treatment, but also during laboratory tests or when writing prescriptions. In the following, we introduce you to specific errors that can occur in the surgeries of general practitioners and specialists in Germany. So, it is not about errors that occur in hospital. In each case, I will ask you, whether, according to your knowledge or assessment, you have experienced such an error while treated by your general practitioner or specialist. Please also think of errors that you learned about later.</i></p>		information text: <i>if the last GP / specialist visit took place during the last 12 months</i>
(B) 12-month incidence of PSPs in 7 areas of medical treatment		
1. Anamnesis / diagnostic procedures		
	Let's get to medical examinations first. Have you had a physical examination, a laboratory examination, a gastrointestinal or colonoscopy or ultrasound, X-ray, or other examinations during the last 12 months?	1: yes 2: no 7: refused to answer 8: don't know
**	If, as far as you can tell, one of the following errors has occurred: Did your physician ... a) <i>... ask important questions about your complaints?</i> b) <i>... make an insufficient physical examination?</i> c) <i>... not make a medically necessary examination?</i> d) <i>... not recognize a serious illness or recognized it too late?</i> e) <i>... make a faulty examination</i> f) <i>... make a wrong examination?</i> g) <i>... make a wrong diagnosis?</i> h) <i>... communicate incorrect test results?</i> i) <i>... communicate results too late or not at all?</i>	1: yes 2: no 6: does not apply 7: refused to answer 8: don't know
**	Where did this error occur? During ... a) <i>... physical examination, including examination talk?</i> b) <i>... laboratory examination, e.g. blood, urine, stool?</i> c) <i>... imaging examination, e.g. X-ray, ultrasound or examination in the tube such as CT or MRT?</i> d) <i>... examination with a catheter, e.g. on the heart, vessels or urethra?</i> e) <i>... endoscopic examination, e.g. examination of the stomach, intestines or lungs?</i> f) <i>... puncture, e.g. of organs or joints?</i> g) <i>... or any other examination?</i>	1: yes 2: no

supplementary file 1 continued CATI survey instrument related to the last 12 months

2. Medication		
**	Did you need drugs from your GP or specialist in the last 12 months? Please remember all drugs prescribed by your physician, e.g. tablets, ointments, creams and sprays, pain patches and suppositories.	1: yes 2: no 7: refused to answer 8: don't know
	If, as far as you can tell, one of the following errors has occurred: Did your physician ...	1: yes 2: no
	a) ... <i>prescribe wrong drugs?</i>	6: does not apply 7: refused to answer 8: don't know
	b) ... <i>not prescribe necessary drugs?</i>	
	c) ... <i>prescribe drugs in the wrong dose or form, e.g. solution instead of tablet?</i>	
	d) ... <i>prescribe drugs, although your physician knew of an intolerance?</i>	
**	e) ... <i>prescribe drugs without considering the interaction with another drug?</i>	
	f) ... <i>discontinue drugs too early, too late, or not at all?</i>	
3. Vaccination, injection, infusion		
**	Have you received a vaccination, injection, or infusion from your GP or specialist in the last 12 months?	1: yes 2: no 7: refused to answer 8: don't know
	If, as far as you can tell, one of the following errors has occurred: Did you (not) get a vaccination, injection or infusion administered...	1: yes 2: no
	a) ... <i>although it was necessary?</i>	6: does not apply 7: refused to answer 8: don't know
	b) ... <i>with a wrong active substance?</i>	
	c) ... <i>in the wrong place, e.g. in muscle instead of blood vessel?</i>	
	d) ... <i>even though the physician knew of an intolerance?</i>	
**	e) ... <i>without noticing the interaction with another medication?</i>	
4. Aftercare		
**	Now we're talking about aftercare. This can be a wound follow-up, a cancer follow-up, or a follow-up after an operation. Did your physician carry out a necessary aftercare treatment incorrectly, belated or not at all within the last 12 months to your knowledge?	6: does not apply 7: refused to answer 8: don't know
	a) <i>yes, wrong</i>	
	b) <i>yes, belated</i>	
	c) <i>yes, not at all</i>	

supplementary file 1 continued CATI survey instrument related to the last 12 months

5. Outpatient surgery		
	Have you been operated by your GP or specialist in the office or in an outpatient clinic in the last 12 months?	1: yes
		2: no
		7: refused to answer
		8: don't know
**	If, as far as you can tell, one of the following errors has occurred: Did your physician ... a) ... perform a surgery too late? b) ... not perform a surgery properly? c) ... perform a wrong surgery? d) ... communicate the results of surgery incorrectly? e) ... not communicate the results of surgery or communicated it too late?	1: yes
		2: no
		6: does not apply
		7: refused to answer
		8: don't know
**	Did this error occur during a surgery on/in ... a) ... the eye? b) ... the nose, ears or sinuses? c) ... a joint? d) ... the heart vessels? e) ... the abdomen or internal organs? f) ... the urinary tract or sexual organs? g) ... the skin? h) ... the muscles? only for women: i) ... the uterus? j) ... the ovaries? k) ... the context of an abortion?	1: yes
		2: no
		7: refused to answer
		8: don't know
6. Office administration		
**	According to your knowledge, we would like to know if it has happened to you during the last 12 months, that ... a) ... you have been confused with another patient? b) ... your examination results were not or not completely available? c) ... your attending physician did not perform a necessary home visit?	6: does not apply
		7: refused to answer
		8: don't know
7. Other areas		
**	In the last 12 months, as far as you can tell, have you experienced another error that we have not yet asked you about?	1: yes
		2: no
		7: refused to answer
		8: don't know

** multiple answers possible.

supplementary file 1 continued CATI survey instrument related to the last 12 months

Detailed questions per reported PSP		
1.	How often has this error happened in the last 12 months?	times 7: refused to answer 8: don't know
2.	Did this error happen with a GP or a specialist? a) GP b) specialist c) both, GP and specialist d) GP or specialist, don't know which one e) error occurred during an outpatient treatment f) error occurred during an inpatient treatment	7: refused to answer 8: don't know
3.	To which group of physicians did the specialist belong who made the error? a) internists b) gynaecologists c) ophthalmologists d) orthopaedists e) ear, nose and throat specialists f) neurologist, psychiatrist, neurologists g) surgeons h) dermatologists i) radiologists j) urologists k) other medical specialists	7: refused to answer 8: don't know
4. **	What do you think caused this error? That ... a) ... the physician is not technically competent? b) ... the physician suffers from stress and lack of time? c) ... the physician does not listen, does not take you seriously, or only uses incomprehensible technical terms? d) ... the patient records are poorly kept? e) ... the practice is badly organized? f) ... other causes?	1: yes 2: no 7: refused to answer 8: don't know
5. **	What harmful consequences have you experienced as a result of this error? a) mild allergic reaction, e.g. skin rash, itching b) severe allergic reaction, e.g. anaphylactic shock c) other side effects, e.g. stomach bleeding d) deterioration of the health status e) unnecessarily prolonged pain f) wound infection / inflammation g) bleeding h) other part of the body has been injured, e.g. an internal organ or nerve i) a serious illness has not been recognized or has been recognized too late j) financial harm, e.g. additional therapy and treatment costs k) temporal harm, e.g. you had to go to the practice again l) mental or social harm m) other harmful consequences	6: no harm occurred 7: refused to answer 8: don't know

supplementary file 1 continued CATI survey instrument related to the last 12 months

6.	Please tell us, how severe or mild your (severest) harm was? a) <i>very mild</i> b) <i>mild</i> c) <i>severe</i> d) <i>very severe</i>	7: refused to answer 8: don't know
7.	How long did it take to recover from (the severest) harm? a) <i>less than a week</i> b) <i>more than a week but less than a month</i> c) <i>more than a month</i> d) <i>or has the harm remained permanent?</i>	6: does not apply 7: refused to answer 8: don't know
8. **	Due to this (severest) harm, did you ... a) <i>... go to see another physician?</i> b) <i>... call the medical on-call service / emergency service?</i> c) <i>... go to the emergency room?</i> d) <i>... go to the hospital overnight for treatment?</i> e) <i>... need rehabilitation?</i>	6: none of it 7: refused to answer 8: don't know
9.	How long have you been in the hospital overnight? a) <i>up to one week</i> b) <i>one to two weeks</i> c) <i>two weeks or more</i>	7: refused to answer 8: don't know
10. **	We would like to know how you dealt with this error/harm. Did you or a relative report the error/harm to someone, for example ... a) <i>... the physician with whom the error occurred?</i> b) <i>... another general practitioner or specialist?</i> c) <i>... your health insurance fund or health insurance coverage?</i> d) <i>... the medical association?</i> e) <i>... an independent patient advisory centre?</i> f) <i>... a lawyer?</i> g) <i>... another person or entity?</i>	6: no one 7: refused to answer 8: don't know
11. **	How did you react to this error/harm? Did you ... a) <i>... complain to the attending physician?</i> b) <i>... lost your confidence in the physician?</i> c) <i>... change physicians?</i> d) <i>... give a negative rating on the Internet?</i> e) <i>... sue the physician?</i> f) <i>... react in another way?</i>	6: didn't respond any further 7: refused to answer 8: don't know

** multiple answers possible.

(C) Socio-demographic Data		
1.	What is your sex? a) <i>male</i> b) <i>female</i> c) <i>diverse</i>	7: refused to answer 8: don't know
2.	Do you have German citizenship?	1: yes 2: no 7: refused to answer 8: don't know

supplementary file 1 continued CATI survey instrument related to the last 12 months

3. Did you acquire German citizenship at birth?	1: yes 2: no 7: refused to answer 8: don't know
4. Did your mother and father both acquire German citizenship at birth? <i>(Those born in the former German eastern territories up to and including 1955 acquired German nationality at birth)</i>	1: yes 2: no 7: refused to answer 8: don't know
5. What is your highest school-leaving qualification? a) Left school without a certificate b) Primary or lower secondary school leaving certificate c) Secondary school leaving certificate d) Polytechnic secondary school (POS), 8th grade diploma e) Polytechnic secondary school (POS), 10th grade diploma f) Specialized secondary school leaving certificate g) University entrance qualification or Extended Secondary School (EOS) with 12th grade degree or vocational training with Abitur (university entrance qualification) h) another school leaving certificate i) still a pupil	7: refused to answer 8: don't know
6. Which main occupation do you have: are you currently... a) employed full-time (35 hours or more) b) employed part-time (15 to less than 35 hours) c) semi-retired, irrespective of timeframe d) in minor employment (less than 15 hours) e) occasionally or irregularly engaged in gainful activity f) in in-company vocational training / apprenticeship g) in retraining h) in military service / federal voluntary service / voluntary social year i) on maternity leave, parental leave, or other leave j) not employed (including students not working for money, unemployed, early retirees, pensioners) k) In school education l) employed in a one-euro job	7: refused to answer 8: don't know
7. To which group does your current or last occupation belong? a) self-employed farmer b) cooperative farmer (formerly LPG in the GDR) c) academics in the liberal profession (physician, lawyer, tax consultant, etc.) d) self-employed in trade, commerce, crafts, industry, services, including "Me Incorporated" e) civil servant / judge / professional soldier f) employee g) worker h) vocational training/apprenticeship i) assisting family members j) never been in employment	7: refused to answer 8: don't know

supplementary file 1 continued CATI survey instrument related to the last 12 months

8.	Are you or were you a civil servant / judge / professional soldier ... a) <i>in the lower or middle grade of the civil service</i> b) <i>in the upper grade of the civil service</i> c) <i>in the higher grade of the civil service</i>	7: refused to answer 8: don't know
9.	Are you or were you an employee ... a) <i>with an activity which is carried out in accordance with instructions</i> b) <i>who works independently and responsibly</i> c) <i>with comprehensive management tasks</i>	7: refused to answer 8: don't know
10.	Are you or were you a worker and namely ... a) <i>unskilled / semi-skilled</i> b) <i>skilled</i> c) <i>foreman</i>	7: refused to answer 8: don't know
11.	In our society, there are population groups that tend to be at the top and those that tend to be at the bottom. Where would you place yourself on a scale from 1 to 10? 1 means that you are at the bottom, 10 means that you are at the top. Use the values in between to gradate. 1: at the bottom ... 10: at the top	7: refused to answer 8: don't know
12.	Please tell me briefly: How many people are currently living in your household, including children and yourself?	(no.) 7: refused to answer 8: don't know
13.	How high is the monthly net income of your household as a whole, i.e. all of those who receive an income? (This refers to the sum of wages, salaries, income from self-employment, pension or annuity, in each case after deduction of taxes and social security contributions. Please also add income from public subsidies, income from renting, leasing, housing benefit, child benefit and other income.) I'll read you some income categories. Please say 'Stop' if a category applies. a) <i>less than 500 Euros</i> b) <i>500 to less than 1,000 Euro</i> c) <i>1,000 to less than 1,500 Euro</i> d) <i>1,500 to less than 2,000 Euro</i> e) <i>2,000 to less than 2,500 Euro</i> f) <i>2,500 to less than 3,000 Euro</i> g) <i>3,000 to less than 4,000 Euro</i> h) <i>4,000 to less than 5,000 Euro</i> i) <i>5,000 Euro and more</i>	7: refused to answer 8: don't know
14.	For this scientific study, it is important to know which treatment errors occur particularly rarely or frequently in which population groups. This also includes the question of whether those affected are more likely to receive a lower or higher income. Can you therefore at least tell us roughly whether your monthly net household income is less or more than 1,500 euros? a) <i>less than 1,500 Euros</i> b) <i>more than 1,500 Euros</i>	7: refused to answer 8: don't know

supplementary table 1 Socio-demographic and socio-economic data

		PAV* (%)	95% CI	GEDA-14** (%)	95% CI
Gender	Male	47.6	46.7-48.6	47.9	47.1-48.7
	Female	52.3	51.4-53.3	52.1	51.3-52.9
Age groups	40-59 years old	51.1	50.1-52.1	53.3	52.6-54.1
	60-79 years old	38.0	37.0-38.9	39.4	38.7-40.2
	80+ years old	10.3	9.8-11.0	7.2	6.8-7.6
Current health status	Very good	15.9	15.2-16.6	9.9	9.5-10.4
	Good	45.3	44.3-46.3	50.9	50.1-51.6
	Mediocre	27.8	27.0-28.7	31.4	30.7-32.2
	Bad	8.0	7.5-8.6	6.2	5.8-6.6
	Very bad	2.8	2.5-3.1	1.0	0.9-1.2
Chronic diseases	Yes	46.6	45.7-47.6	53.7	53.0-54.5
	No	53.0	52.0-53.9	45.3	44.5-46.0
Last GP or specialist visit	During the past 12 months	87.5	85.8-89.1	89.0	88.5-89.4
	More than 12 months ago	12.4	11.8-13.1	10.2	9.7-10.7
Inpatient treatment during the past 12 months	Yes	23.5	22.6-24.3	18.3	17.7-18.9
	No	76.2	75.4-77.1	81.1	80.5-81.7
Citizenship	German	81.9	81.1-82.6	96.2	95.9-96.5
	Non-German	17.0	16.2-17.7	2.6	2.4-2.9
Household size	1-4 persons	95.1	92.1-98.3	95.3	94.9-95.6
	≥5 persons	4.1	3.5-5.1	3.8	3.5-4.1
Monthly net income	Up to less than 1,000 Euro	7.4	6.8-8.2	18.3	17.5-19.1
	1, 000 to less than 5,000 Euro	62.6	59.1-66.2	79.4	76.4-82.5
	5,000 Euro and more	9.7	9.1-10.2	2.4	2.1-2.6
SSS / SES***	Low	11.7	11.1-12.3	21.3	20.7-22.0
	Medium	50.3	49.3-51.3	58.6	57.9-59.4
	High	33.9	33.0-34.8	19.7	19.1-20.4

*PAV, study population of ≥40-year-olds: 10,037 participants

**GEDA-14, study population of ≥40-year-olds: 16,452 participants

***PAV-Study: SSS=subjective social status; GEDA-14: SES=socio-economic status (objective)

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supplementary table 2 Distribution of PSPs by specialist group

Medical specialist group	PSP (n)*	PSP (%)	95% CI
Family physicians	1,101	43.7	41.8 to 45.6
Orthopaedists	367	14.5	13.2 to 16.0
Internists	259	10.3	9.1 to 11.5
Neurologists	129	5.1	4.3 to 6.0
Surgeons	95	3.8	3.1 to 4.6
Gynaecologists	76	3.0	2.4 to 3.7
Urologists	71	2.8	2.2 to 3.5
Radiologists	60	2.4	1.8 to 3.0
ENT specialists	50	2.0	1.5 to 2.6
Dermatologists	42	1.7	1.2 to 2.2
Ophthalmologists	35	1.4	1.0 to 1.9
Other specialists	236	9.4	8.2 to 10.5

*A total of 2,589 PSPs was reported. 2,521 PSPs were uniquely assignable to specialist groups.

supplementary table 3 Subanalysis of PSP 'important questions about complaints not asked': Proportion of PSPs with harm, distribution of harm types, and differentiation of severity, recovery time and additional treatments

PSP 'important questions about complaints not asked'		n	%	95% CI
Persons with this PSP type exclusively*		136	1.5	1.3 to 1.8
Harm and its consequences		n	%	95% CI
Harm / no harm	PSP without harm	36	26.5	19.8 to 34.5
	PSP with at least one harm	100	73.5	65.5 to 80.2
Types of harm	Unnecessarily prolonged pain	49	26.8	20.9 to 33.6
	Deterioration of health status	41	22.4	17.0 to 29.0
	Mental / social harm	32	17.5	12.7 to 23.6
	Serious illness not recognized / recognized too late	19	10.4	6.7 to 15.6
	Other part of the body injured	8	4.4	2.2 to 8.4
	Other side effects	8	4.4	2.2 to 8.4
	Mild allergic reaction	6	3.3	1.5 to 7.0
	Severe allergic reaction	3	1.6	0.6 to 4.7
	Bleeding	2	1.1	0.3 to 3.9
	<i>Total reported harm to health</i>	<i>180</i>	<i>98.4</i>	<i>95.3 to 99.4</i>
	Temporal harm	60	32.8	26.4 to 39.9
	Other harm	25	13.7	9.4 to 19.4
	Financial harm	18	9.8	6.3 to 15.0
	<i>Total reported financial, temporal and other harm</i>	<i>103</i>	<i>56.3</i>	<i>49.0 to 63.3</i>
Severity	Very mild	6	6.0	2.8 to 12.5
	Mild	38	38.0	29.1 to 47.8
	Severe	36	36.0	27.3 to 45.8
	Very severe	19	19.0	12.5 to 27.8
Recovery period	Less than a week	12	14.1	8.3 to 23.1
	More than a week, but less than a month	22	25.9	17.8 to 36.1
	More than a month	14	16.5	10.1 to 25.8
	Permanent harm	34	40.0	30.2 to 50.6
	Don't know	3	3.5	1.2 to 9.9
Additional treatment	None of this	46	46.0	36.6 to 55.7
	Went to see another doctor	44	44.0	34.7 to 53.8
	Medical on-call service / emergency service	7	7.0	3.4 to 13.7
	Emergency room	13	13.0	7.8 to 21.0
	Inpatient treatment (overnight)	12	12.0	7.0 to 19.8
	<i>Up to one week</i>	<i>5</i>	<i>5.0</i>	<i>2.2 to 11.2</i>
	<i>One to two weeks</i>	<i>1</i>	<i>1.0</i>	<i>0.2 to 5.4</i>
	<i>Two weeks and more</i>	<i>6</i>	<i>6.0</i>	<i>2.8 to 12.5</i>
	Rehabilitation	7	7.0	3.4 to 13.7

supplementary table 4 Subanalysis of PSP 'inadequate physical examination': Proportion of PSPs with harm, distribution of harm types and differentiation of severity, recovery time and additional treatments

PSP 'inadequate physical examination'		n	%	95% CI
Persons with this PSP type exclusively*		107	1.2	1.0 to 1.5
Harm and its consequences		n	%	95% CI
Harm / no harm	PSP without harm	37	34.6	26.2 to 44.0
	PSP with at least one harm	70	65.4	56.0 to 73.8
Types of harm	Unnecessarily prolonged pain	38	21.8	16.3 to 28.6
	Deterioration of health status	23	13.2	9.0 to 19.1
	Mental / social harm	15	8.6	5.3 to 13.7
	Serious illness not recognized / recognized too late	14	8	4.9 to 13.1
	Mild allergic reaction	12	6.9	4.0 to 11.7
	Other part of the body injured	7	4	2.0 to 8.1
	Wound infection / inflammation	6	3.4	1.6 to 7.3
	<i>Total reported harm to health</i>	<i>115</i>	<i>66.1</i>	<i>58.8 to 72.7</i>
	Temporal harm	37	21.3	15.8 to 27.9
	Financial harm	12	6.9	4.0 to 11.7
	Other harm	10	5.7	3.2 to 10.3
	<i>Total reported financial, temporal, and other harm</i>	<i>59</i>	<i>33.9</i>	<i>27.3 to 41.2</i>
Severity	Very mild	7	10	4.9 to 19.2
	Mild	40	57.1	45.5 to 68.1
	Severe	16	22.9	14.6 to 34.0
	Very severe	7	10	4.9 to 19.2
Recovery period	Less than a week	15	23.4	14.7 to 35.1
	More than a week, but less than a month	13	20.3	12.3 to 31.7
	More than a month	10	15.6	8.7 to 26.4
	Permanent harm	24	37.5	26.7 to 49.7
	Not applicable	3	4.7	1.6 to 12.9
	Don't know	1	1.6	0.3 to 8.3
Additional treatment	None of this	34	48.6	37.2 to 60.0
	Went to see another doctor	30	42.9	31.9 to 54.5
	Medical on-call service / emergency service	3	4.3	1.5 to 11.9
	Emergency room	10	14.3	7.9 to 24.3
	Inpatient treatment (overnight)	11	15.7	9.0 to 26.0
	<i>Up to one week</i>	<i>3</i>	<i>4.3</i>	<i>1.5 to 11.9</i>
	<i>One to two weeks</i>	<i>8</i>	<i>11.4</i>	<i>5.9 to 21.0</i>
	Rehabilitation	2	2.9	0.8 to 9.8

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

For manuscript: “Patient safety in ambulatory care from the patient's perspective - A retrospective, representative telephone survey”

submitted by Geraedts et al, 161219

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-6 (plus supplementary file 1)
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	N/A
		(c) Explain how missing data were addressed	N/A

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		(d) If applicable, describe analytical methods taking account of sampling strategy	6
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7 (plus supplementary table 1)
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	N/A
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7-11 (plus tables 1-4 and supplementary tables 2-4)
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	7-11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	13-14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.