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Duration of second victim symptoms in the aftermath of a patient safety incident and association with the level of patient harm

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ABSTRACT

Objectives To describe healthcare providers' symptoms evoked by patient safety incidents, the duration of these symptoms, and the association with the degree of patient harm caused by the incident.

Design Cross-sectional survey.

Setting 32 Dutch hospitals that participate in the "Peer Support Collaborative".

Participants 4369 health care providers (1619 doctors and 2750 nurses) involved in a patient safety incident (PSI) at any time during their career.

Interventions: All doctors and nurses working in direct patient care in the 32 participating hospitals were invited via e-mail to participate in an online survey.

Primary and secondary outcome measures Prevalence of symptoms, symptom duration and its relationship with the degree of patient harm.

Results In total 4369 respondents were involved in a PS. Of these, 462 reported having been involved in a PSI with permanent harm or death during the last 6 months. This had a personal, professional impact as well as impact on effective teamwork requirements. The impact of a PSI increased when the degree of patient harm was more severe. The most common symptom was hypervigilance. The three most common symptoms related to teamwork, were having doubts about knowledge and skill, feeling unable to provide quality care and feeling uncomfortable within the team. PSI with permanent harm or death was related to eight-fold higher likelihood of provider-related symptoms lasting for more than one month and nine-fold lasting longer than six months compared to symptoms reported when the PSI caused no harm.

Conclusion The impact of PSI remains an underestimated problem. The higher the degree of harm, the longer the symptoms last. Future studies should evaluate how these data can be integrated in evidence-based support systems.

KEYWORDS

“Patient Safety”, “Stress, Psychological”, “Health Personnel/psychology”, “Hospitals”, “Peer support”

STRENGTHS AND LIMITATIONS

- This study explores an underinvestigated area in the field of patient safety and quality care: duration of health care provider second victim symptoms in the aftermath of a patient safety incident and its relationship with the degree of patient harm.
- The very large sample size (n = 6508) as well as the large number of included Dutch hospitals (n = 32) representing a cross section of urban/rural, small/large, (non)academic, and (non)teaching hospitals.
- In this study the prevalence of symptoms was based on dichotomous questions (Present or absent) and not evaluated by means of validated questionnaires.
- This study is based on data of approximately one third (n = 32) of all Dutch hospitals. The results are not representative for all the health care organizations in the Netherlands or anywhere else in the world.
- Response bias is an inherent limitation related to surveys, as also pertains to the study now reported, as well as recall bias since the self-reported presence or absence of symptoms was purely based on the respondents' recollection.

INTRODUCTION

It is estimated that Patient Safety Incidents (PSI) occur in at least 1 out of 7 hospitalized patients.[1] This mostly includes incidents that cause no harm (near misses) but also incidents with temporary harm, permanent harm or death (adverse events).[2] In addition to the tremendous impact on patients and their family (first victims), the well-being of involved healthcare providers (second victims) may also be significantly affected.[3] Moreover, PSI may harm the reputation of the healthcare department and entire organization (third victims) and reduce trust in healthcare providers in general.[4]

Recent studies indicate that almost 80% of healthcare professionals have been involved in a near miss or adverse event at least once in their career and report to be emotionally affected by this.[5, 6] The psychological impact depends on individual, situational and organisational aspects and affects both personal well-being and professional functioning.[7-9] Anxiety, fear, guilt, distress, frustration, anger and feeling insufficient are the most frequently cited symptoms.[10, 11] In addition, health care providers report a significant work-home interference, greater risk of burnout and higher intention to leave the job.[12]

More and more hospitals realise that they have role in providing an institutional support system to meet second victims needs.[11, 13-15] Healthcare professionals involved in a PSI may have an increased likelihood to develop post-traumatic stress disorder (PTSD).[13] One of the criteria for PTSD, based on the latest criteria set by the Diagnostic and Statistical Manual of Mental Disorders (DSM 5), is that the symptoms last for more than one month.[14] Current literature is lacking in information on duration of symptoms suffered by second victims. This hinders the development of evidence-based institutional support programs. This study aims to describe the prevalence and duration of health care provider self-reported symptoms evoked by PSI, and the association between these symptoms and the degree of patient harm caused by the incident.

METHODS

Setting

This study was conducted at 32 hospitals in the Netherlands that participate in the “Peer Support Collaborative”. The 32 hospitals represent approximately one third of all Dutch

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3 hospitals and comprise a variety of large and small, rural and urban, (non)-teaching and (non)-
4 academic hospitals. These hospitals are amongst the first group of Dutch hospitals who
5 expressed the wish to implement an organisational peer support program for second victims
6 in the aftermath of a PSI, patient complaint or lawsuit. This collaborative aims to determine
7 the needs of their second victims and to define a peer support program that fits their specific
8 organisational patient safety culture and now reports their first insights. As part of the
9 activities of the Collaborative each hospital distributed a standard questionnaire amongst
10 their doctors and nurses in order to determine their specific needs.
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18 **Participants**

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21 Three rounds of data collection were conducted depending on the year of enrolment of the
22 participating hospital in the peer support Collaborative. Ten hospitals conducted the survey
23 between 14th April and 15th June 2016, nine hospitals between 1st February and 30th March
24 2017 and 13 hospitals between 2nd June 2018 and 23rd November 2018. All doctors and nurses
25 working in direct patient care in the 32 participating hospitals were invited via e-mail to
26 participate in an online survey under the auspices of the KU Leuven. Respondents could only
27 participate once. The online survey was available during four weeks. The contact person
28 participating in the peer support collaborative of each hospital distributed the web survey in
29 his or her hospital and one e-mail reminder was sent to all doctors and nurses in the third
30 week of the study period. Participation was entirely voluntary, and confidentiality and
31 anonymity were guaranteed.
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41 **Measurements**

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44 The questionnaire contained four distinct parts. The first part pertained to respondent
45 demographics (profession, years of experience, years of work experience in this hospital, type
46 of ward (surgical of non-surgical) and gender). The second part surveyed the presence or
47 absence of personal involvement in PSI (during the entire career and during the previous 6
48 months) and the degree of harm (impact of PSI on the patient) (no harm, temporary harm,
49 permanent harm and death). Third, personal involvement and symptoms related to the PSI
50 were measured. These 11 symptoms were selected based on a literature research.[8]
51 Response categories for the duration of the symptoms were “none”, “some hours”, “a day”,
52 “a week”, “a month”, “2-6 months”, “6-12 months” and “more than 1 year”.
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Statistics

Demographic variables are reported and descriptive data as well as the recollection of the degree of PSI related patient harm during the entire career and during the previous 6 months. Recollection of the presence or absence of symptoms perceived in the aftermath of a PSI are represented in individual prevalence ratios. This ratio indicates whether the specific symptom lasted for more than 1 month and for more than 6 months, and their prevalence pertaining to PSI with no patient harm, temporary harm, permanent harm and death. We opted to use prevalence ratios as these are less prone to overestimate associations compared with using odds ratios.[15] Descriptive analyses and prevalence ratios were produced using SAS v9.4.

Patient and public involvement

There was no patient or public involvement in this study.

RESULTS

6508 participants in 32 participating hospitals completed the questionnaire. In total 4369 respondents (1619 doctors and 2750 nurses) reported that they had been involved in a PSI at least once during their career and choose to completely fill out the questions regarding symptoms. Table 1 summarizes the demographic information.

Table 1 Demographic information

	Doctors (1619)	Nurses (2750)
Gender		
Female	898 (55.5%)	2531 (92.0%)
Years of experience (mean±SD)	11.2±8.8	18.1±12.1
Type of department		
Surgical department	540 (35.4%)	751 (29.1%)
Nonsurgical department	910 (59.8%)	1506 (58.3%)
Surgical and nonsurgical department	73 (4.8%)	327 (12.6%)

During their entire career, over half of respondents had only been involved in a PSI with no harm whereas approximately 45% had been involved in a PSI with permanent harm or with death (Table 2). During the previous 6 months 80 % of the respondents had only been involved in a PSI with no harm or temporary harm whereas one in 5 reported having been involved in a PSI with permanent harm or death. Doctors reported more involvement in PSI resulting in permanent harm or death compared to nurses.

Table 2 Prevalence for the different degree of harm (Reporting only PSI with the highest reported degree of harm).

Degree of harm	PSI during the entire career (n=4369)			PSI during previous 6 months (n=2379)		
	Doctors	Nurses	Overall	Doctors	Nurses	Overall
No harm	197 (12.2%)	911 (33.1%)	1108 (25.4%)	342 (36.6%)	865 (59.9%)	1207 (50.7%)
Temporary harm	372 (23.0%)	936 (34.0%)	1308 (29.9%)	313 (33.5%)	397 (27.5%)	710 (29.8%)
Permanent harm	363 (22.4%)	293 (10.7%)	656 (15.0%)	128 (13.7%)	66 (4.6%)	194 (8.2%)
Death	687 (42.4%)	610 (22.2%)	1297 (29.7%)	152 (16.3%)	116 (8.0%)	268 (11.3%)

Symptoms

Figure 1 depicts an overview of the 11 symptoms and their frequency of occurrence. The most frequently reported symptom was hypervigilance which bothered 53.0% of the respondents for more than one month. In frequency of occurrence this was followed by doubts about knowledge and skill (27.0%), stress (25.8%), shame (24.7%), flashbacks (23.3%), fear (19.0%), feeling unable to provide quality care (15.6%), feeling uncomfortable within team (15.5%), avoiding risks (13.0%), feeling unhappy and dejected (12.5%) and difficulty sleeping (10.8%). Prevalence of symptoms with a duration of more than six months were respectively hypervigilance (23.6%), flashbacks (8.7%), shame (8.2%), doubts about knowledge and skill (8.1%), stress (6.8%), fear (6.3%), feeling unable to provide quality care (4.8%), avoiding risks (4.5%), feeling uncomfortable within team (4.2%), difficulty sleeping (2.8%) and feeling unhappy and dejected (2.6%). Of note, in total, 3.7% of the responding doctors and 4.0% of the nurses reported never having had any symptom while a significant portion of these providers were personally involved in PSI resulting in permanent harm or death.

Table 3 depicts an overview of the different symptoms which persisted for more than one month for each degree of harm. The impact of a PSI with temporary harm, permanent harm and death are more profound than a PSI with no harm, showing up to two, three, four and eight-fold symptom prevalence. While the reported symptoms demonstrate to have a personal impact (difficulty sleeping, fear, stress, shame etc.) organizations need also be aware that some symptoms have also an impact on the teamwork, patient safety and ability to provide quality care. E.g. 27% of the respondents mentioned that they have doubts about knowledge and skill for more than one month, 15.6% feel unable to provide quality care and 15.5% feel uncomfortable within their team.

Table 3 Overview of symptoms persisting longer than one month

	Doctors (n=1619)		Nurses (n=2750)	
	Prevalence no. (%)	Prevalence ratio (95% CI)	Prevalence no. (%)	Prevalence ratio (95% CI)
Hypervigilance				
<i>No harm</i>	85 (43.2%)	Reference	433 (47.5%)	Reference
<i>Temporary harm</i>	170 (45.7%)	1.06 (0.87, 1.29)	485 (51.8%)	1.09 (0.99, 1.20)
<i>Permanent harm</i>	208 (57.3%)	1.33 (1.11, 1.60)*	162 (55.3%)	1.16 (1.03, 1.32)*
<i>Death</i>	409 (59.5%)	1.38 (1.16, 1.64)*	365 (59.8%)	1.26 (1.15, 1.38)*
Doubts about knowledge and skill				
<i>No harm</i>	43 (21.8%)	Reference	138 (15.2%)	Reference
<i>Temporary harm</i>	102 (27.4%)	1.26 (0.92, 1.72)	184 (19.7%)	1.30 (1.06, 1.59)*
<i>Permanent harm</i>	152 (41.9%)	1.92 (1.43, 2.57)*	76 (25.9%)	1.71 (1.34, 2.19)*
<i>Death</i>	319 (46.4%)	2.13 (1.61, 2.80)*	165 (27.1%)	1.79 (1.46, 2.18)*
Stress				
<i>No harm</i>	32 (16.2%)	Reference	122 (13.4%)	Reference
<i>Temporary harm</i>	84 (22.6%)	1.39 (0.96, 2.01)	170 (18.2%)	1.36 (1.10, 1.68)*
<i>Permanent harm</i>	131 (36.1%)	2.22 (1.57, 3.14)*	84 (28.7%)	2.14 (1.68, 2.73)*
<i>Death</i>	308 (44.8%)	2.76 (1.99, 3.83)*	198 (32.5%)	2.42 (1.98, 2.96)*
Shame				

<i>No harm</i>	33 (16.8%)	Reference	139 (15.3%)	Reference
<i>Temporary harm</i>	87 (23.4%)	1.40 (0.97, 2.00)	187 (20.0%)	1.31 (1.07, 1.60)*
<i>Permanent harm</i>	132 (36.4%)	2.17 (1.55, 3.05)*	75 (25.6%)	1.68 (1.31, 2.15)*
<i>Death</i>	279 (40.6%)	2.42 (1.75, 3.35)*	149 (24.4%)	1.60 (1.30, 1.97)*
Flashbacks				
<i>No harm</i>	22 (11.2%)	Reference	111 (12.2%)	Reference
<i>Temporary harm</i>	52 (14.0%)	1.25 (0.78, 2.00)	182 (19.4%)	1.60 (1.28, 1.98)*
<i>Permanent harm</i>	97 (26.7%)	2.39 (1.56, 3.68)*	83 (28.3%)	2.32 (1.81, 2.99)*
<i>Death</i>	240 (34.9%)	3.13 (2.08, 4.70)*	229 (37.5%)	3.08 (2.52, 3.77)*
Fear				
<i>No harm</i>	23 (11.7%)	Reference	94 (10.3%)	Reference
<i>Temporary harm</i>	39 (10.5%)	0.90 (0.55, 1.46)	150 (16.0%)	1.55 (1.22, 1.98)*
<i>Permanent harm</i>	88 (24.2%)	2.08 (1.36, 3.18)*	63 (21.5%)	2.08 (1.56, 2.79)*
<i>Death</i>	211 (30.7%)	2.63 (1.76, 3.93)*	161 (26.4%)	2.56 (2.03, 3.23)*
Avoiding risks				
<i>No harm</i>	6 (5.3%)	Reference	42 (6.7%)	Reference
<i>Temporary harm</i>	23 (10.1%)	1.93 (0.81, 4.59)	57 (8.9%)	1.33 (0.91, 1.95)
<i>Permanent harm</i>	48 (24.4%)	4.63 (2.05, 10.48)*	25 (13.0%)	1.93 (1.21, 3.09)*
<i>Death</i>	104 (24.9%)	4.74 (2.14, 10.51)*	63 (14.9%)	2.21 (1.53, 3.20)*
Unhappy and dejected				
<i>No harm</i>	9 (7.9%)	Reference	25 (4.0%)	Reference
<i>Temporary harm</i>	18 (7.9%)	1.00 (0.47, 2.16)	56 (8.8%)	2.19 (1.39, 3.46)*
<i>Permanent harm</i>	40 (20.3%)	2.57 (1.30, 5.10)*	26 (13.5%)	3.38 (2.00, 5.71)*
<i>Death</i>	117 (28.1%)	3.55 (1.86, 6.78)*	63 (14.9%)	3.72 (2.38, 5.81)*
Uncomfortable within team				
<i>No harm</i>	10 (8.8%)	Reference	46 (7.4%)	Reference
<i>Temporary harm</i>	26 (11.5%)	1.31 (0.65, 2.61)	82 (12.9%)	1.74 (1.24, 2.46)*
<i>Permanent harm</i>	54 (27.4%)	3.12 (1.66, 5.89)*	31 (16.2%)	2.19 (1.43, 3.35)*
<i>Death</i>	115 (27.6%)	3.14 (1.70, 5.80)*	75 (17.7%)	2.41 (1.70, 3.40)*
Difficulty sleeping				
<i>No harm</i>	3 (2.6%)	Reference	23 (3.7%)	Reference

<i>Temporary harm</i>	11 (4.9%)	1.84 (0.52, 6.47)	50 (7.8%)	2.13 (1.31, 3.44)*
<i>Permanent harm</i>	31 (15.7%)	5.98 (1.87, 19.12)*	27 (14.1%)	3.82 (2.24, 6.50)*
<i>Death</i>	94 (22.5%)	8.57 (2.77, 26.54)*	68 (16.1%)	4.36 (2.76, 6.88)*
Unable to provide quality care				
<i>No harm</i>	8 (7.0%)	Reference	41 (6.6%)	Reference
<i>Temporary harm</i>	21 (9.3%)	1.32 (0.60, 2.88)	85 (13.3%)	2.03 (1.42, 2.89)*
<i>Permanent harm</i>	46 (23.4%)	3.33 (1.63, 6.80)*	39 (20.3%)	3.09 (2.06, 4.65)*
<i>Death</i>	106 (25.4%)	3.62 (1.82, 7.21)*	95 (22.5%)	3.42 (2.42, 4.83)*

* P<0.05

Table 4 presents symptoms that lasted more than 6 months following the most severe PSI that was recollected by the respondent. The impact of PSI with temporary harm, permanent harm and death are more profound than a PSI with no harm, showing up to two, three, four, five, six, seven and nine fold prevalence of symptoms. Hypervigilance is the symptom with remained the most constant, and independent of the degree of harm.

Table 4 Overview of symptoms which persisting longer than six months

	Doctors (n=1619)		Nurses (n=2750)	
	Prevalence no. (%)	Prevalence ratio (95% CI)	Prevalence no. (%)	Prevalence ratio (95% CI)
Hypervigilance				
<i>No harm</i>	30 (15.2%)	Reference	206 (22.6%)	Reference
<i>Temporary harm</i>	52 (14.0%)	0.92 (0.61, 1.39)	206 (22.0%)	0.97 (0.82, 1.15)
<i>Permanent harm</i>	77 (21.2%)	1.39 (0.95, 2.05)	88 (30.0%)	1.33 (1.07, 1.64)*
<i>Death</i>	182 (26.5%)	1.74 (1.22, 2.47)*	191 (31.3%)	1.38 (1.17, 1.64)*
Doubts about knowledge and skill				
<i>No harm</i>	5 (2.5%)	Reference	25 (2.7%)	Reference
<i>Temporary harm</i>	19 (5.1%)	2.01 (0.76, 5.31)	52 (5.6%)	2.02 (1.27, 3.23)*
<i>Permanent harm</i>	47 (13.0%)	5.10 (2.06, 12.62)*	25 (8.5%)	3.11 (1.81, 5.33)*
<i>Death</i>	114 (16.6%)	6.54 (2.71, 15.78)*	69 (11.3%)	4.12 (2.64, 6.44)*
Stress				
<i>No harm</i>	4 (2.0%)	Reference	32 (3.5%)	Reference
<i>Temporary harm</i>	15 (4.0%)	1.99 (0.67, 5.90)	49 (5.2%)	1.49 (0.96, 2.30)
<i>Permanent harm</i>	29 (8.0%)	3.93 (1.40, 11.03)*	26 (8.9%)	2.53 (1.53, 4.17)*
<i>Death</i>	84 (12.2%)	6.02 (2.24, 16.21)*	57 (9.3%)	2.66 (1.75, 4.05)*
Shame				
<i>No harm</i>	6 (3.1%)	Reference	33 (3.6%)	Reference
<i>Temporary harm</i>	21 (5.7%)	1.85 (0.76, 4.52)	67 (7.2%)	1.98 (1.32, 2.97)*
<i>Permanent harm</i>	35 (9.6%)	3.17 (1.36, 7.40)*	31 (10.6%)	2.92 (1.82, 4.68)*
<i>Death</i>	99 (14.4%)	4.73 (2.11, 10.62)*	65 (10.7%)	2.94 (1.96, 4.42)*
Flashbacks				
<i>No harm</i>	7 (3.6%)	Reference	32 (3.5%)	Reference
<i>Temporary harm</i>	17 (4.6%)	1.29 (0.54, 3.05)	68 (7.3%)	2.07 (1.37, 3.12)*
<i>Permanent harm</i>	30 (8.3%)	2.33 (1.04, 5.20)*	31 (10.6%)	3.01 (1.87, 4.85)*
<i>Death</i>	94 (13.7%)	3.85 (1.82, 8.16)*	103 (16.9%)	4.81 (3.28, 7.05)*
Fear				

<i>No harm</i>	3 (1.5%)	Reference	25 (2.7%)	Reference
<i>Temporary harm</i>	8 (2.2%)	1.41 (0.38, 5.26)	48 (5.1%)	1.87 (1.16, 3.00)*
<i>Permanent harm</i>	26 (7.2%)	4.70 (1.44, 15.34)*	24 (8.2%)	2.98 (1.73, 5.14)*
<i>Death</i>	79 (11.5%)	7.55 (2.41, 23.66)*	62 (10.2%)	3.70 (2.35, 5.83)*
Avoiding risks				
<i>No harm</i>	1 (0.9%)	Reference	13 (2.1%)	Reference
<i>Temporary harm</i>	8 (3.5%)	4.02 (0.51, 31.73)	25 (3.9%)	1.88 (0.97, 3.64)
<i>Permanent harm</i>	13 (6.6%)	7.52 (0.99, 56.76)	8 (4.2%)	2.00 (0.84, 4.75)
<i>Death</i>	33 (7.9%)	9.02 (1.25, 65.25)*	27 (6.4%)	3.06 (1.60, 5.87)*
Unhappy and dejected				
<i>No harm</i>	2 (1.8%)	Reference	3 (0.5%)	Reference
<i>Temporary harm</i>	2 (0.9%)	0.50 (0.07, 3.52)	11 (1.7%)	3.59 (1.01, 12.79)*
<i>Permanent harm</i>	7 (3.6%)	2.03 (0.43, 9.59)	5 (2.6%)	5.42 (1.31, 22.46)*
<i>Death</i>	30 (7.2%)	4.10 (0.99, 16.90)	15 (3.6%)	7.38 (2.15, 25.32)*
Uncomfortable within team				
<i>No harm</i>	1 (0.9%)	Reference	8 (1.3%)	Reference
<i>Temporary harm</i>	7 (3.1%)	3.52 (0.44, 28.23)	21 (3.3%)	2.57 (1.15, 5.75)*
<i>Permanent harm</i>	10 (5.1%)	5.79 (0.75, 44.62)	10 (5.2%)	4.06 (1.63, 10.15)*
<i>Death</i>	36 (8.6%)	9.84 (1.36, 71.01)*	26 (6.2%)	4.79 (2.19, 10.49)*
Difficulty sleeping				
<i>No harm</i>	1 (0.9%)	Reference	5 (0.8%)	Reference
<i>Temporary harm</i>	2 (0.9%)	1.00 (0.09, 10.96)	13 (2.0%)	2.54 (0.91, 7.09)
<i>Permanent harm</i>	6 (3.1%)	3.47 (0.42, 28.48)	8 (4.2%)	5.20 (1.72, 15.71)*
<i>Death</i>	26 (6.2%)	7.11 (0.98, 51.82)	18 (4.3%)	5.31 (1.99, 14.19)*
Unable to provide quality care				
<i>No harm</i>	1 (0.9%)	Reference	10 (1.6%)	Reference
<i>Temporary harm</i>	7 (3.1%)	3.52 (0.44, 28.23)	26 (4.1%)	2.54 (1.24, 5.23)*
<i>Permanent harm</i>	9 (4.6%)	5.21 (0.67, 40.58)	16 (8.3%)	5.20 (2.40, 11.27)*
<i>Death</i>	27 (6.5%)	7.38 (1.01, 53.74)*	39 (9.2%)	5.75 (2.90, 11.40)*

* P<0.05

DISCUSSION

The impact of PSI on healthcare professionals remains an underestimated problem. This study adds relevant information on the prevalence and (long-lasting) duration of several self-reported symptoms and their relation with the degree of patient harm. Almost half of the respondents reported their involvement in a PSI resulting in permanent harm or death at least once during their entire career. While one in five reported involvement in a PSI resulting in permanent harm or death during the previous six months. Those latter 462 healthcare professionals were particularly at risk for poor well-being and reduced professional functioning during those previous six months as they were involved in a PSI with such serious sequelae. More than half of all respondents suffered hypervigilance for more than one month, while almost one in four suffered more than six months. The prevalence ratio for all symptoms increased with a higher degree of patient harm. Interestingly, this was also true for all symptoms; except for feeling unhappy and dejected and difficulty sleeping; six months after being involved in a PSI compared to one month.

The results reported are in line with previous prevalence reports pertaining to emotional responses.[6, 8, 16] We found that in addition to earlier publications reporting symptoms such as anxiety, flashback and insomnia, that hypervigilance was the most universally reported symptom (80%). A recent study of 5782 physician mothers found that involvement in a mistake was associated with higher reported burnout.[16] The psychological impact of PSI on the healthcare professional is thought to be similar to that characterizing PTSD.[17] We therefore choose a cut-off set at one month based on the criteria set by DSM-5 for PTSD.[14] Suffering symptoms longer than one month, let alone six months, has a profound impact on health care providers professional and personal life. As personal testimonials reveal health care providers can not provide the quality of care that is needed and they are at risk of being involved in future PSI's.[18]

Healthcare professionals may, at some point, find themselves in a vicious circle. As health care workers involved in PSI are at risk of diminished personal well-being and reduced professional performance adequate institutional and peer support are more and more considered essential components in alleviating the personal and professional impact on these second victims. Health care organizations need more awareness that some of the symptoms, such as doubts

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3 about knowledge and skill, feeling unable to provide quality care, feeling uncomfortable with
4 the team, may seriously impact team performance, patient safety and the provision of quality
5 care. Organizations should therefore play a pro-active role in providing immediate support to
6 healthcare professionals involved in a PSI and should not wait until the healthcare professional
7 gets depressed, develops a burnout or quits the job. The risk of not responding to a PSI in a
8 timely and effective manner can have a significant impact on the involved healthcare
9 professional as well as organisations alike. It can lead to absence of healing, loss of trust, no
10 learning and improvement while it may also increase the likelihood of law suits and patient
11 complaints.[4] Perceptions of second victimness, turnover intentions and absenteeism may
12 be less severe when the healthcare organizations culture is characterized by a non-punitive
13 response to errors. Such non-punitive response may encourage supportive interactions,
14 openness to discuss error and thus mitigate the negative effects of PSI.[17] A recent study
15 amongst Dutch gynaecologists showed that 60% of respondents deemed the current hospital
16 support services after an adverse event insufficient. Two-thirds reported that their
17 department or hospital lacked a support protocol or strategy and they were close to
18 unanimous in preferring support from direct colleagues.[19]

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20 Well-being and Joy In Work receive important attention nowadays in medical journals.[20-24]
21 Well-being in physicians and other healthcare professionals has a direct link with patient
22 outcomes. In general, healthcare may need to focus more on positive dimensions like work
23 engagement and enjoy unexpected small positive experiences like Mangomoment a
24 movement recently described by our department and now getting international attention.[23]
25 The results of this study emphasize that the Triple Aim a framework that describes an
26 approach to optimizing health system performance is expanded to a Quadruple aim. Meaning
27 that next to enhancing patient experience, improving population health and reducing costs,
28 improving the work life of health care providers is added to optimize health system
29 performance.[25] To improve Joy in Work, it is now time for action by senior leaders,
30 managers and healthcare providers alike.

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33 The large sample size (n=6508) as well as the large number of included Dutch hospitals (n=32)
34 strengthen this report. However, there are also some limitations. Even though the
35 participating hospitals vary in size, location and function, the results may not be
36 representative for all hospitals in the Netherlands. In order to keep the questionnaire concise
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3 and little time consuming, we did not make use of extensive validated questionnaires but
4 choose a dichotomous (present or absent) variable to record the symptoms. Since we rely on
5 the recollection and perception of the respondents the data may be subject to recollection
6 bias.
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11 Future studies should focus on how organisations best embed the support of healthcare
12 professionals involved in PSI in their vision, mission and policy regarding patient safety and
13 quality care efforts. Specifically, longitudinal studies focusing on the duration of the symptoms
14 may help in making the current support systems more evidence-based. Future work should
15 also include a screening method in order to individualize institutional and peer support in the
16 aftermath of a PSI. More data are needed in order to identify which actions should be taken
17 to reduce the duration of the symptoms for those who suffer longer than expected. We also
18 need to understand more about the degree of well-being of those healthcare providers,
19 involved in a PSI resulting in permanent harm or death, reporting no symptoms at all.
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28 **CONCLUSION**

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31 In conclusion, the majority of doctors and nurses in approximately one third of Dutch hospitals
32 involved in a PSI at least once during their career and who choose to participate in this study
33 report having suffered several symptoms in the aftermath of the PSI. Some of these symptoms
34 lasted longer than one month while others, eg hypervigilance, even lasted longer than six
35 months. Attention should be given on how to cope with these symptoms as they profoundly
36 affect personal well-being, professional performance as well as teamwork-related efforts
37 directly influencing patient safety and the provision of quality care.
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45 **AUTHOR CONTRIBUTIONS**

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48 Conception and design of the study: KV, SL, MP and GZ. Acquisition of the data: SL, EC and GZ.
49 Analysis and interpretation of the data: KV, DS, LB and EC. Drafting of the manuscript: DS, LS,
50 LB, ZG and KV. All authors critically revised the manuscript for intellectual content and
51 approved the final version.
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54

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19 None declared
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30 No data are available.
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33 **REFERENCES**

- 34
35
36 1. Classen DC, Resar R, Griffin F, et al. 'Global Trigger Tool' Shows That Adverse Events In Hospitals
37 May Be Ten Times Greater Than Previously Measured. *Health Affairs* 2011;30(4):581-89.
38
39 2. Vries EN, Ramrattan MA, Smorenburg SM, et al. The incidence and nature of in-hospital adverse
40 events: a systematic review. *Qual Saf Health Care* 2008;17 doi: 10.1136/qshc.2007.023622
41
42 3. Wu AW. Medical error: the second victim. The doctor who makes the mistake needs help too. *BMJ*
43 2000;320(7237):726-27.
44
45 4. Conway J, Federico F, Stewart K, et al. Respectful management of serious clinical adverse events.
46 IHI Innovation Series white paper. *Cambridge, Massachusetts: Institute for Healthcare*
47 *Improvement* 2011;(Available on www.IHI.org)
48
49 5. Harrison R, Lawton R, Stewart K. Doctors' experiences of adverse events in secondary care: the
50 professional and personal impact. *Clinical Medicine* 2014;14(6):585-90.
51
52
53
54
55
56
57
58
59
60

- 1
2
3 6. Mira JJ, Carrillo I, Lorenzo S, et al. The aftermath of adverse events in Spanish primary care and
4
5 hospital health professionals. *BMC Health Serv Res* 2015;15:151. doi: 10.1186/s12913-015-
6
7 0790-7 [published Online First: 2015/04/18].
8
9
10 7. Coughlan B, Powell D, Higgins MF. The Second Victim: a Review. *Eur J Obstet Gynecol Reprod Biol*
11
12 2017;213:11-16. doi: 10.1016/j.ejogrb.2017.04.002 [published Online First: 2017/05/21].
13
14 8. Seys D, Wu AW, Van Gerven E, et al. Health care professionals as second victims after adverse
15
16 events: a systematic review. *Eval Health Prof* 2013;36(2):135-62. doi:
17
18 10.1177/0163278712458918
19
20 9. Van Gerven E, Bruyneel L, Panella M, et al. Psychological impact and recovery after involvement in
21
22 a patient safety incident: a repeated measures analysis. *BMJ Open* 2016;6(8):e011403. doi:
23
24 10.1136/bmjopen-2016-011403 [published Online First: 2016/09/02].
25
26
27 10. Han K, Bohnen JD, Peponis T, et al. The Surgeon as the Second Victim? Results of the Boston
28
29 Intraoperative Adverse Events Surgeons' Attitude (BISA) Study. *J Am Coll Surg*
30
31 2017;224(6):1048-56. doi: 10.1016/j.jamcollsurg.2016.12.039 [published Online First:
32
33 2017/01/18].
34
35
36 11. Chan ST, Khong PCB, Wang W. Psychological responses, coping and supporting needs of
37
38 healthcare professionals as second victims. *Int Nurs Rev* 2017;64(2):242-62. doi:
39
40 10.1111/inr.12317 [published Online First: 2016/09/30].
41
42
43 12. Van Gerven E, Vander Elst T, Vandebroek S, et al. Increased Risk of Burnout for Physicians and
44
45 Nurses Involved in a Patient Safety Incident. *Med Care* 2016 doi:
46
47 10.1097/MLR.0000000000000582
48
49
50 13. Robertson N, Perry A. Institutionally based health care workers' exposure to traumatogenic
51
52 events: systematic review of PTSD presentation. *J Trauma Stress* 2010;23(3):417-20. doi:
53
54 10.1002/jts.20537 [published Online First: 2010/06/22].
55
56
57 14. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM–5)
58
59 [Available from:
60

1
2
3 https://www.psychiatry.org/psychiatrists/practice/dsm?_ga=1.8367346.1782582538.1481136819.
4
5
6

- 7 15. Tamhane AR, Westfall AO, Burkholder GA, et al. Prevalence odds ratio versus prevalence ratio:
8 choice comes with consequences. *Statistics in medicine* 2016;35(30):5730-35. doi:
9 10.1002/sim.7059 [published Online First: 2016/07/26].
10
11
12
13
14 16. Gupta K, Lisker S, Rivadeneira NA, et al. Decisions and repercussions of second victim experiences
15 for mothers in medicine (SAVE DR MoM). *BMJ Quality & Safety* 2019;bmjqs-2018-
16 008372. doi: 10.1136/bmjqs-2018-008372
17
18
19
20
21 17. Quillivan RR, Burlison JD, Browne EK, et al. Patient Safety Culture and the Second Victim
22 Phenomenon: Connecting Culture to Staff Distress in Nurses. *Jt Comm J Qual Patient Saf*
23 2016;42(8):377-86. [published Online First: 2016/07/28].
24
25
26
27
28 18. Buikema M. When healthcare hurts: doctors share their darkest hours: Zin Publishing 2011.
29
30 19. Baas MAM, Scheepstra KWF, Stramrood CAI, et al. Work-related adverse events leaving their
31 mark: a cross-sectional study among Dutch gynecologists. *BMC Psychiatry* 2018;18(1):73. doi:
32 10.1186/s12888-018-1659-1
33
34
35
36
37 20. Thomas LR, Ripp JA, West CP. Charter on physician well-being. *JAMA* 2018;319(15):1541-42. doi:
38 10.1001/jama.2018.1331
39
40
41 21. Schwenk TL. Physician well-being and the regenerative power of caring. *JAMA*
42 2018;319(15):1543-44. doi: 10.1001/jama.2018.1539
43
44
45
46 22. Perlo J, Balik B, Swensen S, et al. IHI Framework for Improving Joy in Work. IHI White Paper. .
47 Cambridge, Massachusetts: Institute for Healthcare Improvement, 2017.
48
49
50 23. Vanhaecht K. In search of Mangomoments. *Lancet Oncol* 2018;19(2):165. doi: 10.1016/s1470-
51 2045(18)30034-2 [published Online First: 2018/02/08].
52
53
54
55 24. Perlo J, Feeley D. Why Focusing on Professional Burnout Is Not Enough. *J Healthc Manag*
56 2018;63(2):85-89. doi: 10.1097/jhm-d-18-00003 [published Online First: 2018/03/14].
57
58
59
60

- 1
2
3 25. Bodenheimer T, Sinsky C. From Triple to Quadruple Aim: Care of the Patient Requires Care of the
4
5 Provider. *Ann Fam Med* 2014;12(6):573-76. doi: 10.1370/afm.1713
6
7
8
9
10
11
12
13
14
15
16
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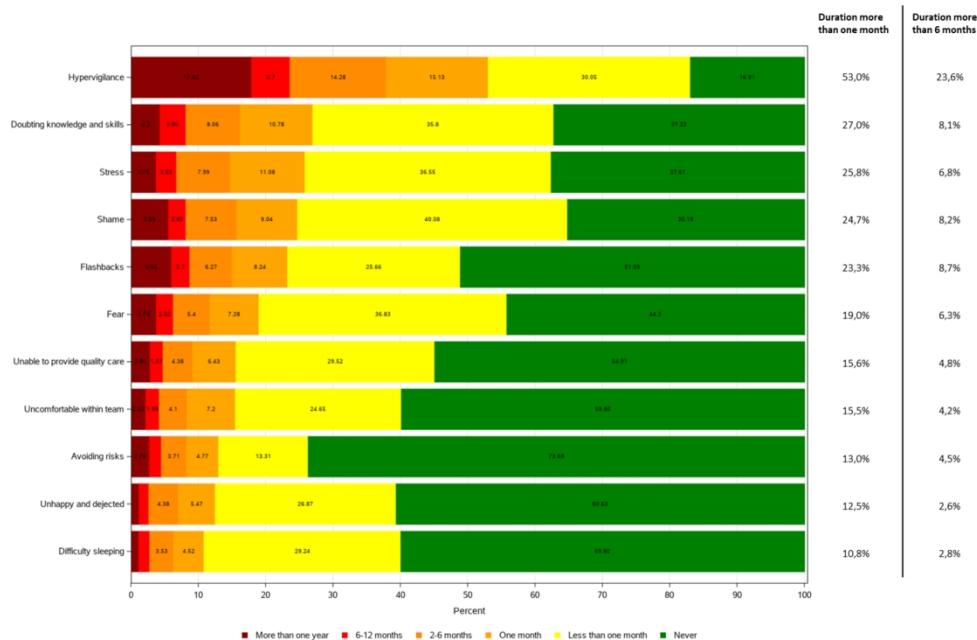
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FIGURE LEGENDS

Figure 1 Symptoms in the aftermath of PSI

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Symptoms in the aftermath of PSI

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the STROBE cross sectional reporting guidelines, and cite them as:

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		Reporting Item	Page Number
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	3
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	3
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	6
Objectives	#3	State specific objectives, including any prespecified hypotheses	6
Study design	#4	Present key elements of study design early in the paper	6-7
Setting	#5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	7
	#7	Clearly define all outcomes, exposures, predictors, potential	7

		confounders, and effect modifiers. Give diagnostic criteria, if applicable	
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3	Data sources /	#8	7
4	measurement	For each variable of interest give sources of data and details of methods	
5		of assessment (measurement). Describe comparability of assessment	
6		methods if there is more than one group. Give information separately	
7		for for exposed and unexposed groups if applicable.	
8			
9	Bias	#9	7
10		Describe any efforts to address potential sources of bias	
11			
12	Study size	#10	n/a
13		Explain how the study size was arrived at	
14	Quantitative	#11	7
15	variables	Explain how quantitative variables were handled in the analyses. If	
16		applicable, describe which groupings were chosen, and why	
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18	Statistical	#12a	8
19	methods	Describe all statistical methods, including those used to control for	
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22		#12b	8
23		Describe any methods used to examine subgroups and interactions	
24		#12c	n/a
25		Explain how missing data were addressed	
26		#12d	n/a
27		If applicable, describe analytical methods taking account of sampling	
28		strategy	
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30		#12e	n/a
31		Describe any sensitivity analyses	
32	Participants	#13a	8
33		Report numbers of individuals at each stage of study—eg numbers	
34		potentially eligible, examined for eligibility, confirmed eligible,	
35		included in the study, completing follow-up, and analysed. Give	
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40		Give reasons for non-participation at each stage	
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42		#13c	n/a
43		Consider use of a flow diagram	
44			
45	Descriptive data	#14a	8
46		Give characteristics of study participants (eg demographic, clinical,	
47		social) and information on exposures and potential confounders. Give	
48		information separately for exposed and unexposed groups if applicable.	
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50		#14b	8
51		Indicate number of participants with missing data for each variable of	
52		interest	
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54	Outcome data	#15	9
55		Report numbers of outcome events or summary measures. Give	
56		information separately for exposed and unexposed groups if applicable.	
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58	Main results	#16a	10-14
59		Give unadjusted estimates and, if applicable, confounder-adjusted	
60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included

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4		#16b	Report category boundaries when continuous variables were categorized
5			n/a
6		#16c	If relevant, consider translating estimates of relative risk into absolute
7			risk for a meaningful time period
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10	Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and
11			interactions, and sensitivity analyses
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14	Key results	#18	Summarise key results with reference to study objectives
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16	Limitations	#19	Discuss limitations of the study, taking into account sources of potential
17			bias or imprecision. Discuss both direction and magnitude of any
18			potential bias.
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21	Interpretation	#20	Give a cautious overall interpretation considering objectives,
22			limitations, multiplicity of analyses, results from similar studies, and
23			other relevant evidence.
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27	Generalisability	#21	Discuss the generalisability (external validity) of the study results
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29	Funding	#22	Give the source of funding and the role of the funders for the present
30			study and, if applicable, for the original study on which the present
31			article is based
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BMJ Open

Duration of second victim symptoms in the aftermath of a patient safety incident and association with the level of patient harm: a cross-sectional study in the Netherlands

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Primary Subject Heading:	Health services research
Secondary Subject Heading:	Medical management
Keywords:	Patient safety, Stress, psychological, Health personnel/psychology, Hospitals, peer support

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3 **TITLE PAGE**
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5 Title of article: Duration of second victim symptoms in the aftermath of a patient safety
6 incident and association with the level of patient harm: a cross-sectional study in the
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39 “Hospitals”, “Peer support”
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ABSTRACT

Objectives To describe healthcare providers' symptoms evoked by patient safety incidents, the duration of these symptoms, and the association with the degree of patient harm caused by the incident.

Design Cross-sectional survey.

Setting 32 Dutch hospitals that participate in the "Peer Support Collaborative".

Participants 4369 health care providers (1619 doctors and 2750 nurses) involved in a patient safety incident (PSI) at any time during their career.

Interventions: All doctors and nurses working in direct patient care in the 32 participating hospitals were invited via e-mail to participate in an online survey.

Primary and secondary outcome measures Prevalence of symptoms, symptom duration and its relationship with the degree of patient harm.

Results In total 4369 respondents were involved in a PSI and completely filled in the questionnaire. Of these, 462 reported having been involved in a PSI with permanent harm or death during the last 6 months. This had a personal, professional impact as well as impact on effective teamwork requirements. The impact of a PSI increased when the degree of patient harm was more severe. The most common symptom was hypervigilance (53.0%). The three most common symptoms related to teamwork, were having doubts about knowledge and skill (27.0%), feeling unable to provide quality care (15.6%) and feeling uncomfortable within the team (15.5%). PSI with permanent harm or death was related to eight-fold higher likelihood of provider-related symptoms lasting for more than one month and nine-fold lasting longer than six months compared to symptoms reported when the PSI caused no harm.

Conclusion The impact of PSI remains an underestimated problem. The higher the degree of harm, the longer the symptoms last. Future studies should evaluate how these data can be integrated in evidence-based support systems.

KEYWORDS

“Patient Safety”, “Stress, Psychological”, “Health Personnel/psychology”, “Hospitals”, “Peer support”

STRENGTHS AND LIMITATIONS

- This study explores an underinvestigated area in the field of patient safety and quality care: duration of health care provider second victim symptoms in the aftermath of a patient safety incident and its relationship with the degree of patient harm.
- The very large sample size (n = 6508) as well as the large number of included Dutch hospitals (n = 32) representing a cross section of urban/rural, small/large, (non)academic, and (non)teaching hospitals.
- In this study the prevalence of symptoms was based on dichotomous questions (Present or absent) and not evaluated by means of validated questionnaires.
- This study is based on data of approximately one third (n = 32) of all Dutch hospitals. The results are not representative for all the health care organizations in the Netherlands or anywhere else in the world.
- Response bias is an inherent limitation related to surveys, as also pertains to the study now reported, as well as recall bias since the self-reported presence or absence of symptoms was purely based on the respondents' recollection.

INTRODUCTION

It is estimated that Patient Safety Incidents (PSI) occur in at least 1 out of 7 hospitalized patients.[1] This mostly includes incidents that cause no harm (near misses) but also incidents with temporary harm, permanent harm or death (adverse events).[2] In addition to the tremendous impact on patients and their family (first victims), the well-being of involved healthcare providers (second victims) may also be significantly affected.[3] Although there is criticism on the term second victims, no alternative term is available.[4] Moreover, PSI may harm the reputation of the healthcare department and entire organization (third victims) and reduce trust in healthcare providers in general.[5]

Recent studies indicate that almost 80% of healthcare providers involved in a near miss or adverse event at least once in their career and report being emotionally affected by this.[6, 7] The psychological impact depends on individual, situational and organisational aspects and affects both personal well-being and professional functioning.[8-10] Anxiety, fear, guilt, distress, frustration, anger and feeling insufficient are the most frequently cited symptoms.[11, 12] In addition, health care providers report a significant work-home interference, greater risk of burnout and higher intention to leave the job.[13]

More and more hospitals realise that they have a role in providing an institutional support system to meet second victims needs.[12, 14-16] Healthcare professionals involved in a PSI may have an increased likelihood developing post-traumatic stress disorder (PTSD).[14] One of the criteria for PTSD, based on the latest criteria set by the Diagnostic and Statistical Manual of Mental Disorders (DSM 5), is that the symptoms last for more than one month.[15] Current literature is lacking in information on duration of symptoms suffered by second victims. This hinders the development of evidence-based institutional support programs. This study aims to describe the prevalence and duration of health care provider self-reported symptoms evoked by PSI, and the association between these symptoms and the degree of patient harm caused by the incident.

METHODS

Setting

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3 This study was conducted at 32 hospitals in the Netherlands that participate in the “Peer
4 Support Collaborative”. The 32 hospitals represent approximately one third of all Dutch
5 hospitals and comprise a variety of large and small, rural and urban, (non)-teaching and (non)-
6 academic hospitals. These hospitals are amongst the first group of Dutch hospitals who
7 expressed the wish to implement an organisational peer support program for second victims
8 in the aftermath of a PSI, patient complaint or lawsuit. This collaborative aims to determine
9 the needs of their second victims and to define a peer support program that fits their specific
10 organisational patient safety culture and now reports their first insights. As part of the
11 activities of the Collaborative each hospital distributed a standard questionnaire amongst
12 their doctors and nurses in order to determine their specific needs.
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22 **Participants**

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24 Three rounds of data collection were conducted depending on the year of enrolment of the
25 participating hospital in the peer support Collaborative. Ten hospitals conducted the survey
26 between 14th April and 15th June 2016, nine hospitals between 1st February and 30th March
27 2017 and 13 hospitals between 2nd June 2018 and 23rd November 2018. All doctors and nurses
28 working in direct patient care in the 32 participating hospitals were invited via e-mail to
29 participate in an online survey under the auspices of the KU Leuven. Respondents could only
30 participate once. The online survey was available during four weeks. The contact person
31 participating in the peer support collaborative of each hospital distributed the web survey in
32 his or her hospital and one e-mail reminder was sent to all doctors and nurses in the third
33 week of the study period. According to the regulations in Dutch hospitals, in the survey it was
34 mentioned that filling in the questionnaire implied informed consent to participate.
35 Participation was entirely voluntary, and confidentiality and anonymity were guaranteed.
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49 **Measurements**

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51 The questionnaire contained four distinct parts. The first part pertained to respondent
52 demographics (profession, years of experience, years of work experience in this hospital, type
53 of ward (surgical or non-surgical) and gender). The second part surveyed the presence or
54 absence of personal involvement in PSI (during the entire career and during the previous 6
55 months) and the degree of harm (impact of PSI on the patient) (no harm, temporary harm,
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3 permanent harm and death). This part started with more information about what a PSI is
4 and the difference with a not-patient safety related dramatic event. Third, personal
5 involvement and symptoms related to the PSI were measured. These 11 symptoms were
6 selected based on a literature research.[9] Response categories for the duration of the
7 symptoms were “none”, “some hours”, “a day”, “a week”, “a month”, “2-6 months”, “6-12
8 months” and “more than 1 year”. The questionnaire was based on previous research [13, 17-
9 19] and redesigned by the participating hospitals during a meeting of the peer support
10 network.
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18 **Statistics**

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21 Only completely filled in questionnaires were included in the analysis, except for the
22 prevalence rate. Demographic variables are reported and descriptive data as well as the
23 recollection of the degree of PSI related patient harm during the entire career and during the
24 previous 6 months. Recollection of the presence or absence of symptoms perceived in the
25 aftermath of a PSI are represented in individual prevalence ratios. This ratio indicates whether
26 the specific symptom lasted for more than 1 month and for more than 6 months, and their
27 prevalence pertaining to PSI with no patient harm, temporary harm, permanent harm and
28 death. We opted to use prevalence ratios as these are less prone to overestimate associations
29 compared with using odds ratios.[16] Descriptive analyses and prevalence ratios were
30 produced using SAS v9.4. This manuscript is compliant to the STROBE recommendations.
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40 **Patient and public involvement**

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42 There was no patient or public involvement in this study.
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45 **RESULTS**

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48 6508 participants in 32 participating hospitals completed the questionnaire. In total 5572
49 respondents (1938 doctors and 3634 nurses) reported that they had been involved in a PSI at
50 least once during their career (85.6%) and 4369 (1619 doctors and 2750 nurses) choose to
51 completely fill out the questions regarding symptoms and were included in this study. Table 1
52 summarizes the demographic information of the 4369 respondents.
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58 **Table 1** Demographic information

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	Doctors (1619)	Nurses (2750)
Gender		
Female	898 (55.5%)	2531 (92.0%)
Years of experience (mean±SD)	11.2±8.8	18.1±12.1
Type of department		
Surgical department	540 (35.4%)	751 (29.1%)
Nonsurgical department	910 (59.8%)	1506 (58.3%)
Surgical and nonsurgical department	73 (4.8%)	327 (12.6%)

During their entire career, over half of respondents had only been involved in a PSI with no harm whereas approximately 45% had been involved in a PSI with permanent harm or with death (Table 2). During the previous 6 months 80 % of the respondents had only been involved in a PSI with no harm or temporary harm whereas one in 5 reported having been involved in a PSI with permanent harm or death. Doctors reported more involvement in PSI resulting in permanent harm or death compared to nurses.

Table 2 Prevalence for the different degree of harm (Reporting only PSI with the highest reported degree of harm).

Degree of harm	PSI during the entire career (n=4369)			PSI during previous 6 months (n=2379)		
	Doctors	Nurses	Overall	Doctors	Nurses	Overall
No harm	197 (12.2%)	911 (33.1%)	1108 (25.4%)	342 (36.6%)	865 (59.9%)	1207 (50.7%)
Temporary harm	372 (23.0%)	936 (34.0%)	1308 (29.9%)	313 (33.5%)	397 (27.5%)	710 (29.8%)
Permanent harm	363 (22.4%)	293 (10.7%)	656 (15.0%)	128 (13.7%)	66 (4.6%)	194 (8.2%)
Death	687 (42.4%)	610 (22.2%)	1297 (29.7%)	152 (16.3%)	116 (8.0%)	268 (11.3%)

Symptoms

Figure 1 depicts an overview of the 11 symptoms and their frequency of occurrence. The most frequently reported symptom was hypervigilance which bothered 53.0% of the respondents for more than one month. In frequency of occurrence this was followed by doubts about knowledge and skill (27.0%), stress (25.8%), shame (24.7%), flashbacks (23.3%), fear (19.0%),

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3 feeling unable to provide quality care (15.6%), feeling uncomfortable within team (15.5%),
4 avoiding risks (13.0%), feeling unhappy and dejected (12.5%) and difficulty sleeping (10.8%).
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6 Prevalence of symptoms with a duration of more than six months were respectively
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8 hypervigilance (23.6%), flashbacks (8.7%), shame (8.2%), doubts about knowledge and skill
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10 (8.1%), stress (6.8%), fear (6.3%), feeling unable to provide quality care (4.8%), avoiding risks
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12 (4.5%), feeling uncomfortable within team (4.2%), difficulty sleeping (2.8%) and feeling
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14 unhappy and dejected (2.6%). Of note, in total, 3.7% of the responding doctors and 4.0% of
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16 the nurses reported never having had any symptom while a significant portion of these
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18 providers were personally involved in PSI resulting in permanent harm or death.
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Table 3 depicts an overview of the different symptoms which persisted for more than one month for each degree of harm. The impact of a PSI with temporary harm, permanent harm and death are more profound than a PSI with no harm, showing up to two, three, four and eight-fold symptom prevalence. While the reported symptoms demonstrate a personal impact (difficulty sleeping, fear, stress, shame etc.) organizations need also be aware that some symptoms also have an impact on the teamwork, patient safety and ability to provide quality care. E.g. 27% of the respondents mentioned that they have doubts about knowledge and skill for more than one month, 15.6% feel unable to provide quality care and 15.5% feel uncomfortable within their team.

Table 3 Overview of symptoms persisting longer than one month

	Doctors (n=1619)		Nurses (n=2750)	
	Prevalence no. (%)	Prevalence ratio (95% CI)	Prevalence no. (%)	Prevalence ratio (95% CI)
Hypervigilance				
<i>No harm</i>	85 (43.2%)	Reference	433 (47.5%)	Reference
<i>Temporary harm</i>	170 (45.7%)	1.06 (0.87, 1.29)	485 (51.8%)	1.09 (0.99, 1.20)
<i>Permanent harm</i>	208 (57.3%)	1.33 (1.11, 1.60)*	162 (55.3%)	1.16 (1.03, 1.32)*
<i>Death</i>	409 (59.5%)	1.38 (1.16, 1.64)*	365 (59.8%)	1.26 (1.15, 1.38)*
Doubts about knowledge and skill				
<i>No harm</i>	43 (21.8%)	Reference	138 (15.2%)	Reference
<i>Temporary harm</i>	102 (27.4%)	1.26 (0.92, 1.72)	184 (19.7%)	1.30 (1.06, 1.59)*
<i>Permanent harm</i>	152 (41.9%)	1.92 (1.43, 2.57)*	76 (25.9%)	1.71 (1.34, 2.19)*
<i>Death</i>	319 (46.4%)	2.13 (1.61, 2.80)*	165 (27.1%)	1.79 (1.46, 2.18)*
Stress				
<i>No harm</i>	32 (16.2%)	Reference	122 (13.4%)	Reference
<i>Temporary harm</i>	84 (22.6%)	1.39 (0.96, 2.01)	170 (18.2%)	1.36 (1.10, 1.68)*
<i>Permanent harm</i>	131 (36.1%)	2.22 (1.57, 3.14)*	84 (28.7%)	2.14 (1.68, 2.73)*
<i>Death</i>	308 (44.8%)	2.76 (1.99, 3.83)*	198 (32.5%)	2.42 (1.98, 2.96)*
Shame				

<i>No harm</i>	33 (16.8%)	Reference	139 (15.3%)	Reference
<i>Temporary harm</i>	87 (23.4%)	1.40 (0.97, 2.00)	187 (20.0%)	1.31 (1.07, 1.60)*
<i>Permanent harm</i>	132 (36.4%)	2.17 (1.55, 3.05)*	75 (25.6%)	1.68 (1.31, 2.15)*
<i>Death</i>	279 (40.6%)	2.42 (1.75, 3.35)*	149 (24.4%)	1.60 (1.30, 1.97)*
Flashbacks				
<i>No harm</i>	22 (11.2%)	Reference	111 (12.2%)	Reference
<i>Temporary harm</i>	52 (14.0%)	1.25 (0.78, 2.00)	182 (19.4%)	1.60 (1.28, 1.98)*
<i>Permanent harm</i>	97 (26.7%)	2.39 (1.56, 3.68)*	83 (28.3%)	2.32 (1.81, 2.99)*
<i>Death</i>	240 (34.9%)	3.13 (2.08, 4.70)*	229 (37.5%)	3.08 (2.52, 3.77)*
Fear				
<i>No harm</i>	23 (11.7%)	Reference	94 (10.3%)	Reference
<i>Temporary harm</i>	39 (10.5%)	0.90 (0.55, 1.46)	150 (16.0%)	1.55 (1.22, 1.98)*
<i>Permanent harm</i>	88 (24.2%)	2.08 (1.36, 3.18)*	63 (21.5%)	2.08 (1.56, 2.79)*
<i>Death</i>	211 (30.7%)	2.63 (1.76, 3.93)*	161 (26.4%)	2.56 (2.03, 3.23)*
Avoiding risks				
<i>No harm</i>	6 (5.3%)	Reference	42 (6.7%)	Reference
<i>Temporary harm</i>	23 (10.1%)	1.93 (0.81, 4.59)	57 (8.9%)	1.33 (0.91, 1.95)
<i>Permanent harm</i>	48 (24.4%)	4.63 (2.05, 10.48)*	25 (13.0%)	1.93 (1.21, 3.09)*
<i>Death</i>	104 (24.9%)	4.74 (2.14, 10.51)*	63 (14.9%)	2.21 (1.53, 3.20)*
Unhappy and dejected				
<i>No harm</i>	9 (7.9%)	Reference	25 (4.0%)	Reference
<i>Temporary harm</i>	18 (7.9%)	1.00 (0.47, 2.16)	56 (8.8%)	2.19 (1.39, 3.46)*
<i>Permanent harm</i>	40 (20.3%)	2.57 (1.30, 5.10)*	26 (13.5%)	3.38 (2.00, 5.71)*
<i>Death</i>	117 (28.1%)	3.55 (1.86, 6.78)*	63 (14.9%)	3.72 (2.38, 5.81)*
Uncomfortable within team				
<i>No harm</i>	10 (8.8%)	Reference	46 (7.4%)	Reference
<i>Temporary harm</i>	26 (11.5%)	1.31 (0.65, 2.61)	82 (12.9%)	1.74 (1.24, 2.46)*
<i>Permanent harm</i>	54 (27.4%)	3.12 (1.66, 5.89)*	31 (16.2%)	2.19 (1.43, 3.35)*
<i>Death</i>	115 (27.6%)	3.14 (1.70, 5.80)*	75 (17.7%)	2.41 (1.70, 3.40)*
Difficulty sleeping				
<i>No harm</i>	3 (2.6%)	Reference	23 (3.7%)	Reference

<i>Temporary harm</i>	11 (4.9%)	1.84 (0.52, 6.47)	50 (7.8%)	2.13 (1.31, 3.44)*
<i>Permanent harm</i>	31 (15.7%)	5.98 (1.87, 19.12)*	27 (14.1%)	3.82 (2.24, 6.50)*
<i>Death</i>	94 (22.5%)	8.57 (2.77, 26.54)*	68 (16.1%)	4.36 (2.76, 6.88)*
Unable to provide quality care				
<i>No harm</i>	8 (7.0%)	Reference	41 (6.6%)	Reference
<i>Temporary harm</i>	21 (9.3%)	1.32 (0.60, 2.88)	85 (13.3%)	2.03 (1.42, 2.89)*
<i>Permanent harm</i>	46 (23.4%)	3.33 (1.63, 6.80)*	39 (20.3%)	3.09 (2.06, 4.65)*
<i>Death</i>	106 (25.4%)	3.62 (1.82, 7.21)*	95 (22.5%)	3.42 (2.42, 4.83)*

* P<0.05

Table 4 presents symptoms that lasted more than 6 months following the most severe PSI that was recollected by the respondent. The impact of PSI with temporary harm, permanent harm and death are more profound than a PSI with no harm, showing up to two, three, four, five, six, seven and nine fold prevalence of symptoms. Hypervigilance is the symptom which remained the most constant, and independent of the degree of harm.

Table 4 Overview of symptoms which persisting longer than six months

	Doctors (n=1619)		Nurses (n=2750)	
	Prevalence no. (%)	Prevalence ratio (95% CI)	Prevalence no. (%)	Prevalence ratio (95% CI)
Hypervigilance				
<i>No harm</i>	30 (15.2%)	Reference	206 (22.6%)	Reference
<i>Temporary harm</i>	52 (14.0%)	0.92 (0.61, 1.39)	206 (22.0%)	0.97 (0.82, 1.15)
<i>Permanent harm</i>	77 (21.2%)	1.39 (0.95, 2.05)	88 (30.0%)	1.33 (1.07, 1.64)*
<i>Death</i>	182 (26.5%)	1.74 (1.22, 2.47)*	191 (31.3%)	1.38 (1.17, 1.64)*
Doubts about knowledge and skill				
<i>No harm</i>	5 (2.5%)	Reference	25 (2.7%)	Reference
<i>Temporary harm</i>	19 (5.1%)	2.01 (0.76, 5.31)	52 (5.6%)	2.02 (1.27, 3.23)*
<i>Permanent harm</i>	47 (13.0%)	5.10 (2.06, 12.62)*	25 (8.5%)	3.11 (1.81, 5.33)*
<i>Death</i>	114 (16.6%)	6.54 (2.71, 15.78)*	69 (11.3%)	4.12 (2.64, 6.44)*
Stress				
<i>No harm</i>	4 (2.0%)	Reference	32 (3.5%)	Reference
<i>Temporary harm</i>	15 (4.0%)	1.99 (0.67, 5.90)	49 (5.2%)	1.49 (0.96, 2.30)
<i>Permanent harm</i>	29 (8.0%)	3.93 (1.40, 11.03)*	26 (8.9%)	2.53 (1.53, 4.17)*
<i>Death</i>	84 (12.2%)	6.02 (2.24, 16.21)*	57 (9.3%)	2.66 (1.75, 4.05)*
Shame				
<i>No harm</i>	6 (3.1%)	Reference	33 (3.6%)	Reference
<i>Temporary harm</i>	21 (5.7%)	1.85 (0.76, 4.52)	67 (7.2%)	1.98 (1.32, 2.97)*
<i>Permanent harm</i>	35 (9.6%)	3.17 (1.36, 7.40)*	31 (10.6%)	2.92 (1.82, 4.68)*
<i>Death</i>	99 (14.4%)	4.73 (2.11, 10.62)*	65 (10.7%)	2.94 (1.96, 4.42)*
Flashbacks				
<i>No harm</i>	7 (3.6%)	Reference	32 (3.5%)	Reference
<i>Temporary harm</i>	17 (4.6%)	1.29 (0.54, 3.05)	68 (7.3%)	2.07 (1.37, 3.12)*
<i>Permanent harm</i>	30 (8.3%)	2.33 (1.04, 5.20)*	31 (10.6%)	3.01 (1.87, 4.85)*
<i>Death</i>	94 (13.7%)	3.85 (1.82, 8.16)*	103 (16.9%)	4.81 (3.28, 7.05)*
Fear				

<i>No harm</i>	3 (1.5%)	Reference	25 (2.7%)	Reference
<i>Temporary harm</i>	8 (2.2%)	1.41 (0.38, 5.26)	48 (5.1%)	1.87 (1.16, 3.00)*
<i>Permanent harm</i>	26 (7.2%)	4.70 (1.44, 15.34)*	24 (8.2%)	2.98 (1.73, 5.14)*
<i>Death</i>	79 (11.5%)	7.55 (2.41, 23.66)*	62 (10.2%)	3.70 (2.35, 5.83)*
Avoiding risks				
<i>No harm</i>	1 (0.9%)	Reference	13 (2.1%)	Reference
<i>Temporary harm</i>	8 (3.5%)	4.02 (0.51, 31.73)	25 (3.9%)	1.88 (0.97, 3.64)
<i>Permanent harm</i>	13 (6.6%)	7.52 (0.99, 56.76)	8 (4.2%)	2.00 (0.84, 4.75)
<i>Death</i>	33 (7.9%)	9.02 (1.25, 65.25)*	27 (6.4%)	3.06 (1.60, 5.87)*
Unhappy and dejected				
<i>No harm</i>	2 (1.8%)	Reference	3 (0.5%)	Reference
<i>Temporary harm</i>	2 (0.9%)	0.50 (0.07, 3.52)	11 (1.7%)	3.59 (1.01, 12.79)*
<i>Permanent harm</i>	7 (3.6%)	2.03 (0.43, 9.59)	5 (2.6%)	5.42 (1.31, 22.46)*
<i>Death</i>	30 (7.2%)	4.10 (0.99, 16.90)	15 (3.6%)	7.38 (2.15, 25.32)*
Uncomfortable within team				
<i>No harm</i>	1 (0.9%)	Reference	8 (1.3%)	Reference
<i>Temporary harm</i>	7 (3.1%)	3.52 (0.44, 28.23)	21 (3.3%)	2.57 (1.15, 5.75)*
<i>Permanent harm</i>	10 (5.1%)	5.79 (0.75, 44.62)	10 (5.2%)	4.06 (1.63, 10.15)*
<i>Death</i>	36 (8.6%)	9.84 (1.36, 71.01)*	26 (6.2%)	4.79 (2.19, 10.49)*
Difficulty sleeping				
<i>No harm</i>	1 (0.9%)	Reference	5 (0.8%)	Reference
<i>Temporary harm</i>	2 (0.9%)	1.00 (0.09, 10.96)	13 (2.0%)	2.54 (0.91, 7.09)
<i>Permanent harm</i>	6 (3.1%)	3.47 (0.42, 28.48)	8 (4.2%)	5.20 (1.72, 15.71)*
<i>Death</i>	26 (6.2%)	7.11 (0.98, 51.82)	18 (4.3%)	5.31 (1.99, 14.19)*
Unable to provide quality care				
<i>No harm</i>	1 (0.9%)	Reference	10 (1.6%)	Reference
<i>Temporary harm</i>	7 (3.1%)	3.52 (0.44, 28.23)	26 (4.1%)	2.54 (1.24, 5.23)*
<i>Permanent harm</i>	9 (4.6%)	5.21 (0.67, 40.58)	16 (8.3%)	5.20 (2.40, 11.27)*
<i>Death</i>	27 (6.5%)	7.38 (1.01, 53.74)*	39 (9.2%)	5.75 (2.90, 11.40)*

* P<0.05

DISCUSSION

The impact of PSI on healthcare professionals remains an underestimated problem. This study adds relevant information on the prevalence and (long-lasting) duration of several self-reported symptoms and their relation with the degree of patient harm. Almost half of the respondents reported their involvement in a PSI resulting in permanent harm or death at least once during their entire career, while one in five reported involvement in a PSI resulting in permanent harm or death during the previous six months. Those latter 462 healthcare professionals were particularly at risk for poor well-being and reduced professional functioning during those previous six months as they were involved in a PSI with such serious sequelae. More than half of all respondents suffered hypervigilance for more than one month, while almost one in four suffered more than six months. The prevalence ratio for all symptoms increased with a higher degree of patient harm. Interestingly, this was also true for all symptoms; except for feeling unhappy and dejected and difficulty sleeping; six months after being involved in a PSI compared to one month.

The results reported are in line with previous prevalence reports pertaining to emotional responses.[7, 9, 20] We found that in addition to earlier publications reporting symptoms such as anxiety, flashback and insomnia, that hypervigilance was the most universally reported symptom (80%). A recent study of 5782 physician mothers found that involvement in a mistake was associated with higher reported burnout.[20] The psychological impact of PSI on the healthcare professional is thought to be similar to that characterizing PTSD.[21] We therefore choose a cut-off set at one month based on the criteria set by DSM-5 for PTSD.[15] Suffering symptoms longer than one month, let alone six months, has a profound impact on health care providers' professional and personal life. As personal testimonials reveal health care providers can not provide the quality of care that is needed and they are at risk of being involved in future PSI's.[22]

Healthcare professionals may, at some point, find themselves in a vicious circle. As health care workers involved in PSI are at risk of diminished personal well-being and reduced professional performance adequate institutional and peer support are more and more considered essential components in alleviating the personal and professional impact on these second victims. Health care organizations need more awareness that some of the symptoms, such as doubts

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3 about knowledge and skill, feeling unable to provide quality care, feeling uncomfortable with
4 the team, may seriously impact team performance, patient safety and the provision of quality
5 care. Organizations should therefore play a pro-active role in providing immediate support to
6 healthcare professionals involved in a PSI and should not wait until the healthcare professional
7 gets depressed, develops burnout or quits the job. The risk of not responding to a PSI in a
8 timely and effective manner can have a significant impact on the healthcare professional
9 involved and organisations alike. It can lead to absence of healing, loss of trust, no learning
10 and improvement while it may also increase the likelihood of lawsuits and patient
11 complaints.[5] Perceptions of second victimness, turnover intentions and absenteeism may
12 be less severe when the healthcare organization's culture is characterized by a non-punitive
13 response to errors. Such non-punitive response may encourage supportive interactions,
14 openness to discuss error and thus mitigate the negative effects of PSI.[21] A recent study
15 amongst Dutch gynaecologists showed that 60% of respondents deemed the current hospital
16 support services after an adverse event insufficient. Two-thirds reported that their
17 department or hospital lacked a support protocol or strategy and they were close to
18 unanimous in preferring support from direct colleagues.[23]

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20 Well-being and Joy In Work receive important attention nowadays in medical journals.[24-28]
21 Well-being in physicians and other healthcare professionals has a direct link with patient
22 outcomes. In general, healthcare may need to focus more on positive dimensions like work
23 engagement and enjoy unexpected small positive experiences like Mangomoment a
24 movement recently described by our department and now getting international attention.[27]
25 The results of this study emphasize that the Triple Aim a framework that describes an
26 approach to optimizing health system performance is expanded to a Quadruple aim, meaning
27 that next to enhancing patient experience, improving population health and reducing costs,
28 improving the work life of health care providers is added to optimize health system
29 performance.[29] To improve Joy in Work, it is now time for action by senior leaders,
30 managers and healthcare providers alike.

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33 The large sample size (n=6508) as well as the large number of Dutch hospitals (n=32) included
34 strengthen this report. However, there are also some limitations. First, even though the
35 participating hospitals vary in size, location and function, the results may not be
36 representative for all hospitals in the Netherlands. Second, the questionnaire was distributed
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3 in several ways (by email, by intranet, by chairman of departments) and this implies that no
4 response rate can be calculated. Third, in order to keep the questionnaire concise and little
5 time consuming, we did not make use of extensive validated questionnaires but choose a
6 dichotomous (present or absent) variable to record the symptoms. Last, since we rely on the
7 recollection and perception of the respondents the data may be subject to recollection bias.
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13 Supporting healthcare professionals in the aftermath of a PSI is an important challenge for
14 healthcare professionals, managers, board members, and policy makers. It should be part of
15 the overall quality management system. For example there should be more awareness about
16 the emotional impact, building a professional support system and improve the notification of
17 the available support mechanisms. This should results in better quality of care to patients and
18 their family as only healthcare professional who are feeling well and supported by colleagues
19 and boards, are able to provide high-quality of care. As the involved patients and family are
20 the main victims of these serious clinical adverse events, all involved clinicians and managers
21 should focus on the needs of these first victims. Open communication on the event and
22 openness about the improvement initiatives should support the safety climate and overall
23 quality of healthcare.
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34 Future studies should focus on how organisations best embed the support of healthcare
35 professionals involved in PSI in their vision, mission and policy regarding patient safety and
36 quality care efforts. Specifically, longitudinal studies focusing on the duration of the symptoms
37 may help in making the current support systems more evidence-based. Future work should
38 also include a screening method in order to individualize institutional and peer support in the
39 aftermath of a PSI. More data are needed in order to identify which actions should be taken
40 to reduce the duration of the symptoms for those who suffer longer than expected. We also
41 need to understand more about the degree of well-being of those healthcare providers
42 involved in a PSI resulting in permanent harm or death, reporting no symptoms at all.
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51 **CONCLUSION**

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54 In conclusion, the majority of doctors and nurses in approximately one third of Dutch hospitals
55 involved in a PSI at least once during their career and who chose to participate in this study
56 report having suffered several symptoms in the aftermath of the PSI. Some of these symptoms
57 lasted longer than one month while others, eg hypervigilance, even lasted longer than six
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3 months. Attention should be given to how to cope with these symptoms as they profoundly
4 affect personal well-being, professional performance as well as teamwork-related efforts
5 directly influencing patient safety and the provision of quality care.
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9 **AUTHOR CONTRIBUTIONS**

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12 Conception and design of the study: KV, LS, MP and GGZ. Acquisition of the data: LS, EC and
13 GGZ. Analysis and interpretation of the data: KV, DS, LB and EC. Drafting of the manuscript:
14 DS, LS, LB, GGZ and KV. All authors critically revised the manuscript for intellectual content
15 and approved the final version.
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40 None declared
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49 **DATA SHARING STATEMENT**

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51 All data relevant to the study are included in the article or uploaded as supplementary
52 information.
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55 **REFERENCES**

- 1
2
3 1. Classen DC, Resar R, Griffin F, et al. 'Global Trigger Tool' Shows That Adverse Events In Hospitals
4
5 May Be Ten Times Greater Than Previously Measured. *Health Affairs* 2011;30(4):581-89.
6
- 7 2. Vries EN, Ramrattan MA, Smorenburg SM, et al. The incidence and nature of in-hospital adverse
8
9 events: a systematic review. *Qual Saf Health Care* 2008;17 doi: 10.1136/qshc.2007.023622
10
11
- 12 3. Wu AW. Medical error: the second victim. The doctor who makes the mistake needs help too. *BMJ*
13
14 2000;320(7237):726-27.
15
- 16 4. Clarkson MD, Haskell H, Hemmelgarn C, et al. Abandon the term "second victim". *BMJ*
17
18 2019;364:l1233. doi: 10.1136/bmj.l1233
19
- 20 5. Conway J, Federico F, Stewart K, et al. Respectful management of serious clinical adverse events.
21
22 IHI Innovation Series white paper. *Cambridge, Massachusetts: Institute for Healthcare*
23
24 *Improvement* 2011;(Available on www.IHI.org)
25
26
- 27 6. Harrison R, Lawton R, Stewart K. Doctors' experiences of adverse events in secondary care: the
28
29 professional and personal impact. *Clinical Medicine* 2014;14(6):585-90.
30
31
- 32 7. Mira JJ, Carrillo I, Lorenzo S, et al. The aftermath of adverse events in Spanish primary care and
33
34 hospital health professionals. *BMC Health Serv Res* 2015;15:151. doi: 10.1186/s12913-015-
35
36 0790-7 [published Online First: 2015/04/18].
37
38
- 39 8. Coughlan B, Powell D, Higgins MF. The Second Victim: a Review. *Eur J Obstet Gynecol Reprod Biol*
40
41 2017;213:11-16. doi: 10.1016/j.ejogrb.2017.04.002 [published Online First: 2017/05/21].
42
43
- 44 9. Seys D, Wu AW, Van Gerven E, et al. Health care professionals as second victims after adverse
45
46 events: a systematic review. *Eval Health Prof* 2013;36(2):135-62. doi:
47
48 10.1177/0163278712458918
49
- 50 10. Van Gerven E, Bruyneel L, Panella M, et al. Psychological impact and recovery after involvement
51
52 in a patient safety incident: a repeated measures analysis. *BMJ Open* 2016;6(8):e011403. doi:
53
54 10.1136/bmjopen-2016-011403 [published Online First: 2016/09/02].
55
56
- 57 11. Han K, Bohnen JD, Peponis T, et al. The Surgeon as the Second Victim? Results of the Boston
58
59 Intraoperative Adverse Events Surgeons' Attitude (BISA) Study. *J Am Coll Surg*
60

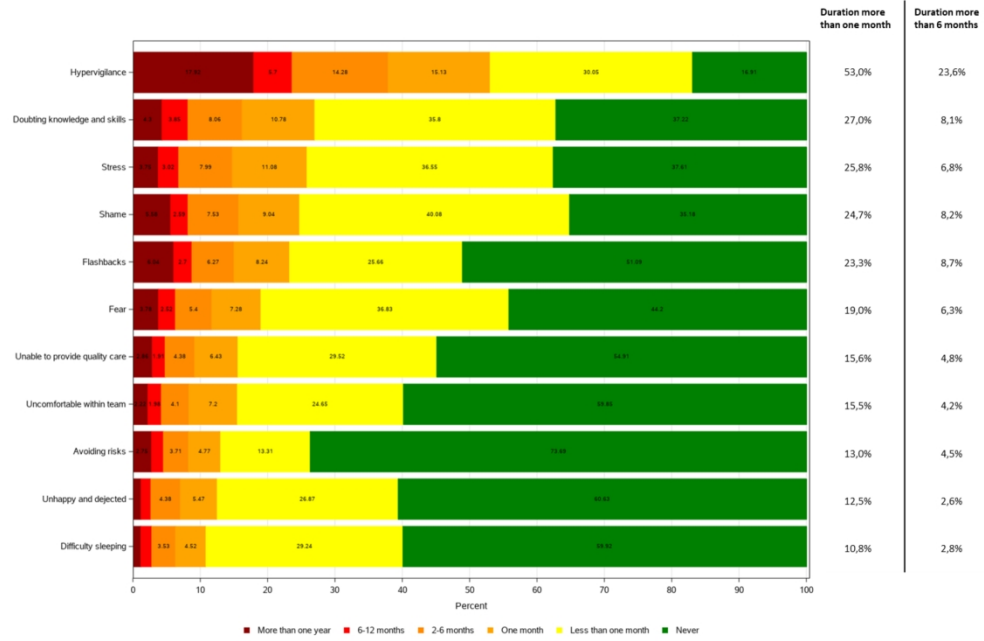
- 1
2
3 2017;224(6):1048-56. doi: 10.1016/j.jamcollsurg.2016.12.039 [published Online First:
4
5 2017/01/18].
6
7
8 12. Chan ST, Khong PCB, Wang W. Psychological responses, coping and supporting needs of
9
10 healthcare professionals as second victims. *Int Nurs Rev* 2017;64(2):242-62. doi:
11
12 10.1111/inr.12317 [published Online First: 2016/09/30].
13
14 13. Van Gerven E, Vander Elst T, Vandebroeck S, et al. Increased Risk of Burnout for Physicians and
15
16 Nurses Involved in a Patient Safety Incident. *Med Care* 2016 doi:
17
18 10.1097/MLR.0000000000000582
19
20
21 14. Robertson N, Perry A. Institutionally based health care workers' exposure to traumatogenic
22
23 events: systematic review of PTSD presentation. *J Trauma Stress* 2010;23(3):417-20. doi:
24
25 10.1002/jts.20537 [published Online First: 2010/06/22].
26
27
28 15. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM–5)
29
30 [Available from:
31
32 [https://www.psychiatry.org/psychiatrists/practice/dsm?_ga=1.8367346.1782582538.148113](https://www.psychiatry.org/psychiatrists/practice/dsm?_ga=1.8367346.1782582538.1481136819)
33
34 [6819](https://www.psychiatry.org/psychiatrists/practice/dsm?_ga=1.8367346.1782582538.1481136819).
35
36
37 16. Tamhane AR, Westfall AO, Burkholder GA, et al. Prevalence odds ratio versus prevalence ratio:
38
39 choice comes with consequences. *Statistics in medicine* 2016;35(30):5730-35. doi:
40
41 10.1002/sim.7059 [published Online First: 2016/07/26].
42
43
44 17. Van Gerven E, Deweer D, Scott SD, et al. Personal, situational and organizational aspects that
45
46 influence the impact of patient safety incidents: A qualitative study. *Rev Calid Asist* 2016;31
47
48 Suppl 2:34-46. doi: 10.1016/j.cali.2016.02.003 [published Online First: 2016/04/24].
49
50
51 18. Van Gerven E, Seys D, Panella M, et al. Involvement of health-care professionals in an adverse
52
53 event: the role of management in supporting their workforce. *Pol Arch Med Wewn*
54
55 2014;124(6):312-20.
56
57 19. Van Gerven E, Vanhaecht K, Euwema M, et al. Health professionals as second victims of patient
58
59 safety incidents: impact on functioning and well-being, 2016.
60

- 1
2
3 20. Gupta K, Lisker S, Rivadeneira NA, et al. Decisions and repercussions of second victim experiences
4
5 for mothers in medicine (SAVE DR MoM). *BMJ Quality & Safety* 2019;bmjqs-2018-
6
7 008372. doi: 10.1136/bmjqs-2018-008372
8
9
10 21. Quillivan RR, Burlison JD, Browne EK, et al. Patient Safety Culture and the Second Victim
11
12 Phenomenon: Connecting Culture to Staff Distress in Nurses. *Jt Comm J Qual Patient Saf*
13
14 2016;42(8):377-86. [published Online First: 2016/07/28].
15
16 22. Buikema M. When healthcare hurts: doctors share their darkest hours: Zin Publishing 2011.
17
18 23. Baas MAM, Scheepstra KWF, Stramrood CAI, et al. Work-related adverse events leaving their
19
20 mark: a cross-sectional study among Dutch gynecologists. *BMC Psychiatry* 2018;18(1):73. doi:
21
22 10.1186/s12888-018-1659-1
23
24 24. Thomas LR, Ripp JA, West CP. Charter on physician well-being. *JAMA* 2018;319(15):1541-42. doi:
25
26 10.1001/jama.2018.1331
27
28 25. Schwenk TL. Physician well-being and the regenerative power of caring. *JAMA*
29
30 2018;319(15):1543-44. doi: 10.1001/jama.2018.1539
31
32 26. Perlo J, Balik B, Swensen S, et al. IHI Framework for Improving Joy in Work. IHI White Paper. .
33
34 Cambridge, Massachusetts: Institute for Healthcare Improvement, 2017.
35
36 27. Vanhaecht K. In search of Mangomoments. *Lancet Oncol* 2018;19(2):165. doi: 10.1016/s1470-
37
38 2045(18)30034-2 [published Online First: 2018/02/08].
39
40 28. Perlo J, Feeley D. Why Focusing on Professional Burnout Is Not Enough. *J Healthc Manag*
41
42 2018;63(2):85-89. doi: 10.1097/jhm-d-18-00003 [published Online First: 2018/03/14].
43
44 29. Bodenheimer T, Sinsky C. From Triple to Quadruple Aim: Care of the Patient Requires Care of the
45
46 Provider. *Ann Fam Med* 2014;12(6):573-76. doi: 10.1370/afm.1713
47
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3 **FIGURE LEGENDS**
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6 **Figure 1** Symptoms in the aftermath of PSI
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For peer review only



Symptoms in the aftermath of PSI

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the STROBE cross sectional reporting guidelines, and cite them as:

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		Reporting Item	Page Number
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1, 3
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	3

1	Background /	#2	Explain the scientific background and rationale for the	6
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3	rationale		investigation being reported	
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6	Objectives	#3	State specific objectives, including any prespecified	6
7			hypotheses	
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11	Study design	#4	Present key elements of study design early in the paper	6-7
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14	Setting	#5	Describe the setting, locations, and relevant dates, including	6-7
15			periods of recruitment, exposure, follow-up, and data collection	
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18	Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of	7
19			selection of participants.	
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26		#7	Clearly define all outcomes, exposures, predictors, potential	7
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33	Data sources /	#8	For each variable of interest give sources of data and details of	7
34	measurement		methods of assessment (measurement). Describe	
35			comparability of assessment methods if there is more than one	
36			group. Give information separately for for exposed and	
37			unexposed groups if applicable.	
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44	Bias	#9	Describe any efforts to address potential sources of bias	7
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48	Study size	#10	Explain how the study size was arrived at	n/a
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51	Quantitative	#11	Explain how quantitative variables were handled in the	7
52	variables		analyses. If applicable, describe which groupings were chosen,	
53			and why	
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1	Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	8
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6		#12b	Describe any methods used to examine subgroups and interactions	8
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12		#12c	Explain how missing data were addressed	7
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15		#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a
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20		#12e	Describe any sensitivity analyses	n/a
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23	Participants	#13a	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. Give information separately for for exposed and unexposed groups if applicable.	8
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26		#13b	Give reasons for non-participation at each stage	8
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30		#13c	Consider use of a flow diagram	n/a
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35	Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	8
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39		#14b	Indicate number of participants with missing data for each variable of interest	8
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42	Outcome data	#15	Report numbers of outcome events or summary measures.	9
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1		Give information separately for exposed and unexposed	
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6	Main results	#16a Give unadjusted estimates and, if applicable, confounder-	10-14
7		adjusted estimates and their precision (eg, 95% confidence	
8		interval). Make clear which confounders were adjusted for and	
9		why they were included	
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16		#16b Report category boundaries when continuous variables were	n/a
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21		#16c If relevant, consider translating estimates of relative risk into	10-14
22		absolute risk for a meaningful time period	
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26	Other analyses	#17 Report other analyses done—e.g., analyses of subgroups and	10-14
27		interactions, and sensitivity analyses	
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31	Key results	#18 Summarise key results with reference to study objectives	15
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35	Limitations	#19 Discuss limitations of the study, taking into account sources of	16-17
36		potential bias or imprecision. Discuss both direction and	
37		magnitude of any potential bias.	
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42	Interpretation	#20 Give a cautious overall interpretation considering objectives,	15-16
43		limitations, multiplicity of analyses, results from similar studies,	
44		and other relevant evidence.	
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50	Generalisability	#21 Discuss the generalisability (external validity) of the study	16
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55	Funding	#22 Give the source of funding and the role of the funders for the	18
56		present study and, if applicable, for the original study on which	
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1 the present article is based

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BMJ Open

Duration of second victim symptoms in the aftermath of a patient safety incident and association with the level of patient harm: a cross-sectional study in the Netherlands

Journal:	<i>BMJ Open</i>
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Primary Subject Heading:	Health services research
Secondary Subject Heading:	Medical management
Keywords:	Patient safety, Stress, psychological, Health personnel/psychology, Hospitals, peer support

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3 **TITLE PAGE**
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5 Title of article: Duration of second victim symptoms in the aftermath of a patient safety
6 incident and association with the level of patient harm: a cross-sectional study in the
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ABSTRACT

Objectives To describe health care providers' symptoms evoked by patient safety incidents, the duration of these symptoms, and the association with the degree of patient harm caused by the incident.

Design Cross-sectional survey.

Setting 32 Dutch hospitals that participate in the "Peer Support Collaborative".

Participants 4369 health care providers (1619 doctors and 2750 nurses) involved in a patient safety incident (PSI) at any time during their career.

Interventions: All doctors and nurses working in direct patient care in the 32 participating hospitals were invited via e-mail to participate in an online survey.

Primary and secondary outcome measures Prevalence of symptoms, symptom duration and its relationship with the degree of patient harm.

Results In total 4369 respondents were involved in a PSI and completely filled in the questionnaire. Of these, 462 reported having been involved in a PSI with permanent harm or death during the last 6 months. This had a personal, professional impact as well as impact on effective teamwork requirements. The impact of a PSI increased when the degree of patient harm was more severe. The most common symptom was hypervigilance (53.0%). The three most common symptoms related to teamwork, were having doubts about knowledge and skill (27.0%), feeling unable to provide quality care (15.6%) and feeling uncomfortable within the team (15.5%). PSI with permanent harm or death was related to eight-fold higher likelihood of provider-related symptoms lasting for more than one month and nine-fold lasting longer than six months compared to symptoms reported when the PSI caused no harm.

Conclusion The impact of PSI remains an underestimated problem. The higher the degree of harm, the longer the symptoms last. Future studies should evaluate how these data can be integrated in evidence-based support systems.

KEYWORDS

“Patient Safety”, “Stress, Psychological”, “Health Personnel/psychology”, “Hospitals”, “Peer support”

STRENGTHS AND LIMITATIONS

- This study explores an underinvestigated area in the field of patient safety and quality care: duration of health care provider second victim symptoms in the aftermath of a patient safety incident and its relationship with the degree of patient harm.
- The very large sample size (n = 6508) as well as the large number of included Dutch hospitals (n = 32) representing a cross section of urban/rural, small/large, (non)academic, and (non)teaching hospitals.
- In this study the prevalence of symptoms was based on dichotomous questions (Present or absent) and not evaluated by means of validated questionnaires.
- This study is based on data of approximately one third (n = 32) of all Dutch hospitals. The results are not representative for all the health care organizations in the Netherlands or anywhere else in the world.
- Response bias is an inherent limitation related to surveys, as also pertains to the study now reported, as well as recall bias since the self-reported presence or absence of symptoms was purely based on the respondents' recollection.

INTRODUCTION

It is estimated that Patient Safety Incidents (PSI) occur in at least 1 out of 7 hospitalized patients.[1] This mostly includes incidents that cause no harm (near misses) but also incidents with temporary harm, permanent harm or death (adverse events).[2] In addition to the tremendous impact on patients and their family (first victims), the well-being of involved health care providers (second victims) may also be significantly affected.[3] Although there is criticism on the term second victims, no alternative term is available.[4] Moreover, PSI may harm the reputation of the health care department and entire organization (third victims) and reduce trust in health care providers in general.[5]

Recent studies indicate that almost 80% of health care providers are involved in a near miss or adverse event at least once in their career and that they were emotionally affected.[6, 7] The psychological impact depends on individual, situational and organisational aspects and affects both personal well-being and professional functioning.[8-10] Anxiety, fear, guilt, distress, frustration, anger and feeling insufficient are the most frequently cited symptoms.[11, 12] In addition, health care providers report a significant work-home interference, greater risk of burnout and higher intention to leave the job.[13]

More and more hospitals realise that they have a role in providing an institutional support system to meet second victims needs.[12, 14-16] Health care professionals involved in a PSI may have an increased likelihood developing post-traumatic stress disorder (PTSD).[14] One of the criteria for PTSD, based on the latest criteria set by the Diagnostic and Statistical Manual of Mental Disorders (DSM 5), is that the symptoms last for more than one month.[15] Current literature is lacking in information on duration of symptoms suffered by second victims. This hinders the development of evidence-based institutional support programs. This study aims to describe the prevalence and duration of health care provider self-reported symptoms evoked by PSI, and the association between these symptoms and the degree of patient harm caused by the incident.

METHODS

Setting

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3 This study was conducted at 32 hospitals in the Netherlands that participate in the “Peer
4 Support Collaborative”. The 32 hospitals represent approximately one third of all Dutch
5 hospitals and comprise a variety of large and small, rural and urban, (non)-teaching and (non)-
6 academic hospitals. These hospitals are amongst the first group of Dutch hospitals who
7 expressed the wish to implement an organisational peer support program for second victims
8 in the aftermath of a PSI, patient complaint or lawsuit. This collaborative aims to determine
9 the needs of their second victims and to define a peer support program that fits their specific
10 organisational patient safety culture and now reports their first insights. As part of the
11 activities of the Collaborative each hospital distributed a standard questionnaire amongst
12 their doctors and nurses in order to determine their specific needs.
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22 **Participants**

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24 Three rounds of data collection were conducted depending on the year of enrolment of the
25 participating hospital in the peer support Collaborative. Ten hospitals conducted the survey
26 between 14th April and 15th June 2016, nine hospitals between 1st February and 30th March
27 2017 and 13 hospitals between 2nd June 2018 and 23rd November 2018. All doctors and nurses
28 working in direct patient care in the 32 participating hospitals were invited via e-mail to
29 participate in an online survey under the auspices of the KU Leuven. Respondents could only
30 participate once. The online survey was available during four weeks. The contact person
31 participating in the peer support collaborative of each hospital distributed the web survey in
32 his or her hospital and one e-mail reminder was sent to all doctors and nurses in the third
33 week of the study period. According to the regulations in Dutch hospitals, in the survey it was
34 mentioned that filling in the questionnaire implied informed consent to participate.
35 Participation was entirely voluntary, and confidentiality and anonymity were guaranteed.
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49 **Measurements**

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51 The questionnaire contained four distinct parts. The first part pertained to respondent
52 demographics (profession, years of experience, years of work experience in this hospital, type
53 of ward (surgical or non-surgical) and gender). The second part surveyed the presence or
54 absence of personal involvement in PSI (during the entire career and during the previous 6
55 months) and the degree of harm (impact of PSI on the patient) (no harm, temporary harm,
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3 permanent harm and death). This part started with more information about what a PSI is
4 and the difference with a not-patient safety related dramatic event. Third, personal
5 involvement and symptoms related to the PSI were measured. These 11 symptoms were
6 selected based on a literature research.[9] Response categories for the duration of the
7 symptoms were “none”, “some hours”, “a day”, “a week”, “a month”, “2-6 months”, “6-12
8 months” and “more than 1 year”. The questionnaire was based on previous research [13, 17-
9 19] and redesigned by the participating hospitals during a meeting of the peer support
10 network.
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18 **Statistics**

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21 Only completely filled in questionnaires were included in the analysis, except for the
22 prevalence rate. Demographic variables are reported and descriptive data as well as the
23 recollection of the degree of PSI related patient harm during the entire career and during the
24 previous 6 months. Recollection of the presence or absence of symptoms perceived in the
25 aftermath of a PSI are represented in individual prevalence ratios. This ratio indicates whether
26 the specific symptom lasted for more than 1 month and for more than 6 months, and their
27 prevalence pertaining to PSI with no patient harm, temporary harm, permanent harm and
28 death. We opted to use prevalence ratios as these are less prone to overestimate associations
29 compared with using odds ratios.[16] Descriptive analyses and prevalence ratios were
30 produced using SAS v9.4. This manuscript is compliant to the STROBE recommendations.
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40 **Patient and public involvement**

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42 There was no patient or public involvement in this study.
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45 **RESULTS**

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48 6508 participants in 32 participating hospitals completed the questionnaire. In total 5572
49 respondents (1938 doctors and 3634 nurses) reported that they had been involved in a PSI at
50 least once during their career (85.6%) and 4369 (1619 doctors and 2750 nurses) choose to
51 completely fill out the questions regarding symptoms and were included in this study. Table 1
52 summarizes the demographic information of the 4369 respondents.
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58 **Table 1** Demographic information

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	Doctors (1619)	Nurses (2750)
Gender		
Female	898 (55.5%)	2531 (92.0%)
Years of experience (mean±SD)	11.2±8.8	18.1±12.1
Type of department		
Surgical department	540 (35.4%)	751 (29.1%)
Nonsurgical department	910 (59.8%)	1506 (58.3%)
Surgical and nonsurgical department	73 (4.8%)	327 (12.6%)

During their entire career, over half of respondents had only been involved in a PSI with no harm whereas approximately 45% had been involved in a PSI with permanent harm or with death (Table 2). During the previous 6 months 80 % of the respondents had only been involved in a PSI with no harm or temporary harm whereas one in 5 reported having been involved in a PSI with permanent harm or death. Doctors reported more involvement in PSI resulting in permanent harm or death compared to nurses.

Table 2 Prevalence for the different degree of harm (Reporting only PSI with the highest reported degree of harm).

Degree of harm	PSI during the entire career (n=4369)			PSI during previous 6 months (n=2379)		
	Doctors	Nurses	Overall	Doctors	Nurses	Overall
No harm	197 (12.2%)	911 (33.1%)	1108 (25.4%)	342 (36.6%)	865 (59.9%)	1207 (50.7%)
Temporary harm	372 (23.0%)	936 (34.0%)	1308 (29.9%)	313 (33.5%)	397 (27.5%)	710 (29.8%)
Permanent harm	363 (22.4%)	293 (10.7%)	656 (15.0%)	128 (13.7%)	66 (4.6%)	194 (8.2%)
Death	687 (42.4%)	610 (22.2%)	1297 (29.7%)	152 (16.3%)	116 (8.0%)	268 (11.3%)

Symptoms

Figure 1 depicts an overview of the 11 symptoms and their frequency of occurrence. The most frequently reported symptom was hypervigilance which bothered 53.0% of the respondents for more than one month. In frequency of occurrence this was followed by doubts about knowledge and skill (27.0%), stress (25.8%), shame (24.7%), flashbacks (23.3%), fear (19.0%),

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3 feeling unable to provide quality care (15.6%), feeling uncomfortable within team (15.5%),
4 avoiding risks (13.0%), feeling unhappy and dejected (12.5%) and difficulty sleeping (10.8%).
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6 Prevalence of symptoms with a duration of more than six months were respectively
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8 hypervigilance (23.6%), flashbacks (8.7%), shame (8.2%), doubts about knowledge and skill
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10 (8.1%), stress (6.8%), fear (6.3%), feeling unable to provide quality care (4.8%), avoiding risks
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12 (4.5%), feeling uncomfortable within team (4.2%), difficulty sleeping (2.8%) and feeling
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14 unhappy and dejected (2.6%). Of note, in total, 3.7% of the responding doctors and 4.0% of
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16 the nurses reported never having had any symptom while a significant portion of these
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18 providers were personally involved in PSI resulting in permanent harm or death.
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Table 3 depicts an overview of the different symptoms which persisted for more than one month for each degree of harm. The impact of a PSI with temporary harm, permanent harm and death are more profound than a PSI with no harm, showing up to two, three, four and eight-fold symptom prevalence. While the reported symptoms demonstrate a personal impact (difficulty sleeping, fear, stress, shame etc.) organizations need also be aware that some symptoms also have an impact on the teamwork, patient safety and ability to provide quality care. E.g. 27% of the respondents mentioned that they have doubts about knowledge and skill for more than one month, 15.6% feel unable to provide quality care and 15.5% feel uncomfortable within their team.

Table 3 Overview of symptoms persisting longer than one month

	Doctors (n=1619)		Nurses (n=2750)	
	Prevalence no. (%)	Prevalence ratio (95% CI)	Prevalence no. (%)	Prevalence ratio (95% CI)
Hypervigilance				
<i>No harm</i>	85 (43.2%)	Reference	433 (47.5%)	Reference
<i>Temporary harm</i>	170 (45.7%)	1.06 (0.87, 1.29)	485 (51.8%)	1.09 (0.99, 1.20)
<i>Permanent harm</i>	208 (57.3%)	1.33 (1.11, 1.60)*	162 (55.3%)	1.16 (1.03, 1.32)*
<i>Death</i>	409 (59.5%)	1.38 (1.16, 1.64)*	365 (59.8%)	1.26 (1.15, 1.38)*
Doubts about knowledge and skill				
<i>No harm</i>	43 (21.8%)	Reference	138 (15.2%)	Reference
<i>Temporary harm</i>	102 (27.4%)	1.26 (0.92, 1.72)	184 (19.7%)	1.30 (1.06, 1.59)*
<i>Permanent harm</i>	152 (41.9%)	1.92 (1.43, 2.57)*	76 (25.9%)	1.71 (1.34, 2.19)*
<i>Death</i>	319 (46.4%)	2.13 (1.61, 2.80)*	165 (27.1%)	1.79 (1.46, 2.18)*
Stress				
<i>No harm</i>	32 (16.2%)	Reference	122 (13.4%)	Reference
<i>Temporary harm</i>	84 (22.6%)	1.39 (0.96, 2.01)	170 (18.2%)	1.36 (1.10, 1.68)*
<i>Permanent harm</i>	131 (36.1%)	2.22 (1.57, 3.14)*	84 (28.7%)	2.14 (1.68, 2.73)*
<i>Death</i>	308 (44.8%)	2.76 (1.99, 3.83)*	198 (32.5%)	2.42 (1.98, 2.96)*
Shame				

<i>No harm</i>	33 (16.8%)	Reference	139 (15.3%)	Reference
<i>Temporary harm</i>	87 (23.4%)	1.40 (0.97, 2.00)	187 (20.0%)	1.31 (1.07, 1.60)*
<i>Permanent harm</i>	132 (36.4%)	2.17 (1.55, 3.05)*	75 (25.6%)	1.68 (1.31, 2.15)*
<i>Death</i>	279 (40.6%)	2.42 (1.75, 3.35)*	149 (24.4%)	1.60 (1.30, 1.97)*
Flashbacks				
<i>No harm</i>	22 (11.2%)	Reference	111 (12.2%)	Reference
<i>Temporary harm</i>	52 (14.0%)	1.25 (0.78, 2.00)	182 (19.4%)	1.60 (1.28, 1.98)*
<i>Permanent harm</i>	97 (26.7%)	2.39 (1.56, 3.68)*	83 (28.3%)	2.32 (1.81, 2.99)*
<i>Death</i>	240 (34.9%)	3.13 (2.08, 4.70)*	229 (37.5%)	3.08 (2.52, 3.77)*
Fear				
<i>No harm</i>	23 (11.7%)	Reference	94 (10.3%)	Reference
<i>Temporary harm</i>	39 (10.5%)	0.90 (0.55, 1.46)	150 (16.0%)	1.55 (1.22, 1.98)*
<i>Permanent harm</i>	88 (24.2%)	2.08 (1.36, 3.18)*	63 (21.5%)	2.08 (1.56, 2.79)*
<i>Death</i>	211 (30.7%)	2.63 (1.76, 3.93)*	161 (26.4%)	2.56 (2.03, 3.23)*
Avoiding risks				
<i>No harm</i>	6 (5.3%)	Reference	42 (6.7%)	Reference
<i>Temporary harm</i>	23 (10.1%)	1.93 (0.81, 4.59)	57 (8.9%)	1.33 (0.91, 1.95)
<i>Permanent harm</i>	48 (24.4%)	4.63 (2.05, 10.48)*	25 (13.0%)	1.93 (1.21, 3.09)*
<i>Death</i>	104 (24.9%)	4.74 (2.14, 10.51)*	63 (14.9%)	2.21 (1.53, 3.20)*
Unhappy and dejected				
<i>No harm</i>	9 (7.9%)	Reference	25 (4.0%)	Reference
<i>Temporary harm</i>	18 (7.9%)	1.00 (0.47, 2.16)	56 (8.8%)	2.19 (1.39, 3.46)*
<i>Permanent harm</i>	40 (20.3%)	2.57 (1.30, 5.10)*	26 (13.5%)	3.38 (2.00, 5.71)*
<i>Death</i>	117 (28.1%)	3.55 (1.86, 6.78)*	63 (14.9%)	3.72 (2.38, 5.81)*
Uncomfortable within team				
<i>No harm</i>	10 (8.8%)	Reference	46 (7.4%)	Reference
<i>Temporary harm</i>	26 (11.5%)	1.31 (0.65, 2.61)	82 (12.9%)	1.74 (1.24, 2.46)*
<i>Permanent harm</i>	54 (27.4%)	3.12 (1.66, 5.89)*	31 (16.2%)	2.19 (1.43, 3.35)*
<i>Death</i>	115 (27.6%)	3.14 (1.70, 5.80)*	75 (17.7%)	2.41 (1.70, 3.40)*
Difficulty sleeping				
<i>No harm</i>	3 (2.6%)	Reference	23 (3.7%)	Reference

<i>Temporary harm</i>	11 (4.9%)	1.84 (0.52, 6.47)	50 (7.8%)	2.13 (1.31, 3.44)*
<i>Permanent harm</i>	31 (15.7%)	5.98 (1.87, 19.12)*	27 (14.1%)	3.82 (2.24, 6.50)*
<i>Death</i>	94 (22.5%)	8.57 (2.77, 26.54)*	68 (16.1%)	4.36 (2.76, 6.88)*
Unable to provide quality care				
<i>No harm</i>	8 (7.0%)	Reference	41 (6.6%)	Reference
<i>Temporary harm</i>	21 (9.3%)	1.32 (0.60, 2.88)	85 (13.3%)	2.03 (1.42, 2.89)*
<i>Permanent harm</i>	46 (23.4%)	3.33 (1.63, 6.80)*	39 (20.3%)	3.09 (2.06, 4.65)*
<i>Death</i>	106 (25.4%)	3.62 (1.82, 7.21)*	95 (22.5%)	3.42 (2.42, 4.83)*

* P<0.05

Table 4 presents symptoms that lasted more than 6 months following the most severe PSI that was recollected by the respondent. The impact of PSI with temporary harm, permanent harm and death are more profound than a PSI with no harm, showing up to two, three, four, five, six, seven and nine fold prevalence of symptoms. Hypervigilance is the symptom which remained the most constant, and independent of the degree of harm.

Table 4 Overview of symptoms persisting longer than six months

	Doctors (n=1619)		Nurses (n=2750)	
	Prevalence no. (%)	Prevalence ratio (95% CI)	Prevalence no. (%)	Prevalence ratio (95% CI)
Hypervigilance				
<i>No harm</i>	30 (15.2%)	Reference	206 (22.6%)	Reference
<i>Temporary harm</i>	52 (14.0%)	0.92 (0.61, 1.39)	206 (22.0%)	0.97 (0.82, 1.15)
<i>Permanent harm</i>	77 (21.2%)	1.39 (0.95, 2.05)	88 (30.0%)	1.33 (1.07, 1.64)*
<i>Death</i>	182 (26.5%)	1.74 (1.22, 2.47)*	191 (31.3%)	1.38 (1.17, 1.64)*
Doubts about knowledge and skill				
<i>No harm</i>	5 (2.5%)	Reference	25 (2.7%)	Reference
<i>Temporary harm</i>	19 (5.1%)	2.01 (0.76, 5.31)	52 (5.6%)	2.02 (1.27, 3.23)*
<i>Permanent harm</i>	47 (13.0%)	5.10 (2.06, 12.62)*	25 (8.5%)	3.11 (1.81, 5.33)*
<i>Death</i>	114 (16.6%)	6.54 (2.71, 15.78)*	69 (11.3%)	4.12 (2.64, 6.44)*
Stress				
<i>No harm</i>	4 (2.0%)	Reference	32 (3.5%)	Reference
<i>Temporary harm</i>	15 (4.0%)	1.99 (0.67, 5.90)	49 (5.2%)	1.49 (0.96, 2.30)
<i>Permanent harm</i>	29 (8.0%)	3.93 (1.40, 11.03)*	26 (8.9%)	2.53 (1.53, 4.17)*
<i>Death</i>	84 (12.2%)	6.02 (2.24, 16.21)*	57 (9.3%)	2.66 (1.75, 4.05)*
Shame				
<i>No harm</i>	6 (3.1%)	Reference	33 (3.6%)	Reference
<i>Temporary harm</i>	21 (5.7%)	1.85 (0.76, 4.52)	67 (7.2%)	1.98 (1.32, 2.97)*
<i>Permanent harm</i>	35 (9.6%)	3.17 (1.36, 7.40)*	31 (10.6%)	2.92 (1.82, 4.68)*
<i>Death</i>	99 (14.4%)	4.73 (2.11, 10.62)*	65 (10.7%)	2.94 (1.96, 4.42)*
Flashbacks				
<i>No harm</i>	7 (3.6%)	Reference	32 (3.5%)	Reference
<i>Temporary harm</i>	17 (4.6%)	1.29 (0.54, 3.05)	68 (7.3%)	2.07 (1.37, 3.12)*
<i>Permanent harm</i>	30 (8.3%)	2.33 (1.04, 5.20)*	31 (10.6%)	3.01 (1.87, 4.85)*
<i>Death</i>	94 (13.7%)	3.85 (1.82, 8.16)*	103 (16.9%)	4.81 (3.28, 7.05)*
Fear				

<i>No harm</i>	3 (1.5%)	Reference	25 (2.7%)	Reference
<i>Temporary harm</i>	8 (2.2%)	1.41 (0.38, 5.26)	48 (5.1%)	1.87 (1.16, 3.00)*
<i>Permanent harm</i>	26 (7.2%)	4.70 (1.44, 15.34)*	24 (8.2%)	2.98 (1.73, 5.14)*
<i>Death</i>	79 (11.5%)	7.55 (2.41, 23.66)*	62 (10.2%)	3.70 (2.35, 5.83)*
Avoiding risks				
<i>No harm</i>	1 (0.9%)	Reference	13 (2.1%)	Reference
<i>Temporary harm</i>	8 (3.5%)	4.02 (0.51, 31.73)	25 (3.9%)	1.88 (0.97, 3.64)
<i>Permanent harm</i>	13 (6.6%)	7.52 (0.99, 56.76)	8 (4.2%)	2.00 (0.84, 4.75)
<i>Death</i>	33 (7.9%)	9.02 (1.25, 65.25)*	27 (6.4%)	3.06 (1.60, 5.87)*
Unhappy and dejected				
<i>No harm</i>	2 (1.8%)	Reference	3 (0.5%)	Reference
<i>Temporary harm</i>	2 (0.9%)	0.50 (0.07, 3.52)	11 (1.7%)	3.59 (1.01, 12.79)*
<i>Permanent harm</i>	7 (3.6%)	2.03 (0.43, 9.59)	5 (2.6%)	5.42 (1.31, 22.46)*
<i>Death</i>	30 (7.2%)	4.10 (0.99, 16.90)	15 (3.6%)	7.38 (2.15, 25.32)*
Uncomfortable within team				
<i>No harm</i>	1 (0.9%)	Reference	8 (1.3%)	Reference
<i>Temporary harm</i>	7 (3.1%)	3.52 (0.44, 28.23)	21 (3.3%)	2.57 (1.15, 5.75)*
<i>Permanent harm</i>	10 (5.1%)	5.79 (0.75, 44.62)	10 (5.2%)	4.06 (1.63, 10.15)*
<i>Death</i>	36 (8.6%)	9.84 (1.36, 71.01)*	26 (6.2%)	4.79 (2.19, 10.49)*
Difficulty sleeping				
<i>No harm</i>	1 (0.9%)	Reference	5 (0.8%)	Reference
<i>Temporary harm</i>	2 (0.9%)	1.00 (0.09, 10.96)	13 (2.0%)	2.54 (0.91, 7.09)
<i>Permanent harm</i>	6 (3.1%)	3.47 (0.42, 28.48)	8 (4.2%)	5.20 (1.72, 15.71)*
<i>Death</i>	26 (6.2%)	7.11 (0.98, 51.82)	18 (4.3%)	5.31 (1.99, 14.19)*
Unable to provide quality care				
<i>No harm</i>	1 (0.9%)	Reference	10 (1.6%)	Reference
<i>Temporary harm</i>	7 (3.1%)	3.52 (0.44, 28.23)	26 (4.1%)	2.54 (1.24, 5.23)*
<i>Permanent harm</i>	9 (4.6%)	5.21 (0.67, 40.58)	16 (8.3%)	5.20 (2.40, 11.27)*
<i>Death</i>	27 (6.5%)	7.38 (1.01, 53.74)*	39 (9.2%)	5.75 (2.90, 11.40)*

* P<0.05

DISCUSSION

The impact of PSI on health care professionals remains an underestimated problem. This study adds relevant information on the prevalence and (long-lasting) duration of several self-reported symptoms and their relation with the degree of patient harm. Almost half of the respondents reported their involvement in a PSI resulting in permanent harm or death at least once during their entire career, while one in five reported involvement in a PSI resulting in permanent harm or death during the previous six months. Those latter 462 health care professionals were particularly at risk for poor well-being and reduced professional functioning during those previous six months as they were involved in a PSI with such serious sequelae. More than half of all respondents suffered hypervigilance for more than one month, while almost one in four suffered more than six months. The prevalence ratio for all symptoms increased with a higher degree of patient harm. Interestingly, this was also true for all symptoms; except for feeling unhappy and dejected and difficulty sleeping; six months after being involved in a PSI compared to one month.

The results reported are in line with previous prevalence reports pertaining to emotional responses.[7, 9, 20] We found that in addition to earlier publications reporting symptoms such as anxiety, flashback and insomnia, that hypervigilance was the most universally reported symptom (80%). A recent study of 5782 physician mothers found that involvement in a mistake was associated with higher reported burnout.[20] The psychological impact of PSI on the health care professional is thought to be similar to that characterizing PTSD.[21] We therefore chose a cut-off set at one month based on the criteria set by DSM-5 for PTSD.[15] Suffering symptoms longer than one month, let alone six months, has a profound impact on health care providers' professional and personal life. As personal testimonials reveal, health care providers can not provide the quality of care that is needed and they are at risk of being involved in future PSI's.[22]

Health care professionals may, at some point, find themselves in a vicious circle. As health care workers involved in PSI are at risk of diminished personal well-being and reduced professional performance adequate institutional and peer support are more and more considered essential components in alleviating the personal and professional impact on these second victims. Health care organizations need more awareness that some of the symptoms,

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3 such as doubts about knowledge and skill, feeling unable to provide quality care, feeling
4 uncomfortable with the team, may seriously impact team performance, patient safety and the
5 provision of quality care. Organizations should therefore play a pro-active role in providing
6 immediate support to health care professionals involved in a PSI and should not wait until the
7 health care professional gets depressed, develops burnout or quits the job. The risk of not
8 responding to a PSI in a timely and effective manner can have a significant impact on the
9 health care professional involved and organisations alike. It can lead to absence of healing,
10 loss of trust, no learning and improvement while it may also increase the likelihood of lawsuits
11 and patient complaints.[5] Perceptions of second victimness, turnover intentions and
12 absenteeism may be less severe when the health care organization's culture is characterized
13 by a non-punitive response to errors. Such non-punitive response may encourage supportive
14 interactions, openness to discuss error and thus mitigate the negative effects of PSI.[21] A
15 recent study amongst Dutch gynaecologists showed that 60% of respondents deemed the
16 current hospital support services after an adverse event insufficient. Two-thirds reported that
17 their department or hospital lacked a support protocol or strategy and they were close to
18 unanimous in preferring support from direct colleagues.[23]

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20 Well-being and Joy In Work receive important attention nowadays in medical journals.[24-28]
21 Well-being in physicians and other health care professionals has a direct link with patient
22 outcomes. In general, health care may need to focus more on positive dimensions like work
23 engagement and enjoy unexpected small positive experiences like Mangomoment a
24 movement recently described by our department and now getting international attention.[27]
25 The results of this study emphasize that the Triple Aim a framework that describes an
26 approach to optimizing health system performance is expanded to a Quadruple aim, meaning
27 that next to enhancing patient experience, improving population health and reducing costs,
28 improving the work life of health care providers is added to optimize health system
29 performance.[29] To improve Joy in Work, it is now time for action by senior leaders,
30 managers and health care providers alike.

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33 The large sample size (n=6508) as well as the large number of Dutch hospitals (n=32) included
34 strengthen this report. However, there are also some limitations. First, even though the
35 participating hospitals vary in size, location and function, the results may not be
36 representative for all hospitals in the Netherlands. Second, the questionnaire was distributed

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3 in several ways (by email, by intranet, by chairman of departments) and this implies that no
4 response rate can be calculated. Third, in order to keep the questionnaire concise and little
5 time consuming, we did not make use of extensive validated questionnaires but choose a
6 dichotomous (present or absent) variable to record the symptoms. Last, since we rely on the
7 recollection and perception of the respondents the data may be subject to recollection bias.
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13 Supporting health care professionals in the aftermath of a PSI is an important challenge for
14 health care professionals, managers, board members, and policy makers. It should be part of
15 the overall quality management system. For example there should be more awareness about
16 the emotional impact, building a professional support system and improve the notification of
17 the available support mechanisms. This should result in better quality of care to patients and
18 their family as only health care professionals who are feeling well and supported by colleagues
19 and boards, are able to provide high-quality of care. As the involved patients and family are
20 the main victims of these serious clinical adverse events, all involved clinicians and managers
21 should focus on the needs of these first victims. Open communication on the event and
22 openness about the improvement initiatives should support the safety climate and overall
23 quality of health care.
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34 Future studies should focus on how organisations best embed the support of health care
35 professionals involved in PSI in their vision, mission and policy regarding patient safety and
36 quality care efforts. Specifically, longitudinal studies focusing on the duration of the symptoms
37 may help in making the current support systems more evidence-based. Future work should
38 also include a screening method in order to individualize institutional and peer support in the
39 aftermath of a PSI. More data are needed in order to identify which actions should be taken
40 to reduce the duration of the symptoms for those who suffer longer than expected. We also
41 need to understand more about the degree of well-being of those health care providers
42 involved in a PSI resulting in permanent harm or death, reporting no symptoms at all.
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51 **CONCLUSION**

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54 In conclusion, the majority of doctors and nurses in approximately one third of Dutch hospitals
55 involved in a PSI at least once during their career and who chose to participate in this study
56 report having suffered several symptoms in the aftermath of the PSI. Some of these symptoms
57 lasted longer than one month while others, eg hypervigilance, even lasted longer than six
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3 months. Attention should be given to how to cope with these symptoms as they profoundly
4 affect personal well-being, professional performance as well as teamwork-related efforts
5 directly influencing patient safety and the provision of quality care.
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9 **AUTHOR CONTRIBUTIONS**

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12 Conception and design of the study: KV, LS, MP and GGZ. Acquisition of the data: LS, EC and
13 GGZ. Analysis and interpretation of the data: KV, DS, LB and EC. Drafting of the manuscript:
14 DS, LS, LB, GGZ and KV. All authors critically revised the manuscript for intellectual content
15 and approved the final version.
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37 **COMPETING INTERESTS**

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40 None declared
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46 This study was carried out with an unconditional grant from VvAA.
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49 **DATA SHARING STATEMENT**

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51 All data relevant to the study are included in the article or uploaded as supplementary
52 information.
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55 **REFERENCES**

- 1
2
3 1. Classen DC, Resar R, Griffin F, et al. 'Global Trigger Tool' Shows That Adverse Events In Hospitals
4
5 May Be Ten Times Greater Than Previously Measured. *Health Affairs* 2011;30(4):581-89.
6
- 7 2. Vries EN, Ramrattan MA, Smorenburg SM, et al. The incidence and nature of in-hospital adverse
8
9 events: a systematic review. *Qual Saf Health Care* 2008;17 doi: 10.1136/qshc.2007.023622
10
11
- 12 3. Wu AW. Medical error: the second victim. The doctor who makes the mistake needs help too. *BMJ*
13
14 2000;320(7237):726-27.
15
- 16 4. Clarkson MD, Haskell H, Hemmelgarn C, et al. Abandon the term "second victim". *BMJ*
17
18 2019;364:l1233. doi: 10.1136/bmj.l1233
19
- 20 5. Conway J, Federico F, Stewart K, et al. Respectful management of serious clinical adverse events.
21
22 IHI Innovation Series white paper. *Cambridge, Massachusetts: Institute for Healthcare*
23
24 *Improvement* 2011;(Available on www.IHI.org)
25
26
- 27 6. Harrison R, Lawton R, Stewart K. Doctors' experiences of adverse events in secondary care: the
28
29 professional and personal impact. *Clinical Medicine* 2014;14(6):585-90.
30
31
- 32 7. Mira JJ, Carrillo I, Lorenzo S, et al. The aftermath of adverse events in Spanish primary care and
33
34 hospital health professionals. *BMC Health Serv Res* 2015;15:151. doi: 10.1186/s12913-015-
35
36 0790-7 [published Online First: 2015/04/18].
37
38
- 39 8. Coughlan B, Powell D, Higgins MF. The Second Victim: a Review. *Eur J Obstet Gynecol Reprod Biol*
40
41 2017;213:11-16. doi: 10.1016/j.ejogrb.2017.04.002 [published Online First: 2017/05/21].
42
43
- 44 9. Seys D, Wu AW, Van Gerven E, et al. Health care professionals as second victims after adverse
45
46 events: a systematic review. *Eval Health Prof* 2013;36(2):135-62. doi:
47
48 10.1177/0163278712458918
49
- 50 10. Van Gerven E, Bruyneel L, Panella M, et al. Psychological impact and recovery after involvement
51
52 in a patient safety incident: a repeated measures analysis. *BMJ Open* 2016;6(8):e011403. doi:
53
54 10.1136/bmjopen-2016-011403 [published Online First: 2016/09/02].
55
56
- 57 11. Han K, Bohnen JD, Peponis T, et al. The Surgeon as the Second Victim? Results of the Boston
58
59 Intraoperative Adverse Events Surgeons' Attitude (BISA) Study. *J Am Coll Surg*
60

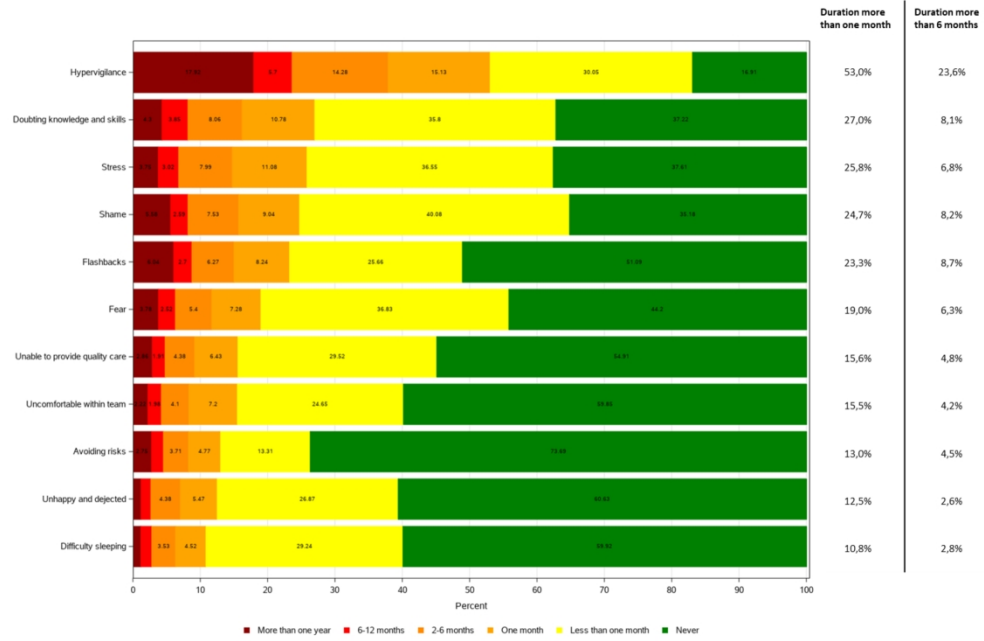
- 1
2
3 2017;224(6):1048-56. doi: 10.1016/j.jamcollsurg.2016.12.039 [published Online First:
4
5 2017/01/18].
6
7
8 12. Chan ST, Khong PCB, Wang W. Psychological responses, coping and supporting needs of
9
10 healthcare professionals as second victims. *Int Nurs Rev* 2017;64(2):242-62. doi:
11
12 10.1111/inr.12317 [published Online First: 2016/09/30].
13
14 13. Van Gerven E, Vander Elst T, Vandebroek S, et al. Increased Risk of Burnout for Physicians and
15
16 Nurses Involved in a Patient Safety Incident. *Med Care* 2016 doi:
17
18 10.1097/MLR.0000000000000582
19
20
21 14. Robertson N, Perry A. Institutionally based health care workers' exposure to traumatogenic
22
23 events: systematic review of PTSD presentation. *J Trauma Stress* 2010;23(3):417-20. doi:
24
25 10.1002/jts.20537 [published Online First: 2010/06/22].
26
27
28 15. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM–5)
29
30 [Available from:
31
32 [https://www.psychiatry.org/psychiatrists/practice/dsm?_ga=1.8367346.1782582538.148113](https://www.psychiatry.org/psychiatrists/practice/dsm?_ga=1.8367346.1782582538.1481136819)
33
34 [6819](https://www.psychiatry.org/psychiatrists/practice/dsm?_ga=1.8367346.1782582538.1481136819).
35
36
37 16. Tamhane AR, Westfall AO, Burkholder GA, et al. Prevalence odds ratio versus prevalence ratio:
38
39 choice comes with consequences. *Statistics in medicine* 2016;35(30):5730-35. doi:
40
41 10.1002/sim.7059 [published Online First: 2016/07/26].
42
43
44 17. Van Gerven E, Deweer D, Scott SD, et al. Personal, situational and organizational aspects that
45
46 influence the impact of patient safety incidents: A qualitative study. *Rev Calid Asist* 2016;31
47
48 Suppl 2:34-46. doi: 10.1016/j.cali.2016.02.003 [published Online First: 2016/04/24].
49
50
51 18. Van Gerven E, Seys D, Panella M, et al. Involvement of health-care professionals in an adverse
52
53 event: the role of management in supporting their workforce. *Pol Arch Med Wewn*
54
55 2014;124(6):312-20.
56
57 19. Van Gerven E, Vanhaecht K, Euwema M, et al. Health professionals as second victims of patient
58
59 safety incidents: impact on functioning and well-being, 2016.
60

- 1
2
3 20. Gupta K, Lisker S, Rivadeneira NA, et al. Decisions and repercussions of second victim experiences
4
5 for mothers in medicine (SAVE DR MoM). *BMJ Quality & Safety* 2019;bmjqs-2018-
6
7 008372. doi: 10.1136/bmjqs-2018-008372
8
9
10 21. Quillivan RR, Burlison JD, Browne EK, et al. Patient Safety Culture and the Second Victim
11
12 Phenomenon: Connecting Culture to Staff Distress in Nurses. *Jt Comm J Qual Patient Saf*
13
14 2016;42(8):377-86. [published Online First: 2016/07/28].
15
16 22. Buikema M. When healthcare hurts: doctors share their darkest hours: Zin Publishing 2011.
17
18 23. Baas MAM, Scheepstra KWF, Stramrood CAI, et al. Work-related adverse events leaving their
19
20 mark: a cross-sectional study among Dutch gynecologists. *BMC Psychiatry* 2018;18(1):73. doi:
21
22 10.1186/s12888-018-1659-1
23
24 24. Thomas LR, Ripp JA, West CP. Charter on physician well-being. *JAMA* 2018;319(15):1541-42. doi:
25
26 10.1001/jama.2018.1331
27
28 25. Schwenk TL. Physician well-being and the regenerative power of caring. *JAMA*
29
30 2018;319(15):1543-44. doi: 10.1001/jama.2018.1539
31
32 26. Perlo J, Balik B, Swensen S, et al. IHI Framework for Improving Joy in Work. IHI White Paper. .
33
34 Cambridge, Massachusetts: Institute for Healthcare Improvement, 2017.
35
36 27. Vanhaecht K. In search of Mangomoments. *Lancet Oncol* 2018;19(2):165. doi: 10.1016/s1470-
37
38 2045(18)30034-2 [published Online First: 2018/02/08].
39
40 28. Perlo J, Feeley D. Why Focusing on Professional Burnout Is Not Enough. *J Healthc Manag*
41
42 2018;63(2):85-89. doi: 10.1097/jhm-d-18-00003 [published Online First: 2018/03/14].
43
44 29. Bodenheimer T, Sinsky C. From Triple to Quadruple Aim: Care of the Patient Requires Care of the
45
46 Provider. *Ann Fam Med* 2014;12(6):573-76. doi: 10.1370/afm.1713
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3 **FIGURE LEGENDS**
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6 **Figure 1** Symptoms in the aftermath of PSI
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For peer review only



Symptoms in the aftermath of PSI

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the STROBE cross sectional reporting guidelines, and cite them as:

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		Reporting Item	Page Number
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1, 3
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	3

1	Background /	#2	Explain the scientific background and rationale for the	6
2				
3	rationale		investigation being reported	
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6	Objectives	#3	State specific objectives, including any prespecified	6
7			hypotheses	
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11	Study design	#4	Present key elements of study design early in the paper	6-7
12				
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14	Setting	#5	Describe the setting, locations, and relevant dates, including	6-7
15			periods of recruitment, exposure, follow-up, and data collection	
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18	Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of	7
19			selection of participants.	
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26		#7	Clearly define all outcomes, exposures, predictors, potential	7
27			confounders, and effect modifiers. Give diagnostic criteria, if	
28			applicable	
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33	Data sources /	#8	For each variable of interest give sources of data and details of	7
34	measurement		methods of assessment (measurement). Describe	
35			comparability of assessment methods if there is more than one	
36			group. Give information separately for for exposed and	
37			unexposed groups if applicable.	
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44	Bias	#9	Describe any efforts to address potential sources of bias	7
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48	Study size	#10	Explain how the study size was arrived at	n/a
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51	Quantitative	#11	Explain how quantitative variables were handled in the	7
52	variables		analyses. If applicable, describe which groupings were chosen,	
53			and why	
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1	Statistical methods	#12a	Describe all statistical methods, including those used to control	8	
2			for confounding		
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6		#12b	Describe any methods used to examine subgroups and	8	
7			interactions		
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11					
12		#12c	Explain how missing data were addressed	7	
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15		#12d	If applicable, describe analytical methods taking account of	n/a	
16			sampling strategy		
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20		#12e	Describe any sensitivity analyses	n/a	
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23	Participants	#13a	Report numbers of individuals at each stage of study—eg	8	
24			numbers potentially eligible, examined for eligibility, confirmed		
25			eligible, included in the study, completing follow-up, and		
26			analysed. Give information separately for for exposed and		
27			unexposed groups if applicable.		
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36		#13b	Give reasons for non-participation at each stage	8	
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39		#13c	Consider use of a flow diagram	n/a	
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42	Descriptive data	#14a	Give characteristics of study participants (eg demographic,	8	
43			clinical, social) and information on exposures and potential		
44			confounders. Give information separately for exposed and		
45			unexposed groups if applicable.		
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52		#14b	Indicate number of participants with missing data for each	8	
53			variable of interest		
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57	Outcome data	#15	Report numbers of outcome events or summary measures.	9	
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1		Give information separately for exposed and unexposed	
2		groups if applicable.	
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6	Main results	#16a Give unadjusted estimates and, if applicable, confounder-	10-14
7		adjusted estimates and their precision (eg, 95% confidence	
8		interval). Make clear which confounders were adjusted for and	
9		why they were included	
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16		#16b Report category boundaries when continuous variables were	n/a
17		categorized	
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21		#16c If relevant, consider translating estimates of relative risk into	10-14
22		absolute risk for a meaningful time period	
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26	Other analyses	#17 Report other analyses done—e.g., analyses of subgroups and	10-14
27		interactions, and sensitivity analyses	
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31	Key results	#18 Summarise key results with reference to study objectives	15
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35	Limitations	#19 Discuss limitations of the study, taking into account sources of	16-17
36		potential bias or imprecision. Discuss both direction and	
37		magnitude of any potential bias.	
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42	Interpretation	#20 Give a cautious overall interpretation considering objectives,	15-16
43		limitations, multiplicity of analyses, results from similar studies,	
44		and other relevant evidence.	
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50	Generalisability	#21 Discuss the generalisability (external validity) of the study	16
51		results	
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55	Funding	#22 Give the source of funding and the role of the funders for the	18
56		present study and, if applicable, for the original study on which	
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1 the present article is based

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