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Enhancing Patient Safety in Spain: Streamlining Adverse Event Detection in Occupational Healthcare Records

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Abstract: Background: Given the lack of previous studies on adverse events (AEs) in the area of occupational healthcare in Spain, it is very important to begin to understand this phenomenon in order to act on it. The objective was to accurately quantify AE occurring in occupational healthcare in MC Mutual during May 2021. **Methods:** We conducted a review of a representative random sample of 250 clinical records to identify AEs through an active search audit, focused on the frequency, type, severity, and preventability of these events, categorized using standardized scales. **Results:** We detected seven AEs in the sample of clinical records, representing 3% AEs per clinical record, while in the APEAS Spanish Study, they were detected in 10% of patients. The most frequent AE type was postoperative, followed by medication and diagnostic delay. The AEs were of intermediate severity and high severity and with a variable degree of being preventable. **Conclusions:** The detection of AEs has been useful in the development of projects and action plans such as specific training courses, safety patient newsletters, ambulatory risk maps, and treatment plans framed in the official certification of patient safety. These results should be evaluated in other companies similar to MC Mutual.

Keywords: adverse events; occupational health; triggers; patient safety; safety culture; ambulatory care; trigger tool; postoperative; medication; diagnostic delay

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1. Introduction

Patient safety, understood as the aim of not causing avoidable harm to the patient when receiving healthcare, is the basis of healthcare quality and a condition for performing any clinical activity. "Primum Non Nocere" is an essential principle of medicine that underlies every act of care, so it should be assumed as a fundamental principle for each professional. However, adverse events may occur more frequently than desired due to increasingly invasive techniques, greater fragility of patients, and increased complexity of pathologies [1].

Quantifying adverse events in the healthcare setting is difficult. Although the World Health Organization (WHO) has been making great efforts for years to improve the taxonomy of adverse events and their management, much work remains to be done [2–4]. Many studies publish adverse event data but in significantly different frequencies [5]. In Spain, adverse events reported in primary care services amount to 1% of visits (APEAS study) [6,7], and the frequency of adverse events rises to 10% when focusing on hospitalized patients (ENEAS study) [8,9]. Even with the precision in the different frequencies mentioned above,

in either case, it is clear that this is a major health issue and an enormous management challenge for all health systems, more so if we consider that between 40% and 70% of these events were preventable [6–9].

In the Spanish National Health System, healthcare for accidents at work and occupational diseases is provided by Occupational Mutual Insurance Companies under the supervision of the Spanish Social Security. These companies were created at the beginning of the 20th century to cover the responsibility of employers for the care of occupational health of their workers [10]. Their development as health entities has followed, with some delay, the development of the country's National Health Service.

The Spanish Society of Quality Care (known by its acronym SECA) has supported the development of healthcare quality in these companies [11]; however, in this specific setting, there is a pending issue, as adverse events are unknown, and their quantification is nonexistent. Moreover, the development of patient safety policies in these companies has followed, with some delay, those established for other devices in the Spanish National Health Service.

MC MUTUAL is one of eighteen existing Occupational Mutual Insurance Companies in Spain [10]. In 2021, 99,584 workers attended out of a protected population of 1,487,586 workers (a frequency of 67 patients attended per thousand affiliated workers) in 86 ambulatory care centers that make up the outpatient care network, where 624 health professionals work. There were 309,894 medical visits and 84,772 nurse visits, most (3.1 average visits per patient attended) in the trauma and orthopedic area specialty [12].

MC MUTUAL has been promoting priorities defined by national and international bodies in patient safety for years. The company began to work systematically on this in 2005 when the movement emerged in Spain [13,14]. In this strategic area, in 2014, the first MC MUTUAL healthcare quality plan was developed for 2014–2016, and patient safety became a strategic orientation that has been consolidated and permanently adapted. The patient safety Commissions were set up to lead the implementation of the patient safety program in both settings of the organization (Ambulatory Care Centers and Hospitals) to spread the patient safety culture. The pragmatic orientation of these actions is based on verifying the usefulness of the risk analyses carried out in North American veterans' centers [15] or pediatrics in Spain [16] to learn from their definition and evolution over time. It is also based on creating Incident-Reporting Systems in obstetric and gynecological devices in the US [17], in anesthesiology in Canada [18], and by District Health Boards in New Zealand [19].

In addition, MC MUTUAL has been committed to corporate transparency as one of the main axes of the organization. Thus, reports of events declared to the Incident-Reporting System are periodically published to communicate their existence, importance, and the possibility of prevention in line with strategies for improving healthcare quality practice [20] and with action protocols recently implemented in Spain [21].

Although recent studies have focused on patient safety in primary care, there is scanty evidence on the incidence and typology of adverse events in occupational healthcare. We started a research cycle to quantify adverse events in occupational healthcare, and the data observed in our previous studies showed a high incidence of adverse events in relation to the Spanish National Health Service [22–25]. The hypothesis of this work focuses on assessing the incidence of adverse events in occupational healthcare, which we believe should be lower.

Given the lack of previous studies on adverse events in the area of occupational healthcare, it is very important to begin to understand this phenomenon in order to act on it. Therefore, the aim of the study is to analyze the presence of adverse events in all of the patients, regardless of their complexity, with the same precision, the frequency of which in the occupational health sector has not been previously described.

2. Materials and Methods

An observational, descriptive, and retrospective study was designed to identify and categorize adverse events in outpatient healthcare provided to patients in May 2021 in the 86 ambulatory care centers of MC MUTUAL.

Since 2016, the annual quality audit program of clinical records has been carried out by a medical reviewer who is an expert in auditing and has a master's degree in *Healthcare quality and safety management and methodology* by Avedis Donabedian-Insituto Universitario UAB, with periodic concordance analysis of a subset of the records reviewed, and also carried out by nurses who are experts in clinical management. This audit focuses on clinical record quality items previously defined by the headquarters technical departments and reported to the whole organization, referring to the work of medicine, nursing, and physiotherapy.

Experts in the audit of adverse events follow the WHO adverse event definition to detect these events, in which care resulted in an undesirable clinical outcome—an outcome not caused by underlying disease—that prolonged the patient stay, caused permanent patient harm, required life-saving intervention, or contributed to death [4].

The days of sick leave and the number of visits are considered administrative triggers. In this study, the clinical triggers are constructed, already discussed above, and have to do with the existence of some diagnoses or clinical practices and their relationship with the administrative triggers.

The 10,419 patients attended during the month of May 2021 were considered as a sampling base, and in the subsequent analysis of the complexity, it was observed that the percentages of types of patients were very similar to those determined in other previous studies [22–25]. We needed a sample size of 237 patients, considering a 95% confidence level, a 5% absolute precision, and an expected proportion of adverse events of 19% [26]. Including a 15% exclusion rate, the final sample size was 273. The expected proportion value was the worst-case scenario observed in a previous study [23]. Of the 273 cases, 23 cases were excluded (8.4%). Three were excluded due to care in other equal companies, three due to emergency care in the National Health Service with no information on their care, and seventeen from cases attended in centers outside the occupational healthcare sector with little or no information on care. Finally, the sample consisted of 250 cases, where 89 were complex patients, 32 were intermediate, and 129 had minor complexity. The complex category includes patients on sick leave for more than seven days and have had more than three medical and nursing attendances during their outpatient process. This group constitutes approximately one-third of all records, accounting for 35% of the cases. The intermediate category comprises patients on sick leave for less than seven days and has 2–3 registered attendances. This group represents 15% of the cases. Lastly, the minor complexity category consists of less complex patients who do not require sick leave and only need occasional attention. They typically have 1–2 registered attendances. This group constitutes the majority, accounting for 50% of cases.

The statistical analyses were carried out with the IBM SPSS software version 28. The statistical test used was Fisher's exact test with $\alpha = 0.05$.

Following ethical approval, data had been collected under strict confidentiality from the patients, who had been anonymized. No information that would allow identification of the participants was included; therefore, obtaining informed consent from the patients did not apply.

The different variables used in the study are described, discarding those considered as identification variables (clinical record number, process number, and discharge date) and those considered as location variables (ambulatory center name).

Qualitative variables are considered for each case (gender—men and women; groups of pathologies—contusions/bruises, fractures and sprains, spinal and inflammatory conditions, wounds, and others; productive sectors—primary sector, commerce, construction, industry, services, and unidentified; and final decision. The final decision is defined as

assistance—with discharge, without discharge, and referred to the National Health Service). Age and days of sick leave are used as quantitative variables.

In the analysis, the final decision is used as a dependent variable in the first phase, then as an independent variable when considering administrative, clinical trigger, and adverse events as dependent variables.

The variables are described and contrasted with the final decision and the presence of triggers. Frequencies of adverse events are calculated based on the presence of administrative triggers, clinical triggers, both, or neither.

Adverse events were also assessed according to severity, understood as the intensity with which harm does not reach the patient or ends with death [4], following the Ruiz-Jarabo Severity Adverse Event Classification. This is a standardized classification of errors, in which nine categories (A through I) are grouped into four main levels of severity: no error, error—no harm, error—harm, and error—death [27].

Preventability, understood as the ease with which it can be detected [4], it was also rated using a 6-point scale ranging from "virtually no evidence of preventability" (1 point) to "virtually certain evidence of preventability" (6 points) used in the APEAS study [6,7].

3. Results

The average duration of sick leave was 31 days (standard deviation, SD of 36.7 days). The cases attended in the sample ranged in age from 19 to 63 years, with a mean of 44 years (SD 10.9 years). In total, 172 cases were men (68.8%), and 78 cases were women (31.2%). The sectors represented include 96 cases for services (38.4%), 73 cases for industry (29.2%), 33 cases for commerce (13.2%), 26 cases for construction (10.4%), and 18 cases for agriculture/fishing (7.2%). The most frequently treated pathologies were 64 cases for contusions/bruises (25.6%), 41 cases for fractures/sprains (16.4%), 41 cases for spine (16.4%), 49 cases for inflammatory pathology (19.6%), 39 cases for wounds (15.6%), and 16 cases for the remaining ones (6.4%). A total of 121 cases needed to take sick leave (48.4%), 76 cases taking sick leave were unnecessary (30.4%), and 53 cases were referred to the Spanish National Health Service as they were considered cases affected by non-occupational pathologies (21.2%) (Table 1).

Table 1. Description of the set of variables.

		Cases	% Total Cases
Days of sick leave (Range 1–286)	Cases	250	
	Mean	31	
		36.7	
Age in years (Range 19–63)	Cases	250	
	Mean (Standard deviation)	44 (10.9)	
Gender	Men	172	68.8%
	Women	78	31.2%
	TOTAL	250	100%
Sector	Agriculture/Fishing	18	7.2%
	Commerce	33	13.2%
	Construction	26	10.4%
	Industry	73	29.2%
	Services	96	38.4%
	Others	4	1.6%
	TOTAL	250	100%

Table 1. *Cont.*

		Cases	% Total Cases
Pathology	Contusions/Bruises	64	25.6%
	Fractures/Sprains	41	16.4%
	Spine	41	16.4%
	Inflammatory	49	19.6%
	Wounds	39	15.6%
	Others	16	6.4%
	TOTAL	250	100%
Final decision	Without sick leave	76	30.4%
	Sick leave	121	48.4%
	Referred to the National Health Service	53	21.2%
	TOTAL	250	100%

The cases reviewed showed that 94 of the administrative trigger cases (37.6%) had more than seven days of sick leave; 140 cases had more than three clinical attendances (56.0%); 89 cases had more than seven days of sick leave and more than three attendances (35.6%); and in the remaining 105 of the cases (42.0%), the sick leave was less than seven days and had less than three clinical attendances (Table 2).

Table 2. Description of triggers and adverse events.

		Number	% Total Group Cases
Administrative triggers	>7 days of sick leave	94	37.6%
	>3 clinical attendances	140	56.0%
	Cases with both	89	35.6%
	Cases with none	105	42.0%
	TOTAL CASES	250	100%
Clinical triggers	Cases without clinical triggers	191	76.4%
	Cases with one clinical triggers	44	17.6%
	Cases with two or more clinical triggers	15	6.0%
	Cases with clinical triggers	59	23.6%
	TOTAL CASES	250	100%
	CLINICAL TRIGGERS	76	100%
	Medication	42	55.3%
	Surgery	11	14.5%
	Treatment change	6	7.9%
	Post-discharge attendance	11	14.5%
	Sick leave after two attendances	6	7.9%
	TOTAL	76	100%
Adverse events	Postoperative	3	42.9%
	Medication	2	28.6%
	Diagnostic delay	2	28.6%
	TOTAL	7	100%

Table 2. *Cont.*

		Number	% Total Group Cases
Severity	Severity C	2	28.6%
	Severity D	3	42.9%
	Severity E	1	14.3%
	Severity F	1	14.3%
	TOTAL	7	100%
Preventability	Preventability 2	2	28.6%
	Preventability 3	1	14.3%
	Preventability 4	1	14.3%
	Preventability 5	1	14.3%
	Preventability 6	2	28.6%
	TOTAL	7	100%

Regarding clinical triggers, 191 of the cases showed no clinical triggers (76.4%), and the remaining 59 cases had one or more clinical triggers (44 cases had one clinical trigger (17.6%) and 15 cases had two or more clinical triggers (6.0%)). In total, 55.3% of the cases with clinical triggers were related to medication, 14.5% to surgery and post-discharge visit, and 7.9% to change of treatment or discharge after two clinical attendances (Table 2).

Seven adverse events were identified, with six from the complex patients group (0.07 adverse events per clinical records) and one from the minor complexity group (0.01 adverse events per clinical records) (Table 3).

Table 3. Comparison of the characteristics of the previous and the current study.

	Previous Study *			Actual Study **		
	Complex Patients	**Intermediate Patients**	**Minor Complexity Patients**	**Complex Patients**	**Intermediate Patients**	**Minor Complexity Patients**
Clinical records	240	60	60	89	32	129
Adverse events	26	1	1	6	0	1
Adverse event/ Clinical record	0.11	0.02	0.02	0.07	0	0.01
Confidence Interval	7.2–15%	0–4.8%	0–4.8%	1.7–12.3%	0.0%	0–2.7%

There were no statistically significant differences between the three groups in the two studies. * Ortner J, Moya D, Manzanera R, Torres M, Vives A, Farrus X, et al. Adverse events in the global healthcare practice of an Occupational Mutual Insurance Company in Spain. Work 2023. https://doi.org/10.3233/WOR-220203 (accessed on 20 April 2023) [25]. ** Moya D, Manzanera R, Ortner J, Torres M, Serfaty JC, Sauri C, et al. Enhancing Patient Safety in Spain: Streamlining Adverse Event Detection in Occupational Healthcare Records. Safety 2024.

Concerning the typology, three were postoperative, two were due to medication, and two were due to diagnostic delay. The adverse events were of intermediate severity (two of severity C and three of D) and high severity (one of severity E and one of F) and with a variable degree of being preventable (two preventable cases in grade 2 and two preventable cases in grade 6 in the extremes) (Table 4).

Table 4. Description of the adverse events detected across severity and preventability scales.

Gender	Age	Sector	Diagnosis	Type of Adverse Event	Severity (A-I)	Preventability (1 a 6)
Men	58	Commerce	Radius fracture	Postoperative	D	5
Men	29	Construction	Hand open wound	Postoperative	D	2
Women	42	Commerce	Neck sprain	Medication	C	3
Men	56	Industry	Ankle fracture	Diagnostic delay	E	6
Men	43	Industry	Vertigo	Diagnostic delay	C	6
Men	44	Industry	Elbow dislocation	Postoperative	F	4
Men	46	Industry	Second degree burn	Medication	D	2

The duration of sick leave was 34 days (SD 41.6) in men and 25 days (SD 33.4) in women. The duration of sick leave was very similar in all productive sectors (from 28 days in construction (SD 26.0) to 33 days in commerce and industry (SD 48.4 and SD 40.8, respectively)). On the other hand, durations varied greatly depending on the pathology, with 14 days for injury-related conditions (SD 10.6), 17 days of sick leave for spinal and inflammatory conditions (SD 15.5 and SD 11.1, respectively), 28 days for contusions/bruises (SD 27.9), and 51 days for fractures/sprains (SD 59.2). When considering how age, gender, production sector, and pathology affect the type of final decision of care (cases without sick leave, with sick leave, and referral to the National Health Service), statistically significant differences were only detected in the various types of pathologies. Thus, for cases referred to the National Health Service, inflammatory pathology predominates (57%); for cases with sick leave, fractures/sprains (71%) dominate; and for cases without sick leave, wounds (51%) were the most common (Table 5).

Table 5. Description of the factors of the cases without sick leave, with sick leave, and referred to the Public Health Service, as well as the average number of days of sick leave.

	Cases without Sick Leave		Cases with Sick Leave		Cases Referred to the National Health Service					Mean of Days of Sick Leave	SD
	Cases	%	Cases	%	Cases	%	Total	%	*p*		
Gender											
Men	52	30%	79	46%	41	24%	172	68.8%	0.296	34	41.6
Women	24	31%	42	54%	12	15%	78	31.2%		25	33.4
Age (range of years)											
(19–40)	28	33%	37	44%	20	24%	85	34.0%		6	10.4
(40–49)	27	32%	43	52%	12	15%	82	32.8%	0.350	23	55.3
(49–63)	21	25%	41	49%	21	25%	83	33.2%		17	26.5
Sector *											
Agriculture/Fishing	4	22%	9	50%	5	28%	18	7.2%		32	22.5
Commerce	13	39%	14	42%	6	18%	33	13.2%		33	48.4
Construction	4	15%	17	65%	5	19%	26	10.4%	0.263	28	26.0
Industry	16	22%	39	53%	18	25%	73	29.2%		33	40.8
Services	35	36%	42	44%	19	20%	96	38.4%		29	33.1

Table 5. *Cont.*

	Cases without Sick Leave		Cases with Sick Leave		Cases Referred to the National Health Service					Mean of Days of Sick Leave	SD
Pathology											
Contusions/Bruises	23	36%	32	50%	9	14%	64	25.6%		28	27.9
Fractures/Sprains	8	20%	29	71%	4	10%	41	16.4%		51	59.2
Spine	7	17%	17	41%	17	41%	41	16.4%	<0.001	17	15.5
Inflammatory	12	34%	17	49%	20	57%	49	19.6%		17	11.1
Wounds	20	51%	19	49%	0	0%	39	15.6%		14	10.6
Others	6	25%	7	29%	3	13%	16	6.4%		56	61.6
TOTAL	76	30%	121	48%	53	21%	250			31	

* Four missing values *p*: *p*-value Fisher's exact.

We reviewed the relationship between the variables gender, age, sectors, pathologies, and final decision with the presence of administrative triggers, clinical triggers, both, and none. Men showed a higher prevalence than women but were only significantly different in the group with both triggers (20% vs. 9%). Young individuals have a lower prevalence of administrative triggers (26% to 43%, clinical triggers (12% to 30%), both triggers (9% to 22%), and a higher prevalence when the group has no triggers (45% to 72%). No differences (9% to 67%) were observed by productive sectors. By pathologies, significant differences are shown in all groups with a higher prevalence of administrative triggers in fractures/sprains (59%), of clinical triggers in fractures/sprains (39%), of both triggers in fractures/sprains (32%), and of no triggers in contusion/inflammatory/spine cases. Evaluating the final decision made for cases, administrative triggers were observed in 74% of cases with sick leave, clinical triggers in 37% of cases with sick leave, and 12% of those without sick leave. With both triggers, all 41 cases were on sick leave, and no triggers were observed in 87% of cases without sick leave, in 91% of cases referred to the National Health Service, and in 22% of cases with sick leave (Table 6).

Table 6. Description of the factors of the cases with administrative triggers, clinical triggers, both triggers, and no triggers.

	Administrative Triggers				Clinical Triggers				Both Triggers				No Triggers			
	Cases	**Prev**	**IC 95% Prev**	***p***	**Cases**	**Prev**	**IC 95% Prev**	***p***	**Cases**	**Prev**	**IC 95% Prev**	***p***	**Cases**	**Prev**	**IC 95% Prev**	***p***
Gender				1.000				0.108				0.042				0.785
Men	63	37%	(29–44%)		45	26%	(20–33%)		34	20%	(14–27%)		98	57%	(49–64%)	
Women	29	37%	(26–49%)		13	17%	(9–27%)		7	9%	(4–18%)		43	55%	(43–66%)	
Age (range of years)				0.036				0.006				0.073				0.001
(19–40)	22	26%	(17–37%)		10	12%	(6–21%)		8	9%	(4–18%)		61	72%	(61–81%)	
(40–49)	35	43%	(32–54%)		25	30%	(21–42%)		15	18%	(11–28%)		37	45%	(34–57%)	
(49–63)	35	42%	(31–54%)		23	28%	(18–39%)		18	22%	(13–32%)		43	52%	(41–63%)	
Sector *				0.116				0.254				0.143				0.266
Agriculture/Fishing	8	44%	(22–69%)		4	22%	(6–48%)		3	17%	(4–41%)		9	50%	(26–74%)	
Commerce	10	30%	(16–49%)		4	12%	(3–28%)		3	9%	(2–24%)		22	67%	(48–82%)	
Construction	15	58%	(37–77%)		8	31%	(14–52%)		8	31%	(14–52%)		11	42%	(23–63%)	
Industry	29	40%	(28–52%)		22	30%	(20–42%)		15	21%	(12–32%)		37	51%	(39–63%)	
Services	30	31%	(22–42%)		20	21%	(13–30%)		12	13%	(7–21%)		58	60%	(50–70%)	
Pathology				0.032				<0.001				0.008				0.004
Contusions/Bruises	23	36%	(24–49%)		6	9%	(4–26%)		5	8%	(3–17%)		40	63%	(50–74%)	
Fractures/Sprains	24	59%	(42–74%)		16	39%	(24–55%)		13	32%	(18–48%)		14	34%	(20–51%)	
Spine	12	29%	(16–46%)		5	12%	(4–19%)		3	7%	(2–20%)		27	66%	(49–80%)	
Inflammatory	12	24%	(13–39%)		9	18%	(9–32%)		7	14%	(6–27%)		35	71%	(32–65%)	
Wounds	14	36%	(21–53%)		14	36%	(21–53%)		9	23%	(11–39%)		20	51%	(17–43%)	
Others	7	44%	(20–70%)		8	50%	(25–75%)		4	25%	(7–52%)		5	31%	(41–89%)	
Final decision				<0.001				<0.001				<0.001				<0.001
Cases without sick leave	1	1%	(0–7%)		9	12%	(6–21%)		0	0%	(0–5%)		66	87%	(77–94%)	
Cases with sick leave	90	74%	(66–82%)		45	37%	(29–46%)		41	34%	(26–43%)		27	22%	(15–31%)	
Cases referred to the Public Health Service	1	2%	(0–10%)		4	8%	(2–18%)		0	0%	(0–7%)		48	91%	(79–97%)	
TOTAL	**92**	**37%**	**(31–43%)**		**58**	**23%**	**(18–29%)**		**41**	**16%**	**(12–22%)**		**141**	**56%**	**(50–63%)**	

* Four missing values *p*: *p*-value Fisher's exact.

4. Discussion

The history of adverse event measurement in Occupational Mutual Insurance Companies is relevant. In an attempt to know the most realistic proportion of adverse events occurring in the institution, a systematic study of adverse events was started in 2019. In a first study [22], the Outpatient Adverse Event Trigger Tool (OAETT) [28,29] was adapted to our workplace and was called clinical triggers. Using the most complex clinical records sample from the clinical records audit [23], the frequency of adverse events observed was double that detected in the APEAS study [6,7] and higher than adverse events detected in trauma (11.4%) and orthopedics (4.1%) [30]. In this study [23], the five clinical triggers, enough to identify adverse events with sufficient accuracy, were determined [24]. A representative sample was then taken from each of the segments of patients treated in MC MUTUAL. This confirmed that the results of the high incidence of adverse events obtained were normalized, similar to that of the APEAS study [6,7] when considering the different types of patients treated [25]. Recent studies have focused on patient safety in primary care, improving the knowledge of the phenomenon at this level of care [31].

In some ways, we can consider administrative triggers as a management tool for the care process, while clinical triggers have a greater interest in the quality of the care process. There is a certain degree of usefulness for both fields in both types of triggers.

The comments made in relation to primary care do not encourage us to make a more exhaustive comparison; the type of pathologies, age, and economic benefits, among the most important, make specific studies of the occupational sector necessary, as is conducted in this study.

The sample used in previous studies showed a prevalence of around five adverse events per 100 clinical records [25], with a clear variability between the subsamples used (complex 11%, intermediate 2%, and minor 2%). If the same groups are used in the current study, the strength of the clustering is evident with somewhat lower values of 3% (7%, 0%, and 1%), although without statistically significant differences (Table 3).

A few years ago, triggers were implemented by the Institute for Healthcare Improvement (IHI) and adapted to the reality of an Occupational Mutual Insurance Company in terms of morbidity, severity, and organizational culture by MC Mutual. Initially, there were eleven clinical triggers, and then five, as they reflected with sufficient accuracy the cases where adverse events were most frequent [22].

At the beginning of our clinical records audit program, biased samples were analyzed and used to review more complex clinical cases, and therefore, with greater clinical activity and clinical needs. These clinical records had been selected based on two administrative criteria (number of visits and days of sick leave), which is why we called them administrative triggers. These limitations, which other samples selected in a segmented manner and with different representativeness, have been cited for the reader to better understand the line of advance in the study of adverse events [22–25].

Reviewing the clinical records in-depth made it possible to detect adverse events in the cases used. Thus, we first used the biased sample, then a biased sample supplemented by subsamples of clinical records less severe. This work analyzes adverse events in an Occupational Mutual Insurance Company based on a representative sample of all the clinical records of the Occupational Mutual Insurance Company.

Figure 1 presents the different areas of the sample of 250 cases concerning administrative triggers and clinical triggers and their various intersections.

In the representative sample of 250 cases, in 154 cases (61.6%), neither administrative nor clinical triggers were detected; in 89 cases, administrative triggers were detected (35.6%), and in 59 cases, clinical triggers were detected (23.6%). For 52 cases (20.8%), administrative and clinical triggers coexist.

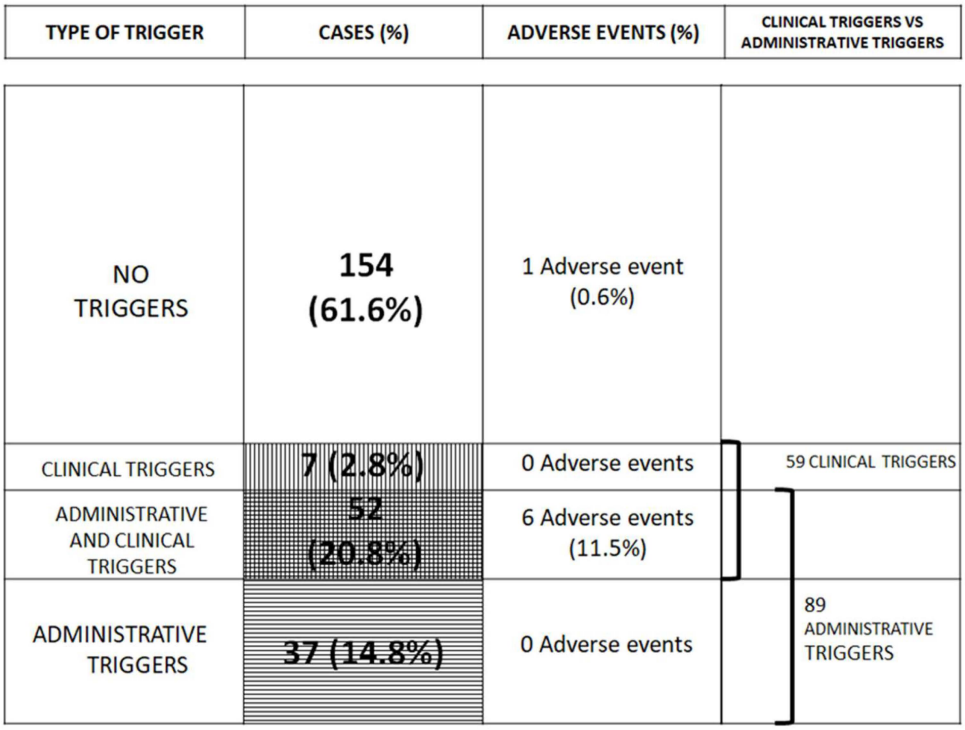

Figure 1. Types of trigger tools (TTs) and adverse events of the sample.

The number of cases with positive clinical triggers and negative administrative triggers is seven clinical records. All of them are from a single visit to the ambulatory care center. Three cases are without sick leave, two are referred to the Spanish National Health Service, and two are on sick leave and discharged on the same day. In all these cases, the positive clinical triggers are of "high-risk medication", with one case for antibiotic therapy, five cases for punctual corticotherapy, and one case for treatment with benzodiazepines.

The number of cases with negative clinical triggers and positive administrative triggers is 37 clinical records. Eleven cases have been referred to the Spanish National Health Service (four with spine pathology, three contusions/bruises, three inflammatory cases, and one case in the group of others), and the rest of the twenty-six cases attended have presented pathologies related to four cases of contusion, two of spine, three in the group of others, six cases of inflammatory pathology, ten wounds, and one case of fracture.

When considering the presence of adverse events of administrative and clinical triggers, it becomes evident that the overall 2.8% of adverse events in the set of clinical records depends strongly on the occurrence or not of triggers. Clinical records with positive clinical triggers have a prevalence five times higher than the total prevalence. Medical records with administrative triggers are 2.5 times higher than the total prevalence. Thus, clinical triggers are twice as efficient in the search for adverse events detected in clinical records. The prevalence of adverse events in clinical records without clinical triggers, administrative triggers, or none shows similar prevalence and a quarter of the total prevalence of adverse events.

Regardless of the discussions on the improvements brought about by patient safety policies at the international level, a study assessed the frequency, preventability, and severity of patient harm in a random sample of admissions from 11 Massachusetts hospitals in 2018. There were adverse events detected in almost one in four admissions, and approximately one-quarter of the events were preventable, which highlights the importance of patient safety and the need for further improvement [32]. Therefore, these findings suggest that the patient safety movement has stalled at best. It is clear that finding harm is very costly, and leadership involvement is key [33]. If quantifying adverse events has already been developed in traditional systems, such as primary care and hospitals, even for some services and pathologies, it has not been developed in entities such as ours.

The pragmatically oriented path of our research used everyday instruments to assess patient safety and clinical appropriateness, which, in addition to the quality of the records, broadens the practical application. The availability of the trigger tools allows us to evaluate their use as a prospective element of clinical care, following their usefulness in the retrospective use reflected in this work.

Detection of adverse events has been helpful in the development of projects and action plans. We have also noted the interest of healthcare professionals in detecting actual adverse events, encouraging declarations on the Incident-Reporting System platform and a greater notion of the reality of risk perception.

Current trends in healthcare quality define general global models that must be adapted to each specific service, center, or sector. Thus, with the sponsorship of the Joint Commission and the IHI [20], the aim is to lead diverse improvements that close gaps in the quality of the care provided, work for evidence in our actions, capture areas for improvement, facilitate the understanding of the process and its socio-cultural fit, make decisions based on data, seek information tools for blurred areas, be agents of change, disseminate and sustain improvement, and publish and consolidate its instruments. This is a good guide for our organization, which is adapted to our specific reality, widely accepted, and used by professionals, with a detected influence between patient safety culture, adverse event detection, and policy outcomes [34].

There are differences between primary health care from the National Health Service and Occupational Mutual Insurance Companies that must be mentioned. Our organization treats an active working population as a younger population (between 16 and 64 years old) rather than the general population, and the diseases treated are more related to trauma and mental repercussions of work activity. Similarities with the health sector are the objectives of care, health recovery, and autonomy in daily life. This includes the ability to carry out work activities, as well as good clinical and quality practices, especially those focused on patient safety.

These findings allow us to enlighten our professionals on the reality of our adverse events, which we declare a small part of our Incident-Reporting System (around one-hundredth part) [25]. Despite the limited availability of data in primary healthcare, which has been repeatedly highlighted [21], local approaches are sufficient to disseminate information to the professional community, consolidate action plans, and incorporate root cause analyses into clinical practice.

We still have a long way to go in organizations like ours in the sense of measuring adverse events to improve their use as an instrument to generate preventive activities, as a justification for such preventive policies, and as a possible predictive use in clinical management (for example, alarms in the electronic medical record) based on a collaborative project turn on among Occupational Mutual Insurance Companies on the use of clinical triggers for the detection of adverse events, based on the work in this study.

5. Conclusions

There are no previous publications on the incidence of adverse events in Occupational Mutual Insurance Companies in Spain. This study shows the existence of 3% of adverse events. There is a marked difference in this incidence according to administrative criteria, with three types of patients (complex 7%, intermediate 0%, and simple 1%). Clinical triggers are applied to appreciate the clinical meaning of this grouping.

The real knowledge of adverse events in these types of organizations, in comparison with other similar or primary care organizations, is of great interest to the professionals who work in them and the owners of the organizations (employers and social security) and their managers.

In mixed organizations and for insurers and healthcare providers, it is common to have administrative data (and, thus, be able to easily use administrative triggers) and more necessary to have clinical data (and, thus, incorporate healthcare data and culture). Anything that can link both data, making them work synergistically, is of great interest to

these types of organizations. The use of relevant and local information provided by studies of this type is of great interest to professionals (training specific programs, clinical commissions, improvement multidisciplinary groups, updating protocols, etc.). Stakeholders and managers also have, at their disposal, precise tools for analyzing improvements and diagnosing problems.

Clinical record auditing systems are useful and effective in obtaining various indicators and standards for monitoring the healthcare quality system. Their development within the framework of clinical record models, also oriented to the collective follow-up of our cases, is a strategy of great value for our organization.

In some ways, local data act as a warning call for clinicians, who are very sensitive to individual clinical information, and also stakeholders and managers, who are very sensitive to local information.

The specific characteristics of Occupational Mutual Insurance Companies offer a field with its own characteristics that must be analyzed and applied to the occupational health sector, which must follow the patient safety trends that are more general and applied to its specific reality.

6. Limitations

The study was carried out in an Occupational Mutual Insurance Company in Spain, which we already know does not reflect the reality of other primary care facilities, nor can we be sure that it expresses the reality of other Mutual Insurance Companies or that the results can be transferable, given that there is no literature on the subject. We hope that the study will be validated in other settings and can be used to increase the knowledge and culture of patient safety in organizations such as ours. We do not have information on the cases where patients attended other institutions. A few clinical records did not receive assistance from our organization, so we do not have information on these cases. Although the accuracy of our administrative information is very good, the information related to clinical aspects should improve in coverage and accuracy, even though the diagnoses used have a high prevalence and degree of management.

Future studies: A collaborative project is underway among Occupational Mutual Insurance Companies on the use of clinical triggers for the detection of adverse events, based on the work in this study.

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References

1. Rocco, C.; Garrido, A. Seguridad del paciente y cultura de seguridad. *Rev. Méd. Clín. Condes* **2017**, *28*, 785–795. [CrossRef]
2. Larizgoitia, I.; Bouesseau, M.-C.; Kelley, E. WHO Efforts to Promote Reporting of Adverse Events and Global Learning. *J. Public Health Res.* **2013**, *2*, e29. [CrossRef] [PubMed]
3. Lapuente, F.P. La Seguridad del Paciente: Un Problema Importante y Actual. 2011. Available online: http://gestionclinica.sespa.es/pdf/jornadas2012/t9_lectura2.pdf (accessed on 19 May 2023).
4. Patient Safety. Who.int s/f. Available online: https://www.who.int/es/news-room/fact-sheets/detail/patient-safety (accessed on 19 May 2023).
5. Figura 1. Relación de estudios realizados para conocer la incidencia de eventos adversos en hospitales. In *Estrategia de Seguridad del Paciente del Sistema Nacional de Salud*; Ministerio de Sanidad, Servicios Sociales e Igualdad: Madrid, Spain, 2016; Gob.es s/f. Available online: https://seguridaddelpaciente.sanidad.gob.es/docs/Estrategia_Seguridad_del_Paciente_2015-2020.pdf (accessed on 14 August 2023).
6. Ministry of Health & Consumer Affairs, Government of Spain. *APEAS Study. Patient Safety in Primary Health Care*; Government of Spain: Madrid, Spain, 2008.
7. Aranaz-Andrés, J.M.; Aibar, C.; Limón, R.; Mira, J.J.; Vitaller, J.; Agra, Y.; Terol, E. A study of the prevalence of adverse events in primary healthcare in Spain. *Eur. J. Public Health* **2012**, *22*, 921–925. [CrossRef] [PubMed]
8. Aranaz-Andrés, J.M.; Aibar-Remon, C.; Vitaller-Burillo, J.; Requena-Puche, J.; Terol-Garcia, E.; Kelley, E.; de Castro, M.G.-V.; The ENEAS Work Group. Impact and preventability of adverse events in Spanish public hospitals: Results of the Spanish National Study of Adverse Events (ENEAS). *Int. J. Qual. Heal. Care* **2009**, *21*, 408–414. [CrossRef] [PubMed]
9. Ministry of Health & Consumer Affairs, Government of Spain. *Estudio Nacional sobre los Efectos Adversos ligados a la Hospitalización (ENEAS 2005)*; Government of Spain: Madrid, Spain, 2006.
10. AMAT. Mutuas Colaboradoras con la Seguridad Social. *Comprometidos con la Salud de los Trabajadores y la Competitividad de las Empresas; AMAT: 2019.* Available online: https://amat.es/wp-content/uploads/2021/03/que-son-las-mutuas.pdf (accessed on 14 June 2023).
11. Sociedad Española de Calidad Asistencial. Calidadasistencial.es s/f. Available online: https://calidadasistencial.es/ (accessed on 22 December 2023).
12. 2021 Memoria. Barcelona: MC MUTUAL. 2022. Available online: https://www.mc-mutual.com/estaticos/Memorias/resources/memoria_2022_es/mobile/index.html (accessed on 20 August 2023).
13. Agra, Y. *Estrategia de Seguridad del Paciente del Sistema Nacional de Salud Período 2015–2020*; Ministerio de Sanidad, Servicios Sociales e Igualdad: Madrid, Spain, 2016. Available online: https://seguridaddelpaciente.es/resources/documentos/2015/Estrategia%20Seguridad%20del%20Paciente%202015-2020.pdf?cdnv=2 (accessed on 22 August 2023).
14. Ministerio de Sanidad, Política Social e Igualdad. Desarrollo de la Estrategia Nacional en Seguridad del Paciente 2005–2011; Oficina de Planificación Sanitaria y Calidad, Agencia de Calidad del SNS, Madrid, Spain; 2011. Available online: https://www.sanidad.gob.es/gl/organizacion/sns/planCalidadSNS/docs/estrategia_sp_sns_2005_2011.pdf (accessed on 22 July 2023).
15. Bender, J.A.; Kulju, S.; Soncrant, C. Combined Proactive Risk Assessment: Unifying Proactive and Reactive Risk Assessment Techniques In Health Care. *Jt. Comm. J. Qual. Patient Saf.* **2022**, *48*, 326–334. [CrossRef] [PubMed]
16. Mora-Capín, A.; Ignacio-Cerro, C.; Díaz-Redondo, A.; Vázquez-López, P.; Marañón-Pardillo, R. Impact of risk mapping as a strategy for monitoring and improving patient safety in paediatric emergency care. *An. Pediatr. (Engl. Ed.)* **2022**, *97*, 229–236. [CrossRef] [PubMed]
17. Committee on Patient Safety and Quality Improvement. Committee Opinion No. 681: Disclosure and Discussion of Adverse Events. *Obstet. Gynecol.* **2016**, *128*, e257–e261. [CrossRef] [PubMed]
18. Pysyk, C.L.; Filteau, L.; Baxter, A. Quality and patient safety committee structure and activities in an academic department of anesthesiology: A narrative description. *Can. J. Anaesth.* **2020**, *67*, 100–108. [CrossRef] [PubMed]
19. Health Quality & Safety Commission. *Learning from Adverse Events: Adverse Events Reported to the Health Quality & Safety Commission 1 July 2018 to 30 June 2019 | Te Ako i Ngā Pāpono Kōaro: Ngā Pāpono Kōaro i Pūrongorongotia ki te Kupu Taurangi Hauora o Aotearoa i te 1 o Hōngongoi 2018 ki te 30 o Pipiri 2019*; Health Quality & Safety Commission (NZ): Wellington, New Zealand, 2019. Available online: https://www.hqsc.govt.nz/assets/Our-work/System-safety/Adverse-events/Publications-resources/Learning-from-adverse-events2019-web-final.pdf (accessed on 2 May 2023).
20. Ogrinc, G.S.; Headrick, L.A.; Barton, A.J.; Dolansky, M.A.; Madigosky, W.S.; Miltner, R.S.; Hall, A.G. *Fundamentals of Health Care Improvement: A Guide to Improving Your Patients' Care*, 4th ed.; Joint Commission Resources: Oakbrook Terrace, IL, USA; Institute for Healthcare Improvement: Boston, MA, USA, 2022.
21. Gens-Barberà, M.; Rey-Reñones, C.; Hernández-Vidal, N.; Vidal-Esteve, E.; Mengíbar-García, Y.; Hospital-Guardiola, I.; Palacios-Llamazares, L.; Satué-Gracia, E.M.; Oya-Girona, E.M.; Bejarano-Romero, F.; et al. Effectiveness of New Tools to Define an Up-to-Date Patient Safety Risk Map: A Primary Care Study Protocol. *Int. J. Environ. Res. Public Health* **2021**, *18*, 8612. [CrossRef] [PubMed]
22. Ortner Sancho, J.; Manzanera López, R.; Grau Balcells, N.; Moya Alcocer, D.J.; Farrús Esteban, X.; Martínez Martínez, J.M. Uso del Trigger Tool para la detección de incidentes y eventos adversos en una mutua colaboradora con la Seguridad Social. *Arch. Prev. Riesgos Laborales* **2020**, *23*, 343–356. [CrossRef] [PubMed]
23. Ortner, J.; Vives, A.; Moya, D.; Torres, M.; Grau, N.; Farrús, X.; Manzanera, R.; Mira, J.J. Frequency of outpatient care adverse events in an Occupational Mutual Insurance Company in Spain. *J. Healthc. Qual. Res.* **2021**, *36*, 340–344. [CrossRef] [PubMed]

24. Ortner, J.; Vives, A.; Moya, D.; Torres, M.; Grau, N.; Farrús, X.; Manzanera, R.; Mira, J. Utilización del Trigger Tool para detectar incidentes de seguridad en una mutua colaboradora de la Seguridad Social en España. *J. Healthc. Qual. Res.* **2021**, *37*, 125–126. [CrossRef] [PubMed]
25. Ortner, J.; Moya, D.; Manzanera, R.; Torres, M.; Vives, A.; Farrus, X.; Grau, N.; Mira, J.J. Adverse events in the global healthcare practice of an Occupational Mutual Insurance Company in Spain. *Work* **2023**, *76*, 1157–1165. [CrossRef] [PubMed]
26. Dhand, N.K.; Khatkar, M.S.; Statulator: An Online Statistical Calculator. Sample Size Calculator for Estimating a Single Proportion. 2014. Available online: http://statulator.com/SampleSize/ss1P.html (accessed on 21 December 2023).
27. Otero, M.J.; Codina, C.; Tamés, M.J.; Pérez, M. Errores de medicación: Estandarización de la terminología y clasificación. Resultados de la Beca Ruiz-Jarabo 2000. *Farm Hosp.* **2003**, *27*, 137–149.
28. Griffin, F.; Resar, R. *IHI Global Trigger Tool for Measuring Adverse Events*, 2nd ed.; Institute for Healthcare Improvement: Cambridge, MA, USA, 2009; Available online: http://www.ihi.org:80/resources/Pages/IHIWhitePapers/IHIGlobalTriggerToolWhitePaper.aspx (accessed on 20 August 2023).
29. Hibbert, P.D.; Molloy, C.J.; Hooper, T.D.; Wiles, L.K.; Runciman, W.B.; Lachman, P.; Muething, S.E.; Braithwaite, J. The application of the Global Trigger Tool: A systematic review. *Int. J. Qual. Health Care* **2016**, *28*, 640–649. [CrossRef] [PubMed]
30. Sathiyakumar, V.; Thakore, R.V.; Greenberg, S.E.; Whiting, P.S.; Molina, C.S.; Obremskey, W.T.; Sethi, M.K. Adverse events in orthopaedics: Is trauma more risky? An analysis of the NSQIP data. *J. Orthop. Trauma* **2015**, *29*, 337–341. [CrossRef] [PubMed]
31. Esmail, A. *Measuring and Monitoring Safety: A Primary Care Perspective*; The Health Foundation: London, UK, 2013; Available online: https://www.health.org.uk/publications/measuring-and-monitoring-safety-a-primary-care-perspective (accessed on 19 July 2023).
32. Bates, D.W.; Levine, D.M.; Salmasian, H.; Syrowatka, A.; Shahian, D.M.; Lipsitz, S.; Zebrowski, J.P.; Myers, L.C.; Logan, M.S.; Roy, C.G.; et al. The Safety of Inpatient Health Care. *N. Engl. J. Med.* **2023**, *388*, 142–153. [CrossRef] [PubMed]
33. Berwick, D.M. Constancy of Purpose for Improving Patient Safety—Missing in Action. *N. Engl. J. Med.* **2023**, *388*, 181–182. [CrossRef] [PubMed]
34. Al-Mugheed, K.; Bayraktar, N.; Al-Bsheish, M.; AlSyouf, A.; Jarrar, M.; AlBaker, W.; Aldhmadi, B.K. Patient Safety Attitudes among Doctors and Nurses: Associations with Workload, Adverse Events, Experience. *Healthcare* **2022**, *10*, 631. [CrossRef] [PubMed]