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# Insurance Claims for Wrong-Side, Wrong-Organ, Wrong-Procedure, or Wrong-Person Surgical Errors: A Retrospective Study for 10 Years

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**Objective:** Serious adverse events, such as wrong-side, wrong-organ, wrong-procedure, or wrong-person errors, still occur despite the implementation of preventative measures. In France, we describe the claims related to such errors based on the database from one of the main insurance companies.

**Methods:** A retrospective analysis of claims declared between January 2007 and December 2017 to Relyens, a medical liability insurance company (Sham), was performed. Their database was queried using the following keywords: “wrong side,” “wrong organ,” and “wrong person.”

**Results:** We collected 219 claims (0.4% of the total claims). The main specialties involved were orthopedics (34% of cases), neurosurgery (14%), and dentistry (14%). The claims were related to wrong organ (44%), side (39%), identity (13%), or procedure (4%). Juridical entity involved were mainly public facility (69%), followed by private facility (19%) or private physician (10%). The mean number of annual claims made has decreased of 20% since the mandatory implementation of the checklist in 2010 (22 versus 17.5 events per year). The main risk factors identified according to the ALARM protocol were factor related to the team (87%) or to the task to accomplish (78%). A direct causal factor was involved in 20% of the files, the main one being the organization (43%) closely related to the medical file (36%). The settlement was performed by conciliation in 69% of the claim and in court in 30%. The compensation was higher during a court settlement.

**Conclusions:** Wrong-side, wrong-organ, wrong-procedure, or wrong-person surgical errors are rare but fully preventable by the implementation of a safety culture.

**Key Words:** patient safety, error, wrong side, wrong organ, wrong procedure

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Patient safety is a key issue in the medical community, which has been highlighted in 2000 by the American report *To Err Is Human*.<sup>1</sup> However, some serious adverse events are fully avoidable (“never events”) and are still observed, such as wrong-side, wrong-organ, wrong-procedure, or wrong-person errors. They

are the consequences of a failure in patient safety, inevitably affecting patients’ confidence.

Preventive measures were implemented in the United States in the early 2000s, such as the process of preoperative verification with the patient, marking of the surgical site, and performing a checklist of the World Health Organization at multiple phases comprising a “sign in,” a “time-out,” and a “sign out.” The efficacy of these changes is apparent from the lowering of the morbidity and mortality rates.<sup>2,3</sup> In France, a safety culture is widely promoted by French National Authority for Health (Haute Autorité de Santé [HAS]). It goes through several national plan and sensibilization campaign to report medical error. Moreover, since January 1, 2010, the HAS has made mandatory to perform a preoperative and postoperative checklist to avoid such event.<sup>4</sup>

Despite these measures, the incidence of errors remains high (0.09 of every 10,000 surgical procedures in the United States).<sup>5,6</sup> In France, there are limited data available, and there have been no French studies of this to date. The aim of this article was to describe the claims related from wrong-side, wrong-organ, wrong-person, or wrong-procedure surgical errors using the database of one of the main French insurance companies.

## MATERIALS AND METHODS

In this observational retrospective study, we analyzed the files for claims relating to wrong-side, wrong-organ, or wrong-person error declared to Relyens (Sham—Hospital Mutual Insurance Corporation, Lyon, France) during a period of 11 years, from January 1, 2007, to December 31, 2017. Relyens is the main insurer for medical liability in France. All claims reported by its customers in France are compiled in a database. The input is from claim managers and forensic physicians, and it constitutes a pertinent source of information.

This study was approved by the ethics committee of the Hospices Civils de Lyon (project no.13-44, approved on March 13, 2019).

From Relyens database, we extracted all claims regarding the following:

- The wrong side: defined as a laterality error; keyword “wrong side”
- The wrong organ: the wrong body part operated on and dental extraction errors; keyword “wrong organ”
- The wrong person: identity error; keyword “wrong person”
- The wrong procedure: error in the procedure; keyword “wrong procedure”

Then, each claim was summarized by a standardized protocol:

- Patient’s characteristics: age, sex, ongoing professional activity, American Society of Anesthesiologists score
- Characteristics of the error: type of error, surgical specialty, type of juridical entity implicated (private facility, public facility, or directly involving the practitioner)

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- Cause of the error: The ALARM procedure was used to identify the risk factors according to the guidelines.<sup>7</sup> This procedure classifies the causes of errors into 7 categories: factor related to the patient (1), to the tasks to be accomplished (2), to the individual (3), to the team (4), to the work environment (5), to the organization (6), or to the institute (7). If a precise contributing factor was identified by a medical expert, information was collected, and classified as related to medical file, human factor, organization, and patient.
- Consequences of these errors: settlement (amicable or through the court), the compensation related to the claim. The consequences of the error were also evaluated as time during which the patient was not able to fully carry out his activities of daily living (temporary functional impairment) and the time until the consequences of the error are considered permanent (consolidation). At the time of consolidation, the definitive reduction in physical, psychosensory, or intellectual capacity resulting from the damage to the integrity is estimated as a percentage, ranging from 0% (no reduction) to 100% (impossibility to perform any action), and is named as the permanent functional impairment (PFI). Temporary functional impairment, consolidation, and PFI were set by a medical expert, based on medicolegal consideration.

Moreover, we collected for each year the number of juridical entities insured by the Sham (mainly health care facility). The exact number of health care professionals insured could not be communicated because of commercial confidentiality.

The analysis of each file was performed to maintain anonymity, and therefore, there might have been several claims related to one professional. Two physicians were involved in this task: one at Relyens center for risk management and the other an anesthesiologist-intensivist doctor, independent of the insurance company.

The results were expressed as median associated with their interquartile range, or as number with their percentage. Any missing information has been labeled as “not available.” The statistical analyses were carried out with R statistical software (version 3.4.6; R Foundation for Statistical Computing, Vienna, Austria).

## RESULTS

From Relyens database, 219 claims were extracted (0.4% of the recorded claims to the insurer during the same period). The data for the studied population are summarized in Table 1.

The claim types were 96 wrong organs (44%), 86 wrong sides (39%), 29 wrong persons (13%), and 8 wrong procedures (4%) (Fig. 1A). The associated juridical entities involved were public facility (151%–69%), private facility (46%–21%), or the private physician (22%–10%) (Fig. 1A). The main specialties involved in claims were orthopedics (75%–34%), neurosurgery (31%–14%), dentistry (30%–14%), visceral surgery (21%–10%), and gynecology (17%–8%) (Fig. 1B). Claims regarding ophthalmology surgery were rare (5%–2%).

On average, 22.0 events per year were observed between 2007 and 2009, compared with 17.5 events per year between 2010 and 2017, corresponding to a 20% decreased since the mandatory implementation of the checklist by the HAS in January 2010. Concomitantly, the number of juridical entities insured constantly increased, from 2313 to 5171 between 2007 and 2017 (Fig. 2).

The median delay in consolidation was 168 (76–364) days. The average rate of PFI was 4%. Most of the settlement occurred during a conciliation procedure (151%–69%), but 67 (30%) occurred in the court. The conciliation procedure led to a compensation in 80% of cases and in 99% of cases during a court procedure.

**TABLE 1.** Patient Characteristics

	Total (n = 219)
Sex	
Male	101 (46)
Female	113 (52)
NA	5 (2)
Age, y	47 (33–62)
ASA	
1–2	157 (72)
3–4–5	31 (13)
NA	31 (15)
Ongoing professional activity	
Yes	103 (47)
No	78 (36)
NA	38 (17)
Consequences	
TFI, d	60 (17–140)
PFI, %	4 (0–10)
Consolidation, d	168 (76–364)
Settlement	
Conciliation	151 (69)
Court	67 (30)
NA	1 (1)
Compensation	
Total amount, €	6179 (2840–15,000)
Conciliation	
No.	121 (80)
Amount, €	4771 (2500–15,000)
Court	
Number	66 (99)
Amount	8446 (3867–15,000)

Results are expressed as the number of patients (n) and percentage (%) or median and interquartile range.

ASA, American Society of Anesthesiologists; NA, not available; TFI, temporary functional impairment.

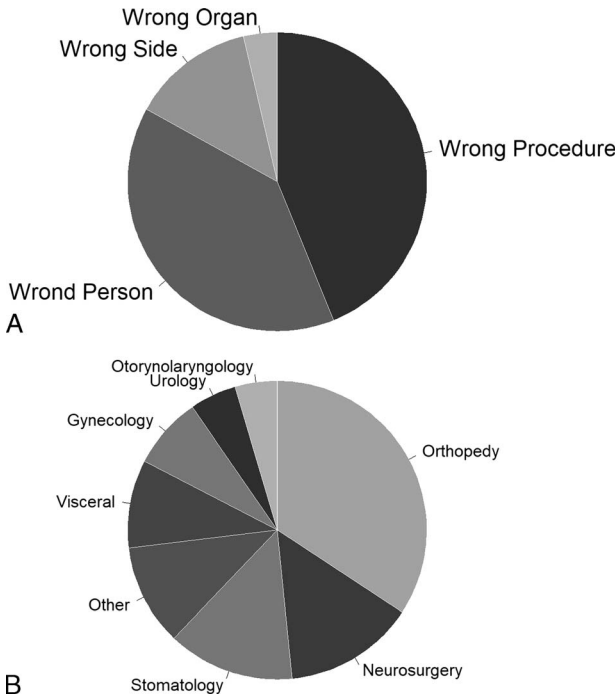
Compensations were higher during a court settlement (4771 [2500–15,000] € versus 8446 [3867–15,000] €; Fig. 3).

Analysis of the 219 files revealed 670 causes listed according to the ALARM protocol (Table 2). The main factors responsible for errors were the team factors, in 190 (87%) cases followed closely by the task related factors (170%–78%). A direct causal factor was found in 44 (20%) of the cases. The main causes were organizational factors (19%–43%), such as failure in the perioperative check list or during transmission of medical information. One other major causal problem was related to the medical file (16%–36%), containing incomplete information or simply containing misleading information.

Notably, 5 of the 6 cases of wrong-side locoregional anesthesia (LRA) led to a wrong-side error during surgery.

## DISCUSSION

This study described the claims in France related to wrong-side, wrong-organ, or wrong-person surgical errors during a period of 11 years based on insurance data. Another preliminary study found results that are consistent with our present data in terms of type consequence frequency.<sup>8</sup> In Spain, there seems to have a similar description of these medical errors.<sup>9</sup> The present



**FIGURE 1.** Repartition of the juridical entity (A) and the specialty (B) involved in the claims.

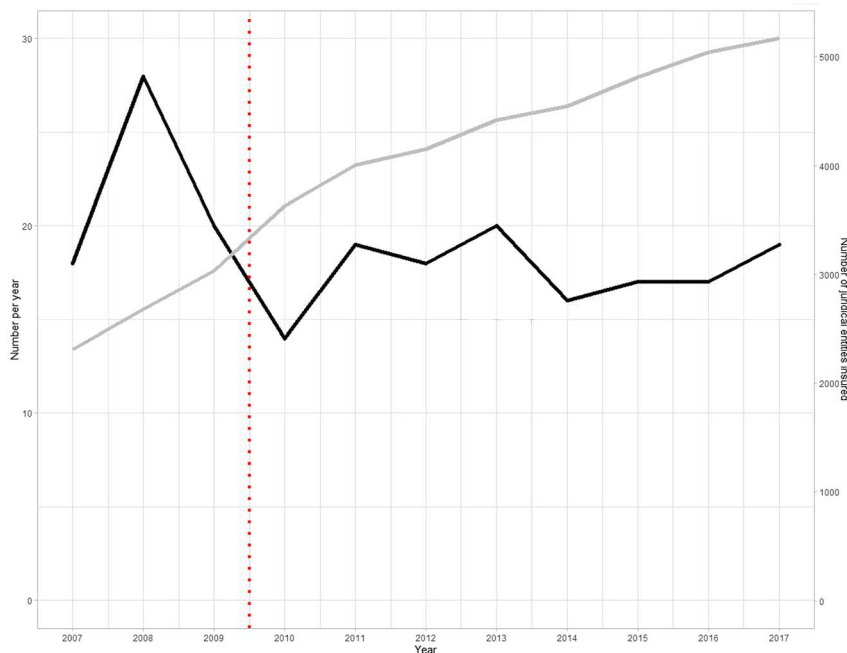
study is the first French report of “never events” surgical procedure errors, accurately described using the ALARM protocol.

First, we noted an overrepresentation of claims regarding orthopedic surgery compared with other surgeries. This may be due to the intrinsic risk of side error and a greater annual volume of interventions.<sup>10</sup> Concerning neurosurgery, the errors were mainly related to vertebral surgery, mainly in the lumbar spine.<sup>11</sup> Although

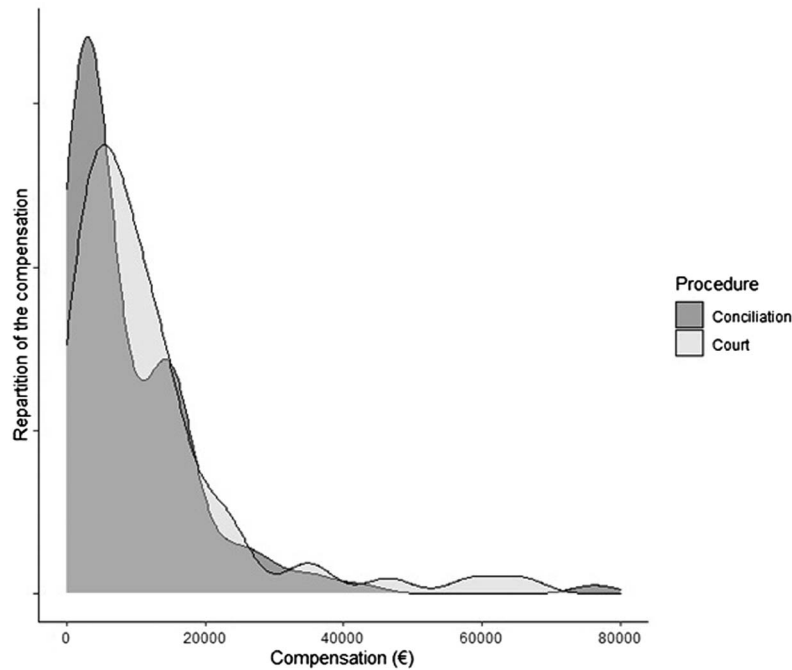
preoperative radiological identification of the level of the lesion in neurosurgery had been part of the guidelines since the publication of the “Sign, Mark & X-ray” protocol in 2001,<sup>5,12</sup> errors remain common because of congenital anatomical variations, overweight, or improper radiological exposure.<sup>12</sup> In dentistry, the errors could be linked to the absence of the availability of orthopantomograms, either because they were often performed at another facility or because the surgeon was not the patient’s usual practitioner.<sup>13</sup> Two percent of the errors in our series were related to ophthalmology surgery. This number is low compared with the substantial volume of interventions carried out. A likely explanation for this lies with the observance of laterality due to the position of the surgeon in relation to the patient’s head, and the fact that the surgeon has the possibility to inspect both eyes, even in the operating room. Moreover, regularly, the intervention require to be performed on both eyes, and the side error might not have been reported regarding the absence of effective damage to the patient. This low number of errors was not expected in light of the literature<sup>14</sup> and is probably explained by a subrepresentation of the ophthalmologist in Relyens customer database.

The compensation during court settlement was higher compared with regular conciliation. This is probably due to higher severity of damage, leading regularly to court settlement.

Wrong-side errors in LRA seemed to be rare in our series, but they are probably underreported. They do not systematically lead to a surgical error,<sup>15,16</sup> and they could be reduced by the introduction of a checklist carried out before the LRA (“stop before you block”<sup>17</sup>), by warnings (posters, stickers), by physical barriers (reminder on the ultrasound apparatus), or by behaviors (simulation, “mock before you block”)<sup>18</sup> actively involving the patient. In our series, 80% of the side error due to LRA led to a surgical error. A meta-analysis carried out by Deutsch et al<sup>19</sup> in May of 2018 revealed that the 5 factors leading to wrong-side errors in LRA are time constraints, distractions, lack of communication, invisible marking of the site, and personal factors (change of the staff, cognitive errors, fatigue). The American Society of Regional Anesthesia and Pain Medicine (ASRA) recently proposed to develop



**FIGURE 2.** Evolution of the claims by years. Red dotted line represents the implementation of the checklist.



**FIGURE 3.** Repartition of the compensation by type of settlement.

specific care processes for LRA to educate medical and paramedical teams, and to encourage the use of checklists and cognitive aids. They also indicated that the safety of the LRA may be improved by the participation of patient representatives and by performing regular audits.<sup>20</sup> Our results regarding the risk factors for errors are consistent with those found in previously published studies (Moshtaghi et al<sup>13</sup> Maloley et al<sup>21</sup>), and those of the HAS during the analysis of the root causes of adverse events associated with care.<sup>22</sup>

We observed a reduction of 20% in the error after the implementation of the perioperative check list. The relevance of such a preventive tool is presently incontestable,<sup>2,23–26</sup> provided that it is used in a compliant manner. The study undertaken by Bergs et al<sup>27</sup> showed a reduction in mortality after introduction of

the checklist, with a relative risk of 0.77 (confidence interval, 0.60–0.98;  $P = 0.04$ ). Haynes et al<sup>2</sup> reported a decrease in mortality of 1.5% to 0.8% and a reduction in complications linked to the patients of 11.0% to 7.0%.

The checklist is underused,<sup>28</sup> and training and practice programs for care staff in regard to communication strategies, such as Team STEPPS (Team Strategies and Tools to Enhance Performance and Patient Safety),<sup>29,30</sup> could allow for the development of a culture of patient safety.<sup>31</sup> These skills are all the more effective when they are taught at an early stage.<sup>32</sup> Improvement in patient safety is a continuing process requiring the highest level of stringency in daily practice. For example, marking of the surgical site should be the general rule, carried out in an area not covered by the operating fields. Some authors even recommend to write the initials of the intervention, such as the initials “H.V.” for the hallux valgus surgery.<sup>21</sup> The time-out could be carried out by the surgeons themselves, preferably with open-ended questions. Recently, there has been a modification of the checklist by the HAS, integrating the notion of overall agreement of the management of the patient by the surgical and anesthesia teams, which contributes to improvement of patient safety.<sup>33</sup> Safety procedures must be continually evaluated to maintain increased oversight of standards by health care professionals. Finally, joint meetings between the care units and the administration could be organized on a regular basis to reduce or eliminate unsatisfactory processes and to increase and optimize good procedures.<sup>14</sup>

The present work has several limitations. As a descriptive and retrospective study only, and hence nonexhaustive reporting, we were not able to estimate the overall incidence of this type of errors. The reporting errors are limited by the methodology of the study and the presence of reports of medical expertise as well as their analysis by 2 independent doctors. There remains a risk of underdeclaration. Indeed, as noted in several files, a surgeon could justify their error in terms of a wrong side by the fact that the unintentionally operated side was, in fact, more affected than the initially intended side and thus needed to be operated on first. We already discuss the case of ophthalmology, but this could also occur

**TABLE 2.** Factor Related to the Case by the ALARM Framework and Causal Factor

	Factors Identified	Among the Cases
<b>ALARM factor</b>		
Patient factors	63 (9)	49 (22)
Task factors	211 (31)	170 (78)
Individual (staff) factors	11 (2)	10 (5)
Team factors	364 (54)	190 (87)
Work environment factors	22 (3)	14 (6)
Organizational and management factors	3 (1)	3 (1)
Institutional context	0 (0)	0 (0)
<b>Causal factor</b>		
Medical file	16 (27)	16 (36)
Human factor	17 (28)	14 (32)
Organization	20 (33)	19 (43)
Patient	7 (12)	7 (16)



in visceral (e.g., inguinal hernias) or orthopedic (e.g., placement of a prosthesis) surgeries. The database of a single insurer, a leader in the French market for medical liability, was extracted, which allowed for a good level of representativeness. The analysis is nonetheless probably biased by the fact that Relyens did not insure the same portion of public and private facilities.

## CONCLUSIONS

Wrong-side, wrong-organ, and wrong-person errors are rare but serious errors. Despite the requirement to perform a checklist during the surgical time-out, these “never events” persist, particularly in orthopedics, neurosurgery, and dentistry. These avoidable errors are multifactorial: lack of communication between the teams and/or with the patient, noncompliance with established protocols, erroneous medical files, and vulnerability of the patient. Care should be taken to avoid wrong-side errors in LRA, which can lead to surgical mistakes. The moral and physical harm is considerable among patients. This study showed the relevance of the systematic use of preventative means (checklist and marking of the site) to improve safety measures in the operating theater.

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