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Clinical risk management – a 3-year experience of team timeout in 18 081 ophthalmic patients

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ABSTRACT.
Purpose: **Clinical risk management aims to identify, analyse and avoid errors and risks systematically to improve patient's safety. Preoperative checklists to prevent mistakes have gained importance in the last few years. A so-called team timeout checklist was introduced in October 2011 at the Department of Ophthalmology, Hietzing Hospital, Vienna. The purpose of the study is to evaluate the benefits and demonstrate the value of team timeout.**
Methods: **After the team timeout had been in use for 6 months, all near misses that occurred over a period of 34 months were assigned to the following groups: wrong side, wrong lens, wrong patient and miscellaneous.**
Results: **Eighteen thousand and eighty-one surgeries were performed in the specified period; 53 cases of 'wrong side' and 52 cases of 'wrong intraocular lens' were noted. Ninety-six near misses concerned the patients' data and 38 concerned documentation. A reduction of near misses was noted after an adaptation phase of 3 months.**
Conclusions: **Team timeout proved valuable, as it improved the patients' safety with minimum effort. Errors may occur despite several preoperative controls and can be detected by performing team timeout.**

Key words: checklist – patient safety – risk management – surgery – team timeout

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Introduction

About 234 million major surgical procedures are performed every year throughout the world (Weiser et al. 2008). Nearly one of every 10 patients experiences iatrogenic events (Kohn et al. 2000; Haugen et al. 2013a,b) and half of these events occur during perioperative care (Kohn et al. 2000; Haugen et al. 2013a,b). At least, half of all surgical complications are avoidable (Haynes et al. 2000).

Most errors occur due to failures in decision-making and awareness, missing teamwork and inadequate communication (Kohn et al. 2000; Panesar et al. 2011; Fudickar et al. 2012; Prabhakar et al. 2012; Haugen et al. 2013a, b). Medical errors like wrong-side surgery are devastating events for patients and surgeons alike (Kelly & Jalil 2011; Cobb 2012; Haugen et al. 2013a,b).

Clinical risk management aims to detect, analyse and prevent mistakes or risks in patient's care in a systematic manner. The so-called Swiss cheese model is a popular tool in clinical risk management (Reason 1995, 2000; Reason et al. 2001; Perneger 2005). According to the model, hazards are prevented by a series of barriers (Perneger 2005).

Checklists to reduce communication failure and increase patient's safety have gained importance in the last few years. In 2007, the World Health Organization (WHO) introduced the Surgical Safety Checklist (de Vries EN et al. 2008; Haynes et al. 2009; Wilson & Walker 2009; Haynes et al. 2011; Fudickar et al. 2012), which is based on three elements: (Haynes et al. 2009; Fudickar et al. 2012):

(1) Sign-in: Before the induction of anaesthesia, the patient confirms his or her identity, the procedure and the surgical site. The signed consent form, the anaesthesia apparatus, blood products and allergies are checked.
(2) Team timeout or timeout: Immediately before the skin incision, the names and functions of the entire team are confirmed. The patient's identity, the procedure and the surgical site are reconfirmed. Critical surgical steps, the duration of the operation, patient-specific concerns and equipment availability are reviewed.
(3) Sign-out: Before the patient leaves the operating room, the procedure is reconfirmed, instrument count and correct labelling of specimens are confirmed, and key concerns in postoperative care are reviewed.

Surgical checklists improve communication, encourage a non-hierarchical team-based approach and permit early detection of near misses (Treadwell et al. 2014).

Ophthalmic procedures are associated with the highest rate of documented complications (1.8/10.000); half of these concern wrong lens implantation (Neily et al. 2009). In fact, 63% of all complaints in ophthalmology are related to the wrong lens (Haugen et al. 2013a,b).

Timeout was implemented at our department in October 2011. The majority of operations in ophthalmology are performed in local anaesthesia. Patients are actively involved in the confirmation of their identity, the procedure and the surgical side. Sign-in is performed in abbreviated form and marked on a checklist. Sign-out is performed if necessary (special directives after complications, positioning after vitreoretinal procedures).

To evaluate the benefits of timeout and demonstrate these to the staff, we recorded the near mistakes or near misses detected by timeout. To our knowledge, no assessment of a preoperative checklist has been performed thus far in ophthalmology.

Materials and Methods

Six months after implementation of the checklists, we started to record all near misses during timeout and then analysed the data collected over a period of 34 months (March 2012 to December 2014).

In patients being operated on in local anaesthesia, the team timeout is performed at our department by the surgeon, the scrub nurse, the circulating nurse and the patient, immediately before the incision. In cases of general anaesthesia, the timeout is performed by the surgeon, the scrub nurse, the circulating nurse and the anaesthetist. The circulating nurse takes the perioperative checklist (in cases of cataract surgery additionally biometry and the selected intraocular lens) and reads the questions aloud. The answers are given aloud and clearly by the team member specified on the checklist. At the timeout, all team members introduce themselves. Then, the patient's identity, the side of the procedure and the procedure are confirmed. In cases of local anaesthesia, the patient is included in the confirmation of the patient's identity, for example, 'Mr. Smith, could you please tell us your name and date of birth?' All other activities are stopped, and the team members focussed on the procedure, as described in the published literature (Cobb 2012).

At our department, we have a variety of checklists for surgery in general anaesthesia and local anaesthesia (cataract surgeries and oculoplastic surgeries), with specific questions for the respective type of operation. Before cataract surgery, the selected intraocular lens is checked. Prior to surgery in general anaesthesia, the anticipated sedation difficulties and the duration of the operation are reviewed. Before intravitreal injections, we use a brief checklist that includes the planned medication. The checklists take about 1 or 2 min to be completed.

For the documentation of near misses, notices were pinned on boards in both operating rooms and the treatment room for intravitreal injections. Once a near miss or an error had been identified, the circulating nurse made an entry on the prepared list.

For analysis, all detected near misses were summarized as follows:

(1) Wrong side:
- (a) Wrong side or no side marked on the patient
- (b) Wrong side or no side marked in the patient's records
- (c) Wrong side or no side marked on the operating room schedule
- (d) Wrong side or no side marked on the operating room list
- (e) Wrong side of pupil dilation

(2) Wrong lens:
- (a) Wrong side or no side marked on biometry
- (b) Lens for the wrong eye chosen
- (c) Wrong refraction chosen
- (d) Biometry and the selected lens do not match
- (e) The selected lens does not fit refraction in the other eye

(3) Wrong patient
- (a) Wrong name (first name/surname) in patient's records and/or biometry
- (b) Wrong birth date in the patient's records and/or biometry
- (c) No documentation of allergy
- (d) No documentation of the planned operation and/or the side of surgery in the patient's records
- (e) Documentation incomplete

(4) Miscellaneous
- (a) Documents of other patients in the patient's records
- (b) Missing red identification wristlet in a case of allergy
- (c) No signature of the patient on the consent form
- (d) Missing consent form
- (e) No signature of the surgeon in the patient's records

Our study followed the tenets of the Declaration of Helsinki.

Results

We performed 18 081 operations in the specified period: 8860 were cataract surgeries and 6052 intravitreal injections; the remaining operations were vitrectomies, glaucoma surgery and oculoplastic surgery. Wrong-side near misses occurred in 53 cases (0.29%), and wrong lens near misses in 52 patients (0.59% of cataract surgeries). Wrong patient's data (such as date of birth, name or no documentation of allergy) were noted 96 times (0.53%), and miscellaneous problems like missing signatures were found in 38 instances (0.21%) (Fig. 1). Details of specific near misses and mistakes are shown in Table 1.

We observed an additional reduction of near misses during the study and tested whether the introduction of controls had affected the relative number of errors after a suitable adaptation phase.

For this purpose, we compared the first 3 months (March to May 2012) with the following 31 months (June 2012 to Dec 2014).

In the first 3 months (our records start on March 15th), there were 1179 surgeries with 33 errors, yielding an error rate of 2.80%.

In the remaining period, there were 16 902 surgeries with 206 errors, yielding an error rate of 1.22%.

We used the standard Welch *t*-test to compare the relative error rates in the first 3 months with those in the remaining months. The test yielded a significant difference at a p-value of <0.001. The 95% confidence interval of the difference between the average error rate in the first 3 months and the remaining months was 0.012–0.019.

Next, we used a binomial test to test whether the error rate of 2.80% (33 errors in 1179 observations) during the first 3 months differed significantly from the error rate of 1.22% in the remaining period. The binomial test yielded significance at a p-value <0.001. The 95% confidence interval of the error rate in the first 3 months was 1.934–3.908%, while the 95% confidence interval of the error rate in the remaining months was 1.059–1.396%.

Therefore, for the subsequent analysis, we excluded the first 3 months of error recording.

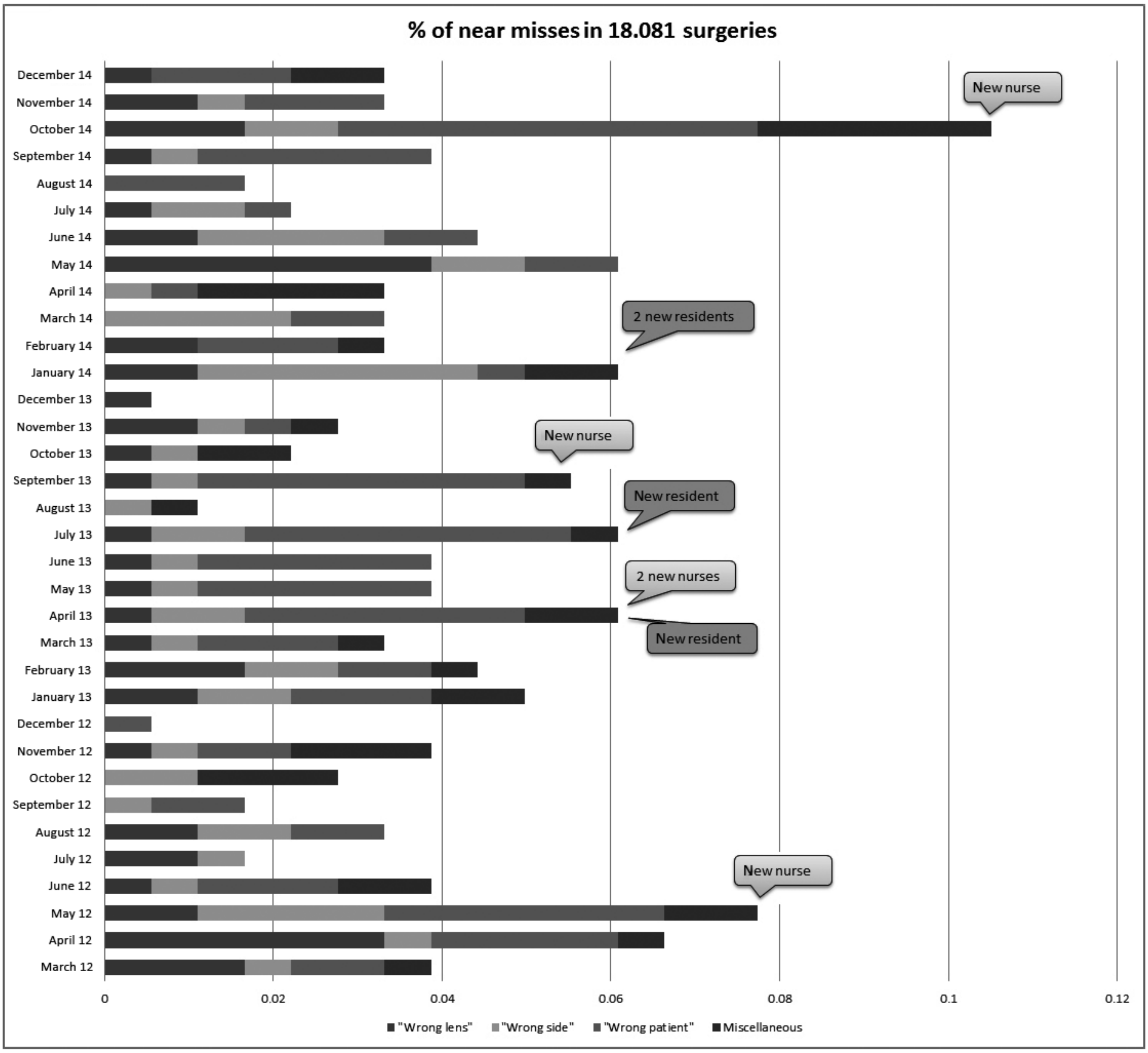

Fig. 1. Near misses found on team timeout 'speech bubbles' – time for the instruction of new team members.

We noted a few error peaks. One of the major causes was the instruction time for new team members. New staff members joined the team in five of 31 months (after the first 3 months of initiation). During the 5 months, there were 62 errors in 2963 surgeries; the error rate was 2.09% as compared to 0.95% in the months without new team members.

The binomial test as to whether the true error rates in the months with new employees could be the same as those in the other months yielded a significant difference at a p-value <0.001; the 95% confidence interval for error rates with new employees was 1.608–2.675%. Table 2 shows the number of detected mistakes in each month, classified by error rate. Every month, new team members rank among the top ten of the highest error rates. In these months, especially, near misses concerning patients' data and incomplete documentation occurred (Table 2).

We also tested whether the number of operations influenced the error rate, based on the hypothesis that a higher workload leads to more errors.

Using a linear model for the error rate in each month and the number of surgeries in the respective month, we obtained a linear coefficient of 0.000021.

Thus, for every 100 additional operations per month, the error rate is expected to increase by 0.214%.

However, this result is only significant at a 10% confidence interval (p-value = 0.084).

Looking at autocorrelations of the time series, we obtained −0.224 as autocorrelation between adjacent months. This might indicate that, following a month with numerous errors, more precautions are taken the following month.

However, the correlation is not significantly different from 0.

Pearson's correlation test yielded a p-value of 0.233 and a 95% confidence interval of −0.541 to 0.148.

Table 1. Number of specific near misses and mistakes.

	n	% (Group)	% (all near misses, n = 239)	% (all patients, n = 18 081)
Wrong side (n = 53)				
Wrong side or no side marked on the patient	12	22.6	5.0	0.07
Wrong side or no side marked in the patient's records	20	37.7	8.4	0.11
Wrong side or no side marked on the operating room schedule	14	26.4	5.9	0.08
Wrong side or no side marked on the operating room list	4	7.5	1.7	0.02
Wrong side of pupil dilation	3	5.7	1.3	0.02
Wrong lens (n = 52)				
Wrong side or no side marked on biometry	8	15.4	3.3	0.04
Lens for the wrong eye chosen	4	7.7	1.7	0.02
Wrong refraction chosen	14	26.9	5.9	0.08
Biometry and the selected lens do not match	15	28.8	6.3	0.08
The selected lens does not fit refraction in the other eye	5	9.6	2.1	0.03
Wrong formula on biometry used	6	11.5	2.5	0.03
Wrong patient (n = 96)				
Wrong name (first name/surname) in patient's records and/or biometry	15	15.6	6.3	0.08
Wrong birth date in the patient's records and/or biometry	22	22.9	9.2	0.12
No documentation of allergy	13	13.5	5.4	0.07
No documentation of the planned operation and/or the side of surgery in the patient's records	32	33.3	13.4	0.18
Documentation incomplete	14	14.6	5.9	0.08
Miscellaneous (n = 38)				
Documents of other patients in the patient's records	2	5.3	0.8	0.01
Missing red identification wristlet in a case of allergy	13	34.2	5.4	0.07
No signature of the patient on the consent form	2	5.3	0.8	0.01
Consent form missing	1	2.6	0.4	0.01
No signature of the surgeon in the patient's records	14	36.8	5.9	0.08
Miscellaneous	6	15.8	2.5	0.03

n = number of patients.
% (Group) = percentage of specific near misses in particular groups, for example wrong side.
% (all near misses) = percentage of specific near misses of all near misses.
% (all patients) = percentage of near misses in the entire study population.

Discussion

The potency of the WHO's Surgical Safety Checklist has been clearly proven in several studies (Fudickar et al. 2012; Haugen et al. 2013a,b), which reported 1.5–0.8% (= −47%) reductions in mortality, and 11–7% (−36%) in morbidity, a 21% reduction of wrong-side errors and 4–7% reductions in overall complication rates.

The implementation and use of safety checklists have been studied extensively in anaesthesiology (Rateau et al. 2011; Fudickar et al. 2012; Bohmer et al. 2013a,b), neurosurgery (Da Silva-Freitas et al. 2012; Oszvald et al. 2012) and orthopedics (Panesar et al. 2011; Lee et al. 2012). Ophthalmology, in contrast, is marked by a small number of studies on the subject. Pikkel et al. (2014) evaluated correct-side identification among experienced ophthalmologists not using a checklist or asking the patients. The doctors could correctly identify the side of surgery by the patient's name in just 73%, and by looking at the patient's face in 83%. Kelly et al. (2013) determined, in a retrospective investigation, the causes of incorrectly implanted intraocular lenses as reported in the National Incident Reporting Database of the United Kingdom (Kelly & Jalil 2011). Inaccurate biometry, wrong intraocular lens selection and transcription errors were the most common causes. In a case series of seven surgeries with wrong lens implantation, Schein et al. (2012) from Wilmer Eye Institute recommended a root cause analysis, mandatory precautions for the future and changes in workflow Cavallini et al. (2013) reviewed the level of adherence to a safety checklist in all cataract surgeries and intravitreal injections over a period of 4 months. Team timeout was performed in 100%, sign-in in nearly 100%.

We focused on the number of detected errors and near misses. 'Near misses' are potentially harmful events for a patient, not causing damage due to chance or mitigation (Yoon et al. 2015). In the published literature, incidents of near misses are reported 300 times more often than actual errors (Haugen et al. 2013a,b). In addition to routine checking of the patient's identification and the side of surgery, selection of the intraocular lens plays an important role in ophthalmology. To detect as many errors and near misses as possible, we used a stringent interpretation of the term *error*. The absence of marks on the side of surgery or the selected lens in biometry was regarded as errors or near miss, although the eye or the lens eventually proved to be correct. We evaluated the full potential of a safety checklist and determined those errors or near misses that actually occur.

Documenting all near misses in a standardized manner was the first step to reduce these errors. After an adaptation period of a few weeks, we started to analyse the documented near misses and to take the necessary steps. So, we gave repetitive instruction about correct and standardized documentation during our team meetings and offered additional trainings for new team members.

Table 2. Number of detected near misses sorted by error rate.

	Lens	Side	Patient	Miscellaneous	Surgeries	New nurse	New resident	Error rate (%)
May 12	2	4	6	2	467	1		2.998
October 14	3	2	9	5	658	1		2.888
March 12	3	1	2	1	258			2.713
April 12	6	1	4	1	454			2.643
April 13	1	2	6	2	558	1	1	1.971
January 14	2	6	1	2	586		2	1.877
July 13	1	2	7	1	602		1	1.827
May 14	7	2	2		627			1.754
September 13	1	1	7	1	572	1		1.748
January 13	2	2	3	2	557			1.616
February 13	3	2	2	1	517			1.547
August 12	2	2	2	0	408			1.471
May 13	1	1	5	0	489			1.431
June 12	1	1	3	2	493			1.420
November 12	1	1	2	3	509			1.375
June 14	2	4	2		595			1.345
June 13	1	1	5	0	538			1.301
March 13	1	1	3	1	504			1.190
February 14	2	0	3	1	557			1.077
December 14	1		3	2	565			1.062
March 14		4	2		579			1.036
November 14	2	1	3		588			1.020
September 14	1	1	5		713			0.982
April 14		1	1	4	619			0.969
November 13	2	1	1	1	548			0.912
October 12	0	2	0	3	557			0.898
August 14			3		409			0.733
October 13	1	1	0	2	589			0.679
July 12	2	1	0	0	468			0.641
September 12	0	1	2	0	474			0.633
August 13	0	1	0	1	354			0.565
July 14	1	2	1		721			0.555
December 12	0	0	1	0	411			0.243
December 13	1	0	0	0	537			0.186

lens = number of near misses concerning the selected lens, for example wrong biometry, wrong refraction.
side = number of near misses concerning the side of surgery, for example wrong or missing mark.
patient = number of near misses concerning patient data, for example wrong name, wrong date of birth.
Miscellaneous = for example, patient's or surgeon's signature missing.
Surgeries = number of operations/month.

As most common near misses and mistakes, we found transcription errors and wrong lens selection in agreement to Kelly & Jalil (2011). No documentation of the planned operation and/or the side of surgery in the patient's records in 13.4%, wrong birth date in patient's documents in 9.2% and mistakes or misses of side marking in patient's records in 8.4% were reported most frequently. New team members might have difficulties filling out all the required documents during their instruction time. For easier adjustment, we designed a script for new team members where our workflow and all necessary documents are described.

Concerning 'wrong lens' near misses, mistakes in choosing the correct refraction in 5.9% and selecting the correct lens from the stock in 6.3% were most common. To reduce the risk of possible wrong lens implantation, the surgeon takes the selected lens out of the stock immediately before entering the operating theatre. The selected lens and the eye are highlighted on the biometry sheet in green colour. During team timeout, the circulating nurse takes the perioperative checklist, the biometry with the green markings and the selected intraocular lens for a recheck.

Safety checklists in ophthalmology will probably not reduce mortality, but preventing wrong-side or wrong lens errors is important enough to expend a minute or two on the patient's safety. Two studies have shown that timeout reduces the frequency of communication breakdowns, which is a cause of delay (Nundy et al. 2008; Prabhakar et al. 2012).

Using team timeout, we found 53 patients with wrong-side near misses, 52 patients with wrong lens near misses and 134 patients with errors or near misses in patient records or identification. Altogether, timeout prevented 239 potential errors or near misses over a period of nearly 3 years. Some of these errors and near misses might have been detected on time without team timeout, but we believe team timeout does enhance the patient's safety and prevent repeat surgery due to avoidable errors and near misses.

Compliance with safety checklists and their performance have been discussed in several studies (Haynes et al. 2009; Oszvald et al. 2012). A survey of members of the Royal College of Ophthalmologists after the introduction of a checklist for cataract surgery in 2010 showed that 93% of the respondents used a checklist, 67% used a team timeout and only 54% used a checklist addressing the selection of the intraocular lens (Kelly & Jalil 2011). In keeping with Oszvald et al. (2012), we did not register decreasing compliance over the years. Frequent revisions of the team members' compliance in using the safety checklists and training new team members are mandatory measures for early detection of problems. Repeated instruction and communication training could further enhance the use of checklists (Bohmer et al. 2013a, b). As higher workloads cause more errors, high-volume surgery departments should pay special attention to timeout.

Conclusion

The use of team timeout has stood the test of time and improves patient's safety with little effort. Despite repeated controls of patient records before the patient is taken to the operating room, some errors and near misses are only detected by the team timeout.

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