Development and Implementation of Checklists for Routine Anesthesia Care: A Proposal for Improving Patient Safety

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Checklists and related cognitive aids have become an integral part of health care safety processes,[1–9] such as the "surgical time out."[1,2] There are good data to support the impact of checklists in improving the quality of health care professional's handoffs of care, as well as adherence to care standards in perioperative crisis situations.[3,10,11] A survey in our own department confirms this trend toward increasing interest in checklist usage, with an overwhelming majority of physicians and certified registered nurse anesthetists (CRNAs) stating that they would use checklists for handoffs and in emergency situations.[12]

Use of crisis checklists in anesthesia often draws parallels to similarities between piloting an aircraft and performing anesthesia.[13–15] However, it is important to mention that the philosophy of using checklists in the cockpit does not originate from their use in emergencies (which by their nature rarely occur in real life), but rather from their use during routine flight management.[16] Commercial airline and private pilots usually complete a series of checklists to confirm the status of their aircraft during each flight cycle[16]: before pushback from the gate, on starting the engines, taxiing, takeoff, after takeoff, top of the climb, before descent, during approach, and before landing. Every flight concludes with a shutdown checklist back at the gate.

Routine and nonroutine cockpit checklists are usually used quite differently: The "abnormal event" ("read-and-do") checklist walks pilots step-by-step through crisis and other, nonfamiliar situations, e.g., an unusual instrument warning. In contrast, routine ("read-and-check") checklists are used to confirm an otherwise routine task typically already completed by the flight crew. This is despite the fact that the flight crew almost always know these tasks from memory.

Contrary to popular belief, the use of checklists in the cockpit as opposed to relying on memory does not originate from the fact that there are too many tasks to memorize reliably. Checklists in commercial airplanes may consist of as few as 2 items.[16] There is a deeply embedded cockpit culture to never rely solely on memory or vigilance to ensure that all vital systems of the aircraft during routine flights are set as required (personal communication with Cpt Ch Sullenberger [ret.] 2012, Cpt Al Langelaar [Aero Consulting Experts] 2013, and Cpt Joerg Krombach [Lufthansa] 2012). From the very early stages of flight training and throughout their ongoing professional evaluations, pilots are consistently taught and trained to refer to written cognitive aids at defined key moments, no matter how familiar they are with the required tasks. Even in single-pilot cockpits from fighter jets to small private planes, the use of checklists is a standard procedure for both routine processes and in emergency situations. However, the consistent use of checklists does not prohibit pilots from critically thinking through specific situations and deviating from the standard procedures when necessary.

Incorporation of checklists for routine operations into aviation was developed from the analysis of adverse outcomes. Even the most competent and experienced crew members can forget simple routine daily tasks because of distraction and fatigue.[16–19] In contrast, many health care professionals still believe that competent providers will always reliably recall and complete all necessary tasks when performing routine anesthesia from memory.[12] Similarly, some anesthesia professionals consider that using a routine workflow checklist is "unnecessary" and an "insult on their practice," which will only create "mindless autobots."[20]

THE PHILOSOPHY OF ROUTINE WORKFLOW ANESTHESIA CHECKLISTS

Performing routine anesthesia often requires a series of tasks, which if omitted can put the patient at an increased risk. Based on Perrow's[21] "Theory of the Normal Accident," the interactions of tasks managing an anesthetized patient are about as tightly coupled, and even more complex, than flying an aircraft.[22] Because adverse events are underreported, the exact rate of mishaps and errors for many critical anesthesia incidents remains unclear. However, studies of the completeness of preparation of the anesthesia workplaces before induction found that 10% to 17% of the time at least 1 important item was either missing or not functioning.[23,24] Thus, it is not surprising that "failure to check

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or inspect" was identified as the cause in 22% to 33 % of all critical incidents with significant negative outcome.[25,26] Existing data, similar to aviation accidents, indicate that the lack of provider competence has rarely been a major contributing factor to anesthesia errors with negative outcome.[26] Instead, there are "temporary and atypical lapses in the vigilance of otherwise competent anesthetists."[26] Haste, distraction, fatigue, inattention, boredom, and failure to check have been factors associated with preventable anesthesia mishaps in >60% of adverse events.[27]

Despite these data, there are few, if any, reports on the development and implementation of a checklist system similar to that used by pilots, designed to prevent errors or omissions during all stages of routine anesthesia care. Introduction of "appropriate protocols" for checking equipment and handoffs were first suggested in the 1980s.[26,28] Although such protocols can certainly help clarifying and standardizing workflows, they usually remain memorized aids rather than printed or electronic checklists.

In 2009, the original World Health Organization Surgical Safety Checklist[1] incorporated some basic aspects of a preinduction checklist, but the scope of this checklist is too broad to cover the specific items that have been shown to be key factors in error or omissions in anesthesia. Others have studied or promoted anesthesia-specific, preinduction checklists.[14,23,24] For example, Hart and Owen[14] published simulation results after developing a preinduction checklist for cesarean delivery under general anesthesia. The authors reported a surprising finding: Although 95% of participants in simulation trials considered the checklist to be helpful, and 80% would like to use it in training situations, only 40% believed that the checklist was useful in real clinical settings. More recently, the Anesthesia Patient Safety Foundation surveyed anesthesia professionals regarding the need for a preinduction checklist. Based on the positive results, a preanesthetic induction patient safety checklist draft was developed, and a grant was offered to study the implementation and performance of this checklist.[20] The bias of anesthesiologists to consider the induction phase as the most critical time of anesthesia is well described.[27] However, this period in fact contributes only to 26% of preventable mishaps in anesthesia.[27] The majority of incidents instead happen during the maintenance of anesthesia,[27,29] and the emergence phase seems to be as hazardous for preventable mishaps as the induction phase (24%).[27] This speaks to the potential utility of checklists for these phases of the anesthesia workflow.

Attempts to implement checklists for routine anesthesia care, including preinduction checklists, seem to have had little traction. This is in part because the culture in health care has not embraced checklists, especially before the success of the surgical safety check in the early 2010s. Flaws in design and implementation of previously developed routine checklists may have played a partial role in their lack of adoption. However, since the earlier reports described above, there has been an increased acceptance of checklists by health care professionals, paralleled by an exponential increase in publications (Fig. 1). On the basis of evidence for checklist use from the aviation industry and the gap observed in the health care industry, we set out to develop and evaluate the utility of a series of routine workflow checklists for the anesthesia workplace.

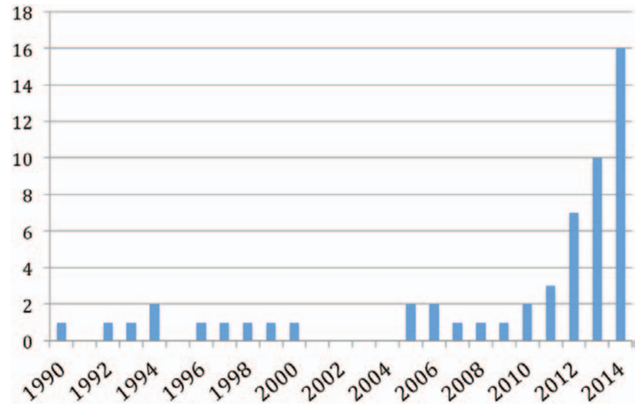

Figure 1. Number of publications indexed in Medline that includes search terms "anesthesia" and either "cognitive aid" or "checklist."

DEVELOPMENT OF A ROUTINE ANESTHESIA WORKFLOW CHECKLISTS SERIES AND INDIVIDUAL CHECKLISTS

Based on the available literature and our own experience and observations at different institutions in the United States and Europe, the Anesthesia Checklist Focus Group at University of California San Francisco/San Francisco General Hospital has developed checklists for routine anesthesia workflow. The underlying design of this checklist series is based on the established processes used in the aviation industry. We combined findings from literature review with the personal knowledge of 2 authors, holding private pilot licenses, of this article. Furthermore, we were able to interview 9 commercial airline pilots (3 of those being instructors) from 4 different airlines and 2 retired military fighter pilots on their insight and experience using routine cockpit checklists. Finally, we also included our own observations of routine cockpit checklist use by professional pilots during 5 routine flights and 8 professional full-scale airplane simulations in 2 major airline training centers. On the basis of these findings, we generated a checklist series for routine anesthesia workflow (Appendix 2). The sequence of checklists includes the following:

1. Technician setup of the anesthesia workplace
2. Provider setup of the anesthesia workplace (including anesthesia machine check)
3. Preinduction
4. Postinduction
5. "Sweep Checklists" (5- and 30-minute interval)
6. Emergence
7. Technician turnover of the anesthesia workplace

In the absence of existing nonemergent checklists in anesthesia, all but one of the individual checklists were created de novo. Although referring to existing examples of preinduction checklists,[14,20,23,24] all individual checklists were created based on the general recommendations from published checklists.[2,4,14,24,30–35] On the basis of the aforementioned work, we concluded that checklists for routine anesthesia workflow should be developed based on the following design concepts:

- Do not exceed 10 items per checklist.
- Reduce wording of each item to a minimum while maintaining specificity to the task being checked.
- Do not incorporate an audit tool into the checklist.
- Do not require written check-off or signature confirmation of completion.

Individual items on each checklist were based on the process described by Thomassen et al.[24]: This, combined with information on common mishaps and omissions from our own departmental "Near-Miss" and "Morbidity & Mortality" database, generated an initial list of potential items for each checklist. The initial checklist drafts were tested and modified to improve checklist utility over a period of 1 year by members of the focus group.

We designed our checklists to be completed within a short period of time (<15 seconds) to maintain focus on the patient, monitors, and anesthesia machine. We avoided the inclusion of additional tasks that were solely audit or documentation requirements. As modeled by the airline industry, we defined best practice "trigger moments" for each individual checklist that facilitates standardized use of routine checklists within our institution (Appendix 2 has individual triggers listed at the bottom of each checklists). Apart from the postinduction checklist, all routine checklists are used during moments when there are no immediate patient care tasks to complete or focus on. With this in mind, we found that completing the postinduction checklist immediately after securing the airway seemed to be the best time to perform the postinduction check.

INTEGRATION OF CHECKLISTS WITHIN THE ANESTHESIA WORKPLACE

Finding a place to store and display checklists in an already packed anesthesia workplace proved to be a significant challenge. We learned that even motivated anesthesia providers will not use checklists stored in a drawer. Instead, we concluded that the checklists must be within the immediate vicinity of the provider and instantly displayed to be used. These findings and conclusion match those described by Goldhaber-Fiebert and Howard[4] regarding the storage and display of emergency manuals. Attempts to display routine checklists through laminated cards, a document holder, or in booklet form were not successful. Therefore, we decided to develop a software application (app) that allows display of the checklists by securely mounted tablet computers attached to the anesthesia machine (Fig. 2). An additional advantage of using this approach was that the routine checklists could be in the same place as checklists for provider handoff and crisis management.

PROJECT PROGRESSION AND CURRENT STATUS

With support from a grant from the University of California Office of the President, and in collaboration with a software design company specializing in health care programs (ChatrHealth, San Francisco, CA), the app was developed and made available in all 10 operating rooms of our institution. The β version was initially tested and refined over a 3-month testing phase in April to June 2014. After education of all faculty, CRNA, and residents, the routine workflow checklists were introduced in the operating rooms at San Francisco General Hospital in July 2014. Within a few weeks, staff members increasingly began incorporating most or all of the routine checklists within their workflow and provided consistently valuable feedback to improve the general design and specific checklists. Updates were made on a weekly basis, and we are currently using the 51st software version.

Six months after initial implementation refinement, the use of checklists for routine anesthesia care became formally incorporated into the normal workflow at our hospital. This decision was supported by reports of events and oversights that were caught when using the routine checklists. The decision was also based on an analysis of anesthesia incidents presented at our morbidity and mortality conference, which occurred when staff members were not using routine checklists.

PROVIDER SURVEY ON THEIR EXPERIENCE AND PERCEPTION USING ROUTINE CHECKLISTS

To better understand factors affecting checklist adoption and usage, we conducted an anonymous electronic survey 8 months after implementation. The survey was approved by our local IRB, and requirements for written informed consent were waived (University of California, San Francisco,

Figure 2. Tablet computer mounted on the anesthesia machine displaying routine and crisis anesthesia checklists at San Francisco General Hospital.

Committee on Human Research, Office of Research Administration, San Francisco, CA; IRB 14-13259). The survey was e-mailed to all faculty and CRNA who worked a minimum of 1 day per week (23 faculty and 16 CRNAs). The response rate was 90% (faculty 82% and CRNA 100%).

Seventy-one percent of respondents agreed that routine checklists are important for patient safety, 3% disagreed, and 26% were neutral. Ninety-two percent reported that they used the checklists at least some of the time, and 43% stated that they used them most of the time or always. Of those not always using the checklists, 61% stated that they simply forgot to use them. Seventy-four percent of staff members responded that routine checklists prevented them from forgetting to prepare or check equipment or complete a task at least once.

Distraction from patient care is a frequently raised concern with any health care checklist, and this was a frequent concern when we presented our project to colleagues or other health care professionals. Thus, the survey also asked if using routine anesthesia checklists might distract them from patient care. No one responded with "definitively yes," and only 1 provider (3%) responded with "probably yes." However, with 34% responding "maybe," we do believe that the long-term success of routine anesthesia checklists will be strongly connected to addressing any remaining concerns related to provider distraction and alteration of the workflow.

LIMITATIONS AND POTENTIAL SIDE EFFECTS

Acknowledging that the health care industry has no established culture for routine workflow checklists, the successful introduction of these in anesthesia cannot occur solely by a mandate from above, but needs to be built and implemented with input from the anesthesia professionals who will use them. The example from San Francisco General Hospital demonstrates that a successful integration of routine checklists is possible through an iterative process that engages providers in design, detailed education and training, constant reminders, feedback on near-miss events, and support by departmental leadership. However, checklists are not "silver bullets" that are able to avert all preventable errors. Diligence is critical because airline incidents and accidents have occurred despite completion of checklists, with investigations revealing that in some instances, pilots just mechanically recited the checklists.

Checklists, especially those for routine workflow, cannot be endlessly extended in an attempt to capture any potential mistake. Instead they need to focus on the most frequent or hazardous omissions. This leads to several consequences: Even when consistently applied, checklists cannot prevent all potential errors or oversights. Furthermore, the specific outline of routine checklists should not be blindly copied. Although certain items on routine checklists are clearly essential, the inclusion or exclusion of others can be debated. Individual workflow and risk assessments of the institution should determine whether a specific checklist item on routine checklists fits their needs and their workflow. The airline industry again exemplifies such a necessity, because checklists for the same type of plane may differ significantly among several airlines.

Our survey results demonstrate that routine checklists are able to catch errors or oversights. However, at this point, we are not able to further substantiate in detail to what extent routine checklists are able to prevent errors. Furthermore, although errors and oversights are common, true patient harm resulting from those errors remains rare, and we are not able to demonstrate the impact of routine checklists on the prevention of actual patient harm; extended, multicenter studies would be needed to obtain sufficient data. Finally, although we were able to demonstrate that routine checklists are able to prevent errors, we cannot assume that the use of routine checklists will not cause any negative side effects.

The need for tablet computers in our app-based approach led to a much higher initial cost (including lockable mounts to secure the iPads from theft). In addition, care must be taken to properly clean the screen and the mount during each case turnover to prevent infections by cross-contamination.[36] However, cross-contamination is not a problem unique to tablet computers, because this can happen when using (laminated) paper checklists. Tablet computers in the operating room raise concerns for theft, misplacement, and distraction of the anesthesia provider from installation and use of apps other than the checklists. For these reasons, we locked the iPad in place with a lockable mount and also locked the iPad user interface to allow only the use of the checklist app ("guided access"). With proper counter measures as described earlier, we believe that the benefits of using a checklist app on a tablet computer outweigh the limitations.

CONCLUSIONS

We report the development of checklists for the routine phases of anesthesia care and their incorporation into the workflow of the anesthesia provider. Checklist design and usage were modeled after checklists used by the aviation industry for their routine workflows. Within a few weeks of implementation, the checklists were being used by most providers for much of their workflow, and their use has helped reduce errors and omissions during routine anesthesia care. It remains to be seen whether the use of checklists for routine anesthesia care in our institution is sustained and becomes permanently incorporated into the culture or whether the concept spreads to other institutions. Additional studies and efforts are needed to validate and quantify checklist utility, their ability to improve anesthesia quality and safety, and the barriers to their becoming routinely used.

DISCLOSURES

Name: Jens W. Krombach, MD.

Contribution: This author helped design the study and write the manuscript.

Attestation: Jens W. Krombach approved the final manuscript.

Conflicts of Interest: Jens W. Krombach consulted for ChartHealth, the application software developer, without compensation. The described checklist application ("app") was developed by the author and is the intellectual property of UCSF. Currently, the software app is only used for research purposes and is not publically available. The plan is to release the app to the public for free without financial gain, although it is conceivable that the author could financially benefit from dissemination of the technology in an unanticipated way.

Name: James D. Marks, MD, PhD.
Contribution: This author helped design the study and write the manuscript.
Attestation: James D. Marks approved the final manuscript.
Conflicts of Interest: This author declares no conflicts of interest.
Name: Gerald Dubowitz, MD.
Contribution: This author helped write the manuscript.
Attestation: Gerald Dubowitz approved the final manuscript.
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Name: Oliver C. Radke, MD, PhD.
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APPENDIX 1

Routine Anesthesia Checklist Survey

I am a
- ○ Facuy (1)
- ○ Certified registered nurse anesthetist (2)

I believe checklists for routine anesthesia care are important for patient safety
- ○ Disagree (1)
- ○ Neither agree nor disagree (2)
- ○ Agree (3)

I use checklists for routine anesthesia care
- ○ Never (1)
- ○ Rarely (2)
- ○ Sometimes (3)
- ○ Most of the time (4)
- ○ Always (5)

In reference to your response to the last question: Why do you not use routine checklists consistently?
- ☐ I simply forget to use them but I want to make them part of my standard workflow as often as possible (1)
- ☐ The software is not user-friendly enough, but I would like to use checklists as often as possible (2)
- ☐ There are often technical difficulties with the app or iPad, but I would like to use the checklists as often as possible (3)
- ☐ I only use part of the routine checklist cycle because some checklists alter my workflow too much (4)
- ☐ I only use part of the routine checklist cycle because not all of them are important (5)
- ☐ I only use them if my attending asks me to do so, otherwise I would not use them at all (6)
- ☐ Other reason (please explain) (7) ____________________

Has 1 or more of the routine checklists saved you from forgetting to perform a task or check something? (e.g., set NIBP cycle, suction working, turning vapor up, timely ABX administration)
- ○ Yes (1)
- ○ No (2)

Do you feel that using routine checklists might distract you from patient care and potentially have a negative affect?
- ○ Definitely yes (1)
- ○ Probably yes (2)
- ○ Maybe (3)
- ○ Probably not (4)
- ○ Definitely not (5)

APPENDIX 2

1. Technician setup of the anesthesia workplace

Tech initial workspace readiness

- Machine on, all hoses connected
- Ambu bag and jet ventilation
- Machine disinfected
- New circuit, suction, sample line
- All cables present (Spo_2, electrocardiogram, blood pressure, temperature)
- Absorber checked/vapors full
- Vent and cart fully stocked
- Cric kit and gum elastic bougie

(trigger: before leaving the operating room [OR])

2. Provider setup of the anesthesia workplace

Provider setup

- Anesthesia machine check
- Monitor prepared
- Medication complete
- Airway equipment complete
- IV/A-line systems prepared
- OR table locked

(trigger: before leaving the OR)

3. Anesthesia machine checklist (GE Aestiva version)

Aestiva machine initial check

- Suction system complete and function check
- O_2 cylinder and pipeline supply
- O_2 sensor calibration and low $F\text{IO}_2$ alarm
- Flowmeter flow test
- Leak check low-pressure system
- Leak check breathing system
- Final status machine

4. Preinduction

Preinduction check

- High-pressure circuit test
- Vent manual mode/APL valve open
- O_2 fresh gas flow
- Suction accessible and functioning
- Airway equipment
- IV patent/induction medication
- Vital signs—blood pressure cycle set

(trigger: before starting to preoxygenate)

5. Postinduction

Postinduction check

- Vent setting, expiratory TV, PIP
- $ETCO_2$ level and tracing
- Fresh gas flow and vapor set
- Vital sign/adjust NIBP cycle
- IV flow adjusted
- Antibiotic order checked
- Line placement

(trigger: immediately after taping the ETT)

6. "Sweep Checklists" q5min

5-minute sweep checklist

- Ventilator: PIP, TV, $ETCO_2$, EtAA
- NIBP and Interval—A-line transducer level
- HR and EKG wave image
- Temperature

7. "Sweep Checklists" q30min

30-minute sweep checklist

- Ventilator: PIP, TV, $ETCO_2$, etAA
- NIBP and interval—A-line transducer level
- HR and EKG wave image
- Temperature
- Head and ETT position, circuit connections
- Pressure points padded, eye check
- Arms: Position, NM monitor, tourniquets?
- Infusion rate, check IV site (infiltration)
- Foley drainage

8. Emergence

Emergence readiness

- Neuromuscular recovery
- Antiemetic agents considered
- Emergency medication ready
- Airway equipment ready
- Team discussion next patient

(trigger: when surgical closure is announced)

9. Technician turnover of the anesthesia workplace

Tech turnover

- Surfaces and cables disinfected
- Vent circuit switched
- Sampling line connected
- New suction and function test
- Cart restocked

(trigger: before anesthesia tech is leaving the OR)

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An Anesthesia Preinduction Checklist to Improve Information Exchange, Knowledge of Critical Information, Perception of Safety, and Possibly Perception of Teamwork in Anesthesia Teams

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BACKGROUND: An anesthesia preinduction checklist (APIC) to be performed before anesthesia induction was introduced and evaluated with respect to 5 team-level outcomes, each being a surrogate end point for patient safety: information exchange (the percentage of checklist items exchanged by a team, out of 12 total items); knowledge of critical information (the percentage of critical information items out of 5 total items such as allergies, reported as known by the members of a team); team members' perceptions of safety (the median scores given by the members of a team on a continuous rating scale); their perception of teamwork (the median scores given by the members of a team on a continuous rating scale); and clinical performance (the percentage of completed items out of 14 required tasks, e.g., suction device checked).

METHODS: A prospective interventional study comparing anesthesia teams using the APIC with a control group not using the APIC was performed using a multimethod design. Trained observers rated information exchange and clinical performance during on-site observations of anesthesia inductions. After the observations, each team member indicated the critical information items they knew and their perceptions of safety and teamwork.

RESULTS: One hundred five teams using the APIC were compared with 100 teams not doing so. The medians of the team-level outcome scores in the APIC group versus the control group were as follows: information exchange: 100% vs 33% ($P < 0.001$), knowledge of critical information: 100% vs 90% ($P < 0.001$), perception of safety: 91% vs 84% ($P < 0.001$), perception of teamwork: 90% vs 86% ($P = 0.028$), and clinical performance: 93% vs 93% ($P = 0.60$).

CONCLUSIONS: This study provides empirical evidence that the use of a preinduction checklist significantly improves information exchange, knowledge of critical information, and perception of safety in anesthesia teams—all parameters contributing to patient safety. There was a trend indicating improved perception of teamwork. (Anesth Analg 2015;121:948–56)

The World Health Organization (WHO) recommended the use of a surgical safety checklist in their 2009 Guidelines for Safe Surgery,[1] and checklists have since become a part of standard surgical care.[2] They have been associated with reduced complications and mortality rates,[3–7] better adherence to safety standards,[8] improved communication and teamwork, and economic benefits.[2,9,10] The WHO Guidelines for Safe Surgery also encourage a formal inspection of the anesthetic equipment, breathing circuit, medications, and a patient's anesthetic risk before each case.

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The reason for introducing the separate anesthesia preinduction checklist (APIC), in addition to the already introduced WHO surgical safety checklist, was that the WHO surgical safety checklist contains only a few supercritical anesthesia items (e.g., checks of saturation sensor, but not electrocardiogram or blood pressure monitoring).

In this study, we sought to evaluate whether the APIC complementing the WHO surgical safety checklist is suited to improve 5 team-level outcomes, each shown to be critical surrogate end points for patient safety: information exchange, knowledge of critical information, team members' perceptions of both safety and teamwork, and clinical performance.

Figure 1 outlines the series of subitems assessed for the outcome scores: information exchange, knowledge of critical information, and clinical performance.

METHODS

This study was approved by the ethics committee of the Canton of Zurich (KEK StV-No. 07/12), Zurich, Switzerland. The requirement for written patient consent was waived. During the study, no information that would identify a team member or a patient was collected.

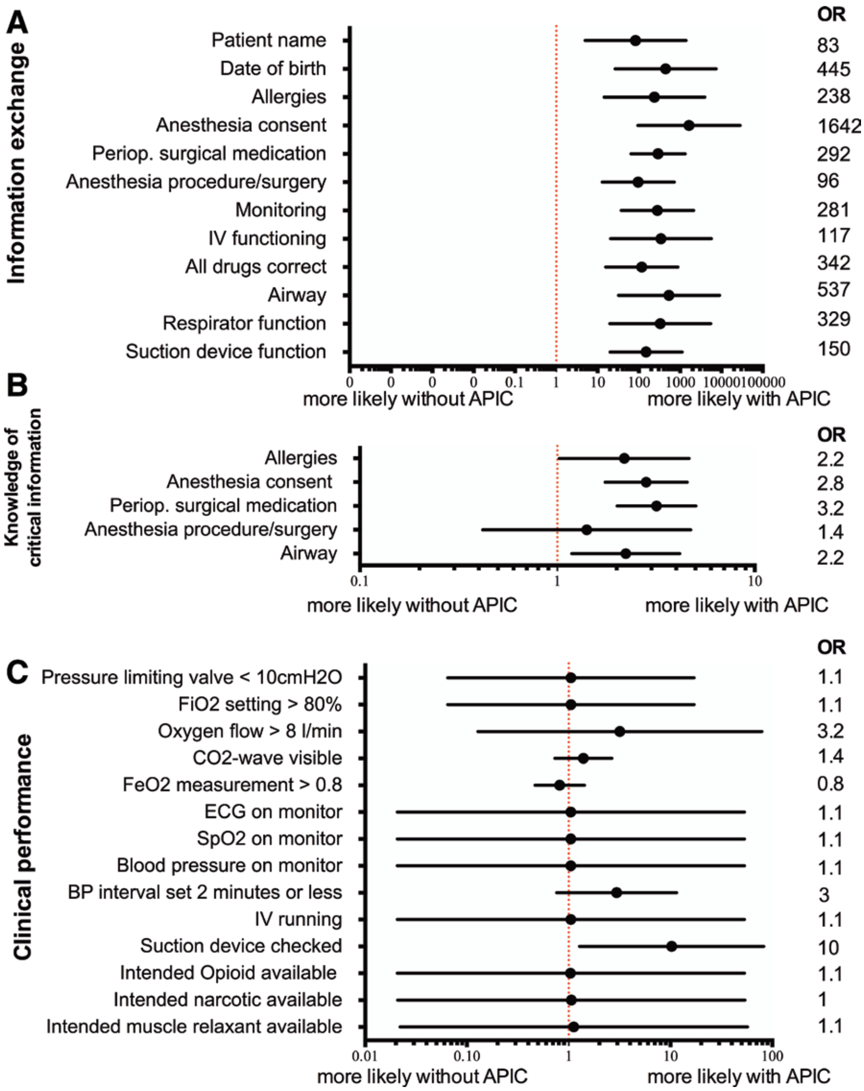

Figure 1. Odds ratios (ORs) with 95% confidence intervals on logarithmic scales of the subitems assessed for the outcomes. A, Information exchange. B, Knowledge of critical information. C, Clinical performance. If a contingency table contained a value of 0, the ORs were calculated by adding 0.5 to each value. The cross-table analyses (Supplemental Table 4, Supplemental Digital Content, http://links.lww.com/AA/B89) showed that information exchange about monitoring and suction device function was associated with improved performance of the respective clinical performance subitems blood pressure interval set to ≤2 minutes and suction device checked. Consequently, the OR for suction device checked was significantly improved in the anesthesia preinduction checklist (APIC) group. ECG = electrocardiogram; BP = blood pressure; Fio_2 = fraction of inspired oxygen; Spo_2 = peripheral capillary oxygen saturation.

The APIC

Supplemental Figure 1 (Supplemental Digital Content, http://links.lww.com/AA/B89) shows the APIC as evaluated in this study. Table 1 provides a description of each checklist item, according to a single-page checklist manual that we distributed with the APIC.

The APIC contains the before-induction-of-anesthesia items of the WHO surgical safety checklist (items 1–4, 11) and additional items (5–10, 12, 13) selected in a Delphi process by 7 consultant anesthesiologists of the study hospital. After several rounds of discussion and evaluation, these experts, each with >10 years of clinical anesthesia experience, identified the minimal items they considered critical to be exchanged and checked before every induction and that were not already included on the WHO surgical safety checklist.

The APIC is available as a laminated card (21 × 15 cm), normally attached to the ventilator, at all anesthesia preparation sites. The check is performed when the entire anesthesia team is present with the patient in the preparation room, preferably during preoxygenation and definitely before any invasive procedures or drug administration. Any team member (i.e., physician or nurse) can start by reading the first checklist item, while any other team member can confirm that they checked a respective item or provide an appropriate answer (e.g., Anesthetic and surgical procedure? and We will perform oral endotracheal intubation for laparoscopic appendectomy.) The team members complete all items in sequence before proceeding with the induction of anesthesia.

The APIC is not intended to be a replacement for a thorough preoperative evaluation, which is performed hours to days before a surgical procedure, and which team members, according to institutional policy, are required to review before each case. The APIC serves as a check and briefing of only safety-critical items at the last possible moment. Its aims are avoidance of omissions and promotion of a common understanding (i.e., shared mental model) of the situation among the team members.

Outcome Parameters

The outcomes evaluated in this study and the rationales behind their selection were as follows:

1. Information exchange (the percentage of checklist items exchanged by a team, out of 12 total items). A recent study found improvements in the exchange of critical

Table 1. Description of Items of the APIC

No. of APIC item	
Patient	
1. Name of the patient	Verify all team members are aware of the patients' identity.
2. Date of birth	
3. Allergies	Brief the patient's allergies. If allergies exist, advise surgical personnel.
4. Informed consent	Verify the patient's signature is visible on the informed consent in the electronic patient record.
5. Perioperative surgical medication	Brief the perioperative surgical medication, i.e., medication specified by the surgeon to be administered, e.g., antibiotics, steroids, or proton pump inhibitors.
Procedure	
6. Anesthesia method/operation	Brief the planned anesthesia procedure and installations, the nature, and side and site of the planned operation. Confirm the anesthesia procedure matches the operation requirements.
7. If regional anesthesia: contraindications	Verify there are no contraindications for the performance of regional anesthesia.
Drugs, equipment	
8. Basic monitoring	Verify ECG, saturation, and blood pressure are visible on the patient monitor, and the interval for automatic BP measurement is set to ≤2 minutes.
9. Infusion	Confirm the infusion is running correctly.
10. All drugs correct	Brief the planned analgesic, hypnotic, muscle relaxant, and if required resuscitation drugs and verify they are available and appropriate.
11. Difficult airway	Brief the expected patient airway and verify the planned and required equipment for airway management is available and operational.
12 Respirator function	Verify positive pressure can be built up when the respirator breathing circuit is closed. Preoxygenate the patient and check that a CO_2 curve is visible.
13. Suction device	Verify the suction device is working and is prepared appropriately for the intended anesthesia procedure, e.g., rapid sequence induction.

The tasks required for the completion of each checklist item according to the checklist manual, which was distributed with the APIC in the operating room areas of the intervention group.
APIC = anesthesia preinduction checklist; ECG = electrocardiogram; BP = blood pressure.

information to be associated with a reduced number of nonroutine events (near misses).[11] Furthermore, several studies have identified the failure to exchange critical information as a common cause for patient harm.[12–14]

2. Knowledge of critical information (the median percentage of critical information items out of 5 total items such as allergies, reported as known by the team members after the anesthesia induction had been completed). Several studies have described the perception of critical information, such as the availability and state of equipment, as the first step in the development of situation awareness.[15–18] One study even found the failure to observe available information as the most common cause of inadequate decision making.[19]
3. Team members' perception of safety (the median scores given by members of a team on a continuous rating scale).
4. Team members' perception of teamwork (the median scores given by members of a team on a continuous rating scale). Improved perceptions of safety climate and teamwork have been associated with improved postoperative outcomes.[20]
5. Clinical performance (the percentage of completed items out of 14 required tasks). Evaluating items for this outcome, such as checking the suction device, is a standard of care in the study hospital and adherence to this standard is a surrogate marker for patient safety.[21]

Procedure

This prospective interventional study comparing anesthesia teams performing inductions using (APIC group) versus not using (control group) the APIC was performed using a multimethod approach. It consisted of on-site observations followed by surveys of the participating team members. Only inductions of general anesthesia for elective adult cases were included.

With the use of iSurvey software (Harvest Your Data, Wellington, New Zealand), a tablet computer–based (iPad®; Apple Inc., Cupertino, CA) data collection tool was created. Using this tool, 5 trained observers (all consultant anesthesiologists) rated information exchange and clinical performance during anesthesia inductions and performed the team member surveys after the observations during a stable phase of anesthesia. Team members were consecutively handed the tablet computer and individually, privately, and anonymously indicated the critical information items they knew by selecting them on a multiple-choice form and rated their perception of safety and of teamwork on 2 continuous scales anchored from 0% (very poor) to 100% (very good). Because of the limited time available to conduct the surveys in the operating areas, 2 simple questions with high face validity were chosen to measure perceptions of safety and teamwork. Single-item measurements for these outcomes have been used in previous studies.[22]

The items used to measure clinical performance were based on a protocol developed by Burtscher et al.[23,24] and validated by using a Delphi approach to measure the performance of teams during induction of general anesthesia. This measure has been tested for interrater reliability and used to assess team performance in a number of studies.[23,25]

Supplemental Table 1 (Supplemental Digital Content, http://links.lww.com/AA/B89) outlines the complete data collection protocol used in this study.

Information exchange was defined as explicit communication about an item between ≥2 team members (e.g., Suction device checked? and Yes, I checked the suction device.). The start of an observation was defined as the arrival of the last member of an anesthesia team at the site of anesthesia induction. The observation ended with the administration of the last drug to induce anesthesia. Data collection took place in 7 operating areas with a total of 34 operating rooms (ORs) in a university hospital setting. In 4 areas with a total of 16 ORs, the APIC was introduced 4 months before the beginning of the study (APIC group). In 3 areas with a total of 18 ORs, the APIC remained absent during the study period (control group). All teams in both study groups used the WHO surgical safety checklist, which was introduced >2 years before the beginning of this study. This checklist did not include the anesthesia-specific items added by the APIC.

Participants

Anesthesia staff consisted of 45 consultants, 90 residents, and 100 certified and student nurses. Only one induction on any one operating list was captured. The observers were instructed to intervene only if predefined safety-critical situations, such as signs of myocardial ischemia, were unnoticed by the anesthesia team.

Interrater Reliability of the Observation Tool

Before starting the data collection, interrater reliability for the instruments of the observation tool used by the observers for on-site observations was tested (i.e., information exchange and clinical performance). To validate the tool and to ensure that observations were standardized and comparable among raters, a simulation involving a full-scale patient simulator and realistic OR environment was used. Three different preinduction scenarios were created and recorded as multiangle videos. All scenarios involved a consultant anesthesiologist, a resident, and an anesthesia nurse performing inductions that involved minor clinical errors (e.g., not setting the automatic blood pressure interval according to standard procedure) and/or omissions of information exchange (e.g., patient allergies were not discussed). Each observer was trained by a psychologist specialized in human factors and received a comprehensive introduction to observational methods, APIC use, and use of the observation tool. Subsequently, all observers watched the recorded inductions and independently rated all 3 scenarios. To assess interrater reliability, Fleiss kappa was calculated with 95% confidence interval (CI) for each scenario. Interrater reliability was high with Fleiss kappa of 1.00 for scenario 1 (absolute agreement between observers), 0.88 (95% CI, 0.78–1.00) for scenario 2, and 0.85 (95% CI, 0.72–0.97) for scenario 3.

Statistical Analysis

Statistical analyses were performed using Stata 11.2 (StataCorp, College Station, TX) and GraphPad Prism 6.0 software (GraphPad Software, La Jolla, CA). Variation of the outcomes was not known before the study. Thus, the sample size was determined by using 2-group Fisher exact test of equal proportions (for binary outcomes) expecting values of 99% for the median outcome scores in the APIC group and values of 89% in the control group. This analysis was repeated for each of the 5 team-level outcomes (information exchange, knowledge of critical information, perception of safety, perception of teamwork, and clinical performance). It showed that with 100 teams in each study group, differences of 10% could be detected for each of the 5 outcomes with ≥83% power and a 0.05 2-tailed significance level. This power analysis was conservative, and the actual power of the study was higher because the Mann-Whitney *U* test uses continuous values to examine the differences between the median outcome scores and has a higher power in comparison with tests that examine binary variables.

To assess the relations between the outcomes, univariate and multivariate regression analyses were performed. To test the statistical significance of the reported odds ratios for the subitems of the outcome scores, Fisher exact test was used. To address clustering of team members within teams, logistic regression analysis was performed with team member knowledge of a subitem as a dependent variable, the use of the APIC as an independent variable, and robust standard error (with team identification number as a cluster). To test the robustness of the results, 4 prespecified subgroup analyses were performed: (1) consultant-led teams using versus not using the APIC, (2) resident-led teams using versus not using the APIC, (3) consultant-led versus resident-led teams using the APIC, and (4) consultant-led versus resident-led teams not using the APIC. Additionally, cross-tables were created to assess the percentages of teams in both study groups that had 0, 1, 2, 3, 4, or all 5 outcome scores, and specific combinations of outcome scores, above a cutoff value of 90%. The cutoff was defined at 90% based on the assumption of the power analysis that the values of the median outcome scores would be 89% before introduction of the APIC.

To assess the relation between information exchange about an item and performance of the respective clinical performance subitems, cross-table analyses were performed.

To test whether there was a difference between information exchange using the APIC, compared with information exchange performed without the APIC, cross-table analyses were performed to compare the percentages of teams in both study groups that exchanged information about an item with or without the APIC, and in which all team members had knowledge about the related subitem or, respectively, performed the related subitem. For the cross-table analyses, *P* values were calculated by applying the 2-group Fisher exact test.

Because, in this study, there were multiple correlated *P* values, *P* values between 0.05 and 0.01 were treated as trends and *P* values <0.01 were considered statistically significant. All *P* values and 95% CIs were computed 2 tailed.

RESULTS

Data Collection

The data collection period spanned 131 days. The average time to complete 1 collection (i.e., on-site observation and team member surveys) was 25 minutes; the average time interval between the last question of the on-site observation and the beginning of the team member survey was 3 minutes.

Study Groups

The APIC group included 105 teams (285 team members), all of which had used the APIC. The control group included 100 teams (272 team members), none of which had used the APIC. Table 2 shows the characteristics and differences of the teams in both study groups.

Table 2. Team Characteristics and Team Compositions

Characteristic	APIC group	Control group	
Median anesthesia experience of team leader in consultant-led teams	>10 years	>10 years	
Median anesthesia experience of team leader in resident-led teams	1–5 years	1–5 years	
Median previous checklist experience	25–50 times	1–10 times	
Median previous survey experience	1–5 times	1–5 times	
Team compositions	**APIC group**	**Control group**	***P***
Three team member teams	75 (71%)	72 (72%)	1.0
Consultant-led teams	99 (94%)	75 (75 %)	<0.001
Consultant, resident, nurse	62 (59%)	49 (49%)	0.16
Consultant, nurse	19 (18%)	11 (11%)	0.17
Consultant, 2 nurses	12 (11%)	11 (11%)	1.0
Resident, nurse	5 (5%)	12 (12%)	0.08
Consultant, resident	5 (5%)	4 (4%)	1.0
Two residents, nurse	0	7 (7%)	0.01
Resident, 2 nurses	0	6 (6%)	0.01
Consultant, 2 residents	1 (1%)	0	1.0
Two residents	1 (1%)	0	1.0

Characteristics and team compositions of the teams in the APIC (n = 105) and control group (n = 100).
APIC = anesthesia preinduction checklist.

Outcomes

Adherence to APIC use in the OR areas in which it was introduced was 88%, with a median completion rate of 100%. The values of all outcome scores with the exception of clinical performance and perception of teamwork were significantly higher in the APIC group. There was a trend indicating that the APIC also positively affected perceptions of teamwork. Figure 2 shows the box plots for these results.

As shown by the regression analyses, information exchange was the most important, independently significant outcome. High information exchange was a strong predictor of APIC use, and the multivariate data suggest a causal relation of information exchange with the other outcomes. Ninety-five percent of the teams in the APIC group achieved 100% information exchange versus only 2% of the teams in the control group. Surprisingly, despite a significant improvement in information exchange, overall clinical performance did not improve with APIC use. Consequently, in the multiple regression, a nonsignificant decline with APIC was observed after adjustment for other outcomes (Fig. 2F). Supplemental Figure 2 (Supplemental Digital Content, http://links.lww.com/AA/B89) shows a scatter plot detailing the relation between information exchange and clinical performance.

The odds ratios for the subitems were significantly >1 when the APIC was used for all of the individual information exchange subitems (all $P < 0.001$), for knowledge of the subitems anesthesia consent ($P < 0.001$) and perioperative surgical medication ($P < 0.001$), and for the clinical performance subitem suction device checked ($P = 0.008$). There was a trend indicating improved knowledge of the subitems allergies ($P = 0.043$) and airway ($P = 0.013$). The odds ratios for the subitems are outlined in Figure 1.

In the subgroup analyses, use of the APIC improved the values of all outcome scores in consultant-led and resident-led teams with statistical significance for information exchange, knowledge of critical information, and perception of safety. Perception of teamwork remained significantly improved in consultant-led teams using the APIC. Table 3 shows the results of the subgroup analyses.

When the APIC was used, the anesthesia teams were significantly more likely to have 4 ($P < 0.001$) and 5 ($P < 0.001$) outcome scores above the cutoff value of 90%. Also, there was a trend showing that anesthesia teams were more likely to have 3 ($P = 0.029$) outcome scores above the cutoff value. Table 4 outlines the results of the cross-table analyses. These results were robust in the subgroups of consultant-led and resident-led teams (outlined in Supplemental Tables 2 and 3, Supplemental Digital Content, http://links.lww.com/AA/B89).

Information exchange about an item was associated with a significantly improved rate of performance for the subitem, suction device checked ($P < 0.001$). This result is outlined in Supplemental Table 4 (Supplemental Digital Content, http://links.lww.com/AA/B89).

When information was exchanged using the APIC, in comparison with information exchange without APIC use, the likelihood that all members of a team had knowledge of the respective information was significantly higher for the subitem perioperative surgical medication (odds ratio, 7; $P = 0.001$) and showed a higher trend for the subitem anesthesia consent (odds ratio, 5; $P = 0.014$). See Supplemental Table 5 for these results (Supplemental Digital Content, http://links.lww.com/AA/B89). For the clinical performance subitems, there was no significant difference between information exchange with versus without APIC (see Supplemental Table 6, Supplemental Digital Content, http://links.lww.com/AA/B89).

In the control group, 2 observers reported the occurrence of critical events. During an induction, the consultant on a team mistook 1 patient for another and realized this error only after induction. During another case, the team accidentally induced anesthesia at the beginning of preoxygenation because the vaporizer was still open from the previous case.

DISCUSSION

We found that the implementation of the APIC was associated with significant improvements in information exchange, knowledge of critical information, and perceptions of safety in anesthesia teams, as well as a trend indicating that the APIC improved perceptions of teamwork. Because the high

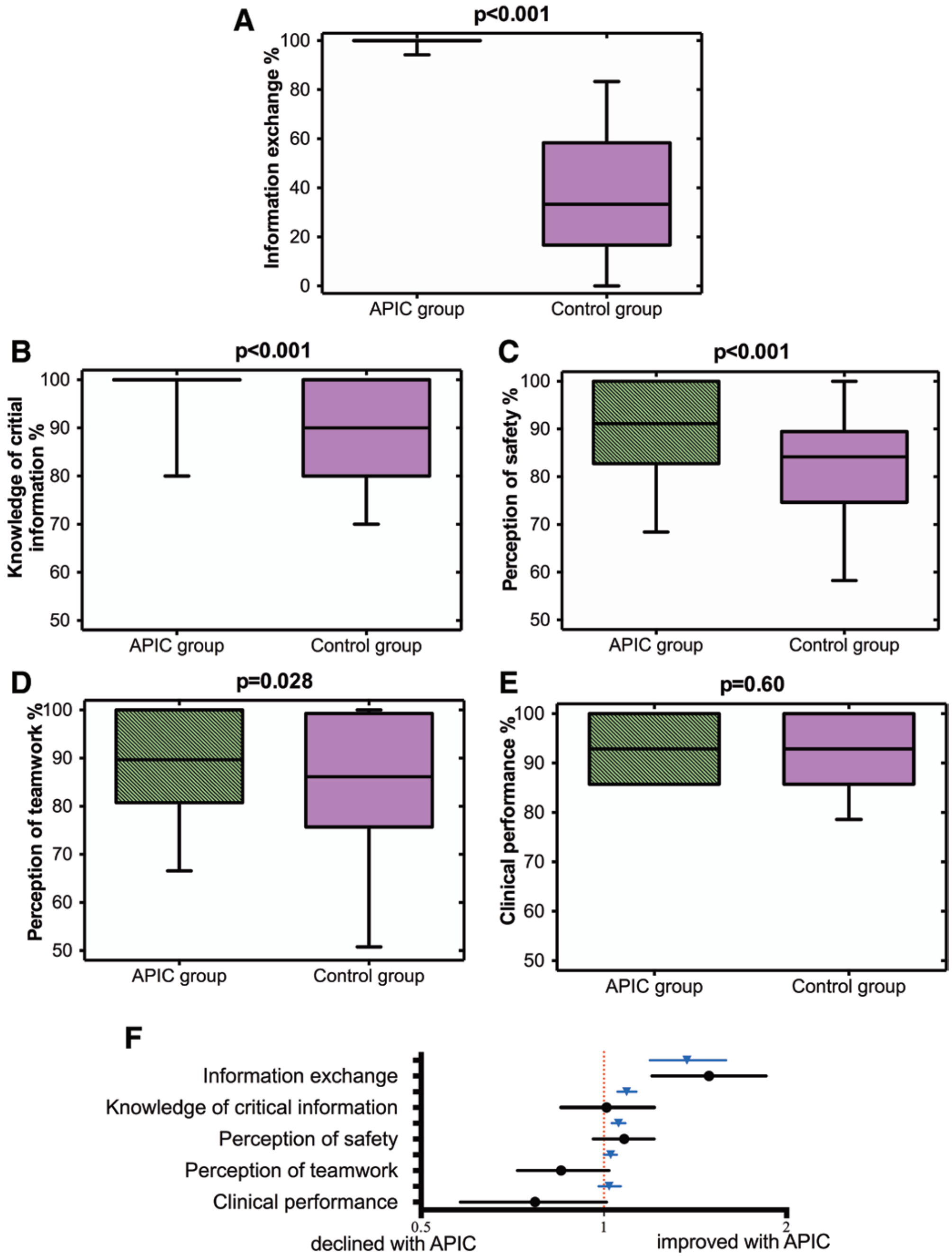

Figure 2. Box plots with whiskers of the median team scores in the checklist group and the control group. The bottoms and tops of the boxes are the 25th and 75th percentiles, and the bands in the boxes are the medians. The ends of the whiskers represent the 5th and 95th percentile. A, Information exchange 100% (range, 83%–100%) vs 33% (range, 0%–100%). B, Knowledge of critical information 100% (range, 60%–100%) vs 90% (range, 60%–100%). C, Perception of safety 91% (range, 33%–100%) vs 84% (range, 30%–100%). D, Perception of teamwork 90% (range, 50%–100%) vs 86% (range, 39%–100%). E, Clinical performance 93% (range, 79%–100%) vs 93% (range, 71%–100%). F, Multivariate assessment of the outcomes: odds ratios (per percent of the corresponding score) for the 5 outcomes with 95% confidence intervals on a logarithmic scale. Black signifies multivariate logistic regression adjusted for the other outcomes; blue shows univariate logistic regression.

degree of information exchange almost entirely correlated with APIC use, we cannot determine whether the suggested causal relation with the other outcomes was caused by this or other factors related to APIC use. For example, both the improved information exchange and the structured review and briefing of critical information conducted by the entire team during APIC performance may have caused the associated improvements in knowledge of critical information. This team process of checklist performance may also be an explanation for why information exchange performed with the APIC—when compared with information exchange without APIC use—was associated with improved likelihoods for all team members to have knowledge of several critical information subitems (e.g., anesthesia consent).

Because medical mishaps and errors are mainly due to communication breakdowns in teams,[12–14] and information exchange and knowledge of critical information have been identified as crucial predictors of team performance,[26,27] we

Table 3. Subgroup Analyses

	1		2		3		4	
	Consultant-led		Resident-led		APIC group		Control group	
	APIC group	Control group	APIC group	Control group	Consultant-led	Resident-led	Consultant-led	Resident-led
Number and percentage of teams	99 (94%)	75 (75%)	6 (6%)	25 (25%)	99 (94%)	6 (6%)	75 (75%)	25 (25%)
Percentage of all teams	85%		15%		51%		49%	
Exchange of information (IQR)	100% (100%–100%)	33% (17%–58%)	100% (100%–100%)	33% (17%–58%)	100% (100%–100%)	100% (100%–100%)	33% (17%–58%)	33% (17%–58%)
P	<0.001		<0.001		0.99		0.55	
Knowledge of critical information (IQR)	100% (100%–100%)	100% (80%–100%)	95% (83%–100%)	90% (80%–100%)	100% (100%–100%)	95% (83%–100%)	100% (80%–100%)	90% (80%–100%)
P	<0.001		<0.001		0.03		0.59	
Perception of safety (IQR)	91% (83%–100%)	84% (75%–90%)	90% (77%–100%)	82% (74%–88%)	91% (83%–100%)	90% (77%–100%)	84% (75%–90%)	82% (74%–88%)
P	<0.001		0.023		0.43		0.91	
Perception of teamwork (IQR)	90% (100%–100%)	87% (74%–100%)	86% (73%–100%)	86% (77%–95%)	90% (81%–100%)	86% (73%–100%)	87% (74%–100%)	86% (77%–95%)
P	0.003		0.95		0.62		0.70	
Clinical performance (IQR)	93% (93%–100%)	93% (86%–100%)	89% (86%–95%)	93% (86%–100%)	93% (93%–100%)	89% (86%–95%)	93% (86%–100%)	93% (86%–100%)
P	0.47		0.42		0.18		0.883	

The subgroup analyses for the median team scores reported with IQRs. Columns 1 and 2 show the results for subgroups of consultant-led teams using the APIC and resident-led teams using the APIC versus not using the APIC. These analyses determined whether the consultant-led and resident-led teams showed consistent results. APIC use improved the values of the outcomes information exchange and knowledge of critical information significantly in consultant-led and resident-led teams. Perceptions of safety and teamwork remained significantly improved in consultant-led teams. There was a trend for improved perception of safety in resident-led teams. Columns 3 and 4 show the results for the subgroups of consultant-led versus resident-led teams using the APIC and consultant-led versus resident-led teams not using the APIC. These analyses determined whether the involvement or absence of a consultant had an effect on the values of the outcomes. The values of the median team scores in consultant-led teams were equal or higher than in resident-led teams. There was a higher trend for knowledge of critical information in consultant-led teams using the APIC.

APIC = anesthesia preinduction checklist; IQRs = interquartile ranges.

propose that the improvements in these 2 outcomes are of great importance.

The overall clinical performance scores did not differ between groups, probably because of a ceiling effect, given that elective anesthesia inductions are a routine task with already low probability for clinical errors and omissions. However, the observers reported critical events only in the control group. The performance of the APIC may have uncovered the factors leading to these events. For example, it seems plausible that the performance of APIC items 1 and 2 (patient identification), with the entire anesthesia team present immediately before anesthesia induction, would have alerted the consultant anesthesiologist about the actual identity of the patient. According to the standard procedure in the study hospital, a team member checked patient identity with the WHO surgical safety checklist at the patient's arrival in the OR area. However, this information was not exchanged with the consultant who joined the team only shortly before the induction and assumed they were treating a different patient. Performing APIC item 12 (respirator function), which includes checking the integrity of the breathing circuit, may have alerted the team that the vaporizer was still open from the previous case. Because information sharing and processing within teams usually tend to be poor and to require rigorous coordination,[28] the performance of the APIC immediately before induction may be helpful for information coordination and provide an opportunity for questioning the status quo and for speaking up with questions, ideas, and corrections. Speaking up is associated with improved clinical performance in anesthesia and surgical teams.[25,29,30]

Because team members do not have to remember items when using the APIC, it serves as a tool for overcoming the limitations of prospective memory; that is, remembering to perform actions at the appropriate time.[31] Prospective memory is susceptible to failure (e.g., forgetting to check the suction device because of imposed time pressure) when disturbances occur.

Previous studies have reported benefits of checklist use during anesthesia for identifying missing items before induction,[32] improving the quality of postanesthesia handovers, and managing simulated cases of cesarean delivery,[33] local anesthetic systemic toxicity, and OR crisis scenarios.[34,35]

One of the major challenges, which will ultimately determine whether a checklist will lead to an improvement in patient safety, is the checklist's acceptance by clinicians. Although use of the APIC was highly recommended by the management of the department during the study, it was not used by 12% of the teams in OR areas where the APIC had been introduced. We suggest several reasons for this omission, including not knowing how to use the APIC, lack of acceptance of checklists in general, or reluctance to adapt to changing organizational routines. To enable the maximal potential of checklists, and to promote their use, we believe that the development and implementation of checklist training initiatives for anesthesia teams could be helpful in the future. Also, we would like to emphasize that the APIC evaluated in this study is one possible example of an anesthesia preinduction checklist, the content and implementation of which should undergo continuous reevaluation and refinement.

Table 4. Cross-Table Analyses

	APIC group	Control group	*P*
Information exchange >90%	104 (99%)	3 (3%)	<0.001
Knowledge of critical information >90%	88 (84%)	49 (49%)	<0.001
Perception of safety >90%	58 (55%)	23 (23%)	<0.001
All outcomes >90%	25 (24%)	1 (1%)	<0.001
4 outcomes >90%	31 (30%)	3 (3%)	<0.001
3 outcomes >90%	37 (35%)	21 (21%)	0.029
2 outcomes >90%	9 (9%)	32 (32%)	<0.001
1 outcome >90%	2 (2%)	37 (37%)	<0.001
No outcome >90%	1 (1%)	6 (6%)	0.12
Information exchange, knowledge of critical information, perception of safety, perception of teamwork >90%	34 (32%)	1 (1%)	<0.001
Information exchange, knowledge of critical information, and perception of safety >90%	49 (47%)	1 (1%)	<0.001
Knowledge of critical information and perception of safety >90%	49% (47%)	13 (13%)	<0.001

The cross-table analyses comparing the numbers and percentages of teams in both study groups that scored 0, 1, 2, 3, 4, or all 5 outcomes >90%. Also shown are the percentages numbers and percentages of teams in both study groups with certain combinations of outcomes >90%.
APIC = anesthesia preinduction checklist.

This study has limitations. It was nonrandomized, and the selection of cases depended on the availability of the observers. Although they were able to choose only from inductions taking place at the time they were available, the occurrence of selection bias cannot be excluded.

There was cross-contamination between the study groups because some team members rotated between OR areas with and without the APIC. However, because team members who previously used the APIC may still implicitly work according to the APIC, even while not explicitly using it, cross-contamination would improve the performance of the control group and bias the results toward an underestimation of the effects and not an overestimation.[36]

The study data may be biased because the data collection took place in 7 separate OR areas. However, inductions are performed according to institutional directives valid in all operation areas; hence, the possibility that certain differences in the areas influenced the results cannot be fully excluded.

Finally, there was an imbalance of consultant involvement (94% in the APIC group and 75% in the control group). The subgroup analyses, however, show that this did not cause the results, because the improvements in information exchange and knowledge of critical information remained consistent and significant in consultant-led teams and resident-led teams. Perceptions of safety and teamwork remained significantly improved in consultant-led teams, and there was a trend indicating improved perception of safety in resident-led teams using the APIC.

CONCLUSIONS

This study provides empirical evidence that the use of a preinduction checklist significantly improves information exchange, knowledge of critical information, and perceptions of safety as well as a trend indicating that the APIC improves perceptions of teamwork in anesthesia teams—all factors contributing to patient safety.

DISCLOSURES

Name: David W. Tscholl, MD.
Contribution: This author helped design the study, analyze the data, and write the manuscript.
Attestation: David W. Tscholl has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.
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