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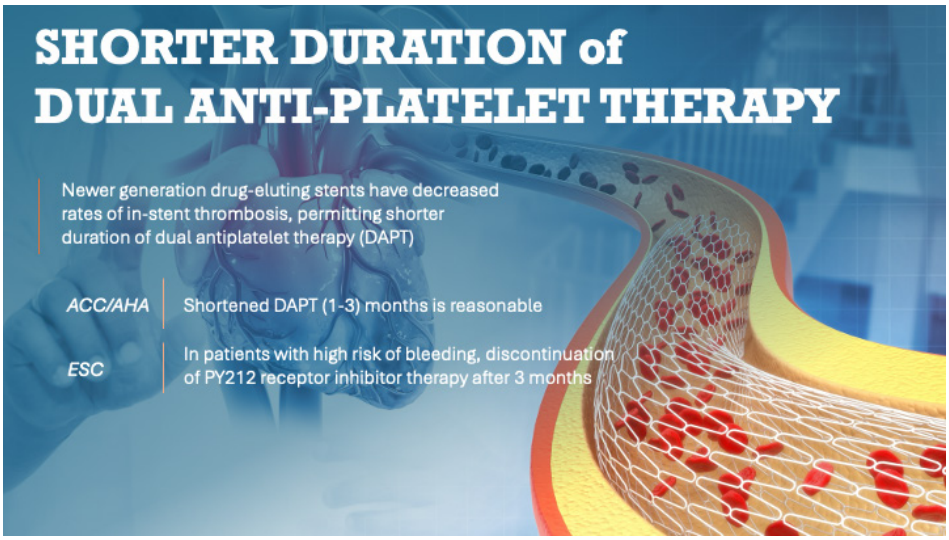
New Drug-Eluting Cardiac Stents and Dual Antiplatelet Therapy: How Short is Too Short?

by Janak Chandrasoma, MD; Abigail Song, BS; Joseph Szokol, MD; and Antreas Hindoyan, MD

INTRODUCTION

The *APSF Newsletter* in 2009 discussed the risk of late thrombosis after drug-eluting stent placement as an ongoing patient safety concern.[1] It found that in-stent thrombosis, though rare, accounted for a 60% myocardial infarction (MI) rate and a mortality of 45% when it occurred. Early animal studies found that complete endothelialization with bare metal stents (BMS) occurred in 28 days, whereas first-generation drug-eluting stents (DES) uniformly showed incomplete healing at 180 days.[2] In 2008, the American College of Chest Physicians (ACCP) recommended delaying elective surgery for 12 months after the placement of a drug-eluting stent,[3] placing burdens on patients needing urgent surgery. As such, the *APSF Newsletter* acknowledged in 2009 the lack of universally accepted protocols for managing patients presenting for noncardiac surgery following recent stent placement. It emphasized the necessity for collaborative decision-making involving the patient, internist, surgeon, anesthesia professional, and cardiologist, stating that this multidisciplinary discussion should consider the type and timing of stent placed, the nature and urgency of the proposed surgery, the management of perioperative antiplatelet therapy, and the choice of facility at which to perform the surgery. If surgery must be performed in patients with recent stent placement, it should ideally take place at a facility with a 24-hour interventional cardiologist available, as emergent percutaneous coronary intervention (PCI) remains the best treatment option for in-stent thrombosis.[1]



DAPT: Dual Antiplatelet Therapy; ACC: American College of Cardiology; AHA: American Heart Association; ESC: European Society of Cardiology

Technology has since evolved dramatically and the recommended duration of dual antiplatelet therapy (DAPT) has changed substantially. First generation stents consisted of a standard bare metallic stent, and a coated polymer mixed with an antirestenotic drug such as sirolimus or paclitaxel.

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Improving Hand Hygiene in the Anesthesia Workspace: The Importance, Opportunities, and Obstacles

by Jonathan Charnin, MD, FASA; Brendan Wanta, MD; Richard Beers, MD; Jonathan Tan, MD, MPH, MBI, FASA; Michelle Beam, DO, MBA, FASA, FACHE; Sara McMannus, RN, BSN, MBA; Desiree Chappell, MSNA, CRNA; and Randy Loftus, MD

Anesthesia professionals have consistently been leaders in patient safety and have long recognized the importance of hand hygiene in the anesthesia workspace.[1] Hand contamination is associated with pathogen transmission across multiple anesthesia workspace reservoirs, and genome analysis of bacteria cultured from provider hands and infection causing pathogens have confirmed that providers transmit pathogens that result in patient infections.[2,3,4] *Staphylococcus aureus (S. aureus)* transmission among anesthesia workspace reservoirs is associated with an increased risk of surgical site infection (SSI).[5] In fact, SSI risk increases over fivefold when the pathogens are sensitive to the prophylactic antibiotic employed and ninefold when the pathogens are resistant to the prophylactic antibiotic employed.[6] In order to reduce this risk, a multifaceted approach is indicated to prevent SSIs.[7] When improved hand hygiene is incorporated as part of a multifaceted program, substantial reductions in *S. aureus* transmission and SSIs can be achieved.[8,9] These findings should provide the impetus for widespread improvements in hand hygiene compliance for all intraoperative personnel, with anesthesia professionals taking the lead.

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The *Newsletter* is published three times a year (February, June, and October). Deadlines for each issue are as follows:

November 1st for the February issue

March 1st for the June issue, and

July 1st for the October issue

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b. Articles preferentially will focus on our top 10 APSF safety initiatives see APSF Newsletter).
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Newer Generation Stents May Permit a Shorter Course of Dual Antiplatelet Therapy Without Compromising Patient Safety

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Newer-generation drug-eluting stents such as biodegradable polymer stents or bioresorbable scaffolds are available, which have been shown to lead to lower rates of stent thrombosis. These newer-generation stents may permit a shorter course of DAPT without compromising patient safety.

Perhaps the most important consideration when deciding on the optimal duration of DAPT is balancing the risk of in-stent thrombosis with the risk of bleeding complications. Studies have shown that prolonged DAPT therapy is associated with an increased risk of bleeding, particularly in elderly patients or those with co-morbidities.[4,5] Bleeding complications significantly increase the risk of morbidity and mortality, and high bleeding risk (HBR) is present in approximately 40% of patients presenting for PCI.[5] Tools that evaluate bleeding risk with DAPT include the PRECISE-DAPT Score[6] and the Academic Research Consortium for High-Risk Bleeding (ARC-HBR) Criteria.[4]

SUPPORTING EVIDENCE FOR SHORTER DAPT DURATION

High Bleeding Risk (HBR) is defined according to the presence of at least 1 HBR criteria (Table 1).[7]

Table 1: High Bleeding Risk (HBR) Criteria.[7]

Defined according to the presence of at least one of the following:
Age ≥ 75 years
Oral anticoagulation planned to continue after PCI
Anemia (Hemoglobin < 11 g/L)
Transfusion within 4 weeks before inclusion
Platelet count < 100,000/mL
Hospital admission for bleeding within the previous 12 months
Stroke within the previous 12 months
History of intracerebral hemorrhage
Severe chronic liver disease
Chronic kidney disease (Creatinine clearance < 40 mL/min
Cancer within the previous 3 years
Planned major, noncardiac surgery in the next 12 months
Glucocorticoids or NSAIDs planned for > 30 days after PCI
Expected nonadherence to >30 days of DAPT

Table 2: Summary of Recent Studies Examining Abbreviated DAPT Regimens.

Study	Stent Type	DAPT Duration	Primary Findings
GLOBAL-LEADERS[8]	Various	1 month	1 month of DAPT, followed by ticagrelor alone improved outcomes vs. standard regimens.
Mehran (2019)[9]	Various	3 months	3 months of DAPT, followed by ticagrelor monotherapy is associated with lower bleeding incidence vs. continued DAPT, with no higher risk of death, MI, or stroke.
STOPDAPT Trial[10]	Cobalt-Chromium Everolimus-Eluting Stent (CoCr-EES)	3 months	3 months of DAPT, followed by aspirin monotherapy in selected patients after CoCr-EES implantation was noninferior to a prolonged DAPT regimen.
POEM Trial[7]	Synergy DES (Bioresorbable Polymer-Coated Everolimus-Eluting Stent)	1 month	1-month DAPT, followed by aspirin monotherapy deemed safe, with low rates of ischemic and bleeding events.
SENIOR Trial[11]	Bare Metal Stent (BMS) vs. Drug-Eluting Stent (DES)	1 or 6 months	1-month of DAPT (stable/silent cases) vs. 6 months of DAPT (unstable cases), followed by aspirin monotherapy. DES with short DAPT duration is associated with lower rates of all-cause mortality, MI, stroke, and ischemia-driven target lesion revascularization compared to BMS with a similar DAPT regimen.
EVOLVE Short DAPT Study[12]	SYNERGY EES	3 months	3 months of DAPT, followed by aspirin monotherapy in high-bleeding-risk patients, found favorable rates of ischemic outcomes supporting the safety of abbreviated DAPT.
XIENCE Short DAPT Program[13]	XIENCE CoCr-EES	1 or 3 months	1 or 3 months of DAPT, followed by aspirin monotherapy was noninferior to 6 or 12 months of DAPT for ischemic outcomes, potentially associated with fewer major bleeding events and low stent thrombosis incidence.
STOPDAPT-2 ACS Trial[14]	CoCr-EES	1–2 or 12 months	1–2 months of DAPT, followed by aspirin monotherapy did not establish noninferiority compared to 12 months of DAPT. Despite a reduction in major bleeding events, there was a numerical increase in cardiovascular events in the 1–2 month DAPT group.

DAPT: Dual Antiplatelet Therapy; DES: Drug-eluting Stent; MI: Myocardial infarction

Two early studies examined high-risk patients who underwent PCI and completed a short duration of DAPT with either ticagrelor monotherapy or ticagrelor plus aspirin. Ticagrelor is a reversible and direct-acting oral P2Y12 receptor antagonist that provides faster, greater, and more consistent platelet inhibition than clopidogrel. The first study found that ticagrelor in combination with aspirin for 1 month, followed by ticagrelor alone, improved outcomes after PCI compared to standard antiplatelet regimens.[8] The second study examined high-risk patients who underwent PCI and completed 3 months of DAPT, determining that ticagrelor monotherapy was associated with a lower incidence of clinically relevant bleeding than ticagrelor plus aspirin, with no higher risk of death, MI, or stroke.[9]

Several other pivotal trials have recently been published that highlight the safety and efficacy of the earlier discontinuation of dual antiplatelet therapy (Table 2). These newer stents are ideal for patients who are at higher risk of bleeding. These studies have uniformly found lower rates of ischemia, allowing shorter duration of DAPT, which lessens patients' bleeding risk. These newer stents also compare favorably to bare metal stents in terms of all-cause mortality, myocardial infarction, stroke, and ischemia-driven target lesion revascularisation.[10-14]

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Newer-Generation Stent Technology Has Led to Less Stent Thrombosis

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SOCIETAL GUIDELINES

Based on the available and updated evidence, The American College of Cardiology (ACC) and the American Heart Association (AHA) give a Class 2a (moderate) recommendation for a shorter duration of DAPT. Select patients undergoing PCI may safely transition to P2Y12 inhibitor monotherapy and discontinue aspirin after 1–3 months of DAPT, where the benefits outweigh the risks.[15]

In contrast, the European Society of Cardiology offers the following guidance on DAPT duration.[16] Following PCI for non-ST-segment elevation acute coronary syndrome (NSTE-ACS), DAPT with a potent P2Y12 receptor inhibitor and aspirin is generally recommended for 12 months, regardless of stent type, unless contraindicated. However, in specific clinical contexts, such as high bleeding risk (e.g., based on the PRECISE-DAPT scoring of > 25 or meeting ARC-HBR criteria), clinicians may consider shortening DAPT duration (<12 months) or modifying the regimen based on ischemic and bleeding risks, adverse events, comorbidities, concomitant medications, and drug availability. Notably, in NSTE-ACS patients with stent implantation at high bleeding risk, discontinuation of P2Y12 receptor inhibitor therapy after 3–6 months should be considered. In cases of very high bleeding risk, such as a recent (past 30 days) bleeding episode or imminent nondeferrable surgery, a regimen of 1 month of aspirin and clopidogrel may be appropriate.

In 2022, the American College of Chest Physicians (ACCP) updated its recommendations regarding the timing of DAPT after DES placement.[17] The ACCP provides a conditional recommendation for patients scheduled for elective surgery who have had stent placement within the last 3 to 12 months and are on DAPT. It recommends the discontinuation of the P2Y12 inhibitor prior to surgery, based on indirect evidence and expert opinion suggesting the safety of stopping P2Y12 inhibitors in patients with stents implanted more than 3 months prior (Table 3).

Table 3: Societal Recommendations for Shortening DAPT Prior to Surgery.

Society	Level of Recommendation	Evidence	Recommendation
ACC/AHA	2a	A	Shorted DAPT (1–3 months) is reasonable.
ESC	IIa	B	In patients with high risk of bleeding, discontinuation of P2Y12 receptor inhibitor therapy after 3 months should be considered.
ACCP	Conditional Recommendation	Very Low Certainty of Evidence	In patients receiving ASA and a P2Y12 inhibitor who had coronary stents placed within the last 3 to 12 months and are undergoing an elective surgery/procedure, we suggest stopping the P2Y12 inhibitor prior to surgery over continuation of the P2Y12 inhibitor.

ACC/AHA: American College of Cardiology/American Heart Association; ESC: European Society of Cardiology; ACCP: American College of Chest Physicians;

CONCLUSION

Paradigms within the field of cardiology regarding the duration of DAPT have changed dramatically since the 2009 *APSF Newsletter.* Newer generation stent technology has led to less stent thrombosis, and cardiology experts have in turn reduced their recommended duration of DAPT on these new drug-eluting stents to 1–3 month courses of anticoagulation in patients with stable coronary artery disease. Due to the enhanced performance of these newer stents, BMS have been rendered relatively obsolete and have fallen out of favor, and therefore, not frequently placed. Decisions of duration of DAPT in the setting of urgent surgery should be made by cardiologists, in close cooperation with surgical and anesthesia teams, and may include a very short course of DAPT. Anesthesia professionals must be mindful of these shorter durations of DAPT and be cognizant of the fact that durations of anticoagulation of as little as one month may be recommended for their recently stented patients, based on the evidence of enhanced safety profile of these newer-generation stents.

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Staphylococcus Aureus Transmission Among Anesthesia Workspace Reservoirs is Associated With An Increased Risk of Surgical Site Infection

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The anesthesia workspace is a complex environment that includes the patient, the surgical bed/table, the anesthesia machine, the intravenous (IV) pole(s) with attached infusion devices, a cart with clean supplies, and medications stored within the cart or a separate medication station. Anesthesia professionals interact with the patient and multiple components of the anesthesia workspace during routine anesthesia practice.[10,11] Given the complexity of this environment, hand decontamination is necessary to interrupt transmission events and reduce infection propagation. The World Health Organization (WHO) defines events, after which hand hygiene should be performed as the, "Five Moments of Hand Hygiene."[12] These moments that call for hand hygiene arethe following: before touching a patient, before a clean or sterile procedure, after touching a patient, after a task with a body-fluid exposure risk, and after touching the patient's surroundings (Figure 1).[12] Compliance with WHO and similar recommendations would require the anesthesia professional to perform hand hygiene as often as 54 times per hour[13] up to 150 times per hour.[11,13] However, studies reveal that anesthesia professionals perform hand hygiene less than once per hour.[14] Clearly, there is substantial opportunity for some improvement. It might seem that fighting against the transmission of pathogens is impossible, given how ubiquitous bacteria are in our environment. However, research suggests that reducing the levels of *S. aureus* on provider hands to less than 100 colony-forming units (CFU) is an achievable goal that can help to protect our patients.[9,15]

The APSF Patient Safety Priorities Advocacy Group: Infectious Disease recommends that anesthesia professionals perform hand hygiene at least approximately eight times per hour during anesthesia care.[16] Washing one's hands or using hand sanitizer at a frequency of eight times per hour optimally reduced environmental and stopcock contamination and subsequent infection development.[14] However, the proper methodology to prompt hand hygiene compliance at this frequency is not clear.[16] Important future research include products (e.g., alcohol-based or soap and water), dispenser locations, cleansing technique, and potential risks.

While hands can be effectively decontaminated using alcohol-based solutions, visibly contaminated hands or potential contact with spore-forming organisms should be decontaminated with soap and water.[14,17] Since scrub sinks must be outside the operating room, alcohol is the primary hand hygiene option for anesthesia professionals, and because it is associated with less skin irritation than soap and water, it may reduce the risk of irritated skin and higher bacterial counts on the irritated skin.[18,19]

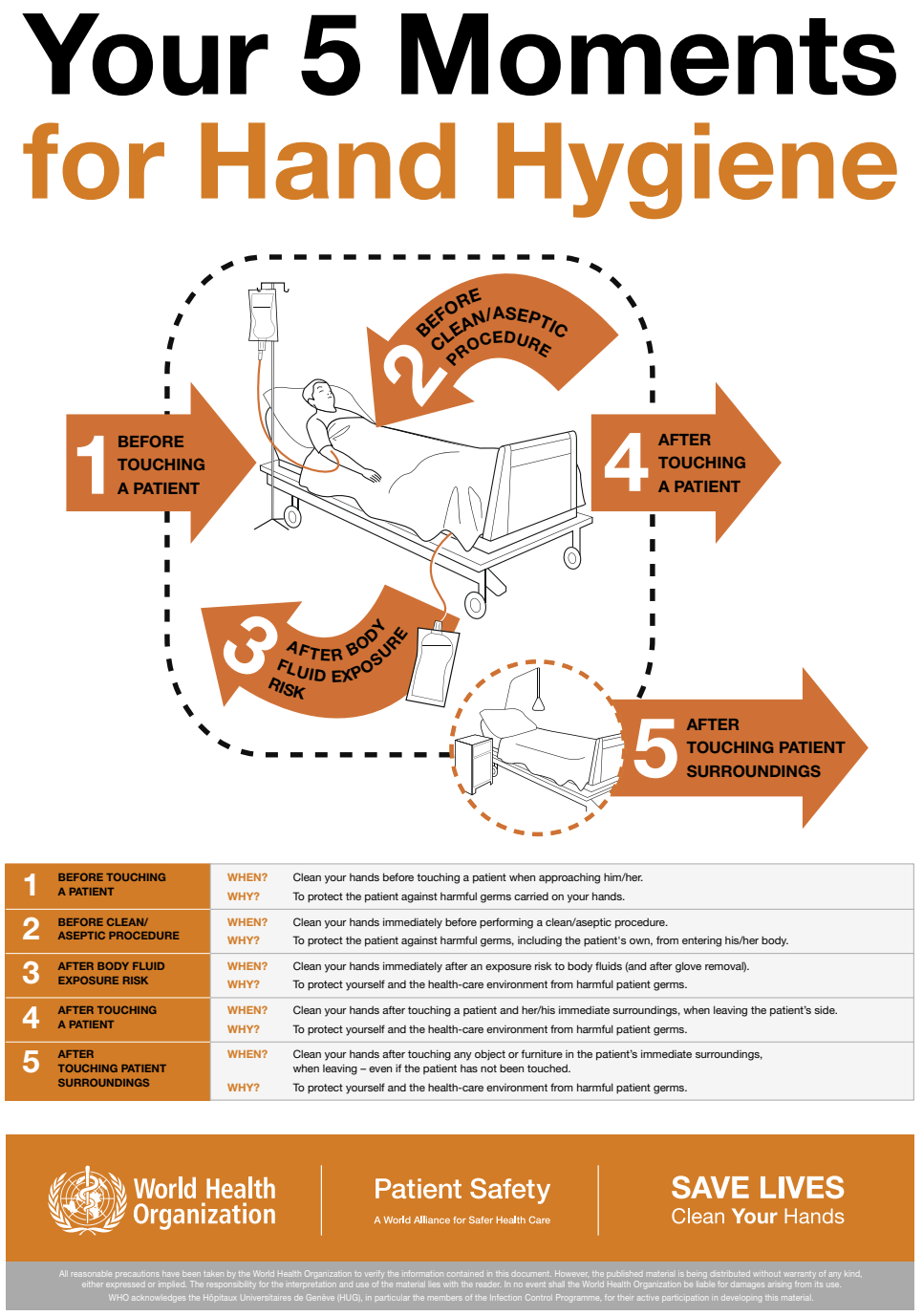

Figure 1: Your 5 Moments for Hand Hygiene. Geneva, Switzerland. World Health Organization. 2009. License: CC BY-NC-SA 3.0 IGO.

Dispenser locations should be determined by task density, which is the number of tasks that need to be done in a period of time. Health care infection prevention organizations recommend dispenser placement in locations that are easily accessible within the patient care arena.[20] Using dispensers placed outside the anesthesia work area (e.g., on the wall or near

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Anesthesia Professionals Should Perform Hand Hygiene At Least Eight Times Per Hour During Anesthesia Care

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the entrance to the operating room) may disrupt patient care. The importance of task density is well-delineated. In one study, anesthesia professional use of a personalized, body-worn alcohol dispenser increased hand hygiene compliance 37-fold, and, in turn, reduced the incidence of environmental and stopcock contamination and health care associated infections.[14] Other investigators evaluated dispenser placement on the intravenous pole to the left of the provider as part of a multifaceted program.[8,9] Dispenser placement in this location reduced the incidence of bacterial transmission and subsequent SSI development.[8,9]

Because provider hand contamination is associated with environmental contamination, improving the frequency and quality of environmental cleaning may also help to augment hand hygiene improvement efforts. In one study, separating the anesthesia workspace into "clean" and "dirty" areas was associated with a reduction in the proportion of sites reaching ≥ 100 CFUs.[14,21] It is intuitive that alcohol dispensers should be placed in areas designated as clean. For example, the dispenser may be secured to the anesthesia machine or supply cart with a mounting rack, or on the intravenous pole. If secured to the intravenous pole, then caution should be taken to protect the patient, surgical field, and underlying electrical plugs from splashes and drips (Table 1).

While anesthesia professionals must have ready access to a hand sanitizer, there are potential hazards to consider. All alcohol-based sanitizers contain 60–80% ethyl or isopropyl alcohol and water. This is because a sufficient water component is necessary to hydrolyze microorganism membranes and slow evaporation of the product.[22,23] Because alcohol products are flammable, fire codes regulate the total volume of sanitizers allowed within a procedure room and the minimum separation distance between alcohol dispensers. Dispensers must be separated by a minimum distance of four feet, and their combined volume in one room must not exceed 1.2 liters.[24] The Centers for Disease Control and Prevention also espouses these fire safety recommendations.[25] The volume for personalized, body-worn alcohol dispensers and one-handed alcohol pumps on an IV pole is less than 3 ounces.[8,9,14] While there have not been reports of fires related to hand sanitizers, it is risk worth considering.

In summary, improved hand hygiene by anesthesia professionals is an essential element of a multifaceted approach to reducing bacterial transmission and infection development. Eight hand hygiene events per hour during routine anesthesia care should be encouraged. Alcohol-based sanitizers in the anesthesia workspace should be placed in clean and easily accessible locations that are clearly visualized by the clinician.

Table 1: Potential Considerations for Hand Sanitizer Locations in the Anesthesia Workspace.

Location	Potential Advantages	Potential Disadvantages	Studies Support This Location?
Attached to IV Pole	Convenient location Can be designated as a clean area Combats task density	Potential for accidental spray onto or over surgical drapes Electrical outlets are also often on IV poles.	Studied and published as part of a bundle[8,9]
Body worn	Convenient location Combats task density	Not a clean area	Studied and published[14]
Attached to or on Anesthesia Machine	Might be easy to attach Always present	May block other equipment	No published data
Attached to or on Anesthesia Cart	Unlikely to cause interference	May be difficult to attach	No published data
Attached to wall near anesthesia area	Wall space is sometimes available	May be hard to reach	No published data

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At the Annual Meeting of the American Society of Anesthesiologists

Anesthesiology 2024
October 18–22, 2024
Pennsylvania Convention Center, Philadelphia, PA
https://www.asahq.org/annualmeeting

apsf Anesthesia Patient Safety Foundation

American Society of Anesthesiologists

Anesthesia Patient Safety Foundation Panel

Medication Errors in the Perioperative Environment—Exploring the Role of Human Factors

Saturday, October 19, 2024
11:00 am–Noon EDT
Room 102AB
Pennsylvania Convention Center

Moderator: Elizabeth Rebello, MD, FASA, FACHE

ASA/APSF Ellison C. Pierce Jr., MD, Patient Safety Memorial Lecture

Four Thousand Years Of Safety Endeavors—Why Have We Not Reached Zero Patient Harm?

Saturday, October 19, 2024
1:30 p.m.–2:30 p.m. EDT
Room 114
Pennsylvania Convention Center

Presented by: Jannicke Mellin-Olsen, MD, DPH

Pediatric Perioperative Medication Errors

by Ying Eva Lu-Boettcher, MD, and Rahul Koka, MD

DEFINITION AND RATES

A medication error is "a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient."[1] In general, perioperative medication errors are underreported. Rates of medication errors are difficult to accurately quantify as few studies have observed anesthesia professionals going through the process of medication ordering and administration. In one large, institutional study of adult patients, the self-reported incidence of medication errors was 0.004% (10/280,488) whereas the direct observation incidence was 5.3% (193/3671), suggesting that only severe medication errors with sequelae may be reported.[2] In pediatric anesthesia, the estimated incidence of medication errors using self-reports is between 0.01% (276/2,316,635) to 1.92% (37/1,925).[3-4,7] Pediatric patients have large variations in body weight resulting in high variability in dosing calculations. This makes children both at higher risk of medication errors as well as higher risk for harm from these errors compared to adult patients.[6]

COMMON CAUSES THAT LEAD TO MEDICATION ERROR

Anesthesia professionals work under high intensity conditions where multiple doses and classes of drugs are given during fast-paced clinical scenarios. This environment predisposes anesthesia professionals to medication errors. Moreover, anesthesia professionals routinely take ownership of the entire drug administration process, including prescribing, preparation, and administration. Hazards exist throughout this process (Figure 1).

Wake Up Safe, a national pediatric anesthesiology quality collaborative, found that sedatives and hypnotics/opioids are the most common medications resulting in an error.

It also found that the highest incidence of medication errors was during administration (N = 179), followed by prescribing (incorrect knowledge of dose, N = 67), then preparation (N = 30) (Figure 2), next page. The most common error type during administration was the wrong dose (N = 84), followed by syringe swap (accidental administration of the wrong syringe, N = 49). Fifty-seven incidents (21%) of reported medication errors involved medication infusions as opposed to bolus administrations. Of note, nearly all (97%) of the medication errors were deemed to be preventable.[7]

MEDICATION ERRORS: PHASES OF HANDLING

Administration Error:

- Wrong Dose
- Syringe Swap
- Duplicate Administration
- Omission
- Overdose
- Wrong Infusion Rate
- Wrong Time/Route/Patient
- Expired Medication

Prescribing Error (Provider Knowledge Gap):

- Wrong Dose/Dose
- Allergy

Preparation Error (Non-Prefilled):

- Labeling Error
- Vial Swap

Figure 1: Primary pediatric medication errors in the perioperative setting during different phases of handling: preparation, prescribing, or administration. Adapted and modified with permission from Lobaugh LMY et al. Anesth Analg. *2017; 125:936–942.*[7]

HOW DO WE CONTROL THE RISK DURING MEDICATION ADMINISTRATION?

The critical step in medication administration occurs once the syringe is pushed or infusion started.[8] Once the drug reaches the patient, there is potential for an immediate and irreversible change to their condition. This administration process comes with inherent possibility for error and harm. Some technological and process-based interventions can help mitigate or even eliminate harm potentially caused by the error (Table 1).

A FOCUS ON PEDIATRIC MEDICATION ERRORS:

For the pediatric population, specific evidence-based mitigation techniques should be considered (Figure 3).

Table 1: Technological and Process-Based Interventions Reduce Medication Errors.

Technology-Based Interventions	Process-Based Interventions
1. Barcode—assisted point of care documentation systems: a. Barcode scanning and labeling b. Audible and visual feedback/cues 2. Drug decision support: a. EMR defaults for drug order sets b. EMR defaults for dosages of routinely administered perioperative medications c. EMR reminders for next dose due d. EMR reminders/alerts of drug interactions with associated patient allergies	1. Formal and consistent way of organizing medications in the anesthesia workspace: a. Anesthesia Medication Template drug organization system[9] 2. Standardization of medication trays and drawers 3. Prefilled syringes (to mitigate dilution errors) 4. Preset medication infusion library 5. Altering time of documentation prior to administration: barcode scanners for identification and documentation of medication into EMR prior to administration 6. Connecting infusions to the most proximal intravenous (IV) port to avoid inadvertent boluses 7. Removal of high-risk medications from Electronic Medication Dispensing cart 8. Verification of drugs with another staff member prior to administration 9. Increase accessibility to easy nonpunitive drug error reporting 10. High-risk medication labeling

Common Preventive Barriers and Mitigation of Harm:[9-12,15-17].
EMR = Electronic Medical Record

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Majority of Medication Errors Are Preventable

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The Anesthesia Medication Template (AMT) drug organization system is a formal and standardized method of organizing medications in the anesthesia workplace. This tool lessens cognitive burden and has been shown to facilitate the selection of correct syringes from the anesthesia workspace as well as correct drug dose administration.[9] During simulation at a freestanding pediatric academic hospital, use of an AMT reduced incidence of overall drug dosing errors from 10.4 to 2.4 per 100 medication administrations. During phase 2 implementation, use of the AMT decreased the mean monthly error rate that reached pediatric patients from 1.24 to 0.65 errors per 1000 anesthetics. Of the errors that reached the patient, the AMT helped reduce the rate of medication swaps, miscalculation, and timing errors from 0.80 to 0.26 per 1000 anesthetics.[9]

Another mitigating technique is using prefilled syringes. Multiple patient safety groups including the APSF and Wake Up Safe advocate for prefilled syringes, which can provide standardized and enhanced labeling, along with ready-to-use medication doses.[10-12] This practice can mitigate ampule/vial swap errors and may also decrease the risk of syringe swap.[11] In a 2016 qualitative research study, System Vulnerabilities (SVs) compared provider-filled and prefilled syringe systems. SV is defined as an "activity or event that has the potential to reduce safety, efficiency of provider workflow, or increase drug costs and waste."[12] More SVs were identified in the provider-filled system compared to the prefilled syringe system, including errors due to illegible handwriting and errors due to similar medication packaging.[12] Despite its safety profile, reports of medication errors related to look-alike prefilled syringes have been published involving select manufacturers. These reports emphasize the importance of selecting prefilled pharmaceuticals that meet standards set by the American Society for Testing and Materials as well as being visually distinguishable once assembled for use.[13-14]

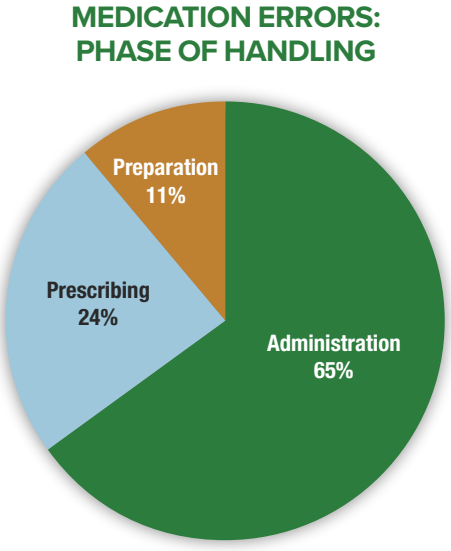

Figure 2: Phase of handling and incidence of perioperative medication errors in pediatric patients: administration, prescribing, and preparation.

Adapted and modified with permission from Lobaugh LMY et al. Anesth Analg. *2017; 125:936–942.*[7]

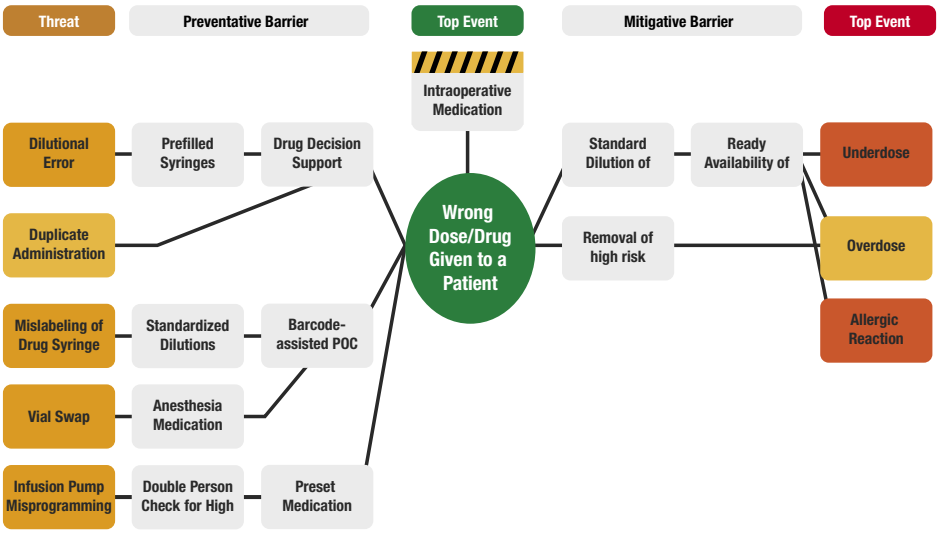

Figure 3: Bow-tie Analysis of Intraoperative Medication Errors.
POC = Point-Of-Care

A third modality is the use of point-of-care barcode scanning systems.[15-17] An observational study investigating the efficacy of barcode medication-verification technology implementation in an inpatient adult population-suggested a 41% reduction in dose, route, documentation, and administration errors and a 51% reduction in potential adverse drug events.[15] In a 2022 study out of a quaternary academic children's hospital, implementation of an electronic labeling system demonstrated a 3.6% reduction in the average daily medication discrepancy rate. Pre-implementation, the average daily medication discrepancy rate was 9.7%, decreasing to a statistically significant 6.1% ($X^2_1 = 43.9$; $P < .0001$) post-implementation.[16] Limitations to these technologies include user feasibility, compliance, cost, and availability.[15-17] Technology, while it can be incredibly useful, needs to be used in the manner for which it was intended to function in a way to mitigate medication errors. When functioning outside of intended purposes, technology can pose a risk. For example, barcode scanning only works well provided that the systems link with the EMR and that the barcode provided registers appropriately. In addition, utilization of point of care barcoding technology requires partnership with pharmacy for system updates, label changes, and medication shortage management.

CONCLUSION

Direct observation via published studies of adult and pediatric anesthesia providers in the operating room estimates a medication error rate of up to 5%.[2] The harm caused by medication errors is reported to be as high as three times more in pediatric patients than adults. The adverse event drug rate is highest among neonates. Potential medication error mitigation strategies include utilizing prefilled syringes, EMR decision support, medication organization aides, and barcode scanning systems.

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Utilizing Prefilled Syringes May Mitigate Medication Errors

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Tailoring Perioperative Care for Patients With Low English Proficiency

by Yasuko Mano, MD, MPH; Nima Saboori, MD; Janak Chandrasoma, MD; and Justyne Decker, MD

Communication failures in the clinical setting lead to poor outcomes in patient care.[1,2] In particular, patients with low English proficiency (LEP) have been shown to experience less patient-centered care, utilize health care less frequently, and face increased risk of adverse events in the health care setting.[3,4] High-risk situations that have been reported to be associated with poorer outcomes for LEP patients include medication reconciliation, discharge from the hospital, obtaining informed consent, emergency department care, and perioperative surgical care, all of which intersect with the work of anesthesia professionals.[5,6] In the perioperative care environment, anesthesia professionals are encouraged to use in-person, telephone, or video interpreters to improve patient-physician communication and ensure the best quality patient care possible.[7]

Although providing care for patients with LEP has become easier with widespread availability of interpreter services, there remain points along the perioperative spectrum that are not easily conducive to their use.[8-13] When looking through the lens of a patient's perioperative journey, there are several settings in which language interpreter use is difficult or lacking. One such point is upon check-in and during the rooming process in the preoperative clinic. Although interpreters are often made available during the clinician encounter once the patient has been roomed, interpreters are rarely used in the process leading up to this point.[11] Another point is within the intraoperative setting, where in-person interpreters often cannot readily enter the operating room, and telehealth interpreters often are not able to be effectively utilized during induction and emergence of anesthesia.[13] While these points make up a relatively small portion of the perioperative spectrum, miscommunication and lack of effective communication along all parts of their perioperative journey can compromise the patient's sense of safety. In response to these identified gaps, we enacted a quality improvement initiative focused on structural changes in the preoperative and intraoperative settings to enhance communication between the anesthesia care team and the LEP patient.

We first aimed to facilitate effective communication in our preoperative clinic, where the patient is first introduced to the anesthesia care team in our health system, by building patient rapport with a welcome message and an individualized greeting. In the immediate check-in process, a translated, laminated welcome message and visit description were provided to

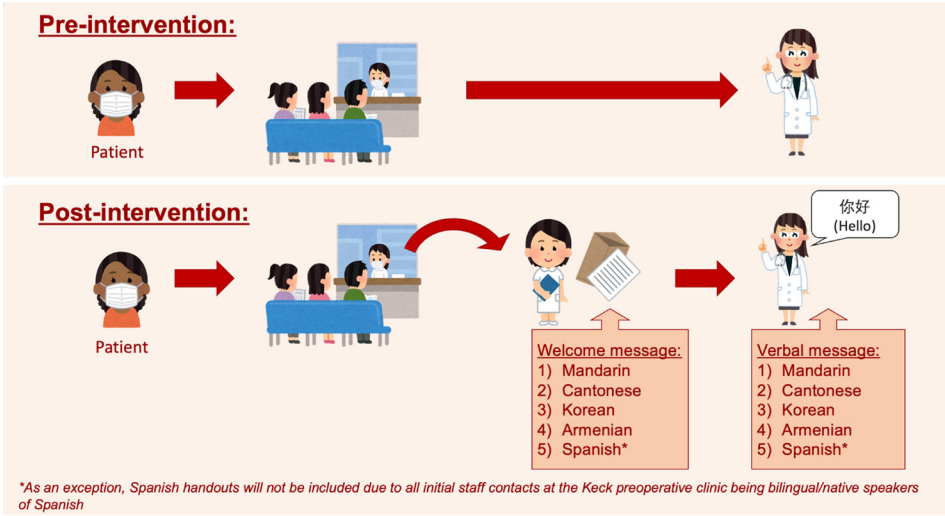

Figure 1: Schematic demonstrating the structural changes we made to the preoperative clinic experience for those with language barriers. Used with permission from the authors.

Welcome to the preoperative clinic. Please fill out the forms as best you can. If unable, return them to the front desk. We can complete them together with a translator. Once roomed, we will go over the forms, instructions, testing (if needed) and answer your questions in (Mandarin, Cantonese, Korean, Armenian, Spanish) with a translator. We will bring the patient to the room first and return for any visitor or family member if needed.

Figure 2: Welcome message (English template) that was translated into the top ten languages encountered at Keck Hospital. Used with permission from the authors.

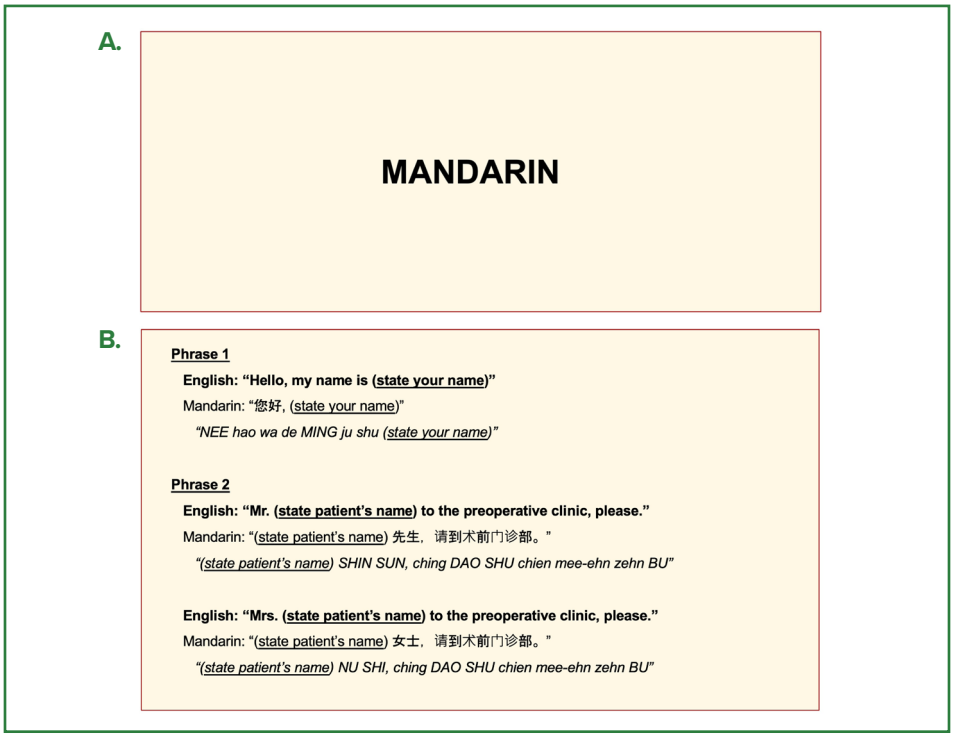

Figure 3: Front (a) and back (b) views of cards placed in each LEP patient's chart. Used with permission from the authors.

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Improving Communication for Patients With Low English Proficiency Enhances Quality of Care

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patients with LEP (Figure 1). The aim of this message was not only to outline the workflow and purpose of the visit, but also to reassure the patient that their health history, preoperative instructions, and questions would be discussed in their preferred language. Translations of the messages in the top ten most encountered foreign languages in our patient population were created by medical professionals who were native speakers (Figure 2). In addition, laminated cards identifying the patient's language were placed in each LEP patient's chart to visually indicate to health care staff the patient's primary spoken language (Figure 3). On the back of these cards, phonetic pronunciations of how to say "Hi, my name is (staff name)" and "Mr./Mrs. (patient name) to the preoperative clinic, please" were printed in each of the ten languages accordingly, with the goal of having the staff greet, introduce themselves and call for patients in their native language. After rooming the patient, the chart would be available to the rest of the preoperative clinic team to also greet the patient in their native language.

Similarly, on the day of surgery, we focused on reducing preoperative anxiety and improving physician-patient rapport by explaining to the patient that, while the in-person or video interpreter will not be accompanying us into the operating room, we will have a few key phrases in their preferred language for when they are going under and waking up from anesthesia. A badge card linguistic tool was crafted, which listed phonetic pronunciations of how to say "breathe", "surgery is finished," and "pain?" in the top ten foreign languages encountered at our institution (Figure 4). These translations were created by medical professionals who were also native speakers of these langauges, and distributed to all anesthesia care team members. Feedback on their use was encouraged. With this additional resource readily available, the anesthesia care team was now able to encourage deep breathing on induction and emergence, and in recovery to facilitate preoxygenation and improve postoperative ventilation. The care team was also able to improve reorientation on emergence by communicating that the surgery was now finished. Finally, they were able to better assess patient pain prior to transfer to the postanesthesia care unit in an effort to minimize untreated or undertreated postoperative pain. Thus, we improved communication with patients with LEP during critical parts of patient care with a few key words or phrases in the patient's preferred language (Figure 5).

Intraop Language Barrier Aid

Keck Medicine of USC

English	Breathe/Deep Breath	Pain	Surgery is Finished
Spanish	respira profundo (res-pi-rah proh-foon-doh)	dolor (doh-lore)	la cirugia ha terminado (la see-roo-hee-ah ah tur-meen-ah-doh)
Mandarin	深呼吸 (shēn-hū-xī)	疼痛 (téng-tòng)	手術完成 (shǒu-shù- wán-chéng)
Cantonese	深呼吸 (sam kap fu)	痛 (tung)	手術完成 (shǒu-shù- zou-wan)
Armenian	khor shoonch (khor shoonch)	ts'av unes (t-sahv oo-nez)	virahatut'yunn verjars'el e (veer-aha-toot-oon-eh ver-chawts-el-eh)
Korean	숨 쉬세요 (soom she sae yo)	아프신 곳 있나요 (ah-poo-sin gos ees-nah-yo)	수술 끝났습니다 (soo-sool kut-not-sum-nee-dah)
Japanese	大きく息してください (ohkiku iki shiteh kudasai)	痛みはありますか？ (itami wa arimasuka?)	手術は終わりましたよ (shujutsu wa owari-mashita-yo)
Vietnamese	thở sâu (tow so)	đau (dow)	phẫu thuật được thực hiện (fow tat dook thook hee-in)
Farsi	nafaseh ameegh (nah-fas-eh ah-meegh)	Dard (dahrd)	amal tamoomshod (ah-mahl tah-moom-shohd)
Arabic	nafs eamiq (naf-seh ah-meegh)	vajaa (vah-jah)	kholsetet amaliyeh (khol-set-eht ah-mahl-ee-eh)
Russian	glubokiy vdokh (gloo-bow-ky vi-dokh)	bol (bol)	operatsiya sdelana (op-er-at-says deel-anah)

Figure 4: Badge card provided to all anesthesia staff at the Keck Hospital of USC. Used with permission from the authors.

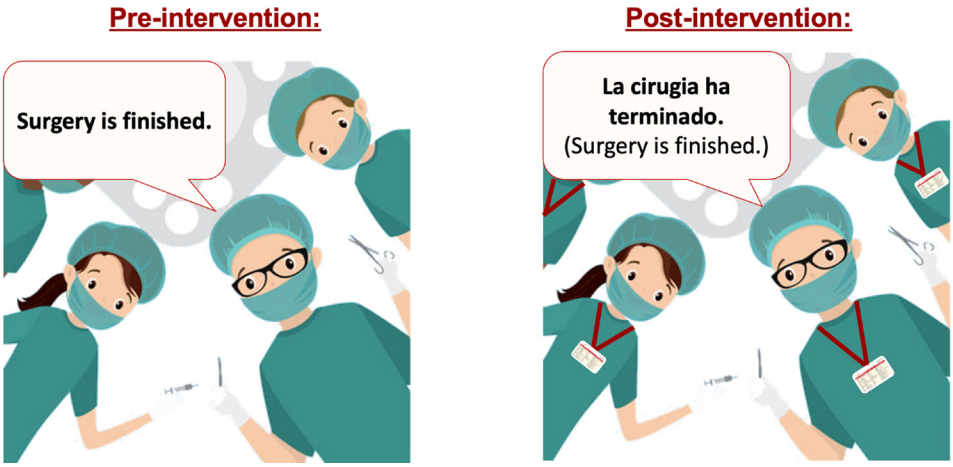

Figure 5: Illustration of the effect of implementing the badge card linguistic tool intraoperatively. Used with permission from the authors.

In order to assess our quality improvement initiative, patients and clinical staff were asked to fill out a five-point Likert scale questionnaire to assess their experience. Survey results were compiled and assessed for patient satisfaction and overall feedback. Overwhelmingly, patients and staff responded that the changes positively impacted their experience. Fifty-three patients completed the survey, with 89% responding with a 5/5 response (strongly agree that our implemented greeting and message was a positive experience and made them feel welcomed). An additional 4% responded with a 4/5, and the remaining 7% responded with a neutral 3/5. There were no responses which indicated a negative impact on their experience. Fifty-six staff members consisting of representation from the preoperative clinic team and anesthesia care team completed the survey, with 88% responding with a 5/5 (strongly agree that the language tools were helpful and made a positive impact on patient interactions) and the remaining 12% responding with a 4/5.

Our initiative produced a few different notable outcomes. First, it demonstrated that it is feasible to introduce structural changes to address language barriers in the perioperative settings at low cost. The total cost incurred to generate the laminated welcome messages, chart cards, and badges was less than $250, which was funded by our department, and no

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Quality Improvement Initiative Improved the Experiences of Patients With LEP

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outside funding or outside personnel were needed for this study. Secondly, this initiative was able to be implemented relatively quickly. It only took a few months to receive approval from the Institutional Review Board, prepare the translations, laminate, print, and distribute materials. Finally, we were able to facilitate improved communication on emergence in patients with LEP—a situation in which the degree of English proficiency is likely to be even lower than their preoperative state.

Overall, our quality improvement initiative demonstrates that these structural changes to the preoperative and intraoperative settings unsurprisingly improved the experiences of patients with LEP. Patients provided positive feedback in response to the changes, and health care staff involved appreciated the user-friendly nature of the language tools, noting that they helped patient greeting and rooming to feel more welcoming and less awkward. Based on the results of our current study, linguistic tools present a simple and practical approach to improving patient-provider communication within the operating room, as well as in the preoperative clinic. Furthermore, our interventions helped add a more personal element to the patient's experience with the anesthesia team within our preoperative clinic and on the day of surgery. Patient-centric improvements to our care help build rapport and trust with our patients and improve the overall perioperative experience for both the patient and anesthesia care team.

Barriers to implementation included finding medical professionals to conduct the translations, as well as orienting health care staff to the new badges, cards, and welcome messages. However, after translations were completed and staff were oriented to the new process changes and available resources, the rest of the process went smoothly. The orientation process included brief in-person training to go over the new workflow and practice using the greeting cards and badges, all of which took around 30 minutes. We recognize that, while our institutional resources included in-house health care staff who speak the top ten languages encountered, this may not be the case everywhere. Therefore, alternative resources that may be considered include paid medical translation services. For the minority of patients (4.7%) who did not speak one of the top ten languages, an interpreter was available for the clinic visit. These languages will be included in future steps of this initiative.

Given the ease of implementation with minimal resources, our initiative demonstrates that similar improvements in the experience for LEP patients is feasible for most perioperative settings. The most common languages will differ at each institution based on patient demographics, but can be easily customized according to the needs of each institution. Overall, by improving communication between the health care staff and patients during the high-risk points during the preoperative assessment as well as during intraoperative care, we were able to achieve improved rapport with and quality of care for the LEP patient. Future steps in our initiative are aimed at increasing the number of languages represented, increasing the variety of phrases used intraoperatively, and finding ways to broaden the accessibility of these translations, such as through digital technology, especially given the recent increase in its use in the health care field.[14,15] While mobile application translations services may go on to replace the hard-copy language aids in addressing the language barrier gap, we remain aware of digital literacy as a potential issue.[14]

In conclusion, our structural changes positively impacted the patient experience for those with language barriers. We demonstrated that these changes improved patient-centered care, whether facilitating communication upon emergence or feeling welcomed and appropriately greeted at our preoperative clinic. Ultimately, we aim to improve the perioperative care of LEP surgical patients one step at a time by identifying the barriers they face and tailoring their care to bridge those gaps.

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Malignant Hyperthermia Moves Out of the OR: The Role of the Anesthesia Professional

by Henry Rosenberg, MD; Anjan Saha, MD; Carla D. Zingariello, DO; Sandra Natalia Gonzalez, MD, FAAP; and Teeda Pinyavat, MD

INTRODUCTION

As an anesthesia professional, you likely know that malignant hyperthermia (MH) strikes out of the blue and can rapidly lead to muscle rigidity, hyperthermia, elevated end tidal CO_2, respiratory and metabolic acidosis, and if not treated promptly and specifically, it can result in death. You also may know that, despite MH being inherited in an autosomal dominant manner, there is a higher incidence in males than females and that the syndrome occurs at a higher rate in children than adults.[1]

Here we present a recent case of MH, give a historical perspective on the success anesthesia professionals have had in furthering our understanding of MH, and propose a future direction in which we may also play a critical role in caring for patients long after their acute episode—to ensure proper workup and understanding of post-episode sequelae.

MH CASE

An otherwise healthy 11-year-old girl presents to the hospital to have an incidentally discovered ovarian teratoma removed laparoscopically. She had no prior surgeries or encounters with anesthesia. Soon after induction of anesthesia with sevoflurane, paralysis with rocuronium, and intubation, she developed persistent tachycardia (heart rate 120 bpm from a baseline in the 80s), her temperature rose to 39.4°C, and her end-tidal CO_2 ($ETCO_2$) climbed to 110 mmHg. Muscle rigidity was also observed in the patient's arms despite having received non-depolarizing neuromuscular blockade. As soon as these MH signs presented, help was called to assist in managing the crisis. The sevoflurane was discontinued, and Ryanodex® (dantrolene sodium, Eagle Pharmaceuticals, Inc., Woodcliff Lake, NJ, USA) was quickly administered. Within a few minutes, her heart rate, temperature, $ETCO_2$, and musculoskeletal tone all improved. Other stabilization measures included starting a total intravenous anesthesia (TIVA), obtaining additional IV access and an arterial line, active cooling with administration of cold IV fluids, and aggressive hydration. Once stabilized, the surgery was quickly completed, and the patient transferred to the ICU. Dantrolene treatment was continued. Notably her first creatine kinase (CK) was abnormally high at 34,000 IU. The patient was extubated the following day. Over the next few days, she continued to improve, and her rhabdomyolysis resolved.

Over multiple visits in the days following the event, the anesthesia professionals learned that the patient had previously had episodes of heat intolerance and that her grandmother had an incidental finding of chronically elevated CK, but had not undergone a muscle biopsy. A comprehensive genetic panel testing 129 genes associated with rhabdomyolysis and metabolic myopathy was ordered along with consultation with a geneticist and neurologist. The genetic testing revealed an alteration in the ryanodine receptor (RYR1), confirming the diagnosis of MH. Interestingly, while she was found to have a RYR1 variant which is officially characterized as a variant of unknown significance (VUS) by the National Human Genome Institute and American College of Medical Genetics, it is considered a pathogenic variant by the European MH group, and has previously been associated with elevated CK levels, rhabdomyolysis, and weakness.[2] She was ultimately discharged on postoperative day 5 with close follow-up with the medical genetics, neurology, and neuromuscular clinics.

Table 1: MH Cart Medication and Supplies.

Perioperative Phase	Recommendations and Considerations
Medications	**Details**
Dantrolene	Ability to administer full dose (up to 10mg/kg) within 10 minutes Dantrium/Revonto (36 vials) or Ryanodex (3 vials)
Sterile water	100mL vials (Not bags to avoid accidental administration of large volume hypotonic solution)
Refrigerated saline	3 liters minimum
Sodium bicarbonate (8.4%)	50mL x 4
Dextrose (50%) and regular insulin	50mL vials x 2
Regular insulin (100u/mL)	1 vial
Calcium chloride (10%)	10mL x 2
Lidocaine (2%)	100mg x 3
Supplies	
Charcoal filters	2 pairs
Disposable cold packs	4 packs
Foley catheter	Various sizes
Clear plastic bags for ice	4 small, 4 large
IV, Arterial line, central line	Various sizes
Temperature probe	Esophageal (or other core temperature monitor)

IV: Intravenous

MH: A SUCCESS STORY

This story of a patient developing MH and being successfully diagnosed and treated reflects the accumulated knowledge from scientific contributions of scientists over many years and from all over the world. Since the first description of MH in Melbourne, Australia, in 1960 by Denborough and Lovell, much progress has been made in terms of defining the pathophysiology, discovering an effective therapeutic treatment, and disseminating information about MH to the anesthesia community.[3] As a result, MH mortality has declined from 70% to as low as about 10% in countries prepared for the syndrome with ready access to dantrolene and other supplies (Table 1),[4] a coordinated approach to diagnosis and management including ICU observation, and post-episode coordination with family members of the person who experienced MH.

FUTURE DIRECTIONS

As in much of science, solving one problem often leads to more questions. In addressing these questions, it has become apparent that we should not think of MH as an episodic, idiosyncratic disorder, but as a pharmacogenetic

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disorder and an inherited myopathy with consequences that may be far removed from the anesthetic experience.

First, what do we know about the implications of RYR1 mutations outside of MH? Further study is needed to understand how RYR1 associated conditions (such as statin-induced myopathy, exertional rhabdomyolysis, heat stroke, and chronically elevated CK syndromes) relate to MH susceptibility (MHS).[5] There is also a need to understand the role and efficacy of dantrolene for the treatment of these other syndromes.

Second, after an MH episode, how should we confirm a diagnosis of MHS? Advances in genetic testing to assess MHS have led genetics to essentially replace the tried-and-true muscle biopsy caffeine halothane contracture test in much of the world. The European MH society formally changed their recommendation to use genetics as the first line test in MHS diagnosis in 2015 and most MH experts around the world have followed this lead.[6] In the US, there are only two centers (located in Minnesota and North Carolina) and the testing can cost up to $20,000 USD, which is generally not paid for by insurance companies. On the other hand, the cost of genetic testing has declined over 99% since the first sequencing of the human genome and is usually reimbursed by insurance companies. Specific costs vary by the type of test selected. A panel test for the three genes associated with MHS (RYR1, CACNA1S, and STAC3) costs less than $500 USD,[7] versus a more comprehensive metabolic and myopathy panel which costs around $1,500 USD.[8]

Third, what is the role of the anesthesia professional in the care of MHS patients after their episode, and how should they interact with other providers such as geneticists and neurologists? Whose responsibility is it to advise family members on the significance of a pathogenic DNA variant predisposing to MH? Specialists who treat patients who have experienced an MH episode can help them to understand whether they are expected to make a full recovery, but they may be less able to address longer lasting questions such as if such patients are predisposed to rhabdomyolysis or muscle weakness, and for how long. A method of flagging an MHS diagnosis, including specific genetic variant, in the electronic medical record should be ensured. Artificial intelligence or third-party services that can process data across genetic testing platforms and improve communication of this critical diagnosis to practitioners can make care safer for MHS patients. Though the incidence of acute MH in MHS patients exposed to triggering agents is unknown and difficult to estimate, all

MHS patients should be treated with a "clean" nontriggering anesthesia technique.[9-11] This includes avoidance of succinylcholine and volatile anesthetics, preparation of the anesthesia machine by flushing the circuit and ventilator with high flows over the manufacturer recommended amount of time or insertion of activated charcoal filters in the breathing circuit, use of fresh CO_2 absorbent, and taping off vaporizers to prevent accidental use. Intraoperative monitors should include EKG, pulse oximetry, blood pressure, core body temperature, and capnography for general anesthesia.[12]

Finally, MH has been reported from countries all over the world and there is no known ethnic propensity to MHS. A broader public health concern is how do resource-limited countries balance the cost of a life-saving drug dantrolene for an infrequent disorder, versus the need for expenditures on more frequently occurring disorders? A report from China in the February 2024 issue of *Anesthesiology* reported mortality from MH over 50% in areas without dantrolene.[13] While it has been questioned in the US as to whether ambulatory facilities who do not routinely use volatile agents and reserve succinylcholine for emergency airway management need to stock dantrolene, there is evidence to show that stocking dantrolene is both cost-effective and optimal for safe patient care where triggering agents may possibly be used.[14-17]

THE FOUR C'S OF MH MANAGEMENT

In our opinion it is time to broaden our perspective on the MH syndrome to regard the problem as not unique to anesthesiology and surgery. We need to expand patient care goals beyond the confines of managing the acute MH episode, to include appropriate follow-up and assessment of other potentially associated skeletal-muscle-related conditions. A multidisciplinary approach to the diagnosis, treatment, and genetic counseling for patients and families is of utmost importance. Therefore, we propose the 4C's of MH Management:

1. **Control** the acute syndrome
2. **Consult** genetic and neurologic colleagues
3. **Confirm** with genetic testing
4. **Communicate** the results and plans for care with the patient, family, and other health care providers.

NEXT STEPS

It is within our scope of practice as anesthesia professionals to take these actions to improve the care of MHS patients going forward. The enlightened management of MH fits with the goals of the APSF and other patient safety organizations. Next steps include: 1) revision of MHS diagnostic testing recommendations by the Malignant Hyperthermia Association of the United States (MHAUS) to include genetic testing after all suspected MH cases, 2) creation of a system to connect anesthesia professionals who manage MH to clinical geneticists, genetic testing platforms, and neurologists familiar with MH, 3) assurance of communication of an MHS diagnosis in electronic medical records, and 4) dissemination of MH education globally, including advocating for stocking dantrolene in all centers where triggering agents may be used.

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Sandra Natalia Gonzalez, MD, has no conflicts of interest.

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RAPID Response
to questions from readers

Replacing CO_2 Absorbent During Surgery—The Risk of Hypoventilation Continues

by Yuki Kuruma, MD

DEAR RAPID RESPONSE:

In 2013, my colleagues and I reported a case of hypoventilation to the *APSF Newsletter* due to a massive leak from a defective Drägersorb disposable absorbent canister (CLIC®) (Dräger-werk AG & Co. KGaA, Lübeck, Germany), which was replaced during surgery while using the Fabius GS premium anesthesia workstation (Drägerwerk AG & Co., Lübeck, Germany).[1] Since our report appeared in the *APSF Newsletter*, similar cases have been reported on other Dräger anesthesia machines such as Perseus A500[2] and Primus.[3] Despite these reports, there have been no specific actions to prevent future occurrences, so the risk of hypoventilation after replacing a CO_2 absorber during surgery has continued. Furthermore, this risk is not unique to Dräger anesthesia machines although the implications of a leaky canister are different depending upon the machine design. In this report, our prior experience is summarized and the impact of a leaky canister on ventilation is described for different machine designs. To inform anesthesia professionals about this risk, a "WARNING" should be added to the Instructions for Use (IFU) for all anesthesia machines that provide the option to change the absorbent canister during a procedure.

When the Fabius GS machines were introduced to our department, it was the first time we could replace the absorbent canister during a procedure. This practice was adopted to more completely utilize the absorbent. For the case we reported in the previous *APSF Newsletter*, the canister was changed during the procedure without apparent problems. At the end of the procedure, when switching to manual ventilation, the breathing bag collapsed and could not be inflated, despite maximizing the fresh gas flow (FGF) or repeatedly pressing the oxygen flush valve. The patient's endotracheal tube was disconnected from the anesthesia machine and ventilation continued with a Jackson-Rees circuit and an external oxygen tank. The patient restored spontaneous breathing and was extubated uneventfully. Investigation revealed a large hole in the absorbent canister as the reason for the inability to create pressure in the circuit. The unique design of the Fabius machine, which incorporates a fresh gas decoupling valve, allowed for adequate mechanical ventilation, but complete ventilation failure in manual mode.

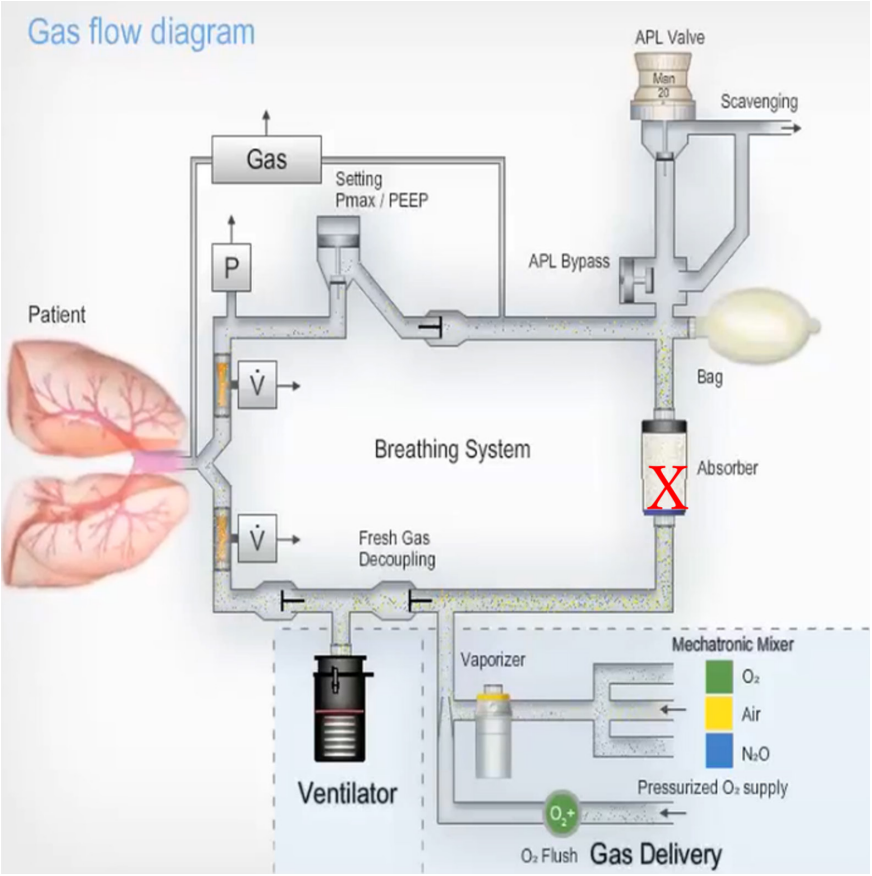

Figure 1: Schematic of Dräger Piston-type Breathing Circuit (Primus/Apollo, Fabius Models) with leak site indicated with an X. During mechanical inspiration, the FGD valve will close preventing gas from leaking via the canister. During exhalation, when the piston draws gas from the reservoir bag, ambient air can be entrained into the circuit through the canister leak. When manual ventilation is attempted, positive pressure from the bag will cause gas to leave through the canister leak making manual ventilation difficult, if not impossible, depending upon the size of the leak. (Courtesy Dräger Medical.)

APL = Adjustable Pressure Limiting; FGD = Fresh Gas Decoupling.

The current anesthesia workstations with piston ventilators manufactured by Drägerwerk AG & Co. have a unique design that uses a fresh gas decoupling (FGD) valve in the breathing system to prevent fresh gas from entering the circuit during inspiration. The CLIC adaptor makes it possible to replace an absorbent canister during surgery. The FGD valve is located between the piston-type ventilator and the fresh gas inlet, and a CO_2 absorber is located between the fresh gas inlet and the breathing bag (Figure 1). The FGD valve ensures inspiratory pressure is maintained during mechanical

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ventilation even if a leaky absorbent canister is correctly attached to the CLIC adaptor. During the expiratory phase of mechanical ventilation, as the piston retracts, ambient air can be drawn from the defect in the absorber into the anesthesia circuit. The gas concentrations in the circuit are altered by the entrained ambient air but, depending upon the size of the leak, the concentration changes may not be readily apparent. With manual ventilation, however, positive pressure is created by the reservoir bag and a defect in the canister can then make ventilation impossible with a collapsed breathing bag and potential injury to the patient.

The anesthesia workstations with turbine-type ventilators (Dräger Perseus and Zeus) do not have a FGD valve, but the breathing bag fills with fresh gas and functions as a reservoir for the ventilator (Figure 2).[4] During mechanical ventilation, inspired gas is taken from the FGF and the reservoir bag. When there is a leak in the absorbent canister,[2] during mechanical ventilation, tidal volume is not altered, but the gas concentrations in the circuit are altered as ambient air can enter the circuit through the canister. The impact on gas concentrations depends upon the size of the leak and the total FGF with a greater impact for larger leaks and lower FGF. Since the breathing circuit has unidirectional flow, fresh gas should continue to fill the reservoir bag during mechanical exhalation. Manual ventilation may be difficult or impossible depending upon the size of the leak.

Dräger is not the only manufacturer to offer absorbent replacement during surgery. GE Healthcare (Madison, WI), Mindray North America (Mahwah, NJ) and Getinge USA (Mahwah, NJ) all offer the same feature, and the machine design will determine the impact on the breathing circuit of placing a canister with an undetected leak. There is a report of leakage occurring in a GE anesthesia machine after replacing a damaged disposable canister.[5] GE and Mindray anesthesia machines have an ascending bellows ventilator and no FGD valve. During mechanical ventilation, the reservoir bag is excluded from the circuit. If there is a leak in the canister, the bellows will collapse during inspiration and make mechanical ventilation impossible (Figure 3).[6] During manual

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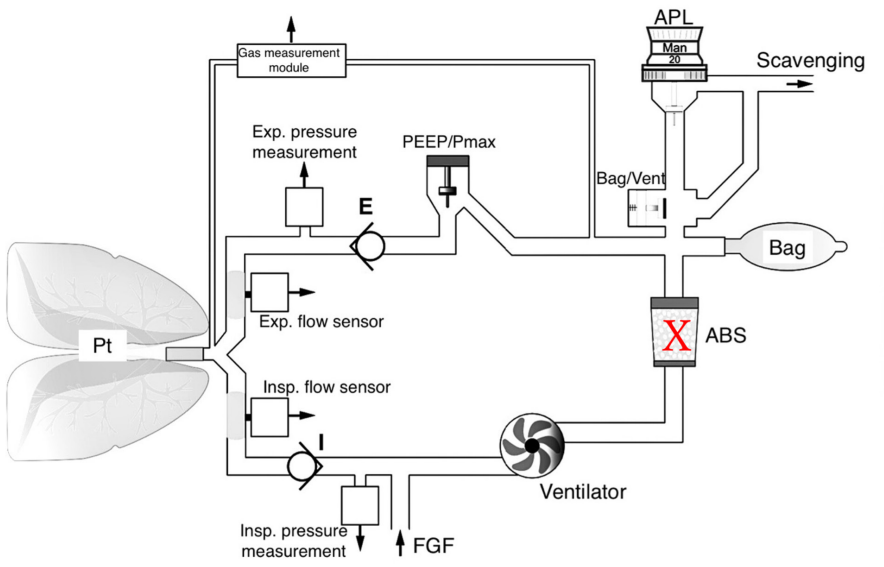

Figure 2: Schematic of Dräger Turbine Type Breathing Circuit (Perseus) with leak site indicated with an X. Mechanical inspiration will continue if there is a canister leak although ambient air can be entrained altering the concentration of gases in the circuit. During exhalation, exhaled and fresh gas will continue to fill the bag. Manual ventilation may be difficult or impossible depending upon the size of the leak. (Courtesy Dräger Medical.)

ABS = Absorbent canister; FGF = Fresh gas flow; APL = Adjustable pressure limiting.

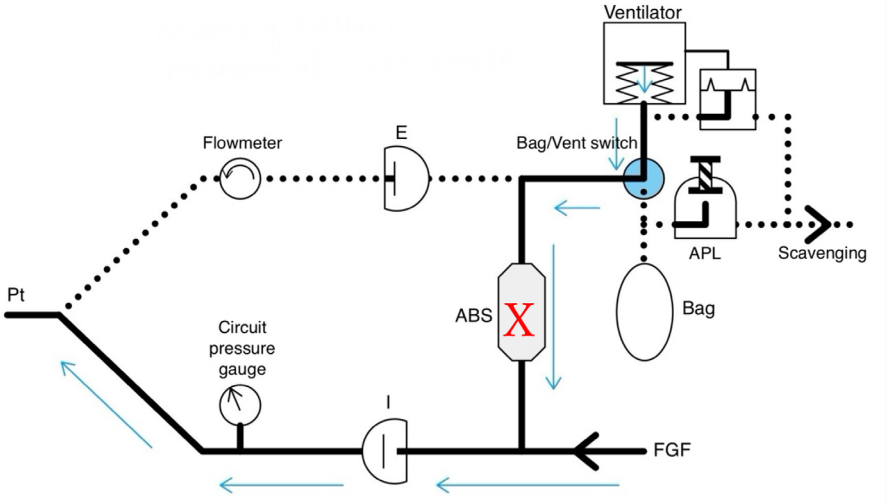

Figure 3: Schematic of Bellows Type Breathing Circuit (GE and some Mindray Models) with leak site indicated with an X. Both mechanical and manual ventilation are impacted similarly if there is a canister leak since they are both in the same place in the circuit and selected by the bag/vent switch. In all cases, positive pressure ventilation can be difficult or impossible depending upon the size of the leak. The leak will be indicated by either collapse of the bellows or collapse of the reservoir bag. (Figure created by Dr. Kuruma.)

ABS = Absorbent canister; FGF = Fresh gas flow; APL = Adjustable pressure limiting.

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ventilation, the bellows is excluded, but the reservoir bag will collapse making ventilation impossible. The size of the leak will determine how quickly either the bellows or reservoir bag collapse, but if either occurs there is a leak until proven otherwise and the canister may be the source if it was recently changed.

Another type of anesthesia machine circuit design is the volume reflector, which is included in Getinge anesthesia machines and the Mindray A9. While there are no published reports of a leaky canister with the volume reflector design, the consequences can be understood by inspecting the circuit design (Figure 4).[7] In this circuit, a ventilator and a breathing bag are located upstream of the absorber. Like the bellows design, during mechanical ventilation, the reservoir bag is excluded from the circuit, and during manual ventilation, the ventilator is excluded. The volume reflector ventilator provides a continuous supply of 100% oxygen as the drive gas. Under normal conditions, the drive gas pushes gas to the patient, but does not enter the patient circuit. In the event of a canister leak, the drive gas may provide some ventilation to the patient depending upon the size of the leak, but will dilute the anesthetic in the circuit and change the oxygen concentration. Manual ventilation may not be possible if there is a large leak, and the bag will collapse.

Current practices intended to reduce the environmental footprint when using a circle anesthesia system include reducing FGF and using the CO_2 absorbent to completion. Achieving the absorbent goal requires waiting to change the absorbent until inspired CO_2 is present,[8] which is the rationale for allowing an intraprocedure exchange. While there is benefit to this feature, our experience and other reports underscore the risks of an undetected canister leak. While a leaking canister will be detected by the preoperative leak test, it is only apparent by ventilation failure and/or changes in gas concentrations when replaced during a procedure.

Therefore, my colleagues and I are reluctant to follow the practice of replacing the absorber during surgery due to the risk of personnel failing to recognize the problem and respond in a timely fashion, potentially leading to patient harm. Instead, we continue to rely upon the color change of the absorbent to determine when to replace the canister. Typically, the canister is replaced before the start of anesthesia and a leak test is done after the replacement. Leaks in the canister will therefore be detected before patient care. When a long procedure is planned, we replace the canister beforehand in order to reduce the possibility of replacement during surgery. Unfortunately, we have not been able to take full advantage of the CLIC adapter on the Dräger anesthesia machine.

The problem of inability to detect a leaky canister until it results in difficulty ventilating is inherent to the design of modern anesthesia machines. Piston ventilators from Dräger with a FGD valve and turbine ventilators without a FGD valve will continue mechanical ventilation and the problem may not be apparent until switching to manual ventilation. Other ventilator designs (bellows and volume reflector) should demonstrate a failure to ventilate fairly soon after canister replacement. Manufacturers who provide the ability to change absorbent during a procedure should inform users about the risk of an undetected canister leak and the problems likely to result depending upon the circuit design. We suggest that all manufacturers add an appropriate "WARNING" to the IFU of their anesthesia workstations. In the case of Dräger piston ventilators, we propose the following example:

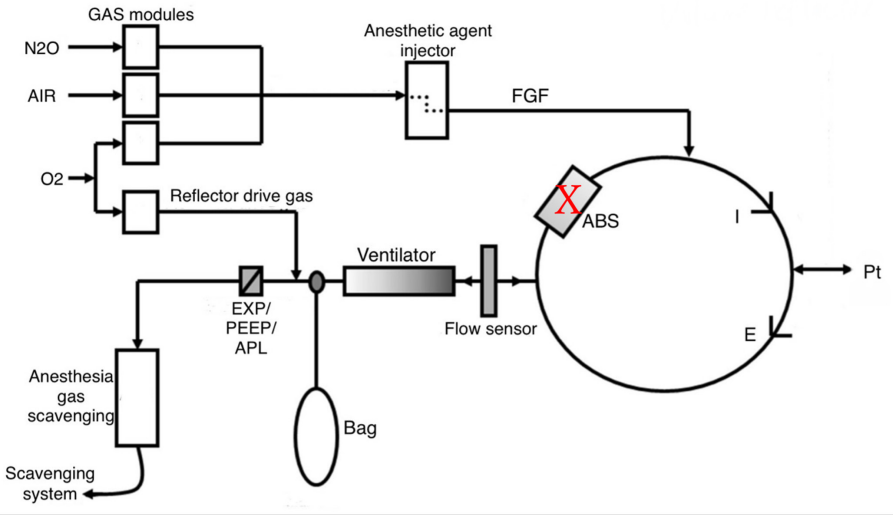

Figure 4: Schematic of volume reflector type breathing circuit (Getinge, Mindray A9) with leak site indicated with an X. During mechanical ventilation, the volume reflector will provide a continuous source of 100% oxygen. If the leak is not too large, some inspired tidal volume may be delivered, but the oxygen can dilute the anesthetic in the circuit and change the oxygen concentration. The bag is excluded during mechanical ventilation. Manual ventilation may be difficult or impossible depending upon the size of the leak. (Courtesy Getinge.)

ABS = Absorbent canister; FGF = Fresh gas flow; APL = Adjustable pressure limiting.

WARNING

Replacement of a CLIC disposable CO_2 absorbent canister during a procedure has the attendant risk of impossible manual ventilation if the replacement has an undetected leak. Due to the FGD valve, mechanical ventilation will not be altered significantly if there is a canister leak. Visual inspection of the canister is essential to detect any defect of the disposable canister before replacement. After intraprocedure canister replacement, tidal volume and inspiratory pressure as well as gas concentrations in the circuit should be carefully monitored for any changes. A manual resuscitation device, auxiliary oxygen supply and intravenous anesthetics should always be readily available to prevent patient injury in the event of an anesthesia machine failure.

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ACKNOWLEDGMENTS

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Yuki Kuruma, MD, is an anesthesiologist at Saiseikai Matsusaka General Hospital, Mie, Japan.

The author has no conflict of interest.

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Editor's Note: Intraprocedure Replacement of CO_2 Absorbent Canisters

by Jeffrey Feldman, MD, MSE

The circle anesthesia system is specifically designed to reduce inhalation agent waste and greenhouse gas pollution by allowing the anesthesia professional to reduce fresh gas flow causing rebreathing of exhaled anesthetics. Carbon dioxide absorption is required to safely and effectively reduce fresh gas flow. Carbon dioxide absorbents also contribute to the waste stream and offset the advantages gained by reducing fresh gas flow although the net benefit favors reducing fresh gas flow.[1] Changing absorbent based upon the appearance of indicator alone increases absorbent waste by discarding unused absorbent. To minimize absorbent waste, it is useful to utilize the absorbent until it becomes ineffective, which is indicated when inspired CO_2 begins to appear in the capnogram.[2] This practice is only practical when using an anesthesia machine designed to allow for absorbent canister replacement without interrupting positive pressure ventilation or anesthetic delivery. The major anesthesia machine manufacturers all provide options that allow for intraprocedure replacement of absorbent canisters.

In this issue of the *Newsletter,* Yuki Kuruma, MD, revisits her previously published report of manual ventilation failure due to replacing the absorbent canister during a procedure with one that has a leak due to a crack or hole in the housing.[3] In the current article, Kuruma emphasizes that the risk of failed ventilation due to replacing a faulty canister intraoperatively has not changed since the original report in 2013. Indeed, all of the existing machine designs have that risk, and Kuruma reviews how the impact of a faulty canister can manifest depending upon the machine design. Furthermore, the manufacturers that offer an option for replacing the absorbent during a procedure have not provided specific warnings about the risks of doing so if the canister has a leak nor any best practice for mitigating the risk.

CO_2 absorbent canisters are typically plastic housings containing absorbent material with engineered adapters unique to each anesthesia machine manufacturer. During shipping and stocking, it is quite possible for these canisters to be damaged in a manner that causes a leak when placed in the breathing circuit. The pre-use checkout, whether it is automated or manual, should detect any leaks in the absorbent canister. When the canister is changed intraoperatively, however, it is not practical to perform a leak test since an alternate method of anesthetic delivery and ventilation would be required. As a result, the clinician must rely upon inspection of the canister to identify any potential leaks as well as vigilance once the canister is changed for any untoward impact. The problem is that it can be difficult to identify all sources of leaks by inspection alone.

Depending upon the machine design, placing a leaky canister into the circuit during a procedure will cause changes in gas or anesthetic concentrations and/or failure to ventilate manually, mechanically or both. Furthermore, even if there is no problem with the new canister, when it is first placed, it contains only room air and will alter the concentrations in the circuit as the volume of gas in the canister reaches equilibrium with the rest of the circuit. This change in concentration is especially noticeable when using low fresh gas flow.

Kuruma's suggestion to provide a warning in the IFU, while desirable, is not likely to prevent problems since the IFU is not reliably read. There are some additional options for practices that could help to identify a leaky canister and mitigate patient risk if a leaky canister is placed intraoperatively.

- Before replacing the canister, inspect the new canister for any signs of damage or cracking. If any are present, select another one from inventory.
- After replacing the canister, reduce fresh gas flow and provide several manual breaths by squeezing the reservoir bag and observing

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the monitored values for inspiratory pressure and delivered tidal volume. If it is difficult to create the desired pressure or deliver the intended tidal volume, a leak in the canister should be suspected. This procedure should be useful for all anesthesia machine designs since manual ventilation is impacted similarly in all of the machines.

- Increase fresh gas flow for a few minutes after the integrity of the canister is confirmed and monitor the gas concentrations in the circuit to foster the mixing of desired gas concentrations inside the new canister.

While these practices should help to identify a leaky canister and prevent patient harm, there are some additional possibilities for ensuring the canister is intact before intraoperative replacement.

- Perform a leak test on a supply of absorbent canisters using an anesthesia machine and store these tested canisters in a protected box to be available for replacement.
- Develop a device that can be used to pressure test a canister before it is placed into service. Since the intraoperative change adapters are standardized for each manufacturer, the companies are well positioned to design a pressure testing device that could reside in a supply room for testing a replacement before it is used.

The practice of changing absorbent canisters intraoperatively based upon an inspired CO_2 threshold is a desirable method to minimize the amount of unused absorbent that is discarded, thereby reducing absorbent waste. The information provided here is not intended to discourage the practice of intraprocedure absorbent replacement, but to ensure that providers are aware of the impact of a canister leak. Guidance is provided to help mitigate the risk to patients. Manufacturers of canisters designed for intraoperative replacement are encouraged to provide an appropriate warning and consider recommending best practices for detecting leaks, or developing methods for testing canisters for leaks before they are placed into service.

Jeffrey Feldman, MD, MSE, is an adjunct professor of clinical anesthesiology at the Perelman School of Medicine, Philadelphia, PA. He is also the chair of the APSF Committee on Technology.

He is a consultant for GE Healthcare, Becton-Dickinson, and Micropore, Inc.

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Dräger Anesthesia Workstations & Intraoperative CO_2 Canister Exchange

by David Karchner, MBA; Hans Ulrich Schuler, MSEE, MBA; and Bjoern Goldbeck, MSEE

Dear Editor,

We would like to thank Yuki Kuruma, MD, for her article in this issue of the *APSF Newsletter* where she reviews the risk of introducing a leak into the breathing circuit following intraprocedure replacement of the CO_2 absorbent canister. We also thank the APSF for the opportunity to respond to Dr. Kuruma's submission.

Sustainable practices that reduce waste are important. In anesthesia practice, CO_2 absorbent canister disposal presents an opportunity to minimize waste. Towards that end, many vendors like Dräger have implemented options that support replacing the CO_2 canister during a procedure, enabling users to utilize a larger percentage of each canister's CO_2 absorbent potential instead of replacing the canister at the beginning of the procedure when the CO_2 absorbent is not completely utilized.

Each of Dräger's anesthesia machines provides the opportunity to choose between the traditional "loose fill" CO_2 absorbent, which are always refilled when the anesthesia machine is not in use, and the "CLIC" canister, which provides the opportunity to replace the canister during a procedure based upon evidence that the absorbent is almost completely utilized like elevated inspired CO_2. The loose fill approach inevitably discards useful absorbent material, whereas the CLIC canister minimizes the waste of useful absorbent. Regardless of the strategy, it is important for clinicians to understand the CO_2 absorbent canister is part of the breathing system, and introducing a canister with a leak can negatively impact the ability to ventilate the patient.

As Kuruma's submission indicated, the option for intraprocedure canister replacement is not unique to Dräger, and there will be different responses from each anesthesia machine design when/if a leak is introduced with a damaged CO_2 absorbent canister. While gas concentrations may change with a leak, the inability to ventilate mechanically, manually, or both could also occur. Kuruma observed that it was possible to continue mechanical, but not manual, ventilation when installing a CO_2 canister with a leak that cannot be overcome by increasing fresh gas flow, in a machine with piston or turbovent ventilators. This author requests that anesthesia machine manufacturers provide a warning in their Instructions for Use ("IFU") outlining

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this risk. In response to the report to APSF in 2013 by Kuruma et. al., various explicit warnings, and additional information have been included in the different IFUs of Dräger anesthesia workstations and into the IFU of the CLIC Absorber itself (Figures 1-3).

Similar warnings are presented in the IFUs for the Perseus A500 and Atlan A350.

In addition to these warnings, Dräger anesthesia workstations are equipped with monitoring devices and associated alarms to help identify problems related to intraoperative placement of a leaky absorbent canister. Gas concentration monitoring is essential to safe anesthesia practice and undesired alterations in oxygen, and anesthetic concentrations are easily detected when using appropriately set alarm limits. Breathing circuit pressure and volume alarms are also important to identifying circuit leaks.

We thank Yuki Kuruma, MD, again for bringing the risk of intraprocedure canister exchange to the attention of the anesthesia community and to our attention as a manufacturer. With this information, we as the manufacturer can continuously improve and update our IFU of the relevant medical devices and support users to be better prepared to avoid patient harm.

David Karchner, MBA, is senior director of marketing North America, at Dräger Inc., Telford, PA.

Hans Ulrich Schüler, MSEE, MBA, is global business development manager, Perioperative Care, at Drägerwerk AG & Co KGaA, Luebeck, Germany.

Bjoern Goldbeck, MSEE, is risk manager, Perioperative Care, at Drägerwerk AG & Co KGaA, Luebeck, Germany.

All three authors are employees of Dräger.

Disposable CLIC absorber (Optional)

The disposable absorber can be replaced during operation. The valve in the mounting ensures that the breathing system remains tightly sealed when the absorber is removed.

Note: Since a leak test cannot be performed during operation, no leak and compliance information on the changed absorber is available. Greater attention is required during operation.

Replace the disposable absorber to ensure continuous CO2 absorption in the breathing system.

Figure 1: Apollo IFU (page 117) outlining the need for "greater attention" when changing the absorber during operation.

WARNING!

Risk of misleading data.

Changing the breathing hoses, vaporizers, or soda lime can modify the calculated leak and compliance values of the anesthesia machine and influence the therapy settings.

Perform a leak test after the breathing hoses, vaporizers, or soda lime have been replaced.

Figure 2: Warning in the IFU of the Apollo Anesthesia Workstation (page 118) informing that changing parts of the breathing system, including the CLIC Absorber, may alter the leak or the compliance of the breathing system.

WARNING!

Risk of patient injury

The medical device must be checked prior to each use.

When parts are damaged or incomplete, the medical device must be replaced.

Figure 3: Several warnings are included with the IFU of the CLIC Absorber and CLIC Adapter intended to mitigate the risk of patient injury. Inspecting the CLIC Absorber for damages before use is an important first step. (Instructions for use. CLIC Absorber 800+ / Infinity ID CLIC Absorber 800+ / CLIC Adapter. Dräger Medical. English page 14.)

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Intraoperative CO_2 Canister Exchange When Using GE HealthCare Anesthesia Systems

by John Beard, MD, and Robert Meyers, BS

GE HealthCare anesthesia systems can support intraoperative exchange of carbon dioxide (CO_2) canisters. GE HealthCare anesthesia systems use a bellows design (conceptual diagram, Kuruma, Figure 3) with either the Compact Breathing System (CBS) or the Advanced Breathing System (ABS) depending on the anesthesia machine family. The CBS (Figure 1) supports intraoperative exchange of a CO_2 canister as a standard configuration while the ABS (Figure 2) requires the addition of the optional EZ Change Canister Module.

The CBS is designed with a cam-style lifting mechanism that raises the lower tray (nest) and aligns the absorbent canister with the breathing system ports. The lifting assembly is designed to seal the canister in the breathing system and resist latching if there is any misalignment. When equipped with the optional EZ Change Canister Module, the ABS uses a rotating mechanism to guide the absorbent canister connectors into the mating ports, and is also designed to resist latching if the absorbent canister ports are not aligned. When the absorbent canister is not latched, both systems will display the informational message "CO_2 Absorber Out of Circuit" in the waveform area.

Additionally, disposable canisters (AMSORB Plus, Coleraine, Ireland) sold and distributed by GE HealthCare, are pressure tested at the manufacturer prior to shipping to ensure that leakage does not exceed 10 mL/min at 30 cmH_2O.

In the rare scenario where an intraoperative exchange of a CO_2 canister is associated with a breathing system leak, the bellows-based design of both the ABS and CBS mitigates the impact of the leak during both mechanical and manual ventilation for the following reasons:

- In scenarios where the fresh gas flow is greater than the breathing system leak, there will not be any impact on ventilation or patient gas concentration. The breathing systems in a bellows-based design are positive pressure in operation. This means room air will not be entrained through a canister leak and thus, patient gas will not be diluted by room air.
- In scenarios where the leak is greater than the fresh gas flow, it may still be possible to provide some positive pressure ventilation by either the bag or ventilator. Depending upon the size of the leak, some or all of the intended tidal volume may not reach the patient, and the bag or bellows will eventually collapse. Alarms will be triggered as described below.
- The bellows is a physical barrier between the patient gas and the ventilator drive gas. In the event of a leak in the canister, drive gas will not enter the breathing system and alter the concentration of patient gas.

GE HealthCare anesthesia systems also may help the clinician recognize the leak for the following reasons:

- The bellows and bag provide visual indicators of a leak.
  - The bellows is always visible to the clinician. When a leak is greater than the fresh gas flow, the bellows will collapse providing a visual indication to the users.
  - When the bag is selected, the bag will collapse when positive pressure ventilation is attempted.
- As outlined in the "Alarms and Troubleshooting" section of the anesthesia machine User's Reference Manual,[3,4] the ABS and CBS systems also provide several alarm messages to help clinicians successfully detect a leak.
  - "System Leak?" alarm: This alarm occurs when the drive gas flow from the ventilator is greater than the flow measured by the inspiratory flow sensor (by ~30%) and will help to detect a decrease in

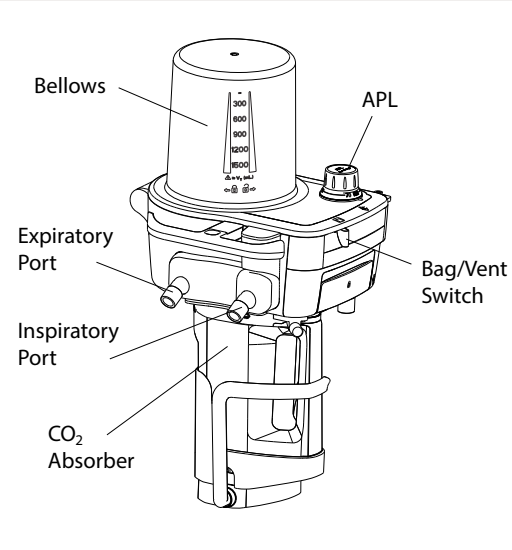

Figure 1: Compact Breathing System.[1]

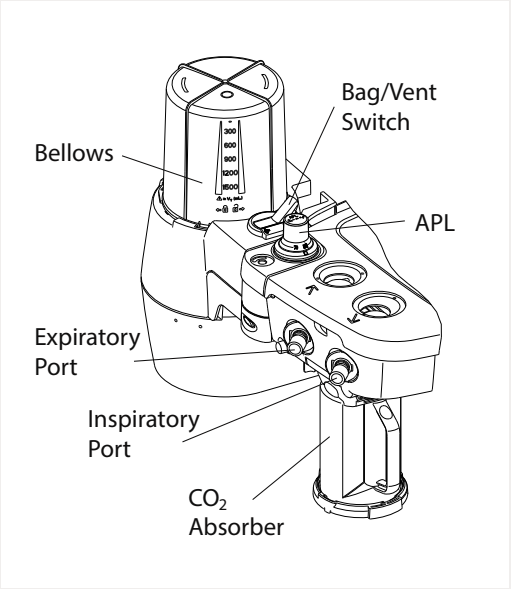

Figure 2: Advanced Breathing System.[2]

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delivered tidal volume. The CO_2 canister is between the drive gas and the inspiratory flow sensor making this the primary alarm to detect this failure prior to the bellows collapsing.

- "TV not Achieved" alarm: This alarm occurs when the volume measured by the inspiratory flow sensor is less than the set tidal volume by ~10% for six mechanical breaths in a row. This alarm will occur in a volume targeted ventilation mode once the bellows collapses far enough to impact ventilation.
- "Unable to Drive Bellows" alarm: This alarm occurs when the system detects that the ventilator driving pressure does not result in an equivalent increase in airway pressure. Like the "TV not Achieved" alarm, this alarm will occur once the bellows collapses far enough to impact ventilation.
- "TVexp Low" alarm: This alarm occurs when the measured tidal volume is less than the user set alarm level. This alarm will occur once the bellows collapses far enough to impact ventilation.

When a clinician identifies a leak with a CO_2 absorbent canister, there are a number of solutions.

- If the leak is not too large, the quickest remedy is to attempt to raise the fresh gas flow above the level of the leak. If that is successful, the bellows (or bag) will reinflate and allow ventilation to continue until the problem can be resolved.
- If the leak is too large to be compensated by increasing fresh gas flow, an alternate method of ventilation (e.g., Mapleson circuit) should be employed and intravenous anesthesia considered.
- Once safe ventilation is assured, the leak in the breathing system can be resolved by exchanging the faulty canister.

In conclusion, GE HealthCare anesthesia systems can support intraoperative exchange of CO_2 canisters. In the rare scenario where an intraoperative exchange of the CO_2 canister is associated with a breathing system leak, the systems are designed to mitigate the impact of the leak, and also provide visual indicators and alarms to help clinicians recognize and address the leak.

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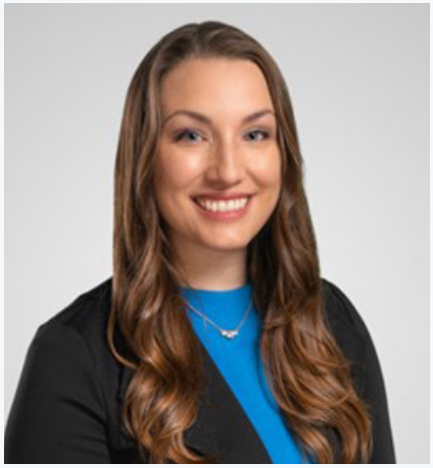
The APSF is eager to connect with patient safety enthusiasts across the internet on our social media platforms. Over the past year, we have made a concerted effort to grow our audience and identify the best content for our community. We've seen increases in followers and engagement by several thousand percent, and we hope to see that trajectory continue in 2024. Please follow us on Facebook at https://www.facebook.com/APSForg/ and on Twitter at https://twitter.com/APSForg. Also, connect with us on LinkedIn at https://www.linkedin.com/company/anesthesia-patient-safety-foundation-apsf-. We want to hear from you, so please tag us to share your patient-safety-related work, including your academic articles and presentations. We'll share those highlights with our community. If you are interested in joining our efforts to amplify the reach of APSF across the internet by becoming an Ambassador, please reach out via email to Emily Methangkool, MD, the APSF Ambassador Program director at methangkool@apsf.org, or Amy Pearson, director of Digital Strategy and Social Media at pearson@apsf.org. *We look forward to seeing you online!*



Amy Pearson, MD, APSF Director of Digital Strategy and Social Media.

SPOTLIGHT on Legacy Society Members

Dr. Eric and Marjorie Ho

Vigilance and safety are integral parts of anesthesia practice. And I had benefited from the *APSF Newsletter* since summer of 1990, both in my practice and teaching of medical students. Now I have retired and want to pay back by joining the APSF Legacy Society.

Drs. Susan and Don Watson

Throughout our careers in pediatric anesthesiology and pediatric cardiac surgery, patient safety has been a fundamental priority. Having trained in the generation before the adoption of pulse oximetry, we have seen vast improvements in monitoring and safety over the decades. The Anesthesia Patient Safety Foundation has been the leader in encouraging, developing and refining safety measures for our patients and our specialty.

We hope that this support of APSF will help the foundation to continue its important mission.

Lynn and Fred Reede

From the first hour of the first day in nursing school and in my nurse anesthesia program, I learned that the care I would provide must be grounded in responsibility to advocate for my patients' safety and best outcomes. Each and every day my classmates and I partnered with patients and their families to understand and improve their plans of care.

I entered anesthesia practice at a time before the routine use of monitors such as pulse oximeters. We had one peripheral nerve stimulator for 16 operating rooms. Fast forwarding across decades, I now celebrate and support the work of many brilliant clinicians, industry partners, and scientists by helping them translate patient and provider safety issues into better techniques, medications, technologies, and quality improvement processes.

Our family's investment in each patient and provider's safety is one of the best gifts we can share for everyone's well-being. We hope that we can all work together to improve our complex and fragmented health care system.

An abiding belief in safeguarding the future of anesthesiology.

Established in 2019, the ***APSF Legacy Society*** honors those who make a gift to the foundation through their estates, wills, or trusts, thus ensuring that patient safety research and education will continue on behalf of the profession about which we are so deeply passionate.

APSF recognizes and thanks these inaugural members who have generously supported APSF through an estate or legacy gift.

For more information about planned giving, please contact Sara Moser, APSF Director of Development at: moser@apsf.org.

Join us! **https://www.apsf.org/donate/legacy-society/**

APSF Announces Development of Third Technology Education Initiative (TEI) Course: Manual External Defibrillation, Cardioversion, and Pacing (MEDCP)

by Michael Kazior, MD; Christopher Samouce, PhD; Daniel Rosenkrans, MD; David Lizdas, BSME; Jeffrey Feldman, MD; Nikolaus Gravenstein, MD; and Samsun Lampotang, PhD

You are taking care of a 64-year-old male undergoing an above-the-knee amputation under general anesthesia. Despite a stable intraoperative course, his heart rhythm suddenly changes to atrial fibrillation with a rapid ventricular response in the 170s. With the change in rhythm, his systolic blood pressure is in the 60s and oxygen saturation is decreasing. You call for help, notify the team, and the operating room nurse brings in the crash cart with the manual external defibrillator. You know that a cardioversion is indicated, and time is of the essence to prevent further decompensation. Do you know where to place the pads? Which setting do you select for mode and at what energy? How will you know you are synchronized for the cardioversion to prevent an R-on-T phenomenon?

Perioperative cardiac arrests are rare and anesthesia professionals play a critical role in timely diagnosis and providing life-saving treatment.[1] An essential skill is the ability to promptly apply and manage the manual external defibrillator (MED). A MED is the device that in-hospital ACLS providers use to perform an indicated defibrillation, synchronized cardioversion, and/or transcutaneous pacing.[2] Since the MED is rarely used, and there is considerable duress in the setting of a life-threatening cardiac event, human error, such as device mismanagement and delay to delivery of therapy, can lead to a failure to rescue.[3-4]

Many hospital systems have transitioned to online, E-Learning programs for Advanced Cardiovascular Life Support (ACLS) certification provided by the American Heart Association (AHA).[5] ACLS providers must complete short, refresher sessions every three months instead of every two years.[5] These online courses do not commonly include education on the use of a defibrillator so many providers no longer maintain or refresh their knowledge of this device. We need easily accessible learning opportunities to teach new providers how to use this device and to allow staff to maintain their knowledge so they are able to quickly and competently use the MED in a crisis.

To meet this educational need, the Anesthesia Patient Safety Foundation (APSF), in collaboration with the American Society of Anesthesiologists (ASA), is announcing the development of a third Technology Education Initiative (TEI) course entitled "Manual External Defibrillation, Cardioversion, and Pacing (MEDCP)". Previous courses have been Low-Flow Anesthesia[6] and Quantitative Neuromuscular Monitoring.[7] These courses use guided interactive simulation to provide an active learning experience for the user to understand complex, technology-based concepts.

The MEDCP course will consist of seven different topics that cover the essentials of understanding and using a MED, each targeted to require about 15 minutes to complete. Like previous TEI courses, guided simulation is used to provide an interactive learning experience. While the topics are recommended to be done in sequence, they do not need to all be completed at the same time for a more convenient learning experience. Highlights of the course include:

Physics of Defibrillators: A brief explanation of the physics behind the device that will allow you to better understand the MED.

Defibrillator Waveforms: Visualize and practice delivering the different types of electricity waveforms emitted from commonly used defibrillators.

Defibrillator Pad (Electrode) Placement: Practice placing defibrillator pads on a simulated patient in the different anatomical locations, including anterior-posterior and anterior-lateral.

Defibrillation, Synchronized Cardioversion, and Transcutaneous Pacing: Use a simulated, generic MED (Figure 1) to practice performing the three main functions of the MED.

The course is projected to be completed in January 2025 and will be available online at the ASA website through the APSF web portal at https://www.apsf.org/TEI/. All the TEI courses are free and readily accessible. Any anesthesia professional or interested party can take any TEI course by creating a free guest account if not already an ASA member. Continuing medical education credits will be available for those that participate including patient safety and quality improvement.

We look forward to completing the course and hope it will be useful in better preparing you to manage a perioperative ACLS event.

Figure 1: Interactive MED Simulation created for TEI 3.

See "TEI Course," Next Page

New Technology Education Initiative

From "TEI Course," Preceding Page

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Allison Bechtel, MD
APSF Podcast Director

Switchover to ISO 80369-6 (neuraxial applications) in Japan: Lessons Learned from Unwittingly Being First

by Sachiko Omi, MD, PhD; Akito Ohmura, MD, PhD; and Katsuyuki Miyasaka, MD, PhD

INTRODUCTION

The International Organization for Standardization (ISO) was established in 1947 as a non-governmental organization (NGO) in the United Nations with the aim of revitalizing the global economy post-World War II. ISO has primarily focused on standardizing industrial products and manufacturing processes to facilitate international trade. Participation and voting rights are on a country-by-country basis, but implementation is worldwide and the way each country aggregates opinions varies.

The ISO standards are formulated primarily by manufacturers, but diverse input from health care professionals is essential in sectors like medical devices. Manufacturers often lead the development of standards due to their expertise in manufacturing processes and regulatory compliance. However, without sufficient input from clinical experts, there is a risk of standards not fully addressing the clinical needs and safety concerns of medical professionals.

Unlike general industrial equipment, many clinical medical devices place greater emphasis on how they are used rather than their technical specifications. It is important to recognize that the ultimate responsibility for the use of medical devices rests with the clinician, who must take full responsibility for the lives of their patients.

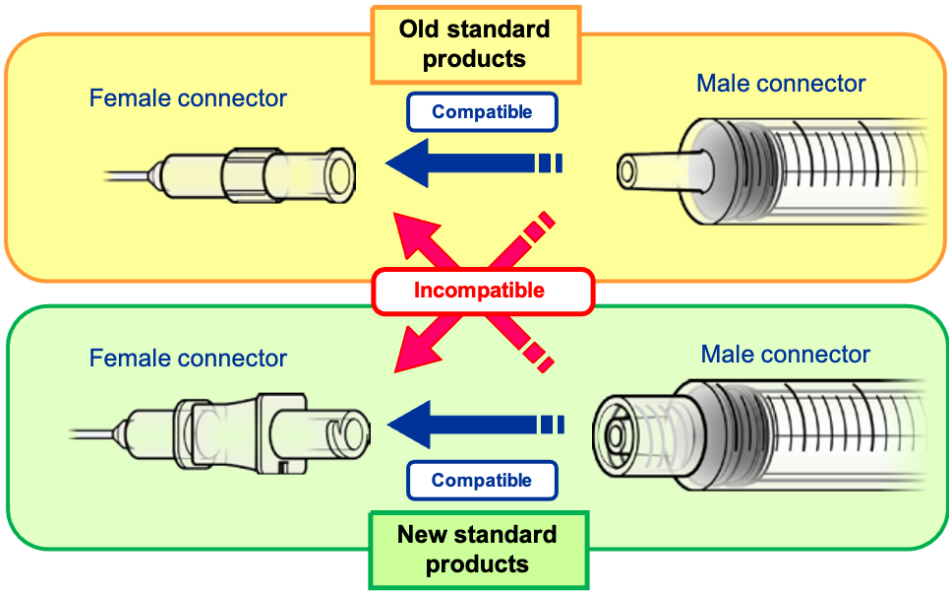

Figure 1: Old standard (Luer) connector and New standard (ISO 80369-6) connector.

PMDA Medical Safety Information, No.55 August 2018, Connections of new and old standard products http://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Despite efforts to integrate the opinions of medical experts through Technical Committees, clinician involvement remains limited in some areas, with manufacturers often driving discussions.

Table 1: ISO 80369:

Small-bore connectors for liquids and gases in health care applications (2016)[2]
• 80369-1 General Requirements and Overview
• 80369-20 Common Test Methods
• 80369-2 Breathing Systems and Driving Gases (Airway and Gas delivery)[a]
• 80369-3 Enteral and Gastric (Stomach)[b]
• 80369-4 Urinary Collection (Urethra) – Postponed
• 80369-5 Limb Cuff Inflation (Tourniquets and BP Cuffs)
• **80369-6 Neuraxial (Spinal, Epidural) – issued March 2016[c]**
• 80369-7 Intravenous (Arterial/Venous)[d]

a) Issued as of April, 2024, but not implemented in Japan.

b) The smaller diameter of the new standard caused multiple practical problems, found after implementation started in 2019. The switchover could not be completed, and in May 2022, Japan was forced into having two standards exist at the same time.

c) Discussed in detail in the text.

d) This was revised to be consistent with previously used and readily available intravenous devices; thus, the adoption in clinical settings was completed without much awareness.

ISO 80369

Growing international awareness of medical safety spurred the ISO to address medical accidents caused by misconnections and misadministration by developing unique connector design standards for enteral, respiratory, urinary, blood pressure, neuraxial, and intravenous patient care systems.[1,2] ISO started releasing the ISO 80369 series of standards in 2016.[2] Participating countries have been encouraged to adopt these international standards without delay (Table 1, Figure 1).

Japan implemented a nationwide introduction of ISO 80369-6 (neuraxial applications) under governmental leadership upon receiving information (source unknown) that the introduction of ISO 80369-6 had begun globally, including parts of the United States. The transition is now almost complete, and while no major accidents involving loss of life have been reported during the transition process, numerous serious issues were experienced. As far as we know, no other country has yet fully switched over to this new standard, so Japan's experience can contribute to patient safety worldwide by raising awareness of the associated problems that can occur.

See "ISO 80369-6," Next Page

The Development of ISO 80369 in Japan Was to Minimize Human Error

From "ISO 80369-6," Preceding Page

NEED FOR NEW STANDARD FOR NEURAXIAL APPLICATIONS (ISO 80369-6)

For many years in clinical practice, the Luer connection (ISO-594) was standard for injections and connecting small-diameter tubing. Health care providers benefited from the convenience provided by its universal connectivity. However, preventing accidental injections due to misconnecting Luer connections depends solely on the vigilance and responsibility of the medical personnel involved.

Human error, an unavoidable cause of patient injury, has therefore led to misconnecting many types of medical devices.[1] Discussions on the ISO 80369 series began around 2005 with the goal of developing purpose-specific connections utilizing physical noninterfacing mechanisms specific to each application to ensure that misconnections are simply not possible.

Discussions on a purpose-specific compatibility standard for preventing misconnections (ISO 80369 series) were undertaken by ISO in Technical Committee 210 (TC 210, quality management), liaising with TC 121 via Joint Working Group 4. TC 210 covers a broader range of topics and is not necessarily an anesthesia-focused TC, especially compared to TC 121 where many prominent anesthesia professionals participate. A joint working group was formed under TC 210 to convey the voices of TC 121 on this matter, but, unfortunately it was ineffective.

Anesthesia professionals have actively participated since the early stages, making significant contributions to the field of anesthesia and intensive care. TC 121 has SC-3 (Subcommittee) that deals with products directly handled by anesthesia professionals, such as ventilators, oxygen concentrators, and related patient monitors.

THE DECISION-MAKING PROCESS FOR THE IMPLEMENTATION OF ISO 80369-6 IN JAPAN

In Japan, the implementation system essentially remains the same as it was when ISO was first established. The main supervisory body for medical devices that affect human lives is the Ministry of Health, Labour, and Welfare (MHLW), which also holds licensing authority. However, the Ministry of Economy, Trade and Industry (METI), which oversees general industries, liaises with ISO. In practice, information flows from METI to MHLW. As a result, there is a lack of supervision and a lack of proactive participation by clinicians on a domestic and international level.

When the implementation of ISO 80369 was first discussed at the Safety Division of MHLW in 2015 with some health care representatives, the switchover to ISO 80369-6 was already assumed. Concerns were raised at the time by anesthesia professionals regarding potential confusion from the switchover, but in practice, there were no meetings that included clinical physicians or the Japanese Society of Anesthesiologists (JSA). The procedures and deadlines for the introduction were determined between MHLW and an industrial organization, MTJAPAN. The Ministry explained that Japan, as a member of the World Trade Organization, has a fundamental obligation to comply or harmonize with ISO standards.[3] Although exceptions do exist, Japan is required to adopt the ISO standard as the national standard without delay after a new standard is issued, and changes that would create international trade barriers are not permitted.

While it is essential to carefully consider the risk-benefit balance in clinical settings before implementing ISO standards, there are no organizations or opportunities to deliberate on these considerations in Japan.

The MHLW issued a notification in December 29, 2017, stating that the sale of old products affected by ISO 80369-6 must cease by the end of February 2020. The deadline for product supply was set at the convenience of the company, so anesthesia professionals had no choice but to comply.

At the strong request of anesthesia professionals onsite, an interchangeable adapter was not introduced for safety reasons. Awareness activities were conducted by the industry association for manufacturers and suppliers (MTJAPAN), targeting relevant academic societies. The Pharmaceuticals and Medical Devices Agency (PMDA) provided specific details on the implementation procedures. Despite these measures, awareness of the need for and possibility of switching was not well known to anesthesia professionals.

MHLW SURVEY ON THE SWITCHOVER TO ISO 80369-6 IN JAPAN

The transition was carried out and the switchover was completed in approximately two years. In June 2024, MHLW released a report on the transition to ISO 80369-6, which began in 2021.[4] The report includes the results of a postal survey of limited scope, of anesthesia professionals and MTJAPAN. The survey was mainly targeted at facilities accredited by the Japan Society of Anesthesiologists (JSA), with 1447 facilities contacted, and 329 valid responses.

The MHLW survey was not intended to ascertain patient-related contingencies, but rather to investigate product-related issues; thus, there was a possibility for under-reporting untoward events handled by anesthesia professionals.

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Numerous Breakages and Leakages of the New Connectors Were Reported

From "ISO 80369-6," Preceding Page

MHLW SURVEY RESULTS AND ISSUES

The main survey results are summarized in Table 2. We were shocked by the number of initial troubles experienced.

Inadequate advisories before the switchover put clinicians at a disadvantage, as they were not prepared for the changes. Numerous cases of breakage and leakage during patient care were reported. No patients were harmed due to quick thinking on the part of anesthesia professionals.

Drug misadministration was a constant worry as connector sets with connectors and prefilled syringes were not fully available.[5] Errors due to incorrect connection to medication were avoided only due to professional diligence.[6]

Incomplete switchovers, due to the nonavailability of all syringes and connectors, created confusion at the bedside, as old and new connectors were placed side by side. Other unnecessary confusion resulted from poor translation, overlap in connector colors, inadequate product availability, and wasted resources. Above all, there were no processes available to clinicians, before or after the switchover, to convey or report problems.

Several issues were raised, as follows:

1. Insufficient clinical involvement

Both the ISO 80369-6 standard formulation process and the Japanese domestic implementation process by the government and manufacturers suffered from lack of practical clinical information.

Once ISO 80369 standards were set, there was little discussion of whether to implement or accommodate the domestic clinical situation by governmental agencies in Japan.

2. Imbalanced perspectives (clinicians, manufacturers, and regulatory agencies)

Manufacturers assumed it was acceptable, indeed unavoidable, to produce fittings that,

Table 2: Issues Encountered With the Change to ISO 80369-6.

Timeline	Issue	Details
Before Switchover	Awareness	ISO and MHLW failed to convey the rationale of their new guidelines to the clinicians who would be most affected. Neither anesthesia professionals* nor academic societies in Japan felt a strong need to change the connection standard, but they had to follow governmental regulations that mandate ISO rules.
	Guidance	The manufacturing organization, MTJAPAN, lacked the product and clinical information needed to adequately guide health care providers through the transition.
	Product range	Some manufacturers discontinued making certain products upon the transition, reducing the range of available products.
	Translation	Mistranslation of "Neuraxial application" as "Neural anesthesia" in Japanese led to confusion that the change only applied to spinal anesthesia, epidural anesthesia, and peripheral nerve block patients. Systems for spinal tap or therapeutic applications were left out.
After Switchover	Initial and ongoing troubles (breakage)	Initial troubles included cracking, leakage, too tight fit, and nondisengagement (MHLW Postal survey of 1447 accredited institutions: 329 responses, 83 cases of connector cracking, 61 of leakage, and 47 of nondisengagement, etc.).[4]
	Errors in drug administration	The switchover to the new standard did not prevent drug misadministration.[5] While the connections at the patient-side were secured, the medication-side was left unchanged. Standard-compatible prefilled syringes or plastic ampules were not available for all situations. The existence of standard-compatible and noncompatible aspiration needles to make up medication mixtures at the bedside created windows for mistakes.
	Different feel in use	Despite differences in feel (fitting force, injection pressure, sensation in the loss of resistance) between new and traditional products, there were no opportunities for clinical testing, requiring users (anesthesia professionals) to adapt on their own. Special advice released by MTJAPAN to avoid cracking was limited to requests to use the product "carefully" and was not helpful.
	Hard to differentiate	The addition of covers to protect mechanical weakness caused by smaller diameters of the syringe tip made it difficult to distinguish between lock and Luer connectors.
	Color confusion	Initial confusion was caused by the adoption of yellow for new neuraxial products because yellow syringes were already used for enteral purposes** in Japan.
	Less convenient	Procedures became more complicated, where single standard products under the old specifications (e.g., autologous blood patches) could no longer be used, reducing convenience, with possible increased risk.
	Increased costs	Disposal of old product stock; inadequate reimbursement for the much more expensive new products: securing new storage space for the increased number of new products; increased costs of producing multiple narrowed specific product lines
	Lack of systems for problem reporting and support	There are no established systems for reporting issues, sharing information, or providing guidance on handling mechanical or clinical problems.

* In Japan, only physicians are allowed to engage in neuraxial anesthesia procedures.

** Japanese old local noninterchangeable enteral products were labeled yellow at the time ISO 80369-6 was introduced.

ISO = International Organization for Standardization; Ministry of Health, Labour, and Welfare = MHLW.

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Japan is First Country to Adopt ISO 80369-6 Standards

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while compliant with the standard, were hard to use, especially by uninformed users. Clinicians, had they been aware of this, would have refused to use products as patient safety was at risk.

The transition to smaller diameters without clinical trials led to confusion in usage related to changes in liquid flow and increased push-in and rotational forces. Problems included difficulty of use and snap breakage of connectors. This forced clinicians to deal with issues like extra-strong fittings and liquid leaks from cracked connectors while working in the field.

3. Lack of clinical feasibility trials

It was absolutely necessary to do clinical feasibility studies across products (between products of various companies) before domestic implementation to avoid patient harm and physician's liability. However, clinical feasibility trials before full-scale introduction were actively denied based on a false and biased perception among regulatory agencies and manufacturers saying this would violate competition laws. Most of the problems Japan experienced during implementation could have been avoided with proper information and preparation. It is regrettable that clinicians were effectively eliminated from this discussion, with their only option being to accept the administrative decision.

4. Lack of transparency

Regulatory agencies were under the mistaken belief that clinical feasibility trials were unnecessary as the newly introduced products already complied to the new authoritative ISO standard. Manufacturers did not see the need to inform clinicians of "small" changes in how the new products fit together. Clinicians were not aware of this situation in Japan and had no place to address these concerns.

The consensus-building process in ISO is not available to those outside the group, but compliance with the standards produced is mandatory and strongly promoted by local administrative agencies in Japan. At present, users (clinicians), who are required to follow the standards, are only able to learn about them after purchasing ISO's official publications.

This process needs to be improved as it not only impedes the timely dissemination of information, but also is too technical for ordinary health care workers to understand. Unaware that the new standards resulted in products that differed significantly from before, clinicians experienced such dire clinical consequences as liquid leaks and cracked connections due to extra-strong fittings. They had to deal with such problems while patients were undergoing procedures.

ROLE OF CLINICIANS IN DOMESTIC IMPLEMENTATION OF ISO STANDARDS

Domestically, challenges arise in ensuring standards meet local health care requirements, usability, and patient safety. These include consideration of product availability, changes in functionality from preexisting standards, education level, and scope of professional responsibility.

Feasibility studies by clinicians before introduction are crucial to protect patients and validate the efficacy of the standards in specific national contexts, but were denied under the pretext of competition law. Effective integration of ISO standards requires balancing manufacturer efficiency with comprehensive clinician involvement and responsive domestic adoption processes. From a clinician's perspective, the lack of clinical usability tests before the implementation was truly regrettable.

A similar issue is happening with ISO 80369-3 (enteral applications). Pediatricians experienced practical problems, such as the inability to administer blended diets or to aspirate stomach contents because of the much smaller diameter of the new standard. The switchover, which started in 2019 and was to be completed by 2021, was delayed. MHLW already had introduced its own noninterchangeable connection in 2000 (MHLW No. 888) that was well-received, but was forced to switch to ISO 80369-3. Japan was forced into allowing both the old and new standards in May 2022.[7] Confusion persists to this day.

Incredibly, such a basic error went unnoticed during the creation of the ISO standard. Japan introduced its own noninterchangeable enteral connection standard in 2000, and it is regrettable that the already-proven Japanese standard was not adopted by ISO.

SUMMARY

ISO issued a series of ISO 80369 standards to physically restrict connections between syringes, needles, and other small-diameter components to their intended purposes only. Japanese administrative authorities started a nationwide initiative to introduce ISO 80369-6 (neuraxial applications) in 2018 as part of the implementation of the new standards. To our knowledge, this is the first country level switchover in the world.

This decision was made without adequate consultation with clinicians or professional anesthesia organizations. New products were approved in Japan if they conformed to the new ISO standards, but were introduced into clinical practice without any preliminary feasibility trials. Anesthesia professionals in the field lacked sufficient information and encountered numerous unexpected problems, such as breakage and leaks.

No disastrous accidents involving human lives were reported during the switchover, but we experienced serious incidents that cannot be ignored.

Clinicians and medical societies, such as JSA and APSF, should become more involved to raise awareness in ISO, industry, and domestic regulatory agencies of the essential importance of clinical input. One of the reasons the government and industries have an overly strong voice in Japan is related to the extreme fragmentation of medical specialties making it harder for everyone to work together.

In a clinical setting, it is very important to consider how a product is used coupled with the quality of the product itself. The most important thing is to protect patients' lives. Anesthesia professionals must not condone situations that threaten patient safety. We should be more involved in the decision-making process of perioperative devices approved by the ISO.

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The authors have no conflict of interest.

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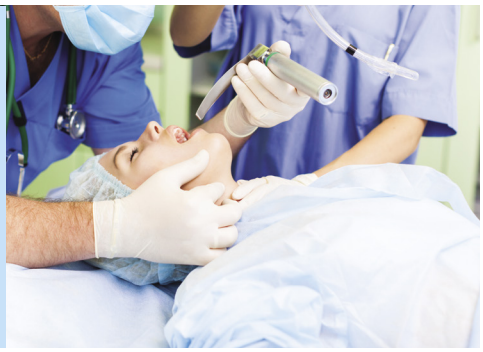

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