Nonoperating room anaesthesia: safety, monitoring, cognitive aids and severe acute respiratory syndrome coronavirus 2

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Purpose of review
With an ageing population, mounting pressure on the healthcare dollar, significant advances in medical technology, and now in the context of coronavirus disease 2019, the traditional paradigm in which operative procedures are undertaken is changing. Increasingly, procedures are performed in more distant, isolated and less familiar locations, challenging anaesthesiologists and requiring well developed situational awareness. This review looks at implications for the practitioner and patient safety, outlining considerations and steps involved in translation of systems and processes well established in the operating room to more unfamiliar environments.

Recent findings
Despite limited nonoperating room anaesthesia outcome data, analysis of malpractice claims, anaesthesia-related medical disputes and clinical outcome registries have suggested higher morbidity and mortality. Complications were often associated with suboptimal monitoring, nonadherence to recommended guidelines and sedationist or nonanaesthesiologist caregivers. More recently, clear monitoring guidelines, global patient safety initiatives and widespread implementation of cognitive aids may have contributed to nonoperating room anaesthesia (NORA) outcomes approaching that of traditional operating rooms.

Summary
As NORA caseloads increase, understanding structural and anaesthetic requirements is essential to patient safety. The severe acute respiratory syndrome coronavirus 2 pandemic has provided an opportunity for anaesthesiologists to implement lessons learned from previous analyses, share expertise as patient safety leaders and provide valuable input into protecting patients and caregivers.

Keywords
anaesthesia in pandemics, cognitive aids and COVID-19, non-operating room anaesthesia, patient safety

INTRODUCTION

Demand for anaesthesia outside the operating room (OR) has increased, and the issue of patient safety in these locations is not new. The American Society of Anesthesiology (ASA) first published guidelines on office-based anaesthesia (OBA) in 1999, recognizing this rapidly expanding area with the expectation of both real and potential complications [1].

Since then, the term nonoperating room anaesthesia (NORA) has become all-encompassing to include not just OBA, but a rapidly expanding variety of technologically advanced procedures now being undertaken within major institutions, small hospitals and clinics – outside of the traditional operating theatre environment (Table 1). Anaesthesiologists no longer just step into the reassuring and familiar environment of the OR, but are often delegated to darkened, unfamiliar surrounds in which new, complex and sometimes 'hidden' minimally invasive procedures require anaesthetic services.

It has been suggested that given the large number of NORA procedures (35.9% of all cases in 2014 in the United States) and rapid growth (the greatest of any sector of anaesthetic caseload), a change in both anaesthetic culture and training curriculums is

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KEY POINTS

- NORA outcomes can fall short of high-reliability organizations or OR standards.
- Modifiable factors include deficiencies in monitoring, environment and communication.
- Addressing infrastructure deficiencies, promoting safety culture and utilizing cognitive aids are effective intervention strategies.
- Widespread use of cognitive aids during the severe acute respiratory syndrome coronavirus 2 pandemic may encourage continued use in the perioperative environment.

warranted [2–4]. Anaesthesiologists have been pioneers of patient safety with their broad interspecialty reach, extensive medical training, crisis management and resuscitation expertise. They must provide guidance in establishing anaesthesia protocols and procedures for locations outside traditional ORs and take a leading role in educating nonanaesthesia providers and supporting staff, to both maintain and improve the specialty's excellent safety record [5].

The recent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic is a prima facie example of anaesthetists providing leadership, protocols and guidance for anaesthesia in emergency departments, ICUs, wards and makeshift field hospitals [6▪▪,7▪▪].

The current review will examine the specific challenges of maintaining the highest standard of patient safety while providing anaesthesia services in a nontraditional operating environment.

Table 1. Table of nonoperating room anesthesia procedures

Radiology	CT scan
	MRI
	PET
Interventional radiology/ neuroradiology	*Vascular*
	Angioplasty
	Stenting
	Embolization
	Thrombolysis
	Vascular imaging/stenting/embolization
	Therapeutic pain procedures
Cardiology	Catheterization
	Angioplasty
	Stenting
	Transcatheter aortic valve implantation
	VAD placement
	Electrophysiological studies/RF ablation
	Pacemaker/Defibrillator insertion
	Transoesophageal echo
	Cardioversion
Gastroenterology	Endoscopy/colonoscopy
	ERCP
	Esophageal dilation/stent insertion
	Gastrostomy feeding tube placement
Others	Radiotherapy
	Electroconvulsive therapy
	Dental work
	Cosmetic procedures
	ED ICU intubation/procedures

Nonoperating room anaesthesia adverse event analysis

In the current pandemic climate, safety issues concern both the patient and caregiver. They can be broadly classified as deficiencies in material equipment, training and staffing resources – all significant contributors to the tragic loss of healthcare workers (HCWs) to coronavirus disease 2019 (COVID-19) [8▪]. Human error is responsible for the majority of preventable anaesthesia mishaps, but equipment design, inadequate familiarity or experience, poor communication, fatigue, failure to complete usual checks, environmental factors and distraction were contributing factors [9]. These factors continue to impact on the safety of frontline workers and patients during the SARS-CoV-2 crisis.

Despite limited NORA-based outcome data, attempts have been made to assess its safety. Analysis of malpractice claims from 1990 to 2002 and 2000 to 2012 indicated NORA locations had a higher proportion of claims for death compared with the OR. Claims for adverse respiratory events, including hypoventilation, aspiration and difficult intubation, occurred with at least twice the frequency [10]. Poor outcomes were often associated with suboptimal care and nonadherence to safe practice [10,11].

Complications in NORA locations may relate to frailty of the patient population, risks associated with the procedure being performed, or deficiencies in translation of systems and processes from the OR to the NORA location. The latter is the most amenable to improvement, with education focussed on recognizing and implementing safety standards regarding equipment, personnel and facilities, as well as the use of cognitive aids such as aviation-style checklists, to improve team performance in routine and crisis situations [12]. Time to prepare, write checklists and protocols, educate and train using simulation is likely to influence morbidity and mortality.

Complications from units in which NORA is conducted exclusively by NORA-experienced anaesthesiologists in relatively young and healthy patients are low, whereas historical cohorts or units in which NORA is provided by nonanaesthesiologists, or in acutely ill patients and those with increasing rates of chronic disease, have higher rates.

ASA Closed Claims Study using database entries from 1990 to 2002 found claims for mortality were almost twice as common (as a proportion of claims) for NORA compared with ORA [13]. Patients were older, sicker and more likely to be emergencies. A retrospective study of 16 383 NORA cases between 2013 and 2017 in a Korean tertiary hospital found mortality rate was similar to operating room cases (4.9 vs. 4.3 per 100 000) [14]. However, characteristics of this NORA cohort were healthier patients and shorter, less invasive procedures, with less emergency cases. All NORA cases were under the care of a dedicated NORA-experienced anaesthesiologist. In comparison, an analysis of anaesthesia-related medical disputes between 2009 and 2014 in a Korean Society of Anesthesiologists Database found a disproportionate number of poor patient outcomes occurred after procedural sedation, the majority conducted by nonanaesthesiologists, and commonly associated with deficiencies in preprocedural testing, intraprocedural monitoring and documentation [11]. However, it is worth noting that more recently, Chang *et al.* [15] reported a lower complication rate for NORA procedures from examination of the National Anesthesia Clinical Outcomes Registry.

Environment characteristics

Increased noise, limited workspace, inadequate lighting, temperature regulation, electrical interference, unfamiliar or outdated equipment, lack of additional resources (equipment, drugs or personnel) are potential challenges in NORA [10]. Notably, working in personal protective equipment (PPE), and confined spaces as well as PPE shortages can all contribute to cognitive load.

Concern about NORA safety includes the lack of fully configured anaesthesia equipment, reduced availability of anaesthesia manpower due to geographical dispersion or illness, an unfamiliar working environment and absence of a properly equipped, geographically-near recovery room. These may predispose practitioners to deliberate violations of standards of care.

MONITORING

There are two critical components to monitoring physiological status in sedated or anesthetized patients: the measuring equipment displaying patient data, and the caregiver who reads, interprets and acts on information provided. Standards of each can vary in the NORA environment. The majority of respiratory closed claims involve monitored anaesthetic care (MAC), and a significantly greater proportion of NORA cases (than OR cases) were judged to be preventable by better monitoring, particularly capnography [10].

Historically, the anaesthetic provider has always been in close proximity to the patient using sight, sound, touch and even smell to assess airway, oxygenation, ventilation, circulation and temperature, as well as equipment function. As both diagnostic and therapeutic technology develops, there is increasing separation between patient and practitioner. Physical separation in locations such as cardiac catheter or MRI suites mandates reliable, appropriately positioned and procedure-specific monitoring equipment.

Standardizing equipment within hospital departments is the ideal and an important step in mitigating risk when anaesthetizing in unfamiliar, crowded and darkened surrounds. Departments having grown through expansion and renovation are more likely to maintain older, nonstandard equipment than NORA locations newly built after appropriate anaesthesia consultation. Regardless, clinicians should be mindful that current ASA guidelines for monitoring in NORA procedures are the same as for the OR [16].

An example of inadequate monitoring is the failure to utilize capnography, despite studies showing superiority of capnography over oximetry in prevention of apnoeic episodes during MAC [17,18]. In one analysis of claims related to anaesthesia, end-tidal CO_2 monitoring was absent in 80% of cases [19].

The second monitoring variable is the skillset of the person responsible for assessing and acting on monitor feedback. In some countries, the rate of growth of NORA procedures has exceeded the supply of qualified anaesthesiologists to service demand. As a consequence, more nonanaesthesiologists are providing sedation and this may be contributing to adverse outcomes. Studies show a higher percentage of MAC-associated complications in gastrointestinal/endoscopy units compared with cardiology or neuroradiological procedures [20]. This may partly be explained by both the increased monitoring and the anaesthetic caregiver's qualifications and experience required for the latter due to procedure-related complexity and risk.

Deepening sedation by nonanaesthesiologists can rapidly lead to general anaesthesia [21,22] (Table 2) and training may not always be adequate

Table 2. Continuum of depth of sedation

	Minimal sedation/ anxiolysis	Moderate sedation/ analgesia (conscious sedation)	Deep sedation/analgesia
Responsiveness	Normal response to verbal stimulation	Purposeful[a] response to verbal or tactile stimulation	Purposeful[a] response after repeated or painful stimulation
Airway	Unaffected	No intervention required	Intervention may be required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained

American Society of Anesthesiology.
Continuum of Depth of Sedation.
[a]Reflex withdrawal from a painful stimulus is NOT considered a purposeful response (excerpted from ASA [22] with permission of the American Society of Anesthesiologists, 1061 American Lane, Schaumburg, Illinois 60173-4973.).

for the task. A review of the Korean Society of Anesthesiology database from 2009 to 2014 revealed avoidable complications in 34 of 39 cases, 92.4% involving nonanaesthesiologists [11].

Advanced monitoring

More complex and technologically advanced NORA procedures generally have a greater risk of potentially catastrophic complications. Cardiac catheterization may only require basic monitoring depending on individual assessment, but percutaneous transcatheter valve replacement, endoluminal vascular stenting and neuroradiological procedures often involve arterial lines, central venous catheters, pulmonary artery catheters or transoesophageal echo placement. Physical access to patients and ability to monitor parameters becomes an issue. Monitors are placed preprocedure (rather than in response to unforeseen complications or catastrophes) and if there is uncertainty regarding indications, a conservative approach to include is prudent. Geographical constraints, limited access, ergonomic challenges, competing priorities and limited anaesthetic support in the NORA location can make subsequent placement exceedingly difficult. Standardizing set ups for procedures (albeit with flexibility) can help reduce anxiety and prevent procedure interruptions.

Finally, the use of video camera monitoring strategically placed when the anaesthesiologist is far removed from the patient can be helpful in detecting patient or limb position changes, movement, or abnormal ventilatory patterns.

SAFETY

Safety in NORA should be approached no differently to the normal OR. In much the same way passengers assume safety when embarking on air travel, patients undergoing procedures in modern healthcare institutions expect similar safety standards.

This assumption of safety was spectacularly dismantled by the 1991 landmark Harvard Medical Practice Study [23] demonstrating adverse events as a consequence of medical care in 3.7% of hospital admissions. Even more concerning was the alarming 16.6% in a follow-up Australian analysis of which 51% were deemed preventable [24]. By comparison, an aviation accident rate of two per 1 million flight sectors and fatality rate of one per 2.6 million flight sectors suggests there is room for improvement in the healthcare-industry pursuit of High Reliability Organisation (HRO) status [25].

Barriers

Although principles of OR safety also apply to NORA, it poses peculiar and specific challenges. These are commonly categorized as those associated with the patient, procedure and infrastructure or environment. Institutional patient safety culture can also influence outcomes [26] and could be considered a fourth category.

Communication

An honest, accurate and clear exchange of information regarding degree of anaesthetic intervention required, type of procedure, potential complications, duration, positioning, potential crisis intervention and planned postprocedure care can help mitigate risk [27,28]. Proceduralists sharing information from discussions with patient, family or friends, enable the anaesthesiologist to carefully plan technique, titrate anaesthesia and anticipate or avoid likely complications such as airway obstruction, worsening or new onset cardiac failure, or procedural catastrophes such as inadvertent aortic, atrial or ventricular puncture during cardiac procedures.

Team communication and planning with a shared mental model has received significant emphasis by pandemic intubation teams to both reduce HCW contamination and patient morbidity.

Procedure

For the anaesthetic caregiver, the remote nature of some NORA procedures provides added incentive for clear, open communication consistent with crisis resource management (CRM) principles [29]. Direct means for communicating with support teams (usually located in the operating complex) are needed. In the context of pandemic intubation, this may require intercom systems or whiteboards clearly visible from an anteroom.

A greater percentage of NORA procedures occur after hours, particularly emergencies [30]. Equipment availability, appropriately trained staff current in knowledge and skillset, as well as availability of extra staff needed during crisis management, may all be compromised during out of hours procedures. However, to date whether after hour starts or the emergency nature of procedure contribute to poorer outcomes is not known [31▪].

Infrastructure

Unlike traditional ORs, constantly evolving NORA locations may not be designed with a clear vision for anaesthesia. Common deficiencies include a small anaesthesia workspace, darkened environment, aging or nonstandard equipment, immovable tables, poor patient access and limited availability of resources commonly accessible in OR complexes. Reasons may include the simplicity of earlier, noninvasive procedures requiring minimal anaesthetic input, the use of nonanaesthesiologist sedationists, and possible department fixation on the evolving complexity of procedures more than support services. The remarkable anaesthesia safety record in developed countries over the last 50 years may also contribute to complacency and lack of understanding of the anaesthesiologist's work, knowledge and skill involved in such an achievement [32]. Regardless, it is incumbent on the anaesthesiologist to be satisfied that the environment and equipment meet current guidelines.

Safety culture

Culture is defined as a set of shared attitudes, values, goals and practices that characterizes an institution or organization and provides the foundation for establishing safe NORA locations.

Although more difficult to assess, institutional or departmental culture may affect patient outcomes [33,34]. Creating a 'just culture' in which organizations approach medical mishaps or errors as a systems failure rather than blaming individual practitioners is considered integral in establishing safe practice. These principles of a just culture apply equally across all healthcare but for reasons outlined above may be especially important in bringing disparate groups of HCWs under one umbrella (as with NORA procedures) with the common goal of best and safe practice [35]. Anaesthesiologists have always played a key role in patient safety leadership and should be consulted in the planning phase of any new NORA procedure or facility [36,37]. Involvement includes location design/layout, equipment, staffing requirements and implementation of safety behaviours including checklists, protocols and adherence to guidelines. Such highly valued input from anaesthesiology leaders has been a crucial component of the SARS-CoV-2 response.

COGNITIVE AIDS

Perhaps there has never been a more compelling incentive for the employment of cognitive aids than COVID-19. The use of cognitive aids, including safety checklists, has been shown to improve mortality and morbidity in healthcare settings. They are considered an integral component of the patient safety movement and initiatives such as the Helsinki Declaration [38]. Particularly relevant for NORA locations, safety checklists can improve communication, reduce adverse events, and result in better adherence to standard operating procedures [39–41]. However, experience during the SARS-CoV-2 pandemic with makeshift isolation rooms, confined and unfamiliar intubation environments and ad-hoc team formation suggest dual benefits – patient safety and protection of HCWs [42▪▪].

Cognitive aids encompass a broad range of written or electronic checklists, protocols or prompts to assist the user in completing complex and 'tightly coupled' tasks (where failure in one system component quickly leads to failure in another) requiring highly synchronized team performance. They present in different forms, from simple diagrams such as the Vortex Approach to Airway Management [43] to the more carefully worded, evidence-based and guideline-directed emergency manuals now seen in the perioperative environment [44,45▪,46]. More recently a return to pictorial format, not unlike aviation passenger emergency cards, has played a key role in PPE training for frontline HCWs [47].

Cognitive aids in HROs and high-risk industry are commonplace. They have also existed in anaesthesia for many years in the form of airway algorithms, malignant hyperthermia protocols and equipment checklists, but with limited success. It is perhaps only since the anaesthesia-lead patient safety movement, introduction of the Surgical Safety Checklist and anaesthesia or perioperative 'crisis manual' concept (collections of context-specific cognitive aids) that renewed interest in

potential benefits to patient outcomes emerged. Despite enthusiasm from the anaesthesiology community, implementation continues with only varying degrees of success [48].

Difficulty in cognitive aid engagement persists but simulation studies continue to demonstrate improved implementation of evidence-based guidelines and less errors of omission. It is likely in the NORA environment, cognitive aids may be particularly beneficial. Unfamiliar staff, infrequent exposure to anaesthetic or perioperative emergencies, managing older or nonstandard equipment and isolation from colleagues may add to the cognitive load of the anaesthesiologist. Cognitive aids may help reduce this load, alleviate stress and provide a shared mental model for those staff members involved [49]. Hospital working conditions during pandemics such as SARS-CoV-2 are particularly challenging and it is exactly this environment in which cognitive aids may contribute to improved outcome for patients and HCWs.

NORA implementation of cognitive aids requires all the lessons learnt and shared by the Emergency Manual Implementation Collaborative [50]. Ideally, each NORA unit should have a local champion to select an emergency manual or cognitive aid; present at meetings; familiarize, motivate and train staff; monitor use, encourage feedback and direct multidisciplinary team debriefings. Simply placing cognitive aids in anesthetizing environments is likely to fail without these measures [51].

Significantly, despite the reluctance by highly educated and skilled anaesthesiologists to routinely use cognitive aids, particularly intubation checklists, there has been widespread adoption in the current crisis. Perhaps, like commercial pilots, the added incentive of injury to oneself as well as patients (going down with the plane) has been the trigger needed to finally change the collective mind.

It is important there is no confusion as to the role cognitive aids play in safety. They are designed to assist the treating clinician during high cognitive load, time sensitive perioperative events, but should not be considered a substitute for well trained, experienced and knowledgeable staff. However, even the most senior clinicians can miss important steps and cognitive aids may be particularly relevant for NORA locations where emergencies are either not expected, occur in isolated environments or staff turnover is high.

CONCLUSION

There is the same patient safety expectation in NORA locations as for anaesthesia in the OR but achieving this requires recognition of additional NORA-specific challenges. Standardization of preanaesthetic assessment, equipment and monitoring to align with requirements for anaesthesia in the OR is an achievable goal. The use of cognitive aids and CRM principles are ideal for overcoming the challenging environment of NORA locations supported by nonoperating room staff, remote from OR infrastructure. In the era of COVID-19 and the threat to both patient and HCW, embedding cognitive aids in all anaesthesiology working environments has never been more important.

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Conflicts of interest

D.B. receives royalties on the sale of The Anesthetic Crisis Manual, The Resuscitation Crisis Manual and The Perfusion Crisis Manual. DB is a director of Leeuwin Press Pty Ltd. P.S. receives royalties on the sale of The Perfusion Crisis Manual.

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