

# **DEPARTMENT OF ANESTHESIOLOGY**

# JOURNAL CLUB

Tuesday November 14, 2017 1800 HOURS

LOCATION: Aqua Terra Restaurant 1 Johnson Street

# **PRESENTING ARTICLES:** Dr. Gregory Klar & Dr. Emma Torbicki

SPONSORED BY: Trudell Medical Marketing Limited – Ms. Maureen Balleny

## SUGGESTED GUIDELINES FOR CRITICAL APPRAISAL OF PAPERS ANESTHESIOLOGY JOURNAL CLUB QUEEN'S UNIVERSITY © Joel Parlow, revised 2010

Two presenters will be assigned to choose and present <u>summaries</u> of their papers. Ideally the two papers will represent similar topics but contrasting research methodologies. The focus remains on critical appraisal of the research and manuscript, more than on the actual contents of the article. Each presenter will then lead an open discussion about the article, based around the guidelines below. The object is to open up the appraisal to wide discussion involving all participants, who will be expected to contribute pending suspension of bar privileges.

### GENERAL

- 1. Title of paper: Does it seem like an important problem? Does it reflect the purpose/results?
- 2. Authors, institution and country of origin

## INTRODUCTION

- 1. What is the problem being addressed?
- 2. What is the current state of knowledge of the problem studied?
- 3. What is the hypothesis being tested?
- 4. How does testing the hypothesis help solve the stated problem?

## METHODOLOGY

- 1. Study design:
- a) Clinical trial vs. systematic review/meta-analysis
- b) Prospective vs. retrospective
- c) Observational vs. Experimental
- d) Randomized or not
- e) Blinded or not
- 2. Population studied: a) Human, animal, other
  - b) Justification
  - c) Control groups: experimental vs. historical
  - d) Is the sample size/power calculated, and how?
  - e) Is the population similar to your own practice?
  - f) Single vs. multi-centre
- 3. Is the study ethically sound?
  - a) Clinical equipoise
  - b) Does treatment meet standard of care (esp controls)?
  - c) Appropriate consent and institutional ethics approval
- 4. Exclusions: what groups are excluded and why?
- 5. Experimental protocol
  - a) Is it designed to test the hypothesis?

- b) Is it detailed enough to be reproducible?
- c) Is the methodology validated?
- d) Are the drugs/equipment used detailed?
- e) How does the randomization take place?
- 6. What are the primary endpoints?
- 7. Is power sufficient to justify secondary endpoints?
- 8. Is the protocol clinically relevant?
- 9. Data collection and analysis
- 10. Statistical analysis: Is it appropriate? Are results

## RESULTS

- 1. Are the groups comparable?
- 2. Were any subjects/data eliminated?
- 3. Analyzed by intent to treat?
- 4. Are adequate details of results provided? data, graphs, tables

## DISCUSSION

- 1. What is the main conclusion of the study?
- 2. Do the results support this conclusion?
- 3. Do the results address the stated purpose/hypothesis of the study?
- 4. How do the authors explain the results obtained?
- 5. Are there any alternative interpretations to the data?
- 6. Are the results clinically as well statistically relevant?
- 7. How do the results compare with those of previous studies?
- 8. What do the results add to the existing literature?
- 9. What are the limitations of the methods or analysis used?
- 10. What are the unanswered questions for future work?

## **APPLICABILITY OF THE PAPER**

- 1. Have you learned something important from reading this paper?
- 2. Will the results of this study alter your clinical practice?
- 3. Was the food and wine up to the high standards expected by self-respecting anesthesiologists?

**REPORTS OF ORIGINAL INVESTIGATIONS** 



## Electronic medical record interventions and recurrent perioperative antibiotic administration: a before-and-after study Interventions dans le dossier médical électronique et administration récurrente d'antibiotiques en phase périopératoire: une étude avant-après

Alexander Hincker, MD · Arbi Ben Abdallah, DES, PhD · Michael Avidan, MBBCH · Penka Candelario, BS · Daniel Helsten, MD

Received: 5 December 2016/Revised: 22 January 2017/Accepted: 12 April 2017/Published online: 18 April 2017 © Canadian Anesthesiologists' Society 2017

#### Abstract

**Purpose** Perioperative antibiotics decrease rates of surgical-site infections. Numerous interventions have improved administration of the first antibiotic dose; however, failures in the administration of subsequent doses frequently occur. We hypothesized that modifications to the electronic medical record (EMR) would improve the administration of the second antibiotic dose and that such improvements would be sustained over time.

Methods This historical cohort before-and-after study of multipronged alerts in the EMR analyzed 1,348 operations on adult patients. The operations lasted  $\geq 240$  min, utilized cefazolin as the perioperative antibiotic-constituting 1,348 second and 182 third intraoperative antibiotic doses-and did not involve cardiopulmonary bypass. A decision support intervention provided dosing recommendations when clinicians documented antibiotics. The reminder intervention displayed a continuous bar in the EMR, starting at the time the antibiotics were dosed and ending 15 min before subsequent doses were indicated. The primary endpoints of the study were the change in the proportion of correctly administered second dose of cefazolin, given in accordance with hospital guidelines in the month after implementing the intervention, and whether

This article is accompanied by an editorial. Please see Can J Anesth 2017; 64: this issue.

A. Hincker, MD (⊠) · A. Ben Abdallah, DES, PhD ·
M. Avidan, MBBCH · P. Candelario, BS · D. Helsten, MD
Department of Anesthesiology, Washington University School of Medicine, 660 S. Euclid Ave, Campus Box 8054, Saint Louis, MO 63110, USA
e-mail: hinckera@wustl.edu

any improvements declined by three to seven months after implementation.

Results Pre-intervention, 51.4% of second doses of cefazolin were correctly administered. In the immediate period, *post-intervention* 68.5% were correctly administered, representing significant a absolute improvement of 17.1% (95% confidence interval, 8.1 to 26.1; P < 0.001). Rates did not decline over time; clinicians correctly administered 73.3% of doses in the delayed post-intervention period (P < 0.001 vs preintervention).

**Conclusions** These inexpensive nonintrusive interventions to the EMR provided modest lasting improvements in proper administration of repeated doses of cefazolin. The fact that only approximately 70% compliance was reached highlights the difficulty in addressing this deficiency.

#### Résumé

**Objectif** Les antibiotiques administrés en période périopératoire réduisent les taux d'infections du site opératoire. De nombreuses interventions ont permis d'améliorer l'administration de la première dose antibiotique; toutefois, l'administration des doses subséquentes pose bien souvent problème. Nous avons émis l'hypothèse que des modifications apportées dans le dossier médical électronique (DME) amélioreraient l'administration de la deuxième dose antibiotique et que de telles améliorations se poursuivraient au fil du temps.

**Méthode** Cette étude de cohorte historique avant-après portait sur l'ajout de messages d'alerte dans le DME et a évalué 1348 opérations réalisées chez des patients adultes. Les opérations ont duré  $\geq$  240 minutes; la céfazoline a été utilisée en tant qu'antibiotique périopératoire – pour un total de 1348 deuxièmes et de 182 troisièmes doses antibiotiques peropératoires; les opérations évaluées n'ont pas nécessité de circulation extracorporelle. Un message d'aide à la décision a émis des recommandations posologiques lorsque les cliniciens ont documenté l'usage d'antibiotiques. Le message de rappel affichait une barre en continu dans le DME, commençant au moment où les antibiotiques étaient dosés et se terminant 15 minutes avant que l'indication des doses subséquentes apparaisse. Les critères d'évaluation principaux de l'étude était le changement de proportion de deuxièmes doses de céfazoline adéquatement administrées, données selon les directives hospitalières au cours du mois suivant l'introduction de cette intervention, et le déclin – ou l'absence de déclin – de toute amélioration dans les trois à sept mois suivant l'introduction de cette intervention.

**Résultats** Avant l'intervention, 51,4 % des deuxièmes doses de céfazoline étaient administrées correctement. Dans la période suivant immédiatement l'intervention, 68,5 % des deuxièmes doses ont été correctement administrées, ce qui représente une amélioration absolue considérable de 17,1 % (intervalle de confiance 95 %, 8,1 à 26,1; P <0,001). Ces taux n'ont pas baissé au fil du temps; les cliniciens ont correctement administré 73,3 % des doses dans la période post-intervention à plus long terme (P <0,001 vs avant l'intervention).

**Conclusion** Ces interventions apportées au DME sont à la fois non intrusives et abordables, et ont procuré des améliorations durables et modestes à l'administration adéquate de doses répétées de céfazoline. Le fait qu'une compliance d'environ 70 % seulement ait été atteinte souligne la difficulté de régler ce manquement dans notre pratique.

Surgical-site infections represent a major morbidity and mortality burden, with an estimated 500,000 infections and 8,000 deaths worldwide per year costing the healthcare system upwards of \$7 billion annually.<sup>1</sup> Approximately 40-60% of these infections are thought to be preventable.<sup>2</sup> Furthermore, as perioperative prophylactic use of antibiotics reduces rates of surgical-site infections,<sup>3–5</sup> both the Joint Commission Surgical Care Improvement Project<sup>6</sup> and the World Health Organization Guidelines for Safe Surgery<sup>7</sup> suggest that appropriately selected and timed antibiotic administration is crucial for safe surgery.

Despite the importance of antibiotic prophylaxis, anesthesia clinicians often fail to comply with guidelines.<sup>8</sup> Studies suggest that appropriately timed antibiotic administration occurs in 12-100% of cases.<sup>8</sup> The electronic medical record (EMR) can be a tool for encouraging compliance for two reasons. First, as

anesthesia clinicians interact with the EMR during their cases, it can serve as an interface through which to educate clinicians regarding current guidelines. Additionally, as the EMR serves as the official record for how medications are administered during the case, oversight organizations rely on the EMR to determine rates of compliance with guidelines.

A retrospective audit at our institution suggested that 85% of first doses of antibiotics but only 40-50% of second and third doses were administered at the correct time. Other groups have created interventions in the EMR to increase clinician compliance with the guidelines for the first antibiotic dose,<sup>9–11</sup> but there is a lack of studies examining compliance for repeated doses. As longer operations (due to either an inherently involved procedure or patient factors prolonging the procedure) carry increased morbidity and mortality,<sup>12–14</sup> these doses represent a key opportunity to protect particularly vulnerable patients.

Cefazolin is an important antibiotic to study in the perioperative setting. It is the most commonly used perioperative antibiotic<sup>15</sup> with a broad spectrum of bactericidal activity.<sup>16</sup> Cefazolin does not require dose reduction in patients with renal or hepatic impairment, so there is little reason to deviate from dosing guidelines.<sup>15</sup> Thus, it is a useful marker of clinician compliance with guidelines.

Based on the aforementioned audit, a quality improvement initiative sought to utilize the EMR to improve compliance with antibiotic guidelines. In a survey of anesthesia clinicians at our institution, 88% of respondents cited either not knowing hospital guidelines or forgetting to administer/chart antibiotics as their primary reason for not administering repeated doses. Thus, we created two interventions to the EMR in our hospital system to address these two key reasons for clinician noncompliance with guidelines. Based on initial positive clinician responses, we formally investigated the effectiveness of the interventions. We used a historical cohort before-and-after study (i.e., before, immediately after, and three to seven months after intervention implementation) to examine clinician compliance with guidelines antibiotic regarding perioperative the administration of cefazolin. We hypothesized that these interventions would significantly improve the proportion of correctly administered repeat doses of cefazolin, defined a priori as at least a 15% absolute improvement. Additionally, we hypothesized that, if improvements occurred, we would see no clinically significant decline in the compliance rate, also defined a priori as at least a 5% absolute decrease in compliance between the immediate and the delayed post-intervention periods.

#### Methods

#### Ethics approval

We obtained approval from the Washington University Institutional Review Board (Study Number 201602006, approved February 1, 2016) to obtain the times and doses of antibiotic administration for the appropriate cases as well as the necessary information to verify that doses were given correctly, including patient weight and time of surgical incision. Our study was granted a waiver of consent as this was a retrospective analysis of a previously implemented quality improvement intervention and no changes were made to patient care for the purpose of this study.

#### Electronic medical record interventions

The study intervention consisted of two changes to the MetaVision EMR (*i*MD*soft*®, Needham, MA, USA), an integrated part of the Anesthesia Information Management System. A decision support tool showed clinicians the recommended dose, redosing interval, and weight-based dosing alterations for commonly used antibiotics (Figs 1 and 2). This information was displayed on the buttons that clinicians clicked to document a dose of antibiotic. These recommendations were drawn from our hospital's perioperative antibiotic dosing guidelines.<sup>13</sup> The reminder portion of the intervention consisted of a pink bar displayed alongside medications and fluids in the Gantt view of the EMR to signify that the patient was covered by the most

recently administered dose of antibiotic (Fig. 3). This reminder was generated automatically when an antibiotic was administered, and its duration was defined by the antibiotic used. The bar closed 15 min before the antibiotic was due to be redosed, cueing the clinician to administer the antibiotic. Neither intervention created extra steps to chart a dose of antibiotic.

#### Study design and case selection

In this historical cohort before-and-after study of a previously executed quality improvement intervention, cases were drawn from procedures performed on the main campus of a 1,158-bed adult teaching hospital (and Level 1 trauma centre) in a United States urban setting. In 2015, 34,288 cases were performed (with 2,614 lasting > 240 min), including all major specialties except obstetrics. The anesthesia staffing model in our institution is comprised of approximately 75% medically directed certified registered nurse anesthetists (median length of service = five years), 20% residents/fellows, and 5% attending anesthesiologists who are the primary anesthesia caregivers. Inclusion criteria for cases were the use of cefazolin as the perioperative antibiotic from the start of the case, case duration > 240 min, the redosing interval for cefazolin per our hospital guidelines, and the anesthesia clinician documented a pre-incision safety time-out, which forced the clinician to document whether or not perioperative antibiotics were indicated for the procedure. We excluded cases involving cardiopulmonary bypass (CPB) as our routine practice is to redose cefazolin

Drugs	CURSOR	TIME v2								
Antibiotics	Sedatives	Analgesics / Opioids	Hypnotics	Muscle Relaxants	Antiemetics	Rate	Vasoactives	Local	Other	
Re-dose interv	als may need to I	be adjusted with l	ow creatinine clea	rance or high EB	L.					
All Drugs / Fl	uids	stem ) Non Sj Infus	ion For cas consect recomm	es exceeding 6 h gested to redos ative doses then nended dosing in	ours in patients e at the indicate proceed with th ntervals.	with normal ren d interval for up e manufacturer	al function, to 3			
Ampicillin Re-d	<b>/Sulbactam</b> ose Q2 hrs	3g Aztre Re-dose	onam A: Q4 hrs Re	<b>ztreonam 2</b> g e-dose Q4 hrs	CeFAZ Re-dose	Colin C Q4 hrs R	e <b>FAZolin 2g</b> atient <120Kg e-dose Q4 hrs	CeFAZol Patient >= Re-dose	<b>in 3g</b> 120Kg Q4 hrs	
Cefepim Patient < Re-dose C	e 1g BOKg Q8 hrs Re-	fepime 2g ent >=80Kg dose Q8 hrs	CefoTEtan Re-dose Q6	2g Cefe hrs Re-do	oxitin se Q2 hrs	Cefoxitin 2 Re-dose Q2	2g CefTRI 2 hrs Re-dose	AXone g Q24 hrs		
Ciproflox Re-dose C	Ciprofloxacin Re-dose Q8 hrs         Ciprofloxacin 400mg in 60 minutes Re-dose Q6 hrs         Clindamycin in 30 minutes Re-dose Q6 hrs         Clindamycin 900mg in 30 minutes Re-dose Q6 hrs         Ertapenem 1g in 30 minutes Re-dose Q2 hrs									
Gentami 1.5 mg/ Re-dose Q	<b>cin Ge</b> r <b>kg 5</b> 8 hrs Re-d	n <b>tamicin mg/kg</b> ose Q24 hrs	Metronidaz Re-dose Q8 I	ole Metr inrs R	onidazole 5 in 30 minutes e-dose Q8 hr	00mg s				
Piperacill Re-de	<b>in/Tazobact</b> a ose Q2 hrs	m Piperac Re-	illin/Tazobac 3.375 g dose Q2 hrs	tam Vand in Pat Re-d	omycin 1g one hour ient <80Kg ose Q12 hrs	Vancomyo in one I Patient > Re-dose C	c <b>in 1.5g</b> hour =80Kg Q12 hrs			
Antibiotics Adult Protocols 2014										

Fig. 1 Decision support portion of the electronic medical record intervention

Fig. 2 Comparison of pre- and post-intervention antibiotic administration buttons



Fig. 3 Redosing reminder portion of the electronic medical record intervention

immediately after terminating CPB. We also excluded pediatric cases as pediatric and adult antibiotic dosing guidelines differ. Finally, we excluded cases in which the anesthesia clinician documented a change in the antibiotic dosing schedule because recently administered antibiotics provided satisfactory coverage for part of the case or because no antibiotics were initially deemed necessary.

We planned the immediate post-intervention period to cover only the first month after implementation of the EMR interventions in April 1, 2015. We planned a minimum of a three-month period from any previous quality improvement interventions to the start of our sampled cases to be sure that the effects of any such interventions would have stabilized. The pre-intervention and delayed post-intervention periods occurred during the same calendar months to control for variability in clinician experience as the academic year progresses at a teaching hospital. Given these parameters, we sampled cases meeting the inclusion and exclusion criteria from three time periods: July 1, 2014 to November 28, 2014 (pre-intervention group); April 1-25, 2015 (immediate postintervention group); and July 1, 2015 to November 28, 2015 (delayed post-intervention group).

#### Case analysis

For each case, we determined whether each of the first three doses of cefazolin was correctly dosed for weight and timed. Our hospital guidelines recommend that patients

#### Statistical methods

There were two co-primary outcomes of this study. First, we examined whether the interventions increased the proportion of correctly administered second dose of cefazolin in the immediate and delayed post-intervention periods. We defined a clinically significant improvement as an absolute increase of 15% in the proportion of correctly administered doses. Second, we examined whether improvements seen in the immediate post-intervention period declined by the delayed post-intervention period. We defined a clinically significant decrease in compliance as a 5% absolute decrease in the proportion of correctly administered doses. As secondary outcomes, we compared the immediate and delayed post-intervention periods with regard to changes in the proportion of correctly administered first dose, third dose, and all repeated doses as well as the stability of these changes.

The sample size for each period was dictated by the aforementioned limitations of when each period was required to start and end. We conducted *post hoc* power analysis based on correctly administering a 50% proportion of the pre-intervention second dose and correctly administering a minimum expected 65% proportion of repeated doses in each of the post-intervention periods. The results suggested that our study included a sufficient number of repeated doses in both the immediate and delayed post-intervention periods to have 80% power to show a minimum of 15% absolute increase or decrease in the proportion of correctly administered repeated doses of antibiotics, with  $\alpha = 0.05$  (two-tailed).

Comparisons were made using the Chi square test, except for situations where the expected frequency of an event was  $\leq$  five, in which case, Fisher's exact test was used. In all cases, P < 0.05 (two-tailed) was used for statistical significance. Bonferroni correction was used to account for multiple comparisons. SAS® version 9.4 (SAS Institute Inc., Cary, NC, USA) was used for all statistical analyses.

#### Results

Case enrolment is displayed in Fig. 4. We initially identified 604 cases during the pre-intervention period,

127 cases during the immediate post-intervention period, and 629 cases during the delayed post-intervention period. We excluded four cases from analysis during the preintervention period, zero cases during the immediate postintervention period, and two cases during the delayed postintervention period because the cases were pediatric patients undergoing surgery at the adult hospital. A further three cases were excluded during the preintervention period, zero cases during the immediate post-intervention period, and three cases during the delayed post-intervention period because no weight was documented for the patient. Thus, 1,348 total cases were analyzed, including 597 from the pre-intervention period, 127 from the immediate post-intervention period, and 624 from the delayed post-intervention period. Eighty, 15, and 85 cases in the pre-intervention, immediate postintervention, and delayed post-intervention groups, respectively, merited a third dose of cefazolin. As such, there were 1,528 opportunities to administer repeated doses of cefazolin correctly, including 677, 142, and 709 in the



Fig. 4 Case enrolment flowchart

pre-intervention, immediate post intervention, and delayed post-intervention groups, respectively.

Proportions of correctly administered second doses of cefazolin are shown by month in Fig. 5. Though month-tomonth variability existed, there was a largely stable preintervention baseline level of compliance with the guidelines. Proportions of correctly administered doses of cefazolin are shown by dose and time period in Table 1 and Fig. 6. Differences between the groups are shown in Table 2. In the pre-intervention period, 51.4% of second doses of cefazolin were correctly administered, and in the immediate and delayed post-intervention periods, 68.5% and 73.3% were correctly administered, respectively. These results represent a clinically significant absolute improvement of 17.1% (95% confidence interval [CI], 8.1 to 26.1) and 21.9% (95% CI, 16.6 to 27.2), respectively (P < 0.001 compared with pre-intervention in both cases). In the delayed post-intervention period, there was a 4.8% absolute increase in the proportion of correctly administered second doses of cefazolin compared with the immediate post-intervention period (95% CI, -4.0 to 13.6; P = 0.27).

The first dose of antibiotic was correctly administered in 91.1%, 92.1%, and 94.1% of cases in the pre-intervention, immediate post-intervention, and delayed post intervention periods, respectively. Where applicable, the third dose of antibiotic was correctly administered in 47.5%, 86.7%, and 70.6% of cases in the pre-intervention, immediate post-intervention, and delayed-post intervention periods, respectively. Combined, second and third doses of antibiotic were correctly administered in 51.0%, 70.4%, and 72.9% of cases in the pre-intervention, immediate postintervention, and delayed post-intervention periods, respectively. These results represent a significant difference between groups with regard to proportions of correctly administered third doses (P = 0.001) and all repeated doses (P < 0.001).

 Table 1
 Proportions of correctly administered antibiotic by time period and dose

Period	First Dose	Second Dose	Third Dose	All Repeated Doses
Pre-intervention	91.1%	51.4%	47.5%	51.0%
	( <i>n</i> = 597; 95% CI, 88.8 to 93.4)	(n = 597; 95%  CI, 47.4  to 55.4)	(n = 80; 95%  CI, 36.6  to -58.4)	( <i>n</i> = 677; 95% CI, 47.2 to 54.7)
Immediate post-	92.1%	68.5%	86.7%	70.4%
intervention	( <i>n</i> = 127; 95% CI, 87.4 to 96.8)	( <i>n</i> = 127; 95% CI, 60.4 to 76.6)	(n = 15; 95%  CI, 69.5  to 100)	( <i>n</i> = 142; 95% CI, 62.9 to 77.9)
Delayed post-	94.1%	73.3%	70.6%	72.9%
intervention	( <i>n</i> = 624; 95% CI, 92.2 to 95.9)	(n = 624; 95%  CI, 69.8  to 76.8)	( <i>n</i> = 85; 95% CI, 60.9 to 80.3)	( <i>n</i> = 709; 95% CI, 69.6 to 76.1)

CI = confidence interval



Fig. 5 Proportion of second doses of cefazolin correctly administered by month. Red line represents date of implementation of electronic medical record interventions. Error bars represent 95% confidence intervals

Fig. 6 Proportion of doses of cefazolin correctly administered by time period and dose. Error bars represent 95% confidence intervals



Table 2 Absolute differences between groups in the proportion of repeated antibiotic doses correctly administered

Period	First Dose	Second Dose	Third Dose	All Repeated Doses
Pre- vs immediate post-intervention	1.0%	17.1%	39.2%	19.4%
	(95% CI, -4.2 to 6.2; <i>P</i> = 0.72)	(95% CI, 8.1 to 26.1; <i>P</i> < 0.001)	(95% CI, 18.8 to 60.0; <i>P</i> = 0.005	(95% CI, 11.1 to 27.9; <i>P</i> < 0.001)
Pre- vs delayed post-intervention	3.0%	21.9%	23.1%	21.9%
	(95% CI, 0.0 to 5.9; <i>P</i> = 0.05)	(95% CI, 16.6 to 27.2; <i>P</i> < 0.001)	(95% CI, 8.5 to 37.7; P = 0.003)	(95% CI, 16.9 to 26.9; P < 0.001)
Immediate- vs delayed post-	2.0%	4.8%	-16.1%	2.5%
intervention	(95% CI, -3.1 to 7.0; <i>P</i> = 0.40)	(95% CI, -4.0 to 13.6; <i>P</i> = 0.27)	(95% CI, $-35.8$ to 3.7; $P = 0.20$ )	(95% CI, -5.8 to 10.6; <i>P</i> = 0.55)
Three way comparison	P = 0.14	P < 0.001	P = 0.001	P < 0.001

CI = confidence interval

Regarding the proportions of correctly administered first dose of antibiotic, there was no significant difference between the pre-intervention group and either the immediate or delayed post-intervention groups (P = 0.72 and 0.05, respectively). Regarding the proportions of correct administration of the third dose of antibiotic and all repeated doses of antibiotic, there was also a significant increase in both the immediate pre-intervention period (P = 0.005 and P < 0.001, respectively) and the delayed post-intervention period (P = 0.005 and P < 0.001, respectively) and P < 0.001, respectively). There was no significant difference in the proportion of correctly administered first, second, third, or all repeated doses between the immediate and delayed post-intervention periods (P = 0.40, 0.27, 0.20, and 0.55, respectively).

#### Discussion

This study investigated the effectiveness of interventions to the EMR designed to increase the proportion of correctly administered repeated doses of perioperative antibiotics. We *a priori* defined a 15% absolute improvement in compliance as being clinically significant. There was no significant improvement in correct administration of the first dose of antibiotic. The improvements for the second and third doses, however, were both statistically significant and clinically meaningful (17-22% and 23-39% absolute increases in the proportions of correctly administered second and third doses, respectively). Importantly, antibiotic dosing compliance should approach 100%. These results suggest that it might be difficult to achieve perfect compliance with repeat antibiotic doses.

Previous studies attempted to address the problem of failure to administer perioperative antibiotics properly,<sup>17</sup> but preliminary reviews of EMR interventions aimed at repeated dosing have only recently been reported. While the proportion of correctly administered pre-intervention first dose of antibiotic was already > 90%, our proportion of correctly administered subsequent doses was only around 50%. Therefore, the current interventions focus on a time when clinicians are more prone to error.

Other previous studies used means beyond the EMR to improve clinician compliance with guidelines. Such methods included pre-surgical checklists or safety timeouts<sup>18–20</sup> and training sessions for perioperative personnel.<sup>21–23</sup> By comparison, our interventions are inexpensive; do not require clinician training, continuing manpower, or financial investment to maintain; do not increase the duration of surgery; and do not interfere with the clinicians' activities. As an inexpensive nonintrusive intervention, the current approach has the advantage of achieving increased perioperative safety without significant

drawbacks. While the current interventions were introduced in the MetaVision EMR, their principles can likely be carried over to other EMRs.

While our interventions led to meaningful improvement, they still fell noticeably shy of ideal levels of proper antibiotic administration. Though conclusions from studies targeting first doses of antibiotics may not apply completely to subsequent doses, lessons from these studies may guide the design of future interventions. In general, successful interventions all involved real-time reminders to clinicians.<sup>9–11</sup> Importantly, one study<sup>9</sup> achieved close to 100% compliance for first dose of antibiotic. This intervention included more intrusive alerts and was notable for its multi-tiered approach, which previous research on human error suggests is important.<sup>24</sup> Our interventions were as nonintrusive as possible by design, as they occurred while surgery was ongoing. More intrusive reminders may increase compliance, but they might also impair how clinicians perform other duties.

This study examined the effect of the interventions on the administration of only one antibiotic, i.e., cefazolin. There were two reasons for our choice. First, cefazolin needed to be adjusted only for patient weight, and its dose does not change for different types of procedures, patient age, or patient comorbidities. As such, clinician deviation from established guidelines was unlikely to represent appropriate clinical judgement. Additionally, cefazolin is the most commonly used perioperative antibiotic.<sup>15</sup> As such, clinicians know well how to dose cefazolin properly, and they are better accustomed with properly remembering to repeat doses. For these reasons, cefazolin administration was less likely to show improvement by our interventions compared with administration of other antibiotics, which may have underestimated the benefit of the study interventions.

The before-and-after design of the study prevents us from definitively concluding that our interventions caused the improvements in guideline compliance. That said, the epochs studied control for changes in trainee experience during the calendar year and were distant from major changes to the EMR, hospital antibiotic guidelines, or similar quality improvement initiatives. The stable pre-intervention baseline, abrupt improvement in clinician compliance starting April 2015, and sustained improvement after the interventions (Fig. 5) suggest a strong temporal relationship between the interventions and the improved clinician compliance.

This study did not examine patient outcomes such as rates of wound infection, hospital length of stay, or mortality. Previous studies have repeatedly shown that improvement in perioperative antibiotic administration translates to decreased rates of surgical-site infection.<sup>2</sup> The number needed to treat to prevent one infection varied

by type of surgery, ranging from 58 for breast and hernia surgery, to 3-9 for gastrointestinal surgery, to 2-3 for cardiac surgery.<sup>7</sup> By including only those cases with a minimum duration of four hours, our study was biased toward longer cases that likely included more involved procedures or sicker patients in whom infection would be particularly devastating. Given that the interventions in this study showed a number needed to treat of five repeated doses of antibiotics to administer one additional correct dose, it is reasonable to infer that these interventions would have significant impact on patient outcomes.

#### Conclusions

In summary, these straightforward inexpensive non-intrusive modifications to the EMR resulted in enduring improvement in anesthesia clinician compliance with guidelines for administration of repeated doses of perioperative antibiotics. The nature of the interventions is such that these advantages can be gained with a minimum of drawbacks. Secondary analyses suggest that the effect size and sustainability of the improvements come from both second and third doses of antibiotics, though the small number of cases requiring third doses of intraoperative antibiotics limits this analysis.

Acknowledgements We thank the INQUIRI group in the Washington University Department of Anesthesiology for providing the quality assurance structure to make this project possible. Special thanks to Aaron Norris MD and Tina Doshi MD for their assistance in the development and implementation of the interventions.

**Conflicts of interest** None to declare.

Editorial responsibility This submission was handled by Dr. Hilary P. Grocott, Editor-in-Chief, *Canadian Journal of Anesthesia*.

**Financial support and sponsorship** This work was supported by the Department of Anesthesiology, Washington University in Saint Louis, Saint Louis, MO.

#### References

- Najjar PA, Smink DS. Prophylactic antibiotics and prevention of surgical site infections. Surg Clin North Am 2015; 95: 269-83.
- 2. *Hawn TH, Vick CC, Richman J, et al.* Surgical site infection prevention: time to move beyond the surgical care improvement program. Ann Surg 2011; 254: 494-9; discussion 499-501.
- 3. Clarke JS, Condon RE, Bartlett JG, Gorbach SL, Nichols RL, Ochi S. Preoperative oral antibiotics reduce septic complications of colon operations: results of prospective, randomized, doubleblind clinical study. Ann Surg 1977; 186: 251-9.
- Kaiser AB, Clayson KR, Mulherin JL Jr, et al. Antibiotic prophylaxis in vascular surgery. Ann Surg 1978; 188: 283-9.
- Pavel A, Smith RL, Ballard CA, Larsen IJ. Prophylactic antibiotics in clean orthopaedic surgery. J Bone Joint Surg Am 1974; 56: 777-82.

- The Joint Commission. Surgical Care Improvement Project Core Measure Site – Effective for Discharges January 1, 2014. Available from URL: http://www.jointcommission.org/assets/1/ 6/SCIP-Measures-012014.pdf (accessed January 2017).
- World Health Organization. WHO Guidelines for Safe Surgery 2009 – Safe Surgery Lives. Available from URL: http://apps.who. int/iris/bitstream/10665/44185/1/9789241598552\_eng.pdf (accessed January 2017).
- Gouvea M, Novaes CO, Pereira DM, Iglesias AC. Adherence to guidelines for surgical antibiotic prophylaxis: a review. Braz J Infect Dis 2015; 19: 517-24.
- Nair BG, Newman SF, Peterson GN, Wu WY, Schwid HA. Feeback mechanisms including real-time electronic alerts to achieve near 100% timely prophylactic antibiotic administration in surgical cases. Anesth Analg 2010; 111: 1293-300.
- O'Reilly M, Talsma A, VanRiper S, Kheterpal S, Burney R. An anesthesia information system designed to provide physicianspecific feedback improves timely administration of prophylactic antibiotics. Anesth Analg 2006; 103: 908-12.
- 11. Wax DB, Beilin Y, Levin M, Chadha N, Krol M, Reich DL. The effect of an interactive visual reminder in an anesthesia information management system on timeliness of prophylactic antibiotic administration. Anesth Analg 2007; 104: 1462-6.
- Wimmer C, Gluch H, Franzreb M, Ogon M. Predisposing factors for infection in spine surgery: a survey of 850 spinal procedures. J Spinal Disord 1998; 11: 124-8.
- 13. Leong G, Wilson J, Charlett A. Duration of operation as a risk factor for surgical site infection: comparison of English and US data. J Hosp Infect 2006; 63: 255-62.
- Turrentine FE, Wang H, Simpson VB, Jones RS. Surgical risk factors, morbidity, and mortality in elderly patients. J Am Coll Surg 2006; 203: 865-77.
- Bratzler DW, Dellinger EP, Olsen KM, et al. Clinical practice guidelines for antimicrobial prophylaxis in surgery. Am J Health Syst Pharm 2013; 70: 195-283.
- National Institute of Health. Daily Med Cefazolin cefazolin injection, powder, for solution (updated 2012 July 20). Available from URL: http://dailymed.nlm.nih.gov/dailymed/drugInfo. cfm?setid=807b03ea-e6c4-4165-991e-8cce036eba8f (accessed January 2017).
- Levy SM, Phatak UR, Tsao KJ, et al. What is the quality of reporting of studies of interventions to increase compliance with antibiotic prophylaxis? J Am Coll Surg 2013; 217: 770-9.
- Nemeth TA, Beilman GJ, Hamlin CL, Chipman JG. Preoperative verification of timely antimicrobial prophylaxis does not improve compliance with guidelines. Surg Infect (Larchmt) 2010; 11: 387-91.
- Lingard L, Regehr G, Cartmill C, et al. Evaluation of a preoperative team briefing: a new communication routine results in improved clinical practice. BMJ Qual Saf 2011; 20: 475-82.
- Rosenberg AD, Wambold D, Kraemer L, et al. Ensuring appropriate timing of antimicrobial prophylaxis. J Bone Joint Surg Am 2008; 90: 226-32.
- Kao LS, Lew DF, Doyle PD, et al. A tale of 2 hospitals: a staggered cohort study of targeted interventions to improve compliance with antibiotic prophylaxis guidelines. Surgery 2010; 148: 255-62.
- McHugh SM, Corrigan MA, Dimitrov BD, et al. Preventing infection in general surgery: improvements through education of surgeons by surgeons. J Hosp Infect 2011; 78: 312-6.
- Wick EC, Hobson DB, Bennett JL, et al. Implementation of a surgical comprehensive unit-based safety program to reduce surgical site infections. J Am Colll Surg 2012; 215: 193-200.
- 24. *Reason J.* Human error: models and management. BMJ 2000; 320: 768-70.

## ASRA Checklist Improves Trainee Performance During a Simulated Episode of Local Anesthetic Systemic Toxicity

Joseph M. Neal, MD,\* Robert L. Hsiung, MD,\* Michael F. Mulroy, MD,\* Brian B. Halpern, RN,† Alison D. Dragnich, MD,\* and April E. Slee, MSc‡

**Objective:** Severe local anesthetic systemic toxicity (LAST) is a rare event, the management of which might best be learned using high-fidelity simulation. In its 2010 Practice Advisory, the American Society of Regional Anesthesia and Pain Medicine (ASRA) created a medical checklist to aid in the management of LAST. We hypothesized that trainees provided with this checklist would manage a simulated episode of LAST more effectively than those without it. A secondary aim of the study was to assess the ASRA Checklist's usability and readability. **Methods:** Trainees undergoing a simulated LAST event were randomized to the checklist group (n = 12) or the no-checklist group (n = 13). Our primary outcome was the number of medical management tasks completed correctly. Secondary outcomes included assessment of the anesthesiologists' nontechnical skills and posttest performance.

**Results:** Trainees receiving the checklist demonstrated superior medical management of the simulated LAST event: the checklist group correctly performed 16.0 (2.6) tasks versus the no-checklist group's 8.8 (3.0) tasks (mean [SD], P < 0.001). The checklist group had higher decision making scores on the anesthesiologists' nontechnical skills assessment (5.2 [1.8] versus 4.0 [1.35] summed rater score, P = 0.037) and had higher knowledge retention 2 months later (P = 0.031). Of those trainees randomized to receive the checklist, 7 of 12 used it fully (versus partially), which was reflected in higher medical and nontechnical performance scores.

**Conclusions:** Use of the ASRA Checklist significantly improved the trainees' medical management and nontechnical performance during a simulated episode of severe LAST. Partial use of the checklist correlated with lower overall performance.

(Reg Anesth Pain Med 2012;37: 8–15)

Life-threatening local anesthetic systemic toxicity (LAST) is an extremely rare event. A large surveillance study noted only 2.2 seizures per 10,000 regional blocks (95% confidence interval [CI], 1.3–3.1) and no occurrence of cardiac arrest in 103,730 regional anesthetics.<sup>1</sup> Despite these reassuring statistics, serious LAST continues to occur and occasionally results in mortality.<sup>2</sup> Prompted in part by the introduction of lipid emulsion as an

Medicine ISSN: 1098-7339

DOI: 10.1097/AAP.0b013e31823d825a

antidote for LAST,<sup>3</sup> the American Society of Regional Anesthesia and Pain Medicine (ASRA) issued a Practice Advisory on LAST in 2010.<sup>4</sup> The practice advisory prepared a checklist intended for inclusion as part of a local anesthetic toxicity kit. The front of this document (henceforth referred to as "the ASRA Checklist") was designed as a simple step-by-step reminder of crucial therapeutic interventions, drugs, and dosages, whereas the back of the document provides rationale for the recommended interventions (Appendix 1).

Creation of the ASRA Checklist was motivated by the aviation industry's long-standing recognition that checklists are crucial for improving human performance during emergency situations. Because anesthesiologists may never treat a lifethreatening episode of LAST during their career, its management might be learned optimally using simulation.<sup>5,6</sup> The availability of a checklist during this stressful event might improve performance by prompting the physician through appropriate stepwise interventions and drug selection rather than using the physician's traditional reliance on memory.7 We therefore undertook this study to test the hypothesis that physician trainees provided with the ASRA Checklist would demonstrate superior performance during a simulated episode of LAST compared to those presented with an identical scenario but without the checklist. The study's secondary aim was to assess the usability and readability of the ASRA Checklist.

#### METHODS

The institutional review board (IRB) of the Benaroya Research Institute at Virginia Mason Medical Center approved this study. The subjects were clinical anesthesia (CA) 1, 2, and 3 residents, plus regional anesthesiology and acute pain medicine fellows, all of whom possessed current Advanced Cardiac Life Support (ACLS) credentials. Potential subjects were informed that they would be participating in a simulation exercise involving an anesthetic emergency and that they could voluntarily choose to participate in a study that was being conducted coincidentally. The IRB stipulated that each subject read the informed consent document before study enrollment. To ensure anonymity of participating trainees, the IRB required that they give their oral consent but not sign the consent form. Thereafter, subjects were tracked by a unique study number; this pairing was known only to an administrative assistant.

#### Simulation Design and Prestudy Testing

Regional Anesthesia and Pain Medicine • Volume 37, Number 1, January-February 2012

The LAST event was constructed in detailed written format and scripted for consistency (LAST Simulation Script, Supplemental Digital Content 1, http://links.lww.com/AAP/A41). Hemodynamic variables and cardiac rhythms were programmed into a manikin-based simulator (SimMan; Laerdal Medical, Gatesville, Tex). The protocol was pretested on 3 occasions before study commencement using nonparticipating subjects and the same team who would perform the actual simulation. These test runs served to refine the simulation script, train the

From the Departments of \*Anesthesiology and †Nursing Education, Virginia Mason Medical Center; and ‡Biostatistics, Axio Research, Seattle, WA. Accepted for publication August 14, 2011.

Address correspondence to: Joseph M. Neal, MD, 1100 Ninth Ave (B2-AN), Seattle, WA 98111 (e-mail: anejmn@vmmc.org).

The authors declare no conflict of interest.

Dr. Neal is the archival investigator for this study; data are archived by the Benaroya Research Institute at Virginia Mason Medical Center.

This study was supported by departmental and institutional funds. Presented at the 2011 ASRA Spring Meeting, Las Vegas, Nev, May 7, 2011. James P. Rathmell, MD, served as acting editor-in-chief for this article. Supplemental digital content is available for this article. Direct URL

citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.rapm.org). Copyright © 2012 by American Society of Regional Anesthesia and Pain

observers, and allow them to agree on standardized grading of various trainee responses.

#### Randomization

Subjects were randomized into 1 of 2 groups: checklist group or no-checklist group. Block randomization was performed by trainee rank (CA1, CA2, CA3, or fellow). Group assignment within each rank was equally balanced and was randomized using a Web-based tool (www.randomizer.com). Randomization assignment was contained in a sealed envelope that was labeled with the unique identifier number (eg, CA1-5).

#### Study Flow

To ensure universal access to the checklist, a copy of the ASRA Practice Advisory executive summary<sup>4</sup> was distributed to every member of the Department of Anesthesiology without fanfare 4 weeks before commencing the study. The ASRA Checklist is also a component of a binder containing "Emergency Situation Checklists" that is available at every anesthesia workstation. Simulation of the LAST event was constructed in 5 stages. Immediately before beginning the study, the trainee was read scripted instructions that emphasized the requirement to clearly vocalize his/her thought processes and his/her requests for assistance, medical interventions, drug dosages, and so on. Individuals in the simulation room included the trainee, a simulation-nurse educator (B.B.H.) who interacted with the trainee as a "nurse conspirator" and provided any requested assistance or equipment, and 3 investigators who performed consistent roles during all simulation episodes and were physically situated in the background, away from the manikin, trainee, and assistant. All 3 investigators scored the trainee's medical (technical) performance. Two investigators (J.M.N., M.F.M.) scored nontechnical performance, whereas the third (R.L.H.) operated the simulator and played the role of the receiving critical care physician.

#### **Stage 1: Prevention and Diagnosis**

Subjects were presented a scripted scenario describing a 73-year-old man with a history of stable coronary artery disease who had consented to a single-injection femoral nerve block followed by a subarachnoid anesthetic for total hip arthroplasty. Subjects were asked to verbally describe how they would place the femoral nerve block. During this stage, subjects were graded on completion of 7 distinct tasks pertinent to the placement of a femoral nerve block-monitoring, test dose, aspiration and incremental injection, and so on.<sup>8</sup> As the patient began to exhibit progressive signs and symptoms of LAST (central nervous system and cardiac excitation), subjects were asked to declare their working diagnosis. If an incorrect diagnosis was given, the subject was told to assume LAST was the correct diagnosis and to proceed accordingly. After the diagnosis was made, the subject was or was not provided (without further instruction) the ASRA Checklist according to randomization. If, during the first 3 stages, subjects asked for the local anesthetic toxicity kit, they were notified that "the kit is on the way," thereby forcing LAST management without immediate availability of lipid emulsion.

#### **Stage 2: Seizure Management**

The patient developed a generalized seizure. In this section, subjects were graded for definitive seizure treatment, including the primacy of airway management.

#### Stage 3: Cardiac Arrhythmia Management

After the seizure was controlled, the patient developed hemodynamically stable ventricular tachycardia (VT). Crucial to management of cardiac arrhythmias secondary to LAST is avoidance of drugs known to worsen local anesthetic toxicity or depress cardiac function (eg, lidocaine, propofol,  $\beta$ -blocker, or calcium channel blocker). If the subject did not specifically verbalize the use or avoidance of a drug, the nurse conspirator tested these thought processes by inquiring about the drug in question (eg, "Would you like esmolol to slow down the heart rate?"). The episode of VT then degenerated into ventricular fibrillation (VF). If necessary, the nurse conspirator asked similar questions to have the subject commit to using or not using a specific drug(s), including (low-dose) epinephrine and vasopressin.

#### **Stage 4: Lipid Emulsion Management**

The nurse announced that lipid emulsion had arrived. Subjects were tested on their knowledge of proper dosing parameters. The initial bolus and infusion of lipid emulsion was unsuccessful, thereby testing secondary bolus/infusion adjustment and prompting notification of the cardiopulmonary bypass (CPB) team.

#### **Stage 5: Stabilization**

The patient's condition stabilized. The subject entered a hand-off conversation with a critical care physician, during which time knowledge of the recommended observation period and the maximum dose and duration of lipid emulsion therapy were tested.

#### **Performance Evaluation**

Our primary outcome was the number of tasks correctly performed during management of the LAST episode. Subject performance was graded using 2 specific tools—a performance evaluation tool and the anesthesiologists' nontechnical skills (ANTS) tool (Data Collection Tools, Supplemental Digital Content 2, http://links.lww.com/AAP/A45). At the end of the simulation, the 3 observers recorded whether those subjects who received the ASRA Checklist used it fully or partially (defined as the trainee who did not refer to the checklist >25% of the time when addressing a specific task that was subsequently performed incorrectly).

The performance evaluation tool assessed the subject's medical (technical) management of LAST. This tool was based directly on the ASRA Checklist and consisted of 28 yes/no answers linked to satisfactory completion of a specific task. The first 7 items tracked stage 1. These items were analyzed separately from the remaining 21 items (the primary outcome measure), which tracked stages 2 to 5. Thus, subjects could score up to 7 points before receiving the checklist (henceforth referred to as "prechecklist") and up to 21 points after receiving (or not) the checklist (henceforth referred to as "postchecklist"). Because the evaluators could not be blinded to receipt or not of the ASRA Checklist, each component of the knowledge evaluation tool was a simple binary instrument allowing the evaluator to record an answer based on the subject properly completing the task or not. Evaluator scores that differed by more than 20% would prompt replay of the disputed responses using a recorded video. If no review was necessary, the video was destroyed.

The *ANTS tool* is a validated instrument developed to evaluate an anesthesiologist's nontechnical skills during performance of a technical exercise.<sup>9</sup> Subjects can score from 4 to 16 points on the ANTS tool, which measures 4 behavioral skills—task management, teamwork, situation awareness, and decision making (Data Collection Tools, Supplemental Digital Content 2, http://links.lww.com/AAP/A45). Two evaluators scored ANTS performance, with the a priori agreement to discuss the subject's

Medical Management of LAST							
Evaluator	Checklist (n = 12)	No Checklist (n = 13)					
RLH	21.1 (2.3)	14.5 (3.2)					
MFM	21.7 (2.7)	14.5 (2.8)					
JMN	21.4 (2.7)	14.3 (3.2)					
ANTS							
Evaluator	Scor	e (n = 25)					
MFM	12.0 (2.4)						
JMN	12.6 (2.55)						

Values are means (SD). Results are not statistically differen

Possible medical management score: 0 to 28.

Possible ANTS score: 4 to 16.

JMN indicates Neal; MFM, Mulroy; RLH, Hsiung.

performance and reconcile scores if they differed by more than 33%.

#### **Postsimulation Evaluations**

Immediately after completion of the simulation, subjects completed a questionnaire designed to record their subjective impressions regarding the value of having a checklist or their perceptions of how a checklist might have assisted them. The questions focused on the overall usefulness and readability of the checklist and the subjects' comfort level using it instead of relying on their memory. Each question offered 5 Likert items to stratify the subject's opinion (ie, strongly agree, agree, neutral, disagree, or strongly disagree). This was followed by open-ended questions regarding how the ASRA Checklist was helpful or could be improved (Data Collection Tools, Supplemental Digital Content 2, http://links.lww.com/AAP/A45). Subjects then underwent standard postsimulation debriefing. Two months after completing the exercise, subjects took a 12-question multiplechoice test based on information found within the ASRA Checklist. Subjects were allowed 15 minutes to complete this closed-book test.

#### **Statistical Analysis**

This study tested the hypothesis that subjects randomized to receive the ASRA Checklist would perform better than those randomized not to receive it. The primary outcome was subject performance on the final 21 of 28 questions from the performance evaluation tool. Secondary outcomes included the effect of the ASRA Checklist on the ANTS and posttest scores, and subgroup analysis of performance as a function of whether subjects randomized to receive the checklist used it fully or partially.

Sample size was based on effect sizes reported by Bruppacher et al<sup>10</sup> and assumed that an effect size greater than 1 would be clinically meaningful. By running several conservative calculations that estimated the number of correctly performed tasks by the checklist versus the no-checklist subjects, we determined that 25 subjects would yield at least 80% power for all reasonable scenarios.

All randomized subjects were included in the analyses. Each item on the performance evaluation was scored as correct if 2 or 3 of the 3 reviewers determined the task was performed correctly and incorrect if 0 or 1 reviewer determined the task was performed correctly. Continuous summaries were compared using the 2-sided t test for independent groups, and categorical variables were compared using the  $\chi^2$  test or Fisher exact test as appropriate. Sensitivity analyses were conducted using mixed models to adjust for the prechecklist score and experience level, with the functional form based on minimizing Akaike information criterion (AIC, "goodness of fit").<sup>11</sup> Separate analyses were performed for LAST and ANTS total scores. Logistic regression was performed to determine whether experience or sex affected use of the checklist among subjects randomized to receive it. Statistical significance was defined as P < 0.05. No adjustments were made for multiple comparisons. Data are presented as mean (SD) unless otherwise noted.

#### RESULTS

Between September 15, 2010, and February 15, 2011, 25 trainees (checklist group n = 12, no-checklist group n = 13;

#### TABLE 2. Performance Data: Checklist Group Versus No-Checklist Group

	Checklist (n = 12)	No Checklist (n = 13)	Р
Medical management of LAST			
Prechecklist subtotal: 7 prevention and diagnostic items	5.4 (0.7)	5.6 (0.8)	0.499
Postchecklist subtotal: 21 patient management and treatment items	16.0 (2.6)	8.8 (3.0)	< 0.001
Total performance: 28 total items	21.4 (2.5)	14.4 (3.0)	< 0.001
ANTS			
Task management	6.7 (1.8)	6.5 (1.7)	0.858
Team working	7.5 (0.8)	7.3 (0.85)	0.567
Situation awareness	6.6 (1.4)	5.5 (1.85)	0.107
Decision making	5.2 (1.8)	4.0 (1.35)	0.037
Total score (average)	13.1 (2.5)	11.65 (2.3)	0.143
Posttest scores	7.0 (1.5)	5.7 (1.4)	0.031

Values are means (SD). *P* values are from *t* tests.

Medical management scores are the average of 3 raters' scores.

ANTS total score is the average, and the component scores are the summed scores, of 2 raters. Components are scored as follows: 4 points for good, 3 points for acceptable, 2 points for marginal, and 1 point for poor.

Posttest scores could range from 0 to 12.

17 males and 8 females) enrolled in and completed all phases of the study. The training level distribution was as follows: 8 CA1s, 6 CA2s, 9 CA3s, and 2 fellows. All trainees agreed to participate in the study. CA1 participation was delayed until those subjects had completed 14 to 24 weeks of residency training. Interrater scores were always within the prescribed 20% and 33% margins of agreement for the knowledge evaluation and ANTS tools, respectively (Table 1).

#### **Primary Outcome**

The checklist group significantly outperformed the nochecklist group as evidenced by higher scores on the 21-item postchecklist performance evaluation. Therefore, having the ASRA Checklist resulted in superior medical management of simulated LAST. The 3 raters' average global scores were as follows: 16.0 (2.6) correctly performed tasks in the checklist group versus 8.8 (3.0) in the no-checklist group, P < 0.001(Table 2). Neither level of training nor postchecklist score was significantly associated with total score, but after adjustment for these covariates, the checklist group outscored the no-checklist group by an average of 7.3 points (95% CI for difference in leastsquares means: 4.9-9.8, P < 0.0001). Table 3 details the intragroup and intergroup comparisons on specific medical task performance. There was no difference in stage 1 performance (prechecklist). Both groups exhibited similar seizure and cardiac arrhythmia management (stages 2 and 3). Notably, more than 30% of subjects in each group incorrectly treated VT and/or VF with local anesthetic or βblocker. The checklist group was more accurate in their use of (low-dose) epinephrine and avoidance of vasopressin (P = 0.039and P = 0.011, respectively), yet more than 40% of both groups performed these tasks incorrectly. Lipid emulsion management was significantly more accurate when the ASRA Checklist was available. None of the no-checklist group and only 50% of the checklist group notified the CPB team (P = 0.005).

#### **Secondary Outcomes**

Although overall nontechnical performance did not differ, the checklist group performed better than the no-checklist group on the decision making component of ANTS: 5.2 (1.8) versus 4.0 (1.35) summed score of 2 raters, P = 0.037 (95% CI, 4.25–6.6 versus 3.2–4.8). There was no difference in unadjusted average total ANTS score, but after adjusting for the level of training and prechecklist score, the checklist group outscored

#### TABLE 3. Specific Task Performance Data

		Checklist (n = 12)	No Checklist (n = 13)	Р
Before receipt of checklist				
Stage 1: Prevention and diagnosis	Applies pulse oximeter	11 (91.7)	10 (76.9)	0.593
	Applies EKG	2 (16.7)	4 (30.8)	0.645
	Establishes intravenous access	6 (50.0)	12 (92.3)	0.030
	Epinephrine test dose	11 (91.7)	12 (92.3)	1.000
	Aspiration of syringe	12 (100.0)	11 (84.6)	0.480
	Incremental injection	11 (91.7)	12 (92.3)	1.000
	Makes correct diagnosis	12 (100.0)	12 (92.3)	1.000
After receipt (or not) of checklist				
Stage 2: Seizure management	Calls for help	10 (83.3)	10 (76.9)	1.000
	Calls for local anesthetic toxicity kit	11 (91.7)	12 (92.3)	1.000
	Primacy of airway management	8 (66.7)	12 (92.3)	0.160
	Seizure suppression with benzodiazepam	12 (100.0)	11 (84.6)	0.480
Stage 3: Cardiac arrhythmia management	Correctly avoids local anesthetics	8 (66.7)	8 (61.5)	1.000
	Correctly avoids β-blockers	8 (66.7)	6 (46.2)	0.428
	Correctly avoids calcium channel blockers	9 (75.0)	6 (46.2)	0.226
	Appropriate CPR (within 1 min)	12 (100.0)	12 (92.3)	1.000
	Appropriate and timely defibrillation	8 (66.7)	7 (53.8)	0.688
	Correct epinephrine dose (≤100 µg)	4 (33.3)	0 (0.0)	0.039
	Correctly avoids vasopressin	7 (58.3)	1 (7.7)	0.011
Stage 4: Lipid emulsion management	Correctly avoids propofol	11 (91.7)	5 (38.5)	0.011
	Correct lipid emulsion preparation (20%)	12 (100.0)	4 (30.8)	< 0.001
	Correct bolus (1.5 mL/kg over 1 min)	10 (83.3)	2 (15.4)	0.001
	Correct infusion (0.25 mL/kg per minute)	8 (66.7)	2 (15.4)	0.015
	Correctly repeats bolus	9 (75.0)	6 (46.2)	0.226
	Correctly doubles infusion (0.5 mL/kg per minute)	6 (50.0)	0 (0.0)	0.005
Stage 5: Stabilization	Continues infusion for 10 min after stable	11 (91.7)	0 (0.0)	< 0.001
	Correct upper limit (10 mL/kg per 30 min)	10 (83.3)	0 (0.0)	< 0.001
	Notify cardiopulmonary bypass team	6 (50.0)	0 (0.0)	0.005
	Monitors ≥12 h after episode	12 (100.0)	10 (76.9)	0.220

P values from Fisher exact test for categorical measures and t tests for continuous measures.

© 2012 American Society of Regional Anesthesia and Pain Medicine

TABLE 4.	Performance	Data: Full	Versus Partial	Use of the	Checklist

	Full Use $(n = 7)$	Partial Use (n = 5)	Р
Medical management of LAST			
Postchecklist subtotal: 21 patient management and treatment items	17.7 (1.25)	13.6 (1.8)	< 0.001
ANTS			
Task management	7.4 (0.8)	5.6 (2.5)	0.096
Team working	7.7 (0.8)	7.2 (0.8)	0.292
Situation awareness	7.6 (0.8)	5.2 (0.8)	< 0.001
Decision making	6.7 (0.8)	3.6 (1.1)	< 0.001
Total score (average)	14.7 (0.8)	10.8 (2.1)	0.001

Values are means (SD). P values are from Fisher exact test for categorical measures and t tests for continuous measures. Medical management scores are the average of 3 raters' scores.

ANTS total score is the average, and the component scores are the summed scores, of 2 raters. Components are scored as follows: 4 points for good, 3 points for acceptable, 2 points for marginal, and 1 point for poor.

the no-checklist group by 1.63 points (95% CI for difference in least-squares means, 0.02-3.47; P = 0.08). Prechecklist score was not significantly associated with average total ANTS score (P = 0.37), but there was some evidence of an association between ANTS and level of training (P = 0.095 across all levels). This result was mostly due to a difference between the CA3s and the CA1s. The CA3s outscored the CA1s by 2.6 points on average (95% CI for pairwise difference, 0.41-4.85; P = 0.023). The checklist group performed better on the 2-month posttest (P = 0.031; Table 2). After adjusting for training and prechecklist score, the checklist group scored 1.26 points higher than the nochecklist group (95% CI, 0.02-2.52; P = 0.047).

#### Subgroup Analysis

Of the 12 trainees randomized to receive the ASRA Checklist, 7 fully used it (3 females and 4 males; 4 of 4 CA3s) and 5 partially used it (all were males). Although there were no differences in individual task performance, the full-use group outperformed the partial-use group on the global 21-item medical management of LAST: 17.7 (0.8) versus 13.6 (1.8) correct tasks, respectively; P < 0.001. The full-use group demonstrated superior situation awareness, decision making, and total scores on the ANTS assessment, P < 0.001 (Table 4).

#### **Subjective Reporting**

Table 5 details the trainees' subjective impressions of undergoing the simulation with or without the ASRA Checklist. Nearly 50% of trainees in both groups agreed with the statement that they should be able to respond appropriately to a medical emergency based on memory alone, yet they were neutral or disagreed with the statement that they felt ill at ease relying on a checklist. Despite the raters' assessment that 5 of 12 subjects failed to fully use the checklist, the subjects themselves perceived that they used it (subjects were not asked to quantify checklist use).

The most frequent open-ended comment regarding checklists was that they were most useful for difficult to remember facts, such as drug dosages or infusion rates. Subjects randomized to the checklist felt it facilitated more rapid and confident decision making. With regard to the ASRA Checklist, the most common observation was that it needed to emphasize that managing LAST-related cardiac arrest differs from ACLS guidelines. Subjects described the ASRA Checklist as concise, organized, and well-flowing. None of the trainees randomized to the no checklist group requested a checklist.

#### DISCUSSION

The ASRA Practice Advisory<sup>4</sup> assimilated scientific studies and expert opinion into guidelines for the management of LAST, but the rarity of this anesthetic complication is such that a clinical study can never validate the guideline's effect on patient outcome. The ASRA Checklist provides an algorithm for the optimal management of LAST based on the Advisory's recommendations. High-fidelity simulation makes it possible to test whether access to the ASRA Checklist improves adherence to the Advisory's recommendations, which may theoretically improve patient outcome by eliminating treatment variation and omissions. In our study, trainees who used the ASRA Checklist demonstrated superior medical management of severe LAST compared with colleagues who did not receive the checklist. This result suggests that using the checklist may enhance medical management and patient safety during an actual clinical LAST event. Using the ASRA Checklist was also associated with trainees demonstrating selectively better nontechnical performance.

Although minor subjective symptoms may occur in 1:1000 patients,<sup>8</sup> severe LAST is a low-frequency, high-consequence event, thus learning its medical management might ideally involve simulation. The unique experiential learning afforded by simulation is used increasingly in anesthesiology training programs and the American Society of Anesthesiologists' educational programs, and it has become a component of the Maintenance of Certification in Anesthesiology process.<sup>12</sup> Like most simulation studies, ours measured performance outcomes in a setting that may or may not predict how the ASRA Checklist will affect management of an actual patient. Although a case report has credited simulator-based training with successful resuscitation from LAST,<sup>13</sup> the rarity of LAST is such that an instrument like the ASRA Checklist can never be fully validated by a controlled clinical trial. Indeed, the recent study of Bruppacher et al<sup>10</sup> that randomized residents to simulatorversus interactive seminar-based training is the first anesthesiology study to link simulation to meaningful improvement in clinical performance (translating simulation to actual patient intervention), and it did so in the relatively common scenario of weaning from CPB.

The secondary aim of this study was to demonstrate the effectiveness of the ASRA Checklist in its usability and readability. Medical organizations frequently create practice advisories to aid practitioners in the management of various clinical scenarios, yet formal testing of these recommendations is

		Checklist (n = 12)	No Checklist (n = 13)	Р
Checklists (in general) are useful	Agree	4 (33.3)	2 (15.4)	0.378
tools in medicine	Strongly agree	8 (66.7)	11 (84.6)	
In emergency situations,	Strongly disagree	1 (8.3)	1 (7.7)	1.000
I should be able to respond	Disagree	3 (25.0)	4 (30.8)	
appropriately from	Neutral	3 (25.0)	2 (15.4)	
memory alone	Agree	5 (41.7)	5 (38.5)	
	Strongly agree	0 (0.0)	1 (7.7)	
I feel ill at ease relying on a checklist	Strongly disagree	2 (16.7)	3 (23.1)	1.000
	Disagree	7 (58.3)	7 (53.8)	
	Neutral	3 (25.0)	2 (15.4)	
	Agree	0 (0.0)	1 (7.7)	
I am confident that the ASRA	Neutral	2 (16.7)	0 (0.0)	0.467
Checklist includes all essential	Agree	7 (58.3)	10 (76.9)	
information to treat LAST	Strongly agree	3 (25.0)	3 (23.1)	
The SINGLE word that would	Comfortable	0 (0.0)	3 (23.1)	0.040
BEST describe your feelings	Confident	0 (0.0)	2 (15.4)	
regarding using the checklist to	Confused	0 (0.0)	1 (7.7)	
describe had you received a checklist)	Neutral	1 (8.3)	0 (0.0)	
desense, had you received a checklisty	Supported	10 (83.3)	6 (46.2)	
	Weak	0 (0.0)	1 (7.7)	
Once I received the ASRA Checklist,	Agree	5 (41.7)		
I used it to manage this simulated patient	Strongly agree	7 (58.3)		
I found the ASRA Checklist	Agree	3 (25.0)		
useful in this situation	Strongly agree	9 (75.0)		
If I had received the ASRA Checklist,	Agree		2 (15.4)	
I would have used it to manage this simulated patient	Strongly agree		11 (84.6)	
I wish I had received the ASRA Checklist	Agree		1 (7.7)	
	Strongly agree		12 (92.3)	

#### **TABLE 5.** Subject-Reported Value of ASRA Checklist

relatively uncommon. Simulation provides the opportunity to identify latent errors in checklists.<sup>12</sup> Although subjects found the ASRA Checklist generally useful and easy to follow, 3 specific visual prominence defects were identified that have resulted in its modification. (The revised ASRA Checklist is published in this issue of *Regional Anesthesia and Pain Medicine* on page 16. Portable document files (pdf) of the checklist are available for free download at the ASRA Web site: www.asra.com.) First, enhanced emphasis has been placed on the differences between pharmacologic treatment of local anesthetic-induced cardiac arrhythmias and more common ACLS cardiac arrest scenarios. Second, the need for mobilization of a CPB team has been emphasized earlier in the checklist. Third, formal checklist boxes have been inserted.

Our subjects' performance offered insights into global issues related to physician use of checklists. Gawande<sup>14</sup> and Winters et al<sup>7</sup> have brought the lessons of aviation to the bedside by promoting checklists for the management of both common medical scenarios and rare emergencies. Severe LAST exemplifies a rare emergency, the proper management of which is different from other forms of cardiac arrest<sup>15</sup> and involves the relatively complicated administration of a drug (lipid emulsion) that is used for no other purpose by anesthesiologists. Not surprisingly, both of our experimental groups exhibited similar and mostly correct preventative and diagnostic patient management

(before receipt of the checklist) and basic management of seizure and cardiac arrhythmias. Performance between groups diverged when subjects began to manage tasks specifically addressed by the ASRA Checklist. The checklist group also performed better on the secondary outcomes—the nontechnical measure of decision making and knowledge retention. We speculate that information emphasized within the checklist contributed to these higher scores but acknowledge that the raters were not blinded, which potentially biased their ANTS assessment.

Our study corroborates previous observations that physician culture stresses autonomy<sup>16</sup> and does not fully embrace checklist use.<sup>7</sup> Physician resistance to adopting checklists has been described previously by Winters et al,<sup>7</sup> who note psychological studies that demonstrate that man's ability to retrieve information from memory is not only limited but also made worse by stress, fatigue, or complexity. Although the ASRA Checklist clearly facilitated superior performance, some of our trainees were reluctant to fully use it—nearly two-thirds were neutral or agreed with the statement that they should be able to respond appropriately to an emergency situation from memory alone. Of those subjects who received the ASRA Checklist, all agreed or strongly agreed that they used it to manage their patient, yet the 3 raters opined that 5 of these 12 subjects used the checklist only partially. Our study design cannot ascertain whether this behavior was the subjects' reluctance to rely on any checklist or simply that they did not use the ASRA Checklist throughout the exercise. For example, 30% to 40% of subjects incorrectly managed cardiac arrhythmias, including subjects provided with the ASRA Checklist. This could reflect either a visual prominence defect in the checklist or the subjects feeling that they should act autonomously when managing something as common as VT or VF. Nevertheless, the consequence of this behavior was reflected in subgroup analysis by lower global management scores and lower total ANTS score, including lower situation analysis and decision making component scores. We speculate that lower component scores reflect a lesser degree of confidence by those subjects who only partially used the checklist. Further study regarding the impact of "medical culture" on safety practices seems warranted.

In summary, anesthesiology trainees randomized to receive the ASRA Checklist provided superior medical management of a simulated episode of severe LAST. This suggests, but does not prove, that clinical management of this rare anesthetic emergency may also be improved by using the checklist. This study also assessed the usability and readability of the ASRA Checklist, which has subsequently resulted in 3 modifications to its structure.

#### ACKNOWLEDGMENT

The authors thank Janine Turner for her administrative assistance during the conduct of this study and Christine S. Park, MD, for her simulation expertise and advice. The authors also wish to thank the Virginia Mason residents and fellows for their valuable participation in this study.

#### REFERENCES

- Auroy Y, Narchi P, Messiah A, Litt L, Rouvier B, Samii K. Serious complications related to regional anesthesia. Results of a prospective survey in France. *Anesthesiology*. 1997;87:479–486.
- Di Gregorio G, Neal JM, Rosenquist RW, Weinberg GL. Clinical presentation of local anesthetic systemic toxicity: a review of published cases, 1979–2009. *Reg Anesth Pain Med.* 2010;35:181–187.
- Weinberg GL. Treatment of local anesthetic systemic toxicity (LAST). Reg Anesth Pain Med. 2010;35:188–193.
- Neal JM, Bernards CM, Butterworth JF, et al. ASRA practice advisory on local anesthetic systemic toxicity. *Reg Anesth Pain Med.* 2010;35:152–161.
- Park CS, Rochlen LR, Yaghmour E, et al. Acquisition of critical intraoperative event management skills in novice anesthesiology residents by using high-fidelity simulation-based training. *Anesthesiology*. 2010;112:202–211.
- Boulet JR, Murray DJ. Simulation-based assessment in anesthesiology. *Anesthesiology*. 2010;112:1041–1052.
- Winters BD, Gurses AP, Lehmann H, Sexton JB, Rampersad CJ, Pronovost PJ. Clinical review: Checklists—translating evidence into practice. *Crit Care*. 2009;13:210.
- Mulroy MF, Hejtmanek MR. Prevention of local anesthetic systemic toxicity. *Reg Anesth Pain Med.* 2010;35:177–180.
- Fletcher G, Flin R, McGeorge P, Glavin R, Maran N, Patey R. Anaesthetist's non-technical skills (ANTS): evaluation of a behavioural marker system. *Br J Anaesth*. 2003;90:580–588.
- Bruppacher HR, Alam SK, LeBlanc VR, et al. Simulation-based training improves physicians' performance in patient care in high-stakes clinical setting of cardiac surgery. *Anesthesiology*. 2010;112:985–992.
- Akaike H. A new look at the statistical model identification. *IEEE Trans* Autom Control. 1974;19:716–723.
- Park CS. Simulation and quality improvement in anesthesiology. *Anesthesiol Clin.* 2011;29:13–28.

- Smith HM, Jacob AK, Segura LG, Dilger JA, Torsher LC. Simulation education in anesthesia training: a case report of successful resuscitation of bupivacaine-induced cardiac arrest linked to recent simulation training. *Anesth Analg.* 2008;106:1581–1584.
- Gawande A. The checklist: if something so simple can transform intensive care, what else can it do? *New Yorker*. December 10, 2007;86–101.
- Butterworth JF. Models and mechanisms of local anesthetic cardiac toxicity. *Reg Anesth Pain Med.* 2010;35:167–176.
- Kennedy TJ, Regehr G, Baker GR, Lingard LA. 'It's a cultural expectation...' The pressure on medical trainees to work independently in clinical practice. *Med Educ.* 2009;43:645–653.

#### APPENDIX 1. LAST CHECKLIST PROVIDED TO SUBJECTS RANDOMIZED TO RECEIVE IT

#### Virginia Mason Medical Center Emergency Management Checklist for LOCAL ANESTHETIC SYSTEMIC TOXICITY

#### Call for Help

- 1. Initial focus:
  - a. Ventilate with 100% oxygen
  - b. Seizure suppression

     i Benzodiazepines preferred
     ii Avoid propofol
  - c. ACLS may require prolonged effort
    - i Epinephrine in small to moderate doses (10-100 µg initially and titrate to effect)
    - ii Avoid vasopressin, calcium channel blockers,  $\beta$ -blockers, local anesthetics
- 2. If clinically unstable or symptoms progress, infuse 20% lipid emulsion
  - a. Bolus 1.5 mL/kg for 1 minutes (~100 mL)
  - b. Continuous infusion at 0.25 mL/kg per minute (does not need to be exact)
  - c. If persistent cardiovascular collapse, repeat bolus once or twice
  - d. Double infusion rate if persistent hypotension
  - e. Continue infusion for at least 10 minutes after cardiovascular stability
  - f. Upper limit for lipid emulsion ~10 mL/kg for 30 min
- 3. Alert cardiac team for potential cardiopulmonary bypass if patient does not respond to initial therapy, particularly if bupivacaine or ropivacaine was used
- 4. Serious toxicity requires prolonged monitoring (>12 hours) because cardiovascular depression can persist or recur

### Supplemental Information

#### **Be Prepared**

• We strongly advise that those using local anesthetics (LA) in doses sufficient to produce local anesthetic systemic toxicity (LAST) establish a plan for managing this complication. Making a *Local Anesthetic Toxicity Kit* and posting instructions for its use are encouraged.

#### Risk Reduction (Be Sensible)

• Use the least dose of LA necessary to achieve the desired extent and duration of block.

Copyright © 2011 American Society of Regional Anesthesia and Pain Medicine. Unauthorized reproduction of this article is prohibited.

- Local anesthetic blood levels are influenced by site of injection and dose. Factors that can increase the likelihood of LAST include advanced age, heart failure, ischemic heart disease, conduction abnormalities, metabolic (eg, mitochondrial) disease, liver disease, low plasma protein concentration, metabolic or respiratory acidosis, and medications that inhibit sodium channels. Patients with severe cardiac dysfunction, particularly very low ejection fraction, are more sensitive to LAST and also more prone to receive "stacked" injections (with resulting elevated LA tissue concentrations) due to slowed circulation time.
- Consider using a pharmacologic marker and/or test dose, for example, epinephrine 5  $\mu$ g/mL of LA. Know the expected response, onset, duration, and limitations of "test dose" in identifying intravascular injection.
- Aspirate the syringe before *each* injection while observing for blood.
- Inject incrementally, while observing for signs and querying for symptoms of toxicity between each injection.

#### **Detection** (*Be Vigilant*)

- Use standard American Society of Anesthesiologists (ASA) monitors.
- Monitor the patient during and after completing injection as clinical toxicity can be delayed up to 30 minutes.
- Communicate frequently with the patient to query for symptoms of toxicity.
- Consider LAST in any patient with altered mental status, neurological symptoms, or cardiovascular instability after a regional anesthetic.
- Central nervous system signs (may be subtle or absent)
- *Excitation* (agitation, confusion, muscle twitching, seizure)
- Depression (drowsiness, obtundation, coma or apnea)
- *Nonspecific* (metallic taste, circumoral numbness, diplopia, tinnitus, dizziness)

- Cardiovascular signs (often the only manifestation of severe LAST)
- *Initially may be hyperdynamic* (hypertension, tachycardia, ventricular arrhythmias), *then*
- Progressive hypotension
- Conduction block, bradycardia, or asystole
- *Ventricular arrhythmia* (ventricular tachycardia, Torsades de pointes, ventricular fibrillation)
- Sedative hypnotic drugs reduce seizure risk but even light sedation may abolish the patient's ability to recognize or report symptoms of rising LA concentrations.

#### Treatment

- Timing of lipid infusion in LAST is controversial. The most conservative approach, waiting until after ACLS has proven unsuccessful, is unreasonable because early treatment can prevent cardiovascular collapse. Infusing lipid at the earliest sign of LAST can result in unnecessary treatment because only a fraction of patients will progress to severe toxicity. The most reasonable approach is to implement lipid therapy on the basis of clinical severity and rate of progression of LAST.
- There is laboratory evidence that epinephrine can impair resuscitation from LAST and reduce the efficacy of lipid rescue. Therefore, it is recommended to avoid high doses of epinephrine and use smaller doses, for example, less than 1 μg/kg, for treating hypotension.
- Propofol *should not be used* when there are signs of cardiovascular instability. Propofol is a cardiovascular depressant with lipid content too low to provide benefit. Its use is discouraged when there is a risk of progression to cardiovascular collapse.
- Prolonged monitoring (>12 hours) is recommended after any signs of systemic LA toxicity, because cardiovascular depression due to local anesthetics can persist or recur after treatment.

Anaesthesia, 2011, 66, pages 255-262

## ORIGINAL ARTICLE A randomised control trial to determine if use of the iResus<sup>©</sup> application on a smart phone improves the performance of an advanced life support provider in a simulated medical emergency\*

### D. Low,<sup>1</sup> N. Clark,<sup>2</sup> J. Soar,<sup>3</sup> A. Padkin,<sup>1</sup> A. Stoneham,<sup>4</sup> G. D. Perkins<sup>5</sup> and J. Nolan<sup>1</sup>

1 Consultant Anaesthetist, 2 Specialist Registrar, Department of Anaesthesia, Royal United Hospital, Bath, UK

3 Consultant Anaesthetist, Department of Anaesthesia, Southmead Hospital, Bristol, UK

4 Medical Student, University of Bristol, Bristol, UK

5 Associate Clinical Professor, Warwick Medical School, University of Warwick, Warwick, UK

#### Summary

This study sought to determine whether using the Resuscitation Council UK's iResus<sup>©</sup> application on a smart phone improves the performance of doctors trained in advanced life support in a simulated emergency. Thirty-one doctors (advanced life support-trained within the previous 48 months) were recruited. All received identical training using the smart phone and the iResus application. The participants were randomly assigned to a control group (no smart phone) and a test group (access to iResus on smart phone). Both groups were tested using a validated extended cardiac arrest simulation test (CASTest) scoring system. The primary outcome measure was the overall cardiac arrest simulation test score; these were significantly higher in the smart phone group (median (IQR [range]) 84.5 (75.5–92.5 [64–96])) compared with the control group (72 (62–87 [52–95]); p = 0.02). Use of the iResus application significantly improves the performance of an advanced life support-certified doctor during a simulated medical emergency. Further studies are needed to determine if iResus can improve care in the clinical setting.

Correspondence to: Dr Daniel Low Present address: Department of Anesthesiology and Pain Medicine, University of Washington School of Medicine, Seattle Children's Hospital, Seattle, WA, USA Email: daniel.low1@me.com \*Presented at European Resuscitation Council Scientific Meeting, Porto, Portugal, December 2010. Accepted: 17 January 2011

Every year, approximately 30 000 people in the UK have an unexpected cardiac arrest in hospital. Despite significant advances in resuscitation research, survival to hospital discharge following cardiac arrest in adults remains poor [1]. The survival benefit of well-performed cardiopulmonary resuscitation (CPR) is well documented. Recent evidence from both resuscitation training and in-hospital cardiac arrest suggests that CPR quality is suboptimal [2, 3].

Human factors affect the quality of CPR and disparity exists between resuscitation theory and its practical application – even experienced teams often perform sub-optimally in simulated resuscitation scenarios [4]. Possible explanations for this include the high-stress environment resulting in poor lead-ership behaviour, failure to delegate tasks explicitly, poor recall of knowledge and inevitable skill decay [5–7].

Resuscitation feedback devices and cognitive aids (visual or auditory prompts to aid recall) can improve the quality of CPR during training and simulated cardiac arrests [5]. Smart phones downloaded with resuscitation algorithms have the potential to improve performance in emergency scenarios. To date, randomised clinical trials have shown them to be of significant benefit only in the training of non-medical 'bystanders' in basic life support [8, 9].

iResus<sup>©</sup> is a free application ('app'), developed by the Resuscitation Council (UK) for the Apple iPhone<sup>™</sup> (Cupertino, CA, USA) and released in January 2010 (http://www.resus.org.uk/pages/iResusDt.

htm). It includes current adult and paediatric algorithms in an interactive and intuitive format whilst remaining entirely faithful to the original content. The 'app' 'pulls' the latest algorithms from a central server, so it is always up-to-date.

The aim of this study was to ascertain whether providing appropriate prompts in a portable, userfriendly format produces better results in a simulated medical emergency than relying upon memory alone.

#### Methods

This study was assessed by the chair of the Royal United Hospital Bath Research and Ethics Committee, who considered full ethical review to be unnecessary. This was an open label, randomised controlled trial using junior doctor volunteers, conducted in the Education Centre at the Royal United Hospital. The study took place over three evening sessions, from February to March 2010, to enable as many junior doctors as possible to attend. While the study groups were waiting for their advanced life support (ALS) scenario, they participated in clinical skills workshops. Participants were randomly assigned to either the intervention arm or the control arm in a 1:1 ratio by receiving shuffled opaque-sealed envelopes.

Eligible participants were Resuscitation Council (UK) ALS-trained doctors (within 5 years of qualification) working in either the Royal United Hospital, Bath or Southmead Hospital, Bristol, at the time the study took place. They were recruited via poster and email. Written, informed consent was obtained from all the participants. They were not blinded as to the purpose of the study. Those who had not completed a Resuscitation Council (UK) ALS course within the last 4 years were excluded.

Participants were invited to join a resuscitation training session after normal working hours. All

participants were briefed in pairs for 10 min, and shown how to use the iResus 'app' (Version 1.0) preloaded on an Apple iPhone. The participants were taught how to operate the smart phone and navigate the 'app', but were not exposed to the bradycardia algorithm that would form the basis of their assessment (they were taught how to switch to the advanced life support algorithm as part of the training). After randomisation, participants in the intervention arm were given an iPhone and encouraged to use the iResus 'app' during the scenario; the participants randomly assigned to the control arm did not have access to any cognitive aids.

Participants were assessed using one of the Resuscitation Council (UK) cardiac arrest simulation tests (CASTest). The CASTest tests the application of resuscitation knowledge and skills during a simulated cardiac emergency. During the assessment, the participant had initially a single nurse helper who would locate equipment and follow instructions; as the scenario progressed, an additional helper became available who could perform CPR, give drugs and defibrillate. Resuscitation equipment and drugs were set out in a standardised ALS scenario assessment format. All candidates had the same scenario (a patient with a recent inferior myocardial infarction, complicated by compromising complete heart block at a rate of 40-50 beats.  $\min^{-1}$  who deteriorated to cardiac arrest – pulseless electrical activity and then ventricular fibrillation, which, if treated successfully, would revert to a perfusing sinus rhythm). A SimMan<sup>TM</sup> simulator (Laerdal, Stavanger, Norway) was used with full defibrillation capability.

Performance during CASTest was measured using the validated CASTest scoring system [10]. The score sheet contains four domains, each with performance criteria within them to characterise the quality of

**Table 1** Advanced life support scenario evaluation criteriascoring system.

Domain	Number of performance criteria	Maximum score	Minimum score
Initial approach to bradycardia	6	24	6
Arrest management (PEA)	7	28	7
Arrest management (VF)	8	32	8
Return of sinus rhythm	3	12	3

PEA, pulseless electrical activity; VF, ventricular fibrillation.

participant performance in further detail (Table 1 and Appendix).

The 24 performance criteria are individually scored out of a maximum of four (1 = unacceptable; 2 =borderline; 3 = acceptable; 4 = excellent). The maximum score was 96. There were at least two assessors for each scenario and scoring was done by consensus between assessors.

Following their resuscitation assessment, the participants were asked to complete a questionnaire. Questions included whether the participants owned an iPhone, (and if they had already downloaded iResus). In addition, regarding the use of the iResus 'app' and their attitude and perceived attitudes of using iResus in clinical situations, the participants were asked to score the statements from 1 (strongly disagree) to 10 (strongly agree).

The primary outcome measure was the score on the CASTest in the two groups. Secondary outcome measures were the participants' iPhone ownership and attitudes towards using the 'app' as assessed by a questionnaire.

A power calculation suggested that 15 candidates in each group would provide 80% power for demonstrating a 20% improvement in CASTest performance. The likely performance of the control group (mean score 57.1, SD 10.5) was estimated using data from a cardiac arrest simulation test (CASTest) scoring study using data from candidates who were retested 12 months after their ALS certification (data provided by Resuscitation Council (UK)).

Subjects were allocated to their group using opaquesealed envelopes, containing a folded strip of paper with 'iPhone' or 'No iPhone' written on it. There were equal numbers of envelopes for the two groups. The envelopes were subjected to simple randomisation. Researchers who were not involved in the scenario assessment process performed sealed envelope preparation and allocation.

It was not possible to blind assessors to allocation groups.

Results were analysed using STATA 10.1 for Macintosh (STATA Corp., College Station, TX, USA). The CASTest scores had a non-normal distribution so the two groups were compared using the Wilcoxon rank sum test (Mann–Whitney).

#### Results

Out of the 47 potentially eligible junior doctors from all specialties who responded to email invitation from January to March 2010, seven were excluded as they had not passed a Resuscitation Council (UK) ALS course within the last 4 years, and an additional nine, who initially expressed interest, failed to attend any of the three organised sessions. Sixteen out of the 31 participants were randomly assigned to perform their ALS scenario with a smart phone (with the iResus 'app' downloaded), and 15 without (see Fig. 1). All the participants completed a feedback questionnaire. There were no losses to follow-up.

The two groups had similar baseline characteristics (Table 2). The CASTest score for the participants in both groups was not normally distributed (Fig. 2), but similar in spread. There was a significant difference in the CASTest scores between the two groups. The median (IQR [range]) CASTest score in the smart phone (iResus) group was 84.5 (75.5–92.5 [64–96]) compared with a score of 72 (62–87 [52–95]) for the control group (p = 0.02).

There were 11 (35%) existing iPhone users in our study population; these were equally distributed (six were randomly assigned to the iResus group and five to the no iResus group). Out of those who already owned an iPhone, only one (9%) already had iResus downloaded on their phone. This participant had been randomly assigned to the smart phone group.

The participant scores are summarised in Tables 3 and 4. Participants stated that the iResus 'app' was easy to use, increased their confidence in making decisions, and that they would be prepared to use it in real clinical emergencies. From their own perspective, they did not think using such an 'app' would be unprofessional or indicate poor training. They expressed a neutral response when asked if the public or other healthcare professionals would view usage in these negative terms.

#### Discussion

iResus improved junior doctors' CASTest scores during a standardised simulated cardiac arrest scenario when compared with those applying purely their own knowledge and experience.

The junior doctors in our study found iResus easy to use and felt that it would provide them with an increased level of confidence in a stressful emergency scenario. They did not consider the use of iResus to be unprofessional or reflect a poor level of training in a real clinical situation. This contrasts findings from a previous study where junior doctors felt that using a cognitive aid would show a lack of knowledge and professionalism [11].



Figure 1 Participant flow through the study.

iResus provides almost instant access to the appropriate algorithms and drug doses for resuscitation situations that may be managed incorrectly if memory alone is relied upon; it has been shown that stressful situations make errors more likely [11]. There is growing literature to support the use of cognitive aids in resuscitation. Two randomised controlled studies involving simulated basic life support (BLS) by laypeople without prior CPR training showed improved performance with the use of mobile phone CPR programmes [8, 9]. A recent review of CPR feedback/prompt devices (including cognitive aids) used during training and CPR performance found no randomised controlled trials of their use during actual cardiac arrests [2].

Our findings are similar to a previous study of animation assisted CPR among laypeople 6 months

after CPR training: those in the animation assisted group had higher checklist scores, demonstrating that those trained with cognitive aids perform better [12]. In another study, medical students who had received CPR training 2 months before were divided into three groups: a control group; a short CPR checklist; and a longer, more detailed version – those in the longer checklist arm performed best [13]. Other groups have investigated the use of cognitive aids in life-threatening 'peri-arrest' scenarios (paediatric anaphylaxis and malignant hyperpyrexia), also with supporting outcomes [11, 14, 15].

Improved recall of factual information is also important for effective ALS; studies undertaken before the development of personal digital assistants (PDAs) PDAs and the iPhone have demonstrated that more simplistic aide memoires are also effective [16, 17].

Table 2	Baselin	e cha	aracteristics	for	the	study	participants.
Data are	e mean	(SD)	or median	(IQI	₹ [ra	nge]).	

	Smart phone (iResus)	No smart phone
Age; years	28 (3.3)	29 (4.5)
Sex; female	10 (63%)	7 (47%)
Months post medical degree qualification	44 (43.8)	46 (30.5)
Months post ALS certification	10 (6–23 [1–40])	11 (5–32 [3–44])
Medical speciality		
Medicine / paediatrics	8 (50%)	9 (60%)
Emergency medicine	1 (6%)	2 (13%)
Anaesthesia/intensive care	4 (25%)	3 (20%)
Surgery	3 (19%)	1 (7%)
Already own an iPhone	6 (38%)	5 (33%)

ALS, advanced life support.



**Figure 2** Cardiac arrest scenario test scores for participants. (■) No smart phone and (■) Smart phone (iResus).

Contrasting evidence also exists. One study of neonatal resuscitation used a poster with resuscitation guidelines as the intervention (versus control – no poster); none of the study participants in either group was able to perform adequately to pass a neonatal resuscitation programme test (based on completion of

five key steps displayed on the poster). It was postulated that infrequent use of cognitive aids had contributed to their results [18]. Potential harm was reported in two further studies, including delay in initiation of CPR and the use of incorrect algorithms; thus the outcome of using a cognitive aid such as a checklist may be specific to the aid or the situation [19, 20]. A recent randomised controlled study using a mobile phone with audio CPR prompts did improve CPR quality (better hand position, compression rate and depth and fewer pauses) in lay rescuers; however, there was a 30-s delay to initiation of CPR [21].

In other high-risk industries (such as aviation or nuclear power), the use of cognitive aids is integral to their standard operating procedures. The safety culture in medicine has changed with respect to checklists, for example the recent wide implementation of the World Health Organization (WHO) surgical checklist within operating theatres. However, a culture still remains in which doctors may be reluctant to use cognitive aids for fear of appearing incompetent. Improved team performance in a simulated anaesthetic emergency relating to the use of cognitive aids has been demonstrated, and the investigators commented on the need to confront negative attitudes within healthcare towards the use of such aids [11].

Our study provides further additional support to the current evidence, suggesting that CPR prompt devices improve skills and therefore potentially, patient outcome.

It is possible that the improved performance was because of the rapid availability of the ALS algorithms and drug doses, rather that the medium with which it was presented (smart phone and iResus), although this is difficult to prove unequivocally. A similar improvement may have been seen with the use of a wall poster. However, as iResus is supported by the Resuscitation Council (UK), the iResus 'app' will always provide the most up-to-date UK guidelines. We chose not to compare iResus with another type of cognitive aid

**Table 3** Participants' views on usage of the iResus 'app' based on scores of 1 (strongly disagree) to 10 (strongly agree). Values are median (IQR [range]).

	No smart phone (n = 15)	Smart phone (iResus) (n = 16)
I found the 'app' easy to use In a clinical emergency would increase	8 (7.5–8.5 [7–10]) 8 (7–8.5 [4–10])	8 (7–8.25 [3–10]) 7.5 (7–9 [3–10])
confidence in decision-making Happy to use in a real clinical emergency	8 (6.5–9 [4–10])	7.5 (5–9 [4–10])

© 2011 The Authors

Anaesthesia © 2011 The Association of Anaesthetists of Great Britain and Ireland

**Table 4** Participants' attitudes and perceived attitudes towards the iResus applications based on score of 1 (strongly disagree) to 10 (strongly agree). Values are median (IQR [range]).

	All participants (n = 31)
'Doctors using iResus in a real clinical situation are unpro fessional and poorly trained'	3 (2–4 [1–8])
'Public will perceive doctors who use iResus in a real clinical situation to be unprofessional and poorly trained'	5 (4–7 [1–10])
'Other healthcare professionals will perceive doctors who use iResus in a real clinical situation to be unprofessional and poorly trained'	5 (4–7 [1–8])

because most cardiac arrests do not occur near a wall poster, and most healthcare professionals do not carry card-based cognitive aids. Thus, we considered a study group using iResus compared with a control group with no cognitive aids to be most representative of the real world.

There was no pre-testing of candidates and therefore we cannot be absolutely certain that the two groups were of equal ability; however, the baseline data suggest that they are similar in terms of clinical experience and time since ALS certification. A potential limitation is that both groups received training on the 'app'. This could serve as revision of the guidelines though neither group trained using the bradycardia algorithm. If training had not occurred in the control group, we would not be able to discern the effect of the 'app' as opposed to teaching/revision of algorithms during the training. The subjects were informed that even though they received training, they might not have access to the 'app' during their assessment scenario.

A further limitation of the study is that the assessors were not blinded to the study group during scenario performance. Blinding would be very difficult to achieve in these circumstances because it was immediately apparent to the assessor when the participant was referring to iResus. An option would have been to make the assessors unaware of the purpose of the study, e.g. they might have been told 'candidates are free to use an 'app' or not, as they wish'. However, the authors were keen to investigate how even a very limited training period on this 'app' (none of the doctors had been exposed to the bradycardia algorithm on the 'app') could affect the performance of the doctors. Hence, those randomly assigned to the iResus group were strongly encouraged to use the 'app'; although it was not mandatory, they uniformly referred to the 'app' and were able to navigate an algorithm that was unfamiliar to them.

Whilst simulation may be a useful training tool, the extent to which results from simulation studies can be extrapolated into clinical practice remains largely unknown. However, one study has shown that a simulation-based educational programme significantly improved performance during cardiac arrest [22].

New technology has changed the way in which we access information. Further studies are required to investigate the effect of cognitive aids on CPR quality (interruption to chest compressions). Further evaluation of the iResus 'app' in real-life emergency scenarios is required.

#### Acknowledgements

We are very grateful to Iain Smith of the simulation laboratory at the Royal United Hospital, Bath, for the loan of simulators, resuscitation training equipment, and for his help with the set up for the assessments.

#### **Competing interests**

Daniel Low, Medical Director of iMobileMedic.com, was commissioned by Resuscitation Council (UK) to develop iResus. During the study, he was not involved with assessment, data collection or analysis, nor did or does he receive any financial gain from the 'app'. iMobileMedic.com received a licence fee from the Resuscitation Council (UK) for the first 50 000 downloads. Jasmeet Soar is Chair, Resuscitation Council (UK), Editor of Resuscitation and co-chair of the Education, Implementation and Teams Task Force of the International Liaison Committee on Resuscitation. Jerry Nolan is Editor-in-Chief of Resuscitation, and Co-chair of the International Liaison Committee on Resuscitation. Natasha Clark, Adam Stoneham, Andrew Padkin and Gavin Perkins declare no competing interest.

#### References

 Husselbee N, Davies RP, Perkins GD. Advanced life support update. *British Medical Bulletin* 2009; 89: 79–91.

- 2 Perkins GD, Boyle W, Bridgestock H, et al. Quality of CPR during advanced resuscitation training. *Resuscitation* 2008; **77**: 69–74.
- 3 Abella BS, Alvarado JP, Myklebust H, et al. Quality of cardiopulmonary resuscitation during in-hospital cardiac arrest. *Journal of the American Medical Association* 2005; 293: 305–10.
- 4 Brown TB, Dias JA, Saini D, et al. Relationship between knowledge of cardiopulmonary resuscitation guidelines and performance. *Resuscitation* 2006; **69**: 253– 61.
- 5 Yeung J, Meeks R, Edelson D, Gao F, Soar J, Perkins GD. The use of CPR feedback/prompt devices during training and CPR performance: a systematic review. *Resuscitation* 2009; **80**: 743–51.
- 6 Leary M, Abella BS. The challenge of CPR quality: improvement in the real world. *Resuscitation* 2008; 77: 1–3.
- 7 Marsch S, Müller C, Marquardt G, Conrad F, Tschan P, Hunziker PR. Human factors affect the quality of cardiopulmonary resuscitation in simulated cardiac arrests. *Resuscitation* 2004; **60**: 51–6.
- 8 Ertl L, Christ F. Significant improvement of the quality of bystander first aid using an expert system with a mobile multimedia device. *Resuscitation* 2007; **74**: 286–95.
- 9 Choa M, Park I, Chung HS, Yoo SK, Shim H, Kim S. The effectiveness of cardiopulmonary resuscitation instruction: animation versus dispatcher through a cellular phone. *Resuscitation* 2008; **77**: 87–94.
- 10 Napier N, Davies RP, Baldosck C, et al. Validation for a scoring system of the ALS cardiac arrest simulation test (CASTest). *Resuscitation* 2009; **80**: 1034–8.
- 11 Harrison TK, Manser T, Howard SK, Gaba DM. Use of cognitive aids in a simulated anaesthetic crisis. *Anesthesia* and Analgesia 2006; **103**: 551–8.
- 12 Choa M, Cho J, Young CH, Kim S, Sung JM, Chung HY. Animation assisted CPRII program as a reminder tool in achieving effective one-person-CPR performance. *Resuscitation* 2009; 80: 680–4.
- 13 Ward P, Johnson LA, Mulligan NW, Ward MC, Jones DL. Improving cardiopulmonary resuscitation skills retention effect of two checklists designed to prompt correct performance. *Resuscitation* 1997; 34: 221–5.
- 14 Berkenstat H, Yusim Y, Ziv A, Ezri T, Perel A. An assessment of a point-of-care information system for the anaesthesia provider in simulated malignant hyperthermia crisis. *Anesthesia and Analgesia* 2006; **102**: 530–2.
- 15 Learner C, Gaca AM, Frush DP, et al. Enhancing pediatric safety: assessing and improving resident com-

petency in life-threatening events with a computer-based interactive resuscitation tool. *Pediatric Radiology* 2009; **39**: 703–9.

- 16 Dyson E, Voisey S, Hughes S, Higgins B, Mcquillan PJ. Educational psychology in medical learning: a randomised controlled trial of two aide memoires for the recall of causes of electromechanical dissociation. *Emergency Medicine Journal* 2004; **21**: 457–60.
- 17 McCallum Z, South M. Development and use of a portable paediatric resuscitation card. *Journal of Paediatric and Child Health* 2004; **40**: 477–80.
- 18 Bould MD, Hayter MA, Campbell DM, Chandra DB, Joo HS, Naik VN. Cognitive aid for neonatal resuscitation: a prospective single-blinded randomised controlled trial. *British Journal of Anaesthesia* 2009; 103: 570–5.
- 19 Zanner R, Wilhelm D, Feussner H, Schneider G. Evaluation of M-AID®, a first aid application for mobile phones. *Resuscitation* 2007; **74**: 487–94.
- 20 Nelson KL, Shilkofski NA, Haggerty JA, Saliski M, Hunt EA. The use of cognitive aids during simulated pediatric cardiopulmonary arrests. *Simulation in Healthcare* 2008; **3**: 138–45.
- 21 Merchant RM, Abella BS, Abotsi EJ, et al. Cell phone cardiopulmonary resuscitation: audio instructions when needed by lay rescuers: a randomized controlled trial. *Annals of Emergency Medicine* 2010; **55**: 538–43.
- 22 Wayne DB, Didwania A, Feinglass J, Fudala MJ, Barsuk JH, McGaghie WC. Simulation-Based education improves quality of care during cardiac arrest team responses at an academic teaching hospital: a case control study. *Chest* 2008; **133**: 56–61.

#### Appendix Cardiac arrest scenario.

#### Candidate is given the following briefing

You are called to see a 60-year-old patient who has developed complete heart block (CHB) after an acute inferior myocardial infarction.

#### Scenario develops as follows

Initially, reduced conscious level, bradycardic, hypotensive, unresponsive to treatment with atropine. Patient deteriorates and collapses. Pulseless electrical activity (PEA) arrest complete heart block (CHB) rate 40–50 min<sup>-1</sup>) that changes into ventricular fibrillation (VF) arrest. Patient reverts to spontaneous circulation after 2nd shock, begins to breathe, but remains hypotensive.

#### CAS test scenario - marking criteria

Initial (CHB)	approach ABCDE approach Oxygen, IV access Recognise compromised bradycardia Atropine 0.5 mg IV Consider up to 3 mg atropine IV Request transcutaneous pacing
Cardia (PEA)	c arrest management Check patient (breathing/circulation) Call resuscitation team/help 2 min CPR (30:2) Airway/ventilation/oxygen Attach ECG monitoring (if not already) Give adrenaline 1 mg IV Recognise and treat relevant reversible causes (drugs/electrolyte disturbances)
(VF)	Check monitor/confirm rhythm First shock (150–200 J biphasic or 360 J monophasic) 2 min CPR (continuous chest compression/ventilation)
(VF)	Check monitor/confirm rhythm Give further adrenaline after 3–5 min Minimise interruptions in CPR Second shock (150–200 J biphasic or 360 J monophasic) 2 min CPR (continuous chest compression/ventilation)
(NSR) (	Check monitor/confirm rhythm Check patient (signs of life/pulse) Post-resuscitation care

NSR, Normal sinus rhythm. Each criteria is graded 1–4 (1 = unacceptable, 2 = borderline, 3 = acceptable, 4 = excellent).