Improving Quality and Safety in Office Based Surgery and Anesthesia

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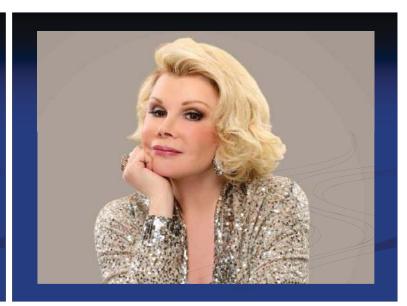


"Wild Wild West of Healthcare"

- Lack of uniform regulation of office based practice
- Increasing number and variety of cases
- Increasing complexity of cases and patients
- Sedation by anesthesia and non-anesthesia personnel
- Widely publicized fatalities and malpractice claims

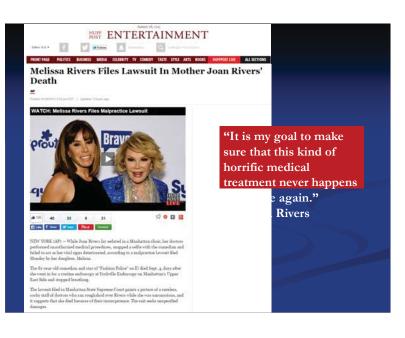
The Institute for Safety in Office Based Surgery

- Non profit organization established 2009
- Purpose:
 - promote patient safety in office-based surgery
 - design tools for advanced detection and prevention of adverse events
 - encourage collaboration across all subspecialties
 - improve physician and patient education
 - generate evidence based standard of care for safer office based practice



Objectives

- A review of the current literature on office based surgical safety
- Understand the necessity and role that team training contributes to a safe office environment
- Measuring quality and safety 2016 updates
- Current research: outcome data analysis from the NACOR (AQI), The Doctor's Company
- The Patient Checklist



Office-Based Anesthesia: Safety and Outcomes

Fred E. Shapiro, DO,* Nathan Punwani, MD,† Noah M. Rosenberg, MD,‡ Arnaldo Valedon, MD,§ Rebecca Twersky, MD, MPH,|| and Richard D. Urman, MD, MBA¶ (Anesth Analg 2014;119:276–85)

The increasing volume of office-based medical and surgical procedures has fostered the emergence of office-based anesthesia (OBA), a subspecialty within ambulatory anesthesia. The growth of OBA has been facilitated by numerous trends, including innovations in medical and surgical procedures and greater convenience for There is a lack of randomized controlled trials rmine how office-based procedures and anesthesia affect patient morbidity and mortality. As a result, studies on this topic are retrospective in nature. Some of the early literature broaches concerns about the safety of office-based procedures and anesthesia. However, more recent data have shown that care in ambulatory settings is comparable to hospitals and ambulatory surgery Enhance quality of care by engaging in proper procedure and patient selection, provider credentialing, facility accreditation, and incorporating patient safety checklists and professional society guidelines into practice. strategies for minimizing patient complications and mortality in OBA, and future developments that could impact the field. (Anesth Analg 2014;119:276–85)

ASA CLOSED CLAIM **PROJECT**

Injury and Liability with MAC cases

Bhananker, SM, et al., Anesthesiology 2006; 104:228-34.

Office-Based Anesthesia: Safety and Outcomes

Fred E. Shapiro, DO,* Nathan Punwani, MD,† Noah M. Rosenberg, MD,‡ Arnaldo Valedon, MD,§ Rebecca Twersky, MD, MPH, and Richard D. Urman, MD, MBA (Anesth Analg 2014;119:276-85)

Recent Studies on the Safety of Office-Based Anesthesia and Procedures

Study	Key Findings
Vila et al. 2003	2 years of adverse events reported to Florida Board; 10-fold relative risk in office compared with ASC
Fleisher et al. 2004	564,267 outpatient surgeries, Medicare population 1-week mortality rates: in the office - 0.035%, ASC - 0.025%, in the hospital - 0.05%. Inpatient admission rate within 7 days of outpatient surgery: in the office - 0.91%, ASC - 0.84%, in the hospital - 2.1%
Bhananker et al. 2006	>40% of MAC claims involved death or permanent brain damage, similar to general anesthesia claims. Respiratory depression: 21% of MAC claims. 46% preventable by better monitoring, eg capnography, improved vigilance, or audible alarms. On-the-patient operating room fires from electrocautery, supplemental oxygen during facial surgery: burn injuries in 17% of MAC cases.
Starling et al. 2012	Six years of adverse event reporting Alabama: 3 deaths, 49 procedure-related complications and hospital transfers, board-certified physicians. Cosmetic procedures = 42% of hospital transfers and no deaths, 86% of hospital transfers associated with a cosmetic procedure involved general anesthesia. Liposuction = no deaths and 2 hospital transfers. Ten years of Florida data: 46 deaths and 263 procedure-related complications and hospital transfers. Cosmetic procedures were liable for half the deaths and hospitals transfers. 67% of deaths and 74% of hospital transfers associated with a cosmetic procedure involved general anesthesia. Liposuction, liposuction with abdominoplasty or other cosmetic procedure = 10 deaths and 34 hospital transfers. 93% of offices reporting an adverse event had board-certified physicians, 98% with hospital privileges.
Soltani et al. 2013	22,000 adverse events, 5.5 million plastic surgery procedures, IBQAP AAAASF accredited. Complication rate 0.4%, 94 deaths (0.0017% death rate); 40 cases pulmonary embolism. Office based abdominoplasty 5.5x risk associated with pulmonary embolism/VTE.

ASA Closed Claims Analysis: MAC Cases

- Respiratory depression-most common mechanism (21%)
- 46% deemed preventable by:
 - better monitoring eg. capnography
 - improved vigilance
 - audible alarms

Vila et al.

Arch Surg 2003;138:991-995 - Tampa, Florida

- Study to compare outcome to determine patient safety between offices and ambulatory surgicenter (ASC)
- All adverse incidents reviewed (April 2000 April 2002)
- Approximately 10-fold increased risk of adverse incident and death in an office based setting

The risk and safety of anesthesia at remote locations: the US closed claims analysis

etzner, Julia: Posner, Karen L: Domino, Karen B

Current Opinion in Anesthesiology

Current Opinion in Anaesthesiology Issue: Volume 22(4), August 2009, p 502-508

We analyzed claims from 1990 and later in the American Society of Anesthesiologists Closed Claims database to assess patterns of injury and liability associated with claims from anesthesia in remote locations (n = 87) compared with claims from operating room procedures (n = 3287).

Recent findings: Compared with operating room claims, remote location claims involved older and sicker patients (P < 0.01), with 50% of remote location claims involving monitored anesthesia care. The proportion of claims for death was

...anesthesia at remote locations poses a significant risk for the patient, particularly related most common specific to oversedation and inadequate oxygenation/ ventilation during monitored anesthesia care.

cation claims (44 vs. location claims were (32 vs. 8% for

m claims), P < 0.001].

Similar anesthesia and monitoring standards and guidelines should be used in all anesthesia care areas.

logists, Closed Claims ignificant risk for the

nilar anesthesia and thesia care areas.





Complications of Non-Operating Room Procedures: Outcomes From the National Anesthesia Clinical Outcomes Registry Chang B. et al. J Patient Saf 2015;00: 00-00

		OR	Non-OR
Patients > age 50		55.56%	61.92%
MAC use		10.89%	20.15%
Sedation		0.57%	2.05%
Minor Complications:			
postop nausea + vomiti	Non-OR Cardiology Mortality: 0.05% Non-OR Radiology Mortality: 0.05%		
Inadequate pain control		0,	
Inadequate pain control Hemodynamic instabilit		0,	•
		0,	•
Hemodynamic instabilit	Non-OR Radio	0,	
Hemodynamic instabilit Major complications:	Non-OR Radio	logy Mortali	ty: 0.05%

ASA Closed Claim Project: 1996-2011

- Patient description: 64 office claims (718)
 - Middle-aged (median = 45 years)
 - Female (65%)
 - ASA I-II (79%)
 - Elective surgery
 - plastic 45% vs 18%
 - eye 16% vs 10%

ASA CLOSED CLAIM PROJECT

Liability with Office-Based Cases

ASA Office-based Claims: 1996-2011

- Inadequate oxygenation: (17% vs 6%)
- Death 27%, perm disabling 17% (similar)
- Substandard care: 52% (vs 37%)
- OBA claims- payment: 72% (vs 56%)
- Payment similar: (\$ 135,800 vs \$ 211,500)

Determining the Safety of Office-Based Surgery: What 10 Years of Florida Data and 6 Years of Alabama Data Reveal

JOHN STARLING III, MD, MAYA K. THOSANI, MD, AND BRETT M. COLDIRON, MD, FACP*† Dermatol Surg 2012;38:171-177

Adverse Event Reporting in Alabama and Florida

Maverse Event Reporting in Madama and Monda				
Alabama (6 years of data)	Florida (10 years of data)			
Medical offices: 3 deaths and 49 procedure- related complications and hospital transfers. All occurred in the offices of board-certified physicians.	Medical offices: 46 deaths and 263 procedure- related complications and hospital transfers.			
Cosmetic procedures: 42% of hospital transfers and no deaths. 86% of hospital transfers caused by a cosmetic procedure involved the use general anesthesia.	Cosmetic procedures: at least half of the deaths and hospitals transfers. 67% percent of deaths and 74% of hospital transfers associated with a cosmetic procedure involved general anesthesia.			
Liposuction: no deaths and 2 hospital transfers.	Liposuction and liposuction with abdominoplasty or other cosmetic procedure: 10 deaths and 34 hospital transfers.			
	93% of offices reporting an adverse event had physicians with board certification, and 98% of them had physicians with hospital privileges			



Outpatient Surgery and Sequelae An Analysis of the AAAASF Internet-based Quality Assurance and Peer Review Database

Ali M. Soltani, MD^a, Geoffrey R. Keyes, MD^{B,C, a}, Robert Singer, MD^{d, a}, Lawrence Reed, MD^f, Peter B. Fodor, MD^g

Clin Plastic Surg 40 (2013) 465–473

Summary:

- 5.5 million plastic surgery cases
- **22,**000 sequelae (0.4% incidence)
- **94** deaths 2001-12 (0.0017%)
- Risk in plastic surgery=1/41,726
- PE most common 40 deaths
- Abdominoplasty incidence 0.925%
- Abdominoplasty 5.5 risk of VTE vs other



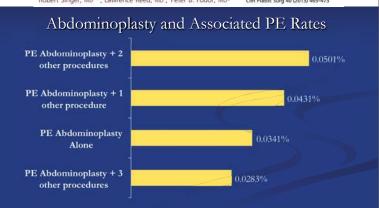
wasn't board-certified - but there was no law to stop him.

- 37 y/o RN goes to MedSpa for liposuction.
- MD performing was trained in Occupational Medicine.
- Took 3-day course in liposuction.
- Lidocaine and propofol administered.
- Patient became unconscious, seizes and dies.

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Clin Plastic Surg 40 (2013) 465–473



Clayman, MA, Seagle BM.

Plast. Reconstr. Surg 2006; 118: 777-785.

- What does board-certified mean?
- Are practitioners doing something other than what their board certification qualifies them to do?

Safety by Educating the Public Clayman MA, et al.

Ann Plast Surg. 2007; 58: 288-291

Suggestions:

- Physicians critically read any medical literature that are read by the public or touted in media.
- Patients should research education, training, certification of person performing the procedure.
- Patients should ask: Do they have surgical privileges to perform the same procedure in an accredited hospital?

Team Training

- Medical team training, involving teamwork training, ongoing coaching, and checklists to trigger operating room briefings and debriefings, was associated with a reduction in mortality.
- Surgical mortality declined 18% at hospitals that implemented the Medical Team Training program (n=74), compared with a 7% mortality reduction in the control hospitals (n=34).

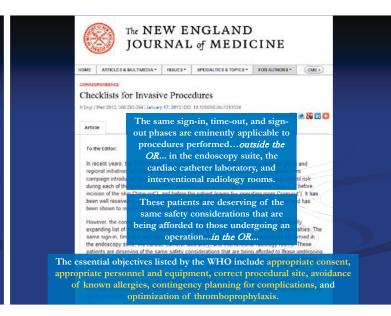
Quarters of Risk-Adjusted Surgical Mortality Rate



Neily, J et al. JAMA. 2010; 304(15):1693-1700.

Value-Based Purchasing

- High quality and cost-effective healthcare
- Construct incorporates The National Quality Strategy's aims:
 - patient safety, patient-centered experience and outcomes, improve care coordination, efficiency and cost reduction, population health



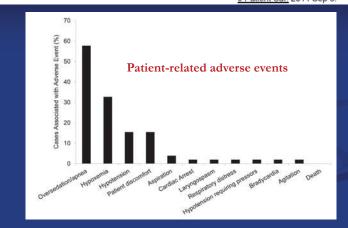
Use of Checklist in ASC

- January 2012, CMS instituted use of a safe-surgery checklist
- Efficacy quality improvement and patient safety in tertiary care.
- ASCs free to select the checklist that meets individual needs.
- CMS uses the name "safe surgery" checklist, applies to all ASC procedures, including those considered to be diagnostic and pain management procedures.
- World Health Organization, Association of the periOperative Registered Nurses (AORN), American College of Gastroenterology, American College of Surgeons, The Institute for Safety in Office-Based Surgery

Analysis of Adverse Events Associated With Adult Moderate Procedural Sedation Outside the Operating Room

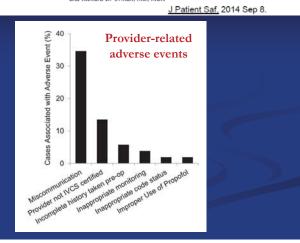
Sergey Karamnov, MD,* Natalia Sarkisian, PhD,† Rebecca Grammer, DMD,* Wendy L. Gross, MD, MHCM, and Richard D. Urman, MD, MBA*

<u>J Patient Saf.</u> 2014 Sep 8.



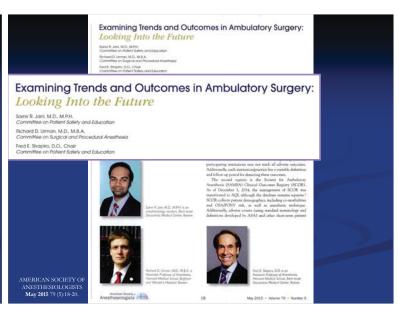
Analysis of Adverse Events Associated With Adult Moderate Procedural Sedation Outside the Operating Room

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Study Results ■ Pre-checklist, 90% missing Percentage of Positive Responses Pre- and Post-Checklist Implementation documentation of three or more elements. 80 ■ 15% of cases had 70 60 adverse events of which 50 pain (3.7%) and 40 bleeding/bruising (3.2%) were most common. ■ Post-checklist analysis: 90-100% increase in documentation of several key indicators and practices. Pre-Checklist positive response Post-Checklist positive response







Effect of an Office-Based Surgical Safety System on Patient Outcomes

Published December 25, 2012

Noah M. Rosenberg, MD, * Richard D. Urman, MD, MBA, * Sean Gallagher, MD, * John Stenglein, MD, * Xiaoxia Liu, MS, * and Fred E. Shapiro, DO*

- 28-element perioperative ISOBS checklist
- Customized to an office-based plastic surgery
- **219** cases
- Baseline and post-op adverse outcomes
- post-checklist implementation chart review

Additional Goals:

- To decrease incidence of adverse outcomes in the perioperative period
- To educate the practitioner and support staff

Initial Results from the National Anesthesia Clinical Outcomes Registry and Overview of Office-Based Anesthesia

Fred E. Shapiro, Doll, Samir R. Jani, MD, MPH $^{\rm l}$, Xiaoxia Liu, MS $^{\rm b}$, Richard P. Dutton, MD, MBA $^{\rm l}$, Richard D. Urman, MD, MBA $^{\rm l}$, $^{\rm l}$

Anesthesiology Clin 32 (2014) 431-444

Table 3 Age distribution of OBA and in non-OBA NACOR cases				
Variable	Office Based (N = 84,461) n (%)	NACOR (N = 12,557,021) n (%)		
Age group (y)				
<1	121 (0.14)	64,951 (0.52)		
1-18	6024 (7.35)	1,302,276 (10.37)		
19-49	35,862 (42.46)	4,397,863 (35.02)		
50-64	29,362 (34.76)	3,218,552 (25.63)		
65-79	10,760 (12.74)	2,682,377 (21.36)		
80+	2152 (2.55)	891,002 (7.10)		

P = <.0001.

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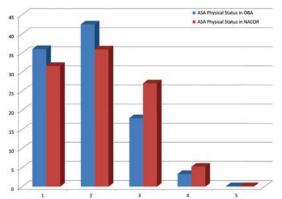


Fig. 1. Distribution of ASA physical status in OBA and non-OBA NACOR cases.

A Comparison Between Office and Ambulatory Practices: Analysis from the National Anesthesia Clinical Outcomes Registry

Samir R. Jani, MD, MPH, Fred E. Shapiro, DO, Hubert Kordylewski, James H. Diaz, MD, MPH, Alan D. Kaye, MD, PhD, Richard P. Dutton, MD, MBA, Richard D. Urman, MD, MBA

- Anesthesia Quality Institute (AQI) has collected patient and procedural characteristics on 19,032,432 anesthetics from all healthcare settings since 2010.
- 108,443 office and 3,647,690 ambulatory cases were isolated and compared.
- Our findings show that although both settings are often grouped together, there are statistically significant differences in patient demographics, procedure types, and reported adverse events.

Initial Results from the National Anesthesia Clinical Outcomes Registry and Overview of Office-Based Anesthesia

Fred E. Shapiro, DO[®], Samir R. Jani, MD, MPH[®], Xiaoxia Liu, MS^D, Richard P. Dutton, MD, MBA^C, Richard D. Urman, MD, MBA^D, **

Anesthesiology Clin 32 (2014) 431-444

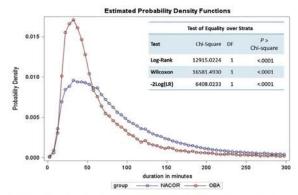
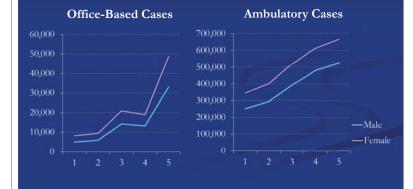


Fig. 2. Distribution of case duration (min) in OBA and non-OBA NACOR cases. DF, degrees of freedom; P, probability; LR, log-rank.

A Comparison Between Office and Ambulatory Practices: Analysis from the National Anesthesia Clinical Outcomes Registry Samir R. Jani, MD, MPH, Fred E. Shapiro, DO, Hubert Kordylewski, James H. Diaz, MD, MPH, Alan D. Kaye, MD, PhD, Richard P. Dutton, MD, MBA, Richard D. Urman, MD, MBA

The number of cases is increasing in both categories



Initial Results from the National Anesthesia Clinical Outcomes Registry and Overview of Office-Based Anesthesia

Fred E. Shapiro, po^a, Samir R. Jani, MD, MPH^a, Xiaoxia Liu, MS^b, Richard P. Dutton, MD, MBAC, Richard D. Urman, MD, MBAD

Anesthesiology Clin 32 (2014) 431-444

Variable	Office Based (N = 44,484) n (%)	NACOR (N = 9,365,286) n (%)		
Anesthesia Type				
ESP	1241 (2.83)	853,823 (9.22)		
GEN	30,638 (69.91)	6,566,028 (70.93)		
LOC	4 (0.01)	10,093 (0.11)		
MAC	11,600 (26.47)	1,537,381 (16.61)		
ОТН	56 (0.13)	96,677 (1.04)		
REG	284 (0.65)	192,662 (2.08)		

Abbreviations: ESP, epidural/spinal; GEN, general anesthesia; LOC, local anesthesia only; OTH, other; REG, regional anesthetic.



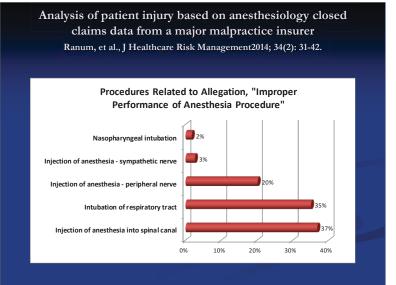
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NACOR Reported Outcomes (2010-14 combined)

Office-Based Ambulatory

Inadequate Post-op Pain Control
Post-op Nausea/Vomiting
Hemodynamic Instability
Airway/Intubation Difficulty
Respiratory Issues
Central Line/Periph IV Problem
Eye Injury
Dental Injury

Dental Injury



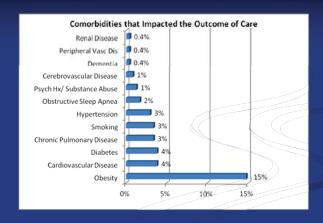
Analysis of patient injury based on anesthesiology closed claims data from a major malpractice insurer

Darrell Ranum, JD, CPHRM, Haobo Ma, MD, Fred E. Shapiro, DO, Beverly Chang, MD, and Richard D. Urman, MD, MBA J Healthcare Risk Management 2014; 34(2): 31-42.

- **Methods:** Review of anesthesia closed claims data as reported by The Doctors Company, 2007 2012. Each claim underwent a review by physician and nurse experts. Each injury was classified into 1 of 9 severity levels. Potential association between injury and patient comorbidity also examined.
- Results: 607 claims analyzed. Most frequent injuries: teeth damage (20.8%), death (18.3%), nerve damage (13.5%), organ damage (12.7%), pain (10.9%), and arrest (10.7%). Obesity was contributing factor in the most number of claims. Injury-to-claim rates were highest in hospitals with fewer than 100 beds, while ambulatory surgery centers had the lowest death-to-claim rate (12%). Average indemnity for an anesthesia claim was \$309,066, compared to \$291,000 for all physician specialties.

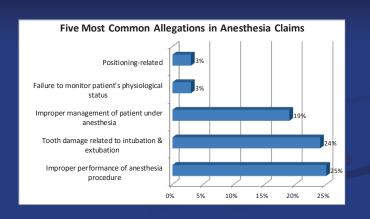
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Ranum, et al., J Healthcare Risk Management 2014; 34(2): 31-42.

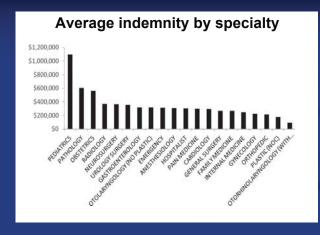


Analysis of patient injury based on anesthesiology closed claims data from a major malpractice insurer

Ranum, et al., J Healthcare Risk Management (in press)



Analysis of patient injury based on anesthesiology closed claims data from a major malpractice insurer Ranum, et al., J Healthcare Risk Management2014; 34(2): 31-42.



PATIENT-CENTERED CARE: Improving Patient Safety in Anesthesia Through Patient Engagement

"Patient engagement at the level of direct anesthesia care includes a number of elements such as education, risk assessment, intervention, patient questions and, ultimately, shared decision-making. By engaging patients early, we can promote better outcomes by identifying risks, educating patients and encouraging healthful decision-making."



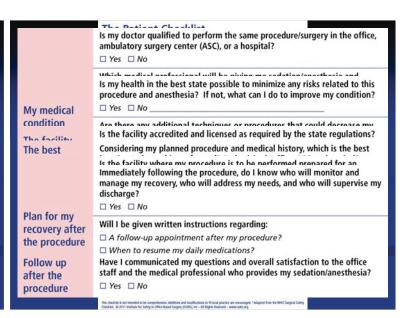


A Survey Analysis of an Ambulatory Surgical

Checklist Designed for Use by Patients Rohesh J. Fernando MD^a, Fred E. Shapiro DO^c, Richard D. Urman MD, MBAe*

- Surveyed 35 patients and 52 providers
- 94% of patients and 83% of providers thought the checklist would be beneficial for patients.
- 37% of providers indicated potential barriers to checklist implementation:
 - fear of confusing the patient
 - making patients doubt the care they were receiving
 - taking too much time
 - lack of resources

The Patient's Checklist for **Ambulatory Procedures** The facility The best place for uld I follow-up with after my visit:



CONCEPTS FOR THE DEVELOPMENT OF A CUSTOMIZABLE CHECKLIST FOR PATIENT USE

Rohesh J. Fernando MDa, Fred E. Shapiro DOc, Noah M. Rosenberg, MDb Angela M. Bader MD, MPHd, Richard D. Urman MD, MBAc

A SURVEY ANALYSIS OF AN AMBULATORY SURGICAL CHECKLIST DESIGNED FOR USE BY PATIENTS

> Rohesh J. Fernando MDa, Fred E. Shapiro DOc, Richard D. Urman MD, MBAe*



Melissa Rivers: Joan's Death was "100% Preventable"

She cites egregious alleged failures in interview

Published: May 4, 2015

Category: Outpatient Surgery News and Trends > General Surgical News and Reports

The death of Joan Rivers was "100% preventable," her daughter, Melissa, tells an

interviewer on the "Today Show" in paying attention to the vital signs? crash cart?"

"[Her] death was 100% preventable... How about paying attention to the vital signs? How about having a properly equipped crash cart?" - Melissa Rivers

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