“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

Recent Media Attention: High-Profile Events

Teen died of malignant hyperthermia during breast surgery; parents suing surgeon and anesthesiologist for not recognizing MH and having enough dantrolene stocked in outpatient surgery center

Eight-year-old died after receiving three times the prescribed amount of sedation medication for a routine checkup and an emergency developed thereafter

25-year-old died due to possible hypoxia and lack of monitoring after Propofol administration for wisdom tooth extraction

Joan Rivers died of hypoxia and cardiac arrest after Propofol administration for endoscopic procedure for vocal changes and acid reflux

Three-year-old died of possible apnea after general anesthesia for tooth extraction

Office-Based Anesthesia: Safety and Outcomes

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 anesthetic drugs, as well as improved provider reimbursement and greater convenience for patients. There is a lack of randomized controlled trials to determine how office-based procedures a As a result, studies on this topic are retros s 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 centers, especially when offices are accredited and their proceduralists are board-certified. Off by en on, an ce. Th as- ingly important as more states, and possibly the federal government, exercise regulatory authority over the ambulatory setting. We explore these trends, their implications for patient safety, strategies for minimizing patient complications and mortality in OBA, and future developments that could impact the field. (Anesth Analg 2014;119:276–85)

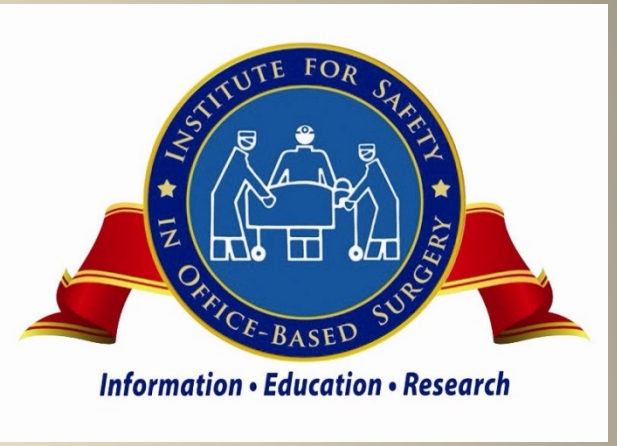
There is a lack of randomized controlled trials

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.

Published by Drs. Fred Shapiro and Richard. Urman

The Institute for Safety in Office-Based Surgery

- An organization established 2009
- Purpose:
  - Promote patient safety and outcomes research
  - Design tools for advanced detection and prevention of adverse events
  - Collaborate across ALL subspecialties
  - Educate physicians and patients
  - Generate evidence-based standard of care for safer office based practice



www.isobs.org

"to promote patient safety in office-based surgery and to encourage collaboration, scholarship, physician and patient education"

Short Term Goals

- **Team Approach:** Create a multidisciplinary organization of leaders of all major professional societies to develop a consensus of opinion to standardize care in the office setting
- **Checklist:** Develop ISOBS surgical safety checklist
- **Oversight:** Office practice oversight to detect lapses in knowledge
- **Trigger Tools:** Develop Trigger Tools (I.H.I.) method to detect potential causative events (i.e. adverse events using a form of retrospective record review)
- **Education:** On-line education and training of office-based personnel

ISOBS 20 years:

Multidisciplinary Network of OBS Experts/Advisors

ISOBS 20 years:
Provider Checklist

Safety Checklist for Office-Based Surgery

from the Institute for Safety in Office-Based Surgery (ISOBS)

Introduction
Preoperative encounter; with practitioner and patient

Patient

Patient medically optimized for the procedure?
- ☐ *Yes*
- ☐ *No, and plan for optimization made.*

Does patient have DVT risk factors?
- ☐ *Yes, and prophylaxis plans arranged.*
- ☐ *No*

Procedure

Procedure complexity and sedation/analgesia reviewed?
- ☐ *Yes*

NPO instructions given?
- ☐ *Yes*

Escort and post-procedure plans reviewed?
- ☐ *Yes*

Setting
Before patient in procedure room; with practitioner and personnel

Emergency equipment check complete (e.g. airway, AED, code cart, MH kit)?
- ☐ *Yes*

EMS availability confirmed?
- ☐ *Yes*

Oxygen source and suction checked?
- ☐ *Yes*

Anticipated duration ≤ 6 hours?
- ☐ *Yes*
- ☐ *No, but personnel, monitoring and equipment available*

Operation
Before sedation/analgesia; with practitioner and personnel*

Patient identity, procedure, and consent confirmed? ☐ *Yes*

Is the site marked and side identified?
☐ *Yes* ☐ *N/A*

DVT prophylaxis provided?
☐ *Yes* ☐ *N/A*

Antibiotic prophylaxis administered within 60 minutes prior to procedure? ☐ *Yes* ☐ *N/A*

Essential imaging displayed?
☐ *Yes* ☐ *N/A*

Practitioner confirms verbally:
- ☐ Local anesthetic toxicity precautions
- ☐ Patient monitoring (per institutional protocol).
- ☐ Anticipated critical events addressed with team.
- ☐ Each member of the team has been addressed by name and is ready to proceed.

Before discharge
On arrival to recovery area; with practitioner & personnel

Assessment for pain?
- ☐ *Yes*

Assessment for nausea/ vomiting?
- ☐ *Yes*

Recovery personnel available?
- ☐ *Yes*

Prior to discharge:
(with personnel and patient)

Discharge criteria achieved?
- ☐ *Yes*

Patient education and instructions provided?
- ☐ *Yes*

Plan for post-discharge follow-up?
- ☐ *Yes*

Escort confirmed?
- ☐ *Yes*

Satisfaction
Completed post-procedure; with practitioner and patient

Unanticipated events documented?
- ☐ *Yes*

Patient satisfaction assessed?
- ☐ *Yes*

Provider satisfaction assessed?
- ☐ *Yes*

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged. *Adapted from the WHO Surgical Safety Checklist.

Published *AORN J* 2013

ASHRM AMERICAN SOCIETY FOR HEALTHCARE RISK MANAGEMENT

A professional membership group of the American Hospital Association

Added to ASHRM Resource Manual in Office-Based Surgery 2016

Safety Checklist for Office-Based Surgery

from the Institute fo

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This checklist is not [illegible] cal Safety Checklist.

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Before Discharge

On arrival to recovery area; with practitioner & personnel

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Assessment for nausea/vomiting? ☐ *Yes*

Recovery personnel available? ☐ *Yes*

Prior to discharge (with personnel and patient)

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Information • Education • Research

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ISOBS 20 years:

Patient Checklist

Patient's Checklist for Office-Based Procedures

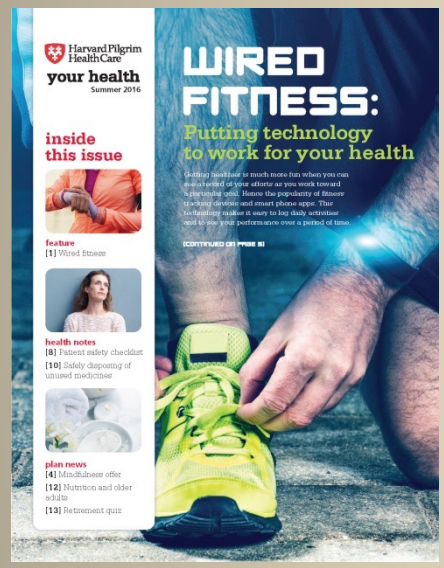
from the Institute for Safety in Office-Based Surgery (ISOBS)

Information • Education • Research

Inquire | **What are**

Does the doctor have privileges to perform the same procedure at a hospital?

Published *AORN J* 2013



Harvard Pilgrim Health Care

Featured in the HPHC newsletter summer 2016 (~400,000 subscribers)

[health notes]

Upcoming surgery?

A safety checklist for patients

Outpatient surgery is convenient, cost-effective and performed more frequently every year. Because outpatient facilities aren't as optimally equipped as hospitals, additional safety guidelines help to ensure the best possible care for patients. As a patient, being proactive and informed are also important in getting the high-quality care you need.

Patient safety advocates Fred E. Shapiro, DO, and Joseph Foley, MD — anesthesiologists at Beth Israel Deaconess Medical Center in Boston, Massachusetts — offer the following advice to patients.

As with flying, when we must place our faith in the expertise of the pilot, undergoing any surgical procedure requires a certain level of trust. With so many procedures now being performed in outpatient facilities, it's also important to understand what the procedure involves and how you can best prepare for it.

Understanding your doctor's experience, asking questions and knowing what to expect in advance will go a long way in helping you feel more confident and ready. Studies show that patients who are engaged and informed are more satisfied with the experience. So don't hesitate to ask questions or address any concerns with your health care team.

Download a safety checklist for your next outpatient procedure at harvardpilgrim.org/yourhealth.

[8] YOUR HEALTH SUMMER 2016

[health notes]

Example questions you may wish to ask the doctor before your procedure:

- Why did you choose this facility? Is it licensed and accredited for this procedure?
- Will I get written instructions when I'm discharged?
- What kind of anesthesia will I be having (local, general or other)?
- Given my history and current health conditions, what can I do to be best prepared physically for my surgery?
- Who will be giving me anesthesia?
- What happens if there is a problem in surgery? Are the right resources on hand at this location if complications occur?
- What should I expect afterward e.g. length of recovery, pain management and follow-up care?

What exactly is outpatient surgery?

/'out,pāSHənt/ /'sərj(ə)rē/

(also called ambulatory surgery) allows a person to return home on the same day a procedure is performed. Outpatient surgery is a convenient option when an overnight stay or the full services of a hospital are not required for a person's procedure or recovery.

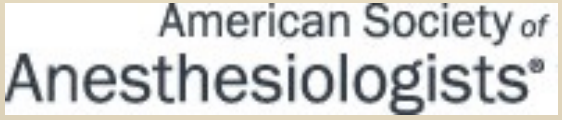
MORE ABOUT DRS. SHAPIRO AND FOLEY

Dr. Shapiro is President of the Massachusetts Medical Society (Suffolk District), Chair of the American Society of Anesthesiologists Committee on Patient Safety & Education, a Founder of the Institute for Safety in Office-Based Surgery and Assistant Professor of Anesthesia at Harvard Medical School. Dr. Foley is a second year resident in anesthesia.

HARVARDPILGRIM.ORG [9]

ISOBS 20 years:

Interspecialty and interprofessional collaborations



ISOBS 20 years:

Public Outreach – ISOBS Website & Newsletters

INSTITUTE FOR SAFETY IN OFFICE-BASED SURGERY

Information, Education, Research

Upcoming Institute of Healthcare Improvement Webinar

Written by john on October 10th, 2017

On Thursday, 10/26/17 @ 14:00 EST (2PM), we will be on air on the upcoming Institute of Healthcare Improvement (IHI) webinar discussing our newly created ISOBS Safety Checklist for Office-Based Anesthesia Crises.

Please join us (Fred E. Shapiro, DO, Chair for ASA Committee on Patient Safety and Education and co-founder of ISOBS; Alex Hannenberg, MD, Faculty, Safe Surgery Program, Ariadne Labs, and Chief Quality Officer of the ASA; and Jennifer Lenoci-Edwards, RN, MPH, director of Patient Safety for IHI) live for this free audio program!

If you miss it, this IHI podcast will be archived and available on iTunes.

Posted in General Information | Comments Off

Introducing ISOBS Safety Checklist for Office-Based Surgery

NEWS ARCHIVES

Select Month

Information • Education • Research

Contact Us

The mission of the Institute for Safety in Office-Based Surgery (ISOBS), a 501(c)(3) nonprofit, independent organization is to promote patient safety in office-based surgery and to encourage collaboration, scholarship, and physician and patient education.

more info>>

ISOBS Newsletter

Information, Education, Research **September 2015**

Information • Education • Research

www.ISOBS.org

In This Issue

Projects

Patients

Personnel

Presentations

A Tribute

Join Our Mailing List!

::

Dear Jane,

We hope this newsletter update finds you well - staying cool during these last hazy hot 90 degree days of Boston summer, recalling your wishes while trekking through 90 inches of snow last winter.

As the 2015-16 academic season approaches, we thought this a perfect opportunity to share an ISOBS update: we continue to **expand our global outreach with new projects, personnel, presentations, publications**, and most recently an **HPHC Patient Safety Leadership Award.**

Projects

Harvard Pilgrim Health Care

In July 2015, ISOBS received an **HPHC Leadership Award** in support of our research and continued efforts to improve patient safety in procedures and surgery performed outside the operating room.

JOURNAL OF PATIENT SAFETY

Fernando RJ, Shapiro FE, Rosenberg NM, Bader AM, Urman RD. **Concepts for the development of a customizable checklist for use by patients.** J Patient Saf 2015 Jun 10.

ISOBS 20 years:

HMS Curriculum development

NEW RESIDENT CURRICULUM IN OFFICE-BASED ANESTHESIA

Jervis K. MD, Kaper J. MD, Urman R. MD, Bernardini J. MD, Green M. BA, McMurray C. MD, Rutkauskas J. MD, Shapiro F. DO.

Department of Anesthesia, Critical Care, and Pain Medicine – Beth Israel Deaconess Medical Center, Harvard Medical School

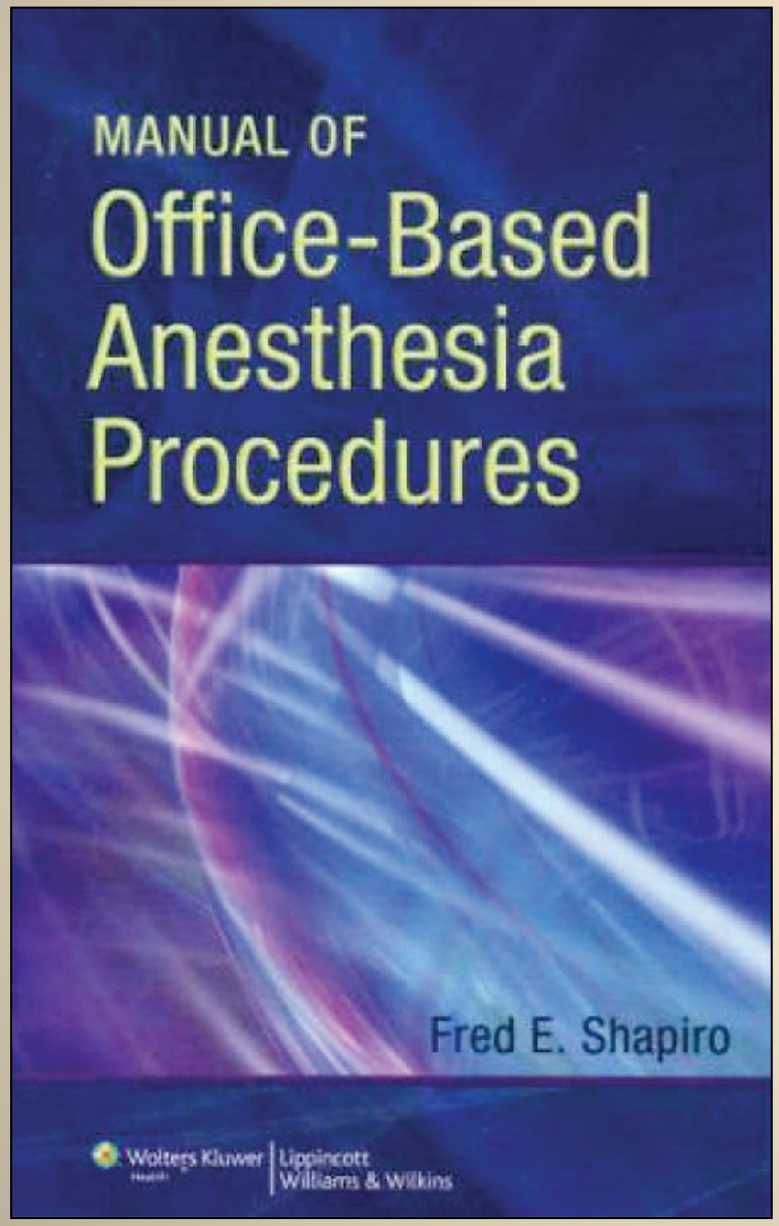
Contact: Fred Shapiro, DO; email: fshapiro@bidmc.harvard.edu; tel: (617)632-3112

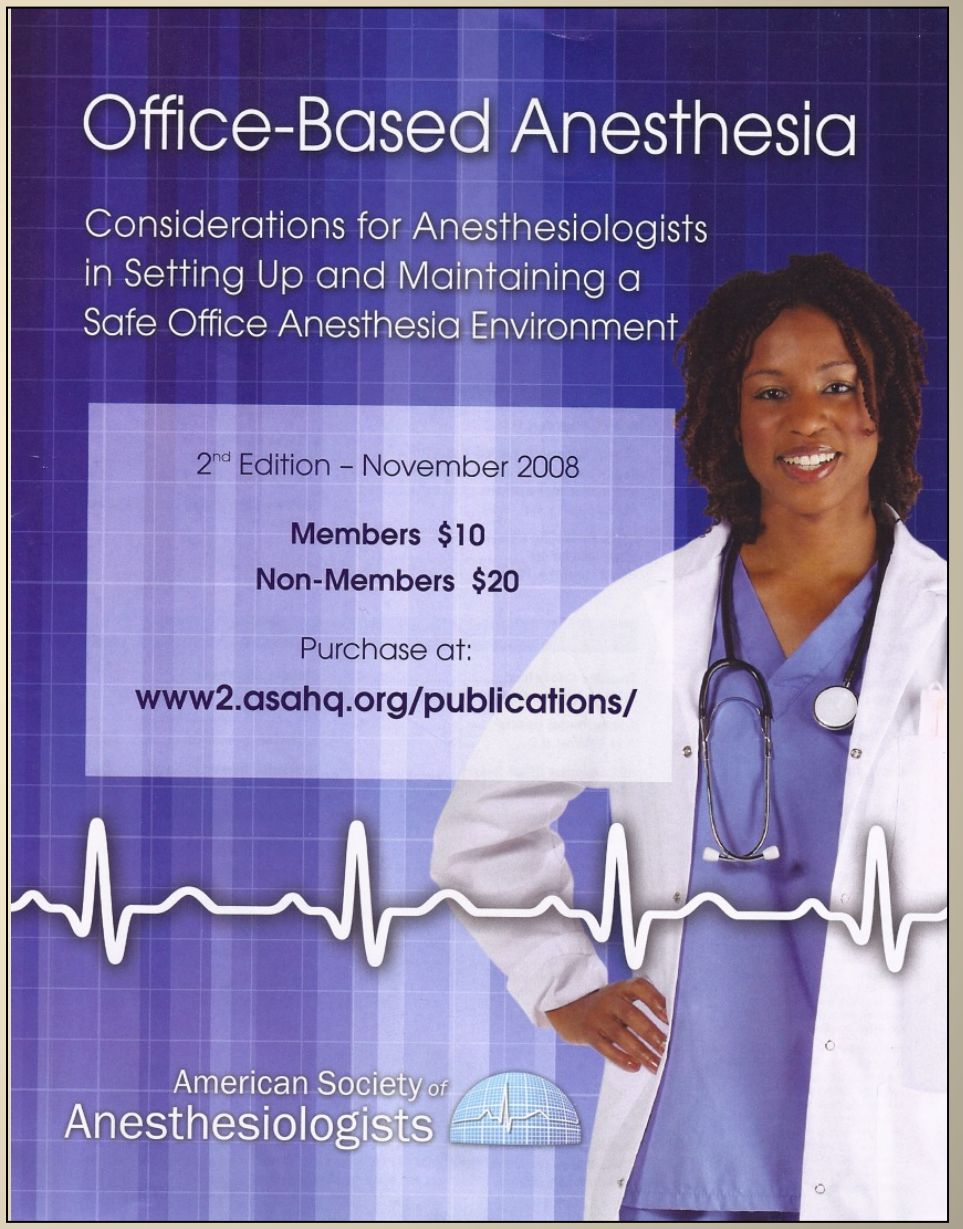
Purpose: The purpose is to provide resident physicians in the anesthesiology training program with the skills and knowledge needed to deliver a safe and appropriate anesthetic to patients undergoing surgery in an office-based setting. The new curriculum will help familiarize residents with various aspects of patient care that is often taken for granted in hospital-based operating facilities, such as building code compliance, occupational safety, appropriate patient and case selection, monitoring, equipment maintenance, and emergency protocols. In order to deliver competent care for these patients, a specific knowledge and skills base that is often inadequately addressed in the traditional anesthesia training curriculum, will be taught.

2005 Harvard Medical School Education Day Curriculum proposal

ISOBS 20 years:

Publications





Authored in 2007

ISOBS 20 years:

Safety Initiatives / CME Courses

Anaesthesia in the Office-Based Setting:

Safe, Simple and Pain Free

September 29, 2007

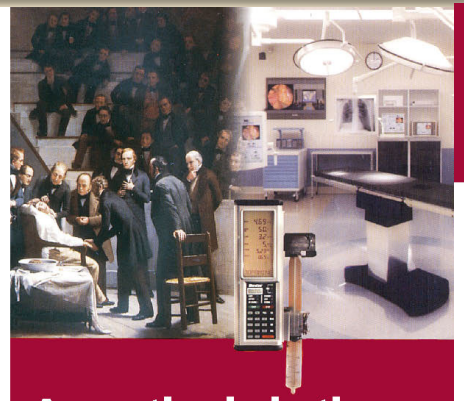
The Conference Center at Harvard Medical
Boston, MA

Course Director
Fred Shapiro, DO

Harvard Medical School
Department of Continuing Education

Beth Israel Deaconess Medical Center
Department of Anesthesia,
Critical Care and Pain Medicine

SAVE THE DATE **September 25 – 26, 2010**



Anaesthesia in the Office-Based Setting:

Keeping it safe, simple and pain free

- Office Safety: appropriate patient, case, and personnel selection
- Current procedures and surgical techniques
- Business: How to set up a successful office practice
- Office-based Simulation: Introducing Part IV MOCA: Crisis Management Skills Laboratory Training
- Hands-on Ultrasound-guided Regional block workshop
- Case Discussion with Recognized Leaders in the field
- Review ASA/SAMBA OBA Manual: Setting Up and Maintaining a Safe Office Anaesthesia Environment
- The Institute for Safety in Office Based Surgery

Information • Education • Research

www.isobs.org

Beth Israel Deaconess Medical Center

Harvard Medical School
Office of Continuing Medical Education

Anaesthesia in the Office-Based Setting:

Keeping it safe, simple and pain free

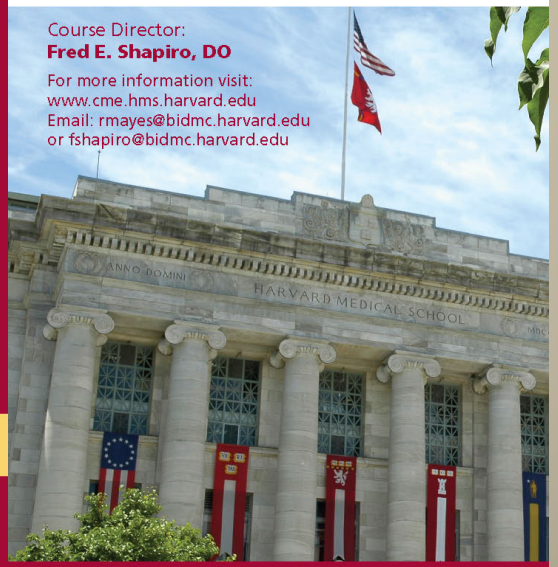
A comprehensive review of the current advances in office-based anesthesia and provide a window into the future developments of this fast growing field. The course will highlight the most common procedures performed, the advances in new surgical techniques and anesthesia technology.

We will discuss the "nuts and bolts" ASA/SAMBA OBA Task Force Manual, *Office Based Anesthesia: Considerations for Setting Up and Maintaining a Safe Office Anesthesia Environment.*

By popular demand, we focus on case discussions, an ultrasound-guided regional anesthesia workshop, and how to create a safe, successful, and accredited office-based business practice. This year, we will introduce our Harvard Crisis Management Skills Laboratory Office-based Simulation, to preview the forthcoming MOCA Part IV requirements.

Course Director:
Fred E. Shapiro, DO

For more information visit:
www.cme.hms.harvard.edu
Email: rmayes@bidmc.harvard.edu
or fshapiro@bidmc.harvard.edu



Registration begins January 2010
http://cme.med.harvard.edu

ISOBS 20 years:

Teaching trainees – curriculum in office-based practice

OFFICE-BASED ANESTHESIA: EDUCATING PRACTITIONERS AND PATIENTS ABOUT CORE SAFETY PRINCIPLES

Beth Israel Deaconess Medical Center · Brigham and Women's Hospital · Harvard Medical School

The Institute for Safety in Office-Based Surgery (ISOBS)

Fred E. Shapiro, DO, Richard D. Urman, MD, MBA, Kate Isselbacher, MD, Harvard Medical School, Boston, MA

ABSTRACT

Purpose: The purpose of this exhibit is to provide an overview of the latest safety initiatives in anesthesia practice, commensurate with advances in surgical technology and procedures in the rapidly growing field of office-based anesthesia. To specifically emphasize core principles of office-based anesthesia practice, including patient selection, anesthetic techniques, policies, regulations, and the personnel.

Background: Office-based anesthesia (OBA) refers to the practice of ambulatory anesthesia in the office setting. OBA is a relatively new and growing field with increasing requests to provide anesthesia services for practitioners who have their own outpatient office-based operating facilities. Such facilities generally have little regulation at the local, state, or federal level - only 22 of 50 states have any regulations regarding OBA. The tremendous growth of OBA has been accompanied by concerns for patient safety. This concern has been escalated by media reports of tragedies that may have been precipitated because the physician's office lacked the same resources (i.e., personnel, equipment, drugs, administrative policies and facilities) that are present in an ambulatory surgical center or hospital. In an attempt to maintain quality and safety standards for office-based anesthesia, the American Society of Anesthesiology (ASA) recently outlined guidelines for an effective system of quality assurance, types of patients suitable for office-based surgery, basic qualifications of office based surgery personnel, monitoring and equipment standards, and the ability for transfers to hospitals in emergency situations.

Educational Objectives: This exhibit reviews the current safety core principles of office-based anesthesia practice. Specifically, it addresses the following:

1. Statistics to outline exponential growth and popularity of the field.
2. The integral role of the anesthesiologist in setting up and managing office-based facilities and members who comprise the anesthesia care team.
3. Latest ASA guidelines statements and publications.
4. Evidence-based review to support safe patient and procedure selection, anesthetic choices and the closed claims project overview.
6. The principles of crisis management, emergent patient resuscitation and transfer, simulation training, and quality assurance.
7. An innovative OBA curriculum for resident physicians in an anesthesiology training program to acquire the skills and knowledge needed to deliver a safe and appropriate anesthetic to patients undergoing surgery in an office-based setting.
8. In 2007, our first HMS OBA CME course, focused practitioners on various clinical and business aspects to establish a safe office environment. Most recent course: Sept 25-26, 2010.
9. The Institute for Safety in Office Based Surgery (ISOBS) is an independent, non-profit organization recently founded in 2009. Our mission is to promote patient safety in office-based surgery through physician and patient education, expert consultation, and research support.

PURPOSE

- To recognize the exponential growth of the office-based practices.
- To inform the anesthesia practitioner of the latest safety initiatives in anesthesia practice, commensurate with advances in surgical technology and procedures in the rapidly growing field of office-based anesthesia.
- To emphasize core principles of office-based anesthesia practice, such as patient selection, anesthetic techniques, policies, regulations, and the personnel.
- To present ideas about educating the anesthesia provider, the physician performing the procedure, office personnel, residents, nurses, and patients.

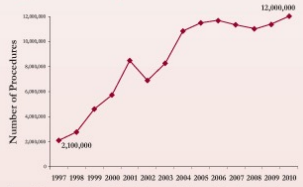
AMA Safety Core Principles for Office-Based Anesthesia

The core principles developed by the AMA are a good starting point when educating the patient care team.

1. Guidelines or regulations for office-based surgery should be developed by the states according to levels of anesthesia defined by the ASA.
2. Physicians should select patients for office-based anesthesia by specified criteria including ASA Physical Status Classification System
3. Where available, offices that perform surgery should be accredited by a state-recognized entity
4. Physicians involved in office-based surgery should have admitting privileges at a nearby hospital or maintain an emergency transfer agreement with a nearby hospital
5. Informed consent guidelines should be followed
6. Continuous quality improvement and adverse incident reporting programs should be kept
7. All physicians in an office-based setting should be board certified and fully trained
8. Physicians performing office-based surgery may show competency by maintaining privileges at an accredited hospital or ambulatory surgical center for the procedures they perform in an office setting
9. At least one physician who is credentialed in advanced resuscitative techniques (ATLS, ACLS, PALS) must be present or immediately available with appropriate resuscitative equipment until the patient has met discharge criteria
10. Physicians administering or supervising the anesthetic should have appropriate education and training.

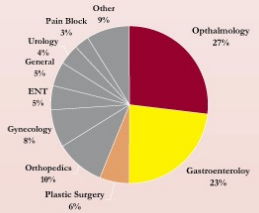
EXPONENTIAL GROWTH AND POPULARITY OF OBA

Cosmetic Surgery Trends:
Surgical and Non-surgical Cosmetic Procedures: Totals



Cosmetic Surgery Trends: Surgical and Non-surgical Cosmetic Procedures: Totals
Source: American Society for Aesthetic Plastic Surgery

Distribution of OBA cases by specialty

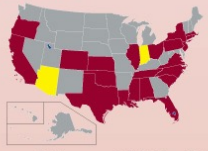


The variety of cases done in the office is growing.

Each type of procedure carries with it unique aspects of patient and anesthetic management that must be taken into consideration when selecting appropriate patients and procedures to be done in the office setting. Some procedures may be inappropriate for the office. In addition, proper patient selection is key for even simple procedures. Practitioners need to familiarize themselves with various types of surgeries typically performed in the office:

- Plastics
- Gastroentorology
- Dentistry
- Podiatry
- Ophthalmology
- Gynecology
- Interventional pain, cardiac, pulmonary and neurosurgical procedures
- Urology

Currently, only 22 states regulate the office-based setting



Alabama, California, Colorado, Connecticut, Florida, Illinois, Kansas, Louisiana, Massachusetts, Mississippi, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Virginia

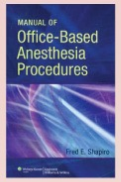
Proposals are being developed in Indiana and Arizona.

RECENT EDUCATIONAL INITIATIVES AT HARVARD MEDICAL SCHOOL

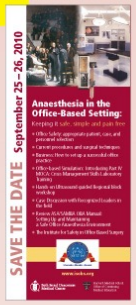
Over the last several years, we have taken the following steps to educate anesthesia practitioners and trainees, and prepare them to take the lead in addressing safety aspects of the Office-Based Anesthesia Practice.

1. **Manual of Office-Based Anesthesia Procedures (Lippincott, Williams & Wilkins)**
2. **Harvard Medical School 2007-10 CME Course: Office-Based Setting: Safe, Simple and Pain Free**
3. **Educational Exhibits at Harvard Academy and Anesthesia Meetings**
4. **Resident Curriculum Proposal addressing ACGME competencies**
5. **Designing of Simulation and OBA Crisis Management Exercises**

Manual of Office-Based Anesthesia Procedures by Fred Shapiro – Lippincott, Williams & Wilkins



HMS 2010 CME Course:



Harvard Medical School Conference Center – Site of the OBA CME Course

Center for Medical Simulation, MIT/Harvard

THE BUSINESS AND LEGAL ASPECTS OF THE OFFICE

In today's environment of managed care and significant liability concerns, the anesthesia provider needs to understand the basic principles of running a financially stable, properly credentialed and efficient office practice. The following must be addressed

1. **Setting up an office-based practice**
2. **Operating room efficiency and productivity**
3. **Legal Aspects of running an office**

ASA BREAKFAST PANEL PRESENTATION

"Improving Safety in Office-Based Practices: The Three P's: Patients, Policy, Personnel"

ACCESSING AVAILABLE RESOURCES

The ASA, with the help of Committees, House of Delegates, and Experts has put out numerous resources. The anesthesia provider must familiarize him or herself with the following:

- **Guidelines for Office-Based Anesthesia**
- **Guidelines for Ambulatory Anesthesia and Surgery** *new!*
- **Office-Based Anesthesia: Considerations for Anesthesiologists in Setting Up and Maintaining a Safe Office Anesthesia Environment**
- **Statement on Qualifications of Anesthesia Providers in the Office-Based Setting**
- **Guidelines for Nonoperating Room Anesthetizing Locations**
- **Position on Monitored Anesthesia Care and Safe Use of Propofol**
- **Statement on the Anesthesia Care Team**
- **Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists**
- **Standards for Basic Anesthetic Monitoring**
- **Standards for Post-Anesthesia Care**
- **Continuum of Depth of Sedation Definitions**

American Society of Anesthesiologists www.asahq.org · Society for Ambulatory Anesthesia www.sambahq.org

THE INSTITUTE FOR SAFETY IN OFFICE-BASED SURGERY

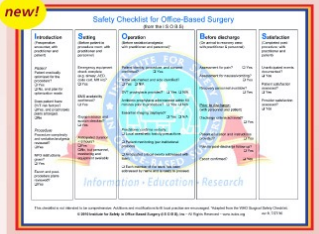
Information • Education • Research

www.isobs.org

Mission:

"to promote patient safety in office-based surgery and to encourage collaboration, scholarship, physician and patient education"

new!

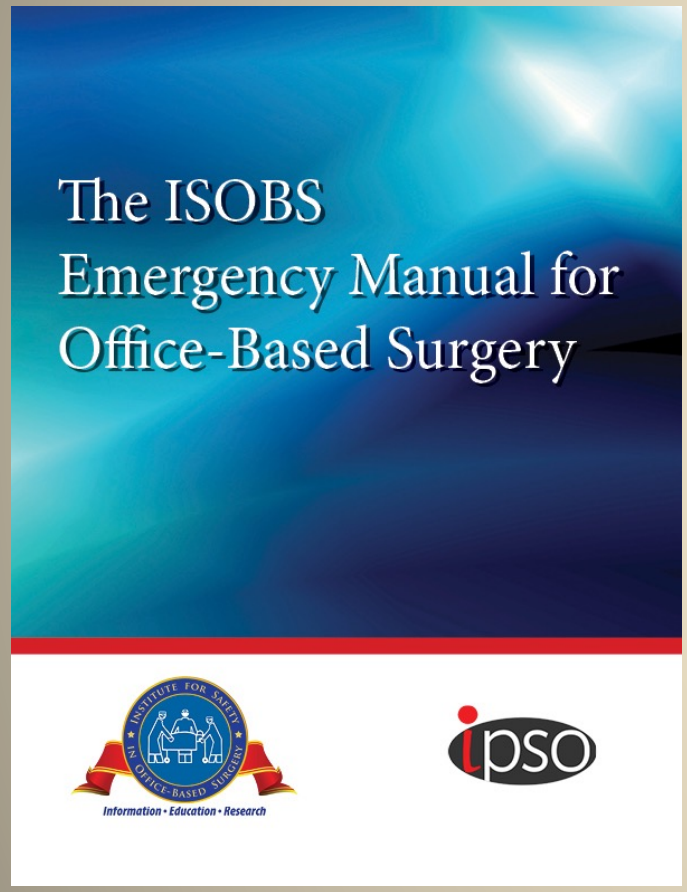


For further inquiries, contact: FShapiro@bidmc.harvard.edu

Drs. Shapiro, Urman and Isselbacher

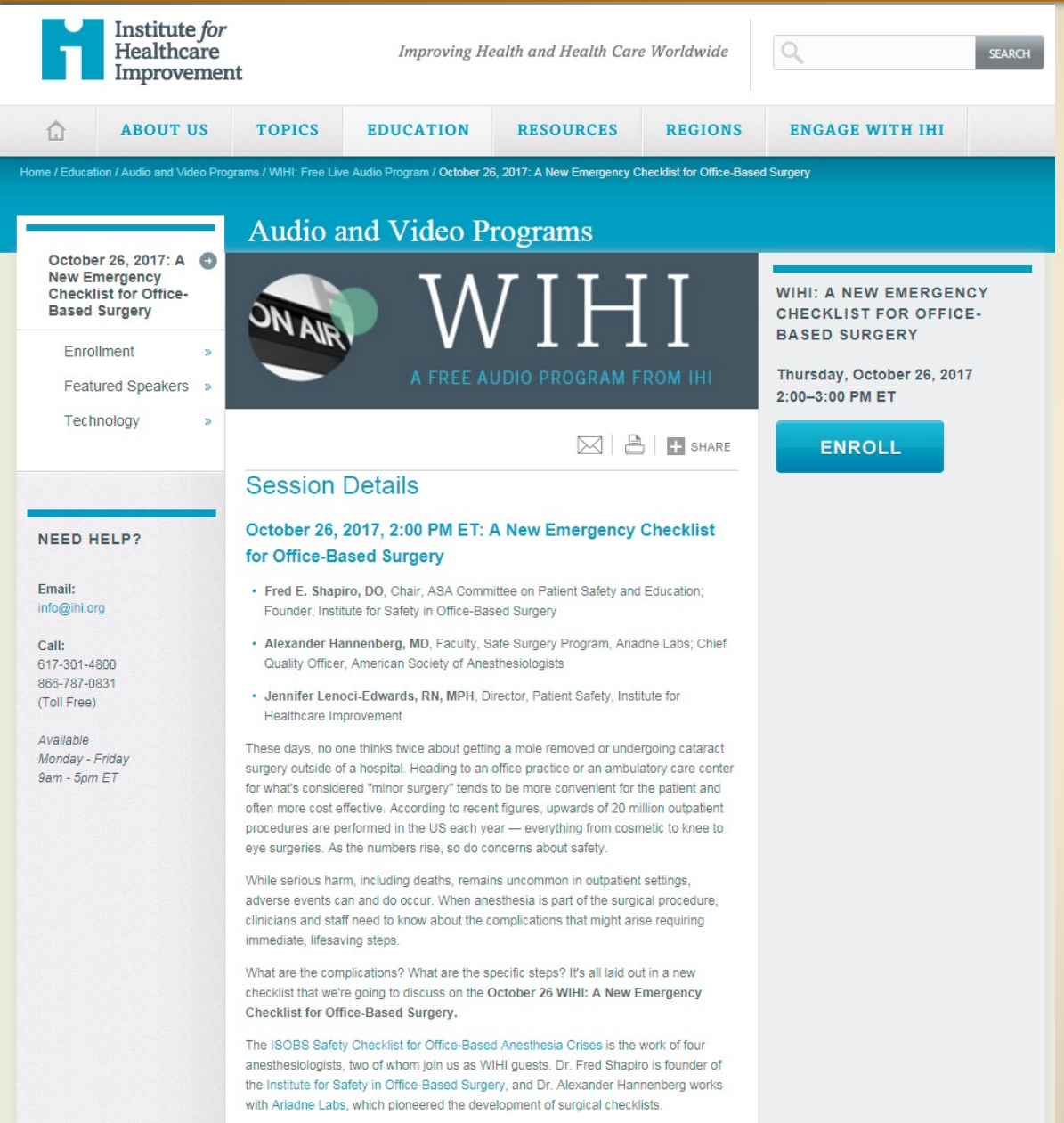
ISOBS Now:

Office-based Emergency Manual



Office-based Emergency Manual	
ACLS	Critical events
Cardiac arrest- VF/VT	Allergies
Cardiac arrest- PEA/asystole	Anaphylaxis (adult + ped dosing)
Bradycardia- unstable	Difficult airway
Tachycardia- unstable	Hemorrhage
PALS	Hypercarbia
Cardiac arrest- VF/VT	Hypotension (adult + ped dosing)
Cardiac arrest- PEA/asystole	Hypoxia
Bradycardia- unstable	LAST (adult + ped dosing)
Tachycardia- unstable	Loss of access
Emergency	Mental status change
Fire- airway or surroundings	MH (adult + ped dosing)
Evacuation and preparedness	Spinal Anesthesia: General Complications
Loss of Oxygen	Administrative
Loss of Power	Transfer of care MH patient
	Transfer of care non-MH patient

ISOBS now:
IHI/NPSF Webinar - October 26, 2017



October 26, 2017, 2:00 PM ET: A New Emergency Checklist for Office-Based Surgery

Fred E. Shapiro, DO, Chair, ASA Committee on Patient Safety and Education; Founder, Institute for Safety in Office-Based Surgery

Alexander Hannenberg, MD, Faculty, Safe Surgery Program, Ariadne Labs; Chief Quality Officer, American Society of Anesthesiologists

Jennifer Lenoci-Edwards, RN, MPH, Director, Patient Safety, Institute for Healthcare Improvement

www.ihi.org

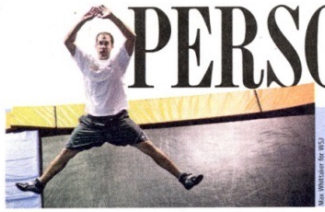
ISOBS Long Term Goals

- **Standardize:** Develop standard clinical practice in all specialties
- **Uniformity:** Legislation in all 50 states
- **Outcomes:** Ensure proper outcomes data collection with mandatory adverse event reporting (AQI, NACOR)
- **Research:** Sponsor research in the area of safety and outcomes in OBS (checklists, costs)

ISOBS 20 years:

ISOBS public educational outreach

PERSONAL JOURNAL.



This Isn't Just Bouncing On Trampolines

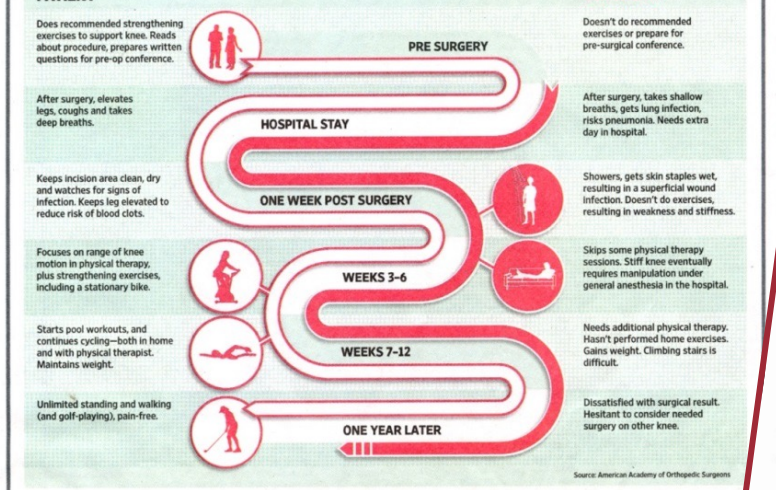
WHAT'S YOUR WORKOUT? D3

Students score a victory in reducing energy use in public buildings — D2

Heavy smoking in middle age poses risk for dementia later, study finds — D3

HOW TO RECOVER (OR NOT) FROM SURGERY

About 581,000 knee replacements are performed every year in the U.S. The average hospital stay has dropped to about three days from up to two weeks in the 1980s. Successful recovery depends on patients following strict instructions for months. Here is how a patient who follows the prescribed regimen may fare versus one who does not.



Source: American Academy of Orthopedic Surgeons

Patient, Heal Thyself

After Shorter Hospital Stays, Doctors Raise Demands and Time for Recovery

By Laura Landro

For Michael Noonan, knee surgery in April was practically a breeze—an outpatient procedure that had the 41-year-old investment banker hobbling home on crutches in a matter of hours after surgeon David Altchek replaced his anterior cruciate ligament using small incisions.

But recovery was another matter. He needed the crutches for three weeks, had 12 weeks of physical therapy three times a week, then six weeks of exercises at home. He rented a strap-on ice compression device to reduce swelling, and wore a brace for about five weeks. Though fully healed now, being responsible for so much of his own rehabilitation, he says, "was like taking a new baby home for the first time—you don't really feel like you're licensed to do it."

Surgery is easier and faster than ever before: Nearly 65% of all surgeries don't require an overnight hospital stay, compared to 16% in 1980. Hospitals that once kept patients for three weeks after some major operations now discharge them within a matter of days. But the body still heals at its own pace, and reduced time in hospital care means patients are assuming more responsibility for their own recovery—and more risks. Patients not only have to perform rehabilitation regimens at home, but they are more often caring for their own incision wounds and dressings and having to watch for signs of infections and blood clots. They also

Please turn to the next page

The Institute for Safety in Office-Based Surgery has developed a checklist that includes assuring that discharge instructions are provided and a plan for follow-up care is clear. "Patients need to be asked things like if there is redness at the incision site, do you know what to do?" says Fred Shapiro, a Harvard anesthesiologist and president of the group. (Redness at an incision site can be a sign of infection.)

searchers have begun a more set of experiments aimed at teaching monkeys to control with their thoughts a full-body avatar projected on a computer screen. Directing the movements of an entire body is much more difficult than controlling just an arm or leg.

The monkeys are implanted with small electrodes in the brain that record signals from hundreds of neurons. They then wear 3-D movie goggles so they can feel as though they are part of the virtual world.

In one trial, monkeys see their entire avatar on the screen and learn to control it. Once the real monkey appears to realize its thoughts control the avatar, the researchers plan to introduce a second digital monkey in the virtual world

Please turn to page D4

WSJ BLOGS

Health Blog

WSJ's blog on health and the business of health.

OCTOBER 26, 2010, 1:51 PM ET

Taming the 'Wild West' of Outpatient Surgery - Doctors' Offices

Article | Comments

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By Laura Landro

Minimally invasive surgical procedures and new anesthesia techniques at outpatient facilities are making it easier than ever before to have surgery - -but recovery can still take weeks or months, putting the onus on the patient to ensure things go well, according to today's Informed Patient column.

Of special concern when it comes to follow-up is the growing number of procedures performed in doctor's offices, a little-regulated side of the fast-growing field of outpatient surgery. At least 15 million procedures are performed at more than 50,000 office-based locations, but only 22 states have any kind of regulations of such practices, and only a fraction of the offices are accredited by any of several independent review boards.

Now, the nonprofit Institute for Safety in Office-Based Surgery (isobsurgery.org), a group led by anesthesiologists and other practitioners, is leading an effort to establish national standards and regulations for office-based procedures. "This is really the wild west of health care," says Fred Shapiro, an assistant professor of anesthesia at Harvard Medical School who is president of the institute. Dr. Shapiro says the group is planning to train office personnel in safety procedures and offer a certificate of quality to offices that meet safety criteria including accreditation by one of three major accrediting organizations.

The ISOBS recently developed a safety checklist, along the lines of those used by hospitals for infection prevention. For example, patients should be evaluated for their risks of deep vein thrombosis — a blood clot –and the physician and staff should go through the same safety procedures used in hospitals, such as marking the surgical site to ensure the right body part is operated on, and making sure emergency supplies and contacts are at the ready.

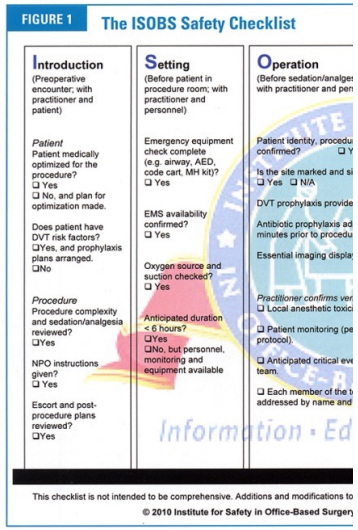
ISOBS 20 years:
ISOBS professional educational outreach

THE INSTITUTE FOR SAFETY IN OFFICE-BASED SURGERY (ISOBS)

Fred E. Shapiro, D.O.
Assistant Professor of Anesthesia, Harvard Medical School, Boston, MA
ISOBS

In recent years, the economic pressures of medicine have incited a paradigm shift in health care delivery, such that surgical procedures are moving from the hospital to the office-based setting. Often called the "wild west of health care," office-based procedures continue to increase at a rapid pace, with an estimated more than 10 million procedures performed in 2010. A grow calls for greater of office-based su who are educated improvement. In found that a cc used in an interd setting resulted in complications as w

FIGURE 1 The ISOBS Safety Checklist



PATIENT SAFETY FIRST

Checklist Implementation for Office-Based Surgery: A Team Effort

FRED E. SHAPIRO, DO; NATHAN PUNWANI, MD, MPH; RICHARD D. URMAN, MD, MBA

Editor's note: *This is Part I of two articles on patient safety considerations in office-based surgery settings. This article discusses the benefits and risks of office-based surgery, as well as how to improve practices and the quality of care through the use of the Safety Checklist for Office-Based Surgery. Part II will be published in a later issue of the* Journal *and will address methods for providing patient-centered care and implementing patient safety checklists in office-based settings.*

Office-based medical and surgical procedures are redefining the health care landscape. From 1995 to 2005, the total volume of office-based procedures doubled from 5 million to 10 million.[1] Procedures such as liposuction, abdominoplasty, and gastrointestinal endoscopy have migrated from hospital settings and are now fixtures in the office health care delivery system.[2] As technology advances and more attention is placed on rising health care costs, the trend of medical and surgical procedures moving to office settings will only intensify.

BENEFITS OF OFFICE-BASED SURGERY

Office procedures offer numerous benefits to patients and providers alike, including greater scheduling convenience, continuity of care, and cost-effectiveness. In addition, sedative agents can be administered and supervised by both anesthesia and non-anesthesia care providers. Despite these advantages, not every procedure is suitable for the office setting and not every patient or practitioner is appropriate for office-based procedures. Patients who are older and have comorbidities may not be proper candidates for invasive office interventions. Physicians' offices may not be adequately staffed or equipped to accommodate complex patients and procedures.

In spite of these concerns, private medical suites are less regulated than hospitals and ambulatory surgical centers (ASCs).[2] Currently, only 28 states have regulations covering office-based practice, and only 27 states recognize or require accreditation of office procedures.[3] Consequently, office procedural practices are potentially more vulnerable to quality lapses (eg, a lack of emergency protocols, suboptimal medication safety practices, inadequately trained personnel) compared with other sites.[2]

A study by Vila et al[4] is one of the most well-known and contentious studies to broach concerns about the safety and quality of office-based procedures. These researchers investigated adverse events reported to the Florida Board of Medicine from 2000 to 2002 that occurred in either an ASC

The AORN Journal *is seeking contributors for the Patient Safety First column. Interested authors can contact Sharon A. McNamara, column coordinator, by sending topic ideas to journalcolumns@aorn.org.*

http://dx.doi.org/10.1016/j.aorn.2013.06.009

THE INSTITUTE FOR SAFETY IN OFFICE-BASED SURGERY PATIENT CHECKLIST (ISOBS PC)

Noah Rosenberg, M.D.
Resident, Department of Family & Community Medicine, University of Massachusetts Memorial Medical Center, Worcester, MA
Fred E. Shapiro, D.O.
Assistant Professor of Anesthesia, Harvard Medical School, Bos

The Institute for Safety in Office-Based Surgery (ISOBS), an independent, non-profit 501(c)(3) organization, has developed a safety checklist for use in the office-based setting. A recent study to be published in the journal *ePlasty* demonstrated a more than 75% reduction in the number of surgical complications with use of the ISOBS Safety Checklist (see below for citation). While this positive effect on surgical complications validates much of the data already collected in the inpatient setting, it also clearly emphasizes the need for a tailored patient safety approach to the office-based setting. For that reason, ISOBS has developed a second checklist for use by patients to engage them in office-based surgical safety.

The ISOBS Patient Checklist (ISOBS PC) contains a number of questions and concerns every patient should raise with their office-based surgeon and other members of their care team, including even possibly their primary care physician. The ISOBS PC mirrors a number of the checklist items in the original ISOBS Safety Checklist, giving patients a framework for taking an informed, active role in their care and safety.

ISOBS has already quantitatively demon-

Patient's Checklist for Office-Based Procedures
from the Institute for Safety in Office-Based Surgery (ISOBS)

Inquire	What are my doctor's credentials?	Does the doctor have privileges to perform the same procedure at a hospital? ☐ Yes ☐ No What is your doctor board-certified in? ☐ Yes ☐ No How many times recently has the doctor performed your type of procedure? ☐ Yes ☐ No What is your doctor's reputation? ☐ Yes ☐ No Who will be giving sedation/anesthesia, if needed, and who will be monitoring me while during sedation? ☐ Yes ☐ No
Stable	Are my medical conditions stable?	Are my medical conditions under control? ☐ Yes ☐ No
Office	Is the office accredited and licensed?	Is the office accredited and the sign posted on the wall? ☐ Yes ☐ No Who inspects and certifies the office for safety and infection control? ☐ Yes ☐ No
Best	Is this office the best place for my procedure?	Is the office the right setting for my procedure? ☐ Yes ☐ No
Suited	Can this office handle an emergency?	Is the office prepared for an unexpected emergency, such as drugs, equipment and training? ☐ Yes ☐ No If I need additional medical care, where will I be transferred? ☐ Yes ☐ No
Plan	What is the plan for my recovery after the procedure?	Who will monitor my recovery and who will supervise my discharge home? ☐ Yes ☐ No
Communication	How will I be able to communicate with the office?	Have you had a follow-up call or visit with your doctor or nurse? ☐ Yes ☐ No Have you communicated your questions and overall satisfaction to the office staff? ☐ Yes ☐ No

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged. *Adapted from the WHO Surgical Safety Checklist. © 2011 Institute for Safety in Office-Based Surgery (ISOBS), Inc – All Rights Reserved – www.isobs.org

PATIENT SAFETY FIRST

Putting the Patient Into Patient Safety Checklists

FRED E. SHAPIRO, DO; NATHAN PUNWANI, MD, MPH; RICHARD D. URMAN, MD, MBA

Editor's note: *This is Part II of two articles on patient safety considerations in office-based surgery settings. This article discusses methods for providing patient-centered care and implementing a patient's safety checklist in office-based settings. Part I was published in the September 2013 issue of* AORN Journal *and addressed the benefits and risks of office-based surgery, as well as how to improve practices and the quality of care through the use of the Safety Checklist for Office-Based Surgery.*

Over the past two decades, there has been a proliferation in the volume of office-based medical and surgical procedures. From 1995 to 2005, the number of office-based procedures increased from 5 to 10 million.[1] During the same period, the Institute of Medicine published *Crossing the Quality Chasm: A New Health System for the 21st Century*.[2] The report initiated a cavalcade of calls for the health care system to be "respectful of and responsive to individual patient preferences, needs, and values."[2] Patients and payers alike are heeding these calls for greater patient-centered care and are putting the onus of responsibility for providing this on medical providers.[3] The Patient Protection and Affordable Care Act[4] authorizes the Centers for Medicare & Medicaid Services (CMS) to develop a hospital value-based purchasing program beginning in 2013; this mandatory payment model will link hospital reimbursement to performance on quality measures, including patient experience.[5] In addition, the CMS accountable care organization initiatives require participating medical provider groups to demonstrate adequate levels of patient satisfaction to be eligible for shared savings.[6]

PATIENT-CENTERED CARE IN VALUE-BASED ENVIRONMENTS

The sustained increase in office-based procedures and the growing chorus of demands for patient empowerment are two trends that are redefining health care. The convergence of these two burgeoning movements implies that office-based procedures will play a more pronounced role in a value-based health care environment and will inevitably be the focus of patient-centeredness and quality improvement activities.

Physicians and nurses who perform office-based surgery must actively partner with patients in quality improvement efforts to deliver high-quality care. Physicians and nurses should take advantage of the idea of *patient activation*—a patient's knowledge, skills, ability, and willingness to manage his or her own health and care—and help patients evaluate and participate in the care they will receive.[7] Research has demonstrated that highly motivated patients are more likely to rate their health care experiences as positive,[8] and higher patient satisfaction is positively linked to better compliance with health regimens.[9] Activated patients

The AORN Journal *is seeking contributors for the Patient Safety First column. Interested authors can contact Sharon A. McNamara, column coordinator, by sending topic ideas to journalcolumns@aorn.org.*

http://dx.doi.org/10.1016/j.aorn.2013.08.003

ISOBS Now:
Decision Aids

Improving Patient-centered Care Delivery in 2017:

INTRODUCING PRE-ANESTHESIA DECISION AIDS

Karen B. Domino, M.D., M.P.H.
Karen L. Posner, Ph.D.
Lindsay K. Sween, M.D., M.P.H.
Fred E. Shapiro, D.O., Chair
Committee on Patient Safety and Education

"I recently had surgery on my ankle. Because my church choir activities are extremely important to me, I was concerned when the surgeon mentioned that the procedure would be done under general anesthesia, as my friend recently had a sore throat and hoarseness for a couple of weeks after her surgery. You can't imagine how relieved I was when my anesthesiologist presented the option of spinal anesthesia. The brochure that explained the block, along with its risks and benefits, clarified the upsides and downsides of my anesthesia choices. I was thrilled with the outcome of the spinal. Please thank my anesthesiologist for offering me this choice."

Patients often have preferences for their medical care, including anesthesia options. Yet patients may feel vulnerable when discussing their care plans with physicians, not speaking up out of fear of being labeled "difficult" or "demanding." This situation may be exacerbated when discussing anesthesia plans on a first meeting with a physician with whom the patient has no prior relationship. Without engaging patients, we will never know their concerns and preferences.

The Institute of Medicine (IOM) named patient-centered care as one of the six aims for health care system improvement in its seminal 2001 report *Crossing the Quality Chasm*. Patient-centered care delivery was defined as "providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions."[1] The Picker Institute undertook a multiyear survey of patients' perceptions regarding the most important health care delivery characteristics with respect to quality and safety. Patients identified respect for an individual's values, preferences, and expressed needs and provision of high-quality information and education for the patient and family as two of the eight most important principles.[2] In order to practice patient-centered care, health care providers need to engage in shared decision-making with patients.

Shared decision-making is a mode of communication with patients to encourage engagement about treatments that have options – options for which patient preferences, as well as physician preferences and professional opinion warrant consideration before a final treatment decision is made. Shared decision-making is appropriate when there is no medically "best" choice; in these instances, the best choice among medically appropriate options for each patient depends on individual patient preferences, including the patient's unique weighing of various risks, benefits and treatment goals. These medical decisions are termed "preference sensitive." The option of regional anesthesia for surgery is often a preference-sensitive choice, as general anesthesia or sedation with local anesthesia may also be a clinically appropriate option.

Karen B. Domino, M.D., M.P.H., is Professor and Vice Chair for Clinical Research, Department of Anesthesiology and Pain Medicine, University of Washington School of Medicine, Seattle.

Karen L. Posner, Ph.D., is Laura Cheney Professor in Anesthesia Patient Safety, Department of Anesthesiology and Pain Medicine, University of Washington, Seattle.

Patient Education

Pre-Anesthesia

Peripheral Nerve Bloc

Decision a

This decision aid is meant to help you decide what type of anesthesia is right for you. It explains the benefits and risks of peripheral nerve blocks. Read this decision aid, fill out the question boxes, and talk with your anesthesiologist to help you decide what type of anesthesia is your best choice.

What are pe

- Anesthesia b
- Peripheral n awake or rec parts of or al
- You may ha nerve block
- For a periph near a nerve supplied by drugs, or a n the drugs.
- Peripheral n operations o procedures.
- You may fee local anesthe
- During your much oxyge blood pressu

Patient Education

Pre-Anesthesia

Epidural and Spinal Anesthesia

Decision aid

This decision aid is meant to help you decide what type of anesthesia is right for you. It explains the benefits and risks of epidural and spinal anesthesia. Read this decision aid, fill out the question boxes, and talk with your anesthesiologist to help you decide what type of anesthesia is your best choice.

What are epidural anesthesia and spinal anesthesia?

Anesthesia blocks pain during your surgery.

Epidural and spinal anesthesia numb large parts of your body. You may stay awake or receive a sedative during your surgery. You may recall parts or all of the procedure.

For both types of anesthesia, medicines are injected into your back near the spinal cord. This numbs regions of the body so you will not feel pain during the procedure.

You may have a general anesthetic in addition to epidural or spinal anesthesia for your procedure.

What are the possible benefits of epidural or spinal anesthesia?

Some possible benefits of epidural and spinal anesthesia are:

- You may choose to stay awake or a little sleepy during your surgery.
- Less nausea, less vomiting, and feel less sleepy compared to general anesthesia.
- Possibly less blood loss during surgery compared to general anesthesia.
- Less risk of infection and pneumonia after knee replacement compared to general anesthesia
- Pain relief - can be used to reduce pain during or after a procedure (for example, after lung or abdominal surgery or childbirth).

ISOBS 20 years: Publications on the safety of surgery and anesthesia in the office-based setting

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The Institute for Safety in Office-Based Surgery

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