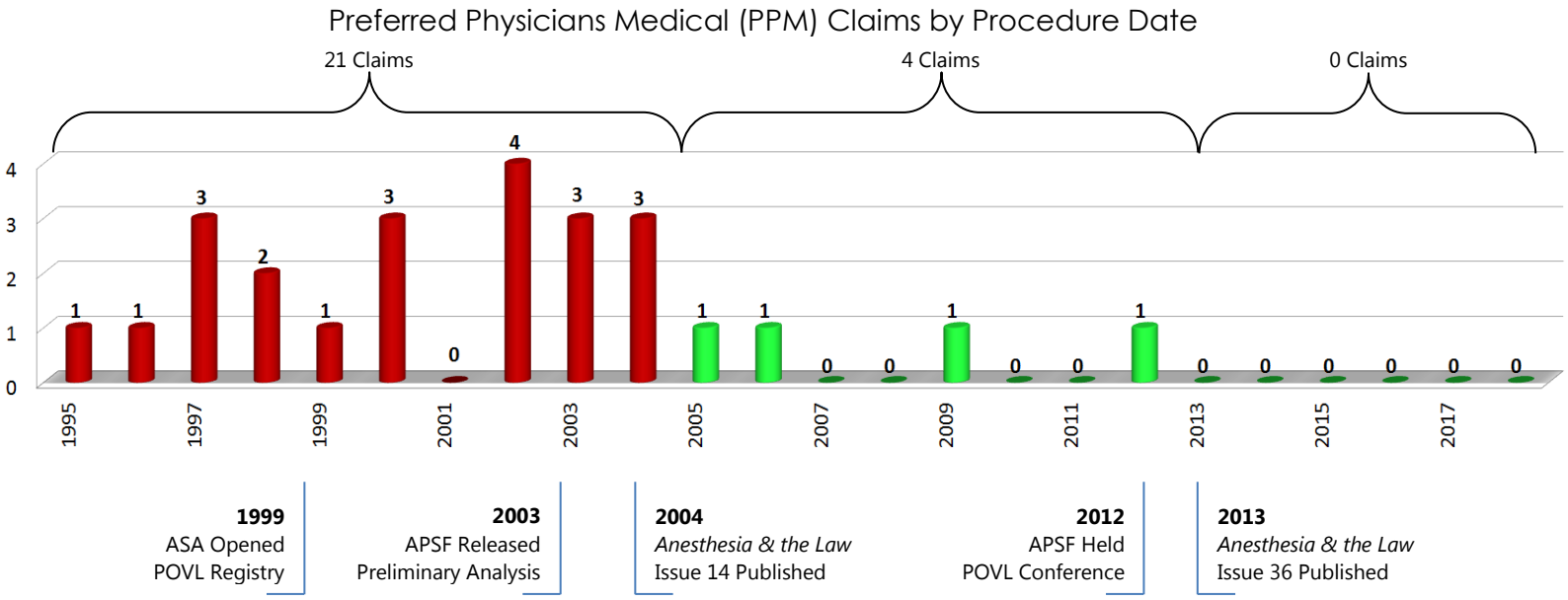
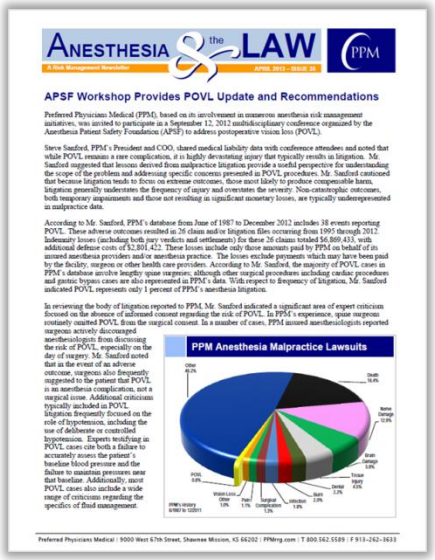
Post-Operative Vision Loss (POVL)



- POVL Claims reported by PPM policyholders steadily increased from 1995-2004
- PPM concentrated risk management activities on POVL including on-site seminars and an *Anesthesia & the Law* focusing on case studies of these injury types starting in 2004
- Further efforts to help policyholders avoid adverse outcomes include a presentation at the 2012 APSF POVL Consensus Conference and *Anesthesia & the Law* issue 36 in 2013
- PPM anesthesiologists had 21 POVL claims in the 10 years prior to risk management efforts followed by just 4 claims in 8 years and zero claims in the 6 years following *Anesthesia & the Law* issue 36

1995-2004: 21 POVL claims were reported to PPM
2005-2018: 4 POVL claims have been reported to PPM
2013-2018: 0 POVL claims have been reported to PPM


ANESTHESIA & the LAW

APSF Workshop Provides POVL Update and Recommendations

Preferred Physicians Medical (PPM), based on its involvement in numerous anesthesia risk management initiatives, was invited to participate in a September 12, 2012 multidisciplinary conference organized by the Anesthesia Patient Safety Foundation (APSF) to address postoperative vision loss (POVL).

Steve Sanford, PPM's President and COO, shared medical liability data with conference attendees and noted that while POVL remains a rare complication, it is highly devastating injury that typically results in litigation. Mr. Sanford suggested that lessons derived from malpractice litigation provide a useful perspective for understanding the scope of the problem and addressing specific concerns presented in POVL procedures. Mr. Sanford cautioned that because litigation tends to focus on extreme outcomes, those most likely to produce compensable harm, litigation generally understates the frequency of injury and overstates the severity. Non-catastrophic outcomes, both temporary impairments and those not resulting in significant monetary losses, are typically underrepresented in malpractice data.

According to Mr. Sanford, PPM's database from June of 1987 to December 2012 includes 38 events reporting POVL. These adverse outcomes resulted in 26 claim and/or litigation files occurring from 1995 through 2012. Indemnity losses (including both jury verdicts and settlements) for these 26 claims totaled $6,869,413, with additional defense costs of $2,801,422. These losses include only those amounts paid by PPM on behalf of its insured anesthesia providers and/or anesthesia practice. The losses exclude payments which may have been paid by the facility, surgeon or other health care providers. According to Mr. Sanford, the majority of POVL cases in PPM's database involve lengthy spine surgeries; although other surgical procedures including cardiac procedures and gastric bypass cases are also represented in PPM's data. With respect to frequency of litigation, Mr. Sanford indicated POVL represents only 1 percent of PPM's anesthesia litigation.

In reviewing the body of litigation reported to PPM, Mr. Sanford indicated a significant area of expert criticism focused on the absence of informed consent regarding the risk of POVL. In PPM's experience, spine surgeons routinely omitted POVL from the surgical consent. In a number of cases, PPM insured anesthesiologists reported surgeons actively discouraged anesthesiologists from discussing the risk of POVL, especially on the day of surgery. Mr. Sanford noted that in the event of an adverse outcome, surgeons also frequently suggested to the patient that POVL is an anesthesia complication, not a surgical issue. Additional criticisms typically included in POVL litigation frequently focused on the role of hypotension, including the use of deliberate or controlled hypotension. Experts testifying in POVL cases cite both a failure to accurately assess the patient's baseline blood pressure and the failure to maintain pressures near that baseline. Additionally, most POVL cases also include a wide range of criticisms regarding the specifics of fluid management.

PPM Anesthesia Malpractice Lawsuits

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ppmrrg.com

Wrong Site & Wrong Patient

Preferred Physicians Medical

Risk Retention Group
A Mutual Insurance Company

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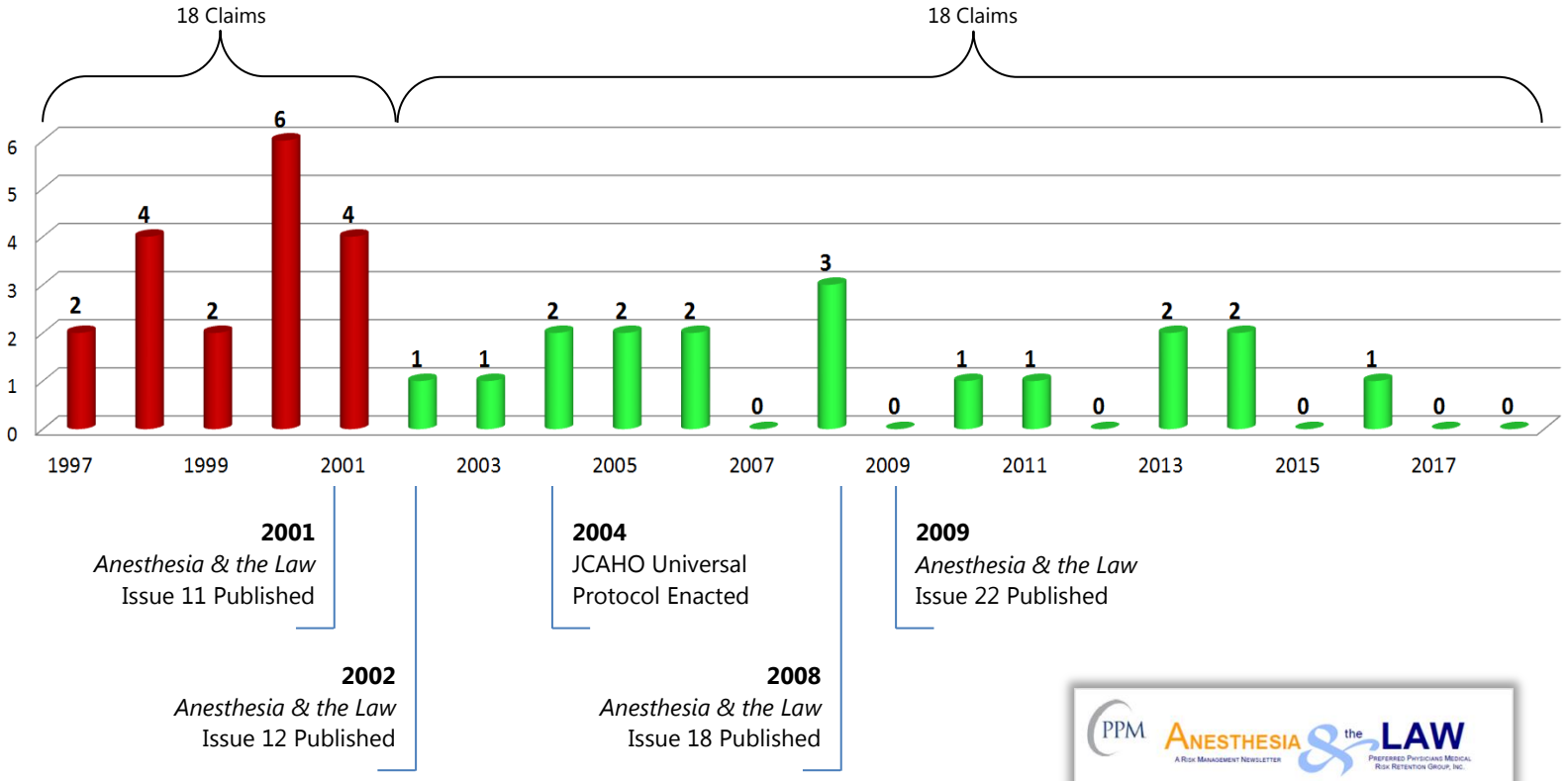
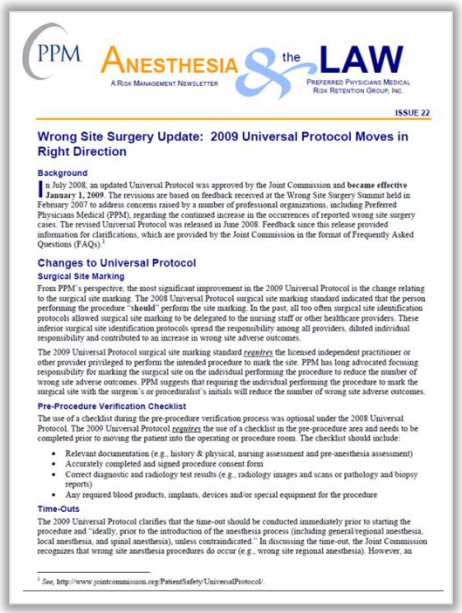
Preferred Physicians Medical (PPM) Claims by Procedure Date



- Wrong Site, Side & Patient Claims reported by PPM policyholders increased from 1997-2001
- PPM released two *Anesthesia & the Law* focusing on case studies of these injury types in 2001 and 2002
- PPM released "Sign the Site" recommendations 3 years ahead of the Joint Commission's 2004 Universal Protocol and highlighted updates for policyholders following Joint Commission's 2009 update
- PPM anesthesiologists had 18 claims in 5 years prior to risk management efforts and had 18 claims in the 17 years after

1997-2001: 18 wrong site, side & patient claims were reported to PPM over 5 years
2002-2018: 18 wrong site, side & patient claims were reported to PPM over 16 years



PPM Anesthesia & the Law
A Risk Management Newsletter
Preferred Physicians Medical Risk Retention Group, Inc.

ISSUE 22

Wrong Site Surgery Update: 2009 Universal Protocol Moves in Right Direction

Background

In July 2008, an updated Universal Protocol was approved by the Joint Commission and **became effective January 1, 2009**. The revisions are based on feedback received at the Wrong Site Surgery Summit held in February 2007 to address concerns raised by a number of professional organizations, including Preferred Physicians Medical (PPM), regarding the continued increase in the occurrences of reported wrong site surgery cases. The revised Universal Protocol was released in June 2008. Feedback since this release provided information for clarifications, which are provided by the Joint Commission in the format of Frequently Asked Questions (FAQs).[1]

Changes to Universal Protocol

Surgical Site Marking

From PPM's perspective, the most significant improvement in the 2009 Universal Protocol is the change relating to the surgical site marking. The 2008 Universal Protocol surgical site marking standard indicated that the person performing the procedure "**should**" perform the site marking. In the past, all too often surgical site identification protocols allowed surgical site marking to be delegated to the nursing staff or other healthcare providers. These inferior surgical site identification protocols spread the responsibility among all providers, diluted individual responsibility and contributed to an increase in wrong site adverse outcomes.

The 2009 Universal Protocol surgical site marking standard ***requires*** the licensed independent practitioner or other provider privileged to perform the intended procedure to mark the site. PPM has long advocated focusing responsibility for marking the surgical site on the individual performing the procedure to reduce the number of wrong site adverse outcomes. PPM suggests that requiring the individual performing the procedure to mark the surgical site with the surgeon's or proceduralist's initials will reduce the number of wrong site adverse outcomes.

Pre-Procedure Verification Checklist

The use of a checklist during the pre-procedure verification process was optional under the 2008 Universal Protocol. The 2009 Universal Protocol ***requires*** the use of a checklist in the pre-procedure area and needs to be completed prior to moving the patient into the operating or procedure room. The checklist should include:

- Relevant documentation (e.g., history & physical, nursing assessment and pre-anesthesia assessment)
- Accurately completed and signed procedure consent form
- Correct diagnostic and radiology test results (e.g., radiology images and scans or pathology and biopsy reports)
- Any required blood products, implants, devices and/or special equipment for the procedure

Time-Outs

The 2009 Universal Protocol clarifies that the time-out should be conducted immediately prior to starting the procedure and "ideally, prior to the introduction of the anesthesia process (including general/regional anesthesia, local anesthesia, and spinal anesthesia), unless contraindicated." In discussing the time-out, the Joint Commission recognizes that wrong site anesthesia procedures do occur (e.g., wrong site regional anesthesia). However, an

[1] See, http://www.jointcommission.org/PatientSafety/UniversalProtocol/.