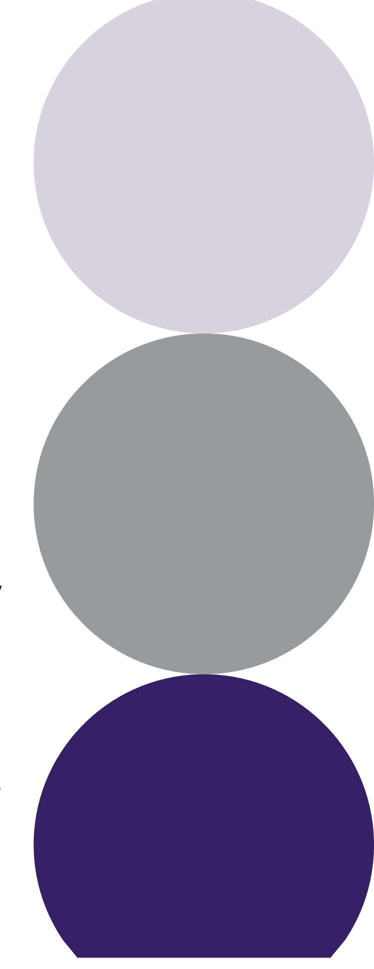
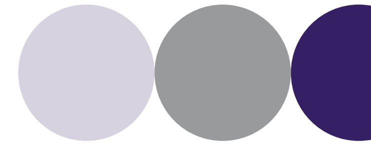
Protecting Sight. Empowering Lives.™

AAO Ethics Committee
Bettman Ethics Lecture Program

2024 Table Rock Regional Roundup

Zelia M Correa, MD PhD
Professor of Ophthalmology
Director Ocular Oncology and Echography Services
Sylvester Cancer Center and Interdisciplinary Stem Cell Institute
Bascom Palmer Eye Institute
University of Miami



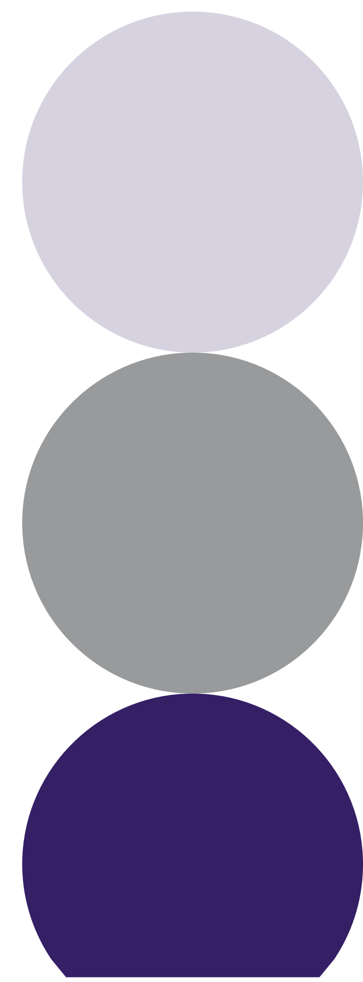


Financial Disclosure

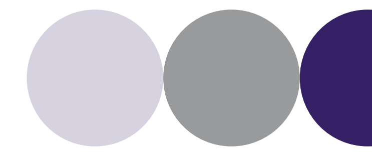
The presenter has no financial interests or relationships to disclose relevant to this presentation.

Protecting Sight. Empowering Lives.™

Disclosing Iatrogenic Errors in Clinical Care

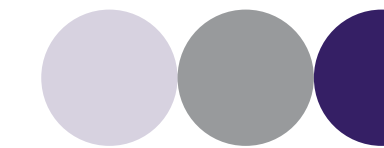


- As physicians we have certain obligations…
  - Obligation to be Truthful
  - Obligation to be Transparent
- Engenders Patient Trust
- Develops Patient Autonomy
- Integrity of the Profession



Informed consent vs. error disclosure

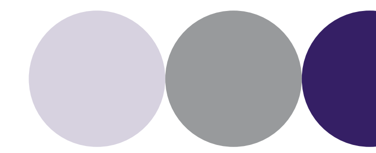
- Informed Consent: discussion including risks, benefits and potential complications
- Disclosure: discussion including the actual complications, why they occurred, and possible solutions
- What constitutes a disclosable error?
  - Every deviation from the game plan?
  - Intraoperative nuances that are overcome?
  - Issues that could affect ultimate outcome?
  - System errors?



Case Study: 72yo male patient

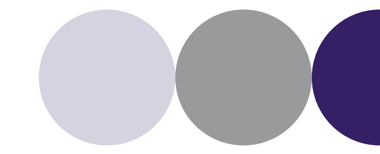
- CC:
  - Decreased vision
  - Light sensitivity
  - Difficulty seeing at night
  - Halos around lights
- Past Medical History:
  - Diabetes
  - Hypertension
  - Family history of glaucoma

- Visual Acuity:
  - Vsc OD: 20/100 PH: 20/60
    - (Vcc : 20/60)
  - Vsc OS: 20/60-2 PH: 20/40
    - (Vcc: 20/40-2)
- Exam reveals:
  - Severe POAG OU
  - Mild Fuchs' corneal dystrophy
  - Visually significant cataracts OU
- Assessment/ Plan: CE/IOL OD



Informed Consent includes:

- Spectrum of surgical outcomes
- Cataract and Fuchs' dystrophy
  - Corneal decompensation
- Glaucoma
- Surgical complication
  - Wound leak
  - Phaco burn
  - Posterior capsule rupture
  - Vitreous loss
  - Infection
  - CME
- IOL complication/options
  - Position, type



Preoperative Biometry Results

- OD

  AL: 25.23
  K1: 40.96
  K2: 42.55 @ 101

- SN60WF 21.50
  (-2.75 D target)

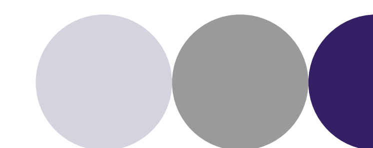
- OS

  AL: 25.26
  K1: 43.56
  K2: 45.74 @ 77

- SN60WF 18.00 D
  (-2.75 D target)

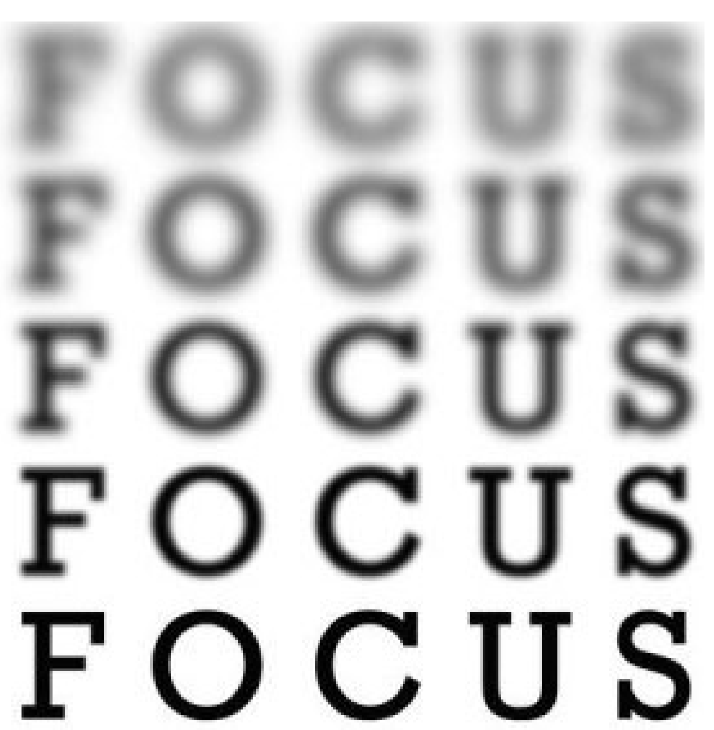
Surgery

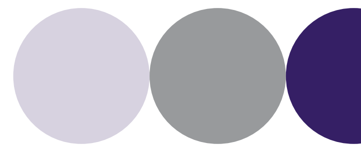
- Cataract surgery is performed in the right eye without complication.
- POD1 Exam:
  - Patient complains of very blurry vision
  - Reports glare, pain in bright light
  - Reports lid swelling, fullness, skin irritation
  - Cannot obtain visual acuity



Postop Day 7

- Distance VA sc: 20/150
- Refraction: - 8.25 + 2.25 x147
- Near VA sc: unable to read Rosenbaum card unless brought very close to patient's face





What happened?

- "We dug a little to find out what was wrong…"
  - Anterior segment exam, lens position and dilated funduscopic exam of the right eye was normal.
  - No evidence of capsular block or sulcus placement of the IOL which could have led to a myopic shift.
  - No evidence of cystoid macular edema which could lead to a hyperopic shift.
  - This led to a review of the lens calculations and the keratometric readings were found to be problematic.
  - Ultimately, we uncovered system errors and erroneous assumptions.

Assumptions made

- Discovery that the patient had unusual keratometric readings from the Pentacam
- However, the IOLMaster K's were *assumed* to be most accurate despite the significant difference in the K's between the two eyes.
    - OD: AL: 25.23, K1: 40.96, K2: 42.55 @ 101
    - OS: AL: 25.26, K1: 43.56, K2: 45.74 @ 77

AL: 24.18 mm (SNR = 4.3)
K1: 41.67 D / 8.10 mm @ 92°
K2: 42.19 D / 8.00 mm @ 2°
R / SE: 8.05 mm / 41.93 dpt
CyL: -0.52 D @ 92°

Status: phakic

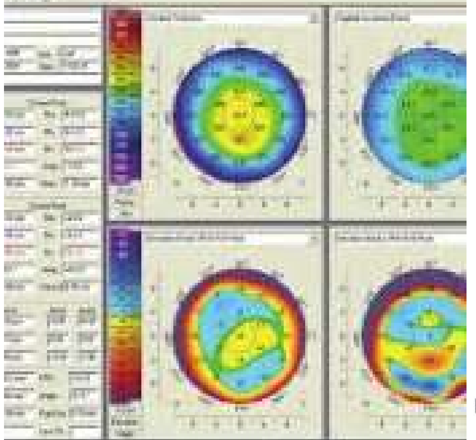
AL: 24.21 mm (SNR = 183.0)
K1: 41.21 D / 8.19 mm @ 105°
K2: 41.98 D / 8.04 mm @ 15°
R / SE: 8.11 mm / 41.59 dpt
CyL: -0.77 D @ 105°

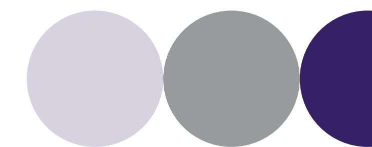
Refraction: -0.50 D +1.75 D x 175°

Eye Status: Pseudophakic Acrylate

ZCB00	Alcon SA60AT		AMO Tecnis ZCB00		Alcon SA60A
2.03	SF:	1.65	SF:	2.03	SF:
REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)
-1.06	22.0	-0.89	23.5	-1.20	22.5
-0.71	21.5	-0.54	23.0	-0.85	22.0
-0.37	21.0	-0.19	22.5	-0.50	21.5
-0.03	**20.5**	**0.16**	**22.0**	**-0.16**	**21.0**
0.30	20.0	0.50	21.5	0.18	20.5
0.63	19.5	0.84	21.0	0.51	20.0
0.96	19.0	1.17	20.5	0.84	19.5
21.45	Emme. IOL: 20.73		Emme. IOL: 21.77		Emme. IOL:

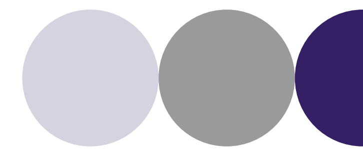
of MA60AC	Alcon SN6CWS		Alcon AcrySof MA60AC		Alcon SN6CV
1.9	SF:	1.84	SF:	1.9	SF:
REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)
-0.90	22.5	-0.98	23.0	-1.03	23.0
-0.55	22.0	-0.63	22.5	-0.68	22.5
-0.20	21.5	-0.28	22.0	-0.34	22.0
0.14	**21.0**	**0.06**	**21.5**	**0.01**	**21.5**
0.47	20.5	0.40	21.0	0.35	21.0
0.80	20.0	0.73	20.5	0.68	20.5
1.13	19.5	1.06	20.0	1.01	20.0
21.20	Emme. IOL: 21.09		Emme. IOL: 21.51		Emme. IOL:





Is There an Ethical Dilemma Here?

- We cannot decide which errors to disclose and which to not disclose.
- We are responsible for whatever happens to the patient, whether it is a personal mistake or a device error.
- Not telling the patient about the error erodes trust.
- Not telling the patient is unethical.

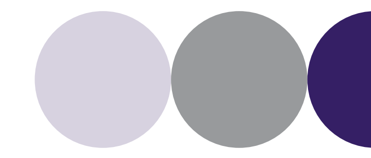


Disclosure vs. non-Disclosure

- The medical literature broadly supports the legal and ethical principles that disclosure of medical errors enhances trust, beneficence, and patient autonomy.
- Studies show from 76% to 98% of outpatient internal medicine patients desired disclosure for even minor errors and for that disclosure to be immediate upon discovery.[1]
- Despite these numbers, a surprisingly low number of errors are disclosed.[2]

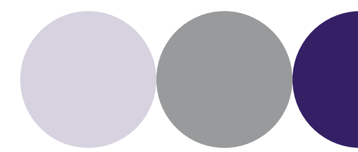
[1]Witman AB, Parc DM, Hardin SB. How do patients want physicians to handle mistakes? A survey of internal medicine patients in an academic setting. *Arch Intern Med*. 1996;156(22):2565-2569.

[2]Wu AW, Folkman S, McPhee SJ, Lo B. Do house officers learn from their mistakes? *JAMA*. 1991;265:2089-2094.



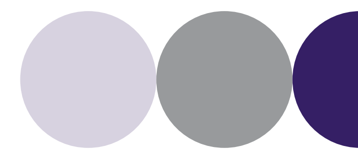
Case Study:

- 87 yo female underwent CE/IOL, complicated by capsular rupture and loss of support for PCIOL, requiring anterior vitrectomy and ACIOL placement
- Post op: Prolonged corneal edema without acknowledgement of the surgical complication. (Return to clinic in 1 month…..repeatedly)
- 2nd opinion obtained. Consultant disclosed the state of the eye and offered opinion about what "should have been done".
- Request and review of medical record: "PC rupture" never mentioned
- Family was very upset, not because of complication but rather, non-disclosure of why poor vision lingered



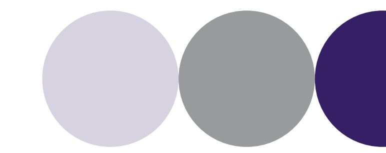
Case review

- Surgeon stated that he does not reveal “minor complications” because they generally don’t make an impact on outcome, he does not want the patients to worry, and his patients are often referred by other patients.
  - Given this philosophy, he and the patient would have been well served to disclose early during postop recovery.
- Omission: Cost him the trust of the patient, potential legal action, loss of patient-generated “good will” referrals, peer reputation damage
- Disclosure: engages the patient and family who can support the patient, possible peer support from second opinions, possible avoidance of legal action



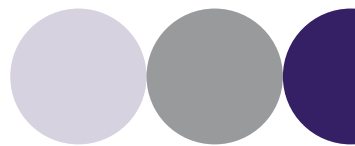
Should you disclose all surgical complications?

- Known complications of a surgical procedure which may or may not impact the outcome
  - YAG capsulotomy pitting of lens
  - Posterior capsule rupture
- If the possibility of complications was discussed in the informed consent process, then there is less surprise for the patient.



Why you should disclose surgical errors

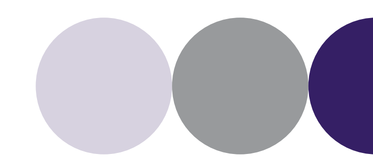
- If all goes well, it ends well.
- If it does not go well, the patient may seek another opinion and find out what you did not tell them, causing anger and distrust
- The patient has a right to seek opinions for their best health. If they do not know about a known issue, time may pass which could decrease a potentially beneficial treatment
- If you have disclosed, and they seek another opinion, they may get the opinion that all was done correctly for a known complication, validating you as a surgeon with integrity



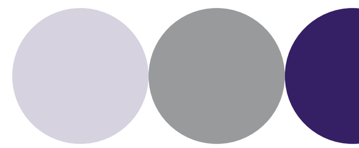
The Disclosure

- Although difficult, disclosure helps to preserve patient autonomy and bolsters the patient-physician relationship.
- Once an error is disclosed, most patients can and want to be active participants in determining the next course of action.
- Most patients appreciate an honest, engaged physician’s efforts to correct complication.
- Physicians have an ethical responsibility to disclose errors to patients.
- But how???

Error communication 101



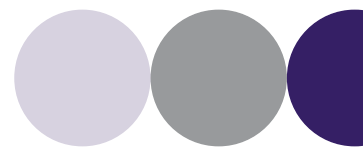
- Patient
  - Truthful, accurate information
  - Emotional support, including apology
  - Follow-up, potentially compensation
- Healthcare workers
  - Communication coaching
  - Emotional support
- Process, not an event
  - Initial conversation
  - Event analysis
  - Follow-up conversation



The SPIKES Protocol

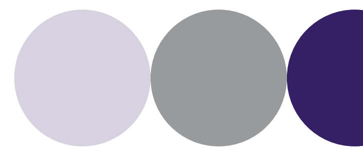
- The most widely recommended approach to deliver bad news is the six-step SPIKES protocol seen below, developed in 1990 to help guide oncologists in the delivery of bad news:[1]
  - **S**: **Setting** up the discussion
  - **P**: Assessing the patient's **Perception**
  - **I**: Obtaining the patient's **Invitation** for details
  - **K**: Providing **Knowledge**
  - **E**: Addressing the patient's **Emotions**
  - **S**: **Strategy** and **Summar**y

[1]Baile WF, et al. *SPIKES-A six-step protocol for delivering bad news. Oncologist* 2000;5(4):302-311.



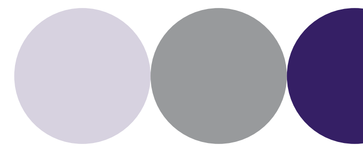
The SPIKES Protocol

- **S**: **Setting** up the interview, including preparing and planning of the space, the presence of others, the seating arrangements, and managing time constraints and interruptions
- **P**: Assessing the patient's **Perception**—finding out how the patient perceives the medical situation
- **I**: Obtaining the patient's **Invitation** to the type and depth of information they want to receive



The SPIKES Protocol

- **K**: Providing **Knowledge** and information to the patients—sharing the information with the patient in a tailored level of communication and vocabulary
- **E**: Addressing the patient's **Emotions** and **Empathic** responses—responding to the patient's emotions with empathy
- **S**: **Strategy** and **Summar**y—planning the next steps, setting goals and treatment plans, and establishing follow-up.

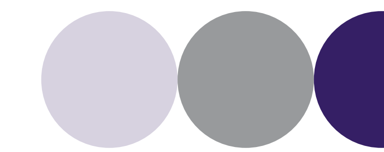


The ABCDE Protocol

An alternative approach, which piggybacks on the popular ABC mnemonic is the ABCDE protocol.[1]

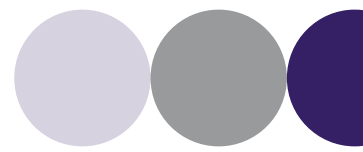
- **A**: **Advance** preparation
- **B**: **Building** a therapeutic relationship
- **C**: **Communicating** well
- **D**: **Dealing** with patient and family reactions
- **Encouraging**/validating **emotions**

[1]VandeKieft GK. Breaking bad news. *Am Fam Physician* 2001;64(12):1975-1978.



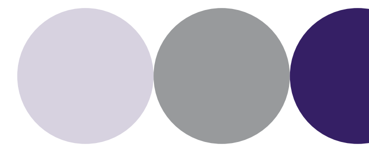
Failure to Disclose Is Difficult to Defend

- Good physician-patient relationships developed *before* potential errors occur lessens patients' anxiety and reduces the risk of liability claims (informed consent)
- Prompt disclosure may also prevent an allegation of *fraudulent concealment*, which could open the door to punitive damages.
- After addressing the error and caring for the patient, it is important for the institution to discover where the system failed and find ways to make it less likely to recur.
- Share the system improvement(s) with the patient.



Back to our K-Reading Errors

- When the error was discovered, the situation was explained in detail to the patient and family. The devices and measurements were reviewed in an understandable manner, and the reason for the error was also explained. He and his family understood and were able to ask questions about the surgical/non-surgical options to optimize the vision in the right eye.
- After a candid discussion about the risks and benefits of all of the options, we decided together and agreed what would be the safest and most effective option – lens exchange.
- Most importantly, we apologized to the patient for our error and for the fact that he would require an additional procedure.



Postop Month 2

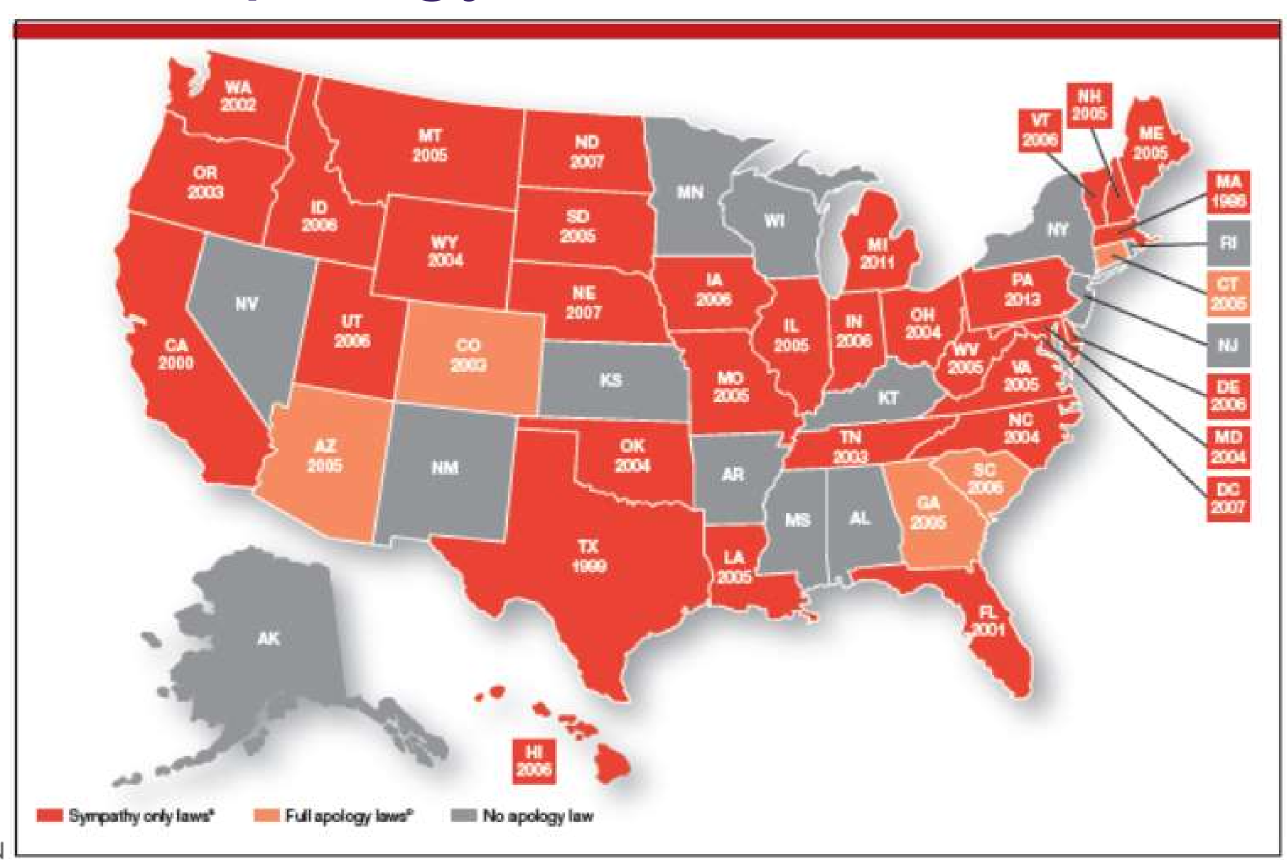
- Post-operatively, approximately 2.5 months after initial CE IOL OD:
  - Vsc OD: 20/70 PH 20/30 (Vcc 20/30 + 2)
  - Vsc OS: 20/150 (Vcc 20/40-1)
  - Vcc OU: 20/25-2
  - Near sc: J1 on Rosenbaum card without spectacles at approx. arm's length with decent lighting

What about “I’m Sorry” Laws?

- Thirty-nine states* have “apology laws” which prohibit certain statements, expressions, or other evidence related to disclosure from being admissible in a lawsuit.
- Most states simply cover expressions of empathy or sympathy, while a few states go further and protect admissions of fault.
- Before you need to know, find out what the laws are in the state in which you intend to practice.

*As of Aug 2021, https://www.ncsl.org/research/financial-services-and-commerce/medical-professional-apologies-statutes.aspx

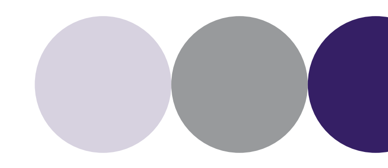
States with Apology Laws and Years Enacted



Protecting Sight. Empowering Lives.™

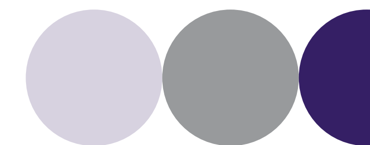
“Apology” Laws May Not Always Protect You

- It is only natural that your first instinct will be to comfort your patients when medical or surgical procedures have unintended outcomes. Be careful to do so in a planned and well-thought-out manner in order to protect yourself.
- OMIC cites a case in which the doctor told a patient’s family that he had “nicked an artery and took responsibility for it.” The patient died after the surgical procedure. During the trial, the defense tried to keep the comments out under the state’s “apology” law which protects physicians who use expressions of apology or sympathy. The court ruled the statement was not an apology, but *an admission of guilt* and an arguably defensible case was ruled in favor of the plaintiff at trial and upheld during appeal.
- We know that not all errors are medical malpractice. Don’t assume that because something went wrong you will be found liable or negligent. Have a plan in place for addressing errors.



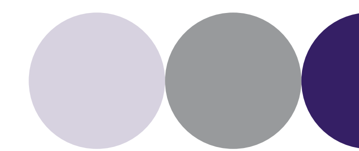
Pertinent Principles and Rules of the Code of Ethics

- Principle 4. *Communication with the Patient*
  "Open communication with the patient is essential…"
- Principle 7. *An Ophthalmologist's Responsibility*
  "It is the responsibility of the ophthalmologist to act in the best interests of the patient."
- Rule 2. Informed Consent
  "The performance of medical or surgical procedures shall be preceded by appropriate informed consent… the operating ophthalmology must personally confirm with the patient… comprehension of this information."
- Rule 6. *Pretreatment Assessment*
  "Treatment shall be recommended only after a careful consideration of the patient's physical, social, emotional and occupational needs…"



Will disclosure and truth always win out?

- 56yo woman with high myopia and 2+ nuclear sclerosis
- BCVA : 20/70 OD 20/80 OS
- Glare : 20/100 OD 20/ 200 OS
- Rx: -11.00 OD - 12.00 OS
- No improvement with refraction
- CE/IOL OS "uncomplicated" surgery

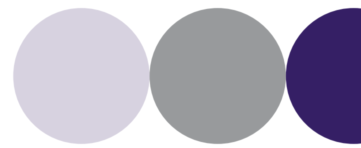


POD 1

- VA 20/200
- Corneal edema
- AC deep and clear
- PCIOL in good position
- Reassurance about VA due to edema.
  - Steroids and antibiotics
  - Return in one week

POD 7

- CC: I am pissed
- I can see very well through my left eye…with my old glasses!!

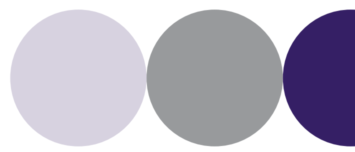


What went right?

- Immediate disclosure (WRONG POWER) with patient in the exam room
- Listened to her frustration
- Explained error and how it happened
- Discussed options: IOL exchange selected
- Uncomplicated IOL exchange 2 weeks post op
- VA sc 20/25

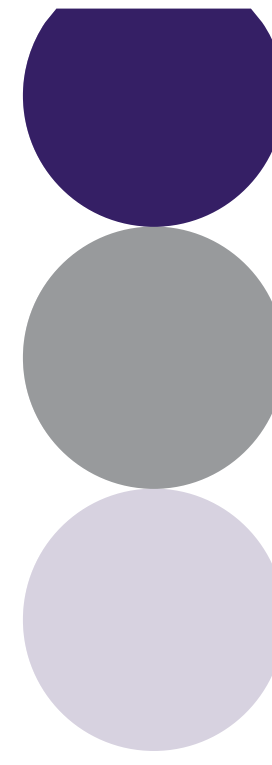
What went wrong?

- Pre-IOL Master era
- K's and axial lengths were obtained separately and transcribed onto a worksheet for calculation
- Axial lengths were switched
- Despite good outcome with reoperation, she opted to go elsewhere for 2nd eye CE
- Lawsuit



Lessons

- Honest disclosure is critical for integrity, patient autonomy, and optimizing the health of the patient.
- Accurate medical records
- Patient and physician engagement are critical. Be attentive
- Plan
- “Sorry” can work (but not all always)
- Make sure your staff understand the situation so that they are part of the support team and solution



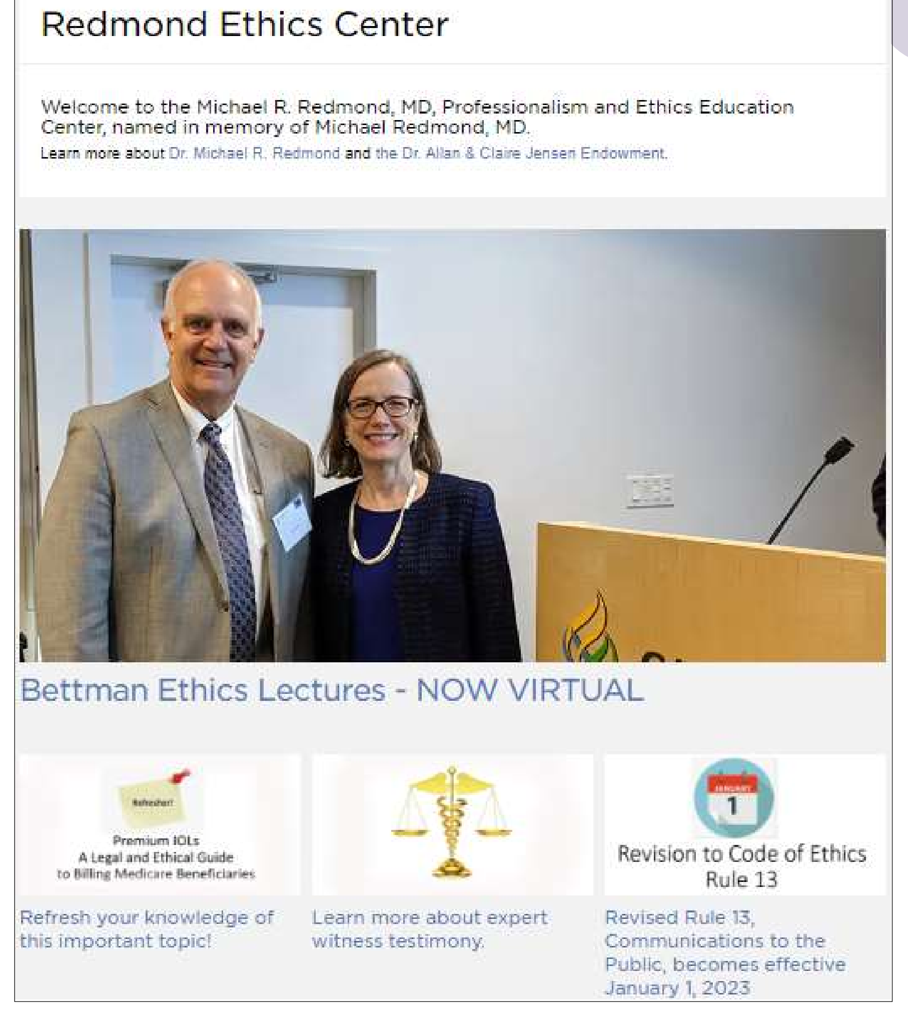
Questions or comments?

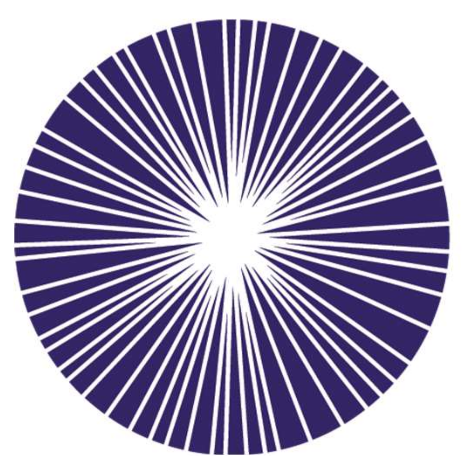
Ethics Resources

The Redmond Ethics Center

http://www.aao.org/clinical-education/redmond-ethics-center

General ethics questions: ethics@aao.org





AMERICAN ACADEMY™
OF OPHTHALMOLOGY

Protecting Sight. Empowering Lives.