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Ethical Communication with Patients: Informed Consent and Error Disclosure

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Financial Disclosure

I have no financial interests or relationships to disclose.

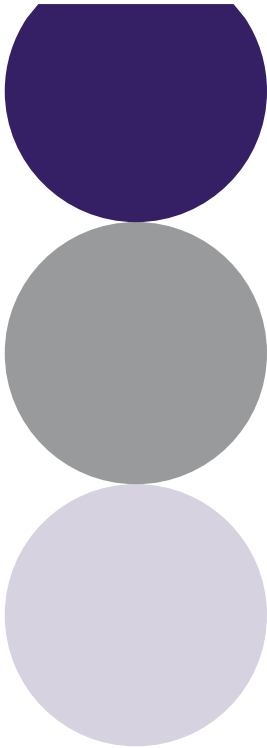
Why is This Topic Important?

We have an obligation to be truthful.

Ethical Communication

- Engenders patient trust
- Develops patient autonomy
- Maintains integrity of the profession

Informed Consent



Principles of Informed Consent

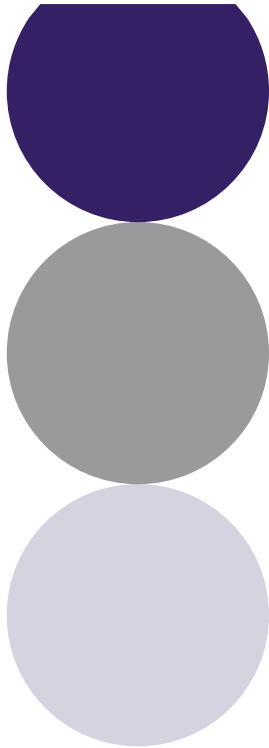
- Informed consent is a dialogue that includes
  1. An assessment of patient competence to decide
  2. Disclosure of relevant information
  3. An assessment patients' comprehension
  4. Affirmatively attain a consent from patient or surrogate
- Informed consent occurs before a patient or surrogate signs anything
- Informed consent is **not** a signature on a document.

Code of Ethics - *Rule 2, Informed Consent*

"Informed consent is the process of shared decision-making between the ophthalmologist and the patient…

- *must precede the performance of medical or surgical procedure.*
- *…pertinent medical and surgical facts, and recommendations consistent with standard of care in medical/surgical practice must be presented in understandable terms to the patient or patient surrogate.*
- *Such information should include the indications, benefits, objectives, risks and possible complications of the procedure, alternatives to the procedure, and the potential consequences of no treatment.*
- *The operating ophthalmologist must personally confirm comprehension of this information with the patient or patient surrogate."*

Informed Consent Inquiries to the AAO Ethics Committee



Inquiry #1

- *"We have patients sign a consent form for various procedures before they see the physician, so that if a procedure is determined to be necessary during the consultation, the consent is already in place.*
- *This allows for an immediate transition to the treatment room.*
- *Are my concerns about the appropriateness of this policy valid?"*

Valid Concerns

- Patients can only give consent after their physician has evaluated them and has recommended a specific procedure
- An informed consent form documents
  - the physician and patient have discussed a specific procedure
  - its *risks, benefits and alternatives*
  - an agreement has been reached about best way to proceed prior to the procedure being performed
- Patients cannot consent to procedures that haven't yet been discussed or may not be necessary.

Inquiry #2

- *"One of my patients consented to surgery over 19 months ago, then debated whether he wanted to go through with the procedure. Now, he has decided to proceed.*
- *Do I need to go through the consent process all over again since I have the patient's consent in writing?"*

Re-Consent The Patient

- There is no strict legal expiration of a signed consent form, but re-consenting after 19 months is advisable.
- Inform the patient of
  - any new risks, benefits, alternatives
  - any health changes affecting treatment plan
- If no changes have occurred
  - re-confirm the patient's understanding and agreement
  - have both parties initial and date the form and document this in the patient’s record

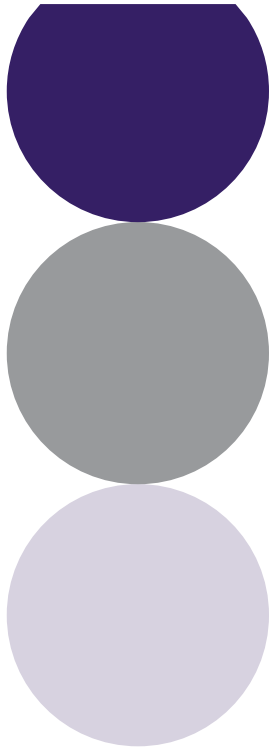
Inquiry #3

- *“I started using light adjustable lens implants (LALs) recently. While most patients have been happy with the results, one experiences glare and has less visual clarity than she expected.*
- *To my chagrin, the informed consent form I used is for a standard cataract extraction and doesn’t even mention the LAL procedure.*
- *Should I have used a consent form specific to LALs that explains their benefits and risks?”*

Use Procedure-Specific Consent Forms

- Be cautious with new technology: standard consent forms might not cover all details of specialized procedures.
- Discuss and document the risks, benefits, and alternatives of any special intraocular lens with the patient.
- To mitigate unmet expectations after surgery, ensure a thorough, ethical, and procedure-specific preoperative consent process.

Case Study



Informed Consent and Surgery

- Dr. P examined a 45 year-old patient for refractive surgery
  - -7D myope with K's: 45D, normal topography, pachy 530, pupils 6mm, TBUT 10secs
- A detailed discussion of LASIK surgery took place including risks, range of potential outcomes, and significant complications (*not an exhaustive list*). Written material given.
  - After asking questions, the patient decided to proceed with surgery
  - The consent for LASIK surgery was witnessed by a family member
- The surgery was uncomplicated, and the patient did well

What Do You think?

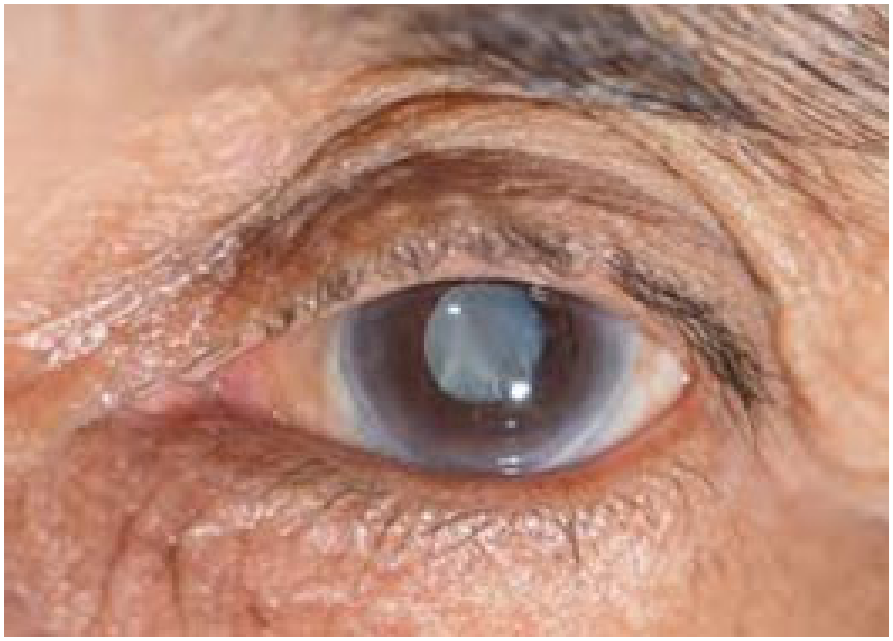
Did Dr. P do a good job?

What Do You think?

- Good model of informed consent process
- Dr P was effective in:
  - explaining condition, treatment, and outcomes in understandable terms
  - assessing patient's comprehension
  - giving the patient time to make decision
- What is the benefit of a 3rd party witness?

Case Study

Informed Consent on the Learning Curve



- A 62 year old male was seen at a large teaching institution
- Hx cataract surgery OD
  - Excellent outcome by a community surgeon
- Presents with visually significant, unremarkable cataract OS
- It looks like a perfect case for a 2nd year resident

Informed Consent

- After the resident examines the patient, the attending ensures the patient understands the procedure and encourages questions.
- The patient asks who will perform his surgery saying, "*I watch TV! Having a resident operate on me makes me nervous!*"
- He then asks if his vision will be 20/20 after surgery if the resident is the surgeon.

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Informing Patients about Resident Involvement

- Half of private practice patients would be comfortable with a supervised resident performing some or all their surgery.[1]
- Agreement to resident participation based on:
  - Trust in the attending
  - Belief in contributing to future physician education
  - Assurance of resident supervision
- Declining resident participation based on:
  - Fear
  - Trust in only the attending

[1]Corwin AM, et al., *JAMA Ophthalmology 2019*

The Ethical Dilemmas

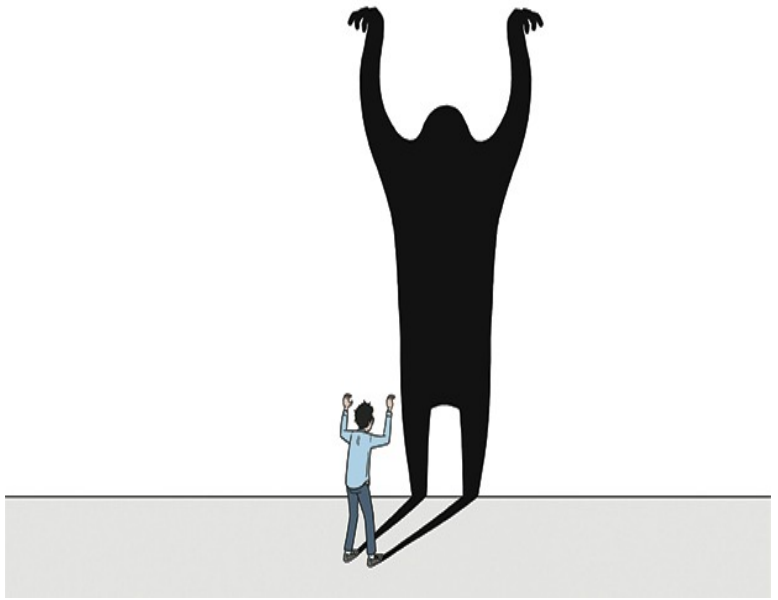
- Is it ethical to expose patients to learning curve risks?
- How should surgical inexperience be disclosed?
  - Complication rate
  - Extent of disclosure
- Academic / Private: A double standard?
- Appropriate patient selection
- Appropriate anesthesia selection

The Learning Curve: Residency

- The patient deserves to know who the primary surgeon is and trust that that individual will perform the surgery.
- Even in a teaching hospital, a patient is entitled to specify that the attending doctor will be the primary surgeon.
- If the issue cannot be resolved, the attending surgeon should perform the surgery and another patient more appropriate for a resident case should be found

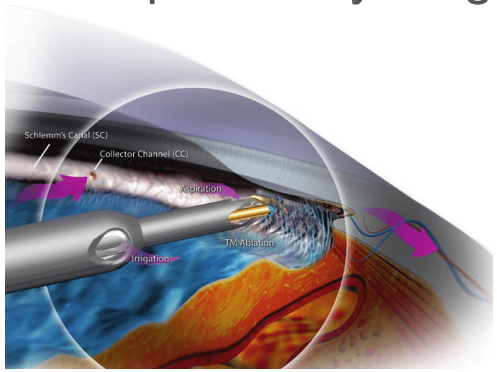
Resident's Discussion with Patient

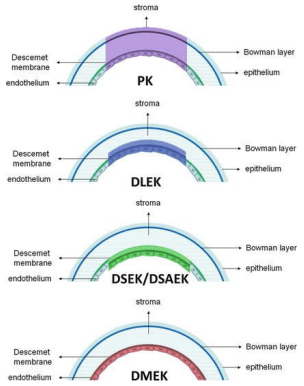
- Explain your training honestly without exaggeration
- Disclose the number of cases you've done
- Confirm that your attending will be present for the entire case
- It's acceptable to state your complication rate is similar to your mentor's
- Disclose resident involvement in private practice cases similarly
- AMA and CMS recommend openly discussing the role and supervision of residents in surgery

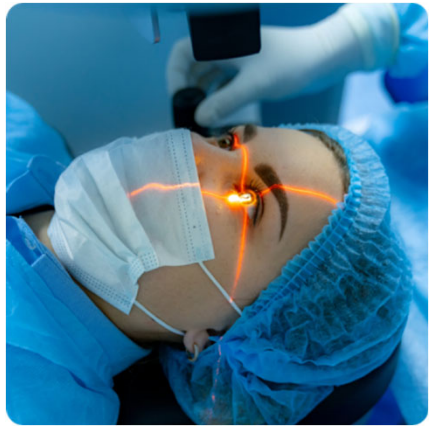


The Learning Curve: Experienced Surgeon

- What should the patient be informed of when an experienced surgeon is incorporating new techniques or procedures into their practice that were not specifically taught during training?







The Learning Curve: Experienced Surgeon

- The following should be discussed:
  - Why the new procedure or technique may be better than an older procedure (benefits and alternatives)
  - What training the surgeon has undergone to learn the technique
    - Vendor provided training, observation and/or training by another surgeon, wet lab, courses, videos etc.
    - Whether the vendor/trainer will be present in the operating room
  - How the technique is similar and differs from techniques the surgeon is experienced with
  - Specific risks of the new procedure
  - How many of the new procedure the surgeon has performed

Honesty and Transparency

- Duty of honesty to the patient is paramount
- Complete, accurate information demonstrates
  - Respect
  - Integrity
  - Empowers patient to make informed decisions

The “Ginger” Effect

- Patients remember approx 50% of informed consent discussions[1]
- How can you overcome this barrier?
  - Encourage the patient to ask questions and repeat facts back to you
  - Send printed material home with the patient
  - Encourage a family member to take part in the informed consent discussion

[1]Wear, S. Informed Consent: Patient Autonomy and Physician Beneficence within Clinical Medicine. Kluwer Acad Publ, 1993.

Error Disclosure

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Informed Consent vs. Error Disclosure

- Informed Consent: discussion including risks, benefits and potential complications
- Error 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?
  - Only issues that could affect ultimate outcome?
  - System errors?

Case Study 1: 72 year-old patient

- CC:
  - Decreased vision
  - Light sensitivity
  - Difficulty seeing at night
  - Halos around lights
- Past Medical History:
  - Diabetes
  - Hypertension
  - Family history of glaucoma
- Exam reveals:
  - Severe POAG OU
  - Mild Fuchs' corneal dystrophy
  - Visually significant cataracts OU
- Pre-Operative VA:
  - BCVA OD: 20/60
  - BCVA OS: 20/40-2
  - Plan: CE/IOL OD

Informed Consent includes:

- Benefits: improved vision
- Risks
  - Common potential intraoperative and postoperative surgical complications
    - Wound leak
    - Posterior capsule rupture
    - Vitreous loss
    - Infection
    - CME
    - RD
  - Reassurance that most cataract surgeries are low risk and uneventful
- Patient Specific Risks
  - Worsening of glaucoma
  - Corneal edema
  - Limited postoperative improvement due to concomitant disease
- Alternatives/Options
  - IOL options appropriate for this patient
  - Potential consequences of not having the surgery

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
  - VA: Count Fingers 3 ft

Postop Day 7

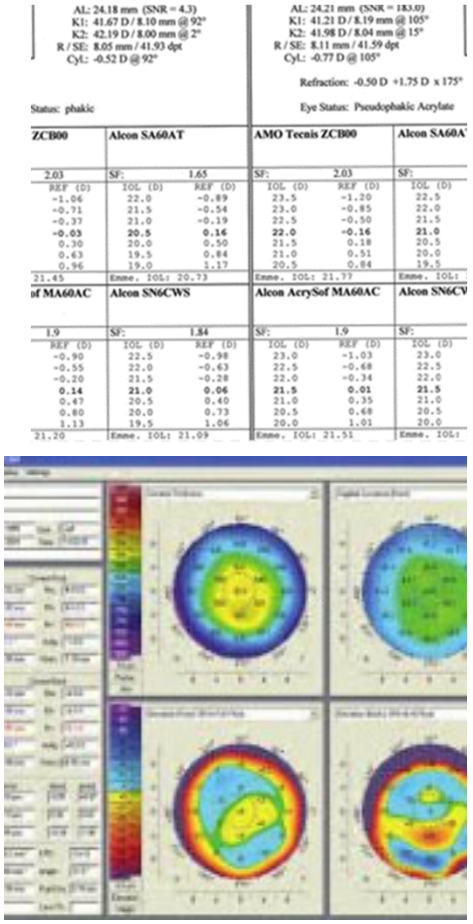
- Distance VA sc: 20/200
- Refraction: - 8.25 + 2.25 x147
- Near VA sc: unable to read near card unless brought very close to patient's face

What happened?

- Confirmation was made that the IOL power chosen based on the pre-op biometry was the IOL that was implanted.
- Anterior segment exam, lens position and dilated funduscopic exam of the right eye was unremarkable.
  - 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.
- A review of the lens calculations and the keratometric readings were found to be problematic.
- Ultimately, system errors and erroneous assumptions were uncovered.

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°

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°

Status: phakic

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 SN6CW
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:

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Is There an Ethical Dilemma Here?

- 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 2: 87 y.o. female

- Patient underwent CE/IOL, complicated by capsular rupture 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.
  - Requested and reviewed medical record: “PC rupture” never mentioned
  - Consultant disclosed the state of the eye and offered opinion about what “should have been done”.
- Family was very upset, not because of complication but rather, non-disclosure of why poor vision persisted

Case review

- The surgeon stated he avoids sharing "minor complications" to prevent patient worry, because they typically don't affect outcomes and may endanger his referrals
- 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 during phaco
- If the potential complications are 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 not, the patient might seek a second opinion
  - Without disclosure, the patient will discover the error leading to
    - anger and mistrust
    - delayed treatment may be less effective
  - With disclosure
    - the patient may learn the surgeon correctly managed a known potential complication
    - the integrity of the surgeon is reinforced

The Disclosure

- Disclosure, though challenging, preserves patient autonomy and builds trust in the physician-patient relationship.
- After an error is revealed, most patients wish to be active participants in the next steps
- Patients value honest, engaged physicians working to correct problems.
- Physicians have an ethical obligation to disclose errors.
- But how?

Error communication 101

- Patient needs
  - Truthful, accurate information
  - Emotional support, including apology
  - Follow-up, potentially compensation
- Physician needs
  - 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 **Summary**

[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 **Summary**—planning the next steps, setting goals and treatment plans, and establishing follow-up.

Failure to Disclose Is Difficult to Defend

- Strong physician-patient relationships formed *before* errors occur help reduce patient anxiety and liability risks.
- Promptly disclosing errors can prevent allegations of *fraudulent concealment* and punitive damages.
- After managing the error, institutions should identify system failures and work to prevent recurrence.
- Inform the patient about any system improvements made.

Back to our K-Reading Errors

- Upon discovering the error, it was clearly explained to the patient and family, including devices, measurements and reasons for the mistake. They understood and asked about medical and surgical options to improve vision OD
- After discussing risks and benefits, they jointly decided to proceed with a lens exchange.
- An **apology** was offered for the error and the additional procedure needed.

Postop Month 2

- Post-operatively, approximately 2.5 months after initial CE IOL OD:
  - Vsc OD: 20/70 PH 20/30 (Vcc 20/25)
  - Vsc OS: 20/150 (Vcc 20/40-1)
  - Near sc: J1 on near card without spectacles with good lighting

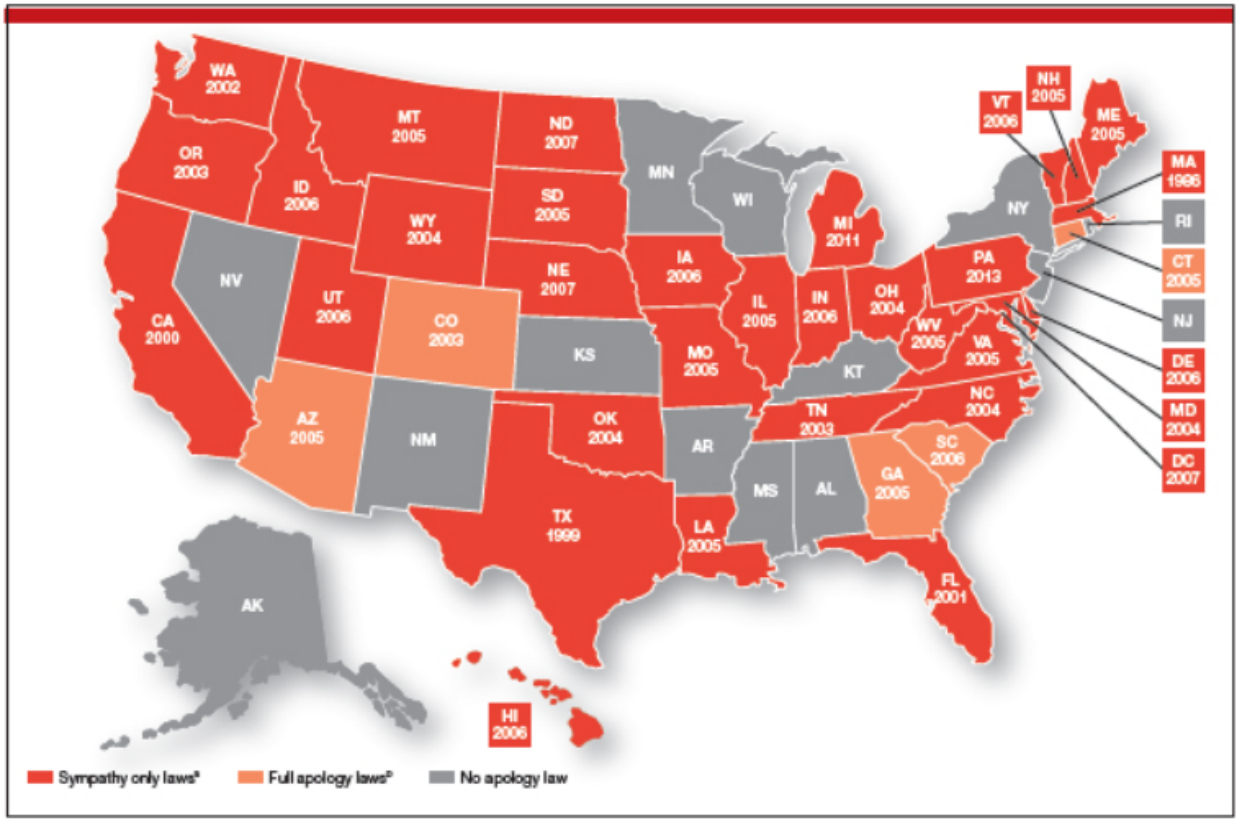
What about “I’m Sorry” Laws?

- 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



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Ohio Revised Code, Section 2317.43

Medical Liability Action - Admissibility of Certain Communications

In part, the statute states:

- "In any civil action brought by an alleged victim of an unanticipated outcome… any and all statements, affirmations, gestures, or conduct expressing apology, sympathy, commiseration, condolence, compassion, error, fault, or a general sense of benevolence that are made by a health care provider… are inadmissible as evidence of an admission of liability.…"

"Unanticipated outcome" is defined as "…. the outcome of a medical treatment or procedure that differs from an expected result or any outcome that is adverse or not satisfactory to the patient."

Disclosure without an Apology Law

- Use "unexpected outcome" or "unexpected complication" instead of "error" or "mistake."
  - ”I know this unexpected outcome is not what we hoped for."
  - ”I am very concerned about this turn of events."
- Use "we”, not ”I” to emphasize a team approach to investigate the cause.
  - "We are committed to understanding what happened. We will keep you informed about what we learn."
- Listen actively: allow emotions to be expressed without interruption. Sit down, maintain eye contact, be aware of body language. Focus on moving forward.
  - "Our priority is your recovery."
  - "Let's discuss the next steps in your treatment."

“Apology” Laws May Not Always Protect You

- It’s natural to want to comfort patients after unexpected medical outcomes, but do so carefully and thoughtfully to protect yourself.
- In one OMIC case, a doctor told a patient’s family he “nicked an artery and took responsibility for it” which was ruled an admission of guilt despite an apology law, leading to a verdict against the doctor.
- Not all bad outcomes are malpractice; having a plan for handling errors is essential.

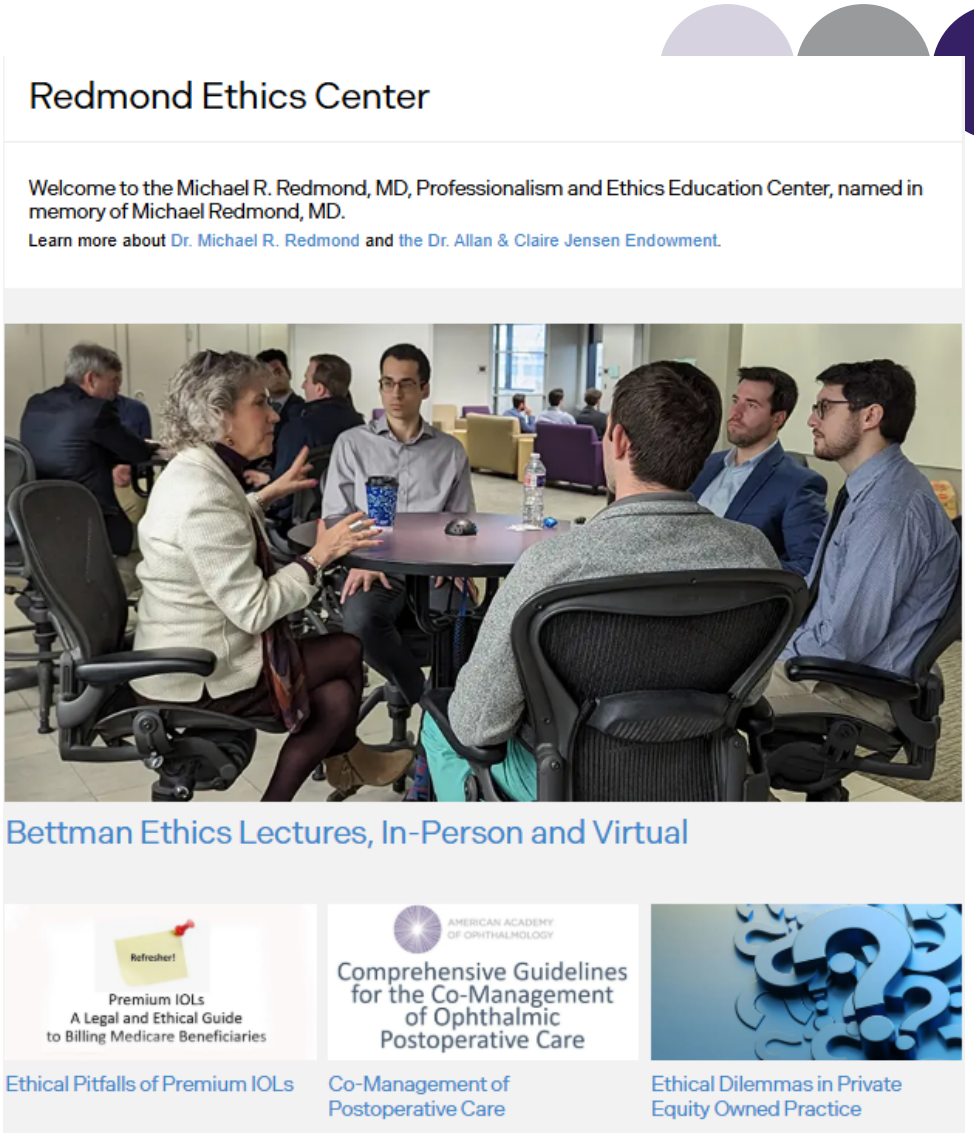
Lessons

- Effective error disclosure begins with a strong physician-patient relationship and appropriate pre-op informed consent.
- Document the consent, the error and the disclosure.
- Ensure staff are informed to support the process.
- Plan the disclosure conversation in advance.
- Engage with the patient attentively; see the patient more, not less
- Honest disclosure maintains integrity and respects patient autonomy.
- An apology can be helpful (but not always)

The Redmond Ethics Center

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

Inquiries & Submissions
ethics@aao.org



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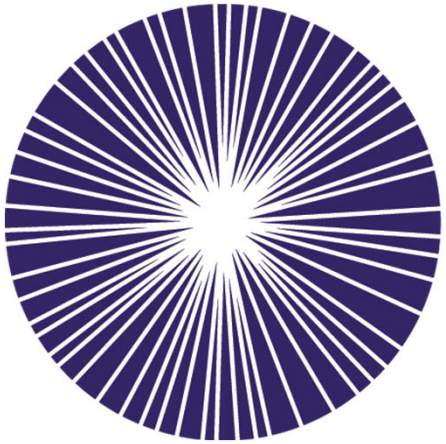

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