First, do no harm, but *to err is human*: Resolution and Restoration in adverse medical outcomes

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What does it mean to be a ”good” doctor?

What does it mean to have an "adverse outcome?"

Adverse Outcomes" are results that run contrary to the expected outcome that have negative consequences.

Adverse outcomes *can* result from mistakes.

Adverse outcomes do not mean a mistake was made *per se.*

Even care that was completely appropriate, compassionate, competent, and *evidence based* can result in an adverse outcome.

Patients are not machines.

Neither are doctors.

Sometimes, despite our best efforts, we get it wrong.

Then What Happens?

Traditional Malpractice Model for resolution

Purposes of a Malpractice Suit:

1. To restore, or if restoration is not possible, to adequately compensate for a loss resulting from medical negligence
2. To establish mechanisms for enhanced oversight and quality assessment aimed at improving the overall quality and safety within our healthcare system.
3. To penalize egregiously wrongful behavior (actual malice, ‘wanton’ or ‘reckless’ conduct).

Limitations to medical malpractice

"To restore, or if restoration is not possible, to adequately compensate for a loss resulting from medical negligence"

- This principle is not applied consistently. There is no clear link between adverse outcomes, actual medical negligence, and legal decisions.
  - The only correlation observed relates to the severity of the adverse outcome, rather than the quality of care provided.
- Legal resolutions are uncertain and typically take several years; financial compensation is unpredictable.
- Monetary compensation represents only one facet of justice but holds disproportionate importance in malpractice cases.
- This process often establishes an immediate adversarial dynamic, which usually prevents meaningful communication between patient and practitioner. Healthcare providers are restricted from discussing the case, outcomes, quality improvement efforts, investigations, or expressing comfort, sympathy, remorse, apology, or empathy.
- There is no opportunity to preserve a sense of community within the patient-practitioner relationship.

Limitations to medical malpractice

"To establish mechanisms for enhanced oversight and quality assessment aimed at improving the overall quality and safety within our healthcare system."

- A meta-analysis reviewing 37 studies on medical malpractice in hospital care found **no clear link** between malpractice liability risk and healthcare quality or patient outcomes.
  - One explanation is the inconsistent enforcement: "The mismatch between claims and actual negligence creates noise in the deterrent effect, reinforcing physicians' beliefs that claims do not accurately reflect the quality of care they provide." Michelle M. Mello et al., *Malpractice Liability and Health Care Quality: A Review*, 323 **JAMA** 352 (2020).

Limitations to medical malpractice

"To penalize egregiously wrongful behavior (actual malice, 'wanton' or 'reckless' conduct)"

- Punitive damages are being claimed more frequently in New Mexico, even in what might be considered "routine" medical malpractice cases.
- These damages are often used as a bargaining tool in settlement negotiations rather than being limited to cases involving truly malicious actions.
- This trend is particularly concerning for individual practitioners who face significant personal financial exposure, risking financial ruin in addition to reputational damage and threats to their professional identity during medical malpractice proceedings.
  - There is a rise in Medical Malpractice Stress Syndrome, PTSD, and second victim phenomena among practitioners, which notably do not correlate with the case outcomes.

Medical Malpractice Stress Syndrome and Second Victim Phenomenology

Esperanza L. Gómez-Durán et al., *Physicians as Second Victims After a Malpractice Claim: An Important Issue in Need of Attention*, 33 *J. Healthc. Qual. Res.* 284 (Sept.–Oct. 2018). DOI: 10.1016/j.jhqr.2018.06.002

Larry H. Strasburger, **The Litigant-Patient: Mental Health Consequences of Civil Litigation**, 22 *J. Am. Acad. Psychiatry L.* 453 (1994

"Second Victim": significant psychological distress associated with health care practitioners that are a part of an adverse event.

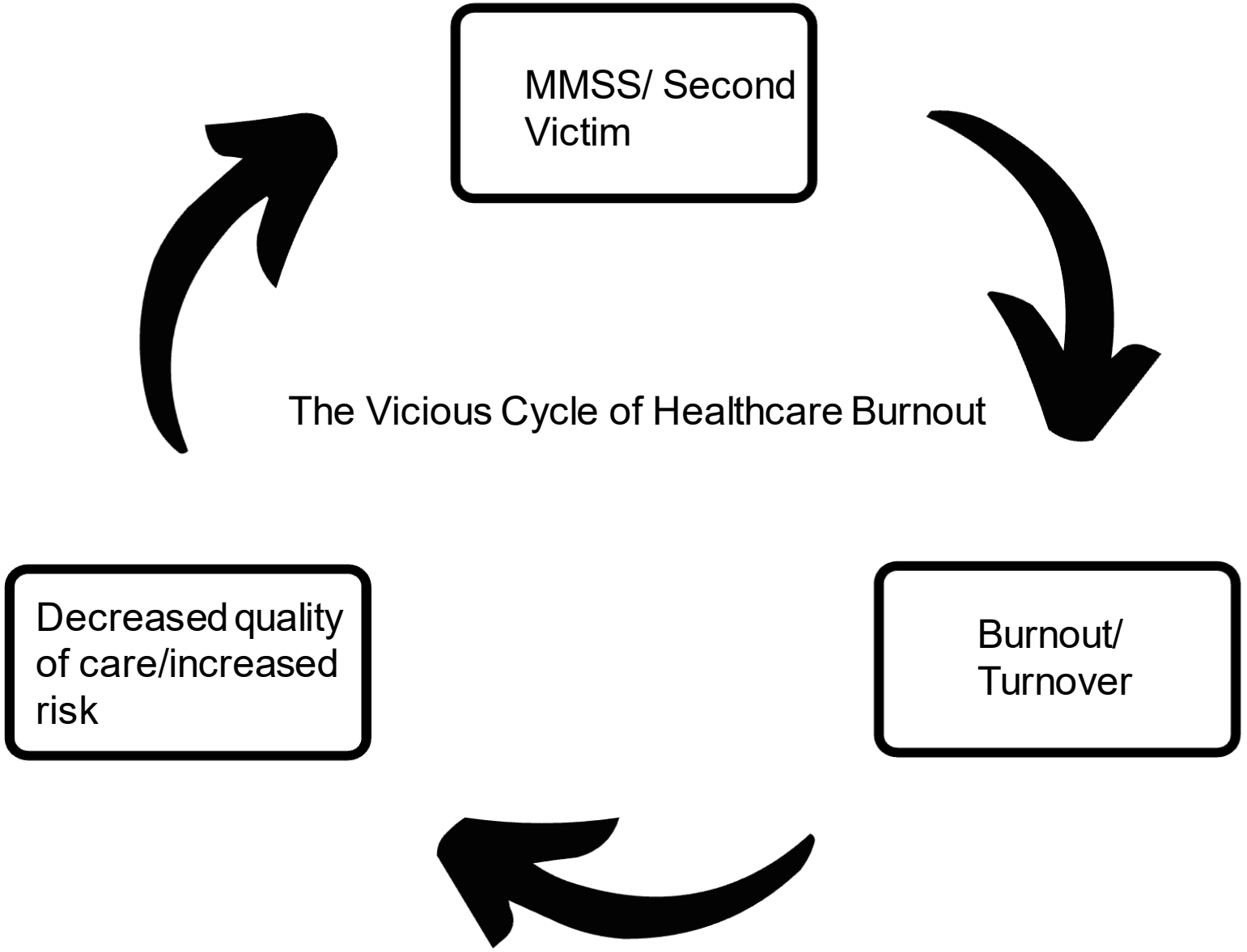
- Not unique to physicians
- Heavily associated with Burnout
  - Associated with turnover, absenteeism, difficulty engaging

MMSS creates similar constellation of symptoms and includes feelings of helplessness loss of control.

- A 2020 study of suicide risk factors published in JAMA Surgery revealed that civil legal problems increase suicide risk by 61% in surgeons and 80% in non-surgeons.

Plaintiff Litigants also may exhibit signs of significant distress and PTSD related to medical malpractice lawsuits.

- Revisiting intensely stressful events
- Concerns over not "being believed"
- Length of time to resolution and uncertain future



The Vicious Cycle of Healthcare Burnout

Other legal malpractice models:

New Zealand Model

New Zealand created a no-fault system for compensation for adverse medical events in that was codified in 2005 to include all injuries caused by treatment, replaced prior reporting duties with a new duty to report "risk of harm to the public" to "the authorities responsible for patient safety".

Allowed doctors to participate and actually assist patients in accessing compensation for adverse events.

No decrease in quality of care was observed after 10 years of the no-fault system.

provides more equitable access to compensation more efficiently than a malpractice system.

Katharine A. Wallis, No-Fault, No Difference: No-Fault Compensation for Medical Injury and Healthcare Ethics and Practice, 67 Br. J. Gen. Pract. 38 (2017).

Other legal malpractice models:

Nordic Model

Also a “no fault” system in that compensation amounts are set and fault is uncoupled from claim or compensation

Obligatory Reporting of Adverse Events

Underlying tenet is that *Personal injury should always be compensated*, individual costs are born by collective agencies with mandatory insurance for high-risk activities, rather than purely by taxpayer dollars.

Used also in traffic injuries, pharmaceutical injuries, and work-related injuries.

Health Care quality and metrics are consistently some of the highest in the world, with life expectancies 2-3 years higher than the United States.

Vibe Ulfbeck, Mette Hartlev & Mårten Schultz, **Malpractice in Scandinavia**, 87 *Chi.-Kent L. Rev.* 111 (2011).

Communication and Resolution Programs

Can exist when adverse events are discovered, practitioners and hospitals work alongside patients to create opportunities for both participation and feedback in solutions.

Recognizes the importance of apology and transparency in the process of addressing harm.

Addresses the importance of honest, timely communication

Preserves the patient-practitioner relationship

Provides resources at the organizational level for practitioner support to maintain a healthy workforce

Does not necessarily foreclose on the tort of medical malpractice, but rather offers an alternative for patients who may be better served by other means of resolution

A Few Words about Apology:

4 main elements

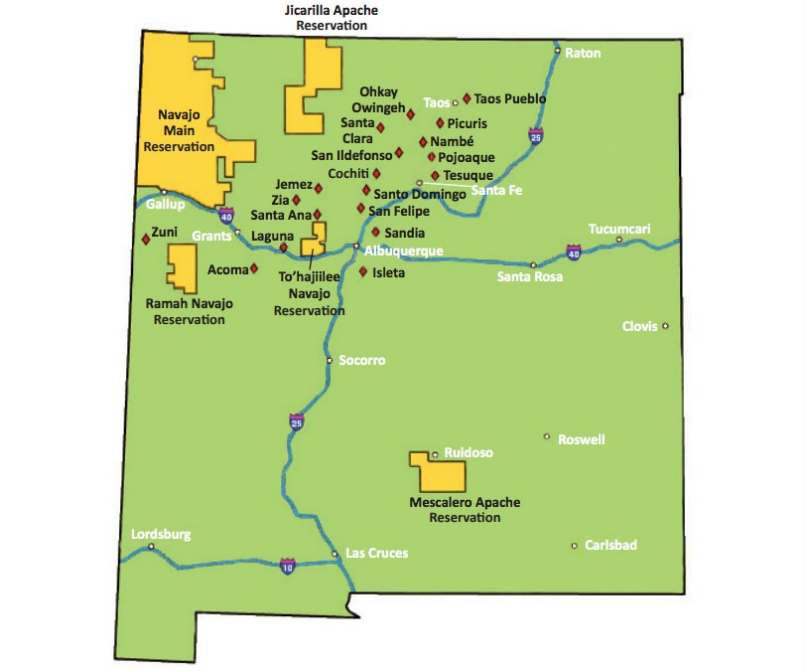
- Recognizing the wrongdoing
- Providing a clear explanation
- Expressing humility, sincerity, or regret*
- Proposing compensation or amends

What happens when we Apologize?

Recipients of effective apologies often show:

- A reduction in anger.
- More positive Perceptions
- Development of Empathy
- More Likely to refrain from retaliatory behavior
- **Effective apologies are ongoing, and contain an element for taking responsibility for wrongdoing.**

Demographics in New Mexico



35% speak a language other than English in the home

10.5% Native Americans (19 Pueblos, 3 Apache tribes, and the Navajo Nation)

Individualist vs Collective cultural paradigms within the State itself

Demographics of physicians are vastly different:

- 77% non-Hispanic white
- 1.7% Native American

Apology may be an important sign of offering community rather than always an admission of fault in collectivist cultures. Practitioners are often reticent to give anything resembling an sincere apology for fear of it being used out of context.

Would an Apology Law Aid in Providing Meaningful Dialogue?

It Depends

Concerns Over Apology Legislation:

Full Apology vs Partial Apology Laws

"For an apology to be sincere, after all, it must include both the transgressor's acknowledgment of wrongdoing and an expression of remorse. Without an admission of fault or other recognition of responsibility for error, an apology is incomplete – it's more like a politician's acknowledgment that 'mistakes were made"

-- Lisa Kearns

Apology laws work best when coupled with a larger disclosure reporting system.

What would make Apology Laws more effective?

The apology laws need to be “full” apology laws:

CO Rev Stat §13-25-135:

In any civil action brought by an alleged victim of an unanticipated outcome of medical care, or in any arbitration proceeding related to such civil action, any and all statements, affirmations, gestures, or conduct expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence which are made by a health-care provider or an employee of a health-care provider to the alleged victim, a relative of the alleged victim, or a representative of the alleged victim and which relate to the discomfort, pain, suffering, injury, or death of the alleged victim as the result of the unanticipated outcome of medical care shall be inadmissible as evidence of an admission of liability or as evidence of an admission against interest.

)

Apology laws appear to be most effective when coupled with Disclosure Programs (DA&O Programs)

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CANDOR Program

"**C**ommunication **And** **O**ptimal **R**esolution" Program"

Specifically Endorsed by CMS

Endorsed by Agency for Health Care Research and Quality

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Public Disclosure of Hospital Errors, CANDOR System Get Giant Boost From Medicare/Medicaid

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New rule taking effect Oct. 1 requires hospital transparency on patient safety and medical errors, encourages use of CANDOR

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RELEASE SUMMARY

CANDOR programs for hospitals to promote patient safety and transparent disclosure of medical errors win important backing from U.S. CMS in new rule.

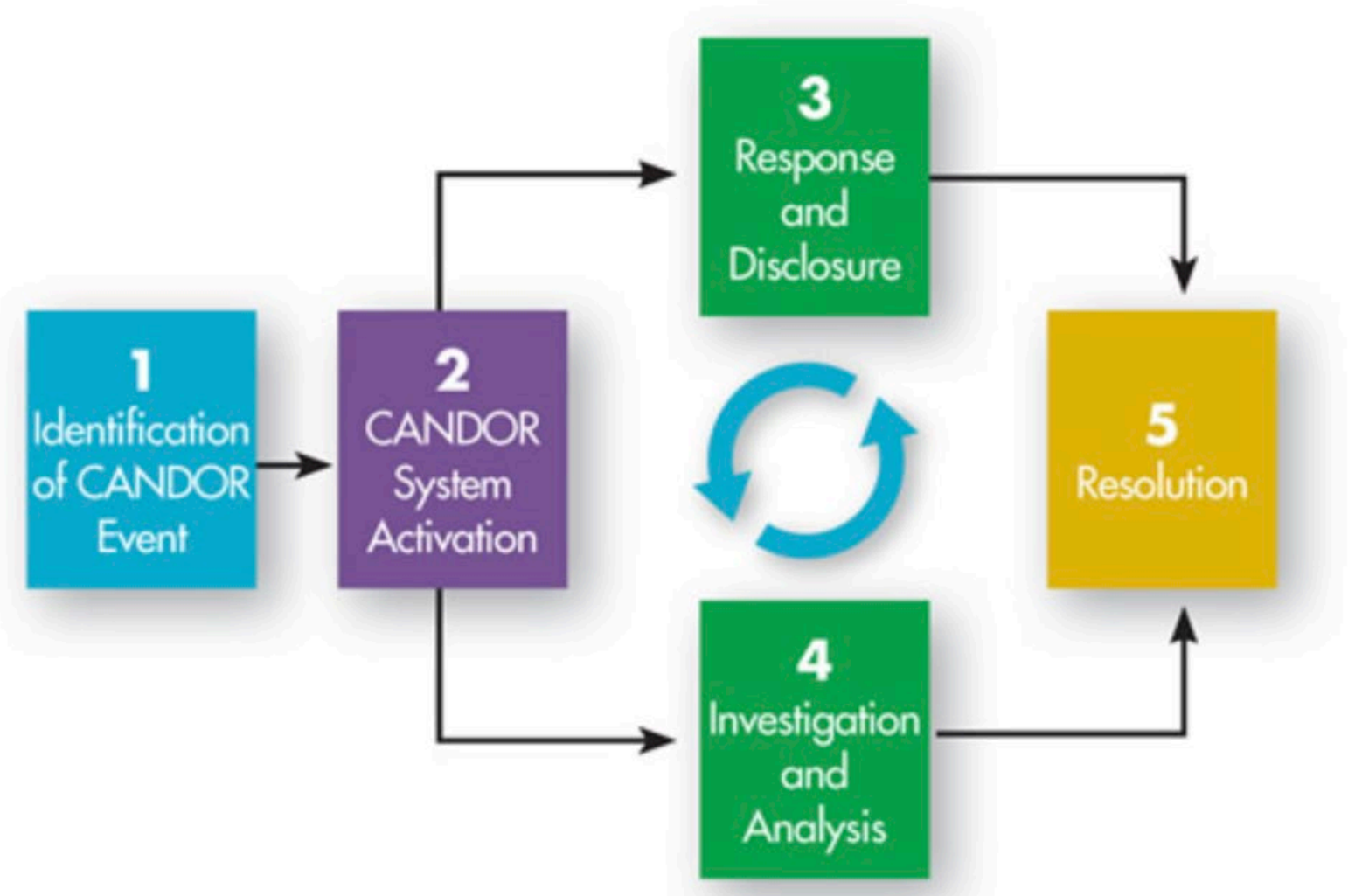
RELEASE VERSIONS

English

AHRQ

Agency for Healthcare Research and Quality

Figure 1: CANDOR Process



CANDOR Impact Case Studies:

- **CommonSpirit Health** Expands CANDOR Toolkit Across Entire Health System. Content last reviewed October 2021. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/news/newsroom/case-studies/202104.html

- CANDOR Promotes Safety Reporting, Employee Support at **Christiana Care Health System**. Content last reviewed April 2018. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/news/newsroom/case-studies/201717.html

- Major Insurance Company Offers **Discount to Customers Adopting AHRQ-Styled Product**. Content last reviewed November 2017. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/news/newsroom/case-studies/201713.html

- CANDOR Helped Significantly Reduce Patient Safety Events, Malpractice Claims at **MedStar Health**. Content last reviewed September 2017. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/news/newsroom/case-studies/201712.html

- **Dignity Health** Expands Use of AHRQ's CANDOR Toolkit. Content last reviewed February 2017. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/news/newsroom/case-studies/201620.html

Example of CANDOR program legislation: Colorado (2019)

Summary of Process. Definition of Adverse Health Care Incident: Physical injury or death related to/arising from patient care. Mandatory versus Optional: Optional initiation of an "open discussion" into an "adverse health care incident" by a health care provider/health facility; patients may then choose to either engage/not engage in the offered open discussion. Suggested contents of open discussion also written in the language of "may" rather than "must".

Impact on Future Litigation: Communication and offers of compensation prepared as part of an open discussion are NOT an admission of liability, cannot be admitted as evidence in a future proceeding, and are privileged and confidential. Furthermore, as a condition of receiving offered compensation, a patient may be required by a health care provider/ health facility to sign a release of liability preventing them from bringing a future claim or cause of action regarding the adverse medical event.

What we know:

Generally, Patients want answers, and they want apologies, and they want reparations.

Generally, Physicians want to talk to patients

Malpractice Lawsuits provide and maintain important avenues for justice in many situations

Other situations may be better served by programs that provide meaningful, holistic, and more timely resolution

The use of Communication and Resolution programs does not bar a patient from suit unless compensation is accepted after investigation of the events.

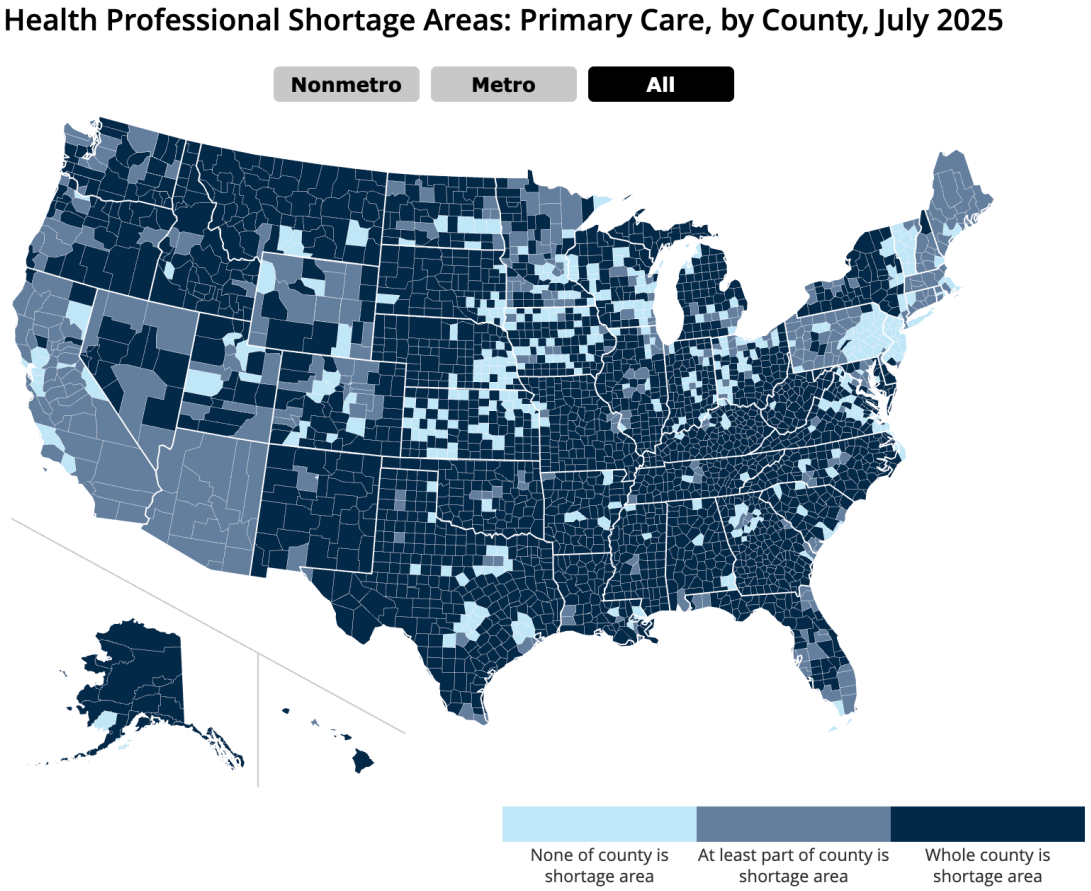
What Else We Know…

Every State in the Union is Experiencing a Health Care Shortage to Some Degree

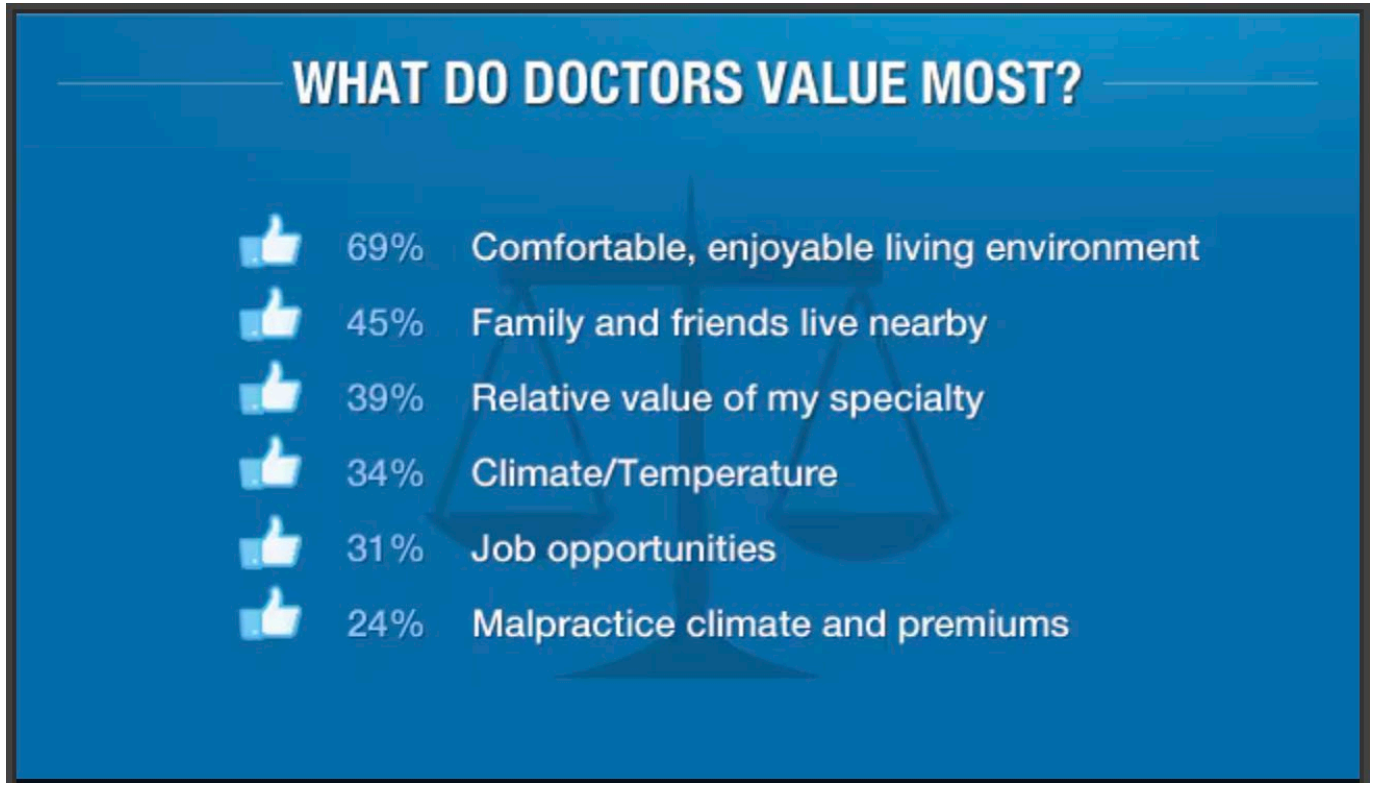
Practitioners in virtually every aspect of medical care have choices in where to settle.

There are multiple factors present in any person's choice of community in which to live and work.

Some of those factors are fixed and some are variable.



In choosing a place to practice, what matters?



What matters most to Patients in choosing a doctor?

Meron Hirpa, Tinsay Woreta, Hilena Addis & Sosena Kebede, *What Matters to Patients? A Timely Question for Value-Based Care*, 15 PLOS One *e0227845* (2020).

Patient-Physician Relationship N = 226	**Percent Respondents**
Humanistic qualities[1]	33%
Fund of knowledge	23%
Explaining things fully and in the way I understand	23%
Involving me in decision-making	8%
Being on time	7%
Spending adequate time with me	6%
Personal Responsibility N = 226	**Percent Respondents**
Exercise, diet and lead a healthy lifestyle	47%
Shared decision making (SDM)[2]	35%
Follow medical recommendations given	18%
Tests and Procedures N = 226	**Percent Respondents**
Shared decision making (SDM)	50%
I want all the tests that could be helpful to understand my condition better	43%
I only want the absolute critical tests to be performed	7%
Medications N = 173*	**Percent Respondents**
Shared decision making (SDM)[3]	80%
I want the absolute minimum that I need to take for my condition	9%
I want to take anything that can possibly help my condition	9%
I want the freedom to try alternative medicine and herbal supplements	2%
Healthcare Cost N = 132**	**Percent Respondents**
I want to know what my health insurance covers	57%
I want to know exactly what I am being charged for	32%
I want to minimize my healthcare expenditure	11%

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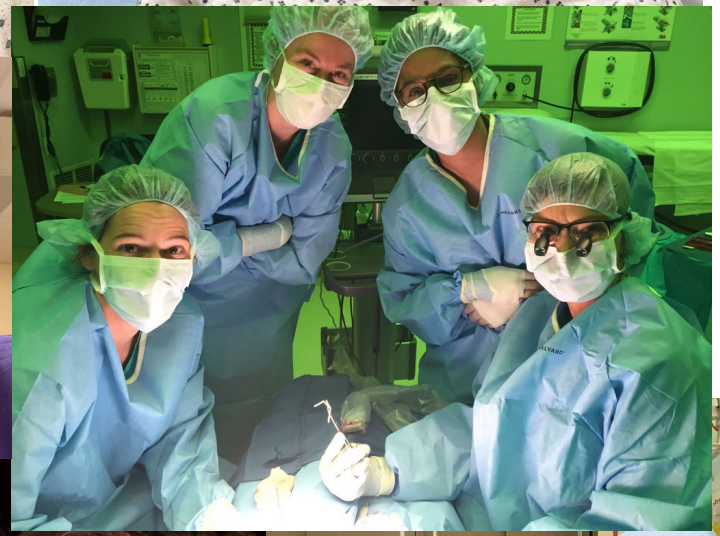
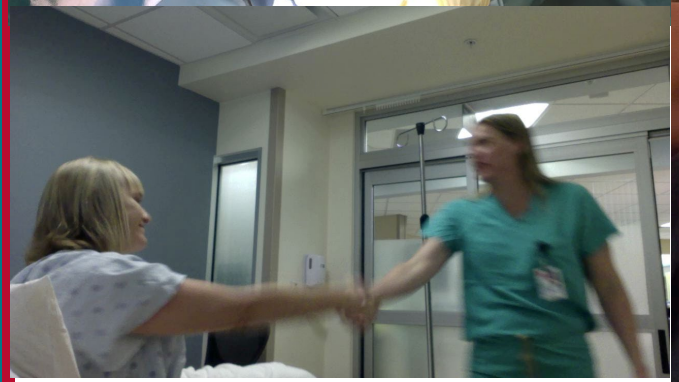
What do we *all* want:

I know this much is true.





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Thank you!

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