CARe Processes and the Pilot Experience

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Massachusetts Alliance for Communication and Resolution following Medical Injury

Evan Benjamin, M.D., M.P.H., and Ken Sands, M.D., M.P.H.

Traditional approach to adverse events

1. Pretend they never happened, or if obvious to the patient, give as little detail as possible to the patient and family.
2. “Deny and Defend,” anything that is already known, and hope patients never show up in court.
3. If there was a true error, do not talk to anyone about it– particularly the patient.

Why? Because of the **fear** of lawsuits and disciplinary actions.

Why do patients sue?

- "Studies show that the most important factor in people's decisions to file lawsuits is not negligence, but **ineffective communication** between patients and providers."

- "Malpractice suits often result when an unexpected adverse outcome is met with a **lack of empathy** from physicians and a **perceived or actual withholding of essential information**."

Clinton & Obama, NEJM 2006
Vincent C, Lancet 1993

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What is Communication, Apology, and Resolution (CARe)?

- **Communicate** clearly and empathetically with patients and families when unanticipated adverse outcomes occur.
- **Investigate and explain** what happened.
- Implement systems to **avoid recurrences** of incidents and improve patient safety.
- Where appropriate, **apologize and offer** fair financial compensation without the patient having to file a lawsuit.

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Principles of CARe

- Compensate patients quickly and fairly when unreasonable medical care caused injury.
- If the care was reasonable or did not adversely affect the clinical outcome, support caregivers and the organization vigorously.
- Reduce patient injuries (and therefore claims) by learning through patients‘ experiences.

Boothman, et al; Frontiers of Health Service Management 28:3; study at the University of Michigan Health System

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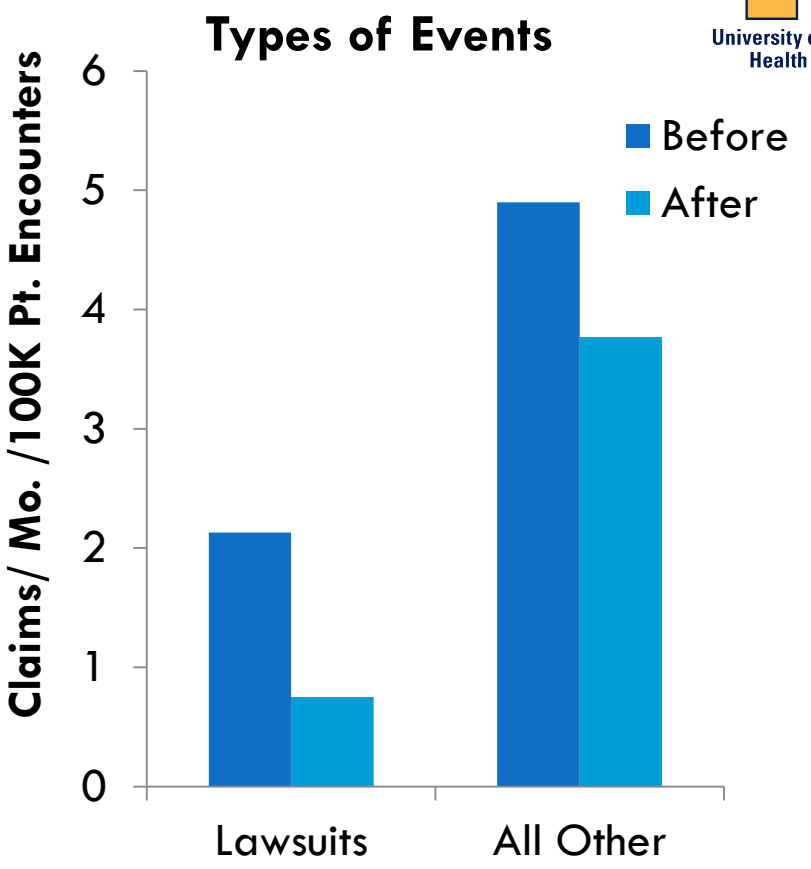
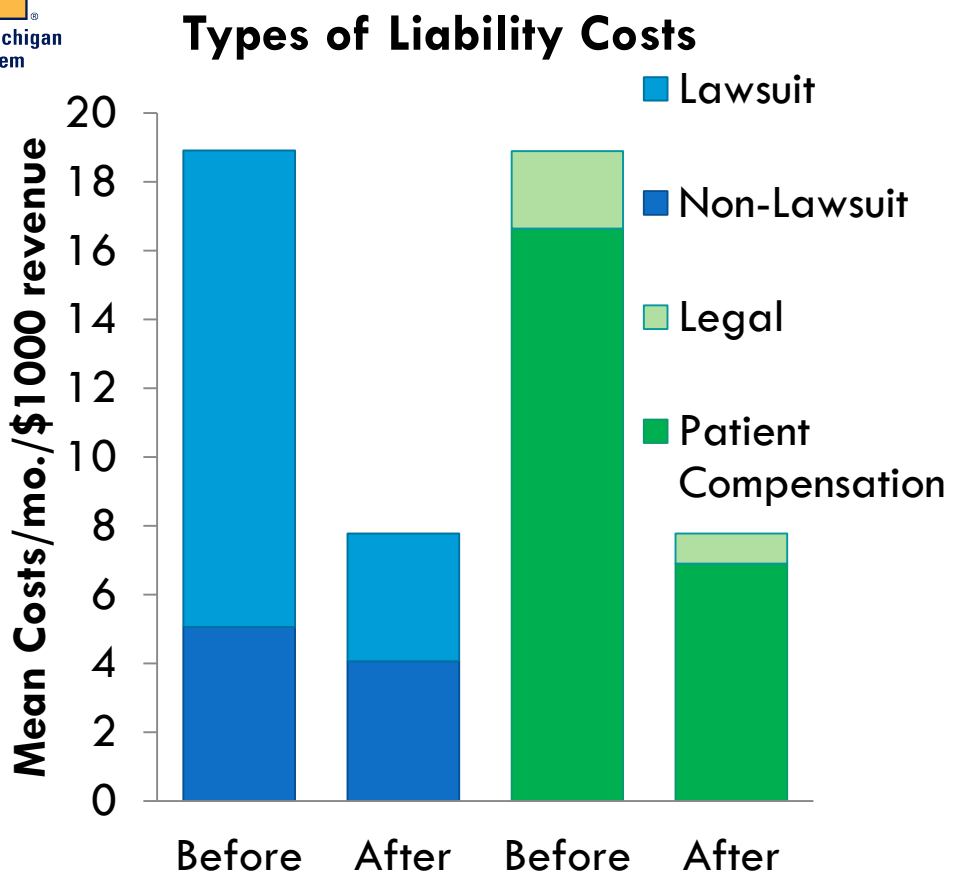
Does CARe work?

- University of Michigan Health System
- Stanford Hospitals and Clinics
- AHRQ Grant Awardees
  - Washington
  - Illinois
  - Texas
  - New York
  - Massachusetts (Planning Grant & MACRMI)
- HSPH Study Massachusetts (in progress)
  - Liability effects and Implementation

University of Michigan Health System





Kachalia et al, Ann Intern Med 2010

Stanford - PEARL Program

Metric	Desired Result	Observed Result	Comment
Reporting Pattern	Faster	Unchanged	Average incident to report lag is one year
Frequency	Lower	Lower	Annual reported claims dropped from 23 to 15
Closing Pattern	Faster	Inconclusive	Small number of closed claims
Severity	Lower	Inconclusive	Some large post-PEARL closed claims
Overall Cost	Lower	Lower	**38% reduction over 5 years**

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A Real Pilot Site Case

- Mr. Negashe calls the hospital Patient Relations office to voice a complaint that his doctor never provided information about blood work drawn during a clinic visit, and that in the meantime he had to be admitted to the hospital.

- He went to the ED when he developed blurry vision, and was admitted to the ICU where he learned that he had diabetes. He is worried that his vision problems are permanent. He is now insulin dependent and thinks that may not have been the case if detected earlier. He works as a driver and has been unable to work for several weeks.

- He is calling to simply to voice his dissatisfaction and alert the hospital to the problem. He does not indicate an expectation.

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A Real Pilot Site Case

- Patient Relations reviews the case and learns that the patient had an elevated HgbA1C several months earlier, and follow-up was encouraged.

- When he did return he was seen by the physician, who drew a repeat test but did not follow-up with the patient. The patient called the clinic twice for results and these calls were forwarded to the physician but no return call was made. The clinic did not have a "closed loop" system to identify whether calls had been returned.

- The HgbA1c was markedly elevated on repeat test.

- Peer review confirmed that immediate follow-up was indicated in this situation, as the patient was at significant risk of becoming acutely ill.

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CARe in Action at the Pilot Sites

CARe Pilot Sites…

- Apply the CARe algorithms to each case that comes to Patient Safety/Risk Management
- Work with their insurers to attempt early resolution if case meets criteria.
- Educate staff in their facilities about the merits of CARe, and action steps.
- Convene with other pilot sites to discuss and work through challenges of applying the CARe approach.

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The Massachusetts Pilot Sites

Site	#Beds	Location	Teaching (Y/N)
Beth Israel Deaconess Medical Center	642	Inner City	Y
BID-Milton	88	Community	N
BID-Needham	58	Community	N
Baystate Medical Center	716	Inner City	Y
Baystate Franklin Medical Center	93	Community	N
Baystate Mary Lane Hospital	31	Community	N
*Atrius Health**	*n/a*	*Ambulatory*	*N*
*Sturdy Memorial**	*128*	*Community*	*N*

**Not yet in implementation phase*

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CARe Algorithms

There are two CARe Algorithms:

- A “filter” to determine whether an adverse event case should go through the full CARe process
  - **“Defining a CARe Case”**
- The full CARe process that will be followed if a case is selected by the filter
  - **“CARe Protocol”**

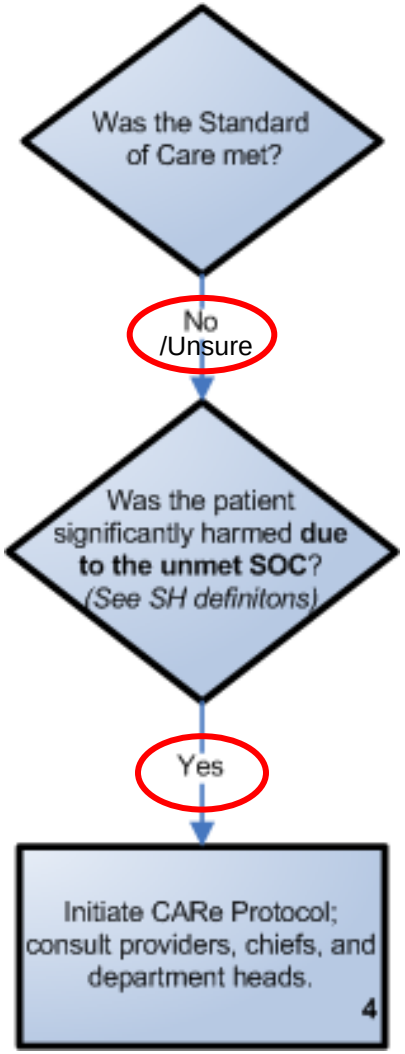
“Defining a CARe Case” –the Filter

If an internal investigation team determines that…

- The standard of care was **not** met, AND
- The unmet standard of care **caused** significant harm

…the case moves to the full **CARe Insurer Case Protocol***

**If this criteria is not met, we still communicate with the patient about the findings and may offer service recovery.*



CARe Insurer Case Protocol

- Case is referred to Insurer as CARe case
- Case reviewed by insurer and external experts
- Insurer makes final decision if case will be resolved with CARe with input from facility
- Insurer makes provider/system allocation of fault
- CARe cases will proceed with a meeting with insurer, patient, patient's attorney, and providers (if applicable) to formally apologize, discuss the case, and offer compensation

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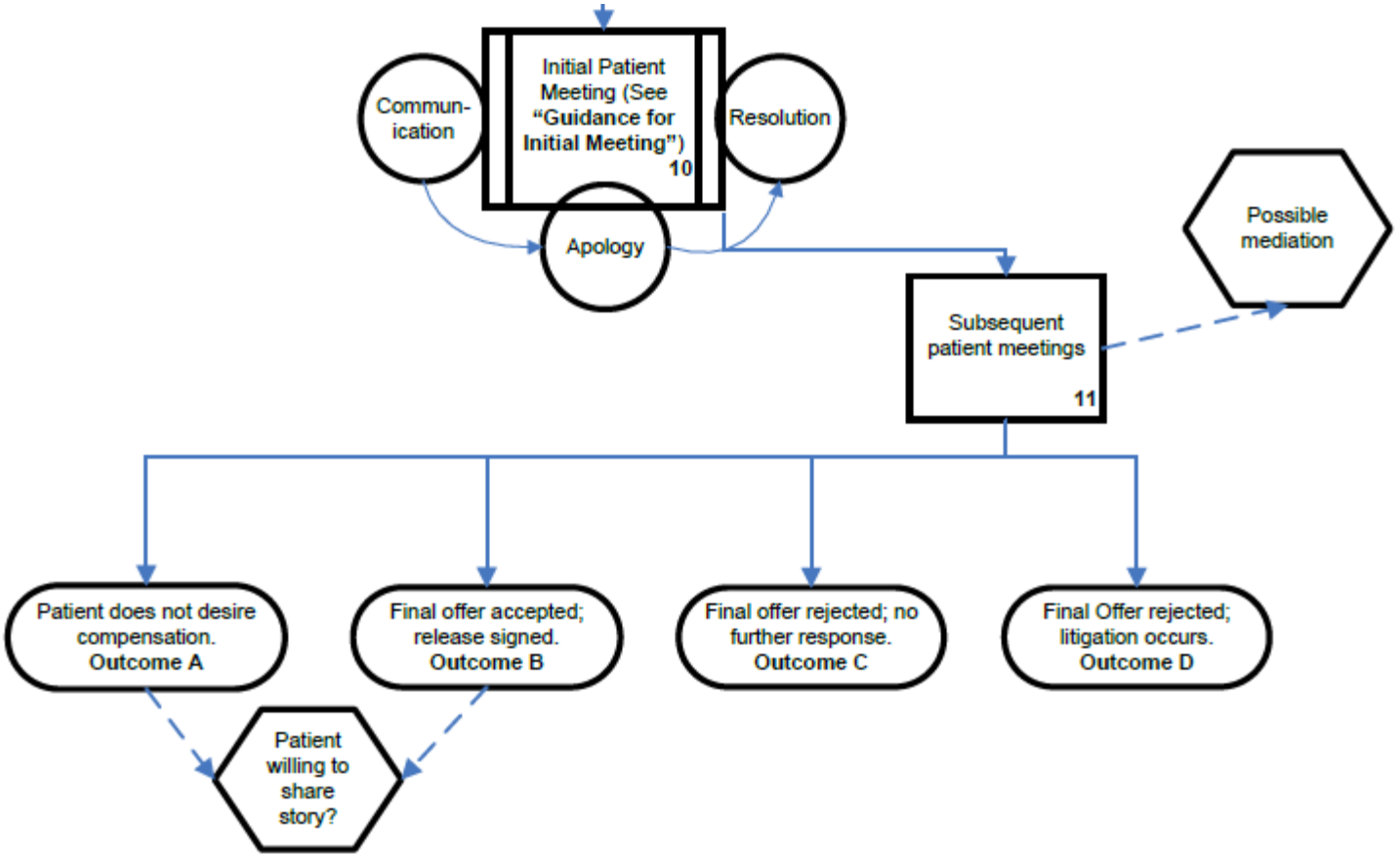
CARe Insurer Case Protocol - Potential Outcomes



Communication, Apology and Resolution Timeline

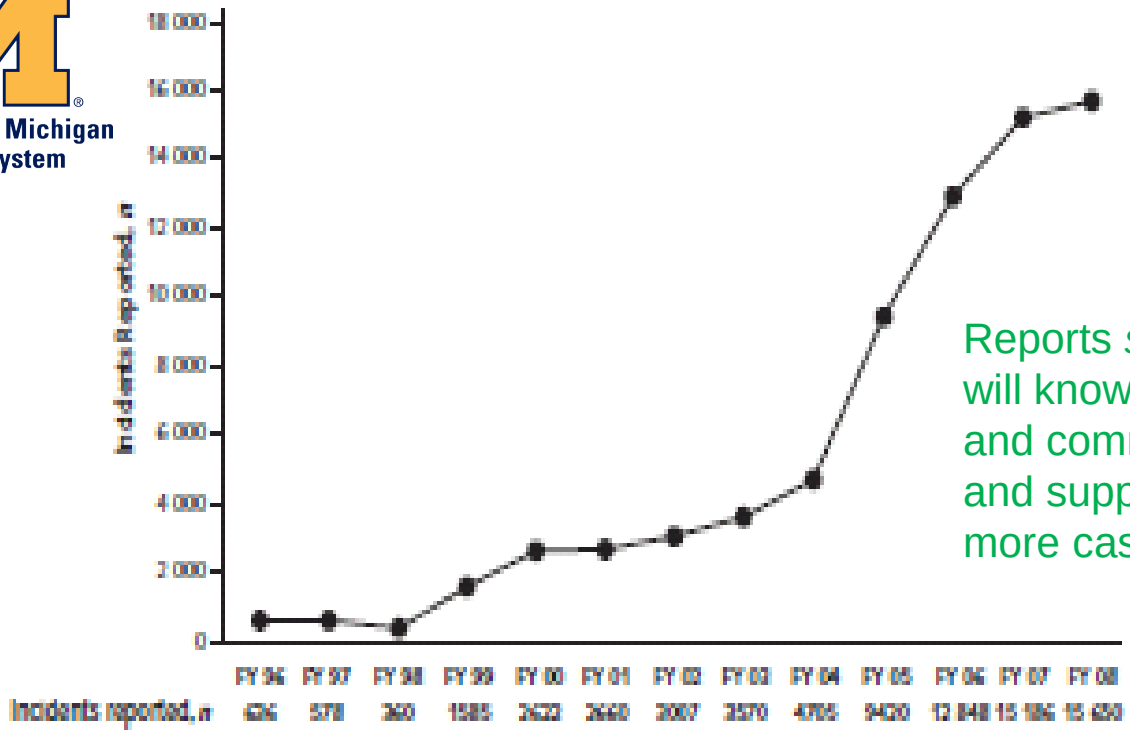
Within…

24-48 hours	2-4 weeks	1-3 months	2-5 months	3-6+ months
Patient Safety Alerted Support services for providers and patients launched Discussion with patient regarding error and known facts **(1,2)**	Internal investigation takes place Patient Safety and Patient Relations maintain contact with providers and patients respectively **(3)**	Determination of CARe criteria fit Providers, Chiefs, and Directors consulted Team huddle; designee conducts Initial CARe Communication with the patient; connects them to Insurer for record release **(4,5)**	Insurer reviews case and develops offer parameters Provider/System Allocation by insurer Insurer invites patient to CARe Initial Meeting; recommends that counsel also attend Lessons learned implemented at site **(6,7,8,9)**	Initial meeting with insurers, providers, patient safety staff, patient, counsel, and other parties. Additional meetings occur as necessary. Final offer to patient made and accepted or rejected. **(10,11)**

For Clinicians:
Steps following an Adverse Event

- **Step 1:** Report the event and get help

University of Michigan Health System



Reports *should* increase; we will know about more events, and communication coaching and support can be offered in more cases.

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Steps following an Adverse Event (cont.)

- **Step 2:** Communicate with the patient/family about the event; be empathetic and use statements of regret ("I am so sorry this happened to you…"); discuss facts known at this time and do not speculate or blame others.

- A note on Apology:
  - 1. Statements of Regret – **Always!**
  - 2. Apology of Fault – **Once facts are known**

(if applicable)

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Steps following an Adverse Event (cont.)

- **Step 3:** Document the communication with the patient/family in the record; facts, who was present, and results of conversation.

- **Step 4:** Check back in with the patient/family and discuss with them the findings and any systemic improvements to be made once all facts are known and root causes have been determined.

CARe Challenges

- Not everyone will engage
- Some may not agree on “value”
- Doing more in-depth investigations early on (resource intense)
- Need mechanism for rapid internal or external case review (ideally with peer review protection)
- Providers are still worried about reporting (BORM, NPDB)

A Real Pilot Site Case

- Mr. Negashe received an explanation, an apology and compensation
  - Compensation based on expenses encountered, lost work, pain and suffering.
- Payment was determined and made by hospital's insurer on behalf of the hospital and physician
- With physician's endorsement, responsibility was apportioned 50/50
- Closed-loop system implemented at practice, and case was shared in multiple institutional forums to prevent recurrence

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Communication is Key

- CARe cases that meet the algorithm's criteria as suitable for compensation, like Mr. Negashe's, are the exception.

- Communicating about the adverse event with the patient, explaining what happened, being empathetic, and following up is really the essential work that allows relationship building and healing, rather than anger and distrust.

Clinician buy-in

- Front line clinicians need to understand that the patient's trust is maintained or destroyed in the first few minutes after an adverse event.
- Communicating with the patient about adverse events is never easy
  - Communication Coaching available 24/7 – but it has to be used to be effective!
- We use four simple steps for clinicians following an adverse event.

Lessons Learned at the Pilot Sites

Lessons learned

- CARe principles and processes must be reinforced daily as cases and action plans are reviewed.
- You might think you're "already doing it" but it's actually very different to really be in a CARe mindset on a daily basis.
- Education of front-line staff is essential.

What else helps CARe succeed?

- Leadership buy-in
- Baseline culture of safety
  - Root cause analysis and safety improvement
  - Integration of risk management and patient relations
- Staff
  - A program manager
  - Commitment from risk management/patient safety
- Support
  - Clinician Peer Support
  - Patient resources (Patient Relations, MITSS, etc.)

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