MACRMI: History, Progress Made, and New Resources

Alan Woodward, M.D. and Melinda Van Niel, M.B.A.

Forum Objectives

- Describe the essential elements of a successful CARe program, and the benefits of the CARe program for patients, clinicians, and hospital administrators, in comparison to a traditional liability model.

- Describe the challenges of everyday implementation of CARe, and ways to overcome those challenges.

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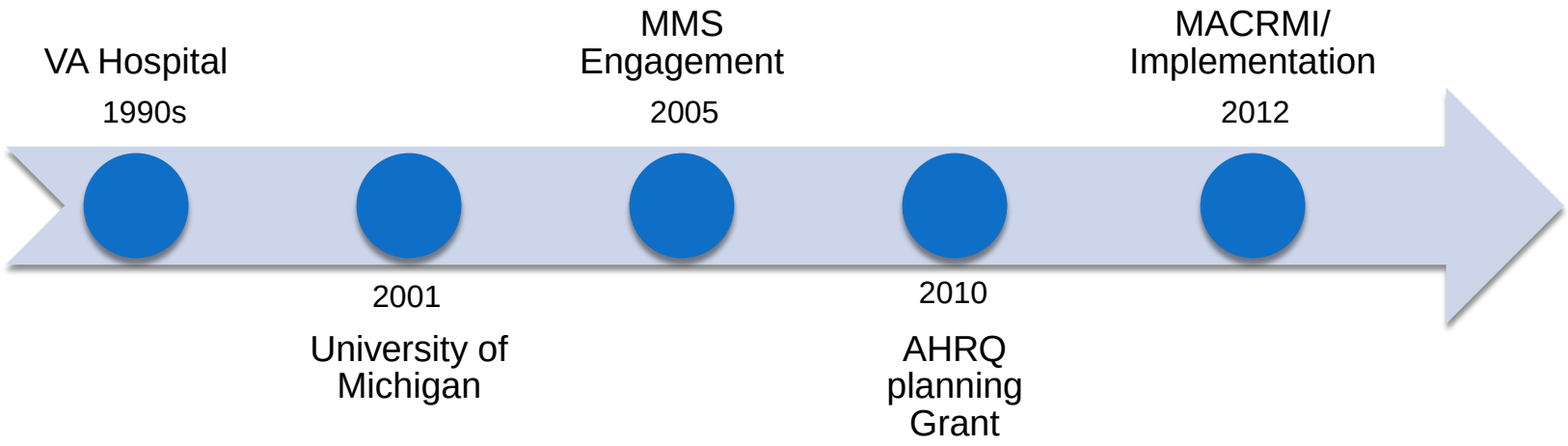
Why are we here today?

CARe Evolution through 2012



AHRQ Planning Grant - Massachusetts

- 1 Yr - 300K AHRQ Planning Grant - MMS - BIDMC
- Key informant interview study of 27 knowledgeable individuals from all leading stakeholder constituencies in Massachusetts
- Twelve significant barriers were identified along with multiple strategies to overcome each one
- Strategies for each barrier were then evaluated and prioritized to develop our Roadmap
- **CARe was the best of all options for malpractice reform**

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Barriers to CARe

Barrier*	# of Respondents
Charitable immunity law	22
Physician discomfort with disclosure & apology	21
Attorneys' interest in maintaining the status quo	20
Coordination across insurers	20
NPDB or state reporting requirements	19
Concern about increased liability risk	16
Forces of inertia	13
Fairness to patients	12
May not work in other settings	11
Insufficient evidence	8
Supporting legislation	8
Accountability for the process	5

** Other barriers, not listed, were mentioned by <4 respondents*

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Roadmap: Overcoming Barriers

- Enabling Legislation - to create a supportive environment for broad adoption
- Education - programs for all involved parties
- Leadership - from all key constituencies
- Best Practices - support consistency
- Collaborative Working Groups - key issues
- Data Collection and Dissemination

MMS/MBA/ MATA

Alliance

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Liability Reform Provisions of Ch. 224

- 6 Month Pre-Litigation Resolution Period*
- Sharing all Pertinent Medical Records*
- Apology Protection - unless contradictory*
- Full Disclosure - significant complication*
- Pre-judgment Interest Reduction - T+2
- Charitable Immunity Cap Increase - 100k

*** MMS, MATA & MBA Consensus**

Signed into law as part of Chapter 224 - Payment Reform Legislation; Effective November 5, 2012

BORM Reporting Language revised July 2013

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MITSS
Medically Induced Trauma Support Services

CRICO RMF
Protecting providers. Promoting safety.

COVERYS

MBA

Massachusetts Medical Society
Every physician matters, each patient counts.

Beth Israel Deaconess Medical Center

Baystate Health

MHA Massachusetts Hospital Association
The leading voice for hospitals.

Board of Registration in Medicine

Massachusetts Coalition for the Prevention of Medical Errors

STURDY MEMORIAL HOSPITAL

Atrius Health

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"**CARe**" (Communication, Apology, and Resolution) is MACRMI's preferred way to reference the process.

Accomplishments since 2013 Forum

- Recruited Two New Pilots
  - Sturdy Memorial Hospital
  - Atrius Health
- Continued to collect data for CARe outcomes/implementation study
- Created Provider Study to roll out in July
- Began using Social Media Marketing
- Began Implementing Provider Peer Support
- Developed multiple new resources; more in process
- Worked with Harvard Negotiation and Mediation Clinical Program to identify ideal form of representation for patients in the CARe process
- Continued working to clarify NPDB reporting criteria

Resources developed since April 2013

- Potential CARe Site Readiness Checklist
- Best Practices for Interfacing with Patients in the CARe Process
- DPH Letter Templates
- Implementation guide for new Pilot Sites

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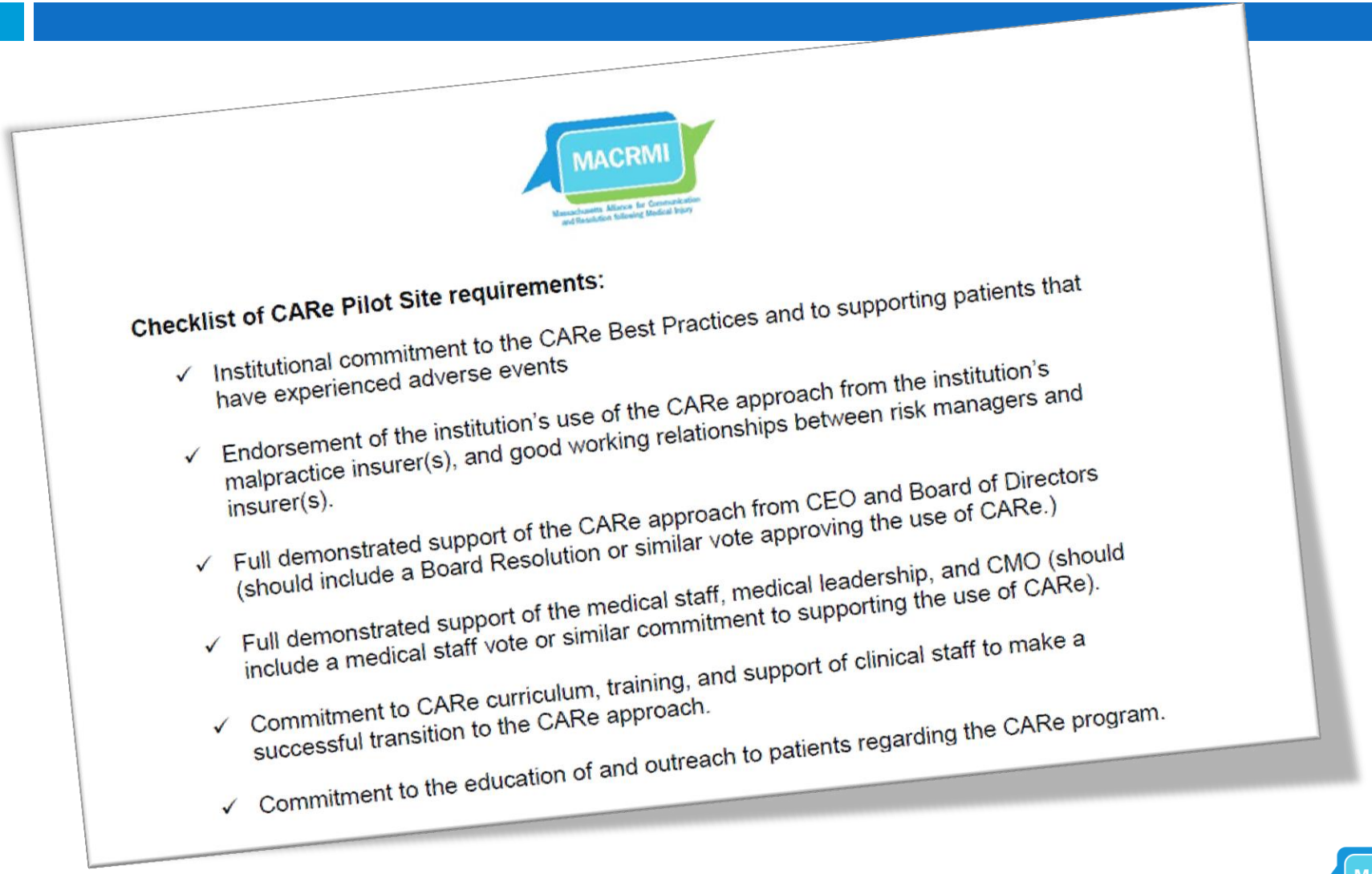
Potential CARe Pilot Site Checklist



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Checklist of CARe Pilot Site requirements:

- ✓ Institutional commitment to the CARe Best Practices and to supporting patients that have experienced adverse events
- ✓ Endorsement of the institution's use of the CARe approach from the institution's malpractice insurer(s), and good working relationships between risk managers and insurer(s).
- ✓ Full demonstrated support of the CARe approach from CEO and Board of Directors (should include a Board Resolution or similar vote approving the use of CARe.)
- ✓ Full demonstrated support of the medical staff, medical leadership, and CMO (should include a medical staff vote or similar commitment to supporting the use of CARe).
- ✓ Commitment to CARe curriculum, training, and support of clinical staff to make a successful transition to the CARe approach.
- ✓ Commitment to the education of and outreach to patients regarding the CARe program.

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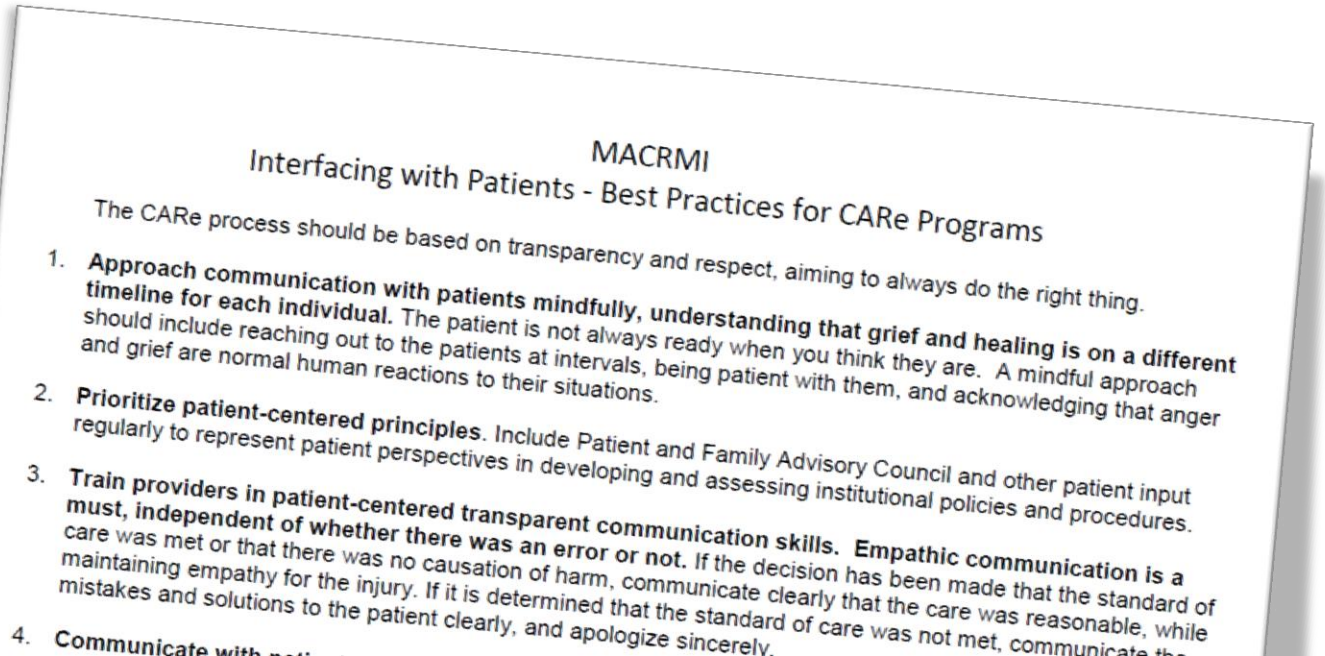
Best Practices for Interfacing with Patients in the CARe Process

- How can I best communicate with patients about an adverse event over time?
- What kind of reactions should I expect from patients?
- How do I prioritize Patient-Centered Principles in my organization?



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Interfacing with Patients - Best Practices for CARe Programs

The CARe process should be based on transparency and respect, aiming to always do the right thing.

1. **Approach communication with patients mindfully, understanding that grief and healing is on a different timeline for each individual.** The patient is not always ready when you think they are. A mindful approach should include reaching out to the patients at intervals, being patient with them, and acknowledging that anger and grief are normal human reactions to their situations.
2. **Prioritize patient-centered principles**. Include Patient and Family Advisory Council and other patient input regularly to represent patient perspectives in developing and assessing institutional policies and procedures.
3. **Train providers in patient-centered transparent communication skills. Empathic communication is a must, independent of whether there was an error or not.** If the decision has been made that the standard of care was met or that there was no causation of harm, communicate clearly that the care was reasonable, while maintaining empathy for the injury. If it is determined that the standard of care was not met, communicate the mistakes and solutions to the patient clearly, and apologize sincerely.
4. **Communicate with pati**

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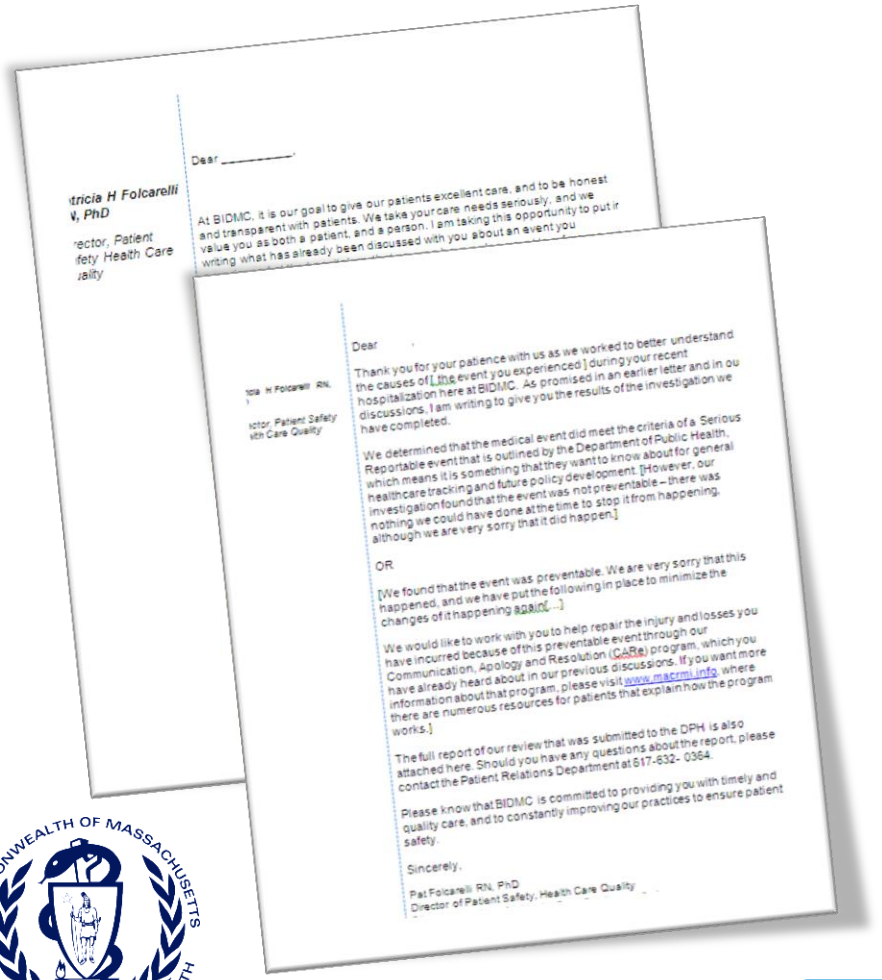
New DPH Letter Templates

- Existing templates for 7 and 30 day DPH letters can appear harsh to patients
- Pilot site PFAC reviewed
- Letters revamped to focus more on “culture of safety” and less about “requirements to inform.”



Dear _____,

At BIDMC, it is our goal to give our patients excellent care, and to be honest and transparent with patients. We take your care needs seriously, and we value you as both a patient, and a person. I am taking this opportunity to put in writing what has already been discussed with you about an event you

Dear

Thank you for your patience with us as we worked to better understand the causes of [the event you experienced] during your recent hospitalization here at BIDMC. As promised in an earlier letter and in our discussions, I am writing to give you the results of the investigation we have completed.

We determined that the medical event did meet the criteria of a Serious Reportable event that is outlined by the Department of Public Health, which means it is something that they want to know about for general healthcare tracking and future policy development. [However, our investigation found that the event was not preventable – there was nothing we could have done at the time to stop it from happening, although we are very sorry that it did happen.]

OR

[We found that the event was preventable. We are very sorry that this happened, and we have put the following in place to minimize the changes of it happening again[…]

We would like to work with you to help repair the injury and losses you have incurred because of this preventable event through our Communication, Apology and Resolution (CARe) program, which you have already heard about in our previous discussions. If you want more information about that program, please visit www.macrmi.info, where there are numerous resources for patients that explain how the program works.]

The full report of our review that was submitted to the DPH is also attached here. Should you have any questions about the report, please contact the Patient Relations Department at 617-632- 0364.

Please know that BIDMC is committed to providing you with timely and quality care, and to constantly improving our practices to ensure patient safety.

Sincerely,

Pat Folcarelli RN, PhD
Director of Patient Safety, Health Care Quality

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

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Implementation Guide for New Pilot Sites

- Designed for new pilot sites joining MACRMI, to be used with personal assistance from our implementation team
- Lays out timeline of important tasks, and links to relevant MACRMI resources for each step in the process

All Resources Available on our Website: **www.macrmi.info**

These resources available for download at our website!

HORIZON INTERACTIVE AWARDS BRONZE WINNER

MARCOM AWARDS

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HARVARD | SCHOOL OF PUBLIC HEALTH

CARe Interim Data Snapshot

Michelle Mello, JD, PhD
Lena Kuznetsov, MA

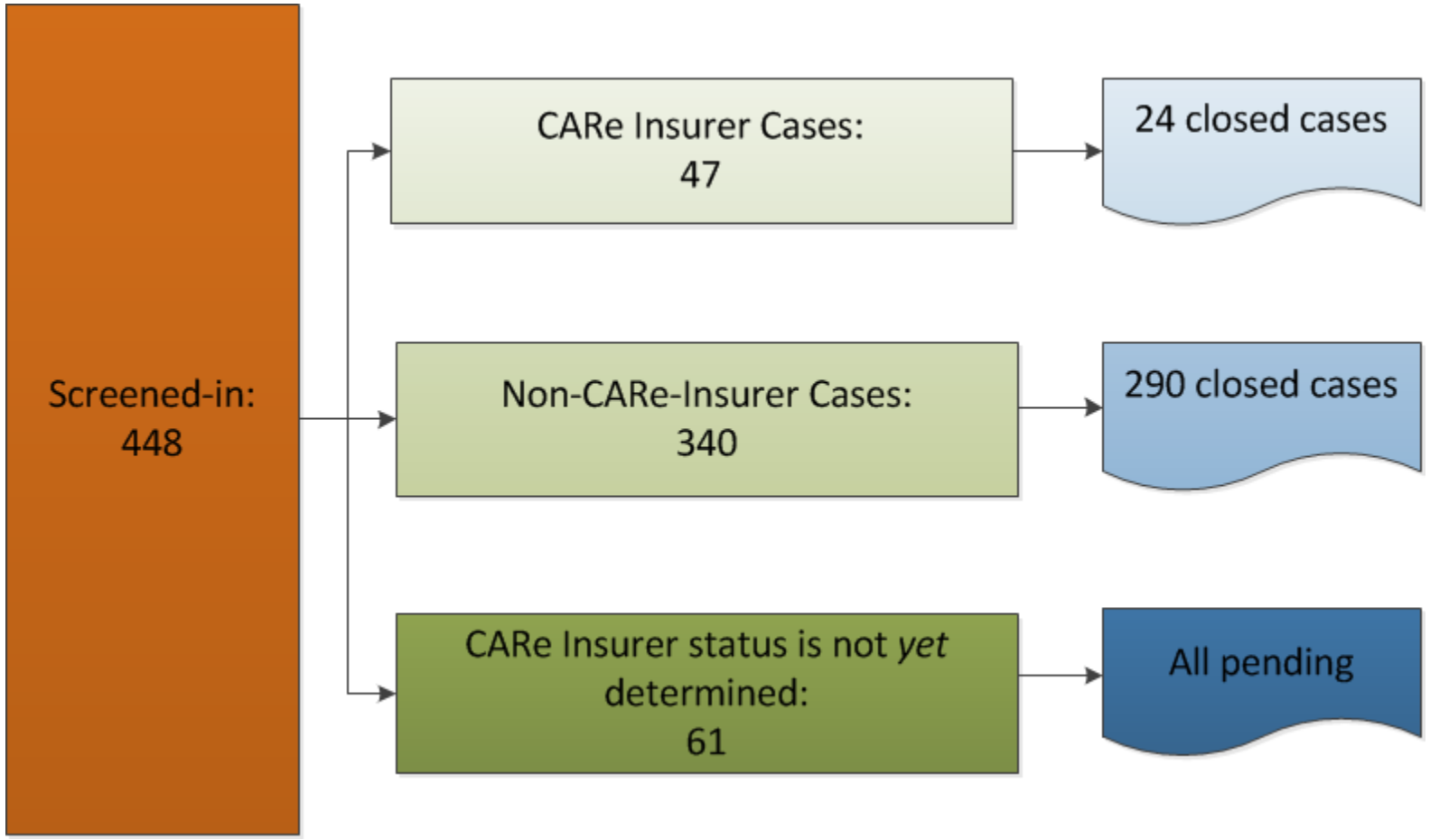
CARe Study Event Criteria

☐ Yes ☐ No	**The event involves harm that has the potential to be "Level E-Significant" or higher.**	**Qualifying Harm Scores:** ▪ Level E-Significant: Temporary harm requiring an intervention consisting of an invasive medical procedure (as an outpatient or inpatient) and/or 3 or more additional visits to a health care provider or center ▪ Level F: Temporary harm requiring initial or prolonged hospitalization (e.g., return to OR) ▪ Level G: Temporary harm requiring life-sustaining intervention (e.g., ICU care) ▪ Level H: Permanent harm (including severe permanent harm) ▪ Level I: Death
☐ Yes ☐ No	**The patient reported the event as involving harm that is "Level E-Significant" or higher.** Elicit information from the patient about what happened to confirm that the harm they're describing meets the definition for Level E-Significant harm or higher.	
☐ Yes ☐ No	**The event seems to be one that must be reported to BORM or DPH.** Include all DPH or BORM reportable events, except for unstageable pressure ulcers that did not represent new harm to the patient.	
☐ Yes ☐ No	**A provider requested the CARe program for this event.** If the specific "CARe" terminology is not used, confirm whether the provider feels the CARe process would be useful for the event.	
☐ Yes ☐ No	**The event was brought to the attention of DPS/RM by a pre-litigation notice.** Exclude an event if the hospital first learns about it through a lawsuit, with no pre-litigation notice.	

Case Volume

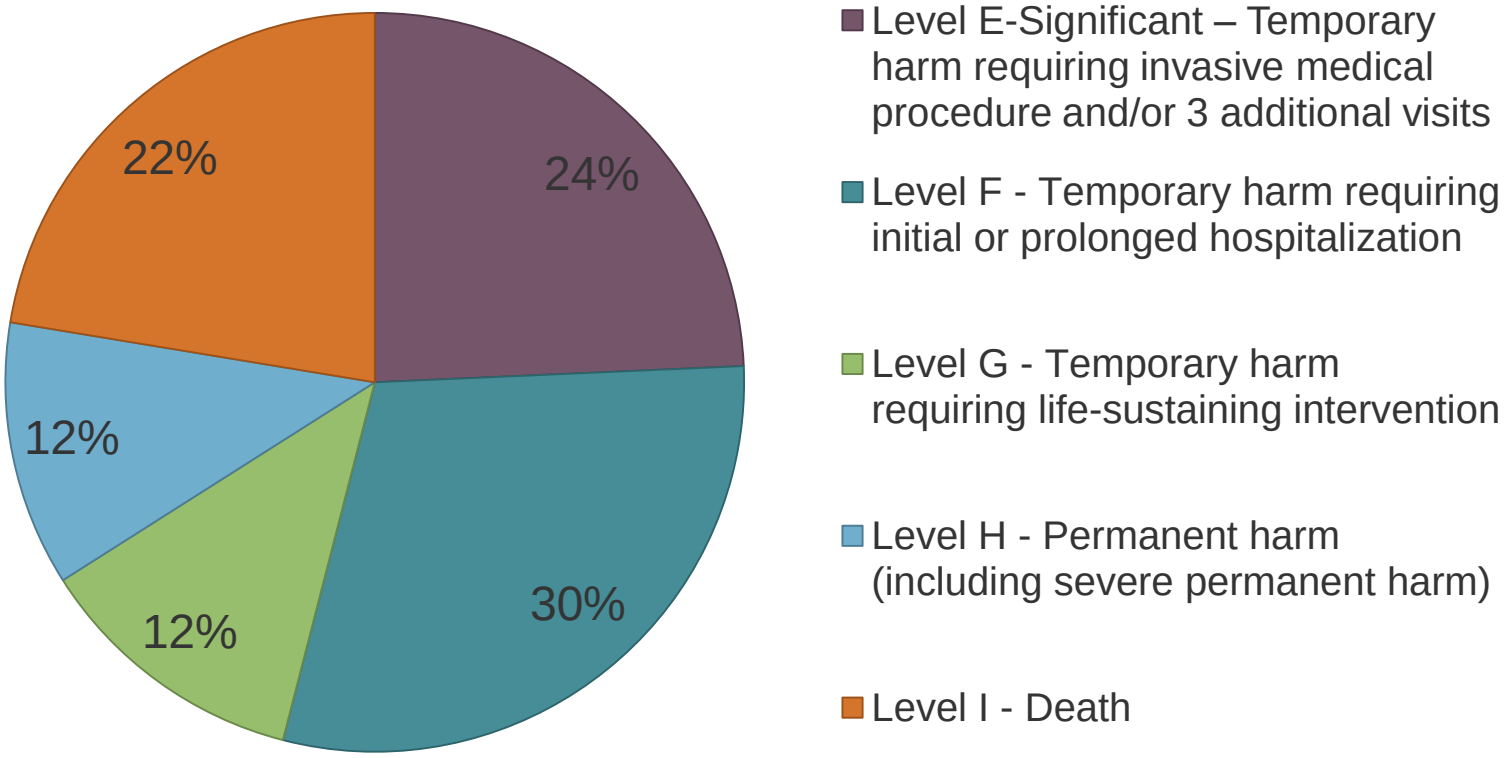
Hospital	Entering Cases Since	n	%
BIDMC	February 2013	199	44.4
BMC	March 2013	223	49.8
BML	May 2013	19	4.2
BF	August 2013	7	1.6

Progress of Cases



Injury Characteristics: Severity

N=259 cases with Level E+ harm or higher



Involved Providers

	Primary		Secondary	
	n	%	n	%
Physician	305	70.8	80	41.2
Nursing	80	18.6	59	30.4
Trainee	15	3.5	32	16.5
Other	31	7.2	23	11.9

Primary n=431 completed responses
Secondary n=194 completed responses

Who First Reported the Event

n=431 completed responses

	n	%
Internally reported	296	68.7
Patient reported	112	26.0
Attorney or insurer	23	5.3

Initial Disclosure Conversation

n=314 closed cases

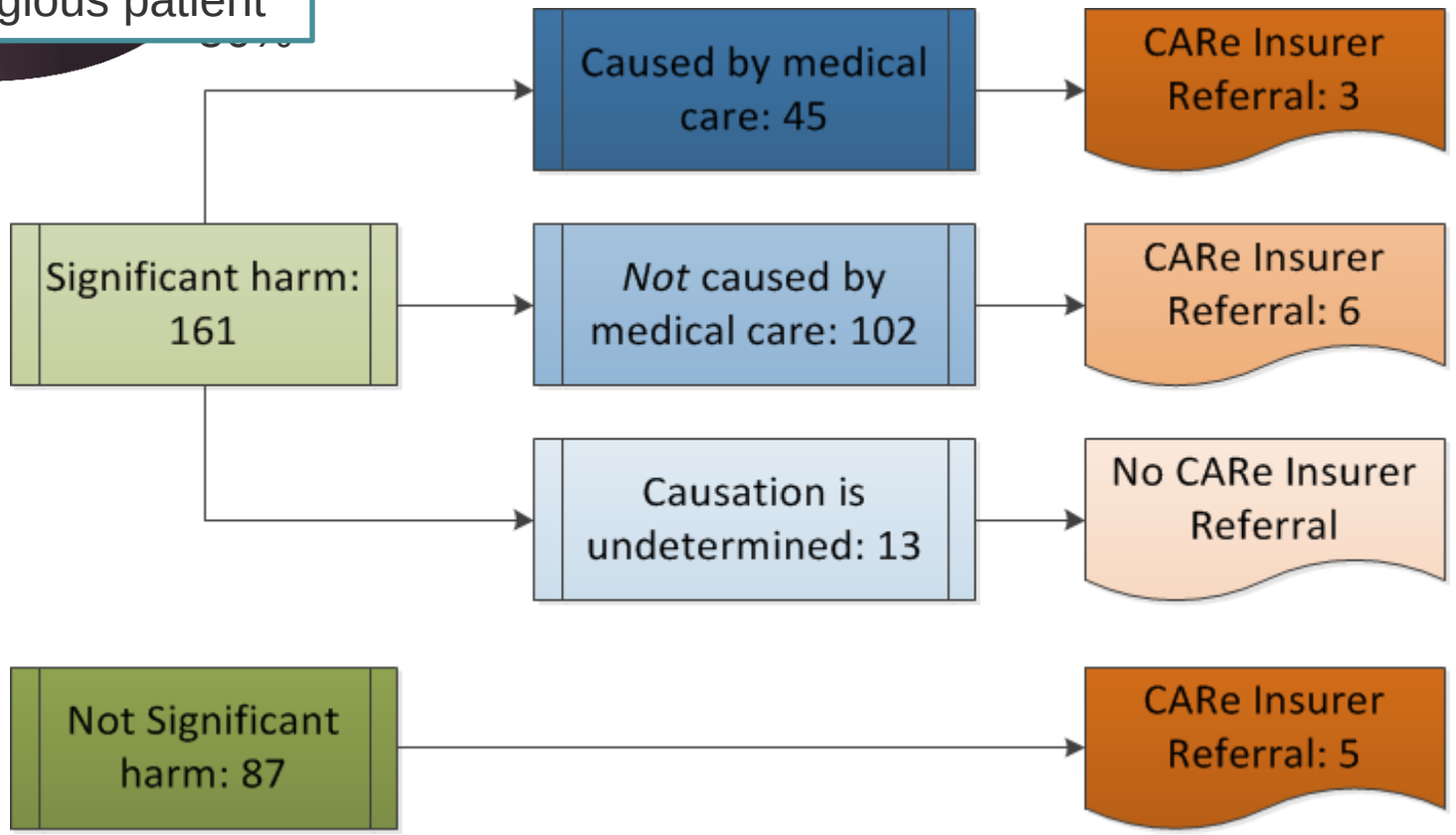
Did one or more disclosure conversations take place?	n	%
Yes	212	67.5
No	44	14.0
Unable to ascertain	58	18.5

Reasons for Insurer referral:

1. Pre-litigation notice
2. Uncertainty regarding SOC determination
3. Extremely angry and/or litigious patient

Hospital Determinations: SOC Met (n=250)

Not met 19%

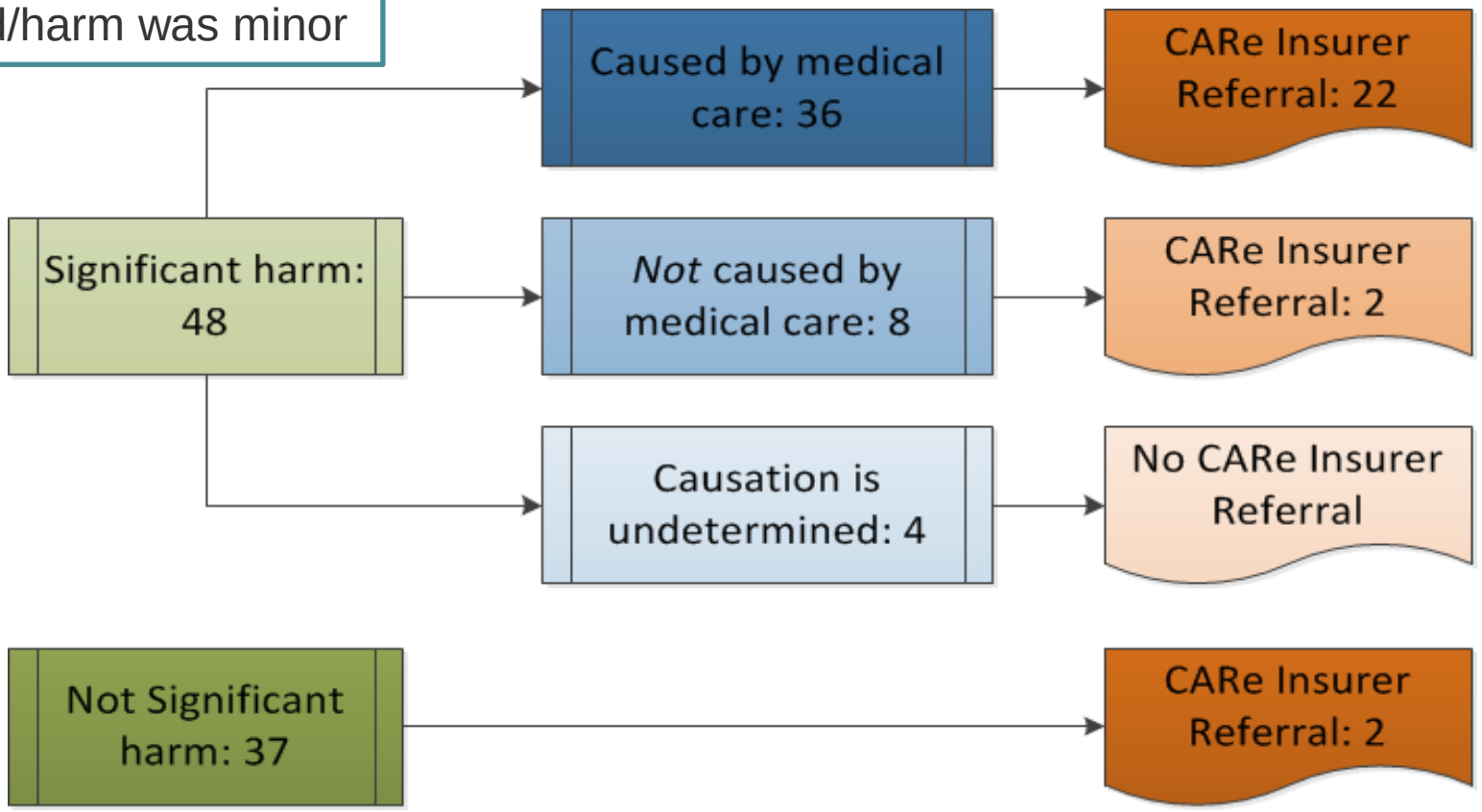


Reasons for no referral:

1. Resolution achieved without insurer
2. Uncertainty regarding harm/causation determination
3. Patient's condition resolved/harm was minor

met
19%

Hospital Determinations: SOC Violated (n=85)



Insurer Action on CARe Insurer Cases

(n=45 with final SOC determination)

CARe Insurer Case Progress	SOC violated	SOC met	SOC ND
Settlement or bill waiver offer made or in progress	10	1	1
Insurer/hospital and patient/family are still talking	6	2	1
Determination that payment is not indicated	3	7	1
Patient/family/attorney is nonresponsive or nonparticipatory	5	4	2
Case is on hold pending stabilization of the patient's condition	2	0	0

Resolution Communications

Oral or written resolution communication delivered	n	%
CARe Insurer Case (N=24 closed cases)	17	70.8
Not CARe Insurer Case (N=290 closed cases)	159	54.8

Resolution Elements Communicated

N=314 closed cases

Resolution element	SOC violated (n=18.5%)	SOC met (n=65%)	SOC ND (n=15.6%)
Offer compensation (other than service recovery)	6	0	0
Offer service recovery	13	20	7
Explanation of whether SOC met or not	24	96	3
Apology offered	28	96	10
Describe patient safety improvements to be implemented	16	4	2
Other	1	14	2
No determination made	0	0	1

Thank You

For further questions: mmello@hsph.harvard.edu

CARe Processes and the Pilot Experience

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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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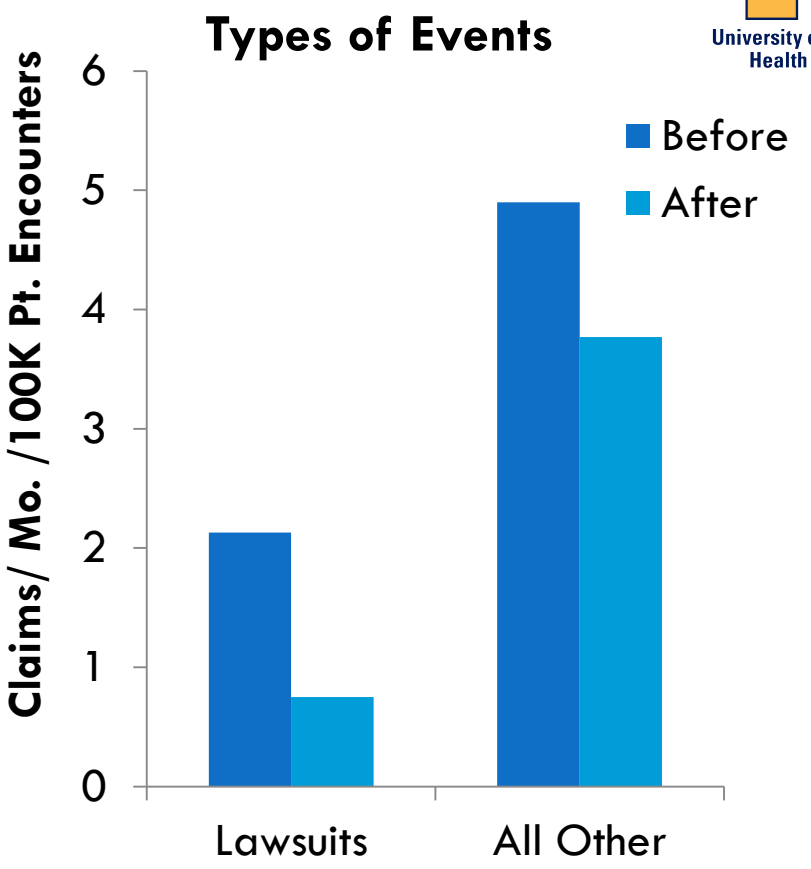
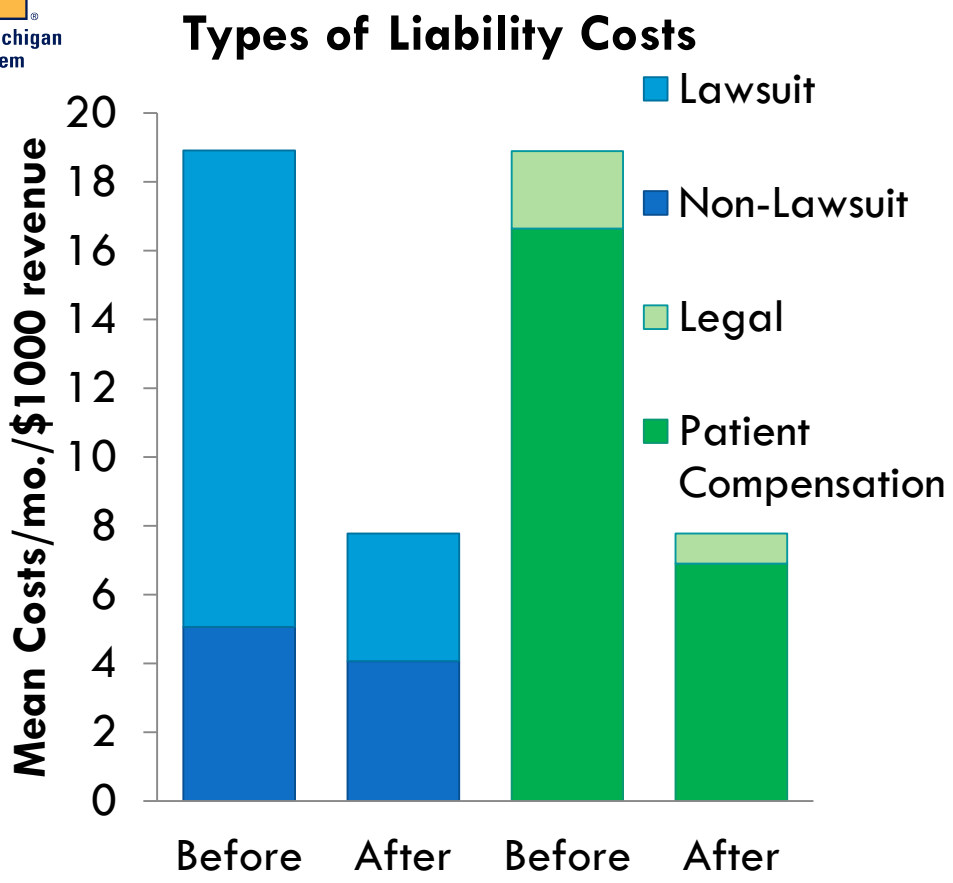
Does CARe work?

- 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”**

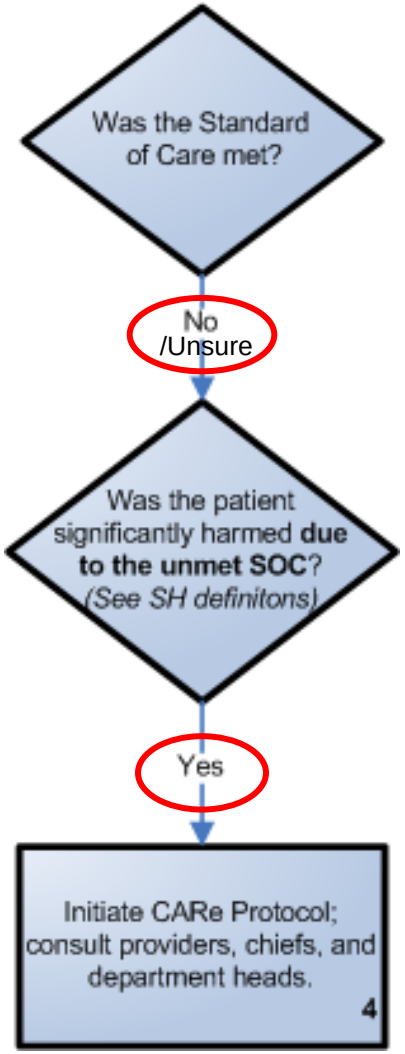
“Defining a CARe Case” –the Filter

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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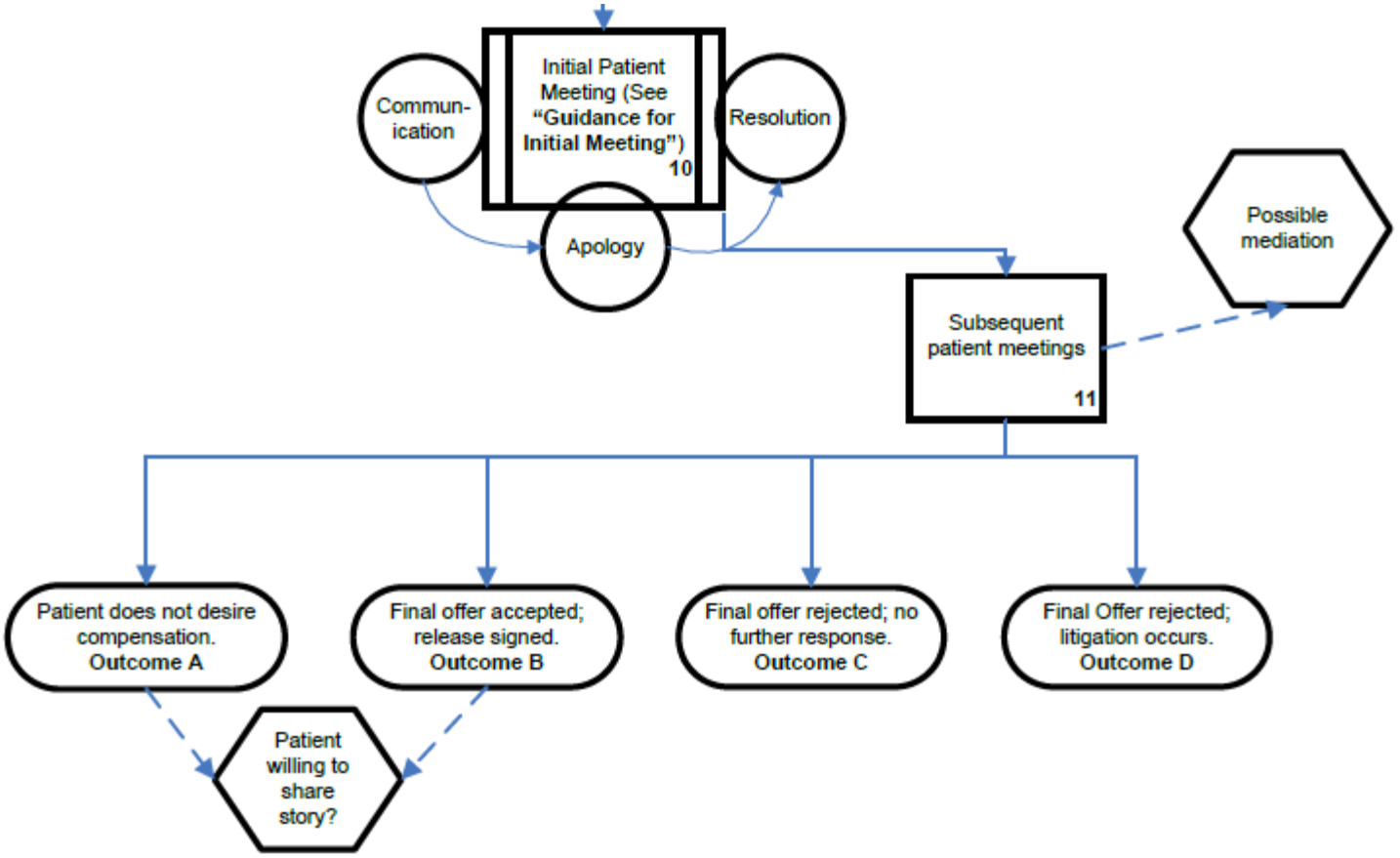
CARe Insurer Case Protocol - Potential Outcomes



Communication, Apology and Resolution Timeline

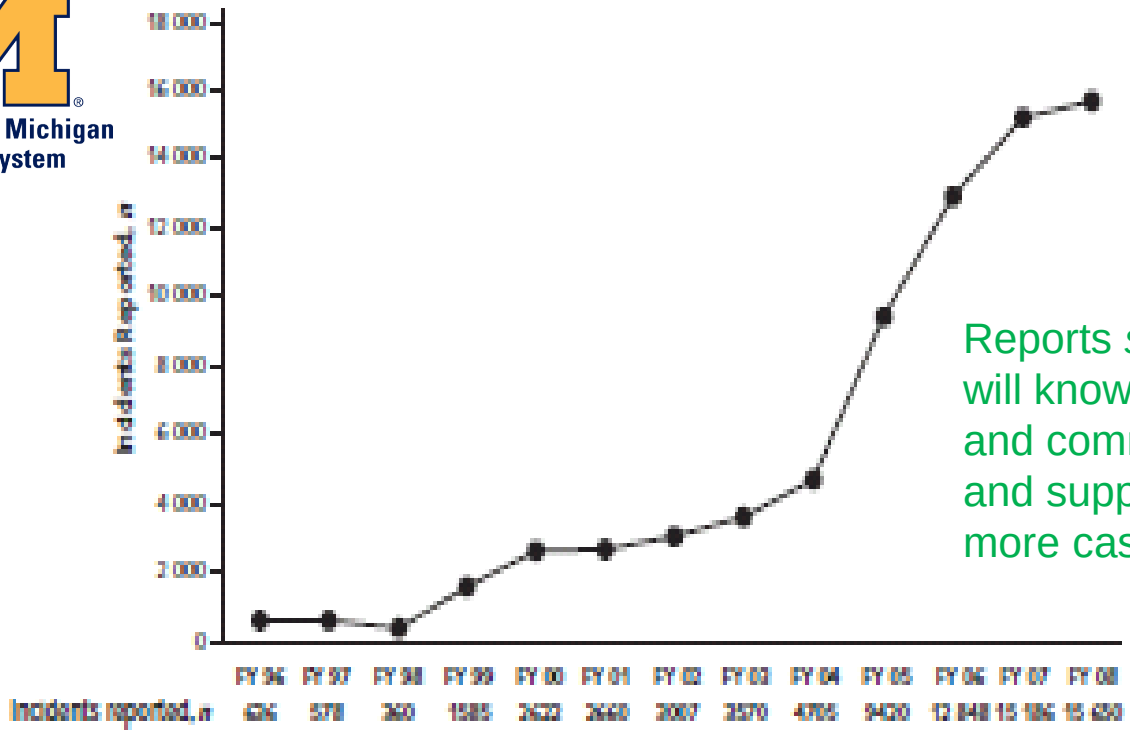
Within…

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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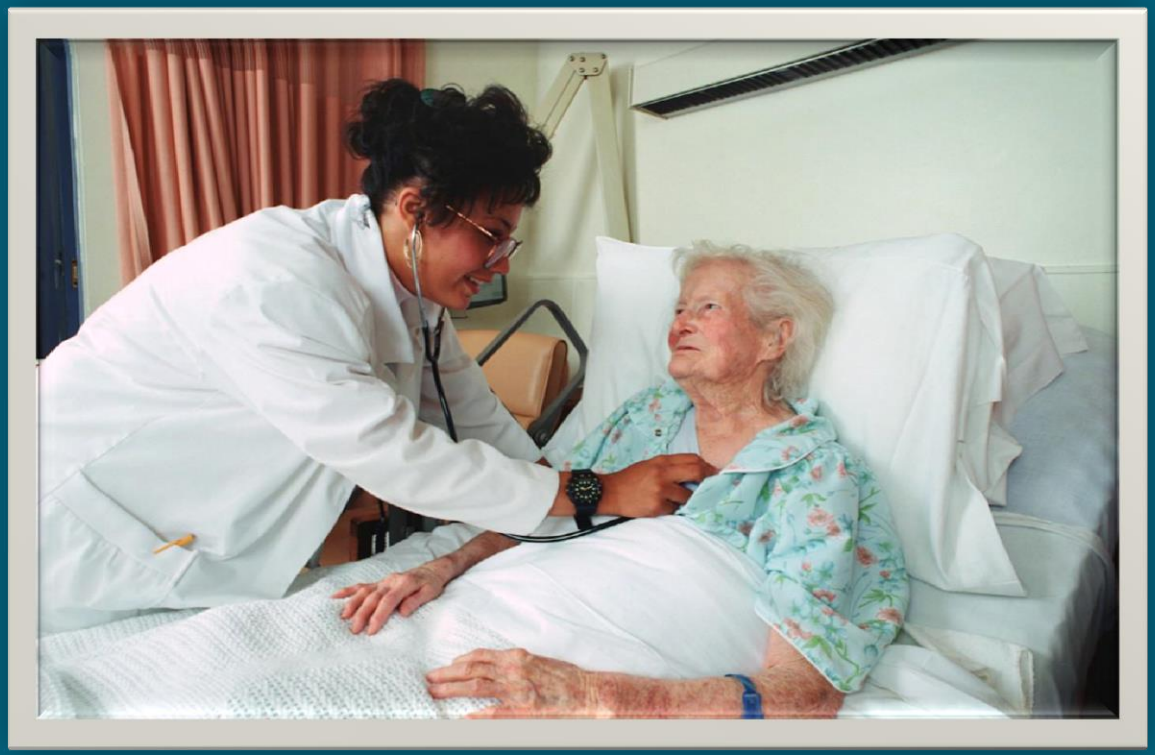
The Human Connection: Looking at Adverse Events from a Patient-Centered Perspective



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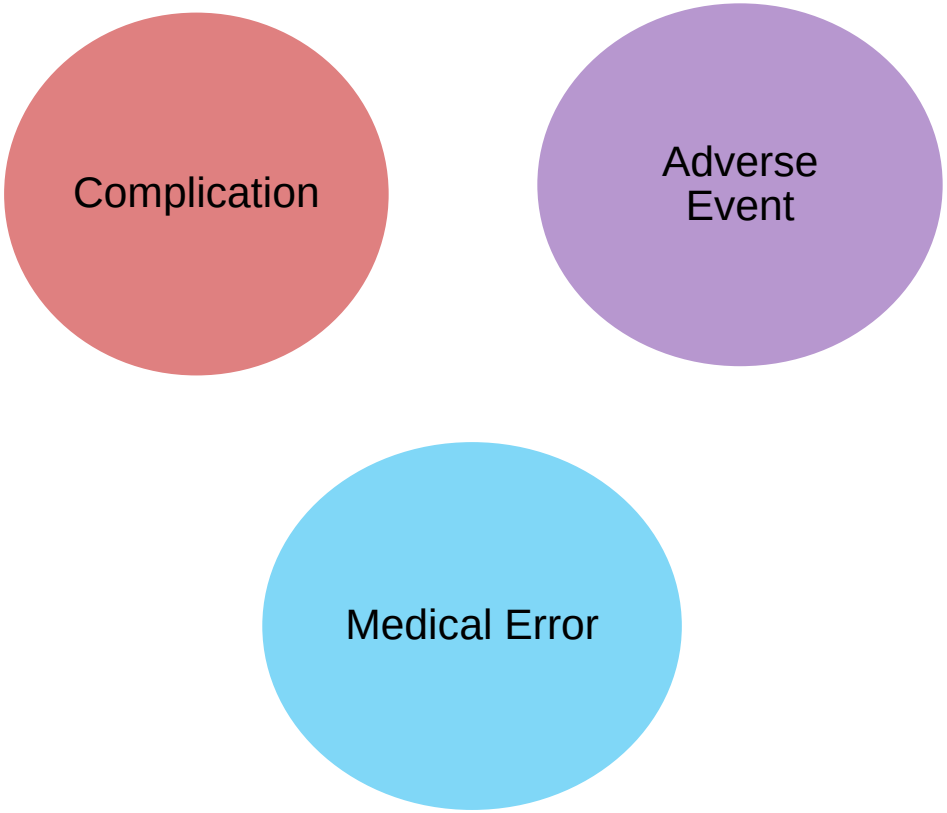
Ashley B. Yeats, M.D., FACEP
Chief Medical Officer, BID-Milton

What is an Adverse Event?



Definitions

Adverse Event	*An injury caused by medical management rather than the underlying condition of the patient … may or may not be as a result of an error.*
Medical Error	*The failure of a planned action to be completed as intended (error of execution)* *or* *the use of a wrong plan to achieve an aim (error of planning)*

Definitions adopted by the Institute of Medicine (IOM) in its report, *To Err is Human*.
Quality Interagency Coordination Task Force: www.quic.gov/report/toc.htm

MACRMI
Massachusetts Alliance for Communication and Resolution following Medical Injury

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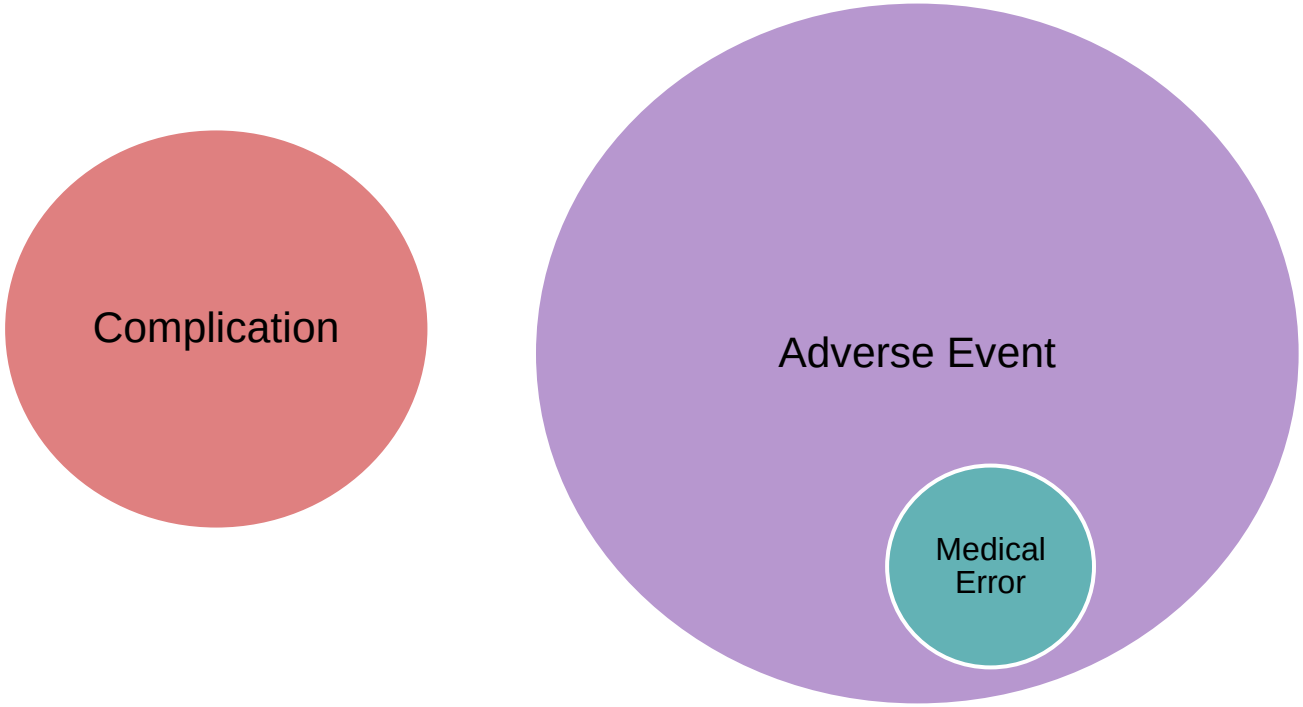

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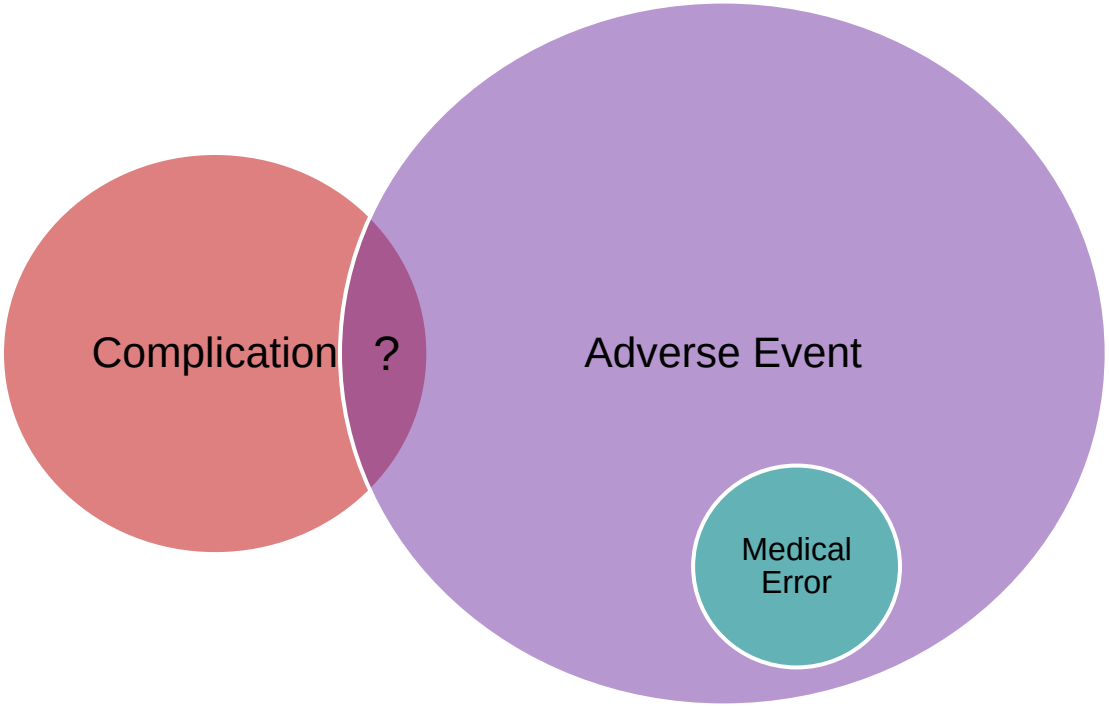

Why are we talking about this?

Adverse Events are identified on 25 - 30% of random chart reviews – The Institute for Healthcare Improvement

Hospital staff did not report 86 percent of Adverse Events to incident reporting systems, partly because of staff misperceptions about what constitutes patient harm.

- January 2012 report from the U.S. Department of Health and Human Services Office of Inspector General

Why are we talking about this?

- Because a better awareness of the different perspectives regarding adverse events can help us all:
  - Provide better patient-centered care
  - Learn from events
  - Do a better job looking after each other

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“Moments of Truth”

- A moment of truth is any experience that has an effect on the patient’s impression of the caregiver
- There are countless numbers of sights, sounds, impressions, events and interactions that every patient experiences in the hospital
- All these interactions and experiences are potential “moments of truth”
- May be mundane, positive or terrifying

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Jerome's Adverse Event

37 yo male who underwent Steriotactic Radio Surgery (SRS) for a Brain Aneurysm (AVM)

Please read the case on the colored paper

What are the emotions the wife in the case could be feeling?

Please write down the emotions on the Post-It provided.

When done, pass your note to the end of the row to be collected.

Patients' & Families' Emotions

After an adverse event, patients and families can feel…

- Sadness
- Anger
- Mistrust
- Isolation
- A desire to connect with others
- Guilt
- Shame
- Fear
- Grief/Loss
- Grateful to Survive
- Ambivalence

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Multifaceted Consequences

- Further Medical Follow-up
- Chronic Pain
- Financial Strain
- Job Loss / Work Stress
- Child Care / Parenting Burdens
- Marital Conflict
- Death of a Loved One

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Two Different Perspectives

PATIENTS Believe Errors Can Be Defined as:	CLINICIANS Believe Errors Can Be Defined as:
Deviations from prescribed standard of care	Deviations from prescribed standards of care **ONLY**
Certain non-preventable adverse events	No
Poor quality of service	No
Poor interpersonal skills of practitioners	No

Put yourself in the Patient's Shoes

Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. JAMA 2003;289:1001-7.

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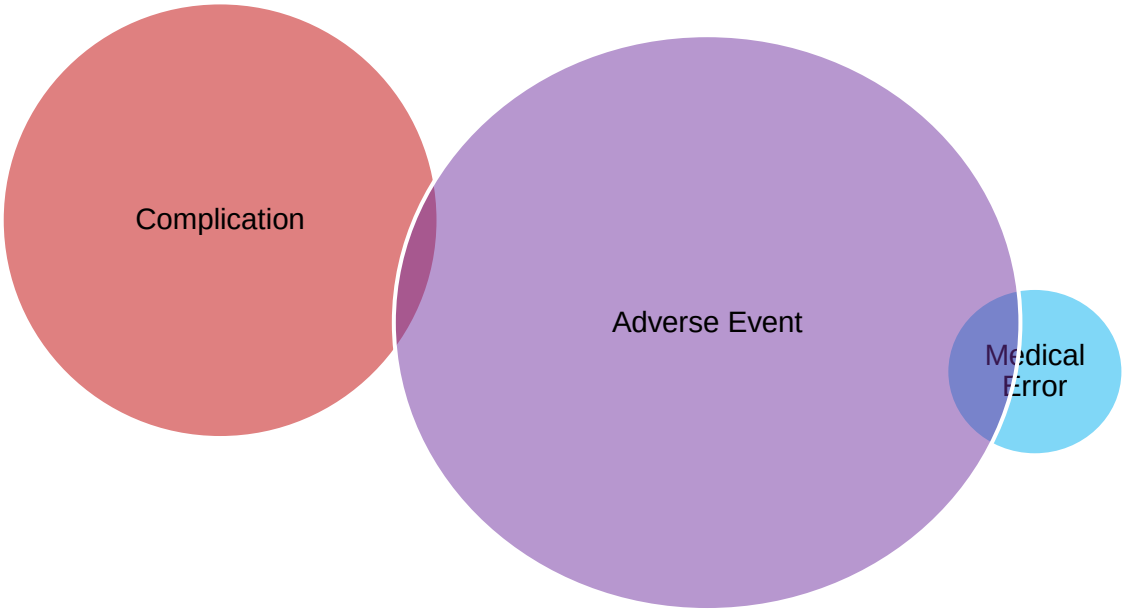
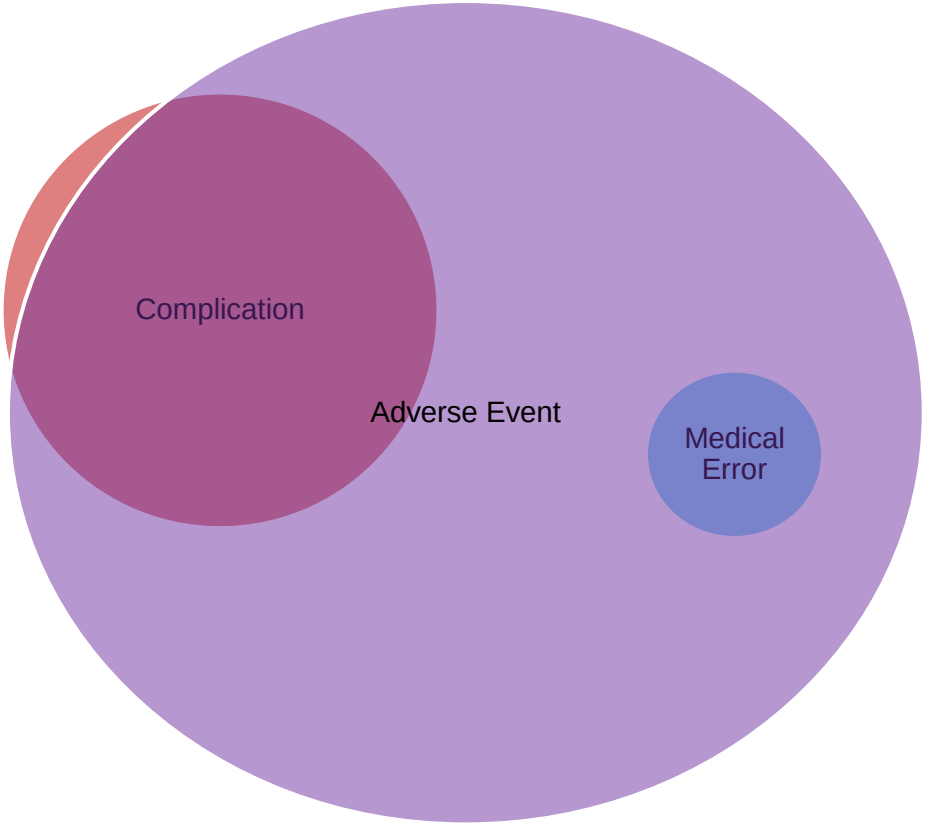
What is an Adverse Event? A Clinician Perspective:



What is an Adverse Event?
A Patient Perspective:



Now what?

- About 90% of the time, the CARe process is just about this communication with the patient and family that works through these different perspectives effectively.

- Negotiating these differences in perspectives is incredibly important to a successful resolution of an event, but it also very challenging.