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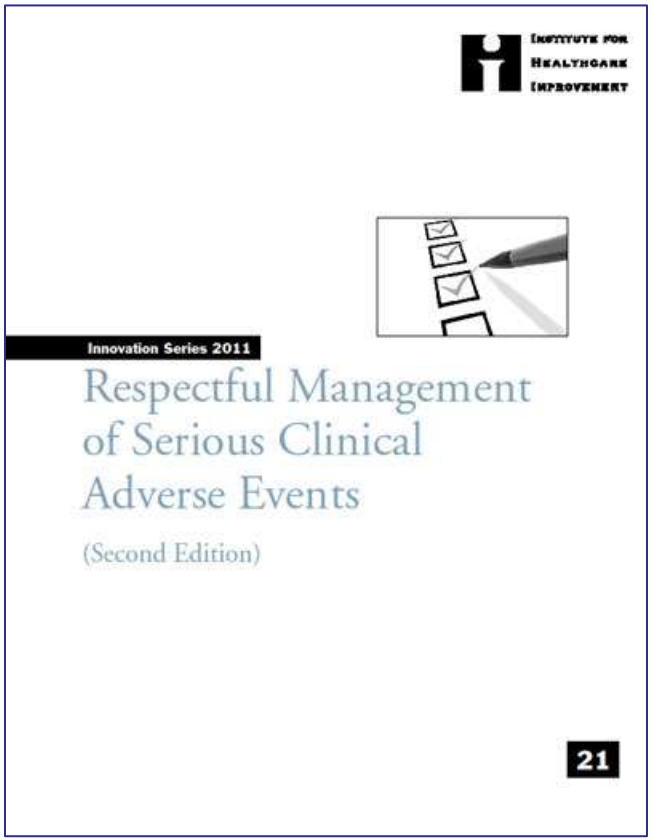
Respectful Management of Serious Clinical Adverse Events

What's Your Crisis Management Plan?



Outline

1. Goals of the White Paper
2. Response to Release and Content
3. The Content
    1. Realities of Practice
    2. Organizational Culture of Safety
    3. The Crisis Management Team and Plan
    4. The Prioritized Organizational Response
    5. Reimbursement and Compensation
    6. What to Do With a Crisis and No Plan
4. Moving Forward: Version 2

Goals of IHI White Paper

- Encourage and help organizations assemble clinical crisis management plans BEFORE they need to use them;
- Provide an approach to integrate these plans into organizations' culture of quality and safety, with a particular focus on patient- and family-centered care and fair and just practice for staff; and
- Provide organizations with a concise, practical resource to inform their efforts in the absence of an organizational clinical crisis plan and/or culture of quality and safety.

Response to October 2010 Release

- Affirmed and interested:
  - 34,000 visits to content, 11,000 downloads
  - 6,000 web links to content
  - Presentations, endorsement, and use
- Recommendations to strengthen
  - Compassion, empathy
  - Reimbursement and compensation
- Challenges in implementation
  - Legal considerations, “trump card”
  - Dealing with “someone else's” error
  - Lack of organizational attention

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"You just heard at this morning's CEO leadership huddle that a 40-year-old father of five children died in the Surgical ICU last night, hours after receiving medication intended for another patient. Everyone is upset. Questions are flying around the hospital: What does the family know? Who did it? What happened? What can we say? Would the patient have died anyway (he was very sick)? Has anyone gone to the press?"

Talk to your neighbor for a few minutes.
What would happen at your organization?

Realities of a Large Complex Imperfect Organization

- Preventable serious harm
- Fatal rare complication
- Violent crime
- Fire
- Drug diversion
- Identity theft
- Other breaches, etc.

Breaking A No-Win Cycle

- Serious clinical adverse event occurs.
- Organization is not transparent
- People close to the incident contact media.
- Media contacts the organization, gets “no comment,” or incorrect or superficial information.
- Media go looking everywhere for any information
- Information is supplied by people who really don’t know
- All parties are further traumatized by the strident, inaccurate media attention.
- The organization’s response becomes as big a story

Serious Clinical Event Defined

- Serious harm, potential serious harm, death, or a clear or present danger to one or more patients and/or to a community (psychological and physical)
- Possible definitions include but not limited to:
  - Harm categories G, H, and I, as measured by the NCC MERP harm index.
  - Sentinel events as defined by Joint Commission
  - The National Quality Forum Serious Reportable Events as a baseline list of serious clinical events.
  - HPI Safety Event Classification .
- Harm is usually, **but not exclusively,** preventable.

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The call to IHI…and many others.

"We've just had a terrible error in the ICU. A patient died who shouldn't have. What should we do?"

How To Respond?

- What should we do?
  - First hour, day, week, month
  - Moving forward
- Who should do it?
- What should we say, and to whom?
- Whose problem is this?

The Burden of the “Call”

- Devastation of the person calling
- Similarities of the stories
- Working with a blank sheet of paper
- Highly reactive, unbalanced response, and
- Underestimating the potential harm to all.

Every event is different, just as every care giver, every patient, every family member is different

In Summary, Crisis Management Steps

1. Avoid the crisis
2. Prepare to manage the crisis
3. Recognize the crisis
4. Contain the crisis
5. Resolve the crisis
6. Profit (by learning) from the crisis

Avoid the Crisis

Leadership and a Culture of Quality and Safety

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A CULTURE OF SAFETY

"No one is ever hesitant to speak up regarding the well being of a patient (psychological safety), and everyone has a high degree of confidence that their concern will be heard respectfully and be acted upon."

Michael Leonard

Assessing Your Policies, Procedures, Practices, Culture

1. Internal Culture of Safety
2. Malpractice Carrier
3. Policies, Guidelines, Procedures, Practices
4. Training
5. Disclosure Processes
6. The Disclosure
7. Ongoing Support
8. Resolution
9. Learning and Improvement

IHI Assessment Tool—A Culture of Respect, Communications, and Disclosure

	Element	Y	+-	N
Internal Culture of Safety	The organization, through its governance and leadership, is grounded in the core values of compassion and respect and the ethical responsibility to always tell the truth.			
	Error is seen as the failure of systems and not people and is considered in a fair and just culture.			
	All get support at the sharp end of unanticipated outcome.			
Malpractice Carrier	There is a commitment to rapid disclosure and support.			
	There is a written understanding of how cases will be managed and handoffs will occur with the patient/family, organization, and carrier.			
	Mechanisms are in place for rapid respectful resolution.			
Policies, Guidelines, Procedures, Practices	There is a policy on patient and family communications.			
	There is a policy on patient and family partnerships.			
	There are policies on disclosure and documentation.			
	Procedures in place for internal and external communication			
	Guidelines/policies support a fair and just culture (non-punitive) and the reporting of adverse events.			
	Root causes analyses commence immediately, are closely managed with an executive sponsor. Results are shared, including with the patient and family.			
	There is a written crisis communication plan. This plan is centrally located and easily accessible by all staff.			
Training	Ongoing training programs are in place for all staff on communication, expectations, policies, procedures, guidelines.			
	There is just-in-time coaching (training) for disclosures			
Disclosure Processes	There is rapid notification of patient/family and activation of support—typically immediately around what is known.			
	There is a team to support staff preparing to disclose			
The Disclosure	The organization is transparent and honest.			
	Responsibility is taken.			
	We are empathetic, apologize and /or acknowledge.			
	There is a commitment to providing follow-up information.			
	The caregiver is supported throughout the process.			
	Ongoing support is provided for the patient/family.			
Ongoing Support	Resources are available to assist families experiencing unanticipated outcomes (not limited to error) – support is defined by needs of the patient and family			
	Resources are available to assist staff at the sharp end of unanticipated outcomes (not limited to error) – support is defined by needs of the clinician			
	Procedures are in place and are known to ensure ongoing communications with patients, families, and staff.			
Resolution	Procedures are in place and are known to bring the case to closure respectfully, as viewed by the patient and family.			
Learning and Improvement	Mechanisms are in place to ensure learning by the board, executive leadership, MSEC, and across the organization.			
	Measurement systems are in place to assess the impact of communication, disclosure, and support on premiums, claims, cases, and payments.			

Revised March 18, 2010

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Manage the Crisis

The Team, The Plan, the Priorities

The Best Way To Manage a Crisis is to Have a Plan

- Create a team for planning
- Determine each potential problem's likelihood
- Create a plan
- Simulate the plan
- Update the plan

Crisis Management: Master the Skills to Prevent Disasters
by Harvard Business Essentials

Model Crisis Management Team

- CEO/COO
- CMO
- CNO
- Communications Officer
- General Counsel
- Patient Representative
- Representatives from: Risk Management / Quality Improvement / Patient Safety, Ethics, Pastoral Care
- Relevant service chief
- Others as appropriate for incident
  - Expert in Hospital Incident Command System

Crisis Management Team: Moving Forward

- Routine check-in daily to multiple times a day
- Maintain highly disciplined documentation and log
- Engage outside help through colleagues and consultants
- Listen and be prepared to hear things you don't want to
- Embrace speed and flexibility
- Stay close to internal and external voices
- Consider implications for hospital/professional billing
- Imagine the worst; mitigate as possible
- Be prepared for inquiry from or the arrival of external accrediting and regulatory agencies
- Ensure knowledge management / improvement

Crisis Management Plan

- Internal notifications
- Crisis Management Team
- Priorities
  - Patient and family
  - Staff
  - Organization
    - External and Internal Communications
- External notifications and unannounced visits

Areas Requiring Focus
(In this order)

1. Patient and family
2. Staff, particularly those at the sharp end of the error
3. Organization

Seeking To Achieve for All
Patient, Family, Staff, Organization

- Empathy
- Disclosure
- Support (including reimbursement)
- Assessment
- Apology
- Resolution (including compensation)
- Learning
- Improvement

Patient and Family

- Team disclosure
- Statement of empathy/sorrow
- Apology
- RCA participation
- Safety and support
- Reimbursement
- Compensation
- Resolution
- Learning

Never lose sight of the patient and family

Staff

- Coaching around disclosure
- Safety and support
- Engage in RCA
- Inclusion of all patient's team
- Bring to resolution
- Assure learning

Never lose sight of the staff at the sharp end of the error

Organization

- Governance and executive team notifications
- Visible CEO & C-Suite
- Activated crisis team and leader
- Engaged Board of Trustees
- RCA underway
- Internal and external communications
- External notifications and unannounced visits
- Ongoing RCA, learning and improvement

Whose Problem Is This?

1. Board of Trustees (Governing Body)
   - Ultimately responsible and accountable for quality and safety
   - Engaged immediately and ongoing in system learning and improvement
   - Must fulfill their responsibility to the patient, family, and community
2. CEO

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"I am accountable for those unnecessary deaths in our NICU"

Paul Wiles

CEO, Novant Health

Risk Assessment and Root Causes Analysis

- Commence immediately
  - Nothing more important on the schedule
- Include executive leadership
  - Comprehensive, fair and balanced process
  - Remove barriers
  - Learning
- Include staff close to the sharp-end
- Include patient / family as possible
- Fully integrate into governance and executive processes
- Assure follow-through on plan of correction

Note: Study conducting effective RCAs now.

Internal and External Communications

- What can we say?
- How can we say it?
- Who are we communicating to?
  - External
  - Internal

What Can We Say
Essential Messages

- Hospital apology, outrage, anger, regret that incident happened
- Disclosed to the patient/family--- informing and supporting them is priority
- Involvement of Board and leadership
  - understanding why systems failed patient and family
  - steps to prevent a similar occurrence
- Working with appropriate authorities
  - NOT a time to fight with authorities or Accreditors
- Understand this as a breech of trust and a failure to our community

How Can We Say It?

- Define your essential messages as clearly and concisely as possible
- Centralize and narrow the flow of information
  - Determine who will speak for the institution
  - All spokespersons must be briefed and prepared
  - Remind all staff to direct outside inquiries to Comm.
  - Communications Dept. should review communications to all core audiences
- Mobilize your allies

Internal Communications Critical

- All staff devastated when these events happen
- Need to understand what's going on as staff, consumers, and sources of information
- The "drop a dime" phenomenon
  - Action not visible around immediate incident
  - Frustration over historical issue resolution
  - Organization not "telling the truth"

Note: Routine communication of errors facilitates communication of serious incidents.

Dealing with the Media

- In advance:
  - Up-to-date, tested media plan / crisis plan
  - Informed internal PR/Communications staff
  - Cultivated media
  - Media training for organization leaders
- On the heels of an adverse event
  - Rapid response
  - Honest; don't stonewall
  - What happened, why, what's being done?
  - Empathetic
  - Provide updates

What to Do When a Crisis Occurs, Without a Plan

Clinical Crisis Plans in Healthcare

- Only about 33% of respondents said their organizations had an “independent” crisis communication plan separate from the organization’s disaster plan.
- Another 37% of respondents said the crisis communication plan was part of the disaster response plan.
- 10% of respondents had no crisis communication or disaster plan

Society for Healthcare Strategy and Market Development, 2008

No Plan

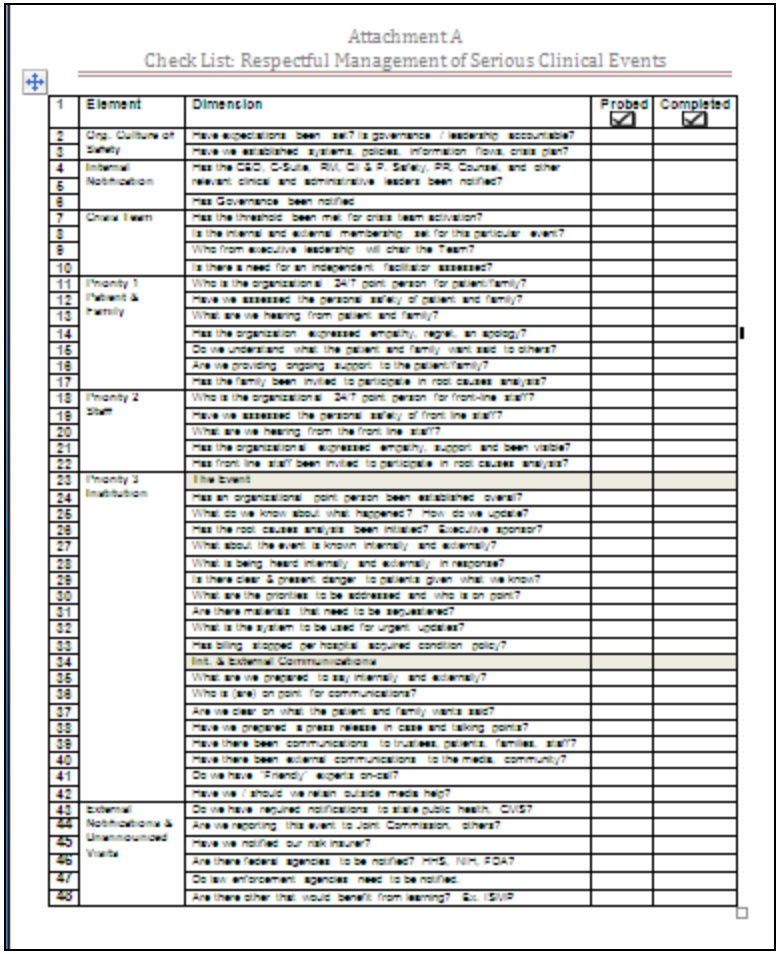
- Notify executive leadership and the Board.
- Establish a sense of urgency.
- Assemble an ad-hoc Crisis Management Team led by the CEO or other C-suite
- Utilize this White Paper (Appendix A&B)
- Review the White Paper.
- Consider outside crisis management help.
- Contact other executive leaders (Appendix D)
- Never lose sight of the patient and family, staff, and organization.

Checklist: Respectful Management of a Serious Clinical Event

PROBING ALL STEPS

COMPLETING ALL STEPS

- Prepared Plans & Systems
- Internal Notification
- Crisis Team Activation
- Priority 1: Patient / Family
- Priority 2: Staff
- Priority 3: Organization
  - AE Management
  - Communications
- External Notification / Visits



Attachment A

Check List: Respectful Management of Serious Clinical Events

	Element	Dimension	Probed	Completed
2	Org. Culture of Safety	Have expectations been set? Is governance / leadership accountable?		
3		Have we established systems, policies, information flows, crisis plan?		
4	Internal Notification	Has the CEO, C-Suite, RM, CI & P, Safety, PR, Counsel, and other relevant clinical and administrative leaders been notified?		
5				
6		Has Governance been notified		
7	Crisis Team	Has the threshold been met for crisis team activation?		
8		Is the internal and external membership set for this particular event?		
9		Who from executive leadership will chair the Team?		
10		Is there a need for an independent facilitator assessed?		
11	Priority 1 Patient & Family	Who is the organization's 24/7 point person for patient/family?		
12		Have we assessed the personal safety of patient and family?		
13		What are we hearing from patient and family?		
14		Has the organization expressed empathy, regret, an apology?		
15		Do we understand what the patient and family want said to others?		
16		Are we providing ongoing support to the patient/family?		
17		Has the family been invited to participate in root causes analysis?		
18	Priority 2 Staff	Who is the organization's 24/7 point person for front-line staff?		
19		Have we assessed the personal safety of front line staff?		
20		What are we hearing from the front line staff?		
21		Has the organization's expressed empathy, support and been visible?		
22		Has front line staff been invited to participate in root causes analysis?		
23	Priority 3 Institution	The Event		
24		Has an organizational point person been established overall?		
25		What do we know about what happened? How do we update?		
26		Has the root causes analysis been initiated? Executive sponsor?		
27		What about the event is known internally and externally?		
28		What is being heard internally and externally in response?		
29		Is there clear & present danger to patients given what we know?		
30		What are the priorities to be addressed and who is on point?		
31		Are there materials that need to be sequestered?		
32		What is the system to be used for urgent updates?		
33		Has billing stopped per hospital acquired condition policy?		
34		Int. & External Communications		
35		What are we prepared to say internally and externally?		
36		Who is (are) on point for communications?		
37		Are we clear on what the patient and family wants said?		
38		Have we prepared a press release in case and talking points?		
39		Have there been communications to trustees, patients, families, staff?		
40		Have there been external communications to the media, community?		
41		Do we have "Friendly" experts on-call?		
42		Have we / should we retain outside media help?		
43	External Notifications & Unannounced Visits	Do we have required notifications to state public health, CMS?		
44		Are we reporting this event to Joint Commission, others?		
45		Have we notified our risk insurer?		
46		Are there federal agencies to be notified? HHS, NIH, FDA?		
47		Do law enforcement agencies need to be notified.		
48		Are there other that would benefit from learning? Ex. ISMP		

Work Plan: Respectful Management of a Serious Clinical Event

Appendix B: Respectful Management of Serious Clinical Events Work Plan: Elements, Dimensions, and Milestones

CTR	A	B	C	D	E	F	G	H
1	Element	Dimension	Pre-Event	First Hour	First Day	First Week	First Month	Activities After First Month
2	Org. Culture of Safety	Governance and Leadership	Trust, Respect, Human Rights, Forgiveness, Repentance					Learning and Improvement
3		[illegible], Policy/Procedure, [illegible]	Approve	Assemble	Annotate	Annotate	Annotate	Revise
4	Internal Notification	[illegible]	Learning System	Activated	Engaged & Visible	Engaged & Visible	Engaged & Visible	Learning and Improvement
5		[illegible]						
6		Governance		Pending	Activated	Updated	Updated	Learning and Improvement
7	Crisis Team	Threshold Met for Activation	Plan	Activated	Meeting	Schedule	Schedule	Stand Down with Plan
8		Membership	Plan	Activated	Refine	Refine	Updated	Formal debrief
9		[illegible]	Plan	Activated	Refine	Ongoing	Ongoing	Revise plan
10		[illegible]	Plan	Activated	Ongoing	Ongoing	Ongoing	
11	Priority 1 Patient & Family	Who's on Point			Establish	Report	Report	To resolution and learning, including any external professional or judicial actions
12		Personal Safety			Assess	Update	Update	
13		Hearing What			Report	Report	Report	
14		Empathy/Apology Extended			Regret	Report	Report	
15		What Do They Want Said			Establish	Update	Update	
16		Providing Ongoing Support			Offer	Report	Report	
17		Root Causes Analysis Participant			Activated	Invited	Complete	
18	Priority 2 Staff	Who's on Point			Establish	Report	Report	To resolution and learning, including recognition of the efforts of staff resolution of any external professional or judicial actions
19		Personal Safety			Assess	Update	Update	
20		Hearing What			Report	Report	Report	
21		Ongoing Support & Visibility			Offer	Report	Report	
22		Root Causes Analysis Participant			Activated	Invited	Complete	
23	Priority 3 Institution	The Event						
24		Who's on Point			Establish	Update	Update	Revise plan
25		What happened			Report	Report	Report	Learning and Improvement
26		RCA and Executive Sponsor?			Activated	Progress	Complete	Closed all risk reduction items
27		Who Knows What			Report	Report	Report	Learning and Improvement
28		Hearing What			Report	Report	Report	Learning and Improvement
29		Patient Clear & Present Danger			Charge	Report	Report	Learning and Improvement

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"If you take my pen and say you are sorry, but don't give me the pen back, nothing has happened."

Bishop Desmond Tutu

Reimbursement and Compensation

- Reimbursement
  - Service Recovery
  - Out of pocket expenses
  - Examples: COPIC & Coverys‘ (formerly ProMutual Group)
- Compensation
  - Financial remedy for avoidable loss
  - Healthcare organization actively involved
  - Examples:
    - Early: VA Lexington and University of Michigan
    - Innovators: Veterans Health System, Stanford, CRICO, KP, many more

Communicating Around Errors that Happened Somewhere Else

- Patients and families needs for respectful treatment should be at the forefront.
- Patients and families should not bear the burden of being fact finders for information about potential problems
- When providers have serious concerns, a responsibility exists to proactively and thoughtfully explore while avoiding a rush to judgment.
- Institutions should develop supports to assist in preparing for conversations and for unbiased investigations in collaboration with other institutions to investigate and resolve quality of care concerns
- Organizations must promote learning for the future with a culture of collective accountability

Thomas Gallagher MD, Talking with Patients about Other Healthcare Workers' Errors: Ethical, Legal, Practical Considerations. 2008 Grant Greenwall Foundation

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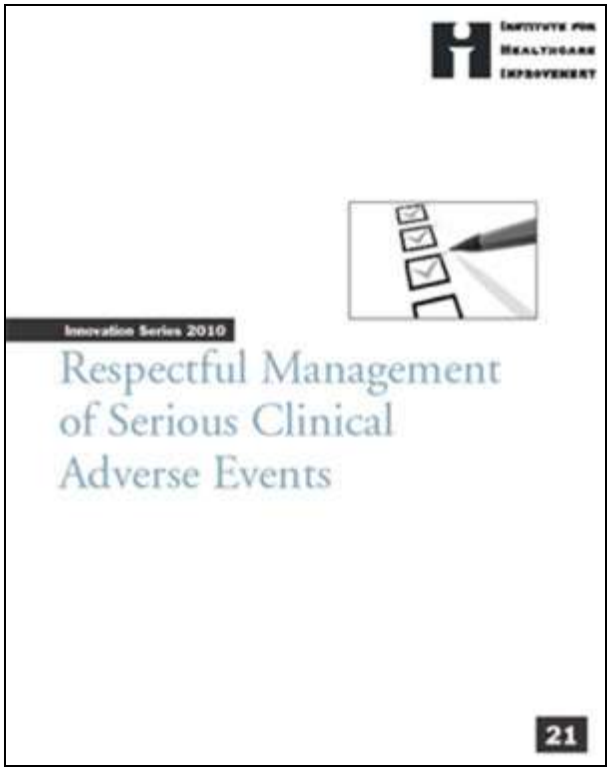
Supporting Organizations Dealing with Serious Clinical Events

Offer support, a helping hand, counsel to others dealing with tragic events and crises.

Learning From Events In Other Organizations: Could It Happen Here?

An IHI Resource Center

Leadership Response to a Sentinel Event: Respectful, Effective Crisis Management



"In the aftermath of a serious adverse event, the patient/family, staff, and community would all say, 'We were treated with respect.'"

http://tinyurl.com/IHIEffectiveCrisisMgmt

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"When something goes wrong it is how the organization acts that redefines and reshapes the culture."

J. Clough, Mt. Auburn Hospital

Comments, Questions, Answers

"Do not go where the path may lead; go instead where there is no path and leave a trail"

Ralph Waldo Emerson