The Changing Landscape of Patient Safety

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Institute of Medicine’s First Quality Report: To Err Is Human – November 1999

Preventable lapses in safety:
- 44,000 to 98,000 Americans die each year
- Eighth leading cause of death in the United States
- Annual cost as much as $29 billion annually

Conclusion: the majority of these problems are systemic, not the fault of individual providers

The Safety Movement in the 2000’s

- Hospital-focused
- Key initiatives to improve safety culture (change from blame to nonpunitive to just)
- Focus on increasing safety reporting
- Systems approach to error
  - Human factors, reliability
  - Team training
- Safety often focused on issues such as wrong-site surgery, wrong procedure, falls, medication errors

The Safety Movement in the 2000’s

- The Joint Commission plays a key role
  - National Patient Safety Goals, Failure Mode and Effects Analysis (FMEA)
- Public reporting begins
  - Serious Reportable Events (SREs), Leapfrog, Hospital-Acquired Infections (HAIs)

Timeline: National Patient Safety Goals

Public Reporting

- More than half of states are required to report HAI rates to the Centers for Disease Control and Prevention (CDC)
- More than half of states are required to report some version of SREs to the state
2009 Survey Results

The Changing Landscape of Safety

- All of the same concepts are still relevant and extremely important
  - Culture
  - Reporting
  - Systems
  - Regulations
  - Transparency

So where does safety go from here?

Changing Landscape: New or Expanded Focus

1. Care across the continuum
2. Patient/family engagement and experience
3. The workforce
4. Transparency and metrics
5. Use of health information technology

What’s driving the future?

- Hospitals face ever-increasing numbers of existing and new priorities
  - Healthcare Reform - Accountable Care Organizations (ACOs) - cost reduction
  - Health Information Technology (HIT) - meaningful use
  - Reducing Readmissions - bundled payment, public reporting
  - 30-Day All-Cause Mortality - public reporting
  - Hospital-Acquired Conditions (HACs) - nonpayment
  - AHRQ Patient Safety Indicators (PSIs) - public reporting
  - CMS National Hospital Quality Measures (NHQMs) - Acute Myocardial Infarction, Congestive Heart Failure, Pneumonia, Surgical Care Improvement Project and more to come

- Population Health/Care across the continuum is a new focus

Changing Landscape: 1

Care across the Continuum
Ambulatory Safety—What is “Ambulatory”?  
- Most studies done in primary care setting  
- But we can’t forget...  
  - Specialty practices  
  - Ambulatory surgical centers  
  - Dialysis centers  
  - Nursing homes  
  - Rehabs  
  - Care in the home (including large variety of devices)  
  - And many others...

What is different about ambulatory care?  
- Long feedback loops  
- Episodic (from provider and patient perspective)  
- Signal to noise ratio is low  
- Widely distributed  
- Limited resources, redundancies  
- Patients and providers have many degrees of freedom

What do we know about ambulatory safety?  
- Medication safety  
- Transitions of care  
- Missed and delayed diagnosis  
  - Test result follow-up  
  - Referral management  

Just the tip of the iceberg...

Outpatient Medication Safety  
- Adverse drug events are common and often ameliorable (25% of patients in one study)  
- 1,879 prescriptions reviewed  
  - Medication errors 143 (7.6%)  
    - Potential ADEs 62 (3%)  
      - Life-threatening 1 (2%)  
      - Serious 15 (24%)  
      - Significant 46 (74%)  

Gandhi TK et al. NEJM 2003, JGIM 2005

Impact of E-Prescribing  
- Study of 15 providers before and after implementation of e-prescribing  
  - Error rates reduced from 42/100 prescriptions to 6/100 prescriptions  
  - Largest reductions:  
    - Illegibility  
    - Inappropriate abbreviations  
    - Missing information  

Kaushal R et al. JGIM 2010
Devine E et al. JAMIA 2010

Nonadherence  
- In one study of 195,000 newly prescribed e-prescriptions, only 72% were filled  
  - Nonadherence was common for medications for chronic conditions such as hypertension, diabetes, hyperlipidemia  
  - Fischer M. et al. JGIM 2010  

“Medication nonadherence: A diagnosable and treatable condition”  
- Often undetected and untreated  
- Clinicians not trained to screen or treat  
- Need to understand patient beliefs and values  
- Now tied into quality measures  

Marcum ZA et al. JAMA editorial 2013
Missed and Delayed Diagnosis Errors

- Most common type of ambulatory malpractice cases
- Most-often missed cancer
- Occur in primary care practices

Overview of ambulatory dx-related cases

<table>
<thead>
<tr>
<th>RESPONSIBLE SERVICE</th>
<th>% CASES</th>
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<tbody>
<tr>
<td>Medicine</td>
<td>40%</td>
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<tr>
<td>Family Medicine</td>
<td>21%</td>
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<tr>
<td>Internal Medicine</td>
<td>16%</td>
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<tr>
<td>Gastroenterology</td>
<td>5%</td>
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<tr>
<td>Surgery</td>
<td>17%</td>
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<tr>
<td>Orthopedic</td>
<td>9%</td>
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<tr>
<td>General Surgery</td>
<td>7%</td>
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<tr>
<td>Urology Surgery</td>
<td>5%</td>
</tr>
<tr>
<td>Radiology</td>
<td>16%</td>
</tr>
<tr>
<td>Pathology</td>
<td>7%</td>
</tr>
</tbody>
</table>

Top Diagnoses in Ambulatory cases
- Cancer
- Cardiac care (including MI)
- Injury (Ortho / head & spine)

Diagnostic Process of Care in Ambulatory Setting

- Physician performs history / physical
- Ordering of diagnostic / lab tests
- Performance of tests
- Interpretation of tests
- Receipt / transmittal of test results
- Follow-up plan & referral (if indicated)
- Patient adherence to plan

Preventing Missed and Delayed Diagnosis Errors

- Strategies to reduce cognitive errors
  - Double checks
  - Decision support
- Strategies to reduce systems errors
  - Closed-loop test result management
  - Closed-loop referral management
- Patient engagement

Transitions of Care

- Handoffs and transitions are particularly high risk for adverse events
  - Adverse events after discharge
  - Medication issues
  - Pending tests
  - Unresolved medical issues
Strategies to error-proof high-risk transitions

- Improve handoffs in care
  - Standard templates for transitions
  - Improved discharge processes and handoffs (SBAR)
  - Improved safeguards for post-discharge period
    (phone calls, appointments, etc.)
  - Medication reconciliation
    • TJC requirements
    • Should be done in inpatient and outpatient settings

All potentially leading to reduced readmissions!

Safety Issues in Home Care

- Home care adverse event rate per client-year is 10%
- 56% of AEs were judged preventable.
  - The most frequent were injuries from falls, wound infections, psychosocial, behavioral or mental health problems, and medication errors.
  - Clients’ decisions or actions contributed to 48.4% of AEs, informal caregivers 20.4% of AEs, and healthcare personnel 46.2% of AEs.

Blais et al. BMJ Qual Saf 2013

Safety Issues in Nursing Homes

- Nearly 1 in 3 Medicare beneficiaries who went to SNFs (35 days or fewer; avg 15 days) experienced an adverse event (OIG report 2014)
  - 59% preventable: many as a result of failure to monitor or delay in care
  - More than half of the residents who experienced harm were hospitalized
  - Most common: Medication related (37%), resident care (37%), infections (26%)

Safety Issues in Ambulatory Surgery

- Surgical site infection rate in ambulatory surgery is 3/1000 procedures
- However, millions of procedures done each year so still significant numbers affected

Owens et al. JAMA 2014

Safety Issues in Office Procedure Settings

- Checklists not uniformly used in the office settings that perform procedures (small study)
- Top barriers:
  - No incentive to use a checklist (78%)
  - No mandate from a federal or local regulatory agency (44%)
  - Time consuming (33%)
  - Lack of training (33%)


- Need more research to better identify safety concerns across all settings
Outpatient Safety Infrastructure

- Many principles in place in inpatient settings
  - Culture change
  - Event identification and analysis
  - Systems approach
  - Proactive assessment
- Need to transfer these to all outpatient settings
  - Procedure areas
  - Nursing homes, rehab centers
  - Ambulatory and office

Safety Is Personal: Partnering with Patients and Families for the Safest Care

From NPSF’s Lucian Leape Institute Roundtable on Consumer Engagement

Available for Download at http://www.npsf.org/lli-safety-is-personal/

Changing Landscape:

Patient/Family Engagement and Experience

The Value of Patient- and Family-Centered Care

- Patients are the only source of information about many aspects of safety and quality
- The patient’s experience is linked to improved clinical outcomes and ability to manage chronic conditions, as well as reductions in readmissions, mortality, and malpractice
- Partnering with patients and families to redesign and/or improve care brings a wealth of knowledge to care
- Partnerships with patients inspire and energize clinicians, staff, and leaders, while grounding them in reality, focused on the “right” solutions

Edgman-Levitan S. NQF April 2012

Background on the Issue

What is patient and family engagement?

“Patients, families, their representatives, and health professionals working in active partnership at various levels across the health care system—in direct care, organizational design and governance, and policy making—to improve health and health care.” (adapted from Carman 2013):

Studies link patient engagement with patient satisfaction, safer care, improved work experience for caregivers, and better health outcomes.

Barriers to Patient and Family Engagement

- Fragmented health care system
- Historically paternalistic/dysfunctional culture in health care
- Lack of understanding/knowledge/commitment on the part of health care leaders to embrace patient and family engagement as an essential part of their mission
- Workflow design flaws
- Lack of effective engagement tools and training
- Lack of awareness among patients and families
- Problems with health literacy, limited social support, or fear of speaking up on the part of patients
Observations from the LLI Roundtable

- Move the system from asking patients “What’s the matter?” to “What matters to you?”
- It is very hard to speak up, even for the most empowered
- Burden cannot be off-loaded to patients
- Engagement is a shared responsibility
- Patients who are alone are at highest risk
- Don’t scare the patient – they need to feel they are safe and do not have to be constantly vigilant

Tools for Health Systems

- Patient family advisory councils
- Shared decision making tools
- Health literacy tools/training
- Bedside rounds
- Patient activated rapid response systems
- Patient reporting systems
- Patients on root cause analyses

Whitepaper Recommendations

Based on evidence that patient engagement improves patient safety

For Leaders of Health Care Systems

- Establish patient and family engagement as a core value for the organization
- Involve patients and families as equal partners in all organizational improvement and redesign activities
- Educate and train all personnel to be effective partners with patients and families
- Partner with patient advocacy groups and other community resources

For Patients, Families, and the Public

- Ask questions about the risks and benefits of recommendations until you understand the answers
- Don’t go alone to the hospital or to doctor visits
- Document and share your medications, including names, why, how, and dose with all providers
- Be very sure you understand the plan of action for your care
- Repeat back to clinicians in your own words what you think they have told you
- Arrange to get any recommended lab tests done before a visit
- Determine who is in charge of your care

For Health Care Clinicians and Staff

- Provide information and tools that support patients and families to engage effectively in their own care
- Engage patients as equal partners in safety improvement and care design activities
- Provide clear information, apologies, and support to patients and families when things go wrong

For Health Care Policy Makers

- Involve patients in all policy-making committees and programs
- Develop, implement, and report safety metrics that foster transparency, accountability, and improvement
- Require that patients be involved in setting and implementing the research agenda

Whitepaper Recommendations

For Health Care Policy Makers

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Patient Engagement in End-of-Life Care

“Our system of technological medical care has utterly failed to meet the needs of patients with terminal illness, and the cost of this failure is measured in far more than dollars. The hard question we face, then, is not how we can afford this system’s expense. It is how we can build a health-care system that will actually help dying patients achieve what’s most important to them at the end of their lives.”

Gawande A. Letting Go. New Yorker. 2010
Location of death
- 70% of Americans state that they wish to die at home surrounded by their loved ones*
- In Massachusetts, more than 70% die in hospitals or nursing homes*
- Fewer than 25% of patients actually die at home*

Prolonged suffering
- Inadequate pain relief and symptom control
- Inappropriate use of modern technologies can prolong the dying process and diminish the quality of life during a patient’s final days

Ineffective use of hospice
- 15% of patients are not referred to hospice until their last week of life, the median length of stay (LOS) for patients with lung cancer was 4 days
- While referrals to hospice have increased, the LOS have decreased

Common Failures of Health Care Systems at End of Life

Changing Landscape: 3

A Focus on the Workforce

End-of-Life Care
- “Disregard of Patients’ Preferences Is a Medical Error”
  - Allison TA, Sudore RL. JAMA Intern Med editorial 2013
  - This is a safety issue!
  - In one study, more than 2/3 of patients’ preferences were either not documented or documented incorrectly in the medical record
    - 70% of MD orders concerning CPR/intubation were discordant with current patient wishes
  - Also a substantial cost issue . . .
  - Heyland DK et al. JAMA Intern Med editorial 2013

Joy and Meaning in Work
- Joy and meaning are not sentimental notions
- “Workplace safety is inextricably linked to patient safety. Unless caregivers are given the protection, respect, and support they need, they are more likely to make errors, fail to follow safe practices, and not work well in teams.”

End-of-Life Care
- Need to ensure earlier and better-documented conversations with patients about their goals and values
  - Relates to improving care across the continuum
- Then ensure that the care we provide is meeting those goals and values

Joy and Meaning in Work
- Currently health care workers suffer harm
  - Emotionally (bullying, demeaning)
  - Physically (injuries, assault)
    - Up to 1/3 of nurses experience back or musculoskeletal injuries in a year
  - Stress from complex and demanding tasks under severe time constraints
  - Costs of burnout, litigation, lost work hours, turnover are high
How Hazardous Is Health Care?

<table>
<thead>
<tr>
<th></th>
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<th>REGULATED</th>
<th>ULTRA-SAFE (&lt;1/1000)</th>
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Number of encounters for each fatality

Total lives lost per year

REGULATED (>1/1000)

ULTRA-SAFE (<1/100K)

In 2011, U.S. hospitals recorded 58,860 workplace injuries and illnesses that caused employees to miss work. In terms of lost time case rates, it is more hazardous to work in a hospital than in construction or manufacturing. "Days away from work" includes only the more severe injuries, and they do not account for injuries where an employee continues to work, but on modified duty. Thus, the problem is even larger than the graph below suggests.

Injury and Illness Rates, 1989–2011

Vulnerable Workplaces

Physical Harm

- Health care workforce injuries 3D times higher than other industries
- More FTE days are lost due to occupational illness and injury in health care each year than in industries such as mining, machinery manufacturing and construction
- 76% of nurses in national survey indicated that unsafe working conditions interfere with the delivery of quality care
- An RN or MD as a 5-6 times higher chance of being assaulted than a cab driver in an urban area

Vulnerable Workplaces

Psychological Harm

- Lack of respect
  - A root cause, if not THE root cause, of dysfunctional cultures
  - 95% of nurses report it; 100% of medical students report it
- Lack of support
- Lack of appreciation
- Non-value added work
- Production pressures
- Scheduling demands and fatigue
- Poor design of work environments and work flows

How Happy are RNS with their Jobs?

Costs of Inaction

- Burnout, lost work hours, turnover, inability to attract newcomers to caring professions
- Less vigilance with regard to safety practices – both for patients and for workforce
- Increased opportunities for medical errors
- Impact on patient experience
What are the seven things an organization must do?

1. Develop and embody shared core values of mutual respect and civility; transparency and truth telling; safety of all workers and patients; and alignment and accountability from the boardroom through the front lines.

2. Adopt the explicit aim to eliminate harm to the workforce and patients.

3. Commit to creating a high-reliability organization (HRO) and demonstrate the discipline to achieve highly reliable performance.

What are the seven things an organization must do? – cont.

4. Create a learning and improvement system and adopt evidence-based management skills for reliability.

5. Establish data capture, database, and performance metrics for accountability and improvement.

6. Recognize and celebrate the work and accomplishments of the workforce, regularly and with high visibility.

7. Support industry-wide research to design and conduct studies that will explore issues and conditions in health care that are harming our workforce and patients.

The Kaiser Workplace Safety Index

The index is linked directly to workplace safety injuries

Can be used to predict vulnerable departments

Identify areas to improve in the work environment in order to potentially prevent injuries

Simpler and more straightforward direction than previous indices

Slides courtesy of Kathy Gerwig - Kaiser Permanente Vice President, Employee Safety, Health and Wellness and Environmental Stewardship Officer

The Kaiser Workplace Safety Index

The 3 Rs: Resources, Respect, and Recognition

- Necessary steps are taken in my department or work unit to ensure employee and physician safety.
- My immediate supervisor recognizes me when I do a good job.
- Kaiser Permanente provides the resources necessary for me to work effectively (hardware, tools, equipment, supplies, etc.).
- The people with whom I work treat each other with respect despite differences.

Paul O’Neill ALCOA Example:

Can every person in your organization answer YES to the following questions each day?

1. Am I treated with dignity and respect by everyone, every day, by everyone I encounter, without regard to race, ethnicity, nationality, gender, religious belief, sexual orientation, title, pay grade, or number of degrees?

2. Do I have the things I need: education, training, tools, financial support, encouragement, so I can make a contribution to this organization...that gives meaning to my life?

3. Am I recognized and thanked for what I do?

2013 Higher Scores = Lower Workplace Injuries
Educating the Workforce

- Educating, training, and supporting people in the system so that they can help change the system
- Many online and in-person curriculum options
  - NPSF Online Patient Safety Curriculum, IHI Open School, PSEP
  - CME/CE courses
- How to make this a requirement/boost enrollment/train everyone?
  - Maintenance of certification
  - Clinical Learning Environment Review (CLER) program with ACGME
- New advanced training options (certification, fellowship)
- How to have leadership value these programs

Transparency

- A practiced value in everything we do
- The most important characteristic of a safe culture
- A precondition to safety

Transparency

- With colleagues
  - Sharing performance data, adverse events between providers, departments, and at all levels of the organization
- With patients and families
  - Clinical transparency re: shared decision making, risks and benefits
  - Adverse events/early disclosure
  - Financial incentives

Changing Landscape: 4

- Increased Transparency and Metrics That Matter

Transparency

- Between organizations
  - Quality, safety data
  - Adverse event data – Patient Safety Organizations (PSOs), HIT Safety Center
  - Credentialing
  - Medicare claims data
- With the public
  - Quality, safety, cost measures for doctors or institutions
    - Most websites are confusing and hard to follow
Challenges

- Cultural
- Fear of scaring patients/demoralizing staff
- Malpractice environment
- Lack of data/metrics
- Lack of understanding of best way to capture or present the information
- Upcoming Lucan Leape Institute white paper to start to address...

Metrics

- What should we be measuring for ambulatory or cross-continuum safety?
  - Measures that matter: to clinicians, administration, patients and families?
- How do we capture patient reported outcomes/ measures that matter to patients?
  - Patient-Centered Outcomes Research Institute (PCORI)
- How do we create metrics that are useful and not overwhelming?

Changing Landscape: 5

Optimizing the Use of HIT to Improve Safety

Optimize the Use of HIT

- We know that some technologies reduce errors significantly
  - Computerized provider order entry (CPOE)
  - Barcoding
  - Electronic prescribing
  - Handoff tools
  - Test result management systems
  - Referral management systems
**Optimize the Use of HIT**

- Need to optimize these systems
  - Reduce over-alerting
  - Variability across vendors
  - Improve interoperability

- Also, we know there can be unintended consequences
  - Clinical documentation/cut and paste—16% of attending's notes, 8% of residents' notes, and 38% of nurses' notes went unread by other users, and overall, 16% of notes were never read by anyone (Hripcsak et al. JAMIA 2011)
  - Accurate medication and problem lists
    - Who owns them?

**Sociotechnical Model**

- 8 components
  - Hardware and software
  - Clinical content
  - Human computer interface
  - People
  - Workflow and communication
  - Policies, procedures, culture (internal)
  - Rules, regulations (external)
  - Measurement and monitoring (Sittig, Singh BMJ Qual Safety 2010)

**Unintended Consequences: Inpatient CPOE**

- Workflow/work-arounds
- More work/new work
- Communication
- Overdependence on technology
- Shift in power
- Never-ending technology demands
- Emotions
- New errors
- Cost creep

(Nanji, et al. JAMIA 2011)

**Unintended Consequences**

- Study showed that 10% of electronic prescriptions had errors
  - 1/3 with potential for harm
  - Most frequent were omission errors
  - Significant variation across different vendor systems

- Forcing functions, decision support, and calculators could reduce these errors
- Always a continuous improvement opportunity

**Optimize the Use of HIT**

- National focus
  - Meaningful use incentives/certification
  - IOM report 2011 “Health IT and Patient Safety”
    - User-centered design principles
    - Promote sharing of safety issues
    - Criteria to judge the safe use of HIT
    - Mechanism for reporting HIT related adverse events
Optimize the Use of HIT

- ONC HIT safety plan 2013 (building on IOM report) includes the following:
  - Make it easier to report HIT hazards
  - Conduct post marketing surveillance
  - Establish HIT patient safety priorities for research
  - R&D for tools and best practices for implementation
- ONC SAFER guides 2013
- ECRI Collaborative 2014
  - Sharing and analyzing HIT safety hazards/taxonomies

Optimize the Use of Health IT

- FDASIA Health IT Report 2014
- Recommended the creation of a Health IT Safety Center
  - Goal of assisting in the creation of a sustainable, integrated health IT learning system

Conclusions

- The landscape of patient safety is changing
  - Scope (cross-continuum)
  - Broader definition of safety: “How care should be”
  - Incentives/penalties
- Key to focus on evolving areas
  - Care across the continuum
  - Patient engagement
  - The workforce
  - Transparency
  - Tools such as HIT
- Patient safety is more important than ever
  - Need to ensure the safest care and experience for patients while trying to reduce costs and reform care